Evaluation of Hospital-Setting HCIA Awards

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First Annual Report
Final

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Executive Summary

Abt Associates is evaluating the 10 Hospital Setting HCIA Awards, 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 facilities. These Awards focus on high utilization and high acuity patients. The initiatives range from improving critical (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 utilization such as rehospitalizations and repeat emergency department 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 first Annual evaluation report is based on the following source materials:

- 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 analysis of Medicare episode spending for the three largest Awardees

- Trend analysis of intervention and comparison groups for six of the smaller programs

- 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.

This report is not informed by clinician or patient surveys, which will take place in late 2014 and early 2015, respectively. Analysis of Medicaid claims will be added in future Annual reports, when those data become available to us for both baseline and intervention periods.

We assessed evaluability of each Award and revised the evaluation design for each. The major evaluability challenges presented by these 10 Awardees can be summarized as follows:

- Most of the Hospital Setting HCIA Awards have too few patients (through Q1 2014) to support quarterly analyses with tests of statistical significance. All but three are too small to support such analyses on an annual basis, and even pooling data across the entire intervention period, most are unlikely to ever reach the size required for meaningful statistical analysis.

- One program selects patients using clinical information (e.g., blood pressure, fever, pallor) that cannot be observed in claims data to create a comparison or baseline group.

- Several programs are quite heterogeneous across their multiple study sites; analyses pooled across study sites will obscure site-level differences, but pooling is necessary due to small numbers of patients in each site.

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. A trained researcher conducted each interview and a second researcher took notes; all interviews were also audio recorded (not transcribed) for reference. A code book was created for each Awardee and notes were coded using NVivo software and double coding was conducted for a few interviews in each case study to establish inter-rater concordance. Detailed case study reports were created for each Awardee (see **Appendix B.**)

Group-Level Qualitative Findings: Case Studies

Abt researchers conducted case studies with the 10 Hospital Setting Awardees, each of which included interviews with Awardee program staff, trainers, and data analysts, as well as interviews or focus groups with clinicians responsible for implementing the innovation. Careful notes and audio recordings were taken during all interviews and focus groups, and coded using NVivo software. Content analysis was conducted on the coded notes and separate case study reports were drafted for each Awardee.

Reports for the 10 case studies are included in Appendix B of this report. 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 Sigma.

Program Effectiveness

- Program staff and clinicians interviewed during case studies advised 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 arise in many programs, and in some cases delay implementation to partner sites.

Workforce Development

- Training continues to occur and evolve, adjusted to match skill sets and practice level of target clinicians. Training efforts must address float staff, residents and other staff turn-over.

- New responsibilities related to innovations challenge clinicians to practice at the top of their degree/certification and bedside staff working on many Awards described enhanced feelings of empowerment and 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. Those that hired or contracted for dedicated staff (e.g., mobility aides, home health aides) will need to demonstrate return on investment to their institutions, to receive continued funding.

- Programs that require extensive and complex technology enhancements/investment may be more challenging to spread.

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.

- It is not yet clear whether more efficient care will translate to savings for CMS. Staff in several programs that focus on reducing length of stay, for example, acknowledge that costs for Medicare under the prospective payment system may not be reduced. This calculus may change with increasing penetration of value-based purchasing and bundled payments.

Group-Level Quantitative Methods: Analysis of Medicare Claims

Abt Associates completed Data Use Agreements or Business Associates Agreements with seven of the 10 Awardees and the other three Awardees did not request such agreements. All data collection and use of secondary data was approved by the Abt Institutional Review Board, and several of the Awardees also asked their own IRBs to review the release of data (e.g., patient registries) to Abt.

Detailed analyses were created for each Awardee (see **Appendix B.**)

The core measures presented in this report for most Awardees include:

- 30-day all cause post-discharge readmissions

- 30-day all cause post-discharge ED visits

- 60-day Medicare total episode spending (absent Part D)

- Inpatient mortality and 30 day mortality

- Inpatient length of stay (LOS)

We do not present planned vs. unplanned readmissions because we expect that few ICU, sepsis, delirium or other conditions of interest for these Awardees would entail planned readmissions. Because most of these interventions take place in the hospital, admissions are not relevant (patients are already admitted when they receive the intervention), with the exception of subpopulations in three Awards: University of Chicago patients enrolled in the community, and long-term and post-acute care (LTPAC) patients in the Methodist Sepsis and Christus programs. 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.

We are able to create well-matched comparison groups for some Awardees, somewhat less well-matched comparison groups for others, and no comparison or baseline group can be created for one (Henry Ford Hospital). Three programs are large enough to support regression-based difference-in-differences analysis and we present intervention and comparison trend lines for the other seven.

We do not present statistical process control (SPC) charts because:

- The intervention and comparisons groups, created using identical criteria, were different in the baseline period for most of these programs. This could in part be due to underlying systematic differences (unmeasurable with claims data) between intervention and comparison groups. Another factor contributing to differences in the baseline period is that many of these Awardees had a history of testing and implementing new tools and approaches to improve care delivery and patient outcomes in their respective areas of focus, prior to the HCIA awards; thus the baseline period may not be completely free of intervention effects.

- Many intervention and comparison groups show volatility from one quarter to the next, during both baseline and intervention periods. This observed volatility is likely a function of small numbers.

Group-Level Quantitative Findings

We see no consistent patterns across these 10 Awardees in any of the core outcome measures, in either the intervention groups over time (pre/post) or in the relationship between intervention and comparison groups. We see no indication of an intervention effect for any one Awardee on any measure, using Medicare data through Q1 2014, although this analysis is hindered by small numbers.

We did not pool secondary data/analyses across the 10 Awardees because the interventions in these 10 programs are very different, and the three largest would overwhelm any influence of the other seven in a pooled analysis.

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
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, electronic surveillance and quality improvement, and reduce ICU complications and cost.
The 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.
The 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, mortality, LOS and cost.
Dartmouth Institute – 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.
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.
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.
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.
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.
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.
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.

All 10 of these programs focus on patients with high acuity needs or who are at high risk for costly utilization, or both. Intensive care units and emergency departments are the main venues for six programs and 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 long-term and post-acute care (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-discharge follow-up care.

With few exceptions, these programs are being 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 discharged from the hospital 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 mix-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. Medicaid claims will be added to the analysis in 2016, when they become available for baseline and intervention periods. Quantitative data sources include Medicare claims, patient registries from Awardees, and administrative data, and in the future we will conduct patient and clinician/worker surveys. 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 to address each research domain, as well as quantitative and qualitative analytic methods.

1.3.1   Data Sources for Research Domains

Exhibit 2 illustrates the data sources that address core research metrics that are the focus of the evaluation.

Exhibit 2: Core Research Domains, Dimensions, and Data Sources

Core Research Metrics	Dimensions	Program Document Review	Interviews Program staff	Interviews clinical and other staff	Focus groups with Intervention clinicians	Intervention clinician Surveys	Patient Surveys	Secondary Data Sources	Method
			Qualitative Data Sources						
Implementation effectiveness	Program drivers (theories of change and action)	✓	✓						Descriptive
	Intervention (components, dosage, fidelity, self-monitoring)	✓	✓	✓a	✓	✓			Descriptive
	Reach (coverage, participation, timeliness, secondary use of tools)	✓	✓		✓	✓			Descriptive
Program effectiveness	Health (outcomes, quality of life, self-reported health)				✓		✓	Awardee-reported data and measures	Difference- In- Difference (DID) or Interrupted time series
	Costs (program costs, health care expenditures and utilization)	✓	✓		✓		✓	Medicare & Medicaid Claims	Difference- In- Difference (DID) or Interrupted time series
	Quality (safety, clinical effectiveness, patient experience/ satisfaction, efficiency, care coordination)		✓	✓b	✓	✓	✓	Medicare & Medicaid Claims	Difference- In- Difference (DID) or Interrupted time series
	Cross-cutting considerations (equity and disparities, subgroup impacts, spillover effects)		✓	✓b	✓	✓	✓	Medicare & Medicaid Claims	Difference- In- Difference (DID) or Interrupted time series
Workforce issues	Development and training		✓	✓b	✓	✓		Awardee narratives	Descriptive
	Deployment		✓	✓b	✓	✓		Awardee narratives	Descriptive
	Satisfaction		✓		✓	✓			Descriptive

Core Research Metrics	Dimensions	Program Document Review	Primary Data Collection			Intervention clinician Surveys	Patient Surveys	Secondary Data Sources	Method
			Qualitative Data Sources						
			Interviews Program staff	Interviews clinical and other staff	Focus groups with Intervention clinicians				
Impact	Populations (medical and non-medical)	✓	✓		✓		✓	Medicare & Medicaid Claims	Difference- In-Difference (DID) or Interrupted time series
	Impact (cost savings, utilization, clinical impact)		✓		✓		✓	Medicare & Medicaid Claims	Difference- In-Difference (DID) or Interrupted time series
Contextual factors	Endogenous factors (leadership, team science, organizational, stakeholder engagement)	✓	✓		✓				Descriptive
	Exogenous factors	✓	✓		✓				Descriptive

[a] Providers in other settings and other workers
[b] Post-acute care providers
Source: Abt Associates analysis of Hospital Setting Awardees, October 2014.

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, discharge destination and mortality 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 3 shows these episode lengths, and the associated claims run-out periods that elapsed for each, in preparation of this report.

Exhibit 3: Episode Duration and Claims Run-Out Intervals

Measures	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
60-day post-discharge total episode costs	Episode		Claims Run-out and SSA death notices/dates						Receive patient lists from Awardees; create analytic files; specify intervention and comparison groups		Diff-in-Diff Regression Analyses	Annual Report
30-day post-discharge Readmissions	Episode		Episode	Episode	Episode	Claims Run-out						
30-day post-discharge ED visits	Episode		Episode	Episode	Episode	Claims Run-out						
Mortality	Episode		Episode	Episode	Episode	Claims Run-out						
Inpatient mortality	Admissions		Admissions	Admissions	Admissions	Claims Run-out						
Inpatient LOS	Admissions		Admissions	Admissions	Admissions	Claims Run-out						

1.3.2 Creating Intervention and Comparison Groups

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 as intervention facilities. For a few intervention facilities, notable those in Dartmouth's New England sites and the Mayo Clinic, there were no similar facilities in the same HRR and we used other facilities in the same or nearby states.

We did not use propensity scoring to create comparison groups because most of these 10 programs affect patients indirectly: intervention technologies, staff training, electronic trigger tools, communication processes and similar improvements apply to entire facilities or to entire units (e.g., ICUs, EDs, SNFs) and all the patients cared for in these units and facilities. We therefore matched first on the types of facilities and units where programs are implemented, and then used other patient factors (e.g., age, DRGs) to more closely approximate each Award's registry population.

Exhibit 4: Criteria for Selecting Comparison Group Providers

Awardee	Provider Size	Teaching Status	Specific Types of Services	Other Factors
University of Chicago	N/A	N/A	N/A	N/A
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
Emory	> 100 beds	N/A	ICU and ED services	
Henry Ford	> 500 beds	Major teaching	N/A	
Mayo Clinic	MA: 100-250 beds NY and MN> 500 beds	Major teaching	ICU and ED services	For MN, select comparison providers from Minneapolis HRR
Methodist-Sepsis: Hospital	> 300 beds	N/A	N/A	
Methodist- Sepsis LTCH	75 or more beds	N/A	N/A	
Methodist- Sepsis: SNF	50-150 beds	N/A	N/A	PRVDR_CTGRY_CD in('03,'04'). There are no SFF facilities in this HRR.
Methodist- Delirium: Hospital	50-150 beds	N/A	N/A	
Mt. Sinai	NY:> 1,000 beds IL, NJ: > 500 beds	Major teaching or graduate	N/A	
St. Lukes- Hospital	100-250 beds	Not a major teaching hospital	ICU services	Must be in Idaho (in Boise or Spokane HRR)
Dartmouth	>30 acute care hospitals, most with 200+ beds	Both teaching and non-teaching	ICU and ED	For NH and ME use all large northern New England and upstate NY; for urban sites, weight comparisons in pooled analyses

Additional Details:

- The Christus program and the Methodist Sepsis program each have multiple types of participating facilities (hospitals, SNFs, LTCHs, nursing homes).

- The University of Chicago program is using random assignment. Our comparison group for this Awardee contains the randomized patients, not patients from comparison providers.

- Provision of ED services is identified using DCTD_ER_SRVC_CD.

- Provision of ICU services is identified using ICU_SRVC_CD

- Teaching status is identified using MDCL_SCHL_AFLTN_CD

- Note that we excluded from the comparison group any providers that are children's hospitals and non-Awardee hospitals that are affiliated with Mayo (both identified based on provider name).

We used Awardee-supplied patient registry data to develop inclusion/exclusion criteria (rules) and then used these criteria to define intervention and comparison populations for both baseline and intervention periods. 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. In some cases, the rules 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., there were clinical criteria applied by Awardees 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. Finally, Awardees serve patients with insurance coverage other than original Medicare and information about these patients is not available to us.

Each Medicare patient in an Awardee's registry was matched to a CMS file that contains the identity of all Medicare beneficiaries from January, 2010 onward, to determine which patients in the registries have corresponding Medicare FFS claims. This match was performed using HIC numbers provided by the Awardees or, for a few Awardees, social security numbers. Approximately 83 percent of Medicare patients in each registry had a valid HIC number or social security number. Exhibit 5 below indicates the number of registry patients each Awardee included in their lists, how many we were able to find Medicare FFS claims for, and the dates covered by the registries.

Exhibit 5: Medicare Intervention Patients with Valid HIC Numbers, and Registry Start Date, by Awardee

Awardee	Number of Medicare Patients	HIC/SSN Match to Medicare claims		Registry Start
		(N)	(%)	
Christus	155	100	65%	9-Oct-13
Emory	1,501	1,126	75%	8-Mar-13
Henry Ford	4,036	3,907	97%	13-Sep-12
Mayo Clinic	2,711	2,302	85%	15-Jan-13
Methodist Delirium	5,587	5,197	93%	8-Apr-13

Awardee	Number of Medicare Patients	HIC/SSN Match to Medicare claims		Registry Start
		(N)	(%)	
Methodist Sepsis	12,409	11,037	89%	8-Apr-13
Mt. Sinai	26,814	26,814	N/A	1-Oct-12
St. Luke's	3,059	2,007	66%	26-Dec-12
University of Chicago	509	487	96%	6-Nov-12
Dartmouth[1]	--	--	--	--

[1]Dartmouth's patient registry contained incomplete data that were insufficient for matching to Medicare claims.
Source: Abt Associates analysis of Hospital Setting Awardees, October 2014.

Invalid HICs were excluded as likely being a Medicaid number[1], private insurance number, or (possibly) a mis-entered Medicare number. We assume that Medicare beneficiaries who have a HIC number but have no FFS claims are enrolled in Medicare Advantage plans.

For each Awardee intervention facility we selected a comparison group of similar facilities in the same Hospital Referral Region (HRR).We considered the following factors in selecting comparison group facilities:

- **Provider type:** Comparison group facilities are the same type of facility as those in the intervention, matched on both prvdr_ctgry_cd and prvdr_ctgry_sbtyp_cd.

- **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 them.

- **Miscellaneous exclusions:** We excluded Special Focus Facilities (SFF) as 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 (there are a few Oklahoma providers in the Christus HRR). Finally, note that no Awardee facilities were eligible to be comparison group facilities for another Awardee's program.

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[1]   Medicaid claims will be added to our analyses when they become available for the intervention period.

Some Awardees are continuing to add study sites. If a new type of study site (e.g., Long Term Care Hospitals) is added in the future, we will broaden the comparison group to add those types of providers.

For patients served by intervention and comparison facilities, we developed inclusion and exclusion criteria to specify the types of patients each Awardee focuses on. 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 and claims lacking a line item charge from the intensive care unit were excluded from the matching analysis.

- **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 program targets patients with sepsis, and in the first two years its study sites focused on the emergency department (ED) and ICU. After the inclusion or exclusion of claims based on ED/ICU revenue centers and transplantation DRGs, 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).

The steps above yielded inclusion and exclusion criteria for each Awardee program except Henry Ford's Mobility program. We then applied these criteria to the intervention and comparison facilities, so that the study populations in each were selected using identical criteria. The table below 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 table 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.

The percentage of estimated intervention patients that match with registry lists partially determines our program evaluation approach. If the match rate is greater than or equal to 50 percent, we feel it is reasonable to use the inclusion/exclusion rules we have developed to create a comparison group. If the match rate is below 50 percent, we are not confident that we can specify the intervention group or an associated comparison or baseline group.

Match Between Estimated Intervention Population and Awardee Patient Registries

For all Awardees but Dartmouth and the University of Chicago[2], 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 eight Awardees.

Exhibit 6: Awardee Registry and Abt-Estimated Counts

Awardee	Christus	Emory	Henry Ford	Mayo Clinic	Methodist Delirium	Methodist Sepsis	Mt. Sinai	St. Luke's
Registry Medicare Patients	155	1,500	4,036	2,711	5,587	12,409	26,814	3,059
Registry Medicare Patients with Submitted Claim	77	1,049	2,162	2,135	4,858	10,868	10,658	1,554
Estimated Patients based on Abt rules	3,292	1,158	8,716	1,817	6,738	14,822	23,067	1,493
Match between Estimated and Registry	72	1,009	1,953	1,733	4,711	10,689	10,616	1,276
Registry Patients, Not Captured by Abt rules	5	40	0	402	147	179	42	278
Estimated by Abt rules, Not in Registry	3,220	149	6,763	84	2,027	4,133	12,451	217

Source: Abt Associates analysis of Hospital Setting Awardees, October 2014.

No rules were required to specify intervention and comparison patients for the University of Chicago randomized trial. We applied award inclusion and exclusion criteria to the Henry Ford claims data in an attempt to replicate the Henry Ford patient registry. Exhibit 6 reports the estimated patient group as a result of the criteria to us by Henry Ford, and verifies that selection criteria applied without additional clinical information overestimates the registry by a factor of 4.3. As a result, Abt researchers concluded that no matching criteria applied to claims data would be sufficient to replicate the registry or to select an appropriate comparison group. Dartmouth's patient registry contained insufficient information to match to Medicare claims.

The best matches we can create for each Awardee, using data available from Medicare claims, yield the following:

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[2] University of Chicago's randomized design provided us with both an intervention and control groups, making it unnecessary to develop inclusion/exclusion criteria. The Dartmouth registry did not contain necessary information to estimate the mismatch between estimated and actual intervention populations.

Strong Matches

- **Emory University's Rapid Development and Deployment of Non-Physician Providers and eICU in Critical Care:** The rules we developed for Emory result in a very close match to their eICU patients. Our analyses reflect the eICU component of the Emory innovation; the larger group of patients who were exposed only to the residency training component and not the eICU are omitted because they were not included in Emory's patient registry. Patients exposed to both the eICU were also exposed to the critical care residents, thus the measures we present apply to the combined impact of both program components, but for a fairly small number of patients.

- **St. Luke's eICU:** The rules we developed for St. Luke's result in a close match to their eICU patients; a couple of hundred 'extra' patients are in the intervention group and a couple of hundred patients are included who did not receive the intervention. Any bias is likely to be balanced and we use these rules to create intervention, comparison and baseline groups for impact analyses.

Matches that May Introduce Bias

- **Mayo Clinic:** The match we achieve using rules based on registry and claims data misses hundreds of intervention patients, and captures a few dozen who did not receive the intervention. Our impact results may be biased in an unknown way for the Mayo intervention.

- **Methodist Hospital Delirium program:** The match we achieve using rules based on registry and claims data is better in later quarters but thousands of patients are included who did not receive the intervention and impact results will tend to be biased toward zero.

- **Methodist Hospital Sepsis program:** The same is true for this program with the match being better in later quarters but still including thousands of patients who did not receive the intervention, which will bias impact results toward zero.

- **Mt. Sinai:** The match we achieve using rules based on registry and claims data captures nearly all intervention patients but also captures more than twelve thousand who did not receive the intervention and will tend to bias impact results toward zero.

No Matching Needed

- **University of Chicago:** No matching was required for this randomized controlled trial, as the Awardee provided both intervention and comparison patient lists.

- **Christus St. Michael's:** The program registry contains too few patients to support a matching exercise. Because program staff advise that all patients in intervention facilities are supposed to be screened/assessed every day, we include all patients admitted to participating facilities in our impact analyses.

Match Unknown

- **Dartmouth Institute's Sepsis program:** The Dartmouth registry contains incomplete information for matching patients to Medicare claims. We base patient selection criteria on information provided by the Awardee (e.g., DRGs, ED use, ICU use) rather than on analysis of registry vs. claims data. We cannot estimate whether these criteria are likely to result in bias, but it is likely that we include patients who did not have severe sepsis which will bias impact results toward zero.

No Match Possible

- **Henry Ford Hospital:** This program uses clinical criteria to select patients that we are unable to replicate using data available in claims. We therefore cannot create baseline or comparison groups and report trends over time for the intervention group during the intervention period.

In summary: For nine of the programs we present trend lines for intervention and comparison groups. For the Henry Ford Hospital mobility program we present intervention-period trends for the intervention group but can create no baseline or comparison group.

1.3.3   Sample Size Considerations

The Hospital Setting HCIA Awardees currently have Medicare FFS volumes that are too small to conduct difference-in-differences analyses because none of the analyses would be powered to detect changes of the size Awardees anticipate achieving, especially with respect to Medicare costs. 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 Q1 2014.

For nine of the 10 Hospital Setting HCIA Awardees[3] 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 only included Medicare spending for 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.

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

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[3]   Because the Henry Ford 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 the Henry Ford Mobility intervention.

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 first 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 appropriate at this time for the Methodist Sepsis program, the Methodist Delirium program, and the Mt. Sinai program, which have a calculated power of .99, .94, and 1.0, respectively. We anticipate that the Dartmouth and Mayo Clinic programs may be large enough in another year to conduct regression analyses. The other programs, however, are not likely to be large enough to support regression analyses, even pooling data for the entire intervention period.

Exhibit 7. Statistical Power to Detect Differences, by Awardee

Awardee	Intervention Size Through Q1 2014 (Medicare FFS Claims)	Baseline Mean	Baseline Std. Dev	Power to Detect 5 % Difference*
Christus St. Michael's	2626	$9,805	$19,338	0.33
Dartmouth Institute	4126	$20,066	$23,803	0.77
Emory University	2817	$19,102	$20,228	0.69
Mayo Clinic	5522	$12,175	$19,156	0.69
Methodist – Delirium	11382	$12,195	$17,661	0.94
Methodist – Sepsis	20072	$12,570	$19,366	0.99
Mt. Sinai	54809	$9,208	$16,954	1.00
St. Luke's	1899	$10,702	$18,642	0.28
University of Chicago	334	$20,952	$45,241	0.14
Henry Ford – no baseline or comparison group possible	--	--	--	--

*p-value = 0.10
Source: Abt Associates analysis of Hospital Setting Awardees, October 2014.

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

1.3.4 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 utilized a difference-in-difference (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). Since the average attributes of patients treated at Awardee or comparison facilities may not remain constant over time, the DD estimator will not capture changes in patient outcomes that are attributable to changes in the makeup of the patient population. 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 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 ith individual during the tth year from the kth index stay at the jth facility.

X_{itk} This is a vector of characteristics for the ith individual in the tth year from the kth index stay.

P_{ikj} This is an indicator variable equal to 1 if the ith individual received services in the kth index stay from an jth facility that is an HCIA Awardee, 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 jth 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:

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

where θ is the vector of estimated HCIA intervention effects. 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 fixed effect that accounts for differences between Awardee and comparison 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 P_{itjk} 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. However, we cannot rule out the possibility that the error term is correlated across observations. For instance, roughly 25% of patients in the sample (pooled across all Awardees) are observed one or more times. Even conditional on X_{itk} it is possible that patient outcomes are correlated across their separate hospitalizations. Additionally, the Awardee and comparison groups are often comprised of multiple facilities at which an index stay may occur. Outcomes within a given facility may be correlated due to unobserved factors such as the average skill level of the staff, efficiency of the administration, etc. Failure to account for any correlation between outcomes may bias estimates of the standard error, which will in turn render hypothesis tests unreliable. We therefore clustered standard errors at both the individual and facility level to account for both types of correlation. Since the two types of correlation are not nested (i.e., individuals observed more than one time may not be exclusively treated at a single facility) we use multi-way clustered standard errors[4]. (Cameron, Gelbach, and Miller, 2009.)

We conducted regression analyses for 60-day total costs; we did not do the same for the other core because each has too much variation to detect changes between the pre- and post-intervention time periods with the current number of observations. Moreover, we only conducted regression analyses for the Methodist Sepsis, Methodist Delirium, and Mount Sinai programs due to the amount of variation in costs and/or lack of sample size for the other seven Awardees (please see power calculations in Exhibit 7).

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% of observations the adjustment process resulted in negative costs accruing to the hospital.[5] In these instances the cost was reset to 0. Based on guidance from CMS, the results presented here do not truncate costs to remove extreme outliers.

Independent Variables:

- Awardee: Binary indicator for whether patient is affiliated with an Awardee

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[4] Cameron, A. Colin, Jonah B. Gelbach, and Douglas L. Miller. "Robust Inference with Multi-way Clustering." *Working Paper*, 2009.

[5] 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.

- 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: 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 (Mt. Sinai only): In the models for Mt. Sinai, we included binary indicators for their program's three intervention facilities due to important differences in the three facilities' interventions.

We estimated the model separately for Methodist Sepsis, Methodist Delirium, and Mt. Sinai, using the Awardee-specific comparison groups assembled according to the methods described above. Because intervention facilities are not large enough for facility-level analyses, all facilities in a given Awardee program were pooled. For consistency with the other HCIA evaluations, total costs were estimated 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**.

1.3.5   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) for HCIA Awardees on a quarterly basis. These Core measures include admissions, readmissions, ED visits and total episode spending by Medicare and/or Medicaid. 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.

1.3.6   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. When Medicaid data become available, future reports will include Medicaid as well as Medicare spending.

- **Readmissions:** For patients who receive a program service while in the hospital, we report on readmissions in 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 are in the hospital and the intervention ends at discharge, making measurement of admissions irrelevant. The University of Chicago program enrolls and randomizes patients in community and ED settings as well as inpatients; 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.

Other measures are important to monitor whether Awardees are meeting other goals such as efficiency and quality. This report also contains the following non-Core measures:

- **Mortality:** Many of these Awardees expect to reduce mortality and we report on in-hospital mortality as well as 30 day post-discharge mortality.

- **Inpatient length of stay:** For programs where the intervention takes place during an inpatient admission, we report LOS.

If claims volumes permit, future reports will contain additional measures that are relevant for one or more Awardees, including:

- Medicare (and eventually Medicaid) spending within episode, stratified by type of covered service.

- Hospital-acquired conditions (e.g., pressure ulcers, ventilator-associated pneumonia).

- Admissions classified as payment outliers.

- Discharges stratified by discharge destination: home, home health, skilled nursing/rehabilitation, LTCH.

We do not present planned vs. unplanned readmissions because we expect that few ICU, sepsis, delirium or other conditions of interest for these Awardees would entail planned readmissions. Because most of these interventions take place in the hospital, admissions are not relevant (patients are already admitted when they receive the intervention), with the exception of subpopulations in three Awards: University of Chicago patients enrolled in the community, and long-term post-acute care (LTPAC) patients in the Methodist Sepsis and Christus programs. 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.

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 for three Awardees.

1.3.7 Presentation of Trends

As shown in Exhibit 7 above, only three programs are large enough at this time to conduct multivariate difference-in-differences analyses. For other programs, only trends can be presented.

Statistical Process Control (SPC) charts display a line indicating the mean and standard deviations of the comparison group outcomes during the pre-period, then compares the intervention outcomes against these means and standard deviations. If the intervention outcomes are within the 95 percent confidence interval of the comparison group, and the two lines never cross in the baseline period, then we say that the intervention process is "controlled" and does not deviate substantially from the comparison process. This technique is useful when we are certain that the intervention and comparison groups had the same "processes" during the baseline period (i.e., the intervention group was always within the 95% confidence interval of the comparison group in the baseline period, and the lines for the two groups never crossed). If the underlying processes were not the same in the baseline period, however, then the initial difference in means could be large enough that the intervention trend line will be outside of the comparison group's outcome range. This is exactly what we observed for these Awardees. This is not surprising, because we learned during case studies that many Awardees were already testing and implementing important components of their interventions prior to receipt of HCIA funding. In addition, we are unable to create absolutely identical comparison groups for each Awardee, and any imprecision may result in unavoidable systematic differences between intervention and comparison groups.

Due to these limitations, SPC charts are inappropriate and we instead present trend lines for intervention and comparison group outcomes, and indicate the demarcation between baseline and intervention (pre/post) periods. For Awardees that adopted their intervention at different times in their participating facilities, we include additional markers to indicate the quarters in which new facilities adopted the intervention. While trend lines do not allow us to infer a statistical effect of an intervention, we can approximate concurrent trends in both sets of outcomes, over time.

1.3.8 Primary Data Collection and Analysis

Patient Survey

The patient survey will be conducted in early 2015, with intervention patients and a matched comparison group, for seven of the ten Awardees (the other three Awardees' patient populations are too small to support a survey). Survey items focus on the experience of care, communication with health care providers, current health and functional status, and satisfaction with care.

For each Awardee we will present descriptive statistics (e.g., averages, standard deviation, frequencies) for each survey item, and test whether responses are significantly different between the comparison and intervention groups. We will use multivariate analysis, controlling for patient characteristics (e.g., age, gender, race, ethnicity, marital status, self-reported health status) that may help explain some of the variance in the dependent variables of interest. We will employ standard econometric methods (e.g., ordinary least squares for continuous dependent variables, logistic regression for binary dependent variables) and software (i.e., SAS Version 9.3, Stata Version 12). Given the individuality of each Awardee's intervention, we do not anticipate conducting comparisons across Awardees.

Clinician Survey

An online clinician survey will be conducted in late 2014, with a random sample of clinicians implementing the HCIA program, for six of the 10 Awardees. The other four Awardees' clinician population is too small to support a survey, or so large that lists cannot be assembled (e.g., Dartmouth). For these programs, qualitative interviews and focus groups with staff will be employed rather than a survey. Survey items include opinions and attitudes about the Awardee-specific HCIA program, adequacy of training and resources to implement the program, changes wrought by the program in staff workflow and workload, and perceived impact of the program on patient outcomes and on cost.

For each Awardee we will present descriptive statistics (e.g., averages, standard deviation, frequencies) for each survey item. As with the patient survey, we do not plan to pool data across Awardees, however, we may compare results for Awardees with similar programs.

Case Studies

In-person case studies were completed with all Awardees in early 2014 and in-person or virtual follow-up case studies will be completed in early 2015, prior to the conclusion of each Award. For the largest Awardees, case studies will include several partner organizations or sites (e.g., three health systems participating in the Dartmouth Institute 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 code book was developed for each Awardee and qualitative data were coded using NVivo. The coding scheme aligned with the topics addressed during case studies, and were tailored to match Awardee-specific, or 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.

1.3.9 Evaluation Challenges

Evaluability

As discussed above, each of these 10 Awardees poses 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 8 below identifies important evaluability issues for each Awardee.

Exhibit 8: 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?	DID regression approach possible?	Intervention/Comparison patient survey possible? Clinician/ staff survey?
Mayo Clinic	Implementation at partner sites is delayed; tool may not be identical at every site, due to underlying differences in EHR 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	Patient and staff survey
Methodist (delirium)	No	No	Yes, moderate match with some bias likely	Yes	Patient and staff survey
Methodist (sepsis)	Sites include hospitals, LTCHs and SNFs. Also, implementation throughout an entire facility is staged and takes several months	No	Yes, moderate match with some bias likely	Yes	Patient and staff survey
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	Patient survey; staff lists unavailable from Awardee for staff survey
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	No patient or staff survey

	Heterogeneity Across Study Sites?	Changes in primary components of the intervention over time?	Claims-based specification of intervention and comparison groups possible?	DID regression approach possible?	Intervention/Comparison patient survey possible? Clinician/ staff survey?
University of Chicago	Only one study hospital	Yes – community recruitment added patients who did not have a hospitalization; home visiting component may be added	Yes, awardee randomly assigned patients to intervention and comparison groups	No, program too small for tests of statistical significance	No surveys: Awardee surveys every intervention and control patient every quarter with an appropriate questionnaire; no need to conduct another survey; no survey necessary for small number of clinicians involved
Emory University	Telemedicine support available in some ICUs but not others; first rural hospital beginning in 2014	Yes, newly trained staff are being added at various times; telemedicine component added in some but not all ICUs	Yes, well-matched	No	Patient and staff surveys
St. Luke's	Intervention includes ICU at most sites, ED at small CAHs	ED component added in CAHs	Yes, well-matched	No, program too small for tests of statistical significance	No surveys. Awardee is conducting patient survey; program too small to accumulate 500+ patients for our survey. Clinician survey also being conducted by Awardee and will provide sufficient information.
Mt. Sinai	Specific intervention components vary considerably at three sites in three states.	Multiple, evolving intervention components over time	Yes, moderate match with some bias likely	Yes	Patient and staff surveys
Christus St. Michael's	New staff at NHs are not being trained and attrition is diminishing the program at NHs. Also heterogeneity in use of the IT tool	No	No matching needed, all patients are supposed to be screened daily	No, program too small for tests of statistical significance	Patient and staff surveys

Source: Abt Associates analysis of Hospital Setting Awardees, October 2014.

2. Cross-Awardee Findings

This chapter contains cross-Awardee findings based on case studies, and cross-Awardee findings from quantitative analyses. Survey findings will be included in our second Annual Report, in 2015.

2.1 Qualitative Findings

A number of cross-Awardee themes were identified during the 10 case studies conducted in 2014. Exhibit 9 shows these common themes, and each theme is described in detail following the exhibit.

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

Exhibit 9: Cross-Awardee Qualitative Themes & Lessons Learned from 10 Case Studies

Themes Identified During Case Studies	Chicago	Christus	Dartmouth	Emory	Henry Ford	Mayo Clinic	Methodist-Sepsis	Methodist-Delirium	Mt. Sinai	St. Luke's	# 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	7
Senior physician 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 implementation delayed at partner sites until innovation perfected and infrastructure in place	No partners			X	No partners	X	X	X		X	5
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

Themes Identified During Case Studies	Chicago	Christus	Dartmouth	Emory	Henry Ford	Mayo Clinic	Methodist-Sepsis	Methodist-Delirium	Mt. Sinai	St. Luke's	# Awardees With This Theme
Workforce Development											
Training continues to occur and evolve; performance feedback promotes innovation	X		X	X	X	X	X	X	X	X	8
Training is adjusted for skill sets of target staff	X	X	X	X	X		X	X	X	X	8
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
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	5
Spread is harder for programs with complex information technology				X		X				X	3

Themes Identified During Case Studies	Chicago	Christus	Dartmouth	Emory	Henry Ford	Mayo Clinic	Methodist-Sepsis	Methodist-Delirium	Mt. Sinai	St. Luke's	# Awardees With This Theme
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 enhances care coordination	No partners	X	X	X	No partners		X	X	X	X	7

Source: Abt Associates analysis of Hospital Setting Awardees, October 2014.

2.1.1 Implementation Effectiveness

Program staff explained to Abt qualitative researchers that most of these programs were not conceived for the purposes of getting 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 its eICU network. We also learned during a case study that the Mt. Sinai emergency department (ED) program was 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 prior to the award told us that this experience helped them modify innovations/systems to address known impediments.** 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.

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 U. of Chicago's program holds daily interdisciplinary rounds, focused on patients with scheduled appointments as well as those in the hospital. When multiple sites are involved, most Awardees convene regular phone or in-person contact between sites or participating units. All levels of staff reported during case studies that the strength of these relationships support feedback about the interventions to program leadership and rapid improvement, which in turn facilitates adoption.

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 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, can facilitate 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 is not mandatory, seem to be experiencing 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 is 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; 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 to address challenges in implementing a new technology reported by Awardees 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 their partners have had difficulty making 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.

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 target 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 can help, posters, and newsletters. We observed that many Awardees display such program materials in work areas, to remind float staff, residents and other new personnel.

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.

Recent graduates and new hires may be more open to adopting innovations. Clinical leaders explained that new staff are fresh and 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 is a challenge for some Awardees, when 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 elderly patient. Selection criteria were implemented to ensure that patients who will benefit most are admitted to this special ED. In another example, the Mayo 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 and Spread

Programs that integrate their innovation into existing technology, practice 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 reported that they will not 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 (e.g., Henry Ford mobility aides, Methodist Delirium home health aides, Mt. Sinai's GERI-ED staffing) or additional grant funding. Based on our case studies, it is not yet clear whether this support can be continued in every case.

Programs that require extensive and complex technology enhancements/investment may be less likely to spread. eICU programs, for example, require hardware, software, internet connectivity and IT system compatibility; complexities that challenge the rural acute and long-term care hospitals that could benefit most. For another example, the Mayo ICU program overlays a clinician-focused information array over an existing EHR data stream, which is complex to implement in partner sites that do not use the same EHR vendor products as Mayo Clinic.

2.1.6   Perceived Impact: Better Care, Better Health, Lower 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 elderly and high-risk patients, or better information with which to make clinical decisions, clinicians in every institution we visited view the innovation as an improvement over prior practice.

Planning for and implementing some innovations reportedly 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. It is not yet clear whether more efficient care will translate to savings for CMS. Several programs that focus on reducing length of stay, for example, and program staff acknowledge that costs for Medicare under the prospective payment system may not be reduced. They anticipate, however, that this calculus will change with increasing penetration of value-based purchasing and bundled payments.

2.2   Cross-Awardee Quantitative Findings

The following sections present findings for multivariate analyses (three programs) and trends (seven programs), based on data through Q1, 2014.

2.2.1   Multivariate Difference-in-Difference (DD) Regression Analysis

The DD regression analysis described in the methods section above was conducted for the three largest programs: the two Methodist hospital programs and the Mt. Sinai program. The dependent variable is the average total Medicare cost per episode from discharge to 60 days post-discharge. We did not test for differences in other outcomes (readmissions, ED visits, LOS). The model includes controls for patient age, squared age, gender, race, HCC score in year of treatment, eligibility for Medicaid at any time during observation period (2010–2014), as well as indicators for quarter of the year in which the episode occurred and, for the Mt. Sinai program, a facility indicator (because the program is distinctly different in the three participating EDs). An indicator is also included for individuals with missing HCC scores. Exhibit 10 presents the results; standard errors (in parentheses) are clustered at the individual and facility level.

Ordinary Least Squares (OLS) regression estimates for the Methodist Sepsis program fail to indicate any significant relationship between the intervention and Medicare episode spending during the 60 days starting with the index admission. Although there was an average reduction in episode spending of roughly $120 per patient, this represents a change of less than 1% compared to the pre-intervention average among Sepsis Awardee facilities, and the standard error of the estimate is too large to reject the null hypothesis that the intervention had no effect on average Medicare episode spending.

For the Methodist Delirium program, the regression estimates fail to indicate any significant relationship between the intervention and Medicare episode spending during the 60 days starting with the index admission. Although there was a slight increase in episode spending of roughly $58 per patient, this is a very small change and the standard error is too large to reject the null hypothesis that the intervention had no effect on average Medicare episode spending.

Regression estimates for the Mt. Sinai program fail to indicate any significant correlation between the intervention and Medicare episode spending, among patients treated in the emergency department. Despite a point estimate suggesting a $90 (or 1%) reduction in post-discharge cost per patient, the standard error of the estimate is too large to conclude that the effect of the intervention was different from zero.

For all three programs we pooled data from participating facilities and did not conduct facility-specific analyses, because none are large enough yet to give us the power to detect facility-level change with reasonable confidence.

Exhibit 10: Effect of Intervention on Medicare Spending During Inpatient Episode and 60-Days Post-Discharge

Methodist Sepsis (pooled across hospitals)	
Intervention Effect	-169.65
	(613.82)
Methodist Delirium (pooled across hospitals)	
Intervention Effect	57.94
	(239.88)
Mt Sinai (pooled across emergency departments)	
Intervention Effect	-93.78
	(188.57)

*p<0.1 **p<0.05 ***p<0.01
Source: Abt Associates, October 2014.

2.2.2   Trend Analysis

For other measures and other Awards, regression models are not yet possible. SPC charts are not appropriate due to differences between intervention and comparison groups in the baseline period. We therefore present pairs of intervention and comparison trend lines, from 2010 through Q1 2014 (see **Appendix B**).

These trends lines do not include tests of statistical significance, but do provide an early indication of potential impact. They generally show little evidence of difference between intervention and comparison groups during the intervention periods of each Awardee. There is also little evidence of change between baseline and intervention periods, for patients treated in intervention facilities. We note a few trend lines that may indicate early program impacts, which we will track as additional quarters of claims data become available. These potential trends include:

Emory

- Readmissions, LOS and Medicare episode spending were all higher in the intervention group in both baseline and intervention periods, with little evidence of change.

- Inpatient mortality was trending lower in the intervention group after implementation, but total 30-day mortality was not.

- Trends for Emory are preliminary as the primary eICU intervention did not start until the second quarter of 2014, which is not yet accounted for in the data.

Henry Ford

- No baseline or comparison group is possible; program staff use entirely clinical selection criteria that cannot be modeled with claims data.

- There is no evidence of change across implementation quarters, in the intervention group.

Mayo Clinic

- The intervention group had higher post-discharge ED visits, and lower mortality and Medicare episode spending than the comparison group, in both baseline and intervention periods, with no evidence of an intervention effect.

- Inpatient mortality and total 30-day mortality were higher in Q1 2014 (for both groups); more quarters of data will indicate whether this is the beginning of a trend.

Methodist Delirium Program

- There was no evidence of an intervention effect on any utilization trends.

- There was no significant DD intervention effect on Medicare episode spending.

Methodist Sepsis Program

- In the LTPAC population, ED visits and hospital admissions trended lower in the intervention group over time, but Medicare episode spending trended higher.

- In the acute care population, there was no evidence of a utilization trend and no significant DD intervention effect on Medicare episode spending.

Mt. Sinai

- ED-to-inpatient admissions were much lower in intervention group than in the comparison group, in both the baseline and intervention periods. This may in part be because one of the three EDs (St. Joseph's) began their program years before the HCIA award and may already have controlled ED return visits, diluting any measured impact of the other two EDs in this pooled trend analysis.

- DD analysis found no significant intervention effect on Medicare episode spending.

St. Luke's

- There is no evidence of an intervention effect and intervention and comparison groups were similar in both baseline and intervention periods, on all measures.

University of Chicago

- The earliest intervention and comparison groups differed in costs and mortality – probably due to very small numbers, rather than imperfect randomization. In later quarters, after more patients entered each group, differences between the groups were minimal.

- With enrollment continuing, it is difficult to identify an intervention effect because each patient is enrolled for differing lengths of time. A future report may take a 'days of exposure' approach and weight each participant's length of program enrollment.

Dartmouth Sepsis program

- The intervention group had lower utilization than the comparison group during the baseline period (readmissions, post-discharge ED visits, LOS) and these trends continued in the intervention period.

- The intervention group had consistently higher Medicare spending in the baseline period than the comparison group, but since the intervention started, the comparison group has had higher Medicare costs. Additional quarters of data are needed to determine if this trend will continue, and to pool enough Medicare patients across sites to support a DD regression analysis.

Christus

- There is no evidence of an intervention effect on any measure, in acute care or LTPAC settings.

- Based on case study data, we know that adoption of the technology component of the intervention is low in LTPAC facilities. All staff were trained initially, but there is little ongoing support for training to keep up with LTPAC turn-over, which may be reducing the strength of the intervention over time.

Appendix B contains a detailed case study report and trend analysis for each Awardee's relevant outcome measures.

3. Conclusions and Next Steps

3.1   Conclusions

At this early stage, with data through Q1 2014, only a few preliminary conclusions are possible, based on a synthesis of qualitative and quantitative data:

- Clinical and operations staff in all programs are quite certain that their programs are improving patient care; they are less convinced that this will in turn yield savings, as measured using Medicare claims. This is consistent with our early results showing no reductions in Medicare episode spending for these programs.

- Staff in several programs emphasized that improved efficiency within their institutions does not reduce spending for FFS Medicare, but in bundled payment or value-based purchasing arrangements, improved efficiency could yield savings. A major efficiency target for many of these programs is reducing LOS, and thus far we see no evidence that this is occurring. Other efficiency enhancements cannot be observed using claims data (e.g., reduced use of lab and radiology tests, shorter ICU stays).

- IT challenges are extreme for multi-site programs, in terms of deploying consistent tools and collecting/aggregating consistent data, 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. Dartmouth's very large program in particular, with 27 intervention hospitals, is challenged to collect patient registry data and participating hospitals' data analysts told us that they are devoting far more time and effort to data collection and reporting than anticipated.

- Most programs did not hire new staff and thus have the potential for sustainability with little additional personnel cost (IT and other costs may continue). In several programs, notably Dartmouth's sepsis improvement program, the intervention is now the "new normal" and will likely continue, with possible refinement as clinical evidence evolves. The few programs that did hire or contract for additional staff may be challenged to sustain this investment, unless there is a clear return to the institutions in improved efficiency.

3.2   Next Steps

In October 2014 we will conduct clinician/staff surveys with individuals directly involved in delivering care in six of the 10 programs, using clinician email addresses supplied by Awardees. There is no comparison group for these surveys, but we expect to learn about uptake, satisfaction with training, and perceived impact on patient care and outcomes. Clinician surveys will not be conducted in four programs because the clinical teams involved are too small, or much too large, for a survey, or because Awardees are conducting their own staff surveys.

In January 2015 we will begin a survey of intervention and comparison patients, for seven Awardees, to be conducted by mail with computer-assisted telephone interviewing of those who do not respond by mail. This survey focuses on patients' care experiences, functional status, and satisfaction. Although most patients will be unaware that they were part of an innovation award, the surveys may reveal whether experiences and satisfaction are better than in similar facilities, and whether patients

achieve better recovery than their counterparts who receive care in other facilities. The intervention and comparison patients will be sampled from the same intervention and comparison groups used for claims analysis, and will therefore be prone to the same matching biases described earlier in this report. Patient surveys are not possible for three programs because we cannot create a comparison group (Henry Ford), or because the patient population is small and the Awardee is conducting their own survey (St. Luke's, University of Chicago).

Each quarter we will add additional data to the quantitative analysis expanding the trend lines for the intervention period. In a future report we will also begin adding Awardee-specific outcome measures as appropriate, including pressure ulcers and falls, discharges to LTPAC and to home, and Medicare spending in different care settings (inpatient, LTPAC, outpatient) that contribute to total Medicare episode spending.

Technical Appendix A

1.1 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.

1.1.1 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 quarter 2014, which span baseline and intervention periods. GVDB Part A institutional claims were extracted for beneficiaries served by HCIA Awardee and comparison facilities. CCW POS files were used to identify facility names and assign them to intervention or provider status. For beneficiaries with Part A claims for HCIA Awardees or comparison facilities, all Part A and B claim, revenue, and line-level data were extracted from the appropriate GVDB 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 HMO indicators, Medicare status codes, and reasons for entitlement (see Exhibit A4 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 measuring utilization core measures. In this file, all claims were limited to those determined to be final action and were processed by the end of the subsequent quarter (e.g., for a claim with a thru date in March 2012, the claim would only be included if it was final action and it was processed by June 30, 2012). The second file was designed to capture episode healthcare spending in the inpatient and post-discharge periods, including Part B claims. For this file, to accommodate the lag in filing of Part B claims, claims were limited to those that were processed by the end of the second subsequent quarter (e.g., a claim with a thru date in March 2012 would be included if the final action was processed by September 30, 2012).

Exhibit A4: Description of Data Sources

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

1.1.2 Definitions

Defining Episodes

Core measure specifications must vary somewhat for individual Awardees. For example, the Mt. Sinai intervention begins with an emergency department (ED) 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 includes 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.

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 does not need to occur during the same time period as the intervention, but rather refers to any treatment over the observed time period that would have been eligible for the intervention if it had occurred at an Awardee facility after the date the intervention program was implemented at that facility.

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.[1] 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 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

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[1] 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

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.

Inpatient claims were clustered into stays using the GVDB stay indicator which groups claims that are overlapping or adjacent with respect to the from and through dates on the claim, and using information from the claim patient discharge status code. Similarly, for Long -Term Post-Acute (LTPAC) claims the GVDB stays indicator 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.

Hierarchical Condition Category (HCC) Risk Scores

One tool that can assist in understanding differences in beneficiaries' health status are the Hierarchical Condition Category (HCC) risk scores used by Medicare to adjust payments and to account for differences in health status among enrollees. Those risk scores are based, in part, on diagnosis codes that are then grouped into related disease categories known as hierarchical condition categories, or HCCs.

The HCC-based risk scores estimate how beneficiaries' spending will compare to the overall average for the entire Medicare population. Age, sex, Medicaid eligibility, reason for eligibility, institutional residence, end stage renal disease (ESRD) status, and previous diagnoses are used to determine a beneficiary's risk score. Monthly HCC scores are normalized so that the average risk score for the population is 1.0; beneficiaries expected to have above-average spending will have HCCs greater than 1.0 and those expected to have below-average spending will have HCCs less than 1.0.

HCC scores are adjusted so that scores of ESRD and non-ESRD months are expressed on the same scale. A coding intensity factor is applied to adjust for the potential over-coding of diagnoses by managed care plans and mediate possible differences between the scores that a group of beneficiaries would have if enrolled in Medicare Advantage (MA) and their scores in fee-for-service (FFS).[2] Finally, monthly HCC scores are averaged to form the annual score in the GVDB, and normalized relative to the FFS population (Office of Policy (OP) population) to produce the final HCC scores used for these analyses.

Medicaid Dual-Eligibility Indicator

The annual Medicaid indicator is based on monthly dual eligibility flags. The annual indicator assigns the type of Medicaid eligibility prioritizing the type most recently recorded in the year. The dichotomous Medicaid eligibility indicator was set for any beneficiary that had at least one month of dual eligibility, including either Full Medicaid, Partial Medicaid or Qualified Medicare Beneficiary (QMB) benefits, during the year.

1.2   Outcome Measure Construction

Most of these 10 Awardee interventions begin when a patient is already hospitalized, and end at hospital discharge. The admission measure is therefore not relevant for most Awardees. Separately estimating planned vs. unplanned readmissions also has little relevance, since it seems unlikely that any physician would deliberately plan repeated sepsis, delirium or ICU admissions, or plan a sequence of ED visits.

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[2]   http://www.cms.gov/mmrr/Downloads/MMRR2014_004_02_a06.pdf

1.2.1 Readmissions

All acute, critical access, or other inpatient episodes were evaluated for inpatient readmissions within 7, 14, 21, 30, 60, 90, and 120 days following discharge from 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.

1.2.2 Hospital Admissions for LTPAC Patients

We computed quarterly hospital admission rates for the skilled nursing facility (SNF) component of the Christus intervention, and the SNF and long term care hospital (LTCH) components of the Methodist Sepsis intervention. These rates measured the proportion of index SNF/LTAC stays after which a patient is admitted to the hospital one or more times within thirty days of the discharge date. 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 facility j in quarter k, and Admission is a binary measure indicating whether 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.

The calendar quarter to which admissions are assigned depends on the calendar quarter in which the relevant index stay began. Therefore, if an index stay began in one quarter, a hospital admission within 30 days of discharge from the index admission counts as an admission, even if the admission occurred in the subsequent quarter.

1.2.3 Hospital Readmissions for Acute Care Patients

We computed 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 thirty 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 hospital 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.

The calendar quarter to which readmissions are assigned depends on the calendar quarter in which the relevant index admission occurred. Therefore, if an index admission began in one quarter, a new admission within 30 days of discharge from the index admission counts as a readmission, even if the readmission occurred in the subsequent quarter.

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. In future reports we will include separate rates of these events for LTPAC patients.

1.2.4   30-Day Post-Discharge ED 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. ED 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 ED. ED use was also measured at intervals during the evaluation period including 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.

Quarterly ED visit rates were computed for each Awardee as the proportion of index hospital admissions after which the patient visited an ED within thirty days after the hospital discharge date. 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 hospital 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.

As with 30-Day Inpatient Readmissions, post-discharge ED visits were assigned to the calendar quarter in which the relevant index admission occurred, rather than the quarter in which the ED visit occurred.

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. In future reports we will include separate rates of these events for LTPAC patients.

1.2.5   60-Day Total Medicare Spending

Calculation of healthcare costs used the second file described above, with longer maturity of claims to accommodate claims submission lags from post-acute settings, and for 30, 60 and 90 day periods following discharge. Standardized payments for inpatient claims were calculated using the following formula:

Actual payment – (IME + DSH) = Standardized Amount

Costs for Part A inpatient claims during the follow up period were 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 3/5ths of the standardized amount of the claim would be attributed to the 30-day cost for the episode. No standardization was performed for either Part B institutional or Part B non-institutional services.

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

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

Where n_{jk} is the total number of index admissions for hospital j in quarter k, and spending refers to the sum of all Medicare costs (as defined in section 1.3.3) incurred by patients during the index admission and the following 60 days. All Medicare spending was assigned to the calendar quarter in which the relevant index admission occurred, rather than the quarter in which the spending occurred.

1.2.6   Inpatient Length of Stay

For all acute, critical access, or other inpatient episodes the length of stay is equal to the number of days between admission to and discharge from the inpatient facility.

Average patient length of stay was calculated by quarter. This is expressed mathematically as

$$\text{Length of Stay}_{jk} = \frac{\sum_{i=1}^{n_{jk}} \text{InpatientDays}_i}{n_{jk}}$$

where n_{jk} is the total number of index admissions for hospital j in quarter k, and InpatientDays$_i$ is the number of days the patient spent in the hospital during index admission i. Inpatient days were assigned to the calendar quarter in which the relevant index admission occurred, rather than the quarter in which the days occurred.

1.2.7   Mortality

Inpatient Mortality

For all acute, critical access, or other inpatient episodes, if the status of the patient upon discharge is "deceased" then the episode is considered to result in inpatient mortality. For SNF and long term care (LTC) providers, inpatient mortality refers to mortality within 30 days of admission at the SNF or LTC facility.

Quarterly inpatient mortality rates are computed for each Awardee as the proportion of index hospital admissions from which the patient status upon discharge is "deceased." This is expressed mathematically as:

$$\text{Inpatient Mortality}_{jk} = \frac{\sum_{i=1}^{n_{jk}} \text{DeceasedIP}_i}{n_{jk}}$$

where n_{jk} is the total number of index admissions for hospital j in quarter k, and DeceasedIP$_i$ is a binary measure indicating whether the patient was discharged as deceased during index admission i. Inpatient deaths were assigned to the calendar quarter in which the relevant index admission occurred, rather than the quarter in which the patient deceased.

Patients whose program intervention began in a LTPAC setting (in the Christus and Methodist Sepsis programs) "inpatient" mortality refers to mortality for the patient within 30 days of admission to the LTPAC.

Total 30- Day Mortality

Total 30-day mortality is calculated for all acute, critical access, or other inpatient episodes. Total mortality consists of episodes that ended with inpatient mortality, as well as episodes in which the patient deceased within 30 days of discharge from the inpatient facility.

Quarterly total mortality rates are computed for each Awardee as the proportion of index hospital admissions from which the patient status upon discharge is "deceased," or in which the patient passes away within 30 days of discharge from the index hospital admission. This is expressed mathematically as:

$$\text{Total Mortality}_{jk} = \frac{\sum_{i=1}^{n_{jk}} \text{DeceasedIP}_i + \sum_{i=1}^{n_{jk}} \text{Deceased30}_i}{n_{jk}}$$

where n_{jk} is the total number of index admissions for hospital j in quarter k, DeceasedIP$_i$ is a binary measure indicating whether the patient was discharged as deceased during index admission i, and Deceased30$_i$ is a binary measure indicating that the patient survived to discharge but passed away within 30 days of discharge (therefore, the two measures are mutually exclusive). Patient deaths were assigned to the calendar quarter in which the relevant index admission occurred, rather than the quarter in which the patient deceased.

1.3   Special Considerations

1.3.1   Mt. Sinai

The intervention for Mt. Sinai occurs during a visit to the ED. We define an index event as an ED visit, some of which go on to become 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 30-day hospital admissions. 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 goes on to become inpatient hospital admission.

1.3.2   University of Chicago

Admissions and ED Visits

The University of Chicago intervention purpose is to reduce total admissions among a specific sample of high risk patients who are enrolled either while in the hospital or 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 per quarter and the average number of ED visits per quarter. 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 or ED visits for patient i observed in quarter k.

Cost

Patients enroll in the University of Chicago program on a rolling basis. In order to estimate the average total Medicare payments for the treatment group and control groups per quarter, we adjust the actual Medicare payment for each beneficiary during the partial quarter during which they are enrolled to reflect costs of the entire quarter. For example, if a patient is enrolled on day 60 of a 90 day quarter and accumulates $10,000 in Medicare spending in that quarter, we multiply the observed cost by 3 (90/30) to reflect costs for the entire quarter.

In the case of a beneficiary death, we do not adjust the beneficiary cost for the quarter. A beneficiary death can reflect an outcome of the program and will be shown in later measures of mortality. We therefore retain deceased beneficiaries in the data set, and give them the same weight as living patients. In future reports we will compare trends in mortality between the intervention and comparison groups.

1.3.3 Patients Whose Intervention Began in LTPAC Settings: Christus and Methodist Sepsis Programs

Two programs begin their interventions with patients in a hospital setting, and also with patients in long term and post-acute settings (nursing and rehabilitation facilities, long term care hospitals or 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. The outcomes of interest for LTPAC patients are 30-day hospital admissions to the hospital, 30-day ED visits, 60-day total Medicare costs, and 30-day mortality. 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. Thirty and 60-day measures for LTPAC refer to time from admission rather than time from discharge.

Appendix B1: Christus Health

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

General Research Domains

The core domains for the Christus St. Michael'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, 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 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.

1. Qualitative Results: Case Study

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

Christus Health was granted an HCIA award to implement the Integrated Nurse Training and Mobile Device Harm Reduction (INTM) Program. INTM combines nurse training and supportive reporting technology that is installed on mobile devices 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, and teach bedside staff in hospitals and nursing homes to recognize signs and symptoms of CHF, sepsis and other high risk conditions. The expectation is that the extensive training will help staff recognize warning signs earlier, begin treatment earlier, avoid preventable conditions/deterioration, and improve outcomes. Outcomes of interest include shorter hospital length of stay, and hospitalization/rehospitalization of nursing home patients.

The mobile reporting technology was developed to guide systematic screening for specific conditions of concern and help hospital and nursing home staff identify problems early. The technology provides prompts to describe symptoms in detail thus helping nursing staff organize their thoughts and relay detailed information more succinctly to physicians. In addition, the mobile reporting technology was designed to help nursing home staff evaluate the need to send a resident 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.

1.1.1 INTM Program Goals

The ultimate goals of the program is to reduce the number and severity of hospital admissions for a base population of approximately 750 nursing home residents, improve quality of care, reduce serious preventable medical conditions, and reduce rates of "failure to rescue" for hospital and nursing home patients in the Christus ARK-LA-TEX service region which spans a 75 mile radius around Texarkana, Texas.

1.1.2 Impetus for the INTM Program

For several years prior to the HCIA Award, the Christus St. Michael's Medical Director, who is the Principal Investigator (PI) for the Award, was intensely focused on reducing poor outcomes, unexpected events (harms) and conditions that were not present on admission; all preventable situations. He wanted to identify patient problems sooner, 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 common causes of mortality, the PI routinely collected data and entered it into a software program that produces fishbone diagrams to illustrate themes. These diagrams revealed repeated occurrences and patterns, particularly for in-hospital cause of death. His next step was

to consider how to reduce these patterns through better and earlier evaluation of emerging high risk conditions.

Approximately three years ago, following an unexpected and potentially avoidable death, St. Michael's Chief Executive Officer (CEO) challenged the PI to make St. Michael's a hospital where these events did not happen. The PI mentioned that he had been collecting information on causes of mortality and thinking about a quick (30 second) evaluation checklist that floor nurses 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 such a checklist tool and adapt it for use on a mobile device (in this case, an iPad) that would be easily accessible to nurses on every unit of the hospital. This 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 mobile device application was tested at St. Michael's Hospital, and the HCIA award funded the purchase of devices and staff training for the hospital and also for the nursing homes that often refer/transfer patients to the hospital.

1.1.3 Christus Health Case Study Methodology

The Christus case study was conducted March 18–20, 2014. The team, composed of two senior staff from Abt Associates and one staff from CFMC, visited Christus' St. Michael Health System (CSMHS) hospital and the Christian Care Center (CCC) nursing home in Texarkana, Texas. Team members conducted 14 interviews (10 at CSMHS, and three at CCC) and two focus groups with nurses (one at each facility); interviews and focus group meetings were audiotaped. The two team members not facilitating a given interview were designated as note takers. Exhibit 1 presents the type of individuals at the hospital and nursing home who were interviewed either individually or as part of a focus groups while on the Christus case study.

Exhibit 1. Type of Respondent Interviewed at St. Michael's and the Christian Care Center.

	Principal Investigator, Trainers and other Educators	Nurse Specialists and other Nursing Leadership	RN, LVN, CNAs	NPs	Rapid Response Teams	Christus Health System Leadership	Data/ Financial Analysts	Program Administrators
CSMHS	✓	✓	✓		✓	✓	✓	✓
CCC		✓	✓	✓				✓

1.2 INTM Program Components

The INTM is comprised of two primary components:

- Four-hour training sessions for bedside nurses and nurse aides, conducted in a lecture hall and simulation laboratory; and

- A device-based Clinical Decision Support (CDS) system software application, to be used by bedside nurses and nurse aides after completing the training session.

1.2.1 Training

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. In the first year of the award, program staff nearly reached their target of 1300 trainees by holding training sessions twice per week; they trained over 1200 bedside nurses in year one. During year two, four training sessions were held in which 75 new-hire staff were trained, and with CMS carryover funds nine additional classes were added in which 197 staff have been trained this year.

> "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

Each class was attended by a mix of caregivers from nursing home and hospital (medical/surgical and ICU) settings, and trainees included licensed practical nurses ((LPNs, known as licensed vocational nurses (LVNs) in Texas)), certified nurse assistants (CNAs) and registered nurses (RNs). Each training session includes an introductory lecture, a simulation, an iPad walk through, and an hour long lecture. The Sisters of Incarnate, a consultant to Christus on the INTM program, developed the training and an accompanying pre- post-training knowledge and feedback survey.

Class-Room Training

The classroom portion of the training is composed of an introductory session, an iPad walk-through, and an hour-long lecture that is generally led by the PI. On rare occasions when he cannot be present, the two program coordinators rely on a video of the PI for the lecture portion of the classroom training. The introductory session begins with a pre-test survey to assess trainees' knowledge of the signs and symptoms the specific conditions such as CHF or sepsis. The introductory lecture covers medication errors, hospital acquired infections, falls, aspiration, pressure ulcers, and failure to rescue. Trainees are introduced to the concept of "touch rounding" which is 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 within 30 seconds that includes pulse rate, blood pressure, skin condition, and breathing. "Touch rounding" also teaches that engaging in a short conversation with the patient helps the nurse assess mental status and pain and identify any unique patient attributes such as a limb amputation or the use of a pace maker which affects pulse rate. The introductory lecture lasts between 15–20 minutes.

Trainees have the opportunity to obtain hands-on experience with the mobile device and checklist using an iPad. They are first instructed on the basics of the iPad and on how to use the software application. The iPad walk-through traces the progression of a sepsis patient. They receive hands-on experience by entering signs and symptoms of a mock sepsis patient simulated over a 24 hour period. Classroom instruction reinforces that the iPad is not a crisis tool; it is a rescue tool and should not be used in an emergency situation. In an emergency situation, trainees are instructed to call the responsible physician or the rapid response team which is a group of experienced nurses trained to respond to early signs of clinical deterioration to prevent respiratory or cardiac arrest.

> "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

Following the simulation laboratory portion of the training (see below), trainees return to the classroom for the hour-long lecture and a debrief about the scenarios that were presented in the laboratory. The lecture covers topics including 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 discuss the signs and symptoms of the targeted conditions and learn how to apply the "touch rounding" approach to detect potential problems. At the end of the hour-long lecture, trainees complete 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 occurs in a simulation laboratory that has four stations, each equipped with a hospital bed, monitors and a simulation manikin. There are six scenarios available and any of the six may be used in a class depending on the trainers' knowledge of the scenario, class size, and/or the number of hospital staff versus nursing home staff. The scenarios (played out in the simulation center) relate 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) enter the simulated patient's room and receive a card with instruction as to the role that he or she will play in the simulation—a family member (who may or may not be challenging) or nursing staff. Those role-playing nurses receive a hand-off from the previous nurse, and practice touch rounding. They interact with the 'patient' asking questions to which the manikin offers "real-time" responses provided by a nurse who is located outside the simulation station and equipped with a speaker and microphone headset. At the end of the simulation, the trainer provides immediate feedback to trainees, and each trainee group rotates to another simulation station where a different scenario is 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

When developing the training, the program staff could not find scenarios that were appropriate for the training required, and those intended for simulations were not sufficiently sophisticated. They instead created their own simulation scenarios and scripts. The PI noted that if he had it to do 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 initial trainees experienced only one or two simulation scenarios, and did not always get a chance to role-play. Once the PI recognized the problem, he adjusted the class sizes and subsequent trainees experienced three or four scenarios and had the opportunity to role-play in each, which makes for a more complete training experience. Based on the pre/post knowledge tests, more exposure—scenarios, repetition—yields better learning.

During our observations, the iPads were not used in the simulation laboratory, which seems to be a missed opportunity. We learned that the iPads are not routinely used in simulation during training classes, although trainees are given the option of using them. Rather, iPads are used in the classroom where trainees practice entering signs and symptoms of a septic. The PI noted that not spending more time on iPad training is probably one of their greatest disappointments, but time constraints made it impossible to include iPad training in the simulation laboratory.

1.2.2 Technology

The technological component of the INTM program is the software application, developed by a vendor for use on mobile devices (iPads). The application offers clinical decision support to help bedside nurses (i.e., RNs, LVNs, CNAs) better identify symptoms of and screen patients for a number of serious health events and conditions. These include "quick" assessment tools for chronic conditions (such as CHF,

respiratory failure and diabetes), and acute illnesses or events (such as a sudden change in mental status, sepsis, pneumonia, urinary tract infection, and internal bleeding).

The application employs a Bayesian decision engine. The user interface facilitates the collection of findings that feed into the Bayesian engine to compute likely diagnostic outcomes, and based on the outcomes, presents a list of suggested actions. Nurses are directed to select a "trigger" or symptom from the eight possible options (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 reasons the patient or nursing home resident is presenting with the symptom, and prompts users to answer a series of yes/no questions. The application calculates the likelihood that the patient has any of the aforementioned conditions or illnesses, and displays a series of probabilities to the user. The nurse may then consider these potential health conditions, and notify the physician or other supervisory staff as necessary.

The application also produces reports for program staff, to assess which staff are using the iPad and whether or not it is being used properly. These reports also can be used to validate the tool itself by checking the information against the electronic medical records (EMR) to confirm patients who are declining. At the time of this case study, on average two nurses per week were using the iPad application (out of more than 1200 trained).

A technological issue that has arisen is related to the functionality of paging the rapid response team directly from the iPad application. In order to page the rapid response team directly, the iPad has to be connected to the secure Christus network. When the mobile devices were first launched in the hospital, it was possible to connect them to the secure network, so the rapid response paging functionality worked very well. However, shortly thereafter, Christus Information Management established a policy whereby wireless devices would not be allowed access to the secure network, restricting their connectivity to the guest network. As a result, the mobile devices lost their capability to page the rapid response team. 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.

In addition to not having access to the secure network, at present, the software application is not integrated into the Christus' hospital EMR. As such, the Bayesian calculation of probabilities is based on aggregated historical medical chart audit data. The lack of integration with the EMR means that nurses cannot use the INTM program from the EMR, but may only access it from the iPad, thus adding another step to their workflow. Although the Christus team would like to integrate the systems, the EMR vendor is very proprietary and will not permit it.

