Evaluation of Hospital-Setting HCIA Awards

Contract # GS-10F-0086K

Second Annual Report
Final

March 2016

Prepared for:
Jennifer Lloyd Wolter
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore MD 21244

Submitted by:
Abt Associates
55 Wheeler Street
Cambridge, MA 02138

In Partnership with:
General Dynamics Information Technology, Inc.
Telligen

Contents

Executive Summary

Abt Associates is evaluating the 10 Hospital Setting Health Care Innovation Awards (HCIA), which share the common feature of taking place, at least in part, in a hospital inpatient or emergency department; two of the 10 Awards also include nursing homes and post-acute care facilities. These Awards focus on high-utilization and high-acuity patients. The initiatives range from improving critical (intensive care unit; ICU) and emergency department (ED) care, to screening for emerging acute conditions in nursing home patients, to team-based inpatient and outpatient services for high-risk patients. Many initiatives rely on information technology to improve adherence to evidence-based best practices, revise pharmacy and laboratory automated order sets, or continuously monitor ICU patients. Although each initiative has unique goals and objectives, all share the goal of improving efficiency and reducing follow-up health care utilization such as rehospitalizations and repeat ED visits. All of the hospital setting initiatives focus on, but are not limited to, Medicare patients.

Our evaluation uses mixed methods to understand the care improvement/redesign processes, information technology, staff training, and other elements of each initiative, as well as impacts on utilization, Medicare and Medicaid spending, and patient and clinician satisfaction with care. This second annual evaluation report is based on the following sources:

- Follow-up and final case studies of 10 Awardees
- Core Measures based on analysis of Medicare claims and patient registries supplied by the Awardees
- Regression-based difference-in-differences (DD) analysis of several outcomes for nine of the 10 Awardees, by quarter and pooled over all intervention quarters
- Trend analysis of an intervention group only, during the intervention period, for one program, for which no baseline or comparison group can be estimated using Medicare claims

We assessed evaluability of each Award and note the following important evaluability challenges across the 10 Awards:

- ***Small programs.*** Most of the Hospital Setting HCIA Awards have too few patients to support quarterly analyses with tests of statistical significance. Even when data are pooled across the entire intervention period, the numbers of patients treated under six Awards are unlikely to reach the size required to detect program effects, although the future addition of Medicaid claims may help to improve the power to detect change in some of these programs. Notwithstanding these size limitations, we report results and examine direction and consistency, and whether quantitative results align with qualitative findings.
- ***Overlapping initiatives.*** Other hospitals nationwide, including those in our comparison groups, are responding to the Centers for Medicare and Medicaid Services (CMS's) Readmission Reduction program. With a DD evaluation design, the HCIA Awardees would need to substantially exceed the efforts of their peers in order to demonstrate a statistically significant reduction in readmissions. Similarly, sepsis detection and treatment is a widespread hospital priority, due to recognition of sepsis as a leading cause of in-hospital mortality, and the efforts of CMS's Hospital Engagement Networks and other quality improvement initiatives. Thus, the two HCIA sepsis programs under study would need to substantially exceed the efforts of their peers in order to demonstrate statistically significant impact on any outcome measures. In addition, many other initiatives, sponsored by CMS, by states,

by commercial payers, or by other entities, may affect patient outcomes. For example, CMS's readmission reduction program is a major contributor to reducing readmissions. Our analysis does not try to attribute impacts to HCIA as distinct from other initiatives. The DD evaluation design does, however, control for other initiatives and external factors that are affecting both intervention and comparison providers and the patients they serve.

- ***Heterogeneous programs.*** Several programs are quite heterogeneous across their multiple study sites; analyses pooled across study sites obscure site-level differences, but pooling is necessary due to the small numbers of patients in each site. We use facility fixed effects to control for some of this heterogeneity.

Qualitative Methods and Results

Qualitative Methods

We conducted detailed in-person case studies with each of the 10 Awardees in early 2014, including individual interviews, focus groups, and review of documents and Awardee reports to CMS. We conducted follow-up interviews (in most cases by phone) in early 2015, just before the grant period ended, to understand the mature programs; and reviewed new Awardee documents (e.g., their quarterly self-reports) throughout the evaluation period. Although these 10 programs have little in common, other than taking place in hospital settings, we observed several cross-cutting themes, described in detail in this report and summarized below:

Implementation Effectiveness

- Innovations were generally pre-existing, promising ideas, for which design/planning/implementation had already begun; HCIA funding provided the impetus to accelerate or expand implementation at the funded sites.
- Awardees that conducted extensive pilot testing of their innovations prior to the Award benefited from this experience and modified their innovations/systems to address known impediments. Programs also benefited from phased implementation of innovations.
- Several programs rely on a care process redesign and continuous quality improvement approach such as Lean Six Sigma.
- Some programs that were designed to meet important needs in large medical centers were not as well matched to the needs and resources of other partners (e.g., rural hospitals, skilled nursing facilities).

Program Effectiveness

- Program staff and clinicians interviewed during case studies advised us that new tools are more likely to be adopted if they are carefully designed to align with clinician workflows.
- Many innovations promote the use of clinical guidelines, often by automating order sets and creating best practice alerts within their electronic information systems.
- Technology challenges arose in many programs, and in some cases delayed implementation to partner sites. Many ongoing challenges are related to integrating a technology innovation into an existing (vendor) electronic health record (EHR) product. Information technology (IT) challenges were extreme for multi-site programs, especially when hospitals and their partners do not share an EHR.

Workforce Development

- Training continues to occur and evolve, adjusted to match the skill sets and practice levels of target clinicians. Training efforts must address float staff, residents, and new employees hired due to staff turnover.
- New responsibilities related to innovations challenge clinicians to practice at the top of their degree/ certification. Direct care staff working on many Awards described enhanced feelings of satisfaction with their jobs, and of empowerment; and reported enhanced mutual respect among members of the care team.

Contextual Factors

- With many competing initiatives in any large hospital, leaders described the importance of their role in demonstrating commitment and holding staff accountable for adopting the intervention. Mandating participation/adoption and monitoring adherence also improved uptake of several innovations.
- Some programs are so well received that they cannot meet the demand for their services.

Sustainability and Spread

- Programs that integrate their innovation into existing technology, practice and workflow are, in the opinion of our research team, the most likely to continue.
- Programs that hired or contracted for dedicated staff using HCIA funds (e.g., home health aides, mobility aides) needed to demonstrate return on investment to receive continued funding from internal sources. The degree to which these program components will be sustained varies.
- Programs that incorporated ongoing competency-based training for staff are more likely to continue than those that offered a one-time training that was continued to accommodate staff turnover.
- Programs that required extensive and complex technology enhancements/investment were more challenging to spread to partner sites, and in a few cases IT challenges were insurmountable.

Impact

- Clinicians across all Awardees shared their conviction that the innovations improve the quality and safety of care they provide to patients.
- Programs seek to either directly or indirectly improve efficiency, focusing on reducing ICU and overall length of stay, up-skilling clinical staff to fill roles that would otherwise require a more costly mix of clinicians, or improving the timeliness of care delivered in urgent/emergent situations.

Quantitative Methods and Results

Quantitative Methods: Analysis of Medicare Claims

For each Awardee and every quantitative outcome measure, we conducted quarterly DD analyses and also analyzed data pooled across all quarters. The pooled analysis increases the sample size, which improves the chance of detecting statistically significant program effects. However, pooled analyses may not provide the full picture of the program's trajectory. Conversely, estimates at the quarterly level are generally too underpowered to detect statistically significant results, but provide additional information regarding trends in outcomes that are not visible from the pooled estimates.

Even after data across all intervention quarters to date have been aggregated (pooled), we find several statistically significant results, as follows:

Statistically significant cross-Awardee themes in utilization changes (pooled analyses):

- The **rate of 30-day** readmissions declined for three programs, relative to their comparison groups.
  - The Mayo Clinic intervention was associated with a reduction of 2.48 percentage points ($p<0.05$).
  - The Methodist Delirium program was associated with a reduction of 1.95 percentage points among patients flagged as at risk for delirium ($p<0.01$.).
  - The St. Luke's program was associated with a reduction of 1.92 percentage points ($p<0.10$).
- **Length of stay** changed significantly for several Awardees, relative to their comparison groups.
  - The acute care component of the Christus intervention was associated with decreased length of stay of 0.22 days ($p<0.10$).
  - The Methodist Delirium screening program was associated with a decrease in length of stay of 0.09 days ($p<0.10$).
  - The Methodist Sepsis screening program was associated with a decrease of 0.17 days ($p<0.01$).
  - The Mayo Clinic program, in contrast, was associated with a 1.31 day increase in length of stay ($p<0.01$), relative to the comparison group.
- **Discharge destination** changed significantly in several programs, relative to their comparison groups.
  - For the Emory program, discharges to home with home health care increased by a statistically significant 2.88 percentage points ($p<0.10$), while discharges to all other destinations decreased over time, indicating that patients were diverted from these other discharge destinations to home health care.
  - Fewer patients were sent home without home health care; instead, they were discharged with home health care, which in turn reduced the rate of post-discharge ED visits for the Mayo Clinic, and also for the Methodist Delirium and Methodist Sepsis programs.
  - We surmise that the two Methodist screening programs in particular may detect other patient needs (beyond delirium or sepsis) that require post-acute care.
- Although program staff and clinicians described several efficiency enhancements, many such improvements will not translate to savings under fee-for-service (FFS) Medicare. For example, several programs significantly reduced length of stay relative to their comparison groups, but this did not reduce Medicare FFS episode spending. This calculus may change with increasing penetration of value-based purchasing and bundled payment initiatives.

Statistically significant Awardee-specific impact results (pooled analysis):

- The Mt. Sinai program (all three EDs combined) **reduced total inpatient admissions from the ED** by a statistically significant 3.49 percentage points ($p<0.01$). This result was evident in all intervention quarters and was highly statistically significant over time. However, t**here was no reduction in the overall hospitalization rate** relative to the comparison group. This suggests that the reduction in admissions from the ED to the hospital was temporary: patients were sent home from their ED visit but were admitted to the hospital in the following days or weeks.

- None of the other HCIA Awardees we evaluated had any statistically significant changes in mean Medicare 60-day total episode spending. However, for the long-term and post-acute care (LTPAC) component of the **Christus Health** program, the intervention was associated with an average **increase** of roughly $1,495 in total **Medicare spending** per episode ($p<0.01$). There were however no accompanying changes in important utilization measures that would explain this increase in Medicare episode spending, and none of our qualitative research suggests that features of this program or the patients it serves are increasing Medicare spending.

Trends to watch in Awardee-specific results:

There is some evidence of an intervention effect for several Awardees at the quarterly level, which, although not statistically significant, may indicate the direction of impact. A few **trends** are particularly interesting, including:

- In the **Emory** University eICU (electronic ICU) program, quarterly DD estimates suggest that total episode spending, 30-day inpatient readmissions, and length of stay were all lower for patients treated at participating hospitals relative to those treated at comparison hospitals, in both of the intervention quarters. (We have only two quarters of Medicare spending data for the Emory intervention period at this time.) Although this difference is not statistically significant for either quarter of results, this program has relatively few observations, and the **consistency of the positive outcomes across the three measures** suggests improvements that may be confirmed with more quarters of data (more patients).
- For the **Methodist Sepsis** screening program, quarterly DD estimates indicate that post-discharge ED visits are lower for intervention patients relative to the comparison patients for all but one quarter since the beginning of the intervention. Moreover, the quarterly estimate corresponding to the last quarter of 2014 indicates a statistically significant decrease of nearly two percentage points in post-discharge ED visits. These results suggest that the program may be reducing post-discharge ED visits, even though the pooled estimate for the entire intervention period is not statistically significant.

Study limitations

These results, and all others showing no program impact, are conservative for two reasons: 1) small sample sizes are generally insufficient to ensure detection of a significant result, and 2) limitations in our ability to specify the intended intervention patients and create matched comparison groups may bias results towards zero. Therefore, a lack of a significant estimate should not be interpreted as confidence that a program did not elicit any change in utilization or Medicare spending.

Synthesis of Qualitative and Quantitative Findings

Clinical and operations staff in all Awardee programs report that their programs are improving patient care. They are less convinced that this will in turn yield savings to Medicare, and this is confirmed with quantitative analysis to date. Other efficiency enhancements cannot be observed using claims data (e.g., fewer ventilator days, different staffing mix) and would not contribute to Medicare savings. For example, the Mayo Clinic AWARE program was quickly adopted by most Mayo Clinic ICU physicians because it reduces cognitive overload, focuses their attention on the most pressing patient needs, and improves communication—all important goals of the program. The University of Chicago program offers better access for patients, including a "hotline" and same-day appointments, which their patients appear to

greatly value, but the small size of the program makes it impossible to measure resulting improvement in utilization or Medicare spending.

Examples in these programs of improved quality without an increase in Medicare episode spending include:

- Bedside nurses and physicians in both the Emory and St. Luke's eICU programs report that the ability to continue intensivist physician-directed care during the night shift contributed to safer and more timely care, and shorter ICU stays (fewer days sedated and ventilated); and possibly to reduced overall length of stay (LOS) for the entire admission. In both programs, quantitative findings at the pooled and/or quarterly level indicate that LOS, readmissions, and post-discharge ED visits are declining, and Medicare episode spending may also be declining.
- ED staff are enthusiastically committed to the Dartmouth sepsis innovations, and their institutions have invested in new IT programming (trigger tools), and changes in laboratory and pharmacy procedures and order sets, which will continue to be supported. No increase in Medicare episode spending was observed.
- In the two Methodist Hospital innovations, program staff report that careful screening often reveals underlying patient needs that perhaps would have been missed in the past (and in comparison facilities), including problems unrelated to the program foci of sepsis or delirium detection. Heightened awareness of patient needs may be contributing to an increase in discharges to home health care or other post-acute services, rather than discharges to home without such services. The added costs of post-acute services may in part be balanced by fewer ED visits in the weeks following discharge, yielding no increase in total Medicare episode spending.

1. Introduction

1.1 Background

CMS contracted with Abt Associates to evaluate the 10 Hospital Setting HCIA Awards, using a mixed-methods evaluation design.

The following are the core research domains for this evaluation, as defined by CMS:

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burn-out and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous, conditions from within the organization, or exogenous, conditions from outside the organization. Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of HCIA funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the goals of better care, better health, and lower costs to CMS (Medicare, Medicaid, CHIP). None of these 10 Awardees target a priority population specifically; they target patients requiring hospital and other institutional services.

1.2 Overview of Awardee Group

The hospital-setting Awardees evaluated under this contract are listed below in Exhibit 1, with a brief description of each innovative model or approach.

Exhibit 1: Research Domains

Awardee Name	Innovation
Christus St. Michael Health System—Integrated Nurse Training and Mobile Device Harm Reduction	Train nurses to recognize early signs of congestive heart failure and sepsis in nursing home and hospital patients, using computerized clinical decision support, and reduce readmissions, LOS and cost.
Dartmouth—Optimizing the Treatment of Septicemia and Sepsis Through Implementation of Care Bundles	Improve care for severe sepsis in emergency departments and hospitals by implementing standardized care bundles, and reduce LOS, adverse outcomes, and cost.
Emory University—Rapid Development and Deployment of Non-Physician Providers in Critical Care	Train and deploy critical care nurse practitioners and physician assistants to address shortages of intensivist physicians, and support these new critical care (ICU) teams through remote monitoring and an eICU.
Henry Ford Health System—Mobility, the Sixth Vital Sign	Encourage and support patient mobility during acute inpatient hospitalizations, and reduce LOS, pressure ulcers, respiratory and other complications and cost.
Mayo Clinic —Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation (ProCCeSs AWARE)	Improve critical care through enhanced presentation and prioritization of clinical information, and electronic surveillance and quality improvement; and reduce ICU complications and cost.
Methodist Hospital Research Institute—Delirium Detection and Prevention	Improve care for patients at risk of delirium and associated complications through early recognition and prevention, and reduce LOS, falls and cost.
Methodist Hospital Research Institute—Sepsis Detection and Prevention	Improve care for patients at risk for sepsis and associated complications through early recognition and more-timely treatment, and reduce organ failure, LOS and cost.
Mount Sinai School of Medicine—Geriatric Emergency Department Innovations in Care through Workforce, Informatics and Structural Enhancements (GEDI-WISE)	Integrate geriatric care with emergency department care in large, urban hospitals, using evidence-based geriatric clinical protocols and decision support, and structural improvements, to reduce hospital admissions, return ED visits, adverse events and cost.
St Luke's Regional Medical Center—eICU	Use remote monitoring and specialist oversight to improve ICU care, standardize clinical practices, reduce ICU LOS and cost, and improve intensive care for rural and urban patients.
University of Chicago—Integrated Inpatient/Outpatient Care for Patients at Risk of Hospitalization	Use multidisciplinary teams led by Comprehensive Care Physicians to provide consistent care to high-risk patients before, during and after hospitalizations, and reduce admissions, readmissions and cost.

Source: Awardee Applications

All 10 of these programs focus on **patients with high-acuity needs or who are at high risk for costly health care utilization,** or both. **Intensive care units and emergency departments** are the main venues for six programs, while three other programs screen **high-risk inpatients** to detect early signs of emerging severe health conditions (e.g., heart failure, sepsis). Two of the 10 programs involve both hospitals and LTPAC providers.

Only the University of Chicago program provides ongoing services to an enrolled population, in both inpatient and ambulatory care settings. The Methodist Delirium prevention program offers one month of post-discharge home aide visits to patients at high risk for delirium. The other **eight programs focus exclusively on patients in institutional settings and provide no post-acute services**.

The implementation date of the innovations varied, and most added additional partner sites over time. Exhibit 2 displays the first date of the first patient in each of the 10 Awards' patient registries and also shows the "go live" date Awardee program staff provided for their first intervention site (all but two Awards have multiple sites).

Exhibit 2: Award Registry and Program Implementation Dates

Award	First Date Observed in Registry	Implementation ("Go Live") Date at First Site
Christus St. Michael's	January 2012	February 2013
Dartmouth	February 2013	February 2013
Emory	March 2013	April 2014
Henry Ford	September 2012	October 2012
Mayo Clinic	January 2013	June 2013
Methodist Delirium	April 2012	November 2012
Methodist Sepsis	April 2012	January 2013
Mt. Sinai	October 2012	October 2012
St. Luke's	December 2012	January 2012
University of Chicago	November 2012	November 2012

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

In most cases, the dates first observed in the registry and the dates of implementation at the first site are within a month or two, but the Christus, Emory, Mayo Clinic, and Methodist Delirium programs have dates that differ by several months. At Emory, a minimal intervention was in place at one hospital in 2013, but the full suite of eICU services (24/7 telemetry, two-way video communication, eICU physicians covering at night) did not begin until April 2014; we use April 2014 as the start date. The Christus program included long-term care residents' admission dates, but no specific intervention dates in the registry; we used February 2013 as the starting date for the LTPAC component of the program, and July 2013 as the starting date for the acute care component. The Mayo Clinic registry included patients who were treated during a ramp-up period in the hospital ICUs before the specified start date of the HCIA-funded intervention, which we used as the official starting date of the program. We used the Awardee-reported first implementation date for the Methodist Delirium program rather than the first date in the patient registry, which was several months prior.

With few exceptions, these **programs were implemented by existing clinical staff** in the hospitals and other participating facilities. In seven programs, few new staff were hired, other than data analysts and program administrators. The two eICU programs (Emory University, St. Luke's) hired nurses to staff the eICU 24/7, the Methodist Delirium prevention program contracted for home health aides to visit patients

after hospital discharge who had screened at high risk for delirium, and the Henry Ford Mobility program hired and trained mobility aides to assist inpatients, particularly ICU patients.

Health information technology is an important component of seven programs, to improve adherence to evidence-based best practices, revise pharmacy and laboratory automated order sets, coordinate screening criteria and corresponding services, or continuously monitor ICU patients. The eight programs that have multiple participating sites were challenged to reconcile incompatible IT platforms and collect symmetrical data.

1.3 Evaluation Data and Methods

In this mixed-methods evaluation, qualitative analyses are used to address questions pertaining to the nature of program participants, care redesign strategies, clinician perspectives, and challenges these complex programs faced in their first years. Qualitative data sources include focus groups, interviews, and review of documents from the Awardees and from the Implementation and Monitoring contractor. Quantitative analyses are used to estimate the impact of the initiative on quality, utilization and cost. Secondary data sources include Medicare claims, administrative data, and patient registries from Awardees. These qualitative and quantitative analytic approaches are complementary, contributing distinct pieces of information to form a larger body of evidence about the innovation and impact of each Award. The qualitative research helps to inform the design of quantitative analyses and also aids in interpretation, while the quantitative analyses inform follow-up qualitative data collection. The sections that follow describe data sources used to address each research domain, as well as quantitative and qualitative analytic methods.

1.3.1 Data Sources for Research Domains

Exhibit 3 illustrates the data sources that address core research metrics that are the focus of the evaluation.

Exhibit 3: Core Research Domains, Dimensions, and Data Sources

Core Research Metrics	Dimensions	Primary Data Collection					Secondary Data Sources	Method
			Qualitative Data Sources					
		Program Document Review	Interviews with program staff	Interviews with clinical and other staff	Focus groups with Intervention clinicians	Patient Surveys, Intervention & Comparison		
Implementation effectiveness	Intervention (components, dosage, fidelity, self-monitoring)	✓	✓	✓	✓	--	--	Descriptive
	Reach (coverage, participation, timeliness, secondary use of tools)	✓	✓	--	✓	--	--	Descriptive
Program effectiveness	Health (outcomes, functional status, self-reported health)	--	--	--	✓	✓	--	Intervention-comparison
	Quality (safety, clinical effectiveness, patient experience/satisfaction, efficiency, care coordination)	--	✓	✓	✓	✓	--	Descriptive
	Spread, sustainability	--	✓	✓	✓	✓	--	Descriptive
Workforce issues	Development and training	--	✓	✓	✓	--	Awardee narratives	Descriptive
	Deployment	--	✓	✓	✓	--	Awardee narratives	Descriptive
	Satisfaction	--	✓	--	✓	--	--	Descriptive
Impact	Utilization (readmissions, ED use, LOS)	✓	✓	--	✓	✓	Medicare & Medicaid Claims	DD or Interrupted time series
	Episode spending, high cost outliers	--	✓	--	✓	✓	Medicare & Medicaid Claims	DD or Interrupted time series
Contextual factors	Endogenous factors (leadership, team science, organizational, stakeholder engagement)	✓	✓	--	✓	--	--	Descriptive
	Exogenous factors	✓	✓	--	✓	--	--	Descriptive

1.3.2 Comparison Group Facilities

For each Awardee intervention facility we selected a comparison group of similar facilities in the same Hospital Referral Region (HRR).We first selected comparison facilities and then, within facilities, specified comparison patients. In selecting comparison facilities, we chose all similar facilities in the same HRR. We matched first on the types of facilities and units where programs are implemented, and then used other patient factors (e.g., age, diagnosis-related groups [DRGs]) to more closely approximate each Award's registry population. For Dartmouth's northern New England sites and for the Mayo Clinic, there were no similar facilities in the same HRRs, so we used other facilities elsewhere in the same or nearby states. We considered the following factors in selecting comparison group facilities (see Exhibit 4):

- **Provider type:** Comparison group facilities are the same type of facility as those in the intervention.
- **Provider size:** Comparison group facilities are similar in size to Awardee facilities (large vs. small). The definition of the size categories varies with respect to Awardee and facility type and is based on the distribution of Awardee-affiliated facilities.
- **Teaching status:** For intervention facilities that are teaching hospitals, we considered teaching status in selecting comparison facilities.
- **Types of services offered:** For Awardees that restrict their program to patients treated in specific units (e.g., ICU, Emergency Department), we restricted comparison group facilities to those that provide such services. To increase the strength of the match, we also restricted the Methodist Delirium comparison group to hospitals that provide both ICU and ED services. Note that, for the most part, larger hospitals provide both ICU and ED services, so there is no need to apply this rule for larger hospitals.
- **Miscellaneous exclusions*:*** We excluded Special Focus Facilities (SFF) from among comparison group nursing homes, and also excluded any facility that specializes in treating pediatric patients. In addition, for Christus, we excluded from the comparison group facilities that are not in Arkansas or Texas, because although Christus's HRR extends into Oklahoma, their participating facilities are all in Arkansas and Texas. Finally, note that no Awardee facilities were eligible to be comparison group facilities for another Awardee's program.

Exhibit 4: Criteria for Selecting Comparison Group Providers

Awardee	Provider Size	Teaching Status	Specific Types of Services	Other Factors
Christus—hospital	>250 beds	N/A	N/A	Must be in AR or TX.
Christus—skilled nursing facilities (SNF)	50-150 beds	N/A	N/A	Must be in AR or TX
Dartmouth	>30 acute care hospitals, most with 200+ beds	Both teaching and non-teaching	ICU and ED	For nursing homes and ME use all large northern New England and upstate NY; for urban sites, weight comparisons in pooled analyses
Emory	> 100 beds	N/A	ICU and ED services	N/A
Henry Ford	> 500 beds	Major teaching	N/A	N/A
Mayo Clinic	MA: 100-250 beds NY and MN> 500 beds	Major teaching	ICU and ED services	For MN, selected comparison providers from Minneapolis HRR
Methodist—Delirium: hospital	50-150 beds	N/A	N/A	N/A
Methodist—Sepsis: hospital	> 300 beds	N/A	N/A	N/A
Methodist—Sepsis long-term care hospitals	75 or more beds	N/A	N/A	N/A
Methodist—Sepsis: SNF	50-150 beds	N/A	N/A	This HRR has no SFF facilities
Mt. Sinai	NY:> 1,000 beds IL, NJ: > 500 beds	Major teaching or graduate	N/A	N/A
St. Luke's Hospital	100-250 beds	Not a major teaching hospital	ICU services	Must be in Idaho (in Boise or Spokane HRR)
University of Chicago	N/A	N/A	N/A	N/A

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

1.3.3 Identifying Intervention and Comparison Group Patients

We did not use propensity scoring to create comparison groups, because most of these 10 programs affect all patients within a given unit of the hospital or with a given condition. There is no "propensity" to be treated: the patient either had the condition of concern (e.g., sepsis) or was treated in a specific unit of the hospital (e.g., ED, ICU) and was therefore exposed to the intervention, or not. A propensity score matching method assigns a propensity of treatment between 0 and 100 percent based on available observable patient information. For programs that have rigidly defined inclusion criteria (e.g., all ED patients) a propensity score match cannot create a better comparison group than direct matching, and may in fact perform much worse. The criteria by which patients are selected or excluded by Awardees for their specific interventions include some factors that are not present on claims. Both propensity

score match and direct matching strategies employ all relevant observable claim information, but cannot address these unobservable factors. In these cases, a direct matching strategy will generally outperform propensity score matching by including only patients who fit specific criteria, rather than widening the potential comparison population to include patients who loosely match the intervention patients on characteristics that are irrelevant to the intervention. Propensity score matching and direct matching both rest on the same primary assumption that the outcome of interest is independent of the intervention, conditional on control variables or matching variables. Regression has the distinct advantage that under the right conditions, it is the most generalizable estimator. Propensity score matching will exclude observations if, for example, some observations have a propensity score that is entirely dissimilar to the estimated propensity of the treatment group, or if observations are too "distant" from each other in propensity score. A regression that meets the correct assumptions will use information from all observations to produce an estimated effect; this regression estimate is likely be closer to the "true" population effect than the estimate produced by propensity score matching followed by regression.

After considering these relative strengths of propensity score versus direct matching, we chose to directly match on intervention facility and patient observable characteristics to specify comparison groups. We used Awardee registries and Medicare claims to define inclusion and exclusion criteria for each program's patient population, and then applied these criteria to define groups for analysis. This approach ensures that the same criteria are used to define intervention and comparison group patients and to define patients from the pre- and post-intervention periods. We considered the following factors in specifying inclusion and exclusion selection criteria.

- **Time Criteria:** Using registry data, we determined the first time a patient was treated in each Awardee facility, during the relevant implementation period for that specific facility. The claims used for creating selection criteria were then restricted to reflect the dates on or after the first treatment date in a facility.
- **Revenue Center Criteria:** Revenue center codes were identified in the claims and used as exclusion or inclusion selection criteria, as appropriate for specific Awardees. For example, St. Luke's program targets patients treated in intensive care units. Only claims with a line item charge from the intensive care unit were included.
- **Diagnosis Related Group Criteria:** Based on correspondence and case studies with Awardee program staff, specific Medicare diagnosis related groups (MS-DRGs) were identified as excluded or included for specific Awardee programs. For example, the Dartmouth Sepsis Improvement Program excludes kidney and liver transplant patients, and we therefore excluded claims that had an MS-DRG code indicating a kidney or liver transplantation.
- **ICD-9 Criteria:** The Dartmouth and Methodist Hospital Sepsis program targets patients with sepsis. In addition to including specific hospital units where the interventions were implemented, we excluded patients from the treatment group for the Dartmouth programs who did not have a diagnosis of sepsis on their claims (based on ICD-9 codes), and did the same for a sub-analysis of the Methodist patient population whose sepsis was detected by screening. (See Appendix A for a complete list of criteria used for each Awardee.)

  ICD-9-based matching criteria were also used to create the analytic samples for Emory University, the Mayo Clinic, and the subset of Methodist Delirium patients who screened positive for delirium and received additional interventions. In these cases we did not match based on specific ICD-9 codes

that the program targeted (i.e., delirium diagnosis), but rather used ICD-9 codes present in the Awardee registries and identified comparison patients with similar diagnoses.

The steps above yielded inclusion and exclusion criteria for each Awardee program except for the Henry Ford Hospital program. In that program, the intervention location within the hospital (e.g., ICU, ED) changed over time, and program staff relied on clinical information to select patients that cannot be observed in claims data. As a result, we are unable to create a comparison group for this program or define patients from the pre-intervention baseline period. Therefore, all analyses for Henry Ford Hospital show only the trends for registry patients, without a baseline or non-intervention comparator.

Exhibit 5 below indicates the number of registry patients each Awardee reported to us, how many we were able to find Medicare FFS claims for, and the dates covered by the registry data. Those marked N/A in the exhibit below either had incomplete registries, or we could not rely on their registries to create intervention and comparison groups.

Exhibit 5: Medicare Intervention Patients with Valid Health Insurance Claim (HIC) Numbers, and Registry Start Date, by Awardee

Awardee	Number of Unique Medicare Patients in Awardee Registry	Number of Unique Medicare Beneficiaries with Claims and Identified by HIC		Registry Start
		(N)	(%)	
Christus	N/A	N/A	N/A	N/A
Dartmouth	N/A	N/A	N/A	N/A
Emory	4,718	1,423	30.16%	March 8, 2013
Henry Ford	5,428	3,906	71.96%	September 13, 2012
Mayo Clinic	5,422	4,159	76.71%	January 15, 2013
Methodist—Delirium (Intervention)	7,168	5,991	83.58%	November 1, 2012
Methodist—Delirium (Screened)	13,211	10,821	81.91%	November 1, 2012
Methodist—Sepsis (Screened)	6,075	5,809	95.62%	January 4, 2013
Mt. Sinai	N/A	N/A	N/A	N/A
St. Luke's	5,409	3,103	57.37%	December 26, 2012
University of Chicago	997	972	97.5%	November 6, 2012

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

In some cases, the best criteria we could apply based on Medicare claims data captured all registry patients but also captured patients who apparently did not receive the intervention—we were unable to refine the selection criteria with sufficient precision to eliminate all of these "extra" patients. This overestimation of the intervention patient population can occur for several reasons.

First, the Awardee registries may not include every eligible patient. For example, the Mayo Clinic registry contains every patient for whom the AWARE tool was used but not every patient for whom it could have been used; a few physicians chose not to adopt the tool (which in itself is an important measure of program success); their patients are not in the registry but are included in our analysis because we use an intent-to-treat approach. Second, our criteria unavoidably capture patients not in the registry because some programs select patients based on clinical information that is not available in Medicare claims. For

example, the Dartmouth registry excludes patients who had Do Not Resuscitate orders, and such orders do not appear on claims and cannot be used to define baseline or comparison populations.

In some cases, the selection criteria we created did not capture all of the registry patients—some patients who receive the intervention do not resemble the majority of patients in the registry and have nothing in common that we can see in claims data (i.e., the Awardees applied clinical selection criteria that are not available on claims). A few Awardees did not record all patients in their registries in the early quarters of implementation, but compiled more-complete lists in later quarters; in these cases we based selection criteria on the later quarters. Some Awardees' registries deliberately include only a subset of patients exposed to the intervention, but Awardee program staff advised us on criteria for specifying the more inclusive intervention group.

Finally, Awardees serve patients with insurance coverage other than original Medicare, and information about these patients is not available to us.

No matching was needed for the following Awards:

- We did not create matching criteria for Christus because their registry is minimal, including only patients who receive care using computerized clinical decision support. Awardee program staff advised that all patients in participating facilities should be considered to be in the intervention group given the nature of their program, which emphasizes both staff training and use of computerized clinical decision support. In a future report, we will consider conducting a second analysis based on the subset of patients in the registry. This will depend on whether the registry data contain a sufficient number of patients to support statistical analyses, and on our ability to create a suitable comparison group for the subset of patients who receive care using computerized clinical decision support.
- We did not create selection/exclusion criteria that match the Dartmouth registry, because Awardee program staff advised that their registry is restricted to a subset (less than half) of intervention patients. Dartmouth program staff suggested criteria that would better define the larger group of patients whom they intended to treat in their sepsis improvement intervention, and agreed that they would not expect these criteria to match their registry.
- Although we used matching to identify the patient population for the Methodist Sepsis screening program, we did not use an additional matching procedure to identify those patients who received the sepsis treatment bundle. Because the program targeted septic patients, any screened patient who presented with sepsis met all criteria necessary to receive the sepsis care bundle, and the program intended to treat them for sepsis. Any patient in the screened sample with ICD-9 codes indicating a sepsis diagnosis is assumed to have also received sepsis treatment interventions.
- The Mt. Sinai program staff advised that their registry contains a subset of all older Medicare beneficiaries who visit the EDs in this program, but that all older ED patients are exposed to elements of their intervention; we therefor consider all beneficiaries over age 65 to be exposed to the intervention, eliminating the need for matching to their registry.
- The University of Chicago provided a registry of all intervention and control patients in their randomized trial, and there is no need for us to specify selection criteria. A slight majority of the intervention and comparison patients served by this program are Medicare FFS enrollees.

For the programs where matching to Awardee registries was possible, our best selection criteria are imperfect, and we therefore estimated the error in each direction. Because of the imperfect criteria, our

results are a conservative estimate of impact: the more imperfect the criteria (matched to the registry) for a given Award, the more conservative are the estimates of results. Exhibit 6 illustrates the match between Awardee registries and the best criteria we can specify using Medicare claims; it reflects the most recent quarter (Q4 2014). The match rates for all intervention quarters are presented in the Awardee-specific results in Appendix B.

Exhibit 6: Match between Awardee Registries and Claims-Based Inclusion Criteria (Q4 2014 only)

--	Emory	Mayo Clinic	Methodist Delirium (Screened)	Methodist Delirium (Treated)	Methodist Sepsis (Screened)	St. Luke's
Registry, total unique patients	866	1,040	3,371	3,159	5,659	853
Registry with Medicare FFS claim (A)	527	770	1,452	845	2,321	404
Registry patients not captured by Abt criteria (B)	35	143	45	22	0	31
Miss Rate (B/A)	**7%**	**19%**	**3%**	**3%**	**0%**	**8%**
Estimated based on Abt Criteria, with Medicare FFS claim (C)	619	911	1,526	1,228	2,574	432
Match between estimated and registry (D)	492	627	1,407	823	2,321	373
Estimated by Abt criteria, not in registry	127	284	119	405	253	59
Accuracy Rate (D/C)	**79%**	**69%**	**92%**	**67%**	**90%**	**86%**

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

Miss Rate = percentage of registry patients with a Medicare FFS claim that are not captured by Abt's inclusion criteria.

Accuracy Rate = percentage of admissions with a Medicare FFS claim and meeting Abt's inclusion criteria that are also in the registry.

The first two rows of Exhibit 6 show the total number of Medicare patients in the Awardee registry, and the number of these patients for whom we could locate a Medicare claim (A). The third row (Registry Patients Not Captured by Abt Criteria) is the number of patients in the registry who had claims, but that our criteria do not classify as intervention patients (B). We call the ratio of the misidentified registry patients to total registry patients with claims (B/A) a "miss rate." The miss rate ranges between 0 and 100 percent and the more precise patient selections are closer to zero.

Exhibit 6 also shows the total number of patients that that our criteria specify as intervention patients (C). The total number of patients that our criteria classify as intervention patients are the "Match Between Estimated and Registry" (D), and the ratio of estimated patients that are also included in the registry (D/C) is reported as the "accuracy rate." The accuracy rate ranges between 0 and 100 percent; 100 percent is the optimal case when all selected patients are also in the registry.

The following summarizes the use of Awardee registries and how well our inclusion/exclusion criteria match the Awardee registries.

Strong Matches

- Emory University: The criteria we developed for Emory result in a strong match (79 percent accuracy rate, 7 percent miss rate). These analyses reflect the eICU component of the Emory innovation only, not the residency training component, because only the patients exposed to the eICU were included in the Awardee registry.
- Methodist Delirium (screened population): The match to the registry misses only 3 percent of patients in the registry, and has an accuracy rate of 92 percent, the highest among all Awardees.
- Methodist Sepsis (screened population): The miss rate is 0 percent, indicating that our criteria do not miss any patients in the registry. The accuracy rate is 90 percent, which suggests that our sample contains few patients who did not receive the screening intervention.
- St. Luke's eICU: The accuracy rate of 86 percent and miss rate of 8 percent indicate that most patients who received the intervention are included in our sample, and most who did not are excluded.

Weaker Matches, Registry Incomplete, or No Match Possible

As noted above, no match was possible, or it was not necessary, for the Christus, Dartmouth and Mt. Sinai programs, due to the incomplete nature of the Christus and Dartmouth registry data and the facility-wide nature of the Christus and Mt. Sinai interventions.

For three Awards, matching on hospital unit or condition is infeasible (e.g., Henry Ford, Emory, Mayo Clinic), because these programs were implemented in only a subset of all ICUs in these hospitals, and claims do not reveal the specific type of ICU in which a patient receives care.

1.3.4 Sample Size Considerations

In order to determine the minimum sample sizes likely to be required to detect statistically significant impacts in regression-based claims analyses, we conducted a set of power calculations using aggregated data through Q3 2014.

For nine of the 10 Hospital Setting HCIA Awards[1] we calculated the statistical power of a regression in which the intervention caused a 5 percent change in 60-day Medicare episode spending. To define episodes, we started with an index admission and included total spending during the 60 days that followed, including the index admission itself and all post-discharge care (except prescription drug costs). After this 60 day episode, we allowed a further 60 days to pass before a patient could be "eligible" for a new index admission. We thus treated a hospitalization more than 120 days after an index admission as the start of a new episode of care and independent from the prior episode, but included Medicare spending for only the first 60 of those 120 days. We used the pre-intervention or baseline period mean, sample size, and standard deviation, and calculated a 5 percent increase in spending. We then applied these numbers, along with the observed intervention patient population count, in a power calculation. As advised by CMS, we used a threshold of 0.8 or above as the probability of determining a statistically significant effect of 5 percent with a p-value of .10.

[1] Because the Henry Ford Hospital Mobility program uses clinical data to select patients, which we cannot replicate with claims, it is not possible to create a comparison or baseline group against which to compare their Mobility intervention.

We did not repeat this exercise using binary utilization outcomes, because the measures (inpatient readmission rates, emergency department visit rates) have a low baseline volume in these programs. A 5 percent increase in a low number cannot be statistically determined with confidence using a regression analysis (for example, a 5 percent increase in a 6 percent readmission rate is approximately 1/3 of a percentage point.)

Unlike the other nine Awards, where patients were exposed to the intervention once at the time of their treatment in a hospital or post-acute care facility, the University of Chicago enrolls patients and serves them continuously thereafter, in both inpatient and outpatient settings. This required a different approach for estimating statistical power. For the University of Chicago's randomized intervention and comparison groups, we determined the mean cost of care, weighted by the number of days that a patient was enrolled in either arm of the study. For example, a patient enrolled on the first day of the program has a weight of 1. A patient who was enrolled halfway between the program's inception and the third quarter of 2014 has a weight of 0.5. Because the cost outcomes are calculated after the beginning of the intervention, the comparison group's outcomes were used as a proxy for what the intervention group costs would have been in the absence of the intervention. Thus, rather than using baseline data as the comparator, we used the randomized comparison group.

Exhibit 7 below shows the power calculations that resulted from these procedures. Based on these results we conclude that regression analyses are powered to detect differences of 5 percent at this time when pooling data through Q3 2014, for the Dartmouth program, Methodist Sepsis acute program, the Methodist Delirium program, and the Mt. Sinai program. Calculated power for these programs, assuming an effect size of five percent and a significance level of 10 percent, are .88, 1.00, .91, and 1.00, respectively.[2] We anticipate that the Mayo Clinic program may be large enough by the end of the intervention period to achieve the appropriate power. The other programs, however, are not likely to be large enough to power regression analyses at the 0.8 level, even pooling data for their entire intervention period.

[2] Power analyses for the Methodist delirium and sepsis programs refer to screened patient populations. Analyses for the subset of patients who received the delirium or sepsis treatment intervention are not powered at the standard 0.8 level.

Exhibit 7: Statistical Power to Detect Differences, by Awardee

Awardee	Intervention Size Through Q3 2014 (Medicare FFS Claims)	Baseline Mean	Baseline Std. Dev	Power to Detect 5% Difference*
Christus St. Michael's (Acute)	5,080	$9,150	$12,724	0.57
Christus St. Michael's (LTPAC)	996	$13,943	$11,310	0.39
Dartmouth	10,122	$15,038	$19,071	**0.88**
Emory University	1,059	$12,657	$18,042	0.21
Henry Ford—no baseline or comparison group possible	--	--	--	--
Mayo Clinic	4,788	$10,570	$15371	0.51
Methodist—Delirium	13,617	$11,695	$16,194	**0.91**
Methodist—Sepsis (Acute)	38,380	$$11,495	$17,288	**1.00**
Methodist—Sepsis (LTPAC)	2,575	$18,057	$21,197	0.45
Mt. Sinai	48,659	$7,894	$13,094	**1.00**
St. Luke's	3,596	$9,822	$15,883	0.37
University of Chicago	423	$53,524	$72,187	0.20

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

We do not pool data across the 10 Hospital Setting Awardees because the programs themselves are very different, and because a pooled result would reflect mainly the four largest programs, with little contribution from the other six programs.

1.3.5 Difference-in-Differences Analytic Approach

To test whether the Awardee interventions are achieving their intended objectives we applied a multivariate regression approach that isolates the effect of the intervention to the fullest extent possible. Specifically, we used a DD estimator that controls for unobservable factors (e.g., cyclical patterns, market trends unrelated to the intervention) that could confound estimates of intervention effects. DD compares changes in patient outcomes at Awardee (intervention) facilities to those at comparison facilities, over baseline and intervention periods. Since comparison facilities are selected to be as much like Awardee facilities as possible (see Exhibit 4 above), these comparisons should capture unobserved market-level and other factors that are external to the Awardee intervention but could affect patient outcomes. The post-intervention change in outcomes for patients at Awardee facilities relative to patients treated at comparison facilities should therefore be attributable to the intervention.

Although matching of comparison and Awardee facilities should account for market-level trends that may confound estimates of the intervention treatment effect, patient-level outcomes will still be influenced by individual patient attributes (e.g., demographics, individual health). A DD estimator matched only on market-level factors would not account for changes in patient outcomes that may be due to changes over time in the characteristics of the patients served by intervention facilities. That is, if the difference in average patient health between Awardee and comparison facilities changes between the pre- and post-intervention periods, changes in outcomes attributed to the intervention may actually be due to a change in average patient health and not to the intervention. To control for this possibility we included a set of variables to control for individual-level factors that may influence patient outcomes (discussed below). The following is the main DD model for the pooled analyses, using a generic outcome measure, Y, that estimates the differential change in Y for Awardee intervention patients between the baseline and post-intervention period relative to that same change for comparison group patients.

First, we define:

Y_{itkj} This is the outcome for the i^{th} individual during the t^{th} year from the k^{th} index stay at the j^{th} facility.

X_{itk} This is a vector of characteristics for the i^{th} individual in the t^{th} year from the k^{th} index stay.

P_{ikj} This is an indicator variable equal to 1 if the i^{th} individual received services in the k^{th} index stay from an j^{th} facility, and 0 otherwise.

A_{ik} This is an indicator variable equal to 1 if the i^{th} individual received services in the k^{th} index stay from an Award participating facility, and 0 otherwise.

Z_{itkj} This is an indicator variable denoting that index stay k for individual i occurred after the start of the intervention at the j^{th} facility. Intervention start dates may vary by facility for each Awardee.

Q_{ik} This is a series of indicators for quarter of the year in which index stay k occurred for individual i.

The intervention effects can then be identified using the following regression model:

$$Y_{itkj} = \beta_{0k} + X_{itk}\beta_X + P_{itkj}\psi + Z_{itkj}\delta + A_{ik}Z_{itkj}\theta + Q_{ik} + \epsilon_{itkj}$$

where θ is the estimated HCIA intervention effect. The variables in X_{itk} include demographic characteristics (age, race, and gender), a proxy for socio-economic status (indicator variable for Medicaid eligibility), and risk adjustment for severity of illness (HCC score). P_{ikj} is a provider fixed effect that accounts for differences between all facilities that are constant over time, while Q_{ik} is a quarter fixed effect that accounts for cyclical trends in patient outcomes that may affect both comparison and Awardee facilities. See section 1.3.6 below and **Appendix A** for additional details about measures.

We assume that the error term ϵ_{itkj} is uncorrelated with A_{ik} and Z_{itjk} conditional on X_{itk}, and the market- and facility-level attributes on which the comparison facilities were selected. Therefore, estimates of θ should be unbiased. We estimate Huber-White robust standard errors for all Awardee programs, to account for heteroscedasticity in the regression residuals.

The regression models included the following variables:

Dependent Variable: The dependent variable for regression analyses is average 60-day Medicare costs. For roughly 0.3 percent of observations the adjustment process resulted in negative costs accruing to the hospital.[3] In these instances the cost was reset to 0.

[3] A negative payment amount may occur in two situations: (1) When a beneficiary is charged the full deductible during a short stay and the deductible exceeded the amount Medicare pays; (2) When a beneficiary is charged a coinsurance amount during a long stay and the coinsurance amount exceeds the amount Medicare pays.

Independent Variables:

- Awardee: Binary indicator for whether patient is affiliated with an Awardee.
- Post-Intervention Period: Binary indicator for whether record is from the post-intervention period, based on Awardee-specific start dates.
- Age, Age^2 : Measured at time of index hospitalization.
- Gender.
- Non-White Race: Binary indicator.
- Medicaid Eligibility: Binary indicator for whether a beneficiary was eligible for Medicaid at any point during the 2010-2013 period covered by our data; indicator of low income.
- HCC Score and squared HCC score: Measured using HCC score for the year of the index admission (or the closest prior HCC score if this is missing). If no HCC score is available, we used the average HCC score from the facility in the treatment quarter.
- Quarter of index hospitalization.
- Facility: We included binary indicators for their program's intervention and comparison facilities to control for unobservable outcome differences that persist through time.

We estimated the model separately for each Awardee intervention using the Awardee-specific comparison groups assembled according to the methods described above. Because intervention facilities do not contain enough observations to support facility-level analyses, all estimated intervention effects refer to the pooled effect of the intervention across all facilities.[4] For consistency with the other HCIA evaluations, we estimated total costs using Ordinary Least Squares (OLS), which allows changes in spending to be interpreted in dollar terms without any retransformation of the data. Results for each Awardee are presented in **Appendix B**.

Presentation of Trends

As shown in Exhibit 7 above, to date only four programs are large enough, when data are pooled across quarters, to conduct tests of statistical significance with reasonable certainty of recognizing a true effect of an intervention. However, at CMS's request we present multivariate DD results for all measures, for all Awardees except Henry Ford Hospital. Estimates at the quarterly level are all underpowered but are presented to demonstrate potential trends in outcomes.

1.3.6 Outcome Measures

In an effort to establish a consistent framework for performance measurement, program monitoring, and quality improvement, CMMI developed specifications for Core measures, to be reported (as appropriate)

[4] Exceptions include the St. Luke's and Emory University programs. St. Luke's intervention was implemented at several rural critical access hospitals that were too different from the large urban medical centers to be included in the pooled sample, but had too few observations to analyze separately. Similarly, the Emory University intervention was implemented at two small, community hospitals that are too different from the large urban medical centers to be included in a pooled analysis, but currently have too few observations to analyze separately. Therefore, results for these two programs exclude participating rural hospitals.

for HCIA Awardees. These Core measures include admissions, readmissions, ED visits and total episode spending by Medicare and/or Medicaid. We further analyzed discharge destination, to understand whether patients served by these interventions require less-intensive services after discharge. CMMI also specified Priority Measures for Monitoring and Evaluation (PMME), intended for use across all CMMI programs. These standardized measures include structure, process, outcome, care experience, and cost-related measures. Alignment of measures across evaluations enables CMMI to compare the overall impact of many initiatives on the health of populations, quality, and efficiency of care, and to compare the effectiveness of different models.

1.3.7 Core and Awardee-Specific Measures

For the evaluation of Hospital Setting HCIA Awards, different Core measures are relevant for subsets of Awardees, and adaptations of some measures are necessary to address unique attributes of specific Awardees. In this first Annual Report, we focus on the following measures:

- **Episode Spending:** We report on 60-day total Medicare episode spending, with the start of an episode defined differently for various Awardees. We anticipate adding Medicaid spending to our analyses for the final summative report, after allowing sufficient time for Medicaid data to accrue. This will be possible only for Awardees in states where Medicaid data are generally complete after two years (e.g., Georgia), and not possible in states where for which Medicaid data are not available (e.g., Texas).
- **Readmissions:** For patients who receive a program service in an acute care setting, we report on readmissions during the following 30 days. We also examined readmissions at 14 days, which were not substantially different from readmissions at 30 days, and we therefore report only the latter.
- **Post-Discharge ED Visits:** For patients who receive a program service while in the hospital, we report on post-discharge ED visits in the following 30 days. We also examined ED visits at 14 days post-discharge, which were not substantially different from ED visits at 30 days, and we therefore report only the latter.
- **Admissions:** Most of these 10 Awardee programs serve patients who have already been admitted to the hospital and the intervention ends at hospital discharge, making measurement of admissions irrelevant. The University of Chicago program is the exception, as it enrolls and randomizes patients in community and ED settings as well as the inpatient setting; for this program we report total admissions and total ED visits for all enrolled participants, rather than the binary measure of whether there were any ED visits or readmissions. The Methodist Sepsis and Christus programs serve patients in LTPAC settings as well as those in acute care settings. For those in LTPAC settings, we report admissions to the hospital. The Mt. Sinai intervention is based in an ED setting, and we report the rate of admission directly from the ED to the hospital.

Other measures are important in monitoring whether Awardees are meeting other goals such as efficiency and quality. This report also contains the following measures:

- **Inpatient Length of Stay:** For programs where the intervention takes place during an inpatient admission, we report LOS.
- **Discharge Destination:** We report on the share of patients who are discharged home without additional health care; home with formal care provided by a home health agency; skilled nursing facility/inpatient rehabilitation facility/long-term acute care/other nursing home; or other discharge destinations (includes, e.g., psychiatric hospital, hospice, left against medical advice).

We investigated the possibility of analyzing hospital-acquired conditions (HACs), such as ventilator-associated pneumonia, catheter-associated urinary tract infections, and pressure ulcers, but concluded that HACs are so infrequent that it is not possible to accurately measure change against baseline, or differences between intervention and comparison groups. The more unlikely an outcome, the larger the population must be to achieve sufficient power to detect a statistically significant change in that outcome. For example, a 10 percent change in an outcome that occurs 0.1 percent of the time is only 0.01 percentage points. It would take an infeasible number of observations (i.e., much larger programs, much longer intervention periods) to shrink the standard error to the point that we could confirm that such a change was statistically significant.

If claims volumes permit, a future report will explore Medicare (and possibly Medicaid) spending within episode, stratified by type of covered service.

In our measure of readmissions we do not differentiate between planned and unplanned readmissions, because we expect that few index episodes corresponding to ICU stays, sepsis, delirium or other conditions of interest for these Awardees would also entail planned readmissions. Similarly, nine of these programs do not follow a panel of patients over time (the exception being the University of Chicago program) and provide no ambulatory care; thus, ambulatory care sensitive admissions and readmissions are not relevant.

1.3.8 Claims Run-Out

It is important to allow time for most providers to submit claims, to avoid bias stemming from differential timeliness of claims submission (e.g., for-profit hospitals submitting claims more quickly than teaching hospitals). For each outcome measure based on claims, we must therefore specify the claims run-out time we will allow to elapse before reporting the measure.

- Claims run-out for utilization, length of stay, and discharge destination measures is **three months**.
- Claims run-out for 60-day total episode spending is **six months**, to allow time for claims to be submitted from post-acute settings.

Exhibit 8 displays these episode lengths, and the associated claims run-out periods that elapsed for each, in preparation of this report. Data presented in this report contain a full three-month run-out on claims to calculate the inpatient LOS, 30-day post discharge ED visits and readmission outcomes for episodes that begin in the first five months of the annual reporting period. We allow a 6-month run-out period for the Medicare episode spending measures, because of delays as post-acute providers submit claims, and in maturity of Part B claims. Episodes that began in the first two months of the annual reporting period will have a full six-month run-out and be included in the episode spending measure for the annual report.

Exhibit 8: Episode Duration and Claims Run-Out Intervals

<table>
<tr><th rowspan="2">Measures</th><th colspan="12">Months</th></tr>
<tr><th>1</th><th>2</th><th>3</th><th>4</th><th>5</th><th>6</th><th>7</th><th>8</th><th>9</th><th>10</th><th>11</th><th>12</th></tr>
<tr><td>60-day post-discharge total episode costs</td><td colspan="2">Episode</td><td colspan="6">Claims run-out and SSA death notices/dates</td><td colspan="2" rowspan="4">Receive patient lists from Awardees; create analytic files; specify intervention and comparison groups</td><td rowspan="4">Diff-in-Diff regression analyses</td><td rowspan="4">Annual Report</td></tr>
<tr><td>30-day post-discharge readmissions</td><td colspan="2">Episode</td><td>Episode</td><td>Episode</td><td>Episode</td><td colspan="3">Claims run-out</td></tr>
<tr><td>30-day post-discharge ED visits</td><td colspan="2">Episode</td><td>Episode</td><td>Episode</td><td>Episode</td><td colspan="3">Claims run-out</td></tr>
<tr><td>Inpatient LOS</td><td colspan="2">Admissions</td><td>Admissions</td><td>Admissions</td><td>Admissions</td><td colspan="3">Claims run-out</td></tr>
</table>

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

Appendix A contains detailed specifications for measure creation, including definition of Index Admissions (or events), creation of core measures, and in a few necessary cases, deviations from core measure specification for specific Awardees. Appendix A also contains specifications for dependent and independent variables used in the regression models that we employ to estimate Awardee-specific intervention effects, along with special considerations for Awards that span more than one geographical region, and estimation of standard errors.

1.3.9 Primary Data Collection and Analysis

Case Studies

In-person case studies were completed with all Awardees in early 2014, and in-person or virtual follow-up case studies were completed in early 2015, prior to the conclusion of each Award.[5] For the largest Awardees, case studies included several partner organizations or sites (e.g., we visited three of the many hospitals participating in the Dartmouth sepsis program). Qualitative data collection focused on the implementation process; impacts on staff workflow and workload; perceived impact on quality, efficiency and other outcomes; any unintended consequences; staff satisfaction with the program; and the potential for sustainability and spread.

A unique codebook was developed for each Awardee, and qualitative data were coded using NVivo. The coding scheme aligned with the topics addressed during case studies, and was tailored to match Awardee-specific, or interviewee role-specific, topics and probes. Information was coded at the most specific theme, and could be coded at more than one theme. The two researchers who participated in an Awardee's case study reviewed the content of all the coded themes to check for inconsistencies, redundancies and imprecision. Analysts were trained to implement the coding structure for all interview and focus group notes and recordings. Data were analyzed by aggregating at the theme level and by type of participant.

The case studies were designed to illuminate specific issues for each Awardee, and the individual respondents and topics addressed vary accordingly. Analyses are therefore within-Awardee, and results are not pooled across Awardees. This report does, however, contain cross-cutting themes from case studies that apply to most or all of the Hospital Setting Awardees.

1.3.10 Evaluation Challenges

Evaluability

As discussed above, each of these 10 Awards posed distinct evaluation challenges related to size, heterogeneity among sites, changes in the intervention over time, ability to specify reasonably similar comparison groups, and other factors. Exhibit 9 below identifies important evaluability issues for each Award.

In addition to these Award-specific evaluability challenges, other challenges were encountered universally, due to the dynamic nature of change in the hospital sector in recent years, in response to other CMS initiatives:

- Hospitals nationwide, including those in our intervention and comparison groups, are involved in other CMS initiatives (e.g., Accountable Care Organizations, Bundled Payments) that also contribute

[5] Six Awardees received No Cost Extensions for 6-12 months, and we will continue to analyze their claims data.

to outcomes such as readmissions and Medicare episode spending. For example, all hospitals are responding to CMS's Readmission Reduction program. With a DD evaluation design, the HCIA Awardees would need to substantially exceed the efforts of their peers in order to demonstrate a statistically significant reduction in readmissions.

- State Medicaid initiatives, other payer initiatives, quality improvement programs, and other external factors also affect intervention and comparison hospitals. For example, sepsis detection and treatment is a widespread hospital emphasis due to recognition of sepsis as a leading cause of in-hospital mortality, and the efforts of CMS's Hospital Engagement Networks and other quality improvement initiatives. The two HCIA sepsis programs would need to substantially exceed the efforts of their peers in order to demonstrate statistically significant impact on outcomes of sepsis care.

Exhibit 9: Evaluability Challenges, by Awardee

--	Heterogeneity across study sites?	Changes in primary components of the intervention over time?	Claims-based specification of intervention and comparison groups possible?	Powered DID regression approach possible?
Christus St. Michael's	New staff at nursing homes are not being trained and attrition is diminishing the program at nursing homes. Also heterogeneity in use of the IT tool	No	No matching needed, all patients are supposed to be screened daily	No, program too small to ever have powered tests of statistical significance
Dartmouth	Screening may be accomplished differently at each study site; care bundle interventions are consistent at all sites. Data collection/reporting varies	No	Yes, although incomplete patient registry data makes it impossible to know the accuracy of our specified intervention and comparison groups	Not yet, intervention too small for tests of statistical significance
Emory University	Telemedicine support available in some ICUs but not others; first smaller community hospital beginning in 2014	Yes, newly trained staff are added at various times; telemedicine component added in some but not all ICUs, smaller community hospitals added,	Yes, well-matched	No
Henry Ford	Only one study hospital, although several different units involved	No	No, claims data contain insufficient clinical detail to specify intervention or comparison groups	No
Mayo Clinic	Implementation at partner sites is delayed; tool may not be identical at every site, due to underlying differences in electronic health record (her) and other technologies	No, although the tool continues to evolve	Yes, moderate match with some bias likely	Not yet, intervention too small for tests of statistical significance
Methodist (delirium)	No	No	Yes: strong match for screened population; match more moderate for at-risk population	Yes

--	Heterogeneity across study sites?	Changes in primary components of the intervention over time?	Claims-based specification of intervention and comparison groups possible?	Powered DID regression approach possible?
Methodist (sepsis)	Yes, Sites include hospitals, long-term care hospitals (LTCHs) and skilled nursing facilities. Also, implementation throughout an entire facility is staged and takes several months	No	Yes, strong match with minimal bias	Yes
Mt. Sinai	Specific intervention components vary considerably at the three emergency departments in three states.	Multiple, evolving intervention components over time.	No matching needed—all ED patients exposed to intervention.	Yes.
St. Luke's	Yes, Intervention includes ICU at most sites, ED at small critical access hospitals (CAHs).	Yes, ED component added in CAHs.	Yes, well-matched.	No, program too small for tests of statistical significance.
University of Chicago	No, only one study hospital.	Yes, community recruitment added patients who did not have a hospitalization; home visiting component was be added.	Yes, Awardee randomly assigned patients to intervention and comparison groups.	No, program too small for tests of statistical significance.

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

2. Cross-Awardee Findings

This chapter contains cross-Awardee findings based on case studies, and cross-Awardee findings based on quantitative analyses.

2.1 Qualitative Findings

A number of cross-Awardee themes were identified during the 10 case studies conducted in 2014 and 2015. Exhibit 10 shows these common themes, and each theme is described in detail below.

Appendix B contains a detailed case study report, as well as results of quantitative analyses for each Awardee.

2.1.1 Implementation Effectiveness

Program staff explained to Abt qualitative researchers that most of these programs were not conceived for the purposes of eliciting federal funding. **Innovations were generally pre-existing, promising ideas for which design/planning/implementation had already begun; HCIA funding provided the impetus to accelerate, or expand, implementation at the funded sites.** For example, the St. Luke's program staff reported that they had completed much of the design phase and were poised to start, with a longer roll-out trajectory and fewer sites, and that HCIA funding was used to accelerate implementation and expand the program's eICU network. We also learned during a case study that the Mt. Sinai ED program had been operational in one of the three sites for several years prior to the Award, while the other two sites used HCIA funding for implementation.

Awardees varied in the amount of pilot testing completed prior to the HCIA. **Awardees that conducted extensive pilot testing of their innovations before HCIA funding told us that this early experience helped them modify innovations/systems to address known impediments,** setting the stage for successful implementation during their HCIA Awards**.** In contrast, Awardees with less extensive (or no) pilot testing of the innovation before Award shared their experiences of obstacles and delays in implementing innovations.

Programs benefited from phased implementation of innovations. Those that started small, or were implemented in one unit or facility prior to expansion, identified and addressed challenges on a smaller scale. Innovations could then be rolled out to additional sites with solutions already in place. For example, the Methodist Delirium program pharmacists explained that they adjusted automated medication order sets in their main hospital and addressed physician concerns there, before altering order sets in other participating hospitals.

Programs benefited from using a care process redesign and continuous quality improvement, whether a formal approach such as Lean Six Sigma, or an informal care redesign process. A deliberate problem identification and system redesign process aided the implementation of several innovations, notably Dartmouth's sepsis program, where clinical staff described both the Lean process and the specific improvements that resulted.

Exhibit 10: Cross-Awardee Qualitative Themes & Lessons Learned from 10 Case Studies

Themes Identified During Case Studies	Christus	Dartmouth	Emory	Henry Ford	Mayo Clinic	Methodist-Delirium	Methodist-Sepsis	Mt. Sinai	St. Luke's	University of Chicago	# Awardees with This Theme
Implementation Effectiveness											
Innovation design/test/implementation began before HCIA Award	X	--	X	X	X	X	--	X	--	--	6
Extensive pilot testing conducted	--	--	--	--	X	X	X	--	--	--	3
Program rolled out in phases	--	--	X	X	X	X	X	X	X	X	8
Innovation developed with a formal or informal care redesign process	--	X	--	--	--	--	X	--	--	--	2
Program Effectiveness											
Innovation promotes clinical guidelines, often by automating order sets and best practice alerts	X	X	X	--	X	X	X	X	X	--	8
Local champions garner clinician buy-in support and institutional support	X	X	X	X	X	X	X	X	X	X	10
Mandatory participation in innovation	--	X	--	X	--	X	X	--	X	X	6
Technology innovation is complicated by integration with EHR and other HIT	X	X	X	--	X	--	--	--	X	--	5
Adoption is facilitated by being embedded in clinical workflows	--	X	--	X	X	X	X	X	X	X	8
Workforce Development											
Training continues to occur and evolve; performance feedback promotes innovation	--	X	X	X	X	X	X	X	X	X	9
Training is adjusted for skill sets of target staff	X	X	X	X	--	X	X	X	X	X	9
Ongoing training targets float staff and residents	--	--	X	X	X	X	X	--	--	--	5
Simulation labs used as a training modality	X	--	X	--	--	--	X	--	--	--	3
Staff are empowered when challenged to work at the top of their licensure	--	X	X	X	X	X	X	X	X	X	9
Recent grads & new hires are among early adopters	X	--	X	X	--	--	X	--	--	--	4

Themes Identified During Case Studies	Christus	Dartmouth	Emory	Henry Ford	Mayo Clinic	Methodist-Delirium	Methodist-Sepsis	Mt. Sinai	St. Luke's	University of Chicago	# Awardees with This Theme
Contextual Factors											
Leadership demonstrates commitment and holds staff accountable	X	X	X	X	X	X	X	X	X	X	10
Succeeding beyond expectations	--	--	--	--	X	--	--	X	--	--	2
Sustainability and Spread											
Sustainability enhanced by integration into existing technology, staffing and practices	--	X	X	--	X	X	X	X	X	--	7
Spread is harder for programs with complex information technology	--	--	X	--	X	--	--	--	X	--	3
Impact											
Clinicians believe that innovation is improving care and improving health	X	X	X	X	X	X	X	X	X	X	10
Innovations explicitly intended to enhance efficiency or reduce cost for the institution	--	X	X	X	X	--	--	X	X	X	7
Partner communications to implement an Innovation also enhance care coordination	X	X	X	No partners	--	X	X	X	X	No partners	7

Source: Abt Associates analysis of Hospital Setting Awardees, July, 2015.

IT challenges were extreme for multi-site programs, especially when hospitals and their partners did not share an EHR. In several programs, IT challenges delayed start-up (Emory's eICU), or prevented or delayed spread to partner sites (Mayo Clinic, St. Luke's); or the innovation could not be integrated with EHRs, necessitating redundant data entry (Christus, Methodist Sepsis). Delays, and incomplete or inefficient implementation at partner sites, further reduced the potential for measurable impact in smaller programs.

2.1.2 Program Effectiveness

Continual communication fosters relationships between different kinds of staff (e.g., physicians, nurses, aides), and those at different institutions. Most Awardees explained that they hold regular in-person, interdisciplinary meetings with their program and clinical staff. For example, the University of Chicago's program holds daily interdisciplinary rounds, focused on patients with scheduled appointments as well as those in the hospital. When multiple sites were involved, most Awardees convened regular phone or in-person contact between sites or participating units during the implementation period. All levels of staff reported that the strength of these relationships supported feedback about the interventions to program leadership and rapid improvement, which in turn facilitated adoption. Communication needs changed over time in many programs. For example, the pharmacy component of the Methodist Delirium program required extensive communication and education by pharmacy leaders at the main hospital when order sets and formularies were being modified, but once physician buy-in was achieved and new order sets were in place, there was less need for involvement by pharmacy leaders.

Many innovations promote adherence to evidence-based clinical guidelines, often by automating order sets and creating best practice alerts within their electronic information systems. Program staff at several Awardees reported that adoption is enhanced when innovations derive from evidence-based guidelines, in part because clinician buy-in is so essential to adoption. To foster consistency and monitor adherence, these guidelines are often implemented electronically. For example, the St. Luke's and Emory eICU software programs alert nurses when patient vital signs and other trends begin to deviate from norms, and when best practice guidelines suggest different treatment is needed. The Mayo Clinic ICU innovation, which we observed in use, reminds clinicians to follow guideline-recommended practices.

Mandating participation in the innovation or use of new technology, and monitoring adherence, facilitated adoption. For example, the Methodist Sepsis program mandates sepsis screening and holds the nurses on each unit accountable by monitoring adherence. St. Luke's intensivist physicians are so convinced of the enhanced safety of the eICU, especially at night, that they told us they will no longer "cover" the patients of attending physicians at night unless those physicians agree to rely on the eICU (i.e., bedside staff call the eICU at night, not the attending physician). Other programs, where participation was not mandatory (e.g., Christus, Mayo Clinic), experienced less complete adoption by clinicians.

The role of senior physician champions is essential in serving as liaisons between program leadership and front-line clinicians. In most of these Awards, leadership by a highly respected senior physician was described by other staff and by hospital executives as being essential in establishing credibility with other clinicians, and garnering institutional backing and resources.

New tools are more likely to be adopted if they are carefully designed to align with clinician workflows. Many Awardees encouraged clinicians to adapt an innovation to make it more useful and useable in practice. For example, the Methodist Delirium program allows staff to use the innovative

screening tool for a broader set of patients than originally planned, so that nurses do not have to decide which patients qualify.

Technology challenges related to compatibility, cost, and infrastructure have been and remain significant barriers to implementation. During case studies we learned of many technology challenges, some of which remain only partially resolved. Upgrades of vendor EHR products caused redesign of innovative applications in a number of Awardee facilities; limited internet connectivity in rural areas required additional contractual arrangements with service providers for Emory's rural partners; and hospitals without enterprise EHRs devised semi-manual approaches to integrating information from multiple sources for the Dartmouth sepsis intervention. Program staff acknowledged that many of these technology challenges were not fully appreciated in the planning phase prior to HCIA Awards, and that solutions have required more technology and IT staff resources than anticipated.

Strategies that Awardees reported to address challenges in implementing a new technology include:

- Rolling out new technology in phases, and/or extensive pilot testing. Adding new technology to partner sites was often smoother after the kinks were worked out in the main site.
- Ensuring partner sites have sufficient local IT support and infrastructure prior to implementing technology. Several partner site implementations were delayed or incomplete due to inadequate technology or an inability to integrate information across institutions.
- Investment (with program funds) in partner sites to facilitate successful rollout of innovation investment can include training, IT support, administrative support and clinical expertise. For example, St. Luke's paid for eICU equipment for rural partner sites, and these sites readily implemented the intervention. In contrast, Emory leadership believes that rural hospitals will feel more ownership if they purchase their equipment, but fewer partners have made this financial commitment.
- Integrating new technology with existing IT systems to avoid redundant data entry and errors, and to facilitate adoption of technology into clinical workflows. Several Awardees (Dartmouth, Emory, St. Luke's, Mayo Clinic) continue to struggle to implement innovative technology solutions—and collect data—across the diverse and incompatible EHR systems used in their study sites.

New information technologies may also engender new safety concerns. For example, the Mayo Clinic IT tool presents information in a more focused way that supports prioritization of patient needs. However some of the data in the tool are updated only one or twice in 24 hours. Medications change frequently for many ICU patients, and to avoid adverse events, clinicians must also remember to check the EHR for the most current medication information. For another example, one of Emory's small community hospital partners does not have an EHR, and there is no electronic "hand-off" to the eICU at night—the eICU staff has no information about the patients in that 14 bed ICU. When an eICU physician needs to read a chart, the bedside nurse tries to hold the paper chart up to the camera, but this is very difficult to read and is time-consuming; important information can be delayed or missed.

2.1.3 Workforce Development

Training continues to occur and evolve as more is learned from program implementation. Educators and trainers at most Awardees explained that feedback from staff is incorporated into on-boarding and continued education opportunities. For example, a shadowing component was added at both the St. Luke's and Emory eICU programs, and is viewed as integral by bedside nurses, who were able to see

the eICU and understand the added value it provides. In most (but not all) Awardees, performance feedback is disseminated regularly to clinical staff; where it is not, clinical staff reported that they would appreciate more feedback to understand whether they are succeeding.

Training is most effective when adjusted for the skill sets of targeted staff, to optimize retention of information and overall value. For example, the training of home health aides for the Methodist Delirium program was initially longer and more clinically in depth, but program staff told us that after receiving feedback from the early trainees, they adjusted the training program to be shorter and more focused on tasks performed by the aides.

New responsibilities challenge clinicians to practice at the top of their degree/certification, leading to feelings of empowerment and enhanced mutual respect among members of care teams, in many settings. For example, the Emory critical care physicians' assistant (PA) and nurse practitioner (NP) residents write orders and perform many procedures that would otherwise be the responsibility of physicians; both physicians and bedside nurses stated that they value this higher competency level of the PAs and NPs.

Training is more comprehensive if it includes float staff and residents. Ensuring that all staff have current information about an innovation, and know where to turn for help, can be accomplished in many ways, including identification of "super users" who are available to provide assistance; posters; and newsletters. We observed that many Awardees display such program materials in work areas, to remind float staff, residents and other new personnel. Some programs also integrated components of training into their regular training for all staff, and/or orientation for new clinical staff, so that all everyone receives program-related training.

Simulation laboratory training is highly valued by staff and considered to be a very effective training modality. Clinical staff enthusiastically reported that the intensive, highly focused, hands-on simulation exercises are an effective training tool, especially when simulations include interdisciplinary role playing. This was especially true for the Christus training program, through which nurses' aides learned to assess patients for signs of emerging high-risk conditions.

Training must be offered to new employees, especially in settings with high staff turnover. Nursing homes in particular have high turnover and the value of even an excellent training program will wane over time unless it is incorporated into new staff orientation training. For example, staff in the nursing homes participating in the Christus program were enthusiastic about the initial training. Opportunity for new staff to receive the same training was, however, minimal, and with turnover of more than 50 percent thus far, most staff currently working in these nursing homes did not experience the training.

Recent graduates and new hires may be more open to adopting innovations. Clinical leaders explained that new staff are still learning care delivery processes, so are more able to integrate an innovation into their workflow. New graduates may also be more comfortable with IT innovations and more accepting of clinical guidelines, as both are now integral components of clinical training programs.

2.1.4 Contextual Factors

During several case studies we learned that most of the HCIA innovations require clinicians to add one more thing to their busy workflows. As a result, clinicians need to be convinced that an innovation will be effective and that leadership is committed to implementing and sustaining the innovation. As one nurse advised, "we need to know that this not just the flavor of the month." With many competing initiatives in

any large hospital, **leaders succeed by demonstrating commitment and holding staff accountable for adopting the intervention.**

Succeeding beyond expectations creates a challenge for some Awardees: an innovation is so readily adopted that it cannot meet the demand for its services. For example, the Mt. Sinai geriatric ED is so popular among clinical staff and patients that the small dedicated space and staff cannot serve every older adult patient. Selection criteria were implemented to ensure that patients who will benefit most are admitted to this special ED. In another example, the Mayo Clinic ICU innovation is popular among many intensivist physicians, who are using it in other ICUs beyond the four where it is being formally tested.

2.1.5 Sustainability

Programs that integrate their innovation into existing technology, practice, staffing, and workflow may be the most likely to continue. Some programs will be sustained because they have become the "new normal" and are accepted practice in their institutions (e.g., the Dartmouth and Methodist Sepsis programs), and clinical staff report that they will not remove electronic order sets and trigger tools, or revert to previous practices. Other programs, especially those that hired new staff to reduce patient-staff ratios or add new skills to the care team, will likely require continued financial investment by the host institution or additional grant funding (e.g., Henry Ford Hospital mobility aides, Methodist Delirium home health aides, Mt. Sinai's GERI-ED staffing). During follow-up case studies in 2015 we learned that some programs plan modifications to reduce the need for additional staff and to support sustainability. For example, Methodist Delirium program staff plan to continue the delirium screenings and modified order set functions of their program, but will reduce services offered through the home aide component.

All Awardees plan to sustain the innovation in some capacity, and Awardees are fine-tuning their innovations by 1) modifying the target population or intent of the innovation, 2) integrating the innovation into staff workflows, and 3) changing workforce composition.

1) Examples of changing target population or innovation intent:

- Christus is modifying the purpose of the Integrated Nurse Training and Mobile (INTM) Program screening tool to be used during rounding by nursing staff, rather than as a reference guide for use when patients' symptoms change.
- Several High Value Healthcare Collaborative members involved in the Dartmouth sepsis initiative members are spreading the sepsis care bundle innovations to general medical units and outlying community hospitals.
- Mt. Sinai program staff are integrating some components of the intervention into the overall ED process for improving care transitions.

2) Examples of integrating the innovation into staff workflows:

- At Henry Ford Hospital mobility services will be incorporated into the work of Certified Nursing Assistants, rather than continuing to fund mobility aide positions.
- The Methodist Delirium screening tool is now fully integrated into the workflow of nurses, and medication order sets have been changed to limit the potential for physicians to prescribe medications that increase patient risk for delirium.

- At the three HVHC members we studied, revisions to trigger tools, order sets, and hand-off protocols are now permanent in the EDs and ICUs.

3) Examples of workforce changes:

- University of Chicago plans to increase their administrative staff to support patient care coordination as the patient population expands, and to expand behavioral health services.
- Emory has a need for additional staff in the eICU to monitor remote sites as the program expands; they will most likely add an FTE Affiliate Provider in the eICU to allow the eICU physicians to concentrate on patients with more-complex medical issues.
- The community hospitals participating in the Methodist-Sepsis program will use charge nurses as second-level responders instead of Acute Care Advanced Practice Nurses, due to workforce shortages.

Sustainability of workforce training programs. Most Awardees plan to continue offering training to new staff during annual core competency training, and/or new staff orientations.

- Christus program staff intend to train hospital clinicians using the simulation laboratory, and hope to offer partner nursing homes training opportunities for new staff, on a small scale.
- At Henry Ford Hospital, Certified Nursing Assistants (CNAs) will receive abbreviated training on mobility assistance, while wound care nurse training will be maintained at the current level.
- Methodist Sepsis program staff will continue current training, Kindred LTC will provide simulation laboratory training for second-level responders, and contractual relationships are being negotiated to develop train-the-trainer modules for other post-acute care sites.
- The three HVHC members we studied that are participating in the Dartmouth sepsis program have all incorporated training on the sepsis program and tools into mandatory annual competency training for ED and ICU staff.
- The Affiliate Care provider training program will continue at Emory. Emory has added a requirement for those who complete the program to commit to working at an Emory hospital upon graduation, or provide payment for their residency education if they leave Emory.
- Methodist Hospitals now offer training on the delirium assessment to new nurses during their orientation, to ensure that all nurses are trained to assess patients.

2.1.6 Spread

Exhibit 11 displays the Awardees that intended to spread their innovations to multiple partner sites during the original project period. We identified several factors that were significant facilitators and/or challenges for spreading innovations to new facilities or sites, as indicated in the Exhibit.

Exhibit 11: Facilitators and Challenges in Spreading Innovations to Participating Partner Institutions*

Themes Identified During Case Studies	Christus	Dartmouth	Emory	Mayo Clinic	Methodist-Delirium	Methodist-Sepsis	Mt. Sinai	St. Luke's
Innovation Characteristics								
Improves care efficiency	--	A	A	A	A	C	A	A
Promotes guideline-based care	A	A	A	A	A	A	A	A
Enhances provider communication	A	A	A	A	A	A	A	A
Successfully implemented at prime site	B	N/A	A	A	A	A	A	A
Embedded in workflow	B	A	C	--	A	A	--	C
Enhances job satisfaction	A	A	C	--	A	A	A	A
Transfer Site Contextual Factors								
Senior leadership support and commitment	C	A	A	C	A	A	A	--
Local champions promote adoption	C	A	A	C	B	A	A	A
Mandatory staff participation	B	A	--	C	A	A	--	A
Culture of innovation	--	A	--	--	B	--	A	--
Sufficient implementation resources	A	A	C	C	--	C	A	--
Sufficient assistance from prime site	A	N/A	C	--	A	A	A	A
Transfer Site Workforce Factors								
Sufficient staff to implement	--	C	C	--	B	C	C	B
Sufficient staff time for training	C	A	A	C	A	A	--	--
Training tailored to the staff members' job	A	A	A	--	A	A	A	A
Training provided to all appropriate staff	C	A	C	C	C	A	--	A
Transfer Site Technological Factors								
Compatible with existing IT systems	B	C	C	C	B	C	--	B
Sufficient IT infrastructure	--	C	C	C	B	C	--	B
Sufficient IT staff or vendor support	--	C	C	C	B	C	--	B

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

*University of Chicago and Henry Ford Hospital did not have partner sites and are not shown in the exhibit.

A = Consistent facilitator of transfer to partner sites

B = Consistent challenge (either prevented or delayed implementation) to successful transfer to partner sites

C = A facilitator of transfer at some sites and a challenge to transfer at some sites

Some characteristics, if present, greatly support spread of an innovation to partner facilities. **If the innovation is shown to be a significant improvement in practice by promoting guideline-based care or improving efficiency, partners are more willing to adopt the innovation** in hopes of achieving the same results. In addition, the ability of an innovation to improve communication among clinical staff, or improve staff satisfaction with their jobs, substantially aids in spreading the innovation.

Other characteristics of innovations posed consistent and ongoing challenges, and **many partner facilities struggled with technological issues when attempting to adopt innovations**. St. Luke's was able to bring the eICU to other ICUs in its hospital system, but certain components were not transferable to small rural hospitals due to EHR differences (or absence), or lack of internet connectivity. They also found that IT support teams did not always have the capacity to respond to compatibility issues, or took longer than expected to implement solutions. Methodist Delirium partner sites also struggled with compatibility issues, but were able to adjust the components of the intervention at each facility so that the innovation could still be adopted. Emory's partner sites do not all use electronic shift-change hand-offs, and some have no EHRs, giving the eICU physicians little information about the patients requiring their attention at night.

2.1.7 Perceived Impact: Better Care, Better Health for Populations, Smarter Spending Cost

Clinicians in all Awards are convinced that the innovations improve the quality and safety of care they provide to patients. Whether the emphasis is on supporting mobility to prevent complications, faster recognition and treatment of sepsis, reduced use of deleriogenic medications, improved physician oversight in ICUs overnight, attention to the specific needs of older and high-risk patients, or better information with which to make clinical decisions, clinicians in every institution we visited view their particular innovation as an improvement over prior practice.

Planning for and implementing some innovations requires new communication between staff in different care settings, which in turn fosters better care coordination. For example, the two Methodist programs and the Christus program include explicit communication between acute and post-acute care providers, to coordinate the care of patients who are transferred between care settings—communication that they described as having been lacking in the past.

Programs seek to either directly or indirectly improve efficiency, focusing on reducing ICU or overall length of stay, up-skilling clinical staff to fill roles that would otherwise require a more costly mix of clinicians, or improving the timeliness of care delivered in urgent/emergent situations. Thus far, improved efficiency is beneficial to the institutions involved, but does not translate to savings for CMS. Several programs focus on reducing length of stay, for example, and program staff acknowledge that this will not reduce costs for Medicare under the prospective payment system.

2.2 Cross-Awardee Quantitative Findings

2.2.1 Multivariate Difference-in-Difference Regression Analysis

Four programs are large enough that we are able to report with some confidence the results of multivariate DD analysis of total episode (60-day) Medicare spending, using data aggregated through Q3 2014 (Dartmouth, Mt. Sinai, and the Methodist Sepsis and Delirium Screening programs). The other six programs lack sufficient power to detect differences with confidence, but their results are also presented

in Exhibits 12-14.[6] We caution that the four core utilization outcomes have less variation within the outcome than does total Medicare spending, and it is likely that most of the results for utilization measures are underpowered.

Many of the Awards operated for at least a year before these analyses were conducted; Emory's was the only intervention with less than a year of data (Exhibit 12). Because Emory has fewer than four full quarters of results, we present these estimates as emerging trends that have the potential for statistical significance after more data accrue.

Exhibit 12: Number of Intervention Quarters by Awardee

Award	Intervention Quarters (Spending)	Intervention Quarters (Utilization)
Christus St. Michael's	5	6
Christus St. Michael's LTPAC	7	8
Dartmouth	7	8
Emory	2	3
Henry Ford	8	9
Mayo Clinic	5	6
Methodist Delirium	8	9
Methodist Sepsis	7	8
Methodist Sepsis LTPAC	5	6
Mt. Sinai	8	9
St. Luke's	11	12
University of Chicago	8	8

Although we see measurable program impact in the episode spending measure, most of these programs are small and the results are not statistically significant, yielding no change in Medicare 60-day episode spending (Exhibit 13). We estimate both the mean and median intervention effects to examine the impact on average episode spending, as well as spending for the median or "typical" patient. The average intervention estimate is influenced by outliers, while the median intervention effect is more representative of a standard patient treated by the intervention. The regression analysis includes both intervention and comparison patients; Exhibits 13 and 14 indicate the percentage that were from Awardee intervention facilities.

Mean and median results are the same for most Awards, but where they differ, this indicates that the average episode spending is influenced by unusually large or small cases (outliers). Additionally, due to

[6] Estimating average Medicare episode spending requires a six-month claims run-out period, rather than the three-month run-out used to create the utilization measures, due to claims submission lags from post-acute care providers. At the time of this report, spending estimates are available only through Q3 2014. For this reason, the analytic sample sizes for the cost regressions vary from the sample size from the regressions of the utilization outcomes.

large standard errors, point estimates that appear to be substantively quite different (mean vs. median) may not truly differ with any statistical confidence.

Estimated changes in episode spending are generally not significant, with one notable exception: the 60-day Medicare episode spending *increased* by an average of $1,494 (p<0.01) for patients treated in the LTPAC component of the Christus program. The significance level for this result is less than 1 percent, and we are therefore reasonably confident that this finding is different from zero. Our other results and qualitative research do not, however, help explain this increase in Medicare spending for the Christus program. The change in median episode spending was much smaller and insignificant, suggesting that the effect is primarily driven by higher-cost patients.

Exhibit 13: Episode Spending

Awardee	N (% Award Cases)	Spending			
		60-Day Total Medicare Spending			
		Mean		50th Percentile	
		DD Estimate	Standard Error	DD Estimate	Standard Error
Christus Acute	31,122 (70.1%)	-295.06	379.64	114.79	218.6
Christus-LTPAC	6,721 (57.6%)	**1,494.84*** **	618.33	732.47	795.09
Dartmouth	101,386 (30.9%)	47.00	348.18	64.70	414.28
Emory	19,457 (31.2%)	-1,279.91	794.81	-201.96	556.16
Mayo Clinic	50,206 (34.1%)	-51.24	560.88	**-1,010.55*** **	307.23
Methodist Delirium (screened)	185,329 (22.4%)	329.74	195.30	-54.72	114.21
Methodist Delirium (delirium prevention)	78,145 (27.4%)	87.42	279.60	24.32	190.58
Methodist Sepsis (screened)	375,817 (32.3%)	-82.69	131.01	53.07	47.34
Methodist Sepsis (received sepsis bundle)	34,637 (31.7%)	229.77	679.21	527.37	694.10
Methodist Sepsis LTPAC	97,572 (15.4%)	323.78	516.18	22.04	728.13
Mt. Sinai	326,614 (38.3%)	-85.34	111.47	33.95	22.89
St. Luke	21,510 (36.5%)	207.61	497.60	82.98	172.40
University of Chicago^	824 (51.3%)	1,199	3,753	2,129	1,764

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

***p<0.01; ^ refers to total spending per patient rather than spending per 60-day episode.

Exhibit 14 shows that the impacts of the programs on 30-day inpatient readmissions (or 30-day inpatient admissions for episodes that started in an LTPAC) are small, with most estimates indicating a change of less than two percentage points. Additionally, there are no statistically significant point estimates for any of the programs. Based on the most up-to-date data, it does not appear that any of the HCIA interventions are associated with changes in the rate of inpatient readmissions. The impact of the Awardee interventions on 30-day ED visits is slightly higher than for 30-day inpatient readmissions, but most results are statistically insignificant after pooling across all quarters. However, three programs did produce significant reductions in 30-day ED visits. The Mayo Clinic intervention is associated with an average reduction of 2.48 percentage points ($p<0.05$). The Methodist Delirium program is associated with an average reduction of 1.95 ($p<0.01$) among patients who screened positive for delirium, and 1.33 percentage points ($p<0.01$) among the entire screened population. The St. Luke's eICU program is associated with an average reduction in ED visits of 1.92 ($p<0.10$) percentage points. Exhibit 14 also shows little correlation between Awardee interventions and inpatient LOS. Point estimates are typically less than ¼ of one day, and most of the results are statistically insignificant. Several exceptions include the acute-care arm of the Christus program, which is associated with an average reduction in LOS of 0.22 days ($p<0.10$), and the Mayo Clinic intervention, which is associated with an average increase in LOS of 1.30 days ($p<0.01$). The Methodist sepsis and delirium screening populations are also associated with significant reductions in LOS of .17 ($p<0.01$) and .09 ($p<0.10$) days, respectively.

Exhibit 14: Hospital and ED Utilization; Inpatient Length of Stay

Awardee	N (% Award cases)	Utilization					
		30-Day Inpatient (Re)Admissions		30-Day ED Visits		Length of Stay	
		DD Estimate	Standard Error	DD Estimate	Standard Error	DD Estimate	Standard Error
Christus-Acute	32,108 (70.1%)	0.31	0.95	2.10	1.15	**-0.22***	0.12
Christus-SNF	6,937 (58.2%)	2.78	2.43	3.47	2.43	-	-
Dartmouth	106,456 (30.9%)	-0.26	0.64	-0.64	0.69	-0.18	0.17
Emory	20,231 (32.1%)	-2.18	1.54	0.39	1.74	-0.45	0.30
Mayo Clinic	51,977 (33.9%)	-0.53	1.09	**-2.48****	1.12	**1.31*****	0.24
Methodist Delirium (screened)	204,101 (27.1%)	0.54	0.41	**-1.33*****	0.42	**-0.09***	0.05
Methodist Delirium (at risk)	87,537 (32.5%)	0.53	0.58	**-1.95*****	0.59	-0.01	0.07
Methodist Sepsis (screened)	388,705 (32.3%)	0.32	0.26	-0.21	0.28	**-0.17*****	0.06
Methodist Sepsis (sepsis confirmed)	36,146 (31.6%)	-0.27	0.86	-1.03	0.88	0.12	0.19

Awardee	N (% Award cases)	Utilization					
		30-Day Inpatient (Re)Admissions		30-Day ED Visits		Length of Stay	
		DD Estimate	Standard Error	DD Estimate	Standard Error	DD Estimate	Standard Error
Methodist Sepsis-LTPAC	100,689 (15.2%)	1.32	0.92	0.54	0.85	-	-
St. Luke's	22,349 (36.3%)	-1.09	0.92	**-1.92***	1.12	-0.26	0.16
University of Chicago^	968 (51.2%)	-0.05	0.45	1.18	1.04	-	-

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

*p<0.1 **p<0.05 ***p<0.01

^-Inpatient readmissions and ED visits for patients in the University of Chicago program refer to total readmissions and ED visits since patient enrollment, rather than readmissions and ED visits within 30 days of a prior hospitalization.

Due to the unique ED-based nature of the Mt. Sinai intervention, the utilization measures analyzed vary from those for the other Awardees. The first measure is hospital admissions within 30 days of episode discharge. We also measure total (rather than binary) ED visits within 30 days of episode discharge, and the rate of inpatient admission directly from the ED. Exhibit 15 shows that the intervention at Mt. Sinai did not affect the rate of admissions to the hospital within 30 days after episode discharge, or total ED visits in the 30 days following episode discharge. However, the program is associated with a statistically significant 3.49 percentage point decrease ($p<0.01$) in the probability of admission to the hospital directly from the ED.

Exhibit 15: Mt. Sinai Utilization

Awardee	N (% Award cases)	Utilization					
		30-Day Post-Discharge Hospital Admission		Total 30-Day ED Visits		Inpatient Admission from ED	
		DD Estimate	Standard Error	DD Estimate	Standard Error	DD Estimate	Standard Error
Mt. Sinai	336,543 (38.4%)	0.18	0.29	0.01	0.01	**-3.49*****	0.42

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.

***p<0.01

The impact of the HCIA interventions on discharge destination following a hospital stay (Exhibit 16) varies across Awardees and is generally small. However, several programs have statistically significant results:

- The acute-care arm of the Christus program is associated with a 2.99 percentage point reduction ($p<0.01$) in the proportion of patients discharged to home health care. This is primarily driven by a significant increase of 1.54 ($p<0.05$) percentage points in the proportion of patients discharged to "other" care (which includes hospice, federal hospital, psychiatric hospital, etc.), suggesting that patients are shifting away from home health care to other, non-LTPAC settings.

- The Dartmouth program is associated with a significant 1.15 percentage point decrease ($p<0.10$) in the proportion of patients discharged to home health. About half of this change appears to be due to an increase in the proportion of patients discharged to other LTPAC settings, although this increase is not a statistically significant result.
- The Emory program is associated with a significant 2.88 ($p<0.10$) percentage point increase in discharge to home health. Over half of this change is due to a decrease in the proportion of patients discharged to other LTPAC settings, but this point estimate is not statistically significant.
- Patients screened for delirium at Methodist hospitals are 3.13 percentage points less likely ($p<0.01$) to be discharged home without additional home health care. This result is driven by a 2.00 percentage point increase ($p<0.01$) in the proportion of patients discharged to home health, and a 1.02 percentage point increase ($p<0.01$) in the proportion of patients discharged to "other" institutional settings (e.g., hospice, federal hospital, psychiatric hospital).
- Patients who screened positive and received treatment at participating Methodist Delirium hospitals are 2.51 percentage points less likely ($p<0.01$) to be discharged home with no additional care, and 2.81 percentage points more likely to be discharged home with home health care.
- The Methodist sepsis screening program is associated with a 2.34 percentage point decrease ($p<0.01$) in the proportion of patients discharged home without additional care. The majority of these patients shifted to "other" institutional care settings (e.g., hospice, federal hospital, psychiatric hospital) (1.85 percentage point increase, $p<0.01$), or to home health care (1.01 percentage point increase, $p<0.01$).
- Among screened patients at Methodist hospitals who had sepsis coded on their claims, we estimate a 1.62 percentage point decrease ($p<0.10$) in the proportion of patients discharged home. None of the point estimates for the other possible destinations are statistically significant.
- We estimate a statistically significant decrease of 5.38 percentage points ($p<0.01$) in the proportion of patients discharged directly home for the Mayo Clinic program. This is primarily driven by a statistically significant 3.01 percentage point increase ($p<0.01$) in the proportion of patients discharged to "other" institutional settings (e.g., hospice, federal hospital, psychiatric hospital).

Exhibit 16: Discharge Destination

Awardee	N (% Award cases)	Discharge Destination							
		Home		HH		SNF/IRF/LTAC		Other	
		DD	SE	DD	SE	DD	SE	DD	SE
Christus-Acute	32,108 (70.1%)	0.09	1.26	**-2.99*** **	0.88	1.36	1.21	**1.54** **	0.71
Dartmouth	106,456 (30.9%)	0.14	0.73	**-1.15***	0.61	0.62	0.81	0.39	0.50
Emory	20,231 (32.1%)	-0.78	1.87	**2.88***	1.68	-1.86	1.50	-0.24	1.09
Mayo Clinic	51,977 (33.9%)	**-5.38*** **	1.23	0.22	1.06	2.15	1.33	**3.01*** **	1.01

Awardee	N (% Award cases)	Discharge Destination							
		Home		HH		SNF/IRF/LTAC		Other	
		DD	SE	DD	SE	DD	SE	DD	SE
Methodist Delirium (screened)	204,101 (27.1%)	**-3.13*** **	0.54	**2.00*** **	0.44	0.11	0.51	**1.02*** **	0.30
Methodist Delirium (at risk)	87,537 (32.5%)	**-2.51*** **	0.74	**2.81*** **	0.63	-0.41	0.75	0.11	0.41
Methodist Sepsis (screened)	388,705 (32.3%)	**-2.34*** **	0.34	**1.01*** **	0.25	-0.53	0.29	**1.85*** **	0.19
Methodist Sepsis (sepsis confirmed)	36,146 (31.6%)	**-1.62***	0.96	0.28	0.71	0.54	1.14	0.80	0.75
St. Luke's	22,349 (36.3%)	0.00	1.35	0.78	0.92	0.04	1.27	-0.83	0.55

Source: Abt Associates analysis of Hospital Setting Awardees, July 2015.
*p<0.1 **p<0.05 ***p<0.01

Appendix B contains Award-specific results, through Q4 2014 for utilization measures, and through Q3 2014 for Medicare 60-day episode spending. Below, we note results of interest that will be investigated further, along with all others, with additional data in future reports:

- The Emory University eICU program had a delayed start and we have just 2-3 quarters of intervention data for outcomes analyses. Although not yet statistically significant, DD estimates suggest that total episode spending, 30-day inpatient readmissions, and length of stay are all decreasing for patients treated at Emory's participating hospitals relative to those treated at comparison hospitals. The consistency of the encouraging outcomes across the board suggests improvements attributable to the program that we are not yet able to detect with statistical precision.
- For the Mayo Clinic program, pooled DD results indicate that inpatient LOS is significantly higher, but post-discharge ED visit rates are significantly lower, as a result of the intervention. Intervention patients are also less likely to go directly home without home care, relative to the comparison group. There is no statistical difference in the average Medicare episode spending, but we estimate a median spending reduction of approximately $1,010 dollars. This suggests that the program has been more successful in reducing costs for the "average" patient than for those at the higher end of the cost distribution. More analyses and further quarters of data are needed to determine the impact of the intervention on the episode cost distribution.
- For the Mt. Sinai GERI-ED program, pooled DD results indicate a significant decrease (3.48 percentage points) in the rate of admissions to the hospital from the ED, which was a main goal of the program. We do not see evidence of reduced hospital admissions overall, reduced ED use overall, or reduced Medicare episode spending, possibly indicating that while program staff are able to attend to patients' needs in the ED, the intervention delays but does not prevent subsequent utilization.
- Based on pooled DD results, the St. Luke's eICU program is associated with a statistically significant reduction in 30-day ED visits.

We caution that these results, and all the others showing no program impact, are conservative given the imperfect matching between claims and patient registry data. They are based on small quarterly sample sizes that are insufficient to determine statistical significance. Results will change as additional quarters of data are added to future reports.

3. Conclusions and Next Steps

3.1 Synthesis of Qualitative and Quantitative Findings

Based on data through Q4 2014, and complete multi-year case studies, the following summarizes cross-Award results.

Clinical and operations staff in all programs report that their programs are improving patient care. They are less convinced that this will in turn yield savings to Medicare, and this is confirmed with preliminary quantitative analysis. For example, a major efficiency target for many of these programs is reducing LOS, and we see evidence that reductions are occurring in five programs, although this reduction is thus far statistically significant in only three programs (Christus, and the two Methodist hospital programs). Reductions in LOS, however, yield no savings to Medicare for services reimbursed under the Medicare prospective payment system, because payment is per admission not per day, and the reduced LOS therefore does not translate to reduced Medicare episode spending. Other efficiency enhancements cannot be observed using claims data (e.g., fewer ventilator days, different staffing mix) and would not contribute to Medicare savings.

To put it another way, the following are examples of improved quality that do not appear to be increasing Medicare spending:

- Bedside staff in both the St. Luke and Emory University eICU programs report that the ability to continue intensivist physician-directed care during the night shift, rather than delaying procedures until morning (e.g., extubations), contributes to fewer days of sedation and ventilation, shorter length of stay in the ICU, and possibly shorter LOS for the entire admission. In both programs we see declines in LOS that are not significant, but if the trend continues in future quarters our analyses may reach statistical significance. We see no increase in Medicare episode spending for either program.
- ED staff are committed to the Dartmouth sepsis innovations, and their institutions have invested in new IT programming (trigger tools), and changes in laboratory and pharmacy procedures, which will continue to be supported. These improvements have not, however, resulted in measurable changes in LOS or Medicare episode spending.
- In the two Methodist Hospital innovations, program staff report that careful screening often reveals underlying patient needs that perhaps would have been missed in the past (and in comparison facilities), unrelated to sepsis or delirium. These newly recognized needs may be contributing to an increase in discharges to home health care or other post-acute services, rather than discharges to home without such services. The added costs of post-acute services may in part be balanced by fewer ED visits in the weeks following discharge, and we see no increase in Medicare episode spending in these programs.
- The Mt. Sinai program offers selected older patients additional social services and supports, and enhanced attention to chronic conditions, which appear to delay the need for hospitalization. After patients leave the ED, however, program impact wanes and there is no overall reduction in hospital admissions, subsequent ED visits, or Medicare episode spending.

Our qualitative research indicates that several programs have achieved important goals that cannot be verified using quantitative analyses. For example, the primary goal of Emory's program is to bring providers with critical care training to ICUs and shifts that lack this resource. Through training of PAs

and NPs in critical care, supported by an eICU physician on the night shift, this goal was met. The Mayo Clinic AWARE program was quickly adopted by most Mayo Clinic ICU physicians because it reduces cognitive overload, focuses their attention on the most pressing patient needs, and improves communication—all important goals of the program. The University of Chicago program offers better access for patients, including a "hotline" and same-day appointments, which are important program goals.

Finally, IT challenges were extreme for multi-site programs, especially when hospitals and their partners do not share an EHR. Health Information Exchanges are not supporting any of these programs, except a small contribution in one of the three Mt. Sinai ED locations. Both eICU programs (Emory and St. Luke's) faced IT challenges with their smallest participating hospitals, which have not been entirely overcome. In several programs, IT challenges variously delayed start-up (Emory's eICU), prevented or delayed spread to partner sites (Mayo Clinic, St. Luke's), or could not be integrated with EHRs (Christus). Delayed or incomplete implementation at partner institutions further reduced the potential for measurable impact in these small programs. Some of these IT challenges have been overcome, and no-cost extensions may give some Awardees time to overcome challenges and generate measurable results.

3.2 Next Steps

Each quarter we will add data to the quantitative analysis, until we have completed analysis of the entire intervention period. We will add a measure of the percent of inpatient stays that reach Medicare cost outlier thresholds. We will also explore the addition of Medicaid data, for Awards in states where such data are available in the coming year.

CMS is extending many of these Awards for an additional 6-12 months. For these Awards, our analysis of Medicare claims will continue, and will be reported in an addendum to our final report.

Appendix A

1. Technical Appendix A

1.1 Selecting Comparison Providers

To conduct difference-in-differences (DD) analyses we selected comparison group patients from non-Awardee providers that are similar to the intervention providers and in the same hospital referral regions (HRRs). We constructed separate comparison groups for each Awardee and provider type (e.g., hospital, skilled nursing facility (SNF), long-term care hospital [LTCH]) to support the separate evaluations of each program that we are conducting. For Awardees with providers in more than one HRR (e.g., Dartmouth, Mt. Sinai), the comparison group includes providers for each HRR in their service area. We do not analyze each site separately but rather pool data for all of an Awardee's intervention sites and compare that against data for its pooled comparison sites. This comparison group specification allows us to estimate the incremental effects of Awardee interventions for fee-for-service Medicare beneficiaries of similar providers within the same market (managed care enrollees are not included in our claims analyses due to incomplete claims). It is a comparison of the community standard of care that represents our best estimate of what might have occurred in the absence of Awardee interventions. A key strength of this comparison group specification is that it ensures that intervention and comparison groups share the same local market characteristics, such as availability of different kinds of care, local provider characteristics, local practice standards, and the provider competitive environment. It also means that it is unnecessary to adjust for wage differences between intervention and comparison groups, because they are drawn from the same wage areas (with the exception of the Mayo Clinic, which has no comparison in its HRR; see discussion below).

We considered the following factors in selecting comparison group providers:

- **Provider type:** Comparison group hospitals are the same type of provider as those in the intervention group.
- **Provider size:** Comparison group providers are similar in size to Awardee providers. The definition of the size categories varies with respect to Awardee and provider type, and is based on the distribution of Awardee-affiliated providers.
- **Teaching status:** For Awardee programs that include teaching hospitals, we considered teaching status in selecting comparison hospitals.
- **Types of services offered:** For Awardees that restrict their program to patients treated in specific units (e.g., ICU, Emergency Department), we restricted the comparison group to those that provide such services. To increase the strength of the match, we also restricted the Methodist Delirium comparison group to hospitals that provide both ICU and emergency department (ED) services.
- **Miscellaneous exclusions:** We excluded Special Focus Facilities (SFF) as comparison group nursing homes and also excluded hospitals that specialize in treating pediatric patients. In addition, for Christus, we excluded from the comparison group providers that are not in Arkansas or Texas. Even though Christus's HRR extends into Oklahoma, Christus participants are all located in Arkansas and Texas, and so we limit the comparison group to these states as well. Finally, note that no Awardee providers were eligible to be in the comparison group for another Awardee's program.

Note also that some Awardees are continuing to add new providers to their programs. As appropriate, we are updating our list of comparison providers to include new HRRs and/or new types of providers, using the methodology described here.

Exhibit A1: Criteria for Selecting Comparison Group Providers

Awardee	Provider Size	Teaching Status	Specific Types of Services	Misc. Exclusions
Christus—Hospital	>250 beds	N/A	N/A	Must be in AR or TX
Christus—SNF	50-150 beds	N/A	N/A	Must be in AR or TX
Dartmouth	>30 acute care hospitals, most with 200+ beds	Both teaching and non-teaching	ICU and ED	N/A
Emory	> 250 beds	N/A	ICU and ED services	N/A
Henry Ford	> 500 beds	Major teaching	N/A	N/A
Mayo Clinic	MA: 100-250 beds NY and MN: > 500 beds AZ and FL: 250-500 beds	Major teaching	ICU and ED services	For MN, selected comparison providers from Minneapolis HRR; FL and AZ comparisons match on size or academic status but not both
Methodist-Delirium: Hospital	50-150 beds or >300 beds	N/A	N/A	N/A
Methodist-Sepsis: Hospital	> 300 beds	N/A	N/A	N/A
Methodist-Sepsis LTCH	75 or more beds	N/A	N/A	N/A
Methodist-Sepsis: SNF	50-150 beds	N/A	N/A	Provider category is SNF; this HRR has no SFF facilities
Mt. Sinai	NY: > 1,000 beds IL, NJ: > 500 beds	Major teaching or graduate	N/A	N/A
St. Luke's Hospital	100-250 beds	Not a major teaching hospital	ICU services	Must be in Idaho (in Boise or Spokane HRR)
University of Chicago	N/A	N/A	N/A	N/A

Additional Details:

- The Christus program and the Methodist Sepsis program each have multiple types of participating facilities.
- The University of Chicago program is using a randomized design. Our comparison group for this Awardee contains the patients who were randomly assigned to the comparison group.
- Provision of ED services is identified using a variable in the Provider of Service (DCTD_ER_SRVC_CD) that reports whether the hospital provides ED services.
- Provision of ICU services is identified using a variable in the Provider of Service file (ICU_SRVC_CD) that reports whether the hospital provides ICU services.
- Teaching status is identified using a variable in the Provider of Service file (MDCL_SCHL_AFLTN_CD) that reports the type of medical school affiliation that the hospital has.

- Note that we excluded from the comparison group any providers that are children's hospitals, and non-Awardee hospitals that are affiliated with Mayo.
- We excluded three providers from the Dartmouth comparison group that are not part of the HCIA intervention, but shared a health care system with a provider that is part of the HCIA intervention, and were judged by the Awardee to have received sufficient exposure to the intervention so as to be "contaminated" and inappropriate as comparison providers.

1.2 Selecting Intervention and Comparison Patients

We used Awardee patient registry data to inform inclusion/exclusion criteria, and then used these criteria to define intervention and comparison populations.

1.2.1 Registry Overview

Contents of Registry Data

Each Awardee uploaded to Abt (using secure file transfer) a registry of intervention patients treated during the HCIA implementation period. These registry files contain patient-level information including: Medicare health insurance claim (HIC) number, Medicaid identification number, or social security number for treated patients; admission and discharge dates for hospitalizations during which a patient received the innovation funded by the Award (and the same for those treated in nursing home innovation settings); a Medicare provider number for the institution in which the patient received intervention services; and patient names and dates of birth. A few Awardees were not able to supply all of this information for every intervention patient.

Each patient in an Awardee's registry was matched to a Centers for Medicare & Medicaid Services' (CMS) file that contains the identity of all Medicare beneficiaries from January 2010 onward to determine which patients in the registries have corresponding Medicare fee-for-service (FFS) claims. This match was performed using HIC or Social Security numbers provided by the Awardees. Approximately 80 percent of Medicare patients in the registries had a valid HIC number or Social Security number (Exhibit A2). The exhibit reports the number of patients each Awardee included in their registry data, the number for which we were able to find Medicare FFS claims, and the dates covered by their registry data. Note that this table excludes registry records that had an invalid HIC (e.g., a Medicaid number,[1] private insurance number, or (possibly) a mis-entered Medicare number). We assume that Medicare beneficiaries who have an HIC number but have no FFS claims are enrolled in Medicare Advantage plans.

[1] Medicaid claims, where feasible and available, will be added to our analyses when they become available for the intervention period; likely in 2016.

Exhibit A2: Medicare Intervention Patients with Valid HIC Numbers (Based on All Registry Data through Q4 2014)

Awardee	Number of Unique Medicare Patients in the Registry	Number of Unique Medicare Beneficiaries with Claims and Identified by HIC	
		(N)	(%)
Christus	N/A	N/A	N/A
Dartmouth	N/A	N/A	N/A
Emory	4,718	1,423	30.16%
Henry Ford	5,428	3,906	71.96%
Mayo Clinic	5,422	4,159	76.71%
Methodist—Delirium (Intervention)	7,168	5,991	83.58%
Methodist—Delirium (Screened)	13,211	10,821	81.91%
Methodist—Sepsis (Screened)	6,075	5,809	95.62%
Mt. Sinai	N/A	N/A	N/A
St. Luke's	5,409	3,103	57.37%
University of Chicago	997	972	97.50%

Inclusion and Exclusion Criteria to Define Study Populations

Registry data with admission dates through December 31, 2014 were matched to Medicare fee-for-service claims and used to develop Awardee-specific inclusion and exclusion selection criteria. We created inclusion and exclusion criteria to replicate—as closely as possible—the registry lists provided by each HCIA Awardee. These criteria were developed using line-item claims with dates between January 1, 2012 and December 31, 2014,

These criteria were then applied to both intervention and comparison hospitals identically, in the baseline and intervention periods, ensuring that the same criteria were used to define both the intervention and comparison groups. Note that selection criteria based on information that is not present on claims (e.g., laboratory tests, observation of patients, clinical judgment) cannot not be replicated in our claims-based inclusion and exclusion selection criteria.

The inclusion and exclusion criteria were generally developed using the following guidelines, although the specific details varied across Awardees:

1. **Time Criteria:** Using registry data, we determined the first time a patient was treated in each Awardee hospital, during the relevant implementation period for that specific hospital. We also used implementation start dates supplied by Awardee program staff. When the two did not align, we opted to use the start dates supplied by program staff. The claims used for creating selection criteria were then restricted to reflect the dates on or after the implementation start date for each hospital (and its matched comparison hospitals).
2. **Revenue Center Criteria:** Revenue center codes were identified in the claims and used as exclusion or inclusion selection criteria, as appropriate for specific Awardees. For example, the St. Luke's program targets patients treated in intensive care units, and patients whose claims did not indicate treatment in an intensive care unit were excluded.

3. **Diagnosis Related Group Criteria:** Based on correspondence and case studies with Awardee program staff, specific Medicare diagnosis related groups (MS-DRGs) were identified as excluded or included for specific Awardee programs. For example, the Dartmouth Sepsis Improvement Program excludes kidney and liver transplant patients, and we therefore excluded claims that had an MS-DRG code indicating a kidney or liver transplantation.
4. **ICD-9 Criteria:** The Dartmouth program targets patients with sepsis, and in the first two years its study sites focused on patients treated in the ED or ICU. After the inclusion or exclusion of claims based on ED/ICU revenue centers and transplantation DRGs (because program staff told us that these patients were not included in the intervention), we further excluded patients from the treatment group for the Dartmouth program that do not have a diagnosis of sepsis (based on ICD-9 codes).

Exhibit A3 shows the specific revenue center, DRG, and ICD-9 criteria used to specify intervention and comparison groups for each Awardee. With the exception of the Christus Hospital Award, the criteria are conditioned on specific hospital units and use revenue center codes to define these units. Only the Methodist Delirium and Mt. Sinai Awards required an age restriction. Clinical inclusions/exclusions were specified for the Dartmouth, Mayo, Methodist Sepsis, and Methodist Delirium Awards, to further refine the study populations. The University of Chicago program randomizes patients to intervention and comparison groups and no other criteria are needed; it is therefore omitted from the table below. The Henry Ford Hospital is also omitted because we were unable to specify criteria based on claims that reflect the highly clinical selection criteria used in that program.

Exhibit A3: Criteria for Patient Inclusion in Intervention or Comparison Group, by Awardee

Awardee	Revenue Centers	Age (18+)	DRG Code Exclusions	Patient Diagnoses for Inclusion (ICD-9)
Christus	Entire Hospital	--	--	--
Dartmouth	ICU Revenue Center: 0200, 0201, 0202, 0206 OR Inpatient and treated in ED	--	Transplant: 001, 005-007 Cardiac: 286-293, 296-278, 306-311 Cardio Thoracic: 215-238, 242-251, 258-262 Stroke: 061-063 AMI (no CC or MCC): 280, 281, 283, 284	Sepsis: 995.91, 995.92, 785.52
Emory	ICU Revenue Center Code: 0200 **OR** CCU	--	--	--
Mayo	ICU Revenue Center: 0200, 0201, 0202, 0206	--	--	List of many ICD-9 diagnoses derived from registry
Methodist Sepsis	One of following: General medical-surgical units, ED, CCU, ICU Revenue Centers: 0200, 0201, 0202, 0206	--	Transplant: 001, 002, 005, 006, 007, 008, 010, 652	Sepsis: 038.0-038.9, 995.91, 995.92, 785.52
Methodist Delirium	Revenue Center: 0110, 0111, 0120, 0121, 0130, 0131, 0140, 0141, 0150, 0151	≥70	--	List of many ICD-9 diagnoses derived from registry
Mt. Sinai	ED	≥65	--	--
St. Luke's	ICU Revenue Center: 0200, 0201, 0202	--	--	--

ICU – Intensive Care Unit; AMI – Acute Myocardial Infarction; CC – Complication or Comorbidity; MCC – Major Complication or Comorbidity; CCU – Coronary Care Unit

The steps described above yielded inclusion and exclusion criteria for each Awardee program.[2] We then applied these criteria to the intervention and comparison hospitals, so that the study populations in each were selected using identical criteria. Exhibit A4 shows the match between Awardee registries and our best approximation of the eligible population from Medicare claims, based on these inclusion and exclusion criteria. The exhibit shows the number of intervention patients that are estimated to be in each Awardee intervention group (based on inclusion/exclusion criteria applied to Medicare claims), the number of patients thus defined who are in the registries, and the percentage of patients who are in both the registry and the estimated intervention group.

Accuracy and Completeness of Inclusion Criteria

The percentage of estimated intervention patients that match with registry lists partially determines our program evaluation approach. Ideally, the Medicare intervention population we estimate with inclusion/exclusion criteria will match Awardee registry Medicare lists. Imperfect matches—patients included as intervention group patients who were not in the registry data, or patients that were in the registry data but not identified as being in the intervention using claims data—add noise to our estimates of program impact. For all Awardees but the University of Chicago, Christus, Dartmouth, Henry Ford, and Mt. Sinai,[3] we assessed the degree to which mismatches between our estimated group and the actual intervention group will bias analytic results toward zero. The table below presents results of this matching exercise for the remaining five Awardees, for the fourth calendar quarter of 2014. Matching results for each quarter are presented in the Award-specific sections in Appendix B.

Exhibit A4: Awardee Registry and Abt-Estimated Counts (Based on Q4 2014 Data Only)

--	Emory	Mayo Clinic	Methodist Delirium (Intervention)	Methodist Delirium (Screened)	Methodist Sepsis (Screened)	St. Luke's
Registry, total unique patients	866	1,040	3,159	3,371	5,649	853
Registry with Medicare FFS claim (A)	527	770	845	1,452	2,321	404
Registry patients not captured by Abt criteria (B)	35	143	22	45	0	31
Miss rate (B/A)	7%	19%	3%	3%	0%	8%
Estimated based on Abt criteria, with Medicare FFS claim (C)	619	911	1,228	1,526	2,574	432
Match between estimated and registry (D)	492	627	823	1,407	2,321	373
Estimated by Abt criteria, not in registry	127	284	405	119	253	59
Accuracy rate (D/C)	79%	69%	67%	92%	90%	86%

[2] The lone exception was Henry Ford Hospital. There, exposure to the intervention depended on clinical criteria that are not observable on claims data, and we were not able to achieve sufficient accuracy with our matching procedure to produce a valid comparison group.

[3] University of Chicago's randomized design provided us with both intervention and control groups, making it unnecessary to develop inclusion/exclusion criteria. Christus sent only a minimal registry but advised that all patients in all participating facilities are subject to the intervention. Likewise, Mt. Sinai sent an incomplete registry but advised that all patients over 65 in participating emergency departments are subject to the intervention. Dartmouth's inclusion criteria were developed through discussion with the Awardee rather than use of the registry. This is because their registry contains only a small subset of all intervention patients; therefore, matching against their registry is inappropriate.

Including in a regression model any estimated intervention patients who were not actually exposed to the intervention both increases the standard errors and impacts the average estimated treatment group impact. For example, suppose that 100 patients are estimated to be in an intervention group but only half were actually exposed to the intervention. If the intervention yields a Medicare spending decrease of $10 but this is true only for the actual intervention patients (and not those we incorrectly estimated for the intervention group), the average estimated effect of the intervention will be a decrease of $5 ($10 spending reduction affecting only half of the patients in the intervention group).

At the same time, it is not always clear why some patients were recorded in an Awardee's registry, while others who are apparently very similar were not. For example, staff from some of the hospitals participating in the Mt. Sinai program staff may be entering only patients seen in the GERI-EDs in their registry, even though other patients receive some GEDI-WISE services in the main EDs. For another example, some hospitals participating in the Dartmouth program excluded patients who became Do-Not-Resuscitate (DNR) status while in the hospital; others excluded only patients who were DNR status when they entered the hospital. Decisions about which patients to record in the registries may be inconsistent in multi-site Awards, which affects the match rates we achieve.

Our inability to perfectly specify inclusion/exclusion criteria using Medicare claims data is a limitation of our analysis that potentially increases the standard errors of our estimates and decreases our estimated treatment effects. We therefore caution that impact estimations in this report are conservative.

1.3 Analytic File Construction

This section describes: a) the data sources for the analytic files, b) the procedures used to identify episodes, and c) methodology for identification of outcome measures.

1.3.1 Data Sources

Medicare enrollment, claims and payment data contained in the Chronic Conditions Warehouse (CCW) and Geographic Variation Database (GVDB) were used for this study. All data files correspond to calendar years 2010-2013, and the first three or four quarters of 2014, which span baseline and intervention periods. We use only through the third quarter of 2014 to measure Medicare spending outcomes. CCW Part A institutional claims were extracted for beneficiaries served by HCIA Awardee and comparison hospitals. CCW point-of-service (POS) files were used to identify hospital names and assign them to intervention or provider status. For beneficiaries with inpatient or SNF stays in Awardee or comparison facilities, all Part A and B claim, revenue, and line-level data were extracted from the appropriate CCW source files. Demographic information about beneficiaries was extracted from the CCW Master Beneficiary Summary File, including date of birth, date of death, as well as eligibility information including monthly indicators for Medicare Advantage enrollment and reasons for entitlement. (See Exhibit A5 below.)

In order to standardize baseline period claims to a comparable level of claims maturity as the intervention period, processing date restrictions were applied to all extracted claim, revenue and line-level claims data. Two files were created; the first file was designed for utilization measures (readmissions, ED visits, length of stay). In this file, claims were limited to those processed within three months of the claim through date. For example, a claim with a thru date of March 15, 2014 would be included only if it was processed by June 15, 2014 and was the final action version of the claim. The second file was designed to measure Medicare episode spending in the inpatient and post-discharge periods, including Part B claims. Post-acute claims can take longer to be submitted to CMS and reach final action status, and we allowed a

six- month claims lag rather than three when calculating total Medicare episode spending. For example, a claim with a thru date of March 15, 2014 would be included in the Medicare episode spending measure if the final action was processed by September 15, 2014.

Exhibit A5: Data Sources

Data Source	Input to Research File
CCW Master Beneficiary Summary File	Demographics, monthly Medicare enrollment information and reasons for eligibility
CCW Part A Medicare Claims	Acute hospitalizations, index and readmission hospitalization indicators, Medicare payments
CCW Part A Revenue Center Medicare Claims	Identification of emergency department visits and intensive care unit stays
CCW Part B Institutional Medicare Claims	Medicare payments and outpatient emergency department visits
CCW Part B Non-Institutional Medicare Claims	Medicare payments
GVDB Beneficiary Summary File	Hierarchical Condition Codes (HCC) Risk Scores
Provider of Services (POS) File 2012	Characteristics of skilled nursing facilities (e.g., size, for-profit status, location)

CCW – Chronic Conditions Warehouse
GVDB – Geographic Variation Database

1.3.2 Episodes

Inpatient claims were clustered into stays using methodology that groups claims that are overlapping or adjacent with respect to the from and thru dates on the claim, and using information from the claim patient discharge status code. Similarly, for skilled nursing facility claims the stay methodology was used to group claims based on claim dates. The period following the beneficiary's discharge from the episode-initiating inpatient stay was evaluated for subsequent acute care hospitals, whereas for SNF providers the start date of the stay defined the beginning of the evaluation period.

1.3.3 Outcome Measures

Readmissions

All acute, critical access, or other inpatient episodes were evaluated for occurrence and number of all-cause inpatient readmissions within 7, 14, 21, 30, 60, 90, and 120 days following discharge from the initial hospitalization. For SNF and long-term care (LTC) providers, beneficiaries were followed for 7, 14, 21, 30, 60, 90, and 120 days following admission to the SNF or LTC for subsequent hospital admission. In this report we focus on 30-day readmissions (for acute episodes) and 30-day admissions (for long-term post-acute care [LTPAC] episodes).

Emergency Department Visits

All Medicare Part A institutional revenue center claims were extracted for beneficiaries with an acute inpatient stay at an HCIA Awardee or comparison provider. Emergency department visits were classified based on the revenue center codes in the institutional revenue center claim data. An indicator was created specifying whether the acute inpatient stay initiating the episode was an admission through the emergency department. ED use was also measured at intervals during the evaluation period including at 7, 14, 21, 30, 60, 90, and 120 days post discharge from inpatient, or post admission for SNF providers. If the Part A revenue center codes for a claim indicated ED use, then the visit was classified as an inpatient visit. In contrast, an outpatient ED visit was counted if the Part B institutional revenue center codes indicated ED use. Observation stays were classified as ED visits.

Medicare Episode Spending

Calculation of Medicare episode spending is based on the initial index admission and the following 60 days. Standardized payments for inpatient claims were calculated using the following formula:[4]

$$Actual\ payment - (IME + DSH) = Standardized\ Amount$$

where IME is the indirect medical education payment amount and DSH is the disproportionate share payment associated with the claim.

Spending for Medicare Part A inpatient claims during the follow-up period was prorated across the days of the stay. For example, if a beneficiary was readmitted to the hospital on the 28th day of the 30-day follow-up period for a 5-day stay, then 3/5 of the standardized amount of the claim would be attributed to the 30-day spending for the episode. No standardization was performed for either Part B institutional or Part B non-institutional services.

Note that we do not adjust Medicare spending to account for inflation. Although this will not affect DD regression results, it may result in an upward trend in Medicare spending over time for both the intervention and comparison groups. Given that our data now cover nearly six years (pre and post intervention), we will revisit this issue in future reports.

1.4 Measure Specification

Core measure specifications must vary somewhat for individual Awardees. For example, the Mt. Sinai intervention begins with an emergency department visit; defining an episode as starting with a particular ED visit (often one among many) is complicated by considerations of whether or not that episode-initiating ED visit went on to become an inpatient admission. For another example, the Christus intervention concerns nursing home patients, whose nursing home stays began some time (weeks or months) prior to the intervention, but about which we have little information because Medicare was not the primary payer. Similar idiosyncrasies arose in implementing the core measure specifications for other Awardees as well. We further note that some of these core measures are not targeted by the Awardees themselves. Many of these Awardees' innovations take place entirely during the course of a single hospitalization, and Awardees focus on reducing mortality, hospital-acquired infections, and length of stay during that admission. We will report on other Awardee-specific outcome measures in future annual reports.

Note that most of the 10 Awardee interventions begin when a patient is already hospitalized and end at hospital discharge. A measure of inpatient admissions therefore is not relevant for most Awardees, and we focus instead on the readmission measure.

1.4.1 Defining Index Admissions

Core outcome measures are defined in reference to an "index" inpatient hospital admission. An index admission is the first time during a 120-day period that a patient who qualifies for treatment in the intervention is treated in either a comparison or intervention (Awardee) hospital. An index admission

[4] IME refers to "indirect medical education," an adjustment made to payments to teaching hospitals to account for the higher per-patient cost at teaching hospitals relative to non-teaching hospitals. DSH refers to "disproportionate share hospital," a payment adjustment that accounts for the share of a hospital's patients covered by supplemental security income (SSI) or Medicaid.

refers to any admission during the observed time period that would have been eligible for the intervention if it had occurred at an Awardee hospital after the date the intervention program began at that hospital.

The discharge date of an index admission is considered to be Day 0, after which the following outcomes are calculated: 30-day Hospital Readmissions, 30-day ED visits, and 60-day total episode spending. A patient discharged from each index admission begins a 120-day "episode" period during which no new index admissions are assigned.[5] The 120-day period is applied as a standard period of time during which a patient's care is likely to be associated with that index admission. For example: if a patient is admitted to an intervention hospital for a specific condition, qualifies for the intervention, and is discharged five days later, we expect that the same condition will not cause another hospital admission more than 120 days later. In future reports we may explore whether this 120-day period should perhaps be allowed to vary for different types of patients.

After 120 days has elapsed, new index admissions are assumed to be independent events, clinically unrelated to the previous index admission. Econometrically, we do not assume that multiple index admissions for a single beneficiary have independent error terms, so we can potentially correct for unobserved correlations in these errors in future analyses.

Index admissions are assigned in chronological order. For each beneficiary the first observed inpatient stay that qualifies for treatment in the intervention is defined as an index admission. The next observed inpatient stay that qualifies for treatment, and that occurs at least 120 days after discharge from the previous admission, is also defined as an index admission. This process continues until all admissions for the beneficiary observed during the sample period have been assigned as index or non-index admissions. Beneficiaries can have multiple index admissions, but this is infrequent.

Beneficiaries who are treated in LTPAC facilities are also assigned index admission dates. The index stay for LTPAC begins upon admission to an LTPAC; core outcomes are analyzed for the 30 and 60 days since admission. Individuals can have more than one index LTPAC stay: subsequent qualifying stays are assigned to individuals who are readmitted from the community more than 120 days after their initial index admission.

1.4.2 Core Outcome Measures

Several utilization and Medicare cost measures are analyzed for each HCIA Awardee. These outcomes are specific to the purpose of each intervention and the evaluation design, and reflect the core measures that the Center for Medicare & Medicaid Innovation (CMMI) specified for the entire HCIA program. For most Awards, we measure 60-day Medicare episode spending (including the index admission or ED visit); for the University of Chicago we created an aggregate cost measure due to the randomized design of the program and ongoing enrollment of patients in it. We did not analyze length of stay metrics for interventions taking place in long-term care and skilled nursing facilities, due to the already long-term nature of care for many of these patients. Lastly, we evaluated the number of hospital admissions that take place through the ED for Mt. Sinai because that intervention focuses on ED patients and efforts to prevent their eventual hospital admission.

[5] For observations missing date of discharge, the date of final service was used in place of discharge date. Observations that were missing both date of discharge and date of final service or that were missing date of admission could not be assigned as index admissions.

Exhibit A6: Awardee-Specific Outcome Measures

--	--	Christus Acute Care	Christus SNF	Dartmouth	Emory	Henry Ford	Mayo Clinic	Methodist— Delirium	Methodist— Sepsis Acute Care	Methodist -Sepsis SNF	Mt. Sinai	St. Luke's	University of Chicago
Cost Measures	60-Day Medicare Cost	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	--
	Total Medicare Cost	--	--	--	--	--	--	--	--	--	--	--	✓
Utilization Measures	30-Day Inpatient Readmissions	✓	--	✓	✓	✓	✓	✓	✓	--	✓	✓	--
	30-Day ED Visits	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	--
	30-Day Admissions from ED	--	--	--	--	--	--	--	--	--	✓	--	✓
	Length of Stay	✓	--	✓	✓	✓	✓	✓	✓	--	--	✓	--
	Inpatient Discharge Destination	✓	--	✓	✓	--	✓	✓	✓	--	--	✓	--
	Total Inpatient Admissions	--	--	--	--	--	--	--	--	--	--	--	✓
	Total ED Visits	--	--	--	--	--	--	--	--	--	--	--	✓

All outcomes are analyzed pooled across the entire intervention period, as well as at the quarterly level (see section 1.5.1). Both types of analysis require a standardized approach to assigning outcomes to a given time period in cases where measurement of an outcome may overlap the boundary between two time periods. For instance, a patient may be admitted to the hospital on March 31, 2013, initiating an index stay, and discharged on April 1, 2013, starting the 30- or 60-day follow-up period for all outcomes (e.g., 30-day readmissions, 60-day Medicare spending). In this case, the index stay started in Quarter 1 of 2013, but the period over which the outcomes were measured occurred completely in Quarter 2. Since the outcomes are referenced to the index stay, all outcomes are included in the calendar quarter in which the index stay began, rather than the quarter in which the outcome occurred. Drawing from the above example, if the patient was readmitted to the hospital on April 29, 2013, we would count this as a readmission for Quarter 1 of 2013, rather than a readmission for Quarter 2. Likewise, all spending that occurred between April 1 and May 30 would be included in Quarter 1 rather than Quarter 2.

Hospital Admissions for Long-Term Post-Acute Care Patients

We computed quarterly hospital admission rates for the SNF component of the Christus intervention, and the SNF and LTCH components of the Methodist Sepsis intervention. These rates measured the proportion of index SNF/LTPAC stays after which a patient is admitted to the hospital one or more times within 30 days of the index admission to the LTPAC. This is expressed mathematically as:

$$\text{Admission Rate}_{jk} = \frac{\sum_{i=1}^{n_{jk}} \text{Admissions}_i}{n_{jk}},$$

where n_{jk} is the total number of index admissions for Awardee *j* in quarter *k*, and Admission_i is a binary measure indicating whether the inpatient hospital admission occurred within 30 days of discharge from index admission *i*. This binary definition of admission limits the numerator in the equation above to containing at most one inpatient admission per index stay, which prevents the admission rate from exceeding 100 percent.

Hospital Readmissions

We computed all-cause quarterly hospital readmission rates for each Awardee as the proportion of index hospital admissions after which a patient is admitted one or more times within 30 days of the discharge date. This is expressed mathematically as:

$$\text{Readmission Rate}_{jk} = \frac{\sum_{i=1}^{n_{jk}} \text{Readmissions}_i}{n_{jk}}.$$

where n_{jk} is the total number of index admissions for Awardee *j* in quarter *k*, and Readmission_i is a binary measure indicating whether another admission occurred within 30 days of discharge from index admission *i*. This binary definition of readmission limits the numerator in the equation above to containing at most one readmission per index admission, which prevents the readmission rate from exceeding 100 percent. This is consistent with the approach used by Hospital Compare and other CMS readmission monitoring programs. Given the nature of these programs, which for the most part provide intervention services while the patient is hospitalized only, and the 30-day timeframe for the readmission measure, we believe that the binary readmission measure is more appropriate than counting the number of readmissions.

Patients whose program intervention began in a LTPAC setting (in the Christus and Methodist Sepsis programs) are not included in the hospital readmission rates presented here.

30-Day Post-Discharge ED Visits

Quarterly ED visit rates were computed for each Awardee as the proportion of ED visits within 30 days after the date of discharge for an index hospital stay. This is expressed mathematically as:

$$\text{Post} - \text{discharge ED Visit Rate}_{jk} = \frac{\sum_{i=1}^{n_{jk}} \text{ED}_i}{n_{jk}},$$

where n_{jk} is the total number of index admissions for Awardee *j* in quarter *k*, and ED_i is a binary measure indicating whether any ED visit occurred within 30 days of discharge from index admission *i* . This binary definition of post-discharge ED visits limits the numerator in the equation above to containing at most one ED visit associated with each index admission, and prevents the post-discharge ED visit rate from exceeding 100 percent. Observation stays are defined as ED visits.

Patients whose program intervention began in a LTPAC setting (in the Christus and Methodist Sepsis programs) are not included in the ED visit rates presented here.

60-Day Total Medicare Spending

Average total Medicare spending for the 60 days after patient discharge was calculated by quarter. This is expressed mathematically as

$$\text{Total Medicare Spending}_{jk} = \frac{\sum_{i=1}^{n_{jk}} \text{Spending}_i}{n_{jk}}$$

Where n_{jk} is the total number of index admissions for Awardee *j* in quarter *k*, and spending refers to the sum of all Medicare spending (as defined in section 1.3.3) incurred by patients during the index admission and the following 60 days. To reduce the impact of high-cost outliers on our results, we truncate Medicare episode spending at the 99th percentile to reduce the influence of very-high-cost outliers, which in the hospital setting can total hundreds of thousands of dollars.

Discharge Destination

Rate of discharge from the hospital to one of five destinations was computed for each Awardee as the proportion of index hospital admissions that ended with the patient being discharged to a given destination. The four destinations include: home without assistance from a home health agency, home health care, skilled nursing facility/inpatient rehabilitation facility/other nursing home/long-term acute-care hospital, and discharge to "other" destination (includes hospice, planned readmissions, etc.). The discharge rate for each of the *l* destinations can be expressed mathematically as

$$\text{Discharge Destination Rate}_{jkl} = \frac{\sum_{i=1}^{n_{jk}} \text{Discharge Destination}_{lj}}{n_{jk}}$$

Where n_{jk} is the total number of index admissions for Awardee *j* in quarter *k*, and discharge destination *l* refers to discharge to the l^{th} location.

Patients whose program intervention began in an LTPAC setting (subpopulations in the Christus and Methodist Sepsis programs) are not included in the discharge destination rates, since the measures apply only to discharges from an acute care hospital.

1.4.3 Special Considerations

Mt. Sinai

The intervention for Mt. Sinai occurs during a visit to the emergency department. We define an index event as an emergency department visit, some of which go on to become inpatient hospital admissions. For the 30 days following an ED index visit, we calculate the mean number of ED visits per beneficiary, as well as the rate of subsequent hospital admissions. In future reports we will also consider the mean number of hospital admissions within 30 days of the ED index visit. For patients whose index ED visit resulted in an inpatient hospital admission, the subsequent hospital admission refers to a new admission within 30 days of discharge from the hospital. For patients whose index ED visit did not result in an inpatient hospital admission, the subsequent hospital admission refers to any admission within 30 days of discharge from the ED. Similarly, total Medicare episode spending is estimated for the index ED visit and all additional spending for 60 days, whether or not the patient was admitted to the hospital immediately following the index ED visit. Finally, we present the proportion of index ED visits that become inpatient hospital admissions. Because this intervention occurs in the ED setting, and not all episodes end with an inpatient admission, we do not analyze inpatient length of stay or inpatient discharge destination.

University of Chicago

Admissions and ED Visits

The purpose of the University of Chicago intervention is to reduce total admissions among a specific sample of high-risk patients who are enrolled either while in the hospital or while in the community. This program targets patients with a high number of ED visits and hospitalizations. Instead of 30-day readmission rates or 30-day ED visit rates, we therefore calculate the average total admissions and the average number of ED visits. This may be expressed mathematically as:

$$\text{Average Admissions}_{k} = \frac{\sum_{i=1}^{n_k} \text{Admissions}_{i}}{n_k}$$

where n_k is the total number of patients participating in the intervention in quarter *k* and admission refers to the total number of admissions for patient *i* observed in quarter *k*. Graphical representations include the sum of admissions or ED visits per 90 days after enrollment.

Medicare Spending

Patients are enrolled in the University of Chicago program on a rolling basis and randomized to intervention or control arms of the study. In order to show the intervention effects by patient quarters, we calculate the total Medicare spending from the point of enrollment, and sum these amounts during every 90-day period. These calculated costs include all enrollees, including those who expire. Aggregate cost and utilization regressions include total spending and utilization by enrollee, while controlling for the amount of time exposed to the treatment.

St. Luke's

Part of St. Luke's intervention takes place at several critical access hospitals (CAHs) in the region, as well as larger urban hospitals, surrounding the flagship regional medical center. We omit the CAHs (and all comparison CAHs) from our analyses. CAHs are fundamentally different from acute care hospitals, in the services they offer and the patients they serve. As a result, we anticipate that the intervention effect for CAHs is different than for the other St. Luke's hospitals. Because the CAH subsample is very small and lacks sufficient power to distinguish a separate intervention effect, we cannot conduct a separate CAH analysis. A model that pools CAHs and larger hospitals produces an estimated intervention effect that is an average combined effect for the acute care and the CAHs, but without any way to disentangle the two effects. We therefore limit the analysis to acute care hospitals so that we can be more confident in the estimated intervention effect. We do not anticipate ever having sufficient power to estimate a separate sub-analysis for the CAHs, but will continue to monitor the number of CAH patients to determine if it large enough to support a separate analysis.

Emory

The Emory program is composed of three large, urban acute care hospitals, and two smaller community hospitals, one of which is part of the Emory system (in the Atlanta suburbs) and the other of which is a rural regional hospital in east Georgia. We omit the two smaller community hospitals from our primary analyses in this report. However, given that these smaller hospitals are still much larger than CAHs, we anticipate eventually achieving a sample size sufficient to allow descriptive sub-analyses in future reports. Given the different approach to matching, the analytic sample used in this report differs from the sample used in the first annual report.

Patients Whose Intervention Begins in Long-Term Post-Acute Settings: Christus and Methodist Sepsis Programs

The Christus and Methodist Sepsis programs include both patients in a hospital setting and patients in LTPAC settings, which include nursing and rehabilitation facilities, long-term care hospitals and LTCHs. Patients who are first exposed to the intervention in an LTPAC setting are accounted for separately from those who are first exposed to the intervention in an acute inpatient setting. Outcomes of interest for LTPAC patients include 30-day hospital admissions, 30-day ED visits and 60-day average Medicare spending. The index cases are defined and assigned in the same way as for the hospital readmission measures, except that in this case the index event refers to an LTPAC stay rather than a hospital admission. However, LTPAC outcomes are defined in reference to the beginning of the episode rather than the end. For example, 30-day admission and ED visits refer to outcomes occurring within 30 days of the start of PAC treatment.

Programs that Span Multiple Hospital Referral Regions: Trustees of Dartmouth College, Mayo Clinic, and Mt. Sinai Programs

Currently three Awardee programs have hospitals (and therefore, comparison hospitals) located in more than one HRR. Since the average of the outcomes of interest (particularly Medicare spending) may vary between HRRs, it is important that the distribution of Awardee episodes across HRRs equal the distribution for comparison episodes, or else the match will be imperfect. To ensure equality between the distribution of Awardee and comparison observations across HRRs, all comparison observations for Dartmouth, Mayo Clinic, and Mt. Sinai are weighted, because these Awards have multiple hospitals involved in the intervention. For all quarterly outcomes displayed in the trend charts, weights are computed and applied on a quarterly basis (such that the distribution of comparison outcomes is weighted to match the Awardee outcomes within each quarter). For regression analyses for these three programs, weights are applied so that the distribution of comparison episodes by HRR in the baseline and post-intervention periods is equal to the distribution of Awardee episodes by HRR in the baseline and post-intervention periods. The weights may be mathematically expressed as:

$$W_{jt} = \frac{P_{Ajt}}{P_{Cjt}},$$

where W_{jt} is the final applied weight, P_{Ajt} is the proportion of Awardee episodes in HRR *j* in time period *t*, and P_{Cjt} is the proportion of comparison episodes in HRR *j* in time period *t*.