1.3   INTM Program Implementation

The INTM program was implemented in one acute care hospital, St. Michael's, and 12 local nursing homes that offer long-term care (LTC) and skilled nursing services. The St. Michael's PI believes it is important to partner with these particular nursing homes for several reasons. First, St. Michael's had a pre-existing relationship with them through a health care coalition. Second, St. Michael's is one of the acute care hospitals to which these nursing homes are most likely to transfer residents. Third, together the 12 nursing homes have approximately 850 residents who experience frequent rehospitalizations.

1.3.1   INTM Program Implementation Process

As noted, there are two components of the INTM program; staff training and the supportive technology software program installed on iPads. A substantial portion of the training was conducted in the first year of the innovation award, although training is ongoing as needed. In St. Michael's hospital, the iPads were deployed in June 2013 on one unit, in July on four more units, and in October in the last three units. The iPad application was not deployed on labor and delivery units, nor was labor and delivery staff trained. Roll-out of the iPads at the 12 participating nursing homes ran from February 2013 through September 2013. On a weekly basis one of the program coordinators reviews the staff utilization report that is generated from the application and makes rounds to every participating hospital unit to troubleshoot workflow and other issues, and encourage the use of the iPad. She meets with staff who have not been using the program as intended (i.e., checking off all categories rather than being selective), or who have not been using it at all, and provides a quick hands-on tutorial. The PI also visits units periodically throughout the hospital to inquire as to whether or not staff are using the iPads and to encourage their use. During initial implementation, the nurse coordinator and the PI visited participating nursing homes on a weekly basis. More recently the nurse coordinator visits on a monthly basis.

1.3.2   INTM Program Implementation Target

The target of the Christus program is hospital patients and nursing home residents at risk for adverse events. To reach the target population, bedside nursing staff at St. Michael's hospital and participating nursing homes receive formal training in recognizing early warning signs and symptoms of high risk conditions, and in the use of the iPad supportive technology to facilitate the early recognition of decline. The training and software application components are relevant for all nursing home and hospital patients except maternity and pediatric hospital patients but focuses on common medical problems of older adults such as CHF, sepsis, urinary tract infection or respiratory failure.

1.3.3   INTM Program Implementation Effectiveness

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

1.3.4   Fidelity of the INTM Program

The PI initially expected that everyone who was trained would be eager to use the iPad application, but this was not the case. When the underuse of the program was recognized, the program staff held focus groups to try to understand barriers and motivators. One issue raised in these focus groups was accessibility of the iPads on nursing home and hospital units. Staff at both the hospital and the nursing homes were worried about theft and locked the iPads in nurses' medication carts or in medication rooms. 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 also asked to have the iPads kept at the nurses' stations, where they would be readily available to the nurses and aides. However, on a tour of the hospital units participating in the

> "We thought that anyone who went through the program couldn't wait to get their hands on an iPad and start using it on every patient – that just didn't happen."
>
> – Principal Investigator

program, we found that none of the iPads were visible and in at least one case, it was still locked in a medication closet.

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. The hospital nurse managers reported that new graduates and nurse aides use the iPad application most often, while experienced nurses who believe in their own patient assessment skills are less likely to use it. ICU nurses reported that they do not use it. One critical care nurse reported that it didn't have the diagnosis or symptoms that are important for her patient population, and felt it did not provide reliable guidance. Many of the nurses who did not use the iPad application felt it was more suited for newly-graduated nurses.

There was some reported variation across shifts at both the hospital and the nursing home. Evening and night shifts were less likely to use the iPad application. Day shift staff reportedly saw the program specialist and PI doing walk-throughs, which served to keep up awareness of the program.

Nursing home policy dictates that nurse aides must report any resident changes to the nurse. According to leadership in the one nursing home we visited, the nurse aides are taught to notify the nurse when there's any change in the resident's condition and that the nurse aides are "not so much hands-on with the iPad." 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."

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

1.4.1 Better Care

Perceptions among program staff and nurses at the hospital and participating nursing homes regarding the program's impact on quality of care were mixed. Program staff felt that the training has allowed all levels of staff to provide better care to patients. Nursing home leadership felt that the program has improved the nurses' assessment skills. In contrast, staff nurses and nurse aides at the nursing home were quick to point out that the program had not affected the quality of care they provide. The nurse aides stated that, "We are already number one on that. We already give quality care." The perception among experienced nurses at the hospital and the nursing home is that they already know the information conveyed by the software application and do not need the iPad. One hospital nurse noted that the program gave her confidence when she first started, but now that she's had more experience, she no longer needs it. In contrast, all levels of nursing found value in the training component of the programs. In fact, the program measurement team noted that a lot of the signs of patient deterioration were missed even by experienced nurses during the training.

A nurse practitioner who cared for a large number of patients in the nursing home we visited, believes that the training and software application have greatly improved the nurses' ability to detect problems early and noted that their reporting to her and to the hospital (upon transfer) was clearer and more detailed. 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 the improved transfer reports.

Both nurses 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 nurses become more skilled at assessing patient status, and more aware of the possible causes for symptoms their patients

are presenting. They believe they have had several 'saves' because of knowledge gained during the training.

1.4.2   Better Health

The PI pointed out that halfway through the grant the trend in sepsis mortality in the hospital was going down. Comparing their historical diagnosis-related group (DRG) sepsis mortality rate to this year, they have improved far more than anticipated and he attributes this change to the training and iPad application. Sepsis rates have increased due to earlier detection, and mortality has decreased (25 fewer sepsis deaths this year than last, at St. Michael's hospital). He reports that they still have "misses" and probably still have one sepsis death per month that could be prevented. At this point they do not have the data to demonstrate whether or not the program has had an effect on hospitalization rates for nursing home patients.

1.4.3   Lower Cost

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

The program staff believe that cost of care is declining, but not dramatically. Their goal is to reduce the DRG weight for patients admitted from the nursing home, so that costs to the Medicare program decrease, and that that has happened. In addition, less need for critical care (ICU) will lower costs for the hospital and improve efficiency because a nurse can care for more patients on a general medical-surgical unit than in the ICU.

Nursing home staff believe that they are not sending as many residents to the hospital as they did prior to program implementation, although they also explained that nurse preferences and nursing home policy influence these transfers. Some nurses, they explained, are just more likely to send a patient to the hospital than others. In addition, nursing home policy dictates sending a patient to the hospital if the nurse thinks they should go, if the patient asks to be transferred, or if the family asks that the patient be hospitalized. The nursing home nurse practitioner noted that due to the high acuity of today's nursing home residents who have multiple comorbidities, there will inevitably be a group of nursing home patients who are repeatedly hospitalized, despite best efforts by staff to keep them out of the hospital.

1.5   INTM Program Workforce Development

In the first year of the award, 2012, the Christus team focused on training. Their goal was to train 1300 nurses and they came close to their target by training 1200. 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 forty-five percent of the nurses trained were from participating nursing homes, and fifty-five percent were from Christus St. Michael's. They exceeded their goal of 1300 trainees by the end of the calendar year.

1.5.1 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 staff be trained in the INTM program, although there did not appear to be any enforcement of this requirement.

Nursing Home Recruitment

The program staff partnered with the 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 the Christus St. Michael's hospital and area nursing homes for the betterment of the community overall, and for enhanced care of their shared patients who are frequently admitted to their hospital. An initial invitation letter was sent to all area nursing homes and currently about 20 regularly participate in coalition meetings although the coalition is open to any area LTC facility.

The INTM program was introduced and discussed at the regularly-scheduled quarterly coalition meetings, prior to the award. Subsequent to the award, nursing homes were recruited into the program by distributing contracts. The first 12 nursing homes who signed the contract were accepted into the program. 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 an 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.

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 home staff, and it is a challenge to keep up with INTM training, especially in nursing homes. Exacerbating the difficulty of keeping nursing home staff trained is the fact that administrative buy-in was not as complete at the nursing homes as at the hospital, so nursing home staff are not routinely encouraged to attend the trainings.

1.5.2 INTM Program Impact on Workflow and Workload

It was reported by the program staff that the iPad application was not significantly integrated into nurses' workflow, nor has it had an impact on their workload. There are iPads on all the participating hospital units and in the nursing homes, but very few nurses are using them.

If the iPad software program were to be more fully assimilated into nursing workflow, it would increase workload as the software is not currently integrated with the EMR. As a result nurses would have to enter the information in two places. However, if the iPad software was integrated with the EMR, there would be no 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.

1.5.3   Barriers, Facilitators, and Lessons Learned Regarding Program Implementation.

The INTM program has encountered several barriers, and many strengths have been identified. Taken together the barriers and facilitators lead to some lessons learned during the process of implementing the INTM program.

Barriers

- Nursing staff turn-over and retraining needs.

- Resistance to using the device among all levels of nursing staff.

- Not enough training sessions and little hands-on scenario based training using the iPad application.

- iPads stored in inaccessible places due to fear of theft.

- Lack of software integration with EMR at the hospital and nursing homes, requiring nurses to enter information in two different systems.

- Lack of hospital and nursing home mandates for use of the iPad application.

Facilitators

- A PI who is a dynamic leader and teacher.

- The simulation laboratory for hands-on training.

- The effectiveness of the training overall.

> "His [the PI's] stories and examples really drive it home because they were real hospital patients."
> *– Nurse Trainee*

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 was needed on the hospital floor than originally anticipated, to encourage the use of the iPad in the work flow.

- Additional iPads are needed that are easily accessible to hospital and nursing home staff.

- It is necessary to identify a champion at each nursing home who is available to provide one-on-one instruction and to encourage the use of the iPad in the work flow.

- Double data entry could be eliminated by integrating the software application into the hospital EMR. Smaller training classes would give everyone an opportunity to participate in the simulation laboratory.

1.6   Context

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

Other situations that may have impacted the INTM program included the long-standing message from nursing home administration and physicians that encouraged nurses to send patients to the hospital whenever requested by the patient or family. In addition, nursing home culture mandates that nurse aides report any resident changes first to the nurse. Use of the iPad could come after that notification had been made, but this may seem to be redundant if the problem has already been recognized.

Lastly, nursing homes had been under the illusion that their new relationship with the hospital would bring a "windfall of patients." Nursing homes aim to fill their beds with as many Medicare patients as possible as the daily reimbursement rates for Medicare are considerably higher than Medicaid rates. Having a solid relationship with a hospital would be thought to greatly enhance a nursing home's chance of admitting these 'prize' patients. As the INTM program was implemented, it became clear to the nursing home leadership that their participation in the program was not going to lead to a stream of Medicare admissions. Furthermore, the nursing home leadership became aware that if the program was successful it could in fact lead to fewer Medicare readmissions. Nursing home residents who are hospitalized may use their Medicare benefit upon return to the nursing home. If the program caught illnesses before hospitalization became necessary, fewer residents would be admitted to the hospital and hence fewer residents using their Medicare benefit upon return.

1.7   Unintended/Unanticipated Impacts of the Program

1.7.1   Enhanced Communication and Coordination Between Nursing Home and Hospital

Although the 12 nursing homes and St. Michael's hospital were part of an existing healthcare coalition, the frequent meetings to implement this program offered more contact 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 grew comfortable 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 understand the nursing home side of the equation and were open to listening and making changes. Program staff, including the PI, visited the nursing homes and made themselves available to listen and act on nursing home staff concerns. For example, a concern was raised about nursing home patients experiencing long waits in the hospital emergency department. It was mutually agreed between the hospital and nursing homes, that nursing home staff would call in advance when preparing to transfer a patient to confirm that the transfer is necessary, discuss the current ED wait time, and allow the ED to prepare to receive the patient. Nursing home staff also requested that the hospital ensure that a discharge summary accompany patients returning to the nursing home after a hospital stay, and that these transfers back to the nursing home not take place at night. Staff at the nursing home we visited report that communication and coordination of care between their facility and the hospital is much improved. The nurse practitioner who cared for a large number of nursing home residents observed that improved communication with the hospital is, in her opinion, the biggest achievement of the project.

1.7.2   Enhanced Communication Between Aides, Nurses and Physicians

There were mixed reports from the hospital staff as to whether or not the use of the iPad application improves communication among clinical staff. Program staff had expected that the program would help communication between nurses and physicians, but focus groups run by the program's measurement team did not find evidence that supports this expectation. Experienced hospital nurses reported to the Abt evaluation team that they felt that physicians with whom they work respond to them based on an

established relationship of trust; the iPad application does not help experienced nurses present patient information to physicians. Other nurses at both the hospital and the nursing home shared that the iPad application is helpful in assembling information to share with physicians, especially for new 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 the 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 felt that the nurses already listened to them and that the iPad application didn't make a difference.

Clinical educators reported that a key point of the training was to give nurse aides the tools to communicate with their nurses, to promote teamwork and maximize the role of nurse aides. Communicating "up" was a key element of the training, and the simulations offered opportunities to practice what the nurse aide (or nurse) would include in a report to the nurse (or physician). They also believe that the iPad application helps nurses plan what to say to a physician, and anticipate what the physician might order. Similarly, the clinical educators believe that the iPad application makes the nurses listen to the nurse aides.

1.7.3 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."

1.8 Conclusions

The INTM program provided caregiver training and access to a mobile decision support device aimed at improving caregiver critical thinking skills so as to improve the staff's ability to recognize pending harm and intervene to prevent or mitigate the level 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 less 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 resulted between the hospital and the nursing

> "I don't want you to look at the numbers of uses of the iPad and think that the program is not effective here or at the nursing homes. The training really gets them to think."
>
> *– Principal Investigator*

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 access was often hindered due to fears of theft. Hospital staff stated that if the mobile device could be integrated into the EMR, it might be more easily incorporated into their workflow. Christus leadership acknowledges the limited usage of the device but feels with a consistent message on expectation of use, the program will continue. Their prime focus appears however to be on the bedside caregivers 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 needed most by bedside caregivers.

2. 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, we present the following core measure:

- Admission (transfers) from SNF or LTCH to the hospital, restricted to patients whose program intervention began in the SNF/LTCH

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, restricted to patients whose program intervention began in an acute care hospital. 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, restricted to patients whose program intervention began in an acute care hospital.

- Total Medicare spending for 60 days including the index admission and all spending for 60 days after discharge, restricted to patients whose program intervention began in an acute care hospital.

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.

2.1 Defining Intervention and Comparison Groups

2.1.1 Registry Information

The Christus program registry contains 17 Medicare patients who were treated in the Christus St. Michael Acute Care Hospital, and 138 Medicare patients who were treated in five nursing homes: Bailey Creek, Christian Care Center, Cornerstone, Edgewood Manor, Golden Villa, Heritage Plaza, Linrock, Reunion Plaza, Rose Haven, and Waterton Plaza. The registry also contains a patient census of patients treated in the acute care hospital and long term facilities. The registry includes patients treated between October 9, 2013 and June 22, 2014. We analyzed observations before April 1, 2014 to specify selection criteria based on Medicare claims.

Christus St. Michael treated 2,572 Medicare patients between October 1, 2013 and June 30, 2014; 0.6 percent of these patients were in the registry. Participating nursing homes treated, in total, 723 Medicare beneficiaries during the same period[1]; 19 percent of these were in the registry. Based on discussions with Awardee program staff, we understand that the tool used for the intervention did not capture patient identifiers, and also that adoption of the tool was not widespread in long-term and post-acute care

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[1] Some Medicare beneficiaries did not have a census date or an admission date associated with their record and are excluded from this count.

(LTPAC) facilities during the period of this analysis. We conclude that the registry provided by Christus is substantially incomplete and cannot support creation of inclusion and exclusion rules.

2.1.2   Selection Rules

Because all staff in participating facilities were trained in the innovative patient assessment protocol (whether or not they use the tool created for this purpose), and the program requires staff to assess every patient every day, we consider all patients in the intervention facilities to be eligible for the intervention.

2.1.3   Estimated Intervention Group

Of the 155 Medicare patients included in the Christus registry, we were able to identify 77 in the Medicare claims data and of these, 72 are in our estimated intervention group. The Christus registry does not include census or admission dates for five patients.

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 by Quarter and Aggregate

Christus	2012		2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):	23	6	7	4	10	9	18	77
Estimated based on Abt rules (N):	332	171	139	128	134	1,289	1,099	3,292
Match between Estimated and Registry (N):	21	5	6	4	9	9	18	72
Registry Patients, Not Captured by Abt rules (N):	2	1	1	0	1	0	0	5
Estimated by Abt rules, Not in Registry (N):	311	166	133	124	125	1,280	1,081	3,220
Estimated by Abt rules that are in Registry (%):	6%	3%	4%	3%	7%	1%	2%	2%

We cannot specify the intervention population further because the registry we received included so few patients. Program staff assure us that all patients in participating facilities are supposed to be assessed daily, and all staff have been trained to do this assessment, whether or not they use the iPAD tool to do so. We therefore define the entire patient population in the nursing homes and hospital as the intervention group. Comparison and baseline groups follow the same inclusive definition.

Data for all patients in all participating facilities are pooled in our analyses. Even pooling data, the numbers are insufficient in a calendar quarter to support a statistically rigorous difference-in-differences analysis. In a future annual report we will aggregate data across the entire intervention period and, if volume is adequate for tests of statistical significance, will perform a difference-in-differences analysis on the aggregated data.

2.2   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.

The hospital admission graph below is restricted to patients whose program intervention began in a LTPAC. 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).

2.2.1   Hospital Admissions – LTPAC Patients Only

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.

Exhibit 3 reflects 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 two populations were reasonably similar throughout baseline and intervention periods, with perhaps a slight downward trend in both. It also shows a dramatic dip in the first intervention quarter, for both the intervention and comparison groups, followed by a return to higher levels, which we suspect is an artifact related to claims processing.

Exhibit 3: Hospital Admissions – LTPAC Patients Only
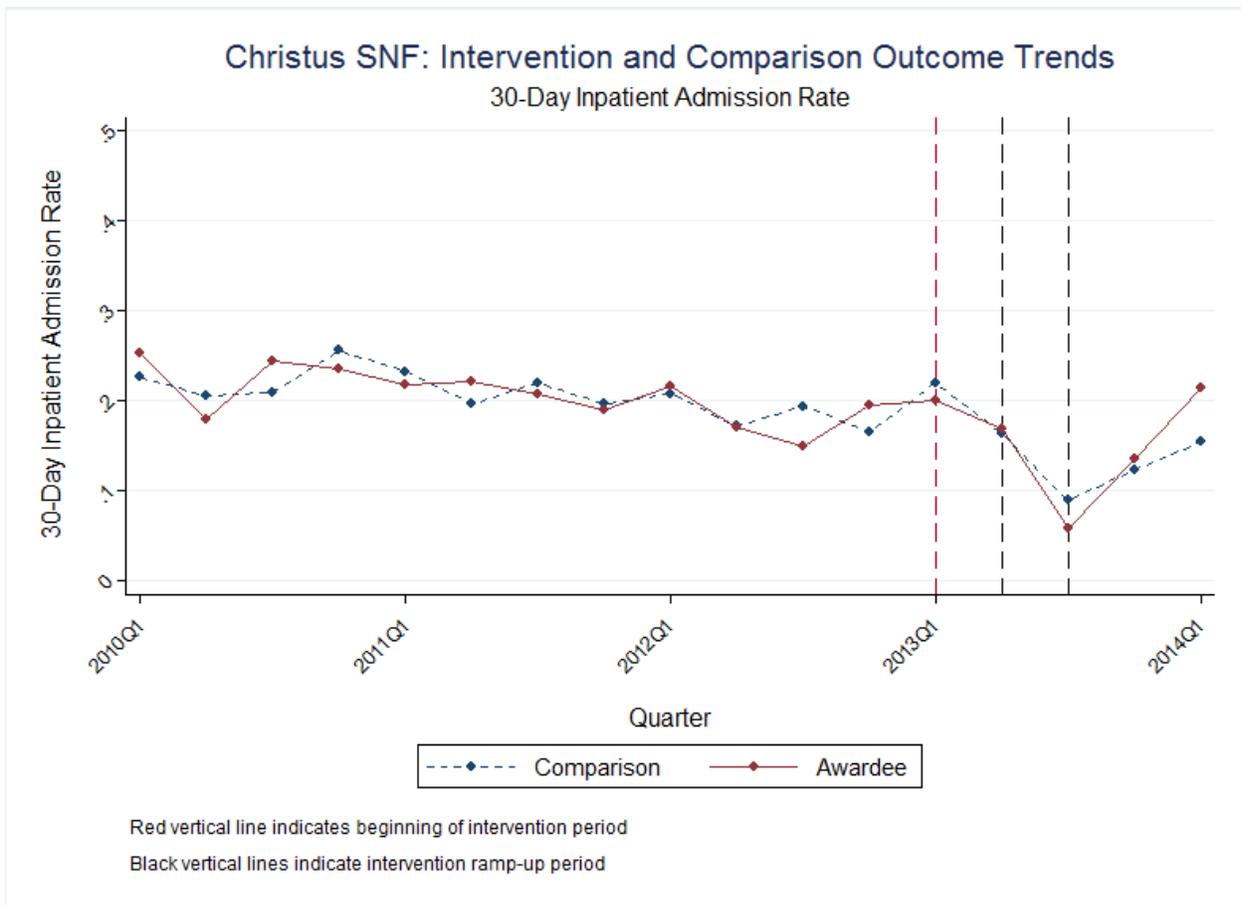
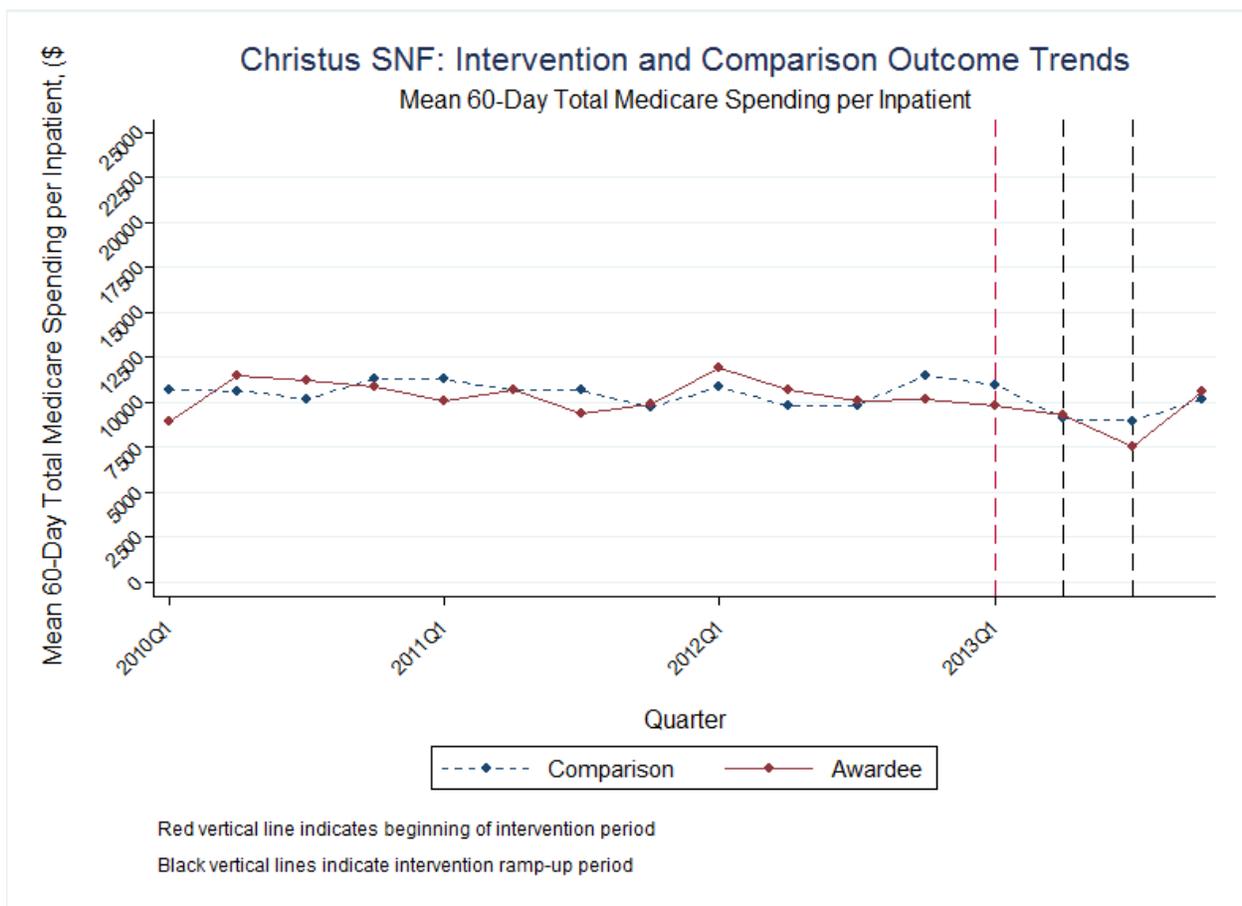Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2   Readmissions – Acute Care Patients Only

Exhibit 4 (hospital discharges followed within 30 days by a readmission) shows that the intervention and comparison sites were somewhat dissimilar in the baseline period and more similar in the intervention period. We note again the dip in one intervention quarter followed by a return to higher levels. This exhibit is restricted to patients whose program intervention began in an acute care hospital setting. 55% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15–30.

Exhibit 4: Readmissions – Acute Care Patients Only
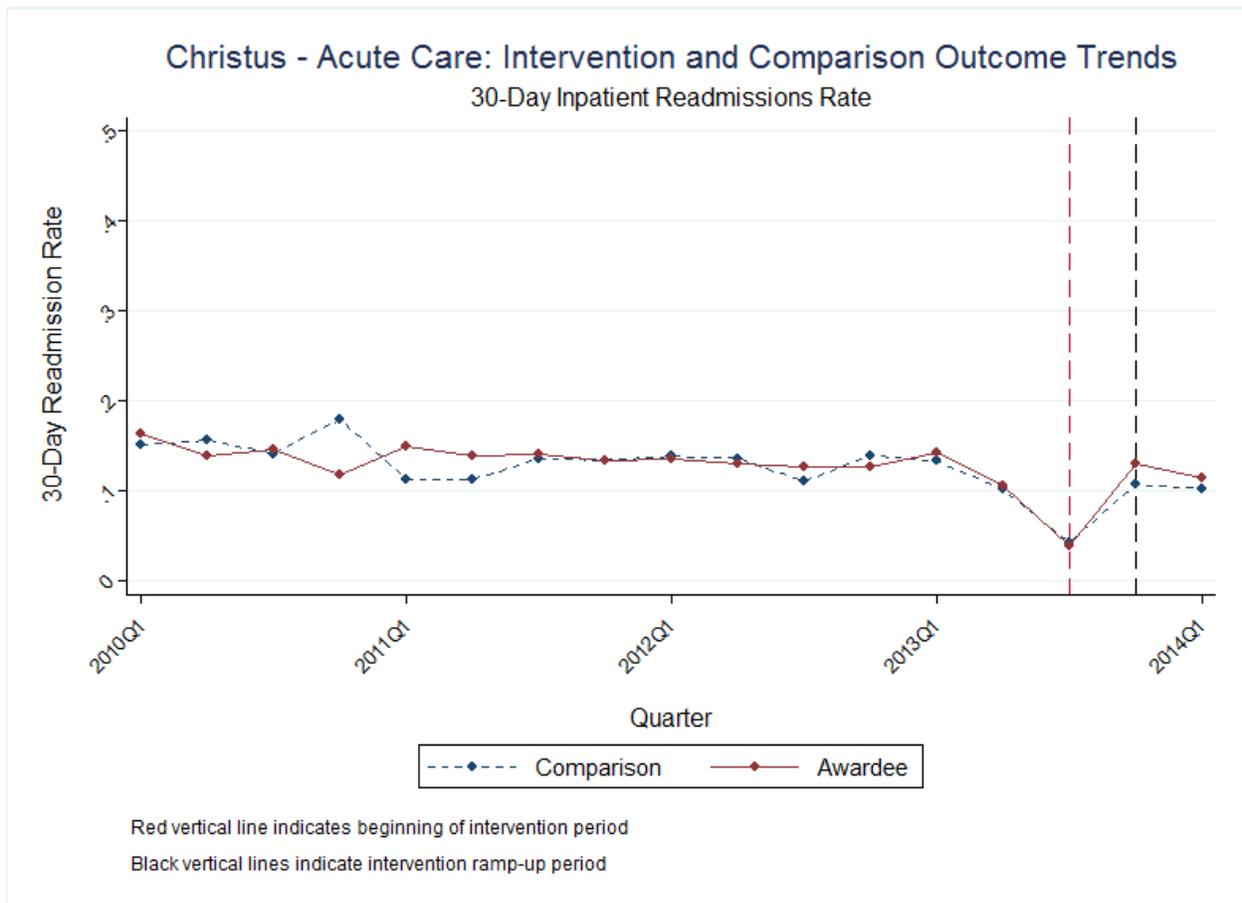
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3   30-day Post-discharge ED Visits – Acute Care Patients Only

Exhibit 5 (discharges followed within 30 days by an ED visit) shows slight differences between intervention and comparison groups in the baseline period and greater volatility from one quarter to the next in the comparison group than in the intervention group. It also shows the dip for both groups in the same quarter and return to higher levels, which may be a claims submission/processing artifact. This exhibit is restricted to patients whose program intervention began in an acute care hospital setting.

Exhibit 5: 30-day Post-discharge ED Visits – Acute Care Patients Only
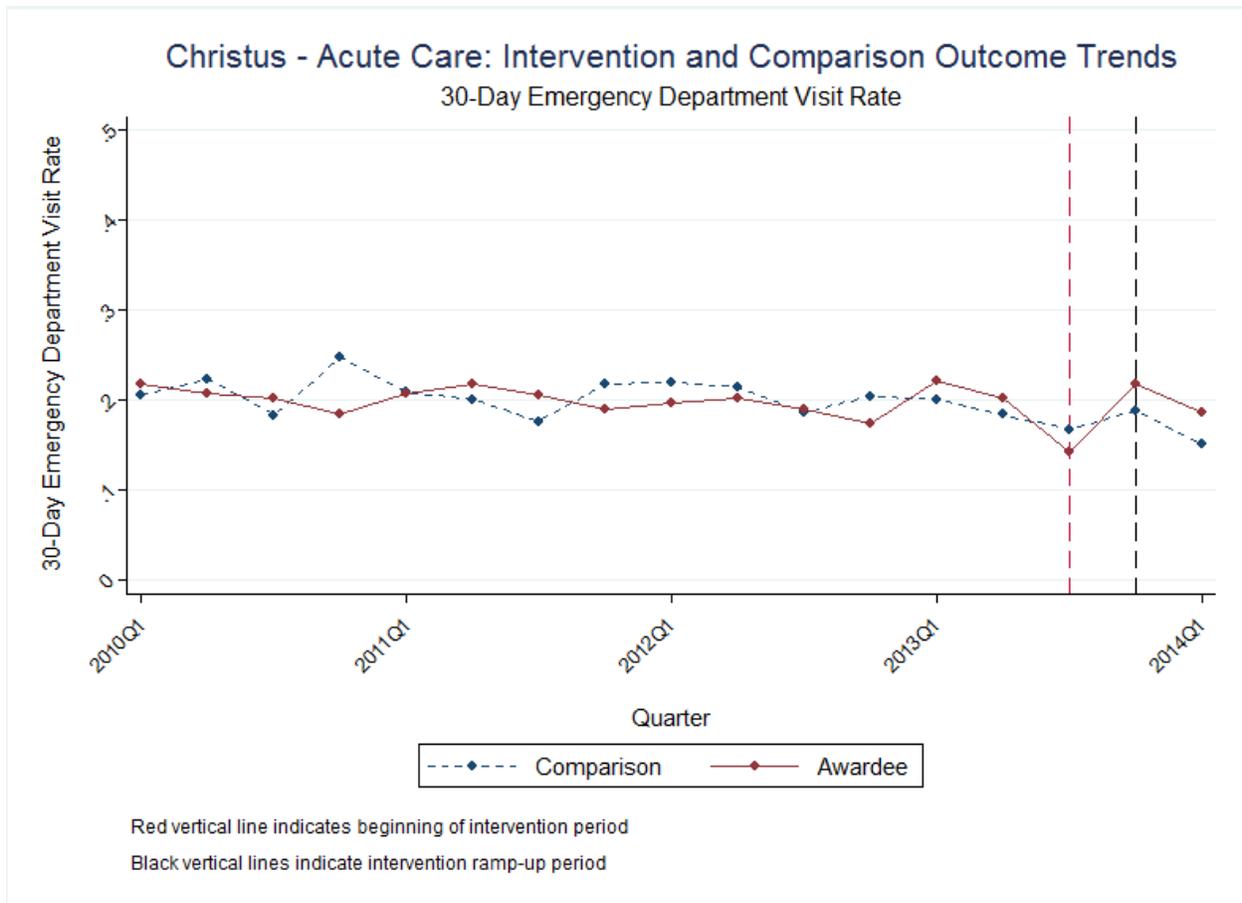
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

All the graphs above show a dip in a recent quarter and then a return to higher levels, and a data or claims processing artifact cannot be ruled out.

2.2.4 Medicare Episode Spending – Acute Care Patients Only

Exhibit 6 (60-day episode Medicare spending) includes the inpatient stay and all Medicare claims in the following 60 days. It shows less difference between intervention and comparison groups in the baseline period than we saw in the utilization graphs above, and no evidence of program impact in the intervention period. This exhibit is restricted to patients whose program intervention began in an acute care hospital setting. 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 6: Medicare Episode Spending – Acute Care Patients Only
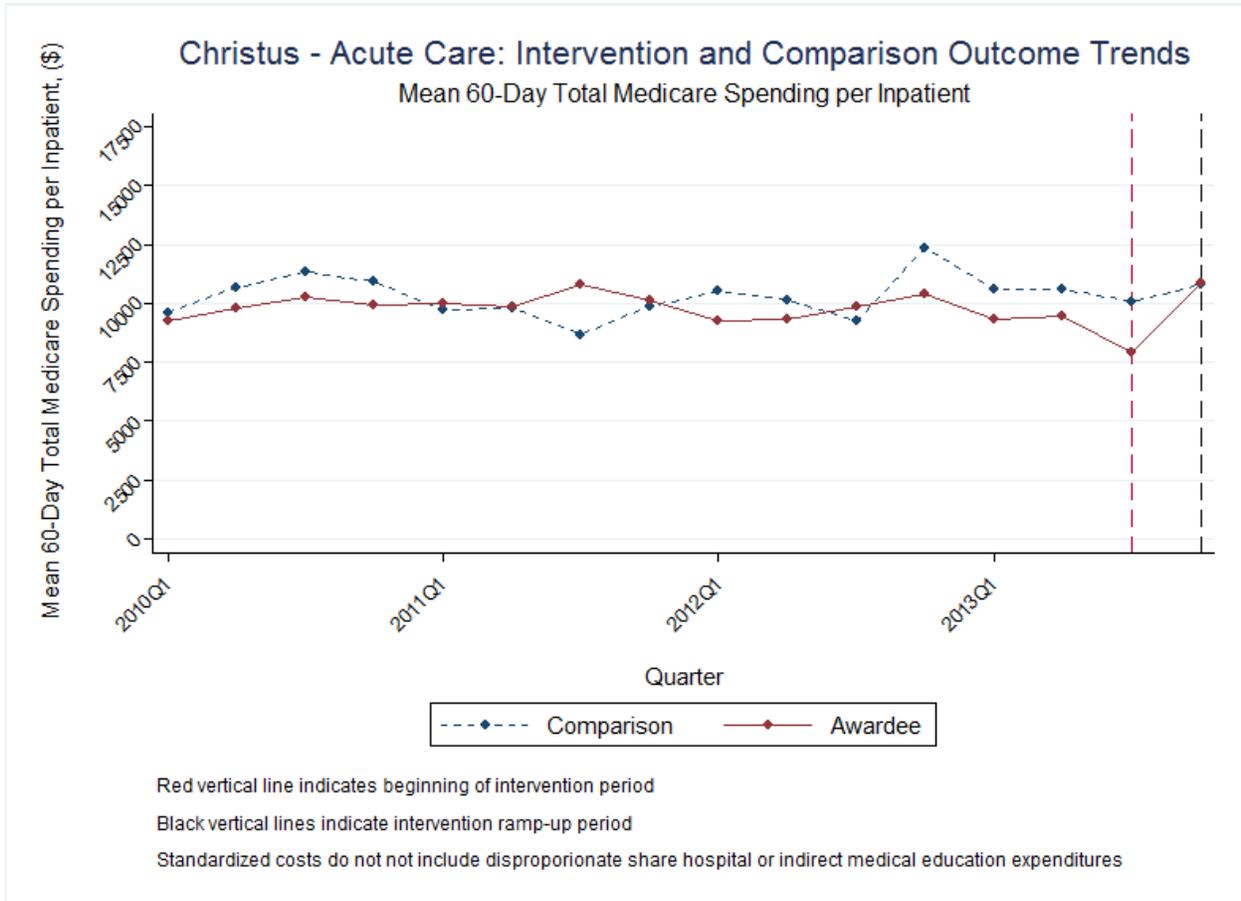
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.5   Medicare Episode Spending – LTPAC Patients Only

Exhibit 7 shows the Medicare episode spending for 60 days after admission to the long-term post-acute care (LTPAC). It includes patients who first encounter the screening program in LTPAC facilities. 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. 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). Again, we see little difference between the intervention and comparison groups in the baseline period. Bother groups exhibit a dip during one intervention quarter followed by a return to higher levels and no indication of program impact on spending during the intervention period.

Exhibit 7: Medicare Episode Spending – LTPAC Patients Only

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

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

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.

Exhibit 8 (LOS following admission to a hospital) includes patients whose program intervention began in an acute care hospital setting. The intervention and comparison groups are quite similar and there is no indication of program impact in the intervention period.

Exhibit 8: Index Admission Inpatient LOS
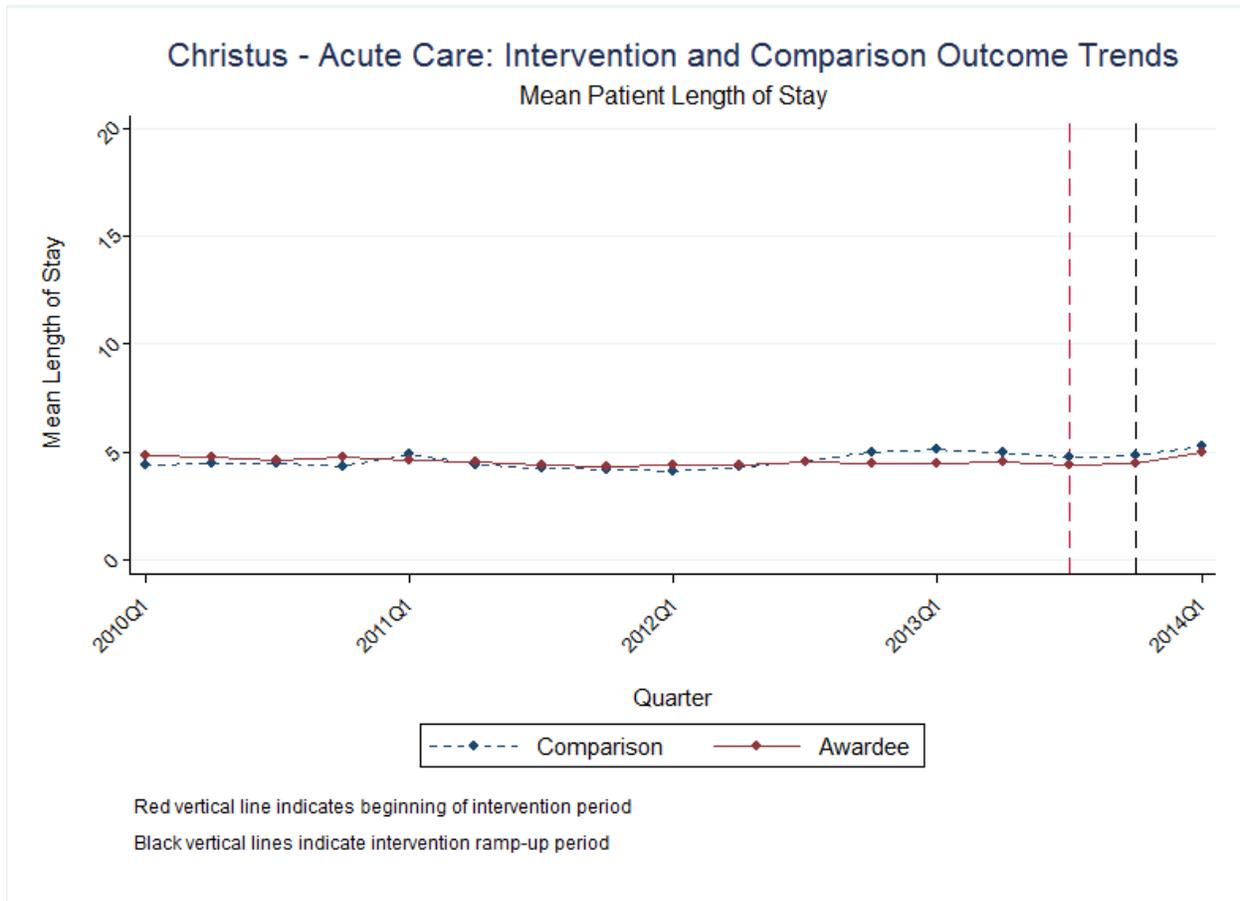
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.7 Index Admission Inpatient and 30-Day Mortality – Acute Care Patients Only

Exhibit 9a (inpatient mortality rate following an index admission) shows that the intervention and comparison groups are somewhat different in the baseline period, and there is no evidence that the program is reducing mortality in the intervention period. This exhibit is restricted to patients whose program intervention began in the acute care hospital setting.

Exhibit 9a: Index Admission Inpatient Mortality
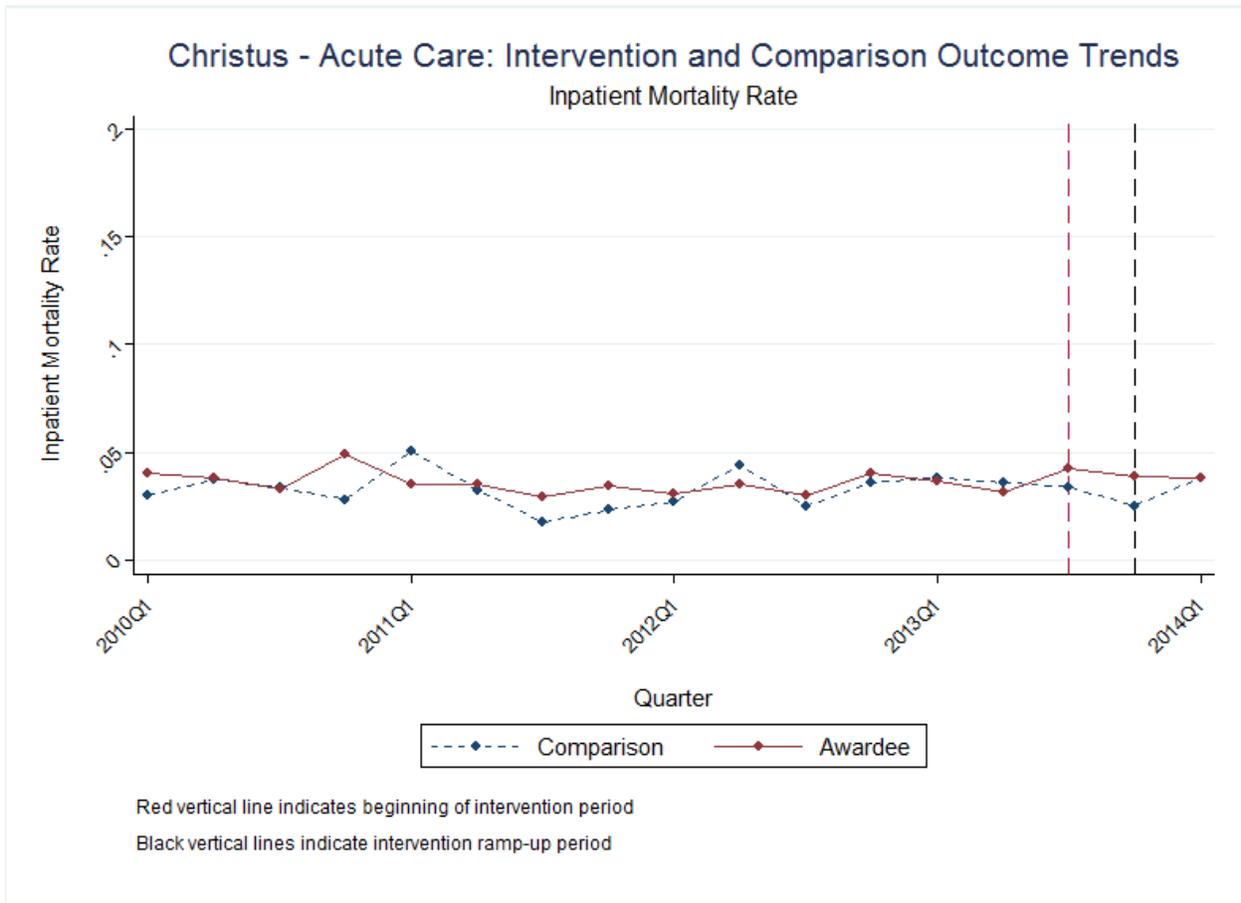
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 9b shows the total mortality including inpatient and the 30-days following the end of the index admission. Again during the baseline period the intervention and comparison groups are somewhat different and there is no indication that the program is reducing mortality in the intervention group. This exhibit is also restricted to patients whose program intervention began in the acute care hospital setting.

Exhibit 9b: 30 day Mortality (including Index admission)
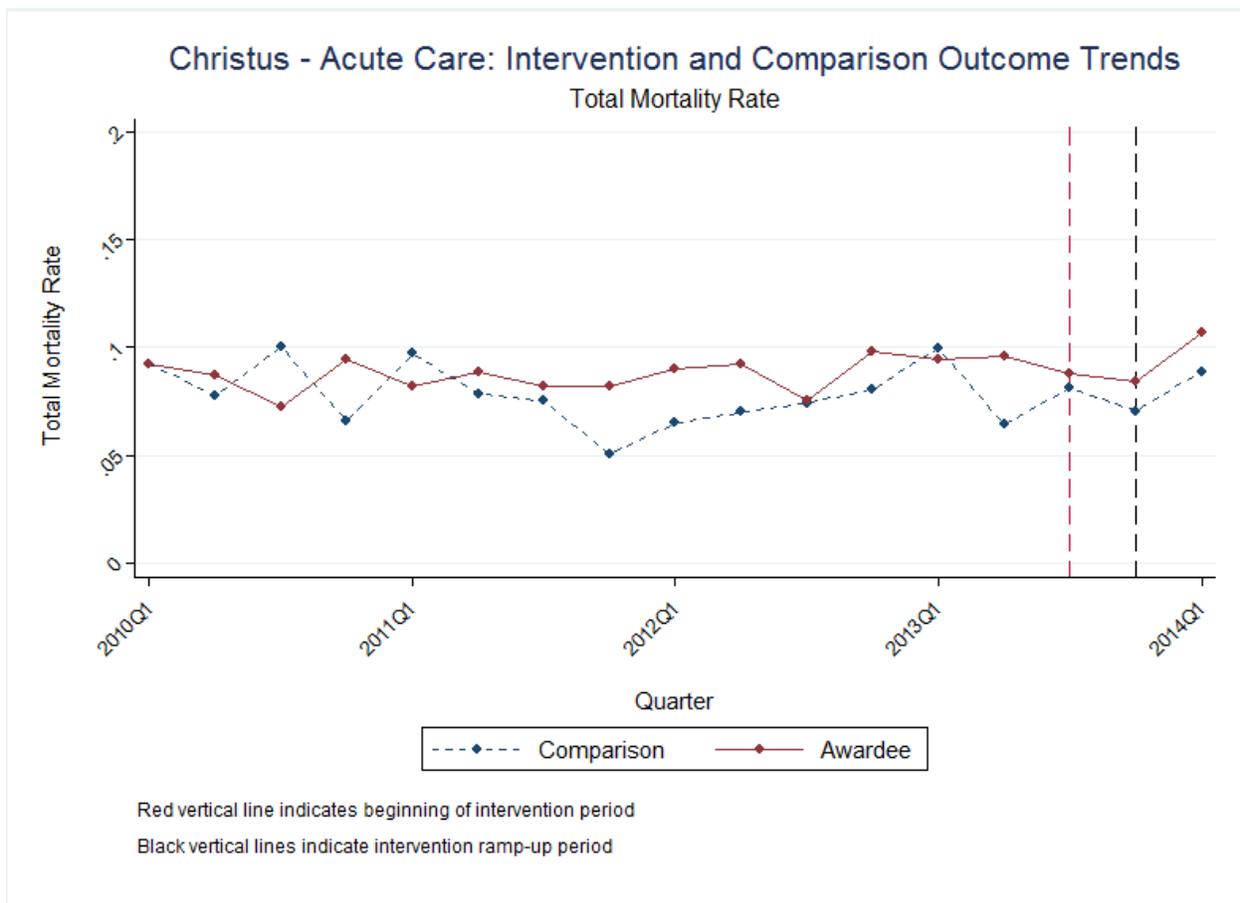
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.8   Mortality – LTPAC Patients Only

Exhibit 10 (30-day mortality rate following the admission to an LTPAC) examined mortality for patients who first encountered the screening program in a LTPAC facility. Again, the episode reported here is from admission to the LTPAC facility, which could have occurred weeks or months prior to program implementation. We assume that all intervention patients who died received at least some days of program screening prior to death. Again, there was little difference between intervention and comparison groups or a change after program implementation.

Exhibit 10: Episode Mortality – LTPAC Patients
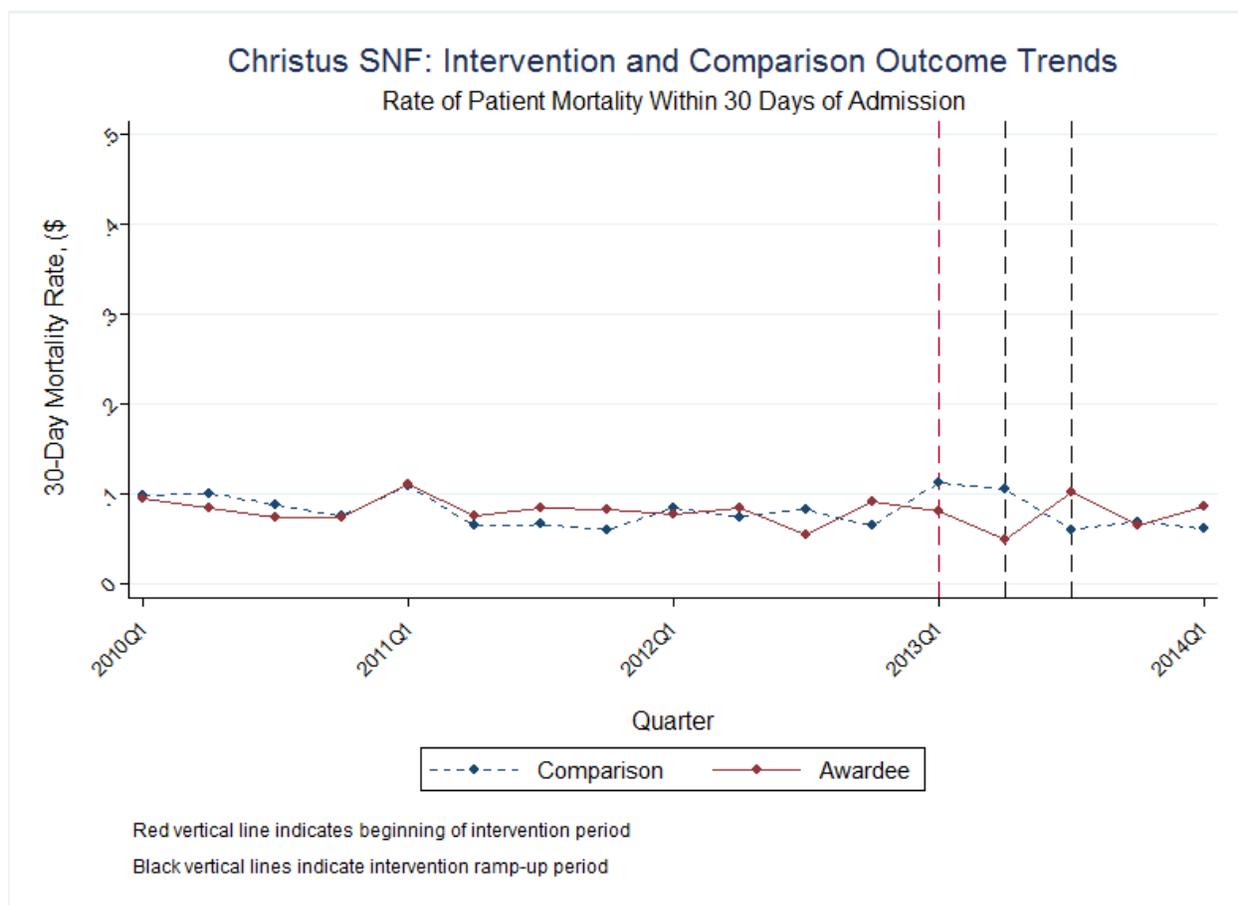
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change. In a future annual report we will aggregate data across the entire intervention period and use regression techniques to try to control for systematic differences in the two groups, although we caution that small numbers may not support such analyses.

Conclusions

- All patients at intervention facilities are considered to be in the intervention group, as the intervention is focused on technology and staff training.

- Adoption of the technology component of the intervention is low in LTPAC facilities.

- All staff were trained initially, but there is little ongoing support for training to keep up with LTPAC turn-over, which may be reducing the strength of the intervention over time.

- There is no evidence of an intervention effect on any measure, in acute care or LTPAC settings.

Appendix B2: Dartmouth College

High Value Healthcare Collaborative: Optimizing the treatment of septicemia and sepsis through implementation of bundled care

General Research Domains

The core domains for the High Value Healthcare Collaborative (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, 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 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.

1. Qualitative Analyses: Case Study

1.1 Background

1.1.1 Description of Program

The HVHC is a consortium of 19 healthcare 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 aim 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.

1.1.2 Methodology

The Dartmouth case study was conducted during the month of June 2014. Abt staff were unable to visit all members of HVHC and strategically selected three participating health systems as well as the HVHC Program Management Office 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 Maine Health 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 communicate with two smaller MaineHealth hospitals (Southern Maine Health 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 Maine Health 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.

Exhibit 1: Dartmouth Sepsis Case Study Sites

Health Institution and Site	City/State	Date of Case Study
The High Value Healthcare Collaborative, Program Management Office (HVHC-PMO)	Hanover, NH	6/3/2014
Dartmouth-Hitchcock Medical Center (DHMC)	Lebanon, NH	6/4/2014
Beth Israel Deaconess Medical Center (BIDMC)	Boston, MA	6/10/2014
Maine Medical Center (MMC)	Portland, ME	6/23/2014

Three to four Abt researchers conducted each one of the site visits: a senior Abt researcher, a nurse researcher, and one or two junior-level research assistants. At each site visit 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, with the majority coming from the Intensive Care Unit (ICU) and Emergency Department (ED). Exhibit 2 summarizes the number and type of individuals who participated in interviews or focus groups.

Exhibit 2. Professional Backgrounds of Interviewees and Focus Group Participants

	ICU Nurses	ED Nurses	Physicians	Hospital Leadership	Pharmacists	Educators	Data Managers	Program Administration	RT
HVHC-PMO Total=9								9	
DHMC Total= 26	1 Chief 4 Nurses	1 Chief 1 Nurse	1 ED Resident 1-ICU	4	2 Pharmacy Techs	2 ICU 1 ED	2	6	
BIDMC Total= 19	1 Chief 1 Nurse	1 Chief 4 Nurses	1 ED Resident 1 ED Physician / IT Specialist	4		1 ED QI Nurse	2	3	
MMC Total= 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

ICU: Intensive Care Unit
ED: Emergency Department
RT: Respiratory Therapist
IT: Information Technology
QI: Quality Improvement

A senior researcher and nurse researcher from Abt led each interview and focus group while 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 specific issues of interest for the Dartmouth Sepsis Program. Interviews and focus groups were recorded after obtaining participant consent, and used to ensure that the team's notes were accurate and comprehensive. At the end of the case study, all notes were finalized, integrated across the note-takers, and reviewed for accuracy by the team's senior researcher. Coding and analysis of the data were conducted using the qualitative data software NVivo. An initial baseline codebook was developed, and nodes and sub nodes were identified a priori for this initial codebook based upon the standard evaluation interview guides. Four people participated in the coding of interview notes, one of whom was the nurse researcher who co-led the case study. To enhance inter-rater reliability, three interviews were coded by multiple people on the team and a coding meeting was held to discuss any differences in coding. The team added new nodes as necessary and revised the original codebook. After consensus was reached on coding, the rest of the interviews and focus groups were divided among the coding team. Throughout the coding process, the senior staff who participated in the case study checked for consistency across coders, and systematically reviewed and corrected any discrepancies.

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.

1.1.3 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 Sepsis Improvement program is being implemented by 13 of the HVHC members, including: Baylor Health Care System, Beaumont Health Systems, Beth Israel Deaconess Medical Center, Dartmouth-Hitchcock, 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 HVHC is a consortium of healthcare delivery systems that collectively serve a market of more than 70 million people across the United States, including Alaska and Hawaii. 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." The HVHC is intended to be a "learning network in which the HVHC members will encourage membership by other organizations, help implement best practices in new member organizations and learn from them, and distribute findings publicly so that they can be more broadly considered for implementation."[1] The HVHC uses the Plan-Do-Study-Act (PDSA) framework for all quality improvement efforts undertaken since it was established in 2010. One reason for the HVHC's adoption of this framework is that it maintains models already in place at institutions and

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[1]   http://highvaluehealthcare.org/who-we-are/

focuses on accelerating improvement and ensuring sustainability."[2] Working in this manner is expected to support quicker, valid changes in the healthcare 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 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 communication.

The sepsis care bundles being implemented under this HCIA Award are not new. The particularly innovative aspect of this Award is that it is being implemented consistently in a large number of health systems serving different patient populations, and as such comes close to a national test of the intervention. The ability to pilot all elements of the program at so many hospitals simultaneously, with consistent data collection/reporting and analysis is intended to support rapid and continuous quality improvement. During Quarter 1 of the program (July, August and September of 2012) the participating HVHC members were surveyed for interest in participating in the Sepsis Improvement program. Interested health systems and their hospitals were then grouped into Year 1 and Year 2 initiators. The sites visited by Abt included a Year 1 initiator (BIDMC) and two Year 2 initiators (Dartmouth-Hitchcock and MaineHealth). Regardless of when a hospital began, all are continuing the Sepsis Improvement program in Year 3 of the Award.

Program Goals

The HCHC sepsis program goals include:

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

2. Improve health: 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).

3. Reduce cost: 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 $12.24M savings at HVHC hospitals for Medicare beneficiaries over the three year program."[3]

Impetus for the Program

The three HVHC health systems Abt visited already had some level of sepsis awareness among the physicians and nurses working in the hospitals. Prior sepsis initiatives ranged from best practice guidance as established in professional literature or by hospital committees to established protocols for managing sepsis patients. Staffs at each hospital were well aware that sepsis is a serious and potentially life-threatening complication of an infection. A main challenge is that sepsis can be difficult to diagnose quickly, and the numbers of patients can be smaller than for other life-threatening health problems (e.g., trauma, myocardial infarction).

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[2] http://highvaluehealthcare.org/how-we-do-it/

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

Each health system had internal goals for implementing the Sepsis Improvement program. Dartmouth-Hitchcock already had a sepsis bundle, devised years earlier, but discovered that bundle compliance was "quite low" and could be improved. Examination of data drove the urgency to improve.

> "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*

The BIDMC had a long-standing commitment to sepsis interventions, having designed the nationally recognized Multiple Urgent Sepsis Therapies (MUST) protocol. That protocol 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, Maine Medical Center 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 bundle offered an approach to making care more consistent among the departments and clinicians managing sepsis patients.

1.2   Program Components & Targets

The targets of the Sepsis Improvement program are patients in the emergency department (ED) and in intensive care units (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.

1.2.1   Primary Program Components

The Sepsis Improvement program consists of three primary components: the three hour and six hour sepsis care bundles, onsite Lean Six Sigma or other process improvement training prior to implementation of sepsis care bundles, and a unified data specification with tools for health systems having differing electronic data capabilities. HCHC-PMO worked with participating health systems to operationalize these components through the following frame work[4]:

1. Clinicians and staff trained by sepsis program

2. Sepsis processes and care tools are evidence-based and impactful

3. Strong network of Lean or equivalent methodology within participating sites

4. Codification/dissemination of best practice methods and measures

5. 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.

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

Exhibit 3: TDI Operational Plan for Sepsis Program Implementation (Source: Trustees Dartmouth College-Sepsis Improvement Quarter 1 HCIA Narrative Progress Report)

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 gives an overview of each of the clinical decision-making and interventions needed at both the three and the six hour bundles.

Exhibit 4: Bundle Protocol (formerly called HV-SB) (Source: Trustees Dartmouth College-Sepsis Improvement Quarter 2 HCIA Narrative Progress Report)

Severe Sepsis 3 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 6 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
   • Measure central venous oxygen saturation
7. Re-measure lactate if initial lactate was elevated

The three hour bundle includes a set of early clinical decisions: a patient is assessed by nursing, then 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 clock starts ticking to track timeliness in completing 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, and 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 any 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 hospitals we visited are substituting non-invasive measures for monitoring CVP, although consensus is still developing about alternative measures. If placing a central line to measure CVP is a physicians' only organizationally-approved option for measuring CVP, and s/he chooses not to place the line, the six hour care bundle is considered incomplete and noncompliant.

Many physicians we interviewed expressed concern about some steps in the 6 hour bundle. In particular, there is concern about the central venous pressure step, which requires placement of 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 central venous pressure. TDI reported in their seventh quarter HCIA Narrative Report, "Multiple members have cited changes in evidence and difficulty with physician adherence surrounding the 6-hour bundle elements. These challenges at member sites because of the evolving science have led us to review the 6 hour bundle as part of mid-course corrections." Finally, some physicians may be uncomfortable ordering the levels of fluid indicated in the protocol, for certain subsets of patients. Many physicians exclude cardiac ICU patients from the bundle, because rapid high volume intravenous fluid could be unsafe. In addition, gauging the correct fluid for obese patients is difficult, as the care bundle calculation method is weight-based and it may yield an unsafe recommendation for fluid administration.

Due to the lack of consensus about CVP monitoring, at the time of our 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. Recently, a large randomized trial was completed by the University of Pittsburgh and published in March of 2014 in The New England Journal of Medicine. Thirty-one academic medical centers participated in the randomized "Protocolized Care for Early Septic Shock (ProCESS)" trial. This study randomly assigned over 1300 septic patients into three study arms: protocol-based Early Goal Directed Therapy (EGDT), protocol-based standard therapy, and 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. Protocol-based EGDT monitored CVP and administered fluids and vasopressors through a central venous catheter, whereas protocol based standard therapy measured CVP and administered fluids and drugs through peripheral venous access. The study outcome measures were 60 day in-hospital mortality and mortality at 90 days. The study found no significant difference in morality across the three groups over the five years of the study (60 day mortality P=.83 & 90 day morality P= .70).[5]

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[5]   n engl j med 370;18 nejm.org may 1, 2014.

In August 2014, after our case study was completed, TDI and the HVHC decided to make care bundle steps related to CVP optional rather than mandatory, to allow flexibility. If CVP is measured using alternative techniques it will still be considered compliant with the 6 hour care bundle.

Onsite 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 HVHC-PMO and the other at Denver Health. An initial training was conducted by the Denver Health sepsis expert 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; the latter drafted by the Year 1 participants in an initial meeting in Denver and 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 Emergency Department 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.

Exhibit 5. Onsite Rapid Improvement Event (RIE) Week Held at Each Participating Year 1 Health System (Source: Trustees Dartmouth College-Sepsis Improvement Quarter 2 HCIA Narrative Progress Report)

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

Dartmouth-Hitchcock and BIDMC conducted Lean rapid improvement events. At BIDMC, the nurses and physicians created an automated sepsis order set during the RIE. During the REI, clinicians also suggested a Sepsis "bug" to physically attach to a patient's white board to signify sepsis. This eventually was discontinued because staff did not find it helpful and was too busy to keep the "bug" updated in real time. We interviewed staff at various levels at BIDMC and Dartmouth-Hitchcock, and all were enthusiastic about the RIE sessions and felt that they were part of the solution. Maine Medical Center did not hold a Lean REI, but did use a similar process redesign approach (Clinical Microsystems Methodology) to address a few key issues in their sepsis care processes.

> "(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 being 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. This electronic tool is 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 below for the most current version of the STAT tool.)

Initially, 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 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 bundle-specific (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. 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, where care bundles are expected to have the most impact.

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 TDI data analysts, HVHC-PMO staff view this effort as being worthwhile. As a HVHC-PMO 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

> "[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."
>
> *– TDI staff*

conference recently 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 hospitals, time stamps from the EHR are important for documenting steps in the care bundle because filling in exact times on the paper form, in real-time, is not feasible. Correct time stamps, to identify delays in the care bundle, 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 trail is completed. Conversely, if a clinician forgets to enter the time on a piece of paper, the time (stamp) is lost forever. The time stamps created by an EHR would reduce the "loss" of data that occurs with hand-written notes and can be missing time of care completed.

1.2.2   Technology
The HVHC Sepsis Improvement program has both health information technology (HIT) and clinically-focused technology. The HIT 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. Each hospital our team visited for this case study differed in terms of these important technologies.

Heath Information Technology

Each of the three hospitals we visited has an EHR: Dartmouth-Hitchcock and Maine Medical Center use Epic, as do several other HVHC members. BIDMC uses a home grown and internally managed EHR. Dartmouth-Hitchcock and Maine Medical Center participate in a HVHC Epic user affinity group to share ideas and best practices. Both Dartmouth-Hitchcock and Maine Medical Center created order sets for the sepsis care bundles in Epic and use a combination of the STAT tool, chart audits and electronic submission of their sepsis data for the unified spec.

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 case study in June 2014, the ED staff reported that there was no routine data recording in real-time for ED patients. Dartmouth-Hitchcock initially transmitted data to HVHC-PMO using alternative means, but has since adopted the web-based STAT tool for data transmission.

Maine Medical Center uses the paper form and chart review, as well as information from the laboratory and pharmacy systems, to complete the unified data spec for each patient, and transmits the information using the web-based STAT tool. Maine Medical Center IT staff utilized the Epic feature of best practice alerts (BPA) to create a trigger that notifies clinicians when a patient seems to match the sepsis criteria. They also built into Epic a feature 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. It was not clear during our case study whether Dartmouth Hitchcock used similar Epic features.

Dartmouth-Hitchcock and Maine Medical Center data analysts reported that the Epic application in the ED contains important information that is not visible to clinicians when patients are transferred to the ICU. Both also reported that their separate applications for clinical laboratory and pharmacy systems contain the lactate level for the unified data spec, which must be manually transferred to the paper form and entered into the STAT tool for every patient. Data analysts at Maine Medical Center reported challenges in finding and recording all of the elements of patient data needed to demonstrate sepsis bundle compliance, and voiced considerable frustration in using the STAT tool for electronic data submission.

The BIDMC is able to submit unified spec data electronically, through the use of an add-on data management tool called REDcap[6] 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 was able to quickly make necessary changes to order sets to support clinical workflows. For example, IT staff built a trigger that alerts clinicians when a patient seems to match the sepsis criteria and will not allow the physician to ignore this trigger; a 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.