Programs with Hospitals that Implemented the Intervention on Different Dates

The majority of Awardee programs began the intervention at different times in different hospitals, sometimes with months or years of lag between the first implementation and adoption by subsequent hospitals. However, within each HRR, each Awardee comparison group is composed of a group of hospitals instead of a single hospital that corresponds to each Awardee hospital. To avoid measurement error that would arise if the entire comparison group were assigned a post-period that corresponds with only one of the Awardee intervention hospitals, we designed an approach that creates a separate comparison group for each Awardee hospital. We implement the following algorithm within each HRR where Awardee hospitals have more than one start date:[6]

- Compute the proportion of Awardee episodes within the HRR that come from each of the K Awardee hospitals within the HRR (P_k).
- Assign all comparison episodes a random number from the uniform distribution.
- Using the random draw, assign all comparison episodes (without replacement) to share a start date with one of the K Awardee hospitals with probability P_k.

This approach constrains the proportion of Awardee and comparison patients in the pre-intervention and post-intervention periods to remain roughly consistent over time, as opposed to the alternative solution of assigning the post-period start to one date for the entire comparison group.

To illustrate, consider the following example with two Awardee hospitals: one that begins at t_1 and one that begins in t_2. Suppose that each hospital contributes exactly 50 percent of the episodes. Each comparison episode is assigned a random number between 0 and 1. If the comparison episode's random

[6] The exception to this rule is Emory University. The intervention began at all three primary facilities within a single week, which we consider too small a time frame to introduce any substantial measurement error.

number is less than 0.5, then it is assigned a start date of t_1. All comparison episodes with a random number greater than 0.5 are assigned a start date of t_2. Therefore, roughly 50 percent of all comparison observations will have a pre-period of 0 to t_1, and roughly 50 percent will have a pre-period of 0 to t_2, consistent with the Awardee episodes.

1.5 Regression Analysis

1.5.1 Regression Estimation and Estimated Intervention Effects

For each of the 10 Awardees we estimate the effect of the intervention on each of the outcomes of interest described above, including total episode Medicare spending, length of stay, 30-day readmissions, 30-day ED visits, and discharge destination. These regressions pool data across all quarters to increase sample size and power, producing a single point estimate of the average cumulative intervention effect for each Awardee. The regression model for each outcome varies based on the nature of the outcome (e.g., binary, continuous), and Exhibit A7 below summarizes the model used for each outcome.

Exhibit A7: Regression Models by Outcome

Model	Outcomes
Logit	30-day admissions (from PAC) 30-day readmissions 30-day ED visits ED to inpatient admission (Mt. Sinai)
Negative Binomial (NB)	Length of stay Total ED visits (U. Chicago) Total inpatient admissions (U. Chicago)
Ordinary Least Squares	Total Medicare spending (U. Chicago) Total 60-day Medicare spending
Quantile	Median total 60-day spending
Multinomial Logit	Discharge destination
Hurdle at Zero Poisson	Total 30-day ED visits (Mt. Sinai)

Each outcome can be generalized as:

$$Y = f(\mathbf{X}\beta + \mathbf{P}\gamma + \mathbf{Q}\alpha + I\theta + (A * I)\delta)$$

where f(·)is the distribution of Y, **X** is a vector of patient-level covariates including gender, race, age, squared age, Hierarchical Condition Category[7] score, squared HCC score, and Medicaid eligibility; **P** is a vector of hospital-level fixed effects; **Q** is a vector of quarter-level fixed effects;[8] I is a binary indicator signaling that an index stay occurred during the intervention period; and A*I is an interaction term indicating that an index stay occurred at an Awardee hospital during the intervention period. We assume that conditional on **X**, **P**, **Q**, and I, that exposure to the intervention is exogenous (i.e., is uncorrelated with anything that might influence Y that is not controlled for in our regression equation) and so δ may be

[7] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g., age, gender).

[8] The quarterly effects control for seasonal trends that affect both the comparison and intervention group. For instance: If there is a bad flu season that affects both the comparison and the intervention group, we have a variable for that effect in the regression. Then, the estimated coefficient that we report shows the difference in outcomes net of all quarterly effects that affect both the comparison and intervention group.

interpreted as the correlation between the intervention and Y.

We interpret the OLS estimate of total Medicare expenditure(δ) as the effect of the intervention on Medicare expenditure. However, the other outcomes are estimated using nonlinear models that require additional calculations to arrive at an estimate of the intervention on the outcome. For each outcome besides total expenditure, we estimate the "Average Treatment Effect" (ATE). The ATE can be expressed mathematically as:

$$ATE_i = \frac{1}{n}\sum_{i=1}^{n}\left(E[Y_i|\mathbf{X}_i, \mathbf{P}_i, \mathbf{Q}_i, A_i * I_i = 1] - E[Y_i|\mathbf{X}_i, \mathbf{P}_i, \mathbf{Q}_i, A_i * I_i = 0]\right)$$

where $E[Y_i|\cdot, A_i * I_i = 1]$ is the outcome Y for individual *i* that would be observed if the individual had been exposed to the intervention, and $E[Y_i|\cdot, A_i * I_i = 0]$ is the outcome Y for individual *i* that would be observed if the individual had not been exposed to the intervention. Since no individual has been both exposed and not exposed to the intervention, the ATE requires estimating a counterfactual prediction of the outcome that would have been observed if the individual had received the opposite level of intervention as actually occurred. We operationalize $E[Y_i|\cdot]$ as f($X_i\hat{\beta} + P_i\hat{\gamma} + Q_i\hat{\alpha} + I_i\hat{\theta}$) where f(·)is the distribution of $E[Y_i]$. The counterfactuals are then generated by imposing $A_i*I_i = 1$ for all patients, and $A_i*I_i = 0$ for all patients, regardless of the observed status of the patient. This yields:

$$\widehat{ATE} = \frac{1}{n}\sum_{i=1}^{n} f\left(X_i\hat{\beta} + P_i\hat{\gamma} + Q_i\hat{\alpha} + I_i\hat{\theta} + \hat{\delta}\right) - f\left(X_i\hat{\beta} + P_i\hat{\gamma} + Q_i\hat{\alpha} + I_i\hat{\theta}\right).$$

We estimate Huber-White heteroskedasticity robust (henceforth "robust") standard errors that account for potential correlation between the variance of Y and the covariates (Greene, 2008a). Due to the inclusion of hospital fixed effects in the regression equation, the robust standard errors also account for the potential correlation of outcomes within a given hospital. Standard errors of the ATE are estimated using the delta method, incorporating the robust covariance matrix estimated for the coefficients (Greene, 2008b). [9]

Quarterly Intervention Effects

At CMMI's request, we graph quarterly estimates of intervention effects. The effects are estimated for each calendar quarter in the period after the intervention was implemented at the first hospital for a given Awardee. Quarterly estimates are produced using the same approach as the pooled estimates described above, except that separate Awardee-interaction terms are included for each intervention quarter in place of a single (pooled) intervention-period Awardee-interaction. Additionally, the ATE is computed using only patients who visited the hospital in that particular quarter, so that the "counterfactual" cases do not extend to patients who visited the hospital in other quarters. The numbers of patients in each quarter are small for most Awardees and the quarterly estimates have less statistical power than the pooled estimates described above.

Since the intervention period is considered as starting in the first calendar quarter that any Awardee facility began the intervention, estimates from quarters in which some but not all facilities had started the

[9] We do not cluster the standard errors at the provider level for each awardee because the number of individual facilities within each award is fewer than 50, the smallest number of clusters recommended in the literature (Bertrand, Duflo, Mullainathan, 2004; Cameron, Miller, 2015). Our solution instead corrects for heteroscedasticity in the error terms, in addition to accounting for mean facility-level effects.

intervention are attenuated by observations from facilities that had not yet begun. Additionally, since the intervention typically began in the middle of a calendar quarter, results in the quarter the intervention started will be attenuated by the inclusion of some observations that occurred in the early weeks of that calendar quarter, prior to the start of the intervention.

Quantile Regression

The OLS estimation of total Medicare spending models the *mean* Medicare spending per episode. Due to the skewed nature of expenditure data even after truncation, the mean may be unduly influenced by a few observations with unusually large expenditures (i.e., outliers). As a robustness check against our results in the pooled-over-time model, we estimate total Medicare spending using quantile regression, which allows us to model the *median* expenditure per episode (i.e., expenditure at the 50^{th} percentile). This helps to limit the influence of outliers in the data.

1.6 Data Challenges

Other important data issues were addressed partially for this report and will require additional work in the future. For example, the use of final action claims vs. submitted claims, and claims run-out/processing cut-offs, is not addressed in detail in CMS's Core measures specifications, but is of considerable importance when trying to create identical measures for baseline and intervention periods. The Core measure specification also does not recommend standardizing Medicare spending to remove the various penalties, incentives, and discounts that may apply to payments related to value-based purchasing, use of electronic health records, bundled payment, and other initiatives and that may vary over time and for intervention vs. comparison hospitals.

Given these data and definitional issues, and especially the fact that we cannot estimate the study population with perfect precision, we caution that all estimates in this report should be considered conservative and may be subject to change.

1.7 References

Bertrand, Marianne, Esther Duflo, and Sendhil Mullainathan. "How Much Should We Trust Difference-in-Differences Estimators." *Quarterly Journal of Economics, CXIX* (2004).

Cameron, A. Colin, and Douglas L. Miller. "A practitioner's guide to cluster-robust inference." *Journal of Human Resources* 50.2 (2015): 317-372.

Greene, William. "Econometric Analysis." *Pearson Prentice Hall*, Sixth Edition. 2008a. p. 153.

Greene, William. "Econometric Analysis." *Pearson Prentice Hall*, Sixth Edition. 2008b. p. 1,055.

Appendix B

Appendix B1: Christus Health

Integrated Nurse Training and Mobile Device Harm Reduction (INTM) Program

1. Executive Summary

This chapter presents the quantitative and qualitative findings of Abt Associates' evaluation of Christus Health's Health Care Innovation Award (HCIA) to implement the Integrated Nurse Training and Mobile Device Harm Reduction (INTM) Program. The INTM combines nurse training and supportive technology to improve the ability of nursing care staff to recognize early warning signs of congestive heart failure, sepsis, and other high risk conditions and intervene to mitigate harmful outcomes. The ultimate goals of the program are to reduce the number and severity of hospital admissions for nursing home residents in 12 partner nursing homes, reduce readmissions for general hospital inpatients, reduce serious preventable medical conditions, reduce rates of failure to rescue for hospital patients and nursing home residents, and reduce Medicare and Medicaid spending.

The INTM program includes intensive classroom and simulation laboratory training, and a software algorithm implemented using mobile devices (iPads). Nursing staff in the St. Michael's acute care hospital, as well as staff at the partner nursing homes, received initial clinical training and instruction on use of the iPad. Adoption and use of the iPad varies by site but overall is very low, and many nurses report that it is neither helpful nor necessary because of their years of experience in recognizing early signs and symptoms. Overwhelmingly, nursing staff report that the training element of the intervention has had the most impact on how they deliver care to patients. However, high staff turnover in nursing homes and limited training opportunities for new employees have caused the impact of the initial training to wane over time. In contrast, in the acute care setting, where the training has been incorporated into new employee orientation and where there is greater use of the iPad technology, the program may have greater impact and be more sustainable.

The Christus program patient registry is largely incomplete because the IT tool used for the intervention did not capture patient identifiers, and adoption of the iPad was minimal in the participating nursing homes. The registry cannot support creation of a comparison group matched on patient characteristics. However, Christus program staff assures us that all patients in all participating facilities are supposed to be clinically assessed every day following a careful protocol, whether or not the iPad is used. We, therefore, include all residents and patients in these facilities, and all those in comparison facilities, in our analyses.

Among patients who first encounter the intervention in nursing homes, our difference-in-differences analysis of Medicare claims shows a statistically significant increase in total Medicare 60-Day episode spending ($1,495) relative to the comparison group. There is nothing in our qualitative research that explains this outcome; we found no significant differences in 30-day inpatient readmissions or emergency department (ED) use between intervention and comparison groups and see no utilization increase that would explain the spending increase.

Among patients who encounter the intervention in an acute care (hospital) setting, we found no significant changes in 30-day inpatient readmissions or post-discharge ED visits relative to the comparison group. Our difference-in-difference analyses reveal a statistically significant decrease of approximately 0.2 days in hospital length of stay relative to the comparison group. It is possible that the training element of the INTM program is helping bedside nursing staff identify and treat emerging problems sooner, thus shortening hospital stays. We also found a significant decrease in the proportion of patients being discharged from the hospital with home health care. This finding was balanced by a significant increase in the proportion of patients being discharged to a destination of "other" which includes other facilities

(e.g., hospice, general hospital, and intermediate care facility), outpatient care, or being left against medical advice.[1] Although these care settings may be more costly than home health care, being discharged to a destination of "other" has not resulted in a significant increase in Medicare 60-day episode spending.

2. General Research Domains

The core domains for the Christus Health's program evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations, and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of HCIA funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to the Center for Medicare & Medicaid Services (Medicare, Medicaid, Children's Health Insurance Program [CHIP]).

The report that follows contains the results of Abt's qualitative evaluation.

[1] We did not run analyses for each of the "other" categories because the number of discharges in each category was too small.

3. Qualitative Results: Case Study

3.1 Introduction: Description of the Integrated Nurse Training and Mobile Device Harm Reduction (INTM) Program

Abt Associates is responsible for evaluating the 10 hospital setting HCIA programs. One component of the mixed methods evaluation is comprehensive case studies.

Christus Health received an Award to implement the Integrated Nurse Training and Mobile Device Harm Reduction (INTM) Program. INTM combines nurse training and supportive mobile device technology to improve the ability of nursing care staff across multiple organizations to recognize early warning signs of congestive heart failure (CHF), sepsis, and other high risk medical conditions, and intervene to mitigate harmful outcomes.

The INTM training is designed to improve nurses' critical thinking skills. Nursing staff (i.e., licensed practical nurses, known in Texas as licensed vocational nurses (LVNs); certified nurse assistants (CNAs); registered nurses (RNs)) in hospitals and nursing homes are taught to recognize signs and symptoms of CHF, sepsis and other high risk conditions. This extensive training is expected to help staff recognize early warning signs, begin treatment earlier, avoid preventable conditions/deterioration, and improve outcomes.

The supportive mobile technology was developed to guide hospital and nursing home staff in conducting systematic screening for specific conditions of concern and help identify emerging problems early. Implemented on an iPad, the technology prompts nursing staff to describe symptoms in detail, thus helping them organize their thoughts and succinctly relay detailed information to physicians. In addition, the mobile technology was designed to help nursing home staff evaluate the need to send a resident[2] to the hospital. By identifying emerging problems sooner, a resident may be treated at the nursing home rather than being sent to a hospital emergency department (ED). Even if an ED visit or hospitalization is necessary, earlier identification of symptomology may reduce severity and hospital length of stay. Outcomes of interest for this program include hospital length of stay and hospitalization/rehospitalization of nursing home residents.

3.1.1 INTM Program Goals

The ultimate goals of the INTM program are to reduce the number and severity of hospital admissions for 12 nursing home residents, as well as general medical and surgical hospital inpatients, improve quality of care, reduce serious preventable medical conditions, and reduce rates of failure to rescue for hospital patients and nursing home residents. The program encompasses the Christus ARK-LA-TEX (Arkansas, Louisiana, and Texas) service region which spans a 75 mile radius around Texarkana, Texas.

3.1.2 Impetus for the INTM Program

For several years prior to the Award, the St. Michael's Medical Director, who is the HCIA Principal Investigator (PI), was intensely focused on reducing poor outcomes, adverse events, and conditions that were not present on admission; all preventable situations. He wanted to identify patient problems sooner

[2] Note that in this report an individual who resides in a nursing home is referred to as a resident. An individual who is admitted to the hospital (including a nursing home resident), is referred to as a patient.

and prevent them from developing into serious conditions such as low blood sugar or sepsis, or any other condition that could precipitate negative outcomes. The PI recognized the need to reduce avoidable complications and mortality.

To understand the problem and identify the common causes of mortality, the PI routinely collected data and entered it into a software program that produced fishbone diagrams to illustrate themes. These diagrams revealed repeated occurrences and patterns, particularly for in-hospital causes of death. For example, he found that nursing home residents were often transferred to St. Michael's after developing severe medical conditions that could have been addressed earlier, avoiding transfer to the hospital. His next step was to consider how to reduce these patterns through better and earlier identification of emerging high risk conditions.

Approximately three years ago, following an unexpected and potentially avoidable patient death, St. Michael's Chief Executive Officer (CEO) challenged the PI to make St. Michael's a hospital where these events never happen. The PI's earlier work prompted creation of a quick (30 second) evaluation checklist that nursing staff could use to determine if a patient was developing a condition of concern. The CEO funded a project with internal resources to hire a third party software company to build a checklist tool and adapt it for use on a mobile device (in this case, an iPad) that would be easily accessible to nursing staff on every unit of the hospital. The checklist was not intended to be a diagnostic tool because diagnosis is outside the scope of nursing practice; rather, it was intended to alert nurses to potential problems requiring immediate attention. The prototype of the mobile-device application was tested at St. Michael's and the HCIA funded the purchase of iPads and staff training for the hospital and for 12 nursing homes that frequently refer/transfer residents to the hospital.

3.1.3 Christus Health Case Study Methodology

The Abt research team conducted the initial case study of the Christus INTM program March 18–20, 2014. The research team, composed of two senior staff from Abt Associates and one staff from Telligen (formerly CFMC; subcontractor to Abt), visited St. Michael's and the Christian Care Center (CCC) nursing home in Texarkana, Texas. Team members conducted eight interviews (seven at St. Michael's, and one at CCC) and seven focus groups (five at St. Michael's, and two at CCC). A total of 59 individuals participated in the interviews and focus groups. One member of the team facilitated the interview/focus group while the other two served as note takers. Exhibit 1 presents the number and type of individuals who participated in our data collection efforts.

Exhibit 1: Number and Type of Respondents Interviewed at St. Michael's and the Christian Care Center (CCC), March 2014.

	Trainers and Educators	Program Coordinators and other Nursing Leadership	RN, LVN, CNAs	NPs	Rapid Response Nurses	Christus Health System Leadership	Data/ Financial Analysts	Program Administrators
CSMHS	11	14	13	0	4	3	2	4
CCC	0	3	3	1	0	0	0	1

CSMHS: Christus St. Michael's Health System.
CCC: Christian Care Center

RN: Registered Nurse • LVN: Licensed Vocational Nurse • CNA: Certified Nursing Assistant • NP: Nurse Practitioner

The evaluation team conducted follow-up telephone interviews with nursing and program staff at St. Michael's and program-affiliated nursing homes March 2–6, 2015, near the end of the three year HCIA Award period. Some individuals, particularly program staff, were interviewed in both phases of data collection. Exhibit 2 presents the number and type of individuals at the hospital and affiliated nursing homes who participated in our data collection efforts.

Exhibit 2: Number and Type of Respondents Interviewed at St. Michael's and Three Partner Nursing Homes, March 2015.

	Trainers and Educators	Program Coordinators and other Nursing Leadership	RN, LVN, CNAs	NPs	Christus Health System Leadership	Data/ Financial Analysts	Program Administrators
CSMHS	0	3	4	0	2	1	2
Affiliated Nursing Homes	1	0	6	1	0	0	0

CSMHS: Christus St. Michael's Health System.

RN: Registered Nurse • LVN: Licensed Vocational Nurse • CNA: Certified Nursing Assistant • NP: Nurse Practitioner

The 2015 follow-up telephone interviews were conducted by four researchers: a senior Abt researcher, two mid-level Abt researchers, and a researcher from Telligen. A total of 20 individuals participated in the seven interviews (five from St. Michael's, and two from partner nursing homes) and four focus groups (two from St. Michael's, and two from partner nursing homes). Three nursing homes participated in the 2015 follow-up interviews. Each telephone interview was attended by at least two staff members, one leading the interview and the other taking comprehensive notes.

Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

3.2 INTM Program Components

The INTM is comprised of two primary components:

- Four-hour training sessions for nursing staff, conducted in a lecture hall and simulation laboratory; and
- A device-based Clinical Decision Support (CDS) system software application to be used by nursing staff after completing the training session.

3.2.1 Training

> "That training really made us pay attention to a lot of things that a lot people could easily overlook. The training should be mandatory."
>
> *– Nurse Trainee, Site Visit*

The training was considered by program staff as well as nurse-trainees to be the most important component of the INTM program. Trainees consistently reported a lasting impact of the training, for which they credited the dynamic teaching style of the PI. Training in all three years occurred in the simulation laboratory at St. Michael's. In the

first year of the Award, the program staff nearly reached their target of training 1,300 staff members by holding training sessions twice per week; they trained over 1,200 nursing staff in year one. During year two, four training sessions were attended by 75 newly hired staff, and with CMS carryover funds, nine additional classes on sepsis were added and attended by 197 staff. During the third year of the award, Christus is on track to meet their goal of training additional 100 staff, bringing the grand total of trained staff to more than 1,500 over the course of three years.

The Sisters of Incarnate, consulting with Christus on the INTM program, developed the training and an accompanying pre- post-training knowledge and feedback survey. Training in each year was attended by a mix of nursing staff from nursing home and hospital (medical/surgical and ICU) settings, and trainees included LVNs, CNAs, and RNs. As part of the sustainability plan, the program was awarded funds from the St. Michael Foundation (the Foundation) to continue the four-hour sepsis training for St. Michael's nursing staff beginning in year three, and extending beyond the end of the HCIA period.

Class-Room Training

The classroom portion of the training is composed of an introductory session, an iPad walk-through, and an hour-long lecture generally led by the PI. On rare occasions when he could not be present, the two program coordinators relied on a video of the PI for the lecture portion of the classroom training. The introductory session began with the pre-test survey to assess trainees' knowledge of the signs and symptoms of specific conditions of concern. The introductory lecture covered medication errors, health care acquired infections and sepsis, falls, aspiration, pressure ulcers, and failure to rescue. Trainees were introduced to the concept of "touch rounding", a practice that enhances the information learned about the patient during hourly rounding. By "touching" the patient - for example to check the patient's pulse - the nurse is able to perform a more complete assessment that includes pulse rate, blood pressure, skin condition, and breathing within 30 seconds. "Touch rounding" also teaches that engaging in a short conversation with the patient improves assessment of mental status and pain, and helps to identify unique patient attributes such as a limb amputation or the use of a pace maker that could affect the heart rate. The introductory lecture lasted between 15–20 minutes.

> "The collaborative approach worked so well, it wasn't a room full of just aides or a room full of just nurses; it was a team approach."
>
> *– Nurse Trainee, Site Visit*

Trainees also had the opportunity to obtain hands-on experience with the iPad checklist. They were first instructed on the basics of the iPad and on how to use the software application. The iPad walk-through traced the progression of a sepsis patient. Trainees received hands-on experience by entering signs and symptoms of a mock sepsis patient simulated over a 24-hour period. Classroom instruction reinforced that the iPad is not a crisis tool but rather an assessment tool, and that it should not be used in an emergency situation. Should an emergency situation arise, trainees were instructed to call the attending physician or the rapid response team (a group of experienced nurses trained to respond to early signs of clinical deterioration to prevent respiratory or cardiac arrest).

Following the simulation laboratory portion of the training (see below), trainees returned to the classroom for the hour-long lecture and debrief about the scenarios presented in the simulation laboratory. The lecture covered clinical topics such as respiratory failure, heart attack, stroke, deep vein thrombosis, pulmonary embolism, sepsis, ischemia, compression and compaction, bleeding, hypoglycemia, fluid overload, and output levels. The lecturer and trainees discussed signs and symptoms of the targeted conditions and how to apply the "touch rounding" approach to detect potential problems. At the end of the

hour-long lecture, trainees completed a post-test survey to evaluate changes in their ability to recognize signs and symptoms of the conditions addressed during the training and to provide feedback on the training session.

Simulation Training

The second part of the training occurred in a simulation laboratory that has four stations, each equipped with a hospital bed, monitors, and a simulation mannequin. For this part of the training, the program staff could not find pre-formulated scenarios that were appropriate for the training required, or they were not sufficiently sophisticated. They instead created six simulation scenarios and scripts to be selectively employed depending on the trainer's knowledge of the scenario, class size, and/or the number of hospital staff versus nursing home staff. The scenarios played out in the simulation laboratory pertained to sepsis, chronic obstructive pulmonary disease, CHF, hypoglycemia, oxygen toxicity, and over- sedation. Three or four trainees, usually an RN, LPN/LVN and nurse aide, entered the simulated patient's room and received a card with instruction regarding the role that he or she would play in the simulation. Roles included a family member (who may or may not be confrontational) or nursing staff. Those role-playing nurses received a hand-off from the previous nurse, and practiced touch rounding. They interacted with the "patient" by asking questions to which the mannequin offered "real-time" responses, simulated by a RN located outside the simulation station and equipped with a speaker and microphone headset. At the end of the simulation, the trainer provided immediate feedback to trainees, and each trainee group rotated to another simulation station where a different scenario was presented.

> "Going through the simulations was very helpful. It was less stressful because no one's life was hanging in the balance. We can talk about the case and debrief."
>
> *– Nurse Trainee, Site Visit*

The PI noted that if he had to do it over, he would include more training because what they are able to offer in four hours is really only an orientation. For example, due to large class sizes, the first cohort of trainees experienced only one or two simulation scenarios, and did not always get a chance to participate in the simulated roleplay. Once the PI recognized this problem, he adjusted class sizes and later cohort of trainees had the opportunity to participate in three or four scenarios and all had the opportunity to roleplay, marking a more complete training experience. The pre/post knowledge tests showed that, more exposure—scenarios, repetition—yielded better learning.

We learned that iPads are not routinely used during simulation training classes, although trainees are given the option of using them. Rather, iPads were used in the classroom where trainees practice entering signs and symptoms of a septic patient. The PI noted that not spending more time on iPad training was probably one of their greatest disappointments, but time constraints prevented inclusion of iPad training in the simulation laboratory.

Over the course of the program, the training component has remained consistent. Small revisions to the training materials (e.g. adding more content to the PowerPoint slides) were made, but the high level training model and content have stayed the same over the three-year Award period. The training plan, however, did not anticipate the high rate of staff turnover in nursing homes, endemic to the nursing home industry. Although program training is now integrated into the orientation for newly hired hospital nursing staff, there is no systematic training process in place to keep up with the high turnover rate in the partner nursing homes.

Christus used carryover funding from the first year of the Award to provide a second round of training on sepsis to St. Michael's nursing staff. This additional four hours of training included both classroom and simulation lab components. Program staff found that after the second round of training, nursing staff grasped the sepsis concepts measurably better than they did after the first round of training. The PI reported that sepsis rates on the units where these individuals work dropped significantly after the second training.

3.2.2 Technology

The technological component of the INTM program is a software application developed by a vendor for use on mobile devices (iPads). The application offers clinical decision support to help nursing staff screen patients and better identify symptoms of serious health events and conditions. The software contains quick assessment tools for chronic conditions (e.g. CHF, respiratory failure, diabetes), and for acute illnesses or events (e.g. sudden change in mental status, sepsis, pneumonia, urinary tract infection, internal bleeding). The use of the iPad is optional for nursing staff, and cannot be made mandatory until the Federal and Drug Administration (FDA) Awards approval which is currently pending, per guidance from Christus Health's internal Institutional Review Board (IRB).

The software's user interface facilitates the collection of patient vital signs that feed into a Bayesian decision engine. A calculation of probabilities based on historical hospital data, computes the likely diagnostic outcomes and presents a list of suggested actions. Nurses start by selecting a "trigger" or symptom from eight possible options that the individual may be experiencing (e.g., abdominal pain, back pain, chest pain, headache, pain in one extremity, shortness of breath, mental status change, increased heart rate). The application then generates a list of possible causes for the symptom and prompts the nurse to answer a series of yes/no questions. Based on these responses, the application calculates the likelihood that the patient has any of the aforementioned conditions or illnesses and displays a series of probabilities. The nurse considers these potential health conditions and notifies the physician or other supervisory staff as necessary. The application also produces reports for program staff to assess which nurses are using the iPad and whether or not it is being used properly. These reports can be used to validate the tool by checking the information against a patient's electronic medical records (EMR), to confirm whether patients assessed to be at high risk were actually deteriorating.

Program staff reported that the use of the iPad in the hospital and in nursing homes has been fairly low. There was an increase in use shortly after Abt's 2014 site visits when refresher trainings on use of the iPad were conducted. Subsequently, however, use of the iPad plateaued or declined in most hospital units and in the nursing homes. According to program staff, of the twelve nursing home partners, only four or five facilities regularly use the iPad. Most nursing staff reported using the iPad only a handful of times since the device was introduced.

When the mobile devices were first introduced in the hospital, it was possible to connect the program to the hospital's secure information network, enabling direct paging of the rapid response team from the iPad. However, shortly after implementation, Christus Information Management established a policy whereby wireless devices were not allowed access the secure network. As a result, the INTM mobile devices could no longer directly page the rapid response team. The PI reported that one proposed solution to this problem was to give rapid response nurses iPhones that would receive text messages directly from the iPads. However, the idea received pushback from the rapid response nurses who already carry one cellular device on which they receive pages and did not want to carry multiple devices. Because the iPad cannot page the rapid response team directly, it is a less appealing technology for hospital nurses. Today,

when nursing staff have concerns about their patients—particularly in the ICUs—they usually opt to immediately page the rapid response team rather than taking the time to employ the iPad to identify the problem. The PI considers this a "failure" of the program. The hospital is currently working with the software developer to devise a way to send a "call" from the iPad to the cellular device carried by the rapid response team.

The lack of integration with the EMR means that nursing staff can access the software program only from the iPad; they cannot use the program from the EMR. This adds another step to their workflow, essentially requiring nursing staff to enter the same information twice, into the EMR and the iPad, if they want to use the program software. The Christus team hopes to integrate the two systems, but the EMR vendor is very proprietary and will not permit it. Although the built-in redundancy may be a helpful double-check for novice nursing staff, Abt learned that more experienced nursing staff find the double-entry burdensome.

3.3 INTM Program Implementation

The INTM program was implemented in several different units at one acute care hospital, St. Michael's, and in 12 local nursing homes that offer long-term care (LTC) and skilled nursing services. The PI believes it was important to partner with these particular nursing homes for several reasons. First, St. Michael's had a pre-existing relationship with these partners through a health care coalition. Second, St. Michael's is one of the acute care hospitals to which these nursing homes frequently transfer residents who need hospital care. Third, the 12 nursing homes have a total of approximately 1,110 residents who experience frequent rehospitalizations, with some being potentially avoidable.

3.3.1 INTM Program Implementation Process

As noted, there are two components of the INTM program: staff training and the supportive technology installed on iPads. A substantial portion of the training was conducted in the first year of the innovation Award, although training continued in years two and three. At St. Michael's, the iPads were deployed in one unit in June 2013, in four additional units in July 2013, and in three remaining units in October 2013. The iPad application was not deployed on the labor and delivery or pediatric units, nor was nursing staff on those units trained. Introduction of the iPads to the 12 nursing home partners took place from February 2013 through September 2013. It is important to note that the rollout of the iPads did not perfectly overlap with the training. Staff who went through the training did not always have access to the iPads when they returned to work. In some cases, more than a year passed between the time of training and when the iPads became available. The lag between training and access to the iPads was described as a substantial barrier to iPad use by some of the nursing staff interviewed.

Each week, one of the program coordinators reviewed a report that is generated from the software application to learn which staff were using the iPad. She then made rounds to every participating hospital unit to troubleshoot workflow and other issues, to confirm that iPads are accessible to staff, and to encourage the use of the iPad. The program coordinator met with nursing staff who were not using the iPad program as intended (e.g., they were checking all categories rather than selectively checking categories) and those that were not using the tool at all, and provided a quick hands-on tutorial. A similar process was carried out at partner nursing homes, albeit the visits were monthly rather than weekly. Nursing staff at the nursing homes reported that the refreshers were helpful in encouraging the ongoing use of the iPad. The PI also visited hospital units and nursing homes periodically to encourage iPad use.

Frequent visits to the hospital units and the nursing homes were an opportunity for program staff to provide continuous training on the iPad, to answer questions, and to provide newly hired staff orientation to the iPad program. Such visits were especially useful in nursing homes since no systematic process was in place to educate and train the newly hired nursing staff at these facilities.

In the hospital, the PI and the program coordinators also served as internal program champions. Several of the hospital nursing staff indicated that the presence of the program staff reminded them of the availability of the iPad and triggered its more frequent use. Program staff attempted to identify unit champions in the hospitals, but that effort was unsuccessful. In the nursing homes, where staff turnover has been higher than expected, several administrators and other nursing home leaders who initially served as champions have since left. Despite support of the nurse educator at some nursing homes and routine visits from program staff, the absence of facility-specific champions emerged as a barrier to effective program implementation in the partner nursing homes.

3.3.2 INTM Program Implementation Target

The targets of the Christus program are hospital and nursing home nursing staff who care for patients and residents at risk for adverse events. The training and software application components are relevant for all nursing home residents and hospital patients except maternity and pediatric hospital patients, but the focus is on common medical problems of older adults such as CHF, sepsis, urinary tract infection, and respiratory failure.

3.3.3 INTM Program Implementation Effectiveness

It is important to distinguish between the training, which focuses on recognizing emerging serious medical conditions, and use of the iPad. Interviewees reported low use of the iPad, however everyone interviewed had participated in the training and their perceptions of the impact of the combined program generally focused on the training. In this section, we describe the fidelity to and impact of the two program components, when these are separable, and on the combined program as a whole.

During follow-up interviews, we noticed that the iPad, while originally intended to provide a bedside checklist to identify early warning signs of high risk conditions, had transformed into a "teaching tool" to retrospectively educate staff about how adverse events might have been handled differently. Nurse managers reported that they frequently recreated a patient scenario using the iPad, and then discuss with nursing staff about what they might have been done differently and how the patient's condition might not have deteriorated, had they used the iPad checklist.

3.3.4 Fidelity of the INTM Program

> "Because [a rapid response nurse] is generally always available, staff rely on the rapid response nurse, rather than using their own critical thinking skills or the iPad program."
>
> *– Principal Investigator, Telephone Interview*

The PI initially expected that every trainee would be eager to use the iPad, but this was not the case. When underuse of the iPad was first recognized, the program evaluator held focus groups with nursing staff to understand the barriers and motivators to using the iPad. One issue raised in these focus groups was accessibility of the iPads on nursing home and hospital units. Nurse managers at both the hospital and the nursing homes were worried about theft and locked the iPads in nurses' medication carts or in medication rooms. In response, the program staff communicated to the units and nursing homes that the goal was to use the iPads and that theft was a lesser concern. They asked to have

the iPads kept at the nurses' stations, where they would be readily available to the nursing staff. Although the accessibility of the iPads was slow to improve, by March 2015 program coordinators reported that they were available at all nurses' stations in every target unit of the hospital and at all partner nursing homes. To ensure their accessibility, program coordinators regularly checked that the iPads were available, charged, and fully functioning when they visited hospital units and partner nursing homes.

Use of the iPad application did not vary across types of patients or over time. However, we did hear many comments that device use varied among the nursing staff, some of whom use it regularly and others not at all. The hospital nurse managers reported that new graduates and nurse aides used the iPad application most often, while experienced nurses who tend to be more confident in their patient assessment skills were less likely to use it. None of the ICU nurses we interviewed used the iPad. One ICU nurse reported that the iPad application does not address the diagnoses and symptoms that are important for her patient population, and does not provide reliable clinical decision support. One nurse practitioner who sees residents at many of the partner nursing homes reported that some of the diagnoses in the software are not particularly appropriate for the long-term care population. For example, she recalled that the iPad frequently instructed staff to look for pulmonary embolism when a resident experienced a change in mental status, when in reality a urinary tract infection is far more common among long-term care residents who experience that symptom. Many of the nurses who do not use the iPad application feel that it is most useful for newly-graduated nurses.

At the hospital, fidelity may have been affected by the presence of the rapid response team. Nurse managers reported that the rapid response team is "an easier resource to use [than the iPad] because they are only a phone call away." The PI reported that St. Michael's recently added a dedicated, full-time rapid response nurse. Because this nurse was generally always available (unless responding to another patient), when nursing staff had concerns about a patient, they relied on the rapid response nurse rather than on the iPad for clinical decision support.

3.4 Achieving the Triple-Aim of Better Care, Better Health and Lower Cost

3.4.1 Better Care

Perceptions about program impact are mixed among program staff and nursing staff at the hospital and participating nursing homes. Nursing home leadership feels that the iPad program has improved nurses' assessment skills. However, nursing staff at the nursing homes were quick to point out that the program has not affected the quality of care they provide. One nurse aide stated that, "We are already number one on that. We already give quality care." The perception among experienced RNs at the hospital and the nursing homes is that they already know the information conveyed by the software application and do not need the iPad. They do, however, acknowledge that if use of the iPad had been made mandatory from the beginning, the impact of the program on quality of care might have been greater.

Program staff believe that the training has allowed all levels of staff to provide better care to patients. Nurses at all levels found value in the training component of the program. In fact, the measurement team noted that a lot of the signs of patient deterioration were missed even by experienced nurses during the training. Thus, according to the program staff, the gain in quality of care in the hospital is mainly attributable to the training component of the program.

Both RNs and nurse aides at the hospital reported several incidents in which a serious complication was averted because of knowledge gained in the training. Training was credited with helping nursing staff

become more skilled at assessing patient status, and more aware of the possible causes for symptoms their patients are experiencing. They believed several "saves" occurred due to knowledge gained during the training. Additionally, nursing staff reported that the informal refresher trainings they received from program coordinators during their routine rounds to the target units and the nursing homes increased the quality of care being delivered to residents.

A nurse practitioner who cares for a large number of residents in the partner nursing homes believes that the training and software application greatly improved the nursing staff's ability to detect problems early and noted that reporting to her and to the hospital upon transfer was clearer and more detailed than it had been prior to the training. Further, the collaborative meetings between nursing home and hospital staff led to more open and improved lines of communication, with better coordination and hand-offs between settings. The program staff reported that they now have a better idea of what is going on with nursing home residents being transferred to the hospital, due to improved transfer reports.

3.4.2 Healthier People

The PI highlighted a decrease in mortality associated with sepsis in the hospital halfway through the Award. Comparing the historical sepsis mortality rate to current rates, the hospital improved far more than anticipated, and the PI attributed this change to the training and iPad application. Sepsis rates had increased due to earlier and better detection, but mortality from sepsis decreased (25 fewer sepsis deaths in the first year of the program than the previous year). He reported that they still have "misses" and probably still have one sepsis death per month that could be prevented. Additionally, the PI noted that this program resulted in less catastrophic harm because fewer patients now required mechanical ventilation. They also observed a decline in readmissions for particular types of patients; for example, there was a reduction in the number of 30-day all cause readmissions for heart failure patients (although the decline cannot necessarily be attributed to the INTM program). Program staff also noted that there has been a significant decrease in sepsis rates, particularly in the hospital units where Christus used rollover funding to provide four additional hours of sepsis training to bedside staff. Most interviewees suggested that the training component of the program, rather than the iPad component, drove these improved outcomes. In either case, the team did not observe any significant changes to the length of stay outcome even though one might expect that a reduction in catastrophic harm is associated with a reduction in length of stay.

The program self-evaluator reported that there has been a reduction over time in the severity of diagnosis related group (DRGs) (i.e., case mix index, CMI) resulting in lower costs to Medicare for nursing home residents admitted to the hospital. At baseline (July–December 2012), the average CMI was 1.46 for all admissions from partner nursing homes. Since April 2013, the average quarterly CMI has been consistently below baseline (1.42, 1.25, 1.29, 1.45, 1.39, 1.26, and 1.33). Program staff attributed this lower CMI to finding and addressing problems earlier in nursing homes, so patients are not as critically ill when they are transferred to the hospital, yielding lower weighted DRGs and lower Medicare payments. The critical thinking skills gained during training, improvements in nursing assessments, and better communication/collaboration between hospital, providers, and nursing homes staff, were all sited as contributing to earlier recognition of emerging high risk conditions. Additionally, the program self-evaluator reported a reduced number of transfers from the nursing homes to the hospital. They do not have data to demonstrate whether or not the program has reduced hospitalization rates, mortality, or other outcomes for nursing home residents.

3.4.3 Smarter Spending

There was general agreement among hospital and nursing home nursing staff that keeping people out of the ICU will reduce costs. Hospital nursing staff explained that preventing sepsis will reduce costs, and nursing home leadership said that even when hospitalization is necessary, admitting residents before their medical condition severely deteriorates will reduce ICU use, length of stay, and costs.

At St. Michael's, the program is credited with reducing the variable cost per patient because the patients being admitted to the hospital from the long-term care facilities are less sick compared to the baseline year. This has resulted in savings since the patients are being sent to the hospital prior to experiencing septic shock (for example) and are discharged with a lower DRG weight (i.e., lower cost to Medicare). The goal is to reduce the DRG weight for patients admitted from nursing homes, so that costs to the Medicare program decrease. In addition to savings for payers, program staff reported that there has been a 10 percent decrease in the costs to the hospital of delivering care, which they attribute to the program.

Nursing home nursing staff expressed that they were not sending as many residents to the hospital as they did prior to program implementation. Still, they also explained that RN and physician preferences and nursing home policies influence these transfers; nursing home policy dictates sending a resident to the hospital if the RN thinks they should go, if the resident asks to be transferred, or if the family asks that the resident be hospitalized. The nurse practitioner noted that due to the high acuity of nursing home residents who have multiple comorbidities, there will inevitably be a group of nursing home residents who are repeatedly hospitalized despite best efforts by staff to keep them out of the hospital.

3.5 INTM Program Workforce Development

In the first year of the Award, 2012, the Christus team focused on training. Their goal for year one was to train 1,300 nurses and they came close to their target by training 1,200. During that first year, they had over 30 trainees in each session, which they felt was too many; some trainees were unable to participate in hands-on laboratory simulations due to the crowded sessions. They have since modified the training so that everyone has a chance to participate in hands-on training. Approximately 45 percent of the nurses trained in year one were from participating nursing homes, and 55 percent were from St. Michael's. In year two, a total of 232 nursing staff were trained, of which 38 percent were nursing home staff and 62 percent were from St. Michael's. The Christus team is on track to meet their year three goal of training an additional 114 staff, with an expected 23percent of nursing staff from nursing homes and 27 percent from St. Michael's. During the third year of the Award, they achieved their operational goal by training a total of over 1,500 nurses and by the end of the Award they will have well exceeded it (expected 1,646 trainees). In addition to HCIA funds, the training of hospital nursing staff in year three was supported by the Foundation Award.

3.5.1 INTM Program Staff

With the exception of one of the two program coordinators, all program staff were recruited from within the Christus Health System. The PI, who conceptualized the software application, has worked in the Christus Health System for 13 years, and the project manager, has been a Christus employee for eight years.

INTM Nurse Recruitment

All levels of nursing staff in target hospital units are required to attend at least one of the four-hour training sessions, and are provided with an iPad in their unit. Similarly, a condition for nursing homes'

participating in the program is that their nursing staff be trained in the INTM program, although there did not appear to be any enforcement of this requirement. For newly hired nurses, the hospital provides training under the Award as part of their new-hire orientation. However, as noted previously, no systematic processes are in place at the nursing homes to ensure that new nursing staff receive the training. Program coordinators volunteered to conduct nursing home staff trainings during new-hire orientations. However, once they learned the frequency with which orientations are held to accommodate staff turnover, they conceded that this would not be a sustainable practice.

Nursing Home Recruitment

The program staff partnered with 12 nursing homes in their health care coalition. The coalition was created in July 2006 by the PI to improve the collaboration and communication between St. Michael's and nursing homes in the same market for the betterment of the community overall, and for enhanced care of their shared patients who are frequently admitted to St. Michael's. The coalition was open for any long-term care facility in the area to join, and an initial invitation letter was sent to all nursing homes there. Representatives from about 20 facilities regularly participate in coalition meetings. The PI noted that the coalition lacked enthusiasm and the meetings had low attendance until about a year before the Award when members began to show interest in the proposed program. When the program was getting off the ground, the frequency of the meetings increased to every month in order to stimulate interest and enthusiasm.

The INTM program was introduced and discussed at the quarterly coalition meetings, prior to the Award. After the Award was granted, nursing homes were recruited into the program by asking for agreement to participate in the program. The first 12 nursing homes who signed an agreement were accepted into the program.

Staff Turnover

There have not been any significant program staffing changes since the Award. In terms of nursing staff, there is inevitable turnover in both the hospital and nursing homes, and it is challenging to keep up with INTM training, especially in nursing homes with a reported 35 percent turnover rate. Although they have met their target goal of training 1,500 nursing staff, the program budgeted less money for training in the second and third years of the Award, and the Foundation Award that they received only covered training for hospital staff. This, coupled with high staff turnover in the nursing homes, resulted in fewer training opportunities for newly hired nursing staff.

Some nursing homes experienced considerable administrative staff turnover that further inhibited the training of new staff. Program buy-in was not as strong among the newly hired administrators who did not always agree to send their nursing staff to the hospital for training. Of the 12 partner nursing homes, only a reported four to five use the iPad. One of the individuals interviewed seemed to believe that these are the facilities with strong administrators who have bought into the program and encourage utilization of the device.

3.5.2 INTM Program Impact on Workflow and Workload

Program staff reported that the iPad application was not integrated into nurses' workflow, and therefore has not had an impact on their workload. While there are iPads on all the participating hospital units and in the nursing homes, very few nurses use them on a regular basis. Program staff reported that incorporating the iPad into the workflow of already "busy and task-laden" nursing staff has been one of the greatest project challenges. If the iPad software were more fully assimilated into nursing workflow,

and widely adopted, it would undoubtedly increase workload as the software is not currently integrated with the EMR and nurses would have to enter the information in two places. However, if the iPad software were fully integrated with the EMR, there would be little increase in nursing workload regardless of the degree to which it was utilized because vital signs and other critical data would not have to be entered twice.

Several hospital RNs reported that the real value of the iPad is as a retrospective teaching tool after an adverse event or other condition has been identified. Nurse managers reported that they recreated the scenario and, using the iPad, discussed with nursing staff about what might have been done differently. Many of the interviewees viewed the iPad as being very valuable in this context. Still, but it is important to note that this was not the original intent of the iPad application. Rather than a retrospective teaching tool, the original goal of the iPad program was to provide a checklist to guide nurses through a systematic screening for specific conditions in order to identify problems early.

In hospital units with more frequent iPad use, nursing staff reported that they are able to more quickly identify patients with high risk conditions and provide faster care and treatment, ultimately reducing nurses' overall workload. Additionally, patient care responsibilities shifted in hospital units that use the iPads. Program staff told us that nurse aides can conduct an initial assessment on a deteriorating patient using the iPad, which allows more time for the charge nurses to care for more clinically complex patients.

3.6 Context

When the INTM program was implemented, there were multiple other initiatives at the hospital and participating nursing homes. Hospital nursing staff reported that they were involved in a number of other quality improvement programs that focused on central line-associated blood stream infections, catheter-associated urinary tract infections, and preventing falls and pressure ulcers. In addition, several nursing homes were also transitioning from paper records to EMRs during the INTM implementation.

Other situations that may have impacted the INTM program include the long-standing policy of nursing home administration and physicians that encourages nursing staff to send residents to the hospital whenever requested by the resident or family. In addition, nursing home culture mandates that nurse aides report any resident changes first to the RN. Use of the iPad could come after that notification had been made, but this may be seen as redundant if the problem has already been recognized.

Nursing home leaders were initially expecting that by participating in this program, their new relationship with St. Michael's would bring a "windfall of new Medicare residents." Nursing homes aim to fill their beds with as many Medicare residents as possible because the reimbursement from Medicare is considerably higher than from Medicaid. Having a solid relationship with a hospital was expected to increase the number of Medicare residents admitted to the nursing homes. As the INTM program was implemented, however, it became clear to the nursing home leaders that their participation in the program was not leading to more Medicare admissions. Rather, if the program was successful in identifying and treating emerging conditions early, it could lead to fewer Medicare readmissions (residents transferred to the hospital and then returned to the nursing home at a higher acuity level, with higher reimbursement).

This past year, the INTM program was implemented as a pilot project at another Christus hospital funded by the iPad software developers, Arkansas Integrated Community Health Network (AICHN). AICHN is a St. Michael's For-Profit entity. This pilot expansion included an enhancement to the iPad software to facilitate rounding. The rounding function guides nursing staff through the steps of entering vital signs

and patient reports of pain. If a combination of entries indicates a potential problem, the program triggers an alert that directs nursing staff to take additional steps. If everything is OK, the iPad software directs nursing staff to move on to the next patient. Program staff reported that use of the iPad was much greater at this other facility because "nurses have a reason to pick up the iPads." This lesson learned from the pilot program is guiding future sustainability plans for the INTM after HCIA funding ends.

3.7 Unintended/Unanticipated Impacts of the Program

3.7.1 Enhanced Communication and Coordination between Nursing Home and Hospital

Although the 12 nursing homes and St. Michael's were already part of an existing health care coalition, frequent meetings to implement this program offered more contact between them than had occurred in the past. As a result, communication and coordination between the hospital and the nursing homes improved beyond what was expected from INTM program collaboration. Because of the frequency of contact, nursing home staff became familiar with the hospital program staff and felt comfortable raising issues of concern that were not directly related to the program. In turn, hospital staff came to better understand the management and operations of the partner nursing homes. They were more open to listening to suggestions and making changes to improve collaboration.

Program staff, including the PI, visited the nursing homes to understand nursing home staff concerns. For example, nursing home staff requested that the hospital ensure that a discharge summary accompanies residents returning to the nursing home after a hospital stay, and that these transfers back to the nursing home not take place at night, when the nursing home has fewer staff working. Staff at the nursing home we visited reported that communication and coordination of care between their facility and the hospital had greatly improved. The nurse practitioner who cares for a large number of nursing home residents offered that she sees improved communication with the hospital as the biggest achievement of the project. Other members of the program staff agreed that these improved relationships will have a lasting impact beyond the life of the Award. The PI underscored the importance of building and maintaining professional rapport with the partner nursing homes and said that he plans to maintain these relationships regardless of whether or not they are able to sustain the INTM program.

Another byproduct of the program is that St. Michael's has become the preferred provider for many long term care facilities in the area. St. Michael's patient load has increased as a result, which may, in turn, have an impact on other non-participating hospitals in the geographic area.

3.7.2 Enhanced Communication between Aides, Nurses, and Physicians

We heard mixed reports from interviewees as to whether the use of the iPad application improved communication among clinical staff. Program staff had expected enhanced communication between nurses and physicians, but focus groups run by the program's self-evaluation and measurement team did not find evidence that this has happened. Experienced hospital nurses told us that physicians with whom they work respond to them based on an established relationship of trust, and the iPad application did not help experienced nurses present patient information to physicians. Other nurses at both the hospital and the nursing homes described how the iPad application is helpful in assembling information to share with physicians, especially for new nursing graduates or new hires that lack an established relationship with the physicians or the experience of reporting to physicians. One nurse aide explained that the iPad application helped when he was having trouble getting a nurse to pay attention to a concern that he was raising. He was able to show the iPad to the nurse as "back up" for his concern. Other nurse aides,

however, felt that the nurses already listened to them and that the iPad application did not make a difference.

A nursing home nurse practitioner felt that training and the iPad improved the assessment skills of the nursing staff and therefore improved the quality of information they were passing along to her about residents in need of medical attention. However, given that the iPad is used infrequently in the nursing home, the program may not have a consistent impact on resident care.

The program clinical educators reported that a key point of the training was to give nurse aides the tools to communicate with their RNs, to promote teamwork, and to maximize the role of the aides. "Communicating up" was a key element of the training, and the simulations offered opportunities to practice how the nurse aide would report to the RN (or physician). They also believed that the iPad application helped RNs plan what to say to a physician and anticipate what the physician might order. Similarly, clinical educators noted that the iPad application prompted the RNs to listen to the nurse aides. Unfortunately, however, the iPad is not used with enough frequency to meaningfully impact these interactions.

3.7.3 Increased Confidence for New Nurse Graduates and New Hires

Clinical educators reported that the information on the iPad helps verify or confirm what new nurses identify as emerging problems and gives them the confidence to speak up "as they're a little scared to say anything." Many individuals we interviewed underscored the fact that the training could be especially beneficial for new graduates or newly hired nursing staff.

3.7.4 Barriers, Facilitators, and Lessons Learned Regarding Program Implementation

The INTM program has encountered several barriers, but many facilitators have also been identified. Taken together, the barriers and facilitators lead to lessons learned about the INTM program.

Barriers

- Nursing staff turnover and retraining needs, particularly in partner nursing homes, were challenging for a training-intensive intervention.
- Resistance to using the iPad has been consistently present among all levels of nursing staff.
- There were not enough training sessions and hands-on scenario based training using the iPad application.
- Lack of software integration with EMR at the hospital and nursing homes required nurses to enter information in two different systems; this impairs adoption and use of the iPads.
- Hospital and nursing home administrators could not mandate use of the iPads, based on guidance from their IRB, until they have received FDA approval for the software program.
- Identifying hospital and nursing home champions to continuously encourage use of the iPad has been challenging.

Facilitators

- The PI, who is a dynamic leader and teacher, has been essential to success of this program.
- The simulation laboratory for hands-on training was viewed by many as a critical component.
- The effectiveness of the training overall, with or without use of the iPad, was cited as the main change driver.

> "They [nursing staff] are providing a safer environment for the hospital patients and are now picking up on some symptoms that were missed before."
>
> *– Principal Investigator, Telephone Interview*

Lessons learned

- Longer training sessions with more simulated scenarios and iPad training could be included in the simulation laboratory portion of the training.
- More one-on-one instruction may be beneficial in hospital units and nursing homes to encourage the use of the iPad in the workflow.
- Program staff could identify a champion at each nursing home and on each hospital unit to provide one-on-one instruction and encourage the use of the iPad in the work flow.
- Sustainability and growth may require eliminating double data entry by integrating the software application into the hospital EMR.
- Smaller training classes may give everyone an opportunity to participate in the simulation laboratory.
- The iPad may be more effective as a retrospective teaching tool than as a bedside tool to identify early warning signs of high risk conditions. Clinical managers could be offered additional training in how to use the iPad application in this teaching capacity.
- Implementing the program in one unit at a time may enable more one-on-one training, which could enhance adoption.
- The iPad may be more regularly used if it is implemented as a rounding tool rather than as a tool to identify early warning signs.

3.8 Conclusions & Sustainability of the Program

The INTM program provided nursing staff with training and access to a checklist on a mobile device to identify early signs of high risk conditions. The INTM program aimed to enhance the critical thinking skills of nursing staff and to improve their ability to recognize pending harm and intervene to prevent or mitigate of the escalation of harm. Implemented at one large hospital and 12 nursing homes, the training was well-received by all participating staff, while the use of the mobile device was lower than expected at all sites. Staff believed that the training should definitely be continued for the clinical knowledge gained and for the improved communication that results between the hospital and the nursing homes. There were a number of reasons offered for limited use of the mobile device. Experienced staff stated that they already knew the clinical content on the device, and its use was not mandatory,

> "Our greatest accomplishment has been the looks on their [the staff] faces when they learn new things and tell us about their rescues. They call us and say, "Look what we did." There are patients now who are doing better and surviving, that may not have before."
>
> *– Principal Investigator, Telephone Interview*

nor was it integrated into staff's daily workflow. If the mobile device was used in rounding, and if it was integrated into the EMR, it might become more integrated into nursing workflows. Christus leadership acknowledges the limited use of the device but also anticipates that with a consistent message about expectations for use, the program will continue. Their prime focus appears, however, to be on the nursing staff and ensuring their continued access to simulation training. They believe that simulation training is the most effective method for developing and practicing the critical thinking skills most needed by bedside nurses.

As Christus approaches the end of the HCIA funding period, staff are optimistic that the program will be sustained in some form. The leadership team has submitted a proposal to the Christus Health System to fund the program at all Christus locations—23 acute care hospitals employing about 7,000 clinical staff. The proposal for ongoing funding incorporates many of the lessons learned over the course of the HCIA Award, including incorporating the iPad into daily rounds, rolling the program out one unit at a time, and identifying unit champions to encourage use of the device and troubleshoot issues as they arise.

The Foundation provided funding in year three to extend the training component of the program to St. Michael's nursing staff using the simulation laboratory. The Foundation funded implementation of the sepsis training that was developed using HCIA roll-over funds, and they are currently looking into conducting an annual fundraiser in order to provide ongoing support for the simulation laboratory training. This will allow St. Michael's to continue to develop training modules in the simulation lab on other topics.

Even if additional funding is not secured to expand the program system-wide, program staff are confident that the program will continue in the hospital units and nursing homes where it has been implemented. The PI plans to retain at least one nurse outreach coordinator to serve as a liaison to the 12 nursing homes and one-on-one iPad trainer for the nursing homes and hospital units. All parties also plan to continue the collaborative meetings between St. Michael's and the nursing homes, to maintain the strong relationships that developed through the program.

The PI has applied for FDA approval of the iPad software. If approval is granted, the health system may make the use of the device mandatory for nursing staff, and the efficiency and effectiveness of the tool will be better realized, according to the PI. The PI also has plans to seek venture capital funding for marketing the device if it receives FDA approval.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode spending. For Christus patients whose program intervention began in a nursing facility (skilled nursing facility (SNF) or long-term acute care hospital (LTACH)), we present the following core measures:

- Admission (transfers) from SNF or LTACH to the hospital
- Total Medicare spending for 60 days including the index admission and all spending for 60 days after admission
- 30-day post-admission (all cause) visits to an acute care hospital emergency department following an index admission

For Christus patients whose program intervention began in an acute care hospital, we present results for the following core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission for a patient eligible for the screening innovation, in either an intervention or comparison hospital.
- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.
- Total Medicare episode spending for 60 days including the index admission and all spending for 60 days after discharge. The Christus Health program aims to reduce length of stay (LOS), and to avoid complications through adherence to best practice guidelines. We present results for the following additional measures:
  - Length of stay (LOS)
  - Discharge destination for inpatient discharges

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. We additionally report median regression estimates of 60-day Medicare episode spending. Results are reported in section 2.2 below.[3]

All regression models include controls for patient age, squared age, gender, race, Hierarchical Condition Category (HCC) score in year of treatment, squared HCC score, eligibility for Medicaid at any time during observation period (2010-2014), as well as indicators for the quarter in which the episode occurred.[4] An indicator is also included for individuals with missing HCC scores.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[5] We believe this is an accurate way to compare time periods.

---

[3] The only exception is discharge destination, where quarterly estimates are reported in table form due to the multitude of possible outcomes.

[4] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g. age, gender).

[5] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

4.1 Defining Intervention and Comparison Groups

4.1.1 Selection Rules

The section below explains how we defined a set of criteria or rules that were used to create both the comparison and intervention groups for the two arms of the Christus program. The criteria were created using information that is available in the Awardee registry and in Medicare claims. These were then uniformly applied to patients from intervention and comparison facilities to select the final intervention and comparison populations.

The Christus program registry is largely incomplete because the IT tool used for the intervention did not capture patient identifiers, and also adoption of the tool was not widespread in long-term and post-acute care (LTPAC) facilities during the period of this analysis (through Q4 2014). We conclude that the registry provided by Christus cannot support creation of inclusion and exclusion rules. However, Christus program staff assures us that all patients in all participating facilities are supposed to be clinically assessed every day following a careful protocol, whether or not the IT tool is used. We therefore include all patients in these facilities, and all those in comparison facilities, in our analyses. In the future, if the IT tool is used more widely, it may be possible to conduct similar analyses for the subset of patients for whom the tool is used.

Exhibits 1 and 2 below provide information on average patient characteristics for the Awardee and comparison groups in both the baseline and intervention periods. Exhibit 1 refers to the acute care component of the intervention, while Exhibit 2 summarizes the LTPAC component of the intervention.

The demographic summary statistics serve two purposes. First, these statistics offer a sense of the population demographics in the Christus acute care and long term care populations. Second, they show that the demographics are similar for intervention and comparison groups, with relatively wide standard deviations. The wide standard deviations reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

For both the LTPAC and acute care sub-populations, we see a decline in the share of patients eligible for Medicaid between baseline and intervention periods, in both the Awardee and comparison groups. We also note that the HCC scores are lower for both groups in the intervention period than they were in the intervention or baseline period.

Exhibit 1: Patient Summary Statistics – Acute Care Patients

	Awardee				Comparison			
	Intervention Period (N=5,080)		Baseline Period (N=16,739)		Intervention Period (N=2,287)		Baseline Period (N=7,016)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.56	0.50	0.58	0.49	0.56	0.50	0.56	0.50
Nonwhite	0.20	0.40	0.19	0.39	0.24	0.43	0.23	0.42
Age	72.86	12.68	72.83	12.70	72.17	12.74	71.95	13.39
HCC Score	1.54	1.56	1.77	1.76	1.58	1.71	1.76	1.87
Missing HCC	0.08	0.27	0.03	0.18	0.07	0.26	0.04	0.20
Medicaid Eligibility	0.41	0.49	0.51	0.50	0.43	0.50	0.53	0.50

Source: Abt Associates, May 2015.

Exhibit 2: Patient Summary Statistics – LTPAC Patients

	Awardee				Comparison			
	Intervention Period (N=996)		Baseline Period (N=2,876)		Intervention Period (N=732)		Baseline Period (N=2,117)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.63	0.48	0.65	0.48	0.63	0.48	0.66	0.47
Nonwhite	0.18	0.39	0.20	0.40	0.14	0.35	0.16	0.37
Age	79.58	11.23	80.08	11.06	79.84	10.68	80.09	10.76
HCC Score	1.75	1.48	2.13	1.69	1.74	1.45	1.93	1.54
Missing HCC	0.06	0.24	0.03	0.17	0.04	0.20	0.02	0.13
Medicaid Eligibility	0.49	0.50	0.79	0.41	0.52	0.50	0.79	0.41

Source: Abt Associates, May 2015.

4.2 Core Measures: Results

The following sections show results separately for the acute care hospitals participating in the Christus program, and for the nursing facilities. The graphs for the acute care hospitals show discharges followed within 30 days by a readmission, and followed within 30 days by an ED visit, as well as Medicare spending for a 60 day episode starting the inpatient admission, length of stay, and discharge destination.

The Medicare episode spending analyses below are restricted to include only patients whose care began in an acute care setting. We analyze only LTPAC patients in separate analyses from those that include acute care patients; It is important to note that the LTPAC patients could have entered those facilities weeks or months before receiving intervention screening, and could be discharged after just a few days—or many weeks—of screening. The episode reported on here is for 60 days after admission to the LTPAC, and we assume that all intervention patients had at least some of the program screening during those 60 days (because few LTPAC stays last longer than 60 days).

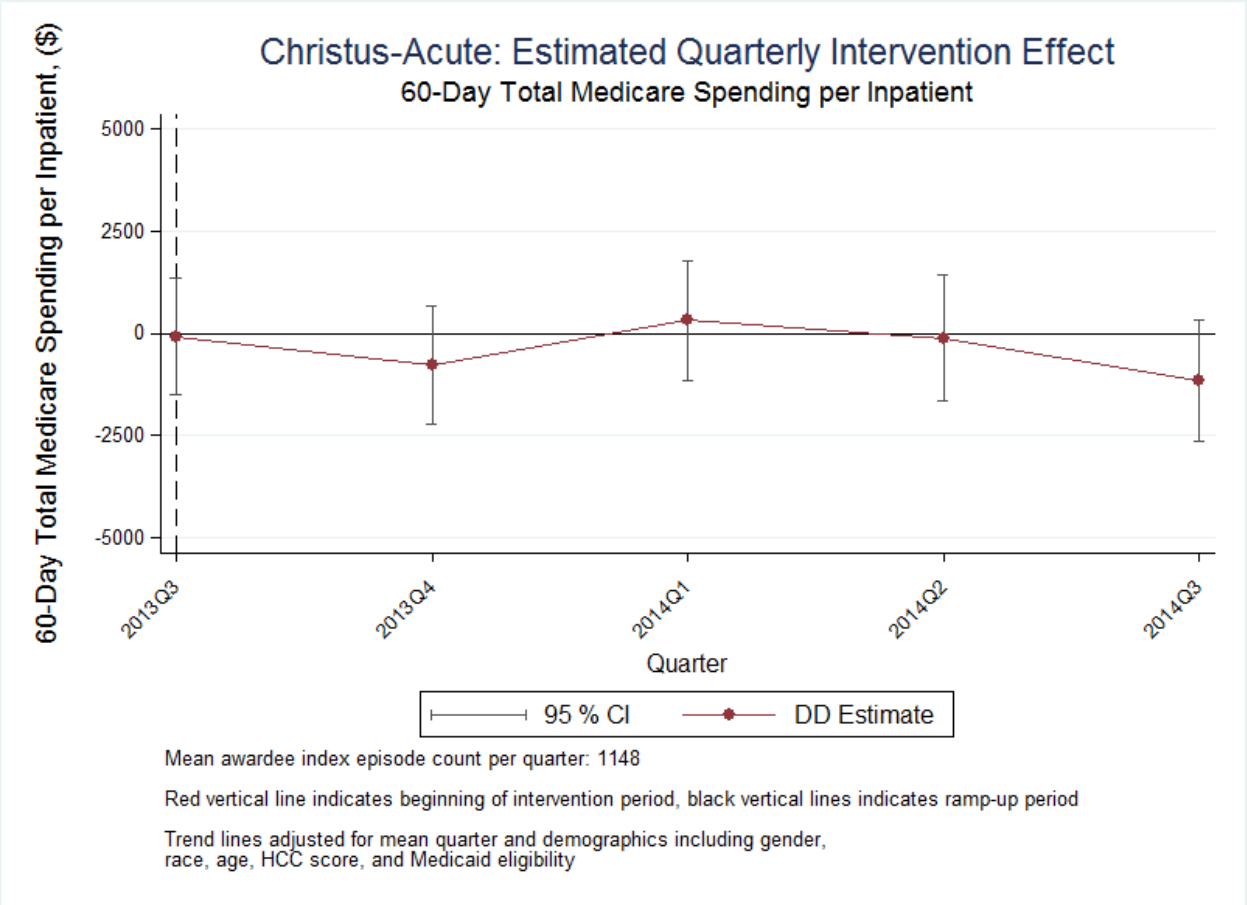
All estimated changes in utilization are based on six quarters of post-implementation data for the acute-care arm of the intervention, and eight for the LTPAC arm of the intervention. One less quarter

of data is included for the spending measure, due to the lag required for post-acute claims to become available for analysis.

4.2.1 Medicare Episode Spending – Acute Care Patients[6]

Exhibits 3 and 4 report episode Medicare spending including the hospital inpatient stay and all costs in the 60 days after discharge. Quarter-level difference-in-difference (DD) estimates in Exhibit 3 show little evidence of program impact. Neither ordinary least squares nor median regression estimates of the pooled effect of the intervention are significantly different from zero, supporting the lack of intervention effect indicated by the quarterly estimates. These exhibits are restricted to patients whose program intervention began in an acute care hospital setting.

Exhibit 3: Mean Medicare Episode Spending - Acute Care Patients



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

[6] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 4: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs

Christus Health – Acute		
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	-295.06 (379.64) [31,122]
Intervention Effect (Median Regression)	Estimate Standard Error Sample Size	114.79 (218.60) [31,122]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.2 Medicare Episode Spending - LTPAC Patients

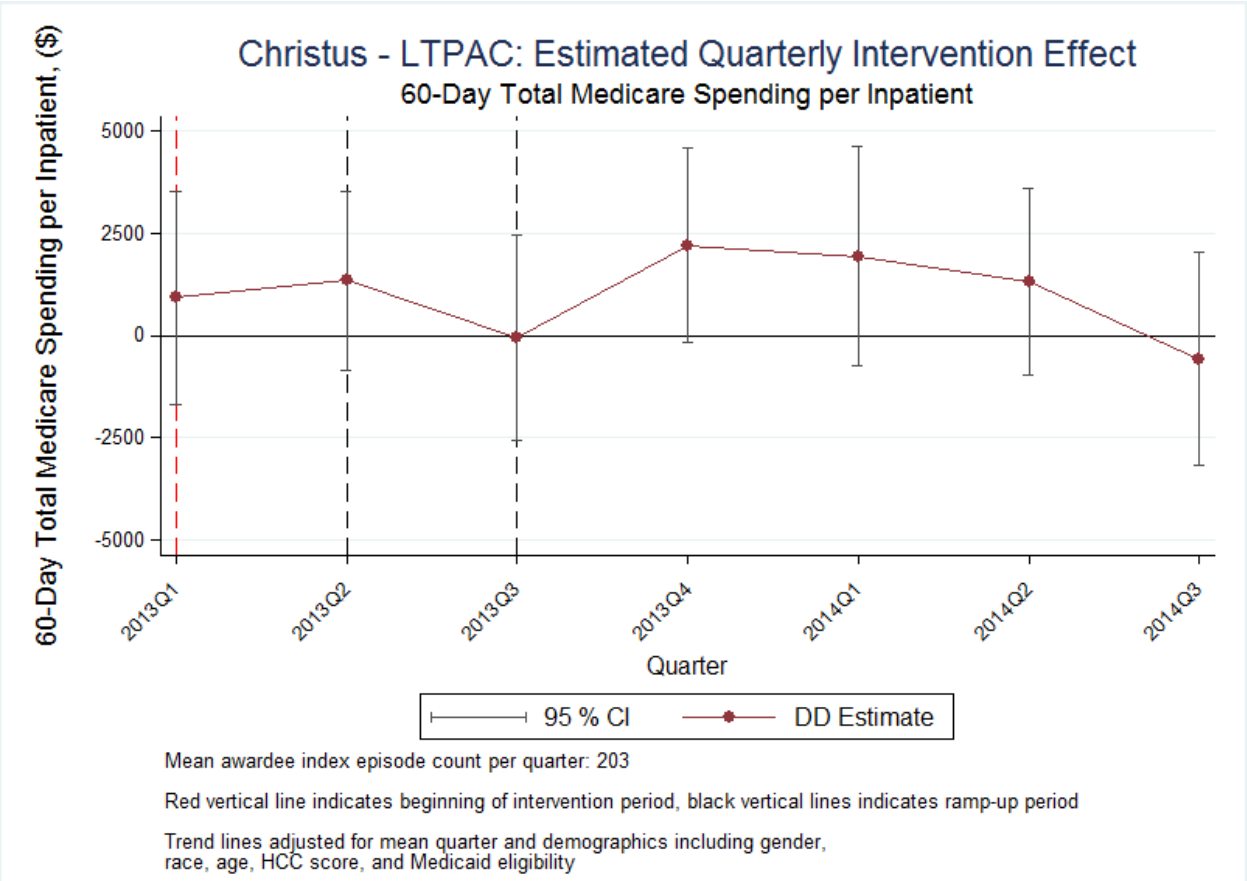
We examined Medicare 60-day episode spending for patients who first encountered the screening program in LTPAC facilities. The episode reported on here is for 60 days after admission to the LTPAC, and we assume that all intervention patients had at least some of the program screening during those 60 days (because few LTPAC stays last longer than 60 days).

Exhibit 5 shows that Medicare spending was consistently higher for patients treated in intervention facilities relative to comparison facilities, and there is no evidence that this difference has changed since the start of the intervention until the last quarter of data currently available. Below we report estimates from a regression model to determine whether the intervention has had any significant impact on Medicare spending. The regression pools estimates across all participating facilities because none of the facilities is large enough to reliably estimate facility-specific effects.

Ordinary Least Squares (OLS) regression estimates for the SNF component of the Christus program indicate a statistically significant relationship between the intervention and Medicare episode spending during the 60 days starting with the index admission. There was an average increase in post-discharge Medicare spending of roughly $1,494 per patient. The median regression estimate also indicates that the intervention is associated with increased Medicare spending per episode, although the result is not statistically significant. This suggests that the increased spending is primarily driven by episodes at the higher end of the cost distribution, which has less influence on median regression estimates.

We conclude that while this program is increasing Medicare spending for SNF patients, it is not affecting Medicare spending for patients who receive the intervention in the acute care setting.

Exhibit 5: Mean Medicare Episode Spending – LTPAC Patients



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 6: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs

Christus Health – LTPAC		
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	1494.84*** (618.33) [6,721]
Intervention Effect (Median Regression)	Estimate Standard Error Sample Size	732.47 (795.09) [6,721]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

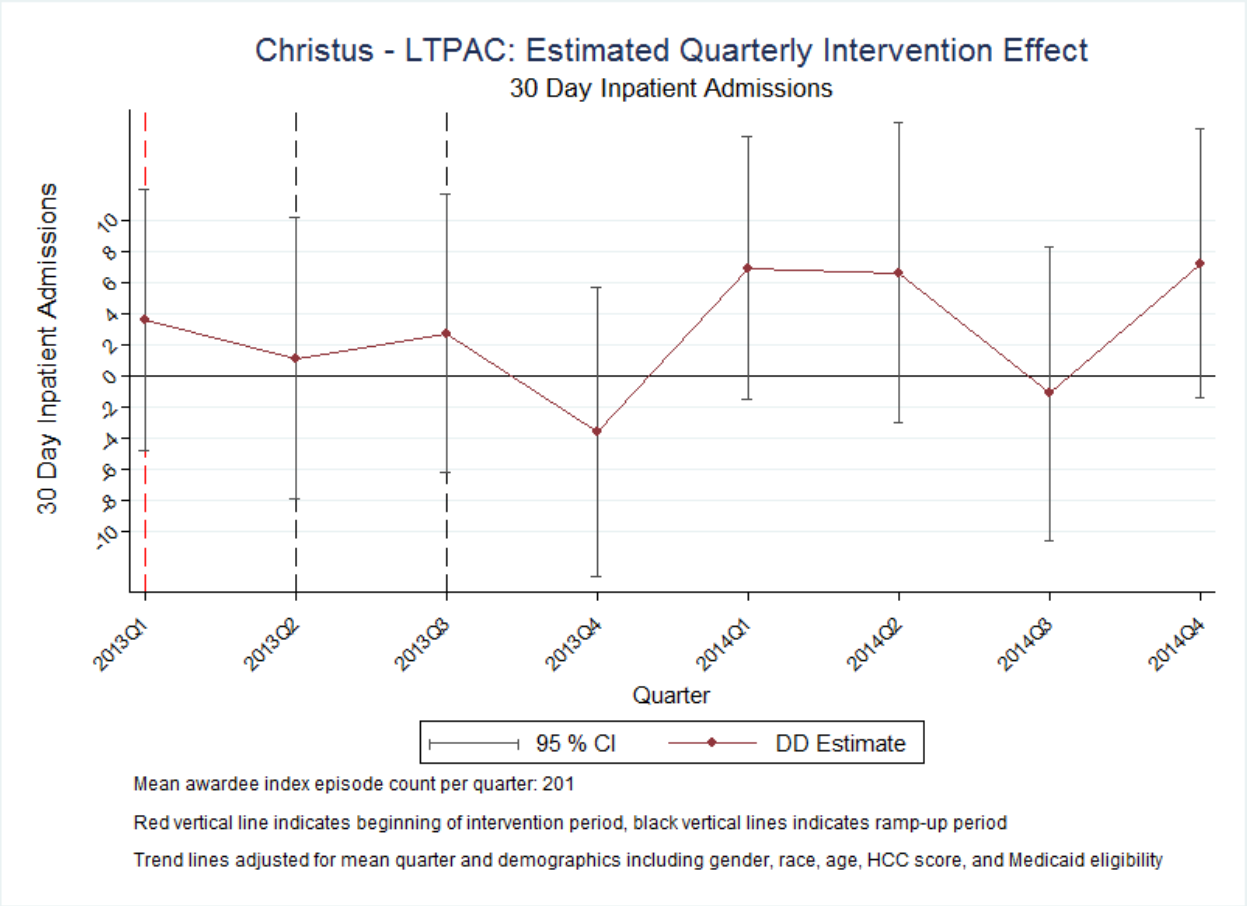
4.2.3 Hospital Admissions – LTPAC Patients

Implementation did not take place on the same day in all participating facilities. In the exhibits that follow, the red vertical line shows the beginning of the intervention period and the black vertical line indicates the date when the participating facilities began program implementation.

Exhibits 7 and 8 reflect only the patients who first received the program intervention while in a long-term post-acute care (LTPAC) facility, and shows admissions (transfers) from that facility to a hospital. The estimated intervention effect is insignificant in all quarters, although inpatient admissions are higher at Awardee LTPAC facilities in six of the eight quarters since the start of the intervention. The intervention

effect reported in Exhibit 7, pooled across all quarters, indicates that there is no statistically significant relationship between the Christus intervention and inpatient admissions from participating LTPAC facilities.

Exhibit 7: Hospital Admissions – LTPAC Patients Only



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 8: DD Estimated Effect of Intervention on Percentage of 30-Day Inpatient Admissions

Christus Health – LTPAC		
Intervention Effect	Estimate	2.78
	Standard Error	(2.43)
	Sample Size	[6,937]

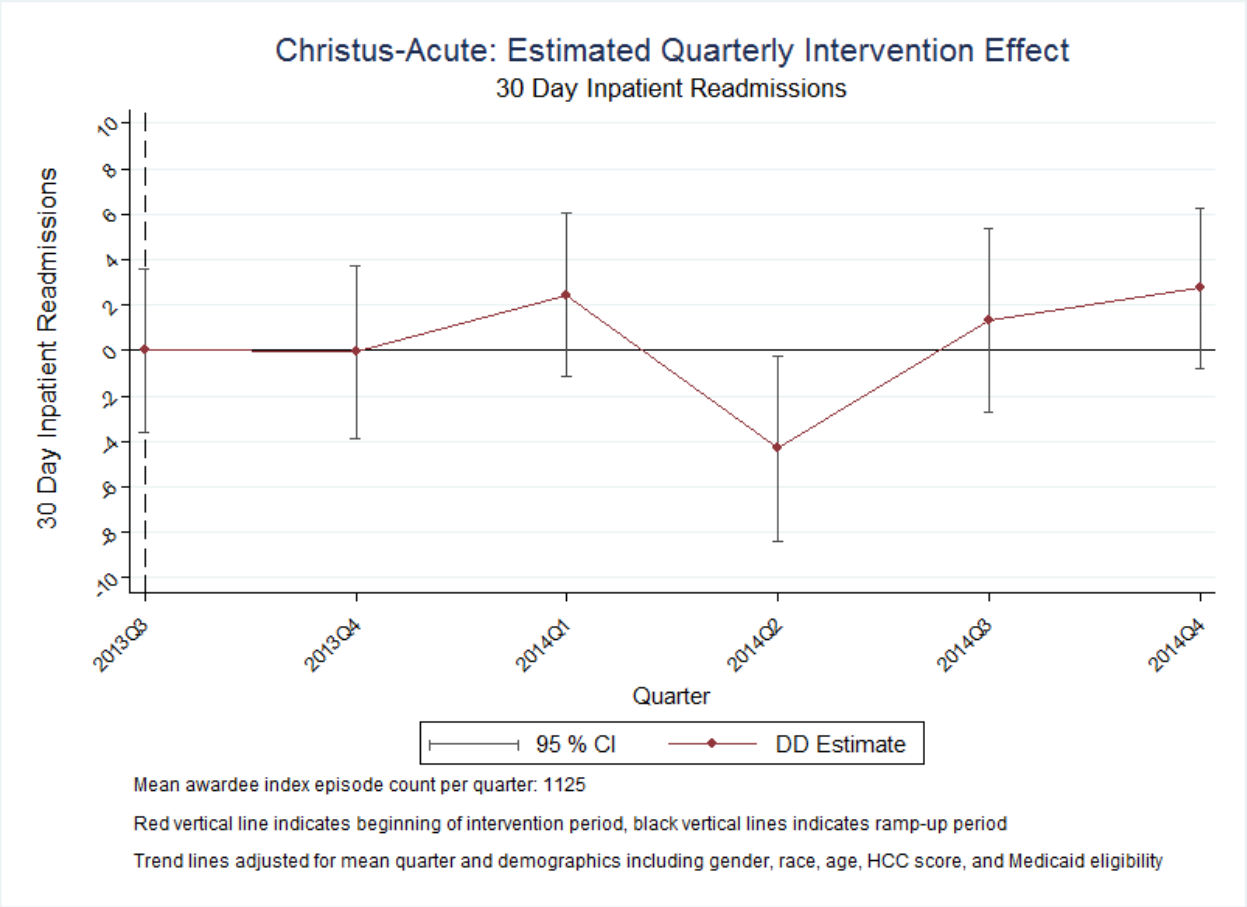
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.4 Readmissions – Acute Care Patients

Exhibit 9 reports the percent of hospital discharges followed within 30 days by a readmission, and shows that the difference in outcomes between the Awardee and comparison group varies substantially from quarter to quarter. Although the DD estimate for one quarter is statistically significant, results from the pooled regression reported in Exhibit 10 indicate no overall effect of the intervention on 30-day readmissions. These exhibits are restricted to patients whose program intervention began in an acute care hospital setting.

Exhibit 9: Readmissions – Acute Care Patients Only



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 10: DD Estimated Effect of Intervention on Percentage of 30-Day Post-Discharge Inpatient Readmissions

Christus Health – Acute		
Intervention Effect	Estimate Standard Error Sample Size	0.31 (0.95) [32.108]

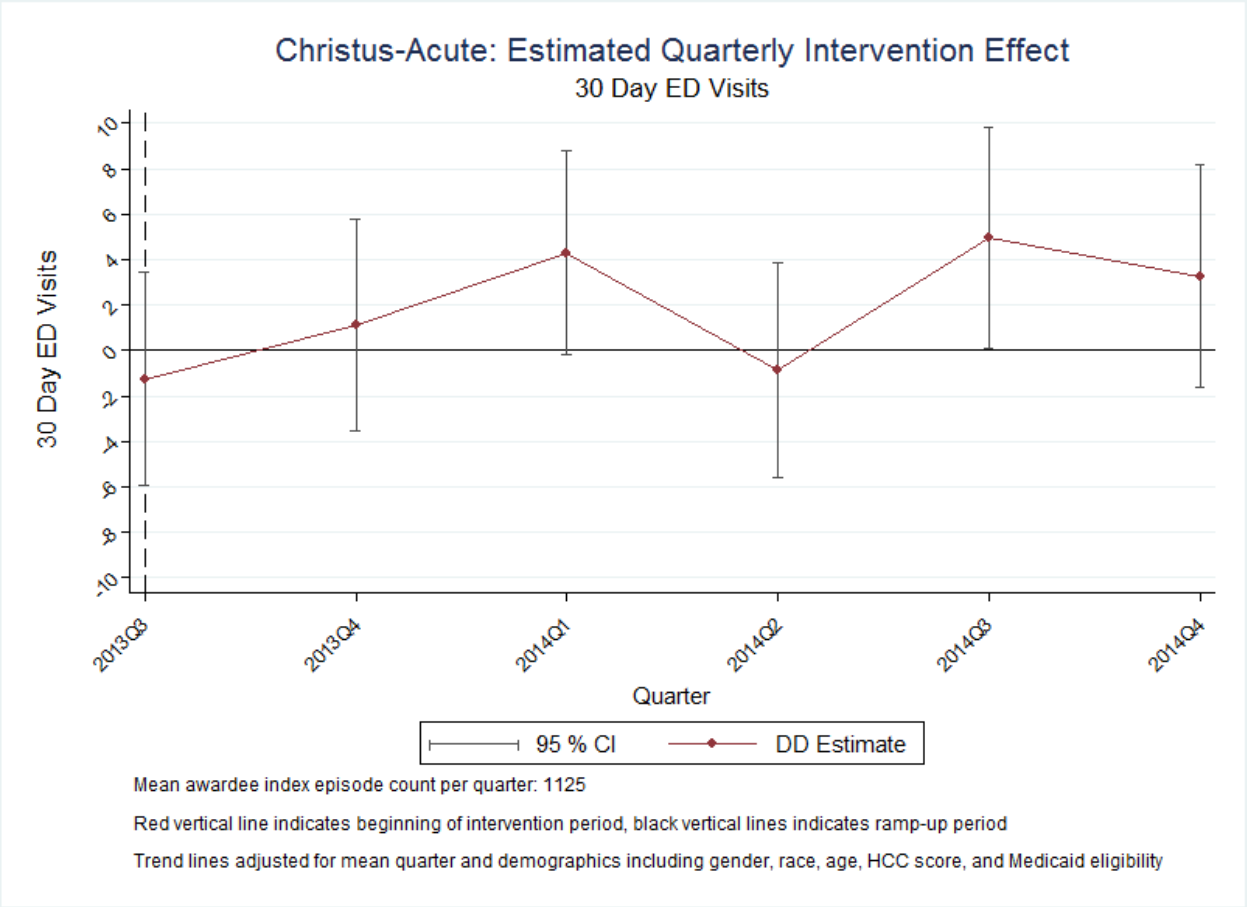
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.5 30-day Post-discharge ED Visits - Acute Care Patients

Exhibit 11 shows discharges followed within 30 days by an ED visit and we see some evidence that 30-day ED visits are higher among intervention patients. However, results from the pooled regression model reported in Exhibit 12 do not indicate a statistically significant effect of the intervention on 30-day ED visits. These exhibits are restricted to patients whose program intervention began in an acute care hospital setting.

Exhibit 11: 30-day Post-discharge ED Visits - Acute Care Patients



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 12: DD Estimated Effect of Intervention on Percentage of 30-day Post-Discharge ED Visits

Christus Health – Acute		
Intervention Effect	Estimate Standard Error Sample Size	2.10 (1.15) [32,108]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.6 30-day Post-discharge ED Visits - LTPAC Patients

Exhibits 13 and 14 (admissions followed within 30 days by an ED visit) are restricted to patients who first encountered the intervention in the LTPAC setting. Although the overall effect of the intervention on 30-day ED visits is statistically insignificant, point estimates of over 4 percentage points for each of the last 4 quarters suggest that the intervention was associated with an increase in ED visits during 2014. Additional quarters of data will reveal whether this is a statistically significant trend.

Exhibit 13: 30-day Post-admission ED Visits - LTPAC Patients

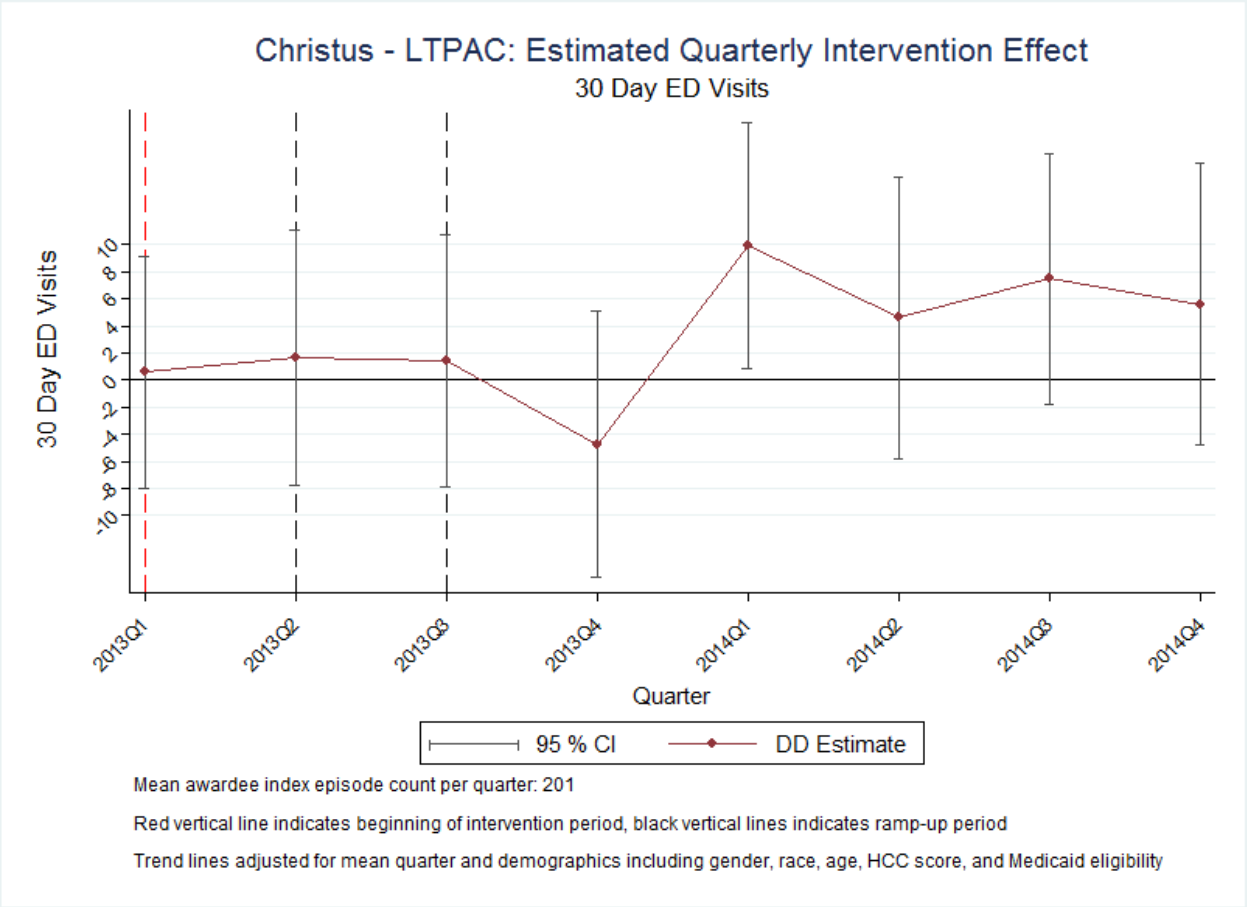


Exhibit 14: DD Estimated Effect of Intervention on Percentage of 30-Day Post-admission ED Visits

Christus Health – LTPAC		
Intervention Effect	Estimate	3.47
	Standard Error	(2.43)
	Sample Size	[6,937]

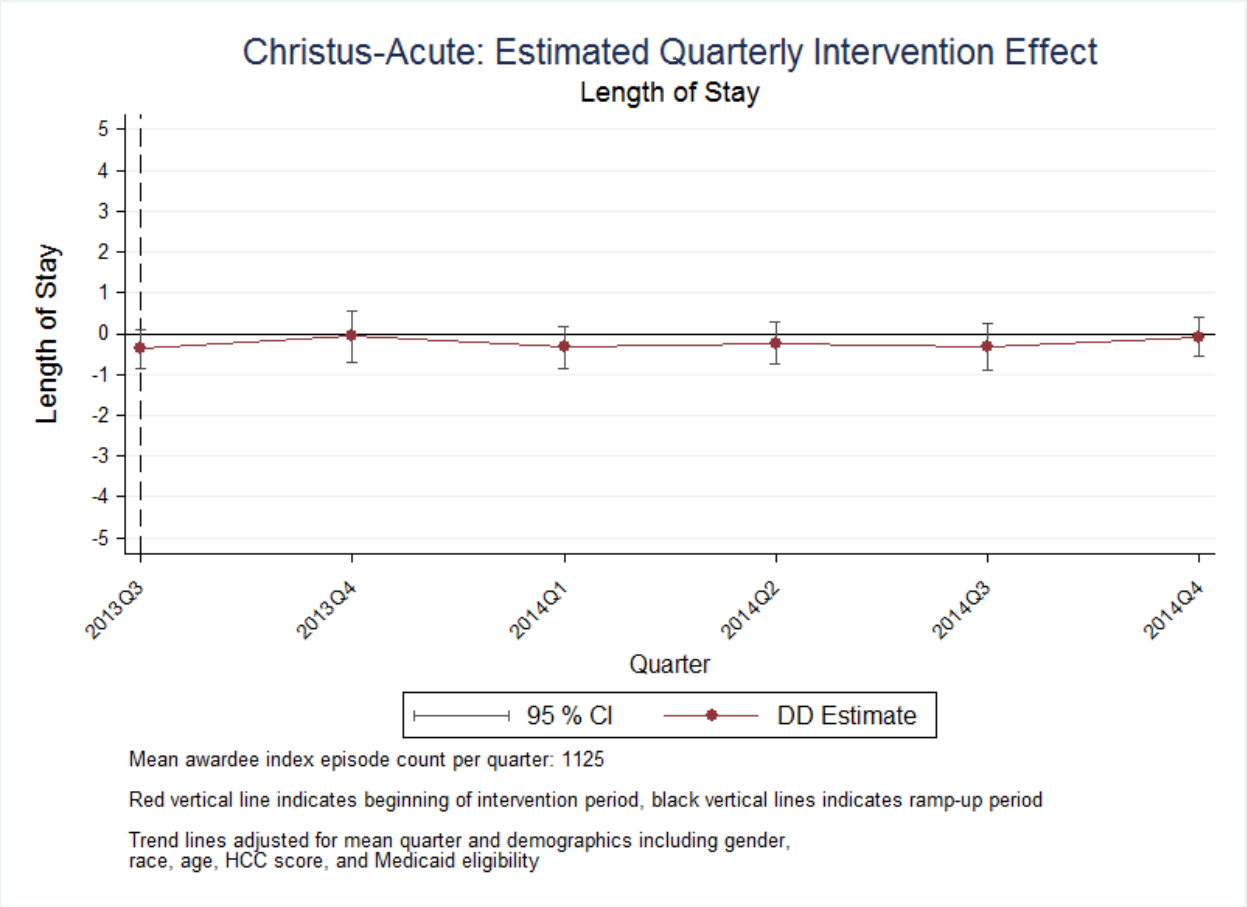
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.7 Index Admission Length of Stay (LOS) – Acute Care Patients

We examined LOS for the acute care patients in the Christus program, to understand whether the careful screening contributes to earlier recognition of emerging problems and lower LOS. In Exhibit 15 below, LOS is consistently lower among intervention patients. Although the effect is not statistically significant in any individual quarter, the pooled regression estimate in Exhibit 16 indicates that, on average, patients subject to the intervention had a statistically significant decrease in LOS of roughly 1/5 of a day. This exhibit is restricted to patients whose program intervention began in an acute care hospital setting.

Exhibit 15: Index Admission Inpatient LOS



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 16: DD Estimated Effect of Intervention on Mean Inpatient Length of Stay

Christus Health – Acute		
Intervention Effect	Estimate	-0.22*
	Standard Error	(0.12)
	Sample Size	[32,108]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.8 Discharge Destination (Acute Care Patients)

Finally, we examined patterns of patient discharge from acute care to other settings. Exhibit 17 below indicates that intervention patients were significantly less likely to be discharged to home health care relative to comparison patients, an overall difference of nearly 3 percentage points. This is primarily driven by an increase in the proportion of intervention patients discharged to "other" settings (e.g., hospice, transfer to a Federal hospital, or discharge to a psychiatric ward) rather than being discharged to home. The rest of the decrease in home health care discharges appears to be driven by greater use of LTPAC facilities, although this increase is not statistically significant. Overall, Exhibit 17 provides evidence that the acute-care arm of the Christus intervention is associated with a shift away from home health towards other care settings.

Exhibit 16: DD Estimated Change in Episode Discharge Destination – Acute Care Patients

	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home							
DD Estimate	4.94*	-1.95	-3.24	0.21	0.84	1.65	0.09
SE	(2.65)	(2.64)	(2.67)	(2.65)	(2.77)	(2.72)	(1.26)
Home Health							
DD Estimate	-2.36	0.21	-0.80	-5.15***	-3.79**	-5.35***	-2.99***
SE	(1.79)	(2.08)	(1.99)	(1.47)	(1.77)	(1.55)	(0.88)
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home							
DD Estimate	-1.00	0.48	3.14	2.80	0.95	-0.43	1.36
SE	(2.41)	(2.54)	(2.64)	(2.60)	(2.64)	(2.59)	(1.21)
Other							
DD Estimate	-1.58*	1.26	0.91	2.13	2.01	4.13**	1.54**
SE	(0.95)	(1.44)	(1.41)	(1.60)	(1.72)	(2.09)	(0.71)

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates May 2015.

4.2.9 Conclusions

- Pooled regression analysis indicates that the intervention is associated with a statistically significant increase in Medicare episode spending per episode for patients who first encounter the intervention in a LTPAC setting: an increase of roughly $1,494.
- We estimate that the intervention is associated with a decrease in inpatient LOS of roughly 1/5 of a day for patients who first encountered the intervention in an acute care setting.
- For patients who encountered the intervention in the acute care setting, there is a significant shift in discharge destination away from home health care to other types of care.

Appendix B2:

High Value Healthcare Collaborative: Optimizing the Treatment of Septicemia and Sepsis through Implementation of Bundled Care

1. Executive Summary

This chapter presents both quantitative and qualitative findings of Abt Associate's evaluation of the High Value HealthCare Collaborative's (HVHC) sepsis improvement program. This program aims to identify patients with signs of sepsis in the emergency department (ED) and intensive care unit (ICU) settings, and begin very specific and rapid interventions with 3-hour and 6-hour components to avert septic shock and save lives. The program is implemented in the hospitals of many HVHC health system members, half of whom began the program in the first year of the Health Care Innovation Award (HCIA) and half of whom began in the second year. The first-year implementers started their work with deliberate program improvement initiatives (Lean, Six Sigma), and shared their insights and implementation strategies with second-year implementers. All participating hospitals collected detailed data about each step in care delivery, with time stamps, that is used by Dartmouth analysts to measure the contribution of each step in the care bundles toward improving patient outcomes.

Program staff and clinicians anticipate that triggers implemented in their electronic health records systems (EHRs), new laboratory and pharmacy order sets, availability of antibiotics in the ED and ICU, and aggressive fluid resuscitation, will combine to yield better outcomes for patients with sepsis. Shorter length-of-stay (LOS), less need for post-acute care, reduced mortality, and lower Medicare spending are all anticipated outcomes of this program.

We visited three of the health systems implementing this program and met with numerous physicians, nurses, data analysts and managers. Clinicians offered overwhelmingly positive feedback about the improvements in sepsis care within their units, workflow changes that were made during the project, and patient care improvements due to the sepsis care bundles. Clinicians attributed the initiative's success to a range of factors, including the simple design of the tool, level of energy and priority surrounding the initiative, increased attention and awareness about sepsis across units (through formal and informal training), and continuous data benchmarking and self-monitoring of progress. Leadership in participating health systems indicated that implementing the program with the HVHC facilitated sharing of best practices among participants and the capacity to benchmark data; it also elevated the priority of the quality initiative at participating institutions. They also noted that while the sepsis program has increased awareness about early sepsis identification at referring community hospitals, lack of EHR system interoperability and associated challenges with timely data input remain barriers to starting the sepsis care bundle at other institutions and providing a seamless continuum of sepsis care.

We conducted a difference-in-differences analysis of Medicare claims pooling data from all participating HVHC hospitals and comparing against a pooled comparison group comprised of hospitals matched to the intervention facilities (matched on location, hospital size and teaching status). All patients with moderate to severe sepsis coded on their claims and who had an ED or ICU stay (or both) were included in the analysis. All participating hospitals are pooled because no single hospital has enough sepsis patients to support this kind of analysis.

Although this program was well-received by clinicians and appears to be firmly embedded in the workflows and IT systems of participating EDs and ICUs, this analysis shows no impact of the program on most quantitative metrics (length of stay, readmissions, post-discharge ED visits, total Medicare episode spending). However, we see a small but statistically significant decline in discharges to home health care, and being replaced by statistically insignificant and increased discharges to alternative destinations.

At least two factors may be contributing to the generally null findings for this program. First, many hospitals now have sepsis programs underway (modeled, as was this HVHC program, on the Surviving Sepsis Campaign) due to the widespread recognition of sepsis as a leading cause of inpatient mortality. The comparison facilities used in our analyses may also have implemented sepsis programs in recent years, and the HVHC program would need to exceed the impact of any comparison programs in order to be detected as significant in our analyses. Second, this program was implemented in many health systems across the country and although it is a concise program it may have been less effective in some locations, diluting the overall effect in our pooled analysis.

2. General Research Domains

The core domains for the HVHC Sepsis program evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of HCIA funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, and CHIP).

- **Impact on Priority Populations** focuses on research questions related to the type of population served by the intervention and the extent to which the intervention focuses on the needs of the medical and non-medical priority groups such as underserved populations.

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Background

3.1.1 Description of Program

The HVHC is a consortium of 19 health care delivery systems and The Dartmouth Institute for Health Policy and Clinical Practice (TDI). The High Value Healthcare Collaborative (HVHC) received an Award led by The Trustees of Dartmouth College to implement a bundle of services related to the care of sepsis patients across 13 HVHC member health care systems around the country.

The overall goal of this program is to utilize process improvement strategies to implement specific clinical services by three and six hours post sepsis diagnosis, as defined by the Surviving Sepsis Campaign (SSC) and National Quality Forum (NQF) guidelines for the care of severe sepsis and septic shock. Over three years, the HVHC members aimed to improve optimal adherence to sepsis bundled care by five percent, reduce the burden of chronic morbidity from sepsis-associated chronic organ dysfunction, and achieve a five percent relative reduction in the percent of patients with sepsis requiring post-discharge long-term acute care or sub-acute nursing care after an incident episode of severe sepsis, resulting in a target savings of $12.24M in Medicare reimbursements.

The Dartmouth HVHC Sepsis Improvement program is focused on the implementation of three-hour and six-hour treatment bundles for sepsis. Patients are screened and receive the initial three hour care bundle if they have clinically suspected infection and two or more indicators of Systemic Inflammatory Response Syndrome (SIRS) AND have hypotension defined as systolic blood pressure 90mmHG or decrease ≥40mmHG from baseline OR Elevated Serum Lactate defined as ≥ 4mmol/L. Lab work is completed before the six-hour care bundle, and any non-septic patients are removed from the intervention prior to receiving the six-hour bundle.

3.1.2 Methodology

The evaluation team conducted case studies in two waves of the Dartmouth Program. The initial site visits took place in June 2014. Because Abt staff were unable to visit all members of HVHC, we strategically selected three participating health systems as well as the HVHC Program Management Office (HVHC-PMO) for this case study. The team visited the Dartmouth Awardee program staff at HVHC (e.g., PI, study coordinator, measurement/data analyst) to learn about the program and its implementation. We also met with the clinical staff at Dartmouth-Hitchcock Medical Center, the only academic medical center in New Hampshire and where the sepsis bundle intervention was implemented early in 2014. Next, the team met with clinical staff at Beth Israel Deaconess Medical Center (BIDMC), a large urban academic medical center in Boston, where the sepsis bundle intervention began in 2013. The BIDMC was among the earliest HVHC implementers of the sepsis bundles.

Lastly, the team met with clinical staff at MaineHealth Medical Center (MMC), the flagship hospital for MaineHealth), where the sepsis bundle intervention began in late 2013. While at Maine Medical Center,

the team was able to interview staff at two smaller MaineHealth hospitals (Southern MaineHealth Care-Biddeford Campus and Penobscot Bay Healthcare) that just joined the collaborative in the spring of 2014. Abt researchers interviewed a physician and nurse from the Southern MaineHealth Care-Biddeford Campus in person during the MaineHealth site visit and teleconferenced with a physician and nurse from Penobscot Bay Healthcare during the same site visit. Exhibit 1 below shows the sites visited in our case study of the Dartmouth sepsis innovation. We conducted follow-up case studies with HVHC, Dartmouth Hitchcock Medical Center, BIDMC and MaineHealth in March-April, 2015.

Exhibit 1: HVHC Sepsis Case Study Sites

Health Institution and Site	City/State	Date Initial Case Study	Follow-up Case Study
The High Value Healthcare Collaborative, Program Management Office (HVHC-PMO)	Hanover, NH	6/3/2014	6/19/2015 (Teleconference)
Dartmouth-Hitchcock Medical Center (DHMC)	Lebanon, NH	6/4/2014	6/9/2015 (Teleconference)
Beth Israel Deaconess Medical Center (BIDMC)	Boston, MA	6/10/2014	4/23/2015 (In-person)
MaineHealth	Portland, ME	6/23/2014	3/4/2015 (In-person)

Three to four Abt researchers conducted each site visit, including a senior Abt researcher, a nurse researcher, and one or two junior-level research assistants. At each site, we met with the lead individuals responsible for the sepsis initiative at that institution and conducted interviews and focus groups with nurses, physicians, educators, pharmacists, respiratory therapists and data managers from different hospital departments; the majority of clinical staff interviewed primarily worked in the Intensive Care Unit (ICU) and Emergency Department (ED). Exhibits 2a and 2b summarize the number and type of individuals who participated in interviews or focus groups. Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

Exhibit 2a: Professional Backgrounds of Interviewees & Focus Group Participants, 2014

Initial Case Study Participants									
	ICU Nurses	ED Nurses	Physicians	Hospital Leadership	Pharmacists	Educators	Data Managers	Program Admin.	RT
HVHC-PMO (n=9)	0	0	0	0	0	0	0	9	0
DHMC (n=26)	1 Chief 4 Nurses	1 Chief 1 Nurse	1 ED Resident 1 ICU	4	2 Pharmacy Techs	2 ICU 1 ED	2	6	0
BIDMC (n=19)	1 Chief 1 Nurse	1 Chief 4 Nurses	1 ED Resident 1 ED Physician / IT Specialist	4	0	1 ED QI Nurse	2	3	0
MaineHealth (n=22)	4	1 (Biddeford) 4	1 ED (Biddeford) 1 ED (Pen Bay) 1 ED	1	2	1	1 (Pen Bay) 1 (Biddeford)	3	1
Total=75	11	12	7	9	4	5	6	21	1

HVHC: High Value Health Collaborative • PMO: Program Management Office • DHMC: Dartmouth Hitchcock Medical Center • BIDMC: Beth Israel Deaconess Medical Center • ICU: Intensive Care Unit • ED: Emergency Department • RT: Respiratory Therapist • IT: Information Technology • QI: Quality Improvement

Exhibit 2b: Professional Backgrounds of Interviewees & Focus Group Participants, 2015

Follow-up Case Study Participants							
	ICU Nurses	ED Nurses	Physicians	Hospital Leadership	Educators	Data Managers	Program Admin.
HVHC-PMO (n=7)	0	0	0	0	0	0	4
DHMC (n=7)	2	2	0	1	0	0	2
BIDMC (n=6)	0	2	0	0	1 ED-QI Nurse	1	2
MaineHealth (n=10)	1	2	3 ED (Biddeford, Pen Bay, MaineHealth)	0	0	1 (Pen Bay) 1 (Biddeford)	2
Total=27	3	6	2	1	1	4*	10

HVHC: High Value Health Collaborative; PMO: Program Management Office; DHMC: Dartmouth Hitchcock Medical Center; BIDMC: Beth Israel Deaconess Medical Center; ICU: Intensive Care Unit; ED: Emergency Department; RT: Respiratory Therapist; IT: Information Technology; QI: Quality Improvement

Analyses were conducted by running node "reports" according to key areas of interest, to identify themes and subthemes. Where relevant, the team explored differences across key program components. For example, technical complexity was composed of both clinical components and health information technology, and each site's health information technology system affected their measurement and

self-monitoring plans. After NVivo results were generated, a detailed outline was shared among all members of the case study team to ensure consensus about the key findings for this report.

3.1.3 Background of Program

The Dartmouth College Board of Trustees and the HVHC received HCIA funding for two programs under one Award. One element funds collaboration with multiple large health care systems around the country to test a shared decision making model; that element of the Award is being evaluated by another contractor. They were also funded to develop and implement a sepsis best practices "bundle" of services. This report focuses on the Sepsis Improvement program.

The HVHC is a consortium of health care delivery systems that collectively serve a market of more than 70 million people across the United States, including Alaska and Hawaii. Twelve of the HVHC members implemented the Sepsis Improvement program, including the following medical systems: Baylor Health Care System, Beth Israel Deaconess Medical Center (BIDMC), Dartmouth-Hitchcock Medical Center, Denver Health, Eastern Maine Healthcare Systems, Intermountain Healthcare, MaineHealth, North Shore-LIJ, Providence Health and Services Oregon, Scott and White Healthcare, University of Iowa Health Care, and Virginia Mason Medical Center. The self-reported goals of HVHC are “to improve care, improve health, and reduce costs by identifying and accelerating the widespread adoption of best-practice care models and innovative value-based payment models.” HVHC is a learning network that facilitates the implementation and dissemination of best practices among members, and more broadly, to non-member health systems.[7] The HVHC uses the Plan-Do-Study-Act (PDSA) framework for all quality improvement efforts undertaken since it was established in 2010. The PDSA framework allows HVHC members to maintain local models already in place at institutions and focus on accelerating improvement and ensuring sustainability.[8] The goal is to support efficient implementation and validated changes in the health care system.

The HVHC Program Management Office (HVHC-PMO) in the Dartmouth Institute for Health Policy and Clinical Practice (TDI) serves as the coordinating center for the two HCIA Award components of shared decision making and sepsis bundle implementation. HVHC-PMO staff work with the HVHC members to manage site selection, onsite quality improvement training prior to implementation, data management and reporting, and communication.

The sepsis care bundles implemented under this HCIA Award are not new. The particularly innovative aspect of this Award is the large-scale implementation across diverse health systems that serve different patient populations, and as such, it comes close to a national test of the intervention. The program’s design—simultaneous program implementation across health systems with consistent data collection, reporting and analysis—is intended to support rapid and continuous quality improvement. During Quarter 1 of the program (July–September, 2012), HVHC surveyed members about participating in the Sepsis Improvement program. Interested health systems were then grouped into Year 1 and Year 2 initiators, based on a site’s interest and an assessment by the HVHC-PMO of adoption readiness. Abt researchers visited both a Year 1 initiator (BIDMC) and two Year 2 initiators (Dartmouth-Hitchcock and MaineHealth). Regardless of when a hospital or health system began, all have continued the Sepsis Improvement program throughout Year 3 of the Award.

---

7 http://highvaluehealthcare.org/who-we-are/

8 http://highvaluehealthcare.org/how-we-do-it/

Program Goals

The HVHC sepsis program goals include:

Better care: Improve optimal adherence to sepsis bundled care by five percent (relative rate) over three years.

Healthier people: Reduce the burden of chronic morbidity from sepsis-associated chronic organ dysfunction, achieving a five percent reduction (relative rate) over three years in the number of patients with sepsis requiring long-term acute care or sub-acute nursing care after an incident episode of severe sepsis (where episode refers to events that are bracketed by the admission and discharge from an inpatient acute care facility).

Smarter spending: Achieve a five percent reduction (relative rate) over three years in the number of patients with sepsis requiring long-term acute care or sub-acute nursing care after an incident episode of severe sepsis. A goal of $12.24M savings for Medicare beneficiaries at HVHC hospitals over the three year program.[9]

Impetus for the Program

The three HVHC health systems selected for the case study already had some level of sepsis improvement activity among the physicians and nurses working in the hospitals. Prior sepsis initiatives involved protocols for managing sepsis patients, derived from best practice guidance in professional literature and established by hospital committees. While hospital staff were aware that sepsis is a serious and potentially life-threatening complication, there were a number of organizational and clinical barriers to timely diagnosis. Sepsis is less common and visible than many other life-threatening health problems (e.g., trauma, myocardial infarction), and therefore, clinical staff were not always identifying patients early enough to receive evidence-based, timely care.

> It wasn't until the septic shock mortality data was front and center that the realization occurred that it was an area for needed improvement.
>
> *– Physician Leader*

Each health system had a distinct history with prior sepsis initiatives, and the initial impetus for participating in the Sepsis Improvement program varied accordingly across systems. Dartmouth-Hitchcock already had a sepsis care bundle, devised years earlier, but discovered that bundle compliance was "quite low" and could be improved. Examination of data drove the urgency to improve. BIDMC had a long-standing commitment to sepsis interventions, having designed the nationally recognized Multiple Urgent Sepsis Therapies (MUST) protocol. MUST is very detailed, and its complexity led to implementation issues at the hospital. BIDMC leaders felt it was time to try something new to improve management of sepsis. In reviewing their patient data, MaineHealth leaders realized that their sepsis patients did well clinically but exceeded norms for both length-of-stay and overall cost. These outlier metrics convinced hospital leaders to implement the program. They also acknowledged that there was no clear "MaineHealth pathway" for treating sepsis. The HVHC sepsis Award offered an approach to making care more consistent among the departments and clinicians managing sepsis patients at MaineHealth.

[9] Trustees of Dartmouth College-Sepsis Improvement Quarter 1 HCIA Narrative Progress Report

3.2 Program Components & Targets

The targets of the Sepsis Improvement program are patients in the ED and in the ICU with early signs of sepsis. We visited hospitals in urban and rural settings in three states to understand how the program may differ in diverse settings.

3.2.1 Primary Program Components

The HVHC Sepsis Improvement program consists of three primary components: 1) three-hour and six-hour sepsis care bundles, 2) on-site Lean Six Sigma or other process improvement training prior to implementation of sepsis care bundles, and 3) a unified data specification with tools for health systems having differing electronic data capabilities. The HVHC-PMO worked with participating health systems to operationalize these components through the following framework:[10]

1. Clinicians and staff trained by sepsis program

   Evidence-based and impactful sepsis processes and care tools

   Strong network of Lean or equivalent methodology within participating sites

   Codification/dissemination of best practice methods and measures

   Transparent and frequent analysis of sepsis process measures to inform improvement (analysis completed and posted internally each quarter)

Exhibit 3 shows the HVHC-PMO operational plan for their Sepsis Improvement program.

Exhibit 3: HVHC-PMO Operational Plan for Sepsis Program Implementation[11]

Year 1 Plan
• Co-lead sites piloting in Year 1 • Development of the Sepsis Bundle protocol • Lean methodology and implementation training delivered to co-lead sites • Implementation of the Sepsis Bundle protocol for co-lead sites using a staggered group sequential design, known as the step-wedge, across the participating institutions • Development of the Sepsis Bundle implementation manual and other operational materials based upon implementations lessons learned and best practices
Year 2 / Year 3 Plan
• Remaining HVHC sites participating as innovation partners • Implementation of Sepsis Bundle protocol by innovation partners using Lean or equivalent processes • Pilot results, collected, analyzed, and distributed to stakeholders • Adjustment of Lean curriculum for implementation; learning shared

Sepsis Care Bundles

A sepsis protocol consisting of two care bundles was developed based on the Institute for Healthcare Improvement (IHI) and the National Quality Forum (NQF) Surviving Sepsis Campaign. Exhibit 4 highlights each of the clinical decision-making and interventions needed for both the three and the six hour bundles.

[10] Trustees of Dartmouth College-Sepsis Improvement Quarter 1 HCIA Narrative Progress Report.

[11] Ibid.

Exhibit 4: Bundle Protocol (formerly called High Volume Sepsis Bundle or HV-SB)

Severe Sepsis Three-hour Bundle
1. Measure lactate level 2. Obtain blood cultures prior to administration of antibiotics 3. Administer broad spectrum antibiotics 4. Administer 30ml/kg crystalloid for hypotension or lactate > or = 4mmol/L
Septic Shock Six-hour Bundle
5. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure > or + 65mmHg) 6. In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate > or = 4mmol/L (36mg/dl): • Measure central venous pressure (Optional as of August 2014) • Measure central venous oxygen saturation (Optional as of August 2014) 7. Re-measure lactate if initial lactate was elevated

Source: Trustees Dartmouth College-Sepsis Improvement Quarter 2 HCIA Narrative Progress Report

The three-hour bundle requires a set of early clinical decisions. First, nurses assess a patient, followed by a physician (usually in that order), for the previously described SIRS criteria, vital signs and lab values. The presence of two or more SIRS criteria, hypotension and/or elevated serum lactate levels—indicates a preliminary diagnosis of sepsis. Once a physician initiates the order set, the timeline begins for both the three and the six-hour care bundles. The six-hour bundle is enacted if the patient's hypotension remains unresponsive to clinical interventions after three hours; it can be implemented prior to the elapse of three hours when indicated (e.g., if the lactate level remains at or above four mmol/L). The main concern is the negative cascading physical implications of severe sepsis, as it can become hard to stop the cascade with even aggressive interventions. The physician must decide when to measure central venous pressure (CVP) and with what tool. The most commonly accepted American method for measuring CVP is to place a central line catheter. This is an invasive procedure with risk of infection, and physicians are often hesitant to place a central line exclusively for this purpose (i.e., no other indication requiring a central line catheter). Some of the programs we visited are substituting non-invasive measures for monitoring CVP, although consensus is still developing about alternative measures. As of August 14, 2014 measurement of CVP is an optional step toward bundle "credit" see Step #6 of Exhibit 4.

Many physicians we interviewed expressed concern about some steps in the six-hour bundle. In particular, there is concern about placing a central catheter to measure CVP. Several physicians told us that when there is no other indication for a central line, the catheterization risks may outweigh the need for a CVP measurement. They also advised that new technology permits alternative non-invasive methods for measuring CVP. HVHC-PMO reported in their seventh quarter HCIA Narrative Report, "Multiple members have cited changes in evidence and difficulty with physician adherence surrounding the six-hour bundle elements. These challenges at member sites because of the evolving science have led us to review the six-hour bundle as part of mid-course corrections." In addition, some physicians may be uncomfortable ordering the levels of fluid indicated in the protocol for certain subsets of patients. Many physicians do not prescribe aggressive fluid resuscitation for cardiac ICU patients because rapid high volume intravenous fluid could be unsafe. In addition, nursing staff noted that gauging the correct fluid for obese patients is difficult, as the care bundle calculation method is weight-based and may yield an unsafe recommendation for fluid administration. This concern surrounding levels of safe fluid resuscitation was mentioned during our 2014 visits and remained an issue at our follow-up site visits in 2015.

Due to the lack of consensus about CVP monitoring, at the time of our 2014 case study the three-hour care bundle was implemented in all hospitals but elements of the six-hour care bundle were being reconsidered by clinicians. In March 2014, University of Pittsburgh published a large-scale randomized trial of 31 academic medical centers that participated in the randomized Protocolized Care for Early Septic Shock (ProCESS) trial.[12] Researchers randomized 1,300 septic patients into three study arms: 1) protocol-based Early Goal Directed Therapy (EGDT), 2) protocol-based standard therapy, and 3) usual care. The three groups differed in CVP and Central Venous Oxygen Saturation monitoring, fluid and vasopressors administration, and the use of red-cell transfusions. For the Protocol-based EGDT patients, CVP was monitored and fluids and vaspopressors administered through a central venous catheter, while the protocol-based standard therapy group had their CVP measured and fluids and drugs administered through peripheral venous access. The study outcomes were 60-day in-hospital mortality and mortality at 90 days. The authors found no significant difference in morality across the three groups over the five years of the study (60-day mortality P=.83 and 90-day morality P= .70). As a result of this and other changes in the science of sepsis care, in August 2014, HVHC-PMO and the HVHC decided to make steps in the six-hour care bundle related to CVP optional rather than mandatory to allow flexibility. If CVP is measured using alternative techniques it is still considered compliant with the six-hour care bundle.

On-site Lean Training Prior to Implementation of Sepsis Care Bundles

The HVHC Sepsis Improvement program has two physician leads who are experts in sepsis care, one at Dartmouth-Hitchcock Medical Center and the other at Denver Health. The Denver Health sepsis expert conducted an initial training for each of the Year 1 HVHC participating health systems. Members from each Year 1 health system selected dates for their on-site Lean training, invited individuals from their member hospitals and agreed to implement the care bundles within 30 days following their Lean week training. This training covered an overview of Lean process redesign techniques, sepsis process measures and Lean implementation curricula sessions. Year 1 participants drafted curricula during an initial meeting in Denver that was accepted by Year 1 health systems (see Exhibit 5). For example, a "waste walk" was conducted at a hospital in each participating health system, during which the entire care process for a sepsis patient in the ED was profiled and reviewed. The on-site Lean training weeks, known as a Rapid Improvement Events (RIE), occurred prior to implementation of the sepsis care bundles in all Year 1 health systems.

Year 2 health systems did not hold a structured RIE as at the Year 1 initiators. They did, however, conduct some sort of process improvement kickoff event using the lessons learned from Year 1. The Year 1 curriculum was available for Year 2 health systems as a guide.

[12] Pro CI, Yealy DM, Kellum JA, et al. A randomized trial of protocol-based care for early septic shock. N Engl J Med. 2014;370(18):1683-93.

Exhibit 5: On-site Rapid Improvement Event Week for Participating Year 1 Health Systems

Day of Week	Curricula
Monday	Examine the current state process Identify areas of waste, non-value added steps Identify metrics
Tuesday	Develop future state process; eliminate identified waste, increase value to the customer, and develop standard work Design rapid experiments
Wednesday	Do rapid experiments Incorporate rapid experiment results into the new processes and standard work Implement new processes and standard work Create production board and communicate standards
Thursday	Observe new process and any change in metrics Adjust and fine-tune new standard work Complete A3*
Friday	Wrap-up

Source: Trustees Dartmouth College-Sepsis Improvement Quarter 2 HCIA Narrative Progress Report

*A3 is a Lean Process Improvement tool that formats a problem, the analysis, the corrective actions, and the action plan down on a single sheet of large (A3-11X17) paper

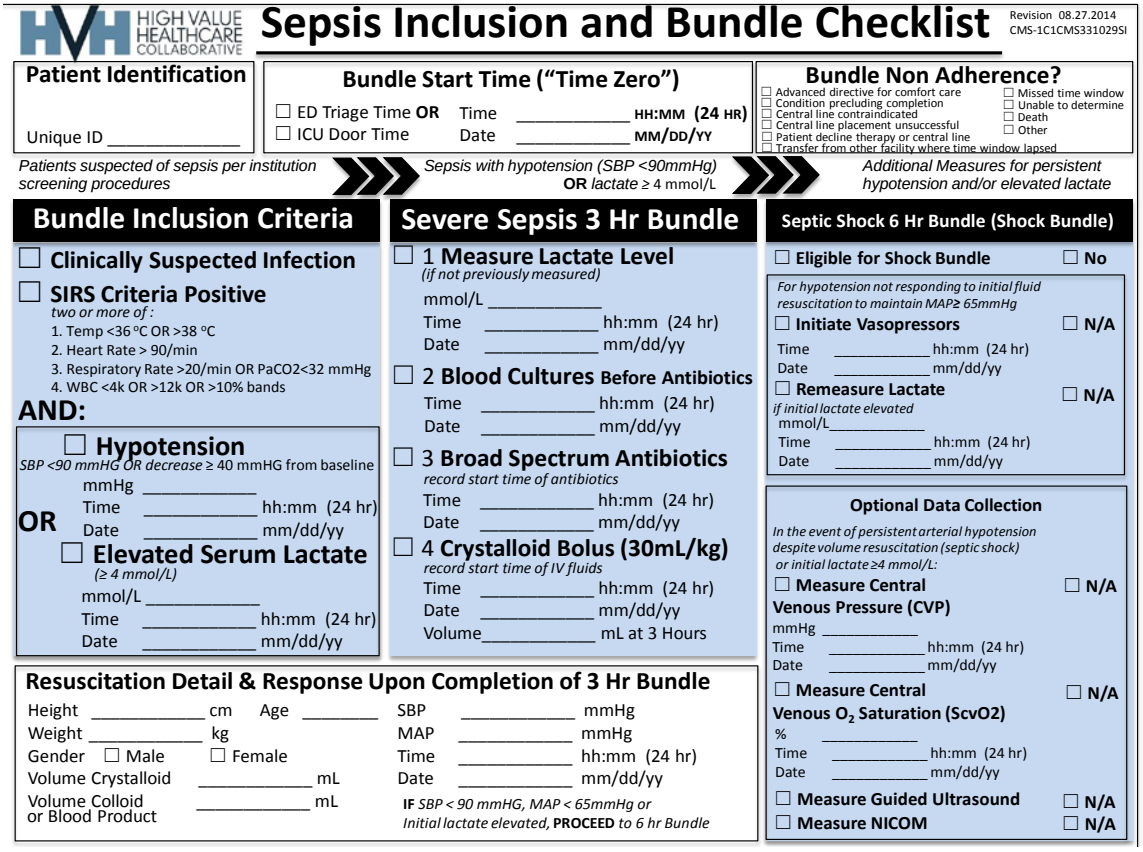
Both Dartmouth-Hitchcock and BIDMC conducted Lean rapid improvement events (RIE) to identify points in the workflow where efficiencies could were possible. At BIDMC, the nurses and physicians created an automated sepsis order set during the RIE. During the RIE, clinicians also suggested a Sepsis "bug" to physically attach to a patient's white board to signify sepsis. This practice was eventually was discontinued because clinicians were too busy to keep the "bug" updated in real time. Staff at BIDMC and Dartmouth-Hitchcock expressed enthusiasm about the RIE sessions. We also visited MaineHealth, where they employed a similar process redesign approach to Lean REI—Clinical Microsystems Methodology—to address a few key issues in their sepsis care processes. Staff there reported that they successfully zeroed in on the most important components of care that needed correction to reduce treatment times in the first three hours of sepsis care.

> Lean process creates buy-in from the staff. We built the process.
>
> *– ED Nurse*

Data Collection/Transmission

Staff from HVHC-PMO worked with the data teams at each participating health system to create a single, consistent data specification that all agreed to complete for every suspected sepsis patient; they call this the "unified data spec." Some hospitals and health systems (e.g., BIDMC) are able to extract most data for the unified spec directly from their EHRs, but others do not have this capability. The HVHC hospitals and health systems use several different vendor EHR products; the most common among HVHC systems are Epic, Cerner, and GE Centricity. The varying EHRs made it difficult to build an automated data "feed," and HVHC-PMO contracted with a software firm to create a stand-alone, web-based tool for data entry and submission called the Sepsis Tracking Administrative Tool (STAT). HVHC-PMO staff also created a paper form that can be filled out on the unit by bedside staff, to collect the information necessary for STAT data submission. (See Exhibit 6 for the most current version of the STAT tool.)

Exhibit 6: STAT Tool



HIGH VALUE HEALTHCARE COLLABORATIVE

Sepsis Inclusion and Bundle Checklist

Revision 08.27.2014
CMS-1C1CMS331029SI

Patient Identification

Unique ID _____

Bundle Start Time ("Time Zero")

☐ ED Triage Time **OR** Time _____ **HH:MM (24 HR)**
☐ ICU Door Time Date _____ **MM/DD/YY**

Bundle Non Adherence?

☐ Advanced directive for comfort care
☐ Condition precluding completion
☐ Central line contraindicated
☐ Central line placement unsuccessful
☐ Patient decline therapy or central line
☐ Transfer from other facility where time window lapsed
☐ Missed time window
☐ Unable to determine
☐ Death
☐ Other

Patients suspected of sepsis per institution screening procedures → *Sepsis with hypotension (SBP <90mmHg) OR lactate ≥ 4 mmol/L* → *Additional Measures for persistent hypotension and/or elevated lactate*

Bundle Inclusion Criteria

☐ **Clinically Suspected Infection**

☐ **SIRS Criteria Positive**
two or more of :
1. Temp <36 ºC OR >38 ºC
2. Heart Rate > 90/min
3. Respiratory Rate >20/min OR PaCO2<32 mmHg
4. WBC <4k OR >12k OR >10% bands

AND:

☐ **Hypotension**
SBP <90 mmHG OR decrease ≥ 40 mmHG from baseline
mmHg _____
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

OR

☐ **Elevated Serum Lactate**
(≥ 4 mmol/L)
mmol/L _____
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

Severe Sepsis 3 Hr Bundle

☐ 1 **Measure Lactate Level**
(if not previously measured)
mmol/L _____
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

☐ 2 **Blood Cultures Before Antibiotics**
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

☐ 3 **Broad Spectrum Antibiotics**
record start time of antibiotics
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

☐ 4 **Crystalloid Bolus (30mL/kg)**
record start time of IV fluids
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy
Volume _____ mL at 3 Hours

Septic Shock 6 Hr Bundle (Shock Bundle)

☐ **Eligible for Shock Bundle** ☐ **No**

For hypotension not responding to initial fluid resuscitation to maintain MAP≥ 65mmHg

☐ **Initiate Vasopressors** ☐ **N/A**
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

☐ **Remeasure Lactate** ☐ **N/A**
if initial lactate elevated
mmol/L _____
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

Optional Data Collection

In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate ≥4 mmol/L:

☐ **Measure Central Venous Pressure (CVP)** ☐ **N/A**
mmHg _____
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

☐ **Measure Central Venous O_2 Saturation (ScvO2)** ☐ **N/A**
% _____
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

☐ **Measure Guided Ultrasound** ☐ **N/A**
☐ **Measure NICOM** ☐ **N/A**

Resuscitation Detail & Response Upon Completion of 3 Hr Bundle

Height _____ cm Age _____
Weight _____ kg
Gender ☐ Male ☐ Female
Volume Crystalloid _____ mL
Volume Colloid or Blood Product _____ mL

SBP _____ mmHg
MAP _____ mmHg
Time _____ hh:mm (24 hr)
Date _____ mm/dd/yy

IF *SBP < 90 mmHG, MAP < 65mmHg or Initial lactate elevated,* **PROCEED** *to 6 hr Bundle*

Most recent STAT tool; source: HVHC-PMO 8-29-14

Initially, the HVHC-PMO started with a single data specification for each of the six conditions involved in both components of their HCIA program (sepsis and shared decision making) which were then merged into the unified data spec. The fully electronic unified data spec is a 150 page complex series of tables requiring many different types of data (e.g., laboratory results, medications, time stamps for key activities). The tables are linked and together show all of the sepsis bundle (or shared decision making) steps in the care provided to each patient. Creation of the unified data spec was detailed and time-consuming, and reflects consensus among more than 50 data analysts from the participating HVHC members, as well as clinical leads for both Award components, regarding essential data for measuring process and outcomes of care. HVHC-PMO staff reported that they "went line by line for each spec for close to three months with site representatives on the measurement team." The sepsis portion of the unified data spec defines sepsis patients as having an ICD-9 code for sepsis (Sepsis 995.91, Severe Sepsis 995.92, or Septic Shock 785.1) and either a lactate level greater than 4 or systolic blood pressure less than 90. These criteria identify cases of severe sepsis, in which care bundles are expected to have the most impact.

> The Sepsis Implementation program is making a huge point about the value of EMR to HVHC members. … [manual] chart reviews are not sustainable long term.
>
> *– HVHC-PMO staff*

The completeness and consistency of data submission varies among participating HVHC members. HVHC-PMO staff told us that:

There are always some measures that are hard for some of the systems to extract so you will see within the process measures there have been times where they simply don't have a way to record it and they have had to do chart reviews since there was no other way around it. Originally, we all hoped that we wouldn't have to have the process measures extracted from chart review, but the reality is that some of the sites simply don't record this information any other way than in notes.

Although these differences presented challenges for the HVHC members, as well as for data analysts, the HVHC-PMO viewed these as worthwhile efforts. As a data analyst explained, "One great thing about this initiative is that it forces standardization across these systems. There was a big decision made at [a 2014 HVHC] conference that we are going to try to get data out of the EMRs. We want to get to a point where participants are chart review independent."

In all three systems, time stamps automated in electronic Health Record (EHR) systems are important for documenting steps and identifying delays in the care bundle because filling in exact times on the paper form, in real-time, is not feasible. Having accurate time stamps for the time-sensitive sepsis care bundles is one of the factors driving HVHC-PMO's desire to have the unfied data spec fully automated.Time stamps are automatic in an EHR on all documentation. When a clinician enters data into the EHR about a step in the care bundle, a time stamp is completed. Conversely, if a clinician forgets to enter the time on a piece of paper, the time (stamp) is lost forever. Automated time stamps in the EHR reduce the "loss of data" and errors that occur with hand-written notes. BIDMC has recently added an electronic medication administration record (EMAR) system in their ED, and ED nurses now use the EMAR to automate time stamps for fluids and medications admistered as part of the sepsis care bundle. ED nursing staff reported that the EMAR significantly improves the accuracy of time stamps through automation. Not only did EMAR improve adherence, but it alleviated workload for ED nurses because time is captured in real time as medication is administered, instead of nursing staff filling it in after the fact, when they have a few free minutes. BIDMC has long had an EMAR system for all inpatient units, which automates time stamps in the records of ICU patients.

> The new EMAR has helped us, as the ED documentation has always been an issue. We usually do the work of completing the bundle, but the timing in particular is not always documented. The EMAR has been great as you have the accurate time of when the medication was given to a patient; before it was a "guestimate" when the medication was given.
>
> *-ED Nurse*

3.2.2 Technology

The HVHC Sepsis Improvement program has both health information technology (health IT) and clinically-focused technology. The health IT components are related to a hospital's EHR, which is important both for automating triggers and care bundle steps, and for data collection. The clinical technology is related to laboratory testing and antibiotic administration. The three hospital systems our team visited differed in terms of the health IT systems and clinical technology in place; and two of the sites (BIDMC and MaineHealth) also had different EHRs among their affiliate hospitals.

Heath Information Technology

Each of the three hospital systems we visited has an EHR. Dartmouth-Hitchcock and MaineHealth use Epic, as do several other HVHC members. BIDMC uses a home-grown, internally managed, web electronic medical record (EMR). Dartmouth-Hitchcock and MaineHealth participate in a HVHC Epic user affinity group to share ideas and best practices. Both Dartmouth-Hitchcock and MaineHealth created order sets in Epic for the sepsis care bundles and use a combination of the STAT tool, chart audits and

electronic submission of their sepsis data for the unified data spec reporting. HVHC-PMO staff reported that the original design of the STAT tool has changed over the course of the initiative in response to staff needs. It was developed to be used in real time at the bedside, but busy ED and ICU staff do not always have time to fill it out as they're providing time-sensitive care to high risk patients; instead, they fill it out retrospectively, usually at the end of their shift. At some of the hospitals, clinicians try to collect data on paper forms in real time and then transfer these data to the STAT tool along with chart auditing. HVHC-PMO noted they are continuing to work with HVHC members to automate the data entry process rather than relying on retrospective entry. Additionally, they have made some updates to the STAT tool, including a new field for time of patient transfer from another facility and a checkbox to adjust time when data are entered retrospectively.

Dartmouth-Hitchcock uses the paper STAT tool to record information for ICU patients, but the ED staff finds it too cumbersome and time-consuming to complete. At the time of our first site visit, in June 2014, the ED staff reported that there was no routine data recording in real-time for ED patients, but Epic had improved these features as of our follow-up visit. Dartmouth-Hitchcock initially transmitted data to the HVHC-PMO using alternative means (emailing an excel spreadsheet), but they have since adopted the web-based STAT tool for data transmission. MaineHealth uses the paper STAT form, chart review, and laboratory and pharmacy data to assemble data with which to complete the unified data spec for each patient. The nurse data manager transmits the information to HVHC-PMO using the web-based STAT tool.

MaineHealth and Dartmouth-Hitchcock IT staff created a best practice alert (BPA) in Epic—a trigger—that notifies clinicians when a patient seems to match the sepsis criteria. They also built a feature in Epic they call "code sepsis," which is a time-sensitive acuity triage that elevates the patient to the highest level of priority and triggers the automated order set for the three-hour sepsis care bundle.

In 2014, data analysts at MaineHealth reported challenges in finding and recording all of the elements of patient data needed to demonstrate sepsis bundle compliance, but in 2015, they noted the user-friendliness and stability of STAT tool for electronic data submission. Dartmouth-Hitchcock has invested time in reminding staff to document in a complete and timely manner to ensure success. Staff members at both MaineHealth and Dartmouth-Hitchcock noted that the STAT tool has improved since the beginning of the program. HVHC-PMO observed that HVHC sites using the STAT tool had better data input than those using other systems.

BIDMC is able to submit the unified spec data electronically, through the use of an add-on data management tool called REDcap[13] that the hospital uses for many research projects. The nurses and physicians we interviewed mentioned that BIDMC's IT staff was a part of the Lean RIE and offered many suggestions for sepsis bundle triggers and automated order sets. They also reported that IT staff made necessary changes to order sets to support clinical workflows. For example, they built a trigger that alerts clinicians when a patient seems to match the sepsis criteria and does not allow the physician to ignore this trigger. An explicit declination is required to move forward in a patient's chart without starting the order set for the three-hour sepsis care bundle. BIDMC clinicians have access to an ED dashboard and voiced positive feedback about the ability to be fast and clear in communicating about a sepsis patient's care needs. BIDMC-affiliated community hospitals, however, use different EHR systems from the main

[13] http://www.project-redcap.org/

campus and there are challenges for transfer patients whose care began at one of the community hospitals prior to transport to BIDMC.

Clinical Technology

The clinical technology was similar at the three hospital systems we visited. All three use automated dispensing systems for decentralized medication distribution in the EDs and ICUs. Meeting the strict timeframes of the three-hour care bundle requires fast access to appropriate antibiotics. Each program had examined antibiotic access before implementing the sepsis care bundles to determine time loss while nurses waited for the pharmacy to deliver antibiotics to the ED. All three determined that having a stocked medication dispensing machine in the ED with commonly needed antibiotics was essential to reduce antibiotic delivery times and meet the three-hour care bundle requirements.

Dartmouth-Hitchcock and MaineHealth ED nurses noticed that they were waiting 30-60 minutes for clinical laboratory results for lactate tests, which jeopardized their ability to meet the three-hour care bundle requirements. BIDMC did not have this issue because they had previously optimized laboratory testing and results delivery during previous work on the MUST protocol. Laboratory directors at Dartmouth-Hitchcock and MaineHealth realized that they could reduce this testing delay through a process change that reduced lactate testing time to six minutes. They also realized that Epic order sets were not marking any of the lactate tests as 'stat' to be completed immediately, and they revised the sepsis order sets to make lab personnel aware of the urgency of these tests. To reduce delays even further, Dartmouth-Hitchcock purchased a point of care lab testing machine that allows ED nurses to process initial lactate tests on the floor instead of sending blood to the lab.

3.3 How the Initiative has Evolved

Exhibit 7 below indicates the changes that the three hospital systems reported between our 2014 and 2015 site visits. All sites began their sepsis improvement program in the ED because it is the major entry point for patients with sepsis; implementation in the ICU followed. The three hospital systems continue to expand the use of the sepsis bundle protocol beyond the ED and ICU to general medical and surgical units. Dartmouth-Hitchcock and MaineHealth are utilizing their rapid response units to triage and activate the sepsis bundle when they encounter patients with sepsis indications on the general hospital units. BIDMC does not use rapid response, but they have a trigger system in the EHR for nurses to notify residents that they need to review vital signs.

MaineHealth, Dartmouth-Hitchcock, and BIDMC also have a significant number of rural community hospitals that transfer patients to their main sites. ED nursing staff at MaineHealth and Dartmouth-Hitchcock reported increased awareness among community providers about the sepsis bundle protocol. BIDMC has recently acquired community hospitals, and the transfer rate of higher acuity sepsis patients has increased. Community hospitals initiate early parts of the protocol, such as drawing a lactate or starting fluid before a patient is transferred, but the ED nurses report that information exchange remains a barrier when patients are transferred from other hospitals. For example, an ED physician explained that it is hard to "receive credit" for elements of the bundle that clinicians initiated at other sites because they do not receive data such as time stamps and test results demonstrating bundle compliance. In order to record accurate time stamps for transfer patients, nursing staff were "sifting through paper records" that accompany transfer patients. Patients can also be transferred directly from a community hospital ICU to an HVHC medical center ICU without passing through the ED.

Exhibit 7: Site-specific Sepsis Bundle Evolution: 2014–2015 Case Studies

Site	Health IT	Inpatient	Community Providers
BIDMC	• New electronic medication administration record (EMAR) implemented in BIDMC ED that automates time stamps	• Sepsis care bundle has not been implemented on general medical and surgical inpatient units	• Health system acquired additional community hospitals that use different EHRs than BIDMC. Increase in acute sepsis transfer patients to their ICU from these new affiliates
MaineHealth	No changes between first and second evaluation case studies	• Roll out of an inpatient sepsis order set (Pen Bay) • Continued use of the inpatient sepsis order set (Biddeford) • Sepsis bundle has not been rolled out to the inpatient units at the main hospital site, but use of rapid response team to support identification of sepsis and bundle initiation is in place	• Reported an increase in community hospital awareness and identification of sepsis; challenges remain with information transfer • Preparing a sepsis early goal-directed therapy presentation to EMS providers across Maine
Dartmouth-Hitchcock	• Ability for triage nurse to enter Super SIRS as a "chief compliant" in Epic; triggers an attending and nurse to go to that patient's room. • New inpatient order set	• Implemented sepsis care bundle on the inpatient units by partnering with the nurse-led Inpatient Team Care Group	• Increase of transfer partnerships with community hospitals that use different EHRs; challenges remain with information transfer.

IT: Information Technology; BIDMC: Beth Israel Deaconess Medical Center; ED: Emergency Department

This sepsis awareness and education is facilitated through the Center for Rural Emergencies and Trauma (CREST) network, 16 critical access hospitals and community hospitals in rural New Hampshire and Vermont. Sepsis awareness and education are also facilitated through New England Alliance for Health (NEAH), a group of community hospitals, behavioral health centers, and home health care agencies that share "a commitment to improve the quality, efficiency, and availability of health care in New Hampshire, Vermont, and western Massachusetts." Dartmouth-Hitchcock is considering the use of a tele-ICU program to reach distant critical access hospitals with potential sepsis patients, to facilitate timely initiation of the sepsis bundle for ICU patients likely to be transferred. Their outreach through the CREST and NEAH networks is another way to encourage outlying hospitals to begin sepsis care bundle steps prior to transfer, and record information such as time stamps in accompanying paperwork.

Nursing homes also transfer patients with emerging sepsis to medical center EDs, and elements of the care bundle could be started prior to these transfers. An ED physician at MaineHealth mentioned that he has been reaching out to community providers and nursing homes about earlier sepsis recognition and documentation of care prior to transfer. He envisions a more robust EMS application of the protocol in the future, but as of our 2015 follow-up visits, sepsis education for EMS providers was mainly occurring informally—at the patient bedside when EMS providers brought them in to the ED—and through presentations at EMS conferences. An ED physician at MaineHealth is in the process of developing a formal training about sepsis for EMS providers; he mentioned there is a lot of enthusiasm among EMS providers about potential training.

3.4 Workforce Development

HVHC-PMO staff focused extensive implementation efforts on building Lean skills among their HVHC members, including RIEs at Year 1 initiators, to support individualized sepsis process redesigns. All three hospital systems described additional workforce development activities, including annual sepsis competency days for nurses, mandatory staff meetings where sepsis process measures and results are discussed, and educational packets about sepsis. At our follow-up visits in 2015, hospital systems had continued implementation of annual training and spread some of the e-learning modules to additional hospital units. Dartmouth-Hitchcock implemented a hospital-wide sepsis e-learning module for all staff members, and also added an order set and inpatient training for sepsis identification and use of the order set. This was the first time Dartmouth Hitchcock required disease-specific e-learning as a compliance module for the entire institution. MaineHealth also developed an e-learning module for rapid response teams at the Biddeford hospital. Site-specific training activities are outlined in Exhibit 8 below.

> The sepsis work at MaineHealth is truly becoming engrained in our culture. It has been integrated into our antimicrobial stewardship program here at the hospital. Emergency medicine is adopting this and educating its physicians and nurses about sepsis. These linkages will help sustain this initiative even after the grant ends.
>
> *– ED Physician*

Exhibit 8: Site-Specific Workforce Development Activities

Site	Initial Workforce Training/Development	Continued Training: 2015 Follow-up Site Visits
Dartmouth-Hitchcock	• Train triage nurses who accept community transfers, to identify sepsis cases early • Train ED Greeters in very basic sepsis signs and symptoms, to speed ED identification of potential sepsis patients (e.g. older patient with a UTI)	• Hospital-wide sepsis e-learning module for all Dartmouth Hitchcock staff • Inpatient sepsis training about recognizing and properly identifying sepsis
BIDMC	• Importance of documentation training, to enhance data completeness and to get credit for meeting three-hour care bundle	• Continued sepsis training for nurses during annual competency fairs
MaineHealth	• Sepsis training is part of new nurse ED orientation • HVHC video sepsis training • "When Does One Equal Seven" ICU pilot; focused on the need to get the antibiotic into the patient-"For every one hour of delay in administration of the antibiotic, there is a 7% increase in mortality." • Badge cards with Sepsis bundle steps • Dinner meeting/educational session about sepsis for MaineHealth staff • Medical newsletter *The Scope* contains quarterly information on the sepsis program • Residents receive sepsis program training when they rotate through the ED	• Continued sepsis training for nurses during annual competency fairs • E-learning sepsis module for rapid response teams (Biddeford)

ED: Emergency Department; ICU: Intensive Care Unit

Most of the hospitals we visited used informal methods for sharing information about sepsis care improvement, such as group huddles, informal conversations with clinical directors, or team meetings. Program and clinical directors communicated any updates to staff through existing channels, such as email notifications or team meetings for larger-scale changes.

3.5 Sepsis Care Bundle Checklist and Communication

We saw little deviation from the bundle checklist across the three hospitals during our 2014 and 2015 visits. Staff in all three hospitals reported that the sepsis care bundles are easy to understand and implement and require little instruction. BIDMC nurses reported that the three-hour and six-hour care bundles are much less complex and labor intensive than the MUST protocol. Compared with MUST, workflows for clinicians are more straightforward and require less decision-making at each step. They also found the care bundles easier to teach to new nurses and rotating medical residents than the previous MUST protocol.

> We are constantly trying to educate physicians—in particular, the hospitalists, who aren't based in the ICU—in regards to identifying sepsis. For the younger nurses, this [paper STAT tool] has given them a script to communicate with the physician. They can say, "This is my national standard."
>
> *– ICU Nursing Director*

Nurses in all three hospital systems were particularly supportive of the sepsis care bundles and agreed that the paper form (see Exhibit 6) is a useful tool to communicate the urgency of starting patients on the sepsis care pathway. With the paper form "in hand," nurses found it easier to cite protocol about documentation and adherence to the care bundle when communicating with physicians. Nurses at other hospitals also use the checklist as a tool to educate, advocate, and improve communication with attending physicians, residents, and nursing staff. At MaineHealth, for example, nurses use the paper form to improve handoffs of patients between the ED and ICU, and focus the entire care team on the key clinical findings that indicated potential sepsis, and progress in meeting care bundle requirements. These processes motivated faster identification and initiation of the evidence-based practice for treatment of patients on the sepsis pathway.

> It makes it a black and white issue. We can say, "This is what the protocol said to order, this is what you ordered, and this is what needs to be ordered, can you please correct your order?" The paper allows us to remind and reorient physicians to the protocol and guidelines.
>
> *– ICU Nurse*

Educators and staff in each facility we visited stressed the importance of visible reminders such as posters, bulletin board presentations, buttons, badge cards, screensavers, and electronic pop-up alerts to keep the topic of timely patient sepsis triage at the forefront for all clinicians. Each facility also devised unique and effective modes of communicating the importance of timely sepsis triage. Dartmouth-Hitchcock instituted nursing-specific mortality and morbidity rounds to assist nurses in analyzing the care given to past sepsis patients. In these morbidity and mortality (M&M) rounds, they analyzed a sepsis case in detail, including: when the bundle was initiated, what went right, what went wrong, and which care processes could be improved. Nursing staff reported that this is an effective way to communicate the latest updates on the sepsis bundle and ensure that all bedside staff learns from recent experiences.

BIDMC uses the traditional medical mortality and morbidity rounds to facilitate communication about sepsis patient care among physicians. They also did a poster presentation, *Implementing a Sepsis Care Bundle in the ED and ICUs*, at their annual in-house quality conference. This presentation stressed the importance of sepsis care to a wider audience and made it more visible to clinicians across the organization.

MaineHealth uses removable plaques that are attached to ICU computers as a means of communication at the point of care. Although MaineHealth did not complete a formal Lean RIE, they did dissect several bottlenecks in their workflow for sepsis care. They also instituted an Adult Medicine service line Sepsis

Workgroup to analyze best practices and challenges in current sepsis care practice and to disseminate the latest information back to clinicians.

3.6 Implementation Effectiveness

In this chapter, we discuss the impact of the sepsis bundle in improving care, improving health, and smarter spending. For each of these categories, we discuss HVHC perceptions, how the HVHC-PMO is measuring the program's impact, as well as measures that Abt Associates is using in the analysis. Finally, we discuss unanticipated impacts that have arisen during the program's implementation.

3.6.1 Better Care

At all three hospital systems, nursing staff reported that the sepsis care bundles improved workflow and quality of patient care. The following are two high-level improvements that many of the nursing staff discussed about the program's impact on patients care.

More Timely Care

As each site began preparing to implement the sepsis care bundles, all hospital systems focused signicant attention on timely completion of the three and six-hour care bundles to reduce harm from sepsis. The purpose of the Lean work prior to implementation was to have all clinicians, laboratory staff and pharmacy staff find efficiencies and remove wasteful steps in their workflows; these changes allowed them to more efficiently carry out the sepsis care bundles. The careful process redesign led to changes and new investments. For example, Dartmouth-Hitchcock decided to invest in ED point of care lactate testing machines to reduce the time to receipt of lactate values. ED staff worked closely with their pharmacies to ensure that antibiotics needed for the sepsis bundle were located on the floors, in close proximity to where the clinicains adminster the medication.

Identification and Early Triage

At all three sites, clinicians emphasized that identifying patients earlier in the sepsis pathway is essential to improving care but easy to miss until symptoms become more acute. Failure to recognize incipient sepsis means critical time lost in initiating the care bundle. ED staff, in particular, mentioned that while they automatically triage an injured trauma patient, an older adult patient with a urinary tract infection who is lucid and afebrile might be overlooked. Sepsis care bundle education trained clinicians to place any patient with two or more SIRS criteria and the specified lactate or blood pressure metrics onto the sepsis care pathway. Clinicians at all hospitals noted that triaging patients in this manner facilitated earlier identification and initiation of the sepsis care bundle faster than would have occurred; patients determined not to have sepsis are removed from care pathway.

> It becomes a race against the clock. … It's like getting a CT scan for a stroke—sepsis is engrained in our ED culture now.
>
> *-ED Nurse*

As of 2015, clinicians continued to report a noticeable change in management of patients with sepsis and noted that it has become the standard of care. The ED nursing staff at all sites associated this "cultural shift" with the establishment of sepsis as a high-level triage priority and the institution-wide standard of tracking the steps in the sepsis bundle. One nurse explained the shift in her unit:

> *I think it has been a whole culture change for nurses. At the triage level, we triage "Super SIRS" patients as triage level one, which is the equivalent to a full cardiac arrest patient or someone requiring resuscitation. That's how important it is. I think some nurses struggled*

> *with that—thinking that a "Super SIRS" patient needs were akin to someone in full arrest. But once we educated staff more and put out education materials, there was a real culture shift. Now we approach it as we're already behind the eight ball with [septic] patients, and we need to get on top of things.*

Nursing staff in both the ED and ICU units underscored that the institutional emphasis on the sepsis initiative elevated the level of knowledge, adoption of evidence-based standards of practices, and priority given to sepsis patients in their units.

3.6.2 Healthier People

HVHC members expect that patient outcomes will improve through adherence to the sepsis care bundles. The HVHC-PMO staff anticipate that the data will show decreased mortality, morbidity, associated complications and a reduced length-of-stay (both ICU length-of-stay and overall length-of-stay). Clinicians at all hospitals expect patients who undergo sepsis care bundles to have fewer co-morbidities, such as long-term respiratory issues due to ventilator-related pneumonia. They also reported that a patient's length of hospital stay should decrease because timely sepsis identification and treatment are tracked as a process measure as part of the bundle.

HVHC Measurement Strategy[7]

The HVHC-PMO collects data on a number of quality measures and they currently report the following to CMS:

- Mortality for patients with a diagnosis of severe sepsis or septic shock
- Percentage of patients requiring long-term acute care or sub-acute nursing care after a hospitalization for severe sepsis or septic shock
- Percentage of complete three and six-hour sepsis bundle protocol patients discharged following an episode of severe sepsis or septic shock

3.6.3 Smarter Spending

The program staff at Dartmouth anticipates that the sepsis bundle program will eventually reduce health system, patient and payer costs. In the short-run, the primary area where program staff reported potential cost savings is likely to be reduced complications (such as Pneumonia), and shorter ICU length-of-stay. Reduced complications may lead to lower hospital readmission rates, as well as a reduction in long-term care and skilled nursing facilities to treat medical complications.

HVHC Measurement Strategy[7]

The HVHC-PMO collects data on one quality measure and they currently report the following to CMS:

- Length-of-stay from diagnosis to discharge for hospitalizations for severe sepsis or septic shock. While shorter length-of-stay does not reduce Medicare's cost for traditional Medicare beneficiaries, it does reduce costs for insurers that pay fee-for-service and for the hospital system.

The three HVHC members we visited shared results of their own internal monitoring and evaluations. BIDMC advised that their length-of-stay increased due to more highly acute transfer patients from newly-acquired affiliate hospitals. Dartmouth-Hitchcock and MaineHealth reported that identifying patients earlier with the bundle eliminated or reduced critical care days. Dartmouth Hitchcock reported

that their baseline institutional costs to treat a patient with sepsis have been reduced from $100,000 to $50,000. HVHC-PMO staff also reported that costs associated with treating a sepsis patient are going down across the collaborative from an estimated $40,000 to $35,000.

3.6.4 Unanticipated Impacts

Beyond perceived improvements in care, health outcomes, and costs, several interviewees discussed unanticipated impacts that the sepsis care bundles are having at their institutions.

The importance of suspecting infection in all patients, even those who do not appear very sick, benefits many patients who are eventually determined not to be septic. Patients with other causes for low blood pressure, high lactate levels, and other SIRS indicators benefit from fast and appropriate treatment with antibiotics and intravenous fluid resuscitation. A nurse provided the example of the "college kid with tonsillitis" or "the 88-pound girl with a UTI" to illustrate the point. Previously, these patients would not have been identified on the sepsis pathway, but now they receive early treatment because of the emphasis on early identification with the care bundles. If their symptoms resolve after starting the three-hour bundle (e.g., after they receive fluids and antibiotics), they are removed from the sepsis pathway. While the HVHC-PMO is not measuring this spillover effect, clinicians in all three EDs mentioned the positive impact of the bundles for many patients that ultimately are not diagnosed with sepsis.

3.7 Context

In each interview and focus group during the site visits, participants were asked about lessons they have learned since the program began. This chapter sorts these lessons learned into two categories: measurement and self-monitoring, and confounding factors.

3.7.1 Measurement & Self-Monitoring

According to hospital IT and data analysts implementing this complex multi-site program, one of the greatest difficulties for HVHC-PMO, is collecting standardized data from all participating HVHC members, whose capabilities and electronic systems differ considerably. Some sites are unable to extract all the necessary time stamps from their EHRs, while others search through separate IT systems for laboratory values and antibiotics administered and are not always able to find these critical data. Data managers described assembling information retrospectively, not in real-time. That is, rather than having the specific time stamps integrated into the order sets and driving the care bundles, the time stamps are retrieved hours or days later for reporting to the HVHC-PMO. Dartmouth-Hitchcock and Maine Medical Center, in particular, reported that they devote extensive (and unanticipated) staff time to assembling all the information required for the unified data spec.

After data are assembled for a patient, transmission to the HVHC-PMO can also be problematic. For example, the web-based STAT tool was created by the HVHC-PMO for HVHC members who cannot extract data directly from their EHRs. In 2014, MaineHealth data analysts reported that the web-based tool was not user-friendly and transmission often failed (with loss of data), but in 2015 the data manager reported that the tool had become a lot easier to use. In our 2015 revisit, MaineHealth reported that the transmission process had improved, though at times the system is slow and there are issues.

3.7.2 Confounding Factors

As described earlier, there are some internal and external factors at each of the sites that may impact the sepsis program. MaineHealth and BIDMC each have multiple hospitals, and both networks include

affiliate community hospitals with distinct EHR systems. MaineHealth's affiliates span a large section of eastern Maine; not all of their community hospitals participated in the Sepsis program. Within a health system, and among all members of the HVHC, there may be differing interpretations and consensus about elements of the sepsis care bundles. Lactate testing methods, CVP monitoring, fluid volume for cardiac and obese patients were all described as clinical issues in which the science and evidence base is changing; the fluidity of the evidence results in clinical disagreement among physicians. In the three institutions we visited, physicians described specific circumstances when they or colleagues deviated from the care bundle in treating individual patients.

Endogenous Factors

BIDMC has an ingrained culture of sepsis identification due to their earlier implementation of the MUST protocol. They entered the HVHC Sepsis Improvement program with an extensive history of sepsis awareness and protocols, well ahead of the starting point for Dartmouth-Hitchcock or Maine Medical Center. BIDMC also has a home grown EHR that allows them to make IT changes internally and quickly, without relying on vendors to make necessary changes.

MaineHealth hopes to incorporate Emergency Medical Services (EMS) into the sepsis care bundle work. The Medical Director of one participating MaineHealth hospital has an EMS background and is driving this outreach to EMS with the philosophy that early detection begins before the hospital door. He feels that educating EMS staff in parts of the sepsis bundle that they can initiate in the ambulance and within their scope of practice will accelerate early identification of septic patients and initiation of the care bundle.

MaineHealth clinicians described a previous tele-ICU program that used continuous telemetry monitoring and best practice alerts (BPAs) for sepsis patients, but was recently discontinued for financial reasons. This was the only ICU program with BPAs of this sort at MaineHealth, and BPAs do not exist for ICU patients in their recent Epic implementation. Several MaineHealth staff mentioned the discontinuation of this tele-ICU program as a loss in terms of adhering to best practices in the care of patients with sepsis.

Exogenous Factors

Each hospital we visited also has unique external factors that may affect adherence to the sepsis care bundles and patient outcomes. Dartmouth-Hitchcock is one of two academic medical centers in the country that has a population density that qualifies as rural. They receive many transfer patients from outlying hospitals whose high acuity needs cannot be met in a smaller community hospital. Dartmouth-Hitchcock is actively engaging their community referral sources to educate them about sepsis care, so that care bundles can begin in the community hospital setting, rather than waiting until the patient is transferred to Dartmouth-Hitchcock

The MaineHealth system is one of only two tertiary hospitals in the state of Maine, and they, too, receive many transfer patients with high acuity care needs. There are no long-term care hospitals in the state of Maine, and patients who require post-acute care beyond what can be provided in a skilled nursing facility (e.g., patients requiring ventilator support and weaning) must remain at the hospital, increasing length-of-stay. Reducing length-of-stay may be more challenging in Maine than in other settings, due to the absence of appropriate post-acute care for this subset of patients.

BIDMC is a large, academic tertiary care medical center in the metro-Boston area, among many other large medical centers in the city. They, too, receive many patients in transfer from smaller community hospitals within their hospital network, and like Dartmouth-Hitchcock and MaineHealth, BIDMC face challenges in assembling data about the first steps in the sepsis care bundle that take place before a patient is transferred to their facility.

3.8 Member Perceptions of HVHC Value

This Award is testing the process of implementing the sepsis care bundles in a large collaborative, as well as testing the care bundles themselves. While all three sites employ standard protocols, each has tailored the implementation approach to fit the organizational culture of their particular care setting. Each also relies on the HVHC-PMO staff for support in different ways and for direction about data reporting. We asked interviewees about the challenges and successes of undertaking a care improvement initiative like this, through the collaborative, and with the support of the HVHC-PMO. Each site completed some variation of process redesign workflows that the sepsis care bundle affects. There seemed to be universal agreement that key aspects of this redesign—e.g., moving antibiotics to the units, increasing efficiency in lab processing time, adapting EHR triggers and clinical decision support features—are successful. Those that experience the REI events led by the HVHC sepsis clinical leads reported that those events were effective in focusing attention, identifying bottlenecks, and especially brainstorming solutions.

> Competiveness among the organizations is a motivator. We were behind the other organizations in many of the sepsis outcome measures and it drove the institution to aim for the high achieving collaborators
>
> *– Quality Improvement Lead*

All three hospitals we visited noted the value of benchmarking their progress against that of their peers in the collaborative. Clinicians with access to benchmarking results at the unit level noted that it helps to maintain energy and focus on the initiative. Some program directors also reported that the benchmarking generates "healthy competition" among the HVHC members.

When asked about the benefits of taking on this initiative as a collaborative rather than individually, one interviewee described how physician-peers shared best practices and learned how others overcame common barriers so they "didn't have to reinvent the wheel." One of the largest benefits of the learning collaborative was the safe environment for participants at all levels (i.e., physicians, nurses, program managers, data managers) to share best practices. Beyond the formal sharing of best practices through annual HVHC meetings and monthly calls, program leads also mentioned the off-line communication was a valuable aspect of participating in the collaborative. One physician gave the example of how easy it has become to pick up the phone and call a physician at another HVHC hospital to ask how they improved the workflow to produce lactate results.

> If we can coordinate at this level, what's to keep us from coordinating successfully at many, many other levels to improve health care overall? Coordination improves the structures behind it [care delivery].
>
> *– Program Lead*

One clinician expressed disappointment that the HVHC-PMO could not provide more value given the cost of membership in the collaborative (annual fees). While the HCIA funding for a staff FTE (usually a data manager) was useful, the leadership team at one of the institutions felt that the sepsis bundle could have been successfully implemented and managed internally as a quality improvement initiative without the HVHC.

We also asked the HVHC-PMO staff about challenges in operationalizing a care redesign program consistently across their diverse members. HVHC-PMO staff noted the challenge in mobilizing twelve unique health systems, each with its own culture, history and reform context. The clinical, IT and data complexities of this program were especially challenging to implement consistently. The biggest challenge they described, which was also echoed by the three hospitals we visited, was in consistent data

collection and reporting. Despite these challenges, HVHC is exploring additional funding to continue the initiative and plans to continue to collect, analyze, and disseminate data.

One unintended consequence of the sepsis work is a marketing and communication impact in local communities. The hospital systems have disseminated their sepsis work through institutional press releases and newsletters, on their websites and through local media. The HVHC also included these press releases in their quarterly reports. This work adds to the stature of HVHC members as national leaders, and focuses considerable attention on the problem of sepsis care.

3.9 Sustainability

Staff at all three hospitals reported that the sepsis care bundles are deeply embedded in their workflows, IT systems and culture; and all plan to continue using the sepsis care bundle after HCIA funding concludes. They all plan to continue informal and formal training to expand awareness to inpatient hospital units and community providers. For example, BIDMC enhanced their electronic order sets to improve sepsis tracking, particularly in ED and ICU settings where medical residents rotate frequently and need to be quickly engaged in the sepsis care bundles.

Program leaders emphasized the importance of adapting the sepsis care bundles as the science of evidence-based practice advances. We saw evidence of this consensus-building and adaptation as HVHC refined the six-hour bundle to address physician concerns and research about CVP lines. Additional flexibility may necessary in revisions to the bundle definition regarding fluid administration for cardiac ICU patients and obese patients.

Program leaders all mentioned that a big challenge when Award funding concludes will be supporting the data manager positions to send data to the HVHC-PMO for continued progress and outcome measurement and benchmarking. They all plan to continue collecting their own internal data, but they may not be able to continue completing the unified data spec and uploading timely data to the HVHC-PMO. A clinician we interviewed at an affiliate community hospital expressed concern that the shared learning and data benchmarking would not be available after the Award ends because “you don’t want to be a community hospital reinventing the wheel.”

The HVHC-PMO is concerned that the sub-Awards to their members are structured to explicitly support data collection and reporting, and most members used the funds to hire data managers. There is concern about continuing these positions and it is likely that the full unified data spec will not be sustainable. A HVHC-PMO staff member anticipated that members will agree on a minimum data spec—a subset of the exhaustive unified data spec—that is essential for benchmarking. This work to trim down the data requirements was in the early stages when we spoke with HVHC-PMO staff in early 2015. The HVHC is also exploring other funding sources to sustain their own data analytic and support staff after HCIA funding ends.

3.10 Conclusion

Abt researchers visited three HVHC member health systems in 2014 and followed-up with site visits and phone interviews in 2015 to understand commonalities and differences in implementing the sepsis care bundles. Each hospital we visited is a large medical center; two are academic medical centers and the third a tertiary care center. Two are the largest medical centers in their respective states and receive many

referrals from smaller community hospitals. The third is one of many large academic medical centers in an urban area, and has recently affiliated with smaller suburban community hospitals.

Across all three HVHC members we studied, clinicians had overwhelming positive feedback about the improvements in sepsis care within their units, workflow changes that were made during the project, and patient care improvements due to the sepsis care bundles. Clinicians attributed the initiative's success to a range of factors, including the simple design of the tool, level of energy and priority surrounding the initiative, increased attention and awareness about sepsis across units (through formal and informal training), and continuous data benchmarking and self-monitoring of progress. The steps within the sepsis bundle appeared to be uniform, with clinicians in all three hospitals taking exception to the step regarding CVP monitoring that has since been revised. Physicians varied in revising the fluid volume specified in the care bundles for cardiac and obese patients. While data reporting and completeness varied across HVHC members, most of the data analysts and program administrators we interviewed reported improvement in quality measures based on their internal metrics; anecdotally, both Dartmouth-Hitchcock and MaineHealth believe that the program has reduced system costs due to earlier detection and aggressive treatment of sepsis, but they do not have data to quantify this impact.

The greatest difference among the three hospital systems in terms of care bundle implementation appears to be in the areas of health IT, data collection and submission, and self-monitoring. Dartmouth-Hitchcock and MaineHealth use Epic EHRs and are not able to completely electronically extract and submit all necessary data directly from their EHR to the HVHC-PMO. It has improved between our first and last visits. They each relied on a combination of paper documentation and manual chart abstraction to complete the data required by HVHC-PMO. In contrast, BIDMC uses a home-grown EHR that extracts data for electronic submission to HVHC-PMO. All three have automated triggers to identify suspected sepsis patients, and/or automated order sets that align with the care bundles.

There were mixed reports about the value of implementing the sepsis bundle protocols within the HVHC collaborative as opposed to implementing as internal quality initiatives. Most of the program leaders found the learning and benchmarking activities of the collaborative quite beneficial, as well as the Award funding to support data collection and reporting. At all of the HVHC sites, both frontline clinicians and leadership expressed overwhelming support for the initiative and are dedicated to ensuring its sustainability, and in some cases, scaling up the initiative after the end of the Award.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode spending. The admission measure is not relevant for the Dartmouth sepsis program, because patients are already admitted when they receive the sepsis care bundle intervention. The results presented below are for the following Core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission for a sepsis patient, in either an intervention or comparison hospital.
- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.

- Total Medicare spending for 60 days including the index admission and all Medicare spending for 60 days after discharge.

The Dartmouth program also aims to reduce length of stay, and avoid complications through adherence to best practice guidelines. We therefore present results for the following additional measures:

- Length of stay (LOS)
- Discharge destination

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. We additionally report median regression estimates of 60-day Medicare episode spending. Results are reported in section 2.2 below.[14] Due to differences in rollout date across the multiple HVHC participants, all quarterly DD estimates prior to 2014Q2 include episodes in the HVHC group where patients did not receive the sepsis bundle. Since pooled regression estimates are able to directly account for the various start dates, they may differ from the quarterly estimates.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[15] We believe this is an accurate way to compare time periods.

4.1 Defining Intervention and Comparison Groups[16]

4.1.1 Selection Rules

The section below explains how we defined a set of criteria or rules that were used to create both the comparison and intervention groups. The criteria were created using information that is available in the Awardee registry and in Medicare claims. These were then uniformly applied to patients from intervention and comparison facilities to select the final intervention and comparison populations.

---

[14] The only exception is discharge destination, where quarterly estimates are reported in table form due to the multitude of possible outcomes.

[15] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

[16] Under the advisement of Dartmouth staff, we dropped three comparison providers from our sample that they felt were potentially "contaminated" by contact with the intervention, but not sufficiently subject to the intervention to include as an award hospital. These include the Long Island Jewish Medical Center (Long Island), Staten Island University Hospital (Manhattan) and Logan Regional Hospital (Salt Lake City). In addition, Dartmouth staff recommended new comparison providers for their Texas and Iowa locations. These include University Medical Center Brackenridge (Austin, TX) and Mercy Hospital and St. Luke's Hospital (Cedar Rapids, IA).

The Dartmouth registry is incomplete. Much of the registry is missing the patient identifiers used to link patients to claims data, and identifiers for the individual facilities participating in the intervention are not provided. In addition, the registry contains only the subset of patients for whom all data points are present to define the 3-hour and 6-hour care bundles; other patients who received the intervention but for whom data were incomplete, are not in the registry. The registry constitutes less than half of all patients who received the intervention, as estimated by Dartmouth staff. We therefore conclude that the registry provided by Dartmouth cannot support creation of inclusion and exclusion rules.
After discussion with the Dartmouth program staff, we developed rules to try to identify the intervention population. We note that the effort to detect sepsis could be preventing sepsis in borderline cases, leaving only those with more severe sepsis coded on their claims; conversely, it is possible that screening leads to increased detection and coding of borderline (mild) cases of sepsis.

The following inclusion and exclusion criteria apply to the Dartmouth population:

Inclusion

Revenue Center Codes
ICU: 0200, 0201, 0202, 0206 (General, Surgical, Medical, and Intermediate)
ED: 045X
ICD-9 codes: 99591, 99592, and 78552

Exclusion

Diagnosis Related Groups for organ transplantation, severe cardiothoracic or cardiac conditions (because the care bundle specifies high volume intravenous fluids which can be dangerous for severely ill cardiac patients). These excluded conditions are:

ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W MCC
A CUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE W CC
ACUTE MYOCARDIAL INFARCTION, EXPIRED W MCC
ACUTE MYOCARDIAL INFARCTION, EXPIRED WCC

We know that these criteria will include patients who were not eligible for the intervention because their blood pressure was not dangerously low or their lactate levels were not dangerously high; these are important selection criteria applied by all Dartmouth program sites that cannot be observed in claims. This definition will also include patients who did not receive the intervention due to their Do Not Resuscitate (DNR) status, which cannot be observed in claims.

Exhibit 1 below provides information on average patient characteristics for the Awardee and comparison groups in both the Baseline and intervention periods. The demographic summary statistics serve two purposes. The first is to provide a sense of the population demographics in the Dartmouth treatment population. The second is to show that the demographics are similar for intervention and comparison. The wide standard deviations reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

Exhibit 1: Patient Summary Statistics

	Awardee				Comparison			
	Intervention Period (N=10,122)		Baseline Period (N=21,192)		Intervention Period (N=24,687)		Baseline Period (N=45,388)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.48	0.50	0.50	0.50	0.50	0.50	0.50	0.50
Nonwhite	0.17	0.37	0.14	0.35	0.21	0.41	0.19	0.39
Age	73.08	13.92	72.88	14.02	73.63	14.26	73.33	14.25
HCC Score	2.19	2.16	2.48	2.39	2.29	2.26	2.58	2.46
Missing HCC	0.11	0.31	0.08	0.27	0.09	0.29	0.05	0.22
Medicaid Eligibility	0.41	0.49	0.59	0.49	0.52	0.50	0.68	0.47

Source: Abt Associates, May 2015.

We see slight differences in race between intervention and comparison groups, and note that HCC scores were higher in the baseline period for both groups than during the intervention period. In addition, there was a decline in the share of patients eligible for Medicaid between baseline and intervention periods, for both Awardee and comparison groups.

4.2 Core Measures: Results

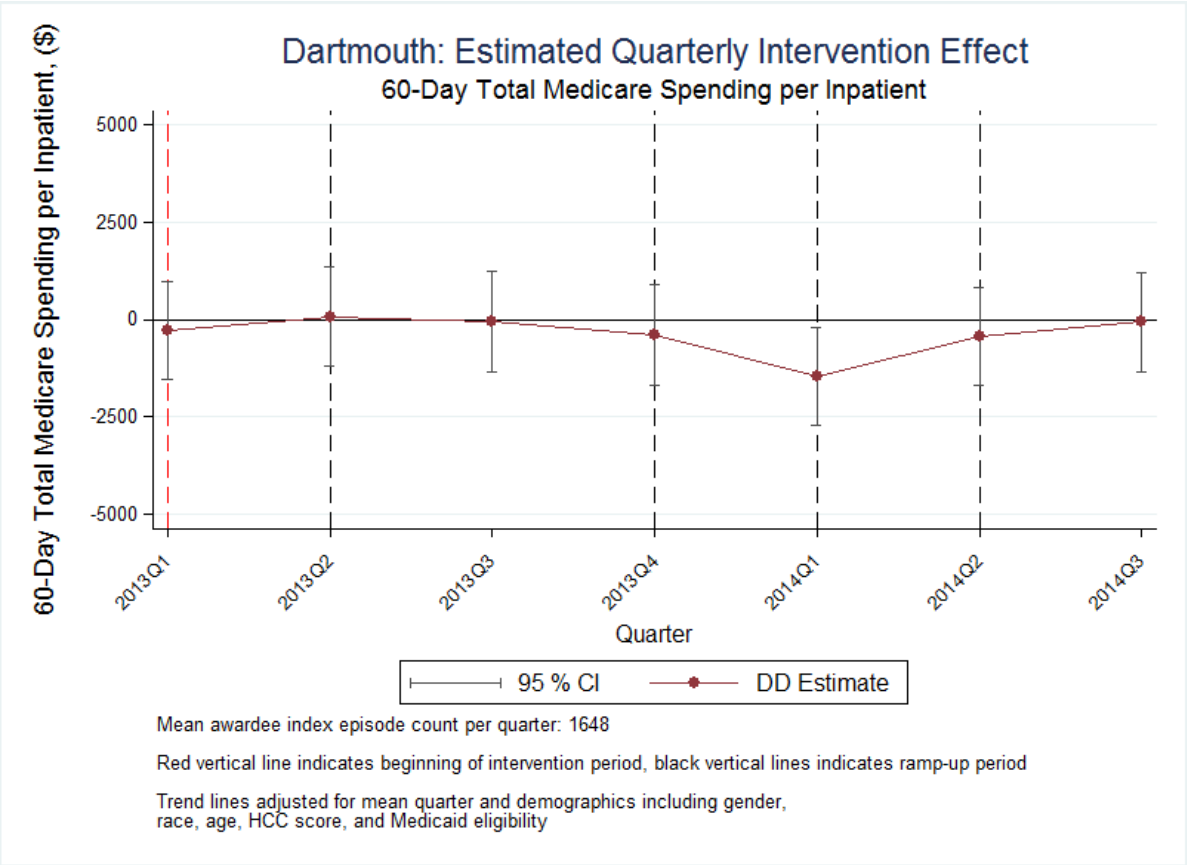
Implementation did not take place on the same day in all participating hospitals. The red vertical line in the graphs below shows the start of the intervention period in the first hospital, and the black vertical lines show the timing of implementation for subsequent groups of implementing hospitals. All estimated changes in utilization are based on eight quarters of post-implementation data. One less quarter of data is included for the spending measure compared to the utilization measures, due to the lag required for post-acute claims to become available for analysis.

4.2.1 Medicare Episode Spending[17]

The Dartmouth program aims to reduce Medicare episode spending by 5 percent. Exhibit 2 (total 60-day episode Medicare spending) shows the estimated intervention effect for each calendar quarter in the intervention. Medicare episode spending includes the inpatient stay and all claims in the following 60 days. The intervention and comparison group show similar costs per episode in nearly every quarter. Although we estimate that the intervention was associated with a statistically significant reduction in average Medicare spending for one quarter (Q1 2014), the small magnitude of the other quarterly estimates suggests that this result is an anomaly and not a reflection of the overall program impact to date.

[17] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 2: Mean Medicare Episode Spending



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Regression estimates pooled over all intervention quarters are shown in Exhibit 3. Ordinary Least Squares (OLS) estimates for the Dartmouth Sepsis program fail to indicate any significant relationship between the intervention and average Medicare episode spending during the 60 days starting with the index admission. Although there was an average increase in Medicare spending of roughly $47 per patient, this finding is statistically insignificant. Median regression estimates show a similarly small and insignificant increase in spending of $65. We conclude that there is no evidence of program impact on total Medicare episode spending based on data currently available.

Exhibit 3: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs

Dartmouth		
Intervention Effect (Ordinary Least Squares)	Estimate SE N	47.00 (348.18) [101,386]
Intervention Effect (Median Regression)	Estimate SE N	64.70 (414.28) [101,386]

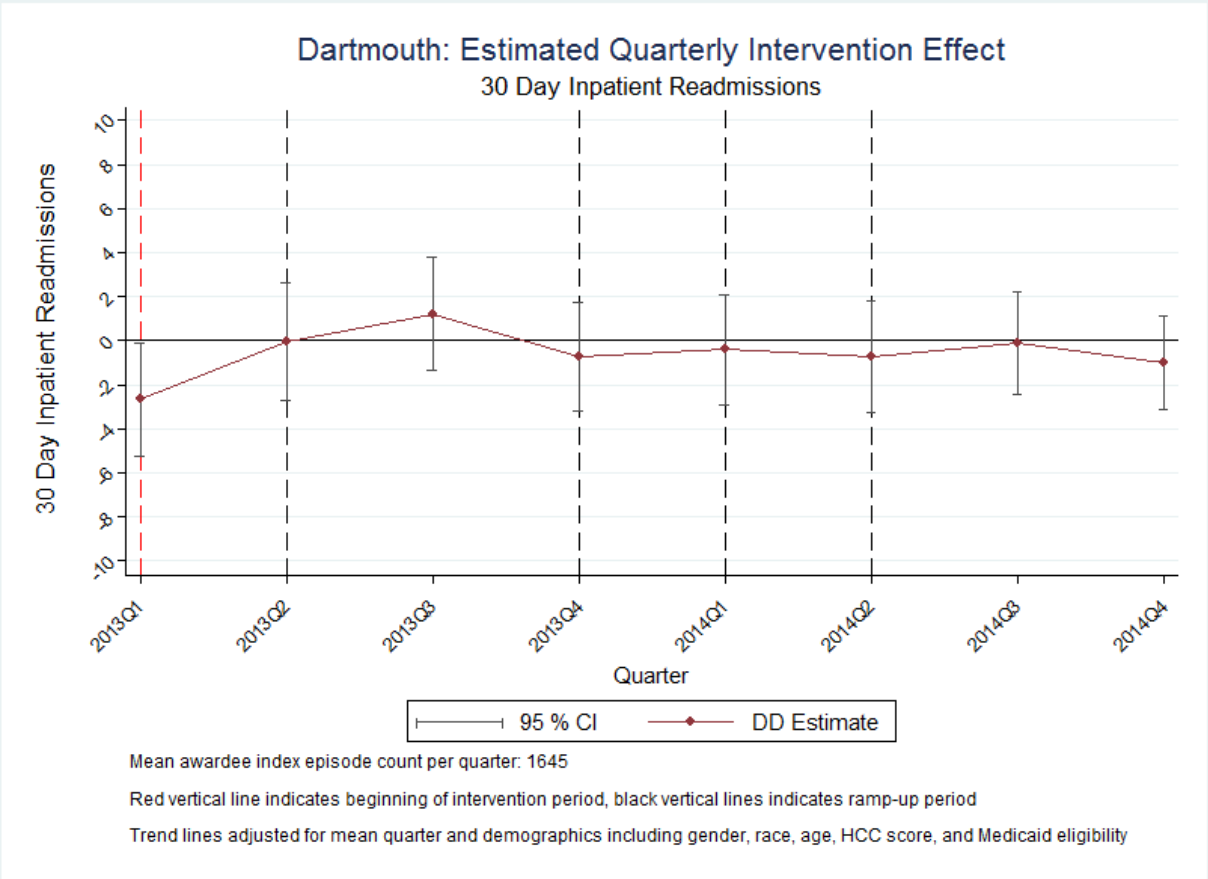
Source: Abt Associates, May 2015.

4.2.2 Readmissions

The Dartmouth sepsis improvement program aims to reduce Medicare spending by reducing complications, readmissions, return ED visits, and need for post-acute care. Exhibit 4 (hospital discharges followed within 30 days by a readmission) shows little difference in readmission rates between the intervention and comparison groups except for the first quarter of the intervention. Since first quarter facilities did not all start on the first day of that quarter, and some began several weeks into the quarter, the first quarter result is probably not important.

Pooling all intervention quarters together, the DD (Exhibit 5) estimated effect of the intervention is a small and statistically insignificant -0.26, and we conclude that the intervention is not correlated with any change in inpatient readmissions based on data currently available.

Exhibit 4: Readmissions



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 5: DD Estimated Effect of Intervention on Rate of 30-day Inpatient Readmissions

	Dartmouth	
Intervention Effect	Estimate	-0.26
	Standard Error	(0.64)
	Sample Size	[106,456]

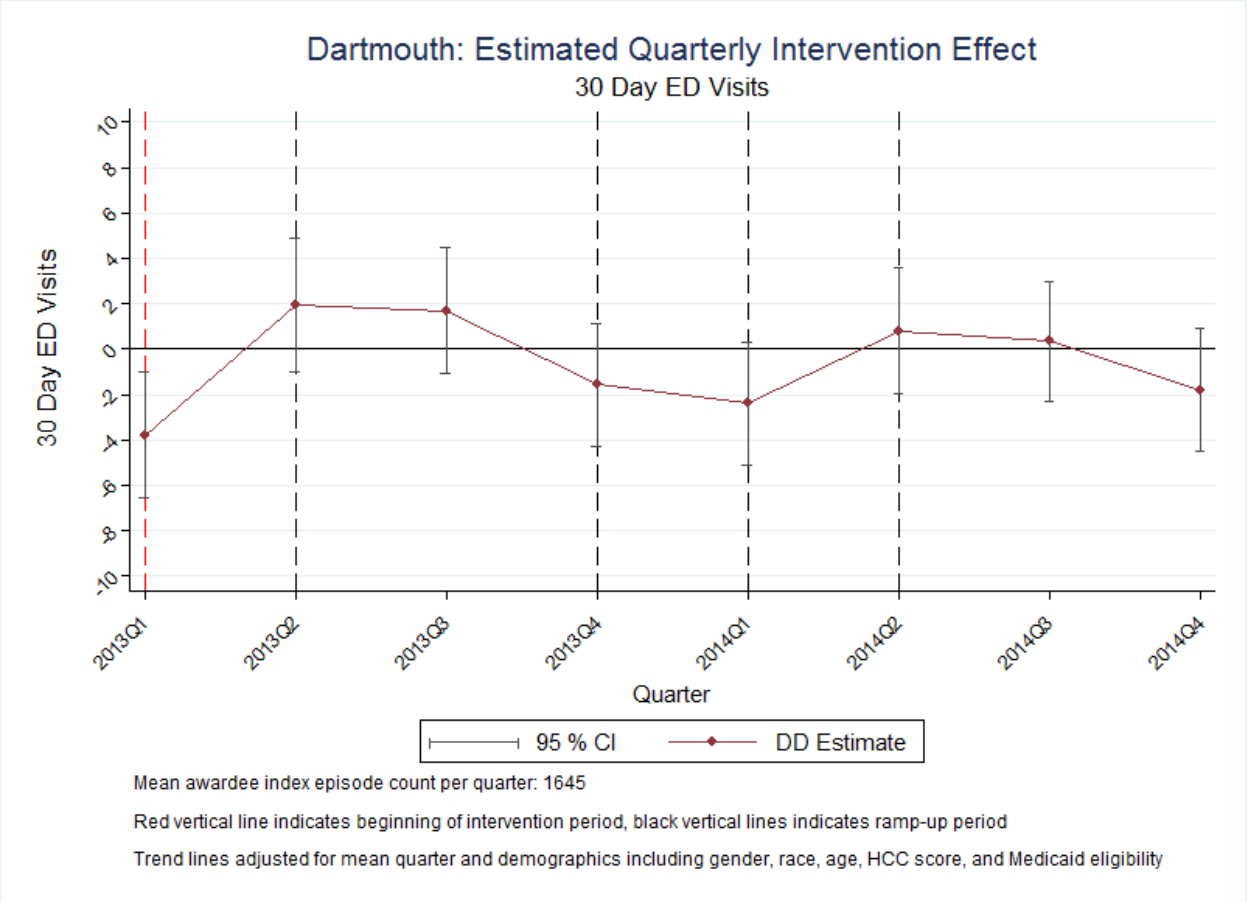
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.3 30-Day Post-Discharge ED Visits

Exhibit 6 (discharges followed within 30 days by an ED visit) shows no statistically significant difference in rate of ED visits between the intervention and comparison group, except for the first intervention quarter, which is probably not indicative of impact. Exhibit 7 presents the estimated effect of the intervention on 30-day ED visits for the entire intervention period. The estimate of -0.64 is statistically insignificant, and the combined results of the two exhibits indicate no impact of the intervention on 30-day ED visits based on data currently available.

Exhibit 6: 30-Day Post-Discharge ED Visits



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 7: DD Estimated Effect of Intervention on Rate of 30-Day ED Visits

	Dartmouth	
Intervention Effect	Estimate	-0.64
	Standard Error	0.69
	Sample Size	[106,456]

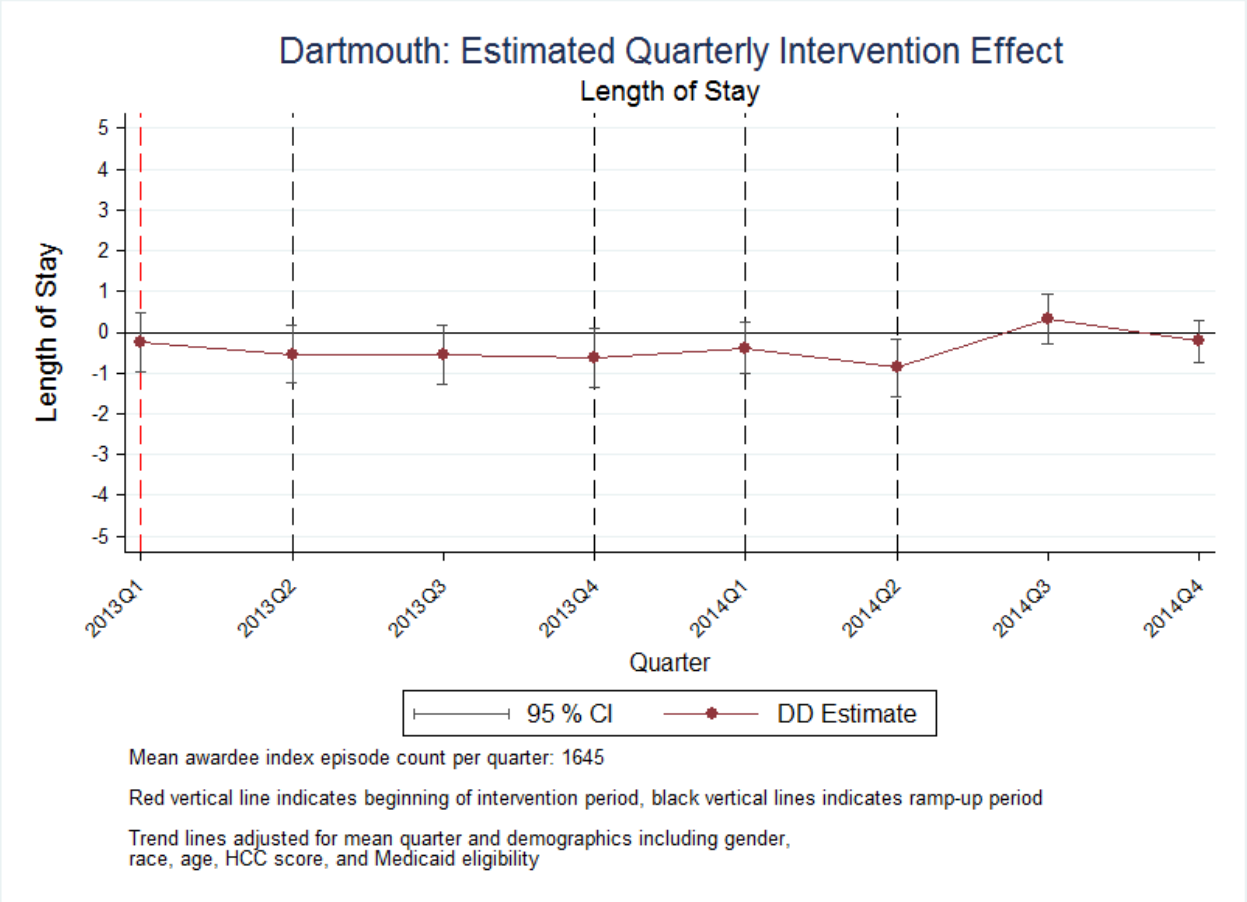
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.4 Index Admission Length of Stay (LOS)

Important goals of the Dartmouth Sepsis Improvement program include early recognition of sepsis and improved adherence to evidence-based best practices, which in turn are expected to reduce LOS. Exhibit 8 shows that the intervention group had consistently lower LOS during the intervention period, except for one quarter, although the estimated differences are not statistically significant. The estimated intervention effect over all quarters combined (Exhibit 9) is also statistically insignificant, and it is not yet clear whether the intervention is having an impact on inpatient LOS.

Exhibit 8: Index Admission Inpatient LOS



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 9: DD Estimated Effect of Intervention on Inpatient Length of Stay

		Dartmouth
Intervention Effect	Estimate	-0.18
	Standard Error	0.17
	Sample Size	[106,456]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.5 Discharge Destination

Finally, we examined patterns of patient discharge from acute care to post-acute settings. Exhibit 10 below indicates that since the start of the intervention there has been a statistically significant decrease of 1.15 percentage points in the proportion of intervention patients discharged to home health. Although the changes in the other three outcomes are not statistically significant, the relative magnitudes of the point estimates suggest that most of this change is driven by an increase in patients discharged to institutional LTPAC and other settings.

Exhibit 10: DD Estimated Change in Episode Discharge Destination

	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home									
DD Estimate	-1.14	-1.06	1.77	0.47	0.54	0.51	-0.91	0.02	0.14
SE	(1.50)	(1.47)	(1.54)	(1.44)	(1.47)	(1.46)	(1.39)	(1.45)	(0.73)
Home Health									
DD Estimate	-1.30	-1.65	-2.35**	-1.94*	-0.49	-1.26	-0.11	-1.14	-1.15*
SE	(1.26)	(1.22)	(1.19)	(1.14)	(1.24)	(1.19)	(1.22)	(1.18)	(0.61)
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home									
DD Estimate	1.21	-0.15	-0.65	-1.30	-0.89	0.23	1.71	1.70	0.62
SE	(1.66)	(1.67)	(1.65)	(1.59)	(1.58)	(1.64)	(1.59)	(1.64)	(0.81)
Other									
DD Estimate	1.23	2.86**	1.22	2.77**	0.85	0.51	-0.69	-0.57	0.39
SE	(1.06)	(1.26)	(1.09)	(1.17)	(1.03)	(1.04)	(0.92)	(0.93)	(0.50)

4.2.6 Conclusions

- After the start of the intervention we see a small but statistically significant shift in discharge destination with discharge to home health care declining and possibly being replaced by discharge to LTPAC and other destinations.
- We find no evidence based on data currently available that the intervention is correlated with changes in total Medicare episode spending, 30-day inpatient readmissions, 30-day ED visits, or inpatient LOS.

Appendix B3: Emory University Hospital

Rapid Development and Deployment of Non-Physician Providers in Critical Care

1. Executive Summary

This chapter presents both quantitative and qualitative findings of Abt Associate's evaluation of Emory University Hospital's Health Care Innovation Award (HCIA) cooperative agreement that expanded a critical care residency program for Physicians' Assistants (PAs) and Nurse Practitioners (NPs)—collectively, Affiliate Providers—and implemented an electronic intensive care unit (eICU) to support ICU clinicians. The two interventions, aim to improve patient care and more efficiently utilize resources to address the critical care physician shortage Georgia. The intervention began in the spring of 2014 in several critical care units in Emory University Hospital, Emory University Hospital Midtown, and St. Joseph's hospital, all in Atlanta. It was expanded to two smaller community hospitals—East Georgia Regional Medical Center and Emory Johns Creek Hospital—in late 2014.

The Emory program staff expected that the addition of critical care trained Affiliate Providers, continuous monitoring of ICU patients, and intensivist physician access at night via the eICU, would shorten ICU length of stay (LOS) and possibly overall hospital LOS. They also expected that patients would eventually be discharged in a better state of recovery due to this program. Most importantly, their goal was to bring clinicians with critical care training to ICUs, particularly in those facilities that had no physicians working in the ICU at night.

The Affiliate Provider training program achieved accreditation in 2015; it is the first such program in the nation accredited by the American Nurses Credentialing Center, and has had more applicants than available positions. The eICU program encountered technological challenges with network connections and interoperability between different EHR systems across the participating hospitals. These IT challenges were largely overcome, although they delayed the launch of the eICU program component. Some team communication issues also emerged as Emory's eICU began to support smaller community hospital ICUs that do not have critical care-trained Affiliate Providers (or physicians), and have different practice styles and communication expectations.

We analyzed the impact of the eICU program, and in the case of Emory, the combined impact of the eICU and the training program by comparing differences between the change in outcomes over three quarters for intervention and comparison group beneficiaries.

There were few significant findings in our analyses possibly because the eICU program launch was delayed until April 2014, restricting the available time for claims data to reach CMS and be included in our analyses. We are only able to analyze three quarters (nine months) of data for this report, which allows us to identify emerging trends but not longer-term effects. There was a decrease in total Medicare 60-day episode spending, relative to the comparison group, but this result is not significant. Hospital length of stay decreased approximately one third of a day, relative to the comparison group; a trend that is consistent with the expected reduction in LOS but not statistically significant. Readmissions to the hospital within 30 days of discharge also decreased slightly relative to the comparison group. Although not significant, these results all point to consistent effects. With additional quarters of data (a larger number of patients), these trends may become statistically significant.

Discharges to home with home health care increased by a statistically significant 2.88 percentage points. This overall finding is primarily driven by the large 5.7 percentage point increase in Q2 2014, although the other quarterly estimates range from roughly 2-3 percentage points. Overall, all other discharge destinations decreased relative to the comparison group levels, indicating that patients were diverted from

these other discharge destinations to home health care. This may be a positive development, as patients no longer needing institutional post-acute care are instead able to go directly home, with home health care.

The Emory program accomplished its main objective of bringing clinicians with critical care specialty training to more ICUs/shifts, through both the training program and the eICU. Moreover, the two combined programs may be having the most impact in ways that are difficult to measure, such as avoiding care delays at night, improving adherence to standardized clinical guidelines, reducing physician burn-out, and enriching communication and critical care knowledge of entire care teams.

2. General Research Domains

The core domains for the Emory University Hospital evaluation are: implementation effectiveness, program effectiveness, workforce issues, contextual issues, sustainability, and impact. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of HCIA funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the aims of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Introduction

Emory's Award, entitled "Rapid Development and Deployment of Non-Physician Providers in Critical Care", contains two primary components: an electronic intensive care unit (eICU) and a residency training program for Physicians' Assistants (PAs) and Nurse Practitioners (NPs), collectively Affiliate Providers. Emory's program seeks to improve critical care in a number of hospitals across Georgia, through leveraging the critical care residency-trained Affiliate Providers, supported by an eICU to provide continuous monitoring and physician consultation during "off hours." Nurses in the eICU monitor patient vital signs 24 hours a day, 7 days a week, and a critical care physician consults from the eICU on weeknights, weekends, and holidays, when few physicians are present in the ICUs. The two interventions, together, aim to improve patient care and more efficiently utilize resources to address the critical care provider shortage in the state of Georgia.

By 2007–2008, Emory recognized that there would be a severe critical care clinician shortage nationwide and in Georgia. There was also internal evidence that quality of care in the Emory ICUs and others in Georgia were suboptimal. The decision was made to transform the paradigm for critical care medicine, focusing on quality, value (delivering care at a price the nation can afford), and access. To achieve the transformation, Emory designed and introduced two interventions: an Affiliate Provider residency training program, and an eICU. The two interventions, though distinct and separate, together are intended to extend the reach of intensivists in Georgia and improve quality of critical care.

The table below presents information on when Emory's eICU intervention began in participating hospitals. Affiliate Providers were already working in some ICUs before the residency program began, and program graduates are continuing to fill vacancies in Emory's ICUs and those of its community hospital partners.

Exhibit 1: eICU "go live" Dates

Site	Date	ICUs
Emory Saint Joseph's Hospital (ESJH)	4/25/2014	1 Medical/Surgical ICU, 1 Coronary Critical Unit (CCU), 1 Cardiothoracic (C-T) Surgery ICU
Emory University Hospital Midtown (EUHM)	4/30/2014 and 3/25/2015 for the CCU	1 C-T Surgery ICU , 1 Medical/Surgical ICU, 1 CCU
Emory University Hospital (EUH)	5/1/2014	2 C-T Surgery ICUs
East Georgia Regional Medical Center (EGRMC)	8/27/2014	ICU (General)
Emory Johns Creek Hospital (EJCH)	11/5/2014	ICU (General)

ICU: Intensive Care Unit; CCU: Coronary Care Unit; C-T: Cardiothoracic

3.2 Case Study Methods

We first conducted a site visit at Emory University Hospital (Emory) and two partner sites, Emory University Hospital Midtown (EUHM) and Emory St. Joseph's Hospital (ESJH) on May 7–9, 2014. On February 9–13, 2015, we conducted follow-up data collection via teleconference with participants from the initial three sites as well as two community hospitals that were added to Emory's eICU program: East Georgia Regional Medical Center (EGRMC) and Emory Johns Creek Hospital (EJCH). The following report encompasses all of the data collected from both the initial site visit and the follow-up telephone interviews and focus groups.

In May 2014, the evaluation team visited Emory University Hospital, Emory University Hospital Midtown, and Emory Saint Joseph's Hospital, where the eICU central monitoring facility is physically located. The hospitals are located in Atlanta, Georgia. In addition to conducting interviews and focus groups, the site visit team observed a simulation module used in the residency training program. In February 2015, the evaluation team interviewed a diverse set of clinicians and program staff at each of the five sites by telephone. Some individuals, particularly program staff, were interviewed in both phases of data collection.

The exhibit below presents information on the number and type of individuals who participated in interviews or focus groups during the two phases of qualitative data collection.

Standard qualitative interview and focus group protocols were tailored to the different informants at each site. Three evaluation staff conducted the initial site visit: a senior Abt researcher, a mid-level Abt researcher, and a researcher from Telligen (formerly CFMC; subcontractor to Abt). All three staff participated in every interview and focus group, with one researcher leading the interview and others taking comprehensive notes. For the 2015 follow-up interviews, four researchers were involved: a senior Abt researcher, two mid-level Abt researchers, and a researcher from Telligen who conducted all of the phone interviews. Each telephone interview was attended by at least two staff members, one leading the interview and the other taking comprehensive notes. All interviews were recorded (with participant consent) and audio-recordings were used to supplement interviewer notes. At the end of each round of data collection, all notes were cleaned and integrated across the note-takers and reviewed for accuracy either by the senior researcher, or the researcher who led the interview for a particular discussion. Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

Exhibit 2: Case Study Participants

Case Study Participants* on May 7–9, 2014							
	ICU Physicians	eICU Nurses	Affiliate Provider Residents	Affiliate Providers	ICU Bedside Nurses	Program Staff / Hospital Leadership	Nurse Director/ Specialists
Emory University Hospital	2	0	4	2	0	7	2
Emory University Hospital Midtown	0	0	0	2	2	2	2
Emory Saint. Joseph's Hospital	0	3	0	2	0	3	0
East Georgia Regional Medical Center (via phone)	0	0	0	1	0	0	0
Total = 34	2	3	4	7	2	12	4

ICU: Intensive Care Unit; eICU: Electronic Intensive Care Unit

*No participant is double-counted although some participants (program staff) participated in more than one interview.

Case Study Participants** on February 9–13, 2015								
	ICU Physicians / Hospitalists	Surgeons	eICU Physicians	eICU Nurses	Affiliate Providers	ICU Bedside Nurses	Program Staff / Hospital Leadership	Nurse Director/ Specialists
Emory University Hospital	1	1	1	0	1	4	5	1
Emory University Hospital Midtown	1	1	1	0	0	2	0	1
Emory Saint. Joseph's Hospital	0	0	0	3	1	1	2	0
East Georgia Regional Medical Center	0	0	0	0	1	4	0	1
Emory Johns Creek Hospital	2	0	0	0	0	3	0	1
Total = 39	4	2	2	3	3	14	7	4

**Participants are associated with the hospital site at which they currently work; or spend most of their time working; or previously worked (if no longer at any of the sites).

Analysis was conducted by running node reports according to key areas of interest (e.g., characteristics and components, impacts of the intervention) to identify themes and subthemes. As relevant, we explored differences across key project components for the themes of interest. For example, we compared information from bedside nurses with that of their peer nurses in the eICU and analyzed data for the eICU separately from data related to the residency program. Abt researchers convened to discuss key findings of the analysis to ensure agreement on major themes and any changes that emerged from data collected in follow-up interviews.

Because the two primary interventions of Emory's program are independent of each other, this report is divided into two separate chapters, each addressing the following domains: innovation components and targets, workforce development, implementation, and sustainability. We discuss implementation effectiveness and anticipated impacts for both interventions in subsequent chapters.

3.3 Residency Training Program

3.3.1 Goals of the Program

For Hospitals

As part of Emory's goal to transform the delivery of critical care, an Affiliate Provider residency training program was introduced in February 2012, to improve the skills and preparation of PAs and NPs for work in the critical care environment, and to expand the supply of critical care providers. This program was inaugurated in response to the recognition that population demographics will make the traditional physician-centric model of critical care unsustainable. The shortage in critical care clinicians is evidenced among Emory's partner hospitals: St. Joseph's often needs Emory to provide coverage when there are not enough intensivist physicians available; East Georgia Regional Medical Center only has one critical care physician available on weekdays; and Emory Johns Creek Hospital has no physician with critical care training. Part of Emory's solution is to improve the skills and numbers of non-physician critical care providers.

Candidates for the residency program are often graduates of Emory's NP and PA training programs or other similar programs. Others are experienced NPs and PAs seeking specific critical care experience that was lacking in their previous training programs. In addition, rural hospitals may send candidates to Emory's residency program with the expectation that they will return to practice critical care in their rural community. A few candidates have expressed interest in working in a particular area in Georgia where there is need for more critical care clinicians. In these cases, Emory contacts the community hospital in that area to ensure that there is a position open for a critical care provider, before accepting that candidate into the program. The residency program's interaction with outlying hospitals is described by the program directors as being a "two-way street." Even though these community hospitals have support from Emory and sufficient financial resources to hire an Affiliate Provider, they still struggle to recruit critical care trained Affiliate Providers. These Affiliate Providers are in high demand and often prefer to work in larger, urban hospitals.

> "The 'on-boarding' [of an Affiliate Provider residency graduate] took weeks rather than months because he was already so familiar with the Emory ICUs from the rotations he did in the program."
>
> *– Critical Care Physician*

For Affiliate Providers

Most PA and NP training programs focus on primary care; students generally receive minimal exposure to critical care medicine, especially the procedures (e.g., central line placement, extubation) that are commonly required in an ICU. Several Affiliate Providers reported feeling that there was a gap in their prior training, especially in terms of these types of procedures. The residency training program aims to build skills and confidence, and to transition Affiliate Providers from being partially responsible for patient care to being more fully responsible. At Emory, program leaders recognized that PAs and NPs were underappreciated and did not have a clearly-defined scope of practice within the critical care team. In response, the program reconceived the role of "Affiliate Provider"—avoiding labels such as "mid-level" and "assistant."

For Other ICU Clinicians (Nurses and Physicians)

ICU bedside nurses are often overextended and working at the limits of their training, especially at night and on weekends when there are few attending physicians or hospitalists present in the ICU. Intensivist physicians are also overextended and routinely on call 24 hours a day for seven consecutive days, with

frequent interruptions at night. The Affiliate Provider residency program intends to improve the skills of NPs and PAs so that they can independently perform many procedures and prescribe in accordance with patients' care plans, without having to call a physician for every order that needs to be placed. Having Affiliate Providers assigned to all shifts ensures that nurses have colleagues available to write orders and perform routine procedures whenever necessary. It also shifts the decision about calling/waking attending physicians to the Affiliate Provider, rather than the bedside nurse, and this is expected to increase nursing satisfaction. Fewer nighttime interruptions are also expected to improve the work-life balance of intensivist physicians and reduce burn-out.

For Patients

Nationally, the population is aging and acuity of care is increasing, but the intensivist workforce is not expanding. As explained by the Emory Principal Investigator, the shortage of intensivist physicians is driving a growing disparity between the care provided to patients in hospitals that are well-staffed with intensivist physicians, and the care available in community hospitals, especially those in more rural areas that lack these resources. In teaching institutions like Emory University Hospital, there are usually intensivist physicians available—albeit often not enough of them and not on every shift. Community hospitals by contrast often rely on hospitalists or general medicine physicians, who lack critical care training. Affiliate Providers trained specifically in critical care can extend the available intensivists in teaching institutions, and also bring critical care expertise to rural and community hospitals, to the benefit of patients. Affiliate Providers trained in critical care can perform routine procedures at night and write orders for tests, medications and procedures, without waiting for physicians to arrive in the morning, making care delivery timelier.

3.3.2 Innovation Components

Background

An NP with 10 years of experience and a PA with 30 years of experience (collectively termed, "Educators" herein) designed and implemented a residency training program to bridge traditional NP or PA training and the job requirements of an Affiliate Provider in critical care. The Educators began by envisioning what they themselves would have wanted to know and be able to do on "day 1" of the job, but had not taught in their prior training. They established a core curriculum collaborated with physicians and existing Affiliate Providers at Emory to establish a mentoring program in each ICU for program residents, created an application process, and continue to improve the program based on feedback from residents and graduates.

Residency candidates may apply for either a 6-month or a 1-year residency. The 6-month residents spend one month in each of several ICU environments, while the 1-year residents spend two months in each of these different ICU rotations. The program was initially conceived as a 1-year residency with biannual applications, but when the 6-month residency was offered, enrollment shifted to a rolling basis. The 6-month program is intended to enhance practical skills and knowledge while the 1-year program also focuses on leadership competencies. The additional leadership training is intended to groom Affiliate Providers to serve as instructors and mentors in this and other residency programs that will train future Affiliate Providers in critical care.

Interest in the Affiliate Provider residency program has grown and applications have increased substantially. Most recently, the program received 30 applications for just two openings. By the end of February 2015, the residency program had graduated a total of 19 resident trainees, most of who work in the Emory Hospital system. Two of the graduates elected to work outside of Georgia—one in Michigan

and the other in Texas—where they plan to start up training programs similar to Emory's program. One recent graduate worked at a rural hospital and then transferred to another hospital outside the Atlanta area.

In January 2015, the Affiliate Provider residency program also became the first residency program in the nation to become accredited by the American Nurses Credentialing Center (ANCC) for PAs and NPs; the accreditation is valid for the next three years.

The residency training program comprises a number of didactic and practical learning experiences that are outlined below.

Knowledge Building

While the residency training program focuses substantially on practical skills and procedures, it also provides educational modules that enhance the residents' knowledge. The curriculum is based on the European Society of Intensive Care Medicine's training program, which the Educators consider to be the most comprehensive curriculum available. Affiliate Provider residents are assigned additional readings each week and are responsible for understanding the topics and actively discussing them in an academic online forum. They are also tested on the material in each component of the curriculum.

The residency program continues to evolve as the Educators modify the curriculum based on feedback from the Affiliate Provider residents. One of the residents who graduated in January 2015 developed a "clinical care boot camp" which comprises a series of lectures on: the role of the Affiliate Provider resident; data collection, documentation, and presentations; arterial blood gas (ABG) interpretations; basic ventilator management; and shock and hemodynamic monitoring. These lectures have been incorporated into the curriculum along with an educational template for integrating non-physician providers in the ICU.

Also based on resident feedback, attending physicians now provide in-person lectures centered on critical care. The lectures may incorporate online patient case presentations that the Educators developed. The online presentations examine different patient scenarios and allow residents to interact online, deciding which laboratory tests to order and determining the appropriate care plan for the patient.

Skills Development

PAs and NPs are assumed to have received a strong didactic background from their previous PA and NP training programs, so the residency in critical care is designed to emphasize skills development and critical thinking. The program initially required Affiliate Provider residents to train in an anesthesia rotation during their first month, and to use their mornings to read and gain exposure to radiology analysis. Presently, the first month of the training entails "shared days of experiences" in which the trainees spend three days with a pharmacist, three days with a registered dietician, and several days learning about respiratory therapy and radiology. Gaining exposure to the different specialties allows resident trainees to develop a team approach to critical care and select an elective rotation after completing required rotations.

Affiliate Provider residents rotate through several Emory ICUs during the course of their training program, and can choose to spend an extra rotation in an ICU of special interest (e.g., transplantation, cardiothoracic surgery, cardiology). While on rotation in an ICU, residents are usually provided with a list of physical competencies they must complete during the rotation, such as intravascular access, chest tube insertion, and feeding tube placement. In addition to practicing these procedures, residents learn to work with a different care team in each ICU rotation, and the special critical care issues involved with each.

Occasionally, the patient characteristics or circumstances while on a particular rotation do not afford a resident the opportunity to perform some of the procedures that s/he must master on that rotation. When this occurs, those procedures for which more practice is needed are communicated to mentors on the resident's next rotation, so that they can be attuned to providing that specific learning opportunity.

Interviewed Affiliate Provider residents explained that across the 20 different ICUs in Emory's health system, they had seen complex and unique cases that they would not have been able to observe without this critical care residency program. Affiliate Provider residents are being trained alongside medical and surgical physician residents; Affiliate Provider residents are expected to lead rounds and learn the same procedures and level of critical thinking just as the resident physicians do, all held to the same standard.

Mentoring

On each rotation, an Affiliate Provider resident is assigned a mentor who works in that ICU. Usually the mentor is another, more seasoned, Affiliate Provider who guides the resident in performing procedures, provides additional information and reference materials, and in general supports the resident in his or her learning process. When an ICU does not have an Affiliate Provider able to serve as a mentor, a physician (fellow) fills this role.

The Affiliate Provider residents we interviewed reported that their mentors want to teach and are actively involved in the resident's professional development. However, the mentors tend to change throughout a rotation, sometimes every day, posing a challenge for mentors to become acquainted with the resident's level of skill and knowledge. One resident noted that having the same mentor throughout a month would be ideal. Another resident suggested that mentors could informally pass along information about the strengths and weakness of the resident to subsequent mentors, so that everyone is more aware of what additional training each resident requires.

> "It's nice to have that security blanket [of mentors] for more advanced procedures like central lines. I didn't have opportunities to do those procedures during graduate school, so it was nice to have someone there to help me."
>
> *– Affiliate Provider resident, May 2014*

Physicians who are especially engaged and interested in the training of Affiliate Providers have suggested and helped conceive additional training components. For example, an anesthesiologist with an interest in ethics offered a module discussing ethical issues often seen in critical care; a radiologist interested in providing a more robust rotation added other skill development trainings to make the program more comprehensive. Affiliate Providers also contribute to the program design by suggesting additions that would make the program more complete. For example, an Affiliate Provider resident suggested giving residents a chart that explains how to dose various antibiotics—a reference item that was not previously available.

Competency and Learning Evaluation

In addition to the knowledge and skills components of the residency training program, residents must complete evaluations and tests throughout the program. There are ICU rotation-specific written exams that residents complete at the end of each rotation; they may retake an exam if they fail to pass (receive a score below 60 percent) at their first attempt. Each 20-question exam consists of short answer or multiple choice questions. Each rotation also includes a clinical simulation in which residents must participate. The residents receive informal feedback from mentors as well as evaluation on the simulation for each rotation. The simulation module was restructured to incorporate a wider set of scenarios that allowed residents to focus on other non-medical skills. Initially, simulations emphasized arriving at

medically correct decisions. After receiving feedback from resident trainees, however, the Residency Program Managers added simulation scenarios that integrated other skills such as team training and interaction, handoffs, and communicating with families in challenging situations. Finally, during the last week of their training, residents deliver a senior presentation in an area of interest.

Moreover, an evaluation form utilizing a Likert scale is completed for each Affiliate Provider resident. The form includes questions such as, "Is this person a team player?" or "Does this person show up to work on time?" Educators have also added a section that is more focused on the trainee's clinical competence, which asks questions such as, "Does the trainee recognize what could potentially be an acute problem and deal with the problem before it becomes a serious illness?" or "Does the trainee recognize errors made on the patient?".

The residency training program administers pre- and post- knowledge and confidence surveys for Affiliate Provider residents. When we first visited in May 2014, the Emory Educators reported that there was an approximately 20 percent gain in knowledge during residency (a statistically significant change according to their analysis). Relatedly, another survey of residents conducted in February 2015 revealed a 70 percent increase in critical learning. Surveys from 2014 and 2015 also show a statistically significant gain in confidence on the part of the residents. In addition surveys discerning changes in residents' levels of knowledge and confidence, residents complete a pre- and post- training self-evaluation and a post-training evaluation of the residency program as a whole.

Emory tracks how long it takes for an Affiliate Provider graduate to become fully oriented when they are hired at Emory, as compared with newly hired Affiliate Providers who were not trained in the program. On average, a graduate of the residency program takes 27 days to become oriented to his or her new unit; a newly hired Affiliate Provider without the residency training typically requires 6 to 10 months of orientation. Thus, the residency program serves, in part, as a structured orientation that prepares the resident for the job requirements of an Emory ICU.

3.3.3 Targets

This innovation targets Affiliate Providers who have recently graduated from NP and PA programs and those who, after some years in practice, wish to augment their critical care skills and transition to working in intensive care.

3.3.4 Workforce Development

In order to successfully implement the Affiliate Provider residency training program, Emory needed "buy-in" from other clinical staff, to ensure that residents would be fully integrated on care teams and receive mentoring and training. Although there were already NPs and PAs working in ICUs at Emory, and some had received specific critical care training elsewhere, the residency program at Emory is new. Obtaining buy-in involved educating ICU physicians and nurses about the purpose of the residency program, the role of mentors, the scope of practice of NP and PA residents, and the value to the entire team of expanding the number of Affiliate Providers working in the ICUs. We observed that the role and title of Affiliate Provider is universally used and embedded in the culture of Emory ICUs.

The role of mentors is essential for the residency program and one Affiliate Provider with more than five years of experience advised that being a mentor increases his workload considerably. Although a new resident is caring for patients, the mentor needs to double check everything done for patients, provide

feedback, and actively train the resident. Workforce development, therefore, can place additional demands on the strained personnel resources of an ICU, as well as augmenting them.

Staff Engagement

When the residency training program was first developed, the Educators worked with attending physicians in the different ICUs to establish clinical rotations. The Educators had been at Emory for many years and had pre-existing relationships with many of the attending physicians, which enabled them to more easily engage physicians and find mentors for residents. To set expectations and maintain engagement, the Educators communicate regularly with attending physicians to review progress of residents and remind physicians about how best to incorporate residents into the ICU care team.

A challenge for the ICU teams was learning how to incorporate Affiliate Provider residents into the existing workflow on each shift. Over time, attending physicians have come to appreciate the value of having a well-trained Affiliate Provider on the team, especially at night and on weekends. There are many procedures that the Affiliate Provider can perform that do not require the presence of the attending physician, enabling physicians to achieve improved work-life balance, with the confidence that a provider trained in critical care can handle the situation and knows when to call. There is thus substantial gain for physicians in learning to incorporate NPs and PAs on the care team, and those we interviewed expressed reasonable acceptance of the training burden required to prepare residents for this role. ICU nurses told us that they have more support when an Affiliate Provider is present, and are accepting of the role of Affiliate Providers, including the effort required to train residents to fulfill this role. The patient-to-nurse ratio in the ICU is often too high for comfort (due to a long-standing regional shortage of ICU nurses) and Affiliate Providers can perform procedures, make timely decisions, and decide when it is truly necessary to call an attending physician. One nurse mentioned how receptive the residency program staff has been to her feedback. She suggested that new Affiliate Provider residents should begin training during the daytime at first, so they are more prepared for night shifts when there aren't as many physicians or Affiliate Providers on the units.

Communication

The residency program stresses communication throughout the rotations and mentors work with residents to help them learn how to communicate with patients and families in the stressful ICU environment. End-of-life issues are especially challenging and it is important that residents learn the necessary communication skills that will elicit patient wishes and preferences, and ensure that families are in agreement about end-of-life care. One Affiliate Provider who had just completed a communications course suggested that the residency training program add more comprehensive communication components to the curriculum and simulation lab exercises. She noted that "communication impacts how you take care of your team, patients, and patient families."

Satisfaction

The Affiliate Provider residents we interviewed reported that the program helped them improve their skills and expand their knowledge, and facilitated their integration on ICU care teams. They also reported that the Educators accept feedback and make changes to enhance the residents' experience.

One Affiliate Provider resident referred to the program leadership as a "home run" while another resident commented that the Educators are very accessible and available to discuss any issues. The program is small enough that the residents feel they can have lengthy discussions about different perspectives in critical care with the Educators. The Affiliate Provider residents described the program's receptiveness

to feedback as one of the aspects they appreciate most. They feel that they are contributing to the growth and development of the program as it matures. This engagement is deliberate on the part of program leadership, as they fully expect some of the program graduates to eventually become educators at Emory, or in similar programs in other parts of the country.

By enhancing Affiliate Providers' clinical skills and giving them more didactic and practical experiences, the residency program has not only made Affiliate Provider residents more confident and capable, but also more marketable in their career as an NP or PA.

> "The [residency program] leadership is very responsive and they will allow you to be part of the change—this is our program, and not their program that we're [just] participating in."
>
> *– Affiliate Provider resident, May 2014*

3.3.5 Staffing

A portion of the HCIA funds was used to support staffing of the Affiliate Provider residency program, and to support residents while they are in training.

Program Staff

A portion of the salaries for the two Educators is supported by HCIA funding, and will need to be replaced with other funding sources when the Award concludes.

Affiliate Provider Residents

Some Affiliate Provider residents become full-time employees of Emory after completing the residency program while others who are sent to the program by their "home institution" community hospital (elsewhere in Georgia), are paid by their home institution. In the latter arrangement, Emory pays a stipend to the home institution hospital that is intended to contribute to the resident's salary while the resident is away at Emory for training. This stipend is made possible by the HCIA and will not be offered in the future, should community hospitals wish to send their staff to the training program.

Engaging physicians in outlying hospitals may pose a different challenge because they do not work with Affiliate Providers on a regular basis, as members of the Emory ICU care team have learned to do. One Affiliate Provider mentioned that it would be good to educate physicians in rural areas to let them know what a residency-trained Affiliate Provider can bring to the team, and address concerns physicians may have about how an Affiliate Provider's scope of practice differs from that of a physician or a nurse. A rural hospital team familiar with the physician-nurse team model may also need assistance in recasting team member responsibilities to make best use of critical care Affiliate Providers.

Currently, neither of Emory's community hospital partners have Affiliate Providers in their ICUs. EGRMC used to have an Affiliate Provider who graduated from Emory's Affiliate Provider residency program, but she has since moved away. All of the ICU nurses at that rural hospital interviewed recognized the value that Affiliate Provider brings and expressed their desire to hire an Affiliate Provider to replace the one who has left.

3.3.6 Sustainability

The residency Program Staff noted that they plan to continue this residency training program and have the support of Emory University Hospital leadership. One potential mechanism for sustaining the program staff positions, and sharing this residency training model with others around the country, may be to package the program's business model, best practices, application materials, exam topics, evaluation tools, and other elements of the program and offer it—at a price—to other academic health systems

interested in starting their own residency programs for Affiliate Providers. Emory has received many inquiries from other health systems, and anticipates that there may be a market for this package of materials and consultation with the Educators from Emory's program. In 2013, Emory held a conference of interested leaders from other training programs (75 attendees), and held a second conference in September 2014 (65 attendees) to share their curriculum, experiences, and lessons learned that may be transferable to others undertaking similar residency programs. Despite the slightly lower number of attendees in 2014, conference attendees comprised leaders from other health systems such as directors of a hospital system, chief medical officers, and other business-oriented professionals and executives at medical centers wishing to implement a training program similar to Emory's program. The Office of Medical Education at Emory has also expressed interest in the training program and the Educators are currently discussing potential collaborations with the Emory School of Medicine to enhance the program. Ideally, the Educators want to provide these tools and expertise to other institutions for free as Emory is an academic institution that values sharing and dissemination of information. But they also recognize the need to generate revenue to support the training program.

Given the high level of interest in and need for critical care trained Affiliate Providers, the Principal Investigator explained that graduates of Emory's Affiliate Provider residency program are actively recruited by other health care systems. While Emory University Hospital leadership is supportive of the training program, its investment in resident trainees needs to be protected through some mechanism. To offset the costs of training for Affiliate Providers who choose to work elsewhere, Program Staff added a clause to new contracts for the 6-month residency program that requires graduates to pay Emory $25,000 if they leave the Emory system immediately after graduation. The residency program Educators acknowledged that Affiliate Provider residents in the 1-year program may eventually leave Emory to start their own programs in other locations, but hope that most will continue to grow their clinical and leadership skills at Emory for a few years, after which they may be prepared to start similar programs elsewhere.

3.4 eICU Program

3.4.1 Goals of the Program

For Hospitals

The goals of the eICU program for hospitals are to improve quality of care, alleviate staffing shortages in critical care, and provide critical care expertise, without a dramatic increase in cost. The eICU addresses the shortage of intensivist physicians by enabling one physician to cover several ICUs during the night shift. It also provides critical care expertise to hospitals that do not have intensivist physicians, especially on the night shift. A secondary goal is to improve work-life balance for intensivist attending physicians and reduce burnout, by reducing the number of calls they must answer at night.

The eICU began by supporting several Emory ICUs at night and then added coverage on weekends and holidays. In mid-2014, the eICU extended ICU coverage to two community hospitals, East Georgia Regional Medical Center (EGRMC) and Emory Johns Creek Hospital (EJCH). The "Hub" for the eICU is at Emory St. Joseph's Hospital, and is staffed by Emory Healthcare nurses and Emory intensivist physicians.

The EGRMC's ICU is always at or above 90 to 95% capacity and has no intensivist physician at night; at night and on weekends there is only one physician in the hospital (in the emergency department). At EJCH, the ICU is usually at capacity, and although there is a hospitalist working at night, there is no one

with critical care training in the hospital at night and on weekends. Neither hospital has residency-trained critical care Affiliate Providers.

For ICU Physicians and Nurses

The traditional critical care model requires an attending physician to be on call 24 hours a day and often one physician has this responsibility for more than a week at a time. The burden and diminished work-life balance make this specialty particularly unattractive for new physicians, further adding to the national shortage. Hospital leadership, program staff, and bedside staff all reported difficulty in hiring qualified critical care specialists, especially in community hospitals. The eICU program brings critical care specialist oversight from Emory to outlying facilities. This oversight can help address the shortage of resources and expertise available to ICU staff.

Emory's eICU program meets two specific needs: 1) spread or deploy critical care clinicians over a larger number of units/patients and 2) expand critical care coverage without greatly increasing costs. The eICU model addresses these issues by having an eICU physician cover several ICUs at night, relieving burden on intensivist physicians. Several physicians have agreed to work in the eICU a few night shifts each month—covering several ICUs rather than a single ICU they would otherwise be responsible for at night—spreading the scarce intensivist physician resource without greatly increasing costs.

In addition to an intensivist physician in the eICU at night, the eICU is staffed day and night by experienced critical care nurses. Automated best practice guidelines and trend monitoring, not otherwise available in Emory's EMR, alert eICU nurses if a patient's vital sign trends are becoming worrisome. This automated monitoring is intended to focus clinician's attention on critical decision-making, rather than struggling to assemble data about a patient's progress. eICU nurses can contact ICU bedside nurses about trends, or refer bedside staff to the eICU physician to address emerging patient needs. eICU nurses are also available to watch one patient while a bedside nurse is occupied with another, acting as an "extra set of eyes" during especially busy times. Finally, ICU nurses in outlying hospitals where there is no Affiliate Provider at the bedside to communicate directly with the eICU physician have educational opportunities to gain more critical care knowledge from eICU physicians.

For Patients

> "The eICU is a smart, ahead-of-its-time technology that will fit into where things are going in the future. It's great to have someone in the room virtually that can attend to the needs of the patient."
>
> *– PA Affiliate Provider, May 2014*

In addition to making better use of scarce intensitivst resources at Emory, the eICU has the potential to improve the quality and timeliness of patient care. With the eICU in place, Affiliate Providers and nurses no longer must decide between waking an exhausted attending physician or delaying care until the morning; they can consult with the eICU physician to get orders written, change medications, and decide when calling an attending physician is unavoidable. ICU bedside staff no longer has to wait for an attending physician to return their calls, because the eICU physician is available (and awake) all night. The potential improvement in patient care includes more rapid recognition of and attention to declining health status, the ability to continue necessary care at night (e.g., extubation to reduce ventilator/sedation time), and reassurance to patients and families that an intensivist eICU physician is always immediately available. Several bedside nurses we interviewed mentioned the value of having a physician at night who can communicate with the family, especially if the family members were unable to meet with the attending physician during the day or if the family is struggling to accept their loved one's deteriorating health status.

For outlying hospitals, the eICU physician can help to determine whether a critical care or emergency/ trauma patient must be transported to a tertiary care facility, or can be safely cared for at the community hospital. Since the cost—to both patients and payers—of transports and longer stays are high, avoiding transports and decreasing length of stay through more timely care has the potential to reduce costs and increase patient and caregiver satisfaction. An Affiliate Provider who completed the residency program and worked at EGRMC for a few months before relocating explained that there were often inappropriate admissions to critical care from the emergency department (ED), because a physician wanted to watch the patient overnight. The eICU can help triage these patients and decide whether admission to the ICU is appropriate or observe the patient in the ED or on the medical/surgical floor (using a mobile eICU cart). There is thus potential that the eICU can avert some unnecessary ICU admissions through augmented monitoring in the ED.

ICU nurses from outlying hospitals reported experiencing fewer code situations after the eICU support began, and noticed that patients were intubated sooner than they would have been in the past. Expedient intubations and other timely care may help to avert cardiac arrest and " code" situations.

3.4.2 Innovation Components

Background

In 2007, the former Chief Medical Officer at ESJH had seen an eICU being tested elsewhere and wanted to invest in the technology to address the shortage of intensivist physicians, and potentially offer eICU services to other hospitals to generate revenue. A predecessor eICU program was established at ESJH in 2007 and operated for two years, but was discontinued in 2009 due to economic constraints. The predecessor eICU at ESJH was seen as an "add-on" and not a transformation of critical care. The equipment remained in place for the eICU and in some patient rooms, but the program was small during its two years of operation and never included other "remote" ICUs outside ESJH. The older equipment in patient rooms at ESJH has since been replaced by current equipment that includes two-way cameras.

Emory's eICU is not characterized as an "add-on," and is expected to transform the traditional critical care delivery model. The eICU began its operation at ESJH, EUHM, and Emory by May 2014. 118 beds in total have been wired for eICU monitoring; the average daily census of monitored beds is between 80-100 patients. Each eICU nurse monitors 30-45 patients at a time and one eICU physician covers the entire array of 118 beds in multiple hospitals and ICUs. Originally, there were two nurses in the eICU, but two more have been added; the eICU Director has added 4.2 full-time equivalent positions in the eICU since May 2014 and is still looking to fill a few more openings.

All of the hospitals supported by the eICU, with the exception of the rural EGRMC, are part of the Emory system and share the same EMR. This uniformity supported the concentrated implementation schedule of bringing several hospitals "live" in the same month. Because these hospitals implemented the eICU program at the same time, there was an "across the board change" that everyone was aware of, and the education and messaging was uniform in both the eICU "hub" and the "remote" ICUs. That broad awareness allowed information technology (IT) staff to engage quickly and work through minor challenges that arose in more than one site. In addition, many of the initial ICUs were surgical units and their patients have somewhat similar needs, which reduced the range of issues to be addressed by eICU staff.

With the addition of two community hospitals, East Georgia Regional Medical Center (EGRMC) and Emory Johns Creek Hospital (EJCH) in August and November of 2014, respectively, the array of

patient issues broadened. Although EGRMC and EJCH have only added 12 and 14 monitored ICU beds respectively, they require a larger proportion of the eICU physician's attention due to resource constraints at the bedside. EGRMC and EJCH have fewer resources available in general, and especially at night and on weekends.

Since neither has extensive subspecialty care, most ICU patients are less seriously ill than patients at Emory. However, there are currently no Affiliate Providers in these two community hospitals to handle lower level issues that do not necessarily require a physician's attention. Every patient ICU admission work-up, medication order, and minor procedure requires a physician at these hospitals, and the eICU is now meeting as many of these needs as much as possible at night and on weekends. In the past, addressing patient needs occurring night and weekend would have been delayed until morning, or local physicians would have been telephoned for orders or called back to the hospital. The eICU physicians report that they spend a great deal of time addressing low-acuity issues at these two community hospitals, leaving less time and attention for higher-level consults at other ICUs. As the eICU program expands to partner with more community hospitals, it will need to accommodate an increasing number of low-acuity needs and consider resource constraints at its partner hospitals. The addition of EGRMC and EJCH demonstrates the importance of resource constraints "on the ground" and how this impacts communication and expectations between the eICU and ICUs, as discussed below.

Resources

When the eICU program supported three large urban medical centers within the Emory system, the availability of resources at the bedside to deliver care, though sparser at night than during the day, were fairly robust. Critical care attending physicians, fellows, Affiliate Providers, and extensive ancillary services (e.g., lab, pharmacy) and sophisticated health information technology are available in all three medical centers.

The number and type of clinicians and ancillary services available at EGRMC and EJCH differ substantially from those available at the three medical centers. EGRMC has a critical care physician in the hospital on weekday shifts on site during the day and a hospitalist at night, but no longer has an Affiliate Provider in the ICU on day or night shifts. EJCH does not have a full-time critical care physician on site and has one hospitalist and an emergency medicine physician in addition to the bedside nurses, and no Affiliate Providers. The physicians at EJCH do not round on the ICU at night.

Without an Affiliate Provider at the bedside, the eICU physician spends a disproportionate amount of time handling lower-acuity issues and must adapt to the limited resources available at night (e.g., no pharmacy or laboratory services, no operating room or surgeon). EGRMC bedside nurses described their hospital as a "9 to 5, Monday through Friday operation" where the pharmacy closes at 7pm on weekdays and 4pm on weekends; the radiology unit has a "skeleton" crew at night; and there is no in-house operating room. Orders that nurses can handle quickly at a major medical center, take much longer to complete at a smaller community hospital, if they can be accomplished at all.

Emory, EUHM, ESJH, and EJCH are all within the Emory system and use the same EMR. EGRMC only has EMR in its labor and delivery unit, and emergency room; the EMR in those two units are not integrated and cannot relay information to each other. The absence of an EMR at EGRMC makes it very challenging for the eICU physician to get good background information about patients. One eICU physician described asking the EGRMC bedside nurses to prop up a paper patient chart in from of the camera, so that she could read the attending physician's notes and orders.

These resource limitations cause a number of issues around communication and expectations between the eICU and ICUs and have been a source of frustration for both clinicians at the bedside and eICU physicians. Expectations about what must be addressed immediately and what can wait until the morning differ in the two settings due to differences in local resources.

Technology

The eICU is physically located in the clinical operations room (COR) in the doctors' office building on the ESJH campus. Initially, there were two nurses in the COR on every shift, and an intensivist physician at night; the COR now has four nurses on every shift and an intensivist physician at night as well as on weekends and holidays. Each eICU clinician has several computer monitors that display real-time data on patients from three sources: the EMR or patient record (except from EGRMC); the live vital sign telemetry data (echoing the bedside physiologic monitors); and the eICU software trend analysis (a vendor product). To assemble data and support interactive consultation, the eICU has several technology components, described below.

EMR Data

The EMR documents patient data and vital signs as they are entered by bedside clinicians. Emory's EMR also has a trend analysis function, but it is viewed by clinicians as inferior to the trend analysis software they use in the eICU because it is based on data entered by clinicians, while the eICU trend analysis is based on near real-time automated waveform and vital sign data. The eICU software requires mapping of interfaces to each hospital's EMR, laboratory and pharmacy systems, as well as the bedside vital signs data. Although building these interfaces requires IT time and resources, the eICU software is agnostic to the different EMR vendor products. EUH, EUHM, ESJH, and EJCH all use the same EMR. EGRMC does not have an enterprise EMR but they do employ a "Monitor Technician," who monitors vital signs displayed on each ICU patient's monitor. The lack of electronic information from EGRMC means that the eICU physician has only the remote vital sign data and must rely on bedside nurses to add background, context, and other information that would otherwise be available directly from the EMR.

For each location, the eICU software pulls select patient data from the EMR, including: vital signs, laboratory results, ADTs (admission, discharge, transfer information), medications, and flowsheet elements. Order entry for patients being monitored by the eICU is performed in the facility's EMR, Computerized Provider Order Entry (CPOE) system.

Trend Analysis Software

The eICU trend software is compatible with most EMRs and is designed for "surveillance" to capture vital signs automatically and continuously via telemetry. eICU Physicians and nurses view this constant near real-time data as superior to vital signs entered sporadically in the EMR by bedside clinicians. The trend software contains best practice protocols and alerts, and also generates an Acute Physiology and Chronic Health Evaluation (APACHE) risk stratification score for each ICU patient. The APACHE score cannot be transferred when a patient moves from one unit to another, and is recalculated when patients are moved from one unit to another within a hospital.

Both sources of data—EMR and real-time telemetry—are important in constructing a full picture of the patient's status. The eICU staff have access to both sources of data. Bedside ICU staff lack the trend data and accompanying best practice guideline alerts, except in one ICU at EUHM where technology has been added to display the same information the eICU nurses see on their monitors.

Both EJCH and EGRMC have long employed Monitor Technicians to watch ICU patient's monitors and observe trends; a function replicated by the eICU nurses and telemetry trend software. The bedside nurses at EGRMC offered that the trend analysis from the eICU may be unnecessary because their Monitor Technician alerts them to the same changes in trends. The nurses occasionally get frustrated because they feel that they have to respond to both the eICU nurses and the Monitor Technicians about the same patient vital sign trends.

The telemetry that the eICU receives from EGRMC does not always refresh automatically. An eICU physician reported that he frequently has to refresh and repopulate the telemetry, which could cause a delay in noticing changes and takes up valuable time that could be spent solving medical issues. While eICU nurses all find the trend analysis software to be useful, they noted that the software could be improved as some of the alerts are caused by normal movements of patients in their beds in absence of clinical problems. Better algorithms that reduce false alarms would enhance the experience of eICU nurses and allow them to focus on alerts that actually require their attention.

Two-way Cameras with Audio and Visual Capabilities

When the eICU first came online, the cameras installed in patient rooms at ESJH did not have two-way capabilities, as they had been repurposed from the predecessor 2007 eICU. The cameras at ESJH have since been upgraded to two-way cameras, and now all monitored ICUs possess the two-way functionality. In general, interviewees expressed preference for the two-way capabilities, which allow a more human interaction between eICU and ICU staff and avoid any disquiet regarding a disembodied "big brother" watching bedside staff at work.

There are also microphones and "doorbells" that announce when the eICU camera is on in a patient's room, so that bedside staff, patients and family members are all aware when they are being observed by eICU staff. After having used the cameras and microphones for almost a year, one eICU physician mentioned that he has some difficulty hearing everyone at the bedside and distinguishing who is speaking, particularly during hectic moments such as a cardiac arrest episode. It is challenging to run a code from the eICU if the eICU physician cannot distinguish the different voices of nurses and Affiliate Providers at the bedside. The microphones are installed on the wall above the patient's head, away from where conversations between clinicians and patient are taking place, which further impedes the eICU physician's ability to hear their voices. One eICU physician also finds that cameras' autofocus and immobility are problematic. Sometimes an object in the patient room can partially block the camera's view. Rather than having to call a nurse or Affiliate Provider at the bedside to remove the obstruction, the eICU physician would prefer being able to move and pivot the camera himself. Finally, the camera's autofocus sometimes adjusts inappropriately in rooms with less light, which requires the eICU physician to spend time trying to fix the focus. While these issues with technology are not major, they are an nuisance that makes the eICU physician's job more difficult.

Internet Connectivity

Internet connectivity and internet service provider capabilities and contracts were perhaps the least anticipated set of implementation challenges faced by Emory's IT staff. The Program Staff did not have a thorough assessment of all the connectivity requirements at EGRMC in particular, or the skills of IT staff at that rural hospital, prior to implementation. Because all connected devices (cameras, monitors, telemetry equipment) related to the eICU require public IP addressing, EGRMC exhausted its public IP address pool. In addition, EGRMC's frontier telecom provider could not connect directly to Emory, and connections had to be established first to AT&T and then to Emory. At each connection, there have been

challenges for data transmission. Working within the constraints of existing internet technology at EGRMC slowed implementation and required some unanticipated workarounds.

The vendor that provides eICU technology and software will not guarantee that its video quality meet expectations unless T1 lines are used to stream high definition real-time video. The T1 line is only needed for high resolution video, and all other data connections work well without this dedicated and costly land line. The cost of running a T1 line to EGRMC is prohibitive and Emory decided to use a VPN for streaming interactive video with remote sites. Emory has absolved the eICU vendor of its guarantee for video quality, because a T1 line is not in place. Within hospitals, there are also data transmission issues. ICU beds and their audiovisual systems are usually hardwired. Remote services to other beds can be provided using portable "carts" (see below). Operation of the mobile carts can be wireless provided there is adequate wireless infrastructure in the hospital, and nothing to block the wireless signals. At EUH, an older hospital, wireless access points are insufficient to handle the traffic, which was particularly problematic for mobile telemetry carts in the ED, and it was simpler to install data jacks at patient beds for the eICU video and telemetry transmission, rather than dealing with wireless technology.

Portable Unit or "Cart" (for EDs)

There are a few portable units or "carts" in the ED and on the floor at ESJH, depending on where the carts are needed. The eICU can monitor, for example, a cardio-thoracic patient who is not in the ICU, but may require extra care and monitoring. While the mobile carts are available for use on the floor at ESJH, they have not been utilized as much as was expected. Moreover, the mobile carts have not been deployed in the ED because of technical issues around both hardware and software.

There is also a portable unit or "cart" with a camera installed at EGRMC to monitor patients who seem to be decompensating in the ED or elsewhere in the hospital. However, this portable unit is still not operational due to network connectivity issues. The mobile unit is intended to allow the eICU monitoring technology to be deployed quickly and provide support to ED physicians or hospitalists who are not trained in critical care.

Team Theater

There is a "team theater" installed in one of the ICUs at EUHM, in the center of the ICU (where a nursing station would otherwise be located). The team theater contains a number of monitors that display the same telemetry trend information that is shown in the eICU, allowing bedside ICU clinicians to view both EMR and trend data sources, just as the eICU clinicians are able to do. Emory envisions the "team theater" as a way for the team to conduct virtual rounds together, looking at the patient trends on the monitors rather than conducting rounds in the hallways outside patient rooms. Bedside nurses participate when the team "cameras in" to a patient room during rounds. The team conducts rounds twice a day in this ICU, once in the morning and again in the late afternoon. When the team theater was first installed, a physician led morning rounds in that team theater, rather than at patient bedsides. However, nurses felt that rounds conducted in this manner were not as educational and informative for bedside staff, and the team reverted back to conducting rounds in a more traditional way, moving from one patient room to the next. In the afternoons, nurses lead in-person rounds. Other ICUs at Emory do not have a team theater and there is no plan to install such theaters; the one team theater is viewed as a "test bed." Bedside staff in other ICUs have only EMR data available and rely on the eICU for trend data.

eICU – Day Shift

The eICU is staffed by nurses during the day shift, who monitor patient telemetry trends and notify bedside nurses if they notice changes that suggest a patient is decompensating. Before starting their shift, the eICU nurses discuss the number and acuity of patients they are monitoring in each remote ICU. The eICU nurses then divide up monitoring responsibilities based on the number and acuity of the patients; sometimes one nurse will monitor two or three ICUs while another watches over just one large ICU. These coverage responsibilities vary from shift to shift as they are based on the patient census.

The eICU nurses can also "camera in" to a patient's room: they activate a doorbell sound, announcing the eICU nurse's request to "enter" the room, and the two-way camera/monitor/audio allows the eICU staff to interact with persons in the patient's room, including staff, visitors, family, and patients. During the day, ICU staffing at the Emory University Hospitals is generally adequate, and includes an intensivist physician, attending physicians and surgeons, Affiliate Providers, bedside nurses, and medical residents and fellows (and in many ICUs, resident Affiliate Providers-in-training). As a result, nurses in well-staffed ICUs rely less on the eICU for support during the day.

During our first visit in 2014, when the eICU had only been operational for a few days, bedside nurses expected to rely on the eICU very little during day shifts, due to this abundance of bedside staff. In follow up interviews almost a year later, the bedside ICU nurses mentioned that while it is helpful to have "an extra set of eyes" on their patient when they are occupied with another patient or have to leave the ICU for some reason, they are typically with their patient and already addressing an issue by the time the eICU alerts them of changes in trends. The bedside ICU nurses at major medical centers did not see a great deal of value in the eICU nurses and monitoring during the daytime. The bedside ICU nurses in the smaller community hospitals with fewer resources echoed this sentiment, even though their resources are not as robust; Monitor Technicians alert them to the same things the eICU nurses notice in their telemetry trend analysis. None of the bedside ICU nurses seemed overly frustrated by the eICU alerts and calls, but they noted that the value might be greater at night and on holidays, when there are fewer physicians present in the ICUs.

eICU – Night Shift

At night, the eICU is staffed by four nurses and one physician intensivist; several Emory critical care physicians rotate the responsibility of covering these night shifts rather than one being designated as the permanent eICU physician. The eICU has the same technological capabilities at night as it does during the day, but has an additional intensivist physician present. Emory University Hospital ICUs each generally have at least one Affiliate Provider working the night shift, who can perform routine procedures and write orders in consultation with the eICU physician. In the community hospitals (EGRMC, EJCH), however, there are no Affiliate Providers. At EGRMC there is one ED physician at night, and at EJCH there is one ED physician and one hospitalist, covering the entire hospital. Because ICUs have fewer staff at night, support from the eICU physician is especially valued.

The eICU physician working at night reviews patient vital sign trends, consults with Affiliate Providers and nurses at the bedside, and can help guide procedures virtually, even running cardiac arrest codes from afar. The eICU physician may also help bedside staff decide when it is essential to call (wake up) an attending physician, and when patient needs can be met without the physical presence of a physician. One Affiliate Provider noted that in the middle of the night, patients do not usually require specialty services that only a physician can deliver. The combination of a critical care Affiliate Provider and oversight from an eICU physician is adequate to meet most patient needs at night. Reduced ICU staffing

at night also spreads each bedside nurse across more patients, and often the newest nurses are assigned to the night shift. The eICU may therefore have more opportunity to fill a staffing gap at night than during the day, and may offer important education and support to newer bedside nurses.

The eICU seemed to be more actively engaged in the care management of patients at night and on weekends for the two participating community hospitals. Night bedside ICU nurses at EGRMC routinely interacted with the eICU physician who is able to write orders, suggested immediate interventions, and telephoned attending physicians when necessary to discuss patient status changes. The bedside nurses at EGRMC described receiving more detailed orders from the eICU physician than they otherwise would from an attending physician over the phone because the eICU physician can actually see the patient. Because there are no Affiliate Providers at EGRMC, the eICU physicians are sometimes frustrated that procedures, such as inserting a central line, may be delayed until the morning because no local physician is available to return to the hospital at night.

3.4.3 Workforce Development

Staff Engagement

Physicians

The Program Staff made an effort to educate community physicians about the eICU, to gain acceptance and ease concerns about quality of care provided by remote colleagues. While most attending physicians at Emory and EUHM are aware of the program and generally accepting of it, some voiced concern that there would be "too many cooks in the kitchen" with the addition of the eICU physician. During our first visit in 2014, attending physicians seemed to understand the purpose of the eICU, but some did not want bedside staff to rely on the eICU at night. One ICU attending physician mentioned that he wanted to know what was going on with his patients; he instructed the Affiliate Providers to call him at night if specific things happen and does not mind being awakened. One Affiliate Provider noted that cardiac surgeons and neurosurgeons tend to be very particular about the care of their patients, and may not welcome opinions from an eICU critical care physician who is unfamiliar with their patients.

A physician we interviewed in May 2014 offered that surgeons "don't really accept the idea of the eICU yet." Another ICU physician noted that surgeons are "apprehensive about this whole thing [the eICU] even if they're open-minded. They're very concerned that it will increase the variability of care." Program staff chose to begin the eICU implementation in a cardiothoracic (C-T) surgery ICU because C-T surgeons have historically been resistant to interference in their care decisions. The reasoning was that if the C-T surgeons could be persuaded to accept the eICU, other attending physicians might do so as well. Follow-up interviews with surgeons indicated that they found the eICU program to be a largely positive adjunct to the care they provide. The eICU has been able to anticipate and avoid a patient cardiac arrest, and the critical care perspective has been beneficial in other instances. One C-T surgeon recalled a situation where the eICU recognized a dysrhythmia that might otherwise have gone unnoticed, called the surgeon, and the surgeon took the patient back for emergency surgery that night to repair an otherwise unidentified life-threatening problem. Having experienced the value of the eICU, he "would not do without the eICU anymore."

> "It gives us eyes and ears and analytical capabilities that a single doctor on the ground could never achieve."
>
> *– ICU physician, Feb. 2015*

In comparing attitudes in 2014 with those a year later, we observed that as physicians grew accustomed to the eICU, they became more accepting of it. One critical care physician offered that she gets more sleep at night when her colleagues are covering in the eICU, and she believes the quality of care patients receive is better, especially at night. A physician at EJCH mentioned that he likes getting input from the eICU physician because the eICU physician provides a critical care perspective and serves as another person to "bounce ideas off of."

Before the eICU was implemented at EGRMC, Program Staff visited to help allay any concerns that physicians had about the eICU technology. In addition, an Affiliate Provider (a graduate of the residency program) who worked for some time at EGRMC, helped to market the eICU program within that hospital. She conducted presentations and led workflow workshops to engage staff in the hospital before implementation began. Despite this introduction, some physicians in the smaller community hospitals prefer that bedside nurses bypass the eICU physician at night and continue the established practice of calling (waking) the local physician. Specialists in particular, at both EGRMC and EJCH, may be less accepting of the eICU than are their colleagues, and we heard several descriptions of situations where a local neurologist, nephrologist or cardiologist was unaccepting of eICU involvement in their patient's care.

The critical care physicians working in the eICU, who also work regular shifts in the Emory ICUs, discussed added responsibility of working in the eICU. One eICU physician expressed feeling greater burn-out from working eICU shifts because it is difficult to establish a regular routine when he works four consecutive night shifts in the eICU each month, and also covers two other weekend day shifts in the ICU, leaving only one weekend a month he is entirely off from work. This eICU physician also described the challenge of trying to interact with so many different ICU teams and local attending physicians remotely, many of whom he has not met in person. Trying to be aware of the bedside nursing talent and training, other available resources in each remote hospital, attitudes among attending physicians, and technology challenges, is difficult when providing eICU coverage for so many different ICUs.

Nurses

> "Nurses in general don't like people looking over their shoulders. And don't like change. But once [they] see the eICU it can help dispel fears, whether rational or not, and makes a huge difference."
>
> *– eICU nurse, May 2014*

During our first visit in 2014, less than one week after implementation, bedside nurses in Emory ICUs expressed some concern about being watched (remotely) while they work. To address this concern, Program Staff invited several bedside nurses to visit the eICU so they could see the data/trend displays the eICU nurses monitor that are not available to ICU nurses. One nurse we interviewed in 2015 who was initially apprehensive about the eICU, noted that she felt better after visiting the eICU and seeing the data that eICU nurses review; she was reassured that eICU nurses do not have cameras on in patient rooms continuously, but only on an as-needed basis. The nurses expressed that the opportunity to visit the eICU was important in gaining their acceptance, and should be offered to all bedside ICU staff as part of the eICU implementation.

At EGRMC, bedside nurses told us that they do not feel the eICU is a resource meant for them because they were not asked whether they wanted the eICU and were not offered an opportunity to meet any of the eICU staff or visit the eICU. They do not recall any efforts being made to gain buy-in from their EGRMC nursing staff or anyone asking for their feedback, although they noted that their manager recently met with the Principal Investigator to offer feedback. They also emphasized that during the first

months of eICU coverage, when they also had an Affiliate Provider in their ICU, the entire interaction was much smoother. The Affiliate Provider interacted directly with the eICU to take orders, perform simple procedures, and serve as liaison with the bedside nursing staff. The departure of this Affiliate Provider and inability to replace her, moved the bedside nurses into a more direct relationship with the eICU. They continue to struggle with interacting with several eICU physicians and have not entirely embraced the eICU concept. We observed none of these issues at EJCH, where there never was an Affiliate Provider and where bedside ICU staff are more accepting and appreciative of both the critical care perspective and the eICU assistance.

Training

Physicians

Physicians in the eICU had not received any formal training for their new role at the time of our first visit in 2014 (the first week of eICU coverage). One physician we interviewed noted that during the first two night shifts he worked in the eICU, he was not familiar with the layout of the eICU, did not know how to review trend data, and spent most of his time responding to new admissions. To familiarize himself with the trend analysis software, he clicked on everything on the various monitors to understand what each button did and which types of data were available. During his shifts in the eICU he monitored an ICU where he also works during daytime shifts as an attending physician. He advised that when on call at night, he would normally "monitor" his patients from home via phone; the Affiliate Providers at night would call him when necessary and he would direct them by phone. He feels the eICU adds more functionality because he can see more data and understand a fuller picture of patient progress than is possible over the phone.

A year later when we conducted follow-up interviews, Emory had put into place a training process to instruct and officially certify eICU physicians. The 26-hour competency-focused training includes an initial two hour orientation; 12 hours in an observer/advisor role, learning to navigate the eICU software and hardware; and 12 hours in an ePhysician role, completing electronic sign-in/sign-out tools and admission forms in collaboration with a previously qualified eICU physician. At the end of the training, the eICU medical director conducts a one-on-one evaluation with the physician, incorporating performance feedback from the eICU staff and bedside clinicians. As of February 2015, 18 physicians had been completed the training and are able to work in the eICU.

Nurses

Bedside ICU nurses at Emory, EUHM, and ESJH received emails and an educational module that explained the eICU, focusing especially on how to use the technology. The Program Director held staff meetings at each hospital and all ICU staff were invited to attend. Staff were also offered opportunities for simulator training and guidance for explaining the system to patients and families. It is not clear how many ICU staff took advantage of these educational opportunities, and given staff rotations and turnover, not all staff were exposed to these training opportunities. One nurse mentioned that she would have liked to see a simulation, a video, or an in-service training that explained how to talk to families about the program and how the nurses at the bedside can take advantage of the eICU. She was not familiar with how to make best use of the eICU and nursing-relevant Use Cases had not been explained to her. For example, she was unaware that she could call on the eICU nurses to "watch" one patient when she is occupied with another. She also expressed confusion about her role in interacting with the eICU. For example, she was not sure what to do if a monitor shows a dark screen or appears broken, and whether it is her responsibility to report technology problems. Finally, although a brochure is available

about the eICU, a nurse we interviewed in 2014 was unaware of it and was unsure how to explain the technology to patients and families.

In 2015, bedside ICU nurses at community hospitals did not appear to have attended any significant trainings. One nurse at EJCH noted that "a little more education about what [the eICU is] and [is] not able to do for [us] would be helpful" and another nurse stated that "the training should be more than a 15-minute presentation…initially, it can be very strange to have someone just come in on the screen." Finally, nurses would appreciate instruction on how to educate patients and families about the eICU. Each has found her own way of explaining the eICU to patients, and they feel most patients and families welcome the added oversight at night, but clearer training on interacting with patients and families would be welcome.

> "There is, in each location, a culture that depends utterly on the perspective, sensitivities, and understanding of what makes the unit unique and not everyone has it. It's why I focus on …bringing people around [for eICU positions]…that really represent the Emory branded perspective."
>
> *– Principal Investigator, Feb. 2015*

Communication

With the addition of the eICU, the need for more and better communication processes has arisen as there are more nurses and physicians involved, from many different ICUs, and relationships among participants continue to evolve. Several themes related to communication arose from our 2015 interviews and focus groups related to physicians with different specialties, peer to peer communication, the relationship between eICU staff and bedside staff, day shifts versus night shifts, and the need for clear communication protocols.

Communication challenges were magnified in community hospitals where resources tended to be constrained. Nurses at EGRMC noted the difference in expectations regarding what must be accomplished immediately at night, and what can wait until the morning. They perceived a disconnect between eICU physicians' sense of urgency and that of the local attending physicians who are awakened to return to the hospital. The eICU physicians we interviewed agreed that they are more likely to think a patient needs an immediate procedure or test, while their colleague in East Georgia might prefer to wait until morning. Despite these challenges related to communication and expectations, the bedside EGRMC nurses acknowledged that there have been several instances when the eICU physician was very helpful, from speaking with families when nurses were too busy managing situations to persuading a local attending physician to return to the hospital when necessary, convincing the ED physician to intubate a patient at night, and aiding the transfer of very sick patients to Emory. The EGRMC bedside nurses also agreed that more proactive patient management at night has resulted in fewer cardiac arrest code situations. There have also been important examples of local physicians and eICU physicians collaborating successfully on complex care plans. One nurse at EJCH reported an experience where the eICU physician and hospitalist collaborated in crafting a care plan for the patient. She remarked that "this is how it [the eICU program] is supposed to be."

Physicians with Different Specialties

Many of the ICUs at Emory, EUHM, and ESJH that are monitored by the eICU are surgical ICUs and follow a model of care in which physicians, surgeons and Affiliate Providers collaborate on each patient's care plan. The two community hospitals generally do not practice a multidisciplinary team approach and are not as familiar with the perspectives of critical care specialists. Since the eICU physicians are all part of the Emory critical care team, these community hospital staff are learning about working with a remote physician, and one whose specialty and training is not otherwise part of their usual care team.

We heard a particular concern about the critical care eICU physicians overseeing care for surgery patients. Bedside clinicians (nurses and Affiliate Providers) who work in surgical ICUs explained that surgeons usually just want to speak with one person—the ICU Affiliate Provider—when directing care. Asking the Affiliate Provider to first call the eICU, and then having the eICU physician call the surgeon, involves a "middle man" (the eICU physician) that many surgeons find unnecessary. Despite this initial hesitation, communication between the eICU and surgeons has not emerged as a major issue. When a patient requires a surgical intervention, the Affiliate Provider contacts the eICU and the eICU physician calls the surgical fellow. The surgical fellow decides whether to telephone the surgeon at night. Surgeons we interviewed noted that if no surgical intervention was required, the eICU physician would take the necessary actions for the patient, sometimes in consultation with the surgical fellow, and the surgeons were informed in the morning.

> "The intensivists in the eICU are probably as close to surgeons as they can be… Most of them are cardiac anesthesiologists and have spent so much time in the OR or ICU that they very well understand the cardiac surgical patients."
>
> *– Surgeon, Feb. 2015*

One element of concern raised by bedside staff in surgical ICUs is whether the eICU physician has experience with post-surgical protocols. In 2014, we interviewed a nurse in a surgical ICU who was alarmed when an eICU physician suggested putting a post-surgical patient on heparin, which is not part of the typical protocol in the first hours after surgery. She suggested that ICU staff should be informed about the specialty of the physician working the night shift in the eICU, and specifically whether that physician had surgical critical care experience. We interviewed surgeons in 2015, after they had a year of experience with the eICU, and most of those we interviewed seemed quite comfortable with the eICU physician's level of expertise and knowledge. Ten of the 18 eICU physicians have training in anesthesia or surgery, which reassures surgeons that the eICU physician is familiar with surgical issues. Still, one physician was dubious about the role of an eICU in overseeing a C-T patient's care, stating that "the C-T ICU is just too complicated. You have to be echo trained and C-T ICU trained—you can't just wing it overnight." And a neurosurgeon at one of the community hospitals also requested that the ICU nurses only call her at night and never the eICU physician.

Bedside ICU nurses and Affiliate Providers all agreed that they will defer to each surgeon's individual preferences regarding whether and when to involve the eICU. Observing these preferences for every surgeon may become challenging as the program grows, and may be confusing at first for newly hired nurses and Affiliate Providers. However, all of the nurses and Affiliate Providers we interviewed concurred that they all generally know the preferences of the attending physicians and surgeons with whom they work most closely. For example, a nephrologist at a community hospital strongly disagreed with the eICU physician over fluid volume management, and afterwards did not want the eICU involved in the care of her patients. As a result, bedside nurses at her hospital do not call the eICU about nephrology patient needs. When a surgeon or physician does not want the eICU involved in their patient's care, the bedside staff do not reach out to the eICU for assistance at night.

The eICU physician may also feel less comfortable overseeing care for an acute patient whose needs are in a specialty other than his/her own. One eICU physician mentioned that he would be concerned if he were looking after a medical ICU because his specialty is surgical critical care, and he would want the attending physician to brief him about each medical patient prior to the night shift.

Peer Communication

Typically, the eICU physician communicates with the bedside Affiliate Providers in those ICUs that have an Affiliate Provider, while eICU nurses communicate with bedside ICU nurses. However, one nurse mentioned that eICU physicians may interact with attending physicians and surgeons as well; surgeons are especially involved in their patients' care and some telephone the eICU at night to request updates about their patients.

Each attending physician specifies whether s/he wishes to be called by the eICU during the night and on weekends. Physicians who designate Level 1 want to be called for everything the eICU notices and does with their patients; physicians who choose Level 2 want to be contacted for big changes, emergent needs, or if the eICU physician thinks it is necessary; physicians who choose Level 3 prefer not to be called until after the eICU has intervened and are generally fine with resuming patient care in the morning. The eICU physician has each attending physician's communication preference readily available and generally follows the attending physician's preferences.

For the two community hospitals, the eICU physician communicates directly with the bedside ICU nurses at night as there are no Affiliate Providers. When an urgent procedure requires a physician, the eICU physician is responsible for contacting the appropriate physician to come in and perform the procedure. Asking a community physician to return to the hospital at night can be fraught with difficulty, from both perspectives. eICU physicians, accustomed to well-staffed and resourced ICUs, expect a fast response when placing orders and want interventions and procedures completed quickly at night and on weekends. Attending physicians at community hospitals, on the other hand, may sometimes feel that procedures can wait a few hours and be handled in the morning, without jeopardizing patient safety. Disagreements about patient care can also arise between attending physicians and critical care eICU physicians. An EGRMC bedside nurse reported seeing a situation where an attending physician returned to the hospital to provide care at night, and eventually left the ICU in frustration because the eICU physician remained on the monitors and stayed involved in the patient's care, making it difficult for the attending physician to assume primary responsibility for the patient. Despite these challenges, the local attending physicians we interviewed in the EGRMC and EJCH communities were very supportive of the eICU. One attending physician at EGRMC expressed appreciation for the eICU and especially the physician availability at night. He felt that patient care is now better at night and on weekends, the critical care perspective is valuable for patients, and he himself has learned a great deal from the different clinical approach an intensivist eICU physician may suggest. In addition, he is no longer awakened as much for minor issues and is well-rested when caring for patients during his day shifts. He offered that he "would not want to go back" to having no eICU.

Relationship between eICU and Bedside ICU Staff

The eICU staff and bedside staff were not all familiar with each other when we conducted our first visit in 2014. One of the Program Staff noted that the relationship with the bedside staff is so important that currently they only staff the eICU with physicians from the Emory System, because the ICU staff in the Emory system hospitals have more confidence in the training and expertise of their own physicians. In a 2015 follow-up interview, the Principal Investigator reiterated the importance of having Emory-branded intensivists in the eICU to ensure that clinicians in outlying hospitals feel confident in the skills and capabilities of the eICU physicians.

Bedside ICU nurses also want to be assured that the eICU physician has some familiarity with the patient population in their particular ICU. One nurse expressed concerns that she is not familiar with the

personalities of the nurses and physician in the eICU—she understands that they have experience, but she does not know their expectations or whether they are affiliated with the hospital, and whether they are allowed to write orders.

An eICU physician interviewed during the early stages of the eICU program remarked that as the program expands and he begins to monitor units at outlying hospitals, he will have to be extra careful about how he comes across to and approaches the surgeons there, as he does not know them or have any working relationship with them. How an eICU physician approaches ICU staff and provides support has become tremendously important with the addition of EGRMC and EJCH. The community hospitals have sparse resources at night and on weekends, which appears to be the primary disconnect between the eICU and the clinicians at these hospitals. The eICU physicians are accustomed to well-resourced hospitals that have clinicians available 24/7 to quickly execute orders, and people in pharmacy and radiology at night to further expedite care. Community hospitals do not have these resources readily available and often postpone less urgent care until morning.

> "Building trust with the units and physicians who do not know us [eICU physicians] is an ongoing issue."
>
> *– eICU Physician, Feb. 2015*

Communication between the eICU and bedside nurses at night can be more in-depth and frequent, but may also be more challenging. In 2015, bedside nurses at EGRMC reported feeling a lack of rapport with the eICU physicians and expressed that the eICU physicians do not always trust the nurses' abilities and judgment. They also noted the difference in expectations regarding what must be accomplished immediately at night, and what can wait until the morning. In addition, nurses also noted that interactions with the eICU were smoother when the Affiliate Provider was working at EGRMC, because she could carry out many of the overnight orders from the eICU physician, and that communication had been more problematic since her departure. Everyone we interviewed at EGRMC and in the eICU agreed that the interaction was better when there was a critical care Affiliate Provider in the EGRMC at night.

Bedside nurses and eICU nurses interact frequently, either when the eICU nurses call to point out a troubling change in patient status, or when the bedside nurses are busy in one room and ask the eICU to "keep an eye on" a patient in another room. Sometimes alerts by the eICU nurses raise a concern the bedside nurse had not yet perceived, which is a valued contribution. Often, however, the bedside nurses are aware of the patient status change and are already responding when the eICU calls; they must interrupt care to take the call, which they perceive as an unnecessary distraction.

Program Staff have been working carefully with eICU nurses to emphasize communication approaches that offer assistance in a helpful way that is less threatening and more likely to be accepted by bedside staff. A similar training may be useful for eICU physicians as the program expands to more community hospitals. In addition, having bedside nurses spend time in the eICU alleviated communication challenges, but a similar resolution has not been achieved for nurses who work at EGRMC and EJCH. In follow-up interviews, bedside ICU nurses at the Emory hospitals seemed more content with interactions with eICU nurses, while those at EGRMC in particular, who had not had an opportunity to meet the eICU nurses or visit the eICU, reported ongoing tension with the eICU nurses.

While expressing challenges related to communication and expectations, bedside nurses at EGRMC and EJCH provided examples of positive interactions with physicians. At EJCH, one bedside nurse commented that the eICU physician is very helpful and [always] explains all his orders to her, expanding her critical care knowledge in a way her local attending physicians do not. He has also spoken to patients

and family members who may have felt more comfortable speaking with a physician about end-of-life issues than with a nurse. The nurses also agree that it is nice to have the eICU contact (wake) the local attending physicians, so that they do not have to call the attending physician themselves.

Standardized Communication Protocols

As all of the communication issues above indicate, there is a need for clearer communication protocols so that both eICU and ICU staff understand when and how to communicate with each other. When the eICU program was first implemented, there was no standard communication protocol concerning whether to call the eICU or the attending physician/surgeon, leaving bedside staff to make these decisions. In our 2015 follow-up interviews, most ICU nurses and Affiliate Providers noted that they generally call the eICU first, unless they are explicitly instructed to do otherwise or they personally know that the attending physician prefers to be called. Even though there are still some instances where the clinicians at the bedside call the attending physician first, the default practice seems to be to call the eICU first.

To improve communication, Emory Program Staff have encouraged clearer "sign outs" whereby the attending physician or surgeon communicates all patients' care plans to the eICU physician, at the start of the night shift. They are instructed to discuss, in a "hand-off" report, which patients are of most concern and how they want each patient to be treated if specific problems arise overnight. Most of these "hand-offs" are relayed via e-mail, a process that, according to one critical care physician, is "less than ideal" given the already high volume of e-mails she receives. One Affiliate Provider noted that e-mailed "hand-offs" do not provide an easy way to ask questions and have a dialog about the patient. Another physician suggested that Emory build a hand-off tool into the EMR or establish a shared drive where physicians can view hand-off notes about patients, rather than exchanging emails. This is especially true as more ICUs are added to the program and the eICU physician is receiving emails from many ICUs at the start of each shift. Some eICU physicians call the attending physicians about specific patients that are particularly concerning. In general, the "sign outs" are brief and only sometimes include a care plan.

The greatest hand-off problem we observed is with EGRMC. The physicians at EGRMC do not utilize the "hand-off" report, despite being encouraged to do so by the CEO of their hospital. When the eICU first launched at EGRMC, there was an Affiliate Provider who worked in the ICU at night who would fill out the hand-off report, and EGRMC physicians were not involved in this task. EGRMC does not have an EMR for electronic charting, and the EGRMC physicians and bedside nurses explained that they do not have the time to complete "administrative" tasks at the end of each day.

3.4.4 Implementation

Overall, the implementation of the eICU progressed as expected, starting with Emory, EUHM, and ESJH coming online within a few weeks of each other, followed by EGRMC in August 2014 and EJCH in November 2014. The most frequently mentioned challenge with implementation involved technology—specifically the compatibility of systems, installation of equipment, and overall ability to engage the appropriate IT staff to carry out the tasks to meet the project schedule. It was very important for the Program Staff to work closely with IT, in bringing up each new remote ICU and ensure that patient rooms are ready for camera and other technology installation. Interfacing each hospital's pharmacy, laboratory and EMR into the eICU has been challenging, but issues were minimized because the first hospitals all use the same EMR. The effort to implement at EGRMC was more complex because it uses different technology and does not have EMR except for in the ED and Labor & Delivery units.

Program leadership decided that outlying or rural hospitals wishing to participate and receive eICU "coverage" would need to 1) have the capacity to send real-time monitoring and telemetry data to the eICU, and 2) pay for the necessary equipment on their end, in the ED and ICU. There was considerable enthusiasm from rural hospitals at the time the Emory HCIA proposal was written. However the unfavorable economic climate in Georgia and reductions in Medicare payments due to the temporary federal budget sequester, made it impossible for several local hospitals to cover the cost of technology and they were forced to withdraw from the eICU collaboration with Emory.

Staffing

To staff the eICU, positions were posted and critical care nurses who were previously at the bedside applied for positions working in the COR. Roughly half of the new positions were filled by Emory ICU nurses, and half were hired from outside the system. This created some vacancies in ICUs when bedside nurses transferred to eICU work. Emory is constantly looking for critical care nurses to fill these and other openings, and staff are acutely aware of the challenges in hiring skilled and experienced nurses.

As the eICU program expanded to cover more community hospitals, a need for an Affiliate Provider in the eICU has developed. Because community hospitals have so few resources at night and do not typically have Affiliate Providers, they require more attention to manage even lower-acuity issues. eICU physicians explained that much of their time at night was spent attending to minor issues at the two community hospitals that do not require physician attention and could be handled by an eICU critical care Affiliate Provider. The Principal Investigator is aware of these additional needs and plans to add Affiliate Providers to the eICU, as more remote hospitals join the program. The Principal Investigator estimates that approximately 3 FTE Affiliate Providers will be needed and these positions will be filled by six to eight individuals. He does not want to have an Affiliate Provider (or physician) working full time in the eICU, without any direct care delivery bedside role.

Administrative Complexity

The eICU involves many entities including the vendors who supply the software, IT staff and internet providers, as well as hospital partners that are part of the Emory health system, and other external affiliates. Often, work cannot go forward until a sequence of contracts is executed and this process has caused delays. Ambiguity surrounding different contracts has also made it difficult to project spending. For example, when IT staff tried to project spending on cameras for patient rooms, the vendor asked for a 50 percent upfront deposit, a 30 percent invoice, and a final 20 percent invoice. Because Emory had not yet executed contracts with all hospital partners, they did not know which entity would participate or how many cameras would be needed, and were forced to make their best estimate in an uncertain environment.

3.4.5 Sustainability

One ICU Director we interviewed believed the eICU program is potentially sustainable given the current model of care. There are many programs at Emory competing for finite resources and it will be important to make a persuasive business case for paying for the eICU technology and personnel. He noted that as reimbursement models shift from fee-for-service to value-based and bundled payments, Emory will have to figure out how to best reallocate scarce resources. In that anticipated context, the eICU program may become increasingly attractive, although this is uncertain. While several clinicians and Program Staff interviewed supported the continuation of the eICU program, they were aware that the program relies on financial resources from the Award and will likely need additional money from grants to continue supporting the program.

There are many outlying hospitals that are interested in partnering with Emory's eICU program. The participation of more hospitals may help sustain the eICU, but revenue earned from those hospitals will be offset by the hiring of additional eICU staff, such as an Affiliate Provider, required to provide coverage to additional hospitals.

As explained by the Principal Investigator, on-site Affiliate Providers can reasonably charge insurers when they provide critical care services, and are compensated, on average, 85% of what a physician would be reimbursed (note: Medicare and Medicaid do not reimburse for tele-critical care). Providing the remote physician to help supervise the Affiliate Providers is an added cost to Emory, but much less than actually having a physician on-site in each ICU.

One alternative to having an eICU is staffing every ICU with a critical care intensivist at night, which costs $1,700–2,000 per 12-hour night shift, a cost that is undoubtedly more expensive than utilizing that same physician in an eICU and spreading him across several units. More importantly, the shortage of critical care physicians makes 24/7 staffing impossible for every ICU around the nation; an eICU may be the only realistic mechanism, cost aside, for bringing this expertise to every ICU. What is yet to be determined is how much a hospital without 24/7 intensivists would be willing to pay, to retain the eICU for night and weekend coverage.

3.5 Implementation Effectiveness

In this chapter, we discuss different areas in which Emory's program staff believe the Residency Training Program and eICU program are making a difference in the quality of care delivery, patient health outcomes, and cost savings. For each of the triple aim categories, we discuss how Emory's team is measuring program's impact, as well as how Abt Associates intends to measure the program's impact. Finally, we discuss impacts that can be measured using claims.

3.5.1 Better Care

Residency Training Program

Emory is monitoring a number of measures that track the quality of care being delivered by the NP and PA residents through various surveys. These surveys and/or measures include:

- Single-item Provider Satisfaction Question
- Documentation of Adverse Drug Reactions (ADRs)
- Family Satisfaction in the Intensive Care Unit (FS-ICU 24)

In multiple interviews, we also learned that participants believe the residency training program improves the quality of care their patients receive. The Affiliate Provider residents rotate through many of the ICUs at Emory, and when they graduate from the residency program, most are hired as full-time staff. We heard repeatedly that these graduates are viewed as competent and trustworthy, and they know the attending physicians and nurses well.

eICU Program

Emory is monitoring a number of measures that track the quality of care being delivered by the eICU, including:

- Compliance with ventilator care bundle

- Cases of ventilator associated events
- Compliance with tidal volume of <8ml/kg (for ventilator-dependent patients)
- Duration of mechanical ventilation and ventilator-free days in the ICU
- Central line usage and cases of central line associated blood stream infections (CLABSI rates)
- Urinary catheter utilization
- Fraction of red blood cell units transfused with prior Hgb > 8gm/dl
- Percent of deceased patients who received palliative care consult before death
- Palliative care consultations

Patients and families generally have very positive reactions to learning that an eICU is monitoring the patient's condition and overseeing care at night. Patients and families are offered a flyer that describes the program generally and informs them, for example, that their identity and personal health data will remain secure. A nurse manager relayed an experience from the first week, of a patient who recognized the eICU nurse when she virtually entered the patient's room: the patient said "hey, [eICU nurse's first name], thanks for checking in on me again—I'll see you later!" This sense of continuous monitoring may be reassuring to patients and family members.

3.5.2 Better Health

Residency Training Program

Patient outcomes may be improved through better trained and experienced critical care NP and PA residents, but it is not possible to attribute changes in patient outcomes to the residency program as distinct from several other ICU quality improvement programs, including the eICU.

eICU Program

Patient outcomes may be improved through eICU oversight and management. Emory collects data on a number of outcome measures, which they regularly report to CMS and use for internal quality improvement. These outcome measures include:

- ICU mortality
- ICU length of stay (severity-adjusted)
- Total hospital length of stay for ICU patients (severity-adjusted)
- Hospital mortality
- Patients discharged to a post-acute care facility, to home with home health care, or needing no post-discharge care.

3.5.3 Lower Cost

Emory plans to measure cost of care using Total Medicare Part A and B claims for all patients cared for by the NP and PA residents. Emory will apply risk stratification using APACHE4 risk stratification scores. A similar calculation will be conducted for the patients in ICUs that are supported by the eICUs.

eICU Program

Emory also tracks lower costs through resource utilization that they regularly report to CMS and use for internal quality improvement. These cost measures include:

- Arterial Blood Gas (ABG) utilization
- Chest radiograph (CXR) utilization

Both of these tests are frequently over-used and Emory recently implemented a program to incentivize lower use. This program was active during the same time period as the residency program and the eICU, and any changes in these two resource measures are likely due to the combined effects of all three programs.

3.5.4 Impacts that Can Be Measured Using Claims

Measuring the impact of the Affiliate Provider residency and eICU programs poses a number of challenges:

- It will be difficult to attribute any impact measured using Medicare claims to the eICU program as distinct from the Affiliate Provider residency program; we may be able to see a combined effect of both programs but cannot disaggregate the two.
- The eICU monitors only some units including a CCU, C-T ICUs, and medical/surgical ICUs in various participating hospitals. Claims do not identify in which ICU a patient receives care, making it difficult to create an accurate intervention or comparison groups. Moreover, the patient population in the few eICU-monitored units is not large enough to conduct an analysis at the ICU level. It may be possible to exclude some patients whom we know were not cared for in any of the eICU participating units (e.g., transplant patients), but even these patients were exposed to resident Affiliate Providers and should therefore be included. We conclude that all ICU patients in participating hospitals were part of at least one of the interventions (e.g., Affiliate Provider residency training), and some were exposed to both.
- There have been other concurrent quality improvement programs taking place in some or all of Emory's ICUs. For example, a quality improvement initiative offered financial incentives to ICU teams that could reduce the over-utilization of chest x-rays, arterial blood gasses, and red blood cell transfusions. This and other initiatives have the potential to improve patient outcomes, change the need for post-acute care, or in other ways affect costs. This complicates the attribution of any impact we may observe. (It is also possible that similar programs are in place at comparison facilities, about which we have no knowledge.)

3.6 Conclusion and Next Steps

3.6.1 Conclusion

> "We could do the eICU program without Affiliates, but the novelty of our program is not the eICU, it is the Affiliate training program."
>
> *– ICU Unit Director, May 2014*

Emory's "Rapid Development and Deployment of Non-Physician Providers in Critical Care" program involves two primary components: an eICU and an Affiliate Provider residency training program for graduates of Physician Assistant (PA) and Acute Care Nurse Practitioner (NP) programs. The eICU staff monitor patients in participating ICUs and alert clinicians at the bedside when they notice any potentially

problematic changes in patient vital signs. At night, the eICU staff have the added capacity of an eICU physician to provide consults and offer additional support to the Affiliate Providers when performing procedures or making decisions about patient care. The eICU, though separate from the training program, relies heavily on having experienced Affiliate Providers working in ICUs to execute orders and decisions made by eICU physicians. The two components together help to relieve the shortage of intensivist physicians by improving Affiliate Provider training, and increasing the breadth of patients one intensivist can cover at night.

The combined programs may have the most impact in ways that are difficult to measure, such as avoiding care delays at night, improving adherence to standardized clinical guidelines, reducing physician burnout, and enriching communication and critical care knowledge of entire care teams. These improvements may also contribute to other measurable outcomes, such as reduced length of stay in the ICU, even if they cannot be measured directly using data available to evaluators.

3.6.2 Next Steps

- Expansion: Emory plans to continue adding hospitals to the eICU program and eventually implement mobile carts in some of the hospitals' emergency departments and medical/surgical floors.
- Implementation of mobile carts: While some mobile carts are available for use at ESJH, most are not utilized. The mobile cart designated for EGRMC has not been deployed. Several mobile carts intended for the Emory ED and medical/surgical floors have not been deployed, due to technology problems. The use cases, communication challenges, and benefits of mobile carts are unknown, and it is not clear whether physicians and nurses in the ED and on the floors will find value in eICU monitoring and oversight from critical care specialists.
- Ongoing communication and relationship concerns between community hospitals and the eICU: Communication issues seem more problematic between the eICU and the rural hospital than between the eICU and the urban medical centers. These challenges largely hinge on resource constraints in the rural hospital, pointing out a problem that may persist as other rural hospitals join the eICU program in the future. Emory may need to develop training and communication approaches for rural hospitals that differ from those used with large medical centers, focusing especially on expectations for night and weekend care in under-resourced hospitals.
- Sustaining the Affiliate Provider training program: Emory is contemplating different ways to continue funding the Affiliate Provider training program. Currently, Program Staff are considering marketing their "program in a box" to other health systems, or charging residents for the cost of tuition.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode spending. The admission measure is not relevant for the Emory program because patients are already admitted when they receive the intervention. The results presented below are for the following Core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission for an ICU patient, in either an intervention or comparison hospital.

- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.
- Total Medicare spending for 60 days including the index admission and all Medicare spending for 60 days after discharge.

The Emory program also aims to reduce length of stay, and avoid complications through adherence to best practice guidelines. We therefore present results for the following additional measures:

- Length of stay (LOS)
- Discharge destination

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. We additionally report median regression estimates of 60-day Medicare cost. Results are reported in section 2.2 below.[18]

All models include controls for patient age, squared age, gender, race, Hierarchical Condition Category (HCC) score in year of treatment, squared HCC score, eligibility for Medicaid at any time during observation period (2010-2014), as well as indicators for the quarter in which the episode occurred.[19] An indicator is also included for individuals with missing HCC scores.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[20] We believe this is an accurate way to compare time periods.

4.1 Intervention and Comparison Groups

4.1.1 Registry Information

During the period of this report (data through Q4 2014) the Emory eICU program was operational in three large hospital ICUs.

---

[18] The only exception is discharge destination, where quarterly estimates are reported in table form due to the multitude of possible outcomes.

[19] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g. age, gender).

[20] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

The full eICU intervention involving telemetry monitoring, two-way video communication and physician night shift consultation was implemented in the first ICUs in late April 2014 and expanded to others in subsequent quarters. For this report, we therefore consider the intervention period to have begun in April 2014. Since the data available for this report are through Q4 2014, we show just three intervention quarters of results, although most of the Emory ICUs were not active with the eICU intervention for the entirety of Q2. We cannot model each specific ICU on the precise date that it "went live" and instead include all of the Emory Hospitals' ICUs as if they were all active in late April, 2014.

The Emory program includes the eICU intervention and also a critical care residency training program for nurse practitioners and physicians' assistants (and the patients they care for). A larger set of patients were 'exposed' to the residency trainees (and recent graduates) than were exposed to the eICU component of the program, but only the eICU patients are listed in Emory's registry. While we focus on patients who received the eICU component of the program, we note that eICU patients at Emory Hospitals are also exposed to the residency trainees.

The Emory registry includes indicators for where in the hospital (which general type of ICU) a patient received care. The Emory program primarily focuses on ICU patients, and on patients in cardiac care units (CCUs) in some participating hospitals.

4.1.2 Selection Rules

The section below explains how we defined a set of criteria or rules that were used to create both the comparison and intervention groups. The criteria were created using information that is available in the Awardee registry and in Medicare claims. These were then uniformly applied to patients from intervention and comparison facilities to select the final intervention and comparison populations.

We selected patients who received care in either an ICU or a CCU, or both. The revenue center codes associated with those units are listed below:

- Intensive care unit revenue center codes: 0200 (general ICU)
- Coronary care unit revenue center codes: 021X

We analyzed Medicare claims from the intervention period between April and December, 2014, to match the dates covered by the Emory registry following the implementation start date; all those with the above revenue centers were considered to be eligible for the eICU intervention. At Emory University Hospital, some ICUs and CCUs are involved in the eICU intervention, and some are not (e.g., the transplantation ICU does not participate). There is inadequate information available on Medicare claims to make these fine distinctions between types of ICUs, so we match based on the general ICU revenue center code.