Clinical Technology

The clinical technology was similar at the three hospitals we visited. All three use automated dispensing systems to support decentralized medication distribution on the units. Meeting the strict timeframes of the three hour care bundle requires fast access to appropriate antibiotics. Each of the sites looked at current state antibiotic access before implementing the sepsis care bundles, to determine time loss while nurses waited for the pharmacy to deliver the antibiotics to the ED. All three determined that having the medication dispensing machine in the ED, and stocked with commonly needed antibiotics, used during the 3 hour care bundle, reduced antibiotic delivery times. Dartmouth-Hitchcock and Maine Medical Center 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, perhaps because they optimized laboratory testing and results delivery during their previous work on the MUST protocol. Laboratory directors at Dartmouth-Hitchcock and Maine Medical Center realized that they could reduce this testing delay by sending their blood work to the lab in a different manner that the lab could process more quickly. This process change reduced lactate testing time to six minutes. Finally, Dartmouth-Hitchcock and Maine Medical Center realized that Epic order sets were not marking any of the lactate tests as 'stat', to be completed immediately. The order sets were revised to make lab personnel aware of the urgency of these tests. To reduce delays even further, Dartmouth-Hitchcock purchased point of care lab testing machines that allow ED nurses to process initial lactate tests on the floor instead of sending blood to the lab.

We heard considerable controversy about the measurement of central venous pressure (CVP) for patients who do not otherwise require insertion of a central line (i.e., the line is being inserted only for the purpose of obtaining a CVP reading). BIDMC chose to collect data on other measures of volume status and hemodynamics when utilized by clinical staff in lieu of traditional CVP measurements. Physicians in the other two hospitals also mentioned the previously-described randomized study and controversy about CVP measurement.

1.3   Workforce Development

HVHC-PMO staff focused extensive implementation efforts toward building Lean skills among their HVHC members, including RIEs in Year 1 initiators, to support individualized sepsis process redesigns. All three hospitals we visited for this case study described similar 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. Some additional site-specific activities are included in Exhibit 6.

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6   http://www.project-redcap.org/

Exhibit 6: Site-Specific Workforce Development Activities

Site	Workforce Training/Development
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)
BIDMC	• Importance of documentation training, to enhance data completeness and to get credit for meeting three hour care bundle
Maine Health	• 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 Maine Health staff • Medical newsletter *The Scope* contains quarterly information on the sepsis program • Residents receive sepsis program training when they rotate through the ED

At all three hospitals we visited, nursing staff reported immense satisfaction with the sepsis care bundles. They reported that the care bundles are easy to understand and to implement, and require little instruction.

The BIDMC nurses reported that the 3 hour and 6 hour care bundles are much less complex and labor intensive than the MUST protocol, and the workflows for clinicians are more straightforward and require less decision-making required at each step. They also find the care bundles easier to teach to new nurses and rotating medical residents. At each hospital, nurses in particular were supportive of the care bundles. We saw little deviation from the bundles across these hospitals (other than the CVP measurement issue mentioned earlier).

Several nurses told us that they use the paper form offered by HVHC-PMO not only for recording data, but as a communication method with tentative physicians and new nurses.

> "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 [the form] has given them a script to communicate with the physician. They can say, 'This is my national standard'."
>
> *– ICU Nursing Director*

2. Implementation Effectiveness

In this chapter, we discuss the different areas in which the HVHC-PMO Sepsis Improvement staff believes the sepsis bundle is making a difference in quality of care, patient health outcomes, and cost savings. For each of these aim categories, we discuss how the HVHC-PMO team is measuring the program's impact, as well as how Abt Associates intends to measure impact. Finally, we discuss unanticipated impacts that have arisen over the first several quarters of the program's implementation.

2.1 Better Care

In multiple interviews, we learned how participants believe the Sepsis Improvement program improves the quality of care that their patients receive. The following are two high-level improvements that were often mentioned during our site visits.

2.1.1 More Timely Care

As each site began preparing to implement the sepsis care bundles, one factor became clear: timely completion of the three and six hour care bundles is the best way 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, to more quickly 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. All three hospitals worked closely with their pharmacies to ensure that antibiotics needed for the sepsis bundle were located on the floors, close to the clinicains adminster them to patients.

2.1.2 Do You Suspect Infection?

At all three sites, clinicians emphasized that patients in early sepsis are easy to miss, until their symptoms become more acute—failure to recognize incipient sepsis means time lost in initiating the care bundle. ED staff in particular mentioned that while they automatically triage an injured trauma patient, they may overlook the older patient with a urinary tract infection who is lucid and afebrile. Training for the sepsis care bundle educated clinicians to place any patient with two or more SIRS criteria and the specified lactate or blood pressure metrics onto the sepsis care pathway. Triaging patients in this manner initiated the sepsis care bundle for many patients who might not otherwise have been recognized as being potentially septic. In some cases, patients are determined not to have sepsis and are removed from the sepsis care pathway; in other cases care is delivered faster than would otherwise have occurred. A nurse described, for example, the "college kid with tonsillitis or the young girl with a UTI who weighs 88 pounds." Previously, these patients would not have been recognized as possibly being septic, but with the care bundles these patients receive early treatment. If their symptoms resolve after starting the 3 hour bundle (e.g., after they receive fluids and antibiotics), they are removed from the sepsis pathway. The treatment they received was appropriate to meet their needs, and they were treated quickly, even though they were not ultimately determined to have sepsis.

2.1.3 HVHC Measurement Strategy[7]

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

- Counts of all attendees at trainings for the sepsis care bundle protocols

- Counts of all attendees at trainings specific to Lean Six Sigma process redesign

Other measures in the HVHC-PMO self-monitoring plan are not currently being reported.

2.2 Better Health

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

2.2.1 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.

Other measures in the HVHC-PMO self-monitoring plan are not currently being reported.

2.3 Lower Cost

The program staff at Dartmouth anticipates that the sepsis bundle 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 complications (such as Pneumonia), and shorter ICU length of stay. Reduced complications may lead to lower readmission hospital rates as well as lower use of LTCH and or SNF for treating these medical complications.

2.3.1 HVHC Measurement Strategy[7]

HVHC-PMO collects data on a number of quality measures 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 LOS does not reduce costs to Medicare for traditional Medicare beneficiaries, it does

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[7] Source: Trustees Dartmouth College-Sepsis Improvement Quarter 7 HCIA Monitoring Measures Plan.

reduce costs for patients whose insurers pay FFS, and reduces costs (increases revenue) for the hospital.

Other measures in the HVHC-PMO self-monitoring plan are not currently being reported.

2.4   Unanticipated Impacts

In addition to perceived impacts related to better care, better health, and lower 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 indications all benefit from fast and appropriate treatment with antibiotics and intravenous fluid resuscitation. While this spill-over benefit is not being measured by HVHC-PMO (or by Abt), it was mentioned by clinicians who work in the three EDs we visited.

2.5   Outcomes That Can Be Measured Using Claims

While some of the expected improvements in care, health outcomes and cost cannot be measured using claims data (e.g., timely completion of process measures), many others, such as reduced length of stay, reduced readmissions, and reduced in-hospital mortality can be measured using Medicare and Medicaid claims. Abt's measurement strategy (Exhibit 8) will select intervention and comparison patients who have one of the three ICD-9 codes for sepsis AND an ED visit or ICU stay (or both). The patient outcomes we will measure using claims data include:

Exhibit 8: Abt Measurement Strategy

7, 14, 21, 30 and 60 day all cause, unplanned, rehospitalizations
30-day ED post-discharge visits
Total healthcare spending per patient (60 day episodes)
In-hospital mortality
30 and 60 day post-discharge mortality

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 four categories: communication, measurement and self-monitoring, confounding factors, and sustainability.

2.6   Communication

Staff at each hospital we visited reported the importance of thorough communication to facilitate timely completion of each step in the sepsis care bundles. Several nurses reported that the paper data form created by HVHC-PMO, which outlines each step in the care bundles, is an excellent tool for communicating the urgency of starting patients on the sepsis care pathway. When faced with an uncertain physician who wants more test results, nurses reported that they refer directly to the paper form and protocol to document the criteria each patient meets and what needs to quickly be ordered to adhere to the care bundle. The paper form is also useful during handoffs of patients between the ED and ICU, and nurses reported using it in the same way they use an SBAR (Situation, Background, Assessment, and Recommendation) to brief their counterparts in the other unit. The paper form focuses the entire care team on the key clinical findings that indicate potential sepsis, and motivate fast initiation of the sepsis care bundle.

3. Context

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 analyze 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.

Maine Medical Center uses removable plaques that are attached to ICU computers as a means of communication at the point of care. Although Maine Medical Center 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 what is and isn't working in current sepsis care practice and to disseminate the latest information back to clinicians.

3.1 Measurement & Self-Monitoring

One of the greatest difficulties HVHC-PMO, hospital IT, and data analysts reported in implementing this complex multi-site program 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. Some must search through separate IT systems for laboratory values and antibiotics administered, and are not always able to find these critical data. All three hospitals 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 days later for data reporting. Dartmouth-Hitchcock and Maine Medical Center in particular 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 HVHC-PMO can also be problematic. For example, the web-based STAT tool was created by HVHC-PMO for HVHC members who cannot extract data directly from their EHRs. Maine Medical Center data analysts reported that this web-based tool is not user-friendly and transmission often fails (with loss of data); they therefore keep duplicate paper records of all data submitted, to avoid having to assemble information a second time.

Finally, EHR and other IT upgrades have caused rework and data loss. Order sets programmed into an electronic system must be transferred or reprogrammed, and retested, after every upgrade.

3.2 Confounding Factors

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; MaineHealths' affiliates span a large section of eastern Maine. Not all units within the 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 where the science and evidence base is changing, or where there is honest clinical disagreement among physicians. In the three institutions we visited, physicians described specific circumstances where they may deviate 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 has a strong desire to incorporate Emergency Medical Technicians (EMTs) into the sepsis bundle practice. The Medical Director of one participating MaineHealth hospital has an EMT 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 identification of septic patients and initiation of the care bundle. MaineHealth described a previous tele-ICU program that contained 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 begin in the community hospital setting, rather than waiting until the patient is transferred to Dartmouth-Hitchcock. This sepsis awareness and education is facilitated through the CREST (Center for Rural Emergencies and Trauma) network, 16 critical access hospitals and community hospitals in rural New Hampshire and Vermont. Sepsis awareness and education are also facilitated through NEAH (New England Alliance for Health), a group of community hospitals, behavioral health centers, and home healthcare agencies that share "a commitment to improve the quality, efficiency, and availability of health care in New Hampshire, Vermont, and western Massachusetts."

Maine Medical Center, the flagship hospital for 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 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 receive many patients in transfer from smaller community hospitals within and outside our hospital network.

3.3   Sustainability

Staff at all three hospitals we visited reported that the sepsis care bundles are now deeply embedded in their workflows, IT systems and culture, and will continue to be used after HCIA funding concludes. All reported similar next steps of spread to medical units throughout their hospitals, beyond the ED and ICU, and also spread to community referral sources.

Each hospital began their program implementation in the ED, as this is the major entry point for patients with sepsis. Those that began in Year 1 expanded the care bundles to the ICU and intend to expand further to other units. Those that began in Year 2 are beginning work in their ICUs. At the time of our visit, there had been little or no implementation of sepsis care bundles on the general medical floors, but all three hospitals report that this is their next area of expansion.

The two rural medical centers we visited are interested in expanding the sepsis care bundles to their community referral sources. 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. Their outreach through the CREST and NEAH networks is another way to sustain the program. MaineHealth is expanding to EMS and to small community hospitals, and has begun discussing the possibility of including local area nursing homes in early identification of sepsis and initiation of care bundles.

BIDMC is planning to enhance electronic order sets to better track progress in treating sepsis, particularly in ED and ICU settings where medical residents rotate frequently and need to be quickly engaged in the sepsis care bundles.

In any clinical protocol, it is important to adjust to changes in science, to keep practices evidence-based. To be sustainable, the care bundles must be adaptable. We saw evidence of this adaptability, as the six hour bundle is being redefined to address physician concerns and recent research about CVP lines. Additional flexibility may need to be incorporated in the bundle definition regarding fluid administration for cardiac ICU patients and obese patients.

3.4   Conclusion

Abt researchers visited three different HVHC member health systems 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.

The steps within the sepsis bundle appeared to be uniform, with clinicians in all three hospitals taking exception to the step regarding CVP monitoring (which has since been revised). Physicians in all three sites appear to vary in revising the fluid volume specific in the care bundles for cardiac and obese patients.

3.5   Conclusion and Next Steps

The greatest difference among the three hospitals we visited in their implementation of the care bundles appears to be in the areas of health IT, data collection and submission, and their efforts in measurement and self-monitoring. Dartmouth-Hitchcock and Maine Medical Center use Epic EHRs and cannot extract and submit all necessary data directly from their EHR. They each use paper documentation and manual chart abstraction to complete documentation required by HVHC-PMO. At the time of our site visit, Dartmouth-Hitchcock had been unable to use even the paper form for data recording in their ED, and Maine Medical Center struggled to use the web-based STAT data submission tool. BIDMC uses a home-grown EHR which 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.

Next Steps

In follow-up interviews planned for 2015, several topics will be revisited and new issues explored, as the HCIA funding nears completion. Topics to explore include:

- *Measurement and self-monitoring*: We heard about site-specific difficulties in transmitting unified spec data to HVHC-PMO via secure file transfer. We will explore whether and how HVHC-PMO staff has modified the unified data spec, or the web-based STAT tool for data submission, based on feedback from HVHC members. We will also follow up with Dartmouth-Hitchcock staff who began using the web-based STAT tool after our site visit.

- *Reach*: We will be interested in the expansion of the program to smaller rural hospitals, EMS, and other community engagement activities.

- *The value of conducting this type of care process improvement through a collaborative, coordinated by an entity such as TD:* This HCIA award is as much about the process of implementing the sepsis care bundles in a collaborative manner, as it is about the care bundles themselves. We will be interested in asking participants about the added value of the HVHC, and TDI, in their efforts to improve sepsis care

- *The value of conducting process improvement pre-work:* We will ask if participants used Lean Six Sigma or another process improvement tool as part of their sepsis care bundle implementation.

4. Quantitative Analyses

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 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, which in turn may reduce mortality. We therefore present results for the following additional measures:

- Length of stay (LOS)

- Inpatient mortality

- Total 30 day (including inpatient) mortality

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.

4.1 Defining Intervention and Comparison Groups

4.1.1 Registry Information

We did not receive a complete patient registry from Dartmouth program staff, identifying which of their 27 intervention facilities each patient was treated in, and containing HIC numbers for matching against Medicare data.

4.1.2 Selection Rules

We developed rules to identify the treatment population after discussion with the Dartmouth program staff. The following inclusion and exclusion criteria apply to the Dartmouth population:

Inclusion
Revenue Center Codes
ICU: 0200, 0201, 0202, 0206, 0207, 0208, 0209
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
ACUTE 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 and their lactate levels were not dangerously high—important selection criteria applied by all Dartmouth program sites—but these clinical indicators are not available on Medicare claims.

4.1.3   Estimated Intervention Group

The Dartmouth sepsis care bundle intervention takes place in 27 hospitals across the country. The comparison group is drawn from similar hospitals in the same HHRs as intervention hospitals. In a few intervention HRRs there are no similar hospitals to form a comparison group (in Maine, New Hampshire and Iowa) and we chose comparison hospitals from elsewhere in these states and nearby states. For the Maine and New Hampshire comparison groups we included hospitals in Vermont and upstate New York; for the Iowa comparison group we included hospitals in Colorado cities that were not already part of the comparison group for Denver Health. Data from all of the participating intervention hospitals are pooled in the pre/post descriptive analysis below, and data from all comparison hospitals are also pooled. We anticipate that the program will be large enough in another year to conduct a pooled difference-in-differences analysis for the Dartmouth sepsis program.

Because Dartmouth program staff were not able to provide a facility identifier for each admission or identification (HIC) numbers for each patient, we are unable to determine how close a match we achieved with the comparison group specification.

4.2   Core Measures: Results

4.2.1   Readmissions

Implementation did not take place on the same day in all participating facilities. The red vertical line in the graphs below shows the start of the intervention period and the black vertical lines show the timing of implementation for subsequent groups of implementing hospitals.

The Dartmouth sepsis improvement program aims to reduce Medicare spending by reducing complications, readmissions, return ED visits, and need for post-acute care.

Exhibit 9 (hospital discharges followed within 30 days by a readmission) shows that the rate was lower in the intervention group than the comparison in both baseline and intervention periods, with no evidence of change in these trends or the relationship between the groups during the intervention period. 60% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15–30.

Exhibit 9: Readmissions
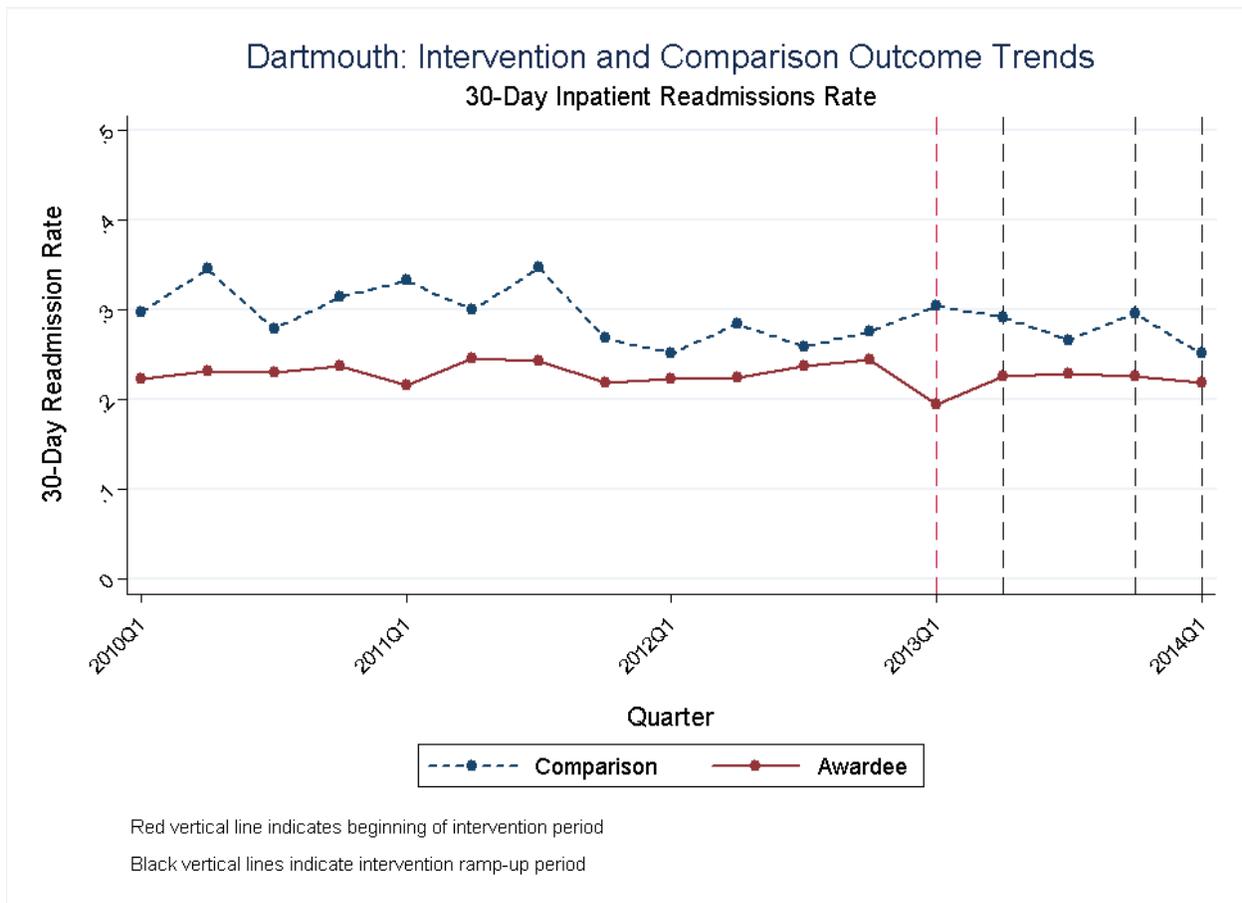
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

4.2.2   30-Day Post-Discharge ED Visits

Exhibit 10 (discharges followed within 30 days by an ED visit) shows that the intervention group had fewer post-discharge ED visits than the comparison group, in both baseline and intervention periods, with no evidence of an intervention effect.

Exhibit 10: 30-Day Post-Discharge ED Visits
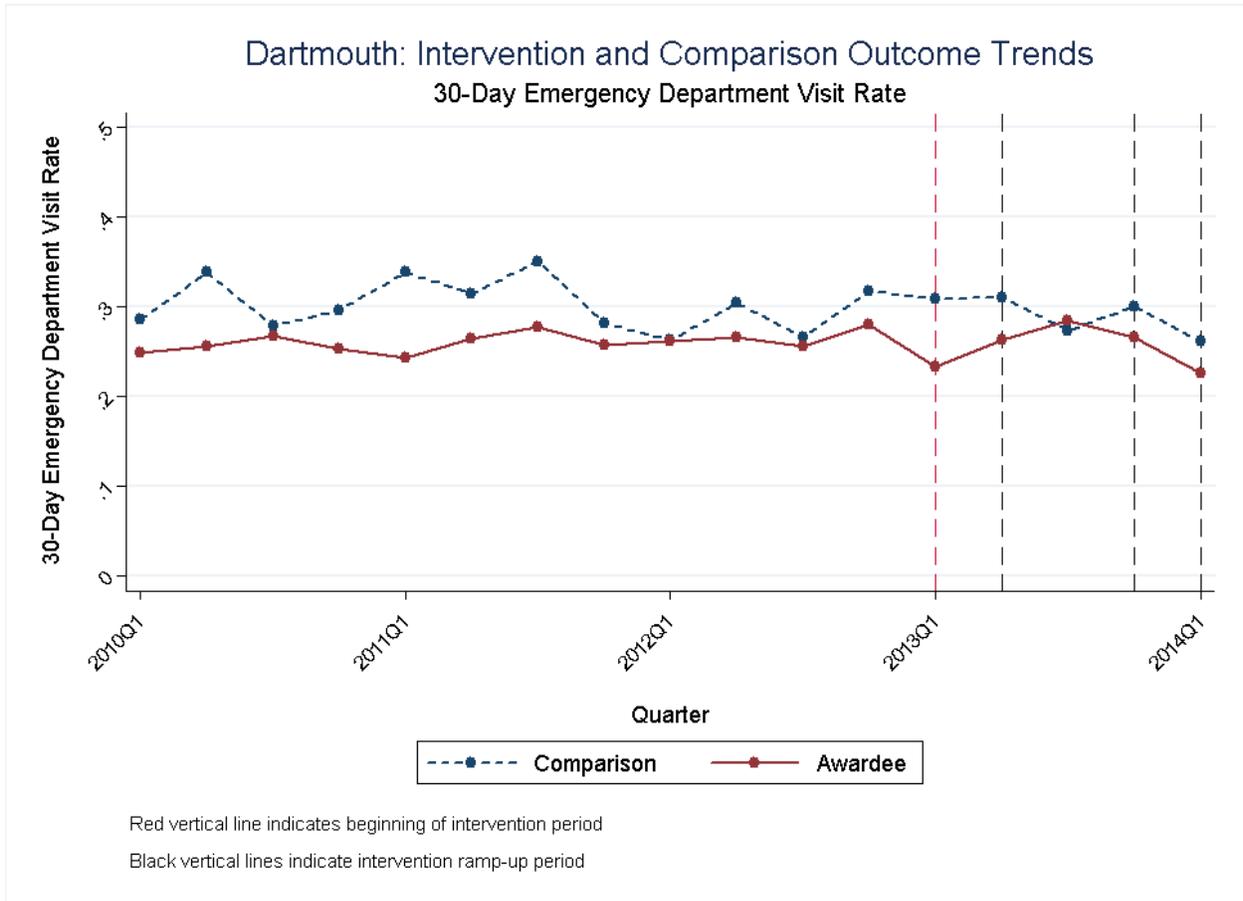
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

4.2.3   Medicare Episode Spending

The Dartmouth program aims to reduce Medicare episode spending by 5%.

Exhibit 11 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days. The intervention group was higher than the comparison group in the baseline period, but in the most recent quarters was a little lower, although this was due to an increase in the comparison group rather than a decrease in the intervention group. 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 11: Medicare Episode Spending
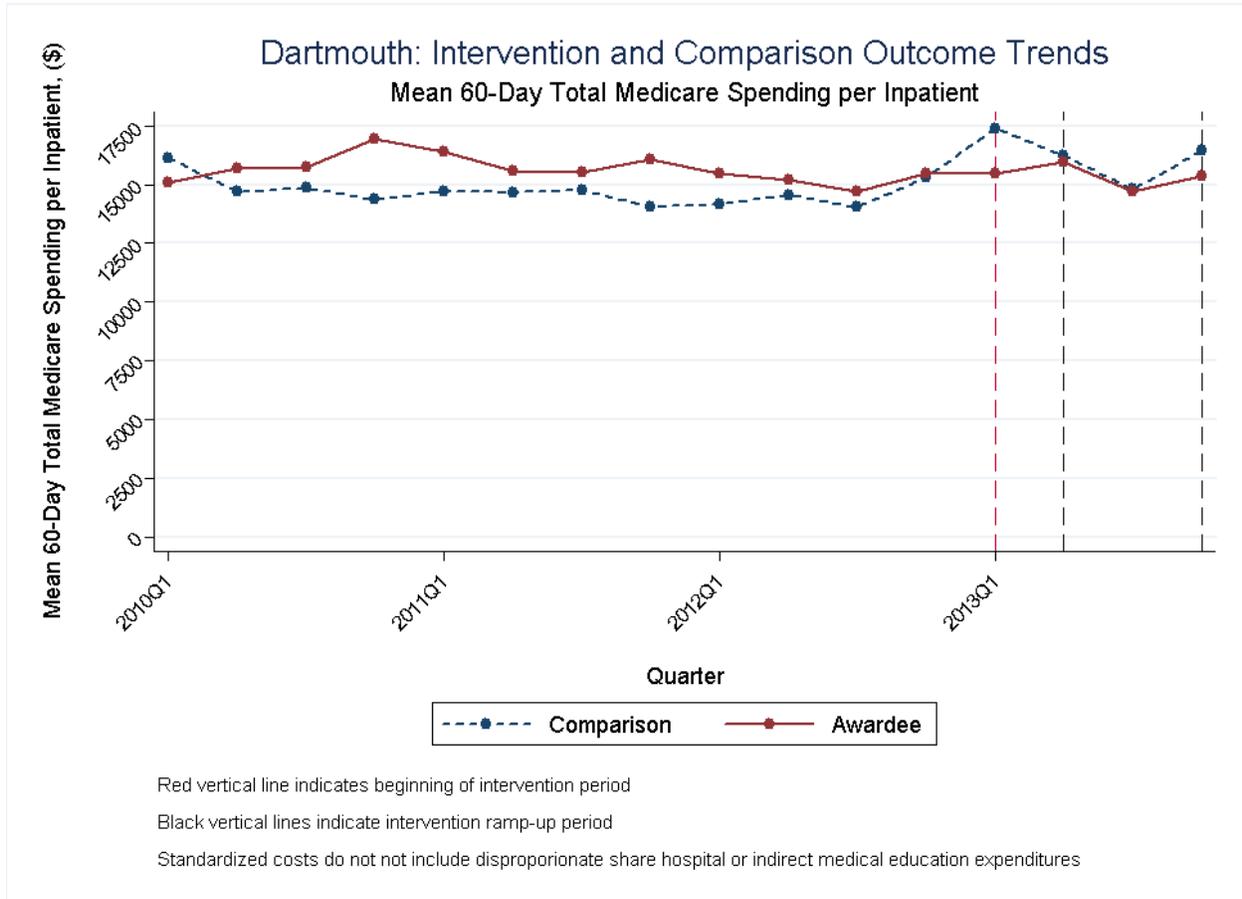
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

4.2.4   Index Admission Length of Stay (LOS)

Important goals of the Dartmouth Sepsis Improvement program include early recognition of sepsis and improve adherence to evidence-based best practices, which in turn are expected to reduce LOS.

Exhibit 12 (length of stay following index admission) shows that the intervention group had a shorter average LOS throughout the baseline and intervention periods, with little evidence of change in either group during the intervention period.

Exhibit 12: Index Admission Inpatient LOS
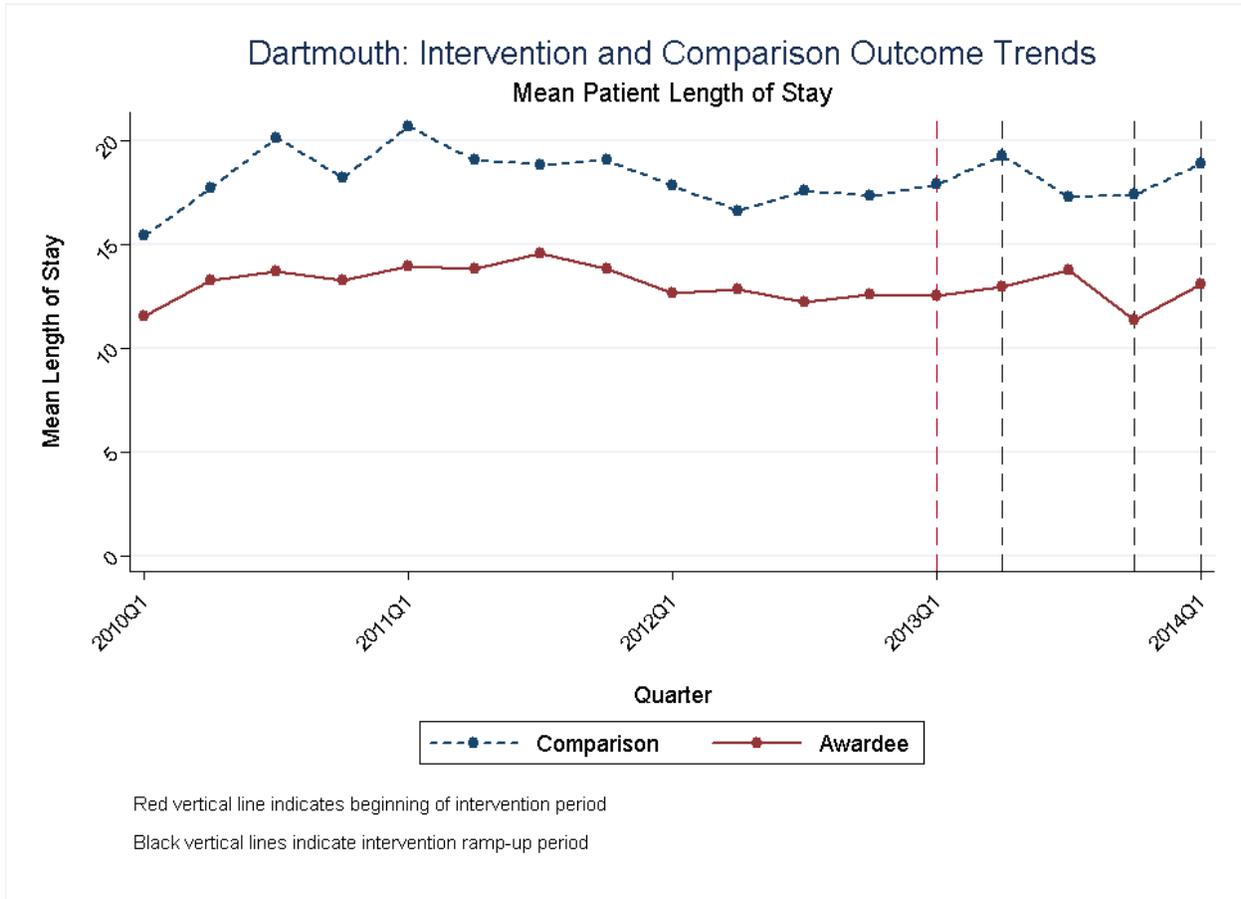
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

4.2.5   Index Admission Inpatient and 30-Day Mortality

Exhibit 13a (inpatient mortality following an index admission) shows that the intervention group had lower mortality than the comparison group, in the baseline and intervention periods. We note that the comparison group was quite volatile from one quarter to the next and appeared to increase in the most recent quarters; there was no similar increase in the intervention group in recent quarters.

Exhibit 13a: Index Admission Inpatient Mortality
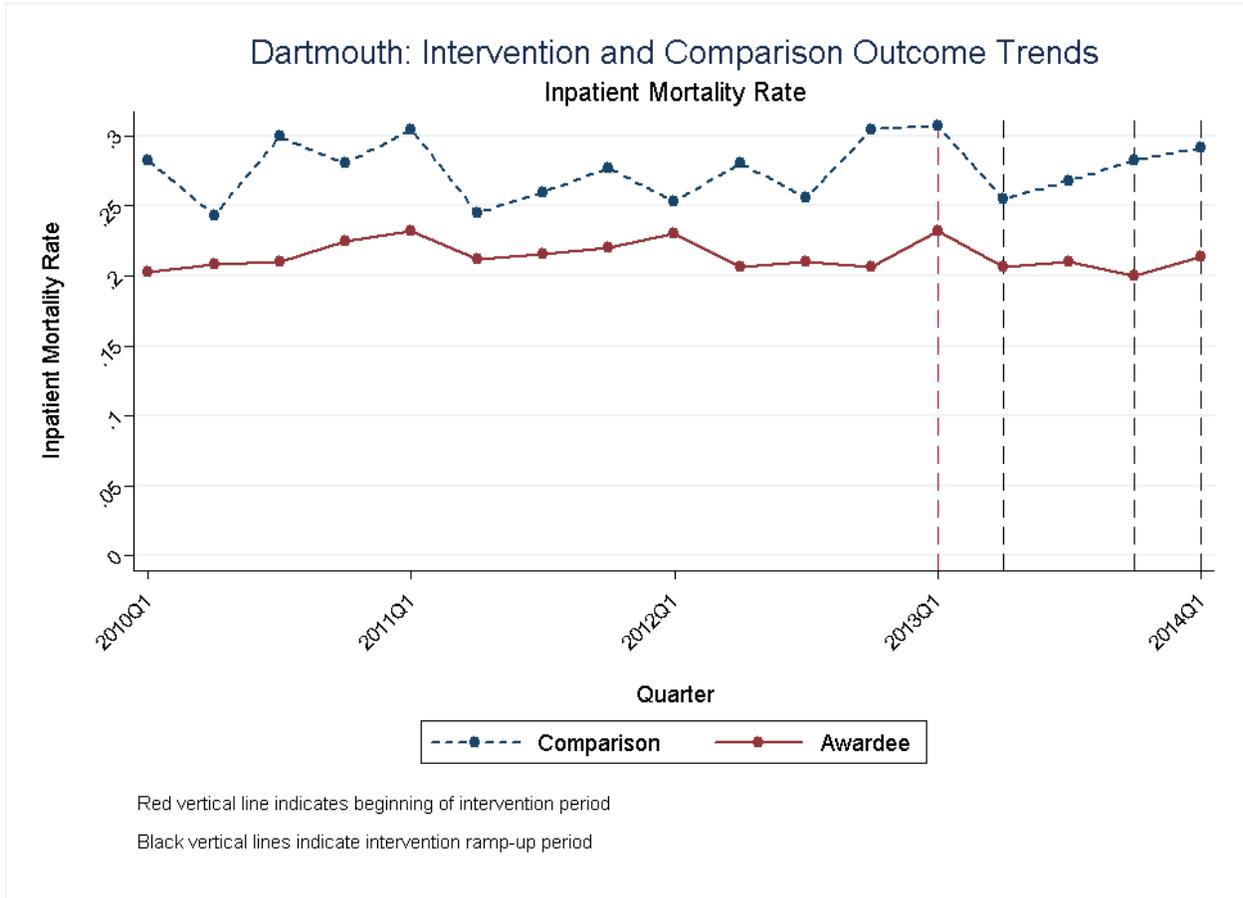
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 13b includes total mortality (inpatient and the 30 days following the end of the index admission) and shows that the intervention group had lower morality than the comparison group, in the baseline and intervention periods. The intervention and comparison groups were quite volatile from one quarter to the next and appeared to increase in the most recent quarters.

Exhibit 13b: 30 day Mortality (including Index admission)
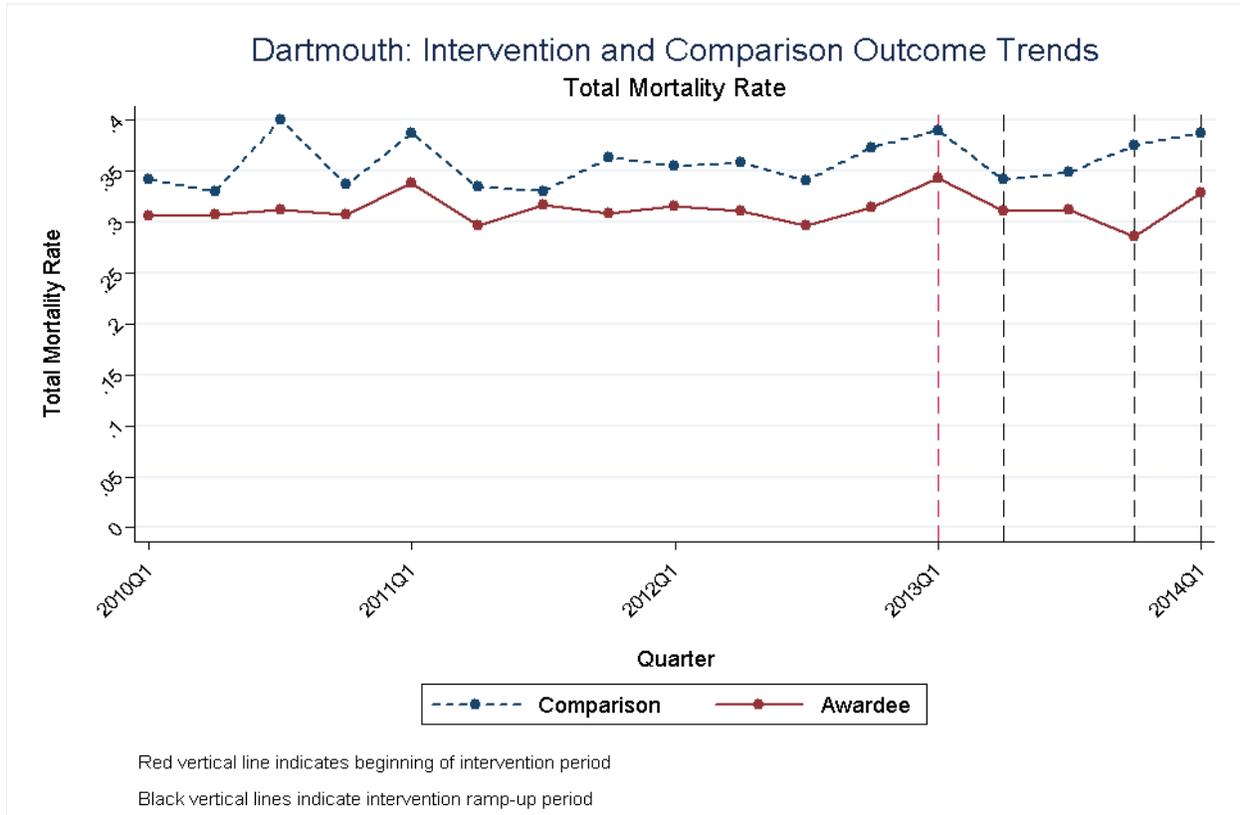
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change. In a future annual report, if numbers permit, we will aggregate data across the entire intervention period and use regression techniques to try to control for systematic differences in the two groups.

Conclusions

- The match/adequacy of the intervention and comparison group, and any resulting bias, is unknown because the Awardee patient registry contained insufficient data to match to Medicare claims. The intervention is spread over many facilities with possibly different patient populations.

- The intervention group had lower utilization than the comparison group during the baseline period (readmissions, post-discharge ED visits, LOS) and these trends continued in the intervention period.

- Intervention group is consistently higher in Medicare spending in the baseline period; since the intervention started, the comparison group has had higher Medicare costs. Additional quarters of data are needed to determine if this trend will continue, and to pool enough Medicare patients across sites to support a DD regression analysis.

Appendix B3: Emory University Hospital

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

General Research Domains

The core domains for the Emory University Hospital 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, 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 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.

1. Qualitative Analyses: Case Study

1.1 Introduction

Emory's HCIA 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). Emory's program seeks to improve critical care in a number of hospitals across the state of Georgia, through leveraging the use of PAs and NPs (collectively, "Affiliate Providers") supported by an eICU to provide continuous monitoring and night shift physician consultation. 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 at night, 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 intensivist clinician shortage nationwide and in Georgia. There was also internal evidence that quality of care in the Emory ICUs and others in Georgia was 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 the state of 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 (EESJH)	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	1 C-T Surgery ICU , 1 Medical/Surgical ICU
Emory University Hospital (EUH)	5/1/2014	2 C-T Surgery ICUs
East Georgia Regional Medical Center (EGRMC)	Mid to late August 2014* (actual, 27 August)	ICU (General)
Emory Johns Creek Hospital (EJCH)	End of August 2014* (actual, 5 November)	ICU (General)

* Planned date

1.2 Case Study Methods

We conducted a case study at Emory University Hospital (Emory) and two partner sites, Emory University Hospital Midtown (EUHM) and Emory St. Joseph's Hospital (EESJH) on May 7–9, 2014. The following is a report from that case study. 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 we visited 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.

The exhibit below presents information on the number and type of individuals who participated in interviews or focus groups.

Exhibit 2: Case Study Participants*

	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

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

Standard qualitative interview and focus group protocols were tailored to the different informants at each site. Three evaluation staff conducted the site visit: a senior Abt researcher, a mid-level Abt researcher, and a researcher from Telligen (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.

Coding and analysis of the data was conducted using the qualitative data software NVIVO. An initial baseline codebook was developed as the standard codebook for the visit and nodes and subnodes were identified a priori for this initial codebook based upon the interview guides developed for the project. Three people participated on the coding team, one of whom participated in the site visit. To enhance inter-rater reliability, four interviews were coded by multiple people on the team and a coding meeting was held to discuss and resolve differences in coding. The team added new nodes as necessary and revised the codebook. Once overall agreement was reached on coding, the rest of the interviews and focus groups were divided among the coding team. Throughout the coding period, the team member who participated in the site visit checked for consistency across the coders, systematically reviewing discrepancies.

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 we analyzed data for the eICU separately from data related to the residency program. After the NVIVO results were generated, a detailed outline was shared among Abt researchers of the initial site visit team to ensure agreement on the key findings of the report.

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 effectiveness, and anticipated impacts.

1.3 Residency Training Program

1.3.1 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, and East Georgia Regional Medical Center does not have any physicians 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. The residency program's interaction with outlying hospitals is described by the program directors as being a "two-way street".

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 lines, extubation) that are commonly required in an ICU. Several Affiliate Providers reported feeling that there was a gap in their training, especially in terms of these types of procedures. The residency training program therefore 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 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, shifts the decision about calling/waking Attending physicians to the Affiliate Provider, and is expected to increase nursing satisfaction. Fewer nighttime interruptions is 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 Principal Investigator, these factors are driving a growing disparity between the care provided to patients in hospitals that are well-staffed with intensivist physicians, and community hospitals in more rural areas that have fewer resources. In teaching institutions like Emory University Hospital, there are usually intensivist physicians available—although 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 more timely.

1.3.2   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 experienced in their prior training. They established a core curriculum, and 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. 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.

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. While on rotation in an ICU, the residents are usually provided with a list of physical competencies they must complete during the rotation, such as intravascular access, chest tube insertion, feeding tube placement, etc. In addition to practicing these procedures, the residents learn to work with a different care team in each ICU rotation, and the special critical care issues involved (e.g., cardio-thoracic surgery, cardiac care). 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.

Resident Affiliate Providers we interviewed explained that across the 20 different ICUs in Emory's health system, they have seen complex and unique cases that they wouldn't experience anywhere else. They are being trained alongside medical and surgical physician residents and in terms of skill acquisition are not treated differently. The Affiliate Provider residents are expected to lead rounds just as the resident physicians do, they are expected to learn the same procedures and critical thinking, and they believe they are held to the same standard as the resident physicians.

Mentoring

On each rotation, the 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 report that their mentors want to teach and are actively involved in the resident's development. However the mentors tend to change throughout a rotation, sometimes every day, so it can be challenging for mentors to know the resident's skill and knowledge level. One resident noted that it would be ideal to have the same mentor for the whole month of a rotation. 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.

Some 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 skills development trainings to make the program more comprehensive. Affiliate Providers also contribute to the program design by suggesting to the Educators additions

> "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*

that would make the program more complete. For example, an Affiliate Provider resident suggested giving residents a chart explaining 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 the first time. Each rotation also includes a clinical simulation module that the residents participate in and are evaluated on, and an evaluation prepared by the residents' mentors to provide informal feedback.

The residency training program includes pre- and post- knowledge and confidence surveys for the Affiliate Provider residents. According to the Educators, there has been an approximately 20 percent gain in knowledge during residency, which is a statistically significant change. The confidence surveys also reveal a statistically significant gain in confidence on the part of the residents. In addition to knowledge and confidence surveys, residents complete a pre- and post- training self-evaluation.

Emory tracks how long it takes to orient Affiliate Provider graduates of its residency program, 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 orient 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 ICU into which s/he will soon be hired.

1.3.3 Targets

This innovation targets individuals, specifically Affiliate Providers, who are newly graduated from NP and PA programs, or who, after some years in practice, wish to augment their critical care skills and transition to working in intensive care.

1.3.4 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.

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 the 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 a reasonable 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 as well as simulation lab exercises. She noted that "communication impacts how you take care of your team, patients, and patient families."

> "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*

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 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.

1.3.5   Staffing

A portion of the HCIA funds are 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 in 2015.

Affiliate Provider Residents

Some Affiliate Provider residents become full-time employees of Emory while completing the residency program, and others who are hosted by a "home institution" from a community hospital in Georgia are paid by their home institution. In the latter arrangement, Emory pays a stipend to the community hospital that is intended to contribute to the resident's salary.

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.

1.3.6   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 curriculum's best practices, application materials 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.

1.4   eICU Program

1.4.1   Goals of the program

For Hospitals

The goal of the eICU program for hospitals is to improve quality of care and alleviate staffing shortages in critical care, 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. A secondary goal is to improve work-life balance for intensivist physicians and reduce burn-out, by greatly reducing the number of calls they must answer at night.

The eICU covers several Emory ICUs at night and will be adding coverage of additional ICUs, and daytime coverage for weekends and holidays as well as nights, in the coming months. The "Hub" for the

eICU is at Emory St. Joseph's Hospital, and is staffed by Emory Healthcare nurses and Emory intensivist physicians. eICU services/coverage are offered to a variety of Emory ICUs. East Georgia Regional Medical Center Hospital and Emory Johns Creek Hospital are expected to be added by the end of August 2014.

The East Georgia Regional Medical Center community hospital ICU is always at or above 90 to 95% capacity. An Affiliate Provider who recently completed the residency program works at East Georgia Regional Medical Center and explained that there are often inappropriate admissions to critical care from the emergency department (ED) because a physician wants to watch the patient overnight. The eICU can help triage these patients and decide whether admission to the ICU is appropriate, or instead observe the patient in the ED, or in the Telemetry and Medical/Surgical floor (using the mobile eICU cart). There is thus potential that the eICU can avert some unnecessary admissions through augmented monitoring in the ED.

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 speciality particularly unattractive for new physicians, adding further 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 combat feelings of isolation among rural ICU staff who may not be sufficiently experienced to address the intensive needs of some patients. Emory's eICU program meets two specific needs: 1) spread or deploy critical care clinicians over a larger number of units/patients and 2) generate enough revenue to compensate these clinicians. The eICU model addresses these issues by having an eICU physician covering several ICUs at night, relieving burden on intensivist physicians. Several physicians have agreed to work in the eICU on occasional night shifts—covering several ICUs rather than the single ICU they would otherwise be responsible for at night—spreading the scarce intensivist physician resource without greatly increasing costs. As explained by the P.I., 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 to 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.

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 EHR, alert eICU nurses if a patient's trends are becoming worrisome. This automated monitoring is intended to focus clinician attention on critical decision-making, rather than struggling to assemble data about a patient's progress. The eICU nurses can contact ICU 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 nurse is occupied with another, acting as an "extra set of eyes" during especially busy times.

For Patients

In addition to making better use of scarce intensitivst resources at Emory, the eICU has the potential to improve the quality and

> "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

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 morning; they can consult with the eICU physician to get orders written, change medications, and decide when calling an Attending physician is unavoidable.   ICU staff no longer 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 ventilaor/sedation time), and reassurance to patients and families that an intensivist eICU physician is always immediately available.

For outlying hospitals, the eICU physician can help 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.

1.4.2   Innovation Components

Background

The eICU went live at ESJH, EUHM, and Emory all within a few weeks. These hospitals use the same enterprise EMR and this uniformity supported this concentrated implementation schedule. 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 are surgical units and their patients have somewhat similar needs, which reduced the range of issues to be addressed by eICU staff. Over time, the plan is to add ICUs with a broader array of patients, and additional eICU nurses and physicians will be needed to meet this increasing demand.

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 worsening 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 at ESJH, but the program was small during its two years of operation and never included other "remote" ICUs outside ESJH.

Technology

The eICU is physically located in a room in the doctors' office building on the EESJH campus ESJHcalled the eICU clinical operations room ("COR"). There are two nurses in the COR on all shifts, and an intensivist physician at night. Each eICU clinician has several computer monitors that display real-time data on patients from three sources: the EMR or patient record (EGRMC will not have an EMR); the live vital sign feed (echoing the bedside physiologic monitors); and the eICU trend analysis software (provided by a vendor). 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 beside 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. The eICU software requires mapping of interfaces to each hospital's EMR. Although building these interfaces requires IT time and resources, the eICU software is agnostic to the different EMR vendor products. Currently, EUH, EUHM, EESJH, and EJCH all use the same EMR vendor product, and East Georgia Regional Medical Center plans to switch to that same product. In the future, other hospitals seeking eICU support from Emory, will likely use a variety of EMRs, which will need to interface with the eICU software.

The eICU software pulls select patient data from the EMR, including: vital signs, labs, ADTs (admission, discharge, transfer information) medications, and flowsheet elements. Order entry for patients being monitored by eICU is performed in the facility's EMR, CPOE system, or in the eICU software which generates a printed version sent (by fax) directly to the monitored facility.

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 trends – 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.

Two-way Cameras with Audio and Visual Capabilities

At EESJH, the cameras presently installed in patient rooms do not have two-way capabilities, as they have been repurposed from the predecessor 2007 eICU. EUH and EUHM both have two-way cameras installed in ICU patient rooms. In general, the participants interviewed prefer 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.

Internet Connectivity

Internet connectivity and internet service provider capabilities and contracts were perhaps the least anticipated set of challenges facing the IT staff. The Program Staff did not have a thorough assessment of all the connectivity requirements at East Georgia Regional Medical Center in particular, or the skills of IT staff at that rural hospital, prior to implementation. Easter Georgia Regional Hospital uses a frontier telecom provider that connects to AT&T and then connects to Emory—at each connection there have been challenges for data transmission. Working within the constraints of existing internet technology at East Georgia Regional Medical Center has slowed implementation and is requiring unanticipated workarounds.

The vendor that provides eICU technology and software has been reluctant to guarantee that its video quality will 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 line. The cost of running a T1 line to East Georgia Regional Medical Center, and to any future

participating rural hospitals, is prohibitive and Emory has 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 related issues. ICU beds and their audiovisual systems are routinely 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 hospitals. At EUH, an older hospital, wireless access points are insufficient to handle the traffic, and this was particularly problematic in the ED, so it was simpler to install data jacks at patient beds for the eICU video and telemetry transmission, rather than dealing with wireless technology. At EUHM, four ED beds will be fully hardwired to emulate ICU rooms.

Portable unit or "cart" (for EDs)

There will be a portable unit or "cart" with a camera installed at East Georgia Regional Medical Center to monitor patients in the ED or elsewhere in the hospital, who seem to be decompensating. This portable unit will 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 trend information that is shown in the eICU, allowing 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. In the morning, they use the team theater and rounds are led by a physician; in the afternoon, nurses lead in-person rounds, in a more traditional manner, moving as a group from one patient room to the next. 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 ave only EMR data available and rely on the eICU for trend data.

eICU – Day Shift

The eICU is staffed by two nurses during the day shift, who monitor patient vital signs and notify bedside nurses if they notice changes that suggest a patient is decompensating. 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, Affiliate Providers, bedside nurses, and medical residents (and in many ICUs, resident Affiliate Providers). As a result, nurses in well-staffed ICUs expect to rely very little on the eICU for support during the day. Although the eICU was available for less than one week at the time of our case study, one day nurse mentioned that she prefers to seek help from physicians or Affiliate Providers who are physically present in the ICU, rather than relying on the eICU as a resource. Because the eICU was very new, none of the bedside staff had yet experienced benefits from eICU trend monitoring and best practice alerts and none had yet had the experience of asking the eICU nurses to "watch" a patient during busy times. The Use Case for the eICU had not yet emerged for bedside ICU

staff. ICU nurses and physicians report that when they are working at the bedside, they tend to react to the most current information available in the EMR. They are aware that the eICU is a more proactive approach, tracking trends and identifying deviations from best practices, but had not yet experienced the benefits of this monitoring.

In ICUs with fewer staff available at the bedside, especially smaller and rural community hospitals, an eICU may have a bigger role in providing support to the staff at the bedside. This will be tested when East Georgia Regional Medical Center joins the eICU network.

eICU – Night Shift

At night, the eICU is staffed by two nurses and one physician intensivist; physicians take turns covering these night shifts rather than one being designated as a permanent eICU physician. The eICU has the same technological capabilities at night as it does during the day, but in addition has an 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.

Because ICUs have fewer staff at night, support from eICU staff, especially the eICU physician, may be more valued than during the day. The eICU physician working at night reviews patient vital signs, consults with Affiliate Providers at the bedside, and can help guide procedures virtually. 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. The eICU physician typically does not enter orders because the Affiliate Provider in the ICU has this capability. 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 nurse across more patients, with less support; the eICU may therefore have more opportunity to fill a staffing gap at night than during the day. Even in the first week, there appears to be more interaction between the bedside ICU staff and those in the eICU at night, and some night shift bedside nurses reported that they have called the eICU to request support or have been contacted by the eICU when a patient's vital signs began to trend downward.

1.4.3   Workforce Development

Staff Engagement

Physicians

The Program Staff have made an effort to educate intensivist 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 are "too many cooks in the kitchen" with the addition of the eICU physician. 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 physician unfamiliar with their patients. A physician we interviewed confirmed 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 because it'll increase the variability of care." Emory chose to begin the eICU implementation in a cardiothoracic 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 critical care physicians might do so as well.

One ICU Attending physician mentioned that he wants to know what is going on with his patients; he instructs the Affiliate Providers to call him at night if specific things are happening and does not mind being awakened. Even though the eICU is now available, this physician prefers to be called and decide for himself whether to come into the hospital at night. After one week of eICU implementation, we observed that while Attending physicians seem to understand the purpose of the eICU, many do not want bedside staff to rely on the eICU at night. One physician did mention that a colleague reported having an entire night of uninterrupted sleep after the eICU went live—an unusual and welcome change. As more physicians have this experience, acceptance of the eICU may increase.

Program Staff visited East Georgia Regional Medical Center to help allay any concerns that physicians had about the eICU technology. In addition, an Affiliate Provider (a graduate of the residency program) is working at East Georgia Regional Medical Center and is helping to market the eICU program within that hospital. She has conducted presentations and led workflow workshops to engage staff in the hospital before implementation begins. The absence of critical care physicians at East Georgia Regional Medical Center may cause beside staff (physicians and nurses) to rely more on the eICU than is thus far the case at the larger Emory University hospitals.

Nurses

Less than one week after implementation, bedside nurses 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 who was apprehensive about the eICU noted that she felt better after visiting the eICU and seeing the data that eICU nurses review; she was also reassured that eICU nurses did 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 ICU staff as part of the eICU implementation.

> "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*

Training

Physicians

Physicians in the eICU had not received any formal training for their new role at the time of our visit (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 the data available. During his shifts in the eICU he monitored a C-T ICU (among others) 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. Plans for a complete training program include: an introduction to the eICU, a session to handle

some of the calls in collaboration with an experienced eICU physician, and a session to handle all the calls "with backup at the elbow" by an experienced eICU physician. A training curriculum was also in development when we visited, but not yet available for review.

Nurses

ICU nurses 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. As each ICU went live with the eICU, an eICU nurse was detailed to each ICU unit. It is not clear how many ICU staff took advantage of these educational opportunities, and given staff rotations and turn-over, not all staff were exposed to these trainings. 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 actually use 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 was unaware of it and was unsure how to explain the technology to patients and families. Program staff agreed that now that the technology is "on", there is work to do with ICU clinicians, to incorporate the eICU into the workflow on all shifts.

Communication

With the addition of the eICU, the need for more and better communication has arisen as there are more nurses and physicians involved in ICU care delivery, and the relationships among this enlarged team are emerging. Several themes surrounding communication arose from our interviews and focus groups related to physicians with different specialties, peer to peer communication, the relationship between eICU staff and bedside staff, day shifts vs night shifts, and the need for clear communication protocols.

Physicians with Different Specialties

Many of the ICUs being 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 eICU physician adds a third layer to this conversation which can be challenging for communication, especially as the eICU physician is not the same person each night. Clinicians 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" that surgeons find unnecessary. Some surgeons are beginning to accept that they will not be in the middle of every decision loop at all hours of the day and night, and trust that the eICU physician will call them when necessary. Others are not yet comfortable with these changes in communication and responsibility. 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.

An element of concern for staff in surgical ICUs is whether the eICU physician has experience with post-surgical protocols. 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. She will be more comfortable relying on the eICU when the physician working there has this experience, and believes the Affiliate Providers and surgeons will feel the same.

The eICU physician may also feel less comfortable when monitoring an ICU that is not in his/her specialty. One 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 patient prior to the night shift. There seem to be concerns related to the expertise of the eICU physician, on the part of both eICU and bedside ICU staff, and a need for the expertise of the eICU physician to be shared with all the ICU teams each night.

Peer to Peer Communication

Typically, the eICU physician communicates with the Affiliate Providers, while eICU nurses communicate with bedside ICU nurses. However one nurse mentioned that eICU physicians may interact a fair amount with Attending intensivists and with surgeons; the latter are especially hands-on in the care of their patients and may want the real time telemetry reports from the eICU.

One physician mentioned that he plans on getting to know each eICU physician and how they respond to certain types of patient conditions; there will be extra variability with the addition of eICU physicians, so the Attending ICU physician wants to become comfortable with whom he trusts at night. He will then instruct his ICU staff whether to call him at night or rely on the eICU, based on his comfort with the expertise of the night eICU physician.

Relationship between eICU and Bedside ICU staff

The eICU staff and bedside staff are not all familiar with each other yet. One of the Program Staff noted that the relationship with the bedside is so important that currently they only staff the eICU with physicians from the Emory System, because they have confidence in the training and expertise of their own physicians.

Nurses want to be assured the eICU physician has some familiarity with the patient population in the ICU. One nurse claimed that she doesn't know 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 therefore can actually write orders. If they are not affiliated with the hospital, they will need to work with ICU Affiliate Providers to write orders.

An eICU physician 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.

Finally, even in nurse-to-nurse communication, it can be a bit of a "dance" according to Program Staff. If an ICU bedside nurse has been working in the cardiac ICU for at least 20 years, and an eICU nurse notifies her that she sees something that the bedside nurse has missed, the bedside nurse may feel defensive or frustrated because she feels that from her extensive personal experience, she knows what to do. Program Staff have been working carefully with eICU nurses to emphasize communication approaches and offering suggestions in a helpful way that is less threatening and more likely to be accepted. In addition, having bedside nurses spend time in the eICU may help to alleviate this issue. Those who have been able to see the monitoring that takes place in the COR stated that it was a good opportunity, and allowed them to understand and appreciate the potential assistance the eICU can offer.

Standardized Communication Protocols

As all of the communication issues above indicate, there is a need to create clear communication protocols so that both eICU and ICU staff understand when and how to communicate with each other. For example, the Affiliate Providers in each ICU do not have a standard protocol concerning whether to call the eICU or the Attending physician/surgeon directly. During several interviews, participants expressed a need to develop a standardized protocol that is explicit about the hierarchy of whom to contact first, and how to resolve disagreements over patient care decisions.

To improve communication, Emory Program Staff have encouraged clearer "sign outs" whereby the Attending physician or surgeon discusses all patients' care plans with the eICU physician, at the start of the night shift. They are instructed to discuss which patients are of most concern and how they want each patient to be treated if specific problems arise overnight. Program Staff are also working on a list of standardized responses for common issues, to standardize communication and care delivery.

Use Cases for nurses are important, to help them benefit from eICU monitoring and support. Finally, nurses would appreciate instruction on how to educate patients and families about the eICU.

1.4.4　Implementation

Overall, the implementation of the eICU progressed as expected, with all current facilities coming online within a few weeks. The most frequently mentioned challenge with implementation involved the 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.

The IT department at Emory works on a number of different projects at any given time, so 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, lab 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 East Georgia Regional Medical Center has been more complex, because it uses different technology, raising new interoperability challenges.

Program leadership decided that outlying or rural hospitals wishing to participate and receive eICU "coverage" would need to a) 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. Although there was considerable enthusiasm from rural hospitals at the time the proposal was written, the unfavorable economic climate in Georgia and ambiguities in Medicare payments due to the sequester, caused financial hardship and several interested rural hospitals were unable to cover the cost of technology and 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. 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.

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 others that are

external. Often work cannot go forward until a sequence of contracts are executed and this has caused some delays. Ambiguities surrounding the different contracts also make it difficult to project spending. For example, IT staff tried to project spending on cameras for patient rooms; the vendor asked for a 50 percent deposit up front, then a 30 percent invoice, and then a final 20 percent invoice. Because Emory had not yet executed contracts with all hospital partners, they did not know which would participate or how many cameras would be needed, and were forced to make their best estimate in an uncertain environment.

1.4.5   Sustainability

One ICU Director we interviewed believes the eICU program is potentially sustainable given the current model of care. There are many programs at Emory that are 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.

1.5   Implementation Effectiveness

In this chapter, we discuss the different areas in which the Emory's program staff believe the eICU program is making a difference in quality of care delivery, patient health outcomes and cost savings. For each of these triple aim categories, we discuss how Emory's team is measuring the 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.

1.5.1   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 how 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; when they graduate from the residency program most are hired as a full-time staff. We heard repeatedly that these graduates are already 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

Patients and families generally have very positive reactions to learning that an eICU is monitoring the patient's vitals. The patients and families are provided a flyer that describes the program generally and informs them that their identity and personal health data will remain secure, etc. A nurse manager relayed an experience from the first week, of a patient who recognized the eICU nurse when she camera'd into 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.

1.5.2   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.

1.5.3   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 severity scores.

A similar calculation will be conducted for the ICUs that are supported by the eICUs. It is not clear how Emory will address patients who are cared for by NPs and PAs in ICUs that are supported by the eICU.

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 (CRX) 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.

1.5.4   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 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 who 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 (Affiliate Provider residency training), and some were exposed to both. Since we cannot use claims to distinguish these groups, all ICU patients will be included in our analyses.

- 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.)

1.6   Conclusion and Next Steps

1.6.1   Conclusion

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 alerts 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

> "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*

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 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 of entire care teams. These improvements may, however, 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.

1.6.2 Next Steps

In follow-up interviews planned for 2015, a few topics will be revisited and new issues explored, as the HCIA funding nears completion. Topics to explore include:

- Implementation at East Georgia Regional Medical Center and Emory John's Creek Hospital: The clinical staff interviewed at EUH often noted how well-staffed their units are, at least during the day. For community hospitals such as East Georgia Regional Medical Center and Emory John's Creek Hospital, where there is no intensivist on staff, the eICU role may be more extensive during both day and night shifts.

- Supporting Affiliate Provider training programs at other institutions: Emory has received numerous requests from other teaching hospitals about the residency training program. We will be interested to learn of engagements Emory commences to provide information, lessons learned, and assistance.

- The use of the eICU during the day vs. night: As bedside ICU staff become increasingly familiar with the eICU nurses and physicians, and the kind of support they provide, reliance on the eICU is likely to evolve on both shifts.

2. Quantitative Analyses

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 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, which in turn may reduce mortality. We therefore present results for the following additional measures:

- Length of stay (LOS)

- Inpatient mortality

- Total 30 day (including inpatient) mortality

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.

2.1 Intervention and Comparison Groups

2.1.1 Registry Information

The Emory interventions take place in large acute care hospitals and in the future, smaller community hospitals will also participate. The registry data provided by Emory program staff include information for 1,677 Medicare patients hospitalized between March 29, 2013 and June 27, 2014, of which 1,500 had a Medicare HIC number. The 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, with some patients in cardiac care units (CCUs) in some participating hospitals. The Emory registry data contains 1,095 Medicare patients admitted to the ICU and 404 to the CCU; 101 patients were treated in both the ICU and the CCU.

The Emory program includes the eICU intervention and also a 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, therefore, on patients who received the eICU component of the program, we note that eICU patients are also exposed to

the residency trainees. The Emory patient registry contains information about patients admitted to Emory University Hospital ICUs and CCUs. As other hospitals join the program, their data (and that of their comparison facilities) will be pooled with data from the Emory University hospital.

2.1.2   Selection Rules

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, 0201, 0202, 0206, 0207, 0208, 0209

- Coronary care unit revenue center codes: 021X

We analyzed Medicare claims from the time period between March 29, 2013 and March 31, 2014, to match the dates covered by the Emory registry; all those with 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, but we did exclude patients with a DRG indicating organ transplantation.

2.1.3   Estimated Intervention Group

Eighty-seven percent of the estimated intervention group, based on the rules above, were also in the Emory registry. We were not able to match 40 admissions (3.8 percent) from the registry to Medicare claims associated with ICU treatment. In addition, our inclusion/exclusion criteria capture 149 admissions in the estimated intervention group that do not appear in the registry. The rules described above result in the following match between registry data and the best specifications we can create using Medicare claims:

Exhibit 3: Match Rates by Quarter and Aggregate

Emory								
	2012		2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):				220	294	291	239	1,049
Estimated based on Abt rules (N):				328	295	297	238	1,158
Match between Estimated and Registry (N):				209	289	287	224	1,009
Registry Patients, Not Captured by Abt rules (N):				16	5	4	15	40
Estimated by Abt rules, Not in Registry (N):				119	6	10	14	149
Estimated by Abt rules that are in Registry (%):				64%	98%	97%	94%	87%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

The high overlap between the estimated and registry group indicates that our rules are sound and can be used to select appropriate comparison and baseline groups.

The size of the intervention group thus specified is insufficient thus far to support a statistically rigorous difference-in-differences analysis.

2.2   Core Measures: Results

The registry submitted by Emory program staff included patients with admission dates in 2013 and 2014 Based on that registry, the implementation date for the program was late 2013. During our case study, however, we learned that the eICU was not yet staffed by physicians covering night shifts, and connected "live" in the Emory ICUs until early in Q2, 2014. The following graphs show 2013 as the implementation start date, but this may be incorrect. We will work with Emory program staff to ascertain the correct implementation date at each of their participating ICUs, and to understand why the registry contains patients from 2013.

2.2.1   Readmissions

Implementation did not take place on the same day in all participating ICUs and hospitals. In the graphs that follow, the red vertical line shows the beginning of the intervention period and the black vertical lines indicate the dates when other participating hospitals began their eICU implementation.

Exhibit 4 (hospital discharges followed within 30 days by a readmission) shows that the intervention and comparison sites were similar in the baseline period and after the intervention, and that readmission rates are somewhat more volatile in the intervention group than in the comparison group, with no clearly discernable pattern emerging. 62% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15–30.