We additionally match the first two ICD-9 codes on an Emory registry patient's claim. We listed all of the ICD-9 codes present in these first two positions for registry patients, and then selected comparison patients who had at least one ICD-9 code combination from this list. Patients who had both of these ICD-9 codes in the first two positions on their claims are much like those in the registry. Patients with other ICD-9 codes that are never present in the registry are excluded from all analyses. This strategy further narrows the focus to the types of patients in the Emory registry.

This additional matching step improves precision in creating intervention and comparison groups that reflect the actual treated population, but substantially reduces the available sample size and statistical power. This matching step reduces the number of patients who are included in the sample but who were

not eligible for the intervention, reducing bias in estimates of impact. The new step increases the accuracy of our match (defined below) from roughly 40% to roughly 80%.[21] This step also, however, decreases the statistical precision of our results, making it less likely to find a statistically significant effect. The tradeoff between accuracy and power (sample size) will ease as more data become available over the coming year, due to Emory's no cost extension.

The Emory registry for Q2 through Q4 2014 contains 1,423 patients for whom we located a Medicare FFS claim. The rules described above result in the following match between registry data and the best specifications we can create using Medicare claims:

Exhibit 1: Match Rates by Quarter

	2014		
	Q2	Q3	Q4
Registry with Medicare FFS Claim (A)	382	514	527
Registry Patients Not Captured by Abt Rules (B)	23	32	35
Miss Rate (B/A)	6%	6%	7%
Estimated based on Abt rules, with FFS claims (C)	460	602	619
Match between Estimated and Registry (D)	359	482	492
Estimated by Abt rules, Not in Registry	101	120	127
Accuracy Rate (D/C)	78%	80%	79%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Accuracy rate = Percent of admissions with a Medicare FFS claim that are identified using Abt's rules and are also in the registry (indicates that our criteria are too broad and capture many that apparently did not receive the intervention)

Miss rate = Percent of admissions with a FFS claim that meet Abt's inclusion criteria but are not in the registry (indicates that nearly everyone in the registry meets our criteria—we miss very few)

Our matching criteria miss just 12 of the intervention patients, but many patients meeting our criteria were not in the Emory registry and apparently did not receive the intervention. This may be in part because Emory organizes its ICUs in a way that does not map precisely to the revenue center codes on Medicare claims and we therefore cannot perfectly model the intervention ICUs. Given that our inclusion criteria only miss 1-2 percent of patients contained in the registry we are confident that our analyses contain the relevant intervention population. However, our overestimation of the sample will tend to dilute estimates of the effect of the intervention, biasing towards zero to an unknown degree and any significant results are likely an under-estimate. Exhibit 2 shows average patient characteristics for the intervention and comparison groups in both the baseline and intervention periods. The demographic summary statistics serve two purposes. The first is to provide a sense of the population demographics in the Emory treatment population. The second is to show that the demographics are similar for intervention and comparison groups, with relatively wide standard deviations. The wide standard deviations reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

[21] Previous match not shown; difference in match are determined from previous quarterly reports.

Exhibit 2: Demographic Summary Statistics

	Awardee				Comparison			
	Intervention Period (N=1,059)		Baseline Period (N=5,004)		Intervention Period (N=1,063)		Baseline Period (N=12,331)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.43	0.50	0.44	0.50	0.51	0.50	0.49	0.50
Nonwhite	0.34	0.47	0.41	0.49	0.30	0.46	0.30	0.46
Age	70.64	14.05	70.15	14.24	71.59	13.24	71.91	12.99
HCC Score	2.17	2.63	3.00	3.15	2.23	2.63	2.80	2.86
Missing HCC	0.14	0.35	0.05	0.22	0.14	0.34	0.05	0.22
Medicaid Eligibility	0.36	0.48	0.49	0.50	0.42	0.49	0.52	0.50

Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

We see that HCC scores declined for both Awardee and comparison groups, between the baseline period and the intervention period, as did the share of patients eligible for Medicaid.

4.2 Core Measures: Results

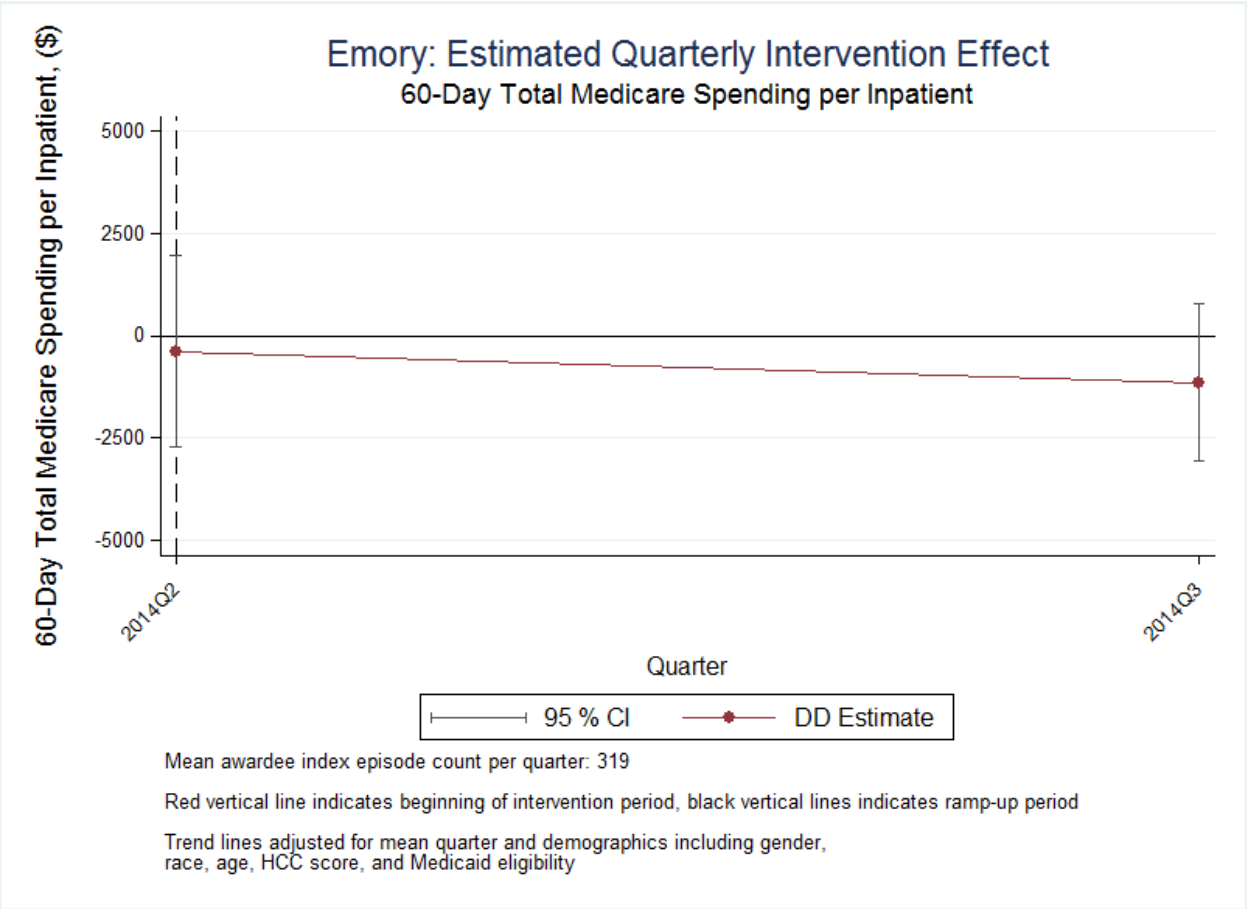
All estimated changes in utilization are based on three quarters of post-implementation data. One less quarter of data is included for the spending measure compared to the utilization measures, due to the lag required for post-acute claims to become available for analysis.

4.2.1 Medicare Episode Spending[22]

Medicare episode spending results are based on 60 days that begin with the initial inpatient admission, and we allow a six month claims run-out so that most of the post-acute care claims have been submitted. Given this longer claims run-out for the spending measure, we have just two quarters of intervention data for Emory (Q2, Q3 2014). However, as Exhibit 3 demonstrates, spending does appear to have declined in the intervention ICUs in both quarters relative to the comparison group. Moreover, the magnitude of the decrease is increasing over time. The pooled point-estimate from the ordinary least squares (OLS) regression in Exhibit 4 indicates a large, but statistically insignificant decrease in total Medicare spending. Although smaller in magnitude than the OLS estimate, and insignificant as well, the median regression result is also negative. This combination of results may suggest a true impact of the program on total Medicare spending that we do not yet have the statistical power (i.e., sample size) to confirm.

[22] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 3: Total Medicare Spending per Inpatient



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 4: DD Estimated Effect of Intervention on Mean and Median 60-day Medicare Costs

Emory University Hospital		
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	-1279.91 (794.81) [19,457]
Intervention Effect (Median Regressions)	Estimate Standard Error Sample Size	-201.96 (556.16) [19,457]

*p<0.1 **p<0.05 ***p<0.01

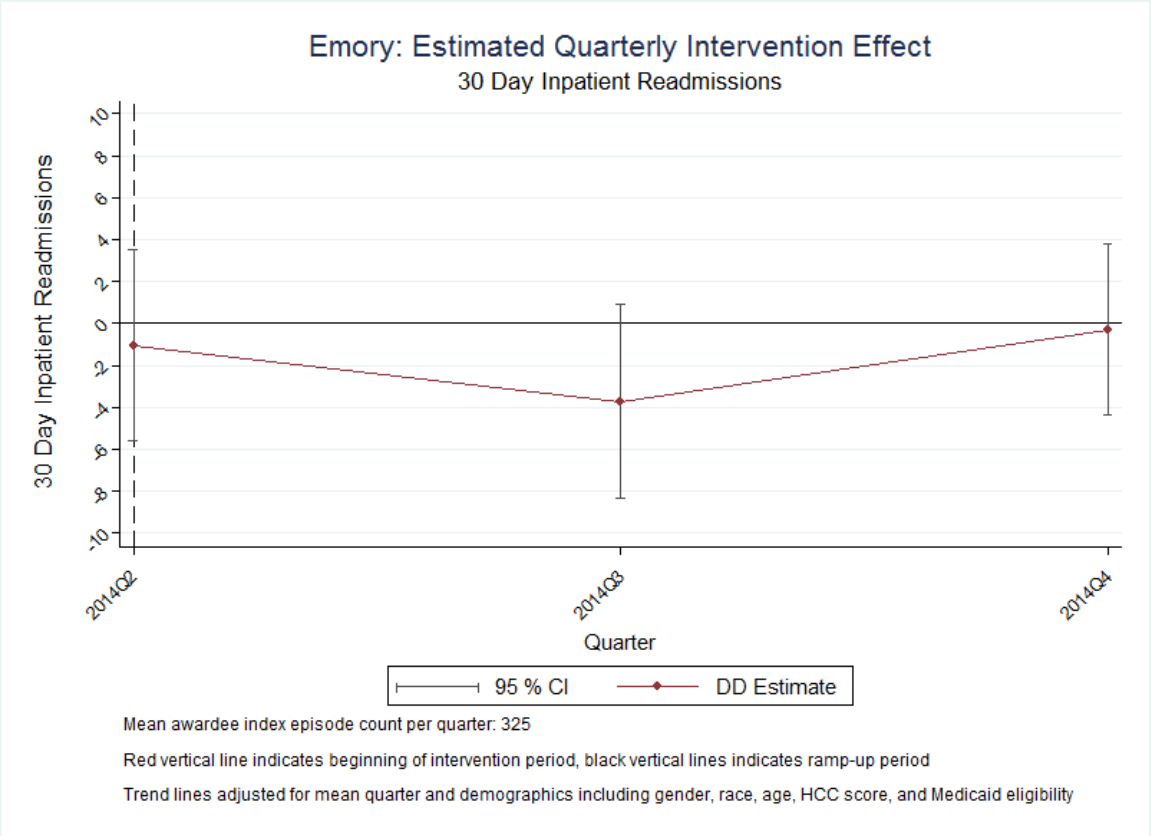
Source: Abt Associates, May 2015.

4.2.2 Readmissions

Exhibit 5 (hospital discharges followed within 30 days by a readmission) shows that patients treated at intervention ICUs were less likely to be readmitted to the hospital after discharge in all quarters since the start of the intervention. This is not a statistically significant result in any one quarter (the estimated impact is less than one percentage point in two out of three quarters). The estimate of the program impact pooled across all intervention quarters (Exhibit 6) is a statistically insignificant 2.18 percentage points.

The consistent direction of the impact is promising and future quarters of data will evaluate whether this pattern represents a true and ongoing impact.

Exhibit 5: Readmissions



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 6: DD Estimated Effect of Intervention on Mean 30-Day Inpatient Readmission Rate

Emory University Hospital		
Intervention Effect	Estimate Standard Error Sample Size	-2.18 (1.54) [20,231]

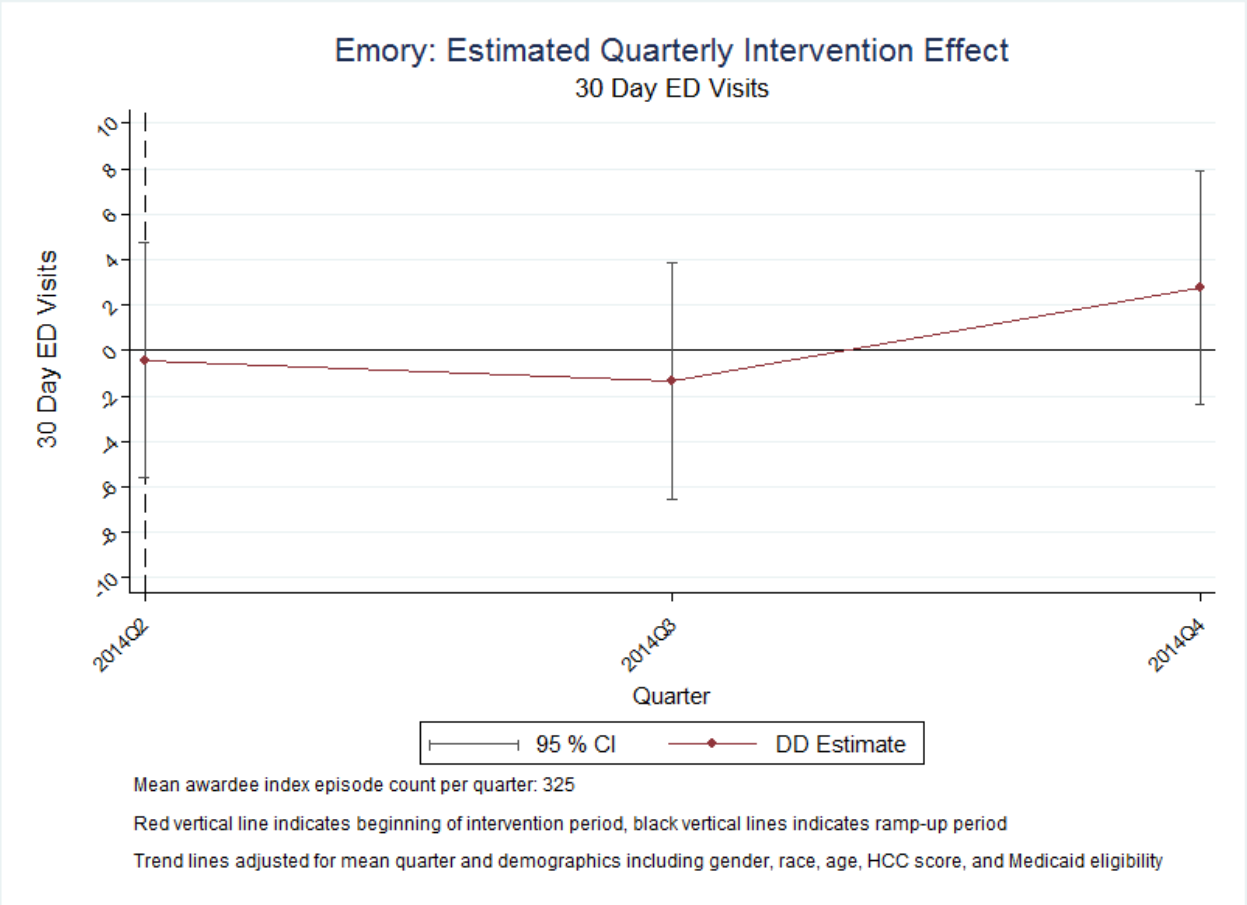
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.3 30-Day Post-Discharge ED Visits

Exhibit 7 (discharges followed within 30 days by an ED visit) shows little difference between intervention and comparison groups since the start of the intervention. Although none of the three individual quarters are statistically significant, we note that the most recent quarterly estimate shows a large increase in the proportion of patients visiting the ED within 30 days of discharge, which may be an anomaly or the beginning of a trend. The point estimate in Exhibit 8 (pooled across all quarters) is small and statistically insignificant.

Exhibit 7: 30-Day Post-Discharge ED Visits



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 8: DD Estimated Effect of Intervention on Mean 30-Day ED Visits

Emory University Hospital		
Intervention Effect	Estimate Standard Error Sample Size	0.39 (1.74) [20,231]

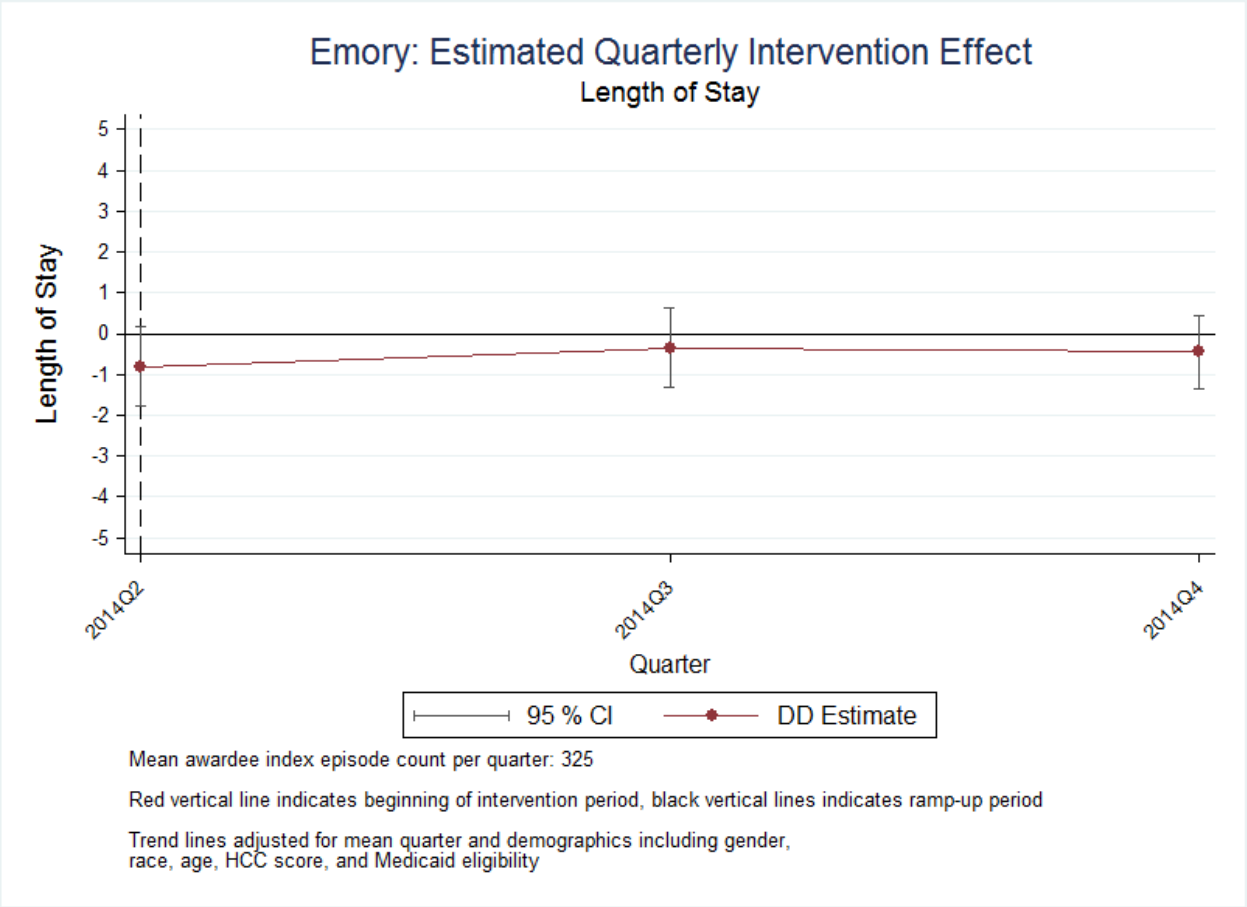
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.4 Index Admission Length of Stay (LOS)

Important goals of the Emory program are to improve the timeliness of care delivery in the ICU, and reduce complications, which together should contribute to shorter length of stay for the Index admission. Exhibit 9 shows lower LOS for intervention patients relative to comparison patients for all three intervention quarters, although the individual quarterly results are not quite significant; Exhibit 10 shows that the pooled effect is also not significant.

Exhibit 9: Index Admission Inpatient LOS



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 10: DD Estimated Effect of Intervention on Mean Inpatient Length of Stay

Emory University Hospital		
Intervention Effect	Estimate Standard Error Sample Size	-0.45 (0.30) [20,231]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.5 Discharge Destination

Below, Exhibit 11 presents the difference-in-differences estimates for discharge destination. We find that in the total intervention period, discharges to home with home health increased by a statistically significant 2.88 percentage points. This overall finding is primarily driven by the large 5.7 percentage point increase in Q2 2014. Overall, all other discharge destinations decreased relative to their baseline levels, which indicates that patients are diverted from these other discharge destinations to home health care. This may be a positive development, as patients no longer needing institutional post-acute care are instead able to go directly home, with home health care.

Exhibit 11: DD Estimated Change in Episode Discharge Destination

	2014 Q2	2014 Q3	2014 Q4	Overall
Home				
DD Estimate	-0.29	-1.18	-1.06	-0.78
SE	(2.95)	(2.87)	(2.91)	(1.87)
Home Health				
DD Estimate	5.70**	1.74	2.87	2.88*
SE	(2.77)	(2.51)	(2.69)	(1.68)
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home				
DD Estimate	-5.34***	-3.01	0.63	-1.86
SE	(2.00)	(2.24)	(2.51)	(1.50)
Other				
DD Estimate	-0.08	2.45	-2.44*	-0.24
SE	(1.61)	(2.23)	(1.36)	(1.09)

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015

4.2.6 Conclusions

- We estimate that total episode spending, 30-day inpatient readmissions, and LOS are all lower for intervention patients relative to comparison patients, in all three quarters for which we have data. Although most of these results are not statistically significant, the consistency of improvement across nearly all outcomes is a promising result.
- The rate of discharge to home health care for intervention patients increased by nearly 3 percentage points since the start of the intervention, a statistically significant result.

Appendix B4: Henry Ford Health System Mobility, the Sixth Vital Sign

1. Executive Summary

This chapter presents both qualitative and quantitative findings of Abt Associate's evaluation of the Henry Ford Health System's program: Mobility, the Sixth Vital Sign. The mobility program aimed to reduce the rate of hospital-acquired pressure ulcers (HAPUs) and its associated costs, decrease the rate of ventilator-acquired pneumonia (VAP), and increase patient satisfaction. Patients who were at risk for developing pressure ulcers while hospitalized were the target of the intervention, which was implemented in several units of the Henry Ford Hospital, an 800-bed tertiary care hospital. To determine patient eligibility for the program, nurses assessed each patient's risk of developing pressure ulcers using the Braden Scale for Predicting Pressure Sore Risk®. Nurses then assessed mobility levels for each patient to determine appropriate mobility interventions. The program employed trained mobility aides to help patients in mobility interventions, and skin/mobility nurses to provide guidance on appropriate dressings and treatment to reduce skin shear and friction, common causes of pressure ulcers. The program evolved over time and by late 2014, the focus was exclusively on ICU patients, rather than those on general hospital units, because ICU patients—many whom are ventilated—were viewed as having more to gain from mobility assistance.

Clinicians and program staff we interviewed believe the mobility program is helping to reduce the rate of HAPUs, decrease the rate of VAP, improve patient satisfaction, and decrease patient deconditioning during hospitalization. Some clinicians reported that the program has improved patient functionality, so that some patients who would otherwise have been discharged to a skilled nursing facility can now be discharged to outpatient rehabilitation, which has the potential to generate Medicare savings.

Abt researchers used a patient list (registry) provided by Henry Ford program staff and attempted to define inclusion/exclusion criteria with which to create a matched comparison group. Henry Ford program staff advised that patients were selected to receive the mobility intervention based on whether they had a Braden Score of 18 or less using the criteria of sensory perception, skin exposure to moisture, activity, mobility, nutrition, and skin friction and shear, which are clinical factors that cannot be observed in claims data. Because the clinical conditions used to identify patients for the intervention cannot be identified using claims data, we were unable to create a well-matched comparison group or measure outcomes from the pre-intervention baseline period. This relatively weak design does not allow for rigorous estimates of program impact. Instead, we examine trends over time for patients in the participating Henry Ford Hospital (HFH) Intensive Care Units (ICUs). Outcome measures for the analysis were created using Medicare claims and include Medicare 60 day episode spending, readmissions, post-discharge Emergency Department (ED) visits and length-of-stay.

Total 60-day Medicare spending, 30-day hospital readmissions, and 30-day ED visits did not change appreciably over the course of the intervention. There was a decrease in LOS in the second quarter, but LOS has remained nearly steady since then. The numbers of VAP and HAPU among ICU patients are too small to reliably measure trends.

We identified a variety of resource and staffing-related issues that may have reduced the impact of this program. The intervention was implemented five days per week, eight hours per day, and not at night or on weekends; assistance may not have been sufficient to markedly improve patient functional status. In addition, the program experienced a number of staffing challenges during the course of the program, which may have diminished its effectiveness in reducing LOS. First, the staffing model changed due to initial dissatisfaction among rehabilitation specialists, causing disruptions in implementation and

workflows. Second, the hiring of skin care/mobility nurses was delayed due to difficulty finding qualified applicants. Finally, retention of patient mobility assistants proved challenging, particularly near the end of the Award period as program staff sought positions that would continue after the Award ends.

2. General Research Domains

The core domains for the Henry Ford Health System (HFHS) evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of HCIA funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Description of Program

In 2012, the HFHS was awarded a *Health Care Innovation Award (HCIA)* to implement a mobility program within its main hospital. According to its application, the primary goals of HFHS' program, Mobility, the Sixth Vital Sign, are to:

- Reduce the incidence of hospital-acquired pressure ulcers (HAPUs) by 50 percent over the three year study period.
- Decrease costs associated with HAPUs by 20 percent over the three years.
- Reduce the occurrence of Ventilator Associated Pneumonia (VAP) by 40 percent in the intensive care units (ICU) over the three years.
- Increase patient satisfaction by 2 percent.

The program employs trained patient mobility assistants (PMAs) to engage patients in mobility interventions, and skin/mobility nurses to provide guidance on pressure ulcer prevention strategies. The HFHS has implemented the program in several units of its largest hospital—Henry Ford Hospital (HFH)—an 800 bed tertiary care hospital located in Detroit, Michigan.

3.2 Case Study Methods

The evaluation team conducted two visits to HFH to collect qualitative data about its mobility program. The first visit, which occurred April 29–May 1, 2014, focused on early implementation of the program. The research team consisted of three research staff that collected qualitative data: a senior Abt researcher, a mid-level Abt researcher, and a mid-level researcher from Telligen (formerly CFMC; subcontractor to Abt). During the visit to HFH, the evaluation team conducted four focus groups and seven interviews with clinicians and other care providers, as well as program administrators.

The same team of researchers conducted a follow-up visit to HFH on February 24-26, 2015 to learn how the program had changed during the intervening ten months and to understand the plans for the mobility program going forward.

Exhibit 1 summarizes the number and type of individuals who participated in either interviews or focus groups during the first visit in 2014.

Exhibit 1: Professional Backgrounds of Interviewees and Focus Group Participants: 2014

	Bedside Nurses	Nurse Managers	Mobility/ Skin Care Nurses	Nursing Aides	Mobility Aides	Rehabilitation Specialists	Program Administrators
Total = 47	7	12	3	8	8	3	6

Exhibit 2 summarizes the number and types of individuals who participated in focus groups or interviews during the evaluation team's follow-up visit to HFH in 2015.

Exhibit 2: Professional Backgrounds of Interviewees and Focus Group Participants: 2015

	Bedside Nurses	Nurse Managers	Mobility/ Skincare Nurses*	Nursing Aides	Mobility Aides	Rehabilitation Specialists	Physicians	Program Administrators
Total = 41	6	10	7	2	6	2	2	6

*Includes one nurse educator

All interviews and focus groups were conducted using standardized protocols developed previously by Abt's qualitative research team and approved by CMS. These protocols were tailored to address the specific issues of interest for the mobility program. Interviews and focus groups were recorded after obtaining participant consent, and used to ensure that the evaluation team's notes were accurate and comprehensive. Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

3.3 Mobility Program Background and Goals

The HFHS mobility program grew from the HFHS' focus on quality improvement and recognition that the hospital's high rate of HAPUs—approximately 5 percent of all admissions—had a substantial financial impact on the institution and on patients. The hospital estimated that each incident of pressure ulcer cost approximately $8,000-10,000 to treat. The hospital's 1,200 HAPU cases in 2010 cost the institution close to $10 million that year.

In 2011, the hospital conducted a root cause analysis to identify potential causes of HAPUs, explore potential interventions, and examine the impact of HAPUs on patient well-being and recovery. The initial analyses showed that factors associated with HAPUs included some that are uncontrollable by health care providers (e.g., co-morbidities and age,), as well as several factors that can be controlled or modified such as nutrition, skin care, moisture regulation, and pressure. They found that HAPUs diminish patient well-being and make recovery more challenging. Patients sustaining HAPUs are at risk for: increased pain and infection, inability to resume activities of daily living, need longer hospital stays, additional nursing resources after discharge, and decreased satisfaction with the hospital experience.

Following a review of the literature, the HFHS quality improvement team developed pilot programs to prevent HAPUs. The most promising of these pilot programs was Mobility Enhancement, initially piloted in the medical intensive care unit (ICU). A multidisciplinary team determined the safest methods for mobilizing all but the sickest patients in the ICU. For some patients, mobility enhancement entails sitting on the edge of the bed and dangling their feet once a day. Other patients, even intubated patients, can be encouraged to walk every day. The results of this ICU pilot showed decreased HAPUs, decreased ventilator days, and decreased length of stay. This promising Mobility Enhancement program was limited, however, by a lack of resources, specifically the staff needed to mobilize patients.

The current mobility program funded by an HCIA cooperative agreement builds on the HFHS experience with the pilot programs and provides financial resources to employ staff as patient mobility aids.

3.3.1 Primary Program Components

The mobility program aims to prevent HAPUs through administration of a mobility bundle of services—standardized activities and patient and caregiver education tailored to a patient's mobility level—and treat any developing ulcers with enhanced skin and wound care. The program consists of the following primary components designed to improve mobility and reduce HAPUs:

- Patient's risk of developing a pressure ulcer is determined using the Braden Scale for Predicting Pressure Sore Risk®, described below.
- Nurses specializing in wound and skin care examine patients at risk of developing HAPUs and advise nurses regarding appropriate treatment and dressings.
- Nurses assess patients' mobility level (ML) using a five point scale, described in the next section.
- Dedicated patient mobility assistants (PMAs) implement risk-stratified interventions based on patient ML score.

The Braden Scale uses six criteria to assess a patient's risk for developing pressure ulcers: sensory perception, skin exposure to moisture, activity, mobility, nutrition, and skin friction and shear. Each category is rated on a scale of 1 to 4, excluding the 'friction and shear' category which is rated on a 1 to 3 scale. This combines for a possible total of 23 points, with a higher score indicating a lower risk of developing a pressure ulcer. Floor nurses conduct the Braden assessment on new patients and daily thereafter. Patients with a Braden score of 18 or lower (indicating risk of developing HAPUs) are eligible for the mobility program.[23]

Role of the Skin/Mobility Nurses

A skin/mobility nurse examines patients with Braden scores of 18 or lower, to determine appropriate preventive measures and treatment of existing pressure ulcer wounds ≤ Stage 2. Directions concerning skin care are entered into the patient record and communicated to bedside nurses and certified nursing aides (CNAs). For patients with Braden scores 18 or lower, the skin/mobility nurse also performs mobility assessments and assigns a mobility level (ML), which is posted in the patient's room, with the mobility score and a picture depicting the patient's ML Since 2014 when the hospital launched its electronic health record (EHR) system, the patient's ML has been entered into the EHR. The skin/mobility nurse then instructs the PMA regarding the patient's mobility activities and goals for the day.

Mobility Level and Plan of Care

Exhibit 3 summarizes the services included in the mobility bundle, by patient mobility level.

[23] On the Braden Scale, a patient's risk level for developing pressure sore is characterized as follows: Very High Risk: Total Score 9 or less; High Risk: Total Score 10-12; Moderate Risk: Total Score 13-14; Mild Risk: Total Score 15-18; and No Risk: Total Score 19-23.

Exhibit 3: Mobility Plan of Care

Mobility Level (ML)	Daily Goal	Exercise/ADLs	Education
ML 1: Lying or Bedrest	Reposition at least every two hours Range of motion exercises every four hours Advance to next ML once acuity diminishes	Start with passive motion, allow patient to do as much on own as possible. Progress to assisted and active exercise. Repeat 5 to 10 times per extremity Encourage patient to complete ADLS with head of bed raised: Patient to wash face, brush teeth and hair with set-up	Encourage patient to reach for side rails to assist with rolling and push with legs to assist with scooting up in bed Educate family about importance of mobility and skin care Shift weight every 30 minutes when up in Stryker chair Encourage proper hydration and nutrition at every level HAPU prevention Basic Skin Care Bed Exercises
ML 2: Dangle or sit at edge of bed.	Two to three times per day for 5 to 30 minutes Initiate assisted or active exercises Reposition when in bed, as for ML1	In addition to above: Bathe upper body Take off and put on gown	Utilize bedside stool so that patient's feet are on solid surface for maximum benefit
ML 3: Stand→Chair	Up in chair three times per day for 30 minutes and/or for all meals Reposition when in bed, as for ML 1 Continue exercises	In addition to above: Use bedside commode when toileting	Remind patient to shift weight every 30 minute when up in chair Chair exercises
ML 4: Walk with Assistance	Walk three times per day Up in chair for all meals Encourage exercises	Assist to toilet/bedside commode Patient to complete own hygiene	Reinforce reposition while in bed or chair Encourage patient to stay active but ambulate safely
ML 5: Walk independently	Encourage patients to walk three or more times per day Up in chair for all meals Encourage patient to continue exercises	N/A	N/A

ADL: Activity of Daily Living; HAPU: Hospital-Acquired Pressure Ulcer

Source: Henry Ford Health System–Mobility Program Plan of Care.

Evolution of the Mobility Program's Staffing Structure

The structure of the mobility program has changed since the HCIA was first implemented. Originally, rehabilitation specialists were an integral part of the mobility team. They were responsible for conducting the patient mobility assessment and working with PMAs to implement the mobility plan of care. Initially, rehabilitation specialists and PMAs rotated from unit to unit to provide mobility services to eligible patients. This model proved difficult for several reasons: rehabilitation specialists' desire to provide therapy rather than just assess for a mobility level, mobilize patients, and oversee the PMAs; confusion

over the roles of the rehabilitation therapists, the PMAs, and the hospital's department of physical and occupational therapy; and duplication of effort among different members of the team. The model was abandoned in favor of the current structure featuring skin/mobility nurses in a leadership role and PMAs assigned to particular hospital units where they work closely with the nurses and CNAs. The PMAs are co-managed by the unit supervisor and skin/mobility nurse. The program manager conducts their evaluations with input from the staff with whom the PMAs work.

3.3.2 Secondary Program Component: The M.A.P.™ System

A secondary component of the mobility program, the M.A.P.™ (bedside pressure mapping) system, was pilot tested briefly in two hospital units during the Award period. The M.A.P. is designed to assist nurses in monitoring pressure ulcer risk among patients in the medical intensive care unit (MICU). The M.A.P. system, a mattress overlay and electronic dashboard, was placed on the 68 beds in the medical intensive care unit (MICU) in September 2012. They were removed in December 2012 when staff found that they were incompatible with the new air-flow mattresses used in the ICUs.

Since the mobility program was unable to fully utilize the M.A.P.™ in any of the ICUs, program managers began a pilot test of the devices on 23 beds in an infectious disease unit (IDU) after receiving IRB approval for the change. During the pilot program, from September to December 2014, the M.A.P.s ™ were used to determine if self-turn patients actually turned themselves and whether the devices reduced the incidence of HAPUs among patients in the IDU. The nurses received in-service training from the M.A.P. company representative so they could use the visual feedback from the bedside monitor to reposition the "staff-assist turn" patients although the primary focus was on the self-turn patients. At the time of Abt's second case study in 2015, the program staff had not yet analyzed the results of the pilot study.

3.3.3 Program Targets

Patients in the hospital's intensive care units (ICUs) and general practice units were the target of the mobility program, but over time the program enrolled patients in the ICUs, exclusively, and not on general hospital units. At the time of our 2014 case study, the mobility program had been implemented in four general practice units (GPUs) and several ICUs at HFH. By the time of our 2015 visit, the hospital had ceased enrolling patients in the GPUs to focus attention on the ICUs, where they believed the program would be more impactful. Over time, additional ICUs were added to the program (see Exhibit 4 below). Although only ICU patients were enrolled in the mobility program, the nurses continued to follow those patients after they transferred to GPUs.

Exhibit 4 below describes when the mobility program began in each hospital unit.

Exhibit 4: Implementation of the HFHS Mobility Program, by Hospital Unit

Unit at Henry Ford Hospital	Month/Year of Implementation
Medical ICU	11/2012
GPU- F1, F2, B1, B2	10/2012*
Cardiac ICU	7/2013
Step down unit	8/2013
Neuro ICU	12/2014
Surgical ICU	11/2014

HFHS: Henry Ford Health System; ICU: Intensive Care Unit; GPU: General Practice Unit

* Discontinued enrollment January 2015.

The program is guided by the general principle that most patients in ICUs have a Braden score of 18 or less and could benefit from the skin/mobility program. Program staff also identified a subset of patients for whom early mobility is not appropriate for medical reasons. These patients are placed on 'hold' for a day and routinely re-evaluated. Exhibit 5 contains the criteria that make a patient ineligible for the program.

Exhibit 5: Criteria for Excluding Patients from Mobility Program

Mobility Level (ML)	Exclusion Criteria For Turning Patients
ML 1	Development of life-threatening arrhythmia with symptomatic response (VFIB/VTACH/SVT). Active fluid resuscitation: (i.e. no volume going in = no systemic blood pressure). Active hemorrhaging: Following Cardiac Surgery/Active Tamponade Massive GI bleeding Active hemorrhage following trauma Change in baseline hemodynamic parameters (BP, HR, Oxygen Saturation, RR, etc.) that do not recover within ten minutes of position change and is not an expected result based on diagnosis.
ML 2,3,4	MD/PA/NP order not to mobilize More than one vasoactive drip Esophageal Tamponade TPA given for acute stroke Pulmonary embolism until therapeutic on heparin Patient receiving paralytics Coma, brain death or actively dying

MD: Medical Doctor; PA: Physician Assistant; NP: Nurse Practitioner; VFIB: Ventricular Fibrillation; VTACH: Ventricular Tachycardia; SVT: Supraventricular Tachycardia; GI: Gastrointestinal; BP: Blood Pressure; HR: Heart Rate; TPA: Tissue Plasminogen Activator

Source: Henry Ford Health System--Mobility Bundle Plan of Care

3.3.4 Measurement & Self-Monitoring

Interviews with program staff identified challenges in measurement and monitoring. During the early part of the Award period, program staff extracted data from paper charts and electronic records to generate self-monitoring data for CMS. Now, more of the data are available in the EHR, which was

implemented at HFH during the course of the Award. A junior-level statistician, under the supervision of a senior statistician, analyzes data for the mobility program, focusing on the self-monitoring measures that HFHS reports to CMS. Additional analyses examine other measures such as hospital readmissions, which have declined since the mobility program began. The statisticians do not work on the mobility program full time and reported that while the program staff sometimes asks them to look at variables outside of the interest of the Award, such as the relationship between the number of daily interventions and HAPU rates, they are not always able to do so.

The cost savings estimates are based on HAPU data extracted from the National Database of Nursing Quality Indicators (NDNQI) monthly skin audits that are compiled by the HFHS corporate data staff, as part of routine reporting.

The program leaders reported that front line staff are encouraged to provide input on the mobility program, consistent with the HFHS' approach to continuous quality improvement. The mobility program uses the plan-do-check-act approach, which incorporates root cause analyses and process changes when actual outcomes differ from desired outcomes. The mobility program has a steering committee, comprised of the Principal Investigator (PI), the co-PI, Project Manager (PM), the Manager of Research Programs, and two nurse specialists that meets monthly to discuss program concerns and progress updates.

The program leaders believe that sharing patient outcomes data with program staff helps build engagement and increases job satisfaction. They have presented results at staff meetings, as well as during one-on-one discussions with unit managers, and at HFHS-wide conferences. Each week, the PM provides nurse managers with a dashboard report that shows HAPUs, interventions, and patient progress from one mobility level to another. Several nurses reported that these dashboard reports are posted on their units; however, a few nurses we interviewed said that they had not seen any reports or heard about the results of the mobility program.

3.4 Workforce Development

Program leaders created the PMA job category expressly for this mobility program; this position did not previously exist in the HFHS and new staff were hired for these positions. The number of PMAs fluctuated throughout the course of the Award due to unexpected departures and subsequent hires to meet the needs of an expanding program. At the time of the second case study in 2015, the mobility program had seven PMAs working eight hours per day, Monday through Friday. Rehabilitation specialists that had previously worked in the HFH physical therapy department transferred to the mobility program when new positions were funded by the Award. They were not content with this assignment, because they felt that they were not practicing to the full potential of their certification, and eventually transferred back to the physical therapy department, where they assumed consultative and training roles in the program.

Skin care/mobility nurses were hired to fill positions funded by the Award. Initially, program staff reported that they have had difficulty filling the nurse positions because the required skills and work experience are uncommon. A few nurses hired by the program transferred out because of the 8- hour per day work schedule and dissatisfaction with the skin/mobility nurse role expectations. At the time of the first case study in 2014, three skin/mobility nurses worked for the program. By the time of the second case study in 2015, six skin/mobility nurses were employed by the program. Like the PMAs, they worked Monday through Friday, eight hours each day.

Training for rehabilitation specialists, PMAs, and skin/mobility nurses, described below, has evolved to reflect changes to the staffing model that have been made over time.

3.4.1 Training for Rehabilitation Specialists

Initially, intensive training was given to rehabilitation specialists when they led the program. That training, led by ICU nurses, focused on special conditions of patients in the ICU and how to safely incorporate movement into patient care there. A senior rehabilitation specialist developed the mobility portions of the training. In the training, rehabilitation therapists learned, for example, how to safely move patients on ventilators from bed to standing and walking. Before working directly with ICU patients, rehabilitation specialists had to demonstrate competency with ventilator patients, described as the most complex of the ICU patients in the mobility program.[24]

3.4.2 Training for Patient Mobility Aides

Most of the PMAs hired for the program had worked previously as CNAs in other hospitals or nursing homes. PMAs participated in an abbreviated CNA training required by the hospital, as well as training specific to the PMA role.

When the mobility program launched, PMAs initially received intensive didactic and practical training, developed by a team consisting of two clinical nurse specialists, a nursing educator, and a rehabilitation specialist. The classroom portion plus additional lectures focused on safe methods for moving patients, appropriate activities for each mobility level, and the importance of movement in preventing HAPUs. At the end of each session, the PMAs practiced what they had learned using mannequins and on each other. Following the classroom training, PMAs started work in the hospital by shadowing an experienced rehabilitation specialist for four weeks. Before working directly with patients, PMAs were required to pass competency tests. PMAs who participated in this early training model perceived the training as being very long. “We spent a few months in training before we even came to the hospital,” said one. A few, who described themselves as being “more hands on” found it challenging to remain focused during the full-day lectures. There was general agreement among PMAs that the practical aspects of the training were more beneficial than the didactic training.

When the mobility program shifted away from using rehabilitation specialists, the focus of the PMA training program became more practical in nature, and was refined over time through collaboration between the physical therapists trainers and mobility program staff. During the second and third years of the Award, two physical therapists worked with program staff to develop detailed guidelines for PMA training. As of 2015, new PMAs receive 80 hours of training consisting of lectures, followed by observation and hands-on exercises in an ICU under the supervision of a physical therapist trainer. The goals of the training are to teach body mechanics, appropriate movements for each patient mobility level, proper approaches to moving patients, and how to use equipment such as gait belts and canes when working with patients. The PMAs also received hands-on training from the team nurses concerning skin care. As before, PMAs are required to pass a competency test before working with patients independently. The practical test, developed by the physical therapists and program staff, is repeated until passed successfully. Additional on-the-job training occurs as PMAs work with nurses and others on the unit to which they are assigned. In the ICUs, PMAs join nurses, nurse managers, and CNAs in regular shift huddles to discuss patient status and anyone needing special attention. ICU managers told us that they

[24] Rehabilitation specialists completed a four-hour class on working with patients on ventilators.

have begun to teach PMAs about common conditions in the ICU, such as ventilator-associated delirium, that affect mobility. When the program was launched in the neuro- and surgical- ICUs, nurse educators and managers provided additional guidance to PMAs to alert them to special concerns when moving patients in these settings (e.g., additional lines, drains). The physical therapy team provided PMAs with additional observation opportunities to be certain that they were confident about how to move patients in these ICUs.

ICU Nurses and CNAs told us that PMAs are well prepared for their jobs; GPU nurses commented repeatedly that "They know what they're doing."

3.4.3 Training for Nurses

Each day, bedside nurses conduct skin assessments on all hospital patients to determine a patient's Braden score. This is part of their normal workflow and is independent of the mobility program. When the program launched, nurse managers provided a brief introduction about the mobility program to the nurses on their units, explaining how the Braden score would be used in the mobility program and the role of the PMAs. Because a patient's Braden score determines eligibility for the program, the skin/mobility nurses provide one-on-one refresher training on the Braden rating system when they find a score (assigned by a bedside nurse) to be inaccurate. The team nurses told us that they would have liked to have received more training about the mobility program. Program staff told us that they are working on a formal training for skin care specialists and bedside nurses, but at this time the training for these care providers is informal.

3.5 Implementation Effectiveness

3.5.1 Better Care

There was widespread agreement among those we interviewed that the mobility program results in better care for patients. The program, and especially the presence of PMAs in the ICUs, enhances patient care in the following ways:

- Facilitates patient movement, which staff had struggled to do previously because of competing clinical demands.
- Provides staff support that frees nurses and NAs to focus on their routine tasks.
- Provides NAs with additional support, as needed, with tasks that require two people.
- Improves patient satisfaction by having more staff, and more staff time, involved in their care.
- Enhances patient and caregiver engagement by empowering them to take an active role in the recovery process.
- Creates the expectation that patients should be mobile while in the hospital and gives hope for recovery.

Nurse Managers told us that the program has changed the culture of attention to skin care. The team nurses often check patients during morning rounds rather than waiting for the results of the bedside nurses' Braden assessment. The team nurse then does the mobility assessment so that the PMA can begin to mobilize their assigned patients.

An ICU physician told us that nurses are often so busy that they are unable to spend adequate time on mobility activities. The mobility program, and the availability of PMAs, makes those activities a priority when they otherwise might be at the bottom of a to-do list. "Having the mobility team there is a godsend," she said.

Henry Ford Health System's Measurement Strategy

Program staff collect data on quality measures that they report to CMS and use for internal quality improvement. The key measures they report are:

- The number of mobility-related interventions performed per patient per day (i.e., repositions, leg dangles, up in chair, ambulation, activity of daily living (ADLs), range of motion (ROM), exercises, equipment and education, and sit.).
- Patient satisfaction.

> The mobility team is able to perform range of motion interventions with patients multiple times a day, whereas we wouldn't be able to do that because of the large number of other tasks that we need to do.
>
> *–CNA*

3.5.2 Better Health

There was general consensus among those we interviewed that the mobility program reduced the rate of HAPUs at HFH. Across all ICUs, nurse managers and nurses reported having observed fewer pressure ulcers among patients, as well as other positive health benefits of the mobility program. In the final year of the Award, program staff briefly considered creating a randomized control-like study to facilitate the comparison of outcomes among patients that had received the intervention and those that did not. This idea was dropped because clinical staff believed that it would be unethical to deny some ICU patients an intervention that was proving beneficial to them all.

The program staff expected the greatest impact of the program to occur in the ICU, where patients are more prone to HAPUs. Several clinicians interviewed—physicians, rehabilitation specialists, skin care nurses, and nurse managers—noted that ICU patients, particularly those who used ventilators and those who were bedbound at the time of admission, benefitted the most from the mobility program. ICU nurses and nurse managers reported a reduction in the number of HAPUs among their patients. "Now, it's a rare event to have a pressure ulcer in the MICU," said one ICU Nurse Manager. Milder deconditioning was mentioned as another positive outcome of the mobility program. "When a patient is in the ICU for a few weeks, there is a strong likelihood that he will not get back to his pre-admission level of mobility before being discharged. The mobility program gives more patients a chance of being as mobile as when they were admitted to the hospital," said one ICU nurse. They also reported that patients are more likely to be discharged to outpatient rehabilitation services than to a nursing home.

> Ten years ago we would not have vented patients sit up in bed. It's [the mobility program] changing our thinking. Patients need less rehab because they're stronger.
>
> *–ICU Nurse*

Program staff shifted emphasis from GPUs to ICUs, because there was more potential to impact mobility-associated outcomes for ICU patients. In 2015, GPU staff who had previously praised the program for reducing the frequency of HAPUs on their units lamented the discontinuation of program services on their units. . "While I understand the focus on the ICUs, it was helpful to have the additional staff on the [GPU] floor." Another added, "[With staffing reductions], nurses don't have as much time for mobility."

Henry Ford Health System's Measurement Strategy

Program staff collect data on patient outcomes that they report regularly to CMS and use for internal quality improvement. The key measures they report are:

- Percentage of patients with HAPU.
- Program leaders identified reduced rates of ventilator associated pneumonia rates, which is measured annually, as a secondary goal of the mobility program.

3.5.3 Smarter Spending

Clinicians and program staff interviewed at HFH all anticipate that the mobility program will result in savings to Medicare and to their institution because fewer HAPUs will yield shorter lengths of stay and fewer resources required after discharge. Prevention of VAPs would also reduce costs.

Henry Ford Health System's Measurement Strategy

Program staff collect data on costs that they report to CMS and use for internal quality improvement, the key measure being:

- Average cost per case of HAPU x number of cases avoided.

3.5.4 Outcomes that Can Be Measured Using Claims

Important outcomes such as HAPU rates, length of stay, and hospital readmissions may be measured using Medicare claims data. Rates of common and serious hospital acquired conditions (e.g., VAP) can also be measured using claims, although the incidence of these conditions that occur in the hospital (i.e., were not present on admission) may be too low to measure change with confidence. The Abt team will have difficulty in specifying criteria for identifying intervention patients and comparison patients because the clinical characteristics used to determine patient eligibility for the mobility program (e.g., Braden score, mobility level) are not included on claims.

3.5.5 Unanticipated Impacts

Program staff mentioned both clinical and cultural consequences of the mobility program. They noted that the mobility program has decreased patient deconditioning (loss of muscle tone and endurance), something they had not anticipated before they began the program. One nurse observed that increased patient mobility and attention to wound care may have decreased the incidence of catheter associated urinary tract infections.

Several nurses and PMAs reported that the program had a positive impact on patients' mental status, particularly reducing the severity of delirium. They described a patient with ICU-induced delirium who was aggressive. After moving the patient to a sitting position with her feet on the floor, the patient became more lucid and calm.

> I'm able to do more things because the PMA and CNA take over the patient bathing. It lets me do more RN things like pass medicine and talk with families. I've seen a huge difference since they've been working together.
>
> *–ICU Nurse*

The mobility program started a culture shift among the nursing staff at the hospital. Some nurses and nurse managers mentioned that originally they did not believe that mobility was important for patients. After seeing results of the mobility program, however, they now make an effort to assist patients in mobility activities when the PMAs are off duty. "While some nurses still believe their patients are too sick to be moved, most have come on board," said one nurse manager. According to one

skin/mobility nurse, the culture shift has made unit nurses too reliant on the mobility team. “The program began with the unit nurses not letting the mobility team into the patient’s room. The mobility team is so good that the charge nurses now believe that only the team can do the care,” said one skin/mobility nurse. This attitude may result in some patients being moved less often, especially on nights and weekends when the PMAs are not working, than if all charge nurses continued to assume some responsibility for patient mobility.

Skin care/mobility nurses noted an increased risk of injury among mobility team members as an unanticipated consequence of the program. There was general agreement among those skin care/mobility nurses we interviewed that they had experienced injuries that they attributed to the number of patients that they had to move daily.

3.6 Impact on Workflow and Workload

The mobility program has had a strong impact on the workflow in the units where it has been implemented. Nurse Managers, nurses, and CNAs have come to view the PMAs as essential to facilitating patient mobility. They told us that the addition of PMAs to the unit care team has allowed nurses and CNAs to focus more attention on their primary duties and, at the same time, patients receive more mobility assistance. In addition, PMAs provide “an extra set of hands” to assist with tasks requiring two people (e.g., bathing a frail patient). In all units, staff reported that PMAs work closely with CNAs to accomplish patient mobility tasks and personal care tasks normally performed by the CNAs alone. “We have 10–12 patients each on our unit. I have to get the patient up, do all their bathing, get them fed, and get them turned. The PMAs help us do our jobs.” said one CNA. There was general consensus among the CNAs that the addition of the PMAs to the care team has made their jobs less stressful. All nurse managers, nurses, and CNAs interviewees expressed that this team approach was successful and improved the workload and flow of work in their units.

When the mobility program first began, the program was mildly disruptive to nurses’ work because there was confusion about the roles of the PMAs, the rehabilitation specialists, and the wound care nurses. Nurses were not sure who was responsible for what and, how to work with these new workers in their units. This concern was not expressed during the second case study.

Establishing trust was another challenge in the integration of PMAs into the workflow. Some staff told us that the initial structure of the mobility program, with PMAs rotating from unit to unit, provided little time for PMAs to demonstrate their competencies and gain the trust of nurses. PMAs, managers, and program staff noted that nurses are very protective of their patients and they need to trust someone before they will let him or her work with their patients. With the PMAs embedded in the ICUs, nurses grew comfortable with the PMAs and viewed them as an asset. Being assigned to one unit enabled the PMAs to provide better care by having the opportunity to develop trusting relationships with patients and family members, as well as staff. GPU staff noted that when the mobility program no longer enrolled patients in their unit but merely followed those enrolled in the ICU, there was less coordination between PMAs and regular GPU staff.

Data collection presented a minor workflow challenge for the skin/mobility nurses due to the project data requirements for the number of patient encounters and collection of self-monitoring process measures for the quarterly reports. The hospital’s electronic medical record (EMR) is not linked to the data collection tool used by the mobility program staff, requiring the patient assessment to be entered separately into the EMR. The hospital’s EMR system is accessed through desktop computers in each unit while data for the

mobility program are captured manually and submitted to the data entry staff who enter it into the study data collection tool (REDCap). Some of the information entered into each system is the same.

3.7 Improvements Suggested by Staff

3.7.1 Expand Working Hours for PMAs

There was widespread agreement among nurses, nurse managers, PMAs, and CNAs that the mobility program would be more effective if the PMAs' schedule was expanded from eight hours per day, Monday through Friday, to 12-hour shifts with 24-hour coverage, Monday through Sunday. Nurses, nurse managers, and physicians stated that patients would progress faster with PMAs working on the weekends. Some noted that they have seen patients regress after a weekend of limited mobility.

CNAs and some nurses and nurse managers explained why it would be helpful to have PMAs for longer shifts each day. CNAs, who often work with PMAs to move patients, said that it would help them to have assistance getting patients back to bed for the night. As one manager pointed out, getting patients out of bed during the evening often does not happen after the PMAs leave for the day. "Imagine if you had to stay in bed from 5pm to 7 the next morning. It would be bad. No one does that [if he/she is able to get out of bed]," he said.

Budgetary constraints prevented the hospital from expanding PMA staff schedules to 12-hour shifts, seven days per week; however, this issue may be addressed by a new staffing model, described in the Sustainability section of this report that will be implemented at the end of the Award.

3.7.2 Provide Additional Equipment

Nurses, nurse managers, and program staff suggested that the hospital needs more mobility equipment and assistive devices, now that more patients are mobile. "Patients are bigger now so equipment is helpful in moving them. We could use a stand-assist device in our unit," said one nurse manager. The need for more stand-assist devices was particularly problematic in the ICUs because patients are often weak, and the units have only a small supply of these devices. Another suggested a specialized walker that would minimize the number of people required to enable a ventilator patient to ambulate. "Now it takes six people to help a vent patient walk. They should consider getting a [special] walker for these patients," he said.

Skin/mobility nurses suggested that having iPads linked to the EHR would reduce duplicative data entry. It would allow them to input the results of the skin assessment directly into the patient's record, which would then be available to the entire care team. "We need everyone to know right away what we think is best for the patient," said a wound care nurse.

3.7.3 Clarify Roles and Performance Expectations

During our 2014 case study, one ICU nurse felt strongly that the mobility program suffered from lack of clear job descriptions and expectations of performance. "The expectations [of the PMA position] aren't clear to me. Sometimes when we have patients that are clinically unstable and cannot be moved, there's nothing for the PMAs to do. So, the PMAs help the CNAs do their job or they go to help a PMA in another unit. Is that okay? Sometimes the partnership between CNAs and PMAs works well, other times, it doesn't. I want to be able to hold them accountable to expectations but I don't know what is expected."

By 2015, the role of the PMAs was clearer among nursing staff. An ICU nurse noted that the PMAs on his unit seemed to be more closely supervised than earlier in the program's implementation. He has observed PMAs working more closely with the skin care nurses, for example, who provide important oversight.

3.8 Context

3.8.1 Endogenous Factors

Communication

Nurse Managers, nurses, and CNAs reported that communication during program implementation was suboptimal. In 2014, confusion about the roles of mobility team personnel, particularly PMAs and rehabilitation specialists, was a common theme among those we interviewed. Posters describing the program that include photos of the PMAs have helped to clarify who they are, and what they do. By the time of the second case study in 2015, the roles of PMAs and rehabilitation specialists were clear to those we interviewed.

During the initial case study, some nurses reported that the results of the program have not been well communicated. The dashboard reports are not sufficient, according to one nurse. "The only way information gets communicated to staff is on a board where we post all the rates. I don't think that people are making the connection. The ICU length of stay and vent days are posted on the boards but the numbers don't necessarily tell the story," she said. This concern was not raised by interviewees during the second case study, but it does not seem that communication improved. According to some staff interviewed during our second case study, later changes to the model were not well communicated and nurse managers working on the GPUs that no longer enrolled patients in the program (the focus having shifted to the ICU) reported that they were not informed about the change.

Staff Buy-in

The program staff and skin/mobility nurses addressed the importance of nurse manager and nurse buy-in for successful program implementation. Support was earned over time, as newly hired staff demonstrated proficiency, data reflected lower HAPU rates, and unit staff became accustomed to the program. During our 2015 case study, which occurred a few months after the mobility program had launched in two new ICUs, skin care nurses and program staff noted resistance to the mobility program among some nurses and physicians in these units. To gain trust, skin/mobility nurses reported assisting floor nurses with their duties, and they also presented results from other mobility studies to convince one skeptical physician of the benefits of mobility. In units where the program was well-established, skin/mobility nurses reported that some nurses have come to depend on the mobility team.

Leadership Buy-in

The program manager noted that the hospital CEO, COO, and VP of the medical group have all been very supportive. The co-PIs have presented results to hospital leadership, including reports to the board of directors. Nurse Managers agreed that hospital leadership demonstrated support for the program from the start; however, they felt program leadership provided inadequate feedback to the staff. They mentioned that early in the program, leadership may have been distracted by the implementation of a new EHR throughout the Henry Ford Health System, and the JCAHO accreditation process, and hope that the focus will shift to providing more feedback to program staff. This concern was not raised during the follow-up case study.

We noted that one of the co-PIs for the mobility program is HFH's chief nursing officer and vice president for patient care services. In this role, she has strong influence over hospital-wide and system-wide operations, which likely contributed to successful implementation of the program.

Culture of Quality Improvement

The mobility program aligns with HFHS' broader quality initiatives and culture of quality improvement. In 2011, HFHS was awarded the Malcolm Baldridge National Quality Award from the U.S. Secretary of Commerce to honor "performance excellence through innovation, improvement and visionary leadership."[25] According to the PI, "Continuous Quality Improvement (CQI) has permeated the culture of HFHS. We have had a set of great leaders that championed [CQI]." The hospital is currently involved in a number of quality-related initiatives that impact the units where the mobility program operates. The co-PIs noted that HFH is a member of the Keystone Group, a consortium of 40 Michigan hospitals working on improving care for ICU-specific conditions. One of the physicians we interviewed also noted several specific quality-related initiatives that have been implemented in recent years, including the Comprehensive Unit-Based Safety Program, run by Johns Hopkins. Other initiatives, such as "sedation vacation," weaning from ventilators, and mobility and delirium assessments, also encourage mobility. Program staff, physicians, and nurses noted that the surgical ICU had conducted a brief mobility pilot prior to the implementation of this program. That pilot program used a different mobility scale, which caused some confusion during early implementation.

3.8.2 Exogenous Factors

Program staff reported some changes in the Detroit marketplace in recent years that have affected HFH. Detroit Medical Center (DMC), located in downtown Detroit and one of the largest health care providers in southeastern Michigan, became a for-profit entity in 2010. William Beaumont Hospital, located just outside of Detroit, merged with two other hospitals. Michigan expanded its Medicaid program while implementing the Affordable Care Act, thereby providing more low-income residents with health insurance. Combined, these changes resulted in a larger patient population for HFH.

The hospital has experienced an increase in the number of seriously ill patients during the Award period, as a result of hiring highly specialized physicians and increasing its heli-transport program. The hospital hired new, highly specialized heart and vascular surgeons who have drawn patients from other parts of the state and beyond. According to program staff, one interventional cardiologist who joined HFH in 2013 is known for treating patients that cardiologists at other hospitals will not take because of the severity of their illness. The program staff reports that the hospital treats more patients using ventricular assisted devices. The heli-transport system brings patients from distant parts of the state and as far away as Chicago. According to a co-PI, HFH "has had tremendous growth in our outstate program, where we are a quaternary referral hospital. We have traveled through Michigan, bought a helicopter, and have tried to capture the difficult population. There has also been an explosion in our heart and vascular institute. We are seeing a sicker, more referral-based patient coming to Henry Ford. Acuity has gotten higher." These changes could impact the evaluation's difference-in-differences analyses, if the increase in acuity at HFH is not also experienced at comparison hospitals.

[25] http://www.nist.gov/baldrige/baldrige_recipients2011.cfm, accessed July 29, 2014.

3.8.3 Sustainability

There was widespread agreement among those we interviewed that the program should continue because it enhances patient care and health outcomes, however, sustainability will require the adoption of a new staffing model when the Award concludes. PMA positions, which are currently funded by the Award, will not be continued. Instead, the hospital will hire several new CNAs who, along with current CNAs, will be trained in mobility and who will perform mobility-related tasks in addition to their CNA duties. Mobility/skin care nurses will also not continue in their positions after the Award has ended, but additional positions on the wound care team have been requested. Program staff believe that this model will be sustainable and will provide more consistent mobility assistance over the course of a week. CNAs work 12-hour shifts, seven-days per week, while the Award-funded PMAs work 8-hour shifts, Monday through Friday.

Maintaining PMA staffing at an adequate level has been the primary challenge to ongoing program success during the last year of the Award. Because PMA salaries are funded by the Award, several PMAs who anticipated the end of Award funding have left the mobility program for more secure CNA positions at HFH and in other settings. The mobility program has begun to offer financial incentives to those PMAs who remain until the end of the Award period. In addition, the program staff mentioned that PMAs have been given more scheduling flexibility and are encouraged to take time off, as needed, in order to keep them on staff.

3.9 Next Steps

- The co-PI, who is the Vice President for Patient Care Services and Chief Nursing Officer, has submitted a proposal to HFH's budget committee to hire additional CNAs for the ICUs where the mobility program operates. At the time of the 2015 site visit, the program staff was optimistic that the proposal would be accepted as the additional staff is part of a hospital-wide effort to improve CAN-patient ratios.
- Once the CNA positions are filled, all CNAs in participating units will receive training in mobility, along with the usual HFH CNA training. The co-PI hopes that these new staff will be on board before the end of the Award period so that there is no discontinuation of service. Current PMAs are eligible, and encouraged to apply for the new CNA positions.
- The co-PI has submitted a budget request to hire one or two additional wound care nurses, who would be incorporated into the wound care team.
- The HFHS intends to incorporate the mobility level tool into the EMR during the next upgrade of the system, which would eliminate double data entry. The co-PI expects this to happen by the end of 2015.
- After the integration of the mobility level tool into the EMR, program staff expect that it will be used in all of the hospitals in the Henry Ford Health System.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode spending. The admission measure is not relevant for the Henry Ford mobility program, because patients are already admitted when they receive the intervention.

The results presented below are for the following Core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission to the Henry Ford Hospital, for a patient listed in the Awardee registry.
- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.
- Total Medicare spending for 60 days including the index admission and all Medicare spending for 60 days after discharge.

The Henry Ford program also aims to reduce length of stay, and avoid complications through earlier mobility. We therefore present results for the following additional measure:

- Length of stay (LOS)

Please see the Technical Appendix for description of how each outcome measure is specified.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[26] We believe this is an accurate way to compare time periods.

4.1 Defining Intervention and Comparison Groups

4.1.1 Selection Rules

Henry Ford Hospital program staff provided registry data for patients admitted to the hospital, who receive mobility assistance, from September 17, 2012 through December 31, 2014. The registry includes admissions to the one hospital in this program.

Henry Ford program staff indicated that different units of the hospital implemented the mobility program at different times. Units implementing the program included general wards, medical-surgical ICUs, and specialty ICUs; over time, the emphasis of the program shifted toward ICUs patients and less on those in the general wards. The mobility assistants were available during 8-hour weekday shifts and only patients they served during those shifts are in the registry.

Even though Henry Ford program staff advised that certain patients with clinical exclusions such as gastrointestinal hemorrhage, severe stroke, or coma would not be candidates for the mobility intervention we found these exclusion criteria too broad because some of these patients improve and become eligible for the interventions. For example, we found that some patients with an ICD-9 code for traumatic

[26] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

hemorrhage are present in the Henry Ford registry (i.e., received mobility assistance), and therefore should be in our matching criteria as well. Basically, patients receive the mobility intervention based on their Braden Score and other clinical factors that cannot be observed in claims data.

We know from our qualitative work that Henry Ford staff used meaningful clinical criteria to select patients for mobility assistance. We are not able to observe these criteria in claims data. As more quarters of data accumulate, we have decided that our previous strategy for creating a matched comparison group is not sufficiently precise to yield valid difference-in-difference estimates. Although we will continue to hone our approach for future reports, in the current report we only present risk-adjusted trend lines for patients from the Henry Ford registry, for whom we can locate Medicare claims; we do not try to create baseline or comparison groups or conduct tests of statistical significance.

The Henry Ford registry contained 5,295 observations with Medicare IDs. From this, we identified 3,252 index episodes.[27] Exhibit 1 below presents summary statistics for the patient demographics we use to risk-adjust the trend charts presented below.

Exhibit 1: Patient Summary Statistics

Variables	Awardee Intervention Period (N=3,212)	
	Mean	SD
Female	0.52	0.50
Nonwhite	0.65	0.48
Age	71.90	13.54
HCC Score	2.52	2.41
Missing HCC	0.08	0.27
Medicaid Eligibility	0.55	0.50

1.2 Core Measures: Results

In the graphs below, the red vertical line on the far left shows the beginning of the intervention period and the black vertical lines indicate the quarters when various units within the hospital began program implementation. Reported intervention results are for Henry Ford's intervention patients only.

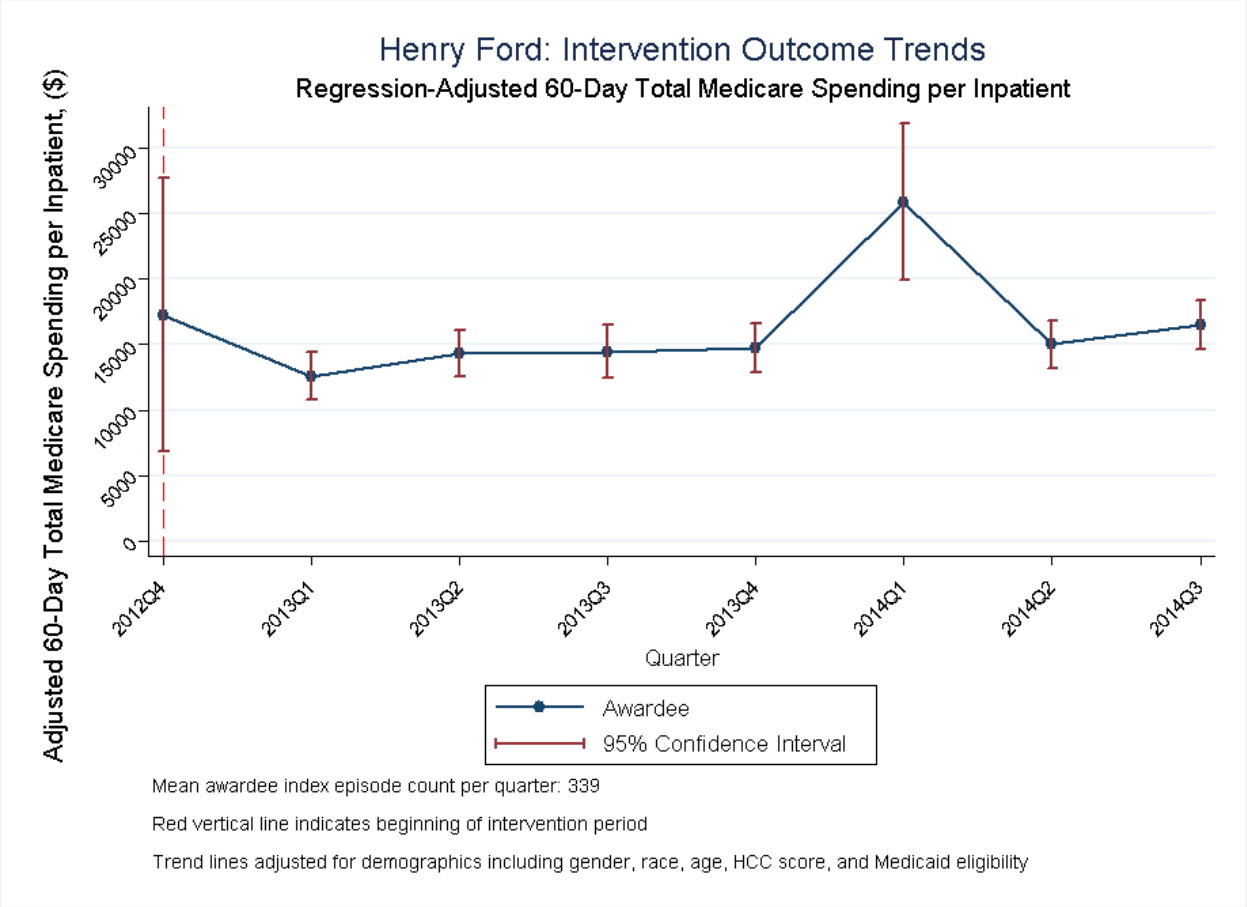
The Henry Ford program did not begin on the first day of Q4 2012, and the first quarter in all exhibits below does not reflect full program implementation.

[27] If a registry patient was admitted more than once during a 120-day window, we assign the first observed admission as an index admission and treat subsequent admissions as outcomes of the intervention. In addition, we based episodes on a 3-month claims run out; in some cases the admission date reported on the registry does not exactly match the episode start date. To best capture registry patient admissions, we matched episode start dates within 2 days of the registry admission date, but the flexibility in admission date still misses some registry patients.

4.1.2 Medicare Episode Spending[28]

Exhibit 2 (total Medicare 60-day episode spending) includes the inpatient stay and all claims in the following 60 days. Spending was roughly constant in all quarters, except for the first quarter of 2014 when there is a significant increase. However, this appears to be an anomaly and not the beginning of a new trend in spending. Note that one less quarter of data is included for this spending measure, due to the lag required for post-acute claims to become available for analysis.

Exhibit 2: Mean Medicare Episode Spending



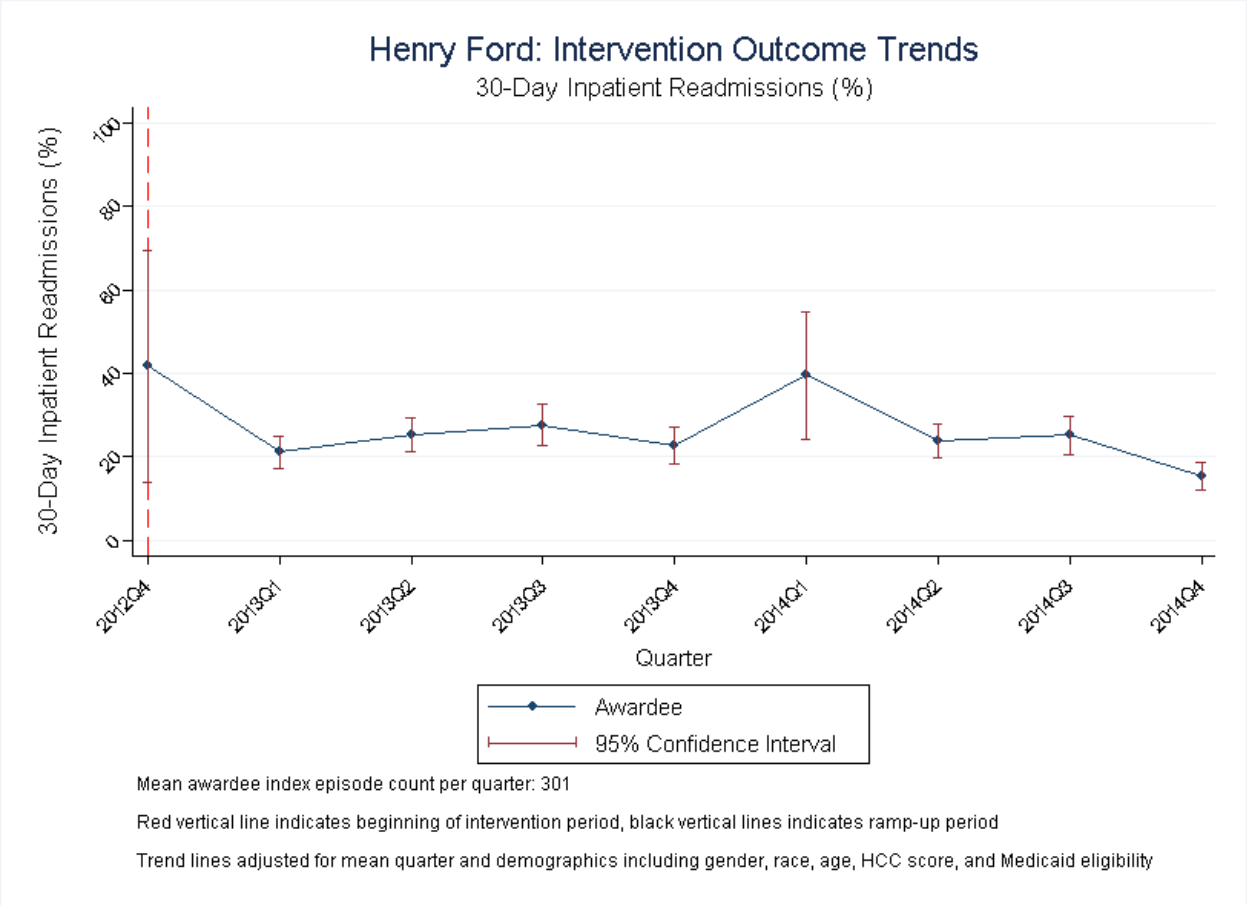
Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

[28] We do not adjust for inflation in measures of Medicare spending. This may cause spending in later quarters to appear slightly larger than they otherwise would, and give the illusion of increased spending over time.

4.1.3 Readmissions

Exhibit 3 (hospital discharges followed within 30 days by a readmission) shows an initial decrease after the start of the intervention that is maintained in all quarters except for one quarter at the start of 2014. We observe an additional, statistically significant decrease in readmissions in the final quarter of 2014, although we caution that without pre-intervention data or patients from comparison hospitals, we cannot attribute this change directly to the intervention.

Exhibit 3: Readmissions

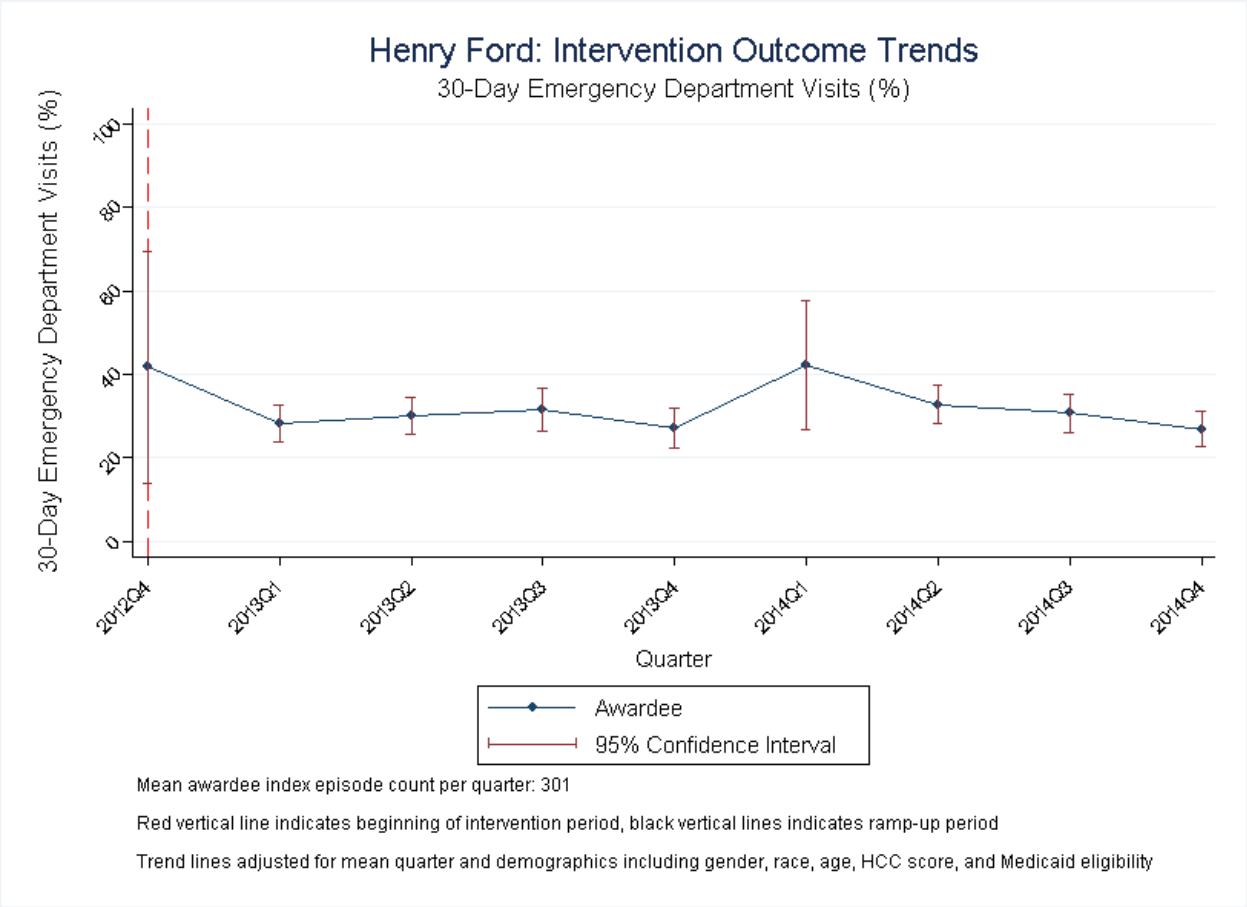


Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

4.1.4 30-Day Post-Discharge ED Visits

Exhibit 4 (discharges followed within 30 days by an ED visit) shows a similar pattern as readmissions. After the first implementation quarter, the rate of ED visits was relatively constant near 30 percent, except for a spike in Q1 2014. Overall there does not appear to be much evidence of change in the rate of ED visits since the start of the intervention.

Exhibit 4: 30-Day Post-Discharge ED Visits

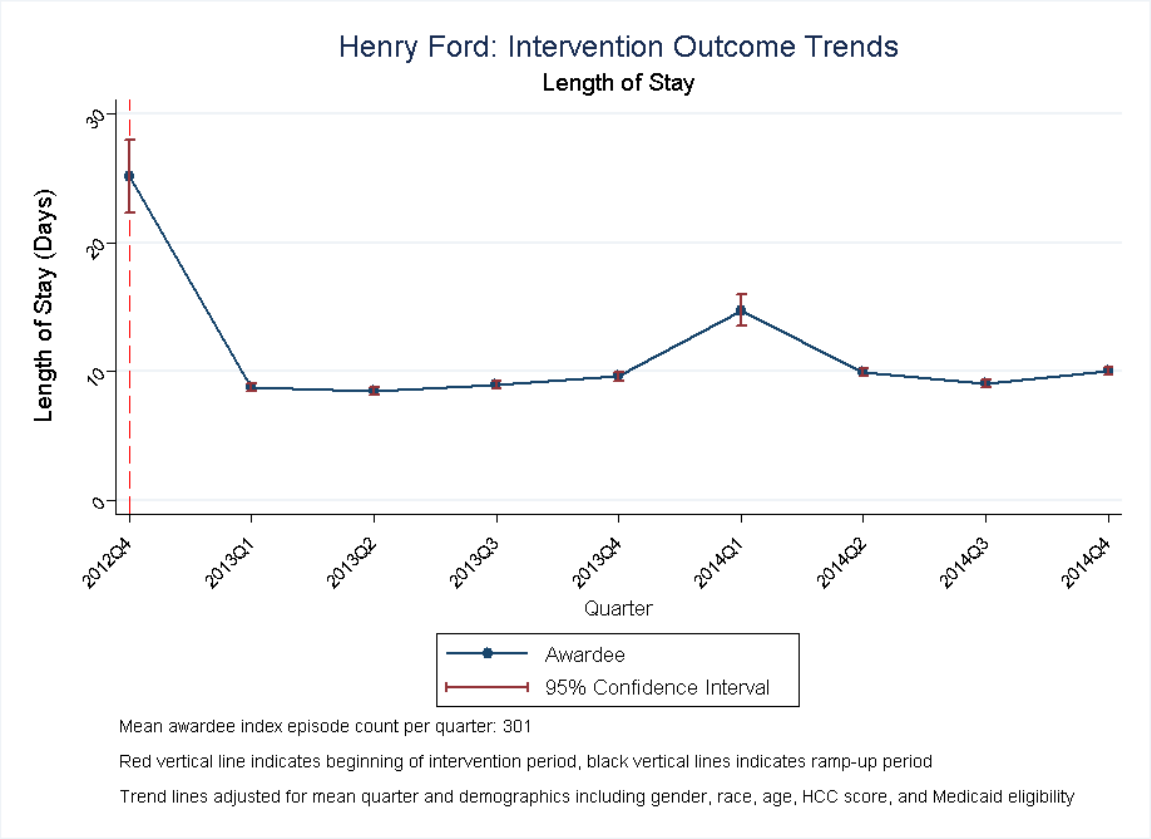


Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

4.1.5 Index Admission Length of Stay (LOS)

Important goals of the Henry Ford program are to improve mobility and reduce respiratory and other complications, which together should contribute to shorter length of stay during the Index admission. After the first incomplete quarter, Exhibit 5 shows little change in LOS, except for repeating the pattern of a spike in Q1 2014 that we saw in other measures.

Exhibit 5: Index Admission Inpatient LOS



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

4.1.6 Conclusions

- We find some evidence that the readmission rate may be decreasing significantly in the last quarter, although we cannot attribute this change to the intervention.
- We see no evidence of changes since the start of the intervention for any of the other utilization and spending outcomes.

Appendix B5: Mayo Clinic

Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation (ProCCESs AWARE)

1. Executive Summary

This chapter presents quantitative and qualitative findings of Abt Associate's evaluation of The Mayo Clinic's Hospital-Setting Health Care Innovation Award (HCIA) to develop *ProCCeSs AWARE*, or the *Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation* (hereafter referred to as "AWARE"). AWARE is an electronic interface used in intensive care units (ICUs) that displays dynamic, real-time data for all patients in the unit. The layout and presentation of data in AWARE is designed to improve clinicians' ability to prioritize and respond to patients' needs within the unit. The goals of the AWARE program are to reduce physician cognitive overload and resulting errors, improve communication between nurses at shift hand-offs, and improve patient health outcomes.

The program was first implemented at the Mayo Clinic in Rochester, MN. Overall, clinicians who oversaw implementation report that AWARE is easy to use, improves clinician efficiency and focus, supports better communication between clinicians, and enables bedside nurses to spend more time with patients. While training of ICU staff to use AWARE was not universal, many clinicians who were trained became AWARE "super- users" and informally trained their colleagues and promoted daily use of AWARE in their units.

AWARE was expanded to three additional acute care hospitals with which the Mayo Clinic has partnerships and to two other Mayo Clinic locations; these other sites will be included in future analyses if data become available.

AWARE was developed with input from ICU physicians and nurses, and applications and interfaces meet many of their needs, as evidenced by widespread adoption. In less than one and one-half years since roll-out in the Mayo Clinic Rochester, over 80 percent of users in participating ICUs consistently use AWARE. Program staff anticipate that widespread use of AWARE will lead to shorter length of stay (LOS), reduced need for post-acute care after hospital discharge, and reduced Medicare spending.

We analyzed the impact of the AWARE program using Medicare claims data. We developed inclusion and exclusion criteria for intervention and comparison groups based on the patient registries supplied by program staff, and compared the change in outcomes over time for intervention and comparison group beneficiaries. The outcomes that we examined included Medicare 60-day episode spending, 30-day hospital readmissions and emergency department (ED) visits, inpatient LOS, and discharge destination. We consider results to be conservative estimates of the true program impact, because we could not perfectly match intervention and comparison groups using data available in Medicare claims.

Difference-in-differences regression analyses using Medicare claims showed no significant change over time for Mayo Clinic patients in average 60-day Medicare episode Medicare spending. The estimated inpatient LOS for Mayo Clinic Rochester patients increased significantly as a result of the intervention. There was no impact on 30-day readmissions, but estimated ED visits in the 30 days following discharge declined as a result of the program. Analysis of discharge destination indicates that over time, intervention patients were less likely to be sent directly home without home care, and more

likely to be discharged to "other" destinations not including institutional post-acute care (e.g., short-term hospitals, intermediate care facilities, hospice, outpatient care)[29] relative to the comparison group.

Increased LOS and fewer patients being able to go home without additional services seem to indicate that the ICU population at the Mayo Clinic became sicker over time, relative to the comparison group—probably for reasons unrelated to the AWARE program. We note that the Mayo Clinic draws patients from across the nation and internationally, while the comparison facilities (in Minneapolis) of similar size and teaching status most likely do not. The decline in post-discharge ED visits may be because more patients were discharged with additional services such as home health care, which reduced the need for ED visits in the weeks following discharge.

2. General Research Domains

The core domains for the Mayo Clinic evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of HCIA funding; the business case and funding

[29] We did not run analyses for each of the "other" categories because the number of responses in each category was too small.

opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.

- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Description of the Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation (ProCCESs AWARE)

The Mayo Clinic (Mayo) was awarded a Hospital-Setting Health Care Innovation Award (HCIA) to develop and test an electronic data dashboard in its intensive care units (ICUs). ProCCeSs AWARE, or the Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation scans Mayo's electronic medical record (EMR) and other ICU data systems for relevant clinical information and presents it on a single screen, organized by organ system. AWARE offers clinicians built-in best practice alerts for error prevention, practice surveillance, decision support and reporting. It provides real-time access to critical information necessary for effective medical decision-making. The AWARE prototype investigated in this case study has been implemented to varying degrees in the ICUs of three Mayo clinic sites and three partner hospital sites.

3.1.1 AWARE Program Goals

AWARE aims to help clinicians process and prioritize patient information by streamlining data display to reduce "cognitive overload," reduce provider errors, and improve patient health outcomes. The primary goals of the project funded by the HCIA are to modify the program based on pre-Award pilot test feedback, expand the program's software capabilities, and implement the program in the ICU setting. The program was first implemented in four ICUs at Mayo's primary campus (Mayo Rochester); AWARE was expanded in 2014 to Mayo hospitals in Scottsdale, Arizona (Mayo Arizona) and Jacksonville, Florida (Mayo Florida). Although these sites were not originally part of the Mayo Award, HCIA funds supported training and some technical support at these sites. AWARE was then expanded to ICUs in three additional acute care hospitals with which the Mayo clinic has partnerships: Montefiore Medical Center in New York (Montefiore), Lawrence General Hospital in Massachusetts (Lawrence General), and the University of Oklahoma Medical Center (Oklahoma). The overall project team has set specific goals for AWARE that include achieving 90 percent adherence to ICU best practices (which are programmed into AWARE), and reducing preventable ICU complications by 50 percent. The project team also anticipates that costs of caring for ICU patients will decrease by up to 20 percent, with a three-year savings of $81 million.

3.1.2 Impetus for the AWARE Program

The impetus for the AWARE program was the inefficiency of accessing information from EMRs and multiple ICU data systems. EMRs often contribute to "information overload" through delayed and out-of-context presentation of an enormous amount of data rather than streamlining and prioritizing presentation of information contained in patient records. Difficulty assimilating and acting on this poorly-organized information can disrupt provider workflows and impede patient safety. The problem is particularly acute in the ICU where the pace and intensity of care necessitates the use of multiple monitors, life-sustaining equipment and interventions, which increase the amount of data that accumulates for each patient. The

AWARE program was designed to save clinician time by displaying the most relevant and high priority patient data from multiple data systems in a single application, and present the information in an organized dashboard format.

3.2 Mayo Clinic Case Study Methodology

The HCIA Mayo case studies were conducted in two parts. On May 14 and 15, 2014, a team composed of two staff from Abt Associates and one physician consultant with Telligen (formerly CFMC; subcontractor to Abt) visited Mayo's Saint Mary's Hospital in Rochester, Minnesota. Team members conducted seven interviews and one focus group on site, and observed eight physicians and two nurses using AWARE in an ICU setting. Interviewees included physicians and physician assistants (PAs), nurses and nurse practitioners (NPs), Registered Respiratory Therapists (RRTs), IT specialists, and program leadership. All interviews and focus groups were audiotaped, with participant consent. A team member not facilitating a given interview took notes. Exhibit 1 presents information on the number and type of individuals who participated in individual interviews and focus groups, or were observed at Mayo Rochester during the 2014 site visit.

On January 28 and 29, 2015, Abt and Telligen staff conducted a second round of interviews with Mayo staff by teleconference. Through these calls, the team was able to engage with the majority of AWARE program staff interviewed in 2014, and additional program, IT, and clinical staff not previously contacted. In total, we conducted seven interviews with Mayo staff, including core program leadership; IT specialists; a program trainer; MDs, charge nurses, a PA, NPs, and RRTs. Additional telephone interviews with Lawrence General, Montefiore, and Oklahoma staff were conducted in April and May 2015. For each site, we conducted one interview with project managers and one interview with IT staff. All interviews were audiotaped, with participant consent. A team member not facilitating a given interview took notes. Exhibit 2 presents information on the number and type of individuals who participated in all 2015 telephone interviews.

As noted previously, AWARE was expanded to ICUs at Mayo hospitals in Scottsdale, Arizona and Jacksonville, Florida. However, the research team did not speak to program staff at these sites; rather they gleaned information about implementation processes from IT and program staff from Mayo Rochester who supported implementation at these partner sites.

Exhibit 1: Type and Number of Respondents Interviewed/Observed at Mayo Rochester: 2014

Principal Investigator MDs**	RNs	MDs*	PAs	NPs	RRTs	Pharmacists	Program Administrators/ Managers	IT Staff	Total
3	5	16	2	2	4	2	3	2	39

MD: Doctor of Medicine; RN: Registered Nurse; PA: Physician Assistant; NP: Nurse Practitioner; RRT: Registered Respiratory Therapist • IT: Information Technology

*Includes Consultants (attending), residents, and fellows.

**Includes one telephone interview with the Montefiore PI, although the information collected was not included in the report because Montefiore had not yet implemented the AWARE program.

Exhibit 2: Type and Number of Respondents Interviewed at Mayo Clinic and its External Affiliates by Teleconference: 2015

Principal Investigator MDs	RNs	MDs*	PAs	NPs	RRTs	Pharmacists	Program Administrators/ Managers**	IT Staff**	Total
3	2	5	1	2	2	0	6	6	27

MD: Doctor of Medicine; RN: Registered Nurse; PA: Physician Assistant; NP: Nurse Practitioner; RRT: Registered Respiratory Therapist; IT: Information Technology

*Includes Consultants (attending), residents, and fellows.

**Includes staff from Mayo and from external affiliate sites

3.3 AWARE Program Components

The AWARE software aggregates and displays the most pertinent, actionable information about every patient in the target ICUs to create a user-friendly electronic dashboard for ICU clinical teams. This technological solution, designed to efficiently display data, was created in response to the common ICU staff experience of feeling overwhelmed by having to sift through multiple electronic data sources when swift action is needed.

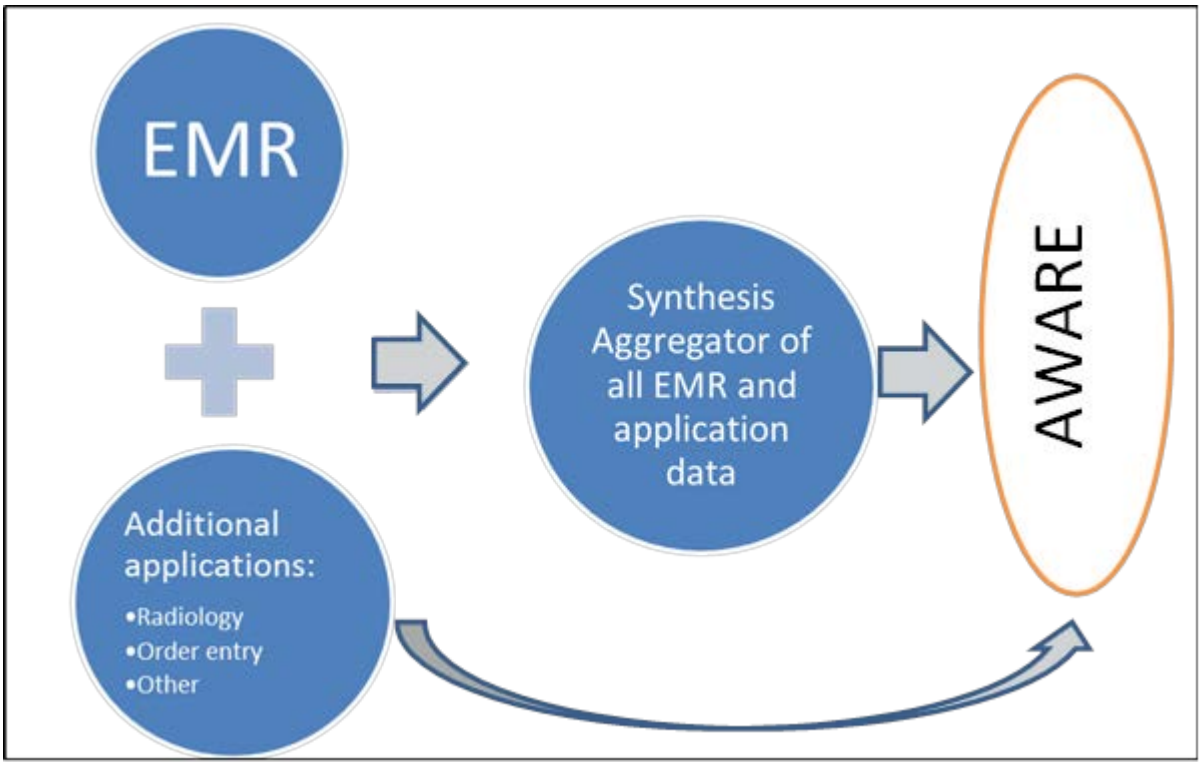
3.3.1 AWARE Design

The AWARE tool is intended to improve decision-making and efficiency in the ICU by assembling relevant information from multiple ICU data systems. It pulls data from the existing patient EMR and other supporting systems (e.g., lab results, radiology, pharmacy, ventilators, monitoring devices) and aggregates the information into a single application. AWARE is available through internet access and can function on multiple platforms including mobile devices via wireless access. It displays data in real time as they are entered into the underlying data repositories/systems. See Exhibit 3 for a visual representation of the systems and their interactions.

> "[Before AWARE] there was no tool that presented data by specialty to enable viewers to see data in a format to improve decision-making and enhance efficiency."
>
> *– Physician AWARE User*

Mayo's EMR and supporting applications (radiology, pharmacy, order entry, eMAR) are available to all Mayo's clinicians. Prior to implementation of AWARE, Mayo used Synthesis, an application that synthesizes information from underlying data repositories. However, Synthesis was not a "smart" tool that organized or prioritized information, or identified deviations from best practice guidelines. In contrast, AWARE aggregates all of the data contained in underlying applications and lives "on top" of the Synthesis application, organizing information into organ-specific presentations and displaying critical values in the summary patient view. Additionally, AWARE has the capacity to allow updated information to flow bi-directionally to the EMR. However, this function was not yet available at the time of site visit or telephone follow-up interviews.

Exhibit 3: Health Information Technology Systems and their Interaction at Mayo Clinic



Source. Abt Associates Inc. Based on May 2014 site visit at the Mayo Clinic, Rochester, MN

AWARE not only syncs with underlying data sources, but also highlights data that are the most relevant to the patient's care needs. By clicking on an organ system icon on the entry screen, the clinician can obtain full access to a patient's data for that system. For example, if a patient entered the ICU due to heart failure, AWARE would highlight recent data related to his or her cardiac system (see Appendix B5.A for a detailed description of the navigation panes of the AWARE tool). Further, AWARE contains embedded best practice algorithms (clinical decision support) that recognize when a patient's values (e.g. vital signs, labs, etc.) are out of normal range and present these critical values on the screen. The most important data are highlighted using colored borders that identify the level of urgency (green, yellow, red). Additionally, important information is also accompanied by symbols (e.g., a heart symbol would be displayed alongside the values for the cardiac system in the patient example above) to signal which organ system is in need of immediate attention. With this design, clinicians can easily identify which organ systems should be addressed first, and the urgency or care without having to synthesize this information from less relevant values.

The AWARE application was rolled out at the Mayo clinic and its partner sites after an evaluation of an earlier prototype of the AWARE application suggested that the software tool had the potential to reduce cognitive load and improve clinical workflows. According to AWARE's physician co-inventor, the traditional EMR structure was designed to support billing and organize data based on the source (e.g., laboratory, radiology, pharmacy) rather than how data was used in care delivery. The AWARE team believes that information displayed by body organ system is more consistent with how clinicians process data and make decisions.

The principal investigators (PIs) and co-inventors of AWARE worked with cognitive psychologists while designing the tool to meet the needs and workflows of an ICU care team. Additionally, the PIs solicited extensive feedback from clinical ICU leaders to incorporate the perspectives of clinicians in the development of AWARE. Furthermore, because the developers were physicians with ICU experience, they understood firsthand the needs of busy clinicians working in that setting. Mayo also enlisted two organizations, Philips Healthcare[30] and Brandix, as consultants to implement the program at sites external to Mayo Rochester. Philips developed the cloud-based (online) version of AWARE that is being used by external sites, and manages data-matching from the cloud to external servers. Brandix manages the user interface of the cloud-based version of AWARE, or what appears on the screen.

3.3.2 AWARE Functionality and Use

One of the benefits of AWARE is its innovative display of patient data. The majority of clinical users we interviewed at Mayo Clinic expressed that AWARE is intuitive, easy to navigate and learn, and improves workflow and efficiency. One resident physician emphasized that she is "addicted" to the tool because it simplifies rounds and improves her ability to care for patients. Training and extensive feedback from staff has helped the project team and application programmers improve AWARE.

Despite positive feedback from physicians, non-physician clinicians (e.g., bedside nurses and RRTs) reported that the tool was too tailored for physicians and did not always address the levels of detail other clinicians require when practicing at the bedside (as opposed to overseeing a unit or doing rounds).To address concerns voiced by non-physicians, more recent iterations of the AWARE tool were customized to incorporate additional applications to record and share data. For example, in January 2015, an application was created specifically for RRTs to record pulmonary data. Other applications have been created to meet the needs of nurses.

Applications are the means by which data are *entered in real-time into* AWARE by staff utilizing the program. The main AWARE applications through which staff enter data or check when tasks have been completed include the checklist, the white board, the task list, and the ability to "claim" a patient. Recently, the Mayo team added a sepsis "sniffer" to alert clinicians of early warning signs for sepsis.

- The checklist function contains items that should be addressed for each patient every day while they are in the ICU. The checklist is reviewed and updated each day during patient rounds. Similar to the AWARE main screen, the checklist is a "smart" tool that can auto-populate specific information from the EMR and other ICU data systems. Checklist data can be copied and pasted into the patient's clinical notes to reduce duplicated data entry. Currently, the IT team is working on designing checklist data that can auto-populate into the notes. The checklist also contains links to a medication order entry system, which allows clinicians to move back and forth between documenting in the checklist and using other data systems.
- The white board was created to allow charge nurses to document their observation notes in an electronic file that was also accessible to the entire team. The electronic white board was also intended to help wean nurses from using handwritten notes. Each ICU has the ability to create customized white board templates for specific teams or patient populations. For example, a Mayo Rochester created templates for common categories of cardiac patients. There are also blank areas

[30] Philips Healthcare's role in AWARE program implementation will be described in more detail in the *AWARE Workforce Development/Training* section

in the templates where nurses can write extra notes, such as concerns about a patient's emotional state. Nurses can now use the electronic white board template to enter care steps and notes. Further, nurses on other shifts can subsequently customize the templates. The white board effectively replaces the need for nurses to pass on handwritten notes, relay messages verbally, or write on a physical white board during shift changes. A next step requested by nurses is that data from AWARE be auto-populated into templates within the white board application.

- A task list can be created and shared with any member of the ICU team to manage personal tasks (i.e., someone making a note to themselves), assign follow-up tasks to others, and communicate when a task or order has been completed.
- AWARE allows ICU physicians to "claim" a patient and take additional oversight responsibility for his or her care. This application allows for clear indication of who should be alerted if the patient's condition changes or if there is a question about a patient. A patient can be claimed by multiple physicians if they have different roles (e.g., attending, fellow, resident); and, each physician can claim multiple patients. If a patient is not "claimed" he or she will still be followed according to the standard protocol by the ICU team. Claiming a patient serves to clarify workflow processes and helps prevent duplicative efforts among members of the team.
- Finally, the sepsis "sniffer" application was designed to track warning signs of sepsis and alert providers if any of their patients are exhibiting septic criteria. This alert includes a care model with steps to take to address the problematic symptoms.

One AWARE application that has not yet been implemented at any hospital is one that is designed for the patient and their family. A patient/family module was proposed in Mayo's HCIA application, and would allow patients and their families to access a portal containing relevant patient data directly from AWARE without the need of assistance from hospital staff. The project team noted that the module is in the testing phase and requires additional work before it is a functional interface for patients and family members.

3.4 AWARE Program Implementation

In this section, we describe the following aspects of AWARE program implementation: targets of program, process, spread, effectiveness, and fidelity.

3.4.1 AWARE Implementation Targets

The AWARE program was first implemented in one acute care hospital, Mayo Rochester. It was then implemented at affiliate sites in Mayo Arizona and Mayo Florida, followed by Lawrence General in January 2015 and Montefiore in March 2015. Oklahoma was not included as a partner in the original HCIA application, but was added at the request of CMS; implementation in Oklahoma is still in process. The breadth and degree of implementation has varied considerably across these targets, as described below:

- Mayo Rochester: The initial targets of AWARE implementation were clinicians who worked in the four Mayo Rochester ICUs: the Medical ICU, Surgical/Trauma ICU, Cardiothoracic Surgical ICU, and a mixed (Medical/Surgical/Transplant) ICU. All clinicians in these units have access to AWARE. Among the 600 clinicians who work in these ICUs, there is an increasing trend in adoption of the AWARE technology. The use of AWARE is spreading to other ICUs at Mayo Rochester, making it difficult to compare intervention ICUs versus control ICUs within the hospital.

- Mayo Florida: AWARE was fully implemented in two mixed-medical/surgical ICUs at Mayo Florida and in one mixed-medical/surgical ICU at Mayo Arizona.
- Lawrence General: Implementation was cut back at Lawrence General from the two ICUs to just the Cardiac ICU. This change in implementation plan occurred because of compatibility issues with the cardiac monitors in one unit that resulted in that unit being dropped as a target for implementation.
- Montefiore: Montefiore is targeting five ICUs across its Moses and Weiler campuses: Moses' Medical, Surgical, and Cardiothoracic Surgical ICUs and Weiler's Medical and Cardiothoracic Surgical ICUs.
- Oklahoma: Four ICUs are targeted for implementation at Oklahoma, but it is unclear whether or not they will be launched before the end of the AWARE contract. According to the Oklahoma physician lead, implementation at their site was put on hold until after AWARE was clinically launched at Lawrence General and Montefiore, and, as noted, implementation is still pending.

3.4.2 AWARE Program Implementation Process

As described at above, interviews were not conducted with Mayo Florida or Mayo Arizona staff. Minimal information regarding program implementation at these sites was obtained during the Mayo Rochester interviews. For this reason, detailed implementation is described below for Mayo Rochester, Oklahoma, Montefiore and Lawrence General, but not for Mayo Florida or Mayo Arizona.

Initial Program Implementation at Mayo Rochester

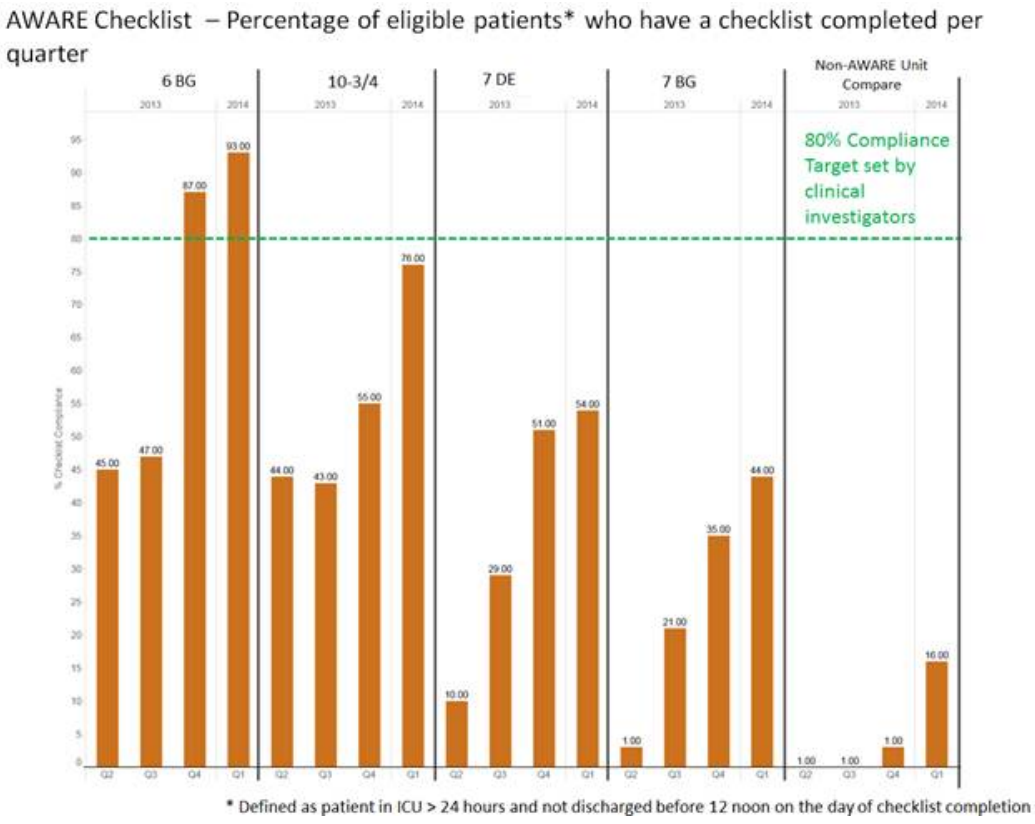
The AWARE program was conceptualized, designed, and developed at Mayo Rochester. An alpha version of the application that displayed information about one patient at a time (i.e., a single-patient viewer) was pilot tested in one Mayo Rochester ICU for six months prior to HCIA funding. Feedback and input from the pilot test were incorporated into a revised version of the application with a multi-patient viewer (i.e., showing summary information for all patients in an ICU on a single screen) and other enhancements such as organ system icons and the ability to view the ICU room layout. Following the Award, AWARE was rolled out in four phases: "go-live," launch, implementation and full implementation at each of the targeted Mayo Rochester ICUs (for details on the launch, please refer to Appendix B5.B, Quarterly Incremental Illustration at Mayo.) Go-live occurred after all hardware and systems were in place (technical go-live) and super-users had access to data (clinical go-live). Launch was comprised of the first few weeks of implementation and involved training and coaching sessions. Implementation was the period of time between the clinical go-live and full implementation. AWARE was considered at full implementation when the checklist function was completed for 80 percent of patient days in the ICU. Formal staged roll-outs occurred in four ICUs; however, clinicians are free to use AWARE in any ICU in the hospital. Currently, use of AWARE is spreading organically as more clinicians experience the advantages of using this tool.

An important component of AWARE is the rounding checklist that was added in Quarter 3 (January–March 2013). The checklist pulls together data from multiple electronic data sources and configures a clinically relevant, patient-specific checklist for structured, multidisciplinary morning rounds. The checklist helps ensure routine consideration of best practices. The checklist was developed for regular daily use to decrease complications and improve patient outcomes, and is monitored by the project team. Checklist use rose steadily in its first year of implementation (March 2013–2014) in the four target ICUs, as shown in Exhibit 4. In its second year (March 2014–February 2015) the use of the checklist in ICUs rose and then plateaued at 85 percent, represented by the green bars in Exhibit 5 (checklist use is

presented by month). While this graphic represents checklist use in one specific ICU, this trend is representative of checklist use in other ICUs.

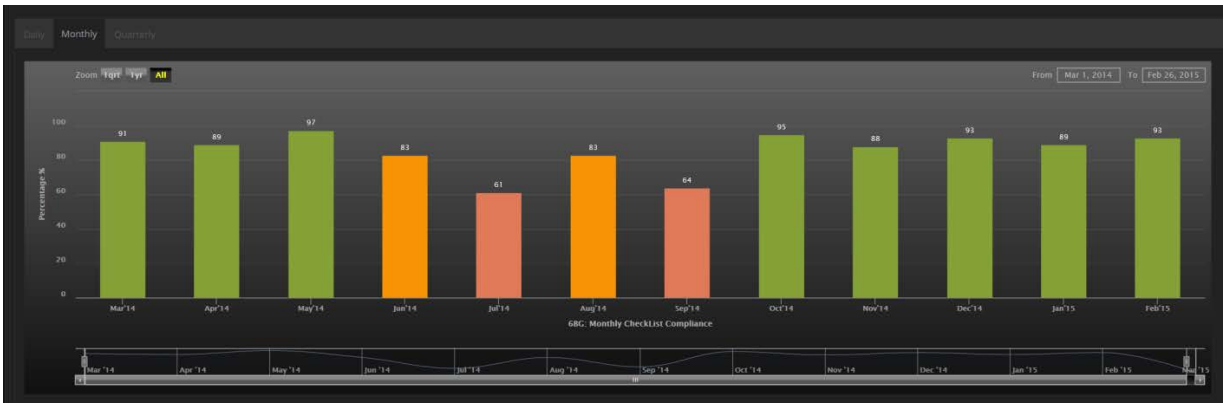
During launch days, the AWARE team set up a specific room in each ICU where nurses, physicians, pharmacists, PAs, and NPs could learn how to use the program, ask questions, and discuss the utility of AWARE. Sessions included an all- day program at the start of the launch, followed by one-on-one coaching as clinicians worked with AWARE in the ICU. Clinicians reported that it was helpful to have a multidisciplinary group of clinicians coming together to discuss AWARE and learn from each other's accomplishments and challenges in using the program. One NP stated that a big hurdle with any new tool is that one group might be more willing than another to implement it. For example, nurses might tend to adopt a new tool but not physicians, or vice versa. This varied adoption of a technology reduces the full potential of the tool and minimizes opportunities for cross-discipline communication among clinicians. Involving the entire ICU team in the launch of AWARE helped to avoid the lack of communication among different types of clinicians. Program staff reported that they have made strides in encouraging new user groups, such as respiratory therapists, to adopt the tool.

Exhibit 4: AWARE Rounding Checklist Completion Results per Quarter for Mayo Target ICUs and non-AWARE Comparison Unit: 2013-2014



Source: HCIA Quarterly Progress Report Narrative submitted by the Mayo Clinic to CMS for Quarter 7

Exhibit 5: AWARE Rounding Checklist Completion Results by Percent Use per Month for One Mayo Target ICU: 2014–2015



Source: Mayo Rochester AWARE Usage Report Q1 2015, submitted by Mayo Clinic to Abt Associates, April 2015

The program staff realized that they needed to understand the implementation environment and workflows in order to optimize the functionality of AWARE and minimize the learning curve. Prior to the HCIA Award, they conducted research in the ICU to gain insight about the potential use of the tool and additional aspects of the implementation process that would facilitate adoption. The AWARE team learned that implementation should be customized for each ICU and each hospital. As such, the team conducted assessments at each Mayo ICU and each partner hospital in order to design appropriate implementation strategies.

One of the most important aspects of implementing the AWARE program was the process of engaging clinical staff and obtaining their buy-in. Although AWARE is easy to use, buy-in and adoption were not immediate because of clinicians' busy schedules and limited time available to devote to learning a new IT application. Initially, non-physicians resisted the program, especially before applications supporting their work were developed and implemented. However, program staff observed that as clinicians began to see the value in AWARE, ease of use and adoption of the system increased among other staff within their units.

Initial Program Implementation at Oklahoma and Montefiore

As noted previously, AWARE has not yet been clinically launched at Oklahoma.

Montefiore was the pilot site for implementation external to Mayo. Montefiore began rolling out AWARE in the fall of 2014 with use steadily increasing to over 900 unique log-ins by April 2015. Montefiore is unique among the non-Mayo sites because it is using physical servers as opposed to virtual servers to house the AWARE data; physical servers were easier to obtain and get up and running than virtual servers. However, using physical servers has slowed data processing, causing overall implementation delays, as described in the Technical Complexity section (11.5), below. Furthermore, some software interfaces are still being evaluated and some functionality still need to be deployed. For example, the sepsis sniffer has not yet been integrated into AWARE and the checklist has been deemed too cumbersome for use by most staff. Despite this initial success, the official clinical launch date of AWARE at Montefiore is under debate. During a May 2015 interview, the Montefiore PI reported that AWARE had not yet been clinically launched at that site. In contrast, the Mayo PI who oversees the entire HCIA Mayo project stated that Montefiore's official launch was March 23, 2015. The discrepancy in the official launch date lies in the fact that although many clinicians are utilizing AWARE,

the tool is not yet fully functioning. The Montefiore PI believes that until all functionalities are available, the clinical start date cannot be assumed. In contrast, the Mayo PI considers AWARE to be clinically live due to the current volume of use.

Initial Program Implementation at Lawrence General Hospital

The implementation of AWARE at Lawrence General has been met with resistance. Although the program was initially launched at Lawrence General in early 2014, several challenges hindered its uptake. First, technical glitches rendered the data unreliable, and support from Philips was not readily available. Once the current project manager was hired, she insisted on support and Philips became more involved in resolving the data issues. Following these efforts, the program became technically stable and officially launched in October 2014.

Despite its official launch, initial use of AWARE at Lawrence General was limited due to few available users and a lack of interest in adding a new tool to clinicians' workload. Although the Lawrence General project manager trained every nurse and RRT in spring 2014, none of the trainees were interested in utilizing the program, citing technical problems that rendered the data unreliable as barriers to adoption. The project manager has since conducted additional one-on-one education sessions, but a lack of interest persists because use of the tool is not mandatory. In addition, the coronary care ICU, the single target unit of the intervention at Lawrence General,[31] lacked a physician to champion responsible for promoting the AWARE program. It was not until January 2015, after a new intensivist was hired to champion AWARE, that the program was utilized with any consistency. There are currently only two users of AWARE in one ICU at Lawrence General, and the project manager does not expect to engage additional users. The project manager noted that, "unless it is required, no one is going to use it."

Finally, Lawrence General experienced two budget cuts during the implementation process that limited the scope of their AWARE training program and limited their ability to purchase needed equipment, such as monitors, to continue implementation as planned.

3.4.3 AWARE Implementation Spread

AWARE was deployed outside of Mayo Rochester beginning in 2014. The implementation process was adapted to fit the context and resource needs of each of the partner sites. Mayo Florida and Mayo Arizona implemented AWARE via a local server in the same fashion as Mayo Rochester. Implementation at these partner sites was faster than at Mayo Rochester, likely because Mayo Rochester conducted pilot testing of the initial versions of the program so the partner sites were able to skip this phase, and implement a beta version of AWARE.

The biggest difference in how AWARE is implemented at non-Mayo sites is that it is executed from a cloud-based format rather than a local server. The cloud program, developed by Philips, is used by all external, non-Mayo sites that use AWARE. However, the same functions work across all systems (internal vs. cloud) when data are transferred from the EMR to the AWARE platform. When implementing cloud-based AWARE, programmers map the site's EMR data and translate it into a format that AWARE can recognize. One technical coordinator is responsible for overseeing the process of cloud-based format implementation across all sites. Although IT staff planned to use the cloud-based

[31] First, it was launched in only one unit rather than two as originally planned. The cardiac monitors in the second unit were incompatible with the AWARE program so that unit was dropped as a target for implementation.

format at non-Mayo sites, they underestimated the length of time required for implementation and did not foresee additional challenges.

3.4.4 AWARE Program Implementation Effectiveness

Overall, AWARE was implemented effectively where sufficient technical and leadership resources were present. Mayo Rochester benefited from having staff that provided oversight and technical assistance and resources in a single centralized location. Additionally, AWARE buy-in was immediate at Mayo Rochester because the inventors and champions of the program are also on site. However, due to the variability in resources, in IT processes and in buy-in, the AWARE team has had to tailor the approach to implementation at external sites, which has presented managerial and technical barriers. According to the clinical PI, "We learned over time that an official implementation strategy, a single universal approach, fails." As a result of the changes in the implementation process, timelines for AWARE implementation have continued to lag behind schedule, resulting in fewer ICUs coming online in the timeframe Mayo originally envisioned. Below, we describe program effectiveness among AWARE users including clinicians, RRTs and nurses across implementation sites. We then we describe specific barriers to successful implementation at each site.

The Mayo Rochester clinicians we interviewed unanimously reported that AWARE is effective in saving time and presenting the most important and clinically relevant information. One PA reported that before AWARE, when patients were first admitted to the ICU, clinicians spent as much as two hours writing lab orders, taking histories, and performing other tasks related to admission. These tasks are still performed; however, the accessible information displays in AWARE have expedited the process. AWARE not only lets users obtain useful reports, but also allows clinicians to gather detailed information about specific organ systems. For example, AWARE has an application that allows users to click a button to see patient data points over time (e.g., fluid balance over the past seven days), which can aid physicians in prescribing. To produce this trend report, AWARE pulls information that has been entered into the EMR from various unit-specific sources and produces one report containing a patient's fluid balance. Similar trend reports for vital signs such as heart rate or blood pressure can be displayed in AWARE.

A few clinicians we interviewed acknowledged flaws in the AWARE application. Some mentioned that medication lists and orders are not always up to date. As a result, clinicians cannot rely on these data and must verify using the underlying medication ordering software or the EMR. One physician conceded that no EMR handles medications well, but pointed out that AWARE takes a useful next step by linking medication lists to the organ systems being targeted. Another clinician wished IT staff would alert users when new features of AWARE went live so they could explore the additions and apply them in clinical practice. Although some users have complained about AWARE's effectiveness, the program has, overall, been a positive or neutral tool for the Mayo Rochester workforce.

Most interviewees explained that the rounding checklist improves communication and quality of care by assuring routine attention to best practices. One physician noted that when he started working as the director of critical care, he challenged each ICU to develop their own rounding structure and checklist, and the result was "a nightmare" because people did not know what to do. They lacked direction and the ability to organize the process in a useful way. AWARE organizes morning rounds by giving the process definition and providing clinically relevant, patient-specific data. However, one physician remarked that he does not think that ICU staff use the checklist and whiteboard effectively for communication. Ideally, a clinician might take advantage of these applications within AWARE and add missing tasks to a patients'

checklist, allowing all the members of the team to view these changes and claim tasks for future completion.

RRTs found the tool to be effective. One RRT stated that AWARE provides a more global picture of the patient; a systems perspective that can be absent when sub-specialist focuses only on his/her specialty concerns. AWARE is credited with helping RRTs spend more time at the bedside because AWARE allows them to easily retrieve information that is only pertinent to respiratory therapy.

> "AWARE presents information visually with the symbols. There are icons for [organ] systems, so at a glance you can see the most intensively sick patients at the start of your shift, and in the ICU a lot could have changed during the time when you are writing notes. With AWARE you are able to bring up information and within 30 minutes you are with your patients."
>
> *– NP AWARE User*

Nurses were mixed in their assessment of AWARE's effectiveness. Bedside nurses have lamented that AWARE's focus on the big picture is less relevant to their work. One beside nurse admitted, "AWARE hasn't changed anything for me at all [in how I do my job]." Bedside nurses still rely more on Synthesis, a nursing-specific application, to retrieve and track data points. One nurse who alternates between being a charge nurse and bedside nurse reported that the relevance of the AWARE tool varied depending on her role in the unit on a given shift. As a bedside nurse she does not use the tool, whereas in her role as a charge nurse she values the ability to see her patients' progress across the unit. However, nurses agreed that AWARE has become more useful over time and, for the most part, nurses view the technology as an effective tool for data collection and collaboration among team members. Even among staff that have been fully trained to use AWARE, not everyone has made the complete switch because some are resistant to using it, or feel that an existing non-AWARE application is more useful. Most notably, as described above, some charge nurses still prefer to use handwritten notes to gather patient information and share the information during shift change. In 2014, we observed AWARE being used in an ICU during the morning shift change and observed night nurses entering notes into AWARE from paper notes they had made during their shift.

Barriers to AWARE Implementation

There have been minor implementation challenges in Mayo Rochester ICUs. Overall, the primary barrier to adoption of AWARE at Mayo Rochester has been overcoming staff resistance to learning a new technology. Program staff encountered reluctance among some clinicians, particularly nurses, to use AWARE because the tool requires that clinicians significantly restructure existing workflow processes (e.g., abandoning hand-written progress notes in favor of tracking them in AWARE's electronic whiteboard). Barriers encountered at Mayo Rochester have largely been overcome with time. Resources were appropriated to develop applications that are fitting for all staff, and staff has had more training and experience using the program. Additionally applications and training have increased staff buy-in. Nonetheless, a small number of staff at Mayo Rochester sees little value in AWARE and remain resistant to learning any new software program.

The challenges encountered at non-Mayo partner sites have been more significant and persistent than those encountered at the Mayo sites. In general, non-Mayo sites have fewer resources to support implementation. These include the absence of a program champion, less program champion time, and/or fewer dedicated program staff. The cloud-based system used by non-Mayo sites has also created implementation challenges because it requires local staff rather than Mayo Rochester staff to oversee the EMR mapping process. Mayo Rochester IT staff explained that implementation has varied across Mayo and partner sites, in part "because they have different levels and styles of management." The Mayo project manager added, "The trick is getting effective champions at the different sites to work through

implementation. [AWARE] is not just a product; it's a different way of working and thinking—so [staff] need support to make that change." For example, the Mayo Rochester trainer explained that leadership had been more compliant and communicative at Mayo Florida than Mayo Arizona, which made progress at the former site much smoother.

It took Mayo Rochester program staff some time to learn each site's organizational structures and approval processes so they could execute the steps needed to move the project forward at sites outside of the Mayo system. As a Mayo IT program staff member explained, "Because we don't have access to the site's EMR systems, we cannot tell if the data are being rendered correctly on-site. That delayed things because we didn't realize there were issues until their staff finally began to use the software and alerted us." On the other hand, all three non-Mayo sites, Lawrence General, Oklahoma, and Montefiore expressed initial difficulty engaging Mayo staff and its consultant partners, Philips and Brandix, which largely served as the liaisons for external sites, to provide technical support. The external sites explained that once Philips and Brandix became more responsive implementation progressed more quickly.

Non-Mayo sites also lacked important information about IT specifications in advance integration. At Montefiore, AWARE data are not being processed properly at the cloud-based level before being integrated into the Montefiore's servers so that data being fed to the Philips server, and later to the Brandix server, is not technically compatible with Montefiore's data specifications; this has required reworking of the technical specifications, in turn causing delays. In addition, competing demands on IT staff at partner sites meant that AWARE was sometimes relegated to a position of lower priority, which slowed implementation progress. For example, in the spring of 2014, when Montefiore should have launched AWARE, they were in the process of implementing a new EMR system which consumed much of their IT staff's time and resources, thus delaying AWARE implementation.

3.4.5 Fidelity of the AWARE Program

While the same AWARE software program is being implemented at each site, rates of implementation and uptake by staff have varied by site and by ICU within sites. Within sites, AWARE is used similarly in all target ICUs and across all clinicians of the same type (i.e., all attending physicians, all charge nurses). However, each group has adopted AWARE into their daily practice at different rates. For example, at Mayo Rochester, RRTs were the first non-physician clinicians to use AWARE in 2014. Eventually, nursing leadership decided to start AWARE implementation with charge nurses followed by bedside nurses; however, this roll-out is still incomplete. Furthermore, bedside nurses reported perceiving less value in AWARE. Bedside nurses said their need to focus on individual patients at a granular level was a barrier to adopting AWARE. In contrast, charge nurses oversee a unit and benefit from the broader view that AWARE provides. In addition, it was reported that some staff nurses, such as those working the 10AM to 3PM shift, use AWARE more frequently because they have had access to the program for a longer period of time. In short, although the program is implemented consistently, use of AWARE among staff within a unit is not consistent.

Since AWARE was only recently implemented at Montefiore and Lawrence General and had not yet been implemented at Oklahoma at the time of this report, it is difficult to gauge fidelity across sites. However, early reports suggest that use and dissemination vary depending on the workforce configurations. Because each partner site has a unique IT infrastructure and different uses for their ICUs, AWARE has not been used in the same way across sites. This variation in use has also been coupled with different rates of adoption of the tool. At Lawrence General, for example, use of AWARE is limited to two physicians in one ICU, undoubtedly a contributor to slower initial uptake of AWARE. Furthermore, lack of a program

champion and lack of interest to use the program were especially problematic at Lawrence General, where the project manager commented that implementation of the AWARE program is profoundly burdensome for such a small hospital. During the pilot phase of implementation at Montefiore, residents and PAs used AWARE for "tasks and goals" as well as morning rounds, and attending physicians and nurses used it at sign-out. The checklist functionality is not yet operational at Montefiore because it is too slow, thus additional IT trouble-shooting needs to be conducted to improve the efficiency of this application. Fidelity of the program cannot be assessed at the Oklahoma site since AWARE has not yet been implemented.

Adoption of AWARE at Mayo Florida and Mayo Arizona has been high. The Mayo Rochester program trainer reported that the use of AWARE has become widespread at Mayo Florida and Mayo Arizona, with staff at all levels using it consistently. These partner sites benefited from implementing a version of AWARE that had been pre-tested at Mayo Rochester. As a result, the new version of AWARE had fewer software bugs and contained new features tailored based on the requests of Mayo Rochester nurse and RRT users. The hospitals at Mayo Florida and Mayo Arizona only implemented the program in one or two ICUs, with multiple users and teams adopting the tool in each unit. From the program trainer's perspective, this focused implementation has allowed for quicker and more widespread adoption of AWARE due to the hospitals' cross-training and cross-functional teams. She noted that "[Mayo Florida] staff is so much more involved in using AWARE; all staff, including the case manager and physical and occupational therapists were trained in AWARE. By contrast, at Mayo [Rochester] even charge nurses, NPs and PAs have been less involved. Having eight ICUs [poses] more barriers to getting approval for training in Rochester."

At all sites, with the exception of Oklahoma, program staff continues to hold trainings to familiarize clinicians with the AWARE tool. At Mayo Rochester, the program trainer has conducted supplemental one-on-one sessions with those initially resistant to using the program to answer questions and alleviate apprehension. Although there are still "non-adopters" across all sites, program staff are confident that the culture has tipped in favor of AWARE. However, as long as new applications continue to be added to the tool, consistent use may be difficult to achieve.

3.5 AWARE Trialability, Adaptability and Technical Complexity

3.5.1 Trialability and Adaptability

The AWARE program and its applications were created and revised in direct response to feedback from clinicians, most notably nurses. Input from physicians has also led to changes that enhanced the scope and robustness of the software. Feedback has come, in large part, from "super-users" who were identified by program leadership or who took it upon themselves to use the tool extensively and to gather feedback from peers. Peer-to-peer training and knowledge sharing with super-users has enabled more effective use of the tool by ICU team members including senior clinicians, NPs, RRTs, pharmacists, residents, fellows and nurses. Wider adoption by clinicians, especially nurses, has in turn led to improved feedback loops between IT and program management. This communication has led to improvements in AWARE's functionality and has also fueled the creation of applications that facilitate patient care and workflow in the ICU.

> "Data consumption is different for every [ICU] because it is based on an internal way of working; it is very complex to work in an ICU. With AWARE, they have built an infrastructure that works for the ICU."
>
> *–AWARE Program Staff*

The need for continual adaptation and customization of AWARE stems from the inherent technical challenge of

presenting complex information in a simplified manner. One of the challenges reported by program staff was how to adapt AWARE for use by different teams and ICUs. Wide variation in the needs of clinical staff has influenced many ICU teams to customize how they use AWARE in their practice. To allow this flexibility, program management does not prescribe a specific workflow for AWARE users and does not implement a training requirement for all staff, although multiple options for training are available.

As noted above, AWARE was developed for adaptation at partner sites through a local server or as a cloud-based application. Mayo Florida and Mayo Arizona implemented AWARE via a local server in the same fashion as Mayo Rochester, so implementation was smoother than a sites that implanted the cloud-based application. However, at non-Mayo sites where AWARE is being executed from a cloud-based format (i.e., housed on a virtual server) rather than a local server, adaptation has been much more technically challenging and has taken considerably more time to implement. The cloud program, developed by Philips, has the same functions as the local server version when data are transferred from the EMR to the AWARE platform, but it has taken longer than expected to program the specifications, map EMR data, and translate the data into a format that the cloud version of AWARE can recognize. In addition, partner sites reported that Philips was not initially responsive to technical needs of the partner sites.

3.5.2 Technical Complexity

AWARE is highly complex in several aspects. The Award itself is complex because it engages subject matter experts in many arenas (e.g., cloud-based technology, database structure, data mapping) that work together to design and implement the program. These partners are not co-located and do not have the resources to travel, thus collaboration must be virtual. Data composition and storage also vary across hospital departments (e.g., EDs, ICUs, and "floor" units), creating challenges when aggregating information and integrating it into workflows that often vary across departments. Further, the sources of data used in the AWARE program are drawn from multiple systems within a single hospital (e.g., EMR, order entry, lab, pharmacy, electronic medication administration systems, ventilators, monitoring equipment).

Technical complexity also arises from barriers to collaboration across locations and variability in the underlying IT systems. These factors have been important barriers to the full implementation of AWARE at Montefiore and Lawrence General, and appear to be factors that would have impeded implementation at Oklahoma, had that site progressed further in its implementation.

Overall, technical complexity at external sites stemmed largely from the fact that each site had to map its internal IT infrastructure to AWARE's specifications. Many sites had multiple systems to map to AWARE, further complicating the integration. For example, at Lawrence General, integration of the program was technically complex because Lawrence General has five Health Level 7 (HL7[32]) interfaces that had to be mapped to AWARE. For each of these interfaces, there is a "send" and "receive" system that was mapped to ensure that the messages coming from the existing "sending" system conform to and can be interpreted by the "receiving" system.

Montefiore's technical complexity stemmed more from missing data and latency in data transfer. Originally, the majority of the issues Montefiore encountered were due to missing data that were lost

[32] HL7 is a comprehensive framework and set of related standards for the exchange, integration, sharing, and retrieval of electronic health information.

or incorrectly populated from Montefiore servers, but those issues have largely been fixed. Now the issues are happening at the cloud-based level, and need Brandix's intervention to be fixed; this has been a persistent problem. Further, there are interoperability problems between the AWARE applications (i.e., checklists, white board data) and the EMR. Data entered into applications that are not in the EMR are not automatically shared with the EMR and EMR data is not automatically uploaded to the applications. Further, AWARE data cannot be downloaded onto systems used in the ED, in step-down units, or in inpatient floor units. Similarly, ED information cannot be uploaded directly into AWARE if a patient is being transferred from the ED to the ICU. Understandably, these data issues have slowed the implementation process and have prevented Montefiore from going clinically live according to the schedule originally anticipated. In early spring 2015, Montefiore reported still needing time to accommodate upgrades and repairs. Montefiore is investigating getting additional hardware to increase Brandix's capacity and performance.

Oklahoma has not progressed far enough in the implementation process to report whether or not technical complexities have been a barrier to implementation. However, initial reports suggest that communication with Mayo Rochester, which is overseeing implementation at all sites, has been strained and that support from Philips and Brandix has been limited. As of now, the Oklahoma PI explained that "the [AWARE] product we [Oklahoma] have developed has really gone beyond our original scope. We now have more data being fed into the AWARE system." For example, patient demographic data, clinical notes, lab results, and cardiology results, and surgical notes are all being fed into AWARE, even though they were not originally included in the scope of work. However, this has caused many servers housing AWARE data at Oklahoma to become overloaded.

3.6 Achieving Better Care, Better Health and Lower Cost

In this section, we discuss the different areas in which program staff believe AWARE is making a difference in quality of care delivery, patient health outcomes and cost savings. For each of these aim categories, we discuss how the Mayo Clinic program team is measuring impact, as well as how Abt Associates intends to measure the program's impact. Finally, we discuss impacts that can be measured using claims.

> "I felt disorganized, but now that I have a clear organized path, the quality of care that I can provide to my patients is much better."
>
> *– PA AWARE "Super User"*

3.6.1 Better Care

The ultimate goal of the AWARE program is to achieve better care by ensuring that clinicians comply with best practice clinical guidelines. Most clinicians we interviewed agreed that AWARE allows them to be at the bedside more than at the computer, which, in turn, is leading to better patient care. One super-user PA said that the quality of patient care he provides has increased dramatically since AWARE was implemented. AWARE presents critical data clearly and in real-time, allowing clinicians to address concerns with the patient right away. One physician reported that "the ability to address clinical concerns quickly leads to better patient outcomes." Physicians, especially residents who are trained using AWARE from the beginning of their residency at Mayo Rochester, enjoy using AWARE, believe it is an effective use of their time in the ICU and think that it improves the quality of patient care delivered. The Program Trainer has also observed that continuity of care has improved with the use of AWARE, with improved communication and information sharing between shifts and across units. One of the program leaders substantiated this observation by noting that they have collected data demonstrating that AWARE saves approximately 15 minutes per patient per day. "It definitely enhances efficiency," he explained.

From the standpoint of a nurse unit manager we interviewed, AWARE is improving care for nurses because it pulls the most relevant clinical data from the EMR and other electronic data systems and presents it clearly to the clinician. "A missed lab value [for example] might harm someone so preventing this by showing more data is helpful," she said. Charge nurses echoed this sentiment, noting that they know more about what is going on with their patients than they did before AWARE. They are more organized because AWARE minimizes telephone and paper information transfer among clinicians. As mentioned above, bedside nurses are more neutral about AWARE, believing it does not directly impact the quality of care they provide.

The Mayo program team collects data on a number of quality measures that are regularly reported to CMS and that are used for internal quality improvement. The measures identified in the Awardee reports to CMS that are used to assess better patient care are listed in Exhibit 6.

Exhibit 6: Mayo Clinic's Quality of Care Measurement Strategy

Compliance with contact and modified contact precautions
Compliance with Ventilator Bundle (VAP)
Central Venous Catheter (CVC) utilization rate
Days of antibiotic use
Days of continuous IV sedation
Hand hygiene, overall compliance
Number of IV device-related bacteremias per 1,000 total IV line days for each Critical Care Unit
Number of "medical events with harm," actual number
Universal protocol, overall compliance
Urinary catheter utilization rate

The program is also documenting utilization rates of its AWARE tool by collecting the data listed in Exhibit 7.

Exhibit 7: AWARE Utilization Rates

Number of Checklists Completed by Clinical Users
Number of clinical user sessions in audit trail log
Number of patients "claimed"
Number of providers trained and using the AWARE system per quarter, by type of provider

3.6.2 Healthier People

The AWARE program is expected to improve health by reducing ICU length of stay, medical errors and associated adverse events, ICU morality, and readmissions.

Some clinicians we interviewed were uncertain that improvements in patient outcomes can be attributed to AWARE because the program is not fully implemented beyond the target ICUs and because not all clinicians are using the tool. In order to attain sufficient power to measure the impact of AWARE in

> "There are so many things happening in parallel so, from a research perspective, attributing these outcomes to AWARE would be a fallacy. Disease-severity and mortality, for example, have improved but I couldn't say this was because of AWARE."
>
> *– Physician AWARE User*

improved health, the program will need to be used on a larger scale with more widespread adoption. Further, according to one physician, it will be hard to attribute changes in quality of care to AWARE, given other concurrent quality improvement initiatives at Mayo. For example, although there has been a decrease in patient length of stay, some staff are reluctant to attribute this to the AWARE program. Mayo is tracking a number of outcomes in their reports to CMS to evaluate better health, as listed in Exhibit 8 below.

Exhibit 8: Mayo Clinic's Better Health Measurement Strategy

Average Hospital Length of Stay (LOS) for ICU Graduates, Unadjusted
Days in the ICU during the index hospitalization
Number of patients admitted to the ICU
Proportion of patients discharged alive from index hospitalization to home
Proportion of patients discharged alive from index hospitalization to hospice
Proportion of patients discharged alive from index hospitalization to long-term care facility
Rate of hospital readmission within 30 days of index hospitalization
Rate of ICU readmission within 30 days of index hospitalization
Rate of mortality during ICU stay, adjusted
Rate of mortality within index hospitalization

3.6.3 Smarter Spending

As noted above, the goals of AWARE include obtaining greater than 90 percent adherence to ICU best practices and reducing preventable ICU complications by 50 percent. Program staff anticipate that these improvements will decrease the cost of providing care by up to 20 percent, translating to $81 million over the three years of the Award. One of the founders of the AWARE program acknowledged that attribution of improvements to AWARE may be challenging. But he pointed out that AWARE "certainly doesn't hurt," and since the data show that length of stay is down, this means costs are down. At this point it is unclear that AWARE is leading to cost saving and if so whether that will translate to lower claims-related payments for Medicare and Medicaid.

3.6.4 Outcomes that Can Be Measured Using Claims

Mayo ICU patients can be identified and described using Medicare and Medicaid claims. By comparing the outcomes of Medicare and Medicaid payments for Mayo patients to the outcomes for a similar cohort of patients from other hospitals, we can begin to measure impact of AWARE on outcomes using a difference-in-differences approach. If similar intervention and comparison groups can be identified, there are a number of outcome measures that can be evaluated using claims, as illustrated in Exhibit 9.

Exhibit 9: Relevant Metrics Available in Medicare Claims Data

7, 14, 21, 30, and 60-day re-hospitalization
7, 14, 21, 30, and 60-day post-discharge ED visits
30-day mortality rate
Inpatient mortality rate
Inpatient length of stay
Percent discharge to LTACH, SNF or home health care
Percent discharge *without* post-acute care
Total 6-month episode costs

3.7 AWARE Workforce Development/Training

The AWARE program has necessitated no direct hiring or acquisition of new resources. Instead, program staff and IT personnel were deployed to work on AWARE from within the relevant hospital system (i.e., Mayo Rochester, Montefiore, Lawrence General, and Oklahoma). AWARE program staff consulted with key ICU team members during the development and implementation stage and have provided training to all staff working in the intervention ICUs. Overall, most staff we interviewed reported improvements in their workloads and workflow after adopting AWARE. Staff that uses AWARE more frequently are more likely to report improved satisfaction with their job as a result of using AWARE.

3.7.1 Workforce Development

AWARE Program Staff

AWARE program leadership includes a program manager, three PIs (the Program PI, the IT Co-Inventor and the Clinical PI), IT leadership staff, and an Implementation Lead/Trainer. In the first year of the project, the team also included a Project Manager whose position was not filled. Instead, the Implementation Lead/Trainer's role was expanded to include the responsibilities of the project manager. All the staff who were interviewed, with the exception of a few members of the IT staff, worked at Mayo prior to the HCIA; however, several of their roles changed or evolved as a result of the Award.

The program manager oversaw federal contracts and Awards for Mayo, including the HCIA. For this Award, she was the liaison between program staff and CMMI. The Project Manager supported the Implementation Lead in planning AWARE roll-out, training, and initial internal marketing/promotion efforts. The Implementation Lead, a senior research fellow and physician, was associated with the AWARE program for three years before the HCIA was awarded. She worked on usability and validation testing of the tool and provided critical feedback to the PIs. She also led the creation of implementation and training plans, first for Mayo Rochester, and then for affiliate sites Mayo Florida, Mayo Arizona, and Lawrence General. In early 2015, the Program Trainer announced her transition to another job assignment at Mayo. As of March 2015, she and other AWARE program staff were orienting a new staff member into the project in preparation for this transition in June 2015.

The Clinical PI is a pulmonary and critical medicine physician and a Vice Medical Informatics Officer at Mayo Clinic with the responsibility of directing the Knowledge and Delivery Center that creates standards and clinical decision-support rules. The Program PI is a Mayo anesthesiologist and ICU physician who specialize in research and development of health informatics for use in intensive care settings. In the initial months of the project, the IT Co-Inventor, Clinical PI and Program PI worked with the AWARE program staff and clinical leaders to develop and iterate the AWARE tool in the alpha test phase and make improvements prior full implementation. At non-Mayo partner sites, program leaders provided oversight for all aspects of the AWARE program. The program at Montefiore was conceptualized and is guided by a physician PI, Oklahoma is directed by a physician leader, and Lawrence General is led by a project manager.

Among clinical users we interviewed in 2014 and 2015, there is a general consensus that there is enough support staff and resources allocated to AWARE implementation and trouble-shooting.

IT staff

When the AWARE project was being implemented at Mayo Rochester, the IT Co-Inventor had a small support staff of informatics specialists. This team was also responsible for overseeing implementation at

Mayo Florida and Mayo Arizona. By late 2014, the staff was pared back to only one full time informatics staff member at Mayo Rochester, both because the initial phase of implementation had ended (and needed less IT support) and because of budget constraints. The original IT staffing plan was to have a site manager at each of the external sites, but this did not come to fruition. Instead, a consultant from Philips Healthcare, who developed the cloud-based version of AWARE, has been overseeing AWARE implementation at external sites. In 2015, this consultant indicated his time was ramped up to a higher FTE over the last year. Non-Mayo partner sites hired IT staff from within their respective hospital/medical center to manage the integration of the cloud-based AWARE with their EMR. None of the sites reported having dedicated IT staff for the AWARE program. As such, AWARE is only one aspect of their job.

Clinicians

While no clinicians were hired specifically for the AWARE project, some physicians were consulted in the early phases to provide feedback on the tool. Subsequently, nurse leadership and other super-users were identified across the four intervention ICUs to provide additional feedback and suggest ways to improve the software. Because there is staff turnover as new fellows and residents begin their rotations each July, continuous training and onboarding to acquaint new staff with AWARE is necessary.

3.7.2 Training

Training of ICU clinicians to use AWARE was designed to be both flexible and to meet user needs. Across Mayo and non-Mayo sites, training is accomplished via a combination of formal training by Mayo staff and one-on-one/train-the trainer programs in the ICU.

At Mayo, in-person, formal training was initially offered to physicians, then to NPs and PAs, charge nurses, and respiratory therapists. Trainers offer each trainee a two-page overview handout with icons and descriptions of how the tool can be used. In-person training takes 30 to 45 minutes and is conducted by either the Implementation Lead or the Program Manager in a classroom setting. Clinical staff are grouped and trained by discipline (e.g., charge nurses are trained with other charge nurses) during these sessions. Training curricula have evolved over time to incorporate feedback and suggestions from clinical leadership and to meet the needs and interests of each trainee provider type.

The following is a list of specific in-person trainings available for Mayo Rochester clinicians:

- Physicians are offered one-on-one training sessions at their convenience.
- NPs, PAs, charge nurses and respiratory therapists can take either on-site training or online training, or both.
- New staff that begin work at Mayo Rochester after program implementation are trained during their initial Mayo orientation.
  - New critical care fellows take a four-hour AWARE boot-camp training when they begin their onboarding, with follow-up trainings on the floor in the ICU.
  - At Mayo Rochester, resident physicians, who rotate into Mayo ICUs for fairly short time periods, receive a training course within three days of their arrival, taught by a super-user in a classroom-based setting.

Mayo Rochester clinical staff acknowledges that there are many opportunities available for training, and that training is informative and delivered effectively. However, several also advised that the training program is not necessarily sufficient for a robust understanding of how to use AWARE in practice. One

individual explained that although he has been working with the tool for over two years, he is still discovering functions that he did not know existed. Similarly, several staff noted that it would be helpful to have access to short and/or "refresher" trainings as new functionalities and refinements to the software are rolled out.

Formal training at Lawrence General and Montefiore was administered by the project manager and PI, respectively. The project manager at Lawrence General trained the three hospitalists during their business meetings and provided them with one-on-one education. In addition, every nurse and RRT received a minimum of one hour of education in 1:1 or 3:1 classes. Montefiore offered one-time training lectures as an introduction to the software, but this approach was viewed as less effective than hands-on training. Due to delays in program development and implementation, Oklahoma has not conducted training.

A clinical staff member at Mayo Rochester explained that although he has been working with the tool for over two years, he is still discovering functions that he did not know existed in AWARE.

In late 2014, IT staff moved the online training materials from Mayo's e-learning system to AWARE itself, so clinicians can now view the materials without logging out of the software. Although some clinical staff were initially offered the option of completing an online training module in lieu of an in-person training session, AWARE program leadership and clinical staff reported that on-site, hands-on training was the most effective method of engaging and educating clinicians about AWARE.

Other sites use train-the-trainer sessions taught by super-users as the primary method for training. Super-users serve as informal AWARE "consultants" who help orient and troubleshoot questions from peers learning to use the program. Mayo Rochester explained that they identify and support super-users to assist with formal training sessions, which was corroborated by Rochester staff. However, of the external sites, only Montefiore reported that this training was offered; all external sites reported that they were using Mayo-provided training by Spring 2015.

At Mayo Florida, they have succeeded in getting almost everyone trained in the ICU via hands-on training. Mayo Arizona has used train-the-trainer sessions to train every incoming staff person working in the ICU, thus people have been using AWARE over time. Montefiore has also provided peer train-the-trainer sessions taught by super-users on a one-on-one basis, and has used print-out fact sheets for staff to have handy with reminders about how AWARE works. These handouts include information such as the meaning of key icons in the interface. This informal, practical basis of training has proven more effective at this site. While the super-user training at Montefiore has been in progress for over a year (since early 2014) with RRTs, PAs, and other ICU staff, the pace of training picked up significantly in spring 2015. Lawrence General has identified a physician champion who is effectively the site-wide super-user. It is important to point out that the model of training a physician as a super-user is likely not sustainable for a larger hospital or in more than one ICU with more than one other user.

A significant component of learning how to use AWARE across all sites has come from peer-to-peer knowledge sharing from super-users, and from extensive reliance on using AWARE during rounds. Some Mayo Rochester clinical users, comparing formal training sessions to hands-on learning, reported that more opportunities for one-on-one, hands-on instruction would improve the training. Super-users who informally train their colleagues agreed that this is the most effective way to disseminate use of the tool. For example, super-users can demonstrate how to incorporate AWARE into rounds or at shift changes. A nurse who recently learned to use the program affirmed that "the biggest hurdle [to AWARE training] is [trainers] standing in front of the room and teaching people how to use AWARE; it's much, much better

to do it one-on-one." However, training can only go so far in disseminating AWARE. Buy-in and practice have been critical to the cultural change required to adopt this complex new tool.

3.7.3 AWARE Program Impacts on Workflow, Workload and Satisfaction

The premise of AWARE is to make the workflow of ICU staff more streamlined and efficient, and to reduce information overload. The program and clinical staff we interviewed all agreed that, despite a few implementation and technological challenges, AWARE has achieved this goal. Because AWARE allows for mobile, real-time data retrieval that is organized in a way that supports care delivery, clinicians have reported spending much less time at computers, and basing more clinical decisions on real-time data.

Clinicians explained that AWARE's simplicity and intuitive navigation has improved workflow. AWARE identifies the patients with the most critical needs, so staff can enter an ICU at the beginning of a shift with an immediate knowledge of where to focus their efforts. Senior clinicians noted that AWARE's ability to gather and clearly present the most important data about each patient limits reliance on junior clinicians (interns and residents) whose responsibility has traditionally been to gather and summarize patient data. Senior clinicians access patient values electronically with a click of a button when they are paged to the ICU and verify information presented by interns at rounds. This limits back-and-forth verification with multiple records and clinicians involved. RRTs that move from one ICU to another have been able to quickly bring up the main AWARE screen with critical data for each patient, reducing their need to interrupt ICU staff for case summaries.

Most clinical staff we interviewed reported that their workload and job satisfaction have improved with the use of AWARE. The staff who are most agile with AWARE and those who reported that using AWARE reduced their workload also said that AWARE improved their job satisfaction. However, some staff believes that they cannot fully depend on AWARE and are not as satisfied with the tool. During the roll-out period, some reporting tools for nurses were not fully optimized in AWARE, making it difficult for them to rely solely on AWARE and requiring them to supplement with "old" methods of documentation (including paper notes). AWARE has been refined over time to include enhancements that help minimize "double" documentation, most notably by implementing the Whiteboard feature for online note taking and sharing. However, some staff continues to report that the software has added another component to their job instead of fully replacing pre-existing workflows. Among clinicians who have successfully transitioned away from paper notes, several reported that doing so substantially decreased their overall administrative burden. This transition required clinical staff to reconsider and reformulate their unit's workflow.

3.8 Context

In the three years prior to receiving HCIA funding, Mayo Rochester laid the groundwork for AWARE. As described previously, a single-patient viewer version of the program was developed and pilot tested prior to the HCIA. Mayo staff conducted research on the potential uses and the feasibility of a dashboard like AWARE. They identified areas where technological and logistical changes were needed to ensure successful program implementation and adoption, and developed site-specific implementation strategies to meet the needs of each participating facilities. The research and pilot study phase, as well as preliminary training and use in one ICU, occurred prior to the HCIA-funded period. HCIA funds were sought to enhance the functionality of the program and extend the program to additional ICUs at Mayo Rochester as well as partner hospitals. AWARE was not previously used in any other quality improvement program at Mayo Rochester, nor was it influenced by Federal and State policies on the HCIA initiative.

3.8.1 Sustainability

The main resources required to sustain the AWARE program in the four Mayo Rochester ICUs will be IT/programming resources to continue making software enhancements and upgrades. In addition, continued training will be necessary as new clinicians are hired or begin rotations in targeted ICUs. Finally, as hospitals invest in new EMRs and other IT systems that integrate with AWARE, additional resources will be required to make sure they properly interface with the AWARE program.

The AWARE program is integrated into the workflow in target ICUs and will likely continue at Mayo Rochester. AWARE program staff and users at Mayo Rochester reported that they received extensive institutional, divisional and IT support from Mayo throughout the implementation process, both before and after the HCIA. Clinicians at Mayo Rochester reported that they believe there are enough resources dedicated to the program currently and in the future to sustain the program.

After Award funding ends, the non-Mayo partner sites will have to determine whether they can maintain AWARE and continue its use in their ICUs. The Mayo Rochester program manager acknowledged that it is likely that their team received more institutional support than some of their partner hospitals. Nonetheless, program staff reported that external sites could receive a sustainability Award from Mayo to continue using the cloud-based solution, or they could implement a commercial version of the AWARE program. The commercial version is essentially an "out of the box" software program allowing external sites to implement the program independently.

If external sites do not continue to use AWARE, Mayo will download all AWARE data from external partner cloud-based repositories and decommission their cloud-based AWARE system. Mayo staff explained that they have already begun to address sustainability with their external partners and have reassured them that maintenance of AWARE is technologically feasible. Sustainability will depend on whether leadership and clinicians at the partner sites believe the AWARE program is a worthwhile investment to maintain.

The long-term sustainability of each of the AWARE programs is projected to vary across the external sites. Mayo Florida and Mayo Arizona are using the institutional version of the AWARE software and can continue drawing on in-house technical support beyond the end of the Award period; the research team did not get any indication that the program would be halted. Given the very narrow spread of AWARE at Lawrence General and the fact that it is a very small hospital, they do not believe the program could be sustained without significant support from Mayo. In contrast, the very large Montefiore Medical Center may have the level of IT and administrative support needed to sustain the program without additional Mayo support.

3.8.2 Unintended/Unanticipated Impacts of the Program

There have been limited unintended consequences from the AWARE program. The most notable is that the AWARE program is in use in ICUs not directly engaged in the intervention. ICU staff who learned to use AWARE in one of the four target ICUs now also use the program in other ICUs and informally share information about the training they received to explain the tool to their colleagues. This informal adoption taking place outside explicit user training is evidence of the ease of use and learning and the value of the tool for clinicians.

3.9 Conclusions and Next Steps

AWARE offers clinicians a data display, communication, and decision support tool to foster best clinical practices in critical care settings. Clinically relevant, patient-specific information is displayed on a dash-

board in a manner that reduces information overload, prioritizes patient needs, and promotes more rapid patient assessments. The goal of AWARE to help clinicians process and prioritize information about critically ill patients to reduce cognitive overload, reduce errors and omissions, and improve patient health outcomes, appears to have been met at Mayo Rochester and its affiliate sites (Florida and Arizona). At the Mayo sites, the same team of program staff oversaw implementation and IT systems were configured specifically to support a software-based AWARE program. At non-Mayo hospitals, the ability to meet the AWARE goals was limited due to delayed implementation and limited, undependable technical support. However, among the small cohort of users at non-Mayo hospitals, the AWARE tool was effective, offering a better ICU experience for clinicians and patients.

The majority of clinician users across sites embraces the goals of AWARE and is able to incorporate it into their workflow. The clinicians we interviewed overwhelmingly reported that the tool improves their efficiency and reduces workload—especially time spent at computers and away from patients. Initially, there was considerable resistance from physicians to learn another IT application, and from nurses who were challenged to replace paper and pencil with electronic notes. These barriers are still being overcome, though improvement has been noted over time.

The flexibility and customization of AWARE's training program to meet the needs of Mayo's disparate provider groups proved to be a major strength of the program, as it has allowed more clinicians to be trained than would have otherwise been possible. However, the perception among some staff that the training is not mandated, may be a limitation in that fewer clinicians are using AWARE than would be if learning to use the tool was required. New residents are systematically trained on AWARE since it is part of their orientation, but there is no systematic approach to training other clinicians. One interviewee noted that leadership is considering making training mandatory for all clinicians working in the target ICUs. In addition, it may be necessary that more complex instruction beyond the basic training be offered to ensure that the tool is used to its maximum potential.

The next steps for the AWARE program are to achieve sustainability through continued Mayo administrative support and to finalize and market a commercial version of the AWARE product. As discussed previously, AWARE is now integrated into the Mayo ICU workflow, and it has been received with overwhelming user support. It seems quite likely that the administration will continue to fund it.

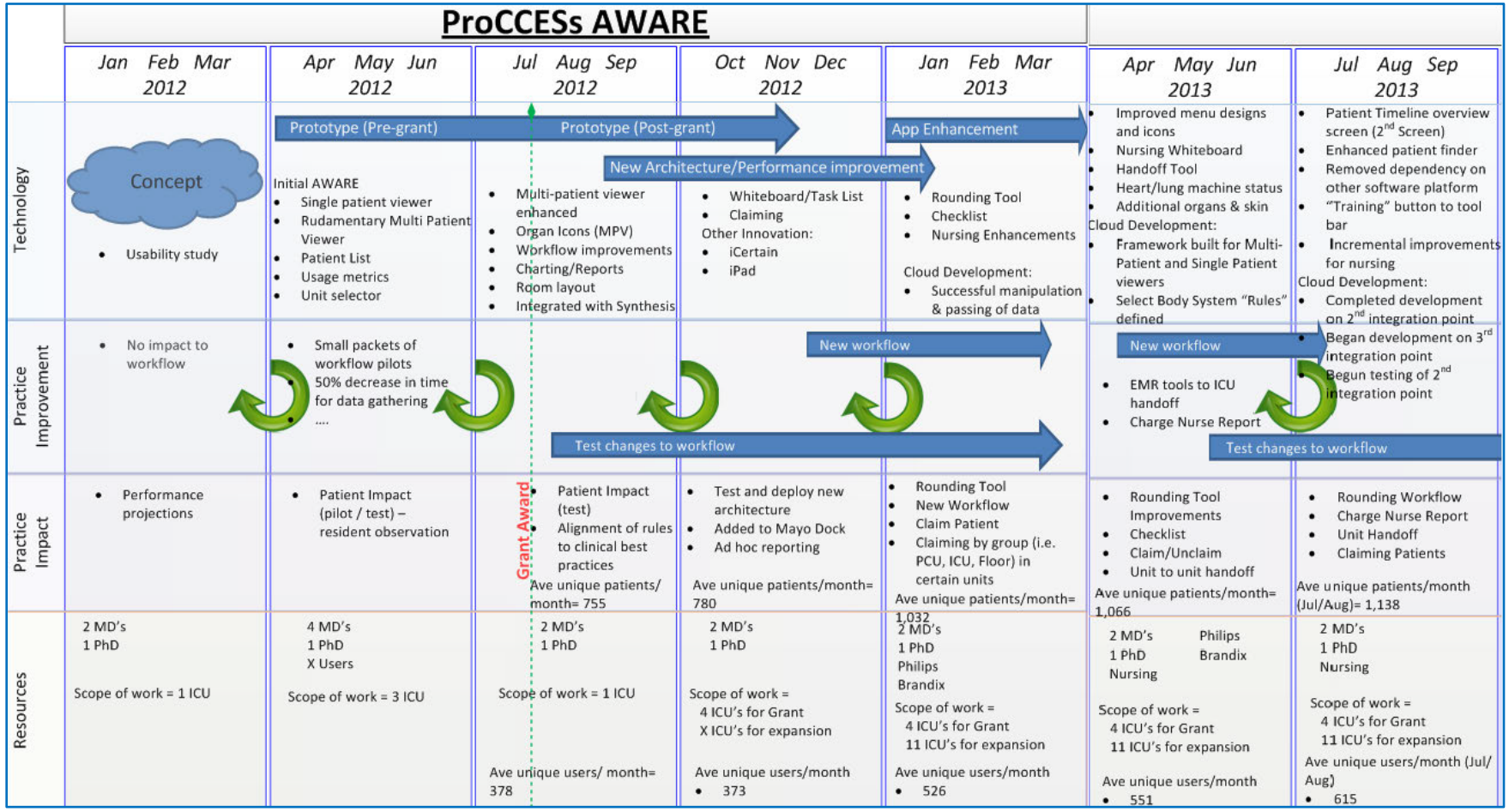
Implementation barriers at partner sites stemmed largely from budget reductions, competing initiatives, and difficulties integrating the cloud-based AWARE program with site-specific EMR systems without adequate communication and technical support. For example, integrating AWARE from the cloud was especially difficult at the smallest hospital, Lawrence General, where a small IT team, inadequate specifications, and lack of response for technical support from Philips Healthcare negatively impacted their successful and timely launch of AWARE. Montefiore did not have issues with the specifications provided by Philips, but they did experience a lack of technical support from both Philips and Brandix. Montefiore also experienced budget cuts that limited their ability to purchase hardware needed for the full and successful clinical launch, and competing demands for the efforts of their IT staff (e.g. migrating to Epic EMR software) has also delayed implementation of AWARE. Program implementation at Oklahoma was severely hobbled by a late start, large budget cuts, and poor communication with Mayo Rochester. In fact, it is unlikely that this site will launch before the end of the Award period. As implementation begins to take hold, the barriers at Lawrence General and Montefiore have been mostly overcome but their impact has caused serious delays in their clinical launch as well as delays in broad uptake of AWARE in target and other ICUs.

Case Study Appendix B5.A: Descriptions of the AWARE Patient Navigation Panes

The tool allows the user to filter data by level of detail and area of interest, as explained below:

- Clinicians using AWARE can begin to drill down into patient data by navigating from the AWARE home screen: The highest-level view allows the user to select the ICU of interest from the list of all 13 Mayo ICUs. [Note: only four ICUs are officially participating in the intervention, however, AWARE is available and can be used in other ICUs at the discretion of clinicians in those units].
- Each ICU-specific screen displays a virtual map of all the beds in the unit (each represented by one square text box) indicating key patient demographic information (name, age, gender) for the patient in a bed, and highlighting the most pressing issues the patient is experiencing. These pressing issues are represented by icons representing organ system(s) (e.g., a heart shape, for a heart failure patient). Patients with critical needs have the respective icon highlighted in red.
- The next level view allows a clinician to click into any patient "box," which then displays a snapshot of patient data categorized by organ system. Like the critical values displayed on the main ICU screen, each organ system snapshot view displays the most relevant values within that organ system.
- Each organ system can then be clicked into, displaying all data available for that system, including historical data from previous episodes of care, as well as graphs and other displays of trends.
  - Once AWARE opens a viewer for a single patient, it is possible to open any of the underlying programs feeding into it, to find additional data. While the premise of AWARE is that it aggregates all data so that users need not access underlying files, clinicians occasionally still wish to review the underlying data in certain cases, primarily for complete lab and radiology reports. *Source. Abt Associates Inc. Based on May 2014 site visit at the Mayo Clinic, Rochester, MN*

Case Study Appendix B5.B: Quarterly Incremental Illustration at Mayo Clinic



Source. HCIA Quarterly Progress Report Narrative submitted by the Mayo Clinic to CMS for Quarter 5.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total Medicare episode spending. The admission measure is not relevant for the Mayo AWARE program because patients are already admitted when they receive the intervention. The results presented below are for the following Core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission for a relevant ICU patient, in either an intervention or comparison hospital.
- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.
- Total Medicare spending for 60 days including the index admission and all Medicare spending for 60 days after discharge.

The Mayo Clinic program also aims to reduce length of stay, and avoid complications through adherence to best practice guidelines. We therefore present results for the following additional measures:

- Length of stay (LOS)
- Discharge destination

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. We additionally report median regression estimates of 60-day Medicare episode spending. Results are reported in section 2.2 below.[33]

All models include controls for patient age, squared age, gender, race, Hierarchical Condition Category (HCC) score in year of treatment, squared HCC score, eligibility for Medicaid at any time during observation period (2010-2014), as well as indicators for the quarter in which the episode occurred.[34] An indicator is also included for individuals with missing HCC scores.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[35] We believe this is an accurate way to compare time periods.

---

[33] The lone exception is discharge destination, where quarterly estimates are reported in table form due to the multitude of possible outcomes.

[34] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g. age, gender).

[35] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

4.1 Intervention and Comparison Groups

4.1.1 Selection Rules

Below, we define a set of rules used to create both the comparison and intervention groups, using information that is available in the Awardee registry. These rules are uniformly applied to patients within intervention and comparison facilities in order to create the final intervention and comparison populations.

The registry provided by Mayo Clinic program staff contains information about patients treated in several medical and surgical ICUs and some patients in the registry spent time in more than one ICU.

Mayo Clinic program staff advised that their program "went live" on July 1, 2013. The registry they provided includes patients who were treated in the ICU before that date. Because Medicare claims data include hospital admission date, but not the dates of ICU service, we included patients who were admitted to the hospital on or after July 1, 2013 when developing selection criteria for our analyses.

In mid-2014 the IT tool was adopted at two other Mayo Clinic facilities in Florida and Arizona. Although these new facilities have been incorporated into the intervention group in the analyses presented below, we do not receive registry data from these facilities, and so they are not included in the registry matching procedure.

The Mayo Clinic has many different types of ICUs and not all are participating in the intervention. Selection of an estimated treatment group therefore was conducted in two stages. First, we determined which ICUs were participating in the intervention by the types of ICUs in which registry patients were treated (using the revenue center codes on Medicare claims). We defined inclusion using ICU revenue center codes 0200, 0201, 0202, and 0206, which indicate general, surgical, medical, and intermediate ICUs respectively.

We additionally match the first two ICD-9 codes on a Mayo registry patient's claim. We listed all of the ICD-9 codes present in these first two positions for registry patients, and then selected comparison patients who had at least one ICD-9 code from this list. Patients who had one of these ICD-9 codes in the first two positions on their claims are much like those in the registry. Patients with other ICD-9 codes that are never present in the registry are excluded from all analyses. This strategy further narrows the focus to the types of patients in the Mayo registry.

This additional matching step substantially reduces sample size and statistical power, however it improves accuracy by reducing the number of patients who are included in the sample but were not actually eligible for the intervention. The new step increases the accuracy of our match (defined below) from roughly 40 percent to roughly 70 to 80 percent.[36]

The rules described above result in the following match between registry data and the best specifications we can create using Medicare claims:

[36] Previous match rates not shown, differences in rates from previously provided quarterly reports.

Exhibit 1: Match Rates by Quarter

	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4
Registry with Medicare FFS claim (A)	10	694	630	563	582	910	770
Registry Patients Not Captured by Abt rules (B)	1	46	58	55	68	158	143
Miss Rate (B/A)	10%	7%	9%	10%	12%	17%	19%
Estimated based on Abt rules, with Medicare FFS claim (C)	42	900	799	758	803	980	911
Match between Estimated and Registry (D)	9	648	572	508	514	752	627
Estimated by Abt rules, Not in Registry	33	252	227	250	289	228	284
Accuracy Rate (D/C)	21%	72%	72%	67%	64%	77%	69%

Source: Abt Associates analysis of Registry and Medicare Claims, May 2015.

Accuracy rate = Percent of admissions with a Medicare FFS claim that are identified using Abt's rules and are also in the registry (indicates that our criteria are too broad and capture many that apparently did not receive the intervention)

Miss rate = Percent of admissions with a FFS claim that meet Abt's inclusion criteria but are not in the registry (indicates that nearly everyone in the registry meets our criteria—we miss few).

The intervention group we are able to estimate misses some of the registry intervention patients, but is broader than the registry; some of the patients captured by our criteria were not in the registry and apparently did not receive the intervention. This may be in part because the Mayo Clinic organizes its ICUs in a way that does not map precisely to the revenue center codes on Medicare claims and we therefore cannot perfectly model the four intervention ICUs. In addition, Mayo Clinic staff advised that some physicians in the four intervention ICUs chose not to use the IT tool. Since adoption is one indicator of program effectiveness, we want to include all eligible patients in our analyses, not only those whose physicians chose to use the IT tool, as this better reflects the impact of the intervention across entire ICUs.

Exhibit 2 below provides information about average patient characteristics for the Awardee and comparison groups in both the baseline and intervention periods. The demographic summary statistics serve two purposes. The first is to provide a sense of the population demographics in the Mayo treatment population. The second is to show that most demographics are similar for intervention and comparison groups, with relatively wide standard deviations. We note that the percentage of non-white individuals and HCC scores are different among the groups. The wide standard deviations reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

Exhibit 2: Demographic Summary Statistics

	Awardee				Comparison			
	Intervention Period (N=47,88)		Baseline Period (N=12,323)		Intervention Period (N=2,881)		Baseline Period (N=30,214)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.42	0.49	0.43	0.49	0.45	0.50	0.48	0.50
Nonwhite	0.04	0.20	0.06	0.24	0.21	0.41	0.21	0.41
Age	73.15	11.83	73.80	11.43	70.98	13.19	72.80	12.81
HCC Score	1.59	1.66	2.01	2.27	2.34	2.45	2.68	2.78
Missing HCC	0.19	0.39	0.10	0.30	0.26	0.44	0.10	0.29
Medicaid Eligibility	0.28	0.45	0.31	0.46	0.44	0.50	0.52	0.50

We see that Medicaid eligibility declined between the baseline period and the intervention period, for both Awardee and comparison groups, and was higher in both periods for the comparison group. In addition, the intervention group has fewer nonwhite patients than the comparison group. It is possible that the Mayo Clinic patients are less likely to be low income and minority than the best comparison group we are able to construct.

4.2 Core Measures: Results

Implementation did not take place on the same day in all participating ICUs. In the graphs below, the red vertical line shows the beginning of the intervention period and the black vertical lines indicate the dates when each of the participating facilities began their program implementation. All estimated changes in utilization are based on seven quarters of post-implementation data. One less quarter of data is included for the spending measure compared to the utilization measures, due to the lag required for post-acute claims to become available for analysis.

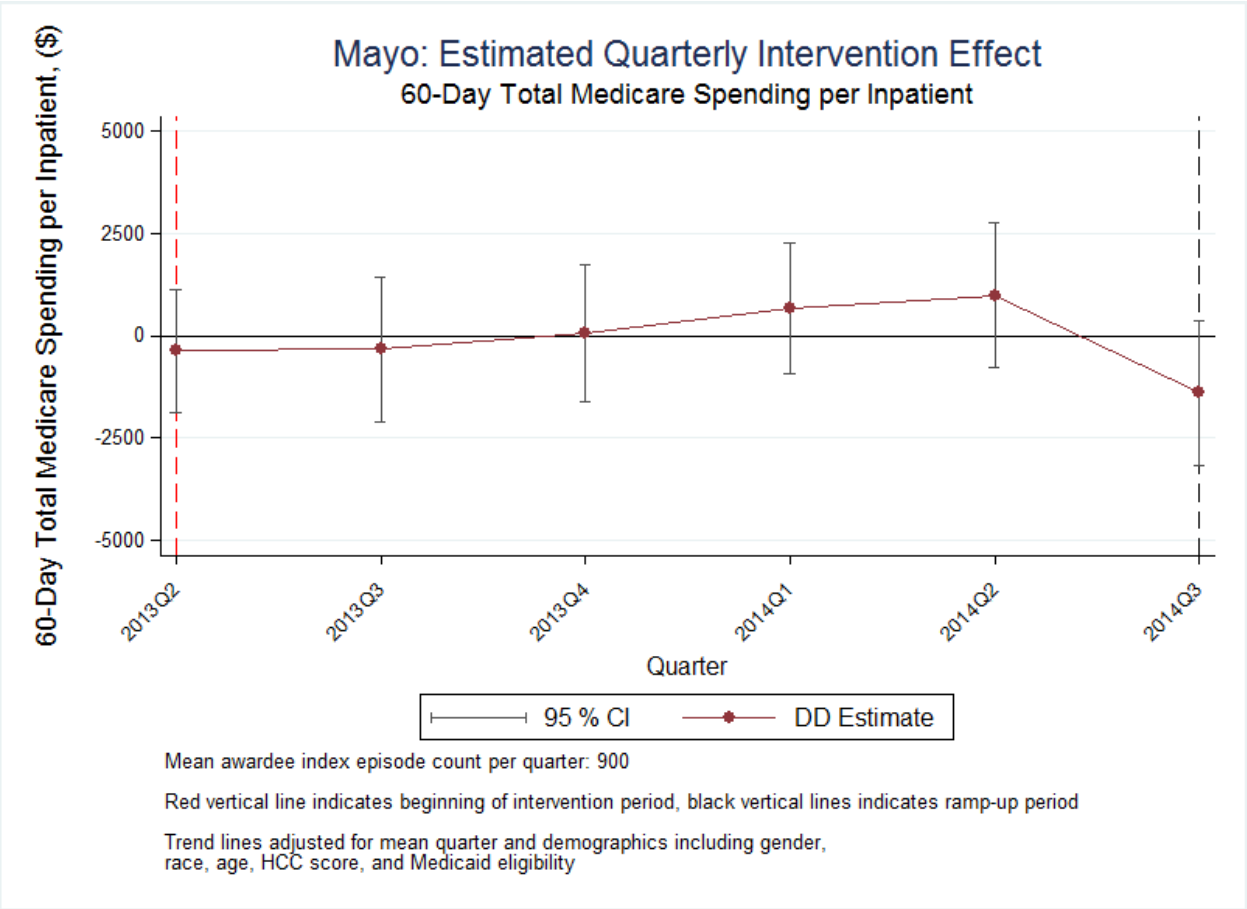
4.2.1 Medicare Episode Spending[37]

Exhibit 3 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days. It shows that average Medicare episode spending for the intervention group is relatively the same as the comparison group, with the exception of a large drop in spending for Q3 2014, the most recent quarter. Additional quarters of data are needed to determine whether this is a one-time decline, or the beginning of a trend.

Note that one less quarter of data is included for this spending measure compared to utilization outcome measures, due to the lag required for post-acute claims to become available for analysis.

[37] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 3: Mean Medicare Episode Spending



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 4 presents the pooled average and median cost regression results; robust standard errors are reported in parentheses. The sample size utilized in the regression analysis is reported in brackets.

Ordinary Least Squares (OLS) regression estimates for the Mayo program do not indicate a significant relationship between the intervention and Medicare episode spending during the 60 days starting with the index admission. There was an average decrease in Medicare spending of roughly $51 per patient, but this result was not statistically significant.

The regressions that estimate the effect of the intervention on the median episode spending show a statistically significant reduction of $1,010 per episode. This result is large, and may reflect the impact of the intervention on patients who are not cost outliers. Future reports will monitor this result and test it for robustness.

Exhibit 4: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs

Mayo Clinic		
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	-51.24 (560.88) [50,206]
Intervention Effect (Median Regressions)	Estimate Standard Error Sample Size	-1010.55*** (307.23) [50,206]

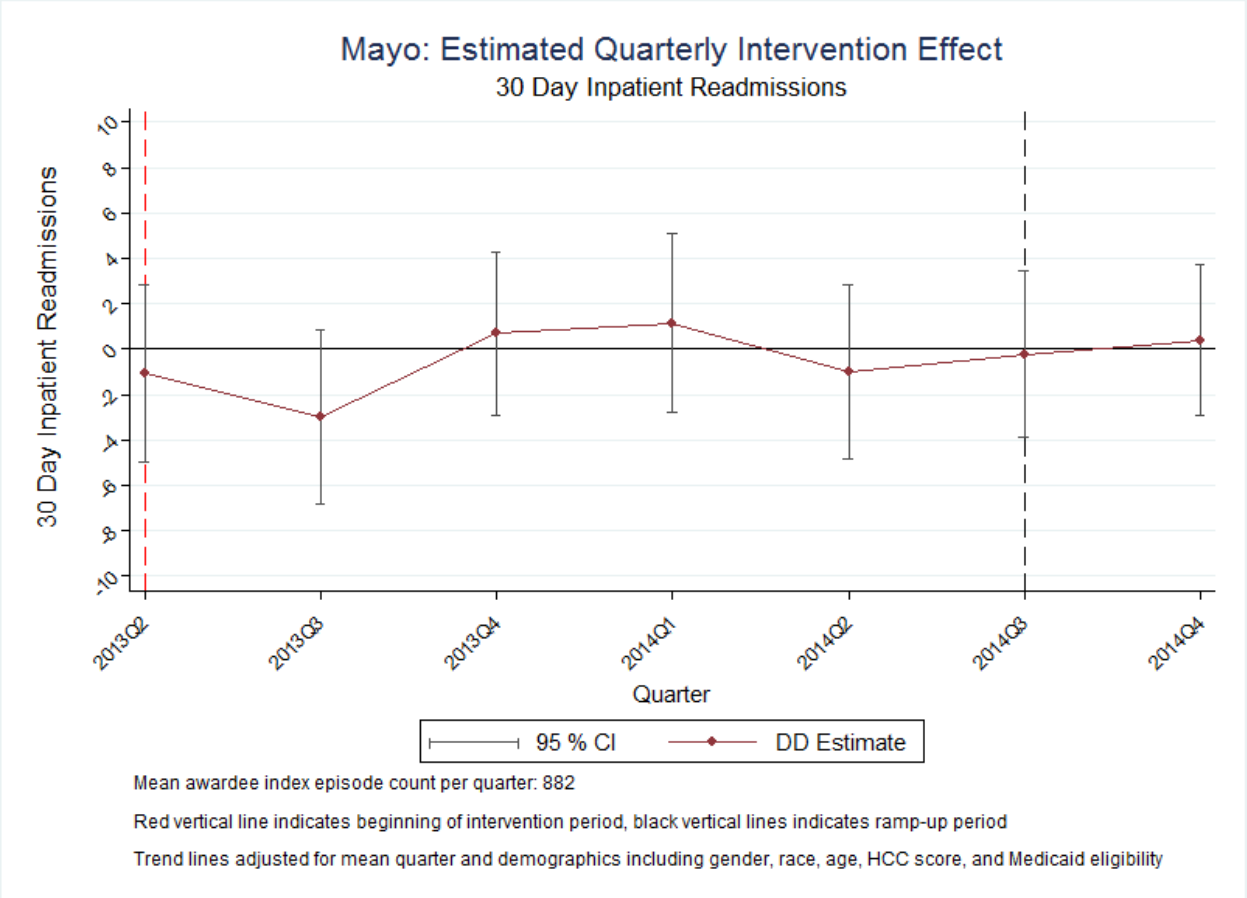
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.2 Readmissions

Exhibit 5 below (hospital discharges followed within 30 days by a readmission) shows that the intervention and comparison ICUs were similar in the baseline period and there is no evidence of a change in this pattern during the intervention or in the relationship between the two groups. Exhibit 6 reports the estimated total effect of the intervention on 30-Day inpatient readmissions, pooled across quarters. We find a statistically insignificant .53 percentage point reduction, indicating that the intervention had close to no impact on inpatient readmissions.

Exhibit 5: Readmissions



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 6: DD Estimated Effect of Intervention on 30-Day Inpatient Readmissions

Mayo Clinic		
Intervention Effect	Estimate Standard Error Sample Size	-0.53 (1.09) [51,977]

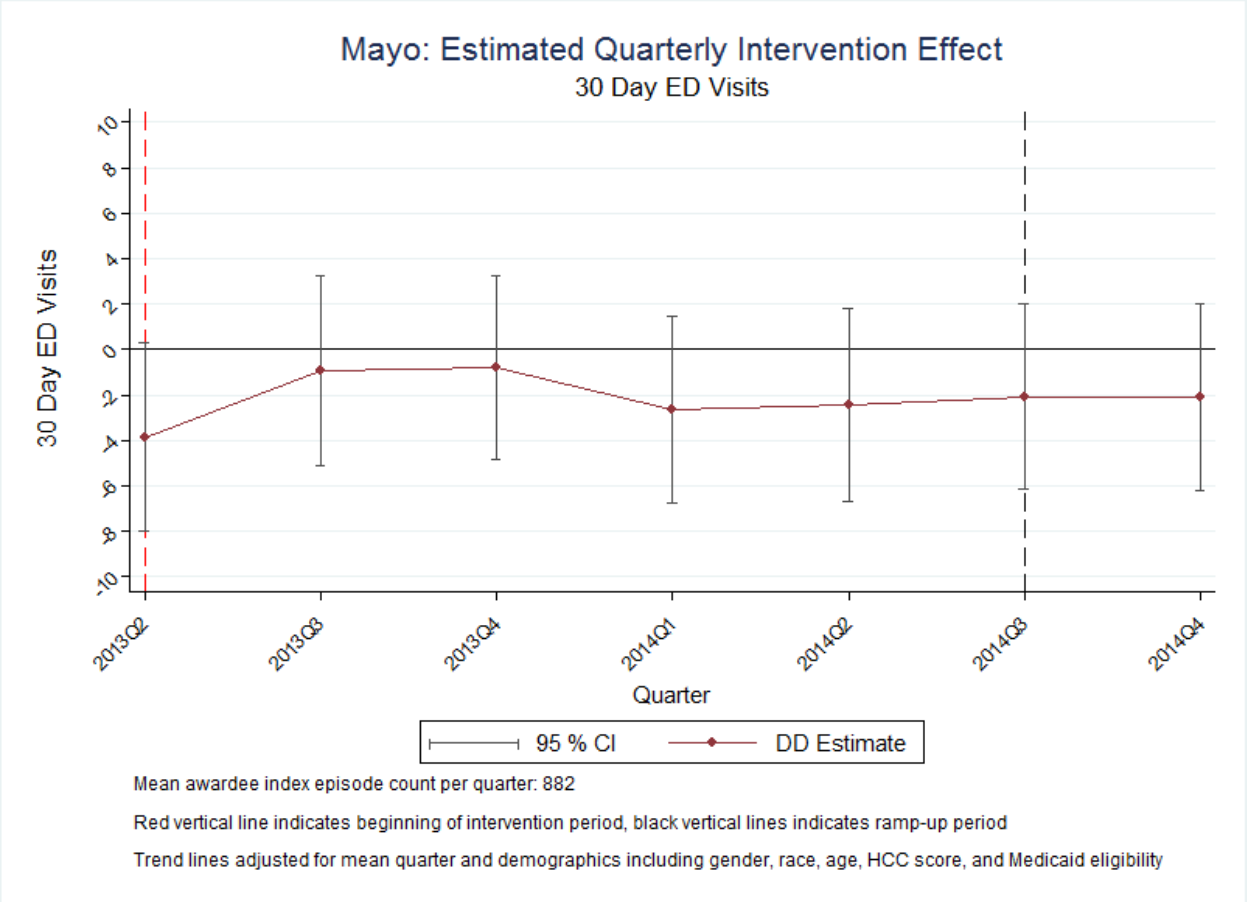
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, May 2015.

4.2.3 30 Day Post-Discharge ED Visits

Exhibit 7 (discharges followed within 30 days by an ED visit) shows the quarterly DD trend for 30-day ED visits since the beginning of the intervention. Although statistically insignificant, the trend shows a general reduction in post-discharge ED visits for every quarter during the intervention. Exhibit 8 reports the pooled estimate of the intervention on ED visits within 30 days after discharge. We find a statistically significant reduction of 2.48 percentage points as a result of the intervention; this point estimate is significant at the 5 percent level. Given the consistent average quarterly results that showing a reduction in ED visits, these pooled results are likely trustworthy and we conclude that the Mayo Clinic program is reducing post-discharge ED visits.

Exhibit 7: 30 Day Post-Discharge ED Visits



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 8: DD Estimated Effect of Intervention on 30-Day Emergency Department Visits

Mayo Clinic		
Intervention Effect	Estimate	-2.48**
	Standard Error	(1.12)
	Sample Size	[51,977]

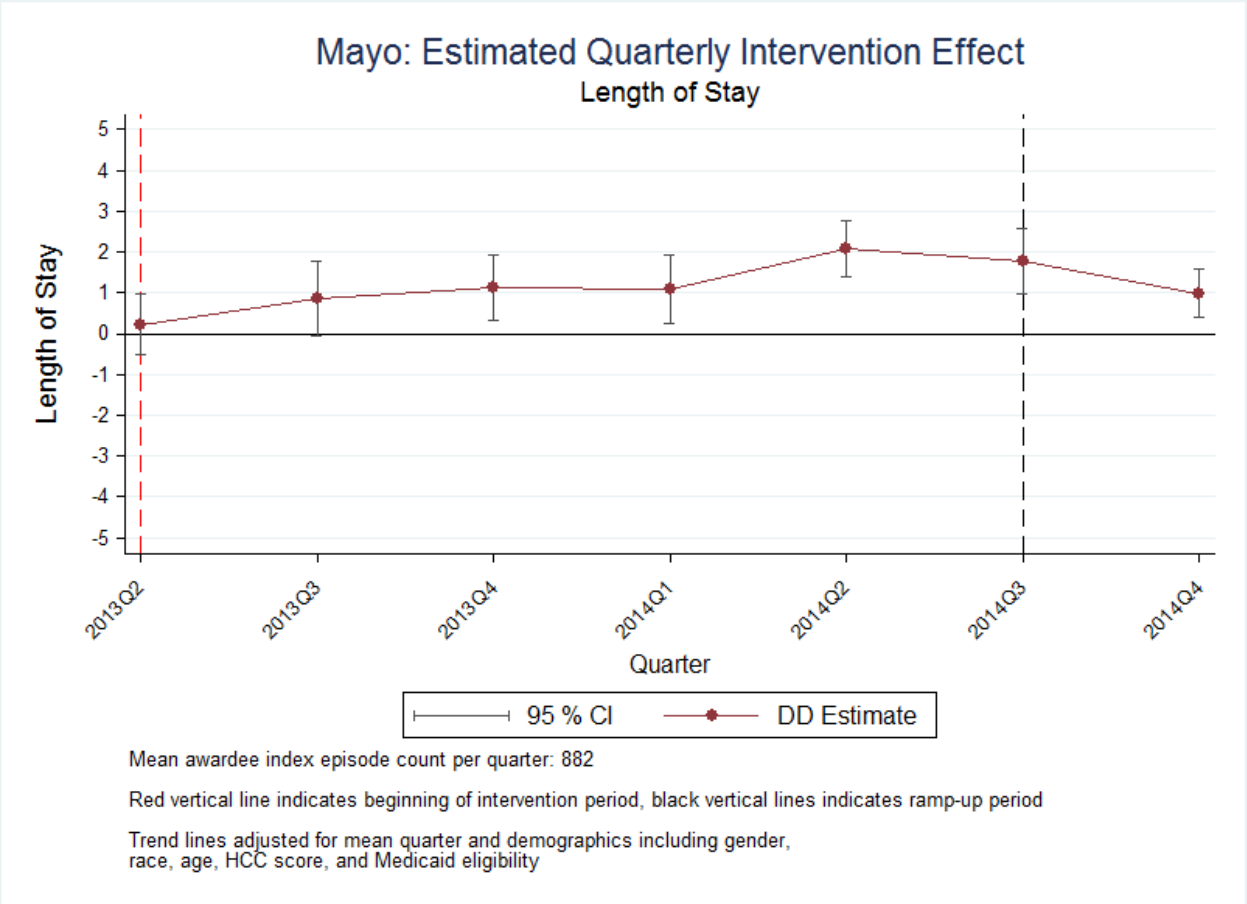
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, May 2015.

4.2.4 Index Admission Length of Stay (LOS)

Exhibit 9 shows LOS during the index admission. The quarterly point estimates show that LOS at Mayo Clinic was consistently higher than the comparison group during the intervention period. Five of the available seven intervention quarters show a statistically significant longer LOS relative to the comparison group. Exhibit 10 reports the pooled point estimate for Mayo's inpatient LOS. LOS was 1.31 days longer on average for all quarters combined. This result is significant at the 1 percent level.

Exhibit 9: Index Admission Inpatient LOS



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 10: DD Estimated Effect of Intervention on Inpatient Length of Stay

Mayo Clinic		
Intervention Effect	Estimate	1.31***
	Standard Error	(0.24)
	Sample Size	[51,977]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.5 Discharge Destination

Below, Exhibit 11 presents the difference-in-differences estimates for discharge destination following the index acute care admission. We find that intervention patients were discharged less frequently to home (without home health care) across all intervention quarters, than were comparison patients. We also observe a higher rate of discharge to "other" destinations, where an "other" discharge destination includes hospice, a within-hospital transfer, or transfer to a federal facility. Overall, we find that discharge to home is a statistically significant 5.38 percentage points lower for intervention patients, and discharge to 'other' destinations is a statistically significant 3.01 percentage points higher. This indicates that ICU patients are less able to go directly home without additional care than are their comparison peers. We note that this is true, despite the fact that the comparison group has a higher proportion of low-income patients (Medicaid eligible) than the intervention group.

Exhibit 11: DD Estimated Change in Episode Discharge Destination

	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home								
DD Estimate	-4.98***	-2.23	-9.84***	-6.38***	-3.91*	-5.83***	-2.31	-5.38***
SE	(2.24)	(2.26)	(2.07)	(2.18)	(2.21)	(2.10)	(2.26)	(1.23)
Home Health								
DD Estimate	0.06	-3.22	1.39	3.16	0.93	1.21	-0.23	0.22
SE	(1.84)	(1.49)	(1.94)	(2.04)	(1.91)	(1.91)	(1.73)	(1.06)
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home								
DD Estimate	1.75	3.79	3.85	-0.18	0.94	1.11	0.01	2.15
SE	(2.48)	(2.40)	(2.44)	(2.26)	(2.33)	(2.28)	(2.40)	(1.33)
Other								
DD Estimate	3.17*	1.65	4.60**	3.40**	2.03	3.51**	2.53	3.01***
SE	(1.82)	(1.52)	(1.96)	(1.72)	(1.52)	(1.79)	(1.66)	(1.01)

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.6 Conclusions

Above, we find statistically significant intervention results for 30-day ED visits, LOS, median episode Medicare spending, and discharge destination.

- Generally, we find that patient' LOS is higher, but post-discharge ED visits are lower, as a result of the intervention**.** There is no statistical difference in the average Medicare episode spending, but we estimate a median spending reduction of approximately $1,010 dollars. More analyses and further quarters of data are needed to determine the impact of the intervention on the episode cost distribution.
- Intervention patients are also less likely to go directly home without home care, relative to the comparison group.

Appendix B6: Methodist Hospital Delirium Detection and Prevention

1. Executive Summary

This chapter presents both quantitative and qualitative findings of Abt Associate's evaluation of the Methodist Hospital's delirium detection and reduction program. The program includes a nurse-administered Delirium Screening Tool and an algorithm-based automated calculation of a Delirium Risk Assessment that are intended to be applied twice-daily for all patients in the hospital aged 70 and older (excluding the ICU). Patients who are screened to be at risk for delirium receive staged interventions depending on their risk level. The highest risk patients receive a nurse's aide home visit after discharge, to complete a thorough safety check and medication reconciliation. In addition, all hospital pharmacy order sets were revised to remove deliriogenic medications, especially when ordered for older patients, and pharmacists work with prescribers to suggest safer medications. The Methodist Delirium program aims to identify and prevent delirium in hospitalized patients, reduce 30-day readmissions, and reduce overall costs. The program might also be expected to reduce length of stay (LOS) and decrease the need for post-discharge visits to the Emergency Department (ED).

We analyzed the impact of the Methodist Delirium program using Medicare claims for both the screened population (all patients over age 69 who received a twice-daily delirium screening) and for the subset of that population that received a delirium-focused intervention (those at medium to high risk). We developed inclusion and exclusion criteria for intervention and comparison groups based on the patient registries supplied by program staff. We consider program estimates to be downward biased approximations of the true program impact, because we could not perfectly match intervention and comparison groups using data available in Medicare claims. The integration of key intervention components occurred in a staged process over time in each participating hospital, allowing time for care teams to adapt their workflows and processes. Quantitative analyses confirm that impact was more significant as the program matured.

We conducted a difference-in-differences analysis comparing changes in key outcomes for the intervention group over time, relative to the matched comparison group and the intervention group baseline period. Our analyses indicate a significant decrease in length of stay (LOS) for the overall screened population, but not for the population who received an actual intervention (high or medium risk patients), relative to matched comparison groups. The screening to identify emerging delirium risks, and safer medication order sets, may be reducing LOS across the board, even if those at higher risk require more interventions and need longer hospital stays. It is also possible that patients at higher risk, who require more intense service to prevent or address delirium, may be more severely ill or have more comorbidities than patients at low risk of delirium.

We find that the Methodist Delirium program screening and interventions are associated with a statistically significant reduction in 30-day post-discharge visits to the ED, relative to the comparison group; this was true for both the overall screened population and the subpopulation at higher risk who received interventions to prevent delirium. Those in both the screened and intervention groups were also significantly more likely to be discharged home with home health care, or discharged to "other" settings—settings that are not skilled nursing, inpatient rehabilitation, long-term acute care (e.g., transfer to another hospital, hospice, outpatient care etc.)—and less likely to be discharged home without home health care, relative to comparison groups. It appears that screening identified patients who could not be safely discharged to home without additional services, and the greater use of home health and other services averted some ED visits. Early detection, referral to home health care, and reduced use of EDs are

evidence of better, more coordinated care. This finding is supported by program staff and bedside clinicians who report that their awareness of delirium and ability to detect it are enhanced by program tools and training. Despite these care improvements, there was no significant reduction in 30-day readmissions, which might have been expected for patients receiving home health care. There was no significant change in Medicare episode spending, possibly because the savings from fewer ED visits were balanced by the increased use of home health and other services.

2. General Research Domains

The core domains for the Methodist Hospital Delirium Program evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations, contextual issues, and sustainability. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of Health Care Innovation Award (HCIA) funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Description of Program

In 2012, the Methodist Hospital System was awarded a *Health Care Innovation Award (HCIA)* to implement a delirium detection and reduction intervention program within its health system. The primary goals of Methodist's Delirium Detection and Prevention across the Continuum (Delirium Program) are to:

- ***Monitor and intercept patients at risk*** for medication-induced delirium by establishing a system-wide pharmacy surveillance system to "flag" patients for clinician review who have been prescribed deliriogenic medications;
- ***Increase recognition of delirium*** by adopting a standardized assessment tool to screen patients at risk for delirium, and by educating providers, caregivers, families, and patients about the diagnosis in general; and
- ***Enhance care transitions*** for patients at high risk for delirium as they leave the hospital, by creating new and complementary roles for care providers to personally assist with and monitor patients throughout the transition process from hospital discharge to subsequent follow-up at home.

By April 2014, the program had been implemented at Houston Methodist Hospital (HMH), the system's largest facility, with approximately 800 beds, and two community hospitals of Houston Methodist San Jacinto (San Jacinto) and Houston Methodist Willowbrook (Willowbrook), which have approximately 375 and 240 beds, respectively. The Delirium Program expanded to two additional community hospitals in October 2014—Houston Methodist Sugar Land Hospital (Sugar Land) and Houston Methodist West Hospital (Methodist West) with roughly 240 and 140 beds, respectively.

3.2 Case Study Methods

We first conducted a case study of Methodist's Delirium Program on April 22–24, 2014 at HMH in central Houston and Willowbrook in northwest Houston. The research team consisted of three staff that collected qualitative data: a senior Abt researcher, a mid-level Abt researcher, and a researcher from Telligen (formerly CFMC; subcontractor to Abt). The team conducted five focus groups and seven interviews with clinicians and other care providers, as well as hospital and program administrators during this visit.

On April 13–17, 2015, we conducted a follow-up case study via teleconference with participants from HMH, Willowbrook, Sugar Land, and Methodist West. A team of four staff collected qualitative data: a senior Abt researcher, two mid-level Abt researchers, and a researcher from Telligen. Together, they conducted six focus groups/group interviews and six individual interviews. Some individuals, particularly Program Staff and the lead Pharmacist, were interviewed in both phases of data collection.

Exhibit 1 summarizes the number and type of individuals who participated in either individual interviews or focus groups during the first round of qualitative data collection.

Exhibit 1: Professional Backgrounds of Interviewees and Focus Group Participants

Case Study Participants on April 22 – 24, 2014								
	Volunteers	Care Navigators	Home Health Aides	Nurse Champions	Physicians	Pharmacists	Hospital Leadership	Program Admin.
H.M.H.	10	8	6	23	2	1	3	4
Willowbrook	0	0	0	15	1	1	1	2
Total = 83	10	8	6	38	3	2	4	6

H.M.H: Houston Methodist Hospital

Exhibit 2 summarizes the number and type of individuals who participated in either individual interviews or focus groups during the follow-up qualitative data collection.

Exhibit 2: Professional Backgrounds of Interviewees and Focus Group Participants

Case Study Participants on April 13 – 17, 2015					
	Nurse Champions	Bedside Nurses	Physician Leadership	Pharmacists	Program Administration
H.M.H.	4	5	2	2	5
Willowbrook	0	0	0	0	1
Sugar Land	0	5	0	0	2
Methodist West	3	0	0	0	0
Total = 29	7	10	2	2	8

H.M.H.: Houston Methodist Hospital

Standard qualitative interview and focus group protocols were tailored to the different informants at each site. Three evaluation staff conducted the initial site visit; all three staff participated in every interview and focus group, with one researcher leading the interview and others taking comprehensive notes. In 2015, four researchers collected data in follow-up interviews over the phone. Each telephone interview was attended by at least two staff members, one leading the interview and the other taking comprehensive notes. All interviews were recorded (with participant consent) and audio-recordings were used to supplement interviewer notes. At the end of each case study, all notes were cleaned and integrated across the note-takers and reviewed for accuracy either by the senior researcher, or the researcher who led the interview for a particular discussion. Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

3.3 Methodist Delirium Program Background

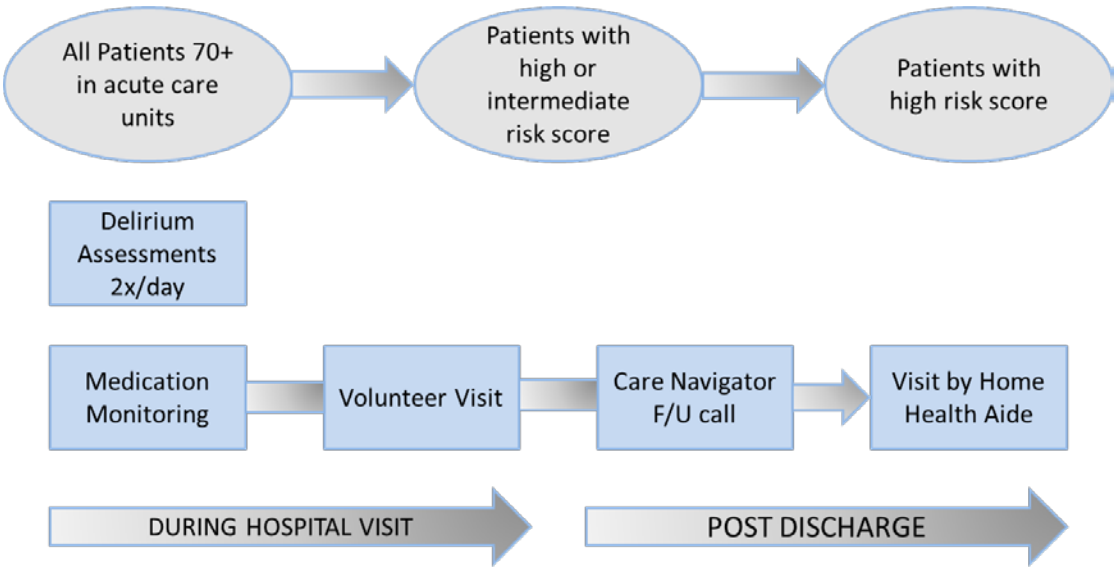
Methodist's Delirium Program grew from an institutional interest in delirium as Houston Methodist Hospital serves a large number of patients 70 years or older (more than 22,000 patients 70 or older admitted in 2012) who are at risk for developing delirium due to advanced age. Delirium can prevent a patient from engaging with, understanding and communicating with clinicians.

The program aims to better prevent, detect and treat delirium in older hospital patients through enhanced monitoring and treatment across the continuum of care (from inpatient to home-based services). The Delirium Program consists of a number of components:

- Medication monitoring and revision of order sets to eliminate or reduce use of deliriogenic medications.
- Two daily delirium screenings by Bedside Nurses are completed, including a quick test of attention and consciousness with two questions the patient answers and two items based on nurse observation. These four items result in a binary score of a positive or negative screen for delirium.
- Visits by Volunteers during patients' hospital stay to educate patients and family members on healthy habits in the hospital, and provide devices such as hearing amplifiers and reading glasses to facilitate patient communication.
- Referral of patients at intermediate or high risk (if s/he declines a home visit) for delirium for post-discharge telephone follow-up by Care Navigators.
- Provision of home health visits transitions of care program for patients at high risk of delirium (who consent to receive a home visit). These patients frequently have cognitive impairment or are at risk of cognitive impairment and require greater support at discharge.

The flow of patients through the Delirium Program components is illustrated in Exhibit 3.

Exhibit 3: Patient Flow Through Intervention Components (Source: Abt Associates)



3.3.1 Program Goals

The primary goals of this program are to identify and prevent delirium, reduce 30-day readmissions and reduce overall costs. A primary focus of the program is to increase awareness of delirium across the spectrum of care, from Bedside Nurses to Pharmacists to Physicians to Home Health Aides, and among patients and family members.

> "Many providers have a perception that a confused elderly person is 'normal and acceptable' behavior for a person at that age… the intervention seeks to change or shift the culture away from assuming that confused behavior is 'normal' by assessing it in a more systematic way, and defining it as 'delirium.'"
>
> *– Program Leadership, April 2014*

A secondary goal of the program is to better coordinate care for patients with or at high risk for delirium; this in turn is expected to reduce readmissions. The intervention components are designed to improve coordination of care *within the hospital*, particularly regarding medication management for those at risk for delirium. In addition, the program emphasizes coordinated *care transitions* following discharge, including contact with the primary care provider to schedule appointments or adjust prescriptions if needed. Medication is a particular focus because although medications are adjusted in the hospital to reduce risk of delirium, patients may take different medications at home that put them at risk. Care Navigators and Home Health Aides focus on the link between hospital-based care and the patients' care at home, to ensure that delirium risks remain low after discharge and that discharge plans are enacted.

3.4 Target of the Intervention & Program Components

3.4.1 Target Population

As noted above, the target population of the Delirium Program is patients 70 years or older admitted to an acute care unit at a participating hospital. Intensive care, psychiatric, emergency, and maternity units are excluded from the intervention. Although the original focus of the program was adults 70 or older, Bedside Nurses and Program Leadership reported during our initial and follow-up case studies that some units have begun using the delirium assessment to screen all adult patients, as part of the daily assessment protocol. They reported three reasons for broadening the program to all adult patients: 1) administering the delirium assessment screen can be helpful for patients at younger ages; 2) nurses want to avoid missing eligible patients due to incorrect documentation of age; and 3) it is easier to incorporate the delirium assessment screening universally into the workflow, rather than only for patients of a certain age.

3.4.2 Primary Program Components

The Delirium Program is a systems intervention (i.e., increasing overall awareness at multiple levels of the hospital system) that spans multiple areas of the hospital and post-acute settings. Pharmacists, Bedside Nurses, Volunteers, Care Navigators, and Home Health Aides each implement a different component of the program. In turn, each program component has specific training protocols and implementation history, with unique challenges and solutions. This section of the report describes each of the five intervention components.

Pharmacists: Electronic Medication Surveillance

A key component of the Delirium Program is medication management, which is incorporated into the hospital's automated decision support and adverse event monitoring system. Hospital pharmacists receive alerts when certain high risk medications are ordered, triggering a discussion between the pharmacist and ordering physician.

To further strengthen medication management, high risk medications have been removed from automated order sets that previously did not require an alert or a discussion with the physician. Delirium Program Physicians can still place orders independently for certain high risk medications, but these orders will trigger an alert to the Pharmacist. The Pharmacist follows up directly with the physician to suggest one of the following: continuation of the medication with care, an alternative dose, an alternative medication, or no medication.

> "We've made it easier to order a better and/or lower risk drug. It's a very important piece, the human factors part—you need to make it easier to do the right thing. All too often medicine makes it harder to do the right thing."
>
> *– Physician Leadership, April 2015*

The objective of the medication alert system is to identify the highest risk medications while at the same time being as efficient as possible. The list has evolved as Methodist Pharmacists added, subtracted or adjusted alerts as the program rolled out. For example, alerts for Lorazepam were being generated with great frequency, adding unnecessarily to the workload of Pharmacists because at a low dose, this medication is often appropriate (e.g., for anxiety before an MRI). The decision support rules were revised so that the alert now only triggers for Lorazepam at higher doses.

Currently, nine "high risk" deliriogenic medications have been identified—7 of which were identified during the first year of the program, and 2 of which were added by January 2014.

Exhibit 4: "High risk" Deliriogenic Medications

By the first year of the program				Added January 2014
Diazepam	Lorazepam	Diphenhydramine	Hydroxyzine	Carisoprodol
Zolpidem	Methocarbamol	Meperidine	--	Cyclobenzaprine

While all of the medications that have been identified as high risk for delirium are the same across the five hospitals, each hospital has a slightly different automated order set.

Bedside Nurses: Delirium Assessment and Risk Stratification

Patients 70 or older on acute care units are screened twice each day by Bedside Nurses, using the delirium assessment. If a patient tests positive for delirium based on the delirium assessment, a nurse informs an ordering provider to initiate a workup for causes, and initiates clinical guidelines for falls prevention: patients at risk for falls wear a special wristband and yellow socks so that hospital staff are aware of this risk. In addition, concurrent with the delirium assessment, a software algorithm assigns a risk stratification score, ranging from 1 to 5, based on clinical data and various criteria to assess risk as outlined in Exhibit 5, the risk score triggers other interventions as part of the Delirium Program (see sections below).

> "[The risk stratification score] is already so useful…as a means for stratifying patients and lining people up with the services they need. Moving ahead, we'll need to think about how to help nurses and interdisciplinary teams use it more."
>
> *– Physician Lead, April 2015*

Exhibit 5: Risk Stratification Scoring Algorithm

Criteria	Points
Age 85 or older	2
Age 70 or older	1
Admitting cognitive diagnosis	4
ICU stay	1
Admission BUN/Cr Ratio > 18	1
Dependent (2 or greater) ambulation	1
PRN, STAT, antipsychotic drug	4
Past medical history of cognitive deficit	4
Positive delirium assessment	4
Rx for dementia medication	4

The patient's risk score is calculated by adding all the points from the criteria he or she has met. The risk score results in a classification of low (1), medium (2–3), or high (4+). A patient then receives an intervention based on his/her risk score. There is no "zero," or no-risk score, as 70+ hospital patients are all considered to be at some risk for delirium.

Physician Leadership have been very satisfied with the risk stratification score's predictive ability—low-risk patients have a 2 percent risk of developing delirium; intermediate-risk patients have a 7 percent risk; and high-risk patients have a 20–40 percent risk. Recognizing the value of this risk stratification score, one physician lead noted that they will need to begin thinking about how to share this information so that nurses and interdisciplinary teams may utilize it.

Volunteers: On-site Hospital Visit

Volunteers, who were specifically trained and recruited for the Delirium Program, visit patients in the hospital who are at risk for delirium, prioritizing those who screen intermediate or high on the risk stratification score. Visits occur within 48 hours of the scoring. During the visit volunteers provide patients and family members a "What MATTERS" handout to educate them about delirium prevention. "MATTERS" is an acronym that suggests different measures a patient can take to help prevent delirium such as sleeping at night, ambulating if possible, reading (and other cognitive activities), using eye shades for sleeping, using hearing amplifiers if needed, using eye glasses if needed, staying hydrated, and eating well. In addition, volunteers provide general support and education for family members, and overall emotional support to the patient, particularly those who do not have visiting friends or family.

The volunteer component of the program has expanded and evolved over time. In April 2014, the volunteer component was only available at HMH. Shortly thereafter, Willowbrook added a delirium specific volunteer program. Initially, Program Staff were concerned that they wouldn't be able to attract enough volunteers at Willowbrook. However, Willowbrook ended up having many more volunteers than needed—sometimes scheduling two volunteers per patient. Currently, Willowbrook has two dedicated volunteers who are managed by the project specialist at Willowbrook. Both the volunteers and the project specialist conduct visits; the team of three is sufficient to meet the volume of patients at Willowbrook.

MATTERS

M: Mobility Matters
A: Awake in Day & Avoid Sleep Aids
T: Thinking Matters
T: Take in Liquids
E: Eat Nutritious Foods
R: Report all Medications
S: Sensory (hear and see)

Modifications at HMH have been made to ensure that high and intermediate risk patients and those who had not been visited received top priority. Originally, identifying priority patients was the responsibility of the volunteers. Now a supervisor makes assignments for the volunteers in order of priority, based on the patient's risk score.

Volunteers have contributed to the evolution of the program by providing feedback to the volunteer supervisor. At the start of the program, each volunteer carried several folders with the names of patients and reported dropping them and having a hard time keeping them organized. Based on this feedback, the volunteer supervisor changed the system so that all the patient names and information have been consolidated to one sheet and one folder.

Other modifications to the volunteer component at HMH involve volunteers' role in distributing supplies such as hearing amplifiers, reading glasses, and materials to patients in contact isolation. Initially, volunteers provided hearing amplifiers and reading glasses for patients to keep permanently. Because those supplies are no longer given to patients to keep, clinicians are now responsible for distributing, collecting, cleaning, and storing the supplies. Volunteers at Willowbrook were initially prohibited from seeing patients in contact isolation. However, after seeing how many patients were missed because of that restriction, the medical-surgical director there decided to allow volunteers to at least leave a packet of delirium-related information for the nurses to bring those patients.

Care Navigators: Post-discharge Follow-up Calls

Patients whose risk stratification score is intermediate and who will be discharged home (and high risk patients who decline home health visits) are referred to a Care Navigator, who follows up with the patient by phone after discharge. When the program first began, Care Navigators sometimes called high-risk patients who were unable to receive a visit due to resource constraints. Since the program has expanded an additional Home Health Aides were trained, Care Navigators now do not call high-risk patients who consent for a visit. Care Navigators are registered nurses employed and trained by Methodist to provide appropriate follow-up care by phone for multiple programs including the Delirium Program. The Care Navigators reinforce discharge instructions, administer a phone assessment for delirium, work with Pharmacists to review post-discharge medications, make sure medication instructions are clear, confirm that a follow-up appointment has been made with the patient's primary care physician, confirm that home health care is in place if needed, and assess needs for additional support. If, for example, a patient is not doing well at home and requires institutional care, the Care Navigator will help coordinate the placement. In addition, the Care Navigator team includes a Pharmacist who provides regular consult regarding medication monitoring issues following discharge.

Home Health Aides: Post-discharge Home Visits

Patients with a high risk score receive a referral for a Home Health Aide visit after hospital discharge, provided by aides specially contracted and trained by the Methodist Delirium Program. These Home Health Aides visit patients (who agree to the visit) twice: within one week after hospital discharge, and the again within two weeks of discharge. These patients also receive a follow-up call from the Home Health Aide within 30 days of discharge from the hospital. The Home Health Aides collect information concerning risk factors in a patient's home, all medications that the patient is taking at home, and environmental factors that could be creating patient safety issues and enter this information into a database. They provide support managing medications to improve compliance, and monitor for any safety or health related concerns that require the attention of a nurse or nurse practitioner.

Home Health Aides are all trained in the importance of delirium and its key features, as well as how to administer a Mini-Cog screen for cognitive impairment which is scored by the supervising Nurse Practitioner (NP). Home Health Aides are also trained to call the supervising NP or MD if they have any concerns with a patient's signs of confusion. The supervising NP or MD then performs a delirium screen and cognitive assessment. The Home Health Aides carry iPads and record information about each home visit into an online documentation tool. However, the Home Health Aides do not make any clinical decisions. In the event that there is a concern that arises during the visit, the Home Health Aides utilize FaceTime on the iPad to connect with a Home Health NP Lead at the hospital who can provide direct clinical assessment and revise the patient's care plan.

The Home Health Aides told us that they provide overall emotional support to patients and family members. It is uncommon for care providers to immediately follow up in the home, and early visits by Home Health Aides is viewed as having an impact on the sense of security that the patients and families feel at home after a hospitalization. The fact that the Home Health Aides can check for safety issues directly (e.g., medication errors, evidence of deteriorating medical status as reported by patient or family) as well as immediately connect the patient with an NP if needed via FaceTime, adds to the overall feeling of support and security provided through this component of the Delirium Program.

3.4.3 Technology

A number of different types of information technology are used in components of the Methodist Delirium Program:

- Pharmacists rely on a commercial clinical pharmacy decision support and adverse event surveillance system to identify and address problematic medication orders. Modifications to automated order sets, changes to recommended medication doses, and medication administration alerts reduce the use of medications and combinations that can cause delirium in older patients.
- Bedside Nurses record the delirium assessments in the patients' electronic health record, noting whether the patient has been screened, and the delirium assessment screen results (positive or negative). Currently, the Methodist Hospital System is migrating from its current electronic health record vendor to a different one; the Nurse Educator is collaborating with the new vendor to build Methodist's delirium assessment to the new electronic health record system.

- Volunteers record their in-hospital visits with patients in an Access database that was created specifically to track the volunteer activities. The volunteer supervisor also uses this tool to prioritize patients for volunteer visits and track the completion of these visits. Volunteers record in the database how many visits were attempted and completed during a shift, reasons for any incomplete visits, and whether patients received devices or tools such as hearing amplifiers or reading glasses.
- Care Navigators contact patients by telephone and record in the EHR whether the patient received home health visits, was readmitted to the hospital or another institution, or has other needs in the home setting.
- Home Health Aides use iPads to collect and report information about key care issues using standardized surveys loaded on the iPad. Everything is written in a 6th grade literacy level and the program is very simple to use. If an immediate consult is needed, Home Health Aides use FaceTime on their iPads to initiate sessions between the patient and NP. In April 2015, the Home Health NP Lead noted that Home Health Aides increasingly rely on basic phone calls and paper forms as many of them could not get sufficient reception on their iPads in more remote locations.
- Additional data collection, analysis and synthesis are conducted on an ongoing basis for reporting and compliance monitoring purposes, and are stored in a separate database created specifically for the Delirium Program. Administrative data are merged into this database, including MSDRG, ICD-9 codes, length of stay, discharge disposition, insurer, charges (billed amount), and revenue (paid amount).

3.5 Workforce Development

One of the key leaders for the Delirium Program described the implementation process as happening "from the ground up." Many of the interview and focus group participants confirmed this observation. Program Leadership described an informal process whereby Program Staff identified challenges on the ground in an ongoing fashion, and communicated these issues to their supervisors. As problems and difficulties were identified, solutions were generated by stakeholder groups in partnership with Program Leadership. By including the staff who work at all levels of the program, training and workflows related to delirium recognition and prevention evolved and improved over time. Across the board, the different stakeholders described an iterative implementation process in which the program components were continuously amended as the program increased in size.

> "The Delirium Program's approach to quality improvement is one of process improvement. They see it as 'doing the right thing for patients' (not just a Lean/Six Sigma kind of thing)."
>
> *– Program Leadership, April 2014*

In this section, we describe the initial training and compliance monitoring efforts, outline the challenges that different types of staff roles experienced during implementation, and describe adjustments made over time to strengthen the program.

3.5.1 Training, Ongoing Improvement and Compliance Monitoring Efforts

The primary training process associated with the Delirium Program is targeted for Delirium Program Staff specific to their role: Pharmacists, Bedside Nurses, Volunteers, Care Navigators, and Home Health Aides. Training, compliance monitoring, and retraining are continuous, to achieve full compliance with the delirium assessment screening protocols and other program components. The Delirium Program utilizes a "train-the-trainer" model, whereby staff is identified to receive in-depth training and then

deliver the information to others, sharing the same roles and responsibilities. Program compliance data are analyzed, shared with Program Leadership, and disseminated to Program Staff by their supervisors. Through this process, retraining of staff and/or system changes is initiated. The Program Leadership team is responsible for all initial training and compliance activities, described in Exhibit 6.

Exhibit 6: Leadership Team and Training/Compliance Activities

Team Leader	Training and Compliance Activities
Program Director	• Collects and analyzes compliance measures • Coordinates feedback to nurses and other staff on compliance and quality improvement
Data Analyst	• Provides continuous analytic support for compliance monitoring • Synthesizes all patient data from five intervention components, pulling together administrative data, pharmacy data, EHR, and clinical data for outcomes reporting and compliance reports
Lead Geriatrician	• Oversees physician education across the program in grand rounds, quality of care study groups, department of medicine or department of surgery meetings, and care management performance improvement meetings. • Guides and supervises program implementation at community hospitals, nurse education, charting reviews and quality control • Develops educational curricula for physicians and nurses, including on-line tools for non-Program Staff to increase delirium awareness across the hospital • Leads monthly chart reviews to assess accuracy of delirium assessment screens by Bedside Nurses; most audits are divided between two geriatric fellows who complete the chart reviews • Provides day-to-day ongoing delirium education and clinical support to Nurse Educator, Home Health Nurse Practitioner Lead, Care Navigator Coordinator, Lead Pharmacist and other Delirium Program Staff
Nurse Educator	• Provides training in administering the delirium assessment screen for Bedside Nurses and Home Health Aides • Oversees the training of Nurse Champions who monitor compliance and oversee delirium assessment screening activities on the units • Monitors compliance with the twice daily screening, by hospital unit, on a weekly basis • Conducts random chart audits—about 1-2 patients per hospital, 2–3 times a week. In addition, each hospital is subject to a weekly random audit. • Administers recognition program that designates the “unit of the month” or the “most improved unit” and gives prizes and parties to unit staff
Home Health Nurse Practitioner Lead	• Coordinates with the subcontracted agency that employs the Home Health Aides who conduct home visits for the Delirium Program • Participates in the development of curriculum/content for the home health component • Participates in monthly chart reviews of delirium assessment screen accuracy with the Lead Geriatrician
Care Navigator NP Lead (position discontinued in Fall 2014)	• Coordinated with the Care Navigator team • Tracked Care Navigator follow-up with patients at intermediate and high risk for delirium • Participated in monthly chart reviews of delirium assessment screen accuracy with the Lead Geriatrician
Lead Pharmacist	• Oversees and implements medication alert system and changes to automated order sets • Oversees pharmacy staff training and ongoing compliance monitoring • Conducts education on deliriogenic medications for physicians • Maintains a database with scientific articles and presentations that Pharmacists and physicians can access
Volunteer Coordinator	• Recruits, interviews and trains volunteers • Identifies patients for volunteer visits and manages the volunteer visit tracking database

The specific training components for every member of the intervention team are as follows:

Pharmacists

The Lead Pharmacist of the Delirium Program conducts training for other hospital Pharmacists about the program. She presents slides and facilitates interactive discussions about deliriogenic medications, automated order sets and medication alerts. Through this training, Pharmacists and physicians learn to think critically about medication management to avoid delirium. High risk medications are discussed and alternatives are presented. Additional educational materials, including scientific articles and presentations, are maintained in a shared database that Pharmacists and physicians can access. The lead Pharmacist periodically touches base with the lead Program Staff and reviews compliance reports. If she notices a concern (e.g., lack of follow-up by a Pharmacist on a higher risk medication prescribed instead of a safer alternative) she uses it as an opportunity to refresh education with Pharmacists and physicians.

Bedside Nurses

> "There is a tradition of nurses getting feedback from each other rather than from doctors and residents, so they're much more receptive to that… the Nurse Educator is a bulldog—she really pushed the nurses to learn."
>
> *– Program Leadership, April 2014*

The Bedside Nurses' training initially included three components: 1) an on-line Learning Management System module; 2) bedside training "huddles" or small gatherings of nurses where actual patient cases are reviewed; and 3) a large group interactive presentation by the Nurse Educator in which she role-plays a patient with delirium and nurses practice administering the delirium assessment. The last component has since been replaced with an online StepStone training module in which nurses go through various scenarios roleplaying the delirium assessment in an interactive way. The StepStone training module was created to help sustain the delirium training after the Award period ends. Details of the StepStone program are described in the Program Fidelity, Sustainability and Reach chapter of this report.

The Nurse Educator identifies a champion for the Delirium Program in each unit at HMH who provides feedback to unit staff on delirium assessment screening compliance. Nurse Champions at other participating Methodist hospitals are identified by Program Staff counterparts in their respective hospitals. An additional specialized training is offered to these champions on each unit, to help them monitor and encourage their unit's compliance. The champions' training includes additional information and videos, which these champions report as being more comprehensive and informative than the initial training. Some nurses commented that it would have been better if the Nurse Champion training had been given to all nurses, as that might have increased their comprehension and awareness of delirium, thereby speeding the implementation process.

Nurses are responsible for entering the results of the two daily delirium assessment screens into the EHR before midnight. Daily audits on compliance by the Nurse Educator are conducted and weekly reports are generated to provide feedback to the nursing staff. These reports identify units or individuals who are less compliant and perhaps need special attention from their Nurse Champion. Compliance with delirium assessment screening has increased from approximately 60 percent at the start of the program to approximately 93 percent. A monthly recognition program designates the "unit of the month" or the "most improved unit" and gives prizes and parties to unit staff. The Nurse Educator leads these components of the program. She thus provides both compliance checks and rewards, and is viewed as both "the stick and the carrot" by the program team and Bedside Nurses.

While compliance has improved since the start of the program, Bedside Nurses at Methodist West mentioned that sometimes non-compliance occurs when "floating" nurses from the ICU, who are not trained to conduct the delirium assessment, work shifts on the floors where the program has been implemented.

At the beginning of the program, leadership did not train Bedside Nurses on the specific medications that should be avoided, but the Bedside Nurses wanted to know how to interact with physicians to discourage deliriogenic medication prescribing. Program leaders prepared a sheet listing common drugs to be avoided for older patients, and alternatives, that nurses can share with physicians as needed.

Much of the training for Bedside Nurses involves understanding, administering, and documenting the delirium assessment; no training has been provided on the risk stratification score, which is not currently shared with nurses. Nurses are only aware of the delirium assessment score. The Nurse Educator mentioned that nurse managers already receive over 25 reports daily, and Nurse Champions receive around 15 reports daily; given the high volume of reports being sent to nurses on a daily basis, she thought that providing nurses with the delirium assessment score alone would be sufficient. However, physician leadership wants to eventually find an effective way to share the risk stratification score with nurses and other clinical members of the interdisciplinary team.

Volunteers

Volunteers attend a general hospital volunteer orientation and a two-hour Delirium Program training class, with written educational information and a video presentation. Volunteers participating in our initial case study reported that the training was very good, especially when anecdotes and examples of recent volunteer experiences were shared that demonstrate how the Delirium Program improves patient care.

Each volunteer also receives mentoring from the Volunteer Supervisor or more experienced volunteers. The mentor accompanies a volunteer for the first few visits with patients, to observe their interactions and offer feedback; the volunteers we met found this mentoring very helpful. The mentor will ask ad-hoc questions of the volunteers periodically to check their understanding of delirium-related issues, and address any concerns about interacting with patients.

Volunteers receive ad hoc guidance from both the Lead Geriatrician, who provides an overview of the program during the initial training session, and from other Program Staff such as the Nurse Educator and the Home Health NP Lead. Presentations are offered for volunteers each quarter about the Delirium Program, personal experiences of other Program Staff, and professional development opportunities at the hospital.

Care Navigators

The hospital-wide Care Navigator team also supports the Delirium Program by providing follow-up calls to patients identified as intermediate risk for delirium, or to those patients at high risk who decline a home visit. The Care Navigators are nurse practitioners who receive formal training provided by the hospital to support multiple programs. Their training for the Delirium Program specifically began as a "learn by doing" process and has evolved over time. Experienced Care Navigators communicate how to approach the subject of delirium with patients and caregivers, and how to document information about delirium in the EHR, as well as lessons learned since program implementation.

During the course of the program, Care Navigators have adjusted the way they approach patients and how they speak with them about delirium. They revised the script they use when speaking with patients

and families about delirium to make questions more natural, using neutral terminology. Neutral language is especially important for telephone conversations because sensitivities or misunderstandings are harder to observe than during in-person conversation.

A nurse practitioner on the Delirium Program Leadership team monitors completion rates of follow-up phone calls to patients at high and intermediate risk for delirium.

Home Health Aides

Home Health Aides' role in the program is to observe and record potential issues related to delirium and report problems or needs to the Home Health NP Lead who can conduct a clinical assessment and make decisions about patient care.

> "Those role-playing pieces of the training were the most valuable components because it all tied everything together when we were actually doing the home visits."
>
> *– Home Health Aide, April 2014*

Home Health Aides were trained in two cohorts. The first group of Home Health Aides received a very intensive 40-hour training that focused on how to record information, didactic lectures about delirium, role-playing exercises and extensive clinical content. They were all trained in the importance of delirium and its key features, as well as how to administer a Mini-Cog screen for cognitive impairment which is scored by the supervising NP. According to the Home Health Aides who participated in a focus group during our first case study, the Nurse Educator was very impressive in raising many possible scenarios and prompting trainees to really consider how they would act in a given situation in a patient's home.

A second cohort of Home Health Aides received a shorter training–24 hours rather than 40 hours–based on feedback from the first group that they did not need so much information about the physiological and clinical components of delirium to do their job well. Basic neurology and delirium education is still emphasized, but the focus is on building proficiency in communicating with and reassuring patients, addressing what can be managed in the home, performing the data collection, and documenting using the iPad. One Home Health Aide noted that "technology bridges the gap between generations." The Home Health Aides report that using an iPad to record and report patient information enhances their responsibility. When they chart, they have to pay more attention to the details, especially concerning medications. This new training focus is less overwhelming for the aides. Program leaders feel strongly that the communication section of the training is the most important, to enable aides to communicate well with older and possibly confused home patients. In December 2013, when iPads were incorporated into the Delirium Program, all aides participated in a 16-hour course about using the device for data collection, as well as troubleshooting.

3.5.2 Training Targeting the Hospital System

Because the Delirium Program is a systems intervention, training activities are available to physicians, case managers, nurses, speech therapists, social workers and other interested health care providers across the hospital, to support the goal of increasing awareness of delirium across the hospital. Program Staff described presentations in multiple meetings across the hospital to raise awareness about delirium and the Delirium Program. Hospital staff is encouraged to register for an on-line training course on delirium, and the Delirium Program tracks participation in this course for those not directly linked to the formal intervention. The Lead Geriatrician developed three different training modules which, once completed, allow continuing education credits for the learners. Availability of this course is disseminated across the hospital system via flyers and e-mail to departments and distribution lists.

3.5.3 Training for Community Hospital Staff

The approach to training community hospital staff has evolved since the program began. When the first community hospital implemented the Delirium Program, the Lead Geriatrician and nurse practitioners from HMH conducted training, monitoring and feedback. This model was not sustainable given the other responsibilities of these Program Staff so they adopted a train-the-trainer approach. The Nurse Educator trains Nurse Champions in each new community hospital joining the program, who then train the nurses on their units. The Pharmacist at HMH trains one Pharmacist at each community hospital who then implements the program with his or her Pharmacist colleagues. Each community hospital also has a physician champion, who has many of the responsibilities held by the Lead Geriatrician at HMH. Most of the Program Leadership stressed that in order to build a sustainable model, the community hospitals must adapt their program to their own setting and build capacity for ongoing training and compliance monitoring.

3.6 Implementation Experience

The Delirium Program was met with some resistance from nurses who were opposed to the risk assessments and from physicians who were troubled by the pharmacy alerts and recommendations. Resistance dissipated with time, and the program was eventually accepted by most nurses and physicians.

Interviewees noted that at first some nurses were defensive about having to implement the delirium assessment as they felt they already knew how to recognize delirium. After the Nurse Champions reminded nurses that the delirium assessment and monitoring are part of a hospital protocol and not designed to be punitive, many nurses realized that it was not any more difficult than their other routine assessments. The delirium assessment gained momentum as nurses were held accountable and received ongoing feedback from compliance checks. In addition, nurses began to recognize that they could not make assumptions about which patients were at risk for delirium, which was validated by the delirium assessment screening results.

This experience of an external, structured validation of delirium risk also improved communication between nurses and physicians. The nurses reported that they felt empowered when speaking with physicians because they had clinical information to support their concerns about patients' risk for delirium. Armed with this new tool, nurses explained the delirium assessment to hospital physicians and one even conducted the delirium assessment on a physician to demonstrate how it works.

Interviewees described some initial push back from physicians when Pharmacists recommended medication changes. Sometimes physicians had legitimate reasons for prescribing deliriogenic medications but other times, they were resistant to change. In these cases, the Pharmacists asked for a meeting between the physician and the Lead Geriatrician, or the department chair if necessary. The Lead Geriatrician would provide peer-to-peer education, offer research articles about medication management to reduce delirium, and address concerns the physician may have about changing prescribing practices. As physicians began to experience the positive impacts of recommended medication changes, initial resistance subsided.

Some interviewees described more buy-in difficulties for nurses and physicians at the community hospitals than at HMH. A few noted that it is easier to make changes at a teaching facility because residents are "spring chickens" and in a learning mode, while physicians in a community hospitals may

be less willing to change. To address this tendency, Program Staff presented clear evidence based on persuasive research, to motivate change.

Although the overall buy-in increased as the intervention progressed, interviewees described new challenges as the scope of the intervention increased. Some workflows that were straightforward at the beginning of the program became more complex as volume increased, and some Program Staff needed to acquire new skills. For example, one project leader described how the volunteer supervisor worked with the data analyst to develop a database to streamline reports; this required the volunteer supervisor to become more facile with Microsoft Excel® and the analyst to learn about delirium. Increased volume also required hiring of additional staff to handle more medication orders, Care Navigator calls and home health referrals. The Program Staff described in some detail the particular administrative, technological, and diagnostic complexities that developed as the program was implemented, and the ways in which they adjusted the program to respond to these complexities.

3.6.1 Administrative Complexity

Case study participants reported administrative complexity related to most roles in the program that were mitigated over the course of the program.

- ***Care Navigators.*** Missing or incorrect patient and physician information emerged as a crucial administrative complexity for the program. These information gaps made it difficult for Care Navigators to follow-up with patients after discharge, coordinate with the patient's primary care provider about follow-up appointments, and manage medications effectively. Incorrect patient contact information also interfered with scheduling Home Health Aide visits. Program leaders were surprised that this simple administrative detail had such an impact on their ability to implement the program.

  To address this problem, the Delirium Program Staff tried adding a new responsibility for the volunteers. When a volunteer visited a patient in the hospital who was at risk for delirium, the volunteer asked the patient and any family members for both the patient contact information and information about the primary care physician, including telephone number. The volunteer recorded the information so it could be corrected in the EHR. Although this presumably solved a problem for Care Navigators, it created other challenges for volunteers. Many patients were annoyed when volunteers asked for their contact information, and the volunteers found it awkward to ask patients for this information because the volunteer was not part of the care team or "official" hospital personnel. Patients were sometimes skeptical of the volunteers' requests, and felt that the hospital should already have the information. Volunteers learned to emphasize that the information was not being sought "for billing purposes." Ultimately, Program Staff shifted this responsibility to other personnel (Bedside Nurses, Nurse Managers, Care Navigators and Home Health Aides) because volunteers were unable to get the necessary information consistently.

  > "The nurse aides and Care Navigators ask about primary care physician [contact] information and try to connect [patients] to follow up with their PCP… [Getting PCP information and coordinating follow-up visits] is an Achilles heel for any inpatient provider. We struggle with that unless you have the benefit of being in a closed organization like a Kaiser."
  >
  > *– Program Leadership, April 2015*

- The Care Navigator component of the program, while adequately staffed when the program was first implemented at HMH, quickly reached capacity as more units began implementing the program. The nurse practitioners in this role were also implementing other programs—they were not solely

dedicated to the Delirium Program and were over-burdened. At first they addressed the problem by hiring an administrative assistant to pre-screen for the Care Navigators, ensure that phone numbers work and are accurate, and make appointments for the patient and Care Navigator to speak by phone. Care Navigators were still unable to keep up as volume increased, and the program has now hired a dedicated Delirium Care Navigator who manages all the patients through this program, rather than adding the Delirium Program to the other responsibilities of hospital Care Navigators. There are still workflow issues; specifically, follow up phone calls do not always take place as quickly as intended. For example, Care Navigators have to catch up with weekend referrals on Monday morning. Additionally, the Care Navigator manager reported ongoing issues with documentation. The tool used by Care Navigators only imports demographic data from the EHR automatically, so Care Navigators have to manually enter clinical data into their documentation tool.

- ***Nurse practitioner:*** The current Home Health NP Lead used to have to manually create referrals in the EHR for intermediate risk patients being discharged home so that the Care Navigator manager could review and assign the referrals. Manually creating referrals and mining through the high volume of patients, especially as more community hospitals were added, became time-consuming. To reduce the burden and complexity of creating these referrals manually, Program Staff streamlined this process by automating a report that identifies home-bound intermediate risk patients.
- ***Data Analyst***: The analyst built a database for the Delirium Program that pulls together administrative data, pharmacy data, EHR clinical information, and measures for reporting to CMS. The data analyst queries the database and develops summary tables. Because CMS' quarterly reporting requirements are greater than anticipated, the Program Leadership mentioned several times that they need, but cannot afford, an additional analyst.

Additional administrative complexities and mitigation strategies are shown in Exhibit 7.

Exhibit 7: Administrative Challenges and Mitigation Strategies

Challenge	Program Staff	Specific Issue	Mitigation Strategy
As the program grew, systems could not keep up with demand	Pharmacist	Pharmacist on the Care Navigator team fielded calls regarding medication orders	Hired extra pharmacy support staff to perform this function
	Volunteers	Volunteer coordinator had to compare lists by hand daily of which volunteers visited which patients and manage volunteer assignments	Data analyst created an Access database to streamline tracking process
Hospital HR department could not accommodate staffing needs	Volunteers	HMH could not incorporate the Delirium Program's volunteer component into its existing hospital volunteer program	Program Staff created the position of volunteer coordinator, who oversees and coordinates the program's volunteer component
	Volunteers	There is a limited pool of Volunteers at a participating community hospitals that are not teaching hospitals and have few medical students	Plan to increase volunteer recruitment and put more effort toward finding a stable pool of volunteers; Willowbrook ended up attracting more than enough volunteers.
	Home Health Aides	HMH did not have a home health license and could not hire aides for home visits	Contracted with a certified home health agency to implement this component of the program

Challenge	Program Staff	Specific Issue	Mitigation Strategy
Timing of hospital administrative processes did not coordinate well with program needs	Bedside Nurses	Bedside Nurses on the night shift only have four hours to enter their delirium assessment data in order to have it count in compliance reports for that day which ends at midnight for each 24-hour period. Nurses on day shift also struggle with finding a time to do the assessment when the patient is available (e.g. not getting tests or meeting with a physician)	Nurse Champions remind nurses regularly and compliance reports are motivators; night nurses are encouraged to enter their delirium assessment info before midnight but chart other information, that is not as time sensitive, later
	Home Health Aides	Window of time between decision to discharge and referral for home health is limited; difficult to know if patients are going home or going to an SNF or LTCH	Home Health NP Lead started tracking patients being discharged and creating a home health referral list until volume rose so much that Program Staff automated a process which produces a report containing a referral list for the Care Navigator Manager
	Pharmacist	Time lapse between alert for medication review and patient starting medication is sometimes too brief to intercept the medication order	Pharmacists revised automated order sets to eliminate ordering of high risk medications and reduce the need for interaction between physicians and Pharmacists
Training required for less skilled staff	Home Health Aides	Higher level of knowledge about medications needed by Home Health Aides than is usually required in this role	Created a medication reference to link generic names of medications with commercial names, to facilitate medication review during home visits

HR: Human Resources; HMH: Houston Methodist Hospital; SNF: Skilled Nursing Facility; LTCH: Long Term Care Hospital

3.6.2 Technological Complexity

The technological components of the program support essential program needs and in general the staff find the new technological tools helpful and useful. However, a few minor technological challenges were raised by Bedside Nurses, Pharmacists, Home Health Aides, and the data analyst.

- ***Pharmacist***: There are hospital-wide problems with medication reconciliation in the EHR because it does not consistently list the generic and brand names for medications together; it is possible for a patient to be prescribed both generic and branded versions of the same drug, regardless of whether those drugs are a "high-risk" deliriogenic drug, without physician or patient being aware of the error. In addition, the IT department has many competing priorities and it can take time to program or revise decision support algorithms and alerts. The lead Pharmacist works directly with the IT department and tries to "work ahead" of the process, to ensure that they have enough time to implement necessary components for the Delirium Program.
- ***Bedside Nurses***: Delirium assessment screens must be documented in the EHR by midnight in order to be included in the compliance reports for that day. This technical component of the program was challenging for Bedside Nurses, particularly on the night shift, as they only have a few hours early in their shift to enter the information before midnight, and they are often too busy with patient care responsibilities during that time to document the delirium assessment screens. At Methodist West, nurses reported that non-compliance tended to be higher on day rather than night shifts because the floor was much busier during the day—patients are often getting tests or meeting with physicians during the day, so nurses occasionally find it difficult to fit in the delirium assessment when the

patient is actually available. This creates a problem, as the unit does not get credit for compliance with the two daily delirium assessment screens if they are not completed timely.

Nurses also reported challenges related to the data entry system. The data entry system for the EHR jumps over the page where the delirium assessment information is entered as the nurses scroll through the record, so the nurses bypass it. Bedside Nurses reported wanting the fields to enter the information from the delirium assessment screening on a more accessible page. Some suggested a hard stop at the delirium assessment section so they would not forget about it. They also suggested adding a comment field to explain a missing delirium assessment (e.g., patient no longer on the floor, patient on narcotic medications). Lastly, the system the Bedside Nurses use does not immediately update when a patient is discharged; nurses inform the Nurse Educator when a patient has left their unit, so that she does not incorrectly record a missed delirium assessment.

The Methodist system is currently migrating to a different EHR vendor, and the Nurse Educator in working closely with the new vendor to integrate the delirium assessment into the new EHR.

- ***Home Health Aides***: Home Health Aides use iPads in their home visits; they report that seniors like the iPad and especially online video sessions with the nurse practitioner via the iPad. Although sometimes they have difficulty accessing the computer system wirelessly from a patient's home in a remote area, this was not reported to be a common problem when we interviewed Home Health Aides in April 2014. However, in follow-up interviews with the Home Health NP Lead, the nurse practitioner noted there were still connectivity issues with the iPads and that more often than not, Home Health Aides contacted her via phone.

3.6.3 Diagnostic Complexity

According to nurses and Program Staff interviewed, the diagnosis of delirium is difficult to make in the hospital setting, which can be a confusing place for any un-well older person. It can be difficult to distinguish between delirium and Alzheimer's disease or other dementias, particularly among patients with multiple disease states. As a result, delirium is often under-diagnosed, and therefore, not well documented. Nurses told our case study team that before the Delirium Program they thought that they knew which patients had delirium and which did not; after a structured delirium assessment tool was in regular use, however, they realized these assumptions were often wrong. Complex medication regimens may both increase risk of delirium and also make it more challenging to diagnose.

> "Health care isn't very good about educating nurses about cognitive impairment and the idea of a baseline. The patient's baseline is the way they were before the episode of illness. This is not something that is very intuitive to nurses and not something they learn in their training."
>
> *– Program Leadership, April 2015*

Program Staff as well as nurses report that there have been challenges in administering the delirium assessment correctly. Nurses often define the patient's baseline differently—some establish a baseline as the patient's condition at the start of their shift while others set the baseline as the way the patient was before entering the hospital. The Nurse Educator routinely conducts chart validations and audits and shares them formally and informally with Nurse Champions and nurse managers so that nurses at the bedside may receive rapid cycle and formal feedback. Through this feedback, they try to remind nurses that a baseline is the way the patient was before s/he became ill.

In addition to accurately establishing a baseline, nurses also emphasized the patient's cognitive variability throughout the day. For example, one nurse explained that the delirium assessment might be more

accurate if the assessment was conducted at the end of a shift, right before a shift change. A nurse who has been with the patient all day is more likely to notice and document changes in the patient than a nurse who has just started her shift. Moreover, patients are often not fully awake in the morning, having just woken up, or having been administered pain medications in the early morning. These factors may impact the results of the delirium assessment if a nurse conducts the assessment at the beginning of her shift during the day.

Care providers report that some patients believe that delirium is a stigmatized condition and are embarrassed by this diagnosis. Many of the care providers in the program discussed being careful about using the word "delirium" around patients and family members, who may react negatively and think that the clinician assumes that the patient is "crazy."

3.6.4 Adaptation and Trialability of Intervention Components

A key characteristic of the Delirium Program is its ongoing adaptation as it expands to new settings, requiring people possessing varying degrees of skill to try and learn new things. The project specialist at Willowbrook, who oversees the volunteers there, described the Delirium Program as one that is continually changing. She remarked that the program "pushes [her] out of [her] comfort zone…it pushes [her] to learn something new and grow." One example of adaptation at Willowbrook occurred when Methodist West suggested all of the facilities use a dashboard system to track volunteer visits. Methodist West's dashboard looked great to the project specialist at Willowbrook but the tool was "completely foreign" to her. She was challenged to create a dashboard and "get it quick!"

Suggestions for program improvement often come from clinical staff responsible for implementing the program. At Willowbrook, implementing the initiative before making it mandatory gave everyone a chance to get used to it, feel less overwhelmed, and learn how to administer the delirium assessment screenings and adjust their workflows. This phased start-up gave them a chance to adapt their processes in a way that best met the needs of their hospital. With Willowbrook's experience in mind, Program Leadership decided to implement the delirium assessment and pharmacy intervention in phases at Methodist West and Sugar Land hospitals. They rolled out the delirium assessment first, and three months later, the pharmacy intervention. Another reason for this phased roll-out was to better measure the impact of the components separately. Most of the Program Leadership emphasize that in order to build a sustainable and effective Delirium Program, the community hospitals must adapt their program to their own setting.

Program Staff have also modified several program components as the Delirium Program evolved. The evolution of each component is described in detail in corresponding stakeholder or workforce development sections. A brief summary of the changes, adjustments, and additions are reviewed below in Exhibit 8:

Exhibit 8: Staff Category and Changes to Training and Implementation

Staff Category	Changes, Adjustments, and Additions to Training
Bedside Nurses	• Nurses requested additional information about medication interactions in order to inform their discussions of delirium with physicians. Program Leadership prepared a sheet listing common high risk drugs to older patients, and medication alternatives.
Home Health Aides	• Receive additional training any time questions in their assessments are updated. • Condensed main training for second wave of Home Health Aides trained based on feedback from those trained in the first wave.

Staff Category	Changes, Adjustments, and Additions to Implementation
Program Staff	• Modified how home health component is explained to patients to increase number of patients who consent to visits; learned that establishing "face-to-face" contact with patient before patient leaves hospital increases likelihood of patient consenting.
Pharmacists	• Alerts for Lorazepam were being generated with great frequency, adding unnecessarily to the workload of Pharmacists because at a low dose, this medication is often appropriate (e.g., for anxiety before an MRI). The decision support rules were revised so that the alert now only triggers for Lorazepam at higher doses.
Bedside Nurses	• To avoid non-compliance at night, nurses are encouraged to conduct and document the delirium assessment before completing the rest of their assessments. • Nurses work together to complete delirium assessments when one nurse is especially busy.
Volunteers	• Volunteers reported having difficulty carrying around and keeping organized several folders with patient names and information. Taking the feedback from volunteers, the volunteer supervisor consolidated the information into one sheet and prioritized volunteer visits by patients at high or intermediate risk. • Volunteers described feeling awkward and ineffective in obtaining contact and primary care physician information from patients; Program Staff expanded the responsibility of collecting this information to include other staff groups who interact with the patients.
Care Navigators	• The growing volume of patients in the Delirium Program prompted Program Staff to request that one Care Navigator be dedicated to only the Delirium Program. Volume has continued to grow with the addition of more community hospitals, which has led to other Care Navigators sharing the responsibility for the Delirium Program with the dedicated Care Navigator. • Program Staff began encouraging several staff groups, in addition to volunteers, to try collecting primary care physician and other contact information from patients.
Home Health Aides	• Home Health Aide component started more slowly than expected, giving them an opportunity to adjust the protocols and learn how to ask questions that patients might not wish to answer in the presence of family members (e.g., "do you feel helpless?"). • Suggested changing questions that were awkward or uncomfortable to ask for the assessment; Program Staff, with input from Home Health Aides, adjusted questions accordingly. Home Health Aides implement newly scripted questions. • Program Staff began encouraging several staff groups, in addition to volunteers, to try collecting primary care physician and other contact information from patients. • The Home Health NP Lead noticed that Home Health Aides were not calling her for consults as often as she expected or wanted, so she worked with them to establish "triggers"—specific situations or patient conditions (e.g., a systolic blood pressure below 90)—that warranted a phone call.

The Delirium Program has maintained its core purpose to better prevent, detect, and treat delirium in older hospital patients through enhanced monitoring and treatment, but has been repeatedly adjusted and enhanced by each of the main stakeholder groups. Many of the changes stem from suggestions from the staff responsible for implementing the program. As a result, Program Staff believe, the program adaptations have been accepted and adopted more quickly than had they come from program administrators.

3.7 Implementation Effectiveness

This section presents areas in which Methodist's Program Staff believes the intervention is making a difference in quality of care delivery, patient health outcomes and cost savings. For each of these aims, we discuss how the Methodist team is measuring the program's impact, as well as how Abt Associates intends to measure the program's impact. Finally, we discuss unanticipated impacts that have arisen over the first several quarters of the program's implementation.

3.7.1 Better Care

Recognition of Delirium Across the Hospital System

All components of the Delirium Program are intended to provide better care by increasing early recognition of delirium and shifting the hospital culture to prioritize delirium as a legitimate and important focus in acute care settings. Across all levels of the program, many staff described the shift in culture that the Delirium Program is trying to achieve, primarily through increased recognition of the condition across the system (see Exhibit 9).

Exhibit 9: Impact of Culture Change Reported by Stakeholders

Stakeholder	Culture Change
Bedside Nurses	• Awareness that they may not know if patient has delirium • Ability to interpret changes in behavior as being delirium-related • Validating clinical intuition and empowering nurses in their interactions with physicians
Pharmacists	• Importance of changing automated order sets • Importance of reinforcing changes through constant communication • Engaging with physicians regarding high risk medications • Comfort in being the "safety net" for delirium-related issues in the hospital
Physicians	• Awareness of medication risks even when a patient seems fine • Shift to a prevention mindset • Willingness to consider different prescribing to reduce deliriogenic medications

Safer Transitions

Participants described safer transitions from hospital to home, better coordination with patients' primary care physicians, improved medication reconciliation, better identification of medication risks in the home setting, and identification of other safety concerns for older patients at home (e.g., wires that could trip a patient). According to Care Navigators and Home Health Aides, improved coordination during care transitions may contribute to improved patient and family member satisfaction with care. Both groups reported receiving feedback from patients indicating that care is more personalized and more supportive than they had received in the past. They described that patients are sometimes surprised that people are being sent to their home or calling them to ensure their needs and concerns are addressed after they have left the hospital. Patients often ask the Home Health Aides from the Delirium Program to keep visiting, and to replace the regular home health agency staff that is providing care.

Reduction of Medication-Related Delirium

Medication-related delirium has decreased as a result of implementing the Delirium Assessment, as well as generally increasing training and awareness of delirium throughout all levels of staff in the hospital system. The Delirium Program Staff described multiple examples of situations where delirium assessment screening led to better care by reducing medication-related delirium. For example, one nurse described an

oncology patient in his 80s who was totally alert and oriented, but then after a procedure that required anesthesia began hallucinating. The Delirium Program helped the nursing staff monitor the change and respond appropriately. Another nurse described a patient who had hip surgery with an ICU stay and became delirious due to narcotics used to control pain; they gave the patient Tylenol instead and all the delirium symptoms resolved. Reductions in medication-related delirium are also due to the success of the Delirium Project's goal to increase awareness about medication-related delirium on the part of the health care team. A Care Navigator noted that when a patient starts taking morphine and his or her behavior changes, the nurses call the Clinical Emergency Response Team and the ordering physician, which did not happen before. Both the Pharmacists and physician leads described the dramatic increase in the use of Ramelteon, a melatonin agonist used as a substitute for sleep medications such as Ambien. Most physicians had never heard of Ramelteon before, and now are prescribing it frequently.

Education of Patients and Family Members

Improved education for patients and family members is another element of better care resulting from the Delirium Program. Nurses reported that family members seemed more educated about medications, and able to explore alternative medicines and holistic strategies for improving sleep. Decreasing stigma around delirium is also viewed by staff as a benefit for family members and patients. According to nurses and physician leadership, caregivers and family members are now more likely to recognize subtle differences in patient behavior and to bring this to the nurse's attention. Many program participants also emphasized that the program led to simple, yet important, improvements in care such as offering reading glasses and hearing amplifiers.

> "…they had initially thought their mom's confusion meant she was just sad or upset …. But now they know that when they see certain signs, they need to bring their mom in to see someone rather than letting it go on for several days."
>
> *–Program Leadership, April 2014*

Program Reach

Although the reach of the program is judged as "good" by Bedside Nurses, Program Staff, and Pharmacists, they noted several examples where the patients did not participate in the program or did not receive the full complement of interventions that were intended.

- ***Pharmacists***: Some patients who present at the hospital on Friday evening or over the weekend may not receive a pharmacy intervention if a high-risk drug is ordered because Pharmacists are a bit more resource constrained on weekends and may not get to the patient in time before s/he is discharged. Pharmacists described challenges in reconciling medications during care transitions, and concern about primary care physicians reintroducing deliriogenic medications. They also can "miss" a patient if s/he is discharged before they have a chance to intervene; these patients usually come in for observation and spend less than 24 hours in the hospital. Coordination with hospital discharge planners and community primary care physicians is a recognized next step for the Delirium Program.
- ***Bedside Nurses***: Nurses reported that some patients refuse to answer the delirium assessment screening questions.
- ***Volunteers***: Volunteers described missing patients because they are sleeping, are in 'isolation' rooms, are getting medical tests, or are meeting with the physician.
- ***Care Navigators***: A similar issue of hours occurs for patients who are discharged home on Friday. If the homebound patient is intermediate risk, s/he may not receive a Care Navigator follow up call within the targeted 48–72 hour window as Care Navigators do not conduct calls on weekends.

Care Navigators initially had difficulty reaching patients by phone but several system changes have improved the accuracy of patient contact information (telephone numbers) and an assistant works with Care Navigators to identify any missing or invalid telephone numbers. Some patients initially declined the home visit, but after adjusting the script multiple times to soften the way they talk about delirium, Program Staff have noticed an increase in patients agreeing to the home visit.

- ***Home Health Aides***: Some patients are discharged from the hospital before a Home Health Aide referral is established and therefore they do not receive this component. Some patients live too far away for Home Health Aide visits: the contract with the home health services company has a geographic coverage area that stipulates aides must visit any patient within a 40 mile radius of each hospital, but not outside of that range.

Methodist's Measurement Strategy

The Delirium Program team collects data on a number of quality measures that they regularly report to CMS and use for internal quality improvement. These measures identified in the Awardee reports to CMS include the following (see Exhibit 10 below).

Exhibit 10: Measuring Better Care

Relevant Metrics Currently Collected by Awardee
Cumulative Dose exposure of high risk deliriogenic medications per patient visit age 70+ on implemented hospital units
Number and percent of patients with 0, 1 or 2 delirium assessment screens completed in a 24-hour period on implemented hospital units
Number of patients identified as high risk patients who have at least one volunteer visit
Number of patients identified as high or intermediate risk discharged home with Care Navigator call
Number of patients identified as high or intermediate risk for delirium with 0, 1, 2 or all appropriate interventions (medication adjustment, volunteer visit, Care Navigator call, Home Health Aide visit)
Number of all patients with volunteer visit (high, intermediate or low risk)
Percentage of patients for whom the pharmacy decision support system triggered alerts
Percentage of medication alerts switched to alternative medications, discontinued orders, necessary continued orders, or reduced dosage
Percentage of medication alerts with pharmacy intervention (alert acknowledged) or without intervention (not acknowledged)

3.7.2 Better Health

Avoiding or addressing delirium reduces risk for many other adverse events. Many of the staff participating in the Delirium Program describe a decrease in falls and a decrease in readmissions, as beneficial outcomes of the program. In addition, patients who are screened are believed to have lower mortality than those who are not.

Methodist's Measurement Strategy

Methodist is tracking a number of outcome measures related to measurement of better health as noted in their reports to CMS (see Exhibit 11 below).

Exhibit 11: Measuring Better Health

Relevant Metrics Currently Collected by Awardee
Baseline rates for falls, discharges home, rehospitalizations and mortality
Number and percentage of encounters with falls and at least two delirium assessment screens in a 24-hour period
Number and percentage of encounters with falls by patients at the high, intermediate or low risk for delirium
Percent of patients 70+ on delirium screening units discharged home, SNF, LTCH, rehab or psychiatric facility
Readmission rate for patients discharged from a delirium screening unit
Mortality for patients at intermediate or high risk for delirium

SNF: Skilled Nursing Facility; LTCH: Long Term Care Hospital

3.7.3 Lower Cost

Program Staff described ways in which the program is reducing costs, by identifying altered mental status early and improving the patients' care trajectory. In particular, reducing readmissions has the potential to reduce costs for Medicare and Medicaid. A program leader estimates that at $25,000 per case of delirium prevented, they will save $10 to 15 million by preventing 20 percent of current delirium cases.

Despite these estimates, many acknowledged the difficulty in measuring and assigning cost savings to delirium cases that are prevented, but also the importance of capturing costs avoided through improved patient outcomes.

Methodist's Measurement Strategy

Methodist is tracking a number of outcome measures related to costs as noted in their data reports to CMS (see Exhibit 12 below).

Exhibit 12: Measuring Cost Savings

Relevant Metrics Currently Collected by Awardee
Average cost (to payers) for patients with delirium at each TMHS facility
Average cost (to payers) for patients with delirium at each TMHS facility that were admitted to a unit with Delirium interventions
Average cost of SNF care, for patients discharged at intermediate and high risk for delirium

TMHS: Texas Medical Hospital System

3.7.4 Unanticipated Impacts

Although the Delirium Program is intended for patients 70 years or older, it has impacted younger patients, also. Automated order sets that reduce deliriogenic medications similarly apply to all patients under 70 years old. In addition, Bedside Nurses use the delirium assessment to assess cognitive status among patients in their 60s as well, who may benefit from early recognition of delirium. If a patient under 70 years is screened to be at risk for delirium, the only other intervention they receive is the delirium medication order sets specific to those at risk for delirium; none of the other program interventions are offered.

Bedside Nurses reported several ways the Delirium Program has had an impact on how they do their jobs. an improved ability to listen as a result of their Delirium Program training, a more personal relationship with patients, and being less likely to assume that a patient does or does not have delirium. One nurse noted that the delirium assessment helps her identify sepsis risk; an altered mental status is often a precursor to sepsis. Another nurse on a neuro unit mentioned that the delirium assessment helps her identify any complications from neurosurgery as well. Nurses also reported unexpected benefits to their own job satisfaction through increased empowerment in their interactions with physicians, accountability to the patient and to each other, and pride when they identify a symptom of delirium or a potential risk factor.

Home Health Aides also reported feeling greater empowerment in their job as a result of the Delirium Program. For example, Home Health Aides explained that in many other Home Health Aide positions, they are not allowed to touch patients' medications, while in this program they have been trained to find and record all of a patient's medications.

Because the Delirium Program causes Pharmacists to review medications when an alert is triggered, it inadvertently creates an environment that allows Pharmacists to recognize other potential medication interactions unrelated to delirium. Because Pharmacists review the patient's entire list of medications when an alert is triggered, they sometimes find other problematic medication issues. Additionally, one alternative medication, Ramelteon (a melatonin receptor agonist), that was a suggested substitute for drugs like Ambien, was virtually unknown by most physicians at Methodist. In one quarter alone, Ramelteon has been prescribed to 1,200 patients.

> "None of the doctors had heard of this drug before! Twelve hundred patients received the drug in the last quarter. It's the biggest thumbprint of the project. No one used it prior. Talk about unplanned things—we're seeing now that the medication is making headway in delirium prevention elsewhere as well."
>
> *–Physician Leadership, April 2015*

Some Bedside Nurses reported that the intervention empowers patients as well, who feel a sense of achievement in being able to answer questions correctly and display appropriate memory abilities.

3.7.5 Outcomes That Can Be Measured Using Claims

It will not be possible to identify direct program participants, and a comparison group, who are screened and classified as being at low, moderate or high risk for delirium using claims data, as the screening program utilizes clinical data and assessments not present on claims. It is important to note that many of those who receive services through the Delirium Program will not reach the threshold of an ICD-9 diagnosis of delirium—ICD-9 codes will not be an effective method for identifying intervention patients, because often the delirium is prevented by the program and hence not coded. It is also important to note that some nurses administering the intervention reported screening and providing Delirium Program services to individuals who were younger than 70 years, but seemed to be at risk.

There are a number of potential outcome measures that can be identified using claims. As noted in Exhibit 13 below, these measures include:

Exhibit 13: Relevant Metrics Available in Medicare Claims Data

7, 14, 21, 30, and 60-day re-hospitalization
7, 14, 21, 30, and 60-day post-discharge ED visits
30-day delirium-associated ED visits
30-day ICD-9 delirium-associated readmissions to acute care hospitals
30-day mortality rate
70+ patients with a (ICD-9) delirium diagnoses
In-hospital mortality rate
Inpatient length of stay
Percent discharge to LTCH, SNF or home health care
Percent discharge *without* post-acute care
Proportion of delirium-associated Medicare stays that reach CMS outlier status
Total 6-month episode costs

3.8 Context

In each interview and focus group during the case study, participants were asked about key contextual factors related to implementation and ongoing execution of the Delirium Program. Several factors informed our understanding about how the context at HMH both shapes and is shaped by the Delirium Program: endogenous factors, staff retention and satisfaction, measurement and self-monitoring, program fidelity and reach, and sustainability.

3.8.1 Endogenous factors

Members of the Delirium project team feel that hospital leadership is supportive of the initiative and, other than needing a second data analyst, they have sufficient resources to implement the project. Although initially it was challenging to get buy-in from physicians, IT, pharmacy committees, and nursing leadership, over time everyone in the Delirium Program came on board.

The Houston Methodist Hospital System has many other concurrent initiatives, including the sepsis early detection program funded through another HCIA Award. In some respects, the nurses found that these other interventions were helpful because they were implemented in a similar way and the nurses are familiar with the implementation process for new initiatives. However, some nurses noted that because sepsis is treated as a "core measure," they prioritize the sepsis screen over the delirium screen because being non-compliant on a sepsis screen carries more consequences.

In addition, some case study participants reported administrative complexities for patients in multiple programs. All patients 70 and older receive the Delirium Program hospital-based interventions, but some patients at intermediate or high risk of delirium who participate in competing programs do not receive the Care Navigator or Home Health Aide visit following discharge. There was some confusion among Care Navigators about when and whether to engage with patients who are also eligible for other programs. The other programs include the following:

- ***Mini-Cog pilot program***: This program was on one unit at HMH (about 20 beds), and began in late January 2014. As part of the pilot, all patients over 70 years received the Mini-Cognition test in addition to Delirium Program screening and interventions. Patients who failed the Mini-Cog test,

scored low or intermediate on the risk assessment, and were home-bound, received a home health referral. Less than 1 percent of patients eligible for the Delirium Program were also eligible for this pilot. This program did not prevent Delirium project participants from receiving services, but provided follow-up care to a few low and intermediate risk patients through the home visits transition care program. This program ended in December 2014.

- ***Health Coach program***: In April 2014, this program had only enrolled patients from Houston Methodist San Jacinto. It is a transition in care program for CHF patients who receive a referral to a care coach to assist with care coordination following hospital discharge. The program began in early 2013. If a patient is in the Health Coach program and screens at intermediate or high risk for delirium, then he or she will not receive Care Navigator or Home Health Aide services through the Delirium Program. About 10 percent of intermediate risk patients at San Jacinto are currently also in the Health Coach program, and do not receive Care Navigator services through the Delirium project. As of our first case study in 2014, there were no high risk delirium patients in the Health Coach program.
- ***Delivery System Reform Incentive Pool (DSRIP) program***: In June 2014, Houston Methodist hospital launched a program aiming to improve transitions in care for patients with behavioral health issues. Under this program, all patients admitted to the hospital who have a history of behavioral health issues will receive a Discharge Decision Support System screen. If a patient screens positive, a social worker will visit the patient to register them for home health visits and follow up phone calls. Most of the patients qualifying for this program are younger than the Delirium project target group. In June 2014, there was only one patient that was eligible for both the DSRIP program and the Delirium Program. In cases of overlap, the clinical teams will coordinate to determine which of the two programs would be best for the patient. According to physician leadership of the Delirium Program, there has been minimal overlap between the programs, even after both were rolled out to West Houston and San Jacinto.
- ***Other Disease Management programs***: If a patient has a chronic disease (e.g., End Stage Renal Disease) or is otherwise receiving Care Navigator or home health follow-up from a care management team, he or she is not eligible for the Delirium project's post-discharge follow-up services. About 3 to 5 percent of the patients eligible for Delirium project services fall into this category.

Through these programs, as many as 20 percent of Delirium Program patients may not receive the full complement of services, but we will be unable to identify which patients fall into each group and which services they do or do not receive. Since some of these programs began at the same time as the Delirium Program, it will be impossible to attribute any observed changes in outcomes or spending to the Delirium Program alone.

3.8.2 Staffing

Impact on Workload

Care Navigators, Pharmacists, Nurse Champions, and Bedside Nurses reported temporary increases in workload, primarily at the beginning of the program. For example, Bedside Nurses experienced an increased workload as they were learning the delirium assessment, but it is now so routine that they feel it saves time by identifying problems early. Program Leadership has increased the number of Care Navigators who conduct follow-up calls for the Delirium Program to accommodate the higher volume of calls needed as the program expands to more hospital units. A Care Navigator position that is dedicated to the Delirium Program has been added. Pharmacists reported increases in their workload to assess alerts

and communicate with physicians, but as automated order sets were adjusted, less follow-up is now needed. An assistant Pharmacist position was added to provide pharmacy support to the Care Navigation team. Delirium Program

A program coordinator was hired at San Jacinto to supervise volunteers, round on high-risk patients, and request consent for home visits. Originally, Program Staff at HMH were responsible for those aspects remotely. Since the program coordinator was hired, Program Leadership noted a noticeable increase in volunteer visits completed and consent forms signed.

One challenge has been maintaining the program components over the weekend and during the night shift. Although the delirium assessment screening, medication management and alerts, and responses to these alerts, all take place seven days a week, 24 hours per day, some components of the program pause during the nights and weekends. Volunteers visit hospital patients Monday through Friday from 7 AM to 9 PM. Care Navigators call patients Monday through Friday between 9 AM and 5 PM. Home Health Aides can visit patients on weekends, but generally schedule visits during weekday work hours. Weekend backlogs were mentioned as a problem for Care Navigator follow-up primarily because they delayed the timing of the follow up calls for intermediate risk patients.

Teamwork

Program Staff report high levels of teamwork in this program that follows at-risk patients throughout their hospital stay and as they return home. Most members of the Delirium Program team at HMH hospital, including the Lead Geriatrician, are located in the same office suite, which facilitates communication.

The key leaders hold two team meetings each week—one for the leadership teams at HMH and its community partner hospitals, and one for the leadership team only at HMH. They work together to inform each other's components of the project. One example of collaboration is an interactive learning case video about the program which will be used to educate staff across the hospital. The Delirium team has all contributed by generating cases to highlight in the video.

The Delirium Program also encourages teamwork across the hospital among Bedside Nurses. Nurses described helping each other remember to enter delirium assessment screens into the system by 11:59 PM each evening. Even though Nurse Champions generally find nurses on their units to be receptive to feedback, Nurse Champions with shorter tenures and less experience reported experiencing some resistance from nurses on their unit who had much more experience and/or longer tenures at HMH. Bedside Nurses and Nurse Champions generally agreed that the dynamic on their units as a whole was one of teamwork and cooperation, with some occasional challenges in communicating with staff of varying levels of experience.

Hiring and Replacement

There were two planned departures of the nurse practitioners who were part of the original Delirium Program team. They left for personal reasons unrelated to the program and were replaced by one nurse practitioner who leads the home health component. Because the process of creating referral lists of intermediate risk home-bound patients (a responsibility of one of the nurse practitioners) was automated, Program Leadership felt that only one nurse practitioner was really needed. That nurse practitioner oversees the home health component and shares the responsibility of answering consults from Home Health Aides with a physician fellow.

The Delirium team's original data analyst and education specialist also left HMH. A new data analyst was hired to replace the one who left. Given that the education components had already been rolled out, the Project Director replaced the education specialist's position with a program manager one. Because program needs have evolved to encompass more business and project management work, the Project Director hired a program manager with a management rather than education background.

In addition to the turnover within the Delirium Program team, there have been some changes to staff in the hospital that also have impacted the Delirium Program. The Chief Nursing Executive at Methodist was replaced, which produced turnover at the director and nurse manager levels. One outcome of these changes was the addition of a nurse manager at night on each unit. The nurse manager, though not specifically hired for the Delirium Program, helps reinforce delirium assessment documentation at night. Finally, the Nurse Educator mentioned that bedside nurse turnover has been higher than expected. Nurses in the Houston region are in high demand, so many nurses leave Methodist to work at other hospitals or to pursue an advanced practice degree. As a result, training of new nurses remains a sizeable ongoing activity.

3.8.3 Measurement & Self-Monitoring

Program Staff dedicates considerable attention to tracking and reporting, to provide constant feedback to staff, and to CMS. Feedback reports to Program Staff include the following:

- ***Automatic medication monitoring***. Both the medication alert and the response to the alert by the Pharmacist are automatically generated, and reports of these activities are produced on a daily basis. The lead Pharmacist monitors these reports closely, and will follow-up in the event that there are concerns. For example, if a particular Pharmacist received 45 alerts in a day, but only responded to 28, the lead Pharmacist will follow-up to determine why the Pharmacist did not contact a physician for the other 17.
- ***Daily compliance checks of delirium assessment screens, with feedback to Bedside Nurses as needed***. Every 24 hours there is an automated system check for compliance. A report is generated showing patients who were and were not screened on every unit that day. The Nurse Champion, unit manager and health educator receives this report and follows up with the nurses on shift at that time to problem solve why any delirium assessment screens did not occur.
- ***Weekly compliance checks of delirium assessment screening***. Weekly, the central leadership team monitors overall delirium assessment screening compliance over time. If after a few weeks, a particular unit has consistently low compliance, the team takes collective action and involves the Nurse Champion to problem solve and improve compliance.
- ***Monthly chart reviews for accuracy of delirium assessment screening***. Early on in the program, the Lead Geriatrician, with assistance from the Care Navigator NP lead and the Home Health NP Lead on the leadership team, met once a month to review records for a random day for every patient on a unit eligible for the delirium assessment screen. Each record was reviewed to assess whether the notes are consistent with the delirium assessment risk stratification score. Because the ICD-9 code of delirium does not increase reimbursement, only 20 to 30 percent of cases who might qualify for this code actually have it listed in their chart. Rather than rely on ICD-9 coding, the physician and nurse notes are closely reviewed to assess how well the nurses are picking up cases of delirium. Feedback on the results of this accuracy check is provided to the Nurse Champions on each unit, and any problems uncovered during the process are addressed with the nurses. Program Leadership, still conducts

monthly chart audits, but now with the help of two geriatric physician fellows rather than the two NP leads who have left the program.

- ***Volunteer monitoring***. As already described above, there is a volunteer database that tracks which patients needs a volunteer visit in the hospital, and who is visited. Each volunteer is expected to make two attempts at visiting a patient before marking that the patient was unavailable. They log the outcome of each visit attempt in the database, and record whether the patient received any materials such as hearing aids or glasses. The volunteer supervisor oversees the tracking database and follows up as needed if there are problems (e.g., low rates of successful volunteer visits on a particular unit).
- ***Care Navigator monitoring***. Twice a month, reports are generated by the Care Navigator team tracking all patients that were referred for follow-up calls, and the status of the referral. Every patient is logged as one of three options: call completed; not eligible (e.g., admitted to SNF, died), or unsuccessful (e.g., unable to reach following discharge). The program manager, the lead Pharmacist, the manager of the NPs, and the individual responsible for writing the Care Navigator reports meet and review the information.
- ***Home Health Aide monitoring***. Once a month, the Home Health Aide contracting service invoices the Delirium Program and includes a visit log of all patient visit activity. The program manager checks the monthly visit log against the list of patients at high risk who consented to receive the Home Health Aide visit. In addition, the leadership team has access to all chart information collected by the Home Health Aides during their home visits. The lead Pharmacist reviews all these patient charts to make sure they are compliant with medication orders.

Many individuals we interviewed reported appreciation for the regular feedback they receive on how the program is working—not only their own compliance with protocols, but also hospital reports, for example on decreased rates of in-hospital falls. Some nurses complained that other initiatives at Methodist do not always provide regular feedback and compliance checks on how they are doing. In their view, the Delirium Program is a model that exceeds the ordinary programmatic feedback that reaches Bedside Nurses. According to the Program Leadership, the Delirium Program is somewhat understaffed to manage the volume of data and reporting, especially given the importance of feedback for staff at all levels.

3.8.4 Program Fidelity, Sustainability and Reach

Program Fidelity

Although the basic components of the Delirium Program are the same across units, shifts and sites, there are adaptations made due to differing patient needs (e.g., neurology versus cardiology). For example, it is more complicated to assess patients in neurology due to other underlying disorders, and the process of assessment may require more input from family or other clinicians to establish the patients' baseline. In addition, some units screen every patient, and other units screen only those 70 and older.

Delivery of the program varies across shifts due to staff availability. As noted in section 3.4.2, nights and weekend shifts have lower staffing levels than weekday shifts, which can be a challenge to program compliance. In addition, physicians are more readily available on weekdays to consult about medication reconciliation, which can facilitate prescription changes to prevent or mitigate delirium during the day. Nurses noted that it is important to have Nurse Champions on both night and day shifts, to encourage compliance with delirium assessment screening. As noted above, although all patients 70 and older on acute care units are eligible for delirium assessment screening and volunteer visits, there are competing

programs at the hospital (e.g., the Health Coach program) that prevent some at-risk patients from receiving follow-up transitional care services through the Delirium Program.

Programmatic differences across hospitals stemmed from broad implementation challenges across settings. Some physicians at community hospitals are described as being more recalcitrant than at HMH. Participants at HMH described their teaching hospital as having more tech-savvy, younger doctors who are accustomed to research protocols and EHR alerts. Community hospitals have a different culture, resulting in challenges to buy-in. Hospital leadership noted that evidence must be particularly clear and convincing during presentations at community hospitals, to persuade physicians that the program will add value. There are also different structures and processes for gaining permission to make changes at community hospitals, and Program Leadership met with more groups at community hospitals, such as hospital committees and clinical departments, to seek approval for program implementation. Whereas at HMH, the meeting structures are more streamlined, with all leadership available in one place at one time, at the community hospitals it may be necessary to attend multiple meetings in order to connect with all key stakeholders necessary to the success of the program. Program leaders stressed the importance of finding champions at a community hospital who will take ownership of the program. Their approach has been to work with each hospital's staff and leaders to create a workable implementation approach, rather than trying to impose the approach that works at HMH.

> "It is kind of scary thinking about when we weren't doing the [Delirium Assessment]; it has helped explain why certain patients are a certain way and why they ended up coming into the hospital again."
>
> *–Bedside Nurse, April 2014*

Sustainability

There was widespread agreement that the program should continue when the Award ends, and the program team has tried to implement the program in a way that will ensure sustainability, however, some modifications will be required once the HCIA funding period ends.

When thinking about sustainability, Program Leadership has considered the operational components: education, technology, and reporting as well as the intervention components by each stakeholder role: nurses, Pharmacists, home health NP and aides, Care Navigators, and volunteers. Plans for sustaining intervention components by stakeholder are described below:

Pharmacists

Order set changes are already built into the system, and will not require ongoing changes. Additionally, alerts for the nine high-risk medications and corresponding responses from Pharmacists will continue as they have already been incorporated into Pharmacists' workflow. As physicians have become accustomed to the order set changes, education about the changes will not be necessary in the future.

Nurses

An online StepStone training module was created and rolled out to train nurses on the delirium assessment. The training module goes through a number of different scenarios that nurses may encounter when conducting the delirium assessment on patients. The StepStone program creates cartoon-like avatars that represent the various people that would be involved. Nurses can complete these modules on their own time. This module replaces the original roleplaying exercises led by the Nurse Educator and helps make training more sustainable by not requiring a full time Nurse Educator to conduct all trainings.

Compliance monitoring of the delirium assessments will continue, but will be the responsibility of each individual facility. A small amount of support from the System Quality Office at HMH will allow for a data analyst to keep track of some basic analysis and monitoring. The in-depth analysis conducted during the Award period is not feasible as the System Quality Office cannot dedicate one data analyst full-time to monitoring delirium assessments.

Volunteers

The volunteer supervisor position will be partially funded through the end of the Award, but funding for volunteer materials such as ice packs and puzzles will phase out. Each facility and its respective volunteer department may determine whether they want to continue supplying these materials.

Care Navigators

Care Navigators are part of an existing department at Methodist, and therefore, will continue to call patients at risk for delirium even after the Award ends.

Home Health NP and Aides

Program Staff are winding down the home health component in the last year of the Award. They plan to coordinate with community-based organizations such as Sheltering Arms and United Way to ensure that older patients have a broader set of resources that extend beyond their home health agency. Program Staff are providing training and education in geriatric assessments to these organizations, targeting a broad set of professional staff such as social workers, care managers, and home health workers. Finally, Methodist plans to link these professionals with a direct hotline from which they can connect with a geriatric specialist should they have questions or concerns.

3.9 Conclusion and Next Steps

The Delirium Program is widely endorsed by participants as effective and worthy of continuation. Key program components that are viewed as being especially successful include:

Attention to workflow: Program components were carefully integrated into existing workflow as capacity issues emerged (e.g., Bedside Nurses conducting the delirium assessment screen on all patients to ensure assessments do not miss the target group; automated medication alerts and order set changes).

Bottom-up implementation process: Program Leadership approached this project as a systems intervention and responded effectively to issues that emerged as the program was implemented. Given the iterative nature of this problem, ongoing adjustments continue to be made in response to operational challenges.

Use of technologies: The technological tools are widely used by the staff, and are considered assets for smooth program functioning. In some cases, technological tools were developed to solve unforeseen problems. For example, the Access database that the volunteers use made it easier for them to record reasons why they did not visit a certain patient and for the volunteer supervisor to sort priority patients for volunteer visits. The automated pharmacy order sets are an extremely effective tool for avoiding the prescribing of deliriogenic medications.

Effectiveness of culture change efforts: Many Program Staff described the culture change that has occurred through the Delirium Program. Nurses described how the delirium assessment screening has changed their perception of which patients do and do not have delirium. Pharmacists described that they have become more comfortable engaging with physicians about medication choices. Physicians became

aware of potential medication risks and shifted prescribing practices. Overall, increased awareness of delirium and a shift to a prevention mindset was frequently cited as an indicator of culture change in the Methodist Hospital system.

Measuring impact: The impact of the intervention for the low risk patients is probably nominal. While impact may be greater for intermediate and high risk patients, it will be impossible to identify these patients—and a matched comparison group—using administrative data. Impact will therefore be measured across the entire older cohort and those where there is no impact (and in many cases, no need for the program) will dilute the measured impact of those for whom the program is successful. More importantly, given that this program is primarily intended to prevent delirium, it will be difficult to measure the impact of cases averted. Many patients who benefit from the program through its prevention efforts will never meet the ICD-9 threshold of delirium (a success), and will therefore be unmeasured in a claims analysis.

Sustainability: The training efforts bode well for the sustainability of the program, at least concerning the key hospital-based components of the intervention (e.g., delirium assessment screening). In addition, the medication order sets are important components that are sustainable. Some components of the program such as Care Navigator follow-up calls will be sustained. The home health visits will be phased out during the last year. Volunteer recruitment, training, and coordination is also a necessary function funded by the Award that may be challenging to sustain.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total Medicare episode spending. The results presented below are for the following Core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission for a patient eligible for the screening innovation, in either an intervention or comparison hospital.
- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.
- Total Medicare spending for 60 days including the index admission and all Medicare spending for 60 days after discharge.

The Methodist Delirium program also aims to reduce length of stay; we present results for the following additional measures:

- Length of stay (LOS)
- Discharge destination

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. All models include controls for patient age, squared age, gender, race, Hierarchical Condition Category (HCC) score in year of treatment, squared HCC score, eligibility for Medicaid at any time during observation period (2010-2014), as well as indicators for the quarter in which the episode occurred.[38] An indicator is also included for individuals with missing HCC scores.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization a outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[39] We believe this is an accurate way to compare time periods.

---

[38] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g. age, gender).

[39] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

Below, we present estimates for both the patient population that is screened by the Delirium program, and the subset of patients who receive delirium intervention treatment.

4.1 Defining Intervention and Comparison Groups

4.1.1 Selection rules

The section below explains how we defined a set of criteria or rules that were used to create both the comparison and intervention groups. The criteria were created using information that is available in the Awardee registry and in Medicare claims. These were then uniformly applied to patients from intervention and comparison facilities to select the final intervention and comparison populations.

The Methodist Delirium program registry includes information from Methodist-affiliated hospitals: Hospital Methodist Hospital and Houston Methodist San Jacinto. Patients admitted to other participating facilities are not in the registry we receive from the Awardee. The Methodist Delirium program screens hospitalized patients who are 70 years of age and older. We therefore determined our registry match rates using Medicare Part A claims from November 1, 2012 through September 30, 2014, for patients admitted to the two hospitals in the registry. Claims for individuals younger than 70 years old were excluded. Beginning in this report we include an additional criterion for inclusion based on new input from the Awardee. Claims included in the analyses must have one of the following medical-surgical or general unit revenue center codes:

0110, 0111, 0120, 0121, 0130, 0131, 0140, 0141, 0150, 0151

The Methodist Delirium registry contained patients who were screened for delirium, and also those who were at higher risk and received additional interventions to prevent or ameliorate delirium. This report contains separate analyses for the screened population, as well as the subset of patients who received additional intervention.

To limit the screened sample to the subset of patients who received the delirium prevention intervention we included an additional step in the matching procedure. We listed all of the ICD-9 codes present in these first two positions for registry patients who received the delirium prevention intervention, and then selected comparison patients who had both ICD-9 codes from this list. Patients who had both of these ICD-9 codes in the first two positions on their claims are much like those in the registry. Patients with other ICD-9 codes that are never present in the registry are excluded from all analyses. This strategy further narrows the focus to the types of patients in the Methodist registry.