Exhibit 4: Readmissions
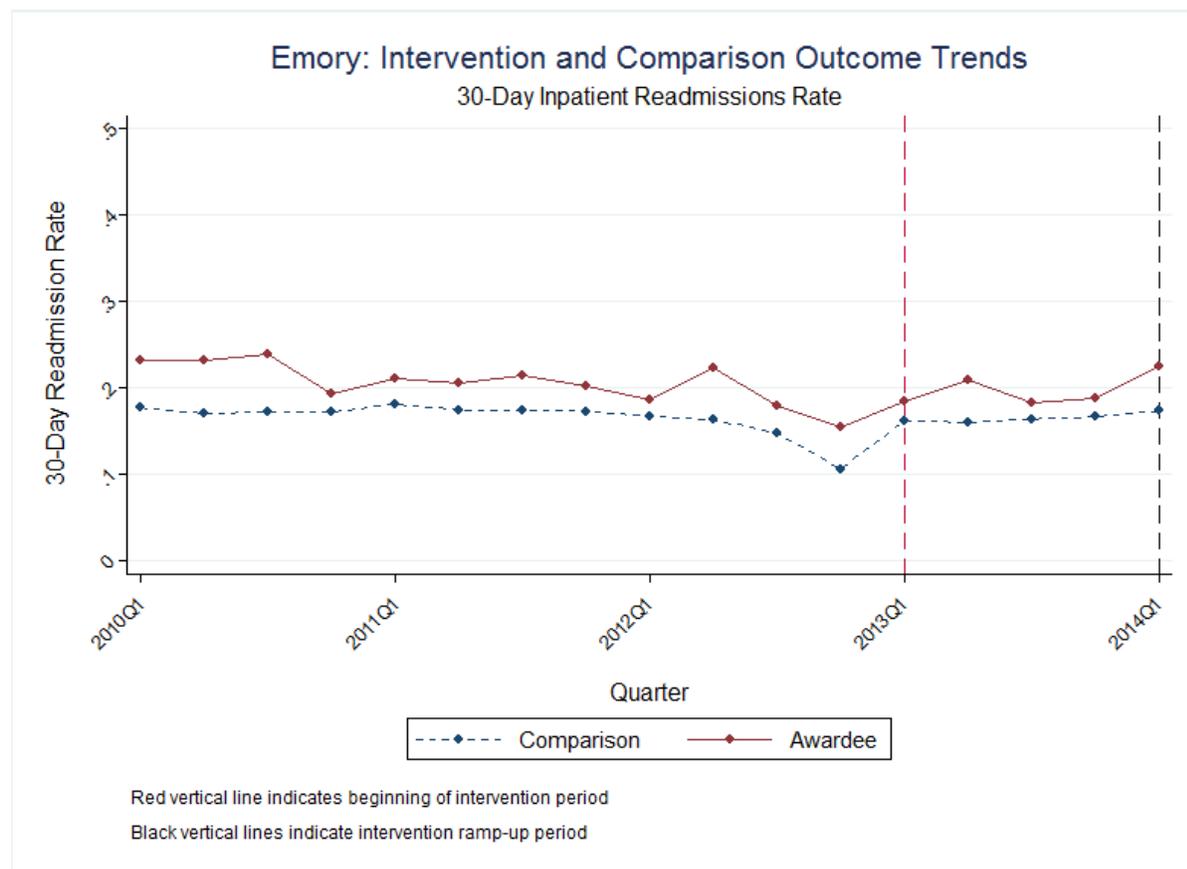
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2   30-Day Post-Discharge ED Visits

Exhibit 5 (discharges followed within 30 days by an ED visit) shows more volatility in the intervention group than in the comparison group, with no trend emerging after implementation.

Exhibit 5: 30-Day Post-Discharge ED Visits
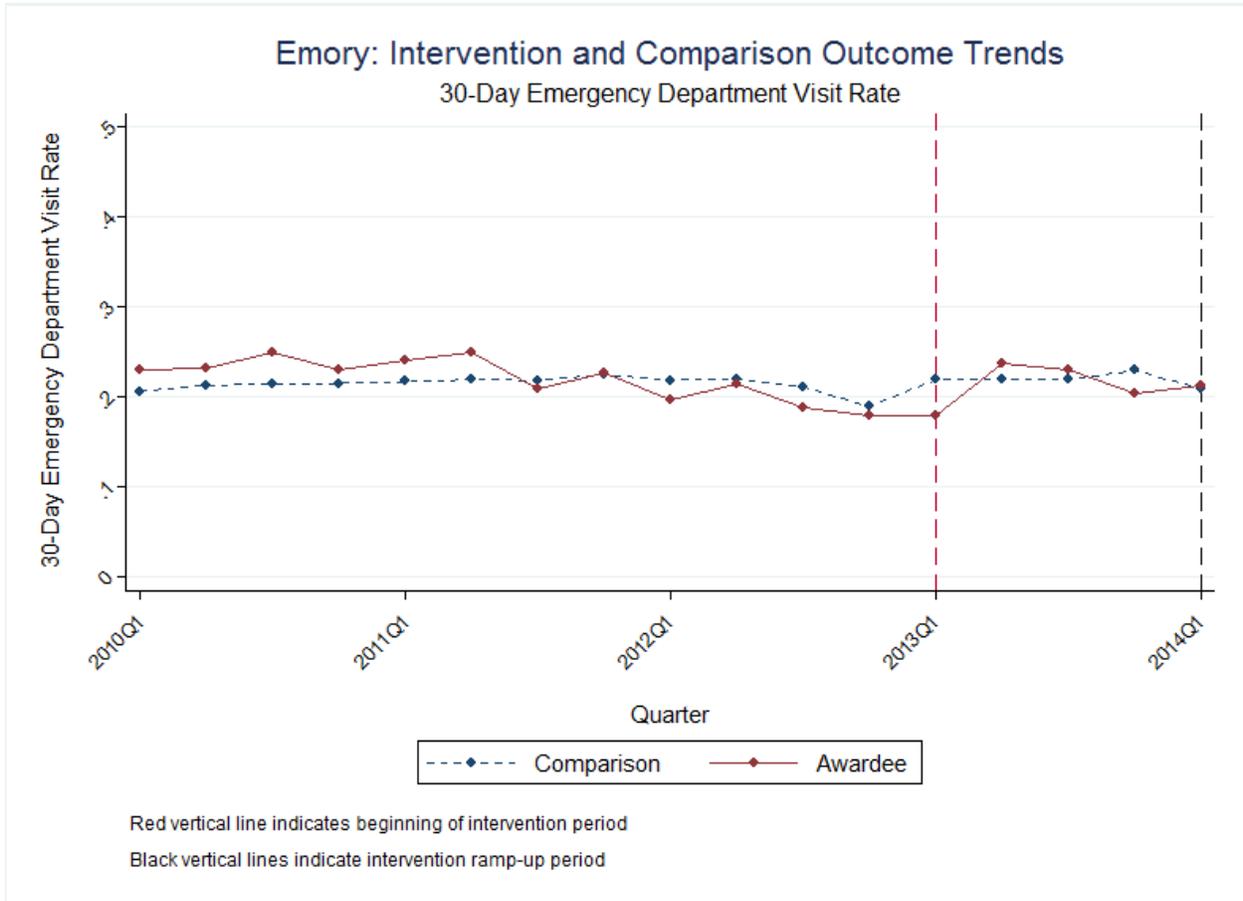
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3 Medicare Episode Spending

Exhibit 6 (Medicare 60-day episode spending) includes the inpatient stay and all claims in the following 60 days. It shows distinct differences between intervention and comparison facilities in the baseline period and the intervention period, with no trend emerging after implementation. 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 6: Medicare Episode Spending
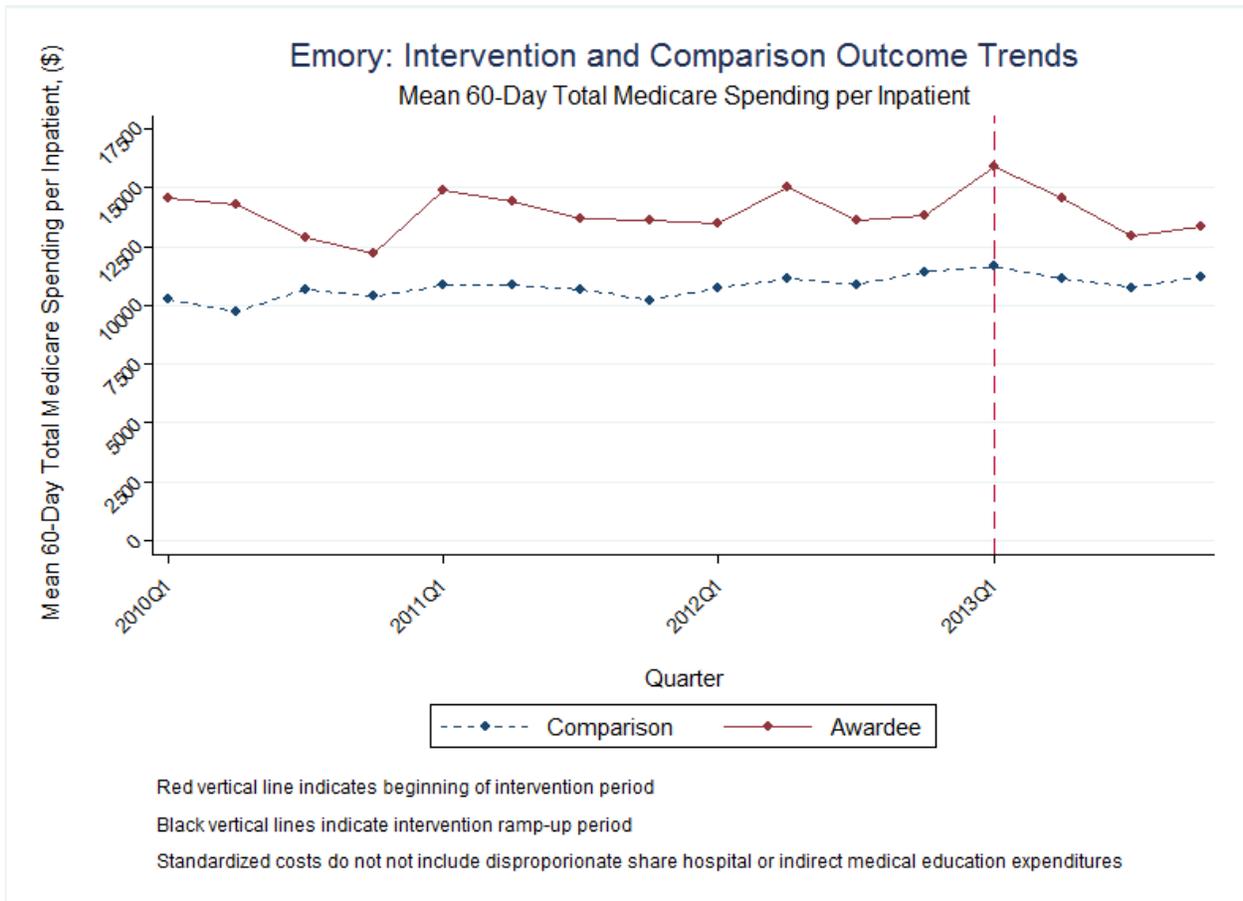
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.4   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 7 (length of stay following index admission) shows longer length of stay in the Emory intervention group than in the comparison group, possibly indicating that the two groups differ in ways that cannot be observed using Medicare claims data. In the graph below, we note that LOS seems to be going up in both groups in the most recent quarter; more data are needed to understand whether this indicates a secular trend.

Exhibit 7: Index Admission Inpatient LOS
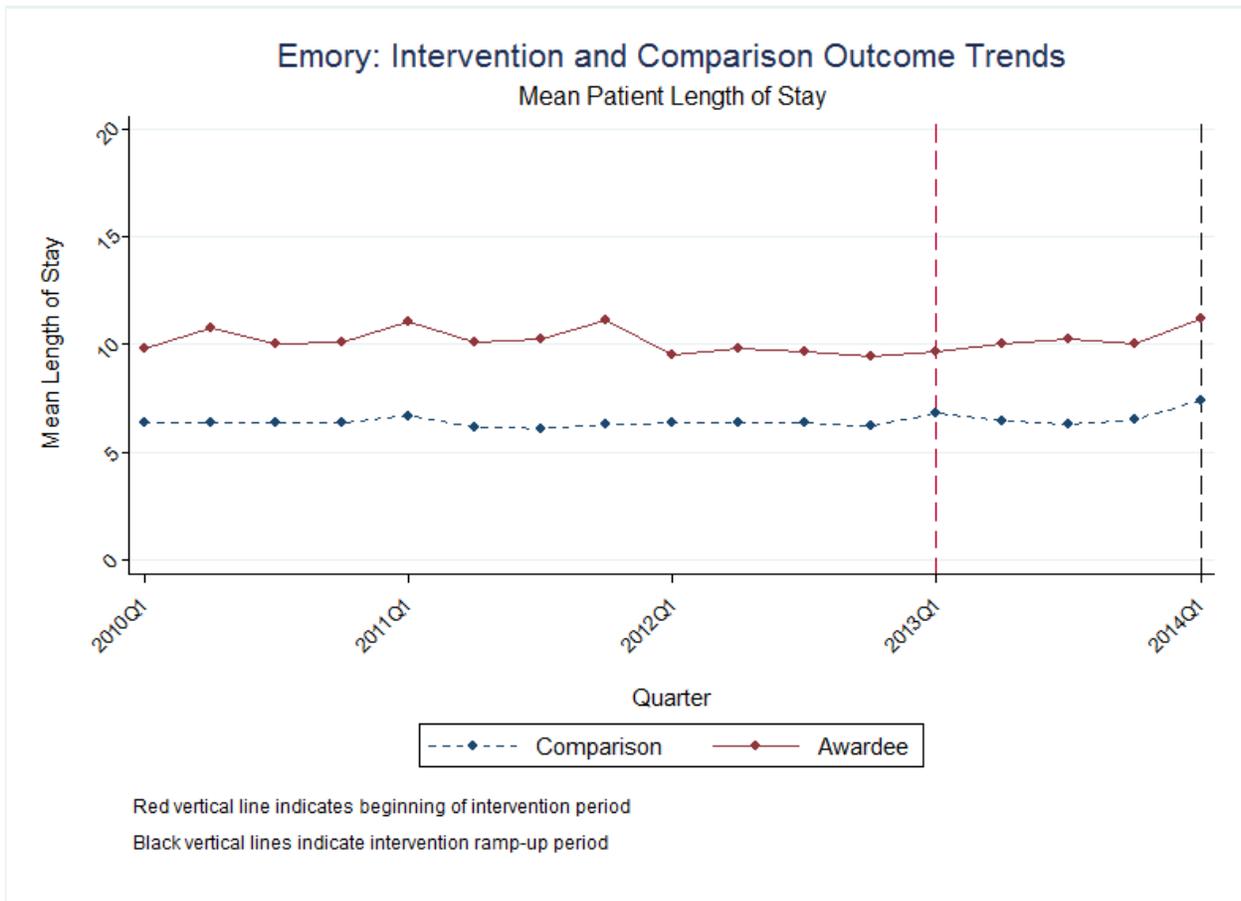
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.5   Index Admission Inpatient and 30-Day Mortality

The Emory intervention, by monitoring ICU patients and prompting attention to deviations from best practice, may reduce inpatient mortality and total 30-day mortality.

Exhibit 8a shows the inpatient mortality rate following an index admission. The graph indicates that mortality rates during the baseline period were higher and much more volatile from one quarter to another in the intervention group than in the comparison group, probably indicating that the best match we can create does not capture important differences in the patient populations that cannot be observed using claims data. It appears that mortality during the index admission may be declining in the intervention group and also reaching a steadier rate than was true in the past.

Exhibit 8a: Index Admission Inpatient Mortality
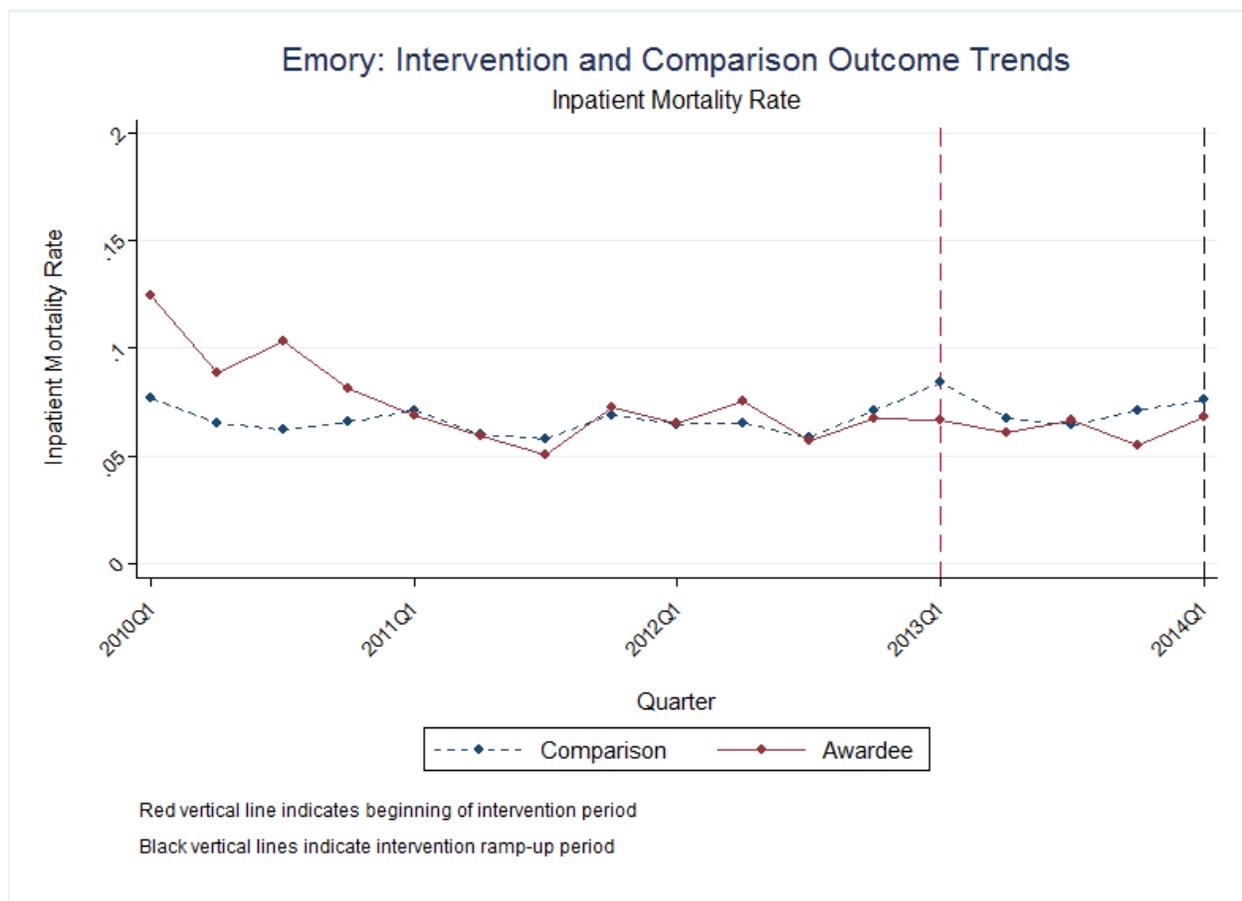
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 8b includes total mortality (inpatient and the 30-days following the end of the index admission). Again the mortality rates during the baseline period were higher and much more volatile from one quarter to another in the intervention group than in the comparison group. Neither of the two trends (inpatient mortality or 30-day total mortality) is pronounced and more quarters of data are needed to understand whether these patterns are important.

Exhibit 8b: 30 day Mortality (including Index admission)
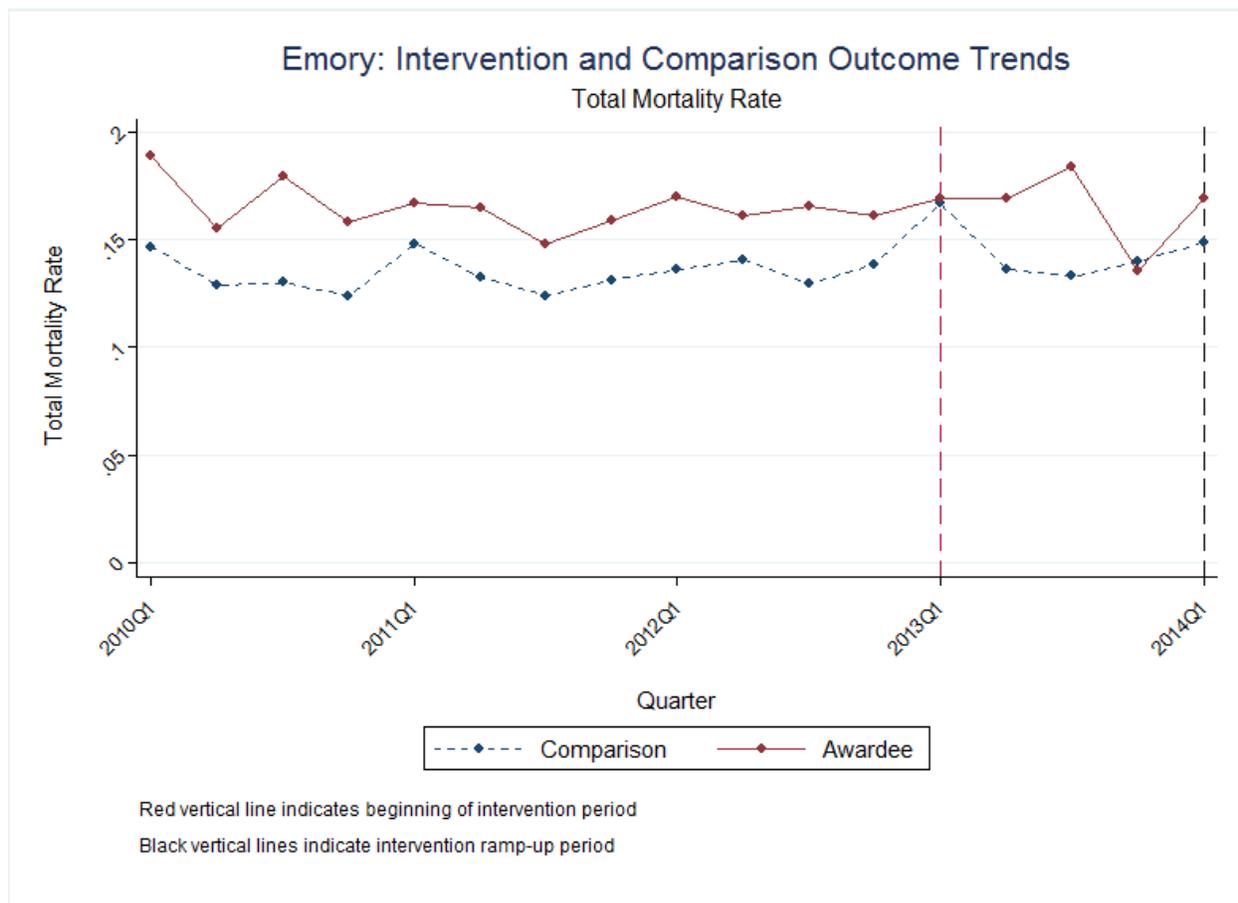
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

The exhibits above do not reflect complete implementation of the eICU, which was fully operational and supporting ICUs as of April (Q2) 2014. For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change. In a future annual report we will aggregate data across the entire intervention period and use regression techniques to try to control for systematic differences in the two groups, although we caution that small numbers may not support such analyses.

Conclusions:

- Strong match gives confidence that findings have minimal bias

- No evidence of impact on readmissions, post-discharge ED visits, episode spending, LOS or mortality.

Appendix B4: Henry Ford Health System
Mobility, the Sixth Vital Sign

General Research Domains

The core domains for the Henry Ford Health System 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, 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 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.

1. Qualitative Results: Case Study

1.1 Description of Program

In 2012, the Henry Ford Health System (HFHS) was awarded a *Health Care Innovation Award (HCIA)* to implement a mobility program within its main hospital. The primary goals of Henry Ford's program, Mobility, the Sixth Vital Sign, are to:

- *Reduce the incidence of hospital- acquired pressure ulcers* (HAPUs) by 40 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 50 percent in the intensive care units (ICU) over the three years.

The program employs trained patient mobility assistants (PMAs) to engage 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 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.

1.2 Case Study Methods

Abt researchers conducted a case study of Henry Ford's mobility program on April 29–May 1, 2014. Three staff collected qualitative data: a senior Abt researcher, a mid-level Abt researcher and a researcher from Telligen (formerly CFMC) (the evaluation team). During the visit to Henry Ford Hospital, the evaluation team conducted four focus groups and seven interviews with clinicians and other care providers, as well as program administrators.

Exhibit 1 summarizes the number and type of individuals who participated in either interviews or focus groups.

Exhibit 1: Professional Backgrounds of Interviewees and Focus Group Participants

	Bedside Nurses	Nurse Managers	Skin Care Nurses	Nursing Aides	Mobility Aides	Rehabilitation Specialists	Program Administrators
Total = 47	7	12	3	8	8	3	6

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 Henry Ford 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. At the end of the case study, all notes were finalized, integrated across the note-takers and reviewed for accuracy by the team's senior researcher. Coding and analysis of the data were conducted using the qualitative data software NVivo. An initial baseline codebook was developed, and nodes and subnodes were identified a priori for this initial codebook based upon the standard evaluation interview guides. Two people participated in the coding of notes, one of whom was the senior

team member who led the case study. To enhance inter-rater reliability, one interview was coded by both people on the team and a coding meeting was held to discuss any differences in coding. The team added new nodes as necessary and revised the original codebook. After consensus was reached on coding, the rest of the interviews and focus groups were divided among the coding team.

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 project components. For example, the team stratified findings across hospital units where the mobility program was implemented: general practice units (GPUs) and intensive care units (ICUs).

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

1.3 Henry Ford 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 include some that are uncontrollable by healthcare 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 grant builds on the HFHS experience with the pilot programs and provides financial resources to employ staff as patient mobility aids.

1.3.1 Primary Program Components

The current 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 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®

- 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

- Patient mobility assistants (PMAs) implement risk-stratified interventions based on patient ML score

The Braden Scale for Predicting Pressure Sore Risk®

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.[1]

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 nursing assistants (NAs). 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. 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 2 summarizes the services included in the mobility bundle, by patient mobility level.

Exhibit 2: Mobility Plan of Care

Mobility Level	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

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[1]   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.

Mobility Level	Daily Goal	Exercise/ADLs	Education
			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		

Source: Henry Ford Health System–Mobility Program Plan of Care.

Evolution of the mobility program's structure

The structure of the mobility program has changed since the HCIA grant 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. Rehabilitation specialists and PMAs rotated from unit to unit to provide mobility services to eligible patients. This model proved difficult for several reasons: the rehabilitation specialists' desire to provide therapy rather than overseeing 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 supervisors and team manager.

1.3.2   Program Targets

Patients in the hospital's intensive care units and general practice units are the target of the mobility program. The program is guided by the principle that most patients in these units have a Braden score of 18 or less and could benefit from the skin/mobility program. Over time, a subset of patients were identified for whom the program is not appropriate. These patients would be placed on 'hold' for the day and routinely re-evaluated.

Exhibit 3 contains the criteria that make a patient ineligible for the program.

Exhibit 3: Criteria for Excluding Patients from Mobility Program

Mobility Level	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

Source: Henry Ford Health System--Mobility Bundle Plan of Care

At the time of our case study, the mobility program had been implemented in many general practice units (GPUs) and intensive care units (ICUs) in the hospital. Exhibit 4, below describes when the program began in each of these units. Implementation will be complete with the introduction of the final unit, the neurological ICU, planned for late 2014.

Exhibit 4: Implementation of Henry Ford Health System Mobility Program, by Hospital Unit

Unit	Month/Year of Implementation
Medical ICU	11/2012
GPU- F1, F2, B1, B2	10/2012
Cardiac ICU	7/2013
Step down unit	8/2013

1.3.3 Measurement & Self-Monitoring

Interviews with program staff identified challenges in implementing systems for measuring and monitoring. During the early part of the grant period, program staff extracted data from a paper chart and an electronic system to generate self-monitoring data to CMS. Now, more of the data are available in the EHR but reports had not been developed by the time of the visit. A new module in the hospital's EHR system, once launched, will greatly facilitate reporting.

A junior-level statistician, under the supervision of a senior statistician, conducts the data analyses for the mobility program. The analyses focus on the self-monitoring measures that HFHS is required to report to CMS, however, they have expanded the analyses to 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 grant, such as the relationship between the number of daily interventions and HAPU rates, they are not always able to do so.

The cost savings data is based on HAPU data extracted from the National Database of Nursing Quality Indicators (NDNQI) monthly skin audits that is compiled by the HFHS corporate data staff.

The program leaders report that front line staff is 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 PI, the co-PI, 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 done presentations at staff meetings, as well as one-on-one discussions with unit managers, and HFHS-wide conferences. Each week, the PM provide 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 said that they had not seen any reports or heard about the results of the mobility program.

1.4　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 was hired for these positions. Rehabilitation specialists had worked in the HFHS physical therapy department and were transferred to the mobility program when new positions were funded by the grant.

Skin care nurses were hired to fill positions funded by the grant. Program staff reported that they have had difficulty filling the nurse positions because the required skills and work experience are hard to find. A few nurses hired by the program transferred out because of the work schedule and dissatisfaction with the skin/mobility nurse role expectations.

The training plan has evolved over time to reflect the evolving staffing model of the program, and to address feedback from staff. Initially, intensive training was given to rehabilitation specialists when they led the program, as well as patient mobility assistants. Nurse training was more informal.

1.4.1　Training for Rehabilitation Specialists

Rehabilitation specialists received training on working with patients in the ICU. The training was conducted by ICU nurses with a focus on special conditions of patients in the ICU and how to safely incorporate movement into patient care. A senior rehabilitation specialist developed the mobility portions of the training. In the training, rehabilitation therapists learn, for example, how to safely move patients on ventilators from bed to standing and walking. Before working directly with ICU patients, rehabilitation specialists must demonstrate competency with ventilator patients, described as the most complex of the ICU patients in the mobility program.[2]

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[2]　Rehabilitation specialists completed a four-hour class on working with patients on ventilators.

1.4.2 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 underwent an abbreviated NA training 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 training program became more practical in nature. New PMAs now shadow a rehabilitation specialist for three weeks to learn more about body mechanics, proper approaches to moving patients, and how to use equipment such as gait belts and canes when working with patients. They receive hands on training from the team nurses concerning skin care. As before, PMAs are required to pass a competency test before working directly with patients. According to the program staff, the PMA training is still a work in progress. Former rehabilitation specialists (in their current role as physical therapists) are now working with the program team to develop more detailed guidelines that can be used in future PMA training.

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 NAs in regular shift huddles to discuss patient status and anyone needing special attention. ICU managers reported that they have begun to teach PMAs about common conditions in the ICU, such as ventilator-associated delirium, that affect mobility. Program staff indicates that the revised training program will have more emphasis on mobility for ICU patients. ICU Nurses and NAs told us that PMAs are well prepared for their jobs; GPU nurses commented repeatedly that "They know what they're doing."

1.4.3 Training for Nurses

Each day, bedside nurses conduct skin assessments on all 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 to 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.

1.5 Implementation Effectiveness

1.5.1 Better Care

There was widespread agreement among those we interviewed that the mobility program results in better care for patients. The program enhances patient care in the following ways:

- Facilitates patient movement, which staff had struggled to do previously.

- 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 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.

- Allows hospice patients to die in comfort (UNIT F5 provides hospice care).

> The mobility team is able to perform range of motion on 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

Nurse Managers have reported 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.

Henry Ford'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.

1.5.2 Better Health

> 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

There was general consensus among those we interviewed that the mobility program had reduced the rate of HAPUs at Henry Ford Hospital. Across all hospital units in the program, nurse managers and nurses reported having observed fewer pressure ulcers among patients, as well as other positive health benefits of the mobility program. While the program staff expected the greatest impact of the program in the ICU where patients are more prone to HAPUs, nurses and nurse managers in the GPUs reported a variety of positive health outcomes among their patients. "We haven't had a HAPU in the past three months," said one GPU nurse. Other GPU nurses mentioned additional health benefits they attributed to the mobility program including fewer cases

of pneumonia, fewer blood clots among patients recovering from knee replacements, and less deconditioning in patients.

ICU nurses and nurse managers have also noticed 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. Patients are more likely to be discharged to rehabilitation services than to a nursing home. An ICU Nurse Manager and PMA recalled a patient whose ICU induced delirium subsidized when she was moved into a sitting position that allowed her feet to touch the floor.

Henry Ford's Measurement Strategy

Program staff collect data on patient outcomes that they report regularly to CMS and use for internal quality improvement. The key measure they report is:

- Percentage of patients with HAPU.

We note that while program leaders identified reduced ventilator associated pneumonia rates as a secondary goal of the mobility program is reported annually.

1.5.3 Lower Cost

Clinicians and program staff interviewed at Henry Ford Hospital all anticipate that the mobility program will result in cost savings to Medicare and their institution because fewer HAPUs will yield shorter lengths of stay, fewer resources and higher patient satisfaction scores. Prevention of VAPs would also reduce costs.

Henry Ford's Measurement Strategy

Program staff collects 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.

1.5.4 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. 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.

1.5.5 Unanticipated Impacts

Program staff mentioned both clinical and cultural consequences of the mobility program. They noted that the mobility program has decreased patient deconditioning, something they had not anticipated before they began the program. One nurse observed that increased patient mobility and attention to wound care may decrease 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.

The implementation of the mobility program has 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 so important for patients. After seeing results of the mobility program, 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.

1.6   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 NAs 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 than before. 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, as needed, 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, however, the program was mildly disruptive to the 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.

Establishing trust was another challenge in the integration of PMAs into the workflow. 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 unit, nurses have grown comfortable with the PMAs and view 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 caregivers.

Data collection presented a minor workflow challenge for the skin/mobility nurses. The hospital's electronic medical record (EMR) is not linked to the system used by the data collection tool used by the mobility program staff to capture data, requiring the patient assessments to be entered into each system. The hospital's electronic medical record EMR system is accessed through desktop computers in each unit. Data for the mobility program are captured manually and submitted to the data entry staff who enter it into the

> 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

data collection tool (REDCap). The information entered into each system is the same. One nurse mentioned that it would be helpful to have the iPad linked to the EMR so they could enter the data one time, at the bedside.

1.7　Improvements Suggested by Staff

1.7.1　Expand working hours for PMAs

There was widespread agreement among nurses, nurse managers, PMAs, and NAs 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 and nurse managers 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.

NAs and some nurses and nurse managers explained why it would be helpful to have PMAs for longer hours each day. NAs, 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.

> Nurses are so busy on the weekends-they don't have time to do what PMAs do. Having them here on the weekends would improve patient satisfaction because it's when family members visit the most. Now, family members ask why their loved one isn't up and moving more.
>
> *–GPU Nurse Manager*

Budgetary constraints prevent expansion of PMA staff schedules.

1.7.2　Provide Additional Equipment

Nurses and nurse managers 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. 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 make their jobs easier and improve quality of care by allowing them to input the results of the skin assessment directly into the patient's record. "We need everyone to know right away what we think is best for the patient," said a wound care nurse.

1.7.3　Clarify Roles and Performance Expectations

One ICU nurse feels strongly that the mobility program suffers 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 lots of patients that can't be moved, there's nothing for the PMAs to do, so they 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."

1.8   Context

1.8.1   Endogenous Factors

Communication

Nurse Managers, nurses, and NAs reported that communication during program implementation was less complete than desired. 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.

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.

Leadership Buy-in

The program staff 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 and data reflected lower HAPU rates. Nurse Managers agreed that hospital leadership demonstrated support of the program from the start; however, they felt program leadership have provided inadequate feedback to the staff. They mentioned that leadership may have been distracted by the implementation of a new EHR throughout the Henry Ford Health System, and the recent JCAHO accreditation process, and hope that the focus will shift to providing more feedback to program staff.

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 Baldrige National Quality Award from the U.S. Secretary of Commerce to honor "performance excellence through innovation, improvement and visionary leadership."[3] 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]."

1.8.2   Sustainability

There was widespread agreement among those interviewed 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 salaries for the PMAs, program manager, and skin/wound care nurses should be funded by the hospital after the grant ends. At the time of our case study, the program manager was preparing a budget justification for the mobility program that will be submitted to hospital leadership for consideration.

1.9   Next Steps

In the follow-up interviews planned for 2015, several topics will be revised and new issues explored. Topics to explore include:

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[3]   http://www.nist.gov/baldrige/baldrige_recipients2011.cfm, accessed July 29, 2014.

- *Role of hospital leadership:* Interview hospital leadership regarding their engagement in the program and views regarding sustainability.

- *Role of physicians:* Interview physicians working in the units where the program has been implemented, to determine whether they concur with nurses' assessments of program impact.

- *Hospital Acquired Conditions:* Interview data analysts to determine whether they are able to report VAP rates (and perhaps CAUTI rates) to CMS, after the conclusion of the EHR upgrade.

- *Sustainability:* Explore whether the mobility program positions/staff will continue, and any adjustments that will be made as HCIA funded concludes.

2. Quantitative Analyses

The HFH uses specific criteria to select patients for the mobility program (e.g., Braden score of 18 or less) and also specific clinical criteria to exclude patients from the intervention (e.g., coma, actively dying). In addition, the intervention takes place on some but not all hospital units and floors. None of these variables are observable in claims, making it impossible to create rules with which to specify intervention, comparison or baseline groups. In addition, there are not enough 'enrolled' cases each quarter to test whether the results in one quarter differ significantly from the results in other quarters. In the absence of a comparison group or a baseline group, and without sufficient volume for tests of changes over time, we present simple trend lines for the HFH mobility intervention group, as defined by the patient registry (list) we received from the Awardee.

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

The HFH program also aims to reduce length of stay, and avoid complications through earlier mobility, which in turn may reduce mortality. We therefore present results for the following additional measures:

- Length of stay (LOS)

- Inpatient mortality

- Total 30-day (including inpatient) mortality

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.

2.1 Defining Intervention and Comparison Groups

2.1.1 Registry Information

Henry Ford Hospital program staff provided registry data for 4,036 patients admitted to the hospital from September 17, 2012 through March 31, 2014. The registry includes admissions to the one hospital in this program.

2.1.2   Selection Rules

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. Henry Ford program staff advised that certain patients with clinical exclusions would not be candidates for the mobility intervention and therefore do not appear in the registry, including patients with: gastrointestinal hemorrhage, severe stroke, or coma. We initially excluded these patients by identifying the MS-DRG, ICD-9, or CPT code associated with these conditions, but found that these exclusion criteria were too broad. For example, we found that some patients with an ICD-9 code for traumatic hemorrhage or a CPT code indicating a vasoactive drip are present in the Henry Ford registry. Henry Ford staff further advised that patients were selected to receive the mobility intervention based on skin shear, skin color, and other clinical factors that cannot be observed in claims data.

We compared a list of the MS-DRGs associated with registry patients with the entire Henry Ford Hospital Medicare FFS population, between September 17, 2012 and March 31, 2014, to identify MS-DRGs that existed in the hospital but not in the registry. These DRGs were excluded from analysis. Even with these steps, we were unable to create inclusion and exclusion rules that capture the intervention population without also capturing many non-intervention patients, because the Henry Ford program selects patients based on clinical indicators.

2.1.3   Estimated Intervention Group

The match rate between Henry Ford registry and our estimated intervention group is 22 percent over six quarters of the intervention. Two thousand one hundred and sixty two patients were treated during the Henry Ford intervention during this period and the rules we developed identified 8,716 patients who were potentially eligible for the intervention. All of the registry patients were identified, but our rules overestimated the registry group by 6,763 patients.

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 5: Match Rates by Quarter and Aggregate

Henry Ford								
		2012	2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):		472	497	422	328	303	140	2,162
Estimated based on Abt rules (N):		2,008	2,228	1,715	837	913	1,015	8,716
Match between Estimated and Registry (N):		623	597	371	173	146	43	1,953
Registry Patients, Not Captured by Abt rules (N):		0	0	0	0	0	0	0
Estimated by Abt rules, Not in Registry (N):		1,385	1,631	1,344	664	767	972	6,763
Estimated by Abt rules that are in Registry (%):		31%	27%	22%	21%	16%	4%	22%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

The best set of rules we can create yields a poor match and we conclude that it is not possible to create an appropriate baseline or comparison group for Henry Ford's intervention, based on inclusion/exclusion

criteria applied to Medicare claims data. We therefore present trends in the intervention group only, for the period after the intervention began.[4]

2.2 Core Measures: Results

2.2.1 Readmissions

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.

Exhibit 6 (hospital discharges followed within 30 days by a readmission) appears to show little change over time. As discussed above, no comparison group and no baseline data can be estimated for this Awardee. 87% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15–30.

Exhibit 6: Readmissions
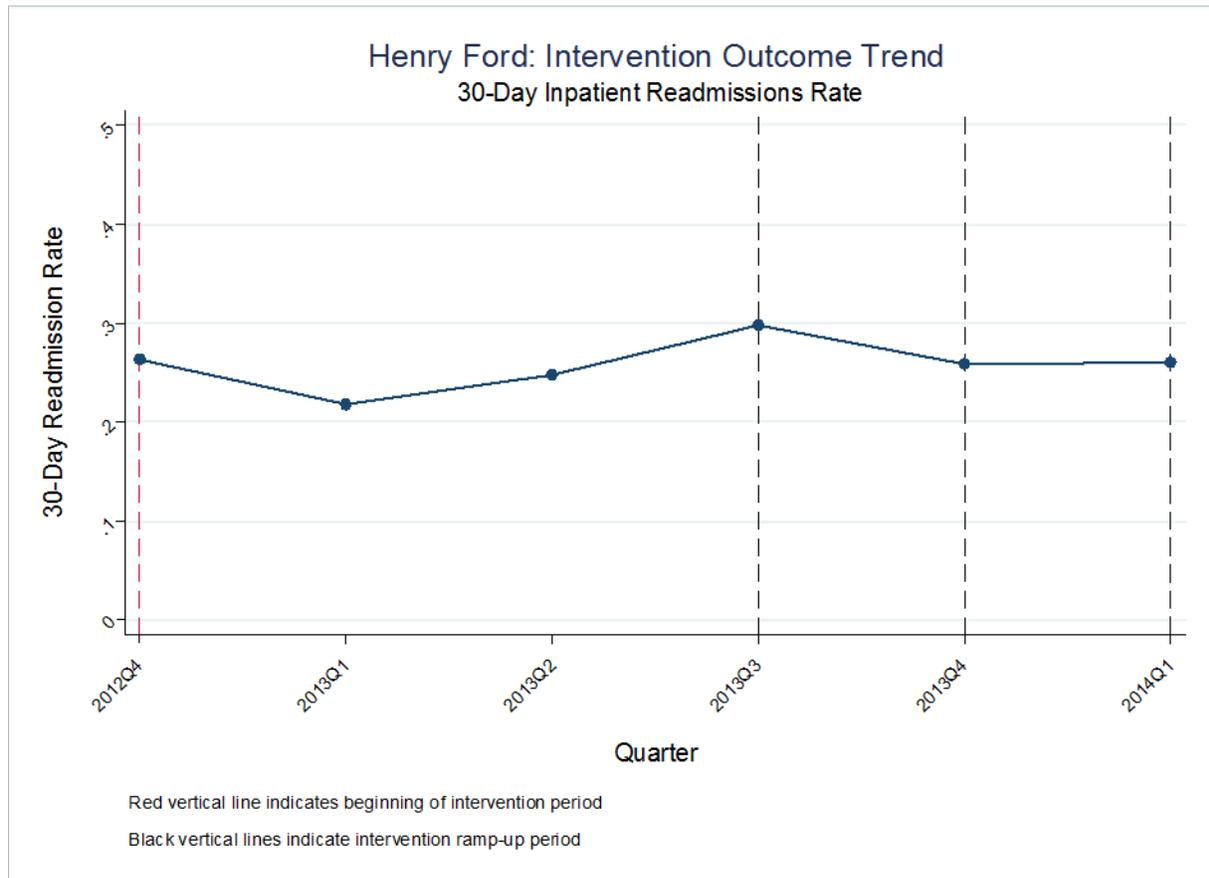
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

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[4] The Henry Ford program staff is working with the evaluation team to identify a suitable comparison group that could be used in future analyses.

2.2.2   30-Day Post-Discharge ED Visits

Exhibit 7 (discharges followed within 30 days by an ED visit) shows little apparent change over time.

Exhibit 7: 30-Day Post-Discharge ED Visits
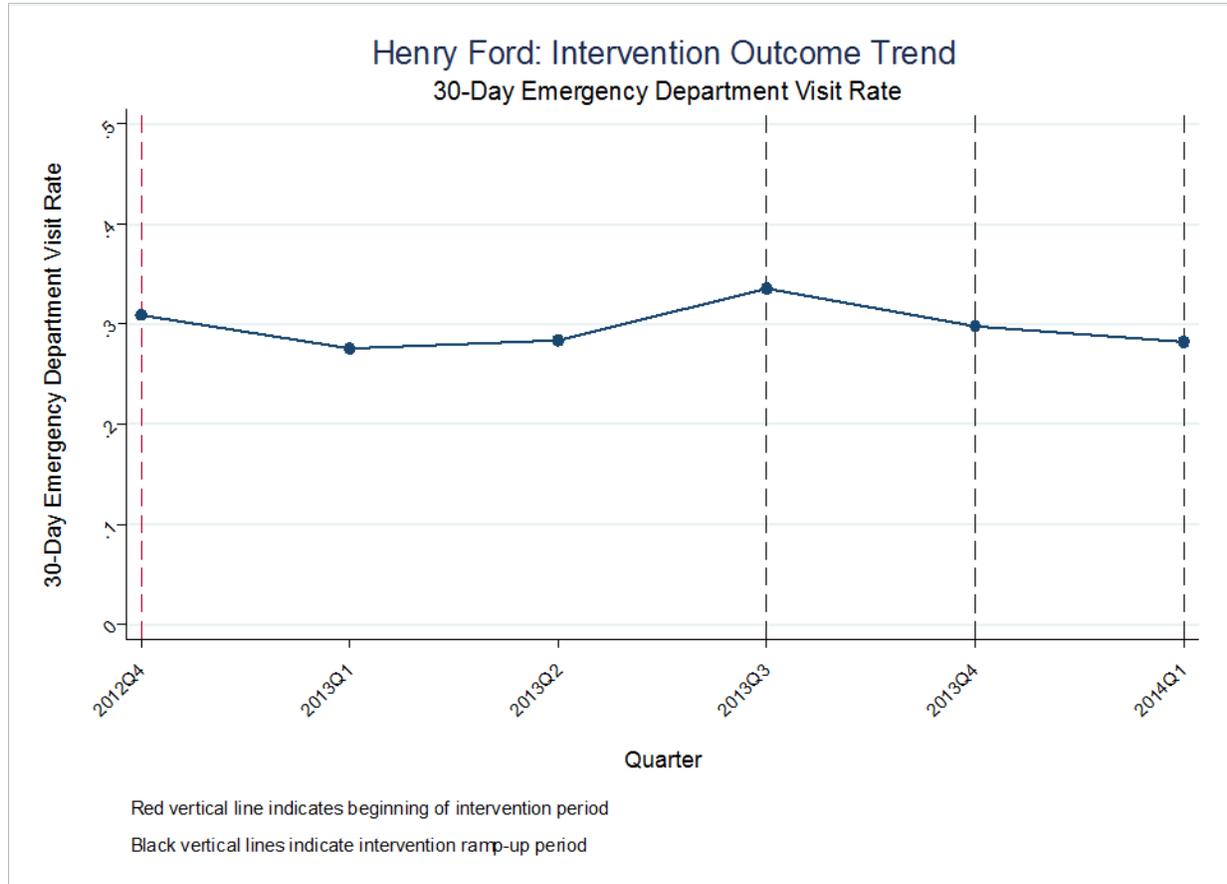
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3   Medicare Episode Spending

Exhibit 8 (Medicare 60-day episode spending) includes the inpatient stay and all claims in the following 60 days. Again, there is no clear trend over time. 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 8: Medicare Episode Spending
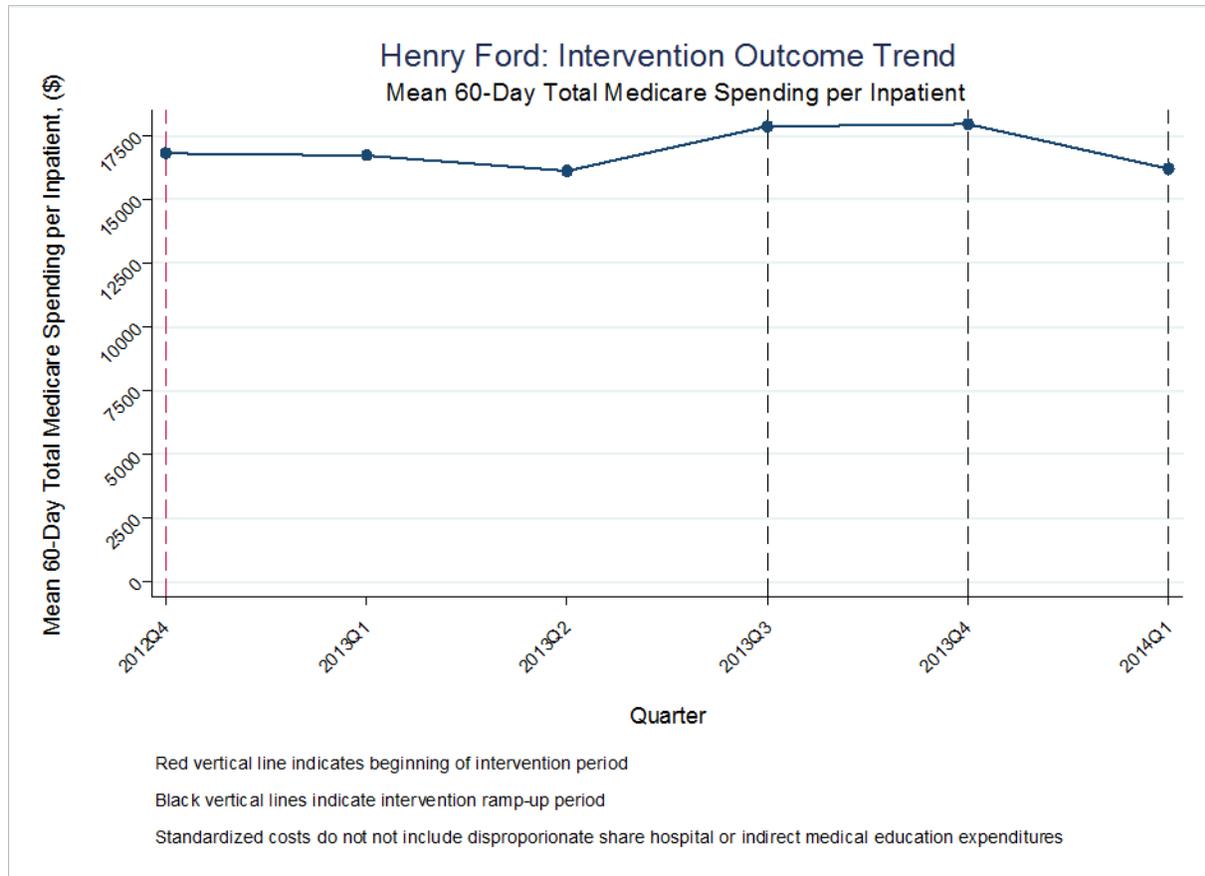
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.4   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 for the Index admission.

Exhibit 9 (length of stay following index admission) shows LOS trending slightly higher, but more quarters of data are needed to determine whether this is temporary or indicates an unexpected impact of the program.

Exhibit 9: Index Admission Inpatient LOS
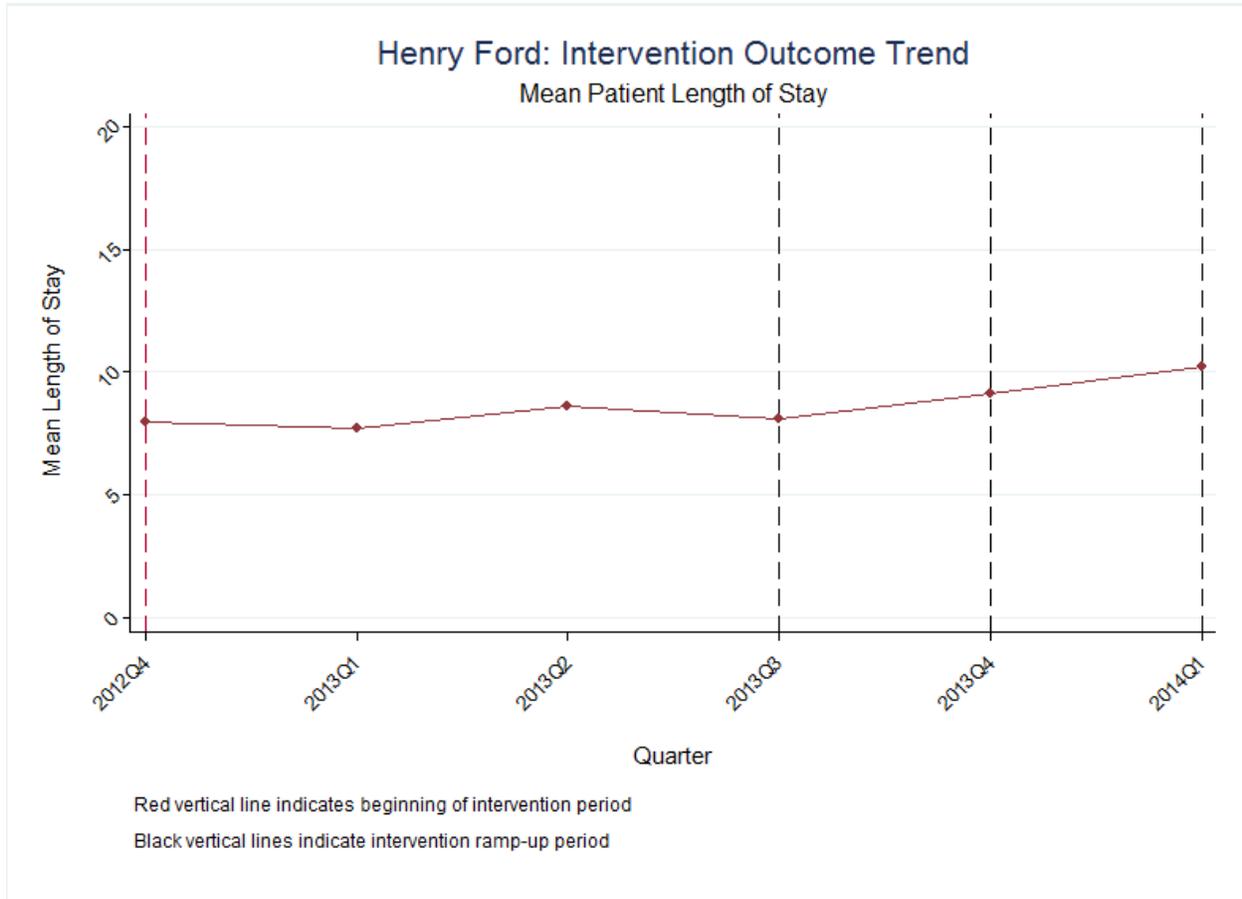
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.5   Index Admission Inpatient and 30-Day Mortality

The Henry Ford intervention aims to reduce complications associated with immobility (pressure ulcers, respiratory complications, other complications), which may also reduce inpatient mortality and total 30-day mortality.

Exhibit 10a (inpatient mortality rate following an index admission) shows no inpatient mortality for patients in the Henry Ford registry.
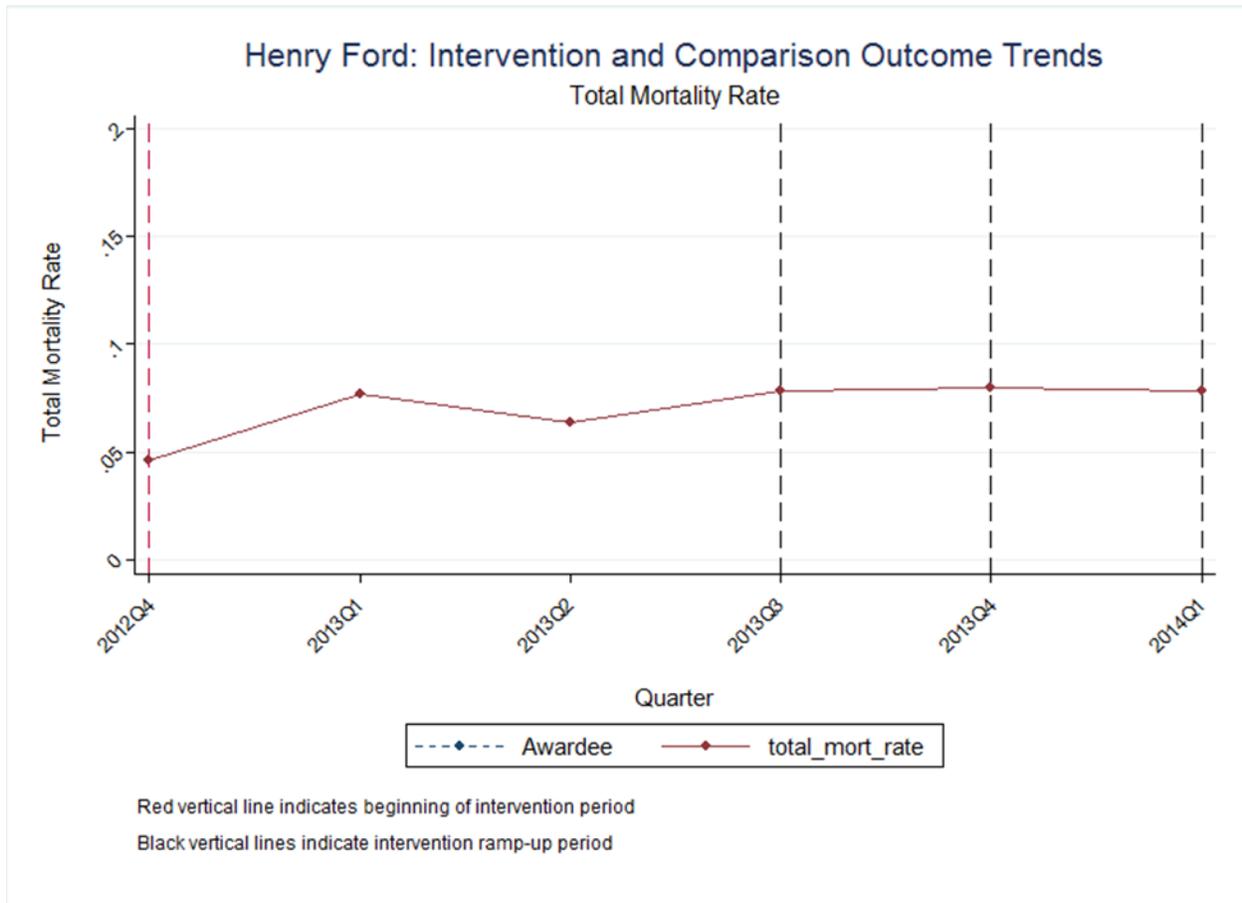
Exhibit 10a: Index Admission Inpatient Mortality
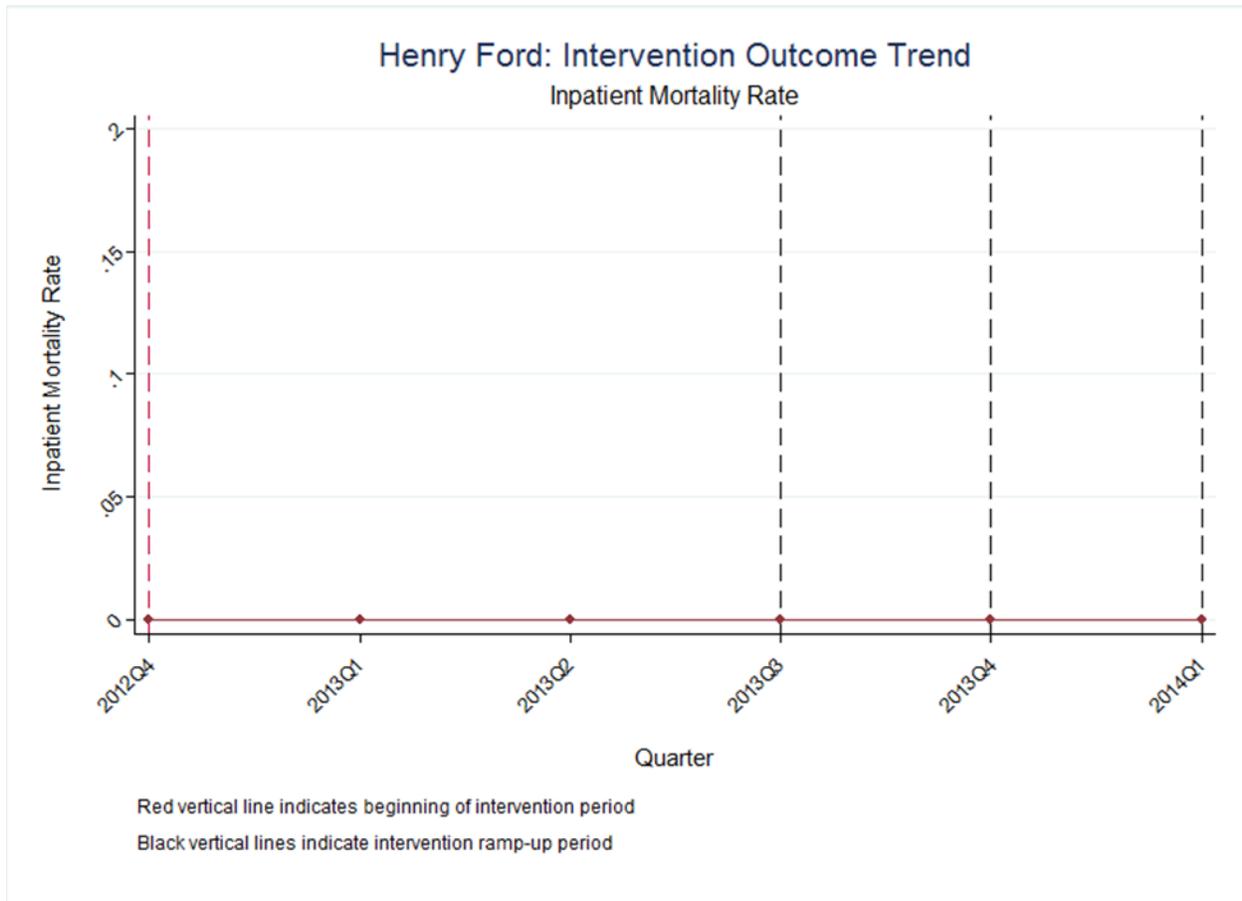
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 10b shows the total mortality including inpatient and the 30 days following the end of the index admission, and there is very little change over time.

Exhibit 10b: 30 day Mortality (including Index admission)

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change. In a future annual report we will aggregate data across the entire intervention period and use regression techniques to try to control for systematic differences in the two groups, although we caution that small numbers may not support such analyses.

Conclusions

- No baseline or comparison group is possible: program staff use entirely clinical selection criteria that cannot be modeled with claims data.

- There is no evidence of intervention impact on utilization or spending trends.

Appendix B5: Mayo Clinic

Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation (ProCCESs AWARE)

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, 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 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.

1. Qualitative Analyses: Case Study

1.1 Description of the Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation (ProCCESs AWARE)

The Mayo Clinic was awarded a Hospital-Setting HCIA grant to develop and test an electronic data dashboard in its intensive care units (ICUs). ProCCeSs AWARE—Patient Centered Cloud-based Electronic System: Ambient Warning and Response Evaluation - is a program that scans the 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 and has the potential to benefit not only ICU patients and clinicians, but those in other acute care environments (emergency department, operating room, hospital floor) as well. The prototype we investigated in this case study is used in targeted Mayo Clinic ICUs.

1.1.1 AWARE Program Goals

AWARE aims to help clinicians process and prioritize information about critically ill patients 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 award are to modify the program based on pre-award pilot test feedback, expand the program's software capabilities, and implement the program in four Mayo Clinic ICUs as well as ICUs in three additional acute care hospitals: Montefiore Medical Center in New York, Lawrence General Hospital in Massachusetts, and the University of Oklahoma Medical Center. The 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 three-year savings of $81 million.

1.1.2 Impetus for the AWARE Program

The impetus for the AWARE program was the inefficiency of accessing information from EMRs and multiple other ICU data systems. Rather than streamlining the presentation of patient records, EMRs contribute to information overloaded through delayed and out-of-context presentation of an enormous amount of data. Assimilating and acting on this poorly-organized information can disrupt workflows and impede patient safety. The problem is particularly acute in the ICU where the intensity of care necessitates the use of multiple monitors and life-sustaining equipment and interventions, which increase the amount of data that accumulates for each patient. The AWARE program was designed to display 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. AWARE allows clinicians to access the most important information about a patient quickly so that he/she can return to the patients' bedside without spending extended time and effort retrieving essential information.

1.2 Mayo Clinic Case Study Methodology

The Mayo Clinic case study was conducted May 14 and 15, 2014. The team, composed of two staff from Abt Associates and one physician consultant with Telligen (formerly CFMC), visited the Mayo Clinic Saint Mary's Hospital in Rochester, Minnesota. Team members conducted seven interviews and one

focus group, and observed eight physicians and two nurses using AWARE in the ICU setting. The exhibit below presents information on the number and type of individuals who participated in individual interviews, focus groups or were observed at the Mayo Clinic, Rochester.

Exhibit 1. Type of Respondent Interviewed/Observed at Mayo Clinic

Principal Investigator MDs	RNs	MDs*	PAs	NPs	RRTs	Pharmacists	Program Administrators	Total
2	3	11	1	1	2	2	3	25

*Includes Consultants (attending), residents, and fellows.

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. The two team members not facilitating a given interview took notes. A telephone interview with the project director of the Montefiore site was also conducted during the case study although the information collected from the interview is not incorporated into this report as the AWARE program had not yet been implemented at Montefiore. Case studies (or telephone interviews) with the Lawrence General Hospital and the University of Oklahoma Medical Center were not conducted because the program had not yet been implemented in those sites.

1.3 AWARE Program Components

The AWARE intervention is a software program that aggregates, displays, and tracks data for ICU patients. The target of this intervention is four ICUs at the Rochester, MN Mayo Clinic and ICUs at three partner sites: Montefiore Medical Center, Lawrence General Hospital, and the University of Oklahoma Medical Center. As noted, only information on the Mayo Clinic implementation of AWARE is included in this report because the program had not been implemented at the partner sites at the time of our case study.

1.3.1 Technology

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 sifting through multiple electronic data sources when swift action is needed.

AWARE Design and Functionality

The AWARE tool is intended to improve decision-making and efficiency in the ICU by aggregating the most 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 an application designed at Mayo that synthesizes the information. AWARE is available anywhere there is

> "All providers have EMRs that display data in disparate ways [but before AWARE] there was no tool with presentation of data by specialty to enable viewers to see data in a format to improve decision-making and enhance efficiency."
>
> – *Physician AWARE User*

internet access, including mobile devices via wireless access, and it displays data in real time as they are being entered into the underlying data repositories/systems. See **Exhibit 2** for a visual representation of the systems and their interactions.