Exhibits 1 and 2 show the quarterly match between the estimated group and the registry provided by the Awardee for both the full screened population, and the subset of patients who received the intervention. The rules described above result in the following match between registry data and the rules we are able to apply based on data in Medicare claims:

Exhibit 1: Match Rates by Quarter

Methodist Delirium – Screened Patient Population

	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4
Registry with Medicare FFS claim (A)	385	567	754	1285	1552	1855	1672	1299	1452
Registry Patients Not Captured by Abt rules (B)	1	3	15	35	39	60	44	40	45
Miss Rate (B/A)	0%	1%	2%	3%	3%	3%	3%	3%	3%
Estimated based on Abt rules, with Medicare FFS claim (C)	1191	1450	1289	1435	1630	1906	1699	1579	1526
Match between Estimated and Registry (D)	384	564	739	1250	1513	1795	1628	1259	1407
Estimated by Abt rules, Not in Registry	807	886	550	185	117	111	71	320	119
Accuracy Rate (D/C)	32%	39%	57%	87%	93%	94%	96%	80%	92%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

Methodist Delirium – Intervention Patient Population

	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4
Registry with Medicare FFS claim (A)	52	187	433	851	933	891	980	819	845
Registry Patients Not Captured by Abt rules (B)	0	1	5	20	20	21	20	14	22
Miss Rate (B/A)	0%	1%	1%	2%	2%	2%	2%	2%	3%
Estimated based on Abt rules, with Medicare FFS claim (C)	227	709	789	1097	1253	1387	1333	1236	1228
Match between Estimated and Registry (D)	52	186	428	831	913	870	960	805	823
Estimated by Abt rules, Not in Registry	175	523	361	266	340	517	373	431	405
Accuracy Rate (D/C)	23%	26%	54%	76%	73%	63%	72%	65%	67%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

Accuracy rate = Percent of admissions with a Medicare FFS claim that are identified using Abt's rules and are also in the registry (indicates that our criteria are too broad and capture some patients who were not in the registry and apparently did not receive the intervention)

Miss rate = Percent of admissions with a FFS claim that meet Abt's inclusion criteria but are not in the registry (indicates that nearly everyone in the registry meets our criteria—we miss very few).

In general, our matching procedure was more accurate for the overall screened population than it was for the subset of patients receiving the delirium intervention. Beginning in the third quarter of 2013 the accuracy rate of our match for the overall screened population is greater than 80 percent. On average, the accuracy rate for the intervention sub-population is about 20 percentage points lower than the accuracy rate for the screened population, although it remains above 60 percent in all quarters beginning in the third quarter of 2013.

For both the overall screened patient population and the subset who received the interventions, our miss rate was 3 percent or less, indicating that there were few patients in either registry that were missed by the matching rules used to define each analytic sample. However, the overly broad definition of those who received the intervention will bias results towards zero.

Exhibit 2 below shows average patient characteristics for the Awardee and comparison groups in both the Baseline and intervention periods. The demographic summary statistics serve two purposes. The first is to provide a sense of the population demographics in the Methodist Delirium treatment population. The second is to show that the demographics are similar for intervention and comparison groups, with relatively wide standard deviations. The wide standard deviations reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

Exhibit 2: Demographic Summary Statistics

	Awardee				Comparison			
	Intervention Period (N=13,617)		Baseline Period (N=27,863)		Intervention Period (N=46,268)		Baseline Period (N=97,581)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.57	0.50	0.59	0.49	0.58	0.49	0.60	0.49
Nonwhite	0.19	0.39	0.19	0.39	0.23	0.42	0.22	0.42
Age	80.23	7.13	80.32	6.98	80.22	7.13	80.19	7.01
HCC Score	1.83	1.96	1.96	1.97	1.77	1.78	1.92	1.84
Missing HCC	0.04	0.19	0.03	0.16	0.05	0.22	0.04	0.19
Medicaid Eligibility	0.14	0.35	0.37	0.48	0.26	0.44	0.47	0.50

	Awardee				Comparison			
	Intervention Period (N=9,100)		Baseline Period (N=12,295)		Intervention Period (N=19,507)		Baseline Period (N=37,243)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.57	0.50	0.59	0.49	0.60	0.49	0.61	0.49
Nonwhite	0.20	0.40	0.21	0.41	0.24	0.42	0.23	0.42
Age	80.85	7.17	80.82	7.09	81.02	7.28	80.93	7.10
HCC Score	1.93	2.08	2.20	2.22	1.96	2.01	2.15	2.12
Missing HCC	0.03	0.18	0.03	0.16	0.05	0.21	0.04	0.19
Medicaid Eligibility	0.15	0.36	0.41	0.49	0.28	0.45	0.51	0.50

For both the screened and intervention patient groups, we see that the rate of Medicaid eligibility is somewhat higher during the baseline period for both Awardee and comparison groups than in the intervention period, and is higher for the comparison group than for the Awardee group. The comparison group also has a slightly higher share of patients who are non-white than does the Awardee intervention group.

4.2 Core Measures: Results

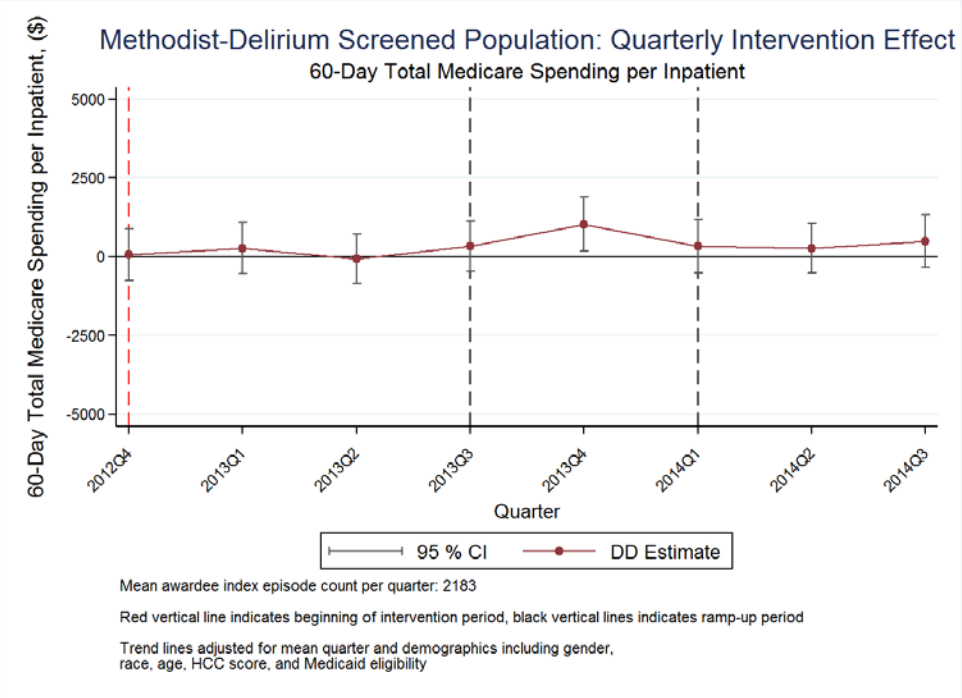
Implementation did not take place on the same day in all participating facilities. In the graphs below, the red vertical line shows the beginning of the intervention period and the black vertical lines indicate the dates when each of the participating facilities began their program implementation. Below, we present graphs first for the Methodist-Delirium Screened Patient Population, then for the Methodist Delirium Intervention Patient sub-population. All estimated changes in utilization are based on nine quarters of

post-implementation data. One less quarter of data is included for the spending measure compared to the utilization measures, due to the lag required for post-acute claims to become available for analysis.

4.2.1 Medicare Episode Spending[40]

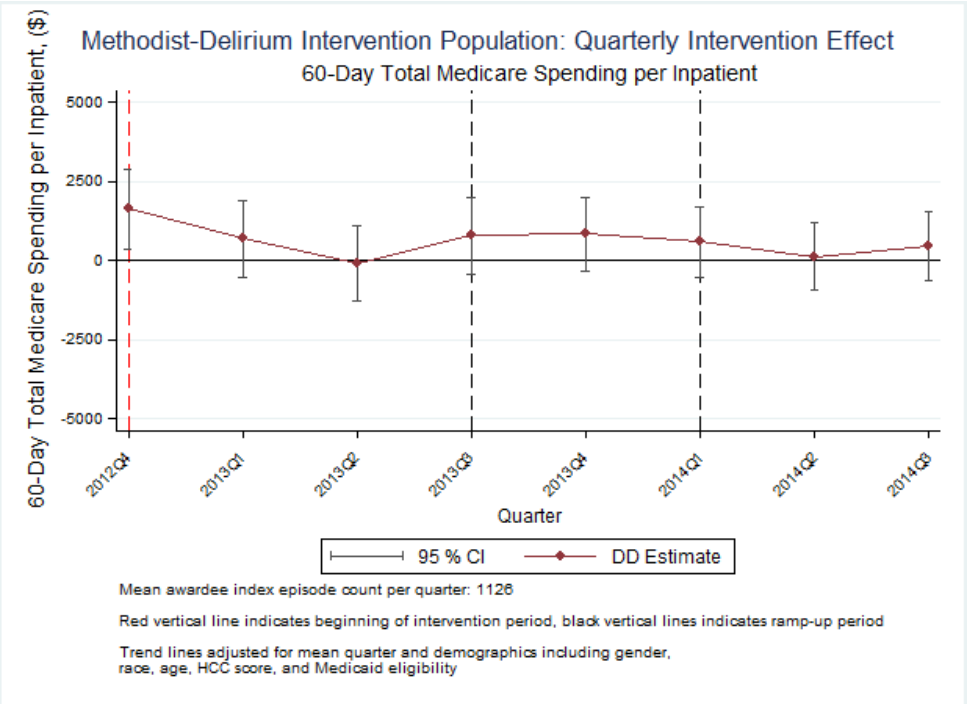
Exhibits 3 and 4 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days. The difference in differences estimate per quarter shows a consistently higher patient episode cost that is attributable to the intervention; however, only one early quarter shows a statistically significant result in either of the two patient populations.

Exhibit 3: Mean Medicare Episode Spending, Screened Population



[40] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 4: Mean Medicare Episode Spending, Intervention Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 5 shows the change in average and median Medicare episode spending attributable to the Methodist Delirium program. After pooling across all quarters, we find an average statistically insignificant increase of $329 and $87 per patient episode for screened patients and intervention patients, respectively. At the median, we find a statistically insignificant decrease of $54 and $24 for the screened and intervention populations. These estimates corroborate the results in Exhibits 3 and 4, which suggested that the estimated differences are not statistically significant.

Exhibit 5: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs

Methodist Hospital – Delirium			
		Screened Population	Intervention Population
Intervention Effect (Ordinary Least Squares)	Estimate	329.74	87.42
	Standard Error	(195.30)	(279.60)
	Sample Size	[185,329]	[78,145]
Intervention Effect (Median Regressions)	Estimate	-54.72	24.32
	Standard Error	(114.21)	(190.58)
	Sample Size	[185,329]	[78,145]

p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, July 2015.

4.2.2 Readmissions

Exhibits 6 and 7 (hospital discharges followed within 30 days by a readmission) show that there was virtually no change in 30-day inpatient readmissions as a result of the intervention. The early quarters show large variation, but the later quarters are very close to zero impact and are statistically insignificant. Exhibit 8 shows a pooled estimate across all quarters for both the screened and intervention patient populations; neither population exhibits any large or statistically significant percentage point change in the readmission outcomes.

Exhibit 6: Readmissions, Screened Population

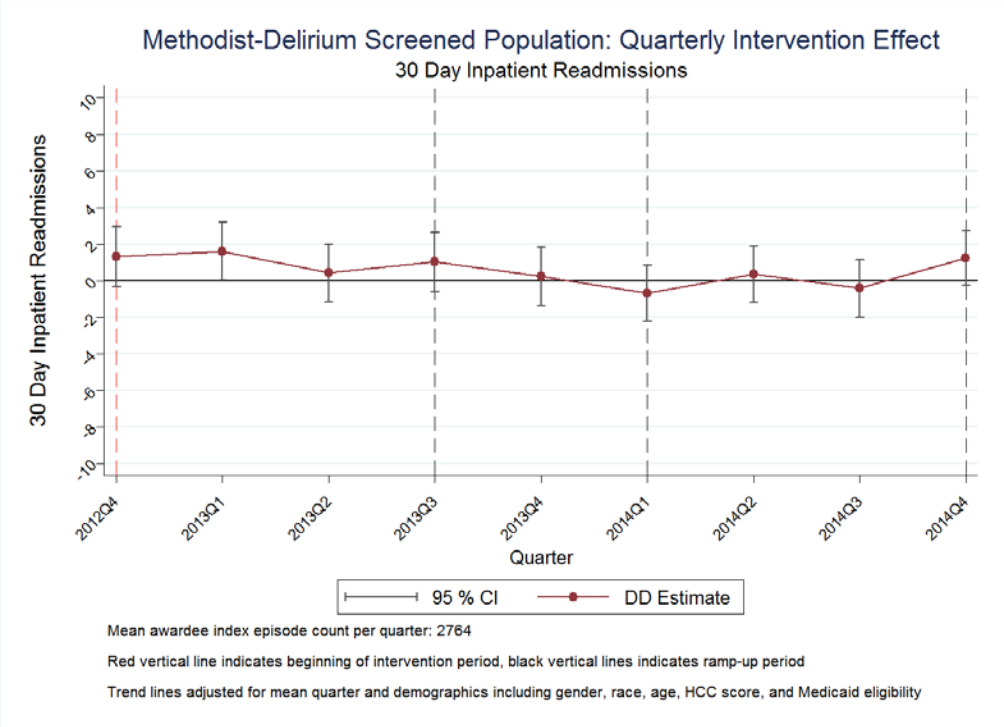
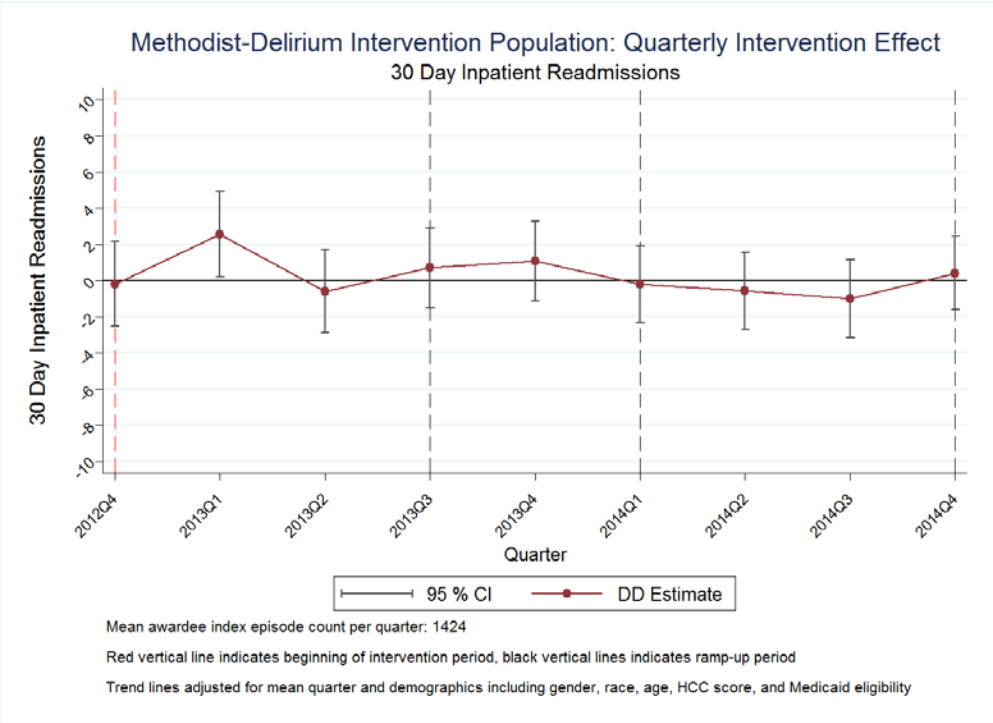


Exhibit 7: Readmissions, Intervention Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

Exhibit 8: DD Estimated Effect of Intervention on Inpatient Readmissions

Methodist Hospital – Delirium			
		Screened Population	Intervention Population
Intervention Effect	Estimate	0.54	0.53
	Standard Error	(0.41)	(0.58)
	Sample Size	[204,101]	[87,537]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

4.2.3 30-Day Post-Discharge ED Visits

Exhibits 9 and 10 (discharges followed within 30 days by an ED visit) show a steady rate of 30-day ED visits in the early quarters of the intervention, but the average estimated effect starts to drop in early 2014. This reduction is visible through 2014, which is the end of our available data. This may be the beginning of an encouraging trend toward fewer post-discharge ED visits for both groups. Exhibit 11 shows the pooled regression estimates across all quarters and we estimate that the treatment group sample had a 2 percentage point reduction in ED visits (significant at the one percent level), while the screened group exhibited a 1 percentage point reduction (significant at the one percent level). This finding is likely driven by the significantly lower rates in the later quarters of the intervention.

Exhibit 9: 30-Day Post-Discharge ED Visits, Screened Patient Population

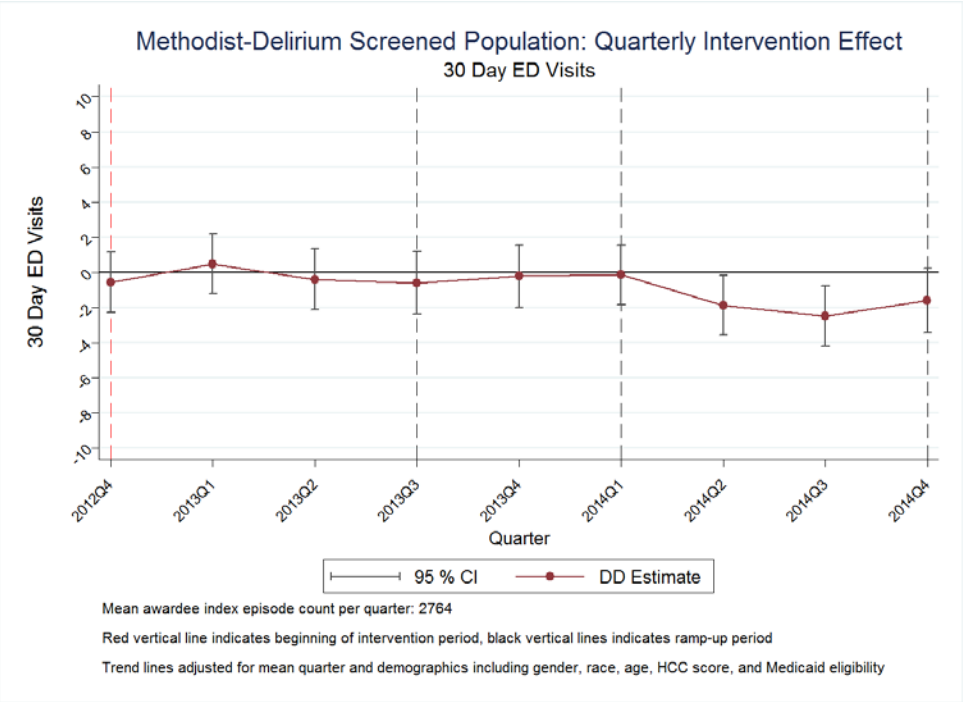
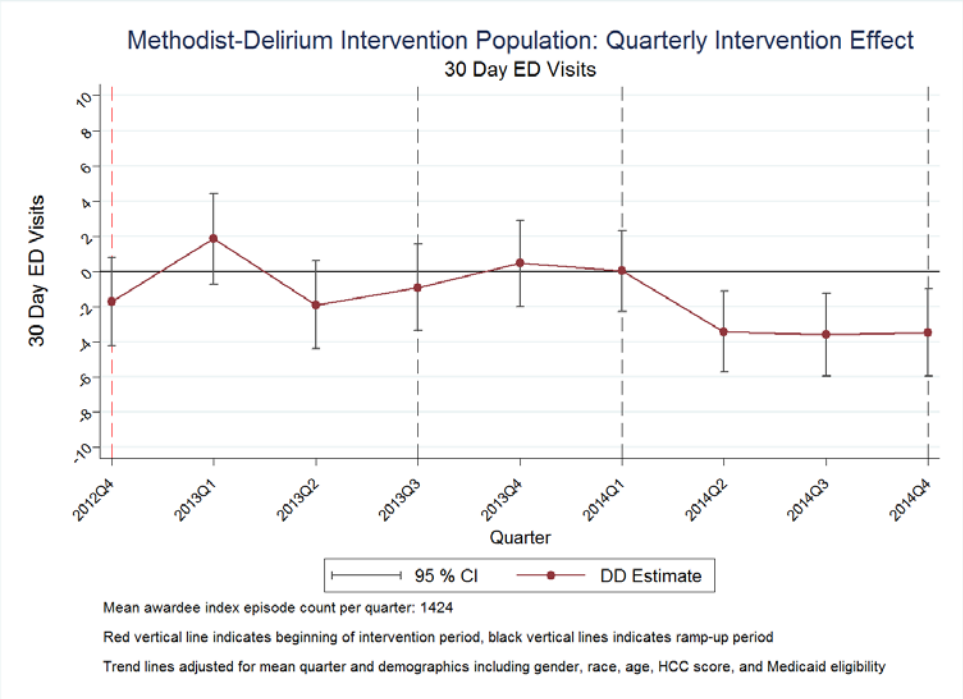


Exhibit 10: 30-Day Post-Discharge ED Visits, Intervention Patient Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 11: DD Estimated Effect of Intervention on 30-Day Emergency Department Visits

Methodist Hospital – Delirium			
		Screened Population	Intervention Population
Intervention Effect	Estimate	-1.33***	-1.95***
	Standard Error	(0.42)	(0.59)
	Sample Size	[204,101]	[87,537]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

4.2.4 Index Admission Length of Stay (LOS)

The Methodist Delirium prevention program has the potential to reduce LOS if patient cognitive status does not deteriorate in the hospital. Exhibit 12 shows some evidence of a decline in LOS among patients screened for Delirium. Although a few estimates are statistically significant, the magnitude of the point estimates is small. Similarly, in Exhibit 13, there is some suggestion of a decrease in LOS, but there are no statistically significant quarterly estimates. Exhibit 14 shows a statistically significant decrease of nearly 0.1 days for the entire screened population, but nothing large or significant for the sub-population receiving the full intervention, a result that is consistent with Exhibits 12 and 13.

Exhibit 12: Index Admission Inpatient LOS, Screened Patient Population

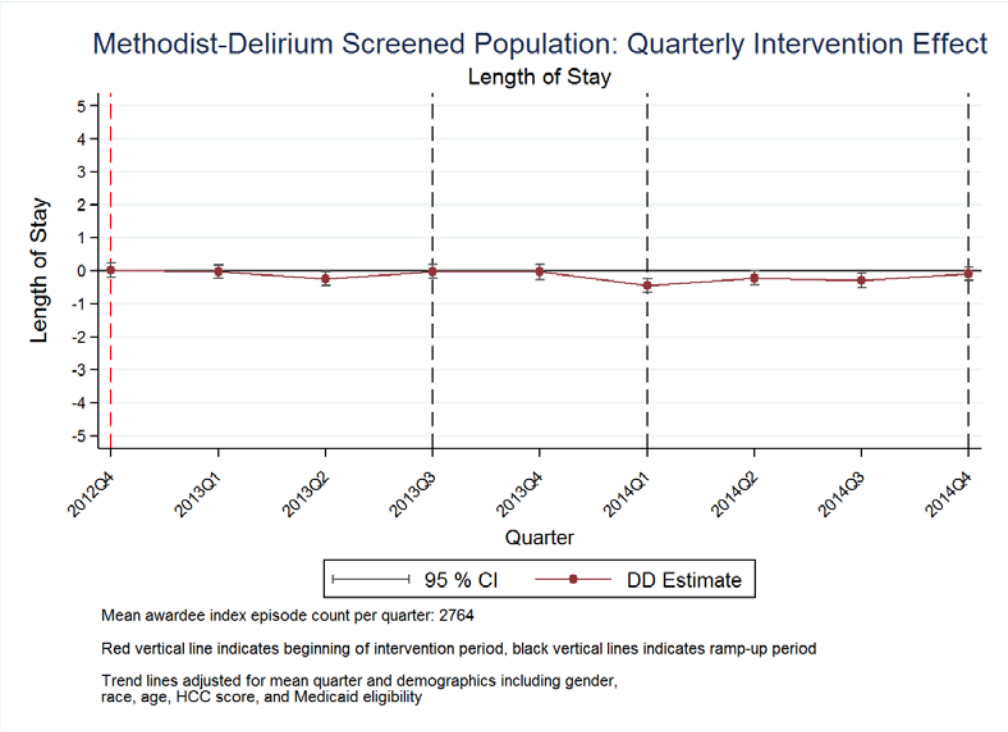
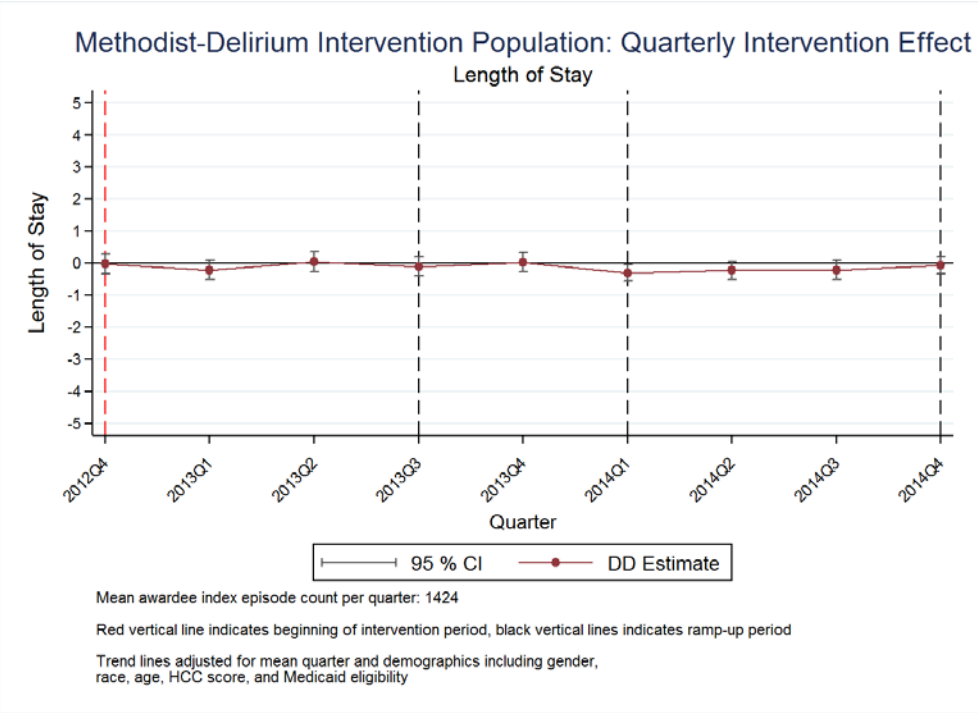


Exhibit 13: Index Admission Inpatient LOS, Intervention Patient Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

Exhibit 14: DD Estimated Effect of Intervention on Inpatient Length of Stay

Methodist Hospital – Delirium			
		Screened Population	Intervention Population
Intervention Effect	Estimate	-0.09*	-0.01
	Standard Error	(0.05)	(0.07)
	Sample Size	[204,101]	[87,537]

p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

4.2.5 Discharge Destination

Below, Exhibit 15 presents the DD estimates for discharge destination, following the index admission. We find that both patient populations are less likely to be discharged home relative to their baseline and the comparison group, in all quarters of the intervention.

For the total screened population, there is a reduction in discharges to home health, and an increase in discharges to "other" discharge destinations in early intervention quarters. "Other" discharge destinations include transfers to other areas of the hospital, transfers to hospice, and transfers to psychiatric facilities. We find statistically significant aggregate increases in discharges to "other" institutional settings and to home health care.

Over the entire intervention period, we find a statistically significant 2.51 percentage point decrease in discharges to home (without home health care), and a statistically significant 2.81 percentage point increase in discharges to home health care for the intervention patient sub-group analyses. Both of these findings are significant at the 1 percent level. Intervention patients are less likely to go directly home

without home health care, and more likely to require home health care, than are their comparison group peers.

Exhibit 15: DD Estimated Change in Episode Discharge Destination

Methodist Delirium – Screened Population

	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home										
DD Estimate	0.97	0.84	-1.46	-2.64**	-2.82**	-2.60**	-2.24**	-2.84**	-5.48***	-3.13***
SE	1.10	1.07	1.06	1.09	1.11	1.09	1.06	1.08	1.10	0.54
Home Health										
DD Estimate	-1.81**	-1.19	-0.05	0.68	1.50*	3.22***	1.66*	0.71	3.78***	2.00***
SE	0.77	0.77	0.79	0.84	0.89	0.93	0.85	0.84	0.96	0.44
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home										
DD Estimate	-1.66	-1.61	-1.49	-0.02	0.91	-0.52	-0.25	0.79	0.35	0.11
SE	1.03	1.00	0.98	1.03	1.05	1.01	0.98	1.01	1.02	0.51
Other										
DD Estimate	2.50***	1.95***	2.99***	1.98***	0.42	-0.11	0.83	1.34**	1.36**	1.02***
SE	0.67	0.64	0.71	0.68	0.62	0.53	0.57	0.63	0.65	0.30

Methodist Delirium - Intervention Population

	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home										
DD Estimate	-0.11	-1.13	-0.18	-5.46***	-0.53	-1.14	-1.75	-0.89	-3.98***	-2.51***
SE	1.62	1.56	1.55	1.51	1.51	1.45	1.42	1.43	1.45	0.74
Home Health										
DD Estimate	-2.26**	-0.84	-1.61	1.25	-0.62	3.59	1.45	-0.36	3.71***	2.81***
SE	1.15	1.18	1.10	1.27	1.12	1.28	1.15	1.07	1.32	0.63
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home										
DD Estimate	0.11	0.78	-0.13	2.60	1.97	-0.98	0.23	1.21	-0.20	-0.41
SE	1.64	1.59	1.55	1.60	1.52	1.44	1.41	1.43	1.46	0.75
Other										
DD Estimate	2.26**	1.19	1.92*	1.61	-0.83	-1.47**	0.07	0.05	0.47	0.11
SE	1.02	0.90	0.98	1.04	0.81	0.70	0.78	0.80	0.86	0.41

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, July 2015.

4.2.6 Conclusions

- There is evidence of an intervention effect in lowering post-discharge ED visits, and also a slight reduction in LOS for the whole population of screened patients. We find no other significant utilization trends.
- We find no significant DD intervention effect on Medicare episode spending.
- Patients receiving treatment for delirium are significantly less likely to be discharged home, and more likely to be discharged to home health care. This result is driven by later intervention quarter results. All patients subject to screening show similar patterns, but are also significantly more likely to be discharged to "other" locations.

Appendix B7: Houston Methodist Hospital Sepsis Early Recognition and Response Initiative

1. Executive Summary

This chapter presents findings for the Houston Methodist Hospital (HMH) Sepsis Early Recognition and Response Initiative (SERRI), a program designed to detect and treat early sepsis in participating acute care hospitals (ACHs); long term care acute care hospitals (LTACHs); and skilled nursing facilities (SNFs). Individuals in these institutional settings are screened daily to identify signs of emerging sepsis such as changes in blood pressure, heart rate, and fever. When patients are identified as possibly becoming septic, the care team quickly initiates evidence-based sepsis treatment bundles (e.g., aggressive fluid resuscitation, multiple sequences of antibiotics). Program staff expect this program to result in reduced rates of organ failure and consequent reduced mortality, shorter length of stay (LOS) in the hospital, fewer readmissions, better patient outcomes, and lower costs for Medicare and Medicaid. For patients in post-acute institutional settings, the program also aims to reduce emergency department (ED) visits and admissions to the hospital.

Clinicians and program staff we interviewed believe the program is helping to identify many at risk patients earlier and initiate care sooner, reducing the incidence of severe sepsis. They also believe patients are being discharged sooner with fewer returning to the hospital, due to early intervention and prevention of severe sepsis. In some post-acute care settings, program staff reported difficulty in hiring and retaining staff to fill the role of the rapid response team, who are alerted when a patient's vital signs are abnormal; lack of staff in these positions may have minimized program effectiveness in some settings.

To examine the impact of the program, we conducted a difference-in-differences analysis of Medicare claims pooling data from the providers participating in this program to a comparison group that was matched based on size and location. We developed inclusion and exclusion criteria for intervention and comparison groups based on the patient registries supplied by program staff.

We conducted two sets of analyses—one that includes the entire screened population of patients in participating facilities and one that includes only patients who had sepsis coded on their claims. We also examined outcomes for ACHs separately from outcomes for patients who first encountered the intervention while in post-acute care facilities (SNFs and LTACHs).

We found no statistically significant change among the screened population of patients that can we attribute to the intervention in overall rates of readmissions or post-discharge ED visits, or in Medicare episode spending, for patients screened in ACH or Post-Acute Care (PAC) settings. For ACH patients, we did find a statistically significant reduction of 0.17 days in average length of stay (LOS). We also found a significant decrease in the percent of ACH patients being discharged to home without additional care, and a corresponding increase in discharges to a care setting such as home health, intermediate care facilities, or other outpatient care.

We conducted a similar analysis of the subset of patients in whom sepsis was detected (and coded on Medicare claims), because this subpopulation had the most to gain from the aggressive treatment of early sepsis. For patients in both ACH and PAC settings, we found no statistically significant change among intervention patients in any of our cost and utilization measures, relative to a matched comparison group and the intervention group baseline outcomes. We did find a statistically significant decrease in septic patients being discharged from ACHs to home without home health care, relative to the comparison group, but this change in discharge was not significantly offset by any other location.

There are four factors that may in part explain the general lack of significant program impacts. First, for various organizational reasons, the participating ACHs did not use the screening tool in EDs and ICUs, potentially lessening the gains the tool might have achieved in these settings. Second, many hospitals and post-acute facilities had sepsis programs in place prior to the intervention due to the widespread recognition that sepsis is a leading cost of inpatient mortality, thus reducing the marginal impact of Methodist's program. The comparison facilities used in our analyses may also have implemented sepsis programs in recent years, and the HMH program would need to exceed the impact of any comparison programs in order to be detected as significant in our analyses. Third, patients in post-acute facilities who show early signs of sepsis cannot usually receive aggressive fluid resuscitation in those settings—physicians are reluctant to order this care and instead prefer to transfer patients to an acute care hospital for safe treatment. The daily screening in these institutions may identify more septic patients, potentially increasing hospital admissions. Early identification should result in shorter hospital LOS in such cases, but even a small increase in hospitalizations would increase Medicare spending. Finally, vital sign monitoring may have detected conditions other than sepsis that required hospital care; conditions that might not have been noticed, or treated as aggressively, in the absence of this screening program. To the extent that other emerging problems were identified and treated, this program improved patient care and may lead to longer-term savings for Medicare (beyond the period that we examined in our analyses).

2. General Research Domains

The core domains for the Houston Methodist Sepsis program evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization), or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder

engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.

- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of Health Care Innovation Award (HCIA) funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Description of Program

The Houston Methodist Hospital (HMH), in partnership with the Texas Gulf Coast Sepsis Network, received an Award to identify and treat sepsis before it progresses. The Sepsis Early Recognition and Response Initiative (SERRI) targets patients who are admitted to participating acute care hospitals (ACHs); long term care hospitals (LTCHs) skilled nursing facilities (SNFs); and rehabilitation facilities; including but not limited to Medicare and Medicaid beneficiaries. Through improved training, evidence-based practices, systematic screening, and more timely treatment, Houston Methodist and its partners hope to identify sepsis cases early and prevent progression of the disease, resulting in reduced rates of organ failure, reduced mortality, reduced length-of-stay, improved patient outcomes, and lower cost.

The SERRI program uses a screening tool (described below) to identify patients at risk for developing sepsis. The program uses standard protocols for patient monitoring by first-level nurse responders, as well as procedures for elevating the case to second-level responders when a patient's screening assessment reaches a standard threshold for beginning treatment and confirmatory tests for sepsis. The standard sepsis bundle is implemented for the patient if it is determined that the patient is in need of treatment for sepsis.

Exhibit 1 presents information on program implementation including when the intervention began, in which units it was implemented, and the approximate percent of Medicare fee-for-service (FFS) patients.

Exhibit 1: Participating Facilities

Facility Name	Facility Type (hospital, SNF, LTCH)	State	City	Units Targeted for Screening (if not the entire facility)	Start Date (month/year)	Approx % Medicare FFS
1. Houston Methodist Hospital (HMH)	Hospital	TX	Houston	Entire in-patient facility (no peds, ob, ed, or icu)	Jan-2013	59%
2. Houston Methodist – Sugar Land	Hospital	TX	Houston	Entire adult in-patient facility (no peds, ob will likely come online later)	Jan-2013	65%
3. Houston Methodist– San Jacinto (HMSJ)	Hospital	TX	Baytown	Entire adult in-patient facility (no peds, no ob)	Feb-2013	63%
4. St. Joseph's Regional Health Center	Hospital	TX	Bryan	Entire adult in-patient facility (no peds, no ob)	Mar-2013	61%
5. HCA – Bayshore/East	Hospital	TX	Pasadena	Entire adult in-patient facility (no peds, no ob)	May-2013	45%
6. HCA – RioGrande	Hospital	TX	McAllen	Entire adult in-patient facility (no peds, no ob)	June-2013	58%
7. Select Specialty – Texas Medical Center	LTCH	TX	Houston	Entire adult in-patient facility (no peds)	Sept-2013	19%
8. Select Specialty – Houston Heights	LTCH	TX	Houston	Entire adult in-patient facility (no peds)	Sept-2013	29%
9. Kindred –Texas Medical Center	LTCH	TX	Houston	Entire adult in-patient facility (no peds)	Oct-2013	56%
10. Kindred – Bay Area	LTCH	TX	Pasadena	Entire adult in-patient facility (no peds)	Oct-2013	77%
11. HMH–SNF/Rehab	SNF & Rehab	TX	Houston	Entire adult in-patient facility (no peds)	Nov-2013	56.2%
12. HMSJ – SNF/Rehab	SNF & Rehab	TX	Baytown	Entire adult in-patient facility (no peds)	Oct-2013	61.4%
13. St. Joseph's – Manor	SNF & Rehab	TX	Bryan	Entire adult in-patient facility (no peds)	Jan-2014	Data not yet available
14. St. Joseph's – Burleson	SNF & Rehab	TX	Caldwell	Entire adult in-patient facility (no peds)	Jan-2014	Data not yet available
15. HMSJ–Willowbrook	Hospital	TX	Houston	Entire adult in-patient facility (no peds, no ob)	Apri-2014	Data not yet available
16. HMSJ – West	Hospital	TX	Houston	Entire adult in-patient facility (no peds, no ob)	May-2014	Data not yet available

SNF: Skilled Nursing Facility; LTCH: Long Term Care Hospital

3.2 Case Study Methodology

The evaluation team conducted two case studies of the SERRI program. The Methodist-Sepsis initial case study was conducted March 24-28, 2014. The evaluation team, composed of one senior- and one mid-level staff person from Abt Associates and one staff member from Telligen (formerly CFMC; subcontractor to Abt), visited Houston Methodist, an acute care hospital (ACH), in Houston, Texas; Kindred Hospital, a long-term care hospital (LTCH) in Houston, Texas; San Jacinto acute care hospital in Baytown, Texas and its affiliated skilled nursing facility (SNF)/rehabilitation facility, also in Baytown. In addition to interviews and focus groups, the case study team observed the Houston Methodist simulation laboratory. The implementation of the SERRI program at other institutions, (Select Rehabilitation

facilities, Hospital Corporation of America institutions, and the Kindred Bay Area Hospital) were discussed but the team did not visit these facilities.

The team conducted three focus groups with first-level responders and three focus groups with second-level responders during the case study which were held at Methodist ACH, Kindred LTCH, and San Jacinto SNF. Additionally, the team held five interviews with physicians and surgeons at Houston Methodist, a group interview with pharmacists at Houston Methodist, and individual interviews with pharmacists at Kindred LTCH and San Jacinto ACH. The team also interviewed the data analyst at Methodist and Kindred LTCH and held group or individual interviews with SERRI program administrators at Methodist ACH, Kindred LTCH, San Jacinto ACH, and San Jacinto SNF. The interviews were audio recorded after obtaining participant consent to ensure accurate notes. At the end of the case study, all notes were cleaned and integrated across the note-takers and reviewed for accuracy by the senior researcher on the team. Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

A follow-up case study was completed via telephone from April 6-9, 2015. The team conducted individual interviews with SERRI program administrators at Methodist ACH, Kindred LTCH, San Jacinto ACH, San Jacinto SNF, and Select Specialty LTCH. The team also had focus groups with second-level providers from Methodist ACH and Kindred LTCH and with certified nursing assistants (CNAs) from Methodist ACH. The interviews and focus groups were audio recorded after obtaining participant consent, to ensure accurate notes. Following each case study, notes were cleaned and integrated across the note-takers and reviewed for accuracy by the senior researcher on the team. After the follow-up case study, analyses also explored changes in the SERRI program since the initial case study, including any difference in findings related to key themes identified in the initial case study.

The exhibit below presents information on the number and type of individuals who participated in either individual interviews or focus groups.

Exhibit 2: Case Study Data Collection

(Initial / Follow-up)	Certified Nursing Assistants	First-level Responders	Second-level Responders	Physicians	Pharmacists	Hospital Leadership	Data/ Financial Analysts	Program Admin.
Houston Methodist	0/6	12/0	5/3	5/0	2/0	0/0	1/2	2/2
Kindred Hospital	0/0	3/0	4/2	0/0	1/0	3/3	1/0	2/2
San Jacinto Skilled Nursing Facility and Rehab Center	0/0	5/0	3/0	0/0	1/0	2/2	0/0	1/1
Initial Case Study Total = 53 Follow-up Case Study Total= 24	0/6	20/0	12/5	5/0	4/0	5/5	2/2	5/6*

· - An administrator from Select Specialty was interviewed at follow-up to ask key questions about implementing using a paper version of the SERRI tool

3.3 Background of Program

3.3.1 Program Goals

Houston Methodist and its partners are training staff to identify sepsis cases early and prevent progression of the disease through appropriate early treatment. Early detection and treatment of sepsis will ultimately result in reduced rates of organ failure, reduced in-hospital mortality, and reduced lengths of stay and readmission rates to short term acute care hospitals from long term care facilities (SNFs and LTCHs), improved patient outcomes, and lower medical costs associated with sepsis. There are separate goals for the ACHs and post-acute settings: the goals in the ACH setting are to reduce the proportion of sepsis patients who reach outlier status (i.e., those eligible for Medicare outlier payments) by 57 percent, reduce the cost of care related to sepsis discharges by 18 percent, and reduce sepsis related illnesses by 37 percent; the goal in the post-acute settings (including SNFs and LTCHS) is to reduce readmissions back to the ACH by 25 percent. An overall goal for all settings involved in the initiative is to create a culture of sepsis awareness.

3.3.2 Impetus for the Program

The primary impetus behind the SERRI program is to save lives and reduce costs through early recognition of sepsis. As a member of the leadership staff for the SERRI project noted, "We were looking at our hospital mortality rate and believed it was too high and needed to be addressed. At the time, sepsis in the Methodist ACH was associated with mortality 35 percent of the time. We had the idea that we could do better." One of the investigators noted that on any given day, 35-40 percent of patients in the Methodist ACH surgical ICU had sepsis, and half of these patients were coming to the ICU from surgery within the hospital. A staff physician conducted a retrospective review and found that septic patients on certain floors of the main Houston Methodist were not identified for an average of 25 hours after onset. Identifying sepsis early in its progression was an opportunity to save both lives and money. As one interviewee described the approach, "It's like preventing an accident while the car is still in the garage." Another interviewee at Methodist succinctly summarized the driving forces behind the program, stating that, "the company [Methodist] is results-oriented and the initial drive was about reducing mortality. They [the SERRI team] were driven by results and the initiative also has shown results. We want to be on the forefront. We want to reduce mortality. 'Lead medicine' is our motto [at Methodist]."

> There is an aspect of critical thinking that is triggered by the screen with the patient's sepsis screening data. There is a lot of information in a hospital that can distract but [the SERRI tool] forces the nurse to check more on their patients.
>
> *– First-level responder, Kindred LTCH, initial case study*

In 2005, Methodist implemented a sepsis initiative, based on a program designed by the Institute for Healthcare Improvement (IHI), which was not successful, in part because Methodist staff found the screening tool cumbersome and time consuming. Perhaps more importantly, the IHI protocol was designed to detect severe sepsis, whereas Methodist aimed to detect and treat early sepsis, a subtle, nonspecific, and often unrecognized clinical syndrome defined as a systemic inflammatory response syndrome due to infection, that is marked by fever, rapid heart and respiratory rates, abnormally high or low white blood cell count, and abnormalities of the coagulation/fibrinolysis system.[41] The SERRI program's focus on early detection and treatment is based on research that shows that for every hour sepsis goes untreated; the patient is accruing morbidity at 7

[41] The Houston Methodist Research Institute, Health Care Innovation Challenge Grant application, p. 16.

percent per hour. Early detection and treatment is therefore critical. Other research emphasized that if sepsis is detected early, it can be prevented from reaching the stage of septic shock. Many of the other sepsis screenings that have been around for years, like the IHI program, are complex and cumbersome, burdensome on staff and therefore difficult to implement.

In developing the SERRI program, which was introduced in 2007, Methodist sought to create an initiative that was both simple and sustainable. Using the APACHE-II scoring system as a model, the team at Methodist determined the salient elements of the APACHE-II scoring system and built a sepsis screening tool based on those elements. SERRI targets heart rate, respiratory rate, minimum and maximum body temperature in the last 12 hours, and white blood cell count. Mental status was added to address general mental status of the patient. Mental status is important, especially in older patients who may not mount an immune response. The current iteration of the tool, which was adjusted for low heart rate and mental status, went live in December 2011.

Initially, from 2007–2009, the SERRI tool was paper-based, which proved to be inefficient: it took 30 seconds to complete screening portions and cost a cent per paper page, plus one minute for nurses to complete the form overall; in addition, "accuracy was not always there." A stand-alone web-based version of the screening tool, which was not integrated with the electronic medical record (EMR), was implemented in 2009. The current iteration of the tool is integrated into the EMR (as of 2011) and takes only 10 seconds to complete.

3.4 Program Components & Targets

The targets of the Methodist SERRI program include patients in acute hospitals, long term care hospitals, and skilled nursing facilities/rehabilitation centers, who are at greatest risk for developing sepsis: (a) post-operative; (b) emergent admission, especially those requiring an emergent operation; (c) age 65 years; (d) multiple medical comorbidities; and (e) patients transferred to Methodist's academic tertiary care referral hospital.[42] Some patients are excluded from screening, including those in pediatric units, obstetrics and gynecology, observational units, psychiatric units, and in some cases, emergency departments and ICU units in which there are already aggressive screening protocols. Some exclusions were adopted between the initial and follow-up case study after assessing screening practices in those units and the impact of the SERRI program there.

3.4.1 Primary Program Components

The core clinical tool of the program is the SERRI electronic screening tool designed to assess a patient's risk for developing sepsis based on the following vital signs: heart rate, respiratory rate, temperature minimum and maximum over 12 hours, white blood cell count, and mental status (mental status is assessed by a bedside nurse). Mental status was added to the screening tool because although older and immunocompromised patients may not mount an immune response that can be measured by the four vital signs, sepsis can present as altered mental status.

The assessment tool generates a SERRI score from zero to 17, with a score of four or greater representing a patient who is potentially at risk for sepsis. The SERRI tool has a dashboard that allows clinicians to review a patient's individual vital signs and overall SERRI score. When a patient has a score of three, the

[42] The Houston Methodist Research Institute, Health Care Innovation Challenge Grant application, p. 22.

SERRI tool shows a yellow alert, indicating that the patient should be monitored for early signs of sepsis risk. When a patient has a score of four or greater at an ACH or LTCH, the dashboard shows a red alert and requires the attention of second-level responders with special training in sepsis care; these responders receive an automatic alert on their mobile phone or pager. A patient with a three or higher at a SNF will trigger a red alert to a second-level responder. The SERRI dashboard also shows the patient's SERRI scores in graphical form to assist in visualizing the trend of a patient's sepsis risk over time. The patient's full record of SERRI scores for their current and prior admissions is also available via the dashboard. The SERRI program could have made the process of SERRI fully automated in the background but intentionally built in nurse review to emphasize the use of critical thinking skills for noticing important changes in a patient's condition.

The SERRI tool was integrated into the electronic medical record (EMR) at Methodist system institutions while, until early April 2015, the tool at the Kindred LTCH facilities was a stand-alone electronic application accessible by a nurse on a computer. Two participating institutions, Select Specialty facilities and St. Joseph SNF, implemented the SERRI tool in paper form. This requires double entry of the vital signs into the patient health record and into a database of SERRI data as well as manual computation of the SERRI score, steps that are labor intensive for staff. The SERRI program staff have strongly discouraged participating institutions from implementing the SERRI tool in paper form because of the difficulty of assessing sepsis risk in real time and reporting aggregated data from the institution that must be manually entered into electronic form. Some facilities such as St. Joseph SNF faced IT challenges and began the screening intervention using paper forms. With the SERRI program nearing its close, these institutions will not likely implement an electronic version before the conclusion of the HCIA, though their intention is to implement the screening process electronically in the future.

Across participating sites, the goal is to have screening occur for every patient in a participating unit within two hours of admission to the facility. For all continuing patients, SERRI screening occurs at least once per 12-hour shift. Differences among participating units and institutions are described below.

First-Level Responder Sepsis Risk Screening

As noted above, bedside nurses, designated as first-level responders for the SERRI program, are responsible for assessing the vital signs used to determine a patient's risk for sepsis. SERRI assessments are completed every shift, at a minimum, either by bedside nurses or by certified nurses' aides (CNA). After entering the patient's vital signs into the electronic tool or ensuring that the vital signs are entered by a CNA, the bedside nurse in the role of first-level responder completes an assessment of the patient's mental status, the final indication needed for the SERRI tool to assess sepsis risk. The first-level responder is also responsible for reviewing a patient's SERRI score and determining the appropriate next step, which may require contacting the second-level responder for further assessment of the patient.

Second-Level Responder Follow-up

The second-level responder is charged with ensuring that SERRI screening is occurring at institutions in a timely manner and also determining when further action is required for patients whose SERRI score suggests a high risk for sepsis. Second-level responders have access to the SERRI dashboard to monitor the status of patients. In some participating institutions such as Methodist ACH, San Jacinto ACH, and Kindred LTCH, second-level responders can order fluids and antibiotics that are part of the sepsis treatment protocol. In these settings, the participating institution has sanctioned the second-level responder's authority to begin sepsis treatment when appropriate. For example, if the second-level

responder, after review of SERRI data and assessing the patient, believes the patient is at risk for sepsis, he or she will notify the patient's physician and initiate early goal-directed interventions (sepsis protocol). The details of the treatment options are described below. Second-level responders in these institutions work with the physician and the first-level responders to manage the care of patients with sepsis. Second-level responders also provide support to first-level responders with questions related to the SERRI program and ongoing sepsis care. In the SNF or long term rehabilitation facility, the second-level responders must contact a physician who is authorized to initiate sepsis treatment and will monitor the patient's response to treatment.

Treatment of Sepsis

At all the institutions, if a second-level responder believes a patient is at risk for sepsis, the second-level responder can begin the process to implement early goal directed interventions either by initiating treatment themselves or by contacting a physician to verify the patient's condition and begin treatment. This includes the ordering of labs necessary to confirm a diagnosis of sepsis, fluid resuscitation, and antibiotics that each institution has established as its standard of treatment for various sources of infection. The second-level responder will remain with the patient to ensure the first treatments are appropriately executed and continue to monitor the patient's vital signs. These initial steps are based on the Surviving Sepsis Campaign (SSC) three hour care bundle for severe sepsis and septic shock, with strong emphasis on checking serum lactate, appropriate fluid resuscitation, and rapid antibiotic delivery.[43] If the patient identified during the screening process is already in severe sepsis or septic shock, the standard three hour and six hour bundles are both implemented. Should the patient be diagnosed with sepsis and their condition progresses to more severe sepsis, the second-level responder in conjunction with the rest of the patient's care team will be prepared to implement the six-hour bundle when appropriate. All second-level responders, as part of their SERRI training, are educated about the SSC Resuscitation and Management Bundles. For a visual flow chart of the screening, see the Exhibit 3 below.

Challenges to Effective Treatment of Sepsis

There have been challenges in implementing the SERRI protocol in all settings. For the ACH and LTCH setting, SERRI program leaders and second-level responders have raised the concern that implementing a full response to the early signs of what may be sepsis has been challenging because physicians are reluctant to support fluid resuscitation as early treatment for sepsis. Physicians are often concerned that excess fluid will lead to fluid overload or fluid backing up in the patient's lungs. Many have not been aware of the accepted research findings that appropriate use of fluid resuscitation is effective in addressing early signs of sepsis. Even when made aware of the established research, some physicians remain skeptical about initiating the SERRI protocol supported by their hospital's medical leadership team. To help to address concerns regarding fluid resuscitation, the nurse staff have begun collecting an accurate record of patient's weight to better calibrate fluid resuscitation based on the body weight of the individual patient. In SNF settings, the second-level response does not include the provision of the care bundle as occurs in the ACH and some LTCHs. Staff in the SNF setting note that if a second response is required in the SNF setting, the nurses responsible for second response will contact the physician responsible for care duties for the day. In most scenarios, if the physician determines that further care

[43] The Surviving Sepsis Campaign is a joint collaboration of the Society of Critical Care Medicine and the European Society of Intensive Care Medicine committed to reducing mortality from severe sepsis and septic shock worldwide. http://www.survivingsepsis.org/About-SSC/Pages/default.aspx, accessed July 25, 2014.

duties will be required, the patient will be sent to an emergency room where more acute care can be offered.

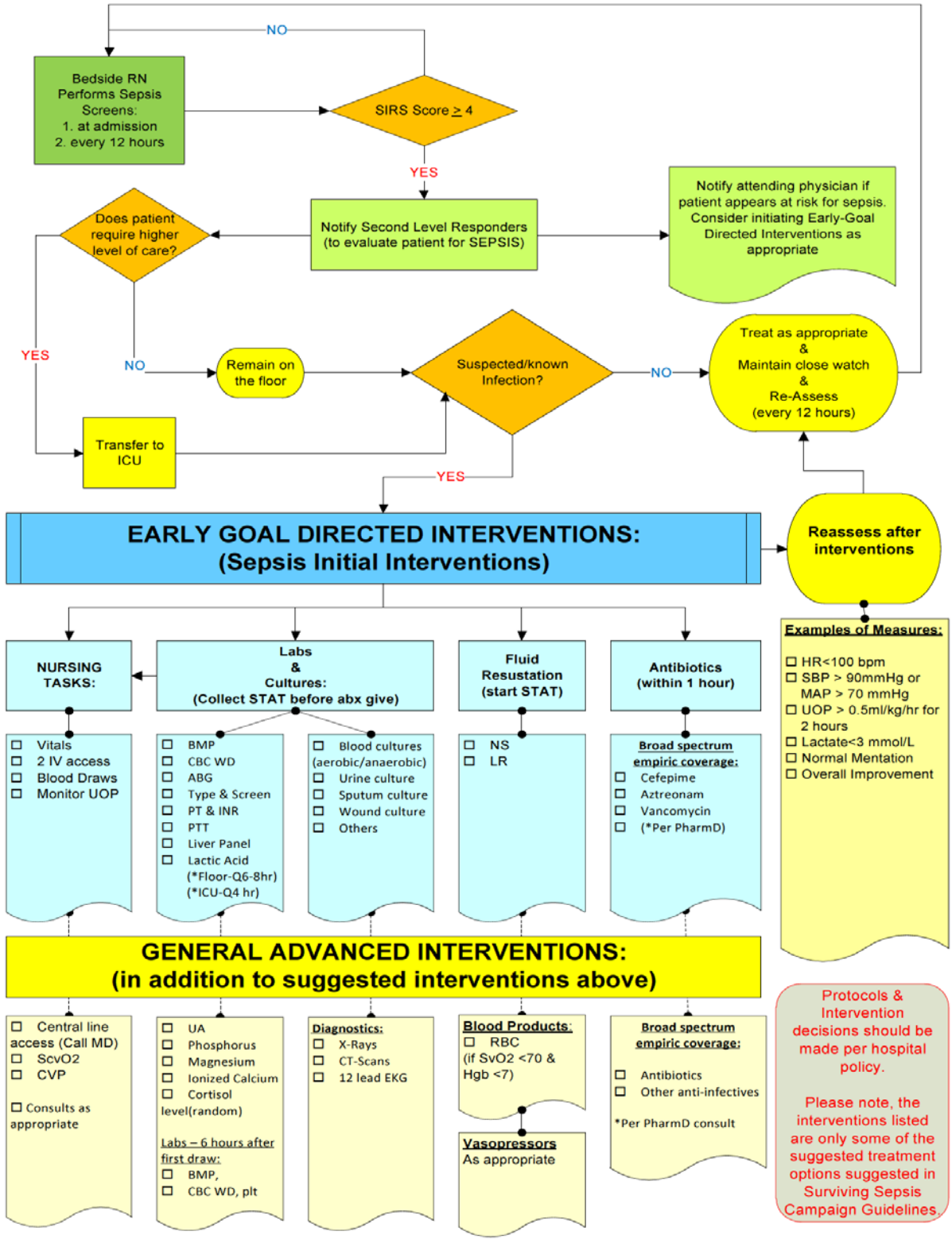
The SERRI program set a goal that initial sepsis interventions (or early directed interventions) are implemented within one hour from when the order for antibiotics is placed. In order for the proper treatment to get to the patient within one hour, some hospital pharmacies had to refine their workflows. At Methodist ACH, the pharmacy team made sure that the early sepsis order set was available in Methodist's health information system. They also trained pharmacy clerks to follow up with SERRI requests listed as STAT orders.[44] The pharmacy team trained all pharmacists and pharmacy residents about the importance of the SERRI program objectives and integrated this training with education regarding medication management, especially related to antibiotics. The pharmacists at Methodist noted that it is a very large hospital and having the staff to get the necessary first antibiotic protocol to the bed side can be challenging. They have reduced the average delivery time to less than one hour through the implementation of computerized physician order entry, a hospital-wide initiative, and creating a multidisciplinary team to examine "points of failure" to optimize the process. According to the Principal Investigator (PI), the creation of a set of antibiotic order sets automatically labelled STAT, unless changed manually, was the most effective change to decrease antibiotic delivery time. The team is now exploring the possibility of keeping a "sepsis crash box" that includes fluids and broad-spectrum antibiotics on each unit.

At Kindred LTCH, a pharmacy manager noted that for STAT orders, they are able to get the antibiotics to patients within 30 minutes. The pharmacy group did not need to change its sepsis protocols but they do monitor to ensure that ordered antibiotics reach the patient bedside in a timely manner. Pharmacists were trained using a presentation that the pharmacy manager adapted for the needs of the pharmacy staff. No additional pharmacy staff was added to support the SERRI program. There had been an expansion of Kindred LTCH's laboratory capabilities prior to the SERRI program, to be able to complete more lab tests at the hospital rather than using an external clinical laboratory. This has helped to reduce the time required to confirm a sepsis diagnosis.

At San Jacinto ACH, the pharmacy manager noted that they modified existing order sets for the treatment of early sepsis. They worked with the hospital's IT team to add the early sepsis order set to the Pyxis system for what is referred to as a beginning sepsis protocol. At San Jacinto ACH, ordered antibiotics reach the patient bedside at San Jacinto ACH within 15-20 minutes of a STAT order. The pharmacy manager there noted that the severe sepsis protocol is rarely used now. He added that there was no change in pharmacy staff needed for SERRI and workload has not significantly changed because of the SERRI program.

[44] STAT is an abbreviation of the Latin *statum*, which means immediately.

Exhibit 3: Flow Chart of SERRI Screening and Treatment Processes



Source: Methodist Research Institute –SERRI Program

3.4.2 Site Specific Implementation

Methodist Acute Care Hospital

Implementation of the SERRI program at Houston Methodist occurred in a number of phases. The initial piloting of a sepsis tool at Methodist was done with paper documents, a process viewed as burdensome by hospital staff. Prior to receiving the HCIA, the Houston Methodist team developed an electronic version of the tool and all implementation to new units within the hospital have since been in electronic form. At Houston Methodist, implementation was completed in blocks of units. One factor considered in relation to readiness was whether the units were beginning implementation of other programs such as the Methodist Delirium project. The implementation of SERRI on each unit was staggered to ensure units were not starting implementation of the SERRI program and other initiatives such as the HCIA Methodist Delirium program at the same time. Implementation was coordinated to include presentations by the SERRI PI who provided education to physicians and build support for the program. The SERRI program is currently implemented in all units at Houston Methodist with the exception of the emergency department, obstetrics, psychiatric, intensive care unit (ICU), and observational unit. The emergency department has different criteria for rapid screening for sepsis and has its own screening process for sepsis separate from the SERRI program due to the wide array of patients that arrive at the ER, some of whom will not require hospital admission. The ICU has specialized nurse intensivists that engage in their own screening protocol as well for its patient population.

First-Level Responders

First-level responders at Houston Methodist are registered nurses who work on medicine, intensive care and surgical units. There are units at Houston Methodist in which CNAs collect the vital signs of patients and others where RNs collect vital signs. In either case, the first-level responder (RN) is responsible for ensuring that the necessary vital signs are completed and SERRI screening occurs within two hours of admission; after that two hour window, the vital signs entered into the hospital tracking system becomes unusable for the current SERRI screening and must be repeated. First-level responders also assess the patient's mental status and complete the sepsis assessment of the patient using the SERRI tool.

Upon completion of the sepsis assessment, the first-level responder reviews the patient's sepsis risk score on the SERRI dashboard. If the SERRI score is at a level three, the first-level responder will monitor the patient to identify any changes in the patient's condition. If a patient's SERRI score is four or higher, a sepsis alert will automatically be sent to the second-level responder assigned to the patient's unit; the first-level responding nurse will also reach out to the second-level responder assigned via mobile phone. The SERRI program built in this redundancy to ensure that a second-level responder is aware of patient's sepsis risk status. Patients at this higher risk schedule will have vital sign monitoring every four hours, rather than the once per shift for all other patients whose SERRI score is lower than four.

First-level responders stated that the decision of when to complete each patient's assessment was determined at the unit level. In some units, managers determined the time in which the group would begin to complete their sepsis assessment. On other units, the entire nursing team discussed time options and selected a time. On day shifts, vital signs and patient assessments are completed between 8am and noon.

First-level responders in general agreed that the sepsis assessment helps them to improve as bedside nurses. They have more resources in the form of follow-up from second-level responders, and the program does not add significantly to their work load. Some first-level responders experienced challenges in assessing all their patients for sepsis on each shift, and noted that there is also a paging system that

reminds them to complete their assessments: if assessments are not done on time, they receive a notice on their hospital-provided mobile phone reminding them of SERRI program requirements.

Second-Level Responders

Second-level responders at Houston Methodist are nurse practitioners who are either employed specifically by the SERRI program or are hospital employees who have been trained by the SERRI program to serve in the role of second-level responders. The nurse practitioners, who are employed by the hospital, are unit nurses who serve as part of a critical emergency response team (CERT) that responds to all types of critical care events throughout the hospital. Second-level responders at Houston Methodist monitor the SERRI dashboard to ensure first-level responders are completing their sepsis assessments on time. They also respond to sepsis alerts and calls from first-level responders, for patients with a SERRI score of three or four. They begin the sepsis treatment protocol when a patient appears to have sepsis and continue to monitor status for patients being treated for sepsis. They also advise first-level responders on whatever questions arise regarding care of their patients.

Certified Nursing Assistants (CNAs)

CNAs at Houston Methodist have the primary role of collecting the vital signs necessary to complete the SERRI assessment needed for a first-level response. They are also responsible for charting the results into the computer interface needed to enter SERRI data. Most CNAs are aware of when the collected vital signs are out of the norm and will alert the first-level responder for their patient if they have a concern. Often CNAs collect vitals without a nurse being present, though a few nurses were noted to prefer to be present when vital signs needed for SERRI are being collected. Some nurses complete the vital signs themselves in scenarios in which knowing the vitals is critical before administering medication (e.g., blood pressure medicine). CNAs maintain ongoing communication with their assigned first-level responder during the time window in which vital signs are collected and can communicate to the bedside nurse when assistance with collecting the vital signs may be necessary. Some CNAs acknowledge experiencing pressure from first-level responders to complete the collection of vital signs during their appointed data collection window but most noted that they worked with the bedside nurses to ensure the vital signs would be collected in a timely manner.

Kindred Long Term Care Hospital

Implementation at Kindred LTCH began after an information technology upgrade that was needed to support an electronic version of the SERRI tool that was separate from the hospital's EMR. Staff were trained at Kindred and ready to implement the program a few months in advance of the IT upgrade. Program implementation occurred on all units simultaneously once the SERRI tool was finalized and the data monitoring infrastructure was in place. Implementation of the program was coordinated with presentations to staff to stress research on the benefits of early detection of sepsis.

> We have seen the cases of septic shock reduced. It's almost gone. That is the biggest quantitative success.
>
> *–Kindred Administrator, initial case study*

First-Level Responders

First-level responders at the Kindred LTCH facilities are registered nurses or licensed practical nurses who work in the medicine, medical surgery, and intensive care units. As with Houston Methodist, there are CNAs on some units who assist first-level responders by collecting patient vital signs. Whether they collect and enter the vital signs themselves or rely on CNAs, the first-level responders at Kindred

complete their assessment early in each shift. They telephone the second-level responder assigned to their unit if a patient scores four or higher, or if they believe the situation is of concern even if the SERRI score is not yet at four. First-level responders noted that the process of assessing the patient for sepsis provides another opportunity to check vital signs and if there are any changes with the patient. Even though a CAN may enter the vital signs, a first-level responder must still check the data inputted and then review the SERRI score after the score is generated. First-level responders on a medicine floor in the LTCH echoed their peers at the ACH, in acknowledging challenges in getting through their assessment of their patients on every shift. First-level responders at Kindred commented that the SERRI tool assists them in determining the condition of their patients and in discussing issues with their colleagues during shift changes.

Second-Level Responders

Second-level responders at Kindred LTCH are registered nurses who supervise first-level responders. Their primary role is to monitor the assessment status of patients and respond to changing sepsis status as necessary. They have access to the SERRI dashboard and the sepsis assessment data it displays. These second-level responders are able to order tests to confirm sepsis and begin the sepsis treatment protocol. The second-level responders also work with physicians and other members of the clinical team to determine next steps for patients who receive sepsis treatment and ensure that physicians are aware of patient status. Second-level responders at Kindred LTCH assign more complex patients to the most highly skilled and experienced bedside nurses, and the SERRI tool helps them to make these distinctions.

San Jacinto ACH, Skilled Nursing Facility, and Rehabilitation Center

Unlike Houston Methodist, implementation of the SERRI program at San Jacinto ACH began with screening in their emergency department (ED). The clinical leaders at San Jacinto ACH were especially concerned with ensuring all admissions to the hospital through the emergency department were screened as they average about 5,000 visits to their ED each month. As part of the Houston Methodist system, they were able to use the same IT staff that implemented the program at Houston Methodist to install equivalent IT infrastructure. The SERRI program PI gave presentations to physicians at San Jacinto, to boost buy-in for the program. Implementation at the San Jacinto Hospital focused on training of first and second-level responders. The program was initially implemented in the ED and in some medicine units but is not hospital-wide because it has taken the time to hire enough advanced practice nurses to serve as second-level responders. By April 2015, the SERRI program was implemented throughout San Jacinto ACH units with the exception of the medical ICU unit and the obstetrics and gynecology units. The rollout to additional units was realized by adding additional sepsis nurse practitioners at the hospital to support the training of staff in completing the SERRI tool at the bedside and responding to the more challenging second-level response cases.

San Jacinto Skilled Nursing Facility and Rehabilitation Center, located a few miles away, utilizes the same electronic medical record and IT system as San Jacinto Hospital. Implementation at San Jacinto SNF and Rehabilitation occurred after the initial successful implementation at San Jacinto ACH. Staff from the ACH aided in the implementation of the program at the SNF and rehabilitation center. The initial focus of implementation was on the training of the first and second-level responders. There is a regular flow of staff between the ACH and the SNF and rehabilitation center, therefore some staff at San Jacinto SNF and Rehab were introduced to the SERRI program at San Jacinto Hospital, before implementation occurred in the SNF and rehabilitation center. A key factor in influencing the timing of implementation at the SNF and rehabilitation center was this partnership with San Jacinto ACH. This would ensure that

screening at the SNF and rehabilitation facility would occur after the ACH program was in place and the NP-level second-level responders at San Jacinto ACH could provide support to staff at the SNF and rehabilitation center. For example, SERRI screening times on SNF and rehabilitation units are staggered so as to not conflict with screening times at the ACH, and the sepsis nurse at San Jacinto responds to the sepsis alerts from the SNF and rehabilitation center for patients requiring early sepsis treatment. The second-level responders at San Jacinto ACH have the authority to initiate treatment and to advise the supervisors at the SNF and rehabilitation center on specific cases. They also have the ability to review all medical records at the SNF and rehabilitation center, using the integrated EMR across the two facilities.

First-level Responders

First-level responders at San Jacinto Hospital SNF and rehabilitation center are licensed practical nurses in the SNF portion of the facility or on a rehabilitation floor. They complete their assessment of patient sepsis risk using the SERRI tool at 8 am for morning shifts and 8 pm for evening shifts. This requires entry of the vital signs in a timely manner by the first-level responders or the CNAs who assist them. First-level responders we interviewed could only recall two cases that triggered a sepsis alert and required special attention due to a SERRI score of four or higher. They see their role as monitoring the care of their patients, and are prepared to call on second-level responders if needed. San Jacinto SNF and rehabilitation center first-level responders stated that the SERRI tool aids them in following up on changes in patient vital signs that may not be sepsis but do indicate worsening patient condition. First-level responders know they will only receive new results for white blood cell counts about once a week and therefore they are more aware of changes in the SERRI score that could require additional monitoring. Without a full-time physician on their units, first-level responders on SNF units are more likely to consider transfer of patients with a SERRI score of four or higher to San Jacinto ACH where they can be seen by a physician. Staff on rehabilitation units have access to physicians and retain and treat patients with a SERRI score of four or higher on their unit when possible.

Second-level Responders

Second-level responders at San Jacinto SNF and rehabilitation center are registered nurses who supervise first responders on SNF and rehabilitation units. They are responsible for monitoring SERRI assessment status for patients and responding to sepsis alerts. They do not initiate treatment as at the ACHs or LTCHs but can contact the designated NP-level sepsis nurse at San Jacinto ACH to further assess a patient at risk for sepsis and begin treatment if needed. Second-level responders in the SNF work to avert patients reaching a level of four while in the SNF. They do not have daily physician support on the SNF floor. From the time a patient's SERRI score reaches three, the second-level responder will try to contact the sepsis nurse practitioner at San Jacinto ACH who has access to all patient records at San Jacinto SNF and rehabilitation center via the EMR. The ACH sepsis nurse can decide whether the patient should stay on the SNF unit for monitoring (e.g., cases where a vital sign was entered incorrectly or a cancer patient has an abnormal white blood cell count) or requires transfer to the ACH. If the second-level responder isn't able to reach the sepsis nurse practitioner at San Jacinto ACH, they can request a transfer to the San Jacinto emergency department, where more complex tests and treatment are undertaken. Second-level responders who work in the rehabilitation units stated that they have physician staff assigned to their units on day shifts to consult on patients with a level three SERRI score or higher. They noted that this physician presence makes it possible to monitor patients who score three or four in the rehabilitation facility rather than transferring the patient to San Jacinto ACH. A key success for the SERRI program is reducing transfers from the rehabilitation units to the ACH.

3.4.3 Health Information Technology

Staff emphasized the importance of implementing the SERRI tool in electronic form. In early pilot testing of the program at Houston Methodist, a paper form was used. This was added burden and workload, and made it difficult to analyze data. The SERRI team created an electronic tool and now requires that all new participating institutions use the electronic tool. As mentioned previously, some facilities such as St. Joseph SNF intend to eventually implement the screening process electronically but have faced IT challenges and therefore began the screening intervention using paper forms.

SERRI Program staff allows each partner institution to decide how to best use the electronic tool, whether as a stand-alone tool or integrated into an EMR. The use of the electronic tool has greatly aided in the fidelity of execution of the SERRI program across different types of institutions and patient populations. In all settings in which the SERRI tool is used in electronic form, the tool is a software application utilized at fixed work stations where the clinical staff enters information into an EMR; no mobile devices are used to enter or view data.

Staff at all facilities stressed the benefit of integrating the SERRI tool into the EMR used at each facility. Staff at Kindred LTCH noted that the stand-alone web-based tool is challenging because it requires the memorization of an additional password. Kindred staff anticipated the time when the SERRI tool will be accessible as part of their standard EMR, which they believe would further reduce the time required to enter and review each patient's SERRI score. The process for this transition to including the SERRI in Kindred's EMR began in late 2014 and the launch of the new platform that would work as at Houston Methodist occurred in April 2015, just as a second round of case studies were being completed. Data analysts working with the SERRI program noted that the Kindred information technology staff were very effective in developing and testing the SERRI tool integration into the Kindred EMR. Kindred staff at both the Methodist and Bay area locations looked forward to the SERRI tool integration into the EMR since it would save time associated with logging patient data in two separate systems and would likely increase the effectiveness of the program as the system would now produce a SERRI score every time a component of the patient's vital signs used to calculate the score is updated.

3.4.4 Measurement & Self-Monitoring

Interviews with SERRI program staff highlighted challenges in implementing systems for efficient measurement and monitoring. After initial implementation, the SERRI team compiled data from multiple sources to help participating facilities have a snapshot of the compliance rate of sepsis early assessment, a very important indicator to bedside staff. During a six month period, the team worked to develop sufficient database and analytic capacity to provide this information back to the sites in a timely manner. The expertise of the SERRI PI in both information technology and clinical factors was essential to this effort. A systematic plan with a health information technology expert at each site to coordinate with the clinical and management teams could have improved the early feedback of results by the SERRI program.

Standardized submission guidelines were a critical requirement for reporting to CMS, which involved substantial effort on the part of SERRI program staff. This same standardized reporting supports the sepsis assessment compliance data that are used by bedside staff and program leaders to determine how well the program's implementation is progressing.

The data tracked by program staff fall into two main categories: clinical data and outcomes data. Clinical data comes from the SERRI screening tool, which collects information about which patients were

screened, the number of times each patient was screened, and patients' vital signs. Most participating facilities send these data to the SERRI office electronically on a monthly basis.

The SERRI program is tracking important information for each participating institution's patients including: admission source, ICD9 codes, charges, revenues, direct costs of patient, length of stay, discharge disposition (alive/deceased), conditions present at admission and acquired in the hospital, and whether an admission reached outlier status (using the Medicare outlier definition). This is data provided by each participating institution.

Clinical and outcome data are shared widely with all staff. For example, the SERRI screening scores are presented during Clinical Care Coordination Rounds and an inter-professional team, including pharmacists, case managers, doctors, and physician advisors (who manage length of stay) all discuss the sepsis scores during their rounds. Staff also discuss program outcomes regularly during quality assurance meetings. Reviewing and disseminating results widely may help program staff assess the degree to which improved outcomes can be attributed to the intervention. Review of the data also allows program managers to make informed changes to the program.

3.5 Workforce Development

The Methodist SERRI training program addresses the diverse training needs for bedside nurses who served as first-level responders, CNAs who in some locations collect patient vital signs for the SERRI tool, second-level responders who need more specialized sepsis detection training, and physicians who work in units where the SERRI program is implemented. Training of first responders was conducted by second-level responders using a train-the-trainer model.

Leaders at each institution stressed the importance of training the entire clinical team about the purpose and value of sepsis early detection. This is especially for physicians, who were often the most skeptical about the early detection initiative, and most in need of being convinced by the scientific findings offered in the SERRI team presentations on the benefits of the program. .

3.5.1 Training Second-level Responders

We interviewed second-level responders in three facilities and all reported that they received five hours of online training regarding sepsis care and then completed a test to demonstrate knowledge. Trainees were able to re-take this test if needed, until attaining a minimum required score. After passing the test, trainees attended an in-person class with simulation exercises and received three CEU credits upon successful completion of the classroom training. All trainees also received a pre-test on their comfort with sepsis issues before the online training, a post-test on their comfort with sepsis issues after the classroom training component, and then took the post-test again six months after completing the training program. These timed tests measure improved comfort and knowledge about sepsis, and retention of comfort and knowledge over time.

The in-person classroom training consists of four hours of class time with 1.5 hours of that time dedicated to simulation exercises using an interactive mannequin that demonstrates sepsis detection and treatment scenarios at the Methodist Institute for Technology, Innovation, and Education (MITIE) lab. The simulation lab can include four trainees at a time and each has the opportunity to confirm a diagnosis of sepsis and treat the mannequin in a sepsis scenario. This four-hour course focuses on the early identification and treatment of patients with sepsis, tissue oxygenation, and the Surviving Sepsis

Campaign Resuscitation and Management Bundles. Simulation scenarios allow participants to apply the SSC guidelines in a team-based environment, improving team communication. Trainees must pass a practical test at the end of their simulation training to be certified as second-level responders, and may re-take the in-class session if they are unsuccessful at passing the test. All second-level responders whose institutions participate in the SERRI program initially traveled to the MITIE lab for the in-class training. With the program having trained the critical mass of second-level responders across institutions, the training staff that runs the MITIE sepsis simulation training has begun bringing the simulation training to some partner institutions. Staff at San Jacinto ACH reported that the simulation lab will soon be set up for a short period of time at their campus, for second-level responder training. SERRI advanced practice nurses facilitate the in–class training for all second-level responders and train individuals who will serve as trainers at other institutions. They received specialized training in order to be able to facilitate the simulation class and second-level responder training.

Second-level responders we interviewed consistently voiced their appreciation of the second-level responder training program. Numerous participants stated that the training was rigorous but also empowering. Some found the individual, online training to be challenging, but with a level of complexity that could be grasped by trainees. Nurses appreciated the content of online training, which gave them a greater understanding of how sepsis occurs, details about the sepsis disease process, and information about appropriate treatment. Before the training, some staff were concerned about the requirement of passing tests before being allowed to function as second-level responders, but no one expressed concern about the difficulty of the test they all completed.

3.5.2 Training First-level Responders

At Houston Methodist, second-level responders who are referred to as “super users” were trained to provide in-service training to bedside nurses acting as first-level responders. Additionally, the SERRI staff provided presentations that emphasized the importance of early sepsis detection. Case scenarios, such as the account of a young boy who died after developing sepsis while in the hospital, were highlighted in the presentations to emphasize the importance of early detection. As a follow-up to training, posters with key messages regarding sepsis early detection and treatment reinforced the training themes. First-level responders from Methodist reported to our case study team that their training was sufficient for their role as first responders.

First-level responders were trained at Kindred LTC Hospital primarily by a nurse educator for the facility. The training involved a PowerPoint presentation regarding sepsis early detection and treatment and also in-service training. Some first-level responders we interviewed missed the in-service training and had different levels of follow-up regarding the SERRI program. Two nurses received a paper handout of the presentation, which they noted did not provide enough information regarding the SERRI program. A third nurse who missed the initial in-service training received one-on-one training from the nurse educator.

First-level responders at San Jacinto ACH and at the SNF and rehabilitation center also received training in the form of a presentation as well as in-service training. In general, first-level responders believed the training provided them with the tools to serve as first responders, however, one clinical manager involved in the implementation of the SERRI program at San Jacinto SNF believed that the training for first-level responders could have been more hands-on and did not contain sufficient background about sepsis early detection. This person noted that “We’re good at telling people what to do but not why. It could have been more organized. The staff processes information differently; they are hands-on learners.”

3.5.3 Training of Nurse Assistants

Nurse assistants and technicians at the four facilities we visited were trained by second-level responders, who had previously received special training from the SERRI staff. CNAs participating in SERRI from Houston Methodist received online training regarding the SERRI program. They noted that it would have been helpful to be clearer about defining their role within the program. Nurse supervisors and nurses who work with the assistants and technicians determined that enhanced training about collecting vital signs was imperative for the success of the SERRI program. After the program was underway, staff reviewed the SERRI dashboard and noted that in many cases, respiration rate was not being accurately entered. Targeted training was provided to assistants/ technicians at each facility. Across the institutions, both first and second-level responders noted an improvement in the collection of the vital signs by nursing assistants, and also that the work of these assistants is a critical component for the success of the program. Across the four institutions, nurses shared how important it is to have accurate vital signs recorded for the SERRI tool to effectively model sepsis risk. Assistants often are the first to identify and signal a change in patient status, even in cases where the SERRI score does not rise to the level of early sepsis. CNAs are required to complete an annual in-service for the SERRI program.

3.5.4 Training Physicians

Program staff and a wide range of SERRI participants throughout discussions described how important it was to train physicians on key aspects of the SERRI program and yet how difficult it was to train adequately the number of physicians who worked with patients receiving the SERRI intervention. Physicians across institutions were seen as the most resistant to the introduction of the treatment protocols outlined by the SERRI program. At Houston Methodist, SERRI staff described using several means to try to persuade physicians. The CME-based lectures are the most effective ways to compel physicians to learn about the details of SERRI and its approach. Not every physician uses the in-person lecture and younger physicians are more likely to use the online training. This training cannot be mandated for physicians, who have far more independence than other staff in hospitals and other clinical settings. At Kindred hospitals, their SERRI program leads and clinical staff have seen a noticeable difference in support for SERRI depending on whether doctors have received training. At Kindred's Houston campus, where more physicians have completed a SERRI training and have received information on SERRI, there are more physicians supportive of the SERRI treatment protocols. A Kindred second-level responder suggested that physician buy-in at Kindred's Houston campus was at about 80%. At Kindred's bay campus, fewer physicians have been trained and clinical staff there noted a lower level of support for the SERRI treatment protocols. At Select Specialty LTCH, the physician leadership has been very supportive of the SERRI program and in pushing out SERRI training to attending physicians. Yet without the ability to mandate SERRI trainings, a low number of these physicians have completed the training and a high number have been resistant to implementing the SERRI treatment protocol. The SERRI staff continue to look for opportunities for physicians to get more information on the SERRI program; planning dinners, multiple lectures by the SERRI PI at each participating institution, and other events to broaden their reach to physicians. This remains an ongoing challenge for the SERRI program.

3.5.5 Staffing

The SERRI team demonstrated that different staffing models can be used to successfully implement the SERRI screening process at different types of institutions. While ACHs rely on advanced practice nurses to serve as second-level responders, the LTCHs and the SNF/rehabilitation facilities use nurse supervisors (RNs) in this role. It is worth noting that the SERRI team trainers serve in an advisory role for second-

level responders who may need further consultation on questions about the SERRI tool or challenging cases that appear to be early sepsis.

3.5.6 Program Impact on Workload and Workflow

The SERRI program has had an impact on the workflow and workload of the second-level responders, first-level responders, and nursing assistants in the various institutions implementing the program. Bedside nurses who serve as first-level responders across the four institutions spoke about the challenges of integrating the collection of vital signs and mental status assessment needed for the SERRI tool into their workflow. This is especially challenging for nurses who complete vital signs assessment themselves and do not have CNAs to help with this task. Each unit participating in the program was permitted to decide at what time of day they require the vital signs to be collected for SERRI screening. Some units polled their staff while others asked managers to make this timing decision. For a number of nurses, the time at which the vital signs must be collected happens when they are busy with a long list of other critical activities: passing medications, completing rounds with the rest of the care team, or checking on patients with priority issues. For nurses who finish their vital sign collection at the very beginning of the day (a sizeable proportion of participants) there are many of these competing tasks. Nurses, whose data collection and entry is timed closer to the noon hour, reported fewer workflow challenges. Nurses acknowledged that the amount of additional work for the SERRI tool was not dramatic for a single patient, but the timing of when the assessment is required can be a problem. There is also a two hour window after collecting vital signs, during which the information must be entered into the SERRI system to be valid. Nursing staff consistently advised that collecting vital signs later in the shift, and allowing a somewhat longer window for data entry, would improve workflow. Some nurses stated that their units discussed changing the time in which vital sign collection and recording is completed, while others hoped that their units would revisit the workflow and establish a time that could work better. Even in the cases when assistants are collecting vital signs, there can be workflow challenges. For example, nurses at San Jacinto SNF and Rehabilitation Center noted that it is not always possible for assistants to complete vital signs in the time frame allowed. At times, the assistants fall behind and the nurse finds that, although she is ready to complete the sepsis assessment, no vital signs have been entered into the SERRI system. Despite these workflow challenges, most first-level responder nurses stated that the additional requirements of the SERRI program were not a significant additional workload burden.

The staff that may have the most significant increase in workload with the SERRI program are the second-level responders. In ACHs such as Methodist, nurse practitioners who respond to critical care emergencies throughout the institution were recruited to serve as second-level responders. The SERRI program also has dedicated second-level responders at Methodist main hospital and Methodist San Jacinto ACH who were hired by the SERRI project. In order to provide around-the-clock coverage, nurses who have other roles in the hospitals outside the SERRI program also serve as second-level responders, carrying the sepsis alert pager on night and weekend shifts. The second-level responders at San Jacinto and Methodist ACHs described a greatly increased workload in responding to sepsis alerts. They must juggle their roles as critical care nurses and respond to critical care pages as well as sepsis alert pages. When a case of sepsis is definitively diagnosed, the second-level responder stays with the patient for an hour or more to ensure that the early sepsis treatment protocol has begun and the patient is responding well. Second-level responders in the ACHs advised that there are not enough staff at their level to address all the sepsis alerts that are triggered by SERRI screening, especially on shifts when there is no dedicated SERRI-hired second-level responder available.

Second-level responders at Kindred LTCH also have additional work in monitoring the timely completion of sepsis assessments and aiding with the collection of vital signs if their supervisees are overwhelmed with other work. In general, these second-level responders along with second-level responders at San Jacinto SNF and rehabilitation center did not express being burdened by the new workload as much as the second-level responders at the ACHs. Because they are not also responding to a wide range of other critical care pages, in addition to sepsis pages, they are able to integrate sepsis screening compliance and follow-up as second-level responders into their normal supervisory duties.

Feedback from a Select Specialty leader outlined the challenges of implementing the SERRI program with the SERRI tool in paper form. The screening process generates a significant amount of paper but with time the team at the LTCH has been able to standardize the process and reduce some of the associated burden. The screening by paper form has added about five minutes of clinical time throughout the day. Staff were initially concerned with the initial paperwork but after seeing the positive benefits of the program, the clinical staff express pride regarding the positive impact the screening process and follow-up treatment has made for their patients.

3.5.7 Staffing Retention

An outcome of the additional burdens of second-level responders at ACHs and LTCHs participating in the SERRI program is an increase in turnover of staff in these positions. SERRI program staff described that it is difficult to recruit nurses with advanced training and experience to fill the role of second-level responders at ACHs. This has resulted in open positions at ACHs being unfilled and the second-level responders bearing a heavier workload in responding to SERRI alerts and other critical alerts that are tied with their job functions. At Methodist San Jacinto, the second-level responders on staff experienced a heavier burden of completing their follow-up work and were not able to implement the screening compliance tracking processes in their hospital as earlier as they would have liked. San Jacinto staff described SERRI NPs leaving their position because of the high workload, which in turn increased the burden of those who remain. The ICU charge nurses have also needed to increase their workload and take on some SERRI response duties, which is an added burden to their already demanding schedule. At Houston Methodist ACH, the hospital leadership has sought to aggressively expand the number of second-level responders hired with limited success. The hospital has approved hiring 10 NPs to serve as second-level responders but has been only able to hire and keep five. Staff at Houston Methodist also perceived a high level of turnover as a result of the workload of the second-level responders on staff. They further express an appreciation with the positive impact of the SERRI program but were dissatisfied with their own high workload. The high workload is a concern for the SERRI NPs and the hospitalist NPs who serve on the CERT for the hospital as a whole and cover for the SERRI staff when they are off. SERRI staff also suggested a special cultural challenge that may lead to especially high turnover of NPs. At hospitals in which it was common to employ NPs as critical care nurses, there is a lower incidence of turnover. In institutions with no history of employing NPs, the NPs face challenges working with physicians and are more likely to leave their positions in frustration. This is especially a challenge in LTCHs who are not accustomed to employing NPs in the roles similar to that of the second-level responder.

> "NPs are stretched thin. They need to hire more but this process takes a long time; it takes two months to credential a new NP once hired"
>
> *– Second-level Responder, Houston Methodist, follow-up case study*

3.6 Implementation Effectiveness

In this chapter, we discuss the different areas in which the Methodist-lead Sepsis program staff believes the SERRI program is making a difference in quality of care delivery, patient health outcomes and cost savings. For each of these aim categories, we discuss how the SERRI program team is measuring the program's impact, as well as how Abt Associates intends to measure the program's impact. Finally, we discuss unanticipated impacts that have arisen over the months since program implementation.

3.6.1 Better Care

Participants we interviewed described a number of improvements in quality of care due to the SERRI program. Nurses described having increased confidence in recognizing sepsis or other health concerns at an earlier stage. Nursing assistants describe being more effective in assessing a patient's vitals and knowing if it is within normal range. They are now more likely to communicate an important change in vital signs to the first-level responder. First-level responders believe that the SERRI program improves care by having a second-level responder who can quickly assess a patient whenever a nurse has a concern about sepsis. Changes in treatment now occur more quickly due to reduced time between when a first-level responder signals a concern and when a follow-up assessment is completed by a second-level responder.

> It's a nurse driven tool. It lands on nursing to identify and notify. Patients could fall through cracks a lot easier if we didn't have the tool. The tool focuses us on sepsis for every patient.
>
> *– First-level Responder, Houston Methodist, initial case study*

Another improvement in the quality of care is the speed of initiating orders for sepsis treatment. A second-level responder nurse can initiate treatment for sepsis within an hour of the SERRI tool returning signs of sepsis, a great improvement in the time required to initiate treatment. A number of staff told us that patients with sepsis are being treated at an earlier point in the sepsis severity continuum. A number of nurses described patients previously "falling through the cracks" and not getting treatment for sepsis at all due to failure to recognize the warning signs of sepsis. Staff believe that more patients are being appropriately treated because of the SERRI program. Participants also observed that changes in the patient's vital signs are now more likely to be discussed at shift changes. Speed in administering sepsis treatment is measured through in-depth chart reviews of cases that screened positive for sepsis and that were determined to be sepsis by the second-level responder. Each month, nurses conduct an audit of 10 percent of these cases using an online auditing tool developed by the SERRI team expressly for this purpose. The tool assists auditors in extracting data from the EMR, linking a positive first-level screen, the second-level assessment, and the timelines on the treatment orders (e.g., fluids, antibiotics, and lactate). The PI noted that even with the data extraction tool, the process is "incredibly time consuming and challenging, but is an important part of program improvement." Clinical staff at participating institutions acknowledged that the process is time consuming but it also is important to improving patient care. At many institutions, the effort is spearheaded by staff that are already extended but a great effort is made to ensure the quality of process of the sepsis early treatment and confirmation remains high.

> "We have better outcomes—before the program came in, we wouldn't call is sepsis until blood pressure was involved at the level of septic shock. Even the physicians wouldn't call it sepsis. Now with the program and education—we are calling it sepsis earlier."
>
> *– Second-level Responder, Kindred Medical Center, follow-up case study*

The SERRI team recognized the importance of having a pharmaceutical team that can meet the increased medication demands that arise from the SERRI program. At each facility, the pharmacist team implemented procedures to review any new orders for a suspected sepsis patient and fill antibiotic prescriptions within one hour. With the fast progression of sepsis from initial presentation, the efficiency of the pharmacy team at each institution is vital to the overall success of the SERRI program in treating patients expeditiously.

At the time of our initial case study, SERRI staff had only recently been able to view compliance with screening requirements. Initially there were few reports available, and tracking compliance consisted of the Program Manager manually checking the number of patients whose screening was completed, which was time-intensive and left much room for error. Since then, the SERRI team has access to data that show the implementation in each of the units where the program is implemented, with very high compliance rates. The process has also been somewhat streamlined with a multiscreen interface allowing staff to transfer and compare data from multiple file locations.

> "The patients are intervened much sooner before the patient has a chance to deteriorate."
>
> *– Second-level Responder, Kindred Medical Center, follow-up case study*

Another way Methodist tries to gauge the success of the program is through the clinical measures performance improvement (CMPI) quality committees that have been tasked with reviewing sepsis measures. These committees are comprised of clinicians and are "protected" meetings (a legal designation that makes the minutes and discussions that occur at these meetings not part of the discovery process, like morbidity and mortality rounds) where very frank discussions about processes, outcomes and missed opportunities occur. While these meetings are not an appropriate venue for patient participation, Methodist has been considering ways to improve patient engagement. It is likely that this will occur after the end of the Award, as part of a hospital-wide effort to improve patient engagement more generally, that is, beyond the sepsis program. Each facility selects clinicians to serve on their equivalent CMPI committee. The meetings are monthly or quarterly, depending on the facility.

Methodist's Measurement Strategy

Methodist Research Institute collects data on quality measures which they regularly report to CMS and use for internal quality improvement. The key measure reported is:

- The percentage of patients screened for sepsis through the SERRI initiative.

3.6.2 Better Health

Between two and four percent of patients screened across all participating institutions are assessed as positive for sepsis. Appropriately intervening and providing care for these patients is a critical goal of the SERRI program. Participants at all institutions we visited at the initial case study and assessed at follow-up discussed their awareness of improvements in patient outcomes that they associate with the SERRI program. At Houston Methodist, a surgeon noted that he saw improvements in surgical patients because of the SERRI program. He stated that in some transplant patients such as liver transplants, the most common cause of death is from sepsis. The SERRI program addresses sepsis before it becomes aggressive in surgical patients. He has looked at data that shows that

> The proportion of patients discharging with lower stages of sepsis has increased. Mortality is trending down.
>
> *– SERRI Program Staff, initial case study*

Methodist's transplant survival rate is 3-4% higher than at other institutions and he believes part of this success is due to the SERRI program.

A SERRI program staffer noted they have seen a reduction in sepsis related mortality at Houston Methodist and five other ACHs, and patients being discharged with a lower stage of sepsis than prior to the SERRI program. There are also more sepsis associated encounters that are going home instead of to another health facility, which is an improvement. A nurse at Houston Methodist described detecting sepsis in younger patients who might not otherwise have been considered to be at risk for sepsis. A similar view was articulated by nurses at Kindred LTCH who observed that patients, who would not previously have been identified as septic, have a better course because their condition is now appropriately recognized. Another nurse at Kindred LTCH described a scenario in which the staff detected sepsis and kept the patient from being admitted to the ICU. Kindred staff referred to an indication of success used within their institution, the number of lives saved by detecting sepsis early, after confirming through lab tests those cases that were in fact sepsis and treated appropriately. They were pleased by the number of cases that were able to have a positive outcome amongst the confirmed cases of sepsis. Nurses and physicians across participating institutions also believe that the SERRI program is decreasing the length of stay for patients diagnosed with sepsis. Nursing staff described the SERRI program as saving lives because patients receive treatment for sepsis before their condition reaches a level of severity at which recovery is less likely. Participants believe that patient outcomes for patients at all stages of sepsis are improving due to the introduction of the SERRI program and there has also been a shift the severity distribution to less severe cases of sepsis. Even for patients who will reach the stage of severe sepsis, their sepsis is more likely to be identified earlier and they are likely to have better outcomes and a faster recovery.

> The program is definitely effective. The tools weren't present before and we have noticed a decrease in the number of patients who have had to go the emergency room for assessment.
>
> *– Second-level Responder, San Jacinto SNF, initial case study*

Methodist's Measurement Strategy

Methodist's collects data on a number of outcome measures, which they regularly report to CMS and use for internal quality improvement. These outcome measures across all institutions include:

- All-cause mortality;
- Proportion of sepsis-associated discharges in each stage of sepsis;
- Percent of sepsis-associated ACH stays that reach outlier status; and
- Percent of SNF patients transferred to ACH care for sepsis.

3.6.3 Smarter Spending

Clinicians interviewed at participating institutions all reasoned that the SERRI program would result in cost savings for their respective institutions and for payers (including Medicare) but may not be discernable based on the current payment approaches in place in the different care settings. The LTCH and SNF and rehabilitation center staff believe that they are better able to retain patients in their institutions, because sepsis is recognized early and does not progress to a higher severity level that could require a transfer to an ACH.

At ACHs such as Houston Methodist, staff believes the SERRI program will reduce the number of severe sepsis cases that require costly treatment. If sepsis is detected early, patients are less likely to require ICU

care and length of stay is likely to be lower. Though some staff acknowledged that a lower length of stay may not benefit Medicare, savings may be substantial for the individual acute care institutions. This is especially true for LTCH institutions whose payment is in a lump sum and it will not be feasible to generate a precise average cost of care. The length of stay between ACHs, LTCHs, and SNFs also will make it difficult to assess the level of cost savings, suggested some hospital leaders with long term care experience. In addition, early detection may mean that some patients are coded/paid in a lower acuity diagnosis related group (DRG), (e.g., sepsis rather than septic shock), which may reduce costs for Medicare. Some physician leaders suggested other ways in which the SERRI would benefit the hospital financially, including decreased likelihood of lawsuits from poor outcomes and increased business as the facility's reputation for high quality care increases. Other SERRI staff suggested that the benefit in cost reductions may not be as significant due to the paradox that by treating sepsis early and averting the demise of a patient, there will be additional cost to the continued care of the patient health care, though the implicit goal of patient survival is achieved.

Methodist's Measurement Strategy

Methodist collects data on a number of cost measures, which they regularly report to CMS and use for internal quality improvement. These cost measures include:

- Average cost of care across all sepsis-associated patient stays; and
- Average amount of outlier payment per outlier sepsis stay.

3.6.4 Outcomes That Can Be Measured Using Claims

Some outcomes such as improvement in prescribing practices and changes in clinical practices cannot be accessed via claims data. Many important outcomes such as all-cause mortality, reduced length of stay, reduced readmissions to acute facilities, and fewer patients reaching outlier status can be measured using Medicare and Medicaid claims. The Abt team will have challenges specifying criteria for identifying intervention and comparison patients, since it is not possible to identify patients who did *not* develop sepsis due to SERRI screening.

3.6.5 Unanticipated Impacts

Several participants discussed unanticipated impacts of the program. SERRI screening has detected patients with other critical conditions that require second-level responder attention, but are not sepsis, such as GI hemorrhage, respiratory distress, arrhythmia, acute myocardial infraction, pulmonary embolism, and adverse reactions to medications. Participants believe these conditions have been detected earlier than they would otherwise have been detected, and patient outcomes are better than would have otherwise been the case.

Over year of using the SERRI tool in multiple clinical settings has revealed scenarios in which the SERRI tool is less effective in detecting early sepsis. SERRI analytic staff have noted that SERRI has limitations in detecting early signs of sepsis in the older adult population that are present in large numbers in SNFs and LTCHs. The vital signs used to derive the SERRI score may have very different implications for patients of the same age who are different in terms of health status. In the SNF setting especially, the tool is returning a higher than expected false negative result. Nurses in the long-term care settings are still able to detect some signs of concern due to their heightened awareness regarding sepsis even if the SERRI tool doesn't reveal the factors of concern. The SERRI program has reached out to geriatricians to help to determine how best to address this challenge. So far the SERRI team has ruled out the potential of

incorporating an age-based threshold. The SERRI tool has also had challenges detecting early sepsis in the case of oncology, extracorporeal membrane oxygenation (ECMO), and transplant patients. In some cases such as in scenarios where white blood cell count may be less of a useful indication, the SERRI team has been able to provide some guidance to clinical staff to use the remaining indicators to assess the patient's risk for sepsis. The SERRI team is committed to exploring meaningful alternatives to address these detection challenges will.

> The challenge was finding a way to infiltrate the culture and make it to be a part of what the hospital does. The SERRI program is a part of the way the facilities work now.
>
> *– SERRI Staff, follow-up case study*

SERRI program staff also noted that a significant success has been the general empowerment of nurses. One staffer noted that over the last twenty five years, nurses' role had been reduced to data entry tasks rather than caregiving. The nurses have information through the SERRI dashboard and from their training that allows them to be more aware of when to call the rapid response teams that are helpful in intervening when a patient's condition begins to change significantly. A staffer stated "This program has brought back some of the critical thinking important in nursing care." The level of empowerment expressed by nursing staff is far greater than the SERRI staff anticipated.

3.7 Context

In each interview and focus group during the initial and follow up case study, participants were asked about the broader context of the program, and lessons they have learned in the year since the program began. This chapter sorts these lessons learned into four different categories: implementation, staffing, measurement and self-monitoring, and sustainability.

3.7.1 Endogenous Factors

Because sepsis-focused programs existed before the introduction of the SERRI program, it may be difficult to define a true baseline period. It may also be challenging to attribute the impact of the SERRI program, given these other sepsis initiatives. This includes the work at the latest Methodist hospitals to implement, Willowbrook and West Houston, which both adopted some components of the SERRI program without having the same processes in place until they received Award funding. For example, Willowbrook did not have second-level responders that were nurses but instead had physicians cover SERRI alerts.

In addition to sepsis programs, Houston Methodist (and some of their affiliated facilities) are also implementing the HCIA-funded delirium prevention program. Both the SERRI program and the delirium initiatives depend on screening by bedside nurses and rely on advanced practice nurses; both require changes in processes and new protocols for nurses. It is unclear if the two initiatives serve to advance the outcomes of both, or if they compete for nurses' time and focus.

Neither Kindred nor Select Specialty suggested any programs within their institutions that they believed to impact the SERRI program implementation in their institutions.

Communication

> The protocol [procedure tied to SERRI screening] standardizes our communication to the physicians and helps us present a case of what to do next. Before, we suspected [but didn't have evidence], now we have indicators to strengthen our case with physicians. We're not as easily dismissed.
>
> *– Second-level responder, Kindred LTCH, initial case study*

A key lesson learned in the implementation process is the importance of building relationships and adequate communication between teams within an institution. Each participating institution appointed a SERRI working group to bring together staff from across the institution and consider how best to educate and inform staff at various levels about the SERRI program. Communication between nurses and physicians is essential for success of the program. The SERRI team ensured that second-level responders and especially nurse practitioners who are responsible for ordering sepsis treatment have standards in place to communicate with physicians. Program administrators at each facility spoke about the importance of communicating that nurses are a part of the care team and not in competition with physicians. There may be ongoing challenges in this area as the SERRI team continue to work to ensure physicians and the rest of the clinical team are speaking the same language with respect to best practices for early sepsis treatment. SERRI administrative staff and clinical staff at participating institutions also conveyed the importance of presenting early results and successes to the broader clinical community so that the benefits of the program are more tangibly understood.

Leadership Buy-in

SERRI program staff also addressed the importance of having leadership buy-in at each phase of implementation. Having physician leaders and the medical executive strongly endorse the new screening and early treatment guidelines went a long way to help define a culture of change at each institution. There were also clinical staff not a part of the SERRI program that served as champions on quality improvement teams and leadership teams throughout each institution. The SERRI program staff stressed the importance of emphasizing the long term commitment of institutions to the program so that staff at each institution wouldn't view the initiative as the latest fad in clinical programs to be implemented at the hospital. The continued symbolic as well as tangible financial support of facility leadership will be critical in maintaining the success of the SERRI program after HCIA funding concludes.

Staffing

This program relies on nurses and assistants to identify early signs of sepsis; the role of advanced practice nurses is also critical to the success of the initiative. The second-level responders—nurse supervisors at the LTCHs and SNF or master's degree trained nurses at the ACHs—use their clinical judgment to confirm sepsis cases and to begin appropriate treatment. Leaders at the ACHs acknowledged the difficulty in hiring critical care nurses for this role, and a shortage of these staff can limit the follow-up response time of the SERRI program at these facilities. At the time of the case study follow-up, the ACHs were seeking to add more sepsis nurses to the staff to broaden the reach of the program and decrease the burden of NPs.

3.7.2 Sustainability

The SERRI leadership reported that Houston Methodist intends to continue the program after the end of the Award. The SERRI program aligns with the hospital's objective to improve patient outcomes and its continuation will contribute to the success of the hospital's new center for health outcomes research. Furthermore, the program has been implemented throughout the hospital and is "part of the culture."

There was widespread agreement among those interviewed at Methodist that the program should continue.

The Methodist SERRI team addressed sustainability from the launch of its program. The Houston Methodist integrated the SERRI tool into its EMR and participating facilities were asked to commit to sustaining the program beyond the period of the CMS Award, including continuing to support necessary information technology for the program. The costs for maintaining the IT infrastructure for the program is low after initial integration into the IT infrastructure at each facility, and ongoing maintenance is expected to be minimal.

A key component to the sustainability of the SERRI program in ACHs such as many Methodist hospitals will be having a plan in place to recruit and retain advanced practice nurses to serve as second-level responders. Staff at all facilities talked about the difficulty of recruiting qualified advanced practice nurses. Advanced practice nurses will be a significant ongoing cost that SERRI program staff believes can be offset by savings due to early sepsis detection. The challenge of hiring, retaining, and paying advanced practice nurses may be the key issue for sustainability of the SERRI program, or its expansion to other settings. The hospital leadership at the Methodist ACHs is prepared to integrate these costs. With some Methodist institutions, the approach going forward will be to adopt the approach of LTCHs, training charge nurses to serve in the role of second-level responders. Methodist West Houston, San Jacinto and Willowbrook can be described as community hospitals with less experience with NPs and lower acuities. They will adopt the charge nurse as second-level responder approach for the time beyond the Award. These institutions will also have the benefit of the SERRI tool integrated into their EMR.

Kindred institutions also committed to the sustainability of the SERRI program at its locations. It built its own simulation lab that will be used for SERRI training following the conclusion of the Award. The integration of the SERRI tool into Kindred's EMR will also aid in the reduction of burden of the SERRI screening process. The Kindred corporate leadership has committed to further expand the SERRI program to eight to ten facilities in the Houston in the near future with the success of the program at facilities currently active with SERRI.

Select Specialty, though it implemented the SERRI tool in paper format, has seen sufficient benefit of the SERRI program that it, too, will continue the program beyond the Award period. Select Specialty staff believe that SERRI processes have been integrated into its culture and accepted as part of how they successfully perform their work as clinicians.

3.8 Potential Improvements Suggested by Program Staff

Some suggested improvements were raised by staff at Houston Methodist, Methodist San Jacinto, Select Specialty, and at Kindred LTCH. Suggested improvements include:

- More systematic training is needed for nursing assistants and technicians. Many first-level responders noted that these assistants are not always able to consistently collect vital signs accurately and that some still do not understand the importance of this task.

- Nurses also suggested that it is important to train nurses who are likely to float to departments in which the program is functioning. These "float" nurses were not trained in the SERRI program practices and often are unaware of the details of how the program functions and of the program benefits. Nurses from observation units, who often float to inpatient units as needed, should receive priority for SERRI training.
- More advance practice nurses are needed to serve as second-level responders. This is especially true at Houston Methodist where nurses who carry the sepsis pager spoke about the burden of the responsibility and the need for more help to reduce their caseload to a manageable level.
- Clinical staff and administrators suggested that the treatment processes associated with early sepsis response need to be codified into each institution's clinical operating guidelines in order for more physicians to be willing to adopt new treatment practices surrounding fluid resuscitation.
- Second-level responders at Houston Methodist believe that there should be more discretion in determining which transfer patients—those admitted from other facilities- to screen at a second-level response in the ACHs. Screening all transfers as a second-level response dramatically adds to the NP staff's burden.
- One medical director suggested the development of targeted treatment guidelines that would fit the types of sepsis scenarios that occur in a given facility to avoid the appearance of a "one-size-fits –all" treatment approach across acute and long term care facilities.

Next Steps

The SERRI program seeks to integrate the key findings from the HCIA study period into best practices for the long term sustainability of sepsis early screening and intervention at institutions actively implementing the SERRI tool. The team is especially concerned with calibrating the tool for patient populations that may not trigger an alert with the SERRI tool. They are also considering alternatives for populations in which the tool will not be effective in detecting the early signs of sepsis. The SERRI program will also continue to search for innovative strategies of engaging physicians, whose buy-in is vital for the practice of early sepsis treatment to be broadly adopted across institutions. There will also be ongoing work to establish a cost-effective model of implementing second-level response to sepsis screening, with charge nurses and other nursing staff with broader experience replacing the current role of NPs in institutions that don't typically include advance practice nurses in their staffing models. The SERRI team hopes that commitment to these issues of concern will maximize the benefits of the SERRI program that have already been established through the past years of implementation.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total Medicare episode spending. For Methodist Sepsis patients whose program intervention began in a skilled nursing facility, rehabilitation facility or long-term acute care hospital (LTACH), we present the following core measure:

- Admission (transfers) from SNF or LTACH to the hospital
- Total Medicare episode spending for 60 days including the index admission and all spending for 60 days after admission

- 30-day post-admission (all cause) visits to an acute care hospital emergency department following an index admission

For Methodist Sepsis patients whose program intervention began in an acute care hospital, we present results for the following Core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission for a patient eligible for the screening innovation, in either an intervention or comparison hospital.
- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.
- Total Medicare spending for 60 days including the index admission and all spending for 60 days after discharge.

The Methodist Sepsis program also aims to reduce length of stay, and avoid complications for patients with sepsis. We therefore present results for the following additional measures:

- Length of stay (LOS)
- Discharge destination

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. All models include controls for patient age, squared age, gender, race, Hierarchical Condition Category (HCC) score in year of treatment, squared HCC score, eligibility for Medicaid at any time during observation period (2010-2014), as well as indicators for the quarter in which the episode occurred.[45] An indicator is also included for individuals with missing HCC scores.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[46] We believe this is an accurate way to compare time periods.

---

[45] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g. age, gender).

[46] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

4.1 Defining Intervention and Comparison Groups

4.1.1 Intervention Start Date information

Methodist Sepsis program staff supplied the start date for each hospital's intervention period. Exhibit 1 includes the dates on which units "went live," and the percentage of patients in each facility that program staff believe will be eligible for the intervention at full implementation.

Exhibit 1: Methodist Sepsis' Program Implementation Timeline

Facility	Go-live Date	Fully Implemented Date	Units and Types of Patients to be Targeted	Est. % of Adult Admissions Eligible for Intervention at Full Implementation
Houston Methodist Hospital	Jan-13	Nov-13	1 ICU, 1 IMCU, 1 Obs unit, 22 medical-surgical units	73%
Houston Methodist Sugar Land Hospital	Jan-13	Dec-13	1 ED, 1 ICU, 6 medical-surgical units	81%
Houston Methodist San Jacinto Hospital and SNF	Feb-13	Feb-13	1 ED, 4 medical-surgical units	87%
HCA Bayshore Medical Center (Hospital)	Jun-13	Jun-13	Bayshore Medical Center facility: 1 ICU, 1 IMCU, 5 medical-surgical units (includes 1 telemetry, 1 surgical, 2 medical, 1 geriatric/psychiatry); East Houston facility: 1 ICU, 1 IMCU, 3 medical-surgical units	98%
HCA Rio Grande Regional Hospital	Jun-13	Jun-13	6 medical-surgical units (includes 2 medical, 1 surgical, 1 stroke, 1 oncology, 1 telemetry)	91%
St. Joseph Regional Health Center (Hospital)	Mar-13	Oct-13	6 medical surgical units: 1 medical, 1 surgical, 1 stroke, 1 oncology, 1 pedi (adult overflow), 1 telemetry)	57%
Kindred Hospital Medical Center (LTCH)	Oct-13	Oct-13	All beds	100%
Kindred Bay Area (LTCH)	Oct-13	Oct-13	All beds	100%
Select Specialty Medical Center (LTCH)	Sep-13	Oct-13	All beds	100%
Select Specialty Heights (LTCH)	Sep-13	Oct-13	All beds	100%

Source: Methodist Sepsis program staff.

SNF: Skilled Nursing Facility; LTCH: Long Term Care Hospital

4.1.2 Selection Rules

The section below explains how we defined a set of criteria or rules that were used to create both the comparison and intervention groups. The criteria were created using information that is available in the Awardee registry and in Medicare claims. These were then uniformly applied to patients from intervention and comparison facilities to select the final intervention and comparison populations.

In this report, we analyze data for the entire screened population, and also conduct an additional sub-analysis of the Methodist Sepsis population with sepsis coded on their claims, to understand whether

the intervention is reducing length of stay, readmissions and total episode costs for septic patients. We note that the effort to detect sepsis could be preventing sepsis in borderline cases, leaving only those with more severe sepsis coded on their claims; conversely, it is possible that screening leads to increased detection and coding of borderline (mild) cases of sepsis.

Facilities participating in this program appear to have used somewhat different patient selection criteria, and implemented the program on different units/floors—the program was not implemented identically in all participating facilities and units—and we lack registry data for several facilities. The most common set of hospital units implementing the program were general Medical-Surgical Units, ICUs, and emergency departments. We used the following revenue center codes to identify these types of hospital units:

- Medical-surgical or general units revenue center codes: 0110, 0111, 0120, 0121, 0130, 0131, 0140, 0141, 0150, 0151
- Intensive Care Units revenue center codes: 0201, 0202, 0206 (surgical, medical, intermediate)
- Observation stays procedural codes: 99234, 99235, 99236

Emergency Department revenue center codes: 045X. Based on new input from the Awardee, beginning in this report we exclude patients with the following diagnosis codes indicating solid organ transplant:

001, 002, 005, 006, 007, 008, 010, 652.

Exhibit 2 shows the quarterly match between the estimated group and the registry provided by the Awardee for the full screened population. The rules described above result in the following match between registry data and the rules we are able to apply based on data in Medicare claims:

Exhibit 2: Match Rates for Methodist Sepsis – Screened Patient Population

	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4
Registry with Medicare FFS claim (A)	2734	2454	2382	2639	2698	2491	2267	2321
Registry Patients Not Captured by Abt rules (B)	0	0	0	0	0	0	0	0
Miss Rate (B/A)	0%	0%	0%	0%	0%	0%	0%	0%
Estimated based on Abt rules, with Medicare FFS claim (C)	4293	3630	3308	3133	3050	2813	2581	2574
Match between Estimated and Registry (D)	2734	2454	2382	2639	2698	2491	2267	2321
Estimated by Abt rules, Not in Registry	1559	1176	926	494	352	322	314	253
Accuracy Rate (D/C)	64%	68%	72%	84%	88%	89%	88%	90%

Accuracy rate = Percent of admissions with a Medicare FFS claim that are identified using Abt's rules and are also in the registry (indicates that our criteria are too broad and capture some patients who were not in the registry and apparently did not receive the intervention)

Miss rate = Percent of admissions with a FFS claim that meet Abt's inclusion criteria but are not in the registry (indicates that nearly everyone in the registry meets our criteria—we miss very few)

Our selection rules did not miss any of the patients in the registry. The accuracy of our matching procedure improved substantially over time, and is consistently above 85 percent for the last year for

which we have data. Although we fail to exactly capture the population subject to screening, the potential for our estimates to be downward biased is mitigated by the high rate of accuracy.

For the sub-analysis of patients treated for sepsis, we used the following criteria to define patients who exhibit symptoms of Stage 1 through Stage 3 sepsis:

- Stage 1 Sepsis: 038.0 - 038.9 (septicemia), 995.91 (sepsis)
- Stage 2 Sepsis: 995.92 (severe sepsis)
- Stage 3 Sepsis : 785.52 (septic shock)

All patients whose claims show a sepsis code were included in the following acute care intervention patient analyses; the larger group of patients whom we estimated were screened, are included in the screened patient analyses. We include all long-term and post-acute care (LTPAC) patients in the LTPAC-specific analyses.

We constructed sepsis intervention patient populations for the analyses below using the diagnosis code, revenue center code, and exclusion criteria described above.

For each outcome measure below, we present first the screened patient population results, followed by the septic patient sub-population results. Lastly, we present the LTPAC patient population results.

4.1.3 Estimated Intervention Group

Exhibit 3 below shows average patient characteristics for the Awardee and comparison groups in both the Baseline and intervention periods. The demographic summary statistics serve two purposes. The first is to provide a sense of the population demographics in the Methodist Sepsis treatment population. The second is to show that the demographics are similar for intervention and comparison groups, with relatively wide standard deviations. The wide standard deviations reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

Exhibit 3: Patient Summary Statistics by Intervention and Awardee Group

Methodist Sepsis – Screened Patient Population

	Awardee				Comparison			
	Intervention Period (N=38,380)		Baseline Period (N=83,108)		Intervention Period (N=81,687)		Baseline Period (N=172,642)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.55	0.50	0.56	0.50	0.54	0.50	0.55	0.50
Nonwhite	0.27	0.44	0.26	0.44	0.31	0.46	0.31	0.46
Age	72.69	13.46	73.00	13.25	71.62	13.47	71.81	13.36
HCC Score	2.19	2.46	2.30	2.54	2.04	2.24	2.21	2.36
Missing HCC	0.07	0.26	0.05	0.22	0.10	0.30	0.06	0.23
Medicaid Eligibility	0.40	0.49	0.50	0.50	0.45	0.50	0.54	0.50

Methodist Sepsis – Septic Patient Population

	Awardee				Comparison			
	Intervention Period (N=3,606)		Baseline Period (N=7,368)		Intervention Period (N=8,567)		Baseline Period (N=15,096)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.53	0.50	0.53	0.50	0.51	0.50	0.52	0.50
Nonwhite	0.33	0.47	0.33	0.47	0.36	0.48	0.37	0.48
Age	72.21	14.34	72.92	14.28	72.53	14.06	72.54	14.17
HCC Score	3.16	3.18	3.52	3.25	2.74	2.79	3.33	3.11
Missing HCC	0.06	0.24	0.05	0.22	0.09	0.28	0.05	0.21
Medicaid Eligibility	0.50	0.50	0.73	0.45	0.54	0.50	0.73	0.45

For both sets of patient populations, we find that the demographics are similar between the comparison and intervention groups during the both intervention periods, with the exception of age and HCC scores. We note that comparison patients corresponding to the Methodist–Sepsis treatment sub-population were more likely to be Medicaid eligible than were Awardee intervention patients, in both the baseline period and the intervention period.

4.2 Core Measures: Results

The following sections show results separately for the acute care hospitals participating in the Methodist Sepsis program, and for the LTCHs and SNFs in the program. The graphs for the acute care hospitals show discharges followed within 30 days by a readmission, and followed within 30 days by an ED visit, as well as Medicare spending for a 60-day episode starting with the inpatient admission. All estimated changes in utilization are based on eight quarters of post-implementation data for the acute-care arm of the intervention and seven for the LTPAC arm. One less quarter of data is included for the spending measure compared to the utilization measures, due to the lag required for post-acute claims to become available for analysis.

4.2.1 Medicare Episode Spending – Acute Care Patients[47]

Exhibit 4 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days, for the entire population that is screened for sepsis. Exhibit 5 reports the average 60-day Medicare spending for patients coded as septic. In neither population do we see a consistent or statistically significant pattern in Medicare episode spending. Exhibit 6 shows estimates of both average and median Medicare episode spending over the entire intervention period. On average, the intervention caused a spending decrease of $83 per patient episode, and an increase of $53 at the median. There was an increase in Medicare episode spending of $229, and a median increase in Medicare episode spending of $529 for the septic patient population. None of these regression results are statistically significant.

This graph is restricted to patients with sepsis whose program intervention began in an acute care hospital.

[47] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 4: Mean Medicare Episode Spending – Acute Care Patients, Screened Patient Population

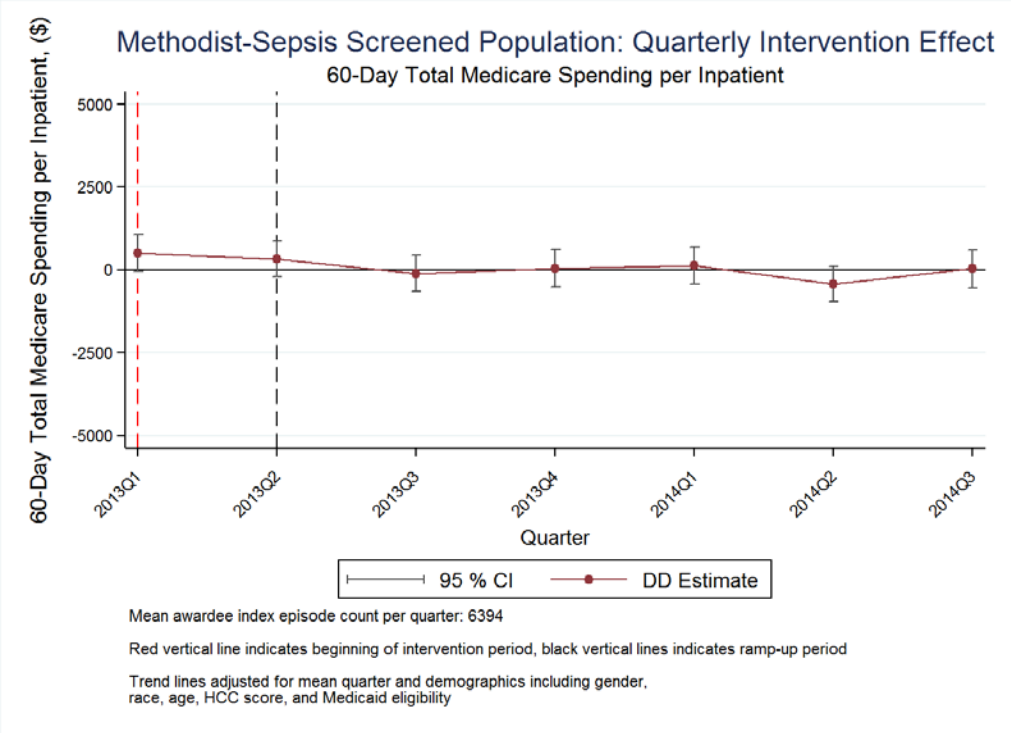
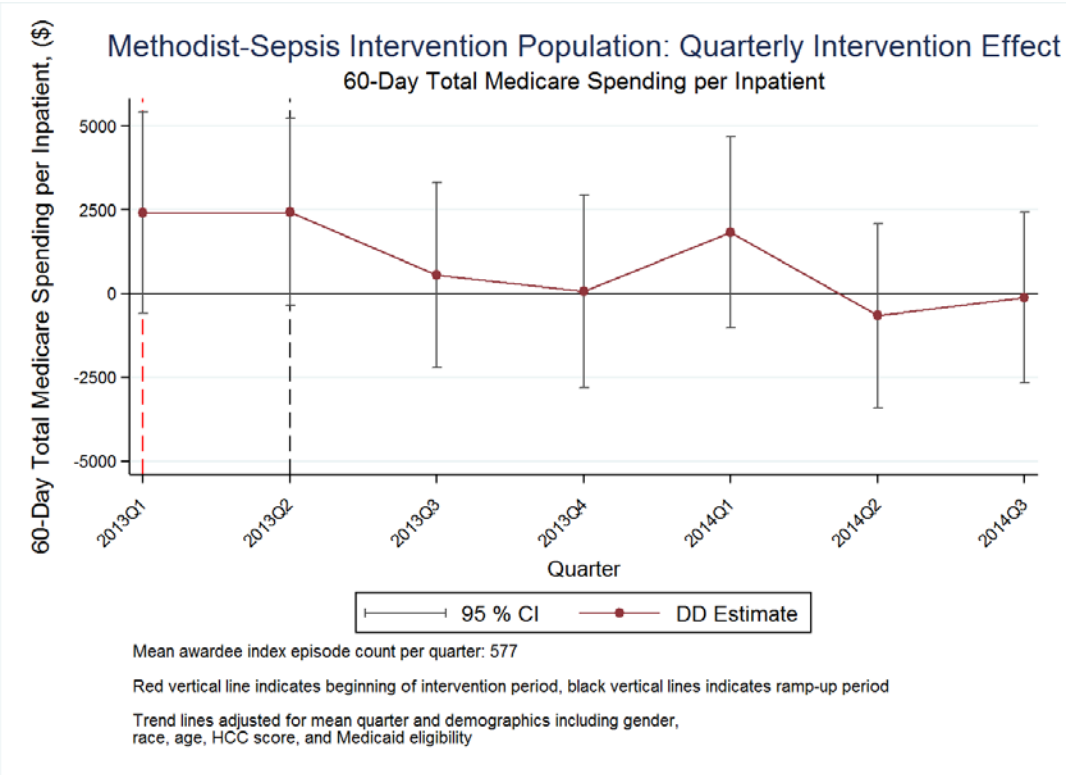


Exhibit 5: Mean Medicare Episode Spending – Acute Care Patients, Septic Patient Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

Exhibit 6: DD Estimated Effect of Intervention on Mean 60-day Post-Discharge Medicare Episode Spending for Screened and Sepsis Acute Care Patient Populations

Methodist Hospital – Sepsis			
		Screened Population	Intervention Population
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	-82.69 (131.01) [375,817]	229.77 (679.21) [34,637]
Intervention Effect (Median Regressions)	Estimate Standard Error Sample Size	53.07 (47.34) [375,817]	527.37 (694.10) [34,637]

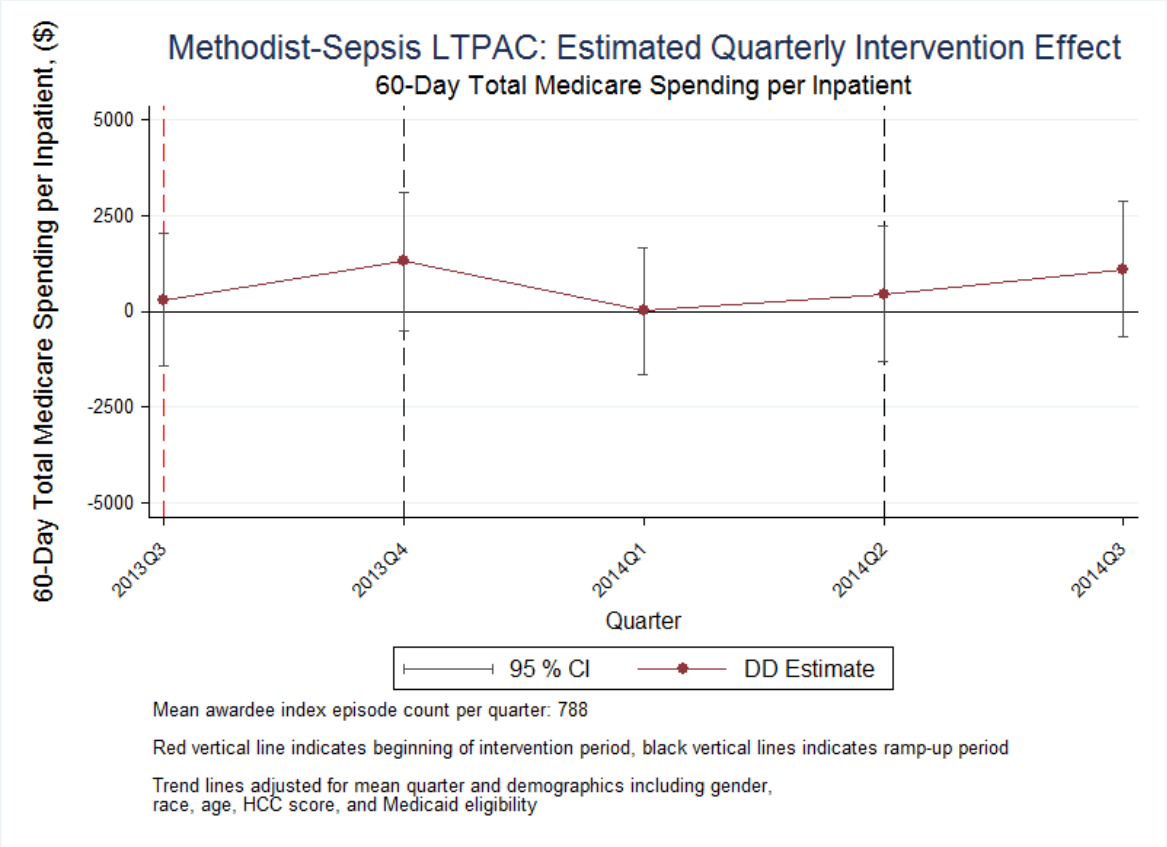
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.2 Medicare Spending – LTPAC Patients

The estimated intervention effect on 60-day episode spending for the LTPAC portion of the Methodist Sepsis population is presented in Exhibit 7 below. We see a consistent increase in average episode spending due to the intervention; however, this increase is statistically insignificant in all quarters. This graph is restricted to patients whose program intervention began in a LTPAC setting.

Exhibit 7: Medicare Episode Spending – LTPAC Patients



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Ordinary Least Squares (OLS) regression estimates for the LTPAC portion of the Methodist Sepsis population (Exhibit 8) shows no significant relationship between the intervention and average Medicare episode spending during the 60 days starting with the index admission. Although there was an average increase in episode spending of approximately $324 dollars per patient at intervention facilities, but is statistically insignificant. We also show regressions that indicate the effect of the intervention at the median patient episode cost; as with the OLS results, we do not find a statistically significant impact of the intervention on Medicare episode spending.

Exhibit 8: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs for LTPAC Patients with Sepsis Only

Methodist Hospital – LTPAC		
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	323.78 (516.18) [97,572]
Intervention Effect (Median Regressions)	Estimate Standard Error Sample Size	22.04 (728.13) [97,572]

*p<0.1 **p<0.05 ***p<0.01

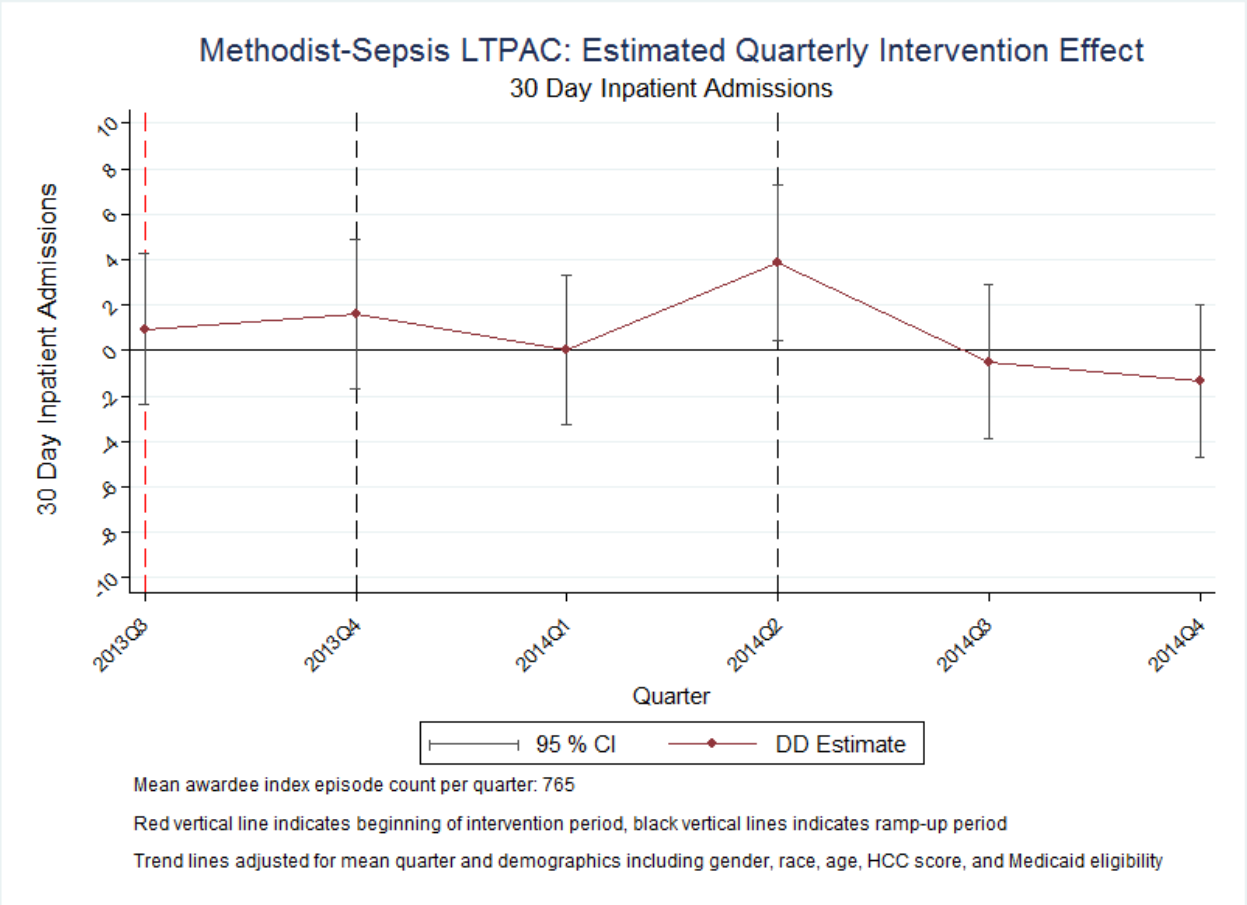
Source: Abt Associates, May 2015.

4.2.3 Hospital Admissions – LTPAC Patients

Implementation did not take place on the same day in all participating facilities. In the graphs below, the red vertical line shows the beginning of the intervention period and the black vertical lines indicate the quarters when various participating facilities began their program implementation.

Exhibit 9 below reflects only the patients who first received the program intervention while in a skilled nursing facility, rehabilitation facility, or LTCH. It shows admissions (transfers) from that facility to a hospital. It is important to note that the long-term and post-acute care (LTPAC) patients could have entered their facilities weeks or months before receiving intervention screening, and could be discharged after just a few days—or many weeks—of screening. The episode reported on here is for 30 days after admission to the LTPAC, and we assume that all intervention patients had at least some of the program screening during those 30 days (because few LTPAC stays last longer than 30 days). Exhibit 10 shows that the intervention had no clear impact on 30-day inpatient readmissions.

Exhibit 9: Hospital Admissions – LTPAC Patients



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 10: DD Estimated Effect of Intervention for Hospital Admissions – LTPAC Patients

Methodist Hospital – LTPAC		
Intervention Effect	Estimate Standard Error Sample Size	1.32 (0.92) [100,689]

p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

4.2.4 Readmissions – Acute Care Patients

Exhibits 11 and 12 (hospital discharges followed within 30 days by a readmission) show no clear program impact on 30-day readmissions for patients who first encounter the intervention in acute care hospitals. Exhibit 13 pools data across all quarters and shows a decrease of less than one percentage points for both patient populations as a result of the intervention; these results are not statistically significant.

This graph and regression are restricted to patients with sepsis whose program intervention began in an acute care hospital.

Exhibit 11: Readmissions – Acute Care Patients, Screened Patient Population

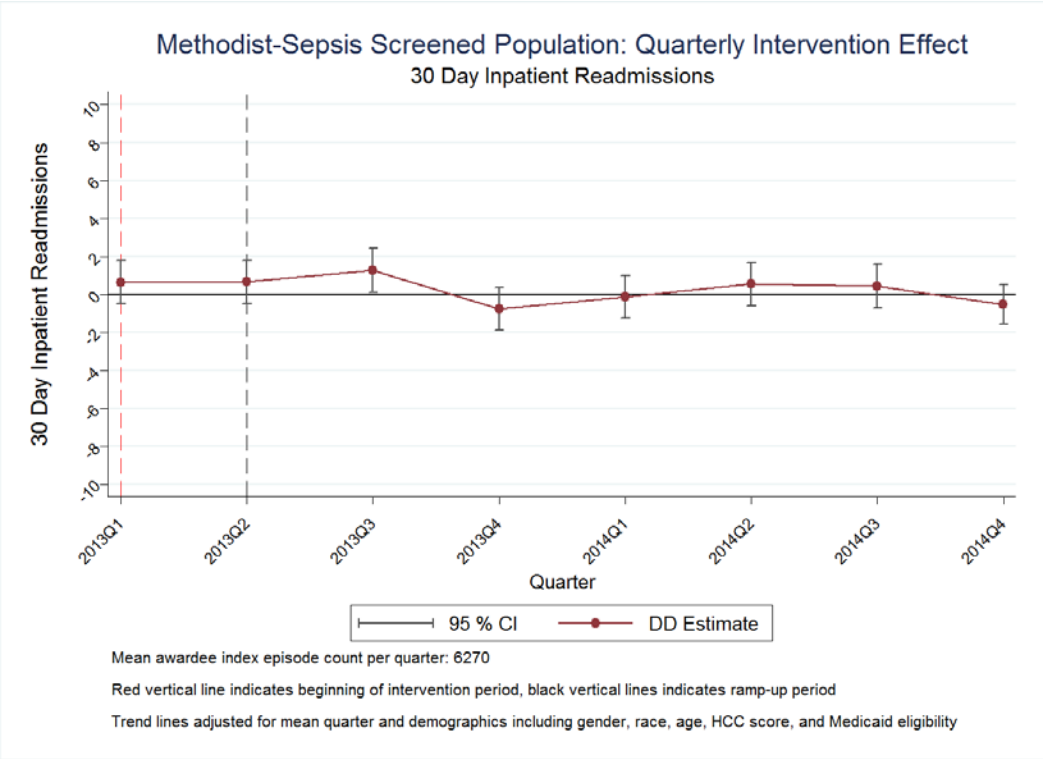
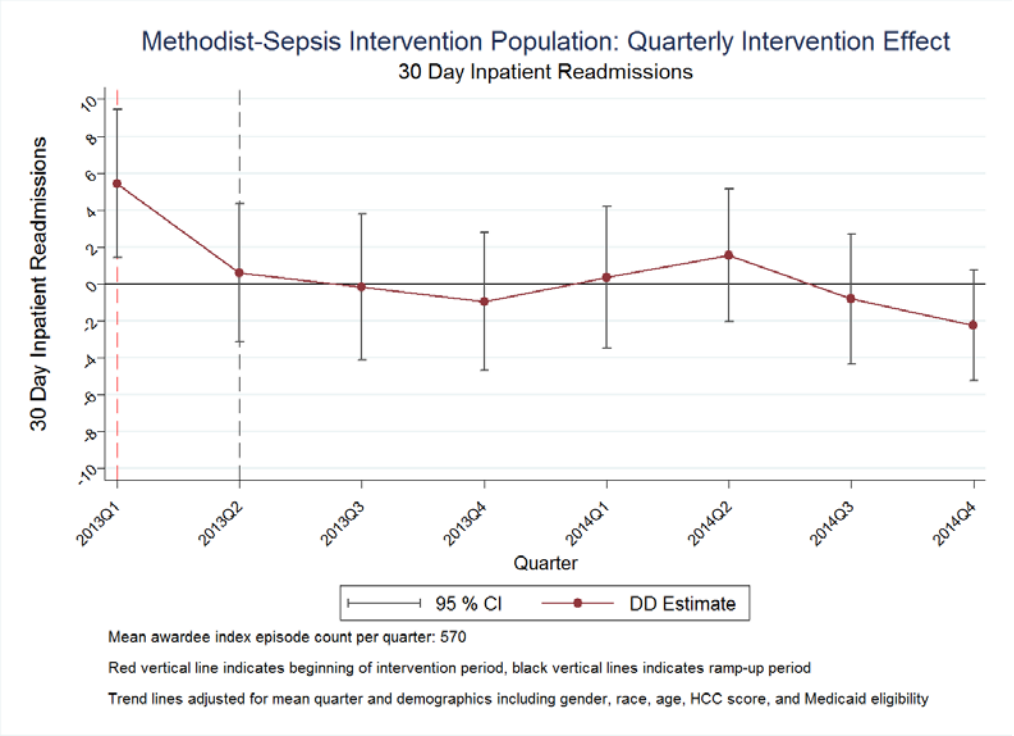


Exhibit 12: Readmissions – Acute Care Patients, Septic Patient Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

Exhibit 13: DD Estimated Effect of Intervention on Readmissions – Acute Care Patients

Methodist Hospital – Sepsis			
		Screened Population	Intervention Population
Intervention Effect	Estimate	0.32	-0.27
	Standard Error	(0.26)	(0.86)
	Sample Size	388,705	36,146

p<0.1 **p<0.05 ***p<0.01

4.2.5 30-Day Post-Discharge ED Visits – Acute Care Patients with Sepsis

Exhibits 14 and 15 (hospital discharges followed within 30 days by an ED visit) show that post-discharge ED visits are generally lower for intervention patients, relative to the intervention group baseline and the comparison group trends. Although we estimate a significant decrease in the last quarter of 2014 in the screened patient population, the regression estimate that pools all observations (Exhibit 16) shows an insignificant 0.21 percentage point drop in any ED visits for the program as a whole. If the recent decline persists, the overall pooled estimates may eventually show a significant result as well.

Exhibit 14: 30-Day Post-Discharge ED Visits , Screened Patient Population

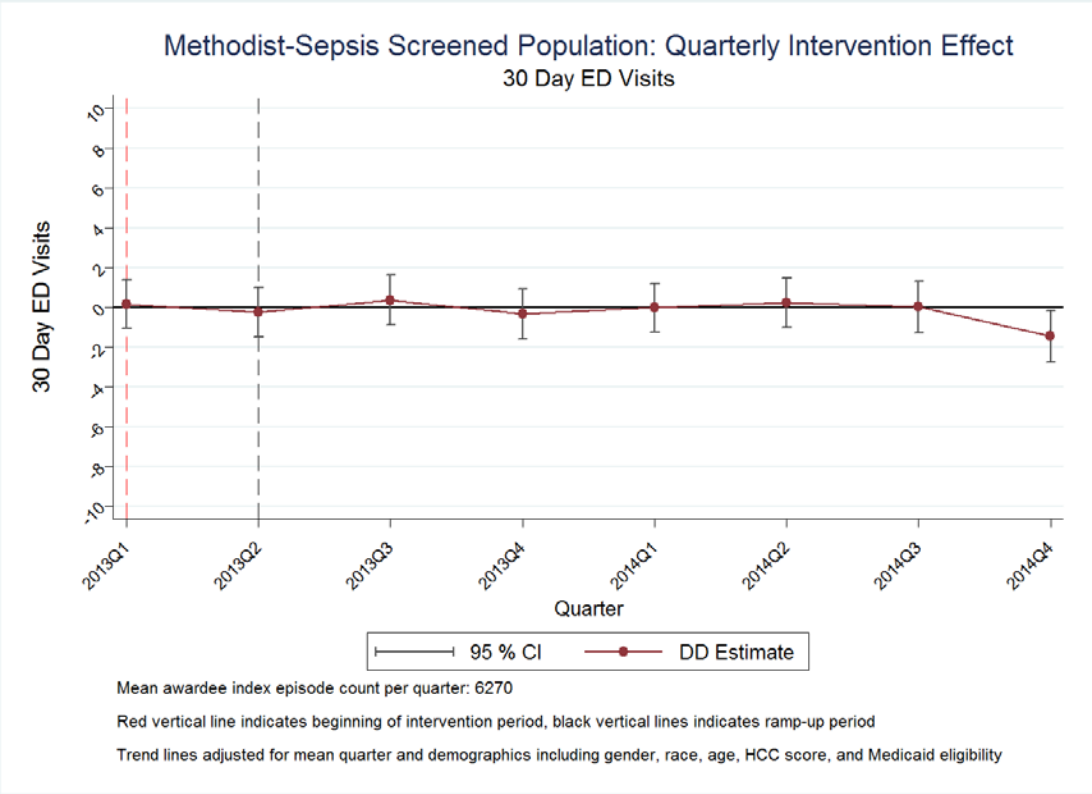
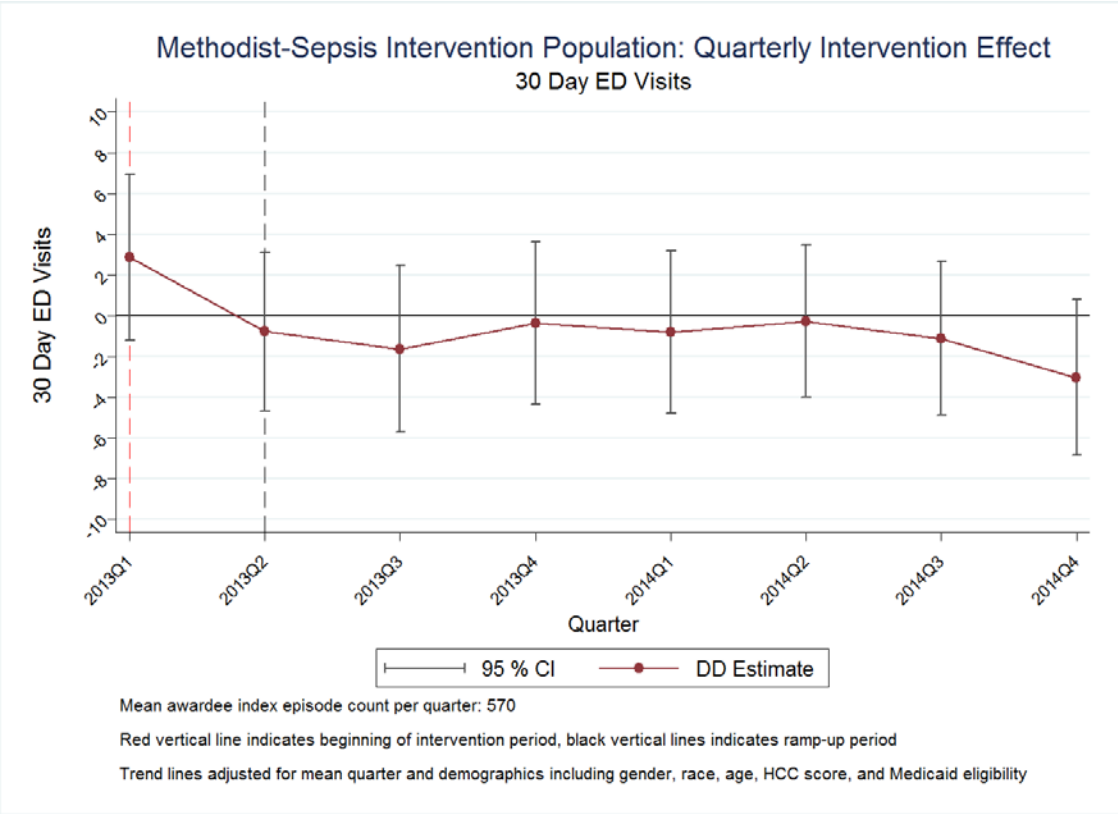


Exhibit 15: 30-Day Post-Discharge ED Visits, Septic Patient Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

Exhibit 16: DD Estimated Effect of Intervention on ED Visits – Acute Care Patients

Methodist Hospital – Sepsis			
		Screened Population	Intervention Population
Intervention Effect	Estimate	-0.21	-1.03
	Standard Error	(0.28)	(0.88)
	Sample Size	[388,705]	[36,149]

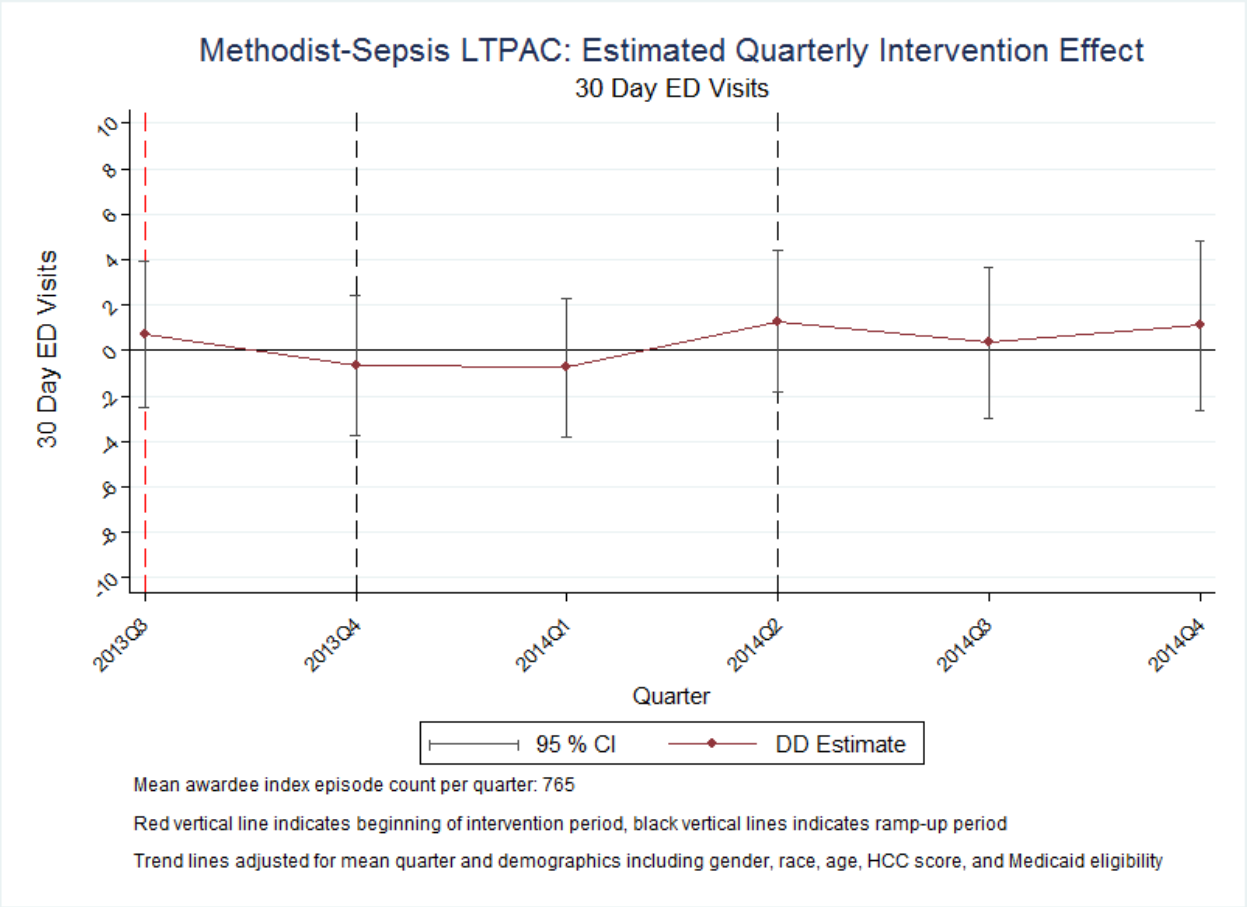
p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in July 2015.

4.2.6 30-Day Post-Admission ED Visits – LTPAC Patients

A sizeable portion of the intervention population receives the sepsis screening program while in a LTPAC facility. The estimated quarterly intervention effect shown in Exhibit 17 indicates no clear trend in 30-day ED visits. Exhibit 18 shows little effect on ED visits when all observations in the study period are pooled.

Exhibit 17: 30-Day Post-Admission ED Visits – LTPAC Patients



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 18: DD Estimated Effect of Intervention on ED Visits – LTPAC Patients

Methodist Hospital – LTPAC		
Intervention Effect	Estimate Standard Error Sample Size	0.54 (0.85) [100,689]

p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

4.2.7 Index Admission Length of Stay (LOS) – Acute Care Patients

The Methodist Sepsis program aims to identify sepsis earlier and prevent its progression to severe sepsis. We might expect to see a reduction in LOS if septic patients are identified and treated early, before the disease progresses—this effect will be most evident in the sub-population of patients with sepsis coded on their claims, if it exists at all. First, we show analyses for the total screened acute care patient population, and then we display results for the septic acute care sub-population.

Exhibit 19 below shows a consistent but small decrease in the length of stay of the Methodist Sepsis screened population, and the point estimates are statistically significant in several quarters. Exhibit 20 shows that among septic patients the change in length of stay is close to zero for most

intervention quarters; the final two quarters of 2014 show an increase in LOS, but the estimates are statistically insignificant.

Exhibit 19: Index Admission Inpatient LOS, Screened Patient Population

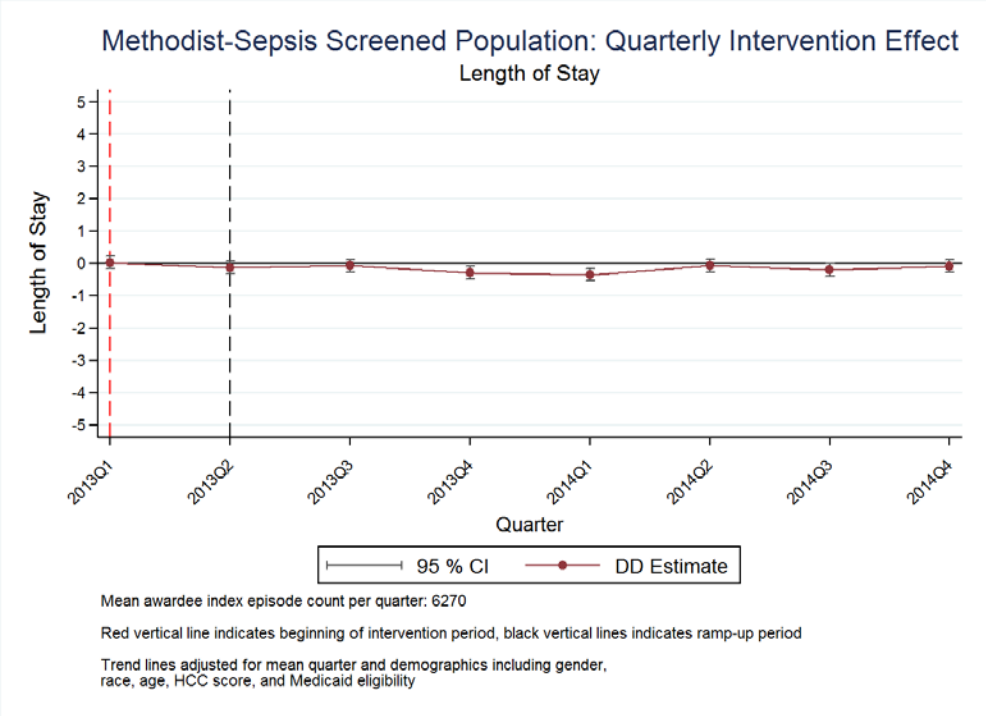
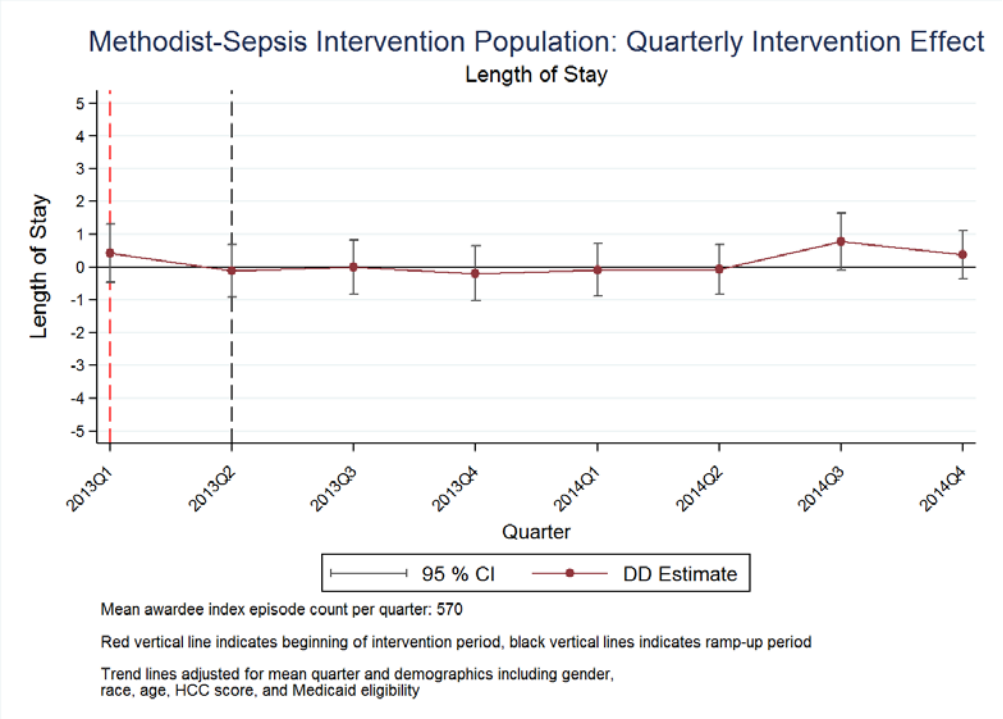


Exhibit 20: Index Admission Inpatient LOS, Septic Patient Population



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 21 shows the aggregated LOS trends in both the screened and septic patient populations. The screened patients have a slight decrease in LOS (0.17 days) that is highly significant; there is no statistically significant difference for the septic sub-population.

Exhibit 21: DD Estimated Effect of Intervention on Length of Stay for Acute Care Patients

Methodist Hospital – Sepsis			
		Screened Population	Intervention Population
Intervention Effect	Estimate	-0.17***	0.12
	Standard Error	(0.06)	(0.19)
	Sample Size	[388,705]	[36,151]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

4.2.8 Discharge Destinations for Acute Care Patients

Below, Exhibit 22 presents the DD estimates for the impact of the program on discharge destination after a discharge from an acute hospitalization, for both Methodist Sepsis patient populations. We find that patients in the entire screened population are approximately 2 percentage points less likely to be discharged home with no additional care, which is almost entirely offset with discharges to "other" discharge destinations. These destinations include intermediate care facilities, transfers, discharges to hospice, discharges to outpatient care, and discharge against medical advice. Screened population discharges to home health care also increased by a statistically significant percentage point.

During the intervention period, we see that the acute care septic population is less likely to be discharged home with no additional care; this is a persistent finding across all quarters except for one, and is offset by increased discharges to all other destinations.

Exhibit 22: DD Estimated Change in Episode Discharge Destination

Methodist Sepsis – Screened Patient Population

	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home									
DD Estimate	-2.59***	-2.90***	-2.03**	-3.14***	-0.77	-2.26***	-2.75***	-2.36***	-2.34***
SE	0.74	0.76	0.77	0.76	0.74	0.76	0.77	0.77	0.34
Home Health									
DD Estimate	1.29**	1.31**	1.18**	2.23***	1.17**	-0.36	0.83	0.67	1.01***
SE	0.55	0.57	0.58	0.60	0.56	0.53	0.57	0.58	0.25
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home									
DD Estimate	0.15	-0.48	-0.60	-0.31	-1.68***	0.45	-1.01	-0.89	-0.53
SE	0.64	0.65	0.65	0.64	0.61	0.66	0.65	0.66	0.29
Other									
DD Estimate	1.15***	2.07***	1.44***	1.22***	1.27***	2.17***	2.93***	2.58***	1.85***
SE	0.39	0.45	0.43	0.39	0.38	0.43	0.48	0.45	0.19

Methodist Sepsis – Septic Patient Population

	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home									
DD Estimate	-4.64**	-1.08	-3.07	-1.44	0.72	-0.19	-2.79	-1.69	-1.62*
SE	2.06	2.17	2.13	2.10	2.20	2.03	1.91	2.01	0.96
Home Health									
DD Estimate	1.46	0.59	0.88	-2.77**	2.06	-1.48	0.60	0.73	0.28
SE	1.75	1.64	1.67	1.29	1.70	1.36	1.56	1.61	0.71
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home									
DD Estimate	2.11	-1.77	2.27	4.78*	-2.88	3.53	-2.69	-2.16	0.54
SE	2.52	2.56	2.57	2.51	2.51	2.40	2.46	2.50	1.14
Other									
DD Estimate	1.06	2.27	-0.08	-0.57	0.10	-1.86	4.88**	3.12	0.80
SE	1.66	1.76	1.65	1.52	1.57	1.34	1.97	1.77	0.75

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, July 2015.

4.2.9 Conclusions

- For the screened patient population, average length of stay decreased by a 0.17 days, a statistically significant result.
- Among the screened patient population, the proportion of patients discharged home decreased significantly, while the proportion discharged to home health care, or to "other" destinations increased significantly. The proportion of septic patients discharged home without home health care also decreased significantly, but this was not accompanied by a significant change in discharge to any other location.
- There is no evidence of change in rates of readmissions, ED visits, or Medicare episode spending, among the acute care or LTPAC patient populations.

Appendix B8: Mt. Sinai

GEDI WISE: Geriatric Emergency Department Innovations in Care through Workforce, Informatics, and Structural Enhancements

1. Executive Summary

This chapter presents both quantitative and qualitative findings of Abt Associate's evaluation of Mt. Sinai's **G**eriatric **E**mergency **D**epartment **I**nnovations in Care through **W**orkforce**, I**nformatics, and **S**tructural **E**nhancements (GEDI WISE) program that enhances emergency department (ED) services for patients aged 65 and older. By training staff and developing enhancements in care, the GEDI WISE program allows more time and staff resources to provide comprehensive care and transition coordination to older patients in the ED, which in turn is expected to reduce admission to the hospital and returns to the ED.

The program was implemented in three hospital EDs—Mt. Sinai hospital in New York City, Saint Joseph's Hospital (SJH) in Patterson, New Jersey and Northwestern Hospital in Chicago, Illinois. The primary program components of the GEDI WISE program are similar in all three sites: additional staff resources with a geriatric focus, improved care team communication, structural enhancements (new or pre-existing), and extensive staff training. Few difficulties with implementation were reported and all GEDI WISE staff we interviewed reported major culture changes in their EDs, with respect to caring for older patients.

We analyzed the impact of the GEDI WISE program using Medicare claims and compared the change in outcomes over time for intervention and comparison group beneficiaries over time. We developed inclusion and exclusion criteria for intervention and comparison groups based on descriptions of the program, which led us to include the majority of ED patients. We consider program estimates to be downward biased approximations of the true program impact, because we could not perfectly match intervention and comparison groups using data available in Medicare claims. We do not see an intervention effect on total hospitalizations in the 30 days following an ED visit (including hospitalizations directly from the ED and those that occurred days after the ED visit). There was also no intervention effect on total 30-day ED (repeat) visits, or total Medicare episode spending. However, the GEDI WISE program was associated with a decrease in admissions to the hospital directly from the ED, relative to the comparison group, a statistically significant difference of 3.49 percentage points. This difference was substantial and statistically significant in every quarter, ranging from 2 to over 5 percentage points.

We conclude that while based on data available to date the GEDI WISE program better met patient's needs in the ED and this resulted in avoiding some hospitalizations, this was essentially a temporary delay that ultimately did not lead to reductions in hospital or ED use, or Medicare spending. There were apparently other benefits in terms of enhanced staff awareness, training, and resources for addressing the needs of older patients, which may be important but do not have an observable impact in outcomes such as utilization and cost to Medicare.

2. General Research Domains

The core domains for the Mt. Sinai evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of Health Care Innovation Award (HCIA) funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Description of GEDI WISE Program

The **G**eriatric **E**mergency **D**epartment **I**nnovations in Care through **W**orkforce**, I**nformatics, and **S**tructural **E**nhancements (GEDI WISE) program focuses on providing a dedicated emergency department (ED) service to patients aged 65 and older. The goal of the GEDI WISE program is to reduce inpatient hospital admissions as well as return visits to the emergency department. The program aims to change the paradigm for treating older adults in EDs who are at risk for admission to the hospital. By training staff and developing enhancements in care, the GEDI WISE program allows more time and staff resources to provide comprehensive care to older patients in the ED and enable a careful decision regarding hospital admission for these borderline cases. Algorithms of patient care and care protocols tailored to treating older patients in the ED are utilized by multiple staff including nurse practitioners, geriatric liaisons, social workers, pharmacists, and physical therapists. As one program leader described the concept, the GEDI WISE program is trying to develop an ED for older patients that is the "front porch" rather than the "front door" to the hospital.

The GEDI WISE Award involves three hospital EDs: Mt. Sinai hospital in New York City, Saint Joseph's Hospital (SJH) in Patterson, New Jersey and Northwestern Hospital in Chicago, Illinois. All three EDs incorporate various innovations as part of their program in five overarching areas:

- Geriatric ED (Geri-ED) structural enhancements to the ED physical environment
- Multidisciplinary care coordination in the ED
- Transitional care: Discharge from the ED to the community
- Workforce education and training on geriatric-specific care protocols
- Informatics-enhanced communication between clinicians and patient monitoring

Despite the overarching similarities in philosophy and areas of focus for the three GEDI WISE sites, there are differences in historical context, program funding mechanisms, specific program components, and processes for implementation. For example, both Mt. Sinai and SJH have structural geriatric EDs where only older patients are treated, which we call Geri-EDs. However, at Mt. Sinai, the Geri-ED is smaller than at that in SJH, and older patients in both the Geri-ED and the main ED receive GEDI WISE services. At SJH, the Geri-ED space is large enough to accommodate all eligible older patients, and the team administers all GEDI WISE services within the Geri-ED. At Northwestern, although there are structural enhancements on the second floor of the ED, patients of all ages are admitted to this space. Hence, there is no dedicated Geri-ED space, and the GEDI WISE services are administered to older patients throughout the ED. We summarize the structure of the GEDI WISE program and the Geri-EDs at each of the three sites in Exhibit 1.

Exhibit 1: GEDI WISE Program and Geri-ED Availability at Each Site

Site	Structural Enhancements in ED	Dedicated Structural Enhancements Only for Older Patients (Geri-ED)	GEDI WISE Services Only in Geri-ED	GEDI WISE Services Throughout the ED
Mt. Sinai	X	X	--	X
SJH	X	X	X	--
Northwestern	X	--	--	X

3.2 Case Study Methods

Abt researchers conducted an initial round of interviews and focus groups for a case study of the GEDI WISE program from June 10-12, 2014. The research team consisted of three staff that collected qualitative data: a senior Abt researcher, a mid-level Abt researcher and a researcher from Telligen (formerly CFMC; subcontractor to Abt). The team visited Mt. Sinai Hospital in New York City and SJH's Healthcare System in New Jersey. The team conducted three focus groups and 13 interviews with clinicians and other care providers, hospital and program administrators, as well as Community Action Board (CAB) members. Staff interviewed at Mt. Sinai included support staff, such as nursing technicians who help support nurses by performing tasks such as changing the beds, and a patient service liaison who provides non-medical patients services such as providing warm blankets and facilitating communication with family members. In addition, the GEDI WISE program staff gave five PowerPoint presentations to the team, including two by the GEDI leaders, one by the CARE Volunteer Director, one by the Transport Plus Program Director, and another by the director of the Informatics Exchange group at Mt Sinai about their work with the Regional Health Information Organization (RHIO). The team also conducted informal observations of operations in the Geri-ED departments at both Mt. Sinai and SJH, conducted observations in the general (non-Geri) EDs at both sites, and observed the holistic medicine components at SJH.

Follow-up interviews and focus groups for the case study were conducted via telephone from March 16-20, 2015 with staff from Mt. Sinai Hospital in New York City and Northwestern Memorial Hospital in Chicago. We did not collect data at SJH for the follow-up phase. Exhibit 2a summarizes the number and type of individuals who participated in either individual interviews or focus groups for the initial case study. Exhibit 2b summarizes interviews and focus group participants for the follow-up.

Exhibit 2a: Professional Backgrounds of Interviewees and Focus Group Participants – Initial Case Study

	GEDI Leadership	Physical Therapists	Social Workers	Nurses	Nurse Practitioners	Physicians	Pharmacists	Community Board Members	Physicians' Assistants	Nurse Technician	Patient Service Liaison	Data Managers
Mt. Sinai initial case study	3	2	3	6	1	9	2	3	3	3	1	2
SJH	3	0	4	2	0	0	0	0	0	0	0	0
Total = 47	6	2	7	8	1	9	2	3	3	3	1	2

Exhibit 2b: Professional Backgrounds of Interviewees and Focus Group Participants – Follow Up

	GEDI Leadership	Physical Therapists	Social Workers	Nurses	Nurse Practitioners	Physicians	Pharmacists	Community Board Members	Physicians' Assistants	Nurse Technician	Patient Service Liaison	Data Managers
Mt Sinai follow-up case study	3	0	2	2	0	3	0	0	0	0	0	0
Northwestern	2	0	1	4	0	0	0	0	0	0	0	0
Total = 91	5	0	3	6	0	3	0	0	0	0	0	0

Similar approaches were used in the initial and follow-up interviews. A senior researcher led each interview and focus group and the other team members took comprehensive notes. All interviews and focus groups were conducted using standardized protocols previously developed by Abt's qualitative research team and approved by CMS; these protocols were tailored to address the specific issues of interest for the GEDI WISE program. Focus groups and interviews were recorded after obtaining participant consent, and used to ensure that the team's notes were accurate and comprehensive. Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

3.3 History of GEDI WISE at Mt. Sinai

The Geri-ED at Mt. Sinai opened in early 2012. One of the key national thought leaders in the research and development of the GEDI WISE program is a member of the Mt. Sinai leadership team. Although the Mt. Sinai program already had the structural components of the Geri-ED in place before the HCIA funding, increases in staff and other resources were supported by the Award. For example, before the GEDI WISE program began, there were two social workers for the entire ED, Monday through Friday, eight hours per day. The GEDI WISE program added two dedicated GEDI WISE social workers, who cover the needs of older patients in both the Geri-ED and the main ED from 8 AM to 8:30 PM, 7 days a week.

Mt. Sinai serves a diverse urban population with significant social needs; about half of the patients arrive at the Mt. Sinai ED without family or friends to help coordinate their visit. The Mt. Sinai GEDI WISE program focuses heavily on the transition of care from the ED back to the home setting, with enhanced social worker and nurse practitioner oversight and networking with community agencies to support transitional care. HCIA funding covered a significant increase in staffing for older patient ED care, including 32 full-time and part-time individuals: 7 clinical staff, 8 physicians, and 17 administrative/ data staff.

3.3.1 Target Population

At Mt. Sinai, any patient aged 65 or older who is admitted to the ED may receive most GEDI WISE services that span the entire ED (e.g., social worker, CARE volunteer visit). However, for admission to the structural Geri-ED, the target population is functional older patients, aged 65 or older. Three criteria

must be met to be considered functional: 1) age ≥ 65 years; 2) not critically ill (operationalized as Emergency Severity Index at triage 3 or greater); and 3) patient knows their own name. If a patient fails one of the three criteria, then he or she is not eligible for admission to the Geri-ED. After admission to the Geri-ED, older patients are given the following assessments during triage to determine their suitability for admission to the Geri-ED: the Identification of Seniors at Risk (ISAR); the Confusion Assessment Method (CAM), and the Get Up and Go (GUG).

3.3.2 Primary Program Components

The primary program components of the Mt. Sinai GEDI WISE program include the following:

Structural Components and Enhancements

Mt. Sinai's dedicated Geri-ED contains 14 beds total—eight in the back of the Geri-ED, and six in the front. The beds in the front are closer to the nursing station, and are reserved for patients who are in more serious condition. The Geri-ED is outfitted with non-slip floors, skylights, diurnal lighting, bars along the walls, larger signage, and beds rather than stretchers. There are three restrooms in the Geri-ED for older patients, in contrast to the two total bathrooms in the entire main ED. During the follow-up interviews, we learned that the Geri-ED is moving to the area where the observation unit used to be. This new space will enable Mt. Sinai to increase the number of Geri-ED beds. The administration is still deciding whether to increase to 20 or 25 beds.

Multidisciplinary Care Coordination

The GEDI WISE program supports a robust staff dedicated to coordination of care. Interdisciplinary rounds are held five days a week in addition to the usual ED rounds that occur at shift sign-out. The entire care management team participates on the interdisciplinary rounds including the Emergency Medicine attending physician, the Emergency Medicine resident physician, the ED Physician Assistant, the GEDI WISE ED Nurse, the GEDI WISE ED Nursing Tech, the GEDI WISE NP, the GEDI WISE social worker, the GEDI WISE Pharmacist, and the GEDI WISE Physical Therapist. The rounds are led by a geriatrician from the main hospital, who provides in-depth consultation about issues specific to older patients. These rounds usually last 30 to 45 minutes, and provide an opportunity to communicate across the team; rounds are also a forum for increasing overall knowledge and awareness of issues regarding care for older patients. During rounds, staff focus first on patients who have particularly complex health conditions (e.g., multiple interacting health conditions, co-occurring psychological conditions, more extreme social needs) which require customized attention beyond the usual standard of care. These patients are considered more likely to benefit from an interdisciplinary team. Once they have been discussed, the providers circle through the remaining patients on the unit. All GEDI WISE staff on the day shift in the Geri-ED participate in these interdisciplinary rounds, including ED physicians, ED nurses, ED physician assistants, nursing technicians assigned to the ED, pharmacists, and social workers.

GEDI WISE staffing throughout the ED exceeds that of the standard ED and includes physical therapy (PT) consults for older patients at risk of falling and volunteers to talk with the patients and provide overall support. This program also provides older patients with access to an iPad to play games while waiting, reading material, hearing amplifiers if necessary, and eyeglasses. A patient service liaison (PSL) works in both the Geri-ED and main ED and provides non-medical support to families and older patients.

Mt. Sinai has pilot programs to enhance the care experience for older patients.

- GEDI WISE funds a pilot project called the "Transport PLUS" program, which trains EMTs to review discharge information during the ambulance ride home and to assess the patient's home for hazards that increase the risk of falling. Since our initial visit, the EMT company that runs the Transport PLUS program decided to automatically provide these services to any older patient being discharged from the main hospital as well.
- Another pilot program funded through the Department of Psychiatry provides consults from a neuropsychologist as part of the Geri-ED daily rounds, and on an as-needed basis in the entire ED.
- A third pilot project, initially funded through other means, linked palliative care services to the ED. High risk patients were identified and referred to an inpatient team that evaluates whether the patient should go directly to hospice from the ED, rather than being admitted to the hospital first. Between our initial and follow-up interviews, this palliative care program was expanded using CMS-approved HCIA carry over funds. A physician now consults three days a week in the Geri-ED to help the patient and family define goals for end of life care.
- Carry over funds have also been used to start a pilot community support/transitional care program for older patients in the community called Project Connect. The program is run in conjunction with the Hunter College School of Social Work and includes both low and high intensity services. When a patient with interest in the program is discharged from the GERI-ED, a social worker is assigned to meet with them. The social worker travels with low-intensity patients to Senior Centers to connect them with other older adults in the community. If the patient is high intensity, the social worker provides home visits. The leadership is currently applying for funding to expand the pilot.
- Lastly, in March 2015, the GEDI WISE program coordinated with a telemedicine program at Mt. Sinai that uses videoconferencing to provide transitional care for patients who use Apple or Android smartphones. Staff upload HIPPA-compliant software on the patients' smartphones so that the nurse practitioners can have face-to-face discussions with patients after discharge from the ED.

Transitional Care: Discharge from the ED to the Community

The GEDI WISE program at Mt. Sinai provides transitional care during the discharge from the ED back to the community, mainly through the care provided by the social worker and nurse practitioner. Social workers work from 8 AM to 8:30 PM, seven days a week, to accommodate evening hours and support night discharges home from the ED. The social workers administer an extensive array of screenings to gauge functional status and need for supports in the home, including: Eastern Cooperative Oncology Group (ECOG) performance status scale, the Katz Activities of Daily Living scale, Instrumental Activities of Daily Living scale, Patient Health Questionnaire (PHQ-9) depression screen, Short Michigan Alcohol Screening Test – Geriatric Version (SMAST-G) alcohol assessment tool, and the Caregiver Strain Index. These assessments are conducted around the medical assessments, and can take up to two hours to administer, depending upon how complicated the patient is. If any of the screen results indicate that it is unsafe for a patient to go home without additional support, the social worker and nurse practitioner start working on transitional care issues immediately, while the patient is still being assessed medically by the GEDI WISE clinicians.

In addition to discharge planning that occurs during the ED visit, there is also follow-up care after the patient returns home. Within 24 to 48 hours of discharge, a GEDI WISE nurse practitioner calls the patient to ensure they have appointments scheduled, prescriptions filled, and other follow-up care completed. She also checks to identify any emerging issues and makes referrals for home care when

necessary. Within seven days of discharge, the nurse practitioner conducts a second follow-up call to ensure that the patient has been seen by a primary care practitioner. Finally, a follow up call is made 28 days after discharge, to ensure that the patient is stable.

The opening of an observation unit at Mt. Sinai this year provides an enhanced opportunity to manage the transitional care process. The observation unit is available for older patients (and other ED patients) for staff to watch their clinical status in case they require inpatient admission after all. The observation unit allows more time to assess the patient medically, but also provides extra time to manage the transitional care back to the home setting, ensuring that all appropriate supports are in place before discharge.

Having social workers scheduled on the weekends enables more effective transitional care for older patients. Mt. Sinai negotiated an arrangement with the administrative nursing personnel at their preferred home health care provider to approve applications on Saturdays and Sundays; the GEDI WISE social worker or nurse practitioner can send patients home on the weekends with an immediate home health visit scheduled. In addition, the team has established relationships with other social workers in the community, especially at long term care facilities, and can coordinate weekend admissions as necessary, without having to wait until a weekday to coordinate the aftercare. The GEDI WISE program at Mt. Sinai has also engaged a local sub-acute rehabilitation facility to accept patients on weekends and later in the day, enabling direct admissions to these facilities from the ED provided there was a qualifying hospitalization within the last 30 days. The vast majority of patients are discharged to the home setting, with less than 5 percent discharged to other facilities. In the event that a patient is discharged to a long term care or post-acute facility, the GEDI WISE nurse practitioner no longer follows the patient, as the facility now provides all care.

Lastly, an important element of the Mt. Sinai program is the Community Advisory Board (CAB) that provides input on design and implementation, and ongoing enhancements and adaptations to the program from the perspective of older patients living in the community. The CAB meets quarterly and provides feedback on the innovations that are part of the GEDI WISE program. For example, one suggestion by CAB requested physicians to give older patients an actual prescription for walking. The CAB members then worked together to provide a thorough mapping of the walking programs for older adults in the area. These community resources interact with the GEDI WISE resources to support and enhance the care experience for older adults by providing a critical link to community based supports as part of the transitional care process.

Workforce Education and Training on Geriatric-Specific Care Protocols

At the beginning the GEDI WISE program at Mt. Sinai, all ED staff (Geri-ED and main ED) received a two-hour interactive lecture about communicating with older patients in the ED. The completion rate for this initial training among all ED staff was 90 percent. Required training for new staff is provided through an on-line 40-minute certification course. In addition, ongoing training consists of periodic didactic training for nurses and ED physicians and intensive training workshops for the GEDI WISE teams, although these trainings are not mandatory. The GEDI WISE pharmacists were trained in a geriatric pharmacy program and received certification, and some of the GEDI WISE nurses took the 8-hour Nurses Improving Care for Healthsystem Elders (NICHE) training, which is an evidence-based training to improve care for older patients. All new residents at Mt. Sinai receive a full-day class as part of their training, which addresses: ageism, communication, geriatric principles applicable to the ED setting, atypical presentations of illness among older adults, delirium, and mobility issues. The dedicated GEDI

WISE workforce also receives on the job education and training on geriatric-care protocols, particularly through training provided by the geriatrician and as part of interdisciplinary rounds.

Informatics-Enhanced Clinical Communication and Patient Monitoring

The GEDI WISE program at Mt. Sinai uses several technological innovations to enhance clinical communication and patient monitoring:

- Results of patient assessments are displayed on the geriatric tracking board in the triage area of the main ED; if patient assessment results meet pre-determined eligibility criteria for the Geri-ED, the geriatric nurse practitioner and pharmacist review the patient's chart to identify patients who would benefit from the services of the interdisciplinary GEDI WISE team interventions and consultations. This screening process ensures that potential Geri-ED patients are easily and quickly identified; if they meet the requirements and there is space available in the Geri-ED, they are admitted to the Geri-ED. Even if not admitted to the Geri-ED, patients identified through this screening process may receive consultations and other program services in the main ED.
- Clinical protocols are embedded in the EMR system to guide patient care. Order sets in the EMR list a standard set of resources available through the GEDI WISE program to address common issues related to the geriatric population. For example, order sets show a list of alternative/safer medications that providers can prescribe to their geriatric patients, to avoid those that may increase risks of delirium, falling, or other problems. Another order set includes a notification for the physical therapist or social workers when an ED patient needs their services (in both the Main ED and the Geri-ED). The order sets and notifications help identify patients eligible for GEDI WISE services and deliver improved and faster care to such patients. For example, since GEDI WISE social workers cover both the Geri-ED and main ED, the order sets ensure that they know when an older patient needs care in another part of the ED.
- The GEDI WISE program developed a special EMR template for the social workers to facilitate improved care coordination for patients in the program. One page shows the patient's upcoming assessments, a snapshot of their medical history, and their primary care provider. This template has now been adopted by the entire ED, and is used by social workers to improve the care coordination of all patients.
- The nurse practitioner uses a publically available appointment scheduling tool to check a patient's insurance information and schedule necessary follow-up ambulatory care visits, before the patient leaves the ED.
- Documentation templates for social workers, and EMR templates developed for the GEDI WISE transitional nurse and pharmacist, facilitate the selection and assessment of patients, and allow staff to report the specific interventions and services provided to each patient in the Geri-ED.

Program staff realized that while their information technology is effective in identifying returning GEDI WISE patients (e.g., frequent fliers), patients also seek care at other EDs around the city, without anyone at GEDI WISE being aware. To address this information gap, the Mt. Sinai GEDI WISE program also uses information from the Regional Health Information Organization (RHIO). Anyone who gets a GEDI WISE intervention and consents is added to the list of Mt. Sinai patients maintained by the RHIO; the GEDI WISE program "subscribes" to be notified whenever one of their patients seeks care elsewhere in the region. The RHIO detects all admissions and discharges of GEDI WISE patients to other hospital EDs or inpatient units, and relays the information to Mt. Sinai. These alerts go into the patient's medical chart,

into a GEDI WISE file for tracking and reporting purposes, and via e-mail to the GEDI WISE nurse practitioner, the Director and Associate Physician Directors of the Geri-ED, and the program assistant who does preliminary follow-up on the overnight alerts. With these real-time notifications, a GEDI WISE clinician can ideally contact another ED where a GEDI WISE patient is seeking care, and confer with that second ED about the decision to admit that patient. There is no equivalent RHIO notification set up for other GEDI WISE program at SJH.

The RHIO alerts provide real-time information that the GEDI WISE program uses to avoid admissions when their patients go to other EDs. Technology breakdowns on-and-off over the past year by the Healthix vendor caused interruptions in these services. Two other EDs in NYC, St. Luke's and Beth Israel, now collaborate more informally with Mt. Sinai. Their ED tracking systems flag GEDI WISE patients on the ED tracking board, and if one of those patients arrives overnight in their ED, they wait until the morning and call Mt. Sinai to discuss the patient before admitting. This practice both avoids a hospital admission for the GEDI WISE patient, and enables the GEDI WISE staff at Mt. Sinai to step in and coordinate care in the best way possible, given the extensive information they have on the patient through their GEDI WISE assessments.

The GEDI WISE program constantly monitors quality improvement using weekly benchmark reports generated by their EMR, which then populate the GEDI WISE dashboard. This information is shared at weekly GEDI WISE leadership meetings. The tracked information includes: number of ED patients 65 or older, number of these 65+ patients with GEDI WISE flags, proportion of hospital admits, wait time to see provider, ED length of stay, estimated proportion of revisits, EMR note recorded by the social worker, nurse practitioner, or pharmacist, physical therapist consult at discharge, number of RHIO notifications and number of patients arriving at Mt. Sinai ED from another local ED as a result of a RHIO notification.

3.3.3 Differences between the GERI-ED and Main ED

Not all patients 65 and older are admitted to the Geri-ED. An older patient may be admitted to the main ED instead of the Geri-ED for a number of reasons:

1. The Geri-ED only has room for 14 patients at a time and may be full;
2. Staffing shortages sometimes limit the number of beds that are available in the Geri-ED;
3. Geri-ED physician coverage is between 11 AM and 7 PM, and night care is provided only in the main ED;
4. Very sick patients and those in acute medical crisis who will likely be admitted to the hospital stay in the main ED; and
5. Patients who would not benefit from the interdisciplinary services provided in the Geri-ED, such as those who are admitted from nursing home or long term care settings, are seen in the main ED.

The PI explained that the Geri-ED is viewed as most beneficial for patients who have complex but not highly acute medical conditions (e.g., multiple chronic conditions, serious but vague symptoms) and social concerns that can benefit from the interdisciplinary care approach. The case study team spent time in both the main ED and the Geri-ED at Mt. Sinai. We noted several differences between the physical structure and care delivery in the two EDs. Structurally, the Geri-ED is noticeably quieter, with different

lighting than in the main ED, and each bed has more space than the closely-packed stretchers in the main ED.

Care Delivery

Geri-ED patients often have a longer length of stay than patients in the main ED, because their needs are often vague but complex, more consults are needed, more assessments are performed, and more staff resources are available to conduct these assessments. Often, diagnosing and treating older patients requires more "detective work" including more labs, longer observations, and more involvement with the patient's family.

> The staff who work in the Geri ED are emotionally supportive - they can't be judgmental. Their interaction involves meeting the patient, listening to them, and staying at the bedside longer to talk to the patient and family.
>
> *– Mt. Sinai Geri-ED Nurse, initial interviews*

The process during rounds is also different in the two EDs. In addition to shift sign-our rounds, in the Geri-ED, staff conduct interdisciplinary rounds which are more intensive and detailed, and involve an inter-disciplinary team that focuses first on problematic or high risk patients. Interdisciplinary rounds take place at the nursing station where there is access to a computer and the EMR. In the main ED, by contrast, the rounding team consists only of one attending or physician assistant, the medical residents and three nurses, and the team circles the ED, going patient to patient only at discharge. The physical therapist also participates in interdisciplinary rounds in the Geri-ED and takes responsibility for PT services.

All GEDI WISE services (except interdisciplinary rounds) are available to older patients in both the Geri-ED and the main ED. Initially there were differences in what was available in the two settings. After 1.5 years, the staffing increased and the culture change efforts made clinicians working in the main ED more aware of GEDI WISE services. Now, the services in the main ED more closely resembled those offered in the Geri-ED. However, the intensity of services can be still be higher for patients in the Geri-ED due to structural differences, and the fact that fewer patients are cared for at one time in the Geri-ED; with a lower patient-to-staff ratio, more individualized attention is possible. In addition, some nurses noted that staff the Main-ED are not as well versed as those in the Geri-ED on when and how to request a GEDI WISE consult. They sometimes write "GEDI WISE" in the chart, instead of formally requesting the consult. GEDI WISE staff scan charts as well, so they generally catch these cases.

The lack of interdisciplinary rounds in the main ED is primarily due to workflow issues. Different physicians take care of patients in the main ED and work a different schedule than that of the Geri-ED, which makes coordination of care more challenging across the physicians in the main and Geri-EDs.

ED Staff Resources

The tone and attention of staff in the Geri-ED are deliberately different from those in the main ED. Staff are required to be more patient and sensitive to patients' needs. Older patients tend to present their problems differently than younger patients. Clinicians explained that older patients tend to present vague symptoms such as "I don't feel well," and it takes more time to reach a diagnosis. The program leadership described how the Geri-ED is not a good fit for emergency medicine physicians who thrive on juggling multiple responsibilities/tasks at once and focusing on the immediate problem first. Instead, Geri-ED is better suited for those who seek to understand complex, comprehensive patient needs. These requirements for staff in the Geri-ED are relevant not only for doctors but also other staff. In hiring a GEDI WISE physical therapist, for example, program leaders sought a flexible and patient person who is also a good communicator. One technician said he enjoys working in the slower paced Geri-ED, where he can talk,

listen and learn about a patient's history. This slower pace in the Geri-ED is possible because the patient-to-staff ratios are better than in the main ED, allowing staff to spend more time with each patient.

Organizational Culture

The main ED is noisy and chaotic, making it difficult for older patients to speak up and ask for help. During the in-person site visit, the Abt team observed dramatic differences between the two ED spaces. The main ED was extremely crowded with beds packed close together, with no privacy. Staff described how older patients sometimes do not like to ask for help, and in the main ED, when staff are busy, older patients can be overlooked. This phenomenon can lead to problems, such as older adult patients not asking to go to the restroom and sitting in waste for a long time. Nurses strive to find a bed where an older patient will have a little more privacy.

The Geri-ED is quite different. Patients have more privacy, staff keep their voices down, and conversations are more private. Staff are also more closely involved with the patients. For example, they accompany them to the restroom, even when patients say that they do not need help. The better staffing ratios in the Geri-ED mean that patients do not spend long periods of time unattended. As a result, in the Geri-ED the older patients are more likely to ask for help and less likely to become agitated because it is quieter, and there is more contact with staff who have time to spend with each patient. There is also an artificial scenic skylight on the ceiling that depicts a blue sky with clouds; the sky light is not only intended to create a calmer, soothing space, but also helps mitigate effects of "sundowning." (Sundowning is a pathopsychological condition that occurs when an older adult becomes confused, restless, or agitated in the evening.) Patients who have experienced the Geri-ED often request to be sent to that designated area, rather than the main ED.

3.4 History of GEDI WISE at St. Joseph's Hospital

3.4.1 History of the Program at St. Joseph's Hospital

The GEDI WISE program at St. Joseph's Hospital (SJH) was in development for some years before the Award, and began before the program at Mt. Sinai. The GEDI WISE director at SJH developed the idea of targeted ED services for older patients in 2002, based in part on experiences he and colleagues had with their aging parents, who had poor experiences in hospital EDs. In the early days of developing the program, these aging parents and their friends provided expert user input into the physical design for the SJH Geri-ED. In 2009, SJH opened one of the nation's first Geri-EDs on the third floor of SJH for functional older patients (e.g., ambulatory, without evidence of delirium). Between 2009 and 2011, the main ED space was redesigned, incorporating elements of the Geri-ED, such as diurnal fluorescent lighting and non-slip floors. Their philosophy is if it is good for frail older patients, it is good for everyone. In October, 2011, the renovated SJH ED opened, with a 24 bed Geri-ED section located in the same renovated space, adjacent to the main ED.

According to the SJH leadership team, the GEDI WISE goal at SJH is to support and advance care for older patients. The overall goals of better care, better health, and lower cost are the organizing principle. SJH is a community hospital, and the care team emphasizes providing support and education about resources available to the older patient and the family, both in the hospital (e.g., falls prevention information; end of life planning) and in the community (e.g., options for transportation).

Because the GEDI WISE program at SJH was well established before 2012, the HCIA funds only 2.4 full time equivalent positions, including one Social Worker and one Advanced Nurse Practitioner, while most

other components of the program are covered by existing hospital resources. The program is already well integrated into the infrastructure at SJH, in contrast to Mt. Sinai where a larger number of staff were hired with HCIA funds, as noted above.

3.4.2 Target Population

The target population of the GEDI WISE program at SJH is all patients 65 and older, except those who are in acute trauma or those who have medical conditions that require resuscitation. In contrast to Mt. Sinai, there are no specific screenings or eligibility criteria for the Geri-ED at this site, and the space and staff are able to accommodate all older ED patients in the Geri-ED.

3.4.3 Primary Program Components

Structural Components and Enhancements

The Geri-ED at SJH has non-shine floors, diurnal lighting, and sound absorbency. Because the entire ED was redesigned in 2011, and the redesign extended these components from the Geri-ED into the main ED, there are few obvious structural differences between the two spaces.

Multidisciplinary Care Coordination

The GEDI WISE program provides interdisciplinary care for adults 65 years of age and older. The care team includes ED physicians, ED nurses, an advanced practice nurse, a nurse navigator who oversees the organization of care, a social worker, and two case managers. In addition to this core staff, there are other staff that also assist in the Geri-ED. A physical therapist and a pharmacist are available for consultation and a Care Transitions Community Liaison (CTCL) oversees transitions from the ED to the community settings, and works with families and patients in the community. The program at SJH includes a holistic health component with harpist who circulates through the ED playing quiet music on a portable harp, as well as several staff who are trained in pranic healing. Following Mt. Sinai's lead with their CARE program, the GEDI WISE team at SJH also added a team of volunteers who provide support and assistance to patients during their stay in the ED. Finally, there is a patient liaison who works in the ED, to help facilitate communication and meet the needs of older patients and their families.

The Geri-ED at SJH also includes two special rooms for patients who are actively dying and require palliative care. This idea came from the ED nurse navigator who had a background in palliative care. The staff utilizes life sustaining management alternatives (LSMA) with dying patients, including a morphine drip, in an effort to avoid admission to the hospital intensive care unit. The room for dying patients has curtains that cover up medical equipment, adjustable lighting, pictures on the wall, and pretty scenes on the TV. There is plenty of room for family members to stay with the dying patient, both in the room and in a family room located in the ED. Even large families are welcome and the patient liaison addresses any questions or needs of family members.

Transitional Care: Discharge from the ED to the Community

As at Mt. Sinai, the social worker plays a key role in facilitating the transition of care back into the community. She works with the family to arrange for home health care as needed, and ensures the patient is aware of the resources that are available in the community. A bilingual Spanish/English Community Transitions Care Liaison is very visible both in the ED and in the community and bridges the transition from ED to home. His community outreach includes conducting educational programs in community settings related to the needs of aging persons (e.g., fall prevention).

A nurse telephones each GEDI WISE patient 24 to 48 hours of discharge from the ED, for a wellness check and to make sure discharge instructions are clear and the patient has an appointment with their primary care physician. An automated call from the Chief Geriatric ED Physician also goes out on the third and seventh days following ED discharge to remind the patient to make an appointment with their primary care physician.

Although SJH does not have an observation unit attached to their ED, they have developed an "admit to home" program for patients. Patients admitted to this program must meet the following criteria: 1) they must be cognitively intact; 2) they must have a telephone or other means of communication; and 3) they must have an illness or injury that is of concern but safe for observation/management at home. These patients need observation care, but this care can be done at home with close nursing supervision and a scheduled re-evaluation. The patients are sent home with orders for care that resemble the services they would otherwise receive as inpatients, such as ambulation instructions, nutrition instructions, instructions for checking their vital signs, and medication instructions. The nurse then follows up and reviews orders with each patient. If there are any complications they are asked to come back to ED immediately. All patients with extended home observation are asked to return to the ED for a follow-up evaluation (usually 24 to 48 hours later).

Workforce Education and Training on Geriatric-Specific Care Protocols

The workforce education and training for SJH is further developed than at Mt. Sinai, particularly for nurses, because it is a more mature program. The nurses at SJH all take the 16-hour (NICHE) training. In addition, each takes a structured 4-hour training every year.

Informatics-Enhanced Clinical Communication and Patient Monitoring

In addition to the regular EMR used to track patients, the computer system automatically generates a fax to their primary care physician in the community, whenever their patient comes into the ER. The program uses a fax simply because this is the technology currently available through their medical record system. Another key component of the SJH program is the Beers criteria (medications to be avoided for older adults), which was added to their order sets to flag medications inappropriate for older patients and identify safer alternatives.

3.4.4 Differences between the Geri-ED and Main ED

> The best staff are in the Geri-ED; they are more compassionate, and the staff is well supported.
>
> *– SJH Geri-ED Nurse, initial interviews*

As mentioned above, there are not many structural differences between the Geri-ED and the main ED at SJH. Older adult patients are prioritized during intake and triaged more quickly into the Geri-ED. As at the Mt. Sinai Geri-ED, the SJH GEDI WISE staff view the Geri-ED as friendlier for patients and staff. One interviewee described a unique sense of family among the Geri-ED staff, and a unified focus on taking care of older patients. The staff feel that the Geri-ED fosters patience and collegiality.

3.5 History of GEDI WISE at Northwestern Hospital

The GEDI WISE program at Northwestern ED began with the less pre-existing dedicated infrastructure for older patients, compared to Mt. Sinai and SJH. Although the Northwestern ED did have structural enhancements, these enhancements were not targeted specifically for older patients. Most aspects of the GEDI WISE program were completely new to Northwestern when HCIA funding commenced. For example, the ED did not have any social workers on staff before the GEDI WISE program. The

Northwestern GEDI WISE program is somewhat different from that at Mt. Sinai and SJH, and centers on nurses who are called GEDI Nurse Liaisons. These nurses work closely with a single ED social worker, and together they implement most of the Northwestern GEDI WISE care management and transitional care interventions.

In the spring of 2014, the original Principal Investigator (PI) at Northwestern left the program and a physician who had been helping GEDI WISE with data analysis became the PI. At the time of this transition, most components of the program had already been implemented, and the Nurse Liaisons were very experienced. The original PI oversaw most of the program implementation before the transition. At Northwestern, the emergency department has accepted the GEDI WISE program quite well. According to the PI, the nurses had already bought into the program when he started.

3.5.1 Target Population at Northwestern

The target population of the GEDI WISE program at Northwestern includes all patients 65 years and older that come to the ED. Patients are screened according to the ISAR (Identification of Seniors At Risk) which happens in triage or by the ED bedside nurse. If the ISAR score is above two, the GEDI WISE worksheet is populated in the EMR, and the Nurse Liaison confers with a physician to assess whether the patient would benefit from a formal GEDI WISE assessment. GEDI WISE consults can also be requested by ED personnel. Five months ago, the team began targeting "bounce backs" for assessments, which include any older patient who go to the ED within 30-days of an inpatient visit at Northwestern. The Nurse Liaisons receive an alert triggered by an icon in the EMR that tells them that the patient was seen recently. They then assess these repeat patients to understand the reason for their ED visit, and assess if it is a medical issue or related to other social issues that have not been fully addressed.

Initially, the Northwestern GEDI WISE team tried to prioritize patients based upon the likelihood of inpatient admission. The Nurse Liaisons did not assess patients who were clearly headed toward inpatient admission. However, during the initial implementation phase, the GEDI WISE care team observed that the GEDI Nurse Liaisons often started a patient assessment and then discovered that the patient was going to be admitted. This assessment process led to inefficiencies, as the Nurse Liaison would move on to the next patient without completing care coordination for the first patient. Furthermore, the GEDI WISE team determined that the care coordination they were doing in the ED was beneficial to the patient regardless of whether the patient was being discharged from the ED or admitted to the hospital; in the latter case, early initiation of care coordination could potentially reduce length of stay in the hospital. Therefore, starting in May 2014, they began to assess all older eligible patients and now complete every assessment they begin, even if they learn midway through the process that the patient is being admitted to the hospital.

3.5.2 Primary Program Components

Structural Components and Enhancements

The GEDI WISE program at Northwestern does not have a defined geriatric space. The ED has two floors: the main floor and a mezzanine on the second level. The mezzanine was renovated a year or two before GEDI WISE was started and has structural enhancements similar to the Geri-EDs at Mt. Sinai and SJH. Any patient that could benefit from the enhancements is sent to the mezzanine level except for patients who are in serious clinical condition, who remain on the main ED floor. Northwestern does not specifically prioritize older patients to the mezzanine, as the GEDI WISE services are brought to the older patient wherever they are in the ED.

Core Staff

Five GEDI WISE ED Nurse Liaisons provide most of the transitional care and geri-specific services in the Northwestern program. Nurse Liaison Two to three Nurse Liaisons have overlapping shifts each day in the ED during the highest volume times, and provide coverage from 8 am to 8 pm on weekdays. In contrast to Mt. Sinai, there is no weekend coverage. The Nurse Liaisons spend 80 percent of their time working on dedicated GEDI WISE shifts where they focus on evaluating older patients, coordinating care in the ED, coordinating care transitions, and conducting call backs to prior GEDI WISE patients. During their GEDI WISE shift they do not provide normal routine bedside nursing. With the exception of one nurse, who was later replaced, all Nurse Liaisons have stayed with the program since its inception two and half years ago.

In addition to the Nurse Liaisons, one social worker supports the GEDI WISE program, as well as the rest of the ED, on weekdays from 8 AM to 8 PM. Prior to the GEDI WISE program, the Northwestern ED had no dedicated social worker. The new social worker played a major role in training the GEDI WISE Nurse Liaisons to perform better patient assessments and ask relevant questions regarding the patient's support system at home. The social worker provided initial training to the Nurse Liaisons on topics such as Medicare Days, the differences between homemakers and home health care and the types of patients admitted to SNFs versus nursing homes. The Nurse Liaisons at Northwestern described how valuable the social worker's input was to their understanding of the needs of older patients.

Multidisciplinary Care Coordination

The GEDI WISE Nurse Liaisons coordinate multidisciplinary care with the social worker, ED physicians, pharmacists, physical therapists, and other ED personnel. Physical therapists are not dedicated to the ED, but they respond very quickly when the GEDI WISE Nurse Liaisons or social workers request their services for an older ED patient. For patients who are admitted to the hospital, the Nurse Liaison will request a PT consult for the next day. Whether admitted to the hospital or not, this process results in a physical therapist seeing a patient earlier, instead of waiting for a physician order. The Nurse Liaisons also work closely with dedicated ED pharmacists, from 8 AM to 8 PM during weekdays. The Nurse Liaisons interact with the pharmacist at the patient's bedside, to evaluate patients' medication lists and counsel patients about their medications. Pharmacists identify medications that might be causing interactions, or that could pose safety concerns for older patients when they return home. The ED also has a few pharmacy students who gather histories and other information from the patient prior to the actual pharmacist evaluation and who review the medication list with the patients so that the pharmacist can spend more time addressing clinical issues.

Transitional Care: Discharge from the ED to the Community

Usually two to three GEDI nurses liaisons work together on an 8 AM to 8 PM weekday shift. They do not work on weekends. Staff explained that for their program, it was most strategic to have full weekday coverage, because nursing homes only take new admissions on weekdays. By clustering staff during the weekday, the program provides more opportunities for Nurse Liaisons to intervene on behalf of patients who have had a 3-day hospital visit within the last 30 days, and might need nursing home care.

The GEDI Nurse Liaisons collaborate with other community resources and set up necessary follow-up appointments such as with the patient's primary care physician or an outpatient physical therapist. Social work issues such as whether to arrange homemaker or caretaker services are also addressed. The GEDI Nurse Liaisons work very closely with the social worker to provide transitional care. Because the social worker serves the entire ED not just GEDI WISE, she has a busy workload and the GEDI Nurse Liaisons

must also understand social work-related patient issues. If the social worker is unavailable, the GEDI Nurse Liaisons interact directly with patients to conduct a home assessment.

Call Backs

The Nurse Liaisons stressed how important it is to call patients in the days after their ED visits, to ensure a smooth care transition. Nurse Liaisons do 24–72 hour and 10–14 day call backs as part of GEDI WISE to reassess the patient and make sure that all follow-up care is taking place. According to the Nurse Liaisons, the call backs have a major impact on the quality of patient care for patients; one Nurse Liaison said "I think it makes them feel like they are cared about." ED physicians know that GEDI WISE patients will be called the next day to make sure they have made a safe transition to home. This practice reassures the physicians, giving them confidence when discharging patients that they are truly sending them home to a safe environment. The call backs are also a great opportunity for the GEDI nurses to troubleshoot patient issues:

> "The patients have been very receptive and they thoroughly enjoy us checking on them and address issues that have fallen through the cracks. I do think it has been nothing but positive."
>
> *– Northwestern Nurse Liaison*

- If the patient cannot reach his or her doctor, the GEDI Nurse Liaison connects with the person who oversees physician referrals to help arrange follow-up appointments.
- If the patient needed a walker or other medical equipment and it was not delivered, the GEDI Nurse Liaison gets the social worker involved.
- If the patient was referred to home health but the home health agency has not initiated care, the GEDI Nurse Liaison contacts the home health agency.
- The GEDI Nurse Liaison also reinforces discharge instructions, makes sure the patient understands their medications, and verifies that the patient has made an appointment with their physician for a follow-up visit.

Staff reported that patients are usually very grateful to receive these call backs from the GEDI Nurse Liaisons, because they feel that someone cares about them and is following through on their specific medical needs. The Nurse Liaisons check in with a few "favorite" patients almost every month, especially those who have limited social connections or family. Some patients refuse resources such as housekeeping services because they do not want strangers in their home, and a few patients do not want to receive any call backs. GEDI Nurse Liaisons also acknowledged that despite the frequent call backs there are still patients who return to the emergency room because they have difficulty self-managing multiple conditions, or because coming to the ED is just the way they that they cope with infirmity.

Workforce Education and Training on Geriatric-Specific Care Protocols

When the GEDI WISE program first started at Northwestern, there was limited formal training for the core GEDI Nurse Liaisons. These ED nurses were skilled in emergency medicine nursing but had not had any formal training in geriatrics. In the beginning they received a number of resources, including videos and articles that the hospital geriatric physicians assembled about geriatric care, and each did individual study to Nurse Liaison better understand the geriatric population. But, as the HCIA-funded program ramped up, GEDI Nurse Liaisons received in-depth education including shadowing, attending in-patient geriatric rounds at a clinic in a nursing facility, and visiting skilled nursing facilities in the area. They received specialized training in palliative care, and 40 hours of NICHE training. Northwestern also

implemented geriatrics training for other ED staff including other (non GEDI WISE) ED nurses, ED physicians and medical residents (see Section 1.7.1 for more detail).

Informatics-Enhanced Clinical Communication and Patient Monitoring

When a patient returns to the ED within 30 days, the GEDI Nurse Liaison checks in the EMR to see if there have been any changes in the patient status. The current workflow is for the GEDI Nurse Liaison to repeat the entire GEDI assessment when there is a return visit. The Northwestern team is working with their IT department to have a "narrative note" incorporated into their EMR, so that they need only update the initial assessment to return visit. The "narrative note" could then be updated for each return visit, specifically addressing the patient's needs for that particular visit. Implementing this change will reduce redundancy in charting.

3.6 Program Implementation

The implementation process for the GEDI WISE program at all sites was very smooth according to stakeholders interviewed during the case study, but there were challenges. At both Mt. Sinai and SJH, physicians and nurses were initially reluctant to sign up for shifts in the Geri-ED, but this resistance was short-lived. Physicians previously in the habit of admitting most older patients to the inpatient units had to learn a new way of managing care, and nurses who had initially thought that the Geri-ED would just be "bedpan alley" quickly acknowledged the improved quality of care older patients receive in the Geri-ED. Both hospitals reported that the tone and pace of work in the Geri-ED is attractive for nurses, and there is a waiting list of RNs wanting to work shifts in the Geri-ED. Although Northwestern does not have a separate dedicated Geri-ED space, the Nurse Liaisons described how the ED nurses and physicians were also initially resistant to the program, because they feared the program would increase their workload. However, once they saw what the resources added for the program, and the way GEDI Nurse Liaisons assess patients' needs, they became more receptive.

At Mt. Sinai, a number of challenges to program roll-out were described. As mentioned above and in Section 3.3.2, the GEDI WISE model requires a different approach to care by ED physicians, many of whom have been trained to focus on the immediate problem at hand rather than taking a more holistic approach. Shifting the ED physician culture was a challenge at Mt. Sinai that required training and reinforcement of GEDI WISE principles.

Another challenge was related to coordination between the main ED and the Geri-ED. Although there is a limit to the number of patients who can be seen in the Geri-ED at Mt. Sinai, triage nurses sometimes assign patients to the Geri-ED without checking to see how many patients are already there. In addition, if the Geri-ED is not full and the main ED is over-crowded, it is difficult for triage nurses to understand why there are specific eligibility criteria for the Geri-ED. While the Geri-ED handles patients with complicated medical and social profiles, it is not equipped to handle older patients with more serious acute illnesses or those with an immediate medical crisis.

The third implementation challenge at Mt. Sinai was integrating new roles, such as the dedicated nurse practitioner, into the complex ED staffing structure. Integrating PT consults was also a challenge. There was a learning process for staff in the ED regarding what services a physical therapist can offer in the short-stay ED setting. Because the physical therapist also works in the hospital and is not always present in the ED, a paging system was instituted to notify the physical therapist of a GEDI WISE patient in need of consult.

At SJH, few implementation challenges were mentioned, perhaps because the program began several years ago. It is likely that there were implementation challenges in the early years that are no longer relevant or even remembered by staff currently working in the Geri-ED. The hospital leadership at SJH is completely supportive of the GEDI WISE program, and as the first Geri-ED in New Jersey, SJH has enjoyed extensive publicity in local media. Staff interest and enthusiasm are enhanced by this media attention, which also serves to educate older adults throughout the community about the Geri-ED at SJH. Similarly, few implementation challenges were mentioned in our interviews with Northwestern. The GEDI WISE program at that site required little change and does not separate older patients in a geriatric-specific space. However, the Abt research team also did not visit the site in-person; some implementation challenges may have become more apparent during an in-person site visit.

3.7 Workforce Development

At all three sites, the GEDI WISE program hired new staff and re-assigned existing ED staff. However, as noted in the previous section, the types of staff vary across the programs. For example, at Mt. Sinai, CARE volunteers reduce the burden on nurses and contribute to the friendly and less rushed atmosphere in the Geri-ED, and interdisciplinary rounds include a neuropsychologist. Between the first in-person site visit and the follow-up interviews, several other shifts occurred at Mt. Sinai with respect to their workforce. In June, 2014, Mt. Sinai had just hired a second nurse practitioner for the program but she subsequently left the program and the leadership team determined that most of the transitional care tasks could be conducted by an RN. They hired an RN but kept the second NP on per diem to fill in gaps on a part-time basis as needed. The GEDI WISE program now has one full-time NP, one full-time RN, and a part-time per diem NP.

At SJH, the GEDI WISE program includes a harpist and a pranic healer to offer holistic elements to the care model, and a Geri-ED based palliative care program. At Northwestern, the program centers around highly trained Nurse Liaisons. Similarly, the training of new staff and process of implementation differed between the three sites.

3.7.1 Training

The GEDI WISE training varies between the three sites. Some staff receive more formal training specific to working with the geriatric population, although much of the training for the GEDI WISE was described as ongoing on-the-job training.

Training at Mt. Sinai

GEDI WISE staff at Mt. Sinai received didactic training on geriatric ED care, as well as ongoing training as part of program implementation. In particular, the daily rounding process is an ongoing component of training regarding the specific needs of older patients, a teaching opportunity led by a geriatrician that would not normally happen in an ED. Raising awareness of the needs of older patients in ED settings across the system is a major goal of the program, and interviewees described how the GEDI WISE program has encouraged ED staff to ask questions about a patient's home setting, lifestyle, and ADLs, and to focus on safe transitions from ED to home.

No formal refresher training is offered by the program. Over the course of the program some training has become more standardized. For example, the first nurse practitioner did not receive specific training in geriatric patient needs, while the second nurse practitioner hired in mid-2014 received a more formal orientation. Although a wide range of on-going education and training is available to staff across the

GEDI WISE program, most is not required and relies on individual initiative to complete. We received inconsistent information about nurse training for the GEDI WISE program. Some but not all nurses received the NICHE training at the beginning of the program, and new nurses now mostly rely on the 30-40 minute on-line training as well as ongoing education as part of the nurse huddles. Specific components of training by role mentioned by staff at Mt. Sinai include the following:

- The primary training for all clinicians and other staff in the ED is a two hour interactive lecture on Ageism and Communication Skills with Older Adults.
- Training for the dedicated ED physicians took place primarily through rounds led by the geriatrician. Physician training continues through mini-lectures, grand rounds, journal clubs and on-line training.
- GEDI WISE clinicians and staff have access to online educational modules on multiple topics, such as how to have conversations about difficult issues (e.g., advanced directives, smoking and substance abuse).
- All five pharmacists who work in the ED took a certification course and exam in geriatric pharmacology.
- CARE Volunteers undergo an intensive seven-hour training, with a focus on delirium prevention to prevent confusion and disorientation among older patients.
- Emergency Medical Technicians were trained in care transition and to conduct home safety assessments as part of the Transport Plus program.
- New ED residents receive a day-long class on geriatrics medicine as part of their residency training.

Initially, Geri-ED staff felt the need to constantly remind colleagues in the main ED about GEDI WISE resources, and posted signs around the ED of patient eligibility requirements for the Geri-ED. Attending physicians had lectures during faculty meetings that introduced the program. Main ED staff received training about issues related to older patients while doing rounds with clinicians who worked in both EDs, and GEDI WISE care is also often discussed at faculty conferences and disseminated in newsletters.

Training at SJH

More specific training for nurses working in the Geri-ED was described by staff at SJH. Given that this program has been in operation for several years, there has been time to identify specific training needs and develop core training materials. Components of the training at SJH include the following:

- Nurses take a 16-hour NICHE training, as well as an annual four hour class on caring for older patients.
- Physicians who work in the Geri-ED have access to a five hour video library with extensive information about caring for older patients.
- There are two fellowship-trained geriatric specialists who are also emergency medicine physicians, and who provide on the job training and education for their colleagues.
- New ED residents now have a core curriculum in geriatric medicine.

Training at Northwestern

Nurse Liaisons received the most intensive training at Northwestern, given the focus of that program. Their training included the following:

> I was a good nurse, but now I am a better nurse because I feel comfortable asking for goals of care, what exactly does the patient want, and how I can best help them.
>
> *– Northwestern GEDI-WISE nurse liaison, follow-up interview*

- An intensive in-depth education including: shadowing Northwestern geriatricians, attending in-patient geriatric rounds at a clinic in a nursing facility, and visiting the skilled nursing facilities in the area;
- Specialized training in palliative care;
- 40 hours of NICHE training.

The social worker was knowledgeable from her years of experience working with various vulnerable patient populations and did not receive any specific GEDI training. She was familiar with many of the assessments done by the GEDI Nurse Liaisons, and described training the GEDI nurses on how to be "mini" social workers. The social worker developed a resource packet about common topics in geriatric care: transportation, adult day care, life alerts etc. The Nurse Liaisons then used this FAQ when interacting with older adult patients and their family members.

GEDI WISE program staff implemented geriatrics training for ED personnel including non GEDI WISE nurses, physicians and medical residents.

- Nurse Liaisons educated other ED nurses during their nursing huddles, presented a geriatric topic every month to the ED team, and educated ED nurses on basic geriatric principles.
- GEDI WISE staff created a Physician Education Module on geriatric principles that all ED physicians completed. They created a six-week geriatric block where physicians and residents go through geriatric modules called "gemstones" and this is now a part of the residency module training curriculum for all hospital residents.

3.7.2 Impact on Workload

At both Mt. Sinai and SJH, better staff ratios and a multidisciplinary team were described as decreasing stress, particularly for the nurses who compared GEDI WISE work with the more stressful environment in the main ED. At Mt. Sinai, staff mentioned that the CARE volunteers and patient service liaison help the nurses communicate with patients and families, and having a separate ED makes their job much easier. Although the social worker assessment takes a long time at Mt. Sinai, it does not interfere with others' workflow, as the social worker can collect the information while the patient is waiting for other medical tests to be completed. During our follow-up interviews, the social worker and NP reported that they had streamlined the GEDI WISE assessment process and now do this together to avoid duplication of effort with information gathering. At SJH, the nurses mentioned that having the social worker enables them to focus on the clinical component and not worry about interacting directly with the family. At Northwestern, the social worker was also called out as a key reason that the workload for Nurse Liaisons is manageable. The social worker provides a resource specifically for transitional care needs that are outside the Nurse Liaisons' familiarity, such as intricate details about Medicare and what is covered for skilled nursing versus sub-acute rehab.

3.8 Implementation Experience

3.8.1 Communication

At all sites, the focus of this intervention is to increase ED resources for older patients. A major emphasis is on improving communication among this larger and more diverse ED care team.

Communication Mechanisms at Mt. Sinai

Rounds

As described above, the primary mechanism for care team communication at Mt. Sinai is the interdisciplinary daily rounds in the Geri-ED. These rounds facilitate communication as they take place with the whole team at the nursing station where information about each high risk patient is easily accessible from the EMR. When our research team observed rounds during the site visit, the geriatrician led the discussion and different staff added their comments. During the discussion, the staff searched the EMR several times for additional information, and used this information to enhance the discussion. Participants in the rounds cited several advantages to this process including the multidisciplinary nature of the team, sharing information with the entire team at one time (reducing repetitive information transmission), and immediate answers to questions from any member of the care team.

> Interdisciplinary rounds have a clear purpose – to get everyone on board with a treatment plan for the patient.
>
> *– Mt. Sinai ED Nurse, initial interviews*

Technological Strategies

The GEDI WISE program has developed order sets in their EMR for medications and to facilitate social worker referrals. These order sets ensure that the patient receives the necessary social supports and are not discharged back into a home environment that will result in recurring ED visits.

Volunteers, Liaisons and Technicians

Another strategy for communication that Mt. Sinai uses is extensive involvement of volunteers and non-professional staff to engage with GEDI WISE patients and families, and notify nurses, social workers, physicians and other senior staff about potential concerns. For example, the patient service liaison and CARE volunteers interact with patients and try to keep them upbeat. The nursing technicians are very involved in communicating with nurses about patient status and notify nurses immediately if the vital signs of a GEDI WISE patient are not normal.

Communication between ED and Hospital Units, and with the Community

GEDI WISE staff described how the enhanced staffing in the Geri-ED ensures adequate communication with inpatient units when patients are admitted to the hospital. For example, if a patient gets admitted to the floor, the GEDI WISE physical therapist tells physical therapists on the floor about the needs of that particular patient. Having dedicated geriatric ED physicians and greater time for assessing patients enables more detailed communications to the inpatient physicians about the needs of patients soon to be admitted to the floor.

Numerous communication strategies are in place with caregivers and other partners in the community. As described above in Section 3.2.3, transitional care is facilitated by relationships that have been built by GEDI WISE staff with personnel at a home health agency and a local sub-acute rehabilitation facility. The Community Action Board meets quarterly to advise the GEDI WISE leadership on program

components from the perspective of older adults in the community and to identify community based services that can be leveraged to support the patients who have gone through the GEDI WISE program. As part of the Transport Plus Pilot program, EMTs perform a "Discharge Comprehension Assessment" to determine whether the patient understands what their next steps should be after returning home. They share the results of these assessments with the GEDI WISE team to inform follow-up care. A recent pilot project called Project Connect focuses on building relationships with social workers in the community, who help older adults attend Senior Centers or visit the older patient in their home, depending upon the patient's needs.

Communication Mechanisms at SJH

Although the same multidisciplinary daily rounds take place at SJH, the team did not stress the rounding process for communication as much as they did at Mt. Sinai. The GEDI WISE team at SJH has fewer individuals, and they are assigned exclusively to the Geri-ED, in contrast to Mt. Sinai where most of the staff works in both the main ED and the Geri-ED. At SJH, there is a dedicated chief physician for the Geri-ED. A team of five nurses work in the Geri-ED and do not cycle through shifts in the main ED. A dedicated nurse navigator, social worker, two case managers and a concierge are also assigned to the SJH Geri-Ed, making communication across the team stable and easy to navigate.

Given that the physical size of the ED is much larger at SJH, one challenge is to alert critical care nurses in other parts of the hospital when the Geri-ED needs back-up. A paging system had been deployed to reach out when more resources are needed in the Geri-ED.

Staff Meetings

At SJH, the entire ED leadership team meets for five hours once a week (including the GEDI WISE leadership team) to talk about cases, review organizational and process issues, and address any challenges. This staff meeting is the primary mechanism for communication across staff involved with the GEDI WISE program.

Outreach in the Community

The Care Transitions Community Liaison (CTCL) is heavily involved in engaging the community. The CTCL engages families of the patients, and the families are now more aware of what is going on. In addition, the CTCL runs workshops in the community. For example, a workshop about advanced directives in a community setting reached about 300 people. GEDI WISE leadership has also spent a lot of time building good relationships and partnerships with their preferred physician groups. They also work with community groups to identify resources available to older patients at home.

Communication Mechanisms at Northwestern

Communication within the team of Nurse Liaisons, and with the ED social worker, is reported to be strong, although the mechanisms are more informal than at the other two sites that employ routine interdisciplinary rounds. The program staff also described a good team dynamic with the physician, resident, and nurses. The interviewees reported that there is a different level of communication and mutual respect and expertise sharing since the implementation of GEDI WISE. There are mini care-plan conferences where the GEDI WISE nurse, attending physician, and social worker convene to discuss what is safe for the patient. All program participants feel they're making

> Without social work we could not do what we do. I feel we are learning from the social worker every day…. She is the backbone to our program.
>
> *– Northwestern nurse liaison*

a difference and nurses are treated respectfully and allowed to be experts in their roles and give physicians recommendations on patients' transitional care needs.

3.8.2 Collaboration among the GEDI WISE Hospitals

An important component of the GEDI WISE program is to support communication and learning among all the GEDI WISE sites funded through the Award. GEDI WISE leadership organizes monthly cross-site calls for the GEDI WISE leadership teams and the data analysts, as well as other training and education calls as needed for specific types of staff. The program organizes yearly in-person meetings that include all sites and is attended by multiple staff including project leaders, physicians, social workers, NPs, RNs, data analysts, and pharmacists. At the time of the follow-up interviews, plans were being made to hold a meeting for all sites focused on data collection, analysis and publication of GEDI WISE findings. Informally, e-mails are exchanged between sites to share approaches to challenging problems. These interactions have led to cross-site sharing of ideas and adoption of program components at different sites. For example, the volunteer program at SJH is based on Mt. Sinai's experiences.

3.8.3 Adaptation and Trialability of Intervention Components

Trialability and Adaptability

During the initial site visits, the GEDI WISE program was described as very flexible and open to new ideas and modifications that will be helpful to the program and/or patients. The GEDI WISE directors described how the innovations continue to evolve over time. One early example at Mt. Sinai was the nurse practitioner role which was continuing to expand so that she can utilize more of her clinical skills instead of focusing entirely on care management. Training for the nurse practitioner was also evolving as that role becomes more well-defined. At SJH the staff described how an initial plan to include aromatherapy in the Geri-ED was abandoned, as not everyone liked the scented workplace.

At the follow-up interviews, many staff at Mt. Sinai described other components of the program that had evolved since our initial case studies in 2014, including:

- Initially, the GEDI WISE notes that were being entered in the EMR at Mt. Sinai did not interface with what was happening on the floor for the patient who was admitted to the hospital. The floor nurses could not read the notes. This glitch was corrected.
- The social work assessment tool was adjusted to better meet the needs of patients. They added more ADL questions, and ask patients if they have a PCP and how they plan to get to their next appointment. They incorporated questions for patients regarding how their ED visit might have been avoided.
- As mentioned above in Section 3.7.2, the social worker and nurse practitioner now do their assessments together.

Culture Change

The follow-up telephone interviews we conducted in 2015 yielded many new examples of how the ED culture had changed in these three sites, with respect to care for older patients. Although it took time to gain traction, the Mt. Sinai GEDI WISE leadership team reported greater collaboration and teamwork across staff. Clinical staff expect interdisciplinary rounds each day, and plan on the nurse practitioner

> From a doctor's perspective, the paradigm shift that resulted from the transitional care component is remarkable.
>
> *– Mt. Sinai ED Physician, follow-up interview*

seeing older patients. Whereas early in the program the GEDI WISE staff had to go looking for patients, now there are patients held overnight in the ED (rather than being admitted to the hospital) on a regular basis so that the GEDI WISE nurse practitioner can see them in the morning. ED physicians described how an older patient presenting to the ED in the past would be a definite admission, but now they can hand the patient off to the NP or social worker with confidence that they will investigate a range of discharge options for the patient. One nurse at Northwestern described that ED physicians now come across the room and say "I have such a GEDI for you!" She noted that she had never felt sought out for her opinion by the physicians before this program.

Social workers also described greater team collaboration and feeling supported and listened to by the ED physicians. One social worker at Mt. Sinai told a story about how a patient came in acting delirious, and the physician wanted to immediately admit the patient. The social worker convinced the physician to wait until she could check with the family, and she determined that the patient was exhibiting behavior that was far from his baseline. They were able to identify that the cause of the delirium was a medication, and they avoided the admission.

During follow-up interviews we noted that the Mt. Sinai Transport Plus project is experiencing the same start-up challenges that the broader GEDI WISE program experienced. Although Transport Plus has become more embedded in the Mt. Sinai culture, social workers still sometimes make follow-up calls without checking the record for the Transport Plus information. It is not yet common culture to consider what an EMS says about a patient's home situation, and scanned EMS notes are not yet transferred into the EMR. The culture change process that is required with innovations such as GEDI WISE and Transport Plus takes time.

3.9 Implementation Effectiveness

Staff at all three sites described a positive impact of the GEDI WISE program for patients, and expressed confidence that the program is reducing unnecessary admissions and repeat ED visits for older adults. Staff from all three EDs described situations where GEDI WISE care significantly affected patients. At Mt. Sinai, one success story was of an older woman who came to the ED nearly every day. Through the care provided by GEDI WISE, the social worker discovered that her son was schizophrenic and was not feeding her well; he had also disconnected her phone service, so it was impossible to conduct follow up care planning by phone. None of this was known to the main ED staff, despite their many interactions with this patient. The GEDI WISE program got her a prepaid cell phone and arranged for services with the visiting nurse service, preventing further visits to the ED.

The GEDI WISE program measures the impact of the intervention at all three sites using quantitative measures. A great deal of effort has been made over the last year to synchronize data across the sites, and measure impact by analyzing the number of "touches" that each GEDI WISE patient receives. The program at Mt. Sinai lost their data manager early in Year 2, and it took several months to hire a replacement. Once the new data manager and a data analyst were hired, the data team has worked to better characterize what services a GEDI WISE patient receives from the program, and to determine which services drive improved outcomes.

There have been difficulties merging claims data and hospital utilization data. A GEDI WISE patient can receive a range of services, and currently even one "touch" such as staying in the Geri-ED without any other consults qualifies the patient as a GEDI WISE patient according to the program criteria. However, within that larger group of GDEI-WISE patients, there are a wide range of services received with varying

levels of intensity. Data analysis at all three sites is a major emphasis in the coming year, as the PIs and the data analysts strive to define and document the true impact of the GEDI WISE program.

3.9.1 Better Care

Indicators of better care that were described by the GEDI WISE team include decreases in polypharmacy, reduction in use of benzodiazepines, patient reports of reduced pain and anxiety following visits from volunteers and other GEDI WISE staff (at Mt. Sinai and SJH). GEDI WISE staff believe they are preventing falls by identifying patients with balance problems, hazards in the home, and inappropriate medications that cause disequilibrium.

GEDI WISE's Measurement Strategy

The GEDI WISE program team collects data on a number of quality measures that they regularly report to CMS and use for internal quality improvement. These measures identified in the Awardee reports to CMS include the following (see Exhibit 3 below).

Exhibit 3: Measuring Better Care

Relevant Metrics Currently Collected by Awardee
Adverse medication events
Length of ED stay (time from ED arrival to ED discharge)
Time from hospital admit decision to ED departure

3.9.2 Healthier People

GEDI WISE staff described how the improved care transition mechanisms decreased hospital admissions. The transitional care available through this program enables patients to go to sub-acute (with a qualifying hospitalization within the prior 30-days), long term care, hospice, or home without a hospital admission. At Mt. Sinai, social workers are available on weekends and at night to help address social and home challenges and reduce unnecessary inpatient admissions. Mt. Sinai has had 36 direct admits from the ED to sub-acute rehab facilities and/or nursing home/long-term care facilities since 2013. At Northwestern, one nurse informally tracks prevented hospital admissions due to home care follow-up or placement in nursing home care. In the last fiscal year she counted 22 prevented admissions, and estimates that one third to one half of these were due in part to GEDI WISE.

GEDI WISE staff also described how the program appears to be reducing returns to the ED. A lot of repeat visitors to the ED are socially isolated and use the ED for social support services and personal interaction. The ability to quickly and efficiently arrange for supports for these isolated patients (e.g., social workers who link the patients to senior centers), and ensure that their home setting is safe, can reduce ED visits.

3.9.3 GEDI WISE's Measurement Strategy

GEDI WISE is tracking a number of outcomes measuring the health of the population served by the program as noted in their reports to CMS (see Exhibit 4 below).

Exhibit 4: Measuring Better Health

Relevant Metrics Currently Collected by Awardee
All-cause inpatient admission rate
30-day readmission rate
72 hour ED revisit rate
Heart failure admission rate
Pneumonia admission rate
Ambulatory care sensitive condition admission rate
Patient fall rate in the ED

3.9.4 Smarter Spending

Although the GEDI WISE program requires increased resources, particularly staff, the program team at Mt. Sinai was unanimous in their belief that these increases are more than offset by decreased costs due to fewer hospital admissions and fewer repeat ED visits. Although the Length of stay (LOS) may be longer in the Geri-ED than in main ED, this too is more than offset by reduced hospital admissions. Connecting patients with community services that meet their needs may also reduce ED use. For example, the SJH team described a patient with repeated ED visits due to high blood pressure, who was connected with an adult day care program where his blood pressure was monitored and stabilized, preventing ED visits.

For patients who do get admitted to the hospital, better coordination between ED and inpatient staff is credited with promoting shorter inpatient LOS.

GEDI WISE's Measurement Strategy

GEDI WISE is tracking a number of outcome measures related to costs as noted in their data reports to CMS (see Exhibit 5 below).

Exhibit 5: Measuring Cost Savings

Relevant Metrics Currently Collected by Awardee
Cost savings due to decreased repeat ED admissions.
Cost savings due to decreased inpatient admissions from the ED.
Cost savings due to decreased 30-day hospital readmissions.
Cost savings due to decreased inpatient LOS.

3.9.5 Outcomes That Can Be Measured Using Claims

The utilization and outcomes listed above can all theoretically be measured using claims, but there will be ambiguities. At SJH, it is not possible to attribute impact to HCIA funding, since that Geri-ED has been operational for many years and the HCIA only funds two staff positions. At Mt. Sinai, many comparison group patients may be exposed to somewhat similar programs because there are multiple transitional care programs offered throughout New York City and an Accountable Care Organization (ACO) program in the Bronx; similar programs serving the comparison group will dilute the measurable impact of GEDI WISE in a difference3-in-difference regression model. In addition, given the range of services provided through the three quite different GEDI WISE programs, if our pooled analysis detects

an effect it will be possible to distinguish which of the many components of the GEDI WISE intervention are driving this effect.

3.9.6 Unanticipated Impacts

There have been several unanticipated impacts for patients served by the GEDI WISE program.

- **Diffusion of GEDI WISE concepts:** Program staff expressed surprise at the degree of diffusion of the GEDI WISE concepts throughout the hospital, and noted that many providers not affiliated with GEDI WISE now routinely ask patients about their home setting, lifestyle, and ADLs in order to ensure a safe discharge to home.
- **Patient reactions:** One nurse noticed that patients are now having fun during their wait time, rather than finding the ED experience stressful.
- **Negotiations between main ED and Geri-ED**: One clinician was surprised by the amount of pushback from the main ED during the start-up of the program. Because the Geri-ED limits the number of patients but the main ED does not, there can sometimes be resentment about burden in one ED setting versus the other.

3.10 Context

In each interview and focus group during the case study, participants were asked about key contextual factors related to implementation and ongoing execution of the GEDI WISE program. Several factors informed our understanding about how the context both shapes and is shaped by the GEDI WISE program: endogenous and exogenous factors, staff satisfaction, program fidelity, and sustainability.

3.10.1 Endogenous Factors

Mt. Sinai

The leadership at Mt. Sinai provides tremendous support for the GEDI WISE program, acknowledging that longer ED stays and more staff are needed to achieve program goals. ED physicians described how the geriatric program in the hospital (Martha Stewart Center for Living) is a great resource, and one that may not be available in many other hospitals.

Other care coordination programs exist at Mt. Sinai, and the GEDI WISE leadership met with representatives from each during the start-up phase to determine the appropriate hierarchy for patient inclusion. The EMR contains information about whether a patient eligible for GEDI WISE is also in another care coordination program, so that the staff can appropriately triage the patient. Although the patient may still be seen in the Geri-ED, and receive certain GEDI WISE interventions such as interdisciplinary rounds and visits from a CARE volunteer, all follow-up social work and care management services are provided by the other care coordination program. The care coordination programs in order of hierarchy are as follows:

- The Community Based Care Transitions (CCTP) program is the smallest but most intensive care coordination program at Mt. Sinai. If a patient visiting the Geri-ED is also enrolled in this program, then CCTP staff are alerted and their social worker conducts all the care coordination activities with the patient. GEDI WISE would never need to "lend" one of its social workers or other staff to CCTP; if anything, the staff sharing relationship might be reversed.

- The Accountable Care Organization program (ACO) at Mt. Sinai has a relatively steady and regular number of patients. ACO patients have Mt. Sinai primary care physicians and see them within 24 hours after ED discharge.

GEDI WISE has by far the largest cohort of patients, especially because GEDI WISE services continue during "off hours" with the social worker and other GEDI WISE staff available in the evenings and during the weekends. Another endogenous factor mentioned by program staff was the influence of the nurses' union on training and staffing the program. Union rules restrict working hours, preventing longer shifts required in the Geri-ED, and requiring that training falls within the work shift, not over and above regular hours.

Finally, the ED recently introduced a "Split Flow" process in the Mt. Sinai ED. Split Flow is an improved workflow where patients are triaged quickly and moved from one part of the ED to another as certain needs are met (e.g., lab tests). This process frees up space for new incoming patients. However the slower pace of the Geri-ED, and the need to assess patients over a longer period of time, is not compatible with this Split Flow approach. At our follow-up interviews, one of the ED physicians mentioned that adoption of the Split Flow process is one of the reasons why the Geri-ED is moving to the former Observation unit. Moving the Geri-ED to the observation unit space will enable adding more beds to the Geri-ED, and at the same time free up space for the implantation of the Split Flow process.

SJH

At SJH the leadership is also extremely supportive of the program. The GEDI WISE Director has been at the hospital for many years and has widespread institutional support. For example, when the palliative care component for the Geri-ED was suggested they had immediate support from leadership. SJH, as a community hospital, has strong ties to patients over the life span, which helps support the Geri-ED initiatives. For example, the Geri-ED Director mentioned that children who were in the maternal and child health program 30 years ago now bring their aging mothers to the Geri-ED.

Northwestern

The leadership at Northwestern is also very supportive of the GEDI WISE program. The GEDI WISE personnel described coordinating with an inpatient program at Northwestern called the Geriatric Fracture Program. They work together to provide care, set up transitional services, and ensure that older patients get discharged as quickly as possible.

3.10.2 Exogenous Factors

A number of different Medicare policies were discussed by the GEDI WISE team that impact program development. The CARE Volunteer Director mentioned that Medicare does not cover hearing aids so having the volunteers provide these has been very important for some patients. Both Mt. Sinai and SJH staff discussed coordination between the Geri-ED and the observation unit at Mt. Sinai and SJH's "observation at home" program. By providing extra resources through the GEDI WISE program, as well as supplemental supports for enhanced observation following the ED admission, the hospitals are trying to improve cost efficiency and avoid Medicare readmission penalties. Both sites also described strong community relationships that enhance their ability to arrange effective community services and reduce reliance on the ED and hospital (preventing admissions and readmissions).

In follow-up interviews conducted in 2015, GEDI WISE staff noted that overall changes in the health policy and insurance environment have helped to facilitate acceptance of transitional care efforts, and

program leaders stressed GEDI WISE program could influence policy. For example, a program leader mentioned that if the program is proven to reduce costs and improve care, higher reimbursement rates might be considered for EDs that offer interventions similar to GEDI WISE. Program leaders suggested that a bundled payment model might be more relevant for EDs than fee-for-service. The requirement of a three day hospitalization in the prior month interferes with obtaining the most effective transition for older adults who could benefit from SNF care and program leaders hope that the data from this program will help advocate for a change in this policy. For example GEDI WISE could help develop criteria for patients to qualify for a sub-acute rehabilitation program without a prior 3-day hospital stay.

3.10.3 Staff Satisfaction

Extremely high levels of satisfaction were evident across all staff associated with the GEDI WISE program in all three sites. Physicians, nurses, nursing techs, patient service liaisons, social workers and support staff feel that the program is meeting its intended objectives and are satisfied that patients are receiving better quality of care. They attributed the success of the program to better staffing ratios, more time to spend with each patient, and a patient population that welcomes this increased attention. Having a multidisciplinary team to support the patient helps individual staff feel that they do not have to solve all of a patient's problems by themselves.

3.11 Program Fidelity and Sustainability

3.11.1 Program Fidelity

The three GEDI WISE programs share the same goals, but follow different pathways to achieve these goals. Although all three sites had pre-existing structural enhancements in place before the Award, funding for and dimensions of other program features varies. Mt. Sinai receives about half the total HCIA funding, Northwestern receives three-eighths of the funding, and SJH (with its long-established program) receives one eighth.

SJH is a Catholic community hospital, while both Mt. Sinai and Northwestern are large urban teaching hospitals. The PI at SJH focuses on operations, whereas the PI at Mt. Sinai focuses on research. The current PI at Northwestern also has a research focus, as he initially helped with the data analysis. These differences in the focus of the PIs lead to different emphases in the components of the GEDI WISE program (e.g., more advanced data analyses systems at Mt. Sinai and more extensive operations, such as the palliative care rooms, at SJH). Program staff emphasized that because the GEDI WISE program is a systems intervention that is attempting to influence a culture change within the ED, the GEDI WISE program is best practiced with an emphasis on local adaptation.

In our follow-up interviews, leaders at the sites described how data analysis and reporting is a primary focus in these last months of the Award, and that an upcoming three-site meeting will focus on data analysis and manuscripts based on the findings from the program.

Program Development and Training Across Sites

Several examples of programmatic differences that were ironed out through early collaboration across the sites were described. For example, at the beginning of the program at SJH, the social worker pre-screened patients for physical therapist consults. This practice led to physical therapist orders being submitted that were not appropriate. In addition, physical therapists were not initially included in patient rounds at SJH. Education and communication between physical therapists at Mt. Sinai and SJH regarding order sets, and integration of the physical therapist into the GEDI WISE program, helped promote the practice of ordering a physical therapist consult. Both programs standardized the processes so that all GEDI WISE

staff understood the role of the physical therapist and could submit orders for physical therapist consults appropriately.

At the same time, the sites also described components of their programming that remain unique to their site. Mt. Sinai uses the interdisciplinary rounds as a primary training and education tool. SJH has a robust alternative medicine program that includes holistic innovations such as pranic healing, and regular visits in the ED from a medical harpist. Northwestern structures their program around the Nurse Liaison model.

Data Collection

At SJH it was a challenge to develop the tracking mechanism to collect data as this hospital had not been reporting the same data points previously that were now needed for the HCIA quarterly reports. They supplemented their original medical record system with a data mining and warehouse program for the GEDI WISE initiative, which enabled them to synthesize the information into the necessary data fields for reporting. Each site has a different EMR system, although now all have integrated GEDI WISE data points into their unique EMR systems.

Reach

The way that the three EDs manage the patient flow into the Geri-ED and the reach of their services varies. SJH has a dedicated Geri-ED that does not screen patients and admits all older adults with little or no waiting. At Mt. Sinai, patients must meet eligibility criteria to be admitted to the Geri-ED section. Although older patients in the main ED receive all of the GEDI WISE services, they may not receive the same intensity of services. Because the Mt. Sinai Geri-ED is fairly small (14 beds), there are instances when eligible older patients are seen in the main ED instead, which is usually far busier and has lower staff-to-patient ratios. Northwestern recently shifted their target population to include patients who are on the way to being admitted to the Northwestern hospital, however, still does not work with patients who are critically ill or enter the ED from a SNF. The Nurse Liaisons acknowledged that on some busy days, they cannot get to all patients and some fall through the cracks. However, they indicated that this did not happen very often.

3.11.2 Sustainability

All three sites reported receiving attention from local and national press about their Geri-EDs, which may build support for sustainability after HCIA funding ends. That said, the program at SJH is far more integrated into the existing infrastructure than the Mt. Sinai program. Maintaining the current level of staffing in the Mt. Sinai Geri-ED after the HCIA ends will be a primary focus of the program leadership in the coming year.

The Northwestern program does not require a board certified geriatrician in the ED, and the Nurse Liaisons and social worker are the core of the program. The Northwestern team hopes that it will be easier for the hospital to support the program after HCIA funding ends. They are interested in spreading the GEDI-ED concept and have recently expanded the program to Lake Forest Hospital to test how feasible it is in other community settings.

> Initially, the challenge was getting people to understand what the GEDI-WISE program was for. Now people understand the value but the challenge will be if the hospital can maintain it when the grant ends.
>
> *– Northwestern GEDI-WISE staff, follow-up interview*

All sites described important services that should continue after the Award ends. Mt. Sinai's program is evolving into a new program called the TRACED program, which offers similar services but includes complex younger patients, such as those with substance abuse disorders. The program leadership at all

sites emphasized that many aspects of the GEDI WISE program will continue after the Award ends, especially the informatics that have been built into their EMR, the board certified pharmacists, and the enhanced workflow triage and assessment process for older patients. Northwestern leadership noted that even after the funding ends, they will likely have 1–2 Nurse Liaisons in their ED to target the most high risk patients.

3.12 Conclusion

- According to GEDI WISE staff, the program appears to be appreciated by older patients and is receiving a great deal of attention from hospitals that want to replicate the program.
- The primary program components consist of creating new roles for current ED staff tailored to older patients, adding some roles (such as the NP and the geriatric physician who leads interdisciplinary rounds), providing new resources such as PT to these patients, and developing explicit mechanisms for communication among these staff. The focus on reducing utilization of a high risk population through geriatric-focused care in the ED is innovative.
- The GEDI WISE program has launched an important conversation about how essential transition services are in preventing recurring ED visits. Key learnings include the following:
  - Decreasing ED visits among older patients requires greater attention to home and community social supports.
  - Effectively coordinating community services requires transition care during off-hours as well as main working hours.
  - Building relationships with care providers in the community is a critical component of supporting transitional care.
  - Creative use of care providers who have access to the home (e.g., through the Transport Plus program) may help reduce safety issues and ultimately ED readmissions.
- The unique needs of geriatric patients in the ED require a different model of emergency care.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode Medicare spending. The results presented below are for the following Core measures, which deviate somewhat from those specified by CMS:

- ED visits that result in a hospitalization
- The rate of hospitalizations in the 30 days after inpatient discharge or discharge from the ED
- The number of additional ED visits in the 30 days after inpatient discharge or discharge from the ED

The Mt. Sinai program also has the potential to costs for patients who visit the ED and therefore present results for the following additional measure:

- Total Medicare spending for 60 days including the index admission and all spending for 60 days after discharge

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. We additionally report median regression estimates of 60-day Medicare cost. Results are reported in section 2.2 below.[48]

All models include controls for patient age, squared age, gender, race, Hierarchical Condition Category (HCC) score in year of treatment, squared HCC score, eligibility for Medicaid at any time during observation period (2010–2014), as well as indicators for the quarter in which the episode occurred.[49] An indicator is also included for individuals with missing HCC scores.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[50] We believe this is an accurate way to compare time periods.

---

[48] The lone exception is discharge destination, where quarterly estimates are reported in table form due to the multitude of possible outcomes.

[49] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g. age, gender).

[50] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

4.1 Defining Intervention and Comparison Groups[51]

4.1.1 Selection Rules

The section below explains how we defined a set of criteria or rules that were used to create both the comparison and intervention groups. The criteria were created using information that is available in the Awardee registry and in Medicare claims. These were then uniformly applied to patients from intervention and comparison facilities to select the final intervention and comparison populations.

The Mt. Sinai program treats Medicare patients in the Emergency Department (ED), some of whom are then admitted to the hospital as inpatients. We therefore used both Medicare Part A (inpatient) and Part B (outpatient) claims to identify ED visits. We included all ED patients aged 65 and older, because Awardee staff advise that all older ED patients are exposed to the intervention in the three participating EDs, some more intensely than others. The Mt. Sinai registry contains fewer than half of the older patients with ED visits. We do not know why some ED patients were entered into the registry and others were not, but based on Awardee guidance we include all older ED patients in our analyses and do not perform a registry match.

The final selection criteria we used to define intervention and comparison groups are:

- Age 65 or greater
- ED revenue code 045X

Exhibit 1 below shows average patient characteristics for the Awardee and comparison groups in both the Baseline and intervention periods. The demographic summary statistics serve two purposes. The first is to provide a sense of the population demographics in the Mt. Sinai treatment population. The second is to show that the demographics are similar for intervention and comparison groups, with relatively wide standard errors. The wide standard errors reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

Exhibit 1: Patient Summary Statistics by Intervention and Awardee Group

	Awardee				Comparison			
	Intervention Period (N=48,659)		Baseline Period (N=76,314)		Intervention Period (N=83,610)		Baseline Period (N=118,031)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.61	0.49	0.62	0.49	0.61	0.49	0.62	0.48
Nonwhite	0.34	0.47	0.34	0.47	0.35	0.48	0.36	0.48
Age	78.08	8.63	78.09	8.48	78.62	8.78	78.69	8.62
HCC Score	1.61	1.64	1.72	1.72	1.64	1.58	1.77	1.70
Missing HCC	0.10	0.31	0.08	0.27	0.09	0.29	0.08	0.26
Medicaid Eligibility	0.44	0.50	0.52	0.50	0.49	0.50	0.59	0.49

[51] One of the comparison hospitals in the Chicago hospital referral region (HRR) that was used in previous reports was found to be missing claims for Part A ED visits for nearly the entire baseline period in the raw claims data. The lack of claims in the baseline period means that the DD assumptions do not hold for this provider and we have dropped it from the analysis. Northwestern University hospital retains a comparison provider in the Chicago HRR, and we intend to include additional comparison providers in future reports to ensure the robustness of our comparison sample.

We see that Awardee intervention and comparison groups are quite similar, in both the baseline period and the intervention period. We note that the share of patients who are Medicaid eligible declined for both intervention and comparison groups.

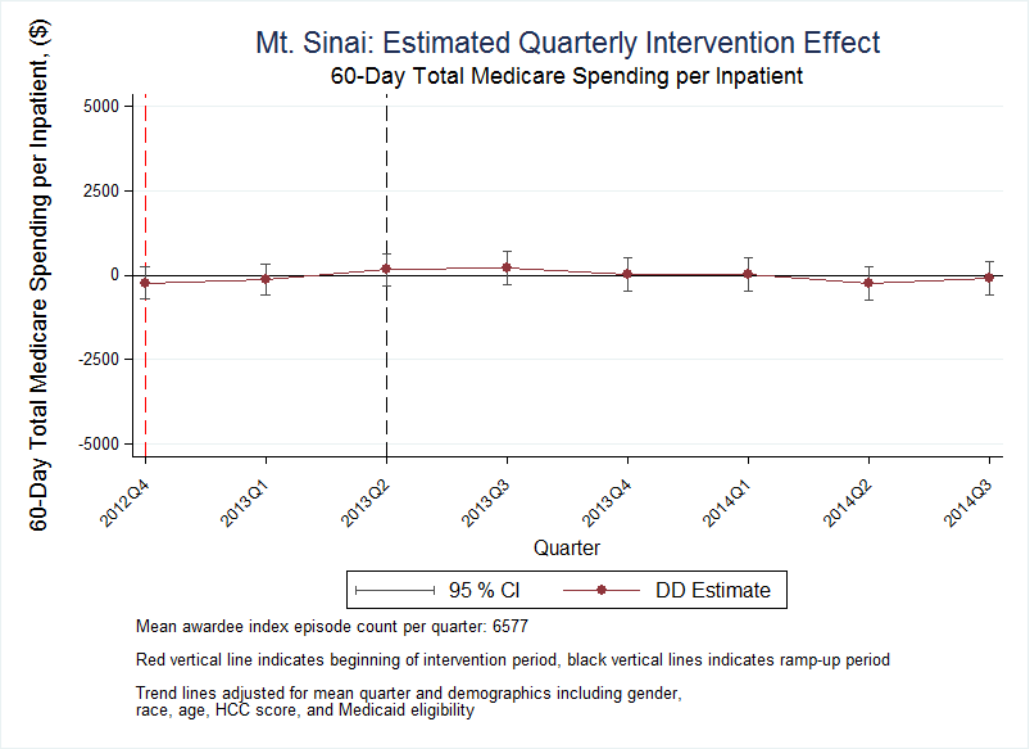
4.2 Core Measures: Results

Implementation did not take place on the same day in the three participating hospital EDs. In the graphs below, the red vertical line shows the beginning of the intervention period and the black vertical lines indicate the dates when the participating hospitals began their ED implementation. All estimated changes in utilization are based on nine quarters of post-implementation data. One less quarter of data is included for the spending measure compared to the utilization measures, due to the lag required for post-acute claims to become available for analysis.

4.2.1 Total Medicare Episode Spending During 60 Days After an Index ED Visit[52]

Exhibit 2 reflects total Medicare episode spending during the 60 days following an index ED visit, whether or not the patient was hospitalized as part of the initial encounter. None of the quarterly point estimates is statistically significant, and we do not observe a consistent pattern in the sign of the estimates. The pooled point estimate in Exhibit 3 indicates a decrease of $85 per episode, but this estimate is both statistically and economically insignificant. The median point estimate shows an increase in Medicare spending per episode, but this increase is small and is not statistically significantly different from zero.

Exhibit 2: Total Mean Medicare Episode Spending During 60 Days After an Index ED Visit



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

[52] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 3: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs

Mt. Sinai		
Intervention Effect (Ordinary Least Squares)	Estimate SE N	-85.34 (111.47) [326,614]
Intervention Effect (Median Regression)	Estimate SE N	33.95 (22.89) [326,614]

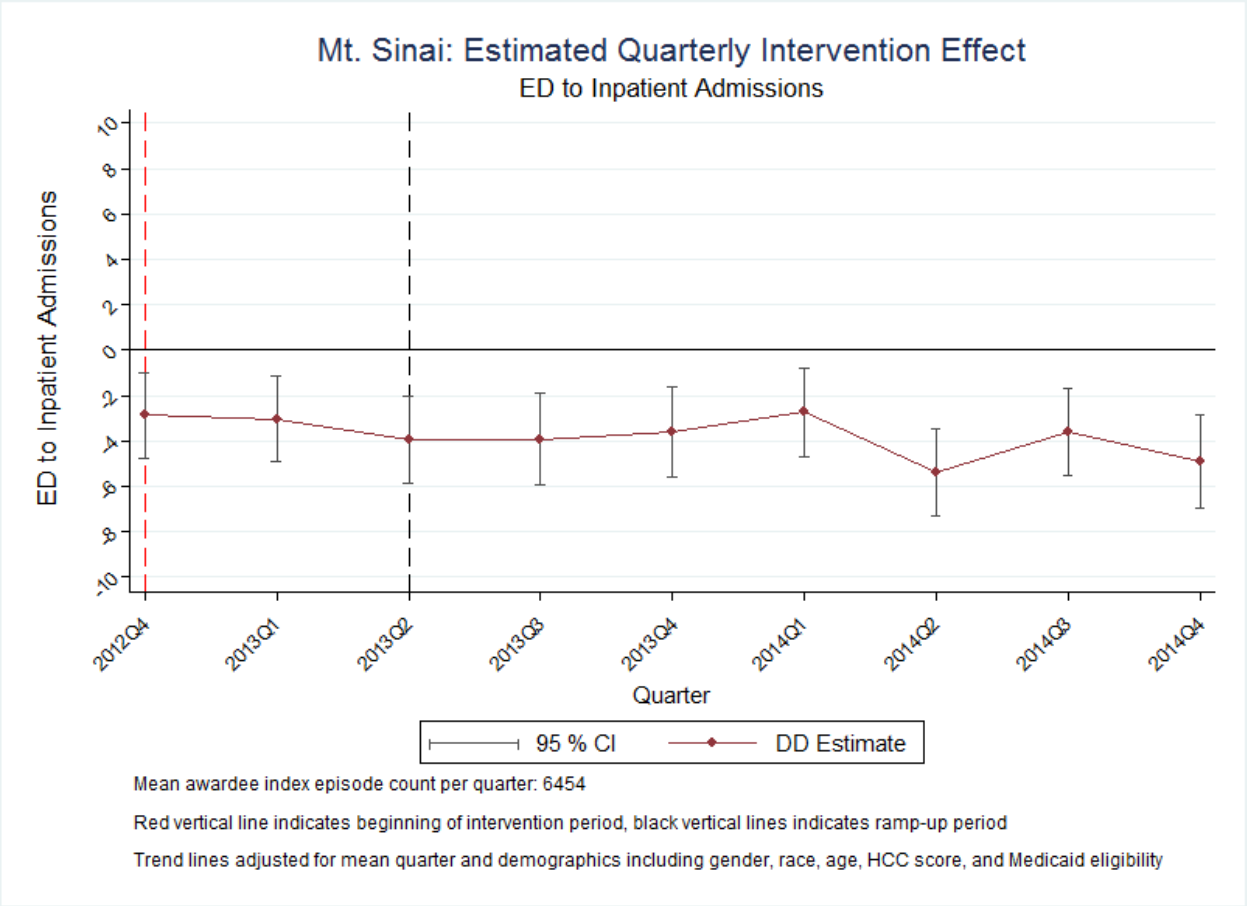
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015

4.2.2 ED visits That Become Hospital Admissions

One goal of the Mt. Sinai program is to avert hospitalizations for ED patients by addressing their care needs in the ED. Exhibit 4 shows that intervention patients were significantly less likely to be admitted from the ED to inpatient treatment relative to comparison patients. This difference is substantial, ranging from 2 to over 5 percentage points, and each individual quarter is statistically significant. The strong pooled estimate reported in Exhibit 5 indicates that the overall impact of the program through 2014 is a 3.49 percentage point reduction in inpatient admissions from the ED, a result significant at the 1 percent level.

Exhibit 4: ED visits That Become Hospital Admissions



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 5: DD Estimated Effect of Intervention on Inpatient Admissions through ED

Mt. Sinai		
Intervention Effect	Estimate	-3.49***
	SE	(0.42)
	N	[336,543]

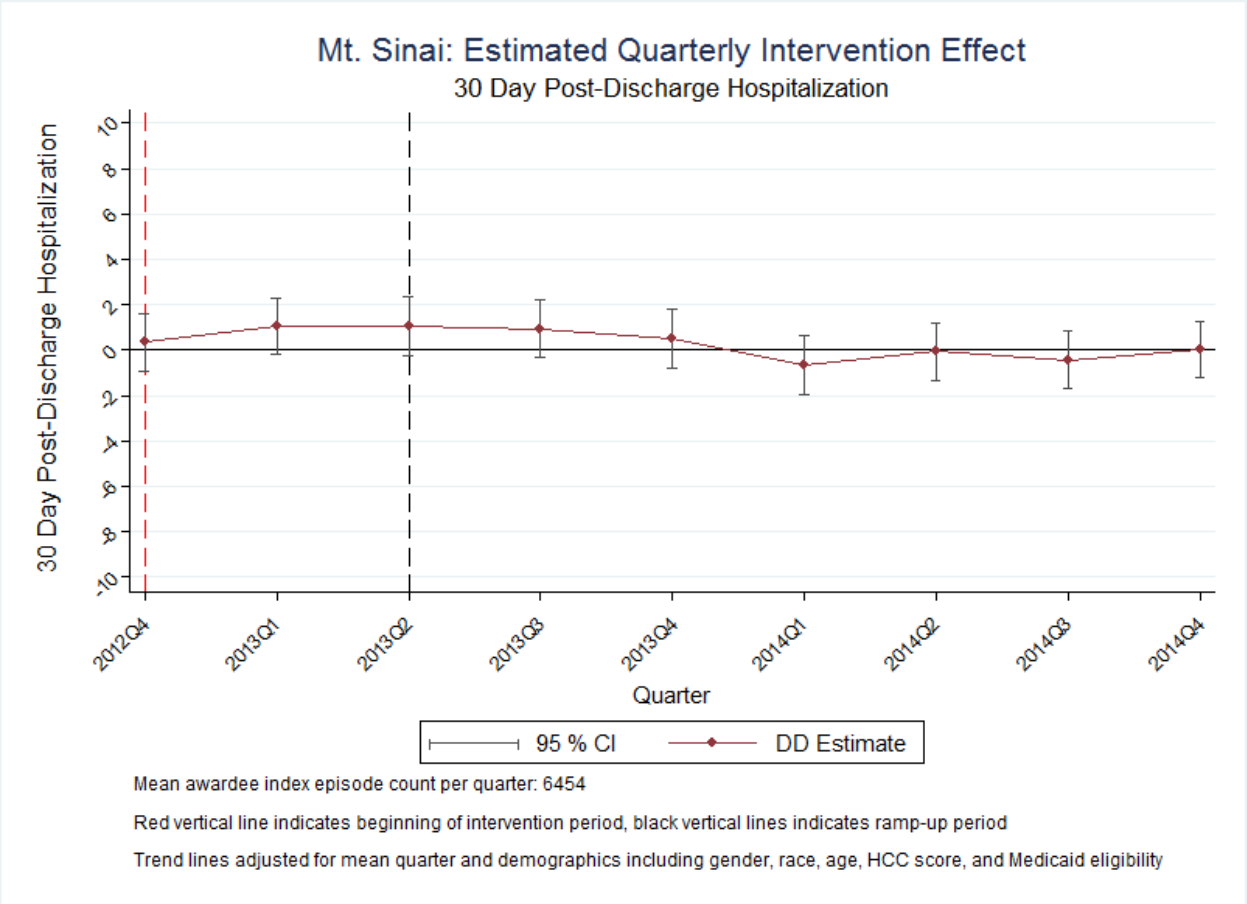
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015

4.2.3 Hospitalization During 30 Days Following an Index ED Visit

Exhibit 6 shows ED visits where the patient had at least one hospitalization in the 30 days after the conclusion of the index ED encounter (whether or not the index ED episode resulted in an inpatient admission). There is some evidence that hospitalizations are decreasing over time, but none of the quarterly point estimates are statistically significant. The pooled estimate of the program impact is small in magnitude and not statistically significantly different from zero, and so we conclude that the program has no impact on inpatient readmission after discharge from the index episode.

Exhibit 6: Hospitalization During 30 Days After an Index ED Visit



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 7: DD Estimated Effect of Intervention on 30-day Hospitalization Following Index ED Visit

Mt. Sinai		
Intervention Effect	Estimate	0.18
	SE	(0.29)
	N	[336,543]

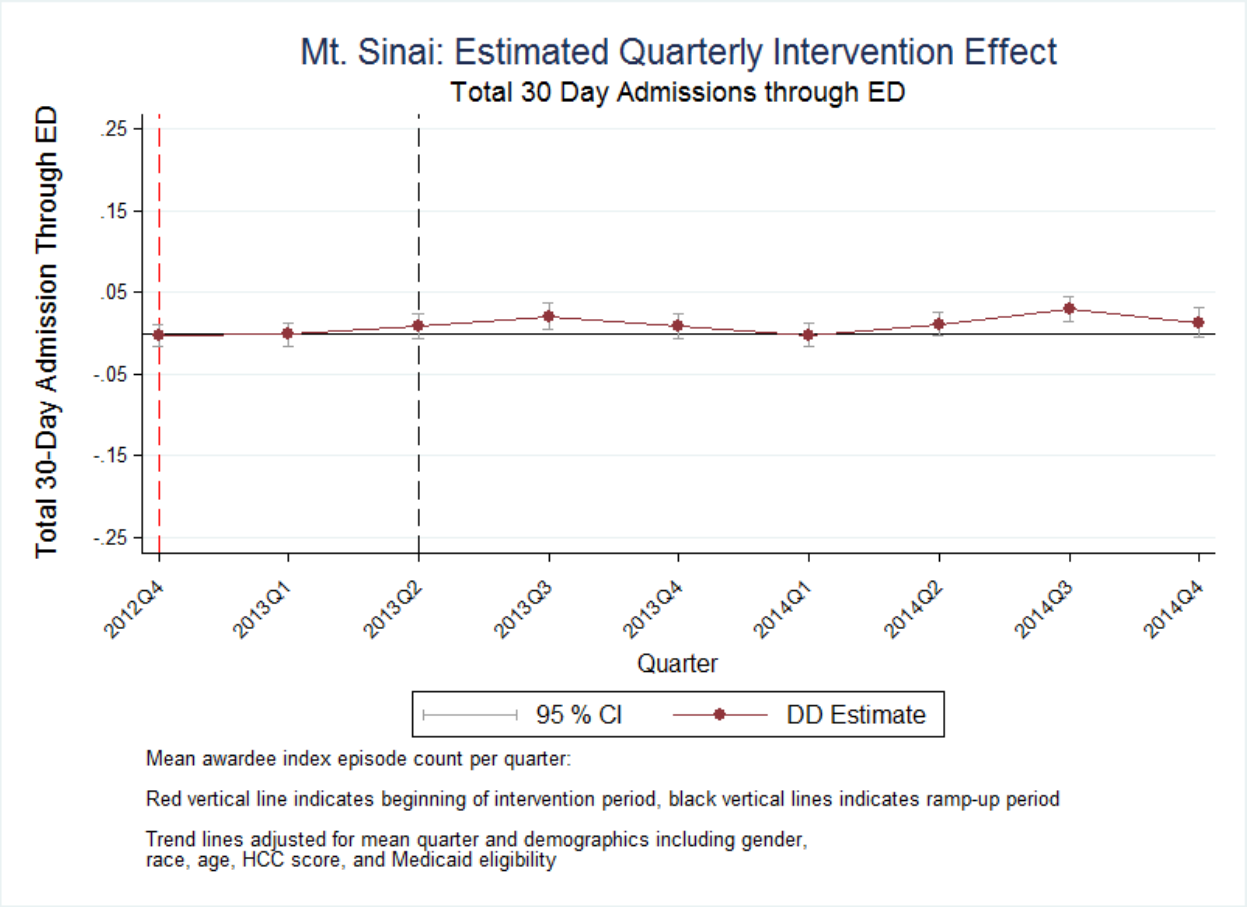
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015

4.2.4 Average Number of ED Visits During 30 Days After an Index ED Visit

Another goal of the Mt. Sinai program is to reduce the total number of ED visits among a population that uses the ED extensively. Exhibit 8 shows the number of ED visits during the 30 days after an index ED visit, irrespective of whether there was also a hospitalization during this period. Intervention patients had more ED visits on average in nearly every quarter since the start of the intervention, than did comparison patients. Although several of the quarterly point estimates are statistically significant they are small in magnitude, and the point estimate reported in Exhibit 9 is statistically insignificant.

Exhibit 8: Average Number of ED Visits During 30 Days After an Index ED Visit



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 9: DD Estimated Effect of Intervention on Total 30-day ED Visits

Mt. Sinai		
Intervention Effect	Estimate	0.01
	SE	(0.01)
	N	[336,543]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015

4.2.5 Conclusions

- We estimate a decreased rate of admissions to the hospital from the ED, a statistically significant difference of 3.49 percentage points.
- Our estimates do not indicate that the intervention is associated with post-discharge hospitalizations, total 30-day ED visits, or total Medicare spending per episode.

Appendix B9: St. Luke's Regional Medical Center eICU

1. Executive Summary

This chapter presents both quantitative and qualitative findings of Abt Associate's evaluation of St. Luke's Regional Medical Center's Health Care Innovation Award (HCIA) cooperative agreement utilizing an electronic intensive care unit (eICU) to improve critical care and emergency services in a number of hospitals across a wide geographic area in Idaho. eICU critical care nurses and physicians offer remote monitoring of patients in participating ICUs and consultations to participant emergency departments. The goal of the program is to better assist bedside caregivers, avoid unnecessary complications and tests, reduce in-hospital mortality, and lower cost. The intervention began in January 2013 in several critical care units in the Boise area, and has since been implemented in several other hospitals including remote critical access hospitals.

By providing continuous monitoring for critically ill patients, and night shift access to intensivist physicians, the eICU has enjoyed wide acceptance in the St. Luke's health system. Intensivist physicians who work the night shift covering three hospitals, and now do so from the ICU, report that they no longer race between hospitals to attend to patients. In addition, they have more information with which to make treatment decisions than could be obtained via telephone. Bedside nurses, and especially those working the night shift, are enthusiastic about the support available from the eICU clinicians. Several hospital and ICU leaders report that this program is a decided improvement in the quality of care they provide to critical care patients across the health system.

The eICU program has encountered many technical barriers over the course of implementation in terms of technology, particularly in expanding the program to long term care hospitals.

St. Luke's program staff expected that continuous monitoring of ICU patients, and intensivist physician access at night, would shorten ICU length of stay (LOS) and possibly overall hospital LOS. Although it is possible that patients would eventually be discharged in a better state of recovery due to this program, there are no post-discharge services or care coordination elements of the program and based on our qualitative research we would not necessarily expect to see significant reduction in post-discharge ED visits, use of post-acute services, or hospital readmissions.

We conducted a difference-in-difference analysis using Medicare claims, comparing changes in the St. Luke's hospitals over time with changes in a matched group of comparison hospitals. We developed inclusion and exclusion criteria for intervention and comparison groups based on the patient registries supplied by program staff. We consider program estimates to be downward biased approximations of the true program impact, because we could not perfectly match intervention and comparison groups using data available in Medicare claims. Our analysis shows hospital length of stay (LOS) trending downward but it has not decreased significantly overall, relative to the comparison group. Our analysis does show a significant decline in the rate of post-discharge ED visits, which is 2 percentage points lower in the intervention group relative to the comparison group, pooled across the entire intervention period. This point estimate translates to approximately 8-9 fewer patients returning to the ED in a given quarter. Although this finding is statistically significant, current data do not show an accompanying change in average 60-day episode Medicare spending, indicating that the decline in ED visits was not sufficient to significantly reduce the average cost of an episode. Based on our qualitative research, we are comfortable drawing a causal inference between the eICU program and shorter LOS, but whether the program is directly responsible for fewer post-discharge ED visits is less clear. We found no significant change over time for intervention patients in 30-day inpatient readmissions, or discharge destination, relative to the comparison group.

2. General Research Domains

The core domains for the St. Luke's eICU program evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of HCIA funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).
- **Impact on Priority Populations** focuses on research questions related to the type of population served by the intervention and the extent to which the intervention focuses on the needs of the medical and non-medical priority groups such as underserved populations.

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Program Description

St. Luke's HCIA Award utilizes a telemedicine approach to improve critical care and emergency services in a number of hospitals across a wide geographic area in Idaho. A remote electronic intensive care unit (eICU) is the core infrastructure for the program. eICU critical care nurses and physicians offer remote monitoring of patients in participating ICUs and consultations to participating emergency departments. The goal of the program is to better assist bedside caregivers, avoid unnecessary complications and tests, reduce in-hospital mortality, and lower cost. St. Luke's program is being implemented in three different settings: ICUs in larger acute care hospitals, ICUs and emergency departments (EDs) in critical access hospitals (CAHs), and starting in mid-2014 ICUs in a long-term acute care hospital (LTACH). In the ICUs at the larger acute care hospitals, all ICU beds are being monitored by the eICU, eICU nurses are available 24/7 and an eICU physician is available at night. Some of the CAHs have dedicated ICU beds that can be monitored by the eICU when in use for a critical care patient. In the CAH's EDs, there is no continuous monitoring/telemetry, but clinicians in the rural EDs may request a consult from an eICU physician at night or can request nursing support at any time.

The table below presents information on when St. Luke's intervention began in participating hospitals.

Exhibit 1: Timing of St. Luke's Regional Medical Center Intervention

Hospital	Month/Year Implementation Start Date
Boise CCU	January 2013
Boise ICU	January 2013
Meridian ICU	January 2013
Wood River (ICU and ED)	ICU: May 2013 ED: November 2013
Magic Valley ICU	August 2013
Magic Valley – Stepdown	August 2013
North Canyon/Gooding (ED)	September 2014
McCall (ED)	December 2013
Jerome (ED)	January 2014
Elmore (ED)	December 2013
Syringa (ED)*	September 2014
Weiser (ED)	January 2014
West Valley Medical Center (ICU)	TBD (estimated summer 2015)
Vibra Hospital (LTACH ICU)	TBD (estimated summer 2015)

CCU: Critical Care Unit; ICU: Intensive Care Unit; LTACH: Long Term Acute Care Hospital; ED: Emergency Department; TBD: To Be Determined

*Site not funded by the HCIA

3.2 Case Study Methods

The Abt team conducted the first in-person data collection at St. Luke's on March 19-21, 2014. The evaluation team visited St. Luke's Boise Medical Center in Boise, Idaho, where the eICU Central Operations Room (COR) is located, as well as St. Luke's Wood River Hospital, a CAH in Ketchum, Idaho where the eICU is monitoring two critical care beds and providing ED consultations. In addition to interviews and focus groups, the site visit team observed operations in the COR and a demonstration of the technology at the Wood River CAH. The team also interviewed nurses from St. Luke's Meridian Hospital (also in Boise) and critical care physicians who cover both Boise hospitals when "on call" and now in the eICU at night, supporting several hospitals.

The exhibit below presents information on the number and type of individuals who participated in either individual interviews or focus groups during the March 2014 data collection.

Exhibit 2: Number and Type of Respondents Interviewed in March 2014

	Bedside Nurses	eICU Nurses	Physicians	Hospital Leadership	Data/Financial Analysts	Program Administration
St. Luke's Boise Medical Center	6 (2 from Boise Meridian hospital)	4	3 ICU/eICU physicians	3	5	5
St. Luke's Wood River CAH	2	0	1 ED physician	0	0	1
Total = 30	8	4	4	3	5	6

The Abt team conducted follow-up telephone interviews with eICU COR staff, and hospital leadership at Boise Medical Center, bedside nurses and attending physicians at the remote sites, including St. Luke's Magic Valley Hospital and St. Luke's Meridian Hospital. Approximately half of the interviews were conducted from January 20–23, 2015 with the remaining interviews taking place between March 30 and April 3, 2015. The latter interviews were delayed in the expectation that a Long Term Care Hospital would join the program in March and we wanted to learn about that facility's participation. Unfortunately, that facility did not begin eICU activity in March, and due to the project schedule we proceeded to complete qualitative data collection. Some individuals, particularly program staff, were interviewed in both phases of data collection. Exhibit 3 presents the number and type of individuals at the hospital and affiliated nursing homes who were interviewed either individually or as part of a focus group during the follow-up interviews.

Exhibit 3: Number and Type of Respondents Interviewed in 2015

	Bedside Nurses	eICU Nurses	Physicians	Hospital Leadership	Data/Financial Analysts	Clinical Educator
St. Luke's Boise Medical Center	3	4	3 ICU/eICU physicians	4	6	1
Remote Sites	1		2			
Total = 23	3	4	5	4	6	1

For both the initial case study and the follow-up interviews, all interviews and focus groups were recorded with participant consent, and audio-recordings were used as backup to the interviewer notes. At the end of each interview, notes were cleaned by the note taker and reviewed for accuracy by the researcher who led the interview.

Standard qualitative interview and focus group protocols were tailored to the different informants at each site. Three staff went on each site visit—a senior Abt researcher, a mid-level Abt researcher and a researcher from Telligen (formerly CMFC; subcontractor to Abt). All three staff participated in every interview and focus group, with one researcher leading the interview and others taking comprehensive notes; all interviews were recorded (with participant consent) and audiotapes were used to supplement interviewer notes. At the end of the site visit, all notes were cleaned and integrated across the note-takers and reviewed for accuracy by the senior researcher on the team. Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

3.3 Program Background

St. Luke's has been a health system for approximately seven years and includes 10 different hospitals spanning a wide geographic range in southern and central Idaho, northern Nevada and eastern Oregon.[53] St. Luke's also has management relationships with several CAHs that are not formally part of the St. Luke's Health System. Many of St. Luke's facilities are located in rural areas, separated from the Boise Medical Center by large distances, mountains, and rivers. Overcoming some of the challenges posed by this geography is one goal of the eICU program. The program also aims to address the shortage of critical care nurses and physicians in the northwest. Hospital leadership, program administrators, and bedside staff all reported difficulty in hiring qualified specialists, especially in rural locations. The eICU program brings critical care specialist oversight from St. Luke's Boise Medical Center to outlying facilities. This oversight aims to reduce feelings of isolation among ICU staff who may be the only critical care trained clinician in a rural area or who may lack the experience to feel comfortable addressing the diversity of patient needs encountered in an ICU.

In addition to leveraging the intensivist resources of the St. Luke's Boise Medical Center, the eICU program aims to improve patient care in rural areas so that patients can be treated in their local communities whenever possible. While many critical care patients and emergency/trauma patients must be transported to an urban medical center, participating CAHs and program administration believe that eICU support may help to avert some transports. Since the cost—to both patients and payers—of transferring from a CAH to the nearest medical center is often very high (especially in the winter when mountain roads may be closed), avoiding transports has the potential to reduce costs and increase patient and caregiver satisfaction by reducing the burden associated with a transport. In addition eICU support will help CAH nurses, who see few critical care patients, improve their skills and competencies in caring for these patients. This too may reduce the need to transport some critical care patients who could safely be cared for in a CAH with eICU support.

Additional goals of the eICU program as outlined by the program administrators include: spreading the costs of the program across the greatest number of patients, standardizing care processes and protocols across settings within the St. Luke's Health System, and creating efficiencies within the health system.

St. Luke's hospital and health system does not have an electronic medical record (EMR) system. Some functions are supported electronically (e.g., pharmacy, lab results, medication administration, order entry)

[53] http://www.stlukesonline.org/about_us/facilities.php

but there is no enterprise EMR and these separate information systems are not integrated. In this context, the eICU physicians feel strongly that they can only safely monitor ICU patients remotely if the necessary information streams can be woven together in near real-time. This posed a substantial challenge for the eICU in the St. Luke's Boise Medical Center and for all of their outlying hospitals. The lack of electronic information has also proven to be a near-barrier for the LTACHs that have almost no automated data that can be transmitted to the COR.

3.3.1 Impetus for the Program

To address the challenges of treating patients across a wide geographic territory, and make best use of scarce critical care physician resources, St. Luke's leadership began considering telehealth shortly after becoming a health system. Hospital leadership did not want to pursue telehealth for the sole purpose of building referral relationships with other hospitals, and they did not believe a program could be sustainable if pursued solely as a "rural strategy." Rather, they saw telehealth as an opportunity to spread finite specialty resources across their system. St. Luke's also offers insurance products, and is part of an Accountable Care Organization and Medicare Shared Savings Plan. The eICU program is seen as a way of expanding the health system's network affiliations, covering more ICUs with existing intensivist physicians (especially at night), and extending critical care expertise to rural hospitals.

In the past, a competitor hospital in Boise that operated an eICU program approached some of St. Luke's facilities about their interest in receiving eICU support. Ultimately the competitor's program was un-successful; St. Luke's clinicians believe this was in part because the eICU physicians were not local, and local physicians did not accept having distant physicians monitoring their patients. However this competing eICU program may have been an initial impetus for the development of the St. Luke's program.

St. Luke's initially planned to implement a limited eICU program with internal funding, but resource and staff constraints delayed start-up for several years. Having already planned to pursue the program, the possibility of HCIA funding caused the program leadership team to prioritize the program, move up the schedule, and expand the program to CAHs (and potentially LTACHs) outside of the St. Luke's Health System.

3.4 Primary Program Components

The St. Luke's eICU program currently consists of two primary program components: 24/7 monitoring of ICU beds in several large and small hospitals, and as-needed consultation for CAH Emergency Departments (EDs). If technology limitations can be overcome at an interested LTACH, monitoring of ICU beds will begin there in summer 2015.

3.4.1 ICU Monitoring

Physicians and nurses explained that the staffing model, activities and value of the eICU monitoring component differ between day shift and night shift.

Day Shift

During the day, the larger hospitals in the St. Luke's system have critical care physicians working their ICUs; no consultation with a remote physician is needed. During the day, the COR serves a critical care quality oversight function and is staffed by two critical care nurses with many years of ICU bedside nursing experience. These nurses are assisted by a Health Care Assistant (HCA) whose role is primarily

data input and processing paperwork for patients who are admitted, transferred or discharged. There is not a physician physically present in the COR during the day, but there is one "on-call" who can be consulted when needed.

During the day, the eICU nurses conduct virtual rounds on all monitored patients at least twice a day and as often as every two hours for unstable patients. During these virtual rounds, the eICU nurses "camera in" to a room to observe the patient visually, answer any questions the patient or family have and consult with the bedside nurses about the patient's care plan for the day, if appropriate. When not conducting virtual rounds, the eICU nurses keep each patient's electronic profile updated by ensuring that orders, pharmacy information, lab results and test results are entered into the eICU vendor information system, so that deviations from evidence-based best practice protocols trigger alerts. For partner sites within the St. Luke's Health System, patient vital signs from bedside monitors automatically interface with the eICU software used in the COR. When these alerts appear, the eICU staff communicate with bedside nurses to ensure that they are aware of next steps and patients who require additional attention. Keeping the patient profiles updated throughout the day is also important, especially in the absence of an EMR, so that when the eICU physician is physically present overnight, he or she has an accurate picture of the patient's care and status throughout the day.

> "It's a huge culture change to feel like it's OK to have someone else help you out with your patient."
>
> *– ICU Bedside Nurse, 2014*

Bedside nursing staff reported that there are four ways that the eICU program provides a valuable service to them during the day. First, eICU nurses alert bedside nurses to incoming lab or test results that they might otherwise not have time to check for (without an EMR, bedside nurses must check several different systems to find the information they need). eICU nurses have access to the many hospital information systems, and since they have no direct patient care responsibilities, they are often among the first to know when lab or test results are ready. This saves bedside nurses from having to repeatedly check whether results are available. In this role, the eICU nurses can also help with admissions to the ICU during the day. Second, eICU nurses monitor patient trends over time, especially across shifts; trends that may not be as obvious to a nurse who spends 8 or 12 hours at a time assigned to two patients on any given shift. Third, eICU staff can literally "watch" a patient when necessary. Bedside ICU nurses typically have responsibility for two patients (in different rooms) and reported that often they get busy with one patient and rely on the eICU staff to check on their other patient periodically. Finally, the eICU nurses can answer questions and provide guidance or advice to less experienced bedside nurses, or when bedside nurses need advice from a peer. Since ICU bedside nurses work independently and all are very busy, they cannot consult easily with each other. The eICU nurses are more readily available for real-time advice than are other bedside nurses.

Night Shift

Before the eICU program, one critical care physician covered multiple ICUs at night in the two Boise area St. Luke's hospitals, driving back and forth between the hospitals when necessary. When this one physician was not present in an ICU and new patient care issues arose, night nurses would wake admitting physicians whenever they had a concern or needed a new order placed. The eICU program has dramatically changed the physician oversight of critical care patients at night. The COR is staffed at night with two experienced critical care nurses and a critical care physician who does not leave the COR. Night shift eICU nurses oversee the monitoring of patient trends and best practice protocols, as their day shift peers do. In addition, the eICU physician is available to consult with bedside nurses in the event of a question or change in patient status, when an order is needed, or when a CAH's emergency room staff

need a physician-consult. Rather than calling and waking up an admitting physician, or waiting for the 'traveling' physician to arrive, bedside nurses in the Boise ICUs can consult with the eICU physician. The eICU physician has the authority to place orders for any ICU patients overnight. In the past, new orders were often delayed until daytime, when physicians were present; now, more care takes place at night because the eICU physician can place orders and oversee care.

Only one of the remote CAHs has critical care beds that are monitored 24/7 by the eICU. In this facility, the eICU physicians are able to provide continuous care at night in much the same way that they do in the larger urban ICU sites. Wood River does not frequently admit patients to their ICU beds, and so they have not utilized the eICU frequently over the course of the program. As part of the larger telehealth strategy at St. Luke's, the telehealth director is encouraging Wood River to use their ICU beds for their highest acuity patients so that they are comfortable with the technology and form good relationships with the eICU physicians working in the COR.