Exhibit 2. Health Information Technology Systems and their Interaction at Mayo Clinic
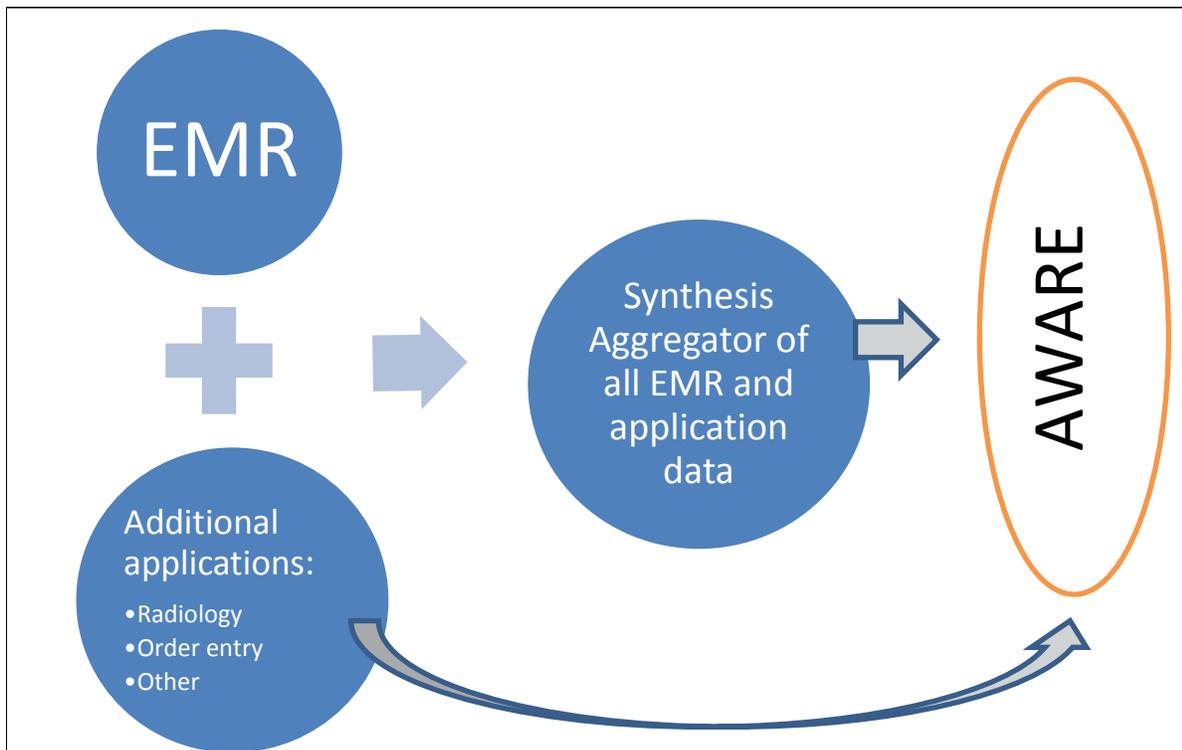
Source. Abt Associates Inc. Based on May 2014 site visit at the Mayo Clinic, Rochester, MN

The Mayo Clinic EMR and all of its supporting applications (radiology, pharmacy, order entry, eMAR) are available to all clinicians at Mayo. There is an application that synthesizes information but it is not a "smart" tool and does not organize information, prioritize information, or identify deviations from best practice guidelines. AWARE aggregates all of the data contained in these underlying applications and lives "on top" of the synthesis application, to organize information into organ-specific presentations, with critical values showing up as most prominent in the summary patient view.

An evaluation of an earlier version of the AWARE application suggested that the software tool had the potential to reduce cognitive load and improve clinical workflows. As AWARE's co-inventor explained, the traditional EMR structure was originally designed to support billing, and organizes data based on where it comes from (e.g., laboratory, radiology, pharmacy), not based on how information is 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.

AWARE is a "smart" tool that not only syncs with its underlying data sources in real time, 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 complete roster of patient values related to that system. For example, if a patient entered the ICU due to heart failure, the most recent, relevant data

related to the cardiac system would appear prominently on AWARE (see below) 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 patient values are out of normal range and brings these critical values to the top level of presentation. The most important data are highlighted using colored borders that identify the level of urgency (green, yellow, red) and are accompanied by symbols (e.g., a heart symbol would be displayed alongside the values for the cardiac system in the patient example above) to trigger an immediate recognition of what organ system is in need of immediate attention. Clinicians can easily identify which organ systems must be addressed first, and how critical the needs are, without having this high priority information cluttered with less relevant values.

AWARE's innovative display of patient data is one of the benefits of this program. Indeed, most clinical users we interviewed at Mayo Clinic expressed that AWARE's intuitive design and simple navigation make it relatively easy to learn, and that it improves workflow and efficiency. One resident physician underscored that if the tool "wasn't easy, I wouldn't use it;" instead she is "addicted" to the tool because it has simplified her ability to conduct rounds and respond to patient needs. Training and extensive feedback from staff have helped the project team and application programmers better align users' needs and AWARE's design.

The principal investigators (PIs) who co-invented AWARE worked with cognitive psychologists to design the tool in a way that would meet the needs and workflows of an ICU care team. The PI solicited extensive feedback from clinical leaders in the ICU. Further, because the developers are physicians with ICU experience, they understood firsthand the needs of busy clinicians working in that setting.

The AWARE tool was also designed to meet the workflow needs of its users by incorporating additional applications to record and share data among users. These applications are the only places in which data are entered into AWARE, instead of being derived from underlying EMR data sources. The main applications that are part of AWARE are the checklist, the white board, the task list and the ability to "claim" a patient.

- A checklist function was added to the AWARE tool in 2013. The checklist contains items that should be addressed for each patient every day that they are in the ICU. The checklist is reviewed and updated each day on patient rounds. As with the AWARE main screen, the checklist is a "smart" tool, auto-populating some information from the EMR and other ICU data systems. Checklist data can be copied and pasted into the clinical notes to reduce duplicative data entry, and the IT team is working on making certain checklist data auto-populate into the nurses' electronic notes. The checklist also contains links to a medication order entry system so that clinicians can easily move back and forth between documentation in the checklist and using other data systems.

- The white board functionality was created in response to charge nurses' requests to be able to document their observation notes in an electronic file that is accessible to the entire team. The electronic white board was also intended to help wean nurses from using hand-written notes, a common practice that had no convenient electronic replacement. Nurses can now use the electronic white board templates to enter care steps, and the templates can be subsequently customized by nurses on other shifts. There are also blank areas in the templates where nurses can write extra notes that don't have places in the EMR, for example concerns about patients' emotional state. The white board effectively replaces the need for nurses to pass on handwritten notes, or relay messages verbally or on a physical white board (hence the application's name) during shift changes.

- 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 so that it is not unintentionally repeated.

- Finally, AWARE allows ICU physicians to "claim" a patient and take additional oversight responsibility for a patient so there is a clear indication of who should be alerted if another team member makes a decision about the patient. Patients can only be claimed by one physician, but 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.

1.3.2   AWARE Trialability, Adaptability and Technical Complexity

Trialability and Adaptability

The AWARE features described above were created in direct response to feedback from clinicians, most notably nurses, about how to improve the AWARE tool, although trialability and adaptability to physician feedback have also enhanced the scope and robustness of AWARE. 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 seek feedback from their 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, nurse practitioners, respiratory therapists and nurses. Wider adoption by clinicians has in turn led to improved feedback loops to IT and program management, to continually improve AWARE functionality.

Part of the need for continual adaptation of AWARE is due to the inherent technical challenge of presenting highly complex information in a simplified display that meets the needs of a wide variety of clinicians, since different members of the ICU team need access to different types of information to do their job effectively. One of the challenges reported by program staff was being able to understand how AWARE can be adapted to different teams and ICUs. Wide variation in the needs of the clinical staff has made it common for each ICU team to adapt how they use AWARE in their practice. To allow this flexibility, program management has not prescribed a specific workflow for AWARE users or implemented a training requirement for all staff, although multiple options for training are available.

> "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*

Technical Complexity

As reported by the program manager, AWARE is highly complex in several aspects. The grant itself is complex because they have engaged subject-matter experts in all arenas (e.g., cloud-based technology, database structure, data mapping) to work together to design and implement the program. These partners are not co-located and do not have the resources to travel, requiring that all collaboration be virtual. Data composition and storage are different across Mayo Clinic departments (e.g., the emergency department, the floor, the ICU), creating challenges in aggregating information and integrating it into workflows that 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). The variability in these underlying systems may raise new complexities for the IT team as AWARE is implemented in new hospitals.

In addition, there are technical complexities in the areas of data quality and data sharing. For example, clinical staff reported that there is a need for improvement in the speed with which data are uploaded from the underlying applications/sources to AWARE, with notable delays in information about medications and ventilator use. Further, there is a lack of interoperability and the AWARE data dashboards, checklists and notes (i.e., any data not in the EMR) cannot be downloaded into systems used in the emergency department (ED), step-down units,[1] or on the inpatient floors. The opposite is also true: ED information cannot be uploaded directly into AWARE if a patient is being transferred from the ED to the ICU. Finally, clinical staff expressed that they want very much for AWARE to be mobile, however wireless connections are unreliable and frequently drop as the clinical team makes rounds throughout the ICU.

1.4   AWARE Program Implementation

The AWARE program was implemented in one acute care hospital, the Mayo Clinic, in Rochester, MN, with the expectation that it will be implemented in Montefiore and Lawrence General Hospital during the summer of 2014, followed by University of Oklahoma Medical Center in the fall of 2014. Oklahoma Medical Center was not included as a partner in the original application, but was added at the request of CMS.

1.4.1   AWARE Program Implementation Process

The AWARE program was conceptualized, designed, and developed at the Mayo Clinic. 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 Clinic 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 about all patients in an ICU on a single screen) and other enhancements were added such as organ system icons and the ability to view the ICU room layout. Following the award, AWARE was rolled out in four phases at each of the targeted Mayo Clinic ICUs: "go-live", launch, implementation and full implementation (for details on the launch, please refer to the Plan-Do-Study-Act roadmap, See below)). Go-live occurred when 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 from the clinical go-live to full implementation, and AWARE was considered to have reached full implementation when the checklist function was completed for 80 percent of patient days in the ICU. Four ICU's were targeted for formal staged roll-outs; however, clinicians are free to use AWARE in any ICU in the hospital, and use is spreading organically as more clinicians experience the advantages of using this tool.

An important function 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. As shown in Exhibit 3, the use of the checklist has increased steadily each quarter in all four ICUs.

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[1]   A step-down unit provides intermediate care between an intensive care unit and a normally-staffed in-patient floor.

During launch days, the AWARE team set up a dedicated room in each ICU where nurses, physicians, PAs, and NPs could learn how to use the program, ask questions, and discuss the utility of AWARE. These were day-long sessions 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 a helpful experience 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, reducing the full potential of the tool, and the cross-discipline communication among clinicians necessary to optimize workflows may not occur. Involving the entire ICU team in the launch helped to avoid the lack of communication among different types of clinicians. Program staff reported that they have made strides in getting new user groups, such as respiratory therapists, engaged in using the tool.

Exhibit 3. AWARE Rounding Checklist Completion Results per Quarter for Target ICUs and non-AWARE Comparison Unit

AWARE Checklist – Percentage of eligible patients* who have a checklist completed per quarter
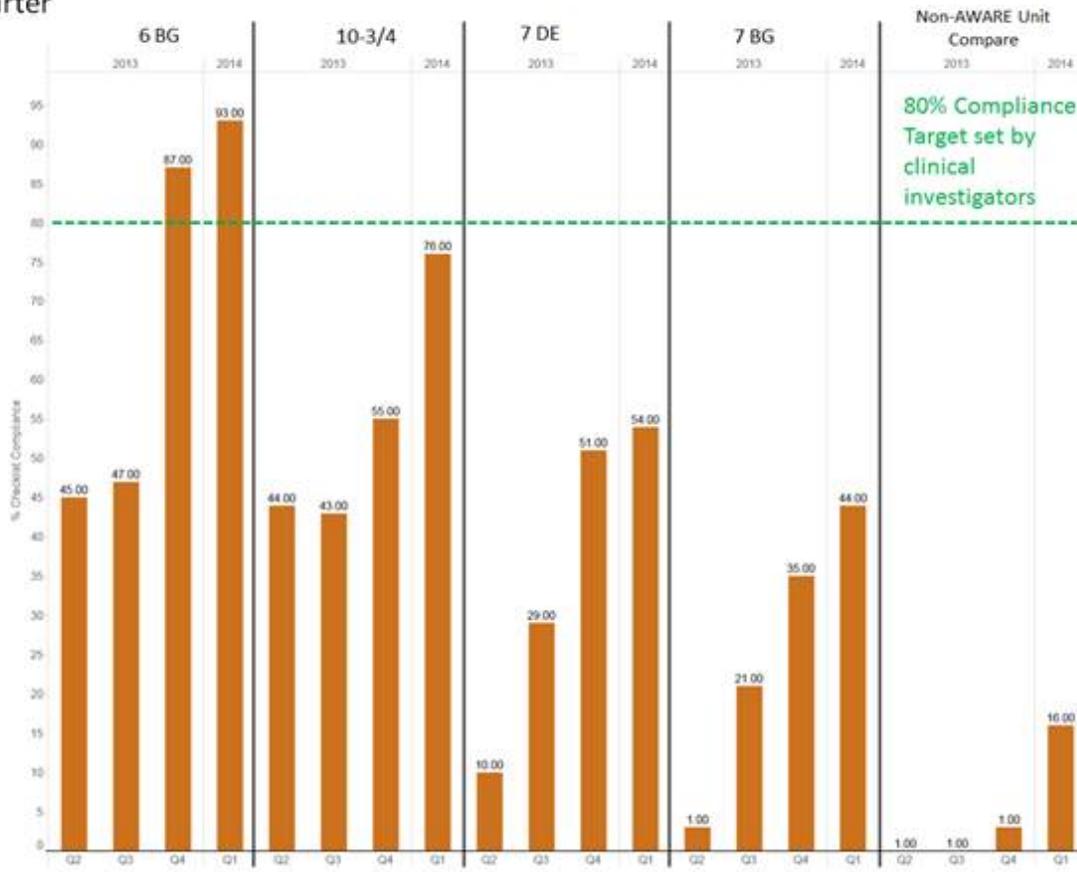
* Defined as patient in ICU > 24 hours and not discharged before 12 noon on the day of checklist completion

Source: HCIA Quarterly Progress Report Narrative submitted by the Mayo Clinic to CMS for Quarter 7

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 on the potential use of the tool and to gain insight about aspects of the implementation process that would facilitate adoption. They also learned that implementation needs to be customized for each ICU and each hospital, and conducted assessments at each Mayo ICU and each partner hospital, to design an appropriate implementation strategy.

One of the most important aspects of implementing the AWARE program was engaging clinical staff and obtaining their buy-in. Program staff reported that engaging clinicians in adopting AWARE was a process: Although AWARE is easy to use, buy-in and adoption were not immediate because it is difficult to approach busy clinicians with a new IT application given that they have little time to devote to learning another tool. However, program staff further noted that when clinicians see the value in AWARE, they begin to use it, and ease of use has led to increasing adoption.

The Mayo Clinic's HCIA application mentioned the development of a family/patient module for AWARE that would allow access to relevant patient data. This module has not been implemented and the project team noted that much work will be required to create a module and interface that will be useful and usable for family members. The goal is that the module can be used by family members without assistance from hospital staff. There will be additional requirements, such as obtaining Institutional Review Board (IRB) approval before a family module is ready to implement. Information for this module has been collected and the program is undergoing testing.

Barriers to AWARE Implementation

There have been minor implementation challenges in Mayo Clinic ICUs. For example, in addition to overcoming resistance to learning new technology, program staff encountered reluctance among clinicians, particularly nurses, to abandon hand-written notes in favor of the electronic white board in AWARE.

> "You will have to break our pencils. We don't know how to stop people from writing things down on paper."
>
> – PA AWARE User

Program staff believe additional challenges may arise at future community hospitals that have fewer resources, or where support from both clinicians and hospital administrators may be less enthusiastic.

1.4.2   AWARE Program Targets

The target of AWARE implementation is clinicians in four Mayo Clinic 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 and adoption by the approximately 600 clinicians who work in these units is increasing. The use of AWARE is spreading to other ICUs in the Mayo Clinic, making it difficult to compare intervention ICUs versus control ICUs within the hospital.

1.4.3   AWARE Program Implementation Effectiveness

The clinicians we interviewed unanimously reported that AWARE is effective in saving time and presenting the most important and clinically relevant information at a glance. One PA reported that when patients are first admitted to the ICU, clinicians spend as much as two hours writing lab orders, taking histories, and other early tasks; tasks that are still necessary but expedited by the accessible information displays in AWARE. AWARE lets users drill down to more detailed information about a specific organ system or to obtain useful reports. For example, AWARE has an application that will produce trend

reports. A user can click a button to see, for example, fluid balance over the past seven days, to aid physicians in prescribing fluids. Nurses may chart fluid balance in different areas of the hospital as the patient is transferred between units, making it hard for the staff in any particular unit to assemble information and understand a trend. AWARE pulls information that has been entered into the EMR from all those unit-specific sources and produces one report of a patient's fluid balance. Similar trend reports for other critical systems such as heart rate or blood pressure can be displayed in AWARE.

> "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*

A respiratory therapist stated that AWARE provides a more global picture of the patient, and a systems perspective that can be missing when a sub-specialist focuses on only his/her specialty concerns. AWARE is credited with helping respiratory therapists spend more time at the bedside than would otherwise be the case because AWARE allows them to easily retrieve only information that is pertinent to respiratory therapy.

Even among staff who have been fully trained to use AWARE, not everyone has made the complete switch because they are resistant to using it, or feel that an existing process is better. Most notably, as described above, some charge nurses still prefer to use handwritten notes to themselves and to colleagues during shift changes. 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.

Interviewees mentioned 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 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 the morning rounds by giving the process definition and providing clinically relevant patient-specific data. However, one physician remarked that he does not think ICU staff use the checklist and white board effectively for communication. Ideally, a clinician might see that they missed something for a patient earlier in the day and add that to the checklist so the whole team can see it, someone can claim the task and do it, and then check it off. This electronic process works and staff are encouraged to use it first instead of paper, but this transition is not complete.

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, instead of relying solely on AWARE. 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.

1.4.4   Fidelity of the AWARE Program

AWARE is similar in all four ICUs and across all clinicians, but its use is inconsistent even within one ICU. For example, nursing leadership decided to start AWARE implementation with charge nurses, and then roll it out to bedside nurses. In addition, it was reported that some staff nurses, such as those working the 10 to 3 shift, use AWARE more because they have had access to the program for a longer period than have some of their colleagues on other shifts.

Program staff continue to hold trainings to familiarize clinicians with the tool, and the program manager conducted supplemental one-on-one sessions with those resistant to using the program to answer questions, alleviate apprehensions, and demonstrate the value of AWARE. Although there are still non-adopters, 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 and users must continue to learn new features, consistent use may be difficult to achieve.

1.5   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.

1.5.1   Better Care

The ultimate central goal of the AWARE program is to achieve better care by ensuring compliance with best practice clinical guidelines. Most clinicians we interviewed agreed that they are providing better patient care because AWARE allows them to be at the bedside more than at the computer. One super-user said

> "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"*

that the quality of patient care he provides has increased dramatically since AWARE was implemented. AWARE presents critical issues clearly and in real-time, allowing him to address concerns with the patient right away. "The ability to address clinical concerns quickly leads to better patient outcomes."

From the standpoint of a nurse unit manager we interviewed, AWARE is improving care 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." 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 cuts down on telephone and paper information transfer among clinicians.

The Mayo program team collects data on a number of quality measures that they regularly report to CMS and use for internal quality improvement. The measures identified in the grantee reports to CMS that are used to assess better patient care are listed in Exhibit 4.

Exhibit 4. 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 5.

Exhibit 5. 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

1.5.2   Better Health

The AWARE program is expected to improve health, by reducing ICU length of stay, reducing medical errors and associated adverse events, reducing ICU morality, and reducing readmissions.

Some clinicians we interviewed are uncertain that improvements in patient outcomes can be attributed to AWARE because the program is not fully implemented beyond the target ICUs, and many clinicians are not yet using it. In order to attain the scale required to have sufficient power to measure impact, the program will need more widespread use. Further, according to one physician, it will be hard to attribute change in quality of care to AWARE, given the other concurrent quality improvement initiatives at Mayo. For example, although there has been a decrease in the length of stay, some staff found it hard to attribute this to the AWARE program.

> "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*

Mayo is tracking a number of outcomes in their reports to CMS to evaluate better health, as listed in Exhibit 6 below.

Exhibit 6. 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

1.5.3   Lower Cost

As noted above, AWARE's goals include obtaining greater than 90 percent adherence to ICU best practices, and reducing preventable ICU complications by 50 percent. The program staff anticipate that these improvements will decrease the cost of providing care by up to 20 percent, or $81 million over three years. One of the founders of the AWARE program acknowledges 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. It is not clear how much of this cost savings will translate to lower payments for Medicare and Medicaid.

1.5.4   Outcomes that Can Be Measured Using Claims

Mayo Clinic ICU patients can be identified and described using Medicare and Medicaid claims, and a comparison group of similar patients from other hospitals can be created, to measure impact 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 7.

Exhibit 7. 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

1.6   AWARE Workforce Development/Training

The AWARE program has necessitated no direct hiring or acquisition of new resources. Instead, AWARE program staff consulted with key ICU team members during the development and implementation stage and provided training to all staff working in the intervention ICUs. Overall, most staff we interviewed reported improvements in their workloads and workflow when using AWARE. Staff who most frequently use AWARE are most likely to report improved satisfaction with their job as a result of using AWARE.

1.6.1   Workforce Development

AWARE Program Staff

The AWARE program staff include a Program Manager, three PIs (the program PI, the IT co-inventor and the Clinical PI), the Implementation Lead/Trainer, and the Project Manager. The Abt team met with all program staff with the exception of the program PI who was out of town during our site visit. We did, however, meet with the clinical co-inventor of AWARE, who is an attending physician at Mayo. All staff listed here worked at Mayo prior to the HCIA grant. However, some of their roles have changed or evolved as a result of the HCIA grant.

The Program Manager manages federal contracts and grants for Mayo, now including the HCIA grant. For this grant, she is the liaison between program staff and CMMI. The Project Manager supports the Implementation Lead in planning the roll-out, training and ongoing internal marketing/ promotion efforts of AWARE. The Implementation Lead is a research fellow and physician, and was associated with the AWARE program for three years before the HCIA grant was awarded. She worked on usability and validation testing of the tool, providing feedback to the PIs, and leads the creation of implementation and training plans. The Clinical PI is a pulmonary and critical medicine physician and Vice Medical Informatics Officer at Mayo Clinic, directing a Knowledge and Delivery Center that creates standards and clinical decision-support rules. Finally, the IT co-inventor and the clinical PI worked with the aforementioned program staff and clinical leaders to develop and iterate the AWARE tool in the alpha test phase and improve it before full implementation. Clinical users we interviewed reported that, in general, there are enough support staff and resources allocated to AWARE implementation and trouble-shooting.

Clinicians

While no clinicians were hired specifically for the AWARE project, some physicians were consulted in 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 and its use. There is staff turnover as new fellows and residents begin their rotations each July which necessitates continuous training and onboarding to acquaint new staff with AWARE, discussed below.

1.6.2   Training

Training of ICU clinicians to use AWARE is intended to maximize flexibility and adaptability to meet user needs. The tool and training program were initially offered to physicians, then to NPs and PAs, and then to charge nurses. Now respiratory therapists and bedside nurses are being trained as well. 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. The training curriculum was designed based on clinical leaders' input and ongoing feedback, and has evolved over time. There is also an online training module which is very short (10 slides) and can be taken at any time by any staff member. Following is a list of specific trainings available for clinicians:

- Attending physicians are offered one-on-one training sessions at their convenience.

- NPs, PAs and charge nurses can take either onsite training or online training, or both.

- New staff who begin work at the Mayo Clinic after program implementation are trained at the 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.

  - Resident physicians, who will be rotating in Mayo Clinic 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.

Clinical staff acknowledge 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 previously know existed.

A significant component of learning how to use AWARE has come from peer-to-peer knowledge sharing from super-users, and from extensive reliance on AWARE during rounds. Some clinician 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 are critical to the cultural change required to adopt this complex new tool that substantially alters workflow in the ICU.

1.6.3   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 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 mobile, real-time information retrieval, organized in a way that supports care delivery, clinicians reported spending much less time at computers, and basing 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, limiting back-and-forth verification with multiple records and clinicians involved. Respiratory therapists moving from one ICU to another have quickly been able to 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 who note a decrease in workload, also report improved job satisfaction. However, some staff feel that they cannot fully depend on AWARE and are not as satisfied with the tool. Some of the reporting tools for nurses have not been fully optimized in AWARE, making it difficult for them to use and requiring them to supplement with "old" methods of documentation (including paper notes). For these staff, AWARE has not necessarily decreased workload; it has added another component to their job instead of fully replacing workflows that already existed.

1.7   Context

In the three years prior to receiving HCIA funding, the Mayo Clinic 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 Clinic staff conducted research on the feasibility of and potential uses for 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 of participating facilities. The research and pilot study phase, as well as preliminary training and use in one ICU, all 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 the Mayo Clinic as well as partner hospitals. AWARE was not previously used in any other quality improvement program at Mayo Clinic, nor was it influenced by Federal and State policies on the HCIA initiative.

1.7.1   Sustainability

The main resources required to sustain the AWARE program in the four Mayo Clinic ICUs will be IT/programming resources to continue making software enhancements and upgrades. In addition, training will continue to be needed, as new clinicians are hired or begin rotations in targeted ICUs.

AWARE program staff and users reported that they received extensive institutional, divisional and IT support from the Mayo Clinic throughout the implementation process, both before and after the HCIA. Clinicians reported that they believe there are enough resources dedicated to the program currently, and in the future to sustain the program. The program manager acknowledged that it is likely that their team received more institutional support than some of their partner hospitals with fewer resources will enjoy.

1.7.2   Unintended/Unanticipated Impacts of the Program

There have been limited unintended consequences from the AWARE program. The one noticeable spillover effect was 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 ICUs, now also use the program in other ICUs and at times informally share information about the training they received, to explain the tool to their colleagues. This informal adoption, taking place without explicit user training, is evidence of the ease of use and learning, and the value of the tool for clinicians.

1.8   Conclusions and Next Steps

The AWARE program offers clinicians a data display, communication, and decision support tool to foster the best clinical practices in critical care. Clinically relevant, patient-specific information is displayed on a dashboard in a manner that reduces information overload, prioritizes patient needs, and fosters more rapid patient assessments. The goal of the program is to help clinicians process and prioritize information about critically ill patients by streamlining data display to reduce cognitive overload, reduce errors and omissions, and improve patient health outcomes.

The AWARE program received institutional support from the Mayo Clinic which funded the conceptualization, development, and pilot-testing of the tool. Administrative support and buy-in from key clinical and IT staff were critical to successfully securing CMS funding and expanding AWARE. Clinicians seem to embrace the goals of AWARE and most who try are 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. There was considerable initial resistance from physicians in learning another IT application, and from nurses who are challenged to replace paper and pencil with electronic notes. These challenges are still being overcome, and will likely be present at partner hospitals when the program expands.

The fact that the training approaches were flexible to accommodate the busy schedules of physicians and other clinical staff, was a strength of the program, and no doubt allowed more physicians to be trained than would have otherwise been possible. However, the lack of mandated training may be a limitation in

that fewer clinicians are using AWARE than would be true if they took the proffered training. One interviewee noted that leadership is considering making training mandatory for physicians and other 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.

We observed clinicians using the AWARE tool and it is clear that it has impressive potential; many users are enthusiastic about this innovation. Remaining issues include wireless connectivity throughout the hospital, assimilation of data from other areas of the hospital (e.g., ED and general floors), and improving the timeliness of medication information. These and other challenges will likely be faced by partner hospitals, where resources and support may not equal those of Mayo Clinic.
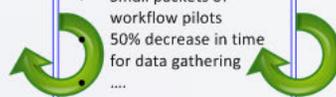
The next steps for the project team are to refine Cloud AWARE and to implement it in partner sites. Several deficient technical interfaces between the host EMR systems and Cloud AWARE were identified during preparations for go-live at partnering Lawrence General Hospital. The project team will work to redesign these interfaces and to refine and prepare Cloud AWARE for broader user access. The team will implement the cloud environment and launch AWARE in two additional acute care hospital settings, Montefiore and Lawrence General during the summer of 2014, followed by implementation at the University of Oklahoma Medical Center in the fall of 2014. The Abt team will follow-up on the progress of the implementation of AWARE at partner sites during the next round of case study interviews.

1.9   Case Study Appendix 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 symbols indicating the organ system(s) of concern (e.g., a heart shape, for a heart failure patient). Patients with critical needs have their representative text boxes 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*

1.10   Quarterly Incremental Illustration at Mayo Clinic.

ProCCESs AWARE

	Jan Feb Mar 2012	Apr May Jun 2012	Jul Aug Sep 2012	Oct Nov Dec 2012	Jan Feb Mar 2013	Apr May Jun 2013	Jul Aug Sep 2013
Technology	• Usability study	Prototype (Pre-grant) → Initial AWARE • Single patient viewer • Rudamentary Multi Patient Viewer • Patient List • Usage metrics • Unit selector	Prototype (Post-grant) → • Multi-patient viewer enhanced • Organ Icons (MPV) • Workflow improvements • Charting/Reports • Room layout • Integrated with Synthesis	New Architecture/Performance improvement → • Whiteboard/Task List • Claiming Other Innovation: • iCertain • iPad	App Enhancement → • Rounding Tool • Checklist • Nursing Enhancements Cloud Development: • Successful manipulation & passing of data	• Improved menu designs and icons • Nursing Whiteboard • Handoff Tool • Heart/lung machine status • Additional organs & skin Cloud Development: • Framework built for Multi-Patient and Single Patient viewers • Select Body System "Rules" defined	• Patient Timeline overview screen (2nd Screen) • Enhanced patient finder • Removed dependency on other software platform • "Training" button to tool bar • Incremental improvements for nursing Cloud Development: • Completed development on 2nd integration point
Practice Improvement	• No impact to workflow	• Small packets of workflow pilots • 50% decrease in time for data gathering	Test changes to workflow →	New workflow → Test changes to workflow →	New workflow → • EMR tools to ICU handoff • Charge Nurse Report	New workflow →	• Began development on 3rd integration point • Begun testing of 2nd integration point Test changes to workflow
Practice Impact	• Performance projections	• Patient Impact (pilot / test) – resident observation	Patient Impact (test) • Alignment of rules to clinical best practices Ave unique patients/ month= 755	• Test and deploy new architecture • Added to Mayo Dock • Ad hoc reporting Ave unique patients/month= 780	• Rounding Tool • New Workflow • Claim Patient • Claiming by group (i.e. PCU, ICU, Floor) in certain units Ave unique patients/month= 1,032	• Rounding Tool Improvements • Checklist • Claim/Unclaim • Unit to unit handoff Ave unique patients/month= 1,066	• Rounding Workflow • Charge Nurse Report • Unit Handoff • Claiming Patients Ave unique patients/month (Jul/Aug)= 1,138
Resources	2 MD's 1 PhD Scope of work = 1 ICU	4 MD's 1 PhD X Users Scope of work = 3 ICU	2 MD's 1 PhD Scope of work = 1 ICU Ave unique users/ month= 378	2 MD's 1 PhD Scope of work = 4 ICU's for Grant X ICU's for expansion Ave unique users/month • 373	2 MD's 1 PhD Philips Brandix Scope of work = 4 ICU's for Grant 11 ICU's for expansion Ave unique users/month • 526	2 MD's Philips 1 PhD Brandix Nursing Scope of work = 4 ICU's for Grant 11 ICU's for expansion Ave unique users/month • 551	2 MD's 1 PhD Nursing Scope of work = 4 ICU's for Grant 11 ICU's for expansion Ave unique users/month (Jul/Aug) • 615

Grant Award

Source. HCIA Quarterly Progress Report Narrative submitted by the Mayo Clinic to CMS for Quarter 5.

2. Quantitative Analyses

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 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 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, which in turn may reduce mortality. We therefore present results for the following additional measures:

- Length of stay (LOS)

- Inpatient mortality

- Total 30 day (including inpatient) mortality

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.

2.1 Intervention and Comparison Groups

2.1.1 Registry Information

The registry provided by Mayo program staff includes 2,711 Medicare patients who were treated in the participating ICUs before April 1, 2014. The registry contains information about patients treated in the cardiac surgery ICU (580 patients), medical ICU (983 patients), mixed medical-surgical ICU (444 patients), thoracic-vascular surgical ICU (454 patients), and the trauma general surgery ICU (424 patients). Some patients in the registry spent time in more than one ICU.

The registry includes patients who were treated in the ICU before the start date of the program. Because Medicare claims data do not include ICU admission date, we only included patients who were admitted to the hospital on or after July 1, 2013 in the matching exercise to specify criteria for selecting intervention and comparison groups.

2.1.2   Selection Rules

The Mayo Clinic has more than one ICU type, but not all ICUs are participating in the intervention. Selection of an estimated treatment group therefore was conducted in two stages. First, we selected all of the ICU patients treated at Mayo Clinic. Next, we examined the major diagnostic category (MDC) for registry patients' claims. There were no patients in the registry with MDC 15 (newborns and other neonates) and we eliminated all such patients from the estimated group.

2.1.3   Estimated Intervention Group

We estimate that 1,817 ICU patients were exposed to the Mayo intervention, but 2,315 patients with Medicare claims were present in the registry. Four hundred and two patients were included in the registry but not in the estimated intervention group. These patients were treated in the cardiac care unit, which is not explicitly part of the Mayo ICU program. Mayo program staff advised that there has been some spillover, with physicians in the CCU also using the new information tool. Since the CCU is not an intended intervention unit, we excluded such patients from impact analyses. After this exclusion, the match between estimated and registry groups is very close and supports creation of appropriate baseline and comparison groups.

Exhibit 8: Match Rates by Quarter and Aggregate

Mayo Clinic								
	2012		2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):					801	717	617	2,135
Estimated based on Abt rules (N):					694	617	506	1,817
Match between Estimated and Registry (N):					667	580	486	1,733
Registry Patients, Not Captured by Abt rules (N):					134	137	131	402
Estimated by Abt rules, Not in Registry (N):					27	37	20	84
Estimated by Abt rules that are in Registry (%):					96%	94%	96%	95%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

The size of the intervention group thus specified is insufficient in a calendar quarter to support a statistically rigorous difference-in-differences analysis. In a future annual report we will aggregate data across the entire intervention period and, if volume is adequate for tests of statistical significance, will perform a difference-in-differences analysis on the aggregated data.

2.2   Core Measures: Results

2.2.1   Readmissions

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

Exhibit 9 (hospital discharges followed within 30 days by a readmission) shows that the intervention and comparison sites were similar in the baseline period and there is no evidence of a change in this pattern during the intervention. 62% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15-30.

Exhibit 9: Readmissions
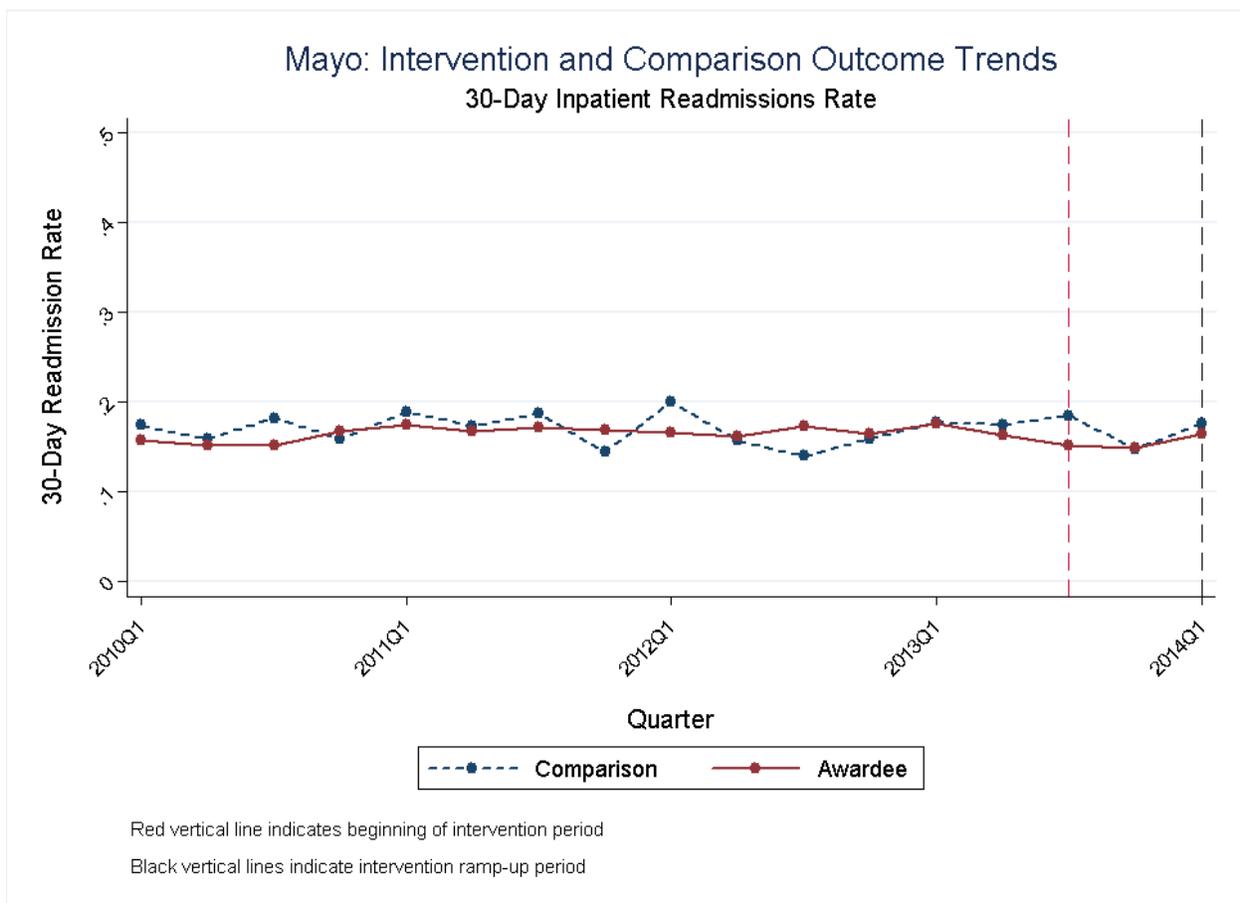
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2   30 Day Post-Discharge ED Visits

Exhibit 10 (discharges followed within 30 days by an ED visit) shows that the intervention group has always been above the comparison group, through all baseline quarters and during the intervention period.
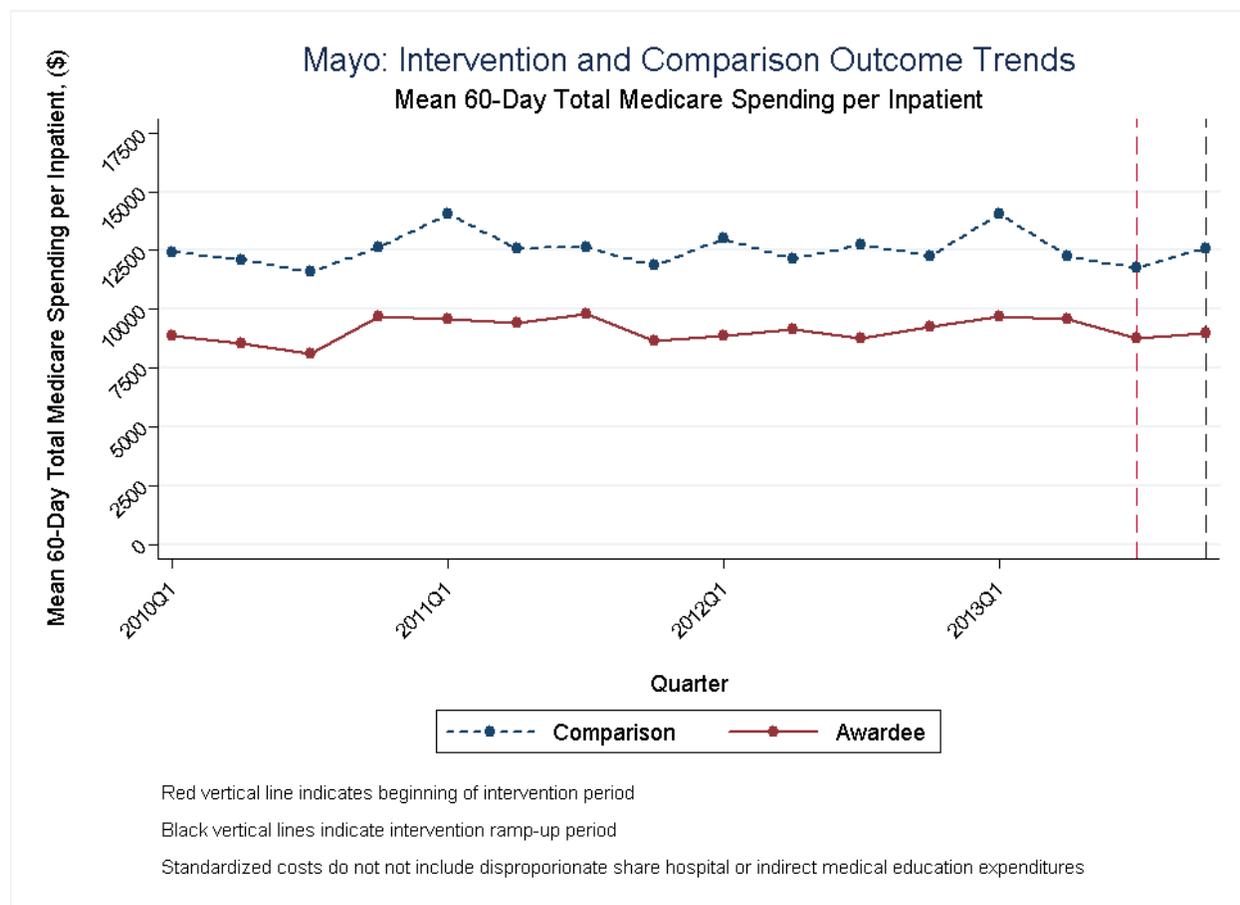
Exhibit 10: 30 Day Post-Discharge ED Visits
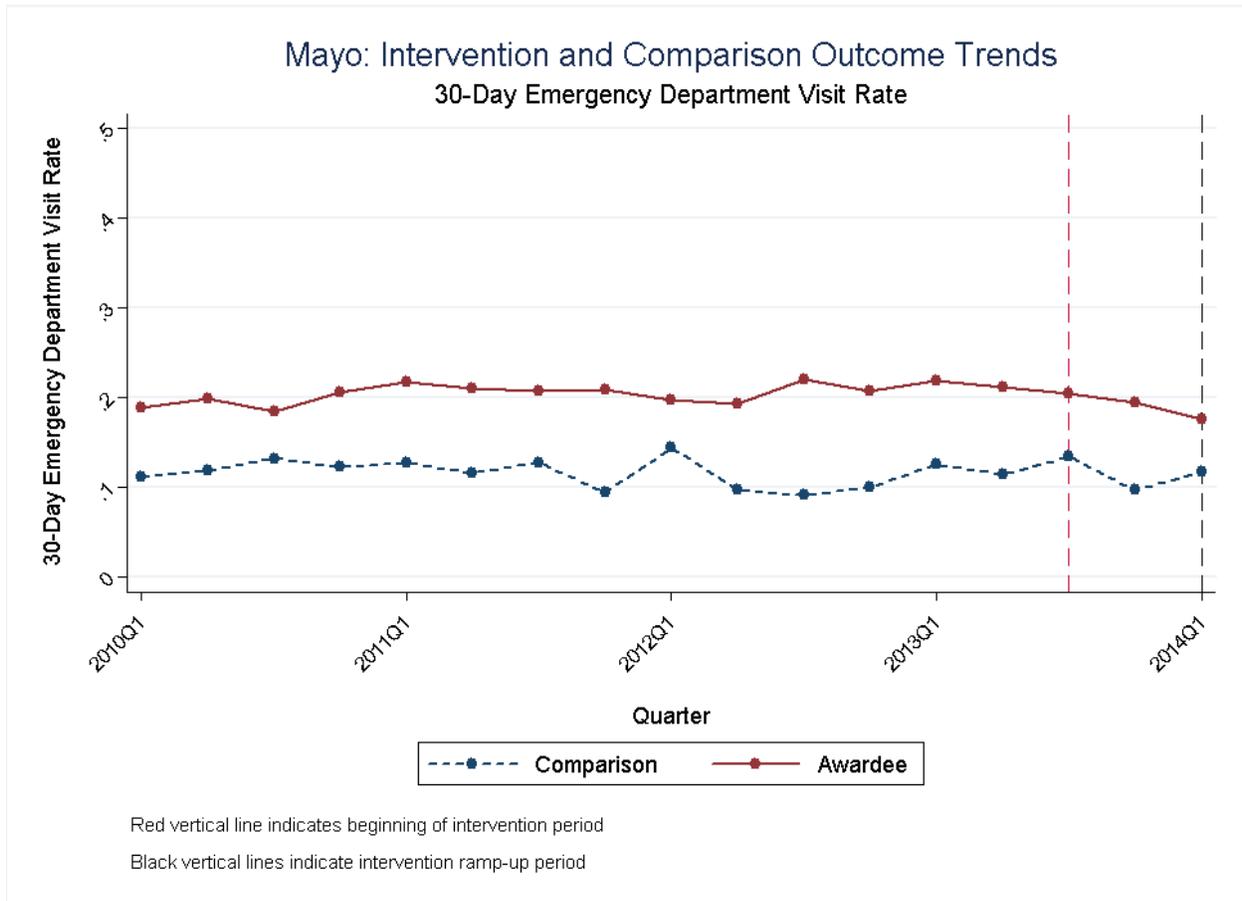
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3   Medicare Episode Spending

Exhibit 11 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days. It shows a dramatic difference between intervention and comparison groups in the baseline and intervention periods, with no evident change in either. 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.

Based on the baseline data in these three exhibits, there appear to be underlying systematic differences between Mayo Clinic and the best comparison group we are able to form.
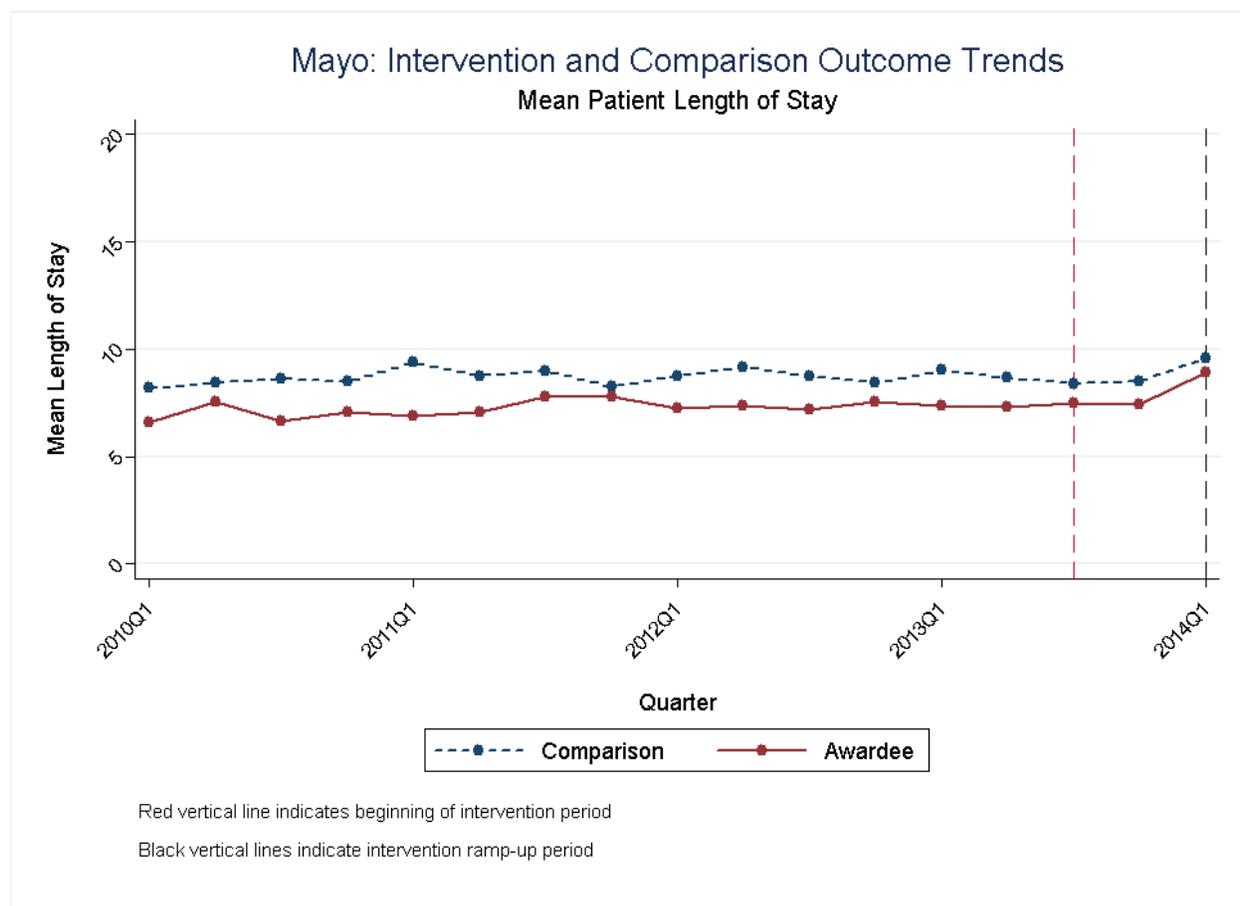
Exhibit 11: Medicare Episode Spending

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.4   Index Admission Length of Stay (LOS)

Exhibit 12 shows LOS during the index admission. LOS at Mayo Clinic was slightly below that of the comparison group throughout the study period, and LOS in both groups appears higher in the most recent quarter; additional quarters of data will clarify whether this is the beginning of a trend.

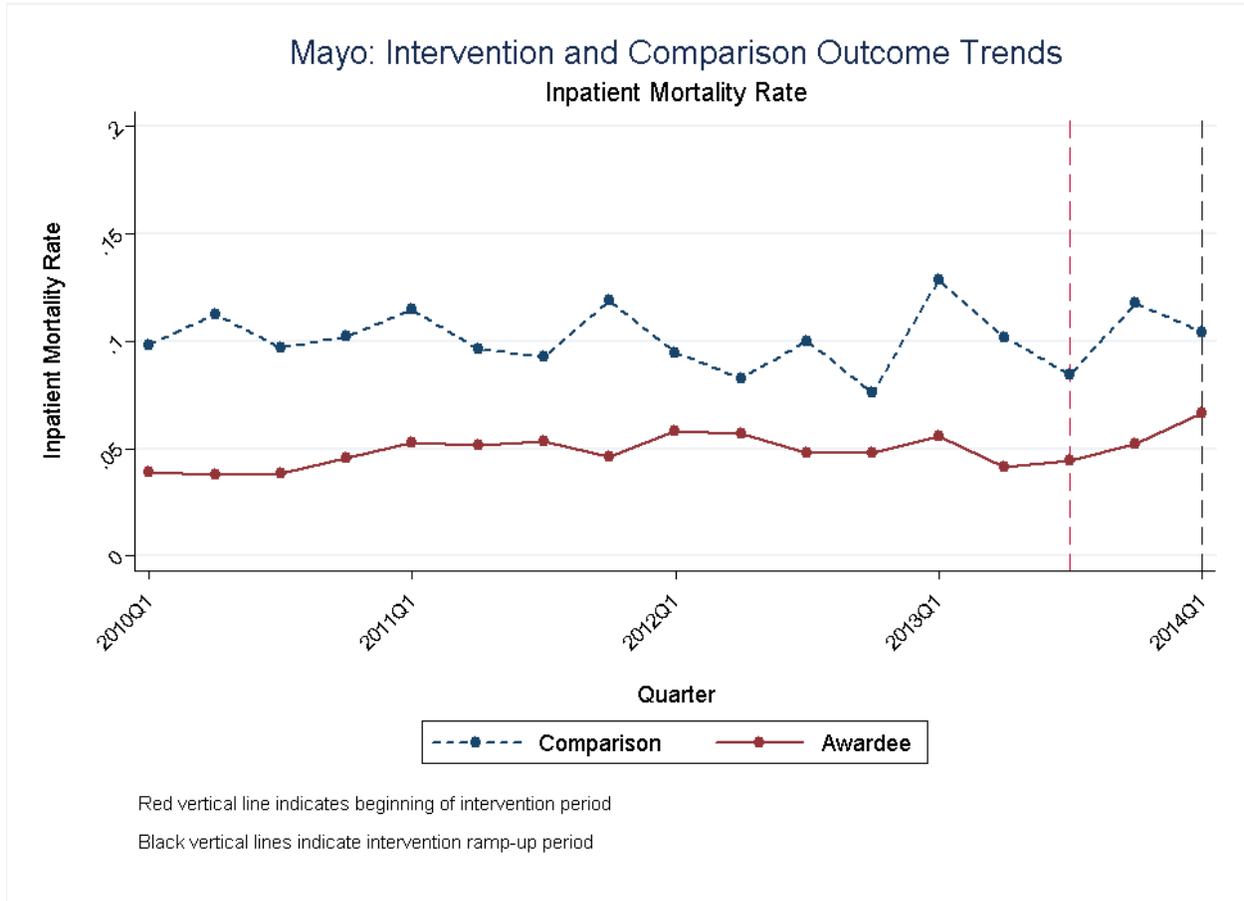**Exhibit 12: Index Admission Inpatient LOS**

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.5   Index Admission Inpatient and 30-Day Mortality

The Mayo Clinic intervention is intended to focus critical care clinicians on each patient's most emergent needs, to improve timeliness of care and adherence to best practice guidelines, which may in turn reduce mortality.

Exhibit 13a shows inpatient mortality following an index admission and shows a slight upward trend in mortality for the intervention group in the most recent quarters, with no similar upward trend in the comparison group.

Exhibit 13a: Index Admission Inpatient Mortality

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 13b includes total mortality (inpatient and the 30 days following the end of the index admission) and shows a similar upward trend for the intervention group in the most recent quarters and no consistent trend for the comparison group.

Exhibit 13b: 30 day Mortality (including Index admission)
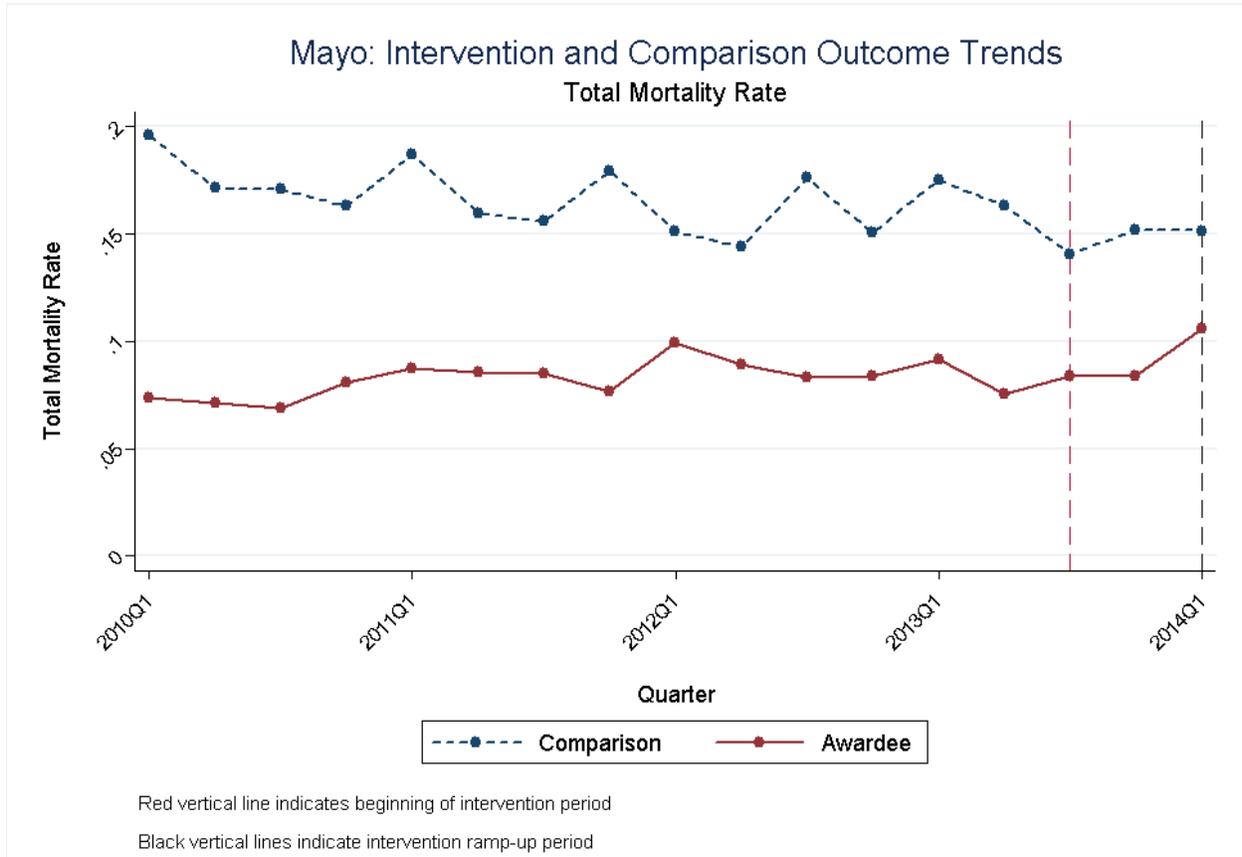
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change. In a future annual report we will aggregate data across the entire intervention period and use regression techniques to try to control for systematic differences in the two groups, although we caution that small numbers may not support such analyses.

Conclusions

- The match is good but misses some intervention patients (direction of bias unknown).

- There is no evidence of change in any intervention group trends, or in the relationship between intervention and comparison groups. The intervention group had higher post-discharge ED visits, and lower mortality and Medicare episode spending than the comparison group, in both baseline and intervention periods.

- Inpatient mortality and total 30-day mortality were higher in Q1 2014 (for both groups) – more quarters of data will indicate whether this is the beginning of a trend.

Appendix B6: Methodist Hospital

Delirium Detection and Prevention

General Research Domains

The core domains for the Methodist Hospital Delirium 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, 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 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.

1. Qualitative Analyses: Case Study

1.1   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.

The program has been implemented at Houston Methodist Hospital (HMH), the system's largest facility, with approximately 750 beds, and the community hospitals of Houston Methodist San Jacinto and Houston Methodist Willowbrook, each of which have approximately 200 beds. The program team plans to expand the intervention to two additional community hospitals (Houston Methodist Sugar Land Hospital and Houston Methodist West Hospital) by the end of 2014.

1.2   Case Study Methods

Abt researchers conducted a case study of Methodist's Delirium program on April 22–24, 2014. Three staff collected qualitative data: a senior Abt researcher, a mid-level Abt researcher, and a researcher from Telligen (the team). The team visited HMH in central Houston and Willowbrook in northwest Houston. The team conducted five focus groups and seven interviews with clinicians and other care providers, as well as hospital and program administrators.

Exhibit 1 summarizes the number and type of individuals who participated in either individual interviews or focus groups.

Exhibit 1. Professional Backgrounds of Interviewees and Focus Group Participants

	Volunteers	Care Navigators	Home Health Aides	Nurses	Physicians	Pharmacists	Hospital Leadership	Program Administration
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

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 Methodist delirium program. Interviews and focus groups were recorded after obtaining participant consent, and used to ensure that the team's notes were accurate and comprehensive. At the end of the case study, all notes were finalized, integrated across the note-takers, and reviewed for accuracy by the team's senior researcher. Coding and analysis of the data were conducted using the qualitative data software NVivo. An initial baseline codebook was developed, and nodes and subnodes were identified a priori for this initial codebook based upon the standard evaluation interview guides. Three people participated in the coding of interview notes, one of whom was the senior team member who led the case study. To enhance inter-rater reliability, three interviews were coded by multiple people on the team and a coding meeting was held to discuss any differences in coding. The team added new nodes as necessary and revised the original codebook. After consensus was reached on coding, the rest of the interviews and focus groups were divided among the coding team. Throughout the coding process, the senior person who participated in the case study checked for consistency across coders, and systematically reviewed and corrected any discrepancies.

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 project components. For example, given the complexity of the different components of the Delirium program, the team stratified findings across six key staff categories for the program: program leadership, pharmacists, care navigators, home health aides, bedside nurses and volunteers. 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.

1.3   Methodist Delirium Program Background

Methodist's Delirium program aims to better prevent, detect and treat delirium in older hospital patients through enhanced monitoring and treatment across the continuum of care. The program begins with surveillance for delirium in the acute care setting, because delirium can prevent an older patient from engaging with, understanding and communicating with clinicians. The delirium program consists of a number of components designed to improve detection and prevention of delirium:

- Twice daily delirium screening by bedside nurses is 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.

- Medication monitoring and revision of order sets to eliminate or reduce use of deliriogenic medications

- 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 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 in the hospital. 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 2.

Exhibit 2. Patient Flow Through Intervention Components (Source: Abt Associates)
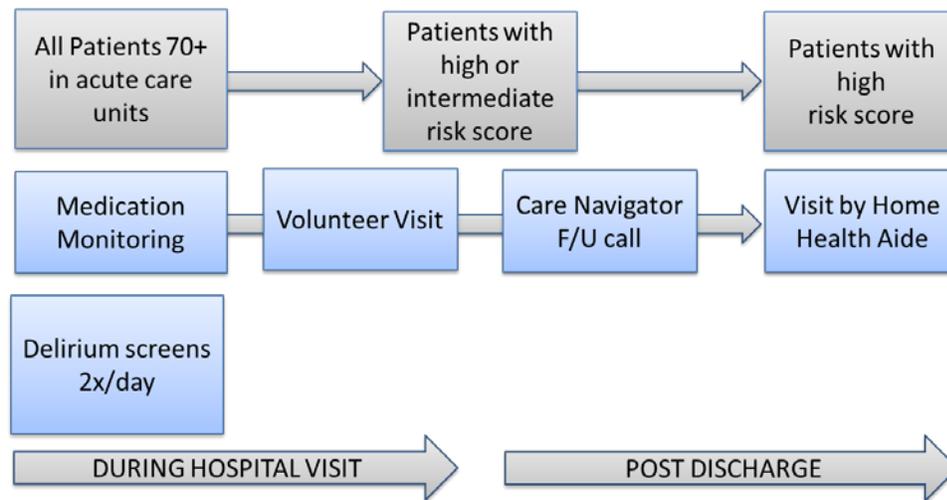
1.3.1 Program Goals

The program initially grew from an institutional interest in delirium, as 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 delirium due to advanced age. 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*

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.

Diagnostic Complexity

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 Alzheimers Disease or other dementias, particularly among patients with multiple disease states, and delirium is often under-diagnosed and 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. Furthermore, nurses noted that it can be hard to establish a baseline for a new hospital patient, in order to

assess whether a particular behavior is unusual for that patient. Complex medication regimens may both increase risk of delirium and also make it more challenging to diagnose.

Some patients experience the delirium diagnosis as a stigmatized condition and are embarrassed by their memory problems. Many of the care providers in the program discussed being careful about using the word "delirium" around some patients and family members, who may react negatively and think that the clinician assumes that the patient is "crazy."

1.4 Target of the Intervention & Program Components

1.4.1 Target Population

The target population of the Methodist program is patients 70 years or older admitted to an acute care unit at a participating Methodist Hospital. Intensive care, psychiatric, emergency, and maternity units are excluded from the intervention. Although the focus is adults 70 or older, bedside nurses and program leadership reported 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.

1.4.2 Primary Program Components

The Delirium program is a systems intervention that spans multiple areas of the hospital and post-acute settings, with interventions implemented by pharmacists, bedside nurses, care navigators, home health aides and volunteers. People with these different roles 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 automated through a vendor decision support and adverse event monitoring system for clinical pharmacy. This software program provides round the clock surveillance of patients to improve medication safety. There are two elements of medication management in the Delirium program: 1) identification of high risk medications and pharmacist alerts when a physician orders one; and 2) review and modification of automated order sets by the pharmacist that permanently removes certain problematic medications from automated order sets that previously did not require an alert or a discussion with the physician. The lead physician and lead pharmacist for the Methodist delirium program wrote rules and alerts for high risk medications to be avoided for older patients in non-ICU units. Removing these medications from the automated order sets prevents physicians from automatically ordering these medications. Physicians can still place orders independently for certain high risk medications, but these orders will trigger an alert. The pharmacist then acknowledges the alert and recommends one of the following: continuation of the medication with care, an alternative dose, an alternative medication, or no medication. The pharmacist follows up directly with the physician to suggest alternatives. Currently, eight "high risk" deliriogenic medications have been identified:

- Zolpidem

- Diphenhydramine

- Lorazepam

- Diazepam

- Methocarbamol

- carisoprodol

- Hydroxyzine

- cyclobezaprine

The objective of the medication alert system is to identify the highest risk medications while at the same time being as efficient as possible (e.g., including both high risk but also commonly prescribed medications). Hence the list has evolved over time as Methodist pharmacists have adjusted the program—adding, subtracting or adjusting 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.

Bedside Nurses: Delirium Assessment Tool and Risk Stratification Score

Patients 70 or older on acute care units are screened twice each day by bedside nurses, using the delirium assessment. Concurrent with the delirium assessment, a risk stratification score is assigned via a software algorithm, ranging from 1 to 5, based on clinical data such as BUN, creatinine ratio, age, ICU stay, and the delirium assessment to assess risk. The risk scores are low (1), medium (2–3), or high (4–5). 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.

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, the risk score triggers other interventions as part of the Delirium program (see below).

Volunteers: On-site Hospital Visit

Volunteers prioritize visits to patients who screen intermediate or high on the risk stratification score, and visit these patients in the hospital within 48 hours of the scoring. Volunteers provide a "What MATTERS" handout to educate the patient and family about how to have a safe hospital stay. "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. Several volunteers described how sitting with patients who are lonely, and just spending time with them, can help lift a patients' spirits, and presumably made them more receptive to the information about delirium risk.

> 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)*

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. 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 are also referred for a home health aide visit, provided by aides specially contracted and trained by the Methodist Delirium program. These home health aides visit patients (who agree to the visit) twice. The first visit occurs within one week after hospital discharge, and the second within two weeks. All patients also receive a final follow-up call from the home health aide within 30 days. 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; they also 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. The information is entered into a database. The home health aides also collect other delirium risk information. They are 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 will then perform 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 Delirium program nurse practitioner 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 nurse practitioner (NP) if needed via FaceTime, adds to the overall feeling of support and security provided through this component of the Delirium program.

1.4.3   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).

- 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.

- 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.

- The 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.

- 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).

1.5   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.

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. As problems and difficulties were identified, solutions were also generated by stakeholder groups in partnership with program leadership. By including the staff who work at all levels of the program in the implementation process, training and workflows related to delirium recognition

> "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

and prevention evolved and improved over time. 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.

In this section, we outline the key leadership staff associated with the program, describe the initial training and compliance monitoring efforts, outline the challenges that different types of participants experienced during implementation, and describe adjustments made over time to strengthen the program.

1.5.1   Training, Ongoing Improvement and Compliance Monitoring Efforts

The primary training process associated with the Delirium program is targeted training for Delirium program staff specific to their role: bedside nurses, care navigators, home health aides, pharmacists, and volunteers. Training, compliance monitoring and retraining are continuous, to achieve full compliance

with the delirium assessment screening protocols and other program components. 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. These individuals and their specific roles are outlined in Exhibit 3.

Many program training protocols utilize a "train-the-trainer" model, whereby staff is identified to receive in-depth training and then deliver the information to others, sharing the same role and responsibilities. The specific training components for every member of the intervention team are as follows:

Bedside Nurse Training

The bedside nurses' training includes 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.

> "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*

The nurse educator identifies a champion for the delirium program in each unit in the hospital who provides feedback to unit staff on delirium assessment screening compliance. An additional specialized training is offered to these champions on each unit, to help them monitor their unit's compliance. The champions' training includes more comprehensive information and videos, which these champions report as being more comprehensive and informative than the initial first training. Some nurses commented that it would have been better if the special champion training had been given to all nurses, as that might have made the implementation process go more quickly.

Exhibit 3. 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. • 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 • 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

Team Leader	Training and Compliance Activities
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 • 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 NP 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	• Coordinates with the Care Navigator team • Tracks care navigator follow-up with patients at intermediate and high risk for delirium • Participates 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

Nurses are responsible for entering the results of the two daily delirium assessment screens into the EHR before midnight. Daily audits by the nurse educator are conducted and weekly reports are generated to provide feedback to the nursing staff. These reports identify units that may be lagging behind and perhaps need special attention from the nurse champion. Compliance with delirium assessment screening has increased from approximately 60% at the start of the program to approximately 93%. 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.

Care Navigators

The hospital-wide care navigator team also supports the Delirium program. 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. More experienced care navigators communicate lessons learned to the new staff who are starting in the care navigator role. They communicate how to approach the subject of delirium with patients and caregivers, and how to document information about delirium in the EHR. For example, although the care navigators haven't changed the formal version of the delirium assessment, they have adjusted the way they approach patients and how they talk with them about delirium. Some of the questions in the initial script were awkward, and care navigators have learned to use more neutral terms in speaking with patients and families about delirium. This is especially important because communication is by telephone with patients and families, and 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

The first group of home health aides received a very intensive 40-hour training that focused on how to use the iPads 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

> "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

health aides who participated in our evaluation focus group, 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. After the home health aides began using iPads to record information (December 2013), there was another 16-hour course with the first group of home health aides about using the iPad and troubleshooting. The second cohort of home health aides received a shorter training (24 hours) based upon 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. 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.

Home health aides do not conduct clinical assessments or make any decisions about patient care. Their role is to observe and record potential issues related to delirium and report problems or needs to the home health NP lead. Once the didactic portion of the Home health aide training is complete, supervisors accompany each home health aide on their first few visits in patients' homes to ensure that the aides are functioning well in their interactions with patients.

Pharmacists

The lead pharmacist conducts training for other hospital pharmacists about the Delirium 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 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.

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 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 receive 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.

1.5.2   Training Targeting the Hospital System

Because the Delirium program is a systems intervention, training activities are available to physicians, case managers, nurses, speech therapist, 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.

1.5.3   Training for Community Hospital Staff

When the first community hospital implemented the Delirium program, the clinical leadership team from HMH conducted training, monitoring and feedback. This model was not sustainable given the other responsibilities of these program staff, and they have adopted a train-the-trainer approach. The program staff described above 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 stress 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.

1.6   Implementation Experience

The initial implementation of the delirium program was well-received. 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 is a hospital protocol and not a punitive one, many nurses realized that is was not any more difficult than their other routine assessments. After compliance checks were added, and nurses started being held accountable, the delirium assessment gained momentum. Nurses began to recognize that they could not make assumptions about which patients were at risk for delirium, and the delirium assessment screening validated this awareness.

This experience of an external structured validation of delirium risk also improved communication between nurses and physicians. The nurses felt empowered as they had the facts to support their concerns about patients' risk for delirium when interacting with the physicians. Nurses described that they explained the delirium assessment to hospital physicians, to increase awareness of delirium surveillance.

One nurse even conducted the delirium assessment on a physician, to demonstrate what it was all about. As everyone saw benefits to doing regular assessments, the initial resistance dissipated. In addition, to encourage staff engagement the nurse educator has instructed nurses that whenever they cannot complete a delirium assessment ("Unable to Assess"), they need to enter an explanation in the comment field (to ensure that staff are not just entering "Unable to Assess" to avoid having to follow-up later).

Interviewees described some initial push back from physicians when pharmacists recommended medication changes. Sometimes physicians had legitimate reasons for prescribing deliriogenic medications, but sometimes 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, where the intervention is just beginning, 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. At community hospitals, program staff learned that it is important to have clear evidence for physicians, based on persuasive research, to motivate change.

Although 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 project staff to handle more medication orders, care navigator calls and home health referrals. The program staff described in some detail the particular administrative and technological complexities that developed as the program was implemented, and the ways in which they adjusted the program to respond to these complexities.

1.6.1 Administrative Complexity

A crucial administrative complexity that emerged for the program was the fact that often the patient contact information and information for a patient's primary care provider was incorrect in the patient record. Missing or incorrect contact information in both cases 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 a visit from the home health aide if necessary. Program leaders were surprised that this simple administrative detail had such an impact on their ability to implement the program.

> "I never expected people to be suspicious of wanting the PCP's info, or to not have their PCP's number and contact information. We had just assumed it would all be there."
>
> –*Program Leadership*

To address this problem, the Delirium program staff created a new responsibility for the volunteers. When a volunteer visits a patient in the hospital who is at risk for delirium, the volunteer now asks the patient and any family members for both the patient contact information and information about the

primary care physician, including telephone number. The volunteer records the information so it can be corrected in the EHR. Although this solved a problem for care navigators, it created other challenges for volunteers. Many patients are annoyed when volunteers ask for their contact information, and the volunteers find it awkward to ask patients for this information because the volunteer is not part of the care team or "official" hospital personnel. Patients are sometimes skeptical of the volunteers' requests, and feel that the hospital should already have the information. Volunteers have learned to emphasize that the information is not being sought "for billing purposes."

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, for example, trying to catch up with weekend referrals on Monday morning, but in general the process works more smoothly with this dedicated resource.

Other administrative complexities and mitigation strategies are shown in Exhibit 4.

Exhibit 4. 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
	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 end at midnight for each 24-hour period	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 now tracks patients being discharged and creates a home health referral list
	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

1.6.2   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. For example, the 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. 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. 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.

A few minor technological challenges were raised by bedside nurses, pharmacists and the data analyst.

- *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. This creates a problem, as the unit does not get credit for compliance with the twice daily delirium assessment screens, even when they are completed.

The data entry system for the EHR sometimes 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

> "When you are part of the tweaking, the program becomes like your 'own baby' because you are part of the process of it evolving…"
>
> –*Bedside Nurse*

assessment screening on a more accessible page, and 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 record this as a missing delirium assessment screening.

- *Pharmacist*: Hospital-wide, there are problems with the medication reconciliation program 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, 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.

- *Data Analyst*: The analyst has 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.

1.6.3 Adaptation and Trialability of Intervention Components

As can be seen from the examples of administrative and technological complexity above, a key characteristic of this intervention is the constant adaptation of the program as it expands. Suggestions for program improvement often come from staff working in the field. At Willowbrook, a participating community hospital, 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 for their hospital.

The home health aide component started more slowly than anticipated. The home health aides expected an immediate and heavy case load, but due to competing initiatives, achieving buy-in, and the fact that many patients went to SNF or LTCH before going home, the case load grew slowly. "Slow was better though" said some of the home health aides. It gave them the 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?"). The home health aides told leadership of their concern about the assessment instruments, and they helped to revise the interview protocols.

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.

A final example of bottom-up adaptation of the program comes from the in-hospital volunteers. Initially, each volunteer carried several folders with the names of patients and reported dropping them and having a hard time keeping them organized. They provided this feedback to the Volunteer Supervisor, and she changed the system so that all the patient names and information have been consolidated to one sheet and one folder. Additionally, volunteers were not prioritizing patients at high or intermediate risk, and/or those who had not yet received any visits. Now patient assignments are arranged for the volunteers in order of priority, based on the patient's risk score.

1.7   Implementation Effectiveness

This chapter 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 aim categories, 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.

1.7.1   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 5).

Exhibit 5. Impact of "Culture Change"

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 • 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 and 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).

Improved coordination during care transitions may also contribute to improved patient and family member satisfaction with care. Both the care navigators and the home health aides described feedback from patients indicating the sense that care is more personalized and more supportive. They described that patients are sometimes surprised that people are being sent to their home, or calling them, to ensure safe transitions. Patients often ask the home health aides to keep visiting, and to replace the regular home health agency staff that is providing care.

Reduction of Medication-Related Delirium

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 80's 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. A care navigator noted that when a patient starts morphine and his or her behavior changes, the nurses call the Clinical Emergency Response Team and the ordering physician, which did not happen before.

> "…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*

Education of Patients and Family Members

Improved education for patients and family members is another element of improved care. The importance of educating patients and family members about medications, and exploring alternative medicines and holistic strategies was stressed, particularly with regards to improving sleep. Decreasing stigma around delirium is also viewed by staff as a benefit for family members and patients, to enhance awareness and reduce barriers in acknowledging confusion and memory lapses. Caregivers or family members now reportedly recognize subtle differences in the patient behavior and feel more comfortable bringing these to the nurse's attention. Many program participants also emphasized the importance of simple improvements in care, such as offering reading glasses and hearing amplifiers.

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 grantee reports to CMS include the following (see Exhibit 6 below).

Exhibit 6. 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)

1.7.2 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 7 below).

Exhibit 7. 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

1.7.3   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 8 below).

Exhibit 8. 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

1.7.4   Unanticipated Impacts

Although the Delirium program is intended for patients 70 or older, 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. Automated order sets that reduce deliriogenic medications similarly apply to all patients under 70. (If a patient under 70 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.)

Beside nurses reported 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. 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. 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. 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.

1.7.5   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 – ICD9 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.

If an appropriate intervention and comparison group can be specified, there are a number of potential outcome measures that can be identified using claims. As noted in Exhibit 9 below, the measures will include:

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 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

1.8   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.

1.8.1   Endogenous factors

Members of the Delirium project team feel that hospital leadership is supportive of the initiative and (with the exception of a needed 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.

There are many other initiatives at the hospital, including the Sepsis program funded through another HCI 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. There are, however, complexities for patients in multiple programs. All patients 70 and over 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 is on one unit at HMH (about 20 beds), and began in late January 2014. As part of the pilot, all patients >70 receive the Mini-Cognition test in addition to Delirium program screening and interventions. Patients who fail the Mini-Cog test, score low or intermediate on the risk assessment, and are home-bound, receive a home health referral. Less than 1 percent of patients eligible for the Delirium program are also eligible for this pilot. This program does not prevent Delirium project participants from receiving services, but provides follow-up care to a few low and intermediate risk patients through the home visits transition care program.

- *Health Coach program*: This program has so far only enrolled patients from Houston Methodist San Jacinto (Willowbrook and West Houston are eligible to participate but have not yet done so). 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. So far, there have been no high risk delirium patients in the Health Coach program.

- *Delivery System Reform Incentive Pool program*: A program aiming to improve transitions in care for patients with behavioral health issues recently began at Houston Methodist (June 7, 2014), and will soon roll out to Willowbrook and San Jacinto. Under this program, all patients admitted to the hospital who have a history of behavioral health issues will receive a Discharge Decision Support System (D2S2) 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, there was only one patient at Houston Methodist that overlapped with the Delirium project. In cases of overlap, the clinical teams will coordinate to determine which of the two programs would be best for the patient. Once the DSRIP program is fully rolled out, they expect that 5 percent of patients may overlap.

- *Other Disease Management programs*: If a patient has a chronic disease (e.g., End Stage Renal Disease) and is otherwise receiving care navigator or home health follow-up from a care management team, they are 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.

1.8.2 Staffing

Impact on Workload

Participants 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 adjusted the staff of care navigators several times to accommodate the need for follow-up calls as the program expands to more hospital units. Pharmacists report increases in their workload to assess alerts and communicate with physicians, but as automated order sets were adjusted, less follow-up is now needed. New positions were created as the program expanded to accommodate these increases, including a dedicated care navigator for the Delirium program and an assistant pharmacist to help with pharmacy support for the care navigator team.

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 so far all visits have been scheduled during weekday work hours. Weekend backlogs were mentioned as a problem for care navigator follow-up primarily.

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 the other satellite 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. Most other hospital programs are unit based, and since the Delirium program spans many units, it facilitates collaboration, primarily through the nurse champions.

1.8.3 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:

- Daily compliance checks of delirium assessment screens, with feedback to bedside nurses. 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 the 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. Once a month, the lead geriatrician, with assistance from the care navigator NP lead and the home health NP lead on the leadership team, review records for a random day for every patient on a unit eligible for the delirium assessment screen. Under the supervision of the lead geriatrician, each record is 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.

- 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 some had no follow-up.

- 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.

- 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).

Many individuals we interviewed during this case study 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.

1.8.4   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 take longer and/or 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 and nights and weekend shifts can be different than weekday shifts as noted in section 4.2.1. Physicians are also more readily available on weekdays to consult about medication reconciliation. Nurses noted that it is important to have nursing 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 are related to implementation challenges rather than specific program components. These challenges include the aforementioned challenges in enlisting volunteers at community hospitals. In addition, some physicians at community hospitals are described as being more recalcitrant than at HMH. Participants 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 and there can be 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, such as hospital committees and clinical departments, to seek approval for program implementation. Whereas in teaching hospitals 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 CAM; it has helped explain why certain patients are a certain way and why they ended up coming into the hospital again."
>
> *–Bedside Nurse*

Sustainability

There was widespread agreement that the program should continue when the grant ends, and the program team has tried to implement the program in a way that will ensure sustainability. Videos and ongoing training modules have been developed for use in the future,

automated pharmacy order sets have been revised, and delirium assessment screenings are part of routine nursing functions.

Ongoing funding will be needed for the staff positions that cannot be absorbed by the hospital system. Once the grant ends, it is likely that many of the positions may need to be maintained by the hospital to continue the high level of service provision, including the home health aides and NP supervisor, the volunteer coordinator, the Delirium program care navigator, the lead pharmacist and the data analyst. The leadership team emphasized that they will also still need to provide funds for the nurse educator to oversee compliance checks, as it is necessary to maintain this component.

Program Reach

Although the reach of the program is judged as "good" by bedside nurses, they noted that some patients refuse to answer the delirium assessment screening questions. From a systems perspective it is easier in some units to screen everyone so no one is missed and no patient feels singled out. Some patients are discharged from the hospital before a home health aide referral is established and 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.

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, more patients now agree to the home visit. Volunteers described missing patients because they are sleeping, are in 'isolation' rooms, or when a physician is in the room with a patient. Pharmacists described challenges in reconciling medications during care transitions, and concern about primary care physicians reintroducing deliriogenic medications. Coordination with hospital discharge planners and community primary care physicians is a recognized next step for the Delirium program.

1.9   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 including:

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 comprehensive assessments; automated medication alerts and order set changes).

Integration: The multiple strategies for providing education about delirium for patients and families, for reducing delirium risks during the hospital stay, and coordinating care at discharge were integrated with one another.

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. The care transition components of the program may be challenging to sustain because they rely on paid positions (care navigators) and subcontractors (home health aides) that are entirely grant funded. While the home health aide function could potentially be transferred to home health agencies, the special training, oversight and tools used in this program would be difficult to replicate effectively with the multiple home health agencies serving the Houston area. The services of care navigators, much like case managers, can possibly be billed to some insurers but not to most. Volunteer recruitment, training and coordination is also a necessary function funded by the grant that may be challenging to sustain.

1.9.1   Next Steps

In follow-up interviews planned for 2015, several topics will be revisited by our evaluation team, and new issues explored, as the HCIA funding nears completion. Topics to explore include:

- Do the program implementation systems continue to evolve and change in the last year of the grant, or, do they settle into a more stable pattern across the five sites?

- Has the program developed a plan for medication reconciliation during discharge transitions? At the time of this case study, program leader were working on strategies to extend the automated medication alert system to discharge reconciliations. As noted above, many patients are taken off high risk medications during their hospital stay, only to be prescribed the same problematic medications at discharge for home use. The expansion of the alert program has been approved by the hospital, and the lead pharmacist was still working with IT on implementation. What is the program staff's experience coordinating with primary care physicians after discharge? Will the program develop new systems to improve this process?

- Has the ongoing tracking of completeness and accuracy of delirium assessment screening continued? Are the patterns largely stable or does compliance wane over time?

- Have other funding sources been identified to continue components of the program after the grant expires – especially components that require new staff positions and subcontracts?

2. Quantitative Analyses

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total 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 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, and although reducing mortality is not an explicit goal of the program, we present results for the following additional measures:

- Length of stay (LOS)

- Inpatient mortality

- Total 30 day (including inpatient) mortality

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.

2.1 Defining Intervention and Comparison Groups

2.1.1 Registry Information

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. Although the program began in October 2012, we used a version of the registry for the matching exercise that contains patient admissions in April 2013 or later.

The registry data contains 5,587 patients, of which 93 percent (5,197) had Medicare HIC numbers and of these, 93 percent had Medicare claims.

2.1.2 Selection Rules

The Methodist Delirium program screens hospitalized patients who are 70 years of age and older. We therefore used Medicare Part A claims from August 8, 2012 through June 30, 2014, for patients admitted to the two hospitals in the registry. Claims for individuals younger than 70 years old were excluded. Since this intervention requires staff to screen all 70+ patients every day, there are no other inclusion or exclusion criteria.

2.1.3   Estimated Intervention Group

We estimated that 6,738 patients are in the Methodist Delirium intervention, but only 4,858 of these are in the registry. Our inclusion and exclusion rules overestimate the number of patients screened for delirium by 1,880 and our rules cannot identify 147 patients (3.1 percent) that are in the registry.

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 10: Match Rates by Quarter and Aggregate

Methodist Delirium								
	2012		2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):				654	1,447	1,529	1,228	4,858
Estimated based on Abt rules (N):				1,806	1,741	1,692	1,499	6,738
Match between Estimated and Registry (N):				626	1419	1512	1154	4,711
Registry Patients, Not Captured by Abt rules (N):				28	28	17	74	147
Estimated by Abt rules, Not in Registry (N):				1180	322	180	345	2,027
Estimated by Abt rules that are in Registry (%):				35%	82%	89%	77%	70%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

In the most recent three quarters, over 75 percent of the estimated patients are also in the registry and the match rate is quite good for the most recent quarters. It is possible that the registry was incomplete when the program was first implemented, and more complete most recently. We conclude that our rules are sufficiently accurate to identify appropriate baseline and comparison groups.

2.2   Core Measures: Results

2.2.1   Readmissions

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.

Exhibit 11 (hospital discharges followed within 30 days by a readmission) shows that the intervention and comparison sites were similar in the baseline period and remain similar in the intervention period. There is no clear pattern of change over time. 86% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15–30.

Exhibit 11: Readmissions
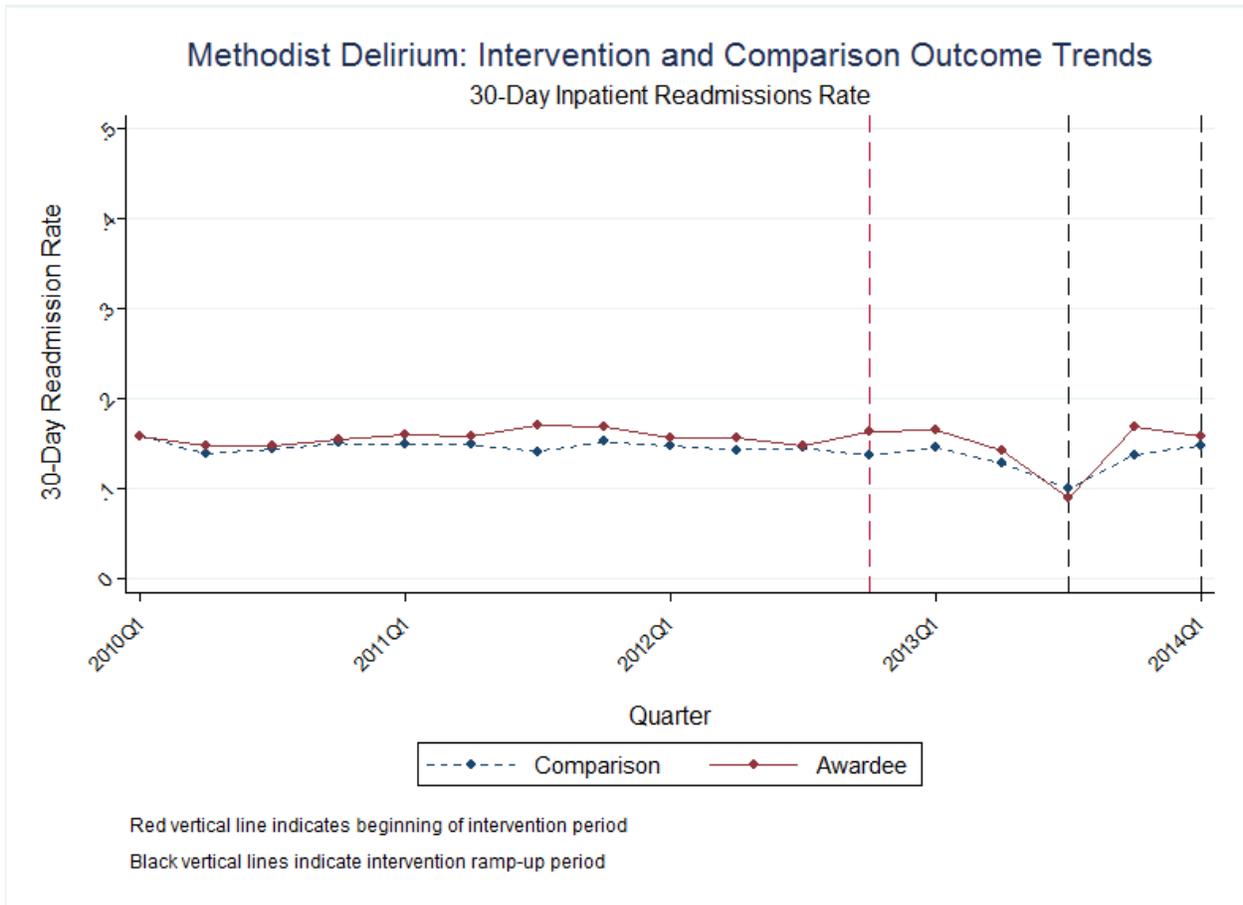
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2   30-Day Post-Discharge ED Visits

Exhibit 12 (discharges followed within 30 days by an ED visit) again shows similar patterns for intervention and comparison groups, and little indication of change in the intervention group that is not present in the comparison group.
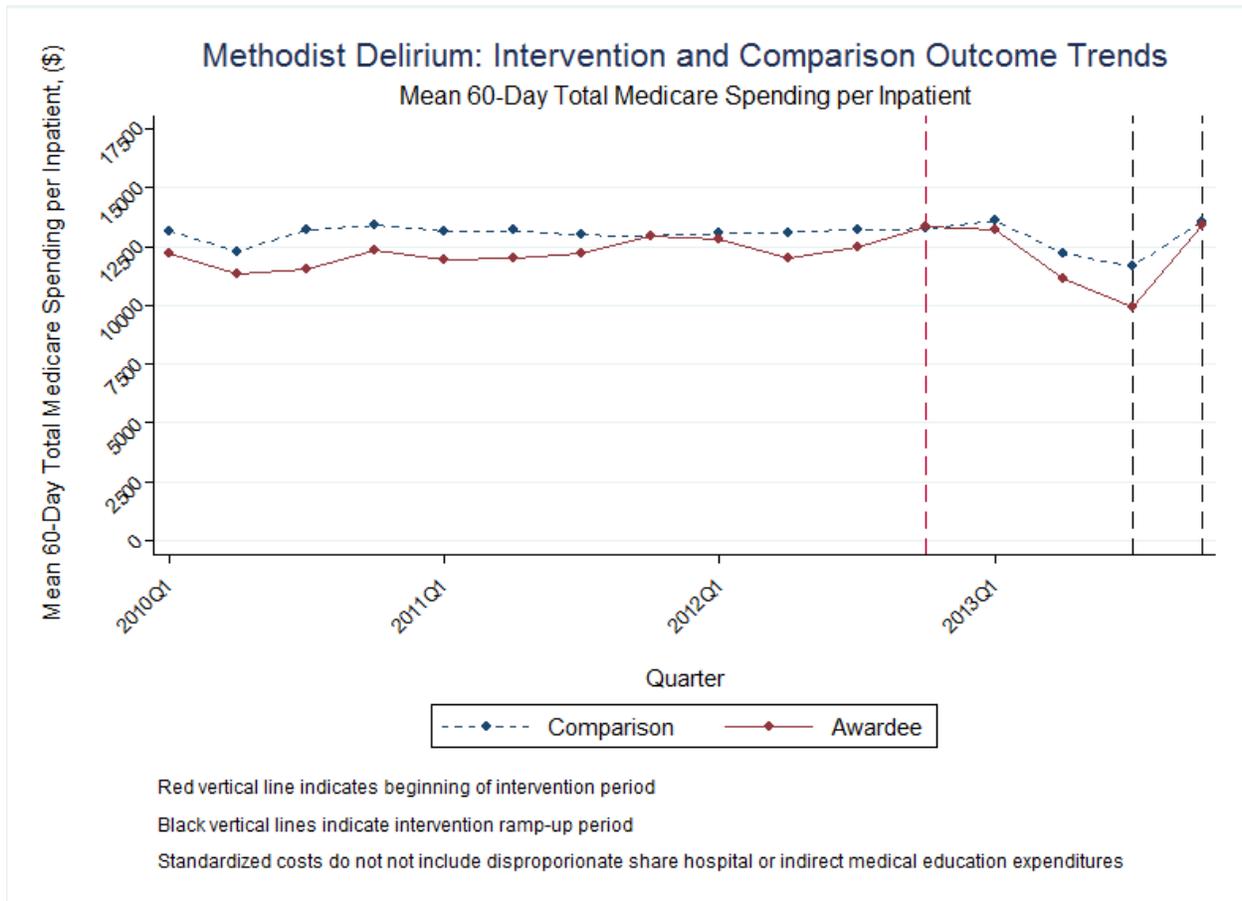
Exhibit 12: 30-Day Post-Discharge ED Visits
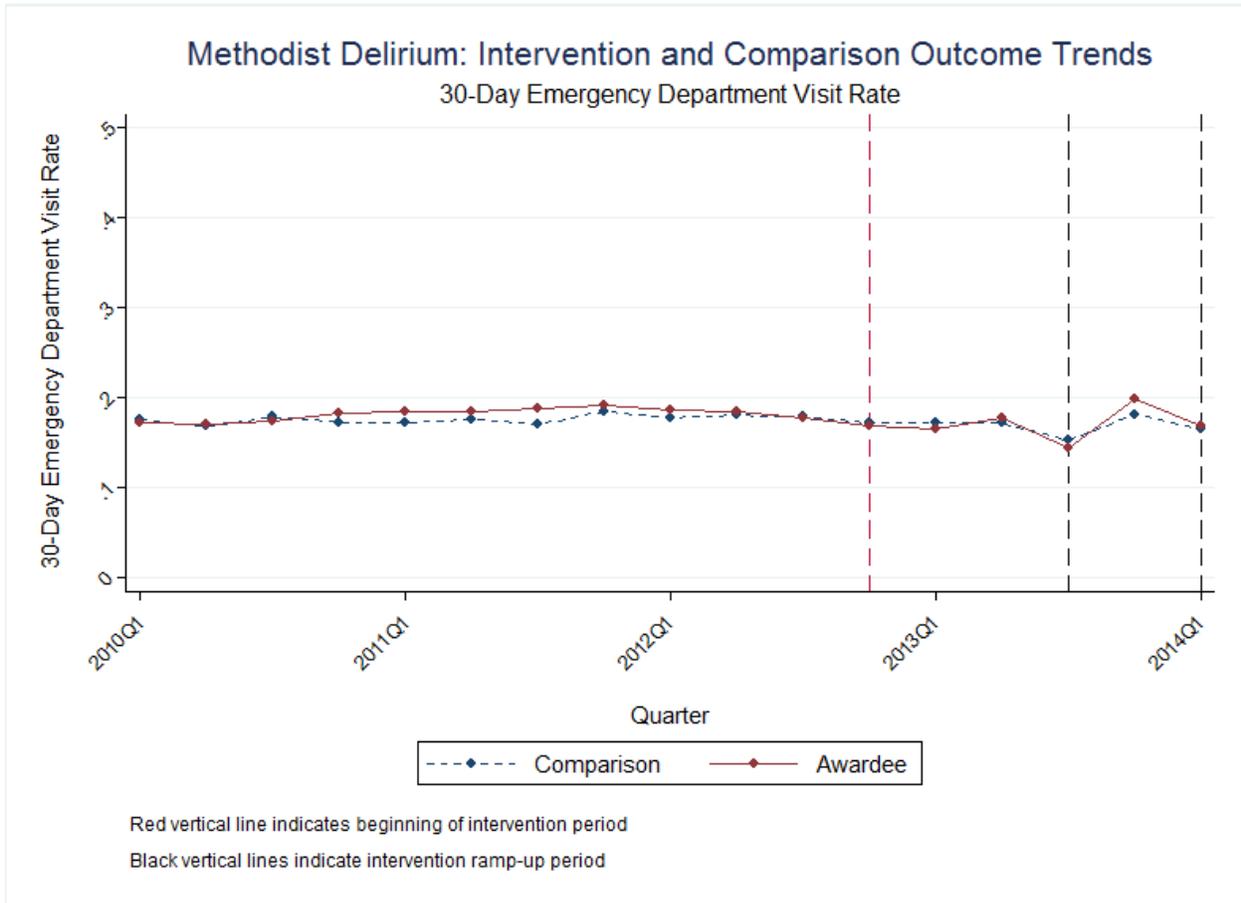
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3   Medicare Episode Spending

Exhibit 13 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days. It shows similar trends for intervention and comparison facilities in the baseline and intervention periods, and some volatility from one quarter to another in both groups, without a clear pattern. 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 13: Medicare Episode Spending

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

A DD regression analysis was conducted to estimate the intervention effect of the Methodist Delirium program on 60 day Medicare total episode spending. We pooled data from participating hospitals and did not conduct facility-specific analyses, because none of the facilities are large enough to give us the power to detect change with reasonable confidence.

The dependent variable in the DD model is the average total Medicare spending per episode from discharge to 60 days post-discharge. The model includes controls for patient age, squared age, gender, race, HCC score in year of treatment, eligibility for Medicaid at any time during the observation period (2010-2014), as well as indicators for quarter of the year in which the episode occurred. An indicator is also included for individuals with missing HCC scores. Exhibit 14 presents the results; standard errors (in parentheses) are clustered at the individual and facility level.

For the Methodist Delirium program, the intervention is not associated with a significant effect on total Medicare episode spending.

Exhibit 14: Effect of Intervention on Mean 60-day Post-Discharge Medicare Costs

Methodist Delirium (pooled across sites)	
Intervention Effect	57.94 (239.88)

*p<0.1 **p<0.05 ***p<0.01
Source: Abt Associates, October 2014.

2.2.4 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 15 (length of stay during an index admission) shows little change in LOS and little difference between intervention and comparison groups.
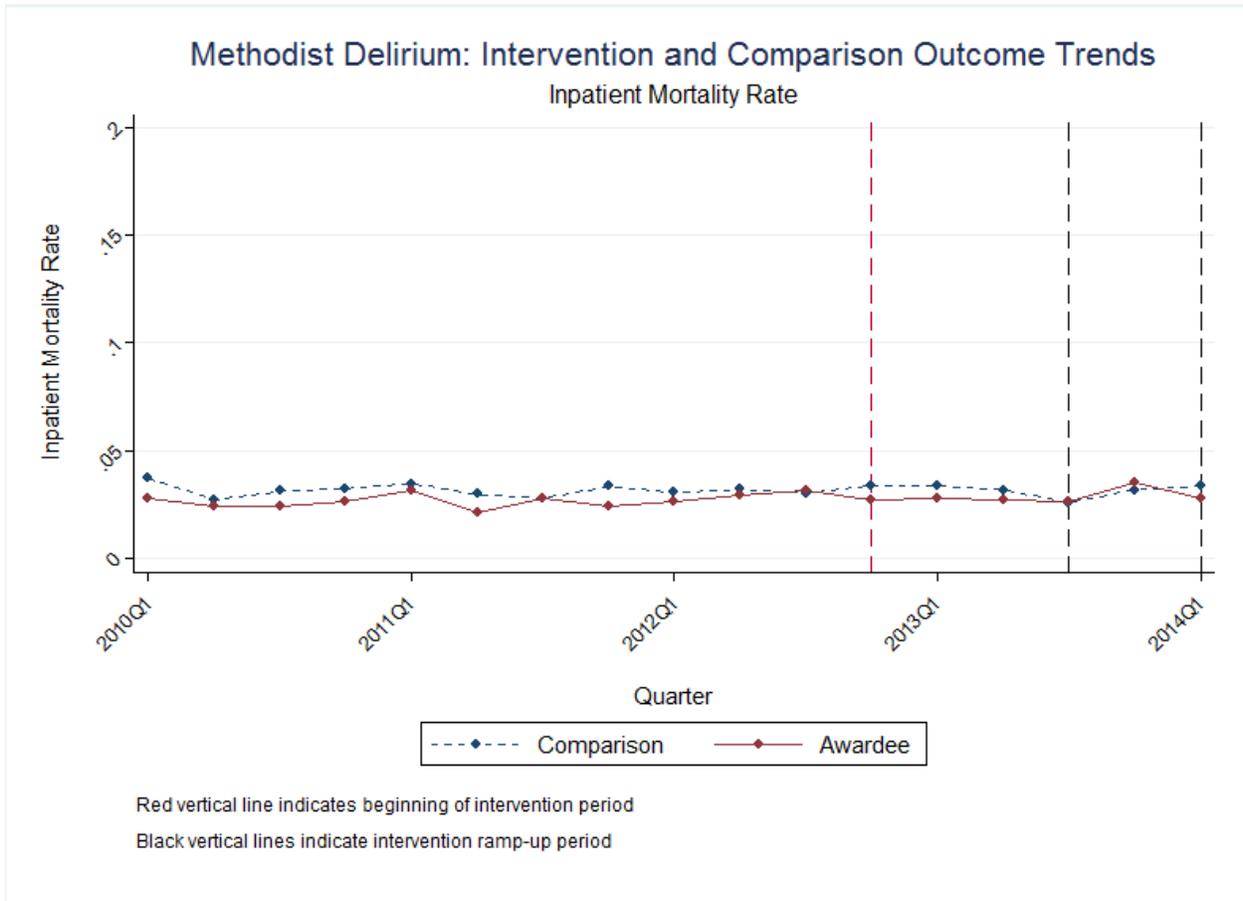
Exhibit 15: Index Admission Inpatient LOS
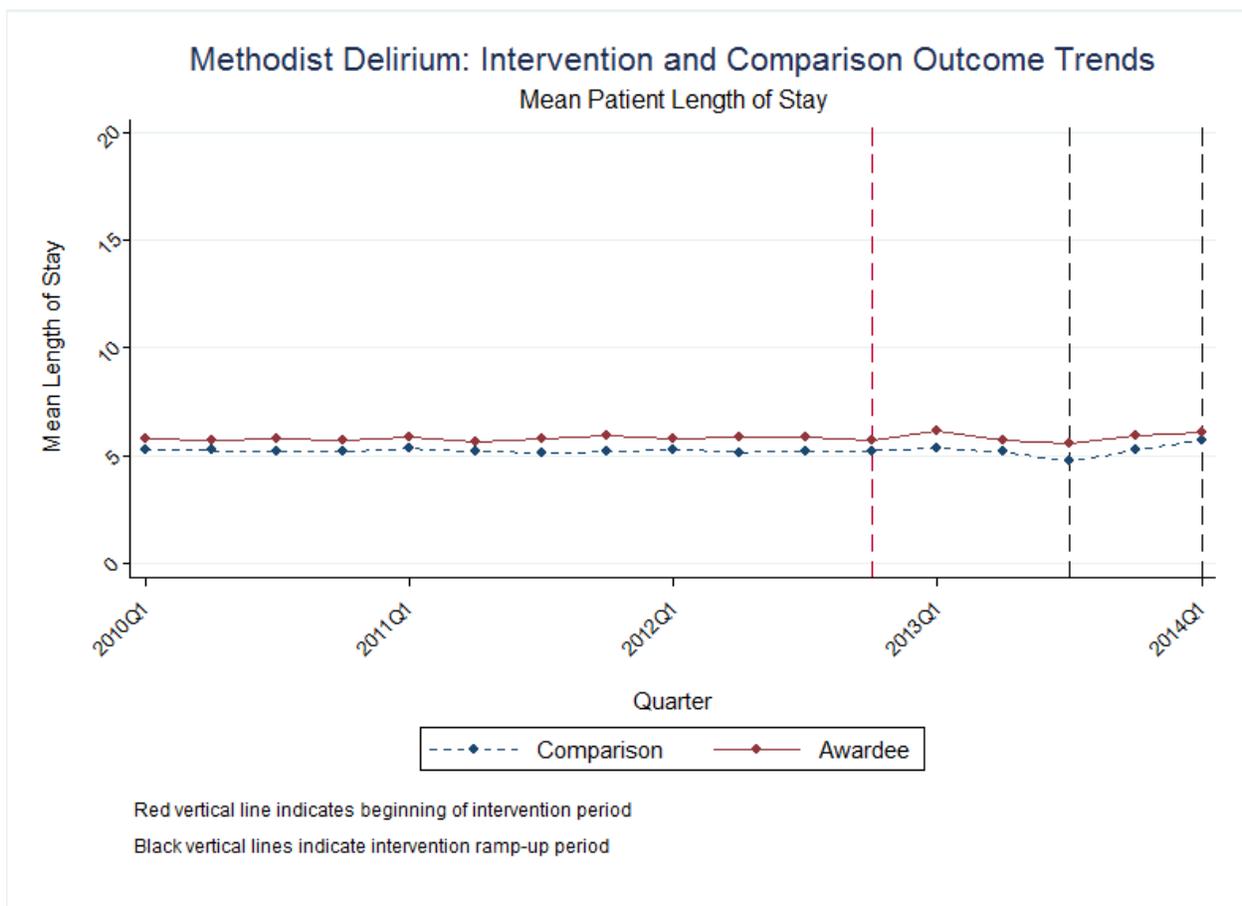
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.5   Index Admission Inpatient and 30-Day Mortality

Inpatient mortality is not high for the patient population served by this intervention and reducing inpatient mortality is not an explicit program objective.

Exhibit 16a shows the inpatient mortality following an index admission and as expected we see little difference between intervention and comparison groups in inpatient mortality and little change in the intervention period.

Exhibit 16a: Index Admission Inpatient Mortality

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 16b shows the total mortality including inpatient and the 30 days following the end of the index admission. It is slightly higher compared to the previous graph of inpatient mortality, but remains unaffected by the intervention.

Exhibit 16b: 30 day Mortality (including Index admission)
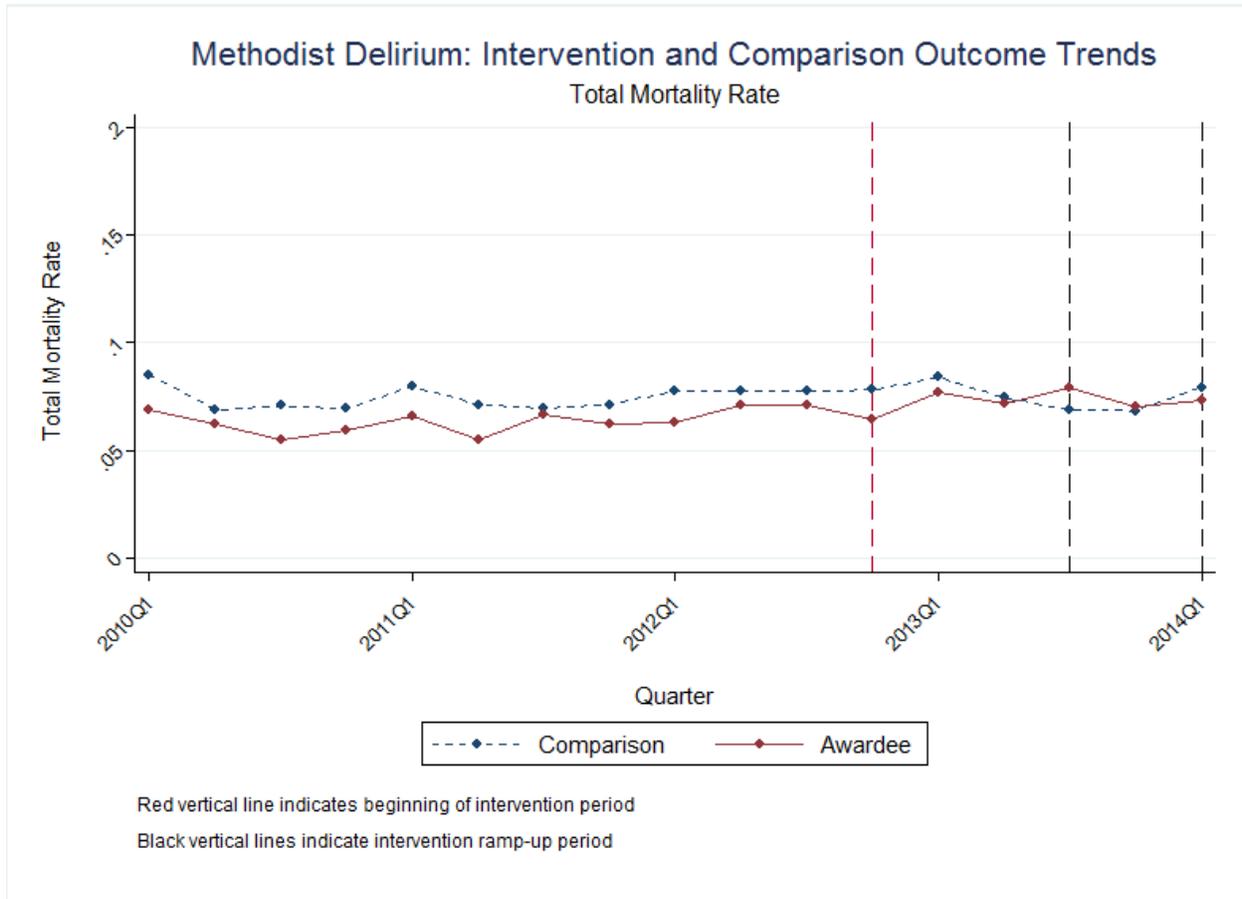
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change.

Conclusions

- Imperfect match: many patients were included in the intervention that were not in the registry and many patients were screened (and in the registry) who are at no risk for delirium; both of these factors bias estimated effects toward zero.

- There was no evidence of an intervention effect on any utilization trends.

- No effect on Medicare episode spending.

Appendix B7: Houston Methodist Hosptial
Sepsis Early Recognition and Response Initiative

INFORMATION NOT RELEASABLE TO THE PUBLIC: The information contained in this report is preliminary and may be used only for project management purposes. It must not be disseminated, distributed, or copied to persons unless they have been authorized by CMS to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

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, 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 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.

1. Qualitative Analyses: Case Study

1.1   Description of Program

The Houston Methodist, 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.

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	TX	Houston	Entire in-patient facility (no peds, no ob, no ed)	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	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 – TMC	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 –TMC	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%

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
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

1.2   Case Study Methodology

The Methodist- Sepsis case study was conducted March 24 through March 28, 2014. The evaluation team, composed of one senior- and one mid-level staff person from Abt Associates and one staff member from CFMC, visited Houston Methodist, an acute care hospital (ACH), in Houston, Texas; Kindred Hospital, a long-term care hospital (LTCH) in Houston, Texas; San Jacinto ACH 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. Focus groups were held at Methodist ACH, Kindred LTCH, and San Jacinto. We also held five interviews with physicians or 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. 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.

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

	First Level Responders	Second Level Responders	Physicians	Pharmacists	Hospital Leadership	Data/ Financial Analysts	Program Administrators
Houston Methodist	12	5	5	2		1	2
Kindred Hospital	3	4	0	1	3	1	2
San Jacinto Skilled Nursing Facility and Rehab Center	5	3	0	1	2	0	1
Total = 53	20	12	5	4	5	2	5

1.3   Background of Program

1.3.1   Program Goals

Houston Methodist and its partners are training staff to identify sepsis cases early and prevent progression of the disease. 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 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.

1.3.2   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 person interviewed described the approach, "It's like preventing an accident while the car is still in the garage." One 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]."

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

> 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*

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[1]. 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% 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, body temperature minimum and maximum 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.

1.4   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

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[1]   The Houston Methodist Research Institute, Health Care Innovation Challenge Grant application, p. 16.

care referral hospital.[2] Some patients are excluded from screening, including pediatric units, obstetrics and gynecology, observational units, psychiatric units, and some cases emergency departments.

1.4.1   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 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 four 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 is integrated into the EMR at Methodist system institutions while at Kindred facilities it is a stand-alone electronic application accessible by a nurse on a computer. Two participating institutions, Select Specialty facilities and St. Joseph SNF, implement 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. These institutions intend to implement the screening process electronically in the future.

Across participating sites, screening occurs 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

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[2]   The Houston Methodist Research Institute, Health Care Innovation Challenge Grant application, p. 22.

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. If the second level responder, after review of SERRI data and assessing the patient, believes the patient is at risk for sepsis, they 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 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.

Treatment of Sepsis

If a second level responder believes a patient is at risk for sepsis, the second level responder can begin to implement early goal directed interventions. 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.[3] 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 2 below.

Pharmacy Support

The SERRI program set a goal of early goal directed interventions 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 pharmacy groups 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.[4] The pharmacy group

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[3]   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.

[4]   STAT is an abbreviation of the Latin *statum,* which means immediately.

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 multi-disciplinary team to examine "points of failure" to optimize the process. According to the 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 for what is referred to as a beginning sepsis protocol. At San Jacinto ACH, the pharmacy manager noted that the severe sepsis protocol is rarely used now. He further outlined that there was no change in pharmacy staff needed for SERRI and workload has not significantly changed because of the SERRI program. Ordered antibiotics reach the patient bedside at San Jacinto ACH within 15-20 minutes of a STAT order.

Exhibit 3. Flow Chart of SERRI Screening and Treatment Processes
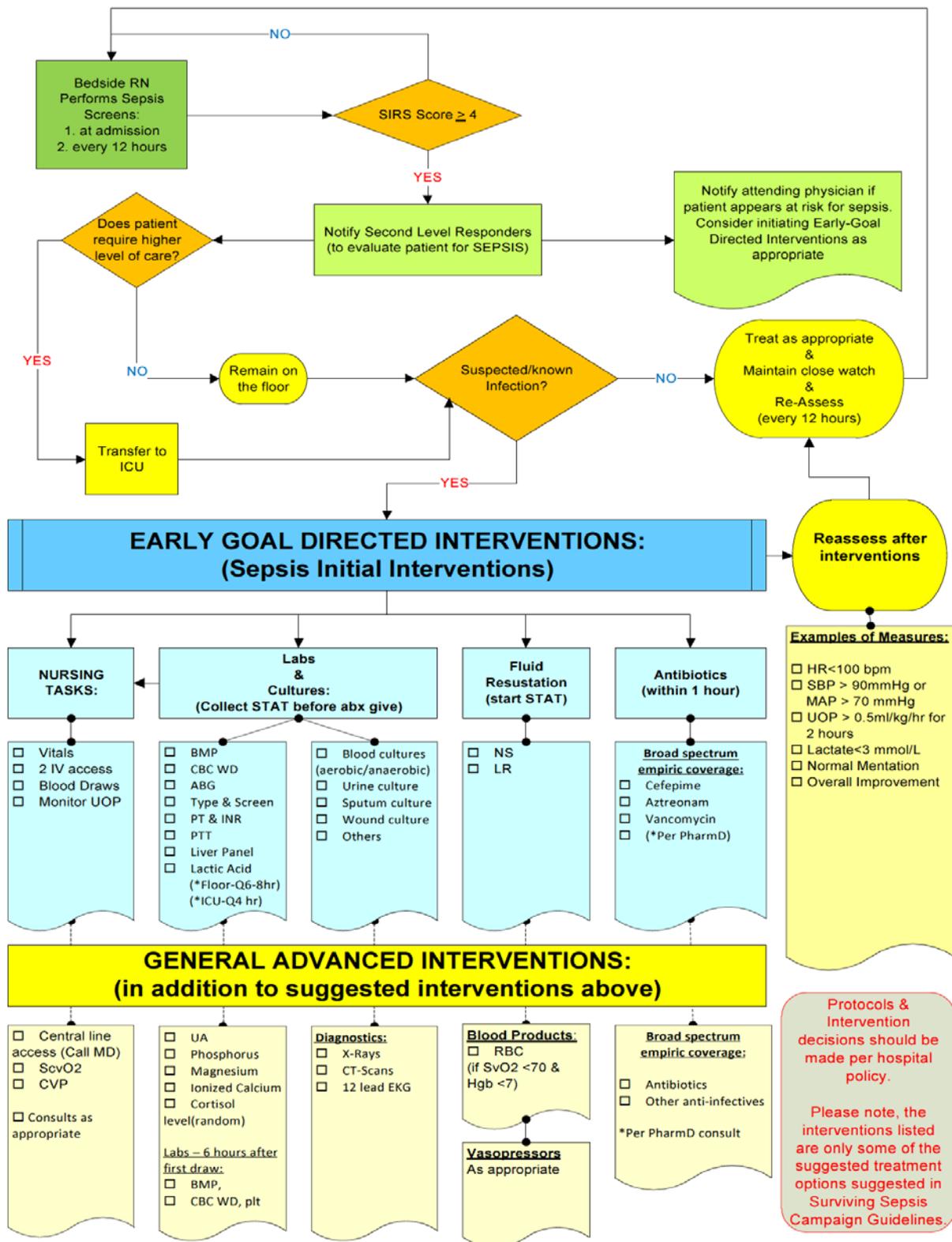
Source: Methodist Research Institute –SERRI Program

1.4.2   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 that was viewed as burdensome by hospital staff. Prior to receiving the HCIA award, 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 Houston Methodist with the exception of the emergency department, obstetrics, psychiatric 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.

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 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.

Kindred LTC Hospital

Implementation at Kindred LTCH began after an information technology upgrade that was needed to support the electronic version of the SERRI tool. 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

> We have seen the cases of septic shock reduced. It's almost gone. That is the biggest quantitative success.
>
> *–Kindred Administrator*

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.

First Level Responders

First 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 CNA 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 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. 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 currently is implemented in the ED and in some medicine units but is not yet hospital-wide because it has taken the time to hire enough advanced practice nurses to serve as second level responders. Further rollout will require an additional sepsis nurse practitioner at the hospital to support the training of staff in completing the SERRI tool at the bedside.

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 also on training of the first and second level responders. There is a regular flow of staff between the ACH and the SNF and rehabilitation center and some staff at San Jacinto SNF and Rehab were introduced to the SERRI program at San Jacinto Hospital, where implementation preceded the SNF and rehabilitation center. A key factor in influencing implementation at the SNF and rehabilitation center was this partnership with   San Jacinto ACH, to ensure that screening at the SNF and rehabilitation facility would occur after the ACH program was in place and second level responders could provide support to staff at the SNF and rehabilitation center. For example, screening times on SNF and rehabilitation units are staggered so that they do 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 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. First responders on SNF units 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 Responder

Second level responders at San Jacinto SNF and rehabilitation center are registered nurses who supervise first responders on SNF and rehabilitation units. Second level responders 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 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 completed. 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 3 SERRI score or higher. They noted that this physician presence makes it possible to monitor patients who score 3 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.

1.4.3   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 to 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.

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 whatever EMR is used at the 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 look forward to the time when the SERRI tool will be accessible as part of their standard EMR, which they anticipate will further reduce the time required to enter and review each patient's SERRI score.

1.4.4   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, an indicator that is very important 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 team 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 determine how well the program's implementation is progressing.

1.5   Workforce Development

The Methodist SERRI training program addresses the diverse training needs for bedside nurses who served as first 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. Physicians who were often most skeptical about the early detection initiative, could be convinced by the scientific findings offered in the SERRI team presentations on the benefits of the program. Improved outcomes have reinforced the value of the program and have enhanced acceptance among physicians.

1.5.1   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 challenging, but with a level of complexity that could be grasped by trainees. Nurses appreciated the content of online training, which gave them 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.

1.5.2   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 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 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 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."

1.5.3   Training of Nurse Assistants

Nurse assistants and technicians were trained across the four facilities we visited by second level responders, who had previously received special training from the SERRI staff. 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 doesn't rise to the level of early sepsis.

1.5.4   Staffing

The SERRI team demonstrated that different staffing models can be used to successfully implement the SERRI interventions 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.

1.6   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.

1.6.1   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 are now more likely to communicate a 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 Responder, Houston Methodist

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."

The SERRI team recognized the importance of having a pharmaceutical team able to 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 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. Now, 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.

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 grant, 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.

1.6.2   Better Health

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.

Participants at all four institutions we visited 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 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.

> The proportion of patients discharging with lower stages of sepsis has increased. Mortality is trending down.
>
> *– SERRI Program Staff*

A SERRI program staffer noted they have seen a reduction in sepsis related mortality at Houston Methodist, and patients being discharged with a lower stage of sepsis than prior to the SERRI program. 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. 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. 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*

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.

1.6.3   Lower Cost

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). 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. In addition, early detection may mean that some patients are coded/paid in a lower acuity DRG (e.g., sepsis rather than septic shock), which reduces 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.

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.

1.6.4   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.

1.6.5   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.

SERRI program staff also noted that a significant success has been the general empowerment of nurses who one staffer noted over the last twenty five years have 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.

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. 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 assistants 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 wasn't 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 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, second level responders 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 second level responders 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.

1.7   Context

In each interview and focus group during the 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.

1.7.1   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.

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.

Communication

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 important messaging that nurses are a part of the care team and not in competition with physicians. 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.

> 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*

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.

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, both ACHs were seeking to add more sepsis nurses to the staff to broaden the reach of the program.

1.7.2   Sustainability

The SERRI leadership reported that Houston Methodist intends to continue the program after the end of the grant. 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 grant, 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. It's the intention of Kindred to further enhance its infrastructure by building its own simulation lab for SERRI training following the conclusion of the grant.

A key component to the sustainability of the SERRI program 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 expansion to other settings.

1.7.3   ScaleUp and Spread

The SERRI program is likely to spread beyond those facilities participating in the HCIA grant program. At the time of our visit, staff at Kindred and the program office reported that Kindred Healthcare intends to implement SERRI in its other hospitals in the region and then, nationally. Program staff reported that HCA plans to launch the program in additional hospitals.

1.8   Suggested Improvements and Next Steps

Some suggested improvements were raised by staff at Houston Methodist, San Jacinto facilities, 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 necessarily trained in the program and often are unaware of the details of how the SERRI program works and the benefits of the program. Nurses from observation units, who often float to over units when 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. San Jacinto ACH may also need more second level responders, since there is only one nurse who serves as the sepsis expert for the entire acute hospital and the partner SNF and rehabilitation center.

Next Steps

In follow-up interviews planned for 2015, several topics will be revisited and new issues explored, as the HCIA funding nears completion. Topics to explore include:

- *Nurse Assistant role*: At each institution, nursing assistants play an important role in collecting the vital signs necessary to assess sepsis risk. There was not an opportunity to meet with nursing assistants and it would be valuable to learn of the nursing assistant's perspective of the program and the training they received.

- *Health and Cost Outcomes*: Program staff discussed the first wave of data needed for completing outcomes analyses. In the coming months, program staff will have a better sense of the health and cost outcomes from the first year of implementation.

- *Status of electronic tool rollout at facilities still utilizing paper forms*: Program staff noted that facilities such as Select and St. Joseph SNF are in the process of developing electronic system to field the SERRI tool in electronic form.

- *Modifying the screening tool for post-acute settings*: In skilled nursing and long term care sites, the white blood cell count is less likely to be populated than in acute care settings, because post-acute care facilities generally rely on external clinical laboratories. The SERRI team has begun educating staff at post-acute institutions to monitor patients with SERRI scores of 2 and to follow up with second level responders for a SERRI score of 3—rather than waiting for laboratory confirmation. Assessment of the impact of this change will be valuable.

2. Quantitative Analyses

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode spending. For Methodist Sepsis patients whose program intervention began in a skilled nursing facility, rehabilitation facility or LTCH, we present the following core measure:

- Admission (transfers) from SNF or LTCH to the hospital, restricted to patients whose program intervention began in the SNF/LTCH

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, restricted to patients whose program intervention began in an acute care hospital. 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, restricted to patients whose program intervention began in an acute care hospital.

- Total Medicare spending for 60 days including the index admission and all spending for 60 days after discharge, restricted to patients whose program intervention began in an acute care hospital.

The Methodist Sepsis program also aims to reduce length of stay, and avoid complications for patients with sepsis, which in turn may reduce mortality. We therefore present results for the following additional measures:

- Length of stay (LOS)

- Inpatient mortality

- Total 30 day (including inpatient) mortality

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.

2.1 Defining Intervention and Comparison Groups

2.1.1 Registry information

The Methodist Sepsis program patient registry includes 10,868 patients hospitalized from April 8, 2013 through March 31, 2014. The patient-level registry contains all admission and discharge dates for a patient, including repeated admissions. Of the patients in the registry, 97 percent had Medicare HIC numbers and of these, 98 percent had Medicare FFS claims for their admissions.

The registry contains information for only the Methodist-affiliated facilities participating in the intervention: Houston Methodist, Houston Methodist Sugar Land, and Houston Methodist San Jacinto. Other participating hospitals that are not affiliated with Houston Methodist did not submit registry data. The hospitals missing from the registry include St. Joseph's Regional Health Center, HCA Bayshore/East,

and HCA RioGrande. Long term care hospitals (LTCHs) participating in the intervention did not supply information for the registry.

Methodist program staff also supplied the start date for each hospital's intervention period. Exhibit 4 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 4: Methodist Sepsis' Program Implementation Timeline

Facility	Go-live date	Fully Implemented date	Units and types of patients to be targeted	Est. % adult admissions eligible for intervention at full implementation (Source: Awardee)
Houston Methodist	Oct-12	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%

2.1.2   Selection Rules

Individual hospitals in this program appear to have used somewhat different patient selection criteria, and implemented the program on different hospital units/floors—the program did not appear to have been consistently implemented in all participating facilities—and we lack registry data for several hospitals and SNF and LTCH facilities. The program is implemented in general Medical-Surgical Units, ICUs, and emergency departments. The following revenue center codes 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: 0200, 0201, 0202, 0206, 0207, 0208, 0209

- Observation stays procedural codes: 99234, 99235, 99236

- Emergency Department revenue center codes: 045X

Every claim in the intervention hospitals during the time frame indicated by the patient registry and associated with one of the above revenue center codes was included in the analysis, for all participating hospitals.

2.1.3 Estimated Intervention Group

The Methodist Sepsis Screening program registry includes 10,868 patients. Using the rules above, we estimated that 14,822 patients were screened between the April 1, 2013 and March 31, 2014. All of the registry patients were captured using our criteria, and 4,133 patients are in the estimated intervention group but not in the registry.

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 5: Match Rates by Quarter and Aggregate

Methodist Sepsis								
	2012		2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):				2,717	2,609	2,813	2,729	10,868
Estimated based on Abt rules (N):				4,485	3,867	3,439	3,031	14,822
Match between Estimated and Registry (N):				2706	2603	2790	2590	10,689
Registry Patients, Not Captured by Abt rules (N):				11	6	23	139	179
Estimated by Abt rules, Not in Registry (N):				1779	1264	649	441	4,133
Estimated by Abt rules that are in Registry (%):				60%	67%	81%	85%	72%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

The match between the estimated group and the registry improved over time. Although data from the first quarter of the intervention yielded a match of 60 percent, the match for the most recent two quarters was 80% or better. It is possible that the registry was incomplete when the program was first implemented, and improved over time. The high match rate in recent quarters indicates that our selection criteria are sound and can be used to identify comparison and baseline groups.

Data from only the hospitals included in the registry are used in our impact analyses. The rules used to select intervention patients are applied to hospitals that were not present in the registry as well, and we assume that all LTCH and SNF patients in participating facilities received the intervention.

2.2 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
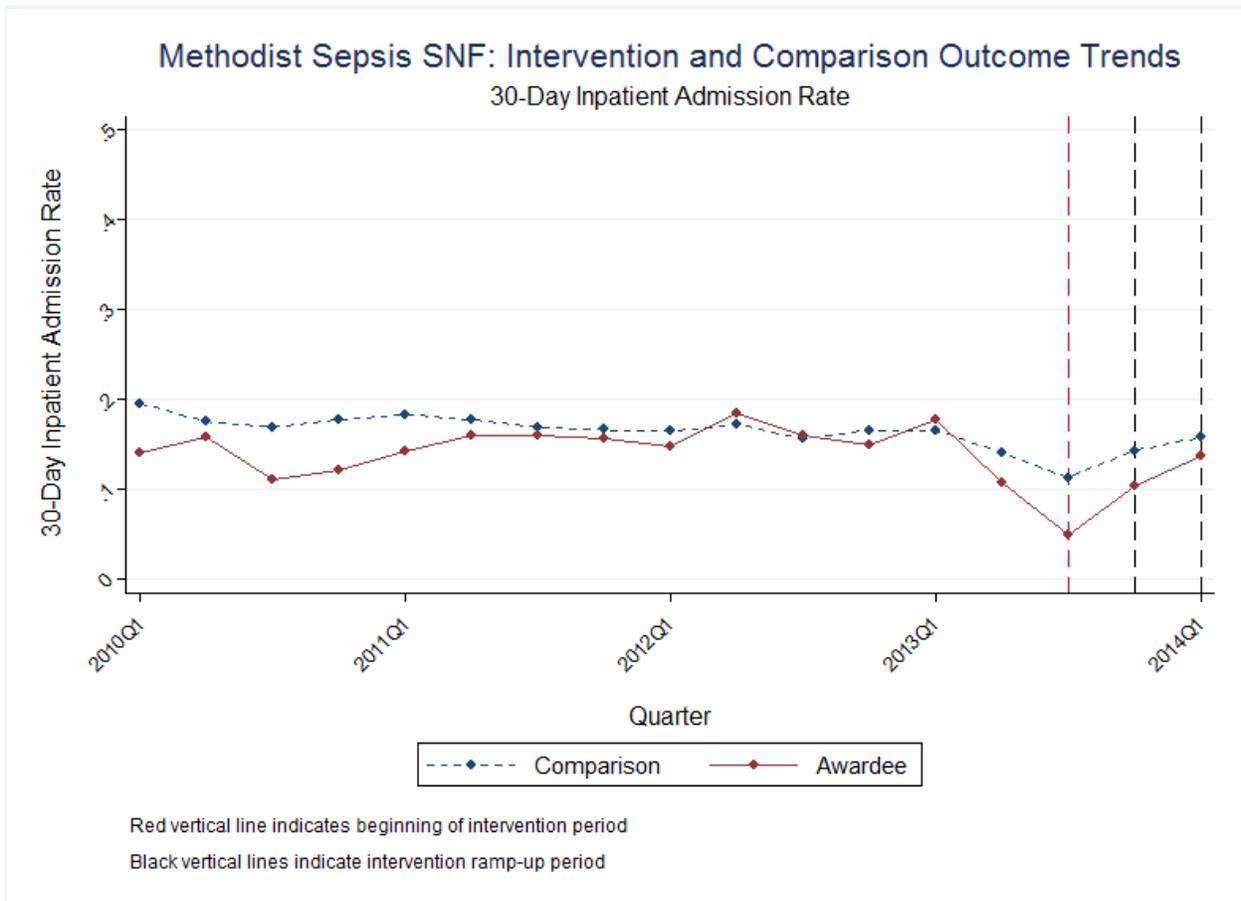
show discharges followed within 30 days by a readmission, and followed within 30 days by an ED visit, as well as Medicare spending for a 60 day episode starting the inpatient admission.

2.2.1 Hospital Admissions – LTPAC Patients Only

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 6 below reflects only the patients who first received the program intervention while in a skilled nursing facility, rehabilitation facility, or an 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 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). The intervention and comparison groups were different in the first quarters of the baseline period, converged for more than a year, but are not as similar now in the intervention period. No clear pattern of program impact is emerging.

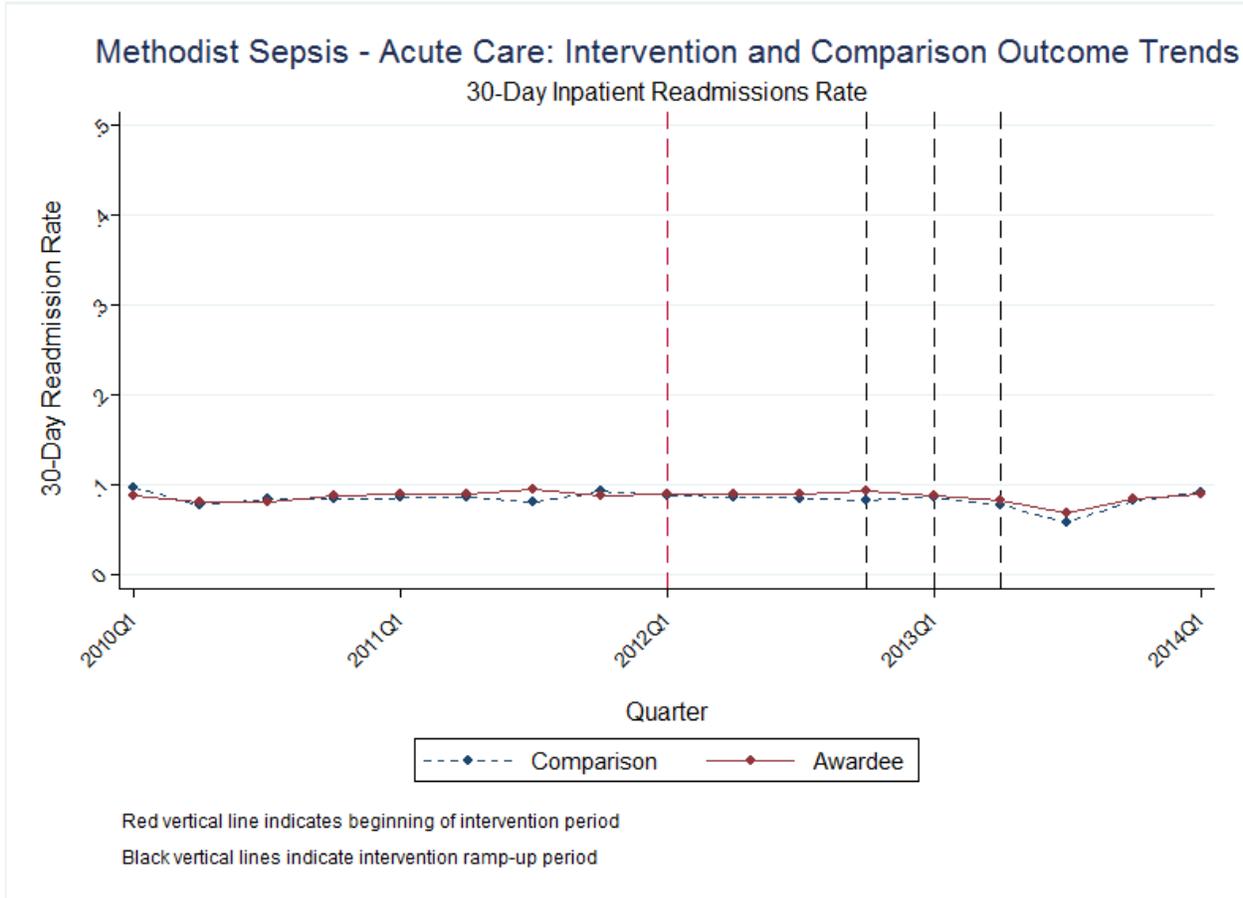**Exhibit 6: Hospital Admissions – LTPAC Patients Only**

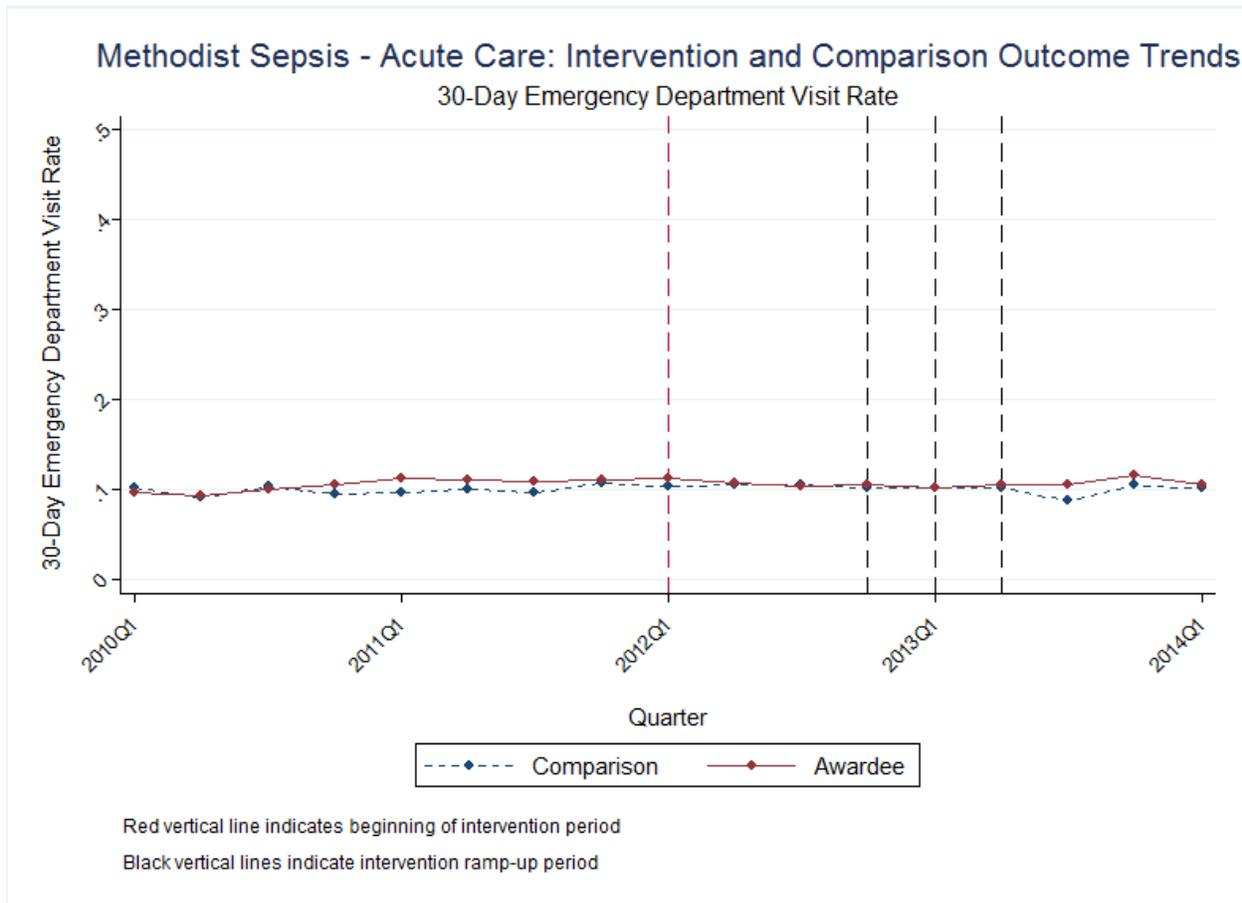Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2 Readmissions - Acute Care Patients Only

Exhibit 7 (hospital discharges followed within 30 days by a readmission) shows that the intervention and comparison sites were quite similar in the baseline period and remain so in the intervention period. This graph is restricted to patients whose program intervention began in an acute care hospital. 58% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15–30.