Another value of the eICU program during the night shift that was frequently mentioned in numerous interviews is the role of the eICU nurses in mentoring and teaching less experienced bedside nurses. Typically, night shift nurses have less experience than day shift nurses, and the night shift eICU nurses serve as a more experienced mentor for the bedside nurses, answering their questions or providing advice when needed. Many of the night shift nurses that we spoke with, both in Boise and Wood River, were aware of their relative inexperience and reported that having the eICU available for consultation was very helpful. Many day shift bedside nurses that we spoke with reported feeling more comfortable handing off their patients to the often less experienced night shift nurses, knowing that the eICU nurses and physician are available in the event of a change in a patient's status.

Hand Offs Between Night Shift and Day Shift

The need to share information between the eICU physicians at night and the ICU physicians on the units during the day led to the creation of a process for physician-to-physician 'hand offs' between the eICU and the ICU units. Within the Boise area hospitals which includes both the Boise Medical Center and the Magic Valley Medical Center, an electronic hand off system gives daytime ICU physicians an update on the progress of the patient while they were being monitored overnight by the eICU. Sometimes this electronic hand off is supplemented by a personal phone call from the eICU physician to the attending physician, if a patient's status is of particular concern or complexity. There is also a more informal nurse-to-nurse hand off system at shift change, primarily between day shift eICU nurses and night shift eICU nurses. Because the eICU nurses work all of their shifts in the COR, the need to a formalized hand off process is not as critical.

With remote sites in rural areas, the hand off process is not as standardized. eICU leadership has proposed a process, but it has not yet been fully implemented in the remote sites where the eICU is providing ongoing monitoring of ICU beds.

3.4.2 Emergency Department Consultation

The eICU program offers consultations to CAH ED staff on an as-needed basis. This component of the program was just beginning at the time of the initial in-person site visit, and St. Luke's had plans to expand it over time. When ED staff request an eICU consult, they use a mobile cart to connect to the COR. The Wood River staff have used the ED consultation at night when the CAH ED physician with a complex case wanted to consult with a physician colleague; they've also consulted with the eICU physician about whether a patient needed to be transferred. eICU staff agreed that the CAH ED staff

will often contact the COR before a critical care patient is transferred to St. Luke's Boise Medical Center. This allows eICU staff to collect some information on the patient's status prior to the transfer, and prepare orders and care plans prior to the patient's arrival in Boise. Both eICU staff and bedside staff reported that this makes the process of accepting a transferred patient much smoother and allows for more continuous patient care.

During follow-up interviews, we learned that uptake of this ED consultation component of the program has not been as widely used by CAHs as the program leadership anticipated. The eICU nurses reported that they receive only one or two requests for ED consultation each week. The mobile carts can be used anywhere in the hospital where there is a critical care patient in need of a consultation. However, only one of the CAHs—Wood River—has critical care beds and admits critical patients on a semi-regular basis. The other CAHs frequently transfer the critical patients to the Boise area ICUs. One potential explanation for the infrequent requests for ED consultation may be that this is not the greatest need for CAHs. Many different interviewees indicated that use of the mobile carts in the CAHs could increase if additional specialty consults, beyond critical care, could be offered by St. Luke's (e.g., neurology, tele-stroke, pediatrics). Program staff are considering adding these capabilities as part of a broader telehealth platform going forward.

3.4.3 Long-Term Acute Care Hospital (LTACH) Monitoring

Although the program has not yet been implemented at any LTACHs, this may begin at one LTACH in summer 2015. This LTACH has critical care (intensive) patients and the COR will monitor them just as they do patients in hospital ICUs. The biggest challenge in implementing the program at LTACHs has been the lack of electronic information systems (computerized order entry, lab systems, pharmacy systems, etc.) in that sector. Without near real-time electronic information, it is not possible for the COR to monitor patients appropriately and safely. These technology issues are discussed further below.

3.4.4 Technology

St. Luke's eICU program depends on hardware and software, including the clinical decision support underlying best practices alerts purchased from a vendor. Any troubleshooting or user concerns with the hardware (cameras, monitors, etc.) are supported by the Information Technology staff at each hospital, with unresolved issues forwarded to the IT specialists at St. Luke's Boise Medical Center; software issues are forwarded to the vendor. At the St. Luke's Boise Medical Center, there is an IT helpdesk available twenty four hours a day to respond to any technology issues identified by the COR staff with any of the hardware used by the program.

In the COR, the vendor eICU software system tracks patient vital signs, lab and other test results, physician orders, pharmacy medication dispensing, and monitors best practice protocols. Bedside vital signs are transferred directly to the COR (telemetry) where eICU nurses are able to track trends in real time. The software uses an algorithm to assign a patient acuity (APACHE) score. This score helps the eICU staff know which patients need more intense or frequent monitoring, and facilitates the handoff of patient care between day and night shifts. The acuity scores can also be used to make decisions about when to move patients from the ICU to general hospital units, which is important during periods of high demand for ICU beds.

Hardware in the COR includes several monitors that display patient vital sign trends, as well as cameras for two-way virtual rounds and consultations with bedside nurses. In each hospital room being supported by the eICU, there is a camera and monitor to facilitate two-way virtual rounding and consultations, and

telemetry from ICU beds to the COR. When a bedside nurse enters a patient room and wants to connect to the COR, s/he pushes a large button located on the wall. When the eICU staff want to "camera in" to a patient's room, they press a button that rings a bell in the patient's room, so everyone there will know the COR is watching. The cameras in patient rooms can be controlled from the COR, so that eICU staff can zoom in to see patients, monitors, etc. The cameras and monitors in the COR and in the patient rooms allow bedside nurses and eICU staff to converse "face to face" and to include patients and families in the conversation when necessary.

In CAHs where the eICU is providing ED consultations, there are mobile carts in the EDs; either the cart is moved to the patient or the patient is moved to the ED bay where the cart is located. The carts are equipped with cameras and monitors to facilitate two-way interactive consultations.

Without an EMR, eICU nurses and their health care assistants spend considerable time manually inputting data into the eICU software, on which the best practice protocols run. The eICU staff reported that there are 14 different systems from which the eICU nurses pull information and manually copy or enter it into the eICU software. This includes physician orders and notes, lab and test results, and other information that is not automatically interfaced from other hospital systems. St. Luke's plans to implement an enterprise EMR solution within the next two years, and eICU program leadership anticipate that this will increase the efficiency of the eICU staff and enable them to monitor more patients.

3.5 Workforce Development

St. Luke's eICU program currently employs one full-time clinical educator who oversees all training and workforce development activities related to the eICU program. The training approach differs in the St. Luke's Boise Medical Center, in other locations with ICU monitoring, and in the CAHs that have no ICU beds and only rely on the program for ED consultations.

For eICU staff, training was primarily conducted by the hardware/software vendor to teach the eICU nurses and physicians how to use the equipment and programs. Because the eICU staff are highly experienced in critical care medicine, they did not require additional clinical training, and the focus was on teaching them to use the technology components of the program. As software updates become available, the clinical educator works with the vendor to train the eICU staff in new features. St. Luke's Boise Medical Center and the remote sites all faced IT challenges with the rollout of the program, which made completing all of the training difficult. These challenges affected staff buy-in since the eICU was frequently unavailable due to IT downtime.

> "There was some angst that the eICU would be "big brother" watching us do our jobs…but that quickly went away."
>
> *– ICU Bedside Nurse, 2014*

In partner hospitals where the eICU program offers ICU monitoring, the training approach has evolved over the first year of the program. In the beginning, staff were educated on the program using a series of e-mails, posters and presentations at staff meetings. This level of training proved to be insufficient, and there was widespread anxiety about the program, particularly among bedside nurses who felt their clinical care was being questioned. In response to these staff concerns, program staff implemented a shadowing program for bedside nurses to spend a four hour orientation shift with their counterparts in the COR, to understand what information eICU staff work with, and how they are monitoring patients and providing consults. Many bedside nurses reported that their attitudes toward the program dramatically improved after their shifts in the COR. As a result, the four hour shadowing shift is now mandatory for bedside nurses in units where the eICU is monitoring patients.

In the subset of CAHs where the eICU offers ED consultations only, the training primarily revolves around teaching staff how to use the mobile cart equipment. Most of the training in the remote sites is conducted by the eICU clinical educator.

After the initial training when the program rolls out in each location, the clinical educator responds to ongoing requests for training based on the specific issues, experiences and needs of each site. Additionally, the clinical educator collects use scenarios based on feedback from bedside staff who rely on the eICU; these scenarios are incorporated into training for new units as the program continues to expand. The operations manager at St. Luke's Boise Medical Center develops and disseminates a bi-weekly newsletter, which includes an *Educator's Corner* to call attention to the different elements of the eICU program. The clinical educator at St. Luke's Boise Medical Center is developing an orientation module that will provide the most comprehensive introduction to new staff who join the eICU program,

The majority of bedside nurses we interviewed did not feel that the eICU program had increased their workload or substantially changed their workflows. The eICU program adds another layer of communication whenever a patient is admitted, transferred or discharged. Bedside nurses are required to make sure the eICU staff are updated whenever a workflow change occurs, but none of the bedside nurses feel this is burdensome.

After the program was implemented, program leadership hosted a number of meetings with bedside nurses, physicians, and other stakeholders to discuss how the program impacts staff workflow. These meetings have surfaced "pain points" or areas where things can be improved to make the program flow more smoothly on a day-to-day basis. For example, early in the program, the eICU physicians would give verbal orders to bedside staff but would not always fax written orders to be included in the patient's paper records. Bedside nurses raised this as an issue, and now eICU physicians always provide written/faxed orders in addition to the verbal instruction given to bedside nurses. The bedside nurses we spoke with reported that things have improved as the program has worked out the minor workflow kinks identified in these stakeholder meetings.

3.6 Implementation Effectiveness

This chapter presents the different areas in which the St. Luke's program staff believes the eICU is making a difference in quality of care delivery, patient health outcomes and cost savings. For each of these aim categories, we discuss how the St. Luke's team is measuring the program's impact, as well as how Abt Associates intends to measure the program's impact. Finally, we discuss unanticipated impacts that have arisen over the first several quarters of the program's implementation.

3.6.1 Better Care

In multiple interviews, we learned how participants believe the eICU program improves the quality of care their patients receive. The following are three high-level categories that were often repeated by case study participants.

Improved Continuity and 24-Hour Care

Numerous participants reported better continuity of care for patients, especially those with multiple complications, through eICU support. It is standard practice in ICUs across the country to perform important procedures and care during the day shift, and delay care at night until the ICU is fully staffed in the morning. A physician covering multiple ICUs at night, sometimes in more than one hospital, can only care for one patient at a time, and would often need to drive from one hospital to another to attend to

time-sensitive patient needs. An eICU physician can oversee care for many patients simultaneously, wherever assistance is needed. Several eICU physicians emphasized the impact that their availability overnight has on patient safety across the health system. Rather than physicians making decisions about patient care using the limited information that can be provided over the phone, the eICU physicians are able to make fully informed decisions about patient care, drawing on lab and test results, their own visual inspection of the patient, and the real-time monitoring of vital signs.

> "When I think back to how we used to handle things at night, it's almost frightening to think of the things we would handle on the telephone driving between hospitals or while taking care of another critical patient."
>
> *– eICU Physician, 2014*

The availability of an eICU physician overseeing care at night makes it possible to deliver care that would otherwise wait until morning. Examples include patients being extubated during the night (resulting in fewer hours ventilated and sedated), and patients being discharged from the ICU as soon as they are ready, rather than waiting until their physicians return the next morning. The eICU physicians have authority to place orders for patients they are monitoring overnight, eliminating the need for a bedside nurse to either wake up a patient's attending physician to place necessary orders, or wait until the start of the day shift. Another benefit of physician availability at night is the ability to provide palliative care for an actively dying patient, removing ventilator and other mechanical support at night rather than waiting until morning to complete end of life care.

> "In the past, I had a lot of anxiety about waking up a doctor…With the eICU, not having to worry about waking someone and having to explain everything in one phone call is a huge improvement. It's a wonderful program that helps our patients."
>
> *– ICU Bedside Nurse, 2014*

The eICU also offers better continuity of care when patients transfer from a rural CAH to the St. Luke's Boise Medical Center. In many cases when a transfer is necessary, the Boise Medical Center already has patient information and background through the eICU monitoring software. This information allows bedside nurses and physicians to place preparatory orders in advance of the patient's arrival, avoiding treatment delays. At St. Luke's Wood River CAH, staff reported that the eICU has been especially helpful in giving bedside nurses an earlier indication of whether a patient needs to be transferred. For example, a bedside nurse reported that the eICU physicians advised early in a patient's stay that a transfer would likely be necessary; the Wood River staff stopped attempting to treat the patient and instead prepared him for transport.

Serving Patients in their Communities

As stated earlier, one of the problems the St. Luke's program aims to solve is the dearth of trained and experienced critical care nurses and physicians, in both urban and rural areas. In rural areas particularly, leveraging the resources of the eICU program has the potential to allow patients to be treated locally, rather than incurring an expensive and potentially traumatic transfer to a tertiary medical center. At Wood River, the only CAH with ICU monitoring (two beds), some critical patients may be able to stay in their community, with the oversight and advice of the eICU staff, rather than being transferred.

Most CAHs do not have intensivist physicians or nurses, even though there may be a few beds equipped to function as an ICU. For these settings, the eICU monitoring and consultation may help to improve the critical care skills of rural bedside nurses through the mentoring and teaching provided by eICU nurses and physicians. At St. Luke's Wood River CAH, several individuals predicted that as the critical care skills of bedside nurses improve through interactions with eICU staff, local clinicians will grow more

confident in the bedside nurses' skills and be more comfortable treating patients locally rather than transferring them.

Adherence to Standard Clinical Guidelines

The monitoring of clinical best practice guidelines by eICU staff is another area in which the program is improving quality of care. The vendor software used in the COR monitors for trends and deviations from established clinical guidelines, for conditions such as sepsis (3 hour care bundles) and processes to prevent ventilator associated events (VAP). Rapid identification of deviation from guidelines, and reminders to bedside nurses of next steps in care protocols, have the potential to enhance care and prevent avoidable complications.

St. Luke's Measurement Strategy

St. Luke's collects data on a number of quality measures which they regularly report to CMS and use for internal quality improvement. These measures include:

- Hospital-acquired complications for ICU patients for central line associated bloodstream infections, deep vein thrombosis, pressure ulcers, and VAE
- Adherence to the best practice protocols for sepsis and VAE
- Patient mobility progression
- Inter-hospital transfers for a higher level of care
- Average number of ventilator days per patient

St. Luke's currently conducts a patient/family satisfaction survey in the tertiary locations where the program is implemented. The survey is not conducted at Wood River or other CAHs, due to the low patient volumes. A baseline survey is fielded for one month before "going live" for all ICU patients and the survey is fielded again for one month, approximately three months after "going live." Every six months, the survey is repeated for all ICU patients seen in the prior 30 days. The survey covers a variety of topics including patient or family perceptions of the quality of care they received while in the ICU. St. Luke's also conducts a web-based physician satisfaction survey on a rolling basis in each of the tertiary sites where the intervention is implemented. A one-time nurse satisfaction survey was conducted to solicit feedback on the staff who work in the eICU.

St. Luke's is considering implementing a new survey tool to monitor the impact of the program. This survey would be solely for staff in CAHs where the program is offering ED consultations. The survey would be administered soon after an ED consult and would ask the CAH physician or nurses involved to provide feedback regarding the value of the eICU consult, in care of the patient.

3.6.2 Better Health

Patient outcomes may be improved through eICU oversight and management. Sepsis management is one area where clinicians told us that patient outcomes are improving, because of the monitoring by the eICU staff. Program staff anticipate that the eICU program will also yield reduced readmissions, reduced length of stay (both ICU length of stay and overall length of stay), and reduced transfers.

St. Luke's Measurement Strategy

St. Luke's collects data on a number of outcome measures, which they regularly report to CMS and use for internal quality improvement. These outcome measures include:

- ICU mortality rates
- ICU mortality ratios (actual versus predicted)
- 48-hour and 30-day mortality rates for patients transferred from the ICU
- Hospital mortality ratio (actual versus predicted)
- ICU, Non-ICU, and Hospital Length of Stay
- Severity adjusted ICU length of stay ratio (actual versus predicted)
- Readmissions rates (30-day and 48-hour)

3.6.3 Lower Cost

Program staff at St. Luke's anticipate that the eICU program will eventually reduce costs for their health system, as well as for patients and payers. In the short-run, the primary area where program staff reported potential cost savings is likely to be reduced medical errors and complications (VAE, sepsis), and shorter ICU length of stay. Many of the individuals we spoke with were confident that the eICU nurses and physicians have caught numerous "near misses" that could have been costly errors. Bedside nurses in both Boise and Wood River described instances where the eICU staff intercepted inappropriate orders for patients before they were administered, improving the quality of care provided to the patient and reducing a potentially costly error and litigation risk.

St. Luke's believes that the eICU program is helping to reduce costs during the first day of an ICU stay (typically the most expensive day), particularly for patients who transfer to the Boise Medical Center, because of improved care coordination prior to transfer facilitated by the eICU.

Reducing costs during the first ICU day, reducing ventilator days, and reducing ICU length of stay, are all potentially important cost reductions. These shorter stays and reduced use of ventilators will not reduce costs for Medicare, because the Inpatient Prospective Payment System reimburses hospitals based on diagnosis related groups (DRGs), regardless of length of stay or resources expended during the admission. These reductions in costs to the hospital could be important, however, in a shared savings or bundled payment context.

As the program has matured, program staff have added a new measure of avoided ICU days. This measure compares a patient's predicted length of stay (based on their APACHE score) with the actual length of ICU stay. The difference is the number of avoided ICU days which is multiplied by the average cost per ICU day, to quantify cost savings to the hospital.

St. Luke's Measurement Strategy

St. Luke's collects data on a number of cost measures, which they regularly report to CMS and use for internal quality improvement. These cost measures include:

- Reduced transfers from remote locations to the Boise Medical Center as a result of the eICU monitoring and ED consultation;

- Reduced ICU and total length of stay;
- ICU costs per patient day and per patient stay
- Total hospital cost per ICU patient
- Ancillary costs per ICU patient
- Reduced readmissions; and
- Avoided ICU days

During initial interviews in 2014, program staff had plans to begin collecting data on total cost savings, benefit-cost ratios, and cost savings due to avoided hospital transfers. During follow-up interviews in 2015, they explained that small sample sizes make most of these measures of limited utility.

3.6.4 Outcomes That Can Be Measured Using Medicare/Medicaid Claims

While some of the expected improvements in care, health outcomes and cost cannot be measured using Medicare/Medicaid claims data (e.g., reduced hospital cost, improved mobility, adherence to best practice guidelines), many others, such as reduced length of stay, reduced readmissions, and fewer patients reaching outlier status, can be measured using claims. One challenge in evaluating the St. Luke's program will be the size of the patient population and whether the combined set of intervention patients will be large enough in any given calendar quarter or year, to measure improvement using a statistically rigorous regression-based difference-in-differences approach.

St. Luke's has other concurrent quality improvement initiatives taking place throughout their health system. Several participants mentioned ongoing programs that compete for time and attention from ICU staff, but that also may improve ICU patient outcomes. One such initiative is a patient mobility program in the Boise Medical Center ICUs. A second evaluation challenge will therefore be attribution: it will not be possible to attribute improved patient outcomes to the eICU initiative alone, in isolation from other concurrent programs in participating hospitals and ICUs.

3.6.5 Unanticipated Impacts

In addition to perceived impacts related to the program aims, several participants discussed unanticipated impacts that the program has had throughout the St. Luke's health system. One example discussed at length by eICU physicians was the ability to observe, and potentially standardize, clinical care protocols across the health system. Lacking a shared EMR, there was previously no mechanism through which physician leadership could observe and understand differences in clinical protocols and order sets. The eICU fosters interaction among clinicians in multiple hospitals, which makes these differences quite apparent.

> "[The eICU] has been such a dynamic learning process. When we first started, we didn't know what we didn't know. Now, we are able to anticipate new issues and work through them."
>
> *– eICU Nurse, 2015*

Between our first and second rounds of interviews, affinity groups were convened across the St. Luke's Health System, with the authority to develop and fast track approval of standardized order sets. Many nurses and physicians we interviewed are developing standardized order sets and procedures that are gradually being implemented across the St. Luke's health system. This is an unanticipated impact of the eICU program that hospital leadership repeatedly emphasized, and which they expect will lead to improved quality of care and patient outcomes.

Finally, as discussed earlier, one of the unanticipated benefits of the eICU program is that eICU staff mentor bedside nurses, particularly at night (when new bedside nurses are often assigned), and in participating CAHs. One night shift nurse explained that when she calls the COR at night with a question about a patient, she is given the reasoning behind the decision the eICU physician is making, which improves her nursing skills and confidence. Such learning opportunities are rarely possible when waking an attending physician during the night.

3.7 Context

In each interview and focus group during the site visit, participants were asked about lessons they have learned in the year since the program began. This chapter sorts these lessons learned into four different categories: communication and stakeholder buy-in, staffing, measurement and self-monitoring, and sustainability.

3.7.1 Communication

Many individuals in program administration and hospital leadership emphasized the importance of relationship building and communication to the success of the eICU program. The program was first implemented in the Boise Medical Center where experienced bedside nurses and physicians were reassigned to the eICU. The eICU staff had preexisting relationships with bedside nurses and attending physicians, fostering an environment of trust and open communication. However, when the program was implemented in remote locations, program staff quickly realized the critical need to build relationships with staff and leadership in those institutions. In each newly-implemented hospital, there were initial feelings of anxiety or mistrust from staff about what the eICU nurses and physicians were watching and monitoring. To overcome these anxieties, the program built time into the implementation schedule to introduce bedside nurses to eICU staff and effectively communicate the goals of the program. A shadowing program allowed bedside nurses in remote sites to visit the COR, so they could observe the data displays used by eICU staff, and watch the video interactions from the other side of the camera. Many bedside nurses emphasized how important those opportunities were in changing their attitude toward the eICU program.

Another lesson learned was the importance of obtaining buy-in from stakeholders at all levels of the program, from bedside nurses to senior hospital leadership. Several bedside nurses in Boise spoke about the importance of having local St. Luke's physicians working in the COR overnight. These physicians had credibility and a reputation with the bedside nurses and hospital leadership already, so they were able to effectively champion the program throughout the health system. Most of the eICU physicians still work the majority of their shifts on the ICU units, so those relationships have been maintained as the program has matured.

> "The greatest advantage of the program is the ability to bring the extra expertise to non-metropolitan areas such as ours. It is useful for rural settings to have access to the expertise of larger metropolitan facilities that offer state or the art services."
>
> *– Attending Physician, 2015*

Buy-in from attending physicians was especially important, because those who were antagonistic toward the eICU concept would instruct nurses not to call the eICU, and instead continue the practice of phoning the attending physician at night. Attending physicians are labeled as "Category 1" (preferring to manage all patient care, and not allowing any orders to be written during the night by the eICU physician with the exception of emergent/life-threatening situations) or "Category 2" (handing off responsibility to the eICU physician at night). eICU physicians and nurses are aware of which category each attending physician

falls into, and bedside nurses are careful to defer to the preferences of attending physicians. Over time, however, the eICU medical director (who also works night shifts in the eICU) has determined that it is impossible for the eICU to monitor patients safely if the eICU physician cannot also act on the information being monitored—if all decisions must be made by the attending physician. Gaining buy-in from "Category 1" physicians required relationship building from the eICU medical director and other eICU physicians, and endorsement from ICU nurses, to persuade physicians of the eICU value. Now, when the eICU program agrees to monitor another hospital's ICU at night, it is now the standard of care that the eICU clinicians can both monitor patient progress and act when necessary. During follow-up interviews, program staff and eICU physicians reported that they have made significant progress in reducing the number of "Category 1" physicians by targeting communications to attending physicians who were uncomfortable or unfamiliar with the eICU concept , answering questions, and demonstrating the effectiveness of the eICU. According to the eICU staff, most of the remaining "Category 1" physicians tend to be those who very rarely admit their patients to the ICUs at St. Luke's.

Similarly, the eICU physicians emphasized the importance of obtaining buy-in from bedside nurses. They believe that the ultimate decision about whom to call when there is a question about a patient falls to the bedside nurse; if nurses do not believe the eICU program adds value, the program could not succeed.

During the initial in-person site visit in 2014, we learned that despite all the lessons learned about relationship building and obtaining buy-in, the eICU physicians had not been successful in obtaining buy-in from St. Luke's neurologists and critical neurology patients are not monitored by the eICU. In 2015 follow-up interviews, program staff reported that many of the St. Luke's neurologists now favor the eICU concept and care cooperating in the development of a pilot telestroke program. In addition to remote monitoring, St. Luke's neurologists will provide consultation.

A final implementation lesson learned was how difficult it is to overcome the St. Luke's health system's underdeveloped electronic information systems. As noted earlier, the eICU program is a technology-dependent program and it was implemented in a setting with multiple electronic and paper-based systems that are not connected. Complex workarounds have been necessary to allow the eICU staff to effectively monitor patients. Examples include manually inputting patient orders, physician notes, lab test results and other information residing in other systems into the eICU vendor software.

3.7.2 Staffing

Program administrators described several lessons learned related to staffing. First, to meet the timeline of the Award implementation, St. Luke's staffed the eICU with highly experienced physicians and nurses who were previously providing bedside patient care; this left openings in the bedside positions and created a need to hire new bedside staff. Many interviewees described this "ripple effect" on ICU staffing. Hospital leadership discussed how time and resource intensive it can be to recruit experienced critical care nurses and physicians. At the time of our follow-up interviews, the eICU physicians are still working some of their day shifts in the ICUs, in addition to rotating the night eICU shifts.

Program administration discussed alternate staffing models for the eICU program that they may explore in the long-run to alleviate some of these staffing concerns. For example, they have discussed the potential for using hospitalists or a combination of critical care trained nurse practitioners and physician assistants either in the eICU overnight in lieu of critical care physicians or to cover openings at the bedside. These discussions are ongoing and may influence the staffing model of the eICU program in the future.

Staff turnover had some implications for program implementation. The absence of a Project Director slowed expansion of the program, and could have dampened the Emergency Department consultation element of the program due to the gap in outreach and leadership advocacy.

3.7.3 Measurement & Self-Monitoring

One difficulty program staff reported with operating this multi-site program has been collecting standardized data from all of the facilities, as their capabilities and electronic systems differ. Over time, program administration has developed a set of standard measures that they share with new sites as they join the eICU program. New partner sites are now required to commit to providing data on this standard set of measures on an ongoing basis, as a prerequisite of their partnership with the eICU. The IT systems analysts at St. Luke's work hard to help all of the partner sites understand the requirements for providing these data and provide detailed data specifications at the beginning of each relationship. Staff turnover, particularly in the remote sites, has also led to delays in collecting the necessary data, especially baseline data, to fully monitor the impact of the program.

Program staff have also adapted how they share results of ongoing self-monitoring with their partner sites. They began by generating site-level reports, providing data on every metric to each site on a quarterly basis. Most site representatives indicated that these voluminous results were "information overload" and requested more user-friendly reports. Program staff now create simplified reports in PowerPoint format for leaders at remote sites, which they can then adapt for their own staff presentations. It is unclear whether the information is widely disseminated. Attending physicians in remote locations reported not having seen any reports on the impact of the program in their local hospital. In addition, reports for the CAHs are challenging due to small numbers of patients supported by the eICU in each of those hospitals.

3.8 Sustainability

The eICU physicians we spoke with saw the eICU as a new "standard of care" for critically ill patients and program administration envisioned that eICU programs (at St. Luke's and elsewhere) would eventually monitor every critical care bed throughout the northwest, because of the value and potential of the program to improve patient outcomes and reduce hospital costs. Recent legislation passed in Idaho has made it easier for health care providers to bill for telephone services, which has spurred many conversations at St. Luke's about how to continue not only the eICU program, but also other telehealth offerings.

Program administrators believe that the eICU program can cover its operating costs ($2.5 million/year) and generate benefit to the health system when the program achieves a size threshold of 80 to 85 critical care beds. They anticipate they will reach this threshold before the HCIA funding ends in 2015. Potential sources of funding to support a growing and sustainable program include: licensing and monitoring fees (paid by partner sites), additional Award funding from private sources, decreased costs to the health system, and increased reimbursement from payers for better outcomes as a result of the program.

> "In a state such as Idaho, sometimes a patient will present to a critical access hospital who really does need intensive care, but due to weather-related conditions that patient will not be able to transfer….This is when telehealth becomes very valuable"
>
> *– Program Staff, 2015*

Participants at St. Luke's Boise Medical Center and St. Luke's Wood River CAH consistently emphasized that they have seen the value of the eICU program and would like additional specialty

services, such as psychiatry, neurology, and pediatric consultation. Hospital leadership became more engaged by the second evaluation of the eICU program. Hospital leadership's initial concern about losing personal relationships due to program expansion did not prevail as the demand for this technology in other settings, especially for rural areas increased. St. Luke's Boise Medical Center is planning a pilot study for teleneurology using mobile carts; leadership has also discussed potentially adding telepharmacy for the critical access hospitals that have no pharmacist available at night.

A long term vision articulated by program administrators and hospital leadership, is to use the eICU monitoring (telemetry) and automated best practice alerts in other settings (e.g., post-acute, home) to provide ongoing monitoring of patients and keep them out of more resource-intense setting.

During follow-up interviews in 2015, it became apparent that St. Luke's is shifting toward a broader telehealth platform, with the eICU being one element in that platform. The eICU is still the only telehealth offering but its success is leading to consideration of specialty telehealth services. This shift aligns with the hiring of a new Telehealth Director at St. Luke's, not limited to the eICU, indicating the priority the St. Luke's Health System places on sustaining and expanding telehealth.

3.9 Conclusion

The St. Luke's eICU program offers different care-enhancements in different types of facilities and at different times of day. In larger urban hospitals, the eICU staff offer daytime monitoring of patient trends and best practice guidelines, the ability to "watch" a patient while a bedside nurse is busy in another room, and support to newer nurses who benefit from consultation with an experienced colleague. At night, the larger urban hospitals are generally staffed by less experienced nurses and the eICU physician provides oversight to support continuing care that would otherwise wait until morning. In the past, the on-call night physician drove between two hospitals, dealing with time-sensitive patient care issues; that same physician now oversees care from the COR, with monitoring and technology that supports faster attention to the needs of patients in multiple ICUs and hospitals.

At St. Luke's Wood River CAH, the daytime monitoring has only taken place for a handful of patients over the past two years, and has likely had little measureable impact on outcomes or cost. The night availability of the eICU physician may have benefited a few more patients, avoiding care delays. The ED consultation component has been used only sporadically at St. Luke's Wood River thus far; there have probably not yet been any measurable impacts on health outcomes or cost from ED consultations.

The eICU program may be having the most impact in ways that are difficult to measure, including preventing medical errors (measuring something that does not happen is difficult and requires a very large patient population), improving adherence to best practice guidelines, and avoiding care delays at night. These improvements may, however, contribute to other measurable outcomes, such as reduced readmissions, even if they cannot be measured directly using data available to Abt evaluators.

4. Quantitative Results

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total Medicare episode spending. The admission measure is not relevant for the St. Luke's eICU program because patients are already admitted when they receive the intervention. The results presented below are for the following Core measures:

- 30-day (all cause) readmissions to an acute care hospital following an 'index' admission. Index admission is defined as an admission for a patient eligible for the eICU innovation, in either an intervention or comparison hospital.
- 30-day post-discharge (all cause) visits to an acute care hospital emergency department following an index admission.
- Total Medicare spending for 60 days including the index admission and all Medicare spending for 60 days after discharge.

The St. Luke's program also aims to reduce length of stay, and avoid complications through adherence to best practice guidelines. We therefore present results for the following additional measures:

- Length of stay (LOS)
- Discharge destination

Please see the Technical Appendix for description of how each outcome measure is specified and our methods for the difference-in-differences (DD) regression analyses for total Medicare episode spending, 30-day hospital readmissions and ED visits, LOS, and discharge destination. We graphically present quarterly DD estimates for each outcome, and report a single DD estimate for the overall (pooled) effect of the program for each outcome in subsequent tables. We additionally report median regression estimates of 60-day Medicare cost. Results are reported in section 2.2 below.[54]

All models include controls for patient age, squared age, gender, race, Hierarchical Condition Category (HCC) score in year of treatment, squared HCC score, eligibility for Medicaid at any time during observation period (2010-2014), as well as indicators for the quarter in which the episode occurred.[55] An indicator is also included for individuals with missing HCC scores.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial

[54] The lone exception is discharge destination, where quarterly estimates are reported in table form due to the multitude of possible outcomes.

[55] The HCC score was developed by CMS to determine an individual's expected Medicare expenditure relative to the average based on their health status as well as demographic information (e.g. age, gender).

claims (i.e., those that are mid-processing) are included.[56] We believe this is an accurate way to compare time periods.

4.1 Intervention and Comparison Groups

4.1.1 Registry Information

St. Luke's program staff provided patient registry information for four hospitals: Wood River, Boise Meridian, Boise Medical Center, and Magic Valley. We analyzed data for the large medical centers: Boise Meridian, Boise Medical Center, and Magic Valley. Wood River hospital had only a few patients in the registry, and both that hospital and its patients are very different from the other three hospitals; we therefore did not include Wood River in this analysis. Boise Medical Center and Boise Meridian share a Medicare provider number, but started their eICU programs at different times. Boise Medical Center's first registry patient was admitted on January 6, 2013, and Boise Meridian's was about one week earlier, on December 26, 2012. The two facilities cannot be differentiated in the claims data due to the identical provider number and thus were estimated to begin at the same time, December 26, 2012. There was one patient treated on December 26, 2012 and this claim was aggregated into the following quarter. Thus the estimated intervention group for the first quarter of 2013 includes patient claims from the December 26, 2012 through March 31, 2013.

4.1.2 Selection Rules

The section below explains how we defined a set of criteria or rules that were used to create both the comparison and intervention groups. The criteria were created using information that is available in the Awardee registry and in Medicare claims. These were then uniformly applied to patients from intervention and comparison facilities to select the final intervention and comparison populations.

Participating hospitals implemented the program in some, but not necessarily all, of their ICUs. A small percent of the Medicare claims associated with the registry patients contain a revenue code indicating CCU (coronary care unit) care but not ICU (intensive care unit) care. Boise Medical Center and/or Boise Meridian included both ICU and CCU patients in their intervention. Patients in the Magic Valley Hospital registry all had revenue codes indicating ICU care and none indicated CCU care. We do not know if this hospital has a dedicated CCU, or whether the program was not active in that unit. Given this uncertainty, we included all Medicare patients with inpatient claims having a revenue code associated with the CCU as well as those with ICU revenue codes, as follows:

- Intensive care unit revenue center codes: 0200, 0206 (General and Intermediate)
- Coronary care unit revenue center codes: 021X

The St. Luke's eICU program is offered to several small critical access hospitals (CAHs), in addition to the urban Boise medical centers. Data from all of the larger acute care hospitals are pooled in our analyses. The small CAHs had very few patients, and the intervention (ED consultation) differs from that in the larger hospitals. We therefore excluded the CAHs from the impact analyses presented below.

[56] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes. Additionally, all outcomes exclude decedents.

The rules described above result in the following match between registry data and the rules we are able to apply based on data in Medicare claims:

Exhibit 1: Match Rates by Quarter

	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4
Registry with Medicare FFS claim (A)	2	252	294	354	455	439	466	437	404
Registry Patients Not Captured by Abt rules (B)	0	7	12	15	15	24	21	26	31
Miss Rate (B/A)	0%	3%	4%	4%	3%	5%	5%	6%	8%
Estimated based on Abt rules, with Medicare FFS claim (C)	20	325	297	381	494	446	474	451	432
Match between Estimated and Registry (D)	2	245	282	339	440	415	445	411	373
Estimated by Abt rules, Not in Registry	18	80	15	42	54	31	29	40	59
Accuracy Rate (D/C)	10%	75%	95%	89%	89%	93%	94%	91%	86%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Accuracy rate = Percent of admissions with a Medicare FFS claim that are identified using Abt's rules and are also in the registry (indicates that a few patients who are captured by our rules were not in the registry and apparently did not receive the intervention)

Miss rate = Percent of admissions with a FFS claim that meet Abt's inclusion criteria but are not in the registry (indicates that nearly everyone in the registry meets our criteria—we miss very few)

In 2013 and 2014 the high accuracy and low miss rates indicate that our rules are sound and can be used to select appropriate comparison and baseline groups.

Exhibit 2 below shows average patient characteristics for the Awardee and comparison groups in both the Baseline and intervention periods. The demographic summary statistics serve two purposes. The first is to provide a sense of the population demographics in the St. Luke's intervention population. The second is to show that the demographics are similar for intervention and comparison groups, with relatively wide standard errors. The wide standard errors reflect the diverse patient populations treated in the intervention and comparison facilities during the entire period of study.

Exhibit 2: St. Luke's Summary Statistics

	Awardee				Comparison			
	Intervention Period (N=4,256)		Baseline Period (N=3,596)		Intervention Period (N=7,531)		Baseline Period (N=6,127)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Female	0.49	0.50	0.47	0.50	0.48	0.50	0.48	0.50
Nonwhite	0.05	0.21	0.04	0.19	0.04	0.21	0.04	0.19
Age	71.90	12.44	73.00	11.80	72.68	12.24	72.97	12.59
HCC Score	1.69	1.91	1.73	1.79	1.61	1.78	1.72	1.82
Missing HCC	0.07	0.25	0.05	0.21	0.08	0.27	0.05	0.22
Medicaid Eligibility	0.38	0.49	0.47	0.50	0.38	0.49	0.48	0.50

The intervention and comparison groups are well-matched demographically, in both baseline and intervention periods. We note that the share of patients eligible for Medicaid declined in both the Awardee intervention and comparison groups.

4.2 Core Measures: Results

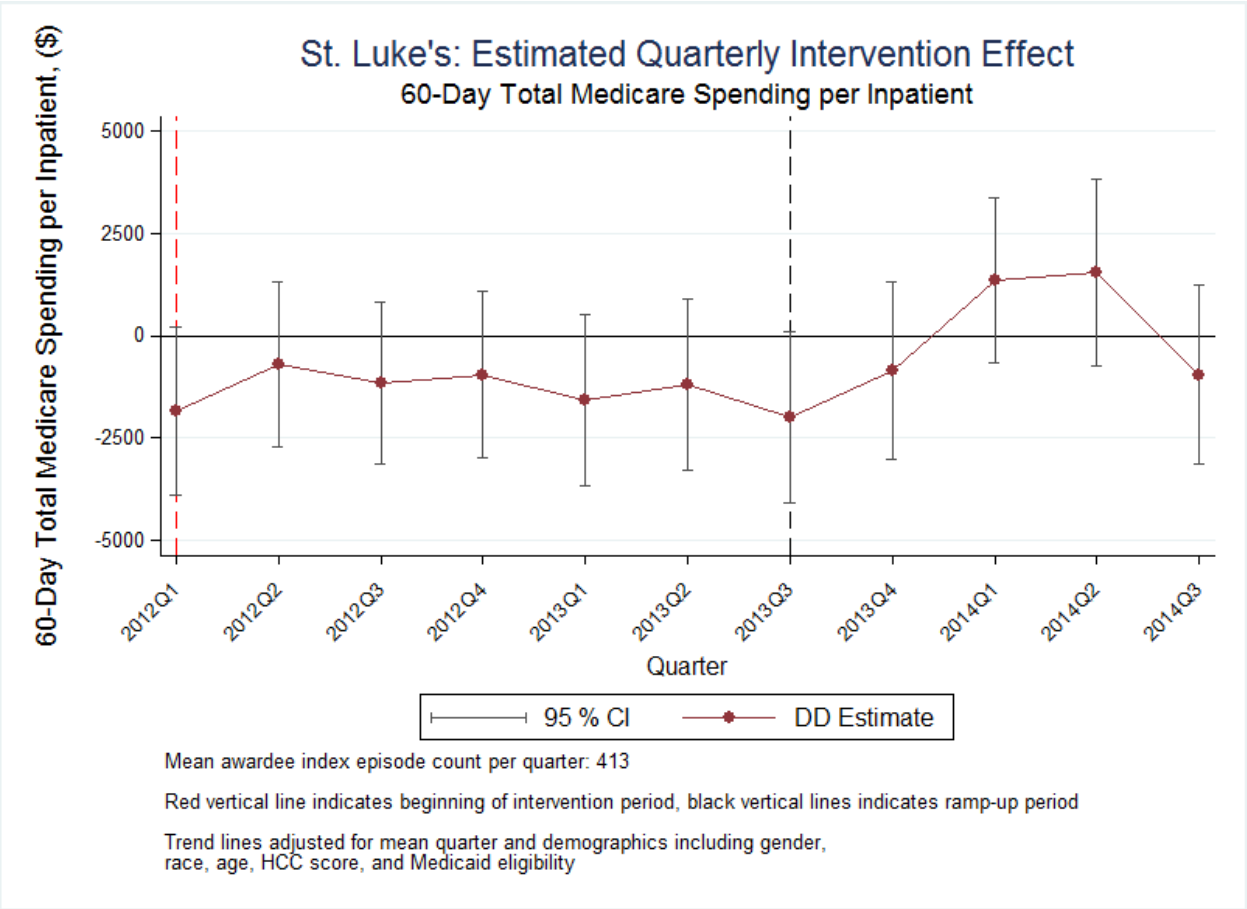
Implementation did not take place on the same day in all participating ICUs and hospitals. In the graphs below, the red vertical line shows the beginning of the intervention period and the black vertical lines indicate the dates when various participating ICUs and hospitals began their eICU implementation. All estimated changes in utilization are based on twelve quarters of post-implementation data. One less quarter of data is included for the spending measure compared to the utilization measures, due to the lag required for post-acute claims to become available for analysis.

4.2.1 Medicare Episode Spending[57]

Exhibit 3 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days. While none of the differences were statistically significant, Medicare spending was consistently lower for intervention patients until the beginning of 2014, after another hospital joined the intervention. By the third quarter of 2014, Medicare spending is once again lower for intervention patients, which may suggest the beginning of a new trend in decreased spending.

[57] We do not adjust for inflation in measures of Medicare spending. The DD regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 3: Mean Medicare Episode Spending



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Ordinary Least Squares (OLS) regression estimates for the St. Luke's program (Exhibit 4) do not indicate a significant relationship between the intervention and Medicare episode spending during the 60 days starting with the index admission. There was an average increase in Medicare episode spending of roughly $208 per patient, but was statistically insignificant.

We additionally estimate the effect of the intervention on median Medicare spending per episode. The intervention increased median Medicare spending by approximately $83 an episode; this result is statistically insignificant.

Exhibit 4: DD Estimated Effect of Intervention on Mean 60-day Medicare Costs

St. Luke's		
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	207.61 (497.60) [21,510]
Intervention Effect (Median Regressions)	Estimate Standard Error Sample Size	82.98 (172.40) [21,510]

*p<0.1 **p<0.05 ***p<0.01

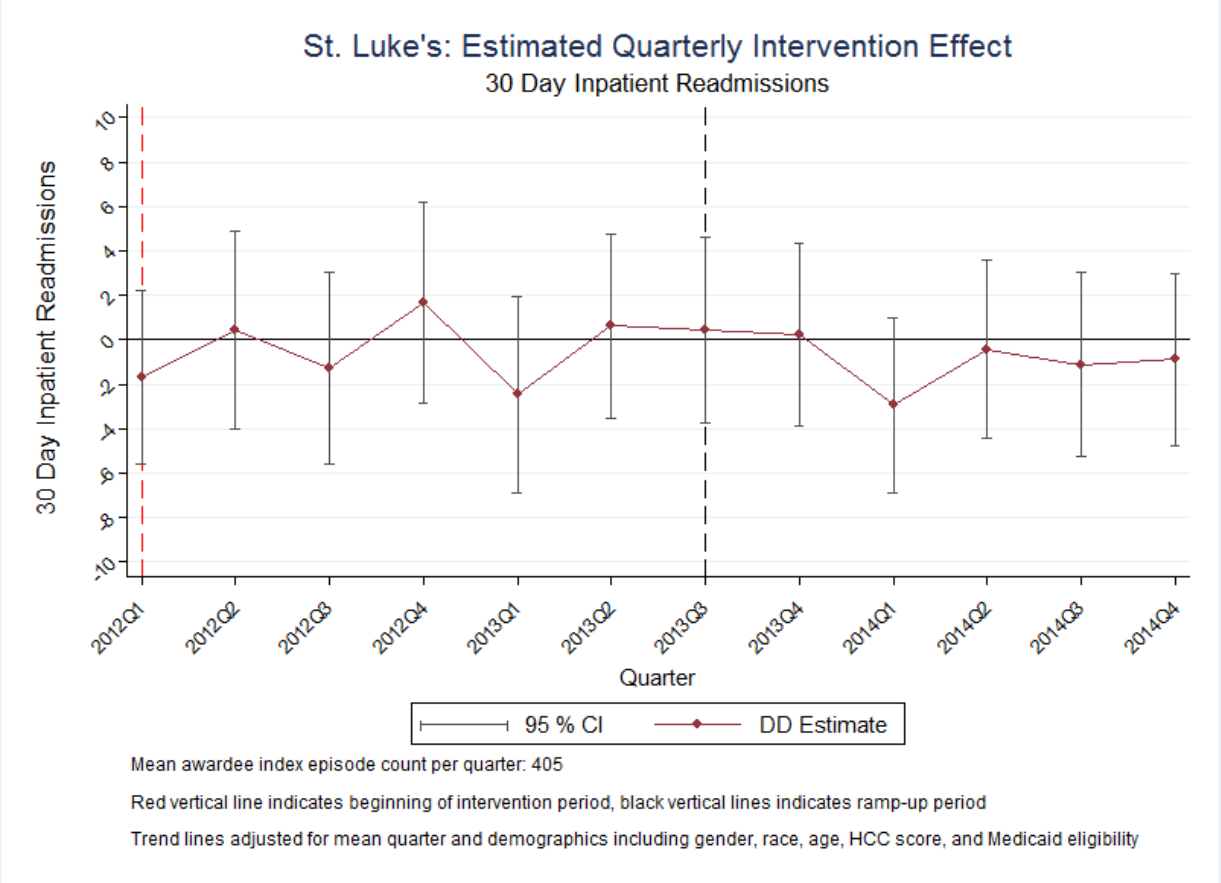
Source: Abt Associates, May 2015.

4.2.2 Readmissions

Exhibit 5 (hospital discharges followed within 30 days by a readmission) shows no clear pattern across quarters, and we do not estimate a significant intervention effect in any quarter.

Exhibit 6 shows the estimated intervention effect pooled across all quarters. We find that the intervention effect reduced the rate of 30 day inpatient readmissions by a statistically insignificant 1.09 percentage point; more quarters are likely needed for greater statistical precision with this estimate.

Exhibit 5: Inpatient Readmissions



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 6: DD Estimated Effect of Intervention on Inpatient Readmissions (All quarters)

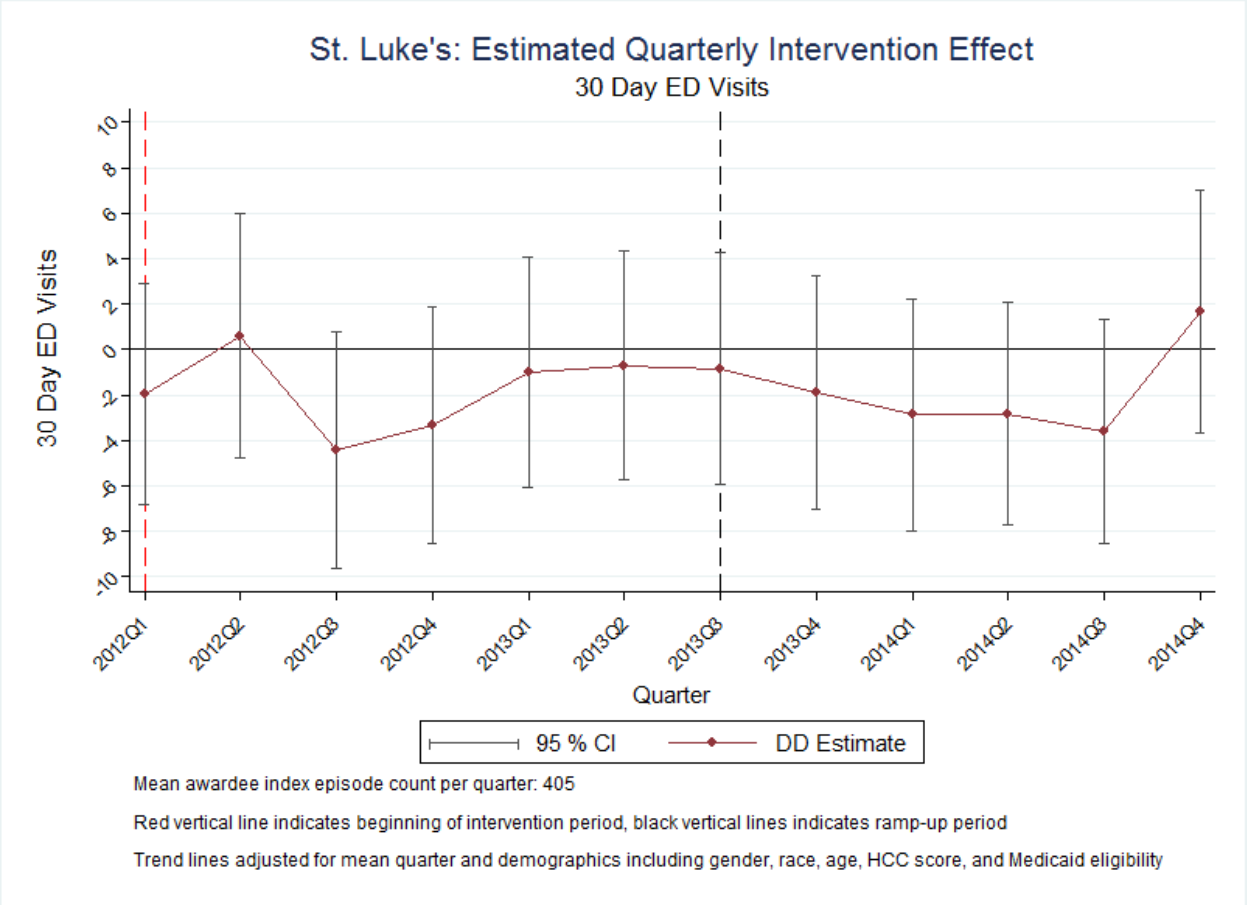
St. Luke's		
Intervention Effect	Estimate Standard Error Sample Size	-1.09 (0.92) [22,349]

*p<0.1 **p<0.05 ***p<0.01

4.2.4 Post-discharge ED Visits

Exhibit 7 (discharges followed within 30 days by an ED visit) shows a consistently lower 30-day ED visit rate for intervention patients relative to comparison and baseline patients, with the exception of Q4 2014. Although this finding is insignificant in all of the individual quarters, we do estimate a statistically significant decrease of 1.92 percentage points for the program pooled across all quarters (Exhibit 8).

Exhibit 7: Post-discharge ED Visits



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 8: DD Estimated Effect of Intervention on post-discharge ED Visits

St. Luke's		
Intervention Effect	Estimate Standard Error Sample Size	-1.92* (1.12) [22,349]

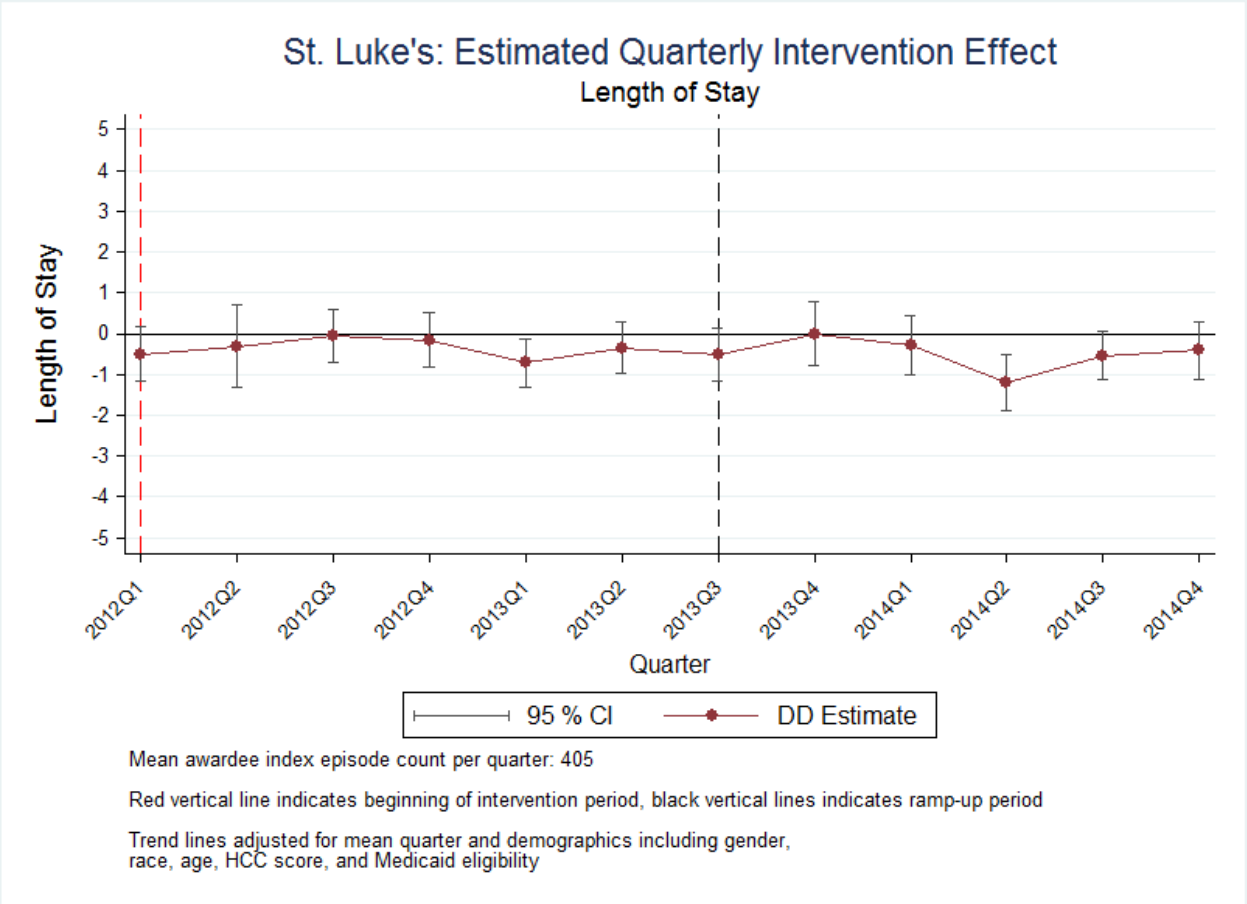
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

4.2.5 Index Admission Length of Stay (LOS)

Important goals of the St. Luke's program are to improve the timeliness of care delivery in the ICU, and reduce complications, which together should contribute to shorter length of stay for the Index admission. Exhibit 9 shows a slight but sustained decrease in patient episode length of stay for all quarters of the intervention, although none are statistically significant. Exhibit 10 pools all data and shows an estimated reduction of 0.24 days, which is also statistically insignificant.

Exhibit 9: Index Admission Inpatient LOS



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

Exhibit 10: DD Estimated Effect of Intervention on Inpatient LOS

St. Luke's		
Intervention Effect	Estimate Standard Error Sample Size	-0.26 (0.16) [22,349]

4.2.6 Discharge Destination

Below, Exhibit 11 shows the DD estimates for discharge destination following the index hospitalization. Overall, we find that there are no large changes in discharge destination as a result of the intervention. We see a few quarters with a statistically significant difference in patient discharge destination patterns, but no sustained trend that is statistically different from zero.

4.2.7 Conclusions

- We estimate that the St. Luke's intervention is associated with a statistically significant reduction in 30-day ED visits, a difference of nearly 2 percentage points.
- Our evidence suggests that the St. Luke's intervention may be reducing inpatient length of stay but the results are statistically insignificant.

Exhibit 11: DD Estimated Change in Episode Discharge Destination

	2012 Q1	2012 Q2	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3	2014 Q4	Overall
Home													
DD Estimate	-0.65	7.68**	2.58	-0.81	-3.00	4.38	0.15	-2.25	-4.71	3.83	0.14	1.53	0.00
SE	(3.30)	(2.94)	(3.01)	(3.11)	(3.08)	(2.97)	(3.07)	(3.08)	(3.07)	(2.94)	(2.95)	(3.08)	(1.35)
Home Health													
DD Estimate	3.47	-0.57	-0.97	-0.37	0.84	0.22	3.48	3.32	3.22	0.44	0.01	2.65	0.78
SE	(2.70)	(1.96)	(1.99)	(1.92)	(2.13)	(2.07)	(2.46)	(2.33)	(2.39)	(1.99)	(1.93)	(2.23)	(0.92)
Skilled Nursing Facility / Inpatient Rehabilitation Facility / Long-Term Acute Care / Other Nursing Home													
DD Estimate	-1.55	-6.52**	-1.54	0.99	0.78	-2.09	-2.80	0.58	1.97	-2.48	0.57	-3.10	0.04
SE	(2.91)	(2.52)	(2.76)	(2.95)	(2.86)	(2.70)	(2.71)	(2.85)	(2.89)	(2.69)	(2.78)	(2.68)	(1.27)
Other													
DD Estimate	-1.27	-0.60	-0.07	0.18	1.38	-2.51***	-0.83	-1.64	-0.49	-1.79*	-0.72	-1.08	-0.83
SE	(1.10)	(1.25)	(1.38)	(1.44)	(1.70)	(0.72)	(1.09)	(0.95)	(1.11)	(0.95)	(1.15)	(1.00)	(0.55)

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates, May 2015.

Appendix B10: University of Chicago

Integrated Inpatient/Outpatient Care for Patients at High Risk of Hospitalization

1. Executive Summary

This chapter presents both quantitative and qualitative findings of Abt Associate's evaluation of the University of Chicago (UC) Comprehensive Care Program study (CCP). The CCP, a randomized control trial study, was established to provide care to older patients with multiple chronic conditions and a pattern of high use of costly hospital services. Patients are enrolled while in the hospital or ED at the university medical center, at health fairs in Senior Housing facilities, and in other community venues. Program staff identify eligible patients and, with their consent, randomize them to intervention or control arms of the study. After enrollment, intervention patients receive program services for all subsequent primary care and acute care at the University of Chicago Medical Center; control patients continue with their usual sources and patterns of care, some of which is also at the University of Chicago Medical Center.

The CCP program aims to improve care continuity by having the same physician (supported by a multidisciplinary team) caring for a patient in both inpatient and outpatient settings at the university medical center. Program staff expect that improved care continuity and 24/7 access to the care team will enable better disease management, which in turn will reduce emergency department (ED) and hospital use, as well as Medicare spending. Care team clinicians, led by hospitalist physicians, are available to their patients by phone at all times, schedule same-day clinic appointments with patients to avert ED visits, meet their patients in the ED when a visit cannot be avoided, and attend to them in the hospital when an admission is necessary. Clinicians report that the relationship they are able to develop with their patients leads to improved compliance with care plans. Patients we interviewed reported feeling confident that their needs will be met 7 days a week, and feel less need to visit an ED to receive urgent care. In addition, many enrolled patients are able to receive mental health services from the care team—services for which there is otherwise a long waiting list and other access barriers at the university medical center. From the perspective of the patients and clinicians we met, this program is successful in better meeting the needs of a high risk population.

Our analysis of Medicare claims compared the outcomes of patients randomized to the intervention relative to patients who received usual care. As such, we are unable to analyze outcomes for individuals enrolled in managed care programs. The analysis did not find a statistically significant impact on any of the outcomes that we examined (Medicare expenditures, ED visits, hospitalizations). Because of the small number of eligible patients identified and randomized into the program and based on data to date, our estimates of program impacts are imprecise, contributing to the lack of statistical significance. A larger population would be needed to observe any small but important changes in utilization. In addition, this population of patients has complex care needs and many have terminal diagnoses (e.g., heart failure, COPD) which tend to require more care over time as the diseases progress. This pattern of escalating care needs may yield only marginally to a comprehensive care team approach.

2. General Research Domains

The core domains for the University of Chicago Hospital program evaluation are: implementation effectiveness, program effectiveness, workforce issues, impact on priority populations and contextual issues. The following is a brief description of these core research domains.

- **Implementation Effectiveness** addresses research questions related to measures of program factors that drive changes in care improvement, adherence to new clinical interventions, and ability to reach the target patients to deliver the intervention.
- **Program Effectiveness** encompasses dimensions of patient and program outcomes as well as cross-cutting considerations such as equality and disparities. Program effectiveness includes research questions that measure physical and functional health, health-related quality of life, patient safety, clinical effectiveness, and patient experience. It also includes questions related to the cost of initiating and maintaining the program; changes in health-care utilization and expenditures; and the extent to which the intervention improves the timeliness, efficiency, and coordination of care. Cross-cutting dimensions measure equality and disparities, differences in the impact of the program on subgroups, and spillover effects.
- **Workforce Issues** explore the dimensions of workforce training and the deployment of effective strategies of working with patients and carrying out the intervention. Research questions related to workforce issues also assess staff satisfaction, burnout, and turnover.
- **Contextual Factors** concern elements that may impact an outcome beyond what can be attributed to the intervention. Contextual factors can be endogenous (conditions from within the organization) or exogenous (conditions from outside the organization). Research questions related to endogenous factors measure leadership and the designation of a program champion, characteristics of the Awardee team (team science), features of the organization such as capacity, and stakeholder engagement. Research questions focusing on exogenous factors measure whether public policy and political environment support or conflict with program implementation.
- **Sustainability and Spread** address research questions related to the potential for the intervention to continue, and possibly expand, after the conclusion of Health Care Innovation Award (HCIA) funding; the business case and funding opportunities that may enhance continuation; and the potential for replication/adoption of the innovation by others.
- **Impact** encompasses measurable qualitative and quantitative results related to the triple aim of better care, better health and lower costs to CMS (Medicare, Medicaid, CHIP).
- **Impact on Priority Populations** focuses on research questions related to the type of population served by the intervention and the extent to which the intervention focuses on the needs of the medical and non-medical priority groups such as underserved populations.

The report that follows contains qualitative and quantitative evaluation results to date.

3. Qualitative Results: Case Study

3.1 Program Description

The University of Chicago Hospital (UCH) Health Care Innovation Award (HCIA) Award is a research study called the Comprehensive Care Program study (CCP). The CCP study is a randomized controlled trial (RCT) within the UCH's hospitalist and primary care programs. The CCP study recruits Medicare-eligible individuals with multiple complex conditions, obtains consent for the study and for randomization, and randomizes patients to receive either the new treatment model of primary care delivered by hospitalists, or a control group receiving usual care. Patients randomized into the treatment group receive care coordination services and clinical services from CCP study staff. The goal of the CCP study is to test whether implementing a program in which a single hospitalist physician treating patients in both inpatient and outpatient settings along with a care coordination team will: improve continuity of care, improve patient outcomes, and reduce costs relative to usual care provided by multiple physicians in the inpatient and outpatient settings.

3.1.1 Impetus for the CCP Research Study

Many Medicare beneficiaries with multiple complex conditions have frequent use of hospital emergency departments (ED) and repeated hospitalizations, circumstances that can lead to poor care coordination among providers and inefficient delivery of care. Often, a number of different clinicians including residents and specialists interact with the patient when in the ED and during a hospital admission. In addition, these physicians may not coordinate with the primary care physician who provides care between hospital episodes.

The patients' history and records may be either not immediately available due to a lack of coordination between multiple care providers across different health institutions, or may be extremely complex, requiring significant time for the admitting hospital to assemble a history and problem list. Clinicians treating unfamiliar patients with complex medical histories may be less comfortable discharging patients than a clinician who is familiar with the patients' baseline health status; as a result, patients with complex medical histories who are seen by a number of clinicians may experience longer hospital stays. Busy clinicians may lack the time to provide the level of follow-up and care coordination that could reduce the likelihood of re-hospitalization.

Complex patients are also likely to have significant mental health and social challenges, in addition to health challenges, that can lead to inconsistent care between acute episodes. The CCP program aims to improve continuity of care by having a single physician and clinical support team follow these complex patients in both inpatient and outpatient settings. The hypothesis being tested is that improved continuity of care will enable better disease management and reduce ED visits and re-hospitalizations.

3.1.2 Approaches to Achieving Program Goals

The CCP study has specific program components to address key program goals. The CCP study strives to provide better care through by providing continuity of care to patients who often have an array of clinicians involved in treatment of multiple complex conditions. Better health outcomes are the expected result of improvement in care coordination and treatment in lower acuity and more appropriate settings, provided by a clinical team who are very familiar with each patient's health care needs. To reduce costs, the CCP program strives to reduce ED visits and re-hospitalizations by providing more comprehensive,

coordinated care in the inpatient and outpatient setting at UCH. In addition to these initial goals, as the program matured an additional goal was identified: laying the groundwork to continue the CCP clinical program after HCIA funding concludes.

3.2 Case Study Methods

The evaluation team conducted two case studies of the CCP program. The initial CCP case study took place June 5-6, 2014. The evaluation team, composed of one senior- and one mid-level researcher from Abt Associates and one researcher from Telligen (formerly CFMC; subcontractor to Abt), visited UCH and also observed an outreach and recruitment event at a Senior Center in a Chicago neighborhood near the hospital. The team conducted group interviews with CCP program administrators, nurses, data and evaluation staff, and emergency department physicians. The team also conducted focus groups with CCP physicians, patients receiving care through the CCP program and caregivers, and CCP outreach workers who recruit participants for the CCP study. A follow-up case study was completed via telephone from January 26 to 29, 2015. The group interviews and focus groups were audio recorded after obtaining participant consent, to ensure accurate notes. Following each case study, notes were cleaned and integrated across the note-takers and reviewed for accuracy by the senior researcher on the team.

Exhibit 1 summarizes the number and type of individuals who participated in either interviews or focus groups.

Exhibit 1: Number of Interviewees and Focus Group Participants, by Type

	Patients/Patient Family Members	CCP Clinical Team	CCP Research Team	CCP Analytics Team	ED Physicians	CCP Hospitalist Physicians	Program Administrators
Initial Case Study Total = 32	7/2	4	7	2	3	5	2
Follow-up Case Study Total = 12	0	4	1	0	0	5	2

Please see the Methods section of the accompanying Annual Report for additional information about qualitative methods.

Additional background information presented in this report was gleaned from review of quarterly reports submitted by the Awardee to the Center for Medicare & Medicaid.

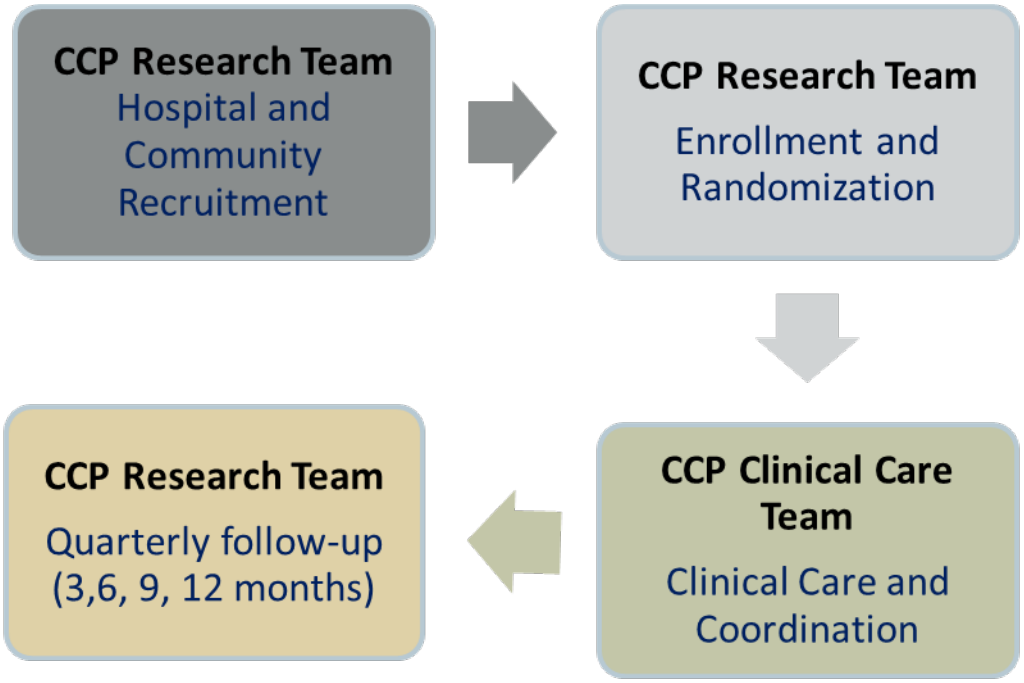
3.3 Program Components & Targets

3.3.1 Primary Program Overview

The CCP study consists of a research team and clinical team. The CCP research team recruits study participants and follows up with both treatment and control groups. Patients are randomly enrolled in either the treatment or control group and an intake survey is completed. From the point of randomization into the treatment or control group, the research team limits engagement with patients in the study to a contact every three months for follow-up interviews. The CCP clinical team provides all clinical care to treatment patients in both the inpatient and outpatient setting. The two teams work jointly on recruitment and the exchange of appropriate contact information for CCP study participants. Exhibit 2 below outlines

the process of implementation of the CCP study and the clinical and research team's responsibilities in each step.

Exhibit 2: CCP Teams and their Implementation Responsibilities



The CCP program is led by a principal investigator (PI) who is a physician and economist who has led lead studies to improve hospitalist care at UCH for the past 16 years. He actively works to troubleshoot challenges that arise during implementation and works with CCP staff to improve both the clinical– and research portions of the study.

Randomization

Randomization into either the treatment or control arm of the CCP study occurred as a part of the intake survey. A special computer program on the tablets used to complete the intake survey assigned patients to the control or treatment group.

3.3.2 CCP Research Study Overview

The CCP research protocol consists of recruiting potential participants, a baseline interview with individuals who qualify for the study and consent to randomization, and three month follow-up interviews with patients who are randomized into the treatment and control arms of the study. The research team also assists participants who randomize into the control group to find a primary care physician at UCH, if they have no current primary care provider. The research staff work solely on research components of the study and recruit both within UCH and in community settings. The vast majority of patients were recruited in the UCH ED or through referral from an inpatient unit at UCH. In recent months, recruitment has averaged 2.5 patients per day during weekdays, half being randomized to the CCP intervention. This is a slight reduction in the recruitment rate compared to the initial case study in June 2014, when about three patients were being recruited per day, on average. The research team hopes to reach its recruitment goal of 2000 patients by sustaining the current level of recruitment activities within UCH.

CCP Research Team

The CCP research team is led by a research manager who manages the overall operations of research activities of the CCP research study. Four research coordinators work with the CCP study team and are responsible for recruitment and data collection activities both in the community and at UCH. The team also includes research assistants who assist primarily with administrative tasks associated with the research study and recruitment at UCH. Two consultants also support the team with recruitment in communities near UCH. One focuses on helping the research team with its media strategy, while the other serves to provide insight into community engagement from the perspective of an older adult.

Eligibility Criteria and Data Collection

Inclusion criteria for the study are as follows: Medicare Part A and B; hospitalization within the past year; residence within the geographic area served by UCH; and willingness to change primary care provider to a CCP physician so that the same physician who oversees care in the inpatient setting is also responsible for primary care in an outpatient setting.

Exclusion criteria are as follows: Primary health coverage through a Medicare Advantage (MA) plan, (since the CCP cannot track health care utilization of these patients); and receipt of care through the oncology department or UCH advanced heart failure program, (as those programs provide comprehensive primary care similar to that of the CCP study, and the research team does not want to conflict or compete with those other programs). A CCP patient may enter the program and at some point may need cancer care or cardiology services and in these cases the patient remains with the CCP study.

Data Collection

The main data collection activities for both the treatment and control arms of the study consist of the intake (baseline) survey and follow-up survey administered every three months. Both the intake and follow-up surveys are administered to the patient by research coordinators using tablet computers and take about 20–30 minutes to complete. The intake survey is normally done in-person while the follow-up interviews are done by phone. The intake survey includes questions about a patient's health status based on the Patient Health Questionnaire (PHQ-SADS), activities of daily living (ADL) and instrumental activities of daily living (IADL), prior and current interaction with medical professionals based on the Ambulatory Care Experiences Survey (ACES), satisfaction based on the Consumer Assessment of Healthcare Providers & Systems (CAHPS®) Clinician & Group Surveys, substance abuse based on the National Institute of Drug Abuse (NIDA) Assist, mental health status based on the Short Portable Mental Status Questionnaire (SPMSQ), and health literacy based on REALM-R. The follow up survey includes questions on patient's health status based on the Patient Health Questionnaire (PHQ-SADS), prior and current interaction with medical professionals based on the Ambulatory Care Experiences Survey (ACES), satisfaction based on the CAHPS® Clinician & Group Surveys, social support based on the Lubben Social Network Scale, and demographic questions.

3.3.3 Recruitment at University of Chicago Hospital

Patients are recruited for the research study in two settings: the University of Chicago Hospital and the community surrounding the hospital. This section describes recruitment for the research study at the UCH followed by recruiting challenges present in that setting. Next, the community recruitment process and its challenges are described.

The recruitment of participants from within UCH has been more successful than recruitment in community settings. Research coordinators discussed a number of recruitment strategies, including staffing tables at hospital events and reaching out to inpatient departments within the hospital and outpatient clinics. They place research recruitment staff in settings across the UCH to identify and recruit new patients who meet study eligibility criteria.

At both assessment periods, the most successful recruitment is in the UCH ED. There, research coordinators cover the morning, afternoon, and evening weekday shifts to identify eligible patients. The CCP research team collaborated with the emergency medicine department to establish guidelines for how research team members would approach patients in the ED. On each weekday shift, research coordinators review a list of patients in the ED using a dashboard system that was developed for the study, which pulls data from the UCH electronic medical record (EMR). The dashboard allows the research team to review patients' eligibility for the CCP research study. After creating a listing of potential candidates for the CCP study, the research coordinator visits patients in the ED to present the program and solicit interest. ED physicians interviewed stated that CCP program staff are welcome in the ED and interact with patients in a manner that does not interrupt their care. ED physicians noted that there have been no complaints from patients about the recruiting practices of the research team.

The research team has organized numerous sessions held within UCH and have set up tables at strategic locations in the hospital (e.g., at the cafeteria, at the entrance to outpatient building) to describe the CCP study. Only a few participants, however, have been recruited through these mechanisms. There is also targeted outreach to specialists within the hospital who may see patients with multiple complex conditions, who could benefit from the CCP program.

Challenges to Recruiting at University of Chicago Hospital

The research coordinators related some challenges in recruiting in the UCH ED. First, there are times when it is difficult to get a response from potential participants because they may be experiencing pain or other symptoms and are focused on their own needs; this is not an opportune time to discuss a research protocol. Second, patients with cognitive, intellectual, or psychiatric impairments require a proxy who can legally consent to research, but this proxy may not be present while the patient is in the ED. Third, patients who may otherwise qualify for the CCP study may already have a primary care physician at UCH and the CCP team does not want to divert patients away from these existing relationships. If a patient expresses interest in the CCP study, the research coordinator will seek patient permission to contact their physician; if the physician provides permission to transfer care of the patient, the CCP study can seek to enroll the patient. A new challenge was presented by the research team during the follow-up case study period. A few patients believed incorrectly that they would be seen faster in the ED if they expressed interest in enrolling in the CCP program. When the CCP staff followed up with such patients later to complete enrollment with their first appointment, they often did not complete it.

For some patients, having a current relationship with a primary care physician outside the UCH system is a barrier to enrolling in the study. Patients are often reluctant or unwilling to switch from their current primary care physician to a CCP physician. To address this recruiting challenge, the CCP team identified opportunities when patients must naturally change care providers. One such time period is when UCH medical residents graduate and their potentially eligible patients are at a natural point of reassignment to another physician.

Another recruitment strategy used by the CCP study team is to leverage its relationships with other hospital units such as the geriatric clinic. At the time of the follow-up case study, the research staff suggested that many more patients could be recruited from the units within UCH but that the team lacked sufficient research team members to expand recruitment into new units in the hospital to engage these potential enrollees.

3.3.4 Recruitment in the Community

Two research coordinators, who worked on the Principal Investigator's prior hospitalist research, led CCP outreach in community settings. The research coordinators partnered with UCH community outreach departments and participated in health and wellness events the hospital holds in the neighboring community. They also built partnerships with community contacts to present the project at civic meetings, churches, Senior Housing, businesses and other community events aimed at seniors. During these community events, the research coordinators presented the benefits of the CCP study, the eligibility requirements, study protocols, and enrollment procedures.

Since February 2013, the outreach team has given presentations about the CCP research study at hundreds of community events. Despite reaching over 7000 community members and establishing contact with more than 200 potential study candidates, less than 20 participants have been enrolled through these community outreach activities (half randomized to the intervention). Near the start of implementation, the CCP research team hired consultants to recommend community recruitment strategies that will be more effective. One consultant has expertise in media and content development as well as experience working with the communities served by UCH. She has revised content such as the CCP study brochure and outreach posters. She worked with the CCP team to simplify the text in the brochure and to increase the appeal of the brochure to the population the CCP study seeks to recruit. According to the consultant, the initial brochure included too much text and had visuals that were not sufficiently appealing to potential CCP patients. A second consultant is a community member with broad connections in the communities served by UCH, who became interested in the work of the program after attending a community event held by the study team. Although he did not qualify for the program, he saw the benefit of the CCP research study and committed to working with the CCP team to better reach eligible individuals in the community. He works with the team to make additional connections in the community, speaks at recruitment events, and serves as an advisor to provide community-based input on potential recruiting strategies.

In response to the lack of success with initial strategies, the CCP research team adopted new recruiting strategies between the times of our first and second sets of interviews. The CCP team conducted an extensive mailing to the zip codes in the South Side of Chicago served by UCH. The team has created radio advertisements targeting areas served by UCH. Both strategies did not significantly improve recruitment totals. With time, the responsibilities of the CCP team shifted from outreach activities to research activities, in part because the response rate for the nine-month follow-up survey was low for the control group and more effort was devoted to locating those patients and encouraging them to respond.

Challenges to Recruiting in the Community

Research coordinators described a number of challenges to successful recruiting in community settings. First, eligible patients can be difficult to identify: they must have Medicare Part A and B, and have been hospitalized in the past year. Second, many patients are satisfied with their current primary care provider and are reluctant to switch from their current primary care physician. A third challenge is a historical ambivalence about participating in UCH research due to the same minority communities constantly being

asked to be the subject of UCH research, a common concern of communities near universities. A fourth challenge related to community recruitment includes difficulty following up with individuals who express initial interest. Specifically, research coordinators carry paperwork in the field to complete the full recruiting process onsite, but in every case thus far the final recruitment and enrollment requires a separate session with the candidate, and patients often do not attend these separate sessions as scheduled. Finally, there is concern among research coordinators that they are not identifying the individuals who could most benefit from the CCP study, because candidates are often unable to get out into the community to attend events due to functional limitations that prevent them from leaving their homes and lack of family or other support to assist with travel and transportation. This has led the research team to consider events in which they may be able to reach more frail community members, such as events in senior housing. The research team sought to engage the community in a targeted initiative with Senior Housing residential buildings but these efforts did not yield the anticipated enrollees.

Other Challenges Related to the Research Study

The CCP team highlighted two challenges to the implementation of the research study. A key challenge for the research team has been working with the UCH's Institutional Review Board (IRB). The team initially desired to refrain from including the word "study" in the title of the program to avoid any negative associations patients may have with that term: however, the UCH IRB required inclusion of "study" in recruitment materials. The process of IRB review and approval of outreach materials and strategies caused some unanticipated delays with implementing new recruitment strategies.

An Illinois policy change regarding coverage for beneficiaries who are dually-eligible for Medicare and Medicaid is another challenge to implementation. At the initial case study visit, not many potential patients were enrolled in Medicare Advantage (MA). Since that visit, the state of Illinois began automatically enrolling individuals dually eligible for Medicare and Medicaid into a MA plan. This policy is part of the state's expansion of health care coverage through the Affordable Care Act. Thus, during follow-up interviews with patients, the CCP program noted that they were finding more individuals who were not eligible for CCP because they were recently enrolled in a MA plan. This change in state policy has also impacted some participants who were already enrolled in the CCP clinical program, rendering them ineligible from the date when their MA coverage was initiated. The CCP clinical team has found it challenging to get newly excluded CCP patients re-enrolled into the CCP clinical program. Recruitment has also become a challenge for the research team to help patients to understand their options related to signing up for the CCP study and switching coverage from MA to Medicare FFS.

3.3.5 CCP Clinical Program Overview

The CCP clinical program is led by CCP hospitalist physicians who provide care in both inpatient and outpatient settings at UCH in consort with a broader CCP clinical team of nurses, social workers, and a program manager. The following components of the CCP clinical program support the overall continuity of care for patients with complex health care:

- CCP physician care in inpatient and outpatient settings at UCH
- Care coordination provided by the CCP clinical program manager, social worker, advanced practice nurse, and registered nurse
- Clinical care and follow-up provided by an advanced practice nurse and a registered nurse in the outpatient CCP clinic

- Best practice alerts whenever a CCP patient presents to the ED, to notify the CCP clinical team to assume care for their patient in the ED (both urgent care and emergency department), or inpatient unit, as appropriate
- Home care visits provided by a CCP physician and a social worker for patients whose health condition poses barriers in traveling to the UCH outpatient clinic for follow-up visits

Physicians. CCP physicians are central to the success of the program. Each CCP physician has a caseload of patients for whom they manage their care in both inpatient and outpatient settings at UCH. The CCP program selected physicians who were prepared to manage the care and treat highly complex patients with multiple conditions and social challenges that can result in reduced adherence to the plan of care. CCP physicians also need strong interpersonal skills and a willingness to establish a trusting relationship with each patient and coordinate all of their care. The CCP program currently has five CCP physicians who each have a unique focus and contribution to the team. One CCP physician, the first physician on the study staff, leads outpatient operations surrounding the CCP outpatient clinic and assists with addressing program challenges through technology. For example, she developed a database to track implementation of the care transitions model called the Bridge Model® intended to reduce re-hospitalizations. Another CCP physician focuses on patient education and is interested in the effectiveness of the CCP model for HIV/AIDS patients. A third CCP physician helped to develop a home care program. A fourth physician worked to increase the provision of mental health services for CCP patients by looking for resources within and outside of UCH. A fifth CCP physician worked to establish the systems and procedures necessary for the CCP team to bill for new codes related to care coordination by physicians as part of chronic disease management. CCP physicians spend part of their time working in a hospitalist inpatient service, in addition to their caseload of CCP patients.

> As a new patient, you are not only getting a new doctor, but a whole team to help you with your health care.
>
> *– CCP Manager, initial case study*

CCP physicians are supported by other members of the clinical team, including a program manager, two social workers, an advanced practice nurse, and a registered nurse, whose roles are described below.

CCP Program Manager. After enrollment in the study and administration of a baseline interview, the CCP program manager is the next point of contact for participants in the CCP treatment group. She conducts a short interview with each new enrollee to determine patient preferences and clinical needs and matches the patient with a CCP physician who can best meet their needs. The manager works to establish rapport with the patient, and if possible completes their intake interview on the same day of their enrollment. The program manager provides a welcome packet and schedules the first outpatient or inpatient appointment with their CCP physician. The CCP manager is also the first staffer who manages the CCP clinical team's phone tree and takes care of many administrative duties of the clinical team including billing and liaison/scheduling with other UCH departments. She intended to spearhead the CCP clinical team's adoption of some principles of TeamSTEPPS®, an evidence-based teamwork system to improve communication and teamwork skills among team members, and finished trainer certification for TeamSTEPPS®. With time, it became clear that the TeamSTEPPS® was not appropriate for the CCP team since the small close-knit team had well-developed communication processes in place. She also assists in managing the other non-physician staff on the clinical team.

> The CCP program has the feel of a small town care and doctor in a big city. [It is] similar to the family practice doctor who birthed her and managed her health throughout her life in a small town.
>
> *– CCP Patient, initial case study*

Social Workers. The CCP team has two social workers—one who works full time on the CCP study and another who works half time for the home care portion of the study. The CCP team social worker addresses the care coordination and social service needs of CCP patients. At the initial case study visit, the CCP program had a social worker who was especially keen on new care coordination approaches. She implemented the Bridge Model that assesses re-hospitalization risk before a patient is discharged from an inpatient setting, and ensures that a follow-up care plan is completed prior to discharge; she also tracked follow-up progress to reduce the likelihood of re-hospitalization. She also provided limited counseling services as needed for both patients and their family members/caregivers. This social worker left in late summer of 2014 and was replaced by a social worker with a stronger clinical focus on providing counseling support to patients. Consequently there has also been less focus on the Bridge Model since this transition. Components of the Bridge Model have been integrated into the care planning tool, however. The home care social worker is committed half to the CCP study working principally with patients receiving home care through CCP. She coordinates necessary home services (e.g., medical equipment; oxygen), participates in some homecare visits with the CCP physician, and addresses any insurance coverage issues. She, along with the home care physician, also works on Award opportunities that will continue funding for the home care program after the HCIA period ends.

Advanced Practice Nurse. The advanced practice nurse on the clinical team sees CCP patients in the CCP outpatient clinic with or without a CCP physician as needed. She is responsible for discharge planning and follow-up with patients after visits. The advanced practice nurse also schedules patient appointments in the CCP clinic and with specialists as needed to support the CCP physicians.

CCP Team Nurse. The CCP team nurse provides patient care in the CCP clinic, provides medical advice, refills patient prescriptions, and assists with triaging patients to the appropriate care setting. She interacts with patients either in the CCP outpatient clinic or by phone.

Within the clinical team, the non-physician staff are cross-trained to be able to function in multiple roles if necessary. The social worker covers for the program manager in completing follow up calls and some administrative tasks related to the team. The registered nurse backs up the CCP advanced practice nurse, and the advanced practice nurse provides CCP clinic visits in some circumstances. All CCP clinical team members cover each other's phone lines to take incoming calls from study patients. The PI is striving for a small, closely knit clinical team that can engage patients personally and minimize fragmentation of care. The clinical team also conducts multidisciplinary rounds each day, attended by the full clinical team, in which they review the care plan for study patients at UCH and any scheduled for clinic visits that day, and discuss care coordination. They consider staff scheduling issues, patients who have missed outpatient clinic appointments, and any logistical challenges in providing care. It is often during daily rounds that new ideas are generated for improving care delivery and coordination.

3.4 Implementation of Clinical Program

Implementation of the clinical program began with the hiring of two CCP physicians and other necessary CCP team staff. The PI worked with the section administrator for hospital nursing, who serves as the main liaison between the CCP study and UCH, to setup the CCP outpatient clinic and other administrative components of the program. This UCH administrator assisted in hiring the first two CCP physicians, the CCP program manager, and the advanced practice nurse. As noted above, this initial team has expanded as the patient population has increased, adding a registered nurse, an additional social worker, and three additional CCP physicians. The PI now considers the program to be fully staffed, although patient

enrollment is continuing. In general, the leadership team told us that they try to solve problems using their current clinical team, rather than hiring additional staff. This philosophy is very important to the team—to try to keep the experience for patients as small and consistent as possible.

The roles of clinical team members shifted over time but findings from the initial case study suggested that because the team is relatively small, these initial transitions were accomplished seamlessly. The advanced practice nurse transitioned to managing all patient medication refills, freeing time of a CCP physician who previously had this responsibility. Assignment of patients to physicians changed when a CCP physician began visiting patients at home, and the team worked through the transition of his schedule and the coverage of his patients who come to UCH clinics when he is out doing home visits.

The team employs multidisciplinary rounds to review clinical strategies, providing an opportunity for continued communication and further process improvements. The CCP team strives to maximize communication in order to ensure that the program runs as efficiently as possible while dealing with the complex health issues and staffing challenges as the program expands. Between June 2014 of the initial case study and January 2015 of the follow-up case study, the program experienced significant growth in the patient enrollment in the intervention. This growth resulted in significant workload challenges for the social workers, nurse, and program manager; a more difficult process than during the initial implementation of the clinical program. These challenges will be further discussed in the section below on clinical program challenges.

> I would like to say this about the entire program—it's the timely response that is the most important thing. [Usually] When you call a doctor's office, you never talk to the doctor and sometimes the nurse doesn't even call you back. This program calls you back right away—it makes a difference.
>
> – CCP Patient, initial case study

3.4.1 Patient Engagement

Developing a medical practice that attends to patient preferences and delivers patient centered care is a central component of the CCP program. As mentioned in Section 3.3.5, the program coordinator "matches" each patient with a specific physician, based upon his or her expressed preferences regarding physician practice style. For example, if a patient wants to be highly involved in care decisions, the program coordinator will assign that patient to a physician whose practice style emphasizes shared decision-making. This matching process is intended to encourage stronger rapport between the physician and the patient, which is expected to promote greater compliance to treatment protocols and lead to better health.

Another important aspect of the CCP clinical program is patients' telephone access to a member of the CCP clinical team at any time during business hours, regardless of whether the team member is in their office or not. CCP patients may reach clinical team members through a telephone number that links to CCP staff members' individual cell phones when they are away from the administrative office. There is a main clinic telephone line through which patients can schedule appointments, discuss emerging health problems and the need for urgent care, seek help with insurance coverage, request prescription refills, or page a CCP clinician after hours. Patients have direct access to CCP support staff with extensive knowledge of the program and the patients rather than an administrative gatekeeper such as a receptionist that other UCH outpatient units typically use to screen calls.

A CCP clinical team member reported that many patients with multiple conditions who are seeking primary care make frequent visits to an ED because they cannot get immediate appointments with their primary care providers. In most cases, CCP staff are able to schedule patient appointments within

24 hours in the CCP clinic, in the effort to avert an ED visit. CCP physicians, along with program staff are highly accessible to patients participating in the treatment component of the CCP program. When a patient's condition is unstable, CCP staff schedule a weekly check-in with the patient, to discuss any emerging issues. Many ED visits can be averted by reassuring patients that their symptoms do not need urgent care, and a next-day appointment is possible.

Several CCP staff noted that this accessibility helps to build rapport and trust with patients. CCP staff noted that one of the most significant additions to the project was the individual mobile phones that allow staffers to be accessible to CCP patients throughout the business day. Patients noted that the phones make CCP staff very accessible and if a call does go to voicemail, it is returned quickly. The CCP manager seeks regular feedback from patients about how well the CCP clinical program is meeting their needs. A CCP staffer described the care provided by the CCP clinical program as a private, solo practice within the hospital, in which the staff know patients personally and patients know the staff providing their care.

3.4.2 Responding to Patients with Complex Clinical Needs

CCP Home Care Program

The CCP Home Care Program is designed to address an important barrier to patients keeping their follow-up appointments: inability to travel to UCH, either due to health problems and conditions or transportation deficits. There are times when patients face functional limitations in leaving their homes and traveling to UCH, and lack family or other support to assist with travel and transportation. This challenge spurred the CCP clinical team to develop a home visiting initiative. A CCP physician with some experience providing home care visits joined the team and handles a caseload of 26 home care patients. This physician sees patients in the hospital in the morning and then completes home visits in the afternoon. He covers occasional visits for patients of other CCP physicians, when there is a short term need. If the CCP clinical staff are unable to contact a patient, the CCP home care physician will visit the patient's home. In one case, this physician visited a cancer patient's home that the CCP team had tried consistently to contact and learned that the telephone was not functioning. By talking his way past a security card and visiting the patient at home, the physician was able to keep the patient engaged in the CCP program.

Since the initial case study, the home care program has gained momentum with partnerships developing between the home care physician and the other CCP physicians. The home care CCP physician sees patients who were a part of other CCP physicians' panel when the patient is too ill to come to clinic regularly or while recovering from some acute event. The CCP physicians described this as a significant benefit to the CCP program, as it provides continuity of care to the sickest patients. To manage the increased case load, the home care program added a social worker, since patients who qualify for home care need even more care coordination than traditional CCP patients. She focuses on care coordination needs and patient support when she does visits with the CCP physician. She also works to understand the experience of caregivers in the home to be able to better address the challenges that arise in care coordination and provision of services to home bound patients.

The home care program has become more established, but the CCP physician who completes home care visits still stressed the need to increase their patient panel to have a more financially sustainable care model for the home care component. They have applied and received funding to support the addition of a care coordinator to expand the reach of the home care program and to actively recruit additional patients who could benefit from the service. This person would help with the recruitment of additional patients; assist with care coordination, and also with the establishment of a more efficient billing process for home

care services. The home care program also supports medical students to shadow the main CCP home care physician on home visits. The home care social worker works on the behavioral health component of the home care program designed to meet the mental health needs specific to individuals who are homebound.

Provision of Mental Health Services

One challenge noted by the CCP clinical staff is the number of CCP patients who have mental health and substance abuse issues. Although the CCP clinical staff have access to a liaison psychiatrist at the UCH psychiatry department, the staff expressed frustration in not being able to offer the level of mental health and substance abuse services their patient panel requires because the clinical team does not include this specialty and UCH discontinued psychiatry inpatient services in recent years. CCP patients may also face problems in accessing inpatient mental health care at other facilities, as some inpatient psychiatric facilities will not accept patients using oxygen or continuous positive airway pressure machines.

The CCP program has adopted a number of strategies to deal with the mental health needs of CCP patients:

- The original CCP social worker provides some psychotherapy sessions with patients, to the best of her ability. During our follow-up case-study, the new social worker explained that she is pursuing further certification for counseling services specific to the needs of CCP patients. As a licensed clinical social worker, she can provide some counseling for CCP patients with mental health challenges. The CCP staff note that the needs of patients exceed the time-limited counseling that the social worker will be able to offer.
- The CCP staff also refer patients to a psychiatric hospital not affiliated with UCH for acute inpatient care. However a CCP staffer noted that patients can wait up to three days for inpatient care if they go to a psychiatric hospital's ED. Psychiatric outpatient care at UCH has a long wait for new patients (up to six months) but CCP staff add their patients to the waiting list, as needed.
- The CCP advanced practice nurse is preparing to attend a conference on care provision for patients with mental health needs. CCP clinical team members also devote more time to following up with individuals with mental health needs to help them follow their care plan.
- During the follow-up interviews, the CCP team noted that they now have a specific psychiatrist at UCH with whom they can consult. This clinician has provided some email and phone consults for the CCP physicians, but the staff as a whole agreed that this was not sufficient for the needs of CCP patients.

In the short term, the strategy that the CCP team believes can best address mental health needs, given limited resources, is to push for additional staff support for care coordination, which would afford the social workers more time to offer counseling to CCP patients.

Managing Prescription Drug Abuse

CCP clinical staff noted a high rate of prescription drug dependency among CCP patients. Program leaders described how some patients tried to switch CCP physicians in the hopes that a different physician would be more amendable to prescribing opioids. The CCP clinical team has developed a strategy to address the care of patients with opioid dependency: such patients must sign a contract with their physician stating that the patient agrees to see only one primary care provider and agrees to toxicology screening. Should the patient refuse to this agreement, the program would closely monitor the care plan of this patient. In the case of a patient being addicted to opioids, the CCP team may consider recommending

a methadone clinic for a patient. The team generally is cautious in adopting this approach since this would introduce further fragmentation of patient care. These strategies allowed for the CCP program to have better control over time of prescription of medications amongst CCP patients as assessed at the time of the follow-up case study.

3.5 Measurement & Self-Monitoring

This section describes the key measures utilized by the CCP study in monitoring the progress of the study's implementation and targeted outcomes.

The CCP analytics team focuses on measurement and program monitoring for needed for the clinical and research teams, and for reporting to CMS. The analytics team described three main sources of data for the CCP research study: survey data (intake and follow-up surveys), clinical data obtained from the hospital EMR, and hospital billing data. A senior analyst focuses on providing the enrollment intake survey data to the clinical team, as they integrated new participants and begin providing services. The analytics team also includes a Medicare Innovation Analyst who focuses on patient outcomes using hospital administrative and EMR data, as well as the patient surveys administered as part of the research study.

The analytics team compiles some data from the dashboard that the CCP clinical team reviews. These data include availability of next appointment for newly recruited patients, completion of follow-up patient surveys, and "no show" rates of patients who miss a scheduled appointment. Analysts noted a particular challenge in completing the quarterly follow-up surveys with patients in the control group, who may have no ongoing relationship with UCH and no reason to comply with the protocol over the years of the study. In addition, because they lack complete information about care CCP patients receive outside the UCH system, they use patient self-reports to augment UCH utilization data. Some measures obtained from patient survey data include:

- Patient experience measures (similar to those in the CAHPs instrument)
- Health status – an assessment for conditions such as anxiety social disorder, description of known health conditions, and assessment of health based on the Patient Health Questionnaire
- Noncompliance with medications
- General health perception (scored from 0 to 100)
- Substance abuse and assessment of prescription drug abuse
- ADLs and IADLs gathered at intake and follow-up

Some measures derived from hospital and claims data that the team is monitoring or intends to report when data is available include:

- Hospitalizations and length of stay
- Number of ED visits
- Total costs of care (to be addressed in the future when claims data become available)

The analytics team believes that the critical measures to focus on for establishing the effectiveness of the program will be health care utilization and patient-reported satisfaction with care. Since most CCP patients have multiple chronic conditions, the change in other health outcomes is not expected to be

dramatic. Based on available self-reported hospitalization data, they assess each patient's risk for hospitalization/
re-hospitalization and this estimated risk has decreased by 17 percent for patients participating in the CCP clinical program relative to those in the control group. During the follow-up case study, a member of the CCP leadership noted that both the control and treatment group improved in some assessment areas. He was very pleased that the study opted for an RCT because the study can still show the impact of the intervention even in a scenario in which both control and treatment groups show improvement.

3.6 Workforce Development

In this section, training for research staff training, program staff training, and physicians is described.

3.6.1 CCP Research Staff Training

Research staff are thoroughly trained on ethical informed consent processes, as well as the specifics of the CCP research study by the CCP research study manager. All new research coordinators and research assistants who help with recruiting in the ED go through an extensive period of shadowing research staff that have experience with the recruiting process, before they recruit in the ED on their own. In addition to shadowing in the ED, the research coordinators also assist new staff to complete follow-up calls, especially with individuals in the control group, for whom continued enrollment in the study is less desirable. The CCP research team also plans to hold a research retreat in the coming month to discuss best practices in recruiting and recruitment strategy for the coming quarter. A key goal is to ensure that everyone is prepared to address the needs of enrollees in both the control and treatment group as the study likely nears its close.

3.6.2 CCP Clinical Program Staff Training

For most CCP clinical staff, there was no specific CCP-program training curriculum, and staff learned their new roles in the following ways:

- The social workers were trained in UCH's social work department and through on the job training even after starting in their positions. The main CCP social worker trained the social worker who focuses on the home care program. They are scheduled to get additional training in counseling to offer more mental health care provision to patients.
- The advanced practice nurse trained by shadowing a CCP physician in the outpatient clinic for a number of months to learn her CCP role in care coordination in an outpatient setting. She described this training as greatly enhancing her skills, and during the initial case-study described how additional training would be beneficial in skin mole removal and biopsies (a service that she has to refer out, but which she feels competent to learn). During the follow-up case study, she noted that she has received training around catheter care and abscesses and still looks forward to training in mole removal and wound care.
- The registered nurse received the same standard training as all new nurses at UCH. She stated that no specific training for the CCP program was necessary.
- The CCP manager received on the job training from staff in the UCH primary care group to learn the administrative requirements and standards of UCH.

CCP staff participate in weekly CCP physician-led training sessions that focus on topics of special relevance for the CCP patient population and clinicians. In June 2014, the major foci of this training were improvement in the care coordination, using components of the Bridge Model and TeamSTEPPS® guidelines for chronic disease management. Since then, staff discovered that the TeamSTEPPS® model is less relevant for their practice since their team is consistently small and communication between team members is robust. The Bridge Model has been integrated into daily care coordination practices; therefore little ongoing training targeting this area has been undertaken in recent months.

3.6.3 CCP Physician Training

The CCP physicians have a designated set of on-boarding lectures provided by a senior physician who provides extensive training at UCH. These lectures focus on topics of special concern, including: end of life care, oncology, substance abuse, care coordination, and other common issues that arise in this serving the CCP patient population. The first CCP physicians received this training in-person, with a senior physician and these sessions were recorded for future trainees. Physicians hired later watch the recorded lectures on their own and use the more seasoned CCP physicians as resources. In January 2015, a CCP staffer stressed that learning didactically may not be the best approach to physician learning but that learning in the clinical environment was very important for the physicians.

All CCP staff attends presentations on a range of topics designed to improve their capacity to provide care to complex patients in the clinical program. Some presentations are led by CCP physicians who take turns facilitating a weekly training session for their CCP physician colleagues and the CCP staff as a whole. In June 2014, staff reported that recent trainings focused on care coordination for patients with HIV/AIDS, special care needs for those with sickle cell anemia, and best practices in patient education. In the January 2015 follow-up case study, staff described group sessions lead by CCP staff on obesity management, patient engagement, and efficiency in the primary care clinic.

The CCP team has also brought in experts to provide training targeted to the needs of the CCP program. They learned from experts such as the president of the American Academy of Home Care Medicine, who presented on best practices in home care medicine. Other topics addressed by experts included effective evaluation of a patient's mobility level, proper usage of an inhaler, and end of life care. The physician staff noted that between the targeted training from the CCP program and their continuing medical education training through UCH, their career development needs are being addressed.

3.7 Implementation Effectiveness

This section describes program effectiveness in terms of better care, healthier people, and smarter spending. Unanticipated impacts of the program are also described.

3.7.1 Better Care

There was widespread agreement among the interviewees that the CCP clinical program resulted in better care for patients. CCP staff believe that the CCP clinical program can improve outcomes for patients, especially in the area of disease management. CCP patients tend to have an array of conditions that require active management of both chronic and acute conditions. The program improved patient care in the following ways:

> [I] used to be on high blood pressure medication and diabetes medication. The CCP program was able to help [me] to manage [my] diseases without taking medication for either problem.
>
> *– CCP Patient, initial case study*

- Additional time spent with patients during outpatient visits.
- Better and more complete care coordination across care settings.
- Rapid appointments; patients typically seen within one day of requesting an urgent care appointment.
- Assistance for ED physicians addressing patients with multiple complex conditions, through consultations with CCP physicians visiting the ED.
- Appropriate end of life care. "Some of the greatest successes have been people who died. They (CCP patient) were able to be in the best setting for them (home)."—CCP Physician

> Quality of care [in the CCP study] is amazing for our patients [since] we know our patients so well. I see a patient now and then in urgent care and can directly admit them to the hospital if I see fit.
>
> *– CCP SW, follow-up case study*

In a focus group with patients and family members of patients, there was universal enthusiasm about the quality of care provided by CCP physicians and staff. They spoke of the CCP physicians being unlike any other physicians they have interacted with and described the physicians as genuinely caring and concerned about patient well-being, beyond their immediate medical challenges. The quality of care provided surpassed their expectations and gave them the confidence to discuss their problems. Patients described physicians taking more time than allotted for their appointments, to answer their questions and take care of their needs. Family members and caregivers of CCP patients expressed how helpful the CCP physicians are in keeping them informed of the care being provided to their loved ones. Many are concerned about what will happen to them when the program ends and whether it will continue, because their care experience had been much better than their past experiences with health care. In the January follow-up case study, staff also expressed some concern that staff responsible for care coordination were not responding to their calls with the speed previously experienced. CCP physicians may not be as accessible to patients as in the early phase of implementation when each physician's patient panel was significantly less, about half the size of what it now is. Yet even with some increase in wait or response time, the staff noted that care was still vastly improved relatively to the traditional care experience. Patients still get significant access to their CCP physician via the phone and in-person if necessary compared to most clinical settings within a shorter period of time than many patients experience. Where patients used to receive a call back within some minutes of leaving a message, they now receive a call back within an hour or two.

University of Chicago's Measurement Strategy

The University of Chicago research team collects data on quality measures that they report to CMS and use for internal quality improvement. They key measures they report are:

- Patient Satisfaction as assessed by questions similar to those in CAHPS

3.7.2 Healthier People

CCP staff noted that the care coordination components of the program have helped patients to be more compliant with their care plan and now patients more often seek care in the CCP clinic rather than the ED. Better adherence to the care plan also is expected to reduce disease exacerbation and the need for hospitalization. The estimated rate of hospitalization and ED visits for CCP patients is

> One of my first patients was hospitalized, had a stroke, hypertension, etc.—three weeks ago she walked down the stairs for the first time—she will graduate out of the home care visits. She will be our first home care graduate.
> – CCP Physician, initial case study

therefore lower relative to the CCP controls. Patients also described having improved wellbeing because of the kind of care received in the program. One patient relating the connection between mental health and physical health stated, "*I think that my medical (outcome) has improved because my stress has improved. Mental health is part of the healing.*" A majority of the patients in attendance at the patient focus group agreed with this sentiment.

University of Chicago's Measurement Strategy

University of Chicago collects data on patient outcomes that it reports regularly to CMS and uses for internal quality improvement. Some key measures that it reports are:

- Participant all-cause mortality rate
- Functional status as assessed by Short Form (SF)-12
- ED visit rate
- Improved Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL)s

3.7.3 Smarter Spending

CCP staff believe that the program will reduce costs for patients with multiple complex conditions. ED physicians told us the program is saving costs by reducing ED visits in this patient population. Patients whose needs are met in the outpatient settings are expected to have fewer hospitalizations. Staff reported that initial findings suggest that hospitalization rates are lower for CCP patients compared to control group patients; they expressed the opinion that reduced hospitalization rates for CCP clinical program participants will eventually realize savings for Medicare and for program participants.

Additional savings may be realized by shorter lengths of stay for CCP clinical program participants when they are hospitalized. Program staff believe that physicians' familiarity with their patients' complex medical histories will lead to shorter lengths of stay compared to patients in the control arm of the study. This familiarity provides physicians with knowledge about their patients' baseline health status and a perspective on when patients can be safely discharged.

The analytics team completed preliminary return on investment analysis and the CCP study has "broken even," when including costs associated with internal evaluation of the CCP program.

University of Chicago's Measurement Strategy

University of Chicago collects data on cost measures that it reports regularly to CMS and uses for internal quality improvement, including:

- Hospital wide all cause unplanned readmission measure
- Total cost of care, per patient per month
- Patient length of stay

3.7.4 Unanticipated Impacts

There were several unintended consequences that have arisen since implementation:

- The CCP team's availability to program participants led to a high volume of calls to the CCP office for health care needs intended for other UCH departments. Program staff reported that even in cases

when a CCP patient intends to reach a medical specialty, he or she will call the CCP line to be transferred to another department at UCH. In addition, some CCP patients come to the CCP clinic with the expectation of making an appointment with a non-CCP care team. Staff began reminding CCP patients that they can contact other medical areas at UCH directly by providing this information as part of their paperwork after a visit.

- CCP staff were surprised by patients' rising expectation of appropriate response time for returning a call to the CCP office. Some patients were unhappy to not receive a call back from the CCP program within minutes of leaving a message. Staff joked that the CCP team had done too good of a job in conditioning the CCP patients to expect near immediate feedback, a scenario that was unsustainable as patient enrollment grew.

> One example is when a patient called and demanded they speak directly to their physician who was busy at that time. I had to remind the patient that in other practices you never get to talk to the physician over the phone and there is only so much we can do.
>
> *– CCP PM, follow-up case study*

- The CCP clinical staff had not anticipated the length of time required for the program manager, nurse, and social workers to assist CCP patients in re-enrollment in the CCP program after their MA status rendered them ineligible. Significant follow-up was required to ensure patients could continue with the CCP program and understood the health coverage implications of a switch back to Medicare FFS. Time was required to assist patients to fill out the appropriate paperwork and to continue to monitor the process—which could take up to a month to complete. The CCP has also sought the input of others who can help to explain the change in health coverage to patients more clearly, but this effort also requires additional coordination.

3.8 Impact on Workflow and Workload

This section describes the impact on the workload of UCH ED physicians, CCP physicians, and CCP care coordination staff since the implementation of the CCP study.

Assistance to ED Staff

Multiple ED physicians reported that the CCP program has had a positive impact in helping them manage the care of ED patients with multiple complex conditions. They further noted that nurses in the ED are especially appreciative of the ability of CCP staff to intervene quickly while patients are in the ED. Other physicians throughout UCH have begun to realize that by referring their most complex patients to the CCP program, they can reduce their workload and time devoted to complex patients, who need the additional attention available through the CCP program, and potentially save money if the care is better coordinated and hospitalizations decrease.

More Balanced Caseload Across CCP Physicians Over Time

Initially, the CCP program considered patient preferences for physician gender when assigning patients to CCP physicians. This resulted in the two female physicians having a considerably higher case load of patients than their three male colleagues. Since the initial case study, the CCP manager has worked to rebalance the case load between the five CCP physicians and no longer asks patients about gender preference in physicians. As the program increased enrollment, the CCP staff has seen that the balance of patients assigned to each CCP physician has been well maintained and the CCP physicians expressed no concern with their panel of about one hundred patients for the traditional CCP physicians and about thirty patients for the home care CCP physician.

Increased Burden for Nurse, Social Workers, and Program Manager

The CCP staff who are first to engage CCP patients by phone or in person have been overwhelmed by the call volume from CCP patients. A key challenge with the growth in enrollment of the CCP clinical program is the attempt to keep a small practice "feel" within a large hospital setting. Many staff noted the challenges that are now required with care coordination due to the increased patient load. Some CCP staff describe that at times it felt as if they were simply trying to stay afloat while managing the call volumes to the CCP phone line. When call volumes first began to increase, the team tried to change the phone tree to provide a general information section, with the hope that this would reduce the volume of callers that needed to speak with a CCP staffer. This change did not reduce calls and the CCP team members principally responsible for managing phone calls struggle to keep up with the call volumes and manage other aspects of their project work. CCP staff expressed concern that the nurse and program manager especially might experience burnout with the current work load, and the leadership hopes to hire new staff to help with care coordination. The addition of new care coordination staff who serve primarily in an administrative role requires going through hospital hiring procedures. Currently, the CCP team has not been fully successful in getting buy-in from hospital administration on the urgent need for new care coordination staff. Though there is recognition of the need for additional staff to support the care coordination role, there has not been relief offered by the UCH in the months since the burden has materialized. Staff consider addressing this concern to be of the utmost importance, if the burnout of critical CCP team members is to be avoided.

> The program is ideally small at the level of the patient but big at the level of the organization. [My] ideal would have been to have five teams of five CCPs rather than one team of five CCPs. Replicable microsystems are what [I] would prefer and it would allow for scaling up of the program that gives more stability in the program when there are natural changes that occur.
>
> *– CCP Leadership, follow-up case study*

3.9 Potential Improvements Suggested by Program Staff

This section outlines suggested improvements outlined by the research and clinical team for their respective components of the CCP study.

3.9.1 CCP Research Team Suggested Improvements

A number of CCP staff suggested that there are opportunities to recruit patients at a number of clinics and inpatient units within UCH. Some, but not all, physicians in the UCH system are aware of the CCP program and it may be beneficial to more actively engage departments beyond emergency medicine and in public spaces of UCH, to identify new patient candidates and physician champions. Some departments in the hospital have expressed interest in being additional areas for recruitment but the research team noted that more staff would be needed if a further expansion of recruiting in the hospital was to be considered. Both the research and clinical team members stressed that the program will function more efficiently when there is no longer a need to randomize patients to control or treatment groups. A key barrier to recruiting remains the challenge of convincing a potential enrollee of the benefit to them when there is a good chance they may not receive more than usual care.

3.9.2 CCP Clinical Team Suggested Improvements

The clinical team made a number of suggestions for improving the functioning of the CCP clinical program going forward:

- Establishing the ability to bill for chronic care management. This would capture work done by the physicians in care coordination both in person and via the phone and is a work in process.
- Streamlining of medication refills for patients.
- Adding a staff person who is dedicated to care coordination would free up some time for the program's social workers to provide psychosocial care to patients in the outpatient clinic.
- Building a more scalable version of the program with multiple teams could have ameliorated some of the staffing burdens that have arisen during the process of building up the program to full capacity.
- Establishing a checklist of the most useful operational improvements would improve the overall functioning of the CCP program. The team intends to review suggestions in upcoming operations meetings and to continue refining the program where possible.
- The clinical team also stressed the need for having the CCP approach based within an academic medical center with a breadth of resources. One such resource that could have strengthened the program was increased availability of mental health consultation within UCH.

3.10 Context

This section describes the internal and external contextual factors that may have impacted the implementation of the CCP study at UCH as well as the CCP staff's perspective on the prospect of the CCP program's sustainability.

3.10.1 Endogenous Factors

Communication

The level of communication within the CCP clinical and CCP research teams is very high. As a small, close-knit unit, the clinical team is able to provide extremely individualized care, which is an important contributor to program success. The roles of team members have shifted over time but because the unit is relatively small, this has been accomplished relatively seamlessly. In the daily multidisciplinary rounds, the team is able to address the many challenges to implementing the clinical program and have the necessary communication to ensure patient needs are addressed appropriately. The CCP Leadership team also worked to improve the communication in the handoff of patients from the research team to the clinical team through some standardized correspondence templates and checklists. The full CCP research and clinical team meet to review enrollment records as well to ensure patients in other UCH comprehensive care programs (cardiovascular disease or oncology) are not enrolled in the CCP study.

> Every time you add a new person you add cost; the cost of communication and cost of error. The more people know each other's jobs, the less time you need to spend communicating information.
>
> *– CCP PI, initial case study*

Leadership Buy-in

The reputation of the CCP leadership team in implementing research at UCH was an important factor in addressing implementation challenges. The team has been able to acquire new space as needed, expand the number of CCP physicians and other staff, and partially fund the home visit initiative. The CCP program has also received support from the UCH leadership in developing a sustainability plan for the home care and the CCP program housed within UCH. Though still in the development phase, the team is optimistic that the positive results of the program and UCH support will allow the clinical care to

continue beyond HCIA funding. The support received from UCH has not been unequivocal as the team efforts in adding necessary administrative staff have been unrealized, despite the evident need. There is some concern also that the CCP program's focus on reducing the number of hospitalization runs counter to UCH's broader financial incentives.

3.10.2 Exogenous Factors

The automatic enrollment of dual eligible beneficiaries into an MA plan created additional burden for both the CCP research and clinical teams. The research team had to determine patients' eligibility based on their insurance status in cases where patients themselves were unaware that their status had changed. For the clinical team, patients with established care in the CCP program could become ineligible for the program without their awareness. Though a relatively small number of patients faced the need to re-enroll in Medicare FFS and resume the CCP study (around ten patients so far), the interim period between the two health coverages was disruptive and detrimental to the care of these patients. One CCP physician stated that it was a challenge to not see a CCP patient who wanted to continue with CCP in the time period before their Medicare FFS was reinstated. The program had to make this decision to not see such patients in the time where the coverage was worked out since the patient would be billed directly for a visit and most patients could not afford this.

Another key factor that affected the CCP study is the presence of a number of physician home visiting programs in the Chicago area. The CCP research team encountered patients who were essentially home bound, and receiving home physician visits through other Chicago programs. In order to recruit and retain those patients, the CCP study needed to also offer a home visit component. The home visit component has been a benefit to the CCP patients who need this service, and has increased the program's appeal and ability to recruit such patients.

3.10.3 Sustainability

> The philosophy of small practice in a large institution is likely sustainable from the doctors standpoint in terms of quality of life of the physician who is able to work in a small team and supporting patients in ways that are meaningful.
>
> *– CCP physician, follow-up case study*

There was widespread agreement among those interviewed at the initial and follow-up case study that the program should continue because it enhances patient care and health outcomes. Program staff, however, are uncertain as to whether or not the savings generated will be sufficient to persuade hospital leadership that the benefits of the program outweigh its costs. In addition, it is not clear that UCH leadership wishes the hospital to become a 'magnet' facility for complex patients, many of whom face mental health and substance abuse challenges. As noted by some staff, Medicare reimbursement is lower than that of other payers, but with the growth of Medicare Advantage and other risk contracts, it behooves UCH to learn how to better manage care for this complex population. Though the CCP study excluded Medicare Advantage patients because the team was unable to track their health care utilization, there was recognition amongst CCP staff that UCH serves an increasing number of patients with complex health conditions and Medicare Advantage coverage. The CCP study offers UCH the opportunity to learn how to provide better care for these most complex patients at a lower cost than typically seen in hospitals.

The CCP team strives to make the program sustainable beyond HCIA funding. The team is working with hospital leadership to determine funding strategies that could sustain the CCP program and a key part of this work is in establishing the necessary procedures to fully bill for care coordination of chronic disease

management. There are efforts underway to establish appropriate billing practices for the home care component and the hospital based outpatient clinic that will help the CCP model to generate more revenue. In order to have sufficient data to appropriately test the value of the program, the CCP team has applied for a no-cost extension of their Award to be able to reach their recruiting goal of 2000 patients. With sufficient size in the control and treatment arms of the CCP study, the CCP team hopes to place the program up for evaluation by the UCH leadership and prove its value based on its positive health outcomes and positive results related to return on investment. The CCP team has presented to patients that the study's intent is to work to keep the care model intact after HCIA funding ends. They have also expressed to CCP patients that the team will work to place patients with care providers if the program is discontinued.

3.11 Next Steps

The CCP study looks to integrate the lessons learned throughout the study's implementation to improve the CCP approach to care that study staff believe already provides excellent results for patients. A key area of consideration for the CCP study is pursuing opportunities to create other small, multidisciplinary teams that would allow the program to expand while remaining effective at patient care. The heavy patient caseload for the nurse staff and program coordinator highlight areas for improvement for future teams. The ratio of support staff to patient likely would need to decrease to work most effectively and the team will be working to see what ratio works best as the program continues to expand. The CCP team also intends to continue expanding the provision of mental health services by increasing the capacity of CCP staff and continuing to work to build partnerships with other organizations that have mental health resources. The CCP team hopes that commitment to these areas will likely improve care and patient outcomes for patients with the most complex chronic health challenges.

4. Quantitative Results

The University of Chicago identified eligible patients and, with their consent, randomized them to intervention or control arms of the study. Most of the University of Chicago patients were enrolled while in the hospital, but some were enrolled when visiting the ED or in the community. After enrollment, intervention patients received program services for all subsequent primary care and acute care at the University of Chicago Medical Center; control patients continued with their usual sources and patterns of care, some of which is also at the University of Chicago Medical Center. Patients continue to be added to the panel over time, and the earliest enrollees have had more quarters of exposure to the intervention than later enrollees. We therefore used a 'rolling entry' approach, and report on episodes of exposure to the program, as suggested by CMS.

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total Medicare episode spending. The results presented below are for the following Core measures, which differ somewhat from the core specifications:

- Average number of quarterly admissions to an acute care hospital for patients in the intervention and control arms of the randomized study.
- Average number of quarterly ED visits for patients in the intervention and control arms of the randomized study; again we count the number of ED visits, not simply whether or not there is one.

- Average quarterly Medicare spending for patients in the intervention and control arms of the randomized study.

Please see the Technical Appendix for description of how each outcome measure is specified.

The analyses in this report are based on data from Medicare claims; patients served by the innovation who have other forms of primary insurance (managed care, Medicaid, commercial, self-pay) are not included. In a future report we may be able to include Medicaid as well as Medicare claims.

The auto-enrollment of dual-eligible beneficiaries into MA plans may bias the intervention estimate through two paths. The first is that dual-eligible beneficiaries in both the treatment and control groups are likely to be relatively more costly than beneficiaries who are not eligible for Medicaid. If the intervention is more effective at reducing costs for the most expensive individuals, then when dually-eligible individuals are removed from the program, the estimated difference in cost between the remaining individuals in the treatment and control groups will likely be smaller than the difference that would be estimated between the total intervention and treatment groups if dual-eligible patients remained in the sample.

A potential second source of bias could be a differential rate of enrollment between the treatment and the control group in MA. That is, if all individuals are not enrolled at the same time (if Illinois took a couple of weeks or months to find enroll beneficiaries), we will not know if the presence of a claim is due to the staggered enrollment or whether an individual didn't need health care during a specific time frame.

We addressed these potential biases empirically by comparing the number of total claims for individuals enrolled in both Medicaid and Medicare. We used two definitions of Medicaid eligibility: the first is beneficiaries observed to be Medicaid-eligible individuals in the year 2013, the second is beneficiaries flagged as Medicaid-eligible on the registry provided by the University of Chicago. During the intervention period we saw no difference between the control and treatment groups in the mean number of submitted claims using either definition of Medicaid eligibility. We cannot conclude whether automatic enrollment into MA resulted in bias when comparing the two groups, but suspect that it is slight and caveat our analytic results accordingly.

In this report we used claims for all periods reflecting final action claims processing as of three months after initial submission for utilization outcomes, and as of six months for Medicare spending—any adjustments processed more than three (six) months after a claim was submitted are excluded, and partial claims (i.e., those that are mid-processing) are included.[58] We believe this is an accurate way to compare time periods.

4.1 Registry Information

The University of Chicago patient registry contains 972 patients who were recruited before December 31, 2014, had at least 90 full days of exposure to program services (intervention group only), and for whom we could locate Medicare claims. More patients were recruited after December 2014, but the period for complete Medicare claims used in this report is through the fourth quarter of 2014. The registry contains patient names, insurance numbers and where the patients were recruited (hospital, ED,

[58] Due to the different run out times the analytic sample sizes will vary slightly between utilization and cost outcomes.

community), as well as an indicator for whether the patient was randomized to the intervention or control group. Through Q4 2014, 972 program enrollees were found the Medicare claims. We were able to include demographics for 968 of these enrollees: 498 patients were randomized to the treatment arm of this controlled trial, and 470 were randomized to the control arm. We compared characteristics of patients in the two groups (age, gender, insurance source, recruitment method), as a check on the adequacy of randomization, and the two groups have quite similar demographics. No other selection rules are required, given the randomized design implemented by the Awardee.

We present results by 'exposure quarter'—how long each enrollee has been served by the program—because enrollment is ongoing (not all at once) and patients receive continuous program services from enrollment onward. The effects of the program are likely cumulative, and impact should be greater after more quarters of exposure to program services.

Exhibit 1 below shows duration of exposure to program services since enrollment, for patients in the two study arms. Through Q4 2014 all enrollees have had at least one quarter of enrollment, while only a few have had eight or more quarters since enrollment. Average outcomes for longer periods of exposure are therefore based on fewer patients, making results less precise than estimates for shorter periods of exposure. In addition, we do not present data for the very few enrollees that now have more than eight quarters since enrollment, because results are too imprecise given the small sample size.

Exhibit 1: Cohort Size, by Quarter (duration of exposure) Since Enrollment through 2014Q4

	Participant Quarters of Enrollment (exposure quarters)							
	1	2	3	4	5	6	7	8
Control Group	498	432	369	288	178	131	91	43
Intervention Group	474	414	347	263	173	125	93	43

Individuals were excluded if they were not enrolled in Medicare. Individuals were included for each quarter during which they were enrolled for the entire quarter; those whose first quarter of enrollment was partial (i.e., not the full three months) were included in the quarter following their enrollment.

4.2 Core Measures: Results

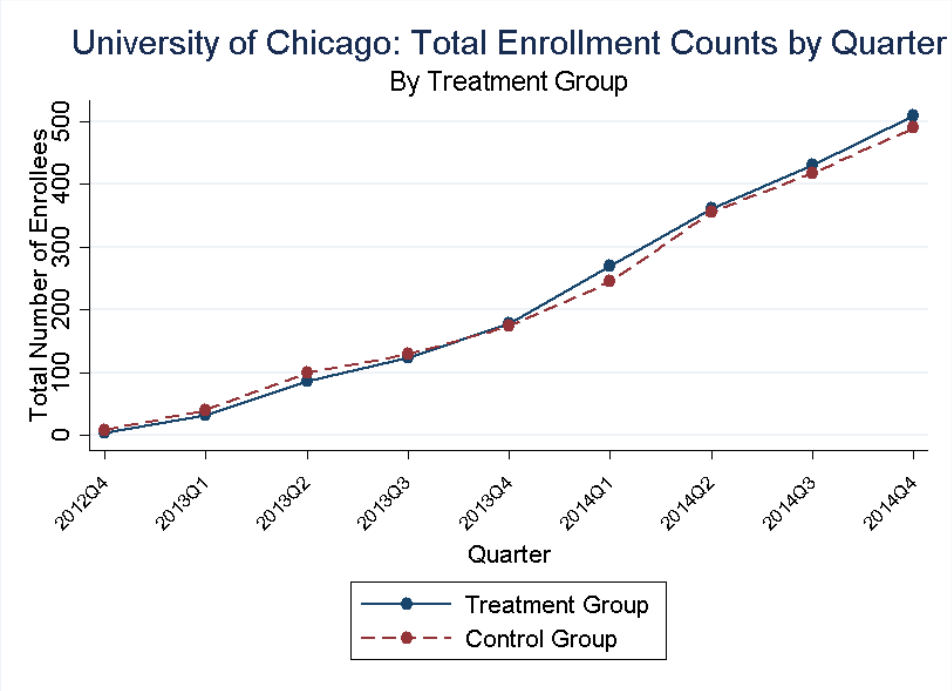
We calculated average per-person quarterly rates of hospital admissions, ED visits, and total Medicare spending. We did not create 'episodes' of care because this program continues to offer services to patients from enrollment onward. We did not calculate the number of readmissions because it is not possible to specify an 'index' admission that is distinct enough from the others to be considered the start of a new episode of care. Since the goal of the program is to prevent hospital admissions altogether, and particularly ED visits that become hospital admissions, the total number of admissions seems more important than whether one or more are readmissions. Given the randomized nature of the program, we show the difference between the control and treatment group, while controlling for patient demographics. We control for patient demographics to account for variation in each outcome that is not attributable to the intervention.

Since reducing mortality is not an explicit goal of the program, we do not view mortality as a program outcome. For all of the outcome trends, however, we retain all patients in the analyses regardless of patient mortality.

4.2.1 Enrollment Trends

Exhibit 2 shows enrollment in the U. Chicago program increasing as new eligible patients were randomized into the two arms of the study. This graph stops with Q4 2014, because that is the period for which claims are available at this time.

Exhibit 2: Enrollment Trend

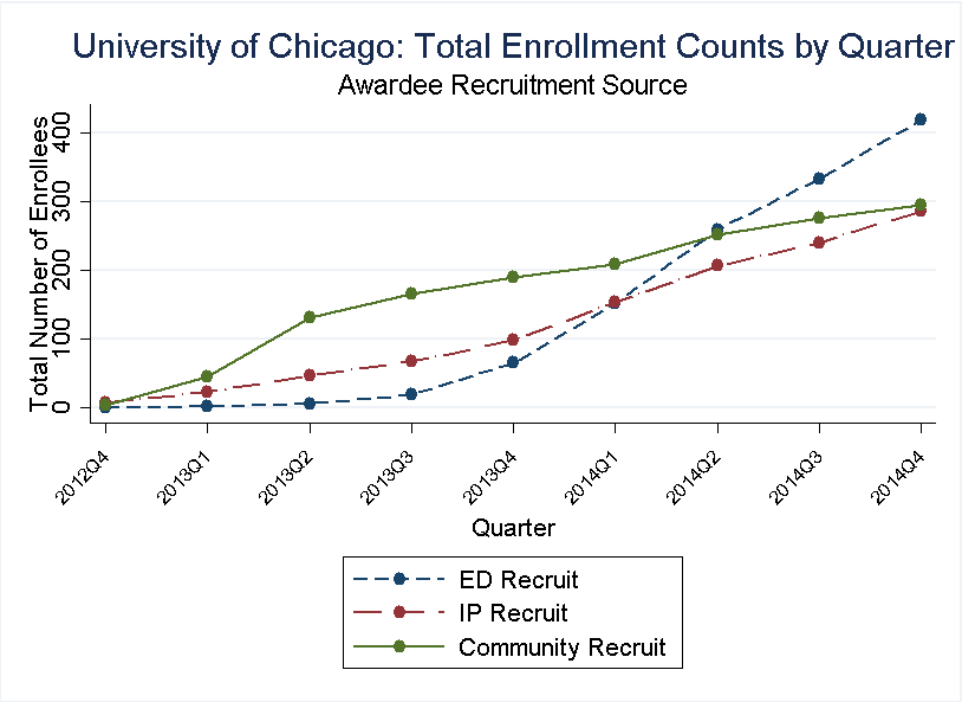


Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

4.2.2 Enrollment/Referral Source

Exhibit 3 shows study enrollment over time, and the locations from which participants were recruited and enrolled. Initially, most patients were recruited and enrolled in this program while in the hospital and from 'community' sources (e.g., physician referrals, recruitment events in senior housing venues) and few were enrolled while in the ED. Recruitment efforts intensified in the ED and in community settings as the program matured. This change over time in the site of enrollment has implications for the Exhibits that follow. For example, those who were enrolled in the ED will have had at least one more ED visit in the enrollment quarter than those who were enrolled in other locations, and those who were enrolled while in the hospital will have had at least one more hospitalization in the enrollment quarter than those who were enrolled elsewhere. Those who were enrolled while in the hospital may also have had higher costs in the enrollment quarter than those who were enrolled in less costly locations.

Exhibit 3: Enrollment/Referral Source



Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

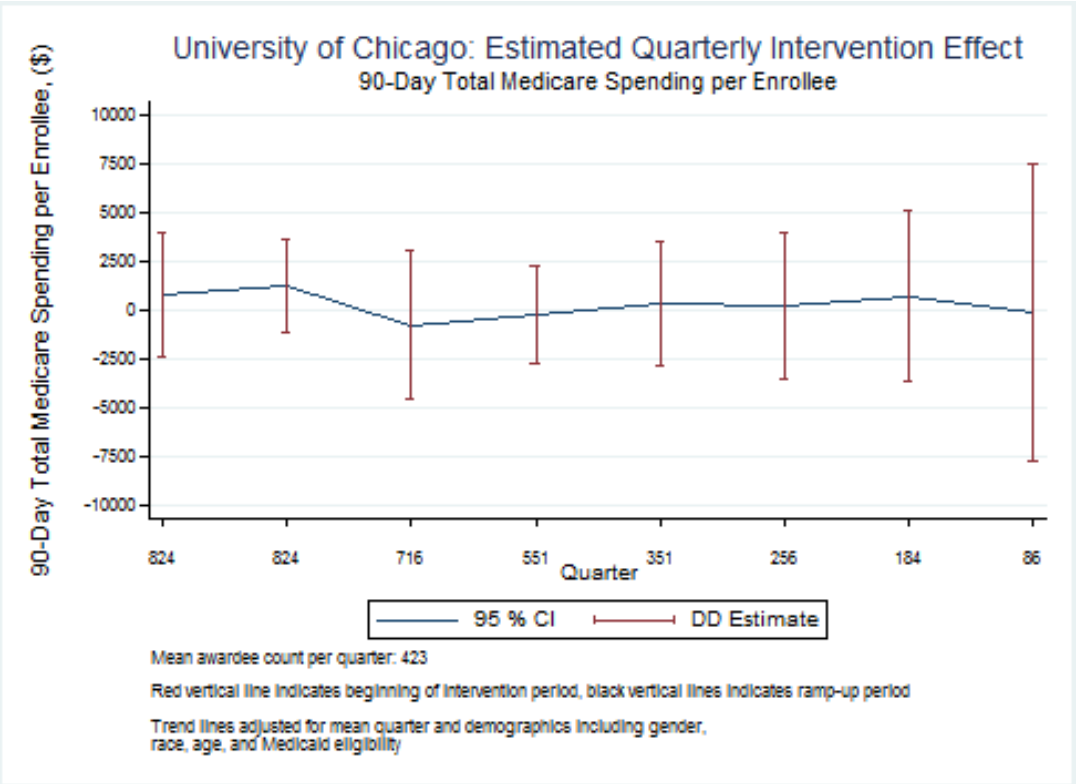
4.2.3 Average Medicare Spending[59]

Exhibit 4 (Medicare spending) shows little difference between the intervention and control through the duration of the program. The X-axis lists the number of individuals who are eligible for inclusion in each quarter since exposure to treatment.

Exhibit 5 shows the average difference between the treatment and control group, with additional covariates added for robustness. We estimate that the mean difference between the treatment and control groups is $1,199 per program enrollee, but is a statistically insignificant change. The median difference in cost for the treatment group relative to the control group is an insignificant $2,129 per treatment group enrollee. In the future, we will examine the sources of spending for each group (e.g., hospital, stays, ED visits, skilled nursing, home care).

[59] We do not adjust for inflation in measures of Medicare spending. The regression estimates are accurate, as inflation applies equally to both intervention and comparison groups.

Exhibit 4: Average Medicare Spending



Source: Abt Associates analysis of Registry and Medicare Claims, completed in June 2015.

Exhibit 5: Estimated Change in Average Medicare Spending per Program Enrollee

University of Chicago		
Intervention Effect (Ordinary Least Squares)	Estimate Standard Error Sample Size	1,199 (3,753) [824]
Intervention Effect (Median Regressions)	Estimate Standard Error Sample Size	2,129 (1,764) [824]

Standard errors in parentheses

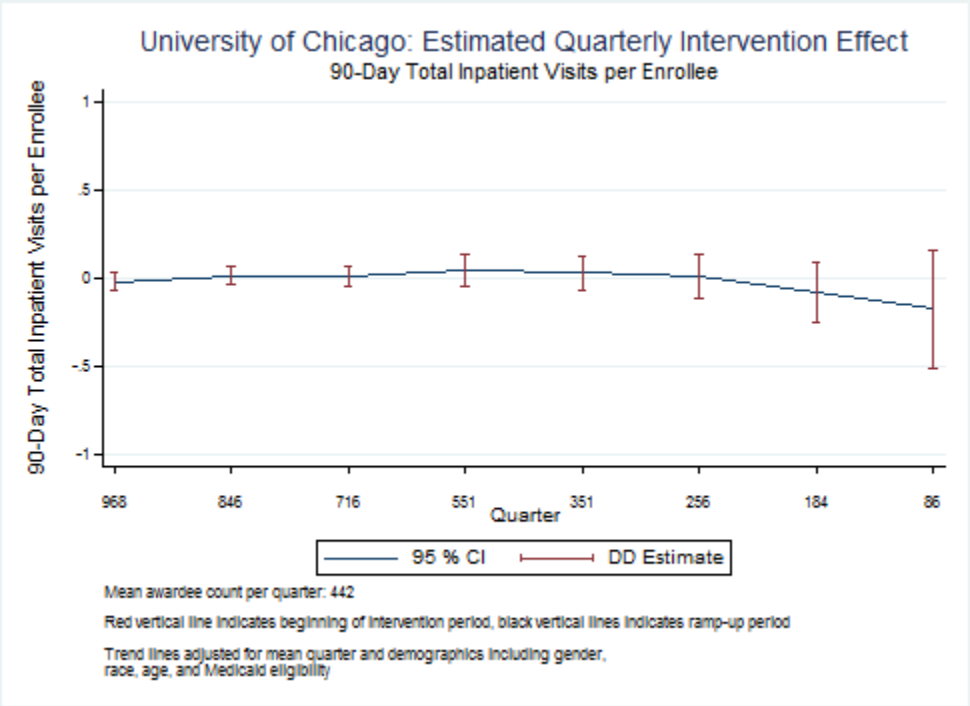
*** p<0.01, ** p<0.05, * p<0.1

4.2.4 Hospital Admissions

Exhibit 6 (hospital admissions) shows that the hospitalization rate is not affected by the intervention for all quarter that an enrollee participates in the program. The total number of patients in each exposure quarter is shown along the-X axis; the regressions included slightly fewer patients in the analyses as a result of incomplete demographic data for all of the patients.

Exhibit 7 shows the difference in the total number of hospitalizations between the treatment and control groups, after controlling for demographics. We find that the difference is statistically insignificant.

Exhibit 6: Hospital Admissions by Duration of Program Enrollment



Source: Abt Associates analysis of Registry and Medicare Claims, completed in June 2015.

Exhibit 7: Total Hospital Admissions, Pooled Estimate

University of Chicago	
Estimate	-0.05
Standard Error	(0.45)
Sample Size	[968]

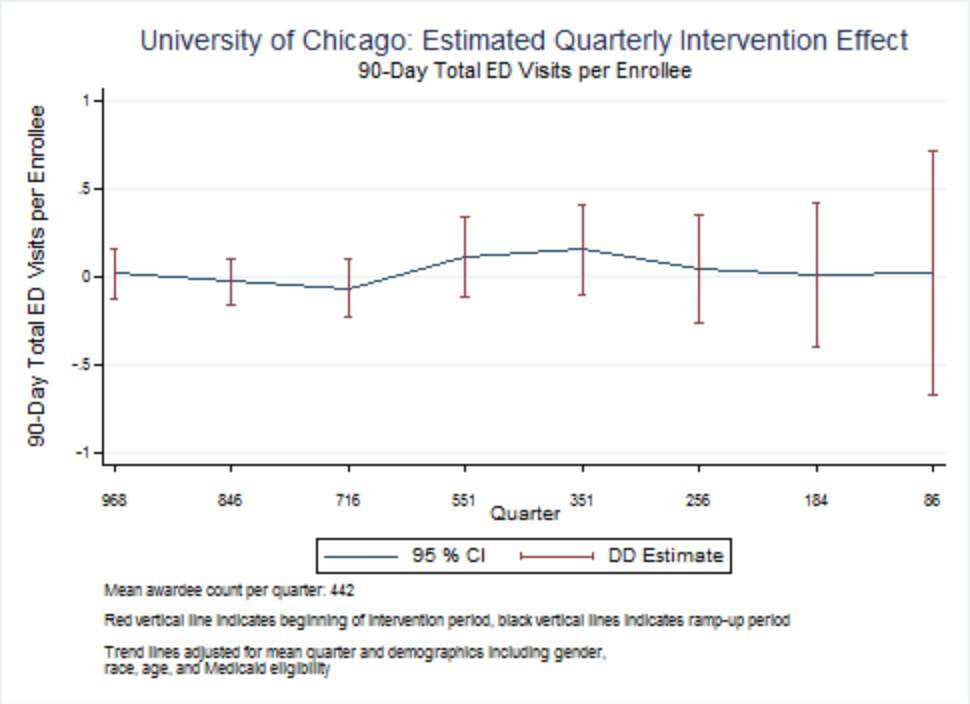
*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in June 2015.

4.2.5 ED Visits

Exhibit 8 (ED visits) shows that the difference in ED visits between the control and treatment groups by intervention quarter. We see a decrease in intervention group ED visits in the later quarters of the intervention, relative to the control group, but the standard error is large due to the small sample size. Exhibit 9 reports a total increase of 1.18 ED visits, which translates to an increase of roughly 25 percent from the control group average of 4.5 visits per enrollee. However, this result is not statistically significant.

Exhibit 8: Average ED Visits by Duration of Program Enrollment



Source: Abt Associates analysis of Registry and Medicare Claims, completed in June 2015.

Exhibit 9: Total ED Admissions, Pooled Estimate

University of Chicago	
Estimate	1.18
Standard Error	(1.04)
Sample Size	[968]

*p<0.1 **p<0.05 ***p<0.01

Source: Abt Associates analysis of Registry and Medicare Claims, completed in May 2015.

All of the preceding results are based on "exposure quarter" rather than chronological quarter, to examine impacts for patients with longer exposure to the intervention. Exposure is reported from 1-8 quarters for the hospital admission and emergency department visit rates, and from 1 to 7 quarters for average Medicare spending.[60]

[60] The reduction in exposure quarters is due to the extra quarter of claims run-out necessary to calculate average Medicare spending per episode.

4.2.6 Conclusions

- There is evidence that Medicare spending may be increasing for the intervention group relative to the comparison group, but the increase is not statistically significant.
- There is limited evidence that total number of inpatient visits are declining among intervention patients with longer program exposure, although again the small sample size precludes conclusions about the statistical significance of these results.
- There is no evidence of other program impacts, although the analyses are limited to traditional Medicare FFS claims.