Exhibit 7: Readmissions - Acute Care Patients Only

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3 30-Day Post-Discharge ED Visits – Acute Care Patients Only

Exhibit 8 (hospital discharges followed within 30 days by an ED visit) again shows that intervention and comparison facilities were similar in the baseline period and remain so in the intervention period. This graph is restricted to patients whose program intervention began in an acute care hospital.

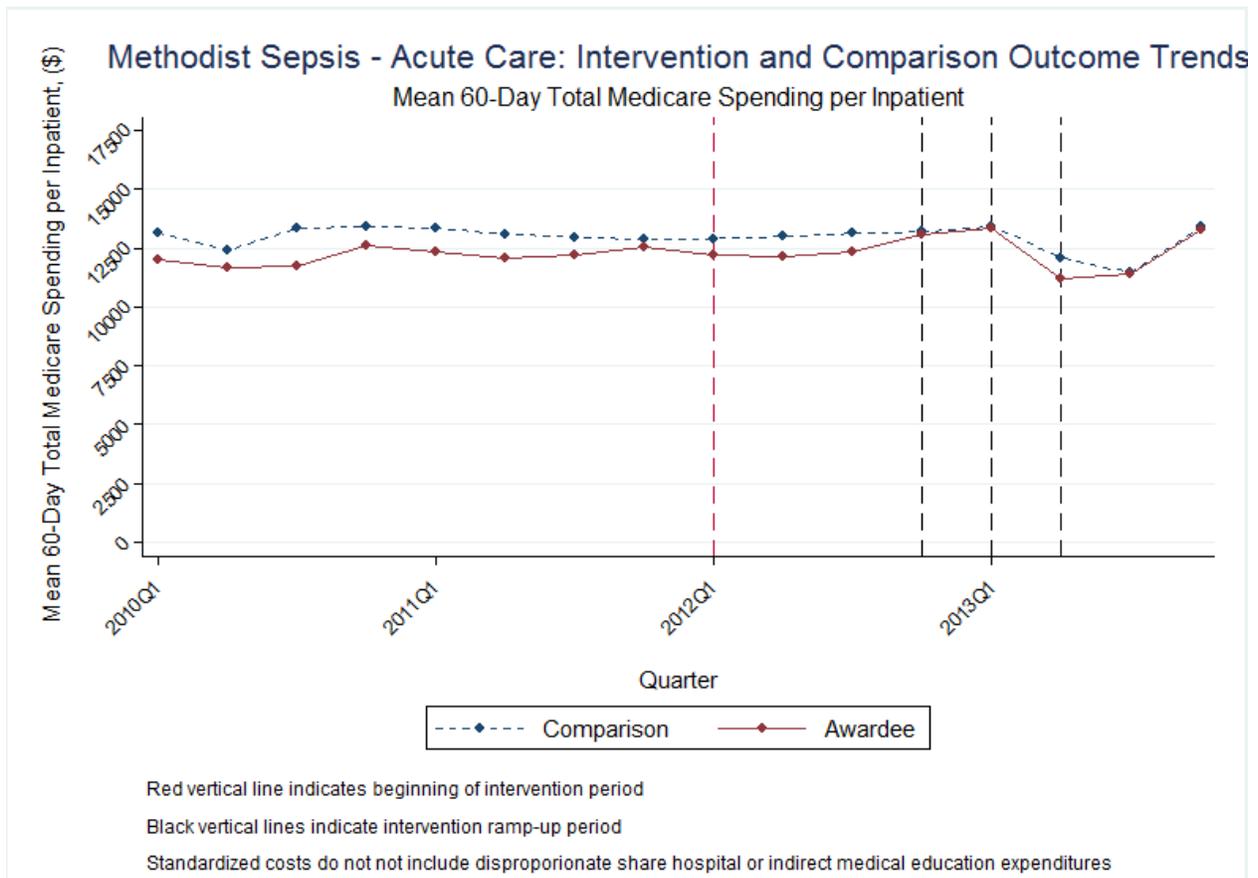**Exhibit 8: 30-Day Post-Discharge ED Visits – Acute Care Patients Only**

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.4 Medicare Episode Spending – Acute Care Patients Only

Exhibit 9 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days, for patients whose program intervention began in an acute care hospital. It shows a consistent difference between intervention and comparison sites in the baseline period, indicating that the best comparison group we were able to form was somewhat different from the intervention group. The most recent two quarters show a slight drop in both groups followed by a return to prior levels. 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 9: Medicare Episode Spending – Acute Care Patients Only

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

A DD regression analysis was conducted for the Methodist Sepsis program, for the acute care hospital patients only. We pooled data from participating facilities and did not conduct facility-specific analyses, because none are large enough yet to give us the power to detect change with reasonable confidence.

The dependent variable is the average total Medicare cost per episode from discharge to 60 days post-discharge. The model includes controls for patient age, squared age, gender, race, HCC score in year of treatment, eligibility for Medicaid at any time during observation period (2010–2014), as well as indicators for quarter of the year in which the episode occurred. An indicator is also included for individuals with missing HCC scores. Exhibit 10 presents the results; standard errors (in parentheses) are clustered at the individual and facility level.

OLS regression estimates for the Methodist Sepsis program fail to indicate any significant relationship between the intervention and Medicare episode during the 30 days starting with the index admission. Although there was an average reduction in post-discharge cost of roughly $170 per patient, this represents a change of less than 2% compared to the pre-intervention average among Sepsis Awardee facilities, and the standard error of the estimate is too large to reject the null hypothesis that the intervention had no effect on average Medicare episode spending.

Exhibit 10: Effect of Intervention on Mean 60-day Post-Discharge Medicare Costs

| Methodist Sepsis (pooled across hospitals)	
Intervention Effect	-169.65
	(613.82)

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

Source: Abt Associates, October 2014.

2.2.5   Medicare Spending – LTPAC Patients Only

A sizeable portion of the intervention population is exposed to the sepsis screening program while in an LTCH or nursing home.

Exhibit 11 shows the Medicare 60 day episode spending after admission for the LTPAC portion of the Methodist Sepsis intervention. The intervention population had higher spending than the comparison group throughout the baseline and intervention period and there is no clear evidence that spending for intervention patients is lower following program implementation.

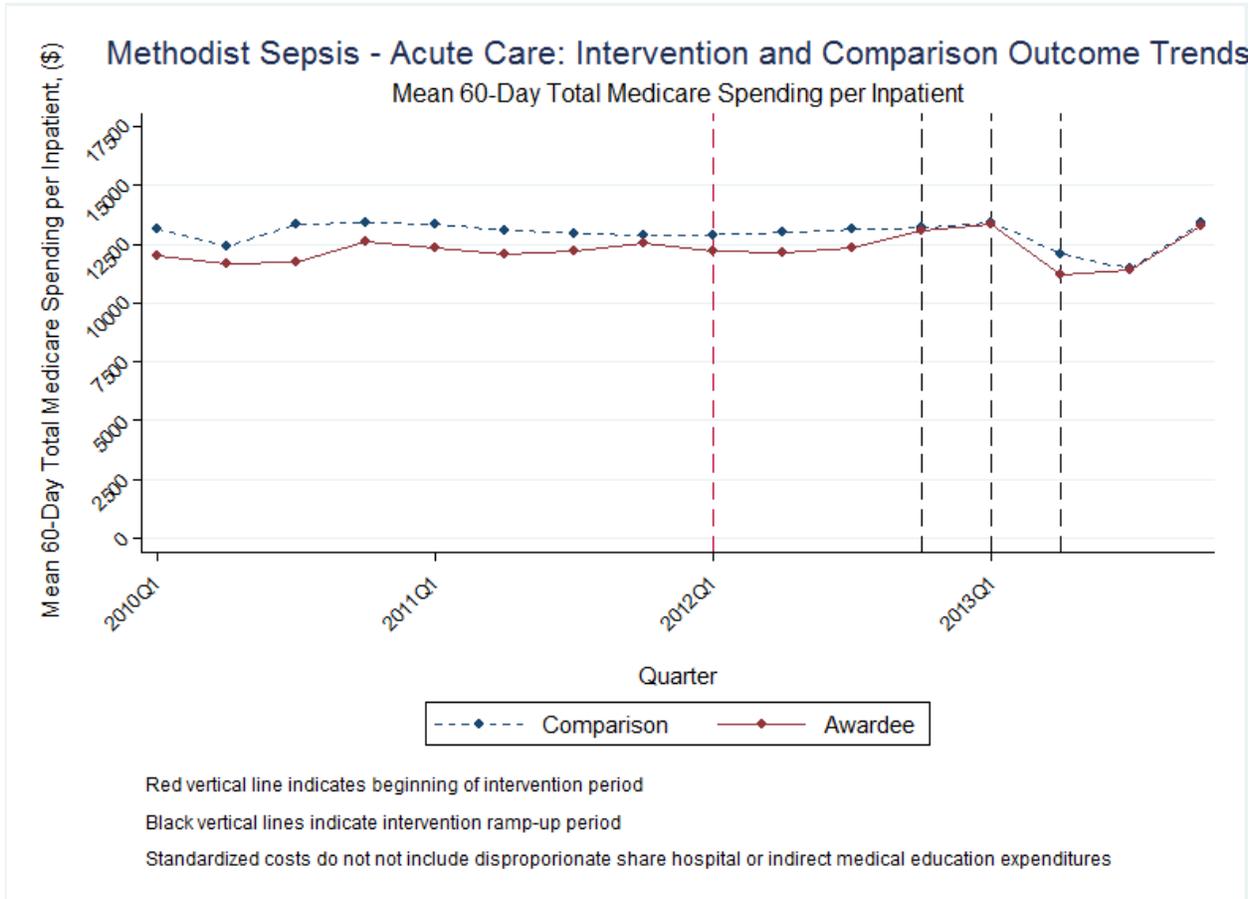**Exhibit 11: Medicare Episode Spending – LTPAC Patients Only**
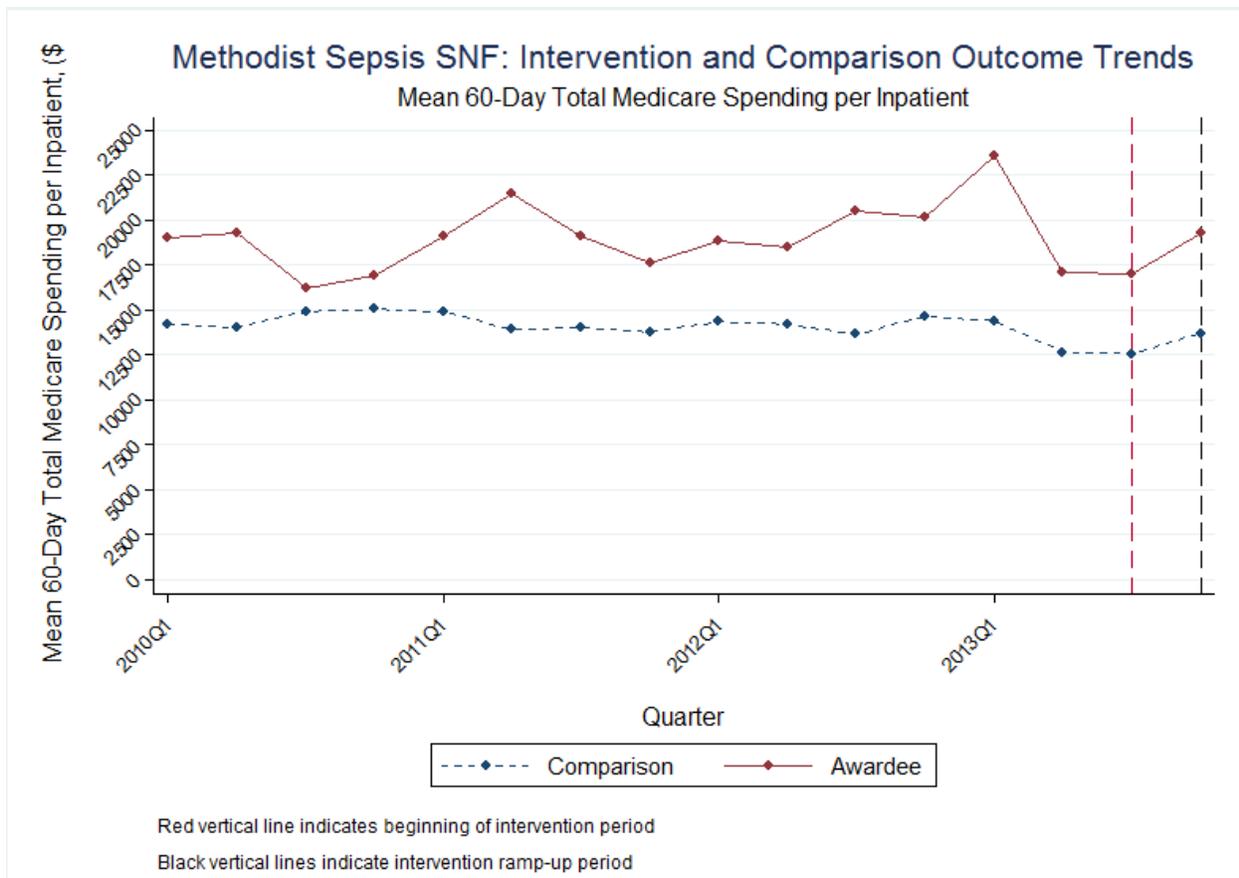
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

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

The Methodist Sepsis program aims to identify sepsis earlier and prevent its progression to severe sepsis. Many patients are screened to identify the few with sepsis, and as a result we would not necessarily expect to see changes in LOS.

Exhibit 12 (length of stay following index admission) shows a decline in LOS for both intervention and comparison groups during the intervention period, with a slightly greater decline in the intervention group; both groups returned to the higher previous levels in the most recent quarter.

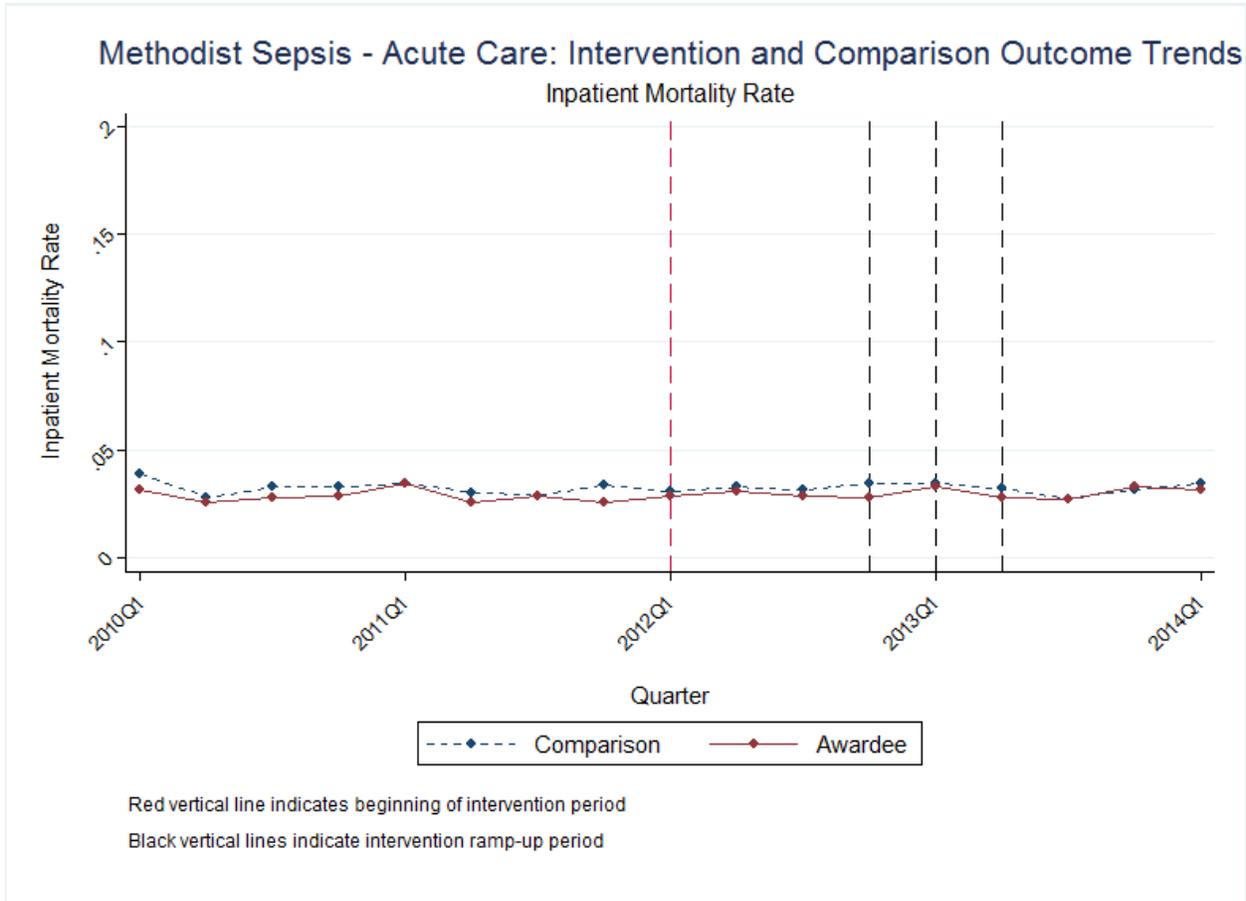**Exhibit 12: Index Admission Inpatient LOS**

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.7 Index Admission Inpatient and 30-Day Mortality – Acute Care Patients Only

Exhibit 13a (inpatient mortality following an index admission) shows no evidence of an impact of the program on inpatient mortality.
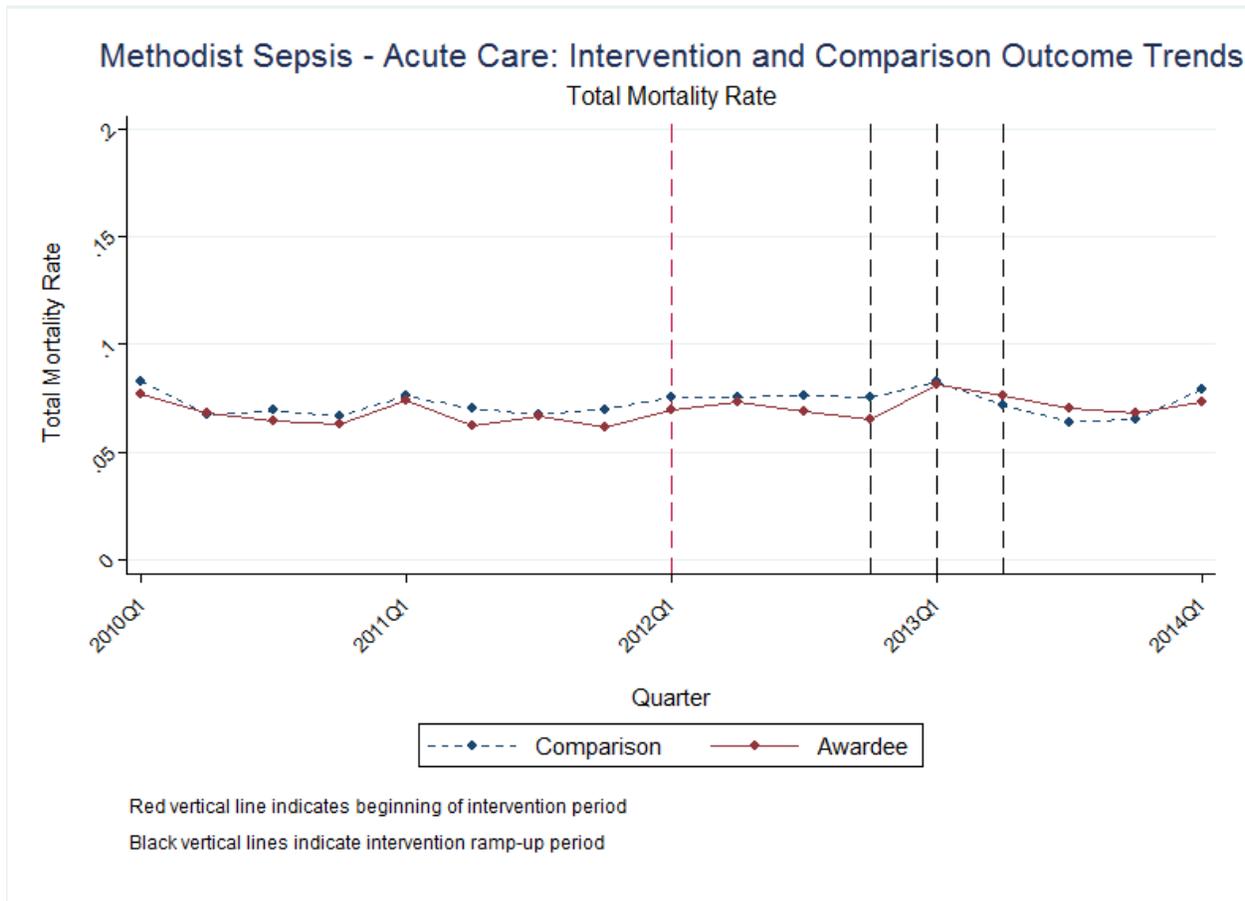
Exhibit 13a: Index Admission Inpatient Mortality

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 13b shows the total mortality (inpatient and the 30 days following the end of the index admission). There is no difference between intervention and comparison groups, nor any impact of the intervention.

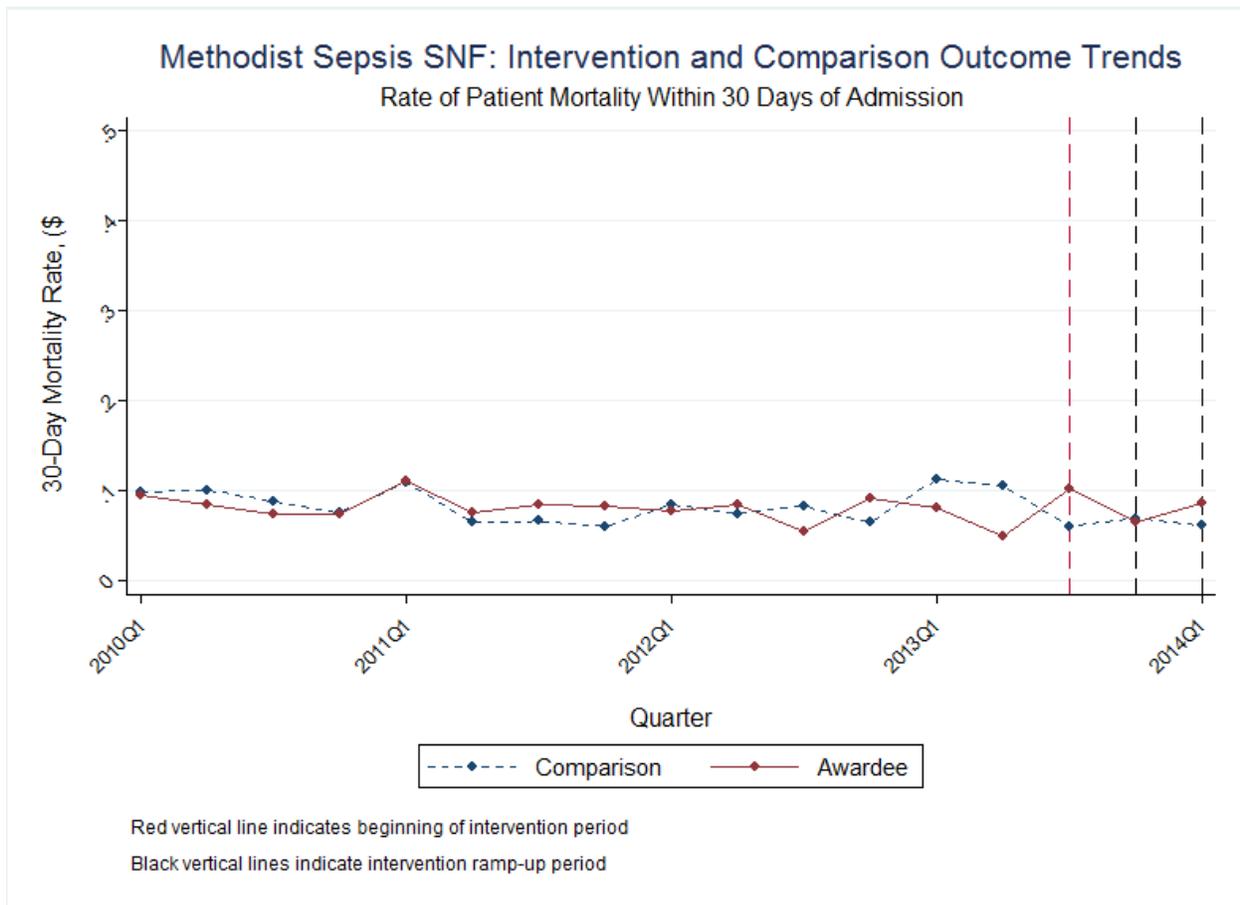**Exhibit 13b: 30 day Mortality (including Index admission)**

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.8 Mortality – LTPAC Patients Only

We also examined mortality for the patients who first encountered the screening program in LTPAC facilities, and a comparison group of similar patients. Again, the episode reported here is from admission to the LTPAC facility, which could have occurred weeks or months prior to program implementation. We assume that all intervention patients who died received at least some days of program screening prior to death.

Exhibit 14 shows the 30-day mortality rate following an admission to LTPAC and the graph shows little difference between intervention and comparison groups before or during the intervention and no evidence of program impact.

Exhibit 14: Episode Mortality – LTPAC Patients Only

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change.

Conclusions

- Imperfect match: many patients were included as intervention that were not in the registry and many patients were screened (and in the registry) who are at no risk for sepsis; both of these factors bias estimated effects toward zero.

- In the LTPAC population, hospital admissions trended lower in the intervention group over time.

- In the acute care population, there was no evidence of a utilization trend and no significant effect on Medicare spending.

Appendix B8: Mt. Sinai

GEDI WISE: Geriatric Emergency Department Innovations in Care through Workforce, Informatics, and Structural Enhancements

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, 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 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.

1. Qualitative Analyses: Case Study

1.1   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, how the programs are funded, specific program components, and processes for implementation. For example, at Mt. Sinai, the Geri-ED is smaller than at 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 the GEDI-WISE services within the Geri-ED. In this case study report, we describe in detail two of the three sites that have implemented the program (Mt. Sinai and SJH), and highlight differences and similarities across these two sites. We did not visit the third site, at Northwestern Hospital in Chicago.

1.2   Case Study Methods

Abt researchers conducted a case study of the GEDI-WISE program from June 10 through 12, 2014. Three staff collected qualitative data: a senior Abt researcher, a mid-level Abt researcher and a researcher from Telligen (the team). 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. For the purposes of this case study report, we describe services available through the GEDI-WISE program to any older patient throughout the ED as "GEDI-WISE program services." However, as noted above, at Mt. Sinai some of the GEDI-WISE services are only provided within the structural Geri-ED; we refer to these services as "Geri-ED services."

Exhibit 1 summarizes the number and type of individuals who participated in either individual interviews or focus groups.

Exhibit 1. Professional Backgrounds of Interviewees and Focus Group Participants

	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	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	4	1	2

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. At the end of the case study, all notes were finalized, integrated across the note-takers, and reviewed for accuracy by the team's senior researcher. Coding and analysis of the data were conducted using the qualitative data software NVivo. An initial baseline codebook was developed, and nodes and subnodes were identified a priori for this initial codebook based upon the standard evaluation interview guides. Three people participated in the coding of interview notes, one of whom was the senior team member who led the case study. To enhance inter-rater reliability, three interviews were coded by multiple people on the team and a coding meeting was held to discuss any differences in coding. The team added new nodes as necessary and revised the original codebook. After consensus was reached on coding, the rest of the interviews and focus groups were divided among the coding team. Throughout the coding process, the senior person who participated in the case study checked for consistency across coders, and systematically reviewed and corrected any discrepancies.

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 project components. For

example, the node reports were stratified across Mt. Sinai and SJH in order to describe the components of the program unique to these two sites. 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.

1.3   History of the Program 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 funds cover a significant increase in staffing for older patient ED care, including 22 fulltime equivalent employees: 12 clinical positions, 2 physicians and 8 administrative/data positions.

1.3.1   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) not critically ill (e.g., not at high risk for heart failure); 2) ambulatory before presenting in the ED; and 3) no evidence of delirium, with good mentation (e.g., they know their name and the date). All elders 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). If a patient fails one of the three criteria, then he or she is not eligible for admission to the Geri-ED.

1.3.2   Primary Program Components

The primary program components of the Mt. Sinai GEDI-WISE program include the following:

Structural Components and Enhancements

The Mt. Sinai 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.

Multidisciplinary Care Coordination

The GEDI-WISE program supports a robust staff dedicated to coordination of care. Interdisciplinary rounds are held at least 3 to 4 times a week in addition to the usual ED rounds that occur at discharge. 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 then 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 consults for elders 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 elders. 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.

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. And a third pilot project funded through other means links palliative care services to the ED. High risk patients are 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.

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: ECOG performance status scale, the Katz Activities of Daily Living scale, Instrumental Activities of Daily Living scale, PHQ-9 depression screen, 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 elders (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% 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 presence of a 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. One example is that the CAB suggested physicians could 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 Mt. Sinai, all ED staff (Geri-ED and main ED) receive a two-hour interactive lecture about communicating with older patients in the ED. In addition, ongoing training consists of periodic didactic training for nurses and ED physicians and intensive training workshops for the GEDI-WISE teams. The GEDI-WISE pharmacists were trained in a geriatric pharmacy program and received certification. The dedicated GEDI-WISE workforce also receives on the job education and training on geriatric-care protocols, particularly through the rounding process led by the geriatrician. As the program continues to mature, the training protocols are also evolving and becoming more refined, as discussed in more detail in Section 2.1.1.

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 determine if they should be admitted to the Geri-ED. 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.

- 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.

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 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 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 information tracked 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.

1.3.3   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) Geri-ED physician coverage is between 11 AM and 7 PM, and night care is provided only in the main ED; 3) very sick patients and those in acute medical crisis stay in the main ED; and 4) 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 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 process during rounds is also different in the two EDs. In addition to discharge rounds, in the Geri-ED, they 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 physical therapy services. Although all services (including interdisciplinary rounds) are available to older patients in both the Geri-ED and the main ED, the intensity of services can 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.

> 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.
>
> – *Geri-ED Nurse*

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 with 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 lots of responsibilities/tasks at once and focusing on the immediate problem first, and is better suited to 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 site visit, the Abt team observed dramatic differences between the two ED spaces, with the main ED extremely packed with beds lined up close together and no privacy. Staff described how older patients do not like to ask for help, and in the main ED, when everyone is busy, they often do not reach out for assistance. This phenomenon can lead to problems, such as not asking to go to the bathroom and sitting in waste for a long time. Nurses described how they used to play a game of "Tetris" when placing older patients in main ED, in an attempt to maximize patient privacy.

Patients have more privacy in the Geri-ED. Staff keep their voices down and try to make the patient comfortable by keeping conversations private. Staff are also 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 ED mean that patients do not spend long periods of time waiting 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 psychological condition that occurs when an older adult becomes confused, restless, or agitated in the evening while the sun is setting. Patients often request to be sent to the Geri-ED instead of the main ED.

1.4   History of GEDI-WISE at St. Joseph's Hospital

1.4.1   History of the Program at St. Joseph's Hospital

The GEDI-WISE program at SJH was in development for some years before the HCIA 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 elders, 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, lower cost are the an 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 to the hospital).

Because the GEDI-WISE program at SJH was well established before 2012, the HCIA award 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 internal hospital funds. 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.

1.4.2   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.

1.4.3   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 Nurses Improving Care for Healthsystem Elders (NICHE) training, which is an evidence-based training to improve care for older patients. In addition, each takes a structured 4-hour training every year.

Informatics-Enhanced Clinical Communication and Patient Monitoring

In addition to the regular EMR that is 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.

1.4.4 Differences between the Geri-ED and Main ED

As mentioned above, there are not many structural differences between the Geri-ED and the main ED at SJH. Older patients are given priority during intake and triaged more quickly into the Geri-ED, compared to younger patients who may wait longer in the main ED. As at the Mt. Sinai Geri-ED, the SJH GEDI-WISE staff view the Geri-ED as friendlier for patients and staff. One

> The best staff are in the Geri-ED; they are more compassionate, and the staff is well supported.
>
> *– Geri-ED Nurse*

interviewee described a unique sense of family among the Geri-ED staff, and a unified focus on taking care of older patients. The personality type of those employed in the Geri-ED is one of patience and collegiality.

1.5   Program Implementation

The implementation process for the GEDI-WISE program at both Mt. Sinai and SJH was very smooth according to stakeholders interviewed during the case study. At both hospitals, 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.

At Mt. Sinai, a number of challenges to program roll-out were described. As mentioned above and in Section 1.3.2, 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 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, 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, and that 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 physical therapy consults was also a challenge. There was a learning process for staff in the ED regarding what services a physical therapist can offer in a 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.

1.6   Workforce Development

At Mt. Sinai and SJH, the GEDI-WISE program hired new staff and also re-assigned existing ED staff. However, as noted in the previous section, in some cases the types of staff vary across the two 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. 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. Similarly, the training of new staff and process of implementation differed between the two sites.

1.6.1   Training

The GEDI-WISE training varies between the two hospitals. 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 on-the-job training. For example, at Mt. Sinai, the daily rounding process is an ongoing

component of training on 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 clinicians and other ED staff to ask questions about a patient's home setting, lifestyle, and ADLs, and to focus on safe transitions from ED to home.

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. The leadership team is reevaluating training needs for new staff coming into the program. So, for example, the first nurse practitioner did not receive specific training, while the newly hired second nurse practitioner had a more formal orientation. 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.

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 a16 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.

1.6.2　Impact on Workload

In both settings, the personnel described how having better staff ratios and a multi-disciplinary team decreases the stress, particularly for the nurses compared with working in the main ED. At Mt. Sinai, staff mentioned how 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 the workflow, as the social worker can collect the information while the patient is waiting for other medical tests to be completed. At SJH, the nurses mentioned that the social worker enables them to focus on the clinical component and not worry about interacting directly with the family.

1.7　Implementation Experience

1.7.1　Communication

At both Mt. Sinai and SJH, 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.

Mechanisms for Communication 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.
>
> *–ED Nurse*

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 1.2.3, 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 really understands what their next steps should be after returning home. They share the results of these assessments to the GEDI-WISE team to inform follow-up care.

Mechanisms for Communication at SJH

Although the same multi-disciplinary 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's 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.

1.7.2   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 HCIA funds. GEDI-WISE leadership organizes monthly cross-site calls for all GEDI-WISE staff, 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. Informally, e-mails are exchanged between sites to share ideas about 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.

1.7.3   Adaptation and Trialability of Intervention Components

Trialability and Adaptability

Across Mt. Sinai and SJH the GEDI-WISE program is 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. For example, at Mt. Sinai, the nurse practitioner role is 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 is 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.

GEDI-WISE supports a culture of innovation and creative ideas to improve ED care for elders and decrease unnecessary hospital admissions. Mt. Sinai has several pilots and they use the program as a laboratory for trying other innovative care management strategies. For example, the Transport Plus program is funded through CMMI carryforward funds as part of the GEDI-WISE program.

1.8   Implementation Effectiveness

Across the board, the staff described a positive impact of the GEDI-WISE program for patients, and confidence that the program is reducing unnecessary admissions and repeat ED visits for older adults. Staff from both hospitals 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.

At Mt. Sinai, the Transport Plus pilot has also been extremely popular and effective. According to data collected as part of this pilot project, 48 percent of patients report making changes based on the information they received about hazards in their home environment and 80 percent reported an improved understanding of their discharge instructions.

1.8.1   Better Care

Indicators of better care that were described by the GEDI-WISE team include decreases in polypharmacy, reduction in use of benzodiazepines, reports of pain reduction following visits from volunteers, and reports that patients with anxiety feel more settled after talking with volunteers and other GEDI-WISE staff. 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 grantee reports to CMS include the following (see Exhibit 2 below).

Exhibit 2: 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

1.8.2 Better Health

GEDI-WISE staff described how the improved transition mechanisms decrease 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 or home hospice without requiring a hospital admission, and also to arrange for home care seven days a week. Social workers are available on weekends and at night to help address social and home challenges and reduce unnecessary inpatient admissions.

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 isolated and have poor social supports and use the ED for social services and personal interaction. The ability to quickly and efficiently arrange for home health care for these isolated patients, and ensure that their home setting is safe, can reduce ED visits.

GEDI-WISE's Measurement Strategy

GEDI-WISE is tracking a number of outcome measures related to measurement of better health as noted in their reports to CMS (see Exhibit 3 below).

Exhibit 3: 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

1.8.3   Lower Cost

Although the GEDI-WISE program relies on increased resources, particularly staff, the team was unanimous in their belief that these increases are more than offset by decreased costs due to lower readmissions. 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 readmissions. Connecting patients with better community services 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 stabilized, preventing ED visits.

For patients who do get admitted to the hospital, a better understanding of the patient and coordination between ED and inpatient staff promotes 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 4 below).

Exhibit 4: 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.

1.8.4   Outcomes That Can Be Measured Using Claims

The utilization and outcomes listed above can all be measured using claims. At SJH, the greatest challenge will be in attributing impact to HCIA funding, since that Geri-ED has been operational for many years and the HCIA grant only funds a small portion of the operating costs. At Mt. Sinai, identification of an appropriate comparison group will be challenging because there are multiple transitional care programs offered throughout New York City and an Accountable Care Organization program (ACO) program in the Bronx. It may be difficult to ensure that none of the patients in the comparison group received services from other comparable case management programs. In addition, given the range of services provided through the GEDI-WISE program, it will be impossible to control for intensity of service provision. In the event that we detect an effect, we will not be able to distinguish which of the many components of the GEDI-WISE intervention are driving this effect.

1.8.5   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.

1.9   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.

1.9.1   Endogenous Factors at 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.

1.9.2   Endogenous Factors at 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.

1.9.3   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 effectively triage patients into the best aftercare arrangements and avoid preventable admissions and readmissions.

1.9.4   Staff Satisfaction

Extremely high levels of satisfaction were evident across all staff associated with the GEDI-WISE programs – 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 ideal quality of care. They attribute 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.

1.10   Program Fidelity and Sustainability

1.10.1   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 HCIA award, and funding for the other enhancements varies. Mt. Sinai receives about half the HCIA funds, and SJH receives only one eighth.[1]

SJH is a community hospital affiliated with the Catholic Church, 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 the research. 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.

Despite differences across the GEDI-WISE sites, the entire program has team meetings every month, which supports consistency across the programs. In addition, the grant supports yearly in-person meetings for all sites, as well as informal communications by e-mail. The approach taken by the GEDI-WISE leadership is that they are building a laboratory for Geri-EDs to continue to develop innovations and ideas to promote better ED care for older patients.

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[1]   Northwestern University Hospital, which is not included in this case study report, receives the remainder of the HCIA award funds.

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.

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 hospital systems 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. 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.

1.10.2 Sustainability

Both sites reported how much attention they have received 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 existing infrastructure than the Mt. Sinai program. Maintaining the current level of staffing in the Mt. Sinai Geri-ED after the HCIA grant ends will be a primary focus of the program leadership in the coming year.

Both sites described important programming that should continue after the grant ends. Mt. Sinai is considering other educational assessments that could be added to Transport Plus program such as medication inventory and emergency preparedness. Another potential outgrowth of this work is the use of telemedicine in this population to facilitate closer follow-ups in the home setting.

1.11 Conclusion and Next Steps

- The GEDI-wise 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, providing new resources such as physical therapy 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 that stem from the first phase of the program 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.

1.11.1 Next Steps

During the site visit, a number of suggestions for next steps in the GEDI-WISE program were raised that will be explored further in the next phase of evaluation interviews.

- More resources (social workers, nurse practitioners, and case managers) in the ED may allow initiation of patient's discharge planning even while they are being admitted to an inpatient unit. The possibility that these services will lead to shorter inpatient LOS is something the GEDI-WISE team intends to explore.

- At Mt. Sinai, the nurse practitioner role is continuing to evolve. The team wants to expand her role to leverage other clinical skills besides current use of just follow up and transitional care skills.

- There is interest from outside agencies and hospitals that want to try and replicate the Geri-ED model. It will be interesting to see how the experience of the HCIA-funded sites is shared with other hospitals over the coming year.

- The Transport Plus program has been very successful and may be expanded. The staff mentioned that medication inventory assessments could be added to Transport Plus program. It will be important to track the outcomes of this pilot and how it is further integrated into the GEDI-WISE program.

- Given that training protocols are still being developed at Mt. Sinai, we will follow-up on these developments with the next set of interviews.

2. Quantitative Analyses

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode 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

- For ED visits that do not result in a hospitalization, the rate of hospitalizations in the subsequent 30 days

- For ED visits that do not result in a hospitalization, the number of additional ED visits in the subsequent 30 days

We do not report readmissions, because this program is trying to reduce the absolute number of hospital visits/stays, not just whether there is one.

The Mt. Sinai program also has the potential to reduce mortality for patients who visit the ED and therefore present results for the following additional measure:

- Total 30 day mortality

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.

2.1 Defining Intervention and Comparison Groups

2.1.1 Registry Information

Mt. Sinai program staff provided registry data for three hospitals: Mt. Sinai, St. Joseph's, and Northwestern University, all of which are included in our analysis. The registry covered the period from October 1, 2012 to March 31, 2014. The registry for the fourth quarter of 2012 contained only data from St. Joseph's, while the first quarter of 2013 also included data from St. Joseph's and Mt. Sinai. By the second quarter of 2013, data from all three hospitals were in the registry.

The registry contained data on 58,417 patients who visited the EDs during the period specified above. Although the registry did not contain Medicare Health Insurance Claim (HIC) numbers for all patients, it did contain social security numbers for 19,945 patient admissions and we used these to develop inclusion/exclusion criteria. We first matched on HIC numbers, and for the remaining patients without a HIC number, we matched on Social Security Numbers. Using the two methods, we estimate that 10,658 unique patients were treated in the ED.

2.1.2 Selection Rules

The Mt. Sinai program treats Medicare patients in the Emergency Department (ED), some of whom are then admitted to the hospital as inpatients. To develop an estimated intervention group, we used both Medicare Part A (inpatient) and Part B (outpatient) claims to identify ED visits. Any claim associated with the below revenue center was included in the estimated intervention group.

- Emergency Department revenue center codes: 045X

2.1.3   Estimated Intervention Group

The Mt. Sinai registry included 10,658 patients with Medicare claims. We estimated that 23,067 patients were eligible for the intervention, based on patient age (aged 65 and older) and presence of an ED revenue code on the claim. Of the registry patients 42 (less than one percent) are not included in the estimated intervention group and 12,451 are included in the estimated intervention group but do not appear in the registry. Program staff explain that elements of the intervention are available throughout the three EDs, as well as in the specially-designated GEDI-WISE ED beds, and patients are exposed to intervention components throughout the ED.   The programs each of the three EDs offer, and the patients who could best benefit from the programs, differ in ways we cannot model using claims data. Our matching criteria for this report therefore combine older patients who were seen in the GEDI-WISEEDs and those that were seen in the main EDs of participating hospitals.

Exhibit 5: Match Rates by Quarter and Aggregate

Mt. Sinai								
	2012		2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):	1	1,575	1,568	2,580	1,860	1,604	1,470	10,658
Estimated based on Abt rules (N):	0	4,765	3,557	4,797	3,718	2,980	3,250	23,067
Match between Estimated and Registry (N):	0	1,567	1,565	2,571	1,849	1,599	1,465	10,616
Registry Patients, Not Captured by Abt rules (N):	1	8	3	9	11	5	5	42
Estimated by Abt rules, Not in Registry (N):	0	3,198	1,992	2,226	1,869	1,381	1,785	12,451
Estimated by Abt rules that are in Registry (%):	100%	33%	44%	54%	50%	54%	45%	46%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

The intervention group we are able to estimate is broader than the registry and more work is needed to better specify the intervention group. For example, some patients spend little time in the ED (e.g., trauma cases) and others are not appropriate for program interventions (e.g., patients actively dying). We would not expect such patients to be included in the registry. In future reports we will consider how to better match the patients in the registry, to exclude those who were not appropriate for program interventions.

Data from the three acute care hospitals are pooled in our analyses. In future reports we will explore the possibility of conducting site-level rather than pooled analyses, because the three hospitals have implemented distinctly different intervention components.

2.2   Core Measures: Results

### 2.2.1   ED Visits That Become Hospital Admissions

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.

One goal of the Mt. Sinai program is to avert hospitalizations for ED patients by addressing their care needs in the ED.

Exhibit 6 shows the ED visits from which the patient was eventually admitted to the inpatient hospital, with or without an observation period in the ED. There is no consistent pattern in either the intervention

or comparison group, but the intervention group's rate of admission from ED to the hospital was much lower than that of the comparison group, in both baseline and intervention periods. This difference may reflect underlying systematic differences between the two groups. For example, if these three hospitals have observation units, and many of the comparison group hospitals do not, the rate of ED-to-hospital admission would be reduced by moving some patients to observation units rather than admitting them to the hospital.

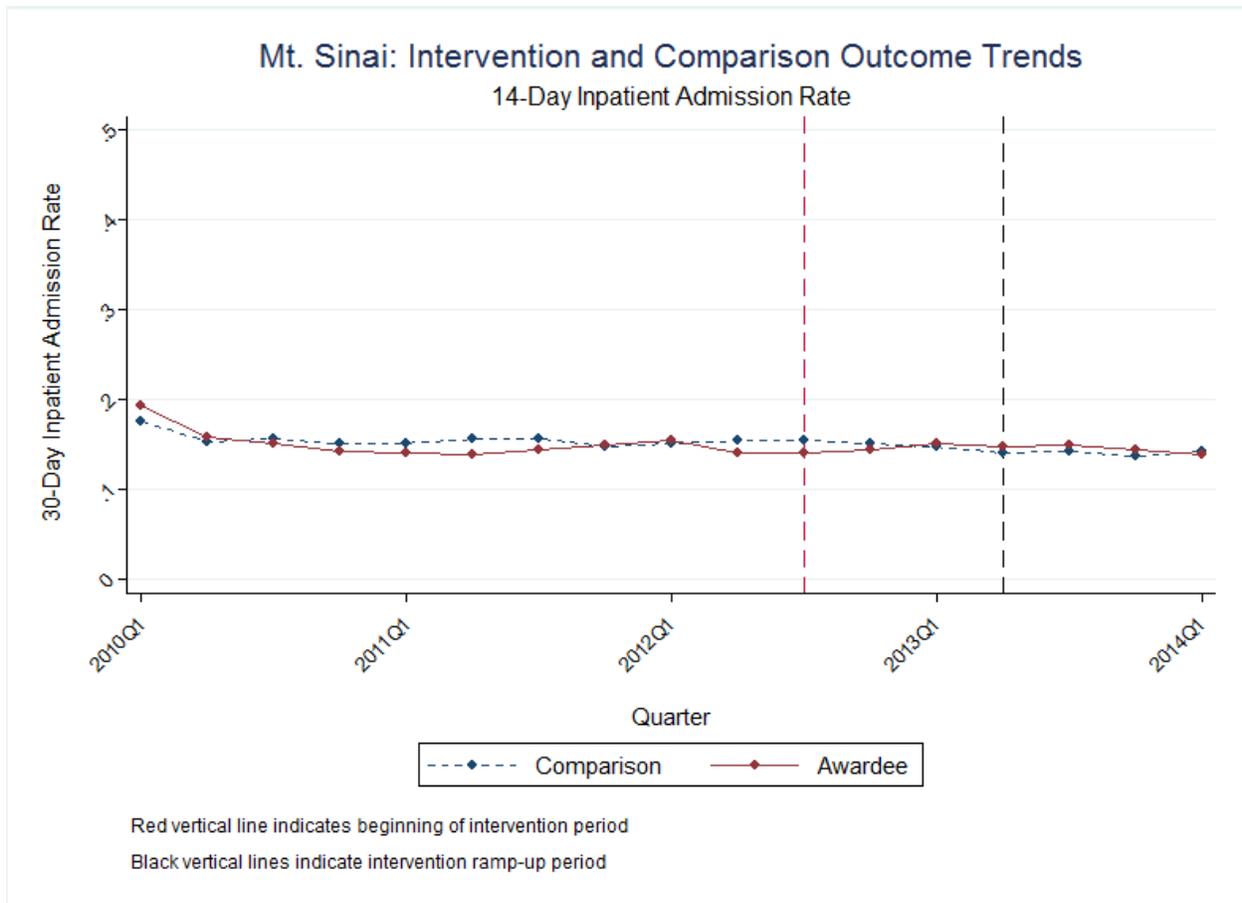**Exhibit 6: ED Visits That Become Hospital Admissions**
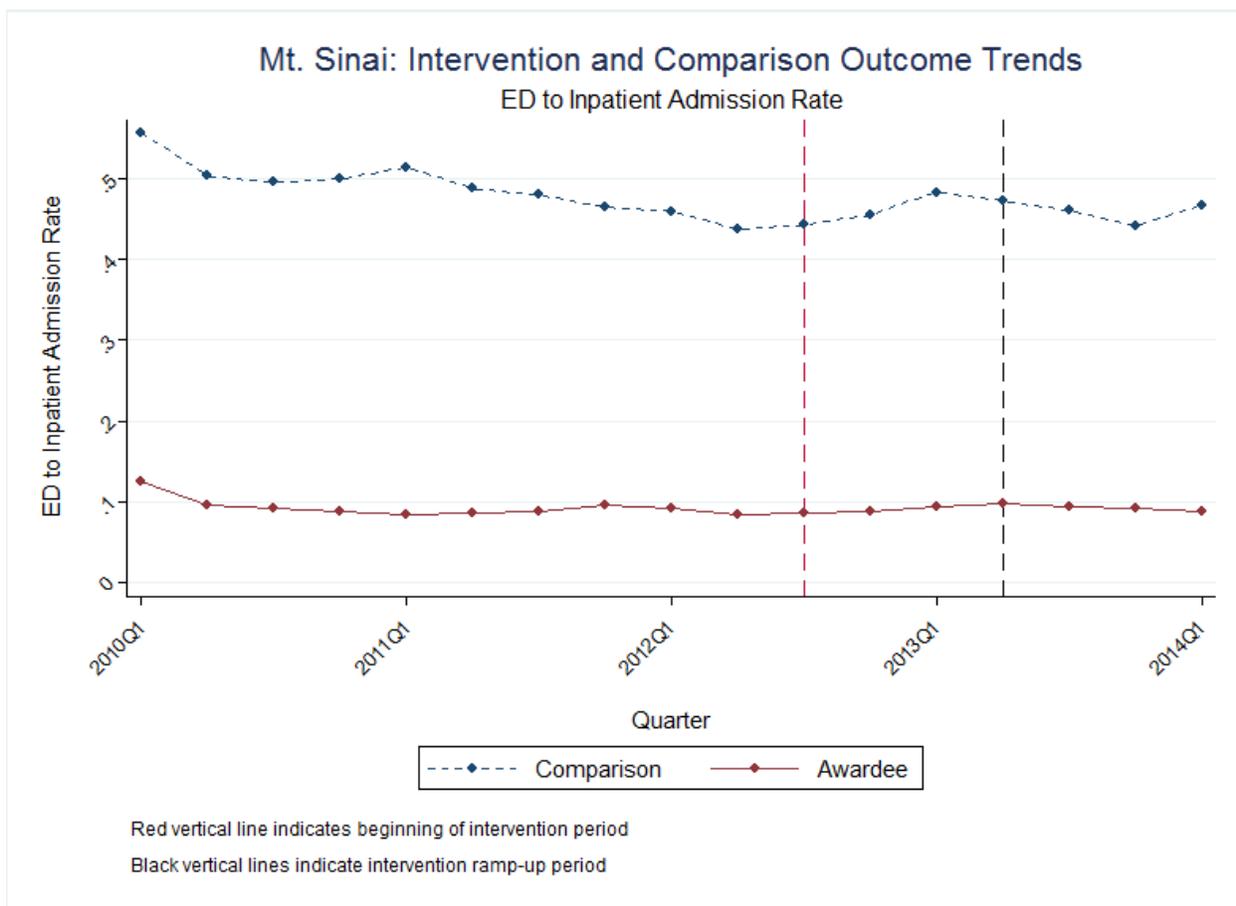
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2   Hospitalization (one or more) During 30 Days Following an Index ED Visit

Exhibit 7 shows ED visits where the patient was not hospitalized (i.e., was sent back to their home, assisted living or nursing home), and the percentage of these patients who had at least one hospitalization in the subsequent 30 days. The rates are nearly identical for the two groups and show little change over time. We conclude that patients in these three cities who visit the ED and return home are at a fairly low but steady risk for hospitalization in the subsequent month, and this general risk is unaffected by the intervention.

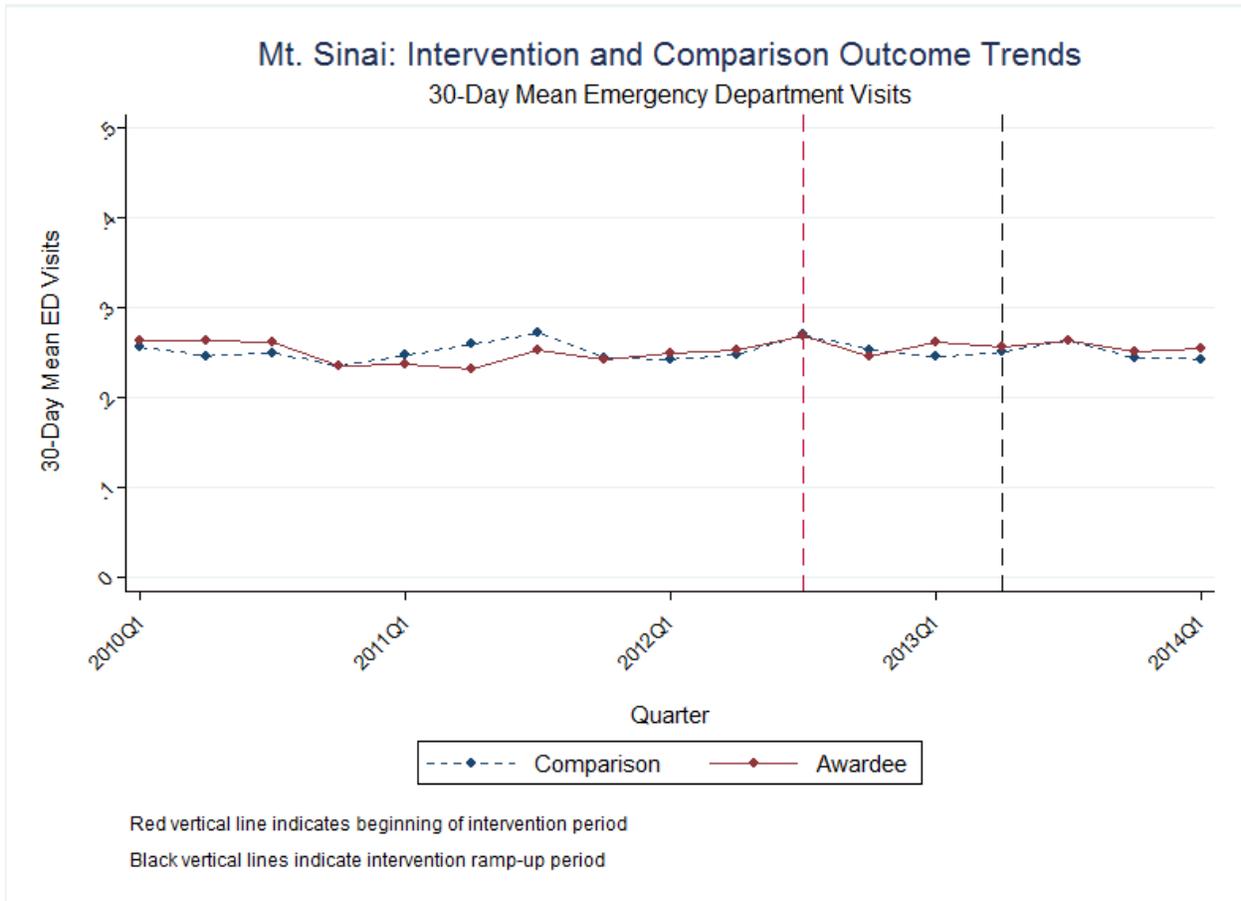**Exhibit 7: Hospitalization (one or more) During 30 Days After an Index ED Visit**

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3 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 of 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. Again, the two groups are very similar and there is no indication of change over time.

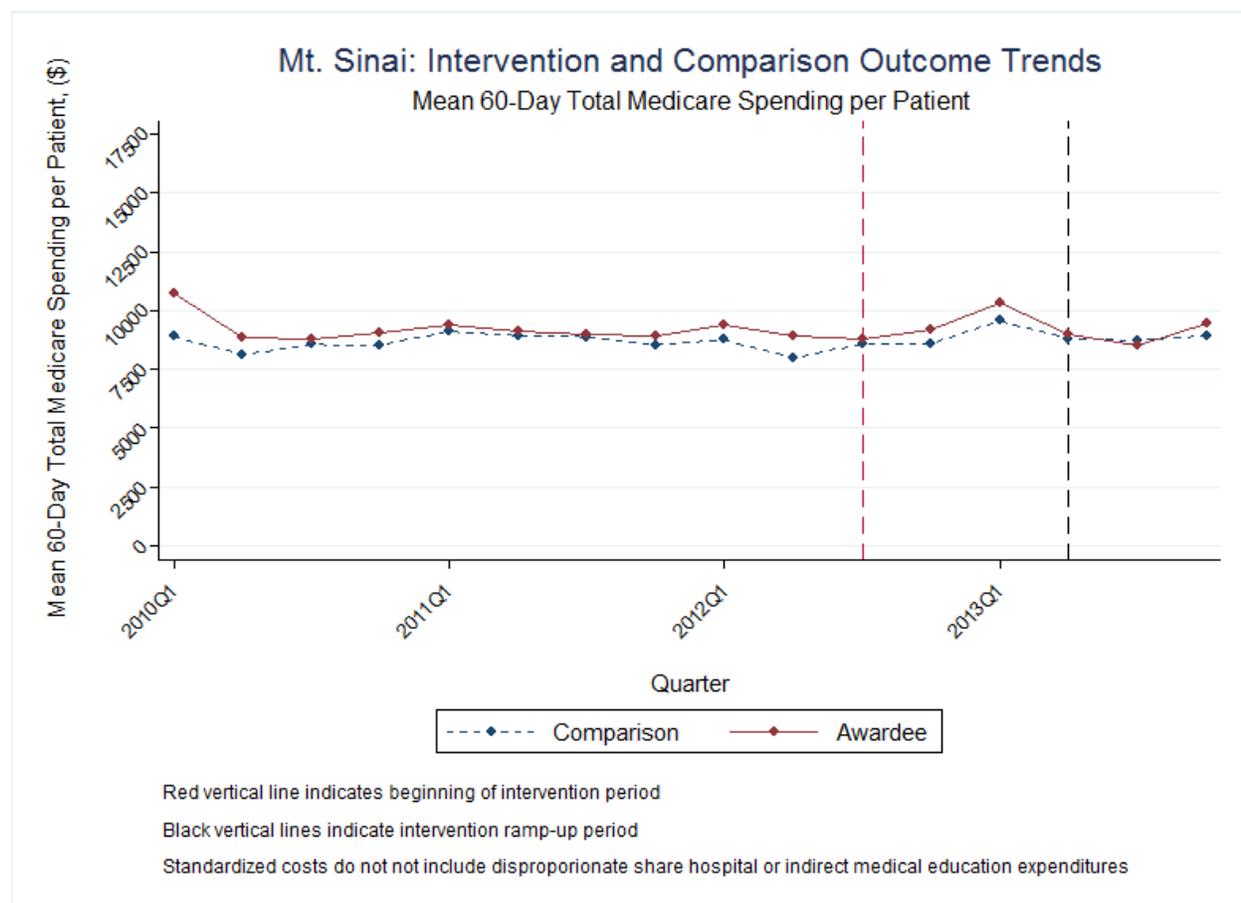**Exhibit 8: Average Number of ED Visits During 30 Days After an Index ED Visit**

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.4 Total Medicare Episode Spending During 60 Days After an Index ED Visit

Exhibit 9 reflects total Medicare spending during the 60 days following an index ED visit, whether or not the patient was hospitalized during the initial encounter. There is little evidence of change over time or between the two groups. 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 9: Total Medicare Episode Spending During 60 Days After an Index ED Visit

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

A DD regression analysis was conducted for the Mt. Sinai program. We pooled data from the three participating hospitals because none have sufficient volume of patients to be powered to detect a change with confidence. We did, however, include a facility indicator in the model because the three EDs offer quite different programs in terms of staff, services, and ED structural adaptations.

In this model the dependent variable is the average total Medicare cost per episode from discharge to 60 days post-discharge. The model includes controls for patient age, squared age, gender, race, HCC score in year of treatment, eligibility for Medicaid at any time during observation period (2010–2014), as well as indicators for quarter of the year in which the episode occurred. An indicator is also included for individuals with missing HCC scores. Exhibit 10 presents the results; standard errors (in parentheses) are clustered at the individual and facility level. Regression estimates for the Mt. Sinai program fail to indicate any significant correlation between the intervention and Medicare episode spending, among

patients treated in the emergency department. Despite a point estimate suggesting a $90 (or 1%) reduction in post-discharge cost per patient, the standard error of the estimate is too large to conclude that the effect of the intervention was different from zero.

Exhibit 10: Effect of Intervention on Mean 60-day Post-Discharge Medicare Costs

| Mt Sinai	
Pooled Intervention Effect: 3 hospitals	-93.78 (188.57)

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

Source: Abt Associates, October 2014.

2.2.5 30-Day Mortality

The Mt. Sinai program goals do not include reducing mortality, as deaths in this population (non-trauma) in the ED would likely be uncommon.

Exhibit 11 shows mortality during the 30 days after the first ED visit, and as expected there is little difference between intervention and comparison groups and no indication of an intervention effect.

Exhibit 11: 30 day Mortality (including Index admission)
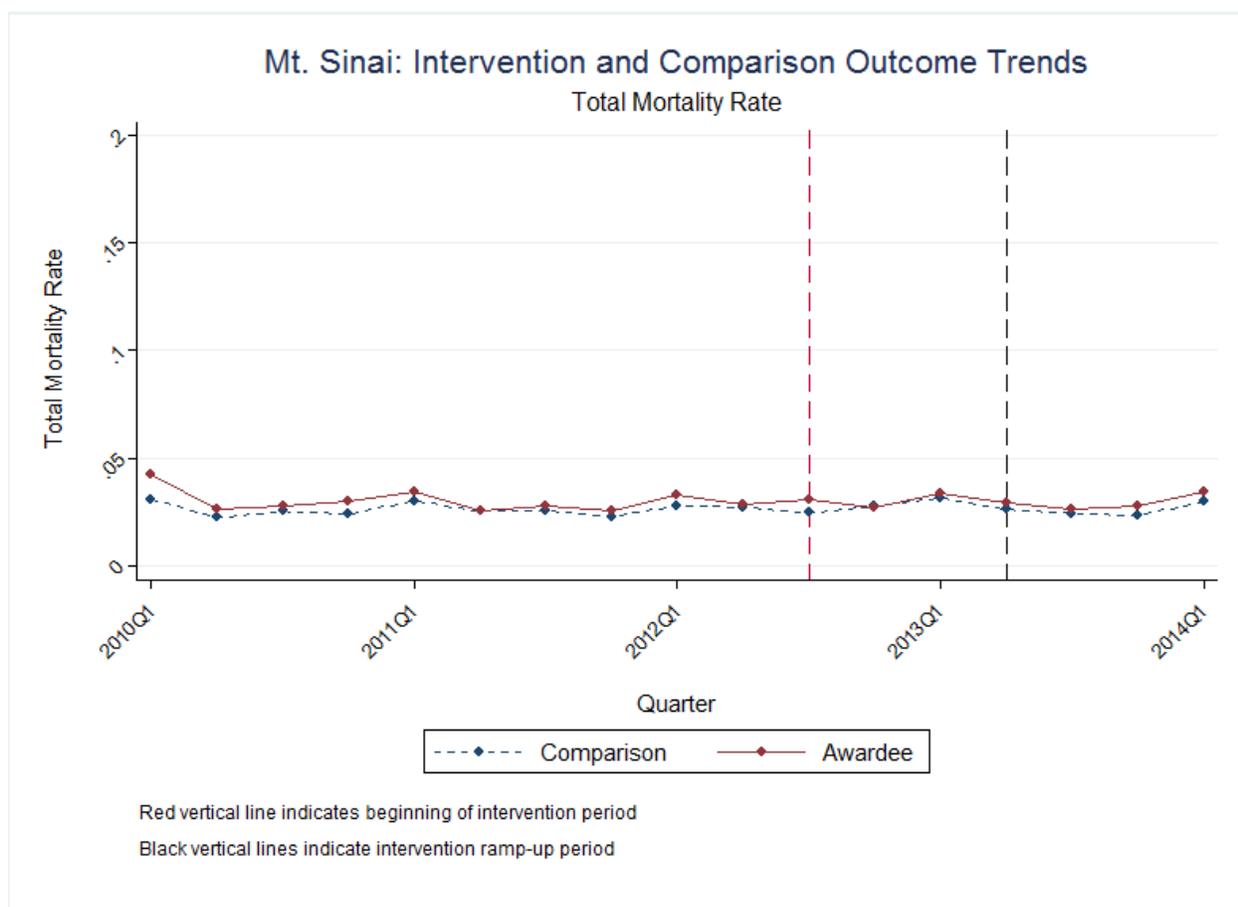
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change.

Conclusions

- Many older patients who visited the three study EDs were not in the registry. Although program staff assure us that all older patients visiting these EDs are exposed to intervention elements, more work is needed to better identify and exclude patients who were not appropriate for program interventions.

- ED-to-inpatient admissions were much lower in intervention group than in the comparison group in both the baseline and intervention periods. This may in part be because the St. Joseph's program predated the HCIA award and had already controlled ED return visits, diluting the impact at that study site and for the entire pooled analysis.

- DD analysis found no significant intervention effect on Medicare episode spending.

Appendix B9: St. Luke's Regional Medical Center eICU

INFORMATION NOT RELEASABLE TO THE PUBLIC: The information contained in this report is preliminary and may be used only for project management purposes. It must not be disseminated, distributed, or copied to persons unless they have been authorized by CMS to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

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, 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 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.

1. Qualitative Analyses: Case Study

1.1 Program Background

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 CAHs 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)	TBD
McCall (ED)	December 2013
Jerome (ED)	January 2014
Elmore (ED)	December 2013
Syringa (ED)*	TBD
Weiser (ED)	January 2014
West Valley Medical Center (ICU)	TBD (estimated summer 2014)

*Site not funded by the HCIA grant

1.2   Case Study Methods

The St. Luke's case study site visit was conducted on March 19 through 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.

Exhibit 2: Case Study Participants

	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

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). 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.

Coding and analysis of the data was conducted using the qualitative data software NVIVO. An initial baseline codebook was developed as the standard codebook for each site visit data collection. The nodes and subnodes were identified a priori for this initial codebook based upon the interview guides developed for the project. Three to four people participated on the coding team; each coding team included at least one person who participated in the site visit. To enhance inter-rater reliability, two to three interviews were coded by multiple people on the team and a coding meeting was held to discuss any differences in coding among team members. The team added new nodes as necessary and revised the base codebook. Once overall agreement was reached on coding, the rest of the interviews and focus groups were divided among the coding team. Throughout the coding period, the senior member of the team who participated in the site visit checked for consistency across the coders and systematically reviewed discrepancies.

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 St. Luke's Boise Medical Center interviewees with that of their peers in the Wood River

rural CAH. Once the NVivo results were generated, a detailed outline was shared among all members of the initial site visit team to ensure agreement on the key findings of the report.

1.3   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.[1] 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) 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.

1.3.1   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

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[1]   http://www.stlukesonline.org/about_us/facilities.php

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 has 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 unsuccessful; St. Luke's clinicians believe this was in part because the eICU physicians were not local, and local physicians did not accepted 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.

1.4   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 mid-2014.

1.4.1   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 will "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 will 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.

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 for whether results are available. 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 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.

> "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

Night Shift

In the past, one critical care physician covered multiple ICUs 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.

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.

1.4.2 Emergency Department Consultation

The eICU program offers consultations to CAH ED staff on an as-needed basis. This component of the program is just beginning and St. Luke's plans to expand it over time. We spoke with a physician and a nurse at St. Luke's Wood River CAH, who had used the program for an ED consultation twice in recent months. They explained that 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.

1.4.3 Long-Term Acute Care Hospital Monitoring

Although the program has not yet been implemented at any LTACHs, this may begin at one LTACH in 2014. 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.

1.4.4 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.

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.

Due to the absence of 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 enabling them to monitor more patients.

1.5   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.

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

> "There was some angst that the eICU would be "big brother" watching us do our jobs…but that quickly went away."
> – ICU Bedside Nurse

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 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.

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 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.

1.6   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.

1.6.1   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.

> "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

Improved Continuity and 24-Hour Care

Numerous participants reported better continuity of care for patients 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.

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

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 "go live" for all ICU patients and the survey is fielded again for one month, approximately three months after "go 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.

1.6.2   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)

1.6.3   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 are 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. While none of these savings will reduce costs for Medicare or Medicaid under DRG-based Inpatient Prospective Payment System, these cost reductions could be important in a shared savings or bundled payment context.

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

In the second year of the project, St. Luke's program staff will begin collecting data on total cost savings, benefit-cost ratios, and cost savings due to avoided hospital transfers. St. Luke's is also developing a methodology for measuring cost savings related to ICU days avoided through eICU monitoring. The eICU program's vendor software has a methodology for calculating cost savings based on severity-adjusted predicted versus actual ICU length of stay.

1.6.4   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.

1.6.5   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.

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.

> "There is variability within the ranks of [St. Luke's] intensivists, there is variability from site to site, variability from region to region…This [eICU] tool has given us the opportunity to see that variability and has spurred conversations about reliability and patient safety that could not have occurred before because we couldn't prove the variability was there."
>
> – eICU Physician

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.

1.7   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.

1.7.1   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. 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 physicians who work in the COR, 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.

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.

Despite all the lessons learned about relationship building and obtaining buy-in, the eICU physicians have not been successful in obtaining buy-in from St. Luke's neurologists and critical neurology patients are not monitored by the eICU. The eICU program plans to implement a telestroke component within the next few months, and originally intended to use local St. Luke's neurologists to provide this service. Because the local neurologists refused to participate, St. Luke's will contract with an external group of neurologists to provide telestroke consultations. It is not clear whether these distant physicians will provide oversight and care that local neurologists find acceptable.

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.

1.7.2   Staffing

Program administrators described several lessons learned related to staffing. First, to meet the timeline of the grant 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.

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.

1.7.3 Measurement & Self-Monitoring

One difficulty program staff reported with operating this multi-site program has been collecting standardized data from all of the facilities, whose 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 measure on an ongoing basis, as a prerequisite of their partnership with the eICU.

1.8 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.

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 grant funding from private sources, decreased costs to the health system, and increased reimbursement from payers for better outcomes as a result of the program.

At St. Luke's Wood River CAH, participants consistently emphasized that they have seen the value of the eICU program and would like to see it expanded to offer more services, such as psychiatry and pediatric monitoring and consultation. This attitude was not as prevalent in Boise, where program administration and eICU physicians frequently returned to the importance of relationship building and how long it takes to obtain buy-in from hospital leadership and staff for the program. The eICU

> "One lesson learned is that the program can get too big and the thing that is sacrificed are the relationships and buy-in…When you have numerous sites to develop relationships with and you can't do that effectively, our model might not work."
>
> – eICU Physician

physicians, particularly, were concerned that the program could get too big, leading to a loss of the personal relationships that they strongly feel have contributed to the success of the program.

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.

1.9   Conclusion and Next Steps

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 year, 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 was used just twice at St. Luke's Wood River thus far, when the local ED staff wanted to consult with a colleague about a complex patient and prior to emergency transport; 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.

1.9.1   Next Steps

In follow-up interviews planned for 2015, several topics will be revisited and new issues explored, as the HCIA funding nears completion. Topics to explore include:

- *The program's measurement and self-monitoring plan*: Program staff discussed several potential changes to their measurement and self-monitoring plans that may be implemented in the next year, including: fielding of a brief survey to CAH physicians and nurses involved in ED consultations; creating a methodology for calculating severity-adjusted savings to the health system; and improving the collection of standardized performance measures across all participating hospitals.

- *Staffing model in the COR*: Program staff discussed potential changes in their staffing model for the eICU program, to address the challenge of backfilling the positions of nurses and physicians who now work in the COR rather than at the bedside.

- *Status of the LTACH component*: The LTACH component of St. Luke's program is scheduled to begin in mid-2014, pending software upgrades at a local LTACH. If this component is successfully implemented, interviews with staff in that facility will be included in our 2015 case study follow-up.

2. Quantitative Analyses

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 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 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, which in turn may reduce mortality. We therefore present results for the following additional measures:

- Length of stay (LOS)

- Inpatient mortality

- Total 30 day (including inpatient) mortality

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.

2.1   Intervention and Comparison Groups

2.1.1   Registry Information

St. Luke's program staff provided patient registry information for four hospitals: Wood River, Boise Meridian, Boise Medical Center, and Magic Valley. This registry includes 3,899 observations corresponding to 3,059 unique Medicare beneficiaries. We analyzed data for the large medical centers: Boise Meridian, Boise Medical Center, and Magic Valley, which together had 3,058 total Medicare patients. Four registry patients from Wood River (a small critical access hospital) were excluded.

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.

2.1.2   Selection Rules

Participating hospitals implemented the program in some, but not necessarily all, of their ICUs. 5.7 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, 0201, 0202, 0206, 0207, 0208, 0209

- Coronary care unit revenue center codes: 021X

2.1.3   Estimated Intervention and Comparison Groups

The patient registry contains 1,554 Medicare patients. Using the revenue codes above, we estimated an intervention group of 1,493 patients. Two hundred and seventy-eight patients (18 percent of the registry) are included in the registry but not identified in our estimated intervention group; 217 patients are included in the estimated intervention group but are not in the registry. Eighty-five percent of the estimated group is composed of registry patients, which indicates that the rules we developed are sufficient to create comparison and baseline groups.

The St. Luke's eICU program is offered to several small critical access hospitals, in addition to the urban Boise medical centers. Data from all of the larger acute care hospitals are pooled in our analyses. The small critical access hospitals had only a handful of patients, and the intervention (ED consultation) differs from that in the larger hospitals. We therefore excluded the critical access hospitals from impact analyses. If the activity in critical access hospitals increases in the future, we may conduct a second, separate analysis of data pooled across these hospitals.

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:

St. Luke's								
	2012		2013				2014	
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Total
Registry Medicare Patients with Submitted Claim (N):			235	182	256	445	436	1,554
Estimated based on Abt rules (N):			335	184	232	403	339	1,493
Match between Estimated and Registry (N):			228	173	212	361	302	1,276
Registry Patients, Not Captured by Abt rules (N):			7	9	44	84	134	278
Estimated by Abt rules, Not in Registry (N):			107	11	20	42	37	217
Estimated by Abt rules that are in Registry (%):			68%	94%	91%	90%	89%	85%

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

The high overlap between the estimated and registry group indicates that our rules are sound and can be used to select appropriate comparison and baseline groups. Even pooling data from the larger hospitals in the St. Luke's program, the numbers are insufficient in a calendar quarter to support a statistically rigorous difference-in-differences analysis.

2.2 Core Measures: Results

2.2.1 Readmissions

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.

Exhibit 4 (hospital discharges followed within 30 days by a readmission) shows that the intervention and comparison sites were somewhat dissimilar in the baseline period, there was some volatility from one quarter to another for both intervention and comparison groups, and no clear pattern is emerging. 74% of these readmissions took place in the first 14 days after hospital discharge and the remainder during days 15–30.

Exhibit 4: Readmissions
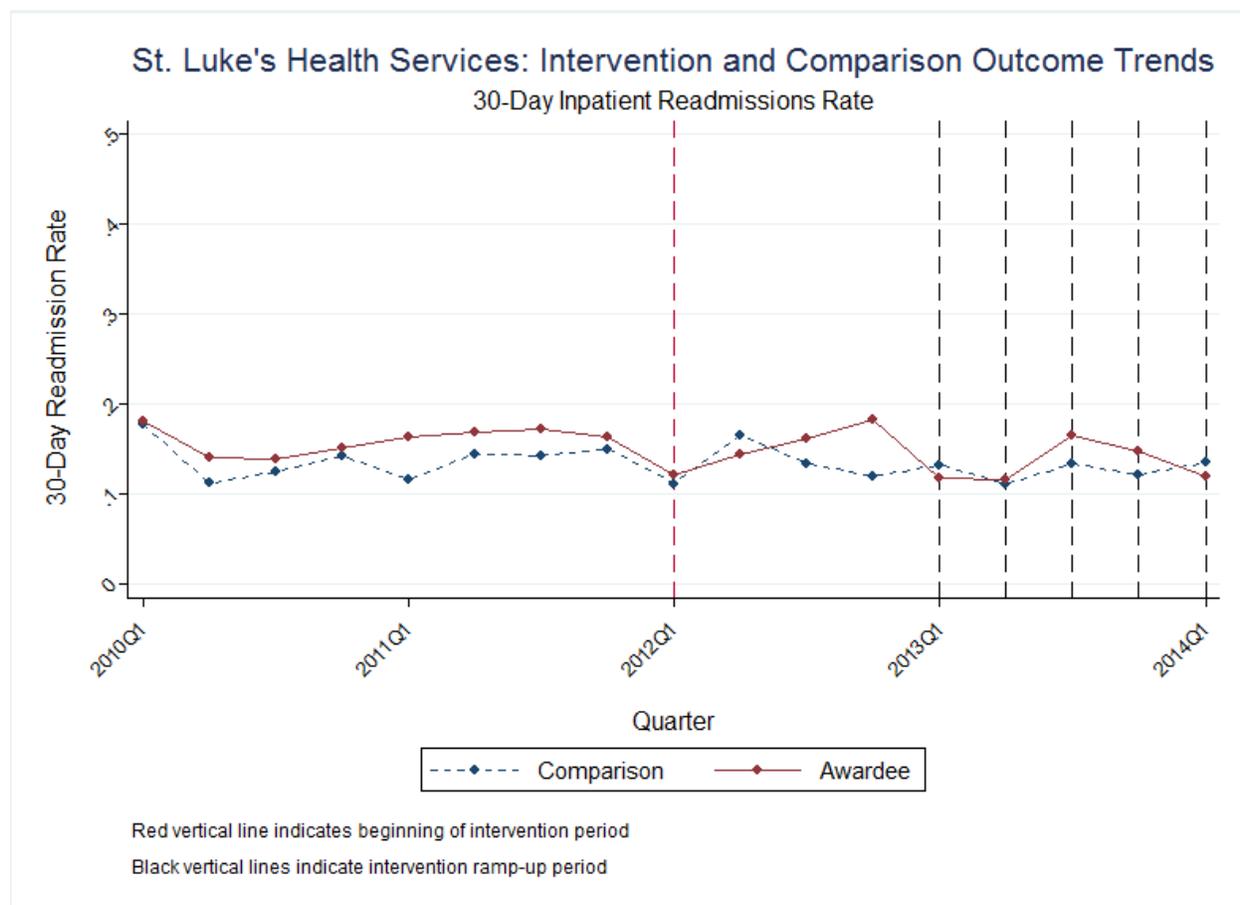
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2   Post-discharge ED Visits

Exhibit 5 (discharges followed within 30 days by an ED visit) also shows differences between the intervention and comparison sites in the baseline period, and volatility from one quarter to another in both groups, without a discernable trend.

Exhibit 5: Post-discharge ED Visits
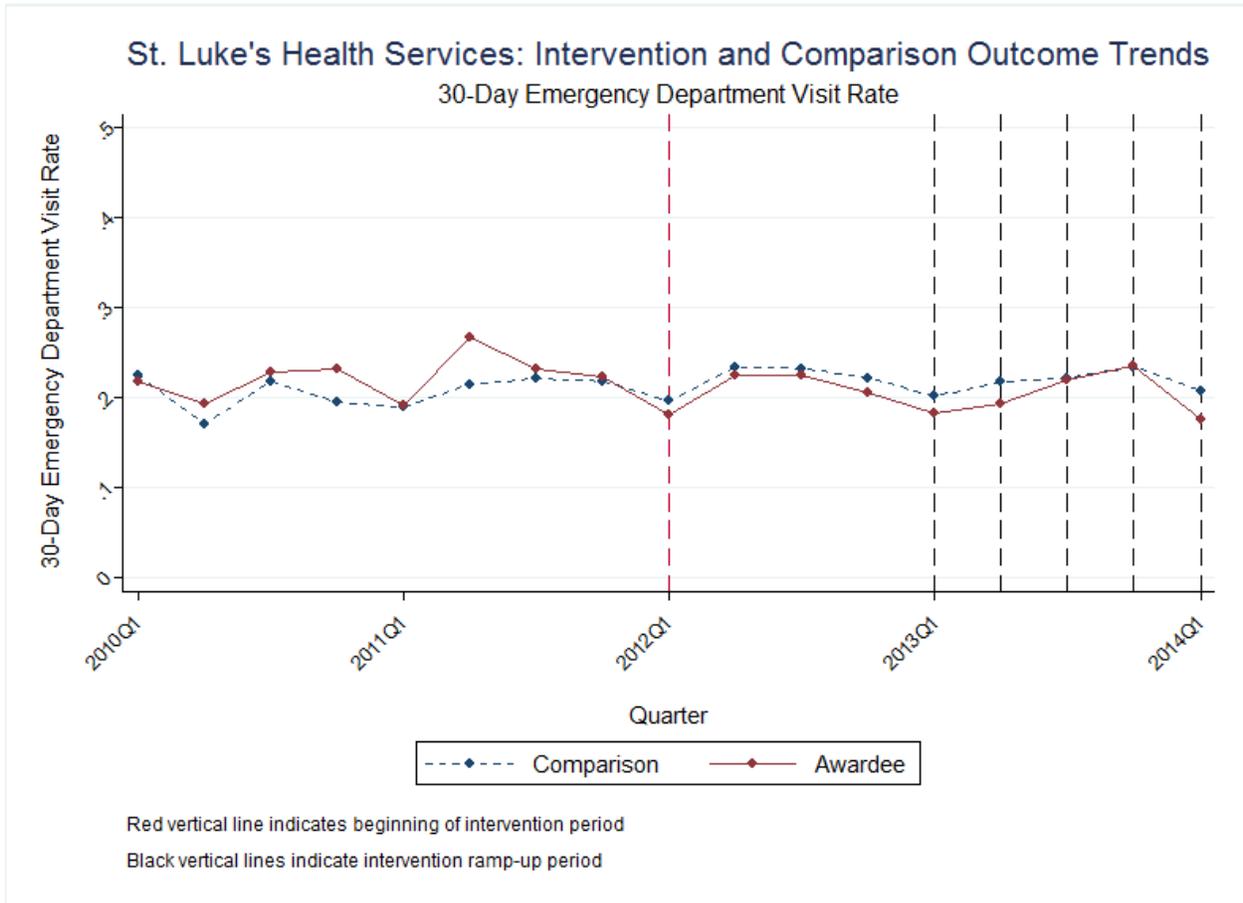
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3   Medicare Episode Spending

Exhibit 6 (60-day episode Medicare spending) includes the inpatient stay and all claims in the following 60 days. It shows a distinct difference between intervention and comparison facilities in the baseline and intervention periods, with costs for the intervention group being lower than those in the comparison group in almost every quarter. We conclude that the best comparison group we can create may be systematically different than the small intervention group, despite the close match described above. 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.

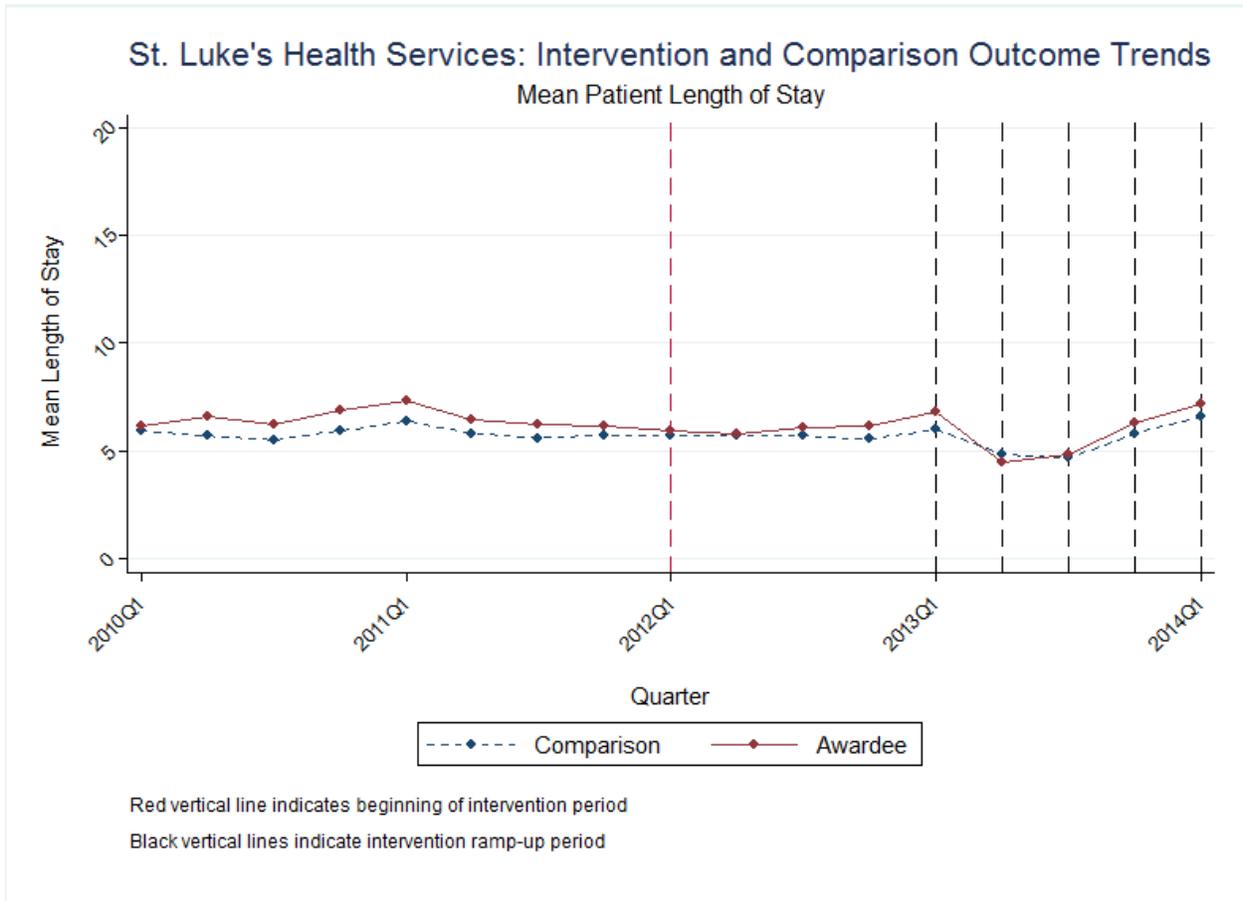**Exhibit 6: Medicare Episode Spending**
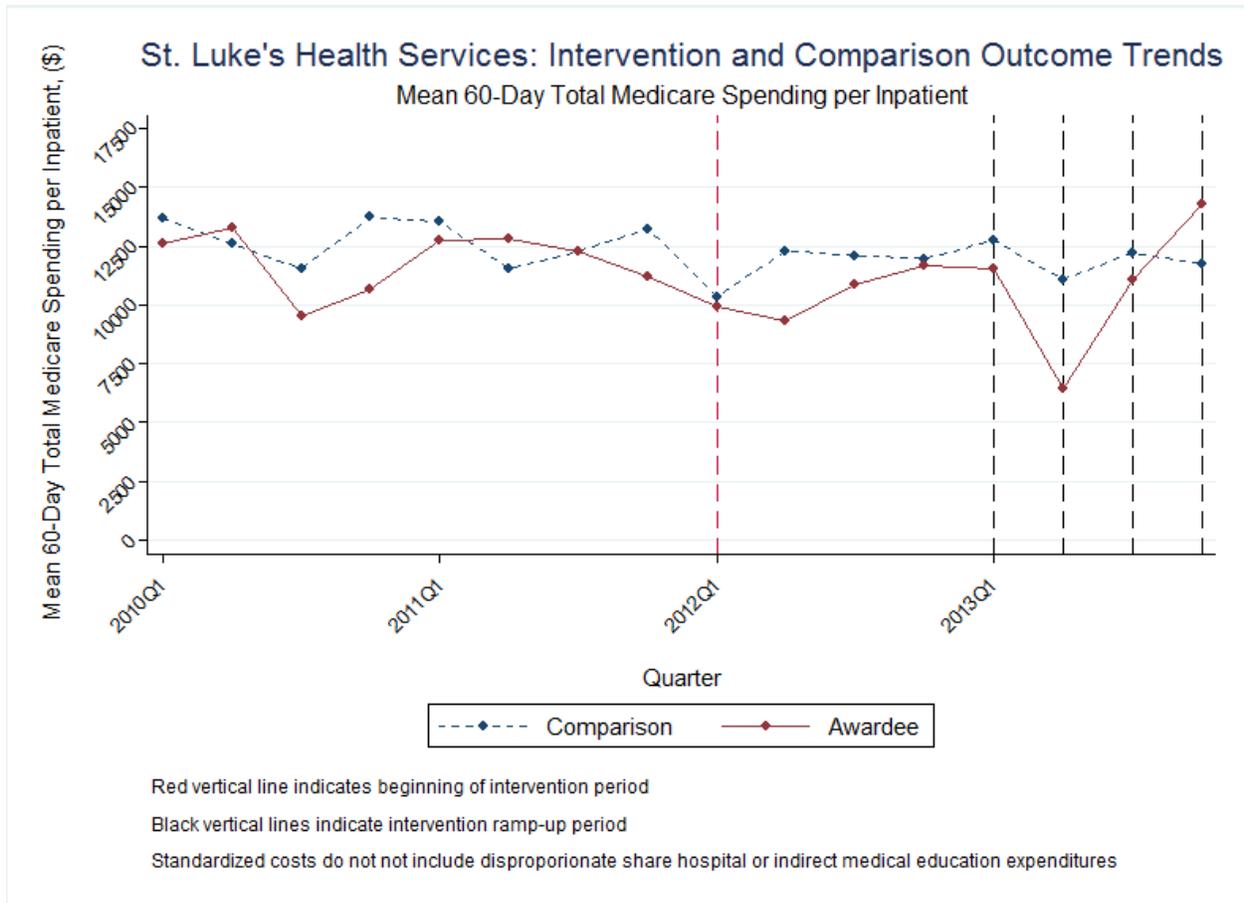
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.4   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 7 (length of stay following an index admission) shows little difference between the intervention and comparison groups in LOS and no indication that the intervention is affecting LOS.
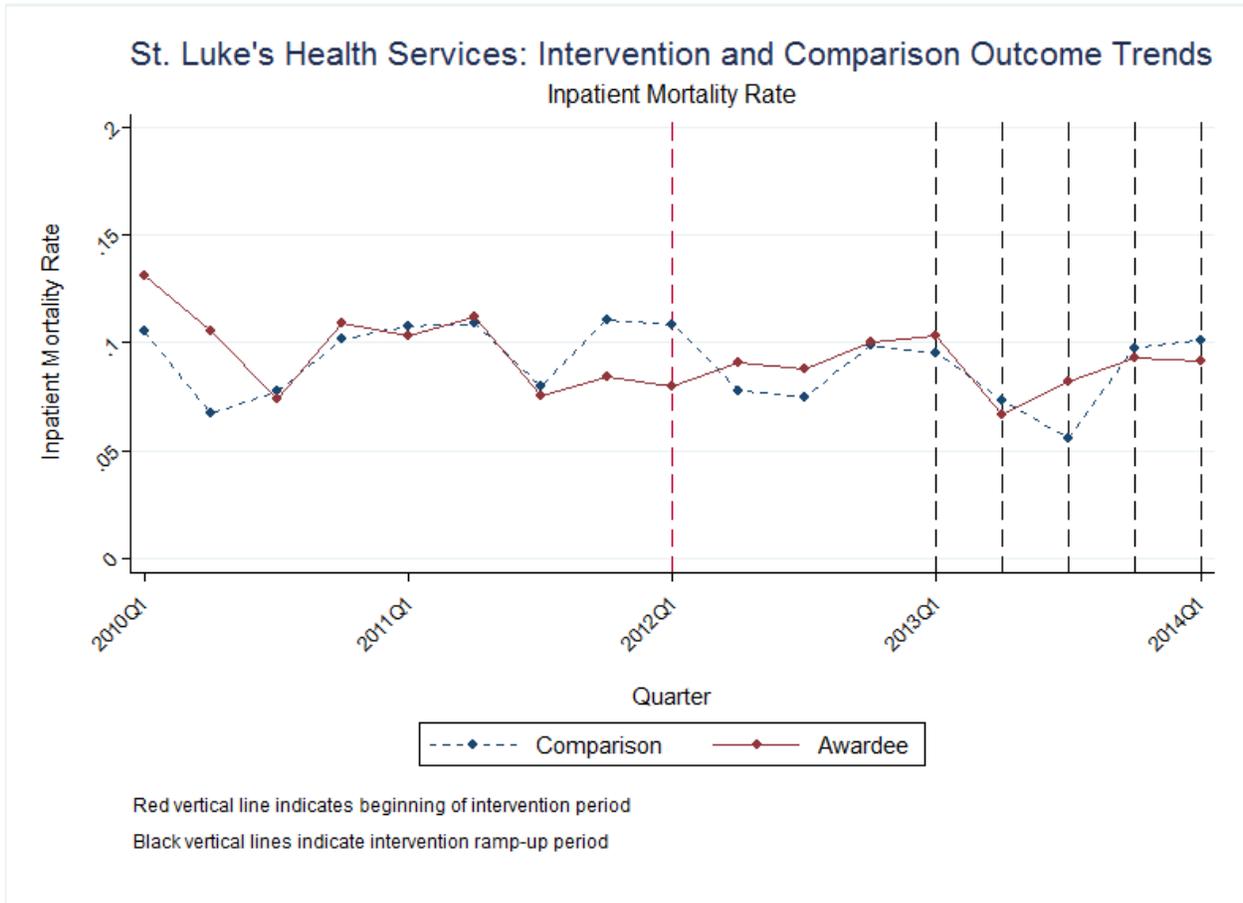
Exhibit 7: Index Admission Inpatient LOS

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.5   Index Admission Inpatient and 30-Day Mortality

Exhibit 8a (inpatient mortality rate following an index admission) shows that mortality rates were volatile from one quarter to another in both the intervention and the comparison groups, probably due to small numbers. There was no obvious change during the intervention period.

Exhibit 8a: Index Admission Inpatient Mortality

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

Exhibit 8b shows the total mortality (inpatient and the 30 days following the end of the index admission). Again, the mortality rates were volatile from one quarter to another in both the intervention and the comparison groups, and there was no evidence of an impact during the intervention period.

Exhibit 8b: 30 day Mortality (including Index admission)
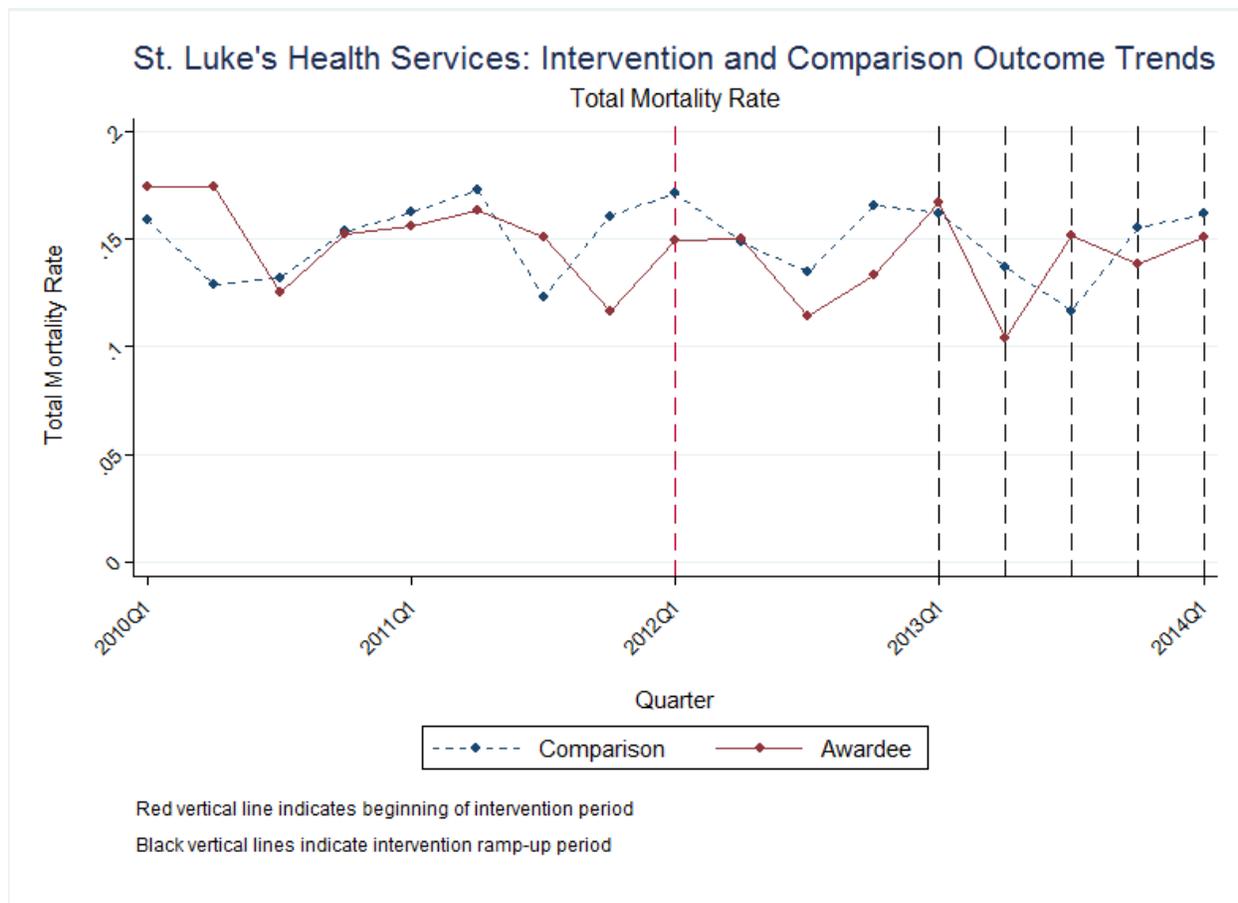
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change. In a future annual report we will aggregate data across the entire intervention period and use regression techniques to try to control for systematic differences in the two groups, although we caution that small numbers may not support such analyses.

Conclusions

- The strong match gives us confidence that results are unbiased.

- There is no evidence of an intervention effect and intervention and comparison groups were similar in both baseline and intervention periods, on all measures.

Appendix B10: University of Chicago

Integrated Inpatient/Outpatient Care for Patients at High Risk of Hospitalization

INFORMATION NOT RELEASABLE TO THE PUBLIC: The information contained in this report is preliminary and may be used only for project management purposes. It must not be disseminated, distributed, or copied to persons unless they have been authorized by CMS to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

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, 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 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.

1. Qualitative Analyses: Case Study

1.1   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 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. All patients enrolled in the CCP study, whether in the treatment group or the control group, are interviewed every three months after enrollment to assess their health status and their opinions about the care they've received. The goal of the CCP study is to test whether implementing a program in which a hospitalist physician treating patients in both inpatient and outpatient settings will increase the continuity of care, improve patient outcomes, and reduce costs of care, relative to usual care provided by separate physicians in the inpatient and outpatient settings.

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. From the point of randomization into the treatment group, the research team limits engagement with patients to a contact every three months for follow-up interviews. The CCP clinical team provides all clinical care to treatment patients. The two teams work jointly on recruitment issues and the exchange of appropriate contact information for CCP study participants.

1.1.1   Impetus for the CCP Research Study

The impetus for the CCP research study is to test whether having an assigned physician manage a patient's care provided by a CCP care team in both inpatient and outpatient settings care improves the quality of care and decreases costs. The target population for this study is a subset of patients with complex health needs who use high levels of hospital care to manage multiple conditions. Many of these patients have frequent use of hospital emergency departments (ED) and repeated hospitalizations, with the potential for poor coordination and other inefficiencies. Often, a number of different clinicians including residents and specialists interact with the patient when in the ED or during a hospital admission, and there may be inadequate coordination with the primary care physician who provides care between hospital episodes. The patients' history and records may be either not immediately available due to multiple care providers, or may be extremely complex, and significant time and tests are required 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. These complex patients are also likely to have significant mental health and social challenges, in addition to health challenges, that can lead to inconsistency in care seeking between acute episodes. The CCP program aims to improve continuity of care by having a single physician along with a clinical support team follow these complex patients in both inpatient and outpatient settings. The hypothesis being tested

is that this improved continuity of care will enable better disease management and reduce ED visits and re-hospitalizations.

1.1.2   University of Chicago CCP Program Goals

The CCP program is focused on the aims of better care, better health and lower costs.   Better care could be realized through the CCP study 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 healthcare needs. To reduce costs, the CCP clinical team strives to reduce repeat ED visits and re-hospitalizations by providing more comprehensive, coordinated care in the inpatient and outpatient setting at UCH.

1.2   Case Study Methods

The UCH case study took place June 5 and 6, 2014. The evaluation team, composed of one senior- and one mid-level staff person from Abt Associates and one staff member from Telligen, visited UCH and also observed an outreach and recruitment event at a senior center in a Chicago neighborhood near UCH. The team conducted group interviews with CCP management staff, 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. The group interviews and focus groups 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.

Exhibit 1 summarizes the number and type of individuals who participated in either interviews or focus groups.

Exhibit 1. Backgrounds of Interviewees and Focus Group Participants

	Patients/Patient Family Members	CCP Clinical Team	CCP Research Team	CCP Analytics Team	ED Physicians	CCP Hospitalist Physicians	Program Administrators
Total = 32	7/2	4	7	2	3	5	2

All interviews and focus groups were conducted using standardized protocols developed previously by Abt's qualitative research team and approved by Centers for Medicare & Medicaid Services (CMS); these protocols were tailored to address the specific issues of interest for the CCP program. Data coding and analysis were conducted using the qualitative data software NVivo. An initial baseline codebook was developed, and nodes and subnodes were identified a priori for this initial codebook based upon the standard evaluation interview guides. Two people participated in the coding of notes, one of whom was the senior team member who led the case study. To enhance inter-rater reliability, interviews were coded by two people on the team and a coding meeting was held to discuss any differences in coding. The team added new nodes as necessary and revised the original codebook. Analyses were conducted by running node reports to identify themes and subthemes. Where relevant, the team explored differences across key project components and CCP participants. Additional background information presented in this report

was gleaned from review of quarterly reports submitted by University of Chicago to CMS as well as written materials distributed by the CCP program team during the site visit.

1.3   Program Components & Targets

1.3.1   Primary Program Components

The CCP program is led by a principal investigator (PI) with extensive experience leading studies to improve hospitalist care at UCH for the past 16 years. He is dedicated to consistently monitoring the progress of the CCP study. He receives daily updates from the program manager on the provision of care and patients served by the CCP clinical team. He also receives daily updates from the research program manager on participant enrollment and status updates on various research recruitment initiatives including development of a radio media campaign and mailings to zip codes served by UCH. He actively works to troubleshoot challenges that arise during implementation and works with CCP staff to improve both the clinical and research portion of the study.

1.3.2   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. Of the 681 participants enrolled at the time of our visit, the majority were recruited in the UCH ED or through referral from an inpatient unit. In recent months, the research team has averaged recruitment of three patients per day during weekdays, half being randomized to the CCP intervention.   The research team hopes to reach their recruitment goal of 2000 patients by continued expansion of recruitment activities within UCH and new community outreach activities. The CCP project also intends to apply for a one year, no-cost extension to provide the extra time needed for additional research strategies to bear fruit.

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 a senior.

Eligibility Criteria

Inclusion criteria for the study are as follows: Medicare Part A and B; hospitalization within the past year; reside 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: If the patient is receiving care through the oncology department or UCH s, they are not eligible for the CCP study because 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. The CCP program excludes patients whose primary health coverage is through a Medicare Advantage plan, since the CCP cannot track healthcare utilization of these patients.

Data Collection

The main data collection activities for both the clinical and control arms of the study consist of the intake survey and follow-up survey administered every three months. Both the intake and follow-up surveys take about 20-30 minutes to complete and are administered electronically by research coordinators using tablets. The intake is normally done in-person while the follow-up interviews are done by phone. The baseline 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 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.

Randomization

Randomization into either the clinical or control arm of the CCP study occurs as a part of the intake survey. A special computer program on the tablets used to complete the intake survey assigns patients to the control or intervention group.

1.3.3 Recruitment at University of Chicago Hospital

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 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.

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 30 sessions held within UCH and have set up tables at strategic locations in the hospital to share information about the CCP study (e.g., at the cafeteria, at the entrance to outpatient

building). Only four 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.

A key challenge with the research component of the study has been the team's working with 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 has caused some unanticipated delays.

1.3.4   Recruitment in the Community

Two research coordinators, who worked on the PI's prior hospitalist research, now lead CCP outreach in community settings. The research coordinators partner with UCH community outreach departments and participate in health and wellness events the hospital holds in the neighboring community. They also build 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 present 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 136 community events, 30 businesses, and at 17 churches. Despite reaching at least 6,762 community members and establishing contact with 145 potential study candidates, only 10 participants have been enrolled through these community outreach activities (half randomized to the intervention). The CCP research team reached out to consultants to help identify new study recruitment strategies in the community. 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 sought to recruit. 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, as a senior, 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.

1.3.5   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 fourth and related challenge is that patients may have a primary care physician outside the UCH system and if they are unwilling to switch primary care physicians to a CCP physician, these patients are not eligible for the study. To address this barrier to recruiting, the CCP team sought opportunities in the care continuum 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 is to leverage the CCP study team's relationships with units such as the geriatric clinic.

1.3.6 Challenges to Recruiting in the Community

Research coordinators described a number of challenges in 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 mid-century studies conducted at the hospital that abused the trust of minority patients. 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 is also planning a large-scale mailing of materials to households in the zip codes served primarily by UCH, as well as radio and other media announcements that may reach community members who are essentially homebound.

1.3.7 CCP Clinical Program

The primary innovation of the CCP program is the management and provision of care to patients with complex health conditions 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 team support the overall continuity of care for patients with complex healthcare needs provided by the CCP physicians and care team:

- 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 section), 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.

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

> 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*

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 and has worked with the team to obtain home care certification for other CCP physicians. CCP physicians spend part of their time working in a hospitalist inpatient service, in addition to their caseload of CCP patients.

The clinical team includes a program manager, social worker, advanced practice nurse, registered nurse, and the CCP physicians. 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

> As a new patient, you are not only getting a new doctor, but a whole team to help you with your healthcare.
>
> *– CCP Manager*

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 also assists in managing the other staff on the clinical team.

The clinical team social worker addresses the care coordination and social service needs of CCP patients. She coordinates necessary home services (medical equipment, oxygen, etc.), participates in some homecare visits, and addresses any insurance coverage issues. She implements 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 tracks follow-up progress to reduce the likelihood of re-hospitalization. She will be spearheading 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 is finishing trainer certification for TeamSTEPPS®. She also provides counseling services as needed for both patients and their family members/caregivers.

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.

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.

1.3.8   Organization of the CCP Clinical Team

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.

1.4   Implementation of CCP Program

Implementation of the 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. 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 team members have shifted over time but because the unit is relatively small, this has been accomplished relatively seamlessly. The advanced practice nurse has 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 daily review of clinical strategy in team multidisciplinary rounds provides opportunity for continued communication about the program's needs and potential further 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.

1.4.1   Patient Engagement

An important component of the CCP program is to develop a medical practice that attends to patient preferences and delivers patient centered care. As mentioned above in Section 1.2.7, the program coordinator "matches" each patient with a specific physician, based upon their expressed preferences. For example, if one patient wants greater involvement in her care decisions, while another prefers the

physician to make most of the decisions, the program coordinator will assign physicians with practice styles that align with these patient preferences. This matching process encourages stronger rapport between the physician and the patient, which ultimately is expected to promote greater compliance to treatment protocols and lead to better health.

A key component of the CCP clinical program is the ability of patients to reach a member of the CCP clinical team at any time via a phone 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 rather than an administrative gatekeeper that other UCH outpatient units typically use to screen calls. 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.

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. CCP physicians, along with program staff were 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.

The PI 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 CCP staff are very accessible and if a call does go to voicemail, it is returned quickly. Several CCP staff noted that this accessibility helps to build rapport and trust with patients. The CCP manager seeks regular feedback from patients about how well the CCP clinical program is meeting their needs. She heard many testimonials regarding the success of the program. A 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.

> 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

1.4.2   Clinical Program Challenges

CCP Home Care Program

The CCP clinical team identified a key 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 now handles a caseload of 18 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.

Provision of Mental Health Services

Another major 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 special problems in accessing inpatient mental health care, as some inpatient psychiatric facilities will not accept patients using oxygen or continuous positive airway pressure (CPAP) machines.

The CCP program has adopted a number of strategies to deal with the mental health needs of CCP patients. The CCP social worker provides some psychotherapy sessions with patients, to the best of her ability. CCP staff refer patients to the psychiatry hospital 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 psychiatry hospital's ED. Psychiatric outpatient care at UCH has a long wait for new patients (up to six months) but CCP staff will try to get the patient on this list. 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. The CCP has recently added a licensed clinical social worker to provide counseling, and also anticipate that UCH will increase psychiatry in the future, to reduce queues.

Managing Prescription Drug Abuse

CCP clinical staff recognize 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.

1.4.3   Measurement & Self-Monitoring

The CCP research analytic team focuses on measurement and self-monitoring needed for both the clinical and research teams, and for reporting to CMS. The analytic 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 analytic 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 analytic 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 analytic team believes that the critical measures to focus on for establishing the effectiveness of the program will be healthcare 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.

1.5   Workforce Development

1.5.1   CPC 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 worker was trained in UCH's social work department and through on the job training even after starting in her position. She in turn will train a second social worker who has begun working with the CCP program part time.

- 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 feels 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).

- 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 some of 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. The major foci of this training are improvement in the care coordination, using components of the Bridge Model and TeamSTEPPS® guidelines for chronic disease management.

1.5.2   CCP Physician Training

The CCP physicians have a designated set of on-boarding lectures provided by a senior physician who does 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 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. All CCP staff are invited to presentations on special topics from experts such as the president of the American Association of Home care Medicine, who presented on best practices in home care medicine. The CCP physicians take turns weekly facilitating a training session for their CCP physician colleagues and the CCP staff as a whole. Presentations have been presented on other topics, including: care coordination for patients with HIV/AIDS, special care needs for those with sickle cell anemia, and best practices in patient education. Some future topics that will either be presented by a CCP physician or outside expert include issues surrounding end of life care and mental health.

1.5.3   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.

1.6   Implementation Effectiveness

1.6.1   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

- 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

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 healthcare.

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

- Improved ADL and IADLs

1.6.2   Better Health

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 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.

> 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

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 SF-12

- ED visit rate

1.6.3   Lower Cost

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, which should lower costs to Medicare. Staff reported that initial findings that hospitalization rates are down for CCP patients relative to control group patients; they expressed the opinion that due to these changes, the CCP program will eventually realize savings for CMS for CCP clinical program participants.

CCP staff also advised that when intervention patients are hospitalized, the length of stay is likely to be lower than for patients in the control arm due to the familiarity the CCP physicians have with their patients' complex medical histories. This familiarity provides physicians with knowledge about their patients' baseline health status and a perspective on when patients can be safely discharged.

The CCP analytic team completed a return on investment analysis that includes the costs associated with evaluating the CCP program, and they report that the CCP study has "broken even".

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

1.6.4   Outcomes that Can Be Measured Using Medicare Claims

Important outcomes such as ED visit rates, all-cause mortality, hospital readmissions and total episode costs can be measured using Medicare claims data. The Abt team will use the CCP intervention and comparison patient lists to identify those in FFS Medicare, for whom claims are available, to estimate impact. Thus far, the CCP does not have sufficient numbers of Medicare FFS patients for rigorous statistical analyses of key outcomes. In addition, patients recruited in the remaining 10 months of the program will have short follow-up periods during which change can occur. We are therefore concerned about the ability to measure impact of this program, beyond comparing trends without tests of statistical significance.

1.6.5   Unanticipated Impacts

There is the potential for more hospitalist physicians at UCH to transfer patients with the most complex conditions to CCP physicians. The CCP team is actively working to present this as an option to different units within UCH that may have these patients. This would likely benefit the UCH hospitalists who may not have the capacity to optimally manage these most complex patients. This would also benefit the CCP program that needs to increase enrollment in the CCP study and has the capacity to invest more time to care of these patients.

Some patients, who enroll and are randomized to the intervention group, agree to leave their previous primary care provider and receive care from CCP. Although the patients we met were uniformly satisfied with this change, it is possible that there could be unanticipated discontinuities in care, when patients leave a provider who was familiar with their complex histories.

1.7   Impact on Workflow and Workload

1.7.1   Assistance to ED Staff

ED physicians reiterated the positive impact that the CCP program has 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.

1.7.2   Disproportionate Burden Among CCP Physicians

Initially, the CCP program asked new enrollees about their preferences for the gender of their assigned CCP physician. This resulted in the two female physicians having a noticeably higher case load of patients than their three male colleagues. The CCP manager is now working to rebalance the case load between the five CCP physicians and no longer asks patients about gender preference in physicians. As the program expands, the CCP staff will need to consider the balance of patients assigned to each CCP physician and at what load is essential to recruit additional physicians.

1.8   Potential Improvements Suggested by Program Staff

1.8.1   CCP Research Team

Community Recruitment Strategies

The liaison spoke highly of the outreach team when introducing them; the endorsement from the liaison promoted the creditability of the outreach team to the seniors. By using a liaison in this capacity, the event convened the largest gathering of community members held to date. That said, community recruitment has been labor intensive and disappointing thus far, and it is not clear whether community settings will be worthwhile recruitment venues.

Recruitment Strategies at UCH

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.

CCP Clinical Team

Since mental health and prescription drug abuse are prominent challenges, it may be worthwhile considering adding clinicians with this specific expertise. A number of CCP staff noted that the care coordination for patients with mental health needs requires special skills, and the queues to access these specialists are too long to benefit CCP patients.

1.9   Context

1.9.1   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.

> Every time you add a new [staff] 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

Leadership Buy-in

The reputation of the PI 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. These successes are the result of the effective relationships between the PI and UCH leadership.

1.9.2   Exogenous Factors

A 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 these 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.

1.9.3   Sustainability

There was widespread agreement among those we interviewed 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 outweigh the cost of the program. In addition, it is not clear that UCH wishes to become a 'magnet' facility for these most complex patients, who face mental health and substance abuse challenges. As noted by some staff, Medicare reimbursement is below that of other payers, but with the growth of Medicare advantage and risk contracts, it behooves UCH to learn how to provide better care at lower cost for this complex population. Though the CCP study excluded Medicare Advantage patients because the team was unable to track their healthcare 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 at a lower cost than typically seen in hospitals for these most complex patients.

1.10   Next Steps

In the follow-up interviews planned for 2015, several topics will be revisited and new issues explored. Topics to explore include:

- *Addressing Mental Health Challenges:* Has there been progress in addressing mental health and substance abuse needs of the CCP patient population?

- *Implementation of care coordination models:* The Bridge® and Team STEPPS® models will have been in place for about a year when we conduct follow up data collection. How have these approaches improved care coordination?

- *New recruiting/outreach initiatives:* Have the new outreach initiatives improved the recruitment in the community? Has working to recruit patients from the panels of outgoing residents proven effective in boosting enrollment in the CCP program?

- *Maintenance of small team structure*: As the number of patients increases, maintain the commitment to increase capacity without hiring more staff? Is the philosophy of a small, private practice within a larger institution able sustainable over time?

- *Decreased inpatient utilization and lower cost*: Will the program achieve sufficient size to measure impact with statistical significance? Are utilization and costs lower for CCP intervention patients as compared with the control group?

2. Quantitative Analyses

The University of Chicago identifies eligible patients and, with their consent, randomizes them to intervention or control arms of the study. Most of the University of Chicago patients are enrolled while in the hospital, but a few are enrolled when visiting the ED or in the community. After enrollment, intervention patients receive program services for all subsequent primary care and acute care at the University of Chicago; control patients continue with their usual sources and patterns of care. 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, as suggested by CMS.

The four Core measures specified by CMS for the HCIA evaluations are admissions, readmissions, ED visits and total episode spending. The results presented below are for the following Core measures, which differ somewhat from the core specifications:

- Average number of monthly admissions to an acute care hospital for patients in the intervention and control arms of the randomized study.

- Average number of monthly 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 monthly Medicare spending for patients in the intervention and control arms of the randomized study.

It is possible that improved care will also reduce mortality for this high risk population, and we therefore present results for the following additional measure:

- Enrollee mortality

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.

2.1 Registry Information

The University of Chicago patient registry contains 509 patients who were recruited before March 31, 2014. More patients were recruited after March, but the period for complete Medicare claims used in this report is through the first quarter of 2014. The registry contains patient names, insurance numbers and where the patients were recruited (hospital, ED, community), as well as an indicator for whether the patient was randomized to the intervention or control group. Through Q1 2014, 270 patients were randomized to the treatment arm of this controlled trial, and 239 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 appear to have quite similar demographics. No other selection rules are required, given the randomized design implemented by the Awardee. We caution that the small numbers of patients and few hospital events in a quarter, make the results below unreliable.

2.2   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 these complex chronic care patients have a great many admissions and 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. In addition, many of these patients have repeated hospitalizations in rapid sequences and the total number of admissions seems more important than whether or not there is one. We show no baseline period because this is a randomized controlled trial comparing intervention and comparison; no difference-in-differences analysis is necessary.

2.2.1   Enrollment Trend

Exhibit 2 shows the enrollment trend in the U. Chicago program, which increased as new eligible patients were randomized into the two arms of the study.
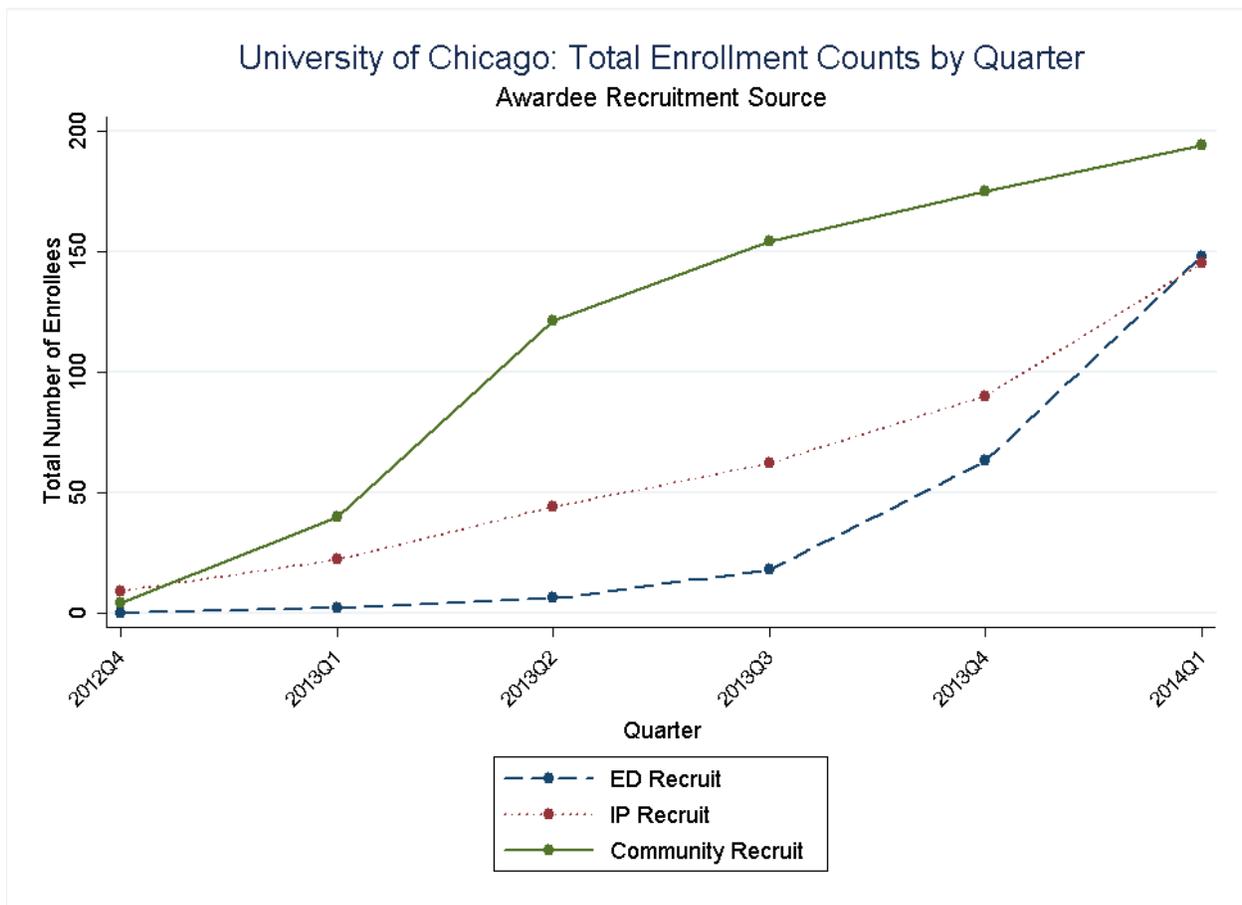
Exhibit 2: Enrollment Trend
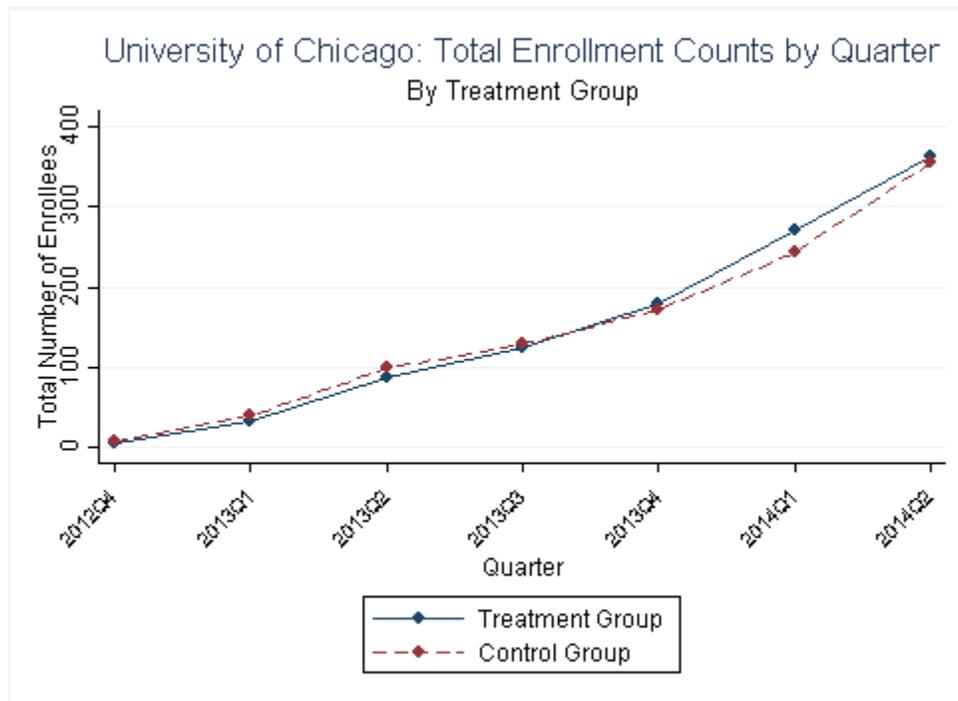
Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.2   Enrollment/Referral Source

Initially, most patients were 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. But as described in the case study report above, 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 higher costs in the enrollment quarter than those who were enrolled in less costly locations.

Exhibit 3 shows study enrollment over time, and the locations in which participants were enrolled.
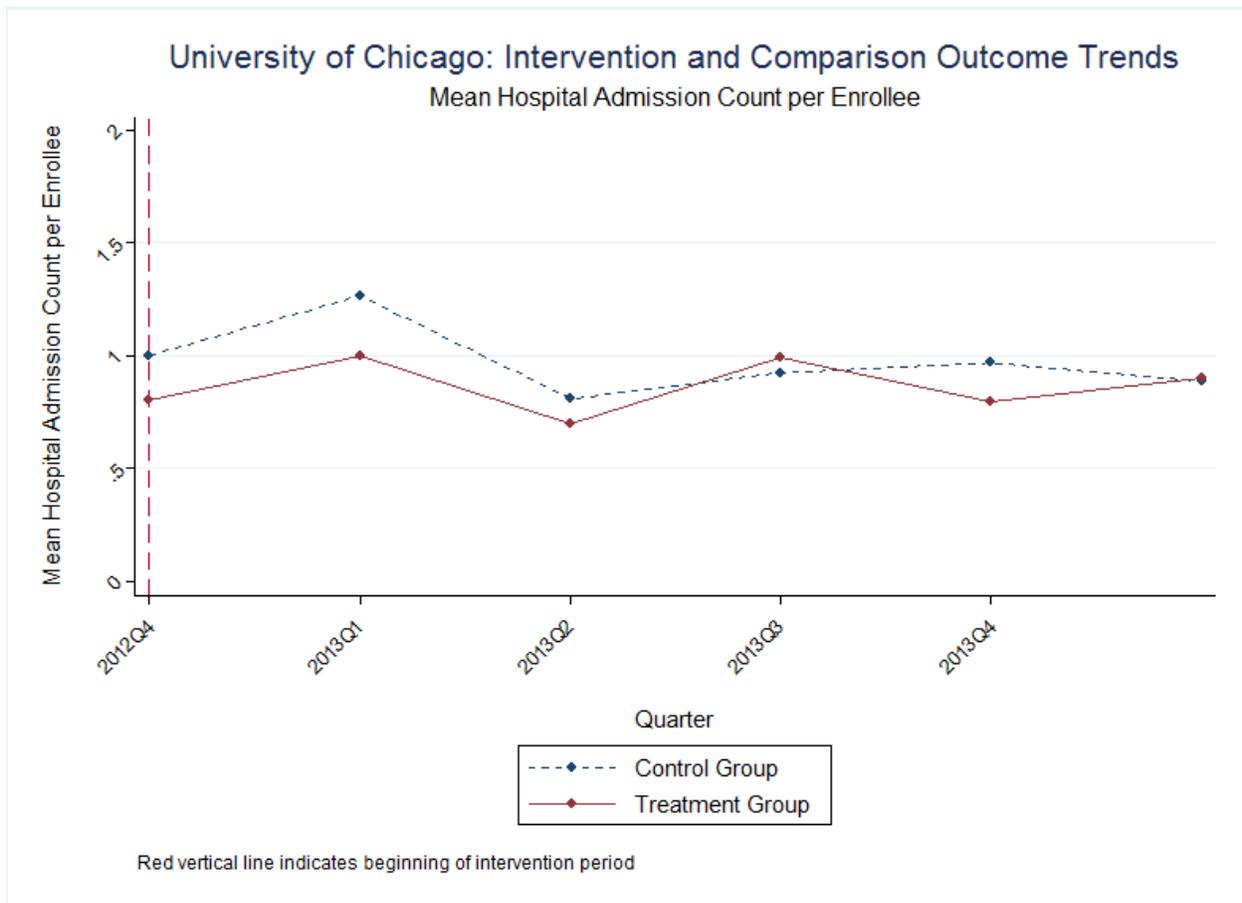
Exhibit 3: Enrollment/Referral Source

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.3   Average Quarterly Hospital Admissions

Exhibit 4 (hospital admissions) shows that the intervention and control groups were similar, but not identical, in the first quarter of the intervention, having an average of 3.8–4 hospital admissions per quarter (more than one per month). Enrollment continued and increased, with new entrants possibly reducing the measured intervention impact of those who entered earlier and had a longer exposure to the intervention. The difference between the two groups overall is not significant at the .10 level.

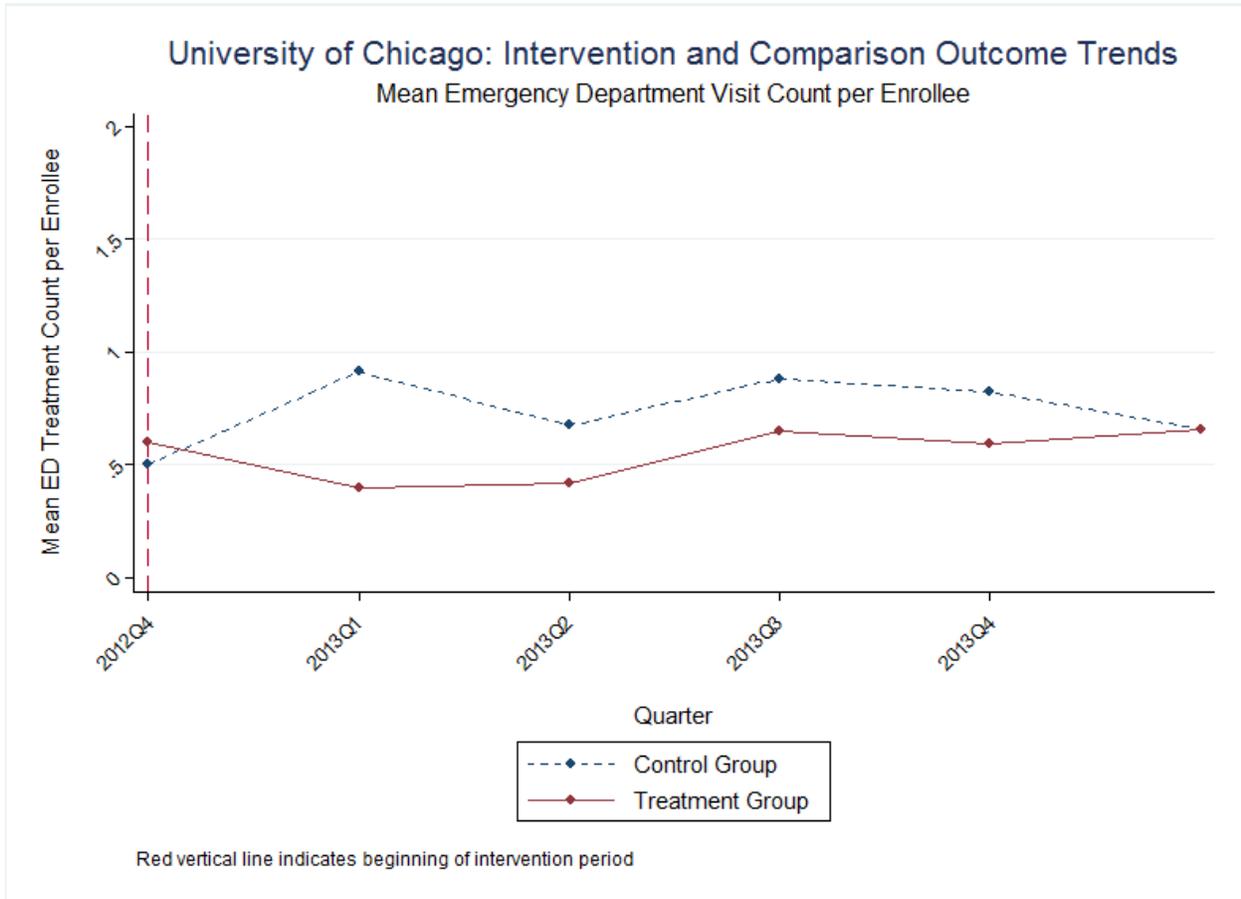**Exhibit 4: Average Quarterly Hospital Admissions**

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.4   Average Quarterly ED Visits

Exhibit 5 shows average ED visits per quarter. During the first quarters the intervention group was quite different from the control group, having a lower average number of quarterly ED visits. This difference was not as evident in later quarters, as the numbers of enrollees in both groups continued to increase and more people were enrolled from the community or in the ED. The difference between the two groups overall is not significant at the .10 level.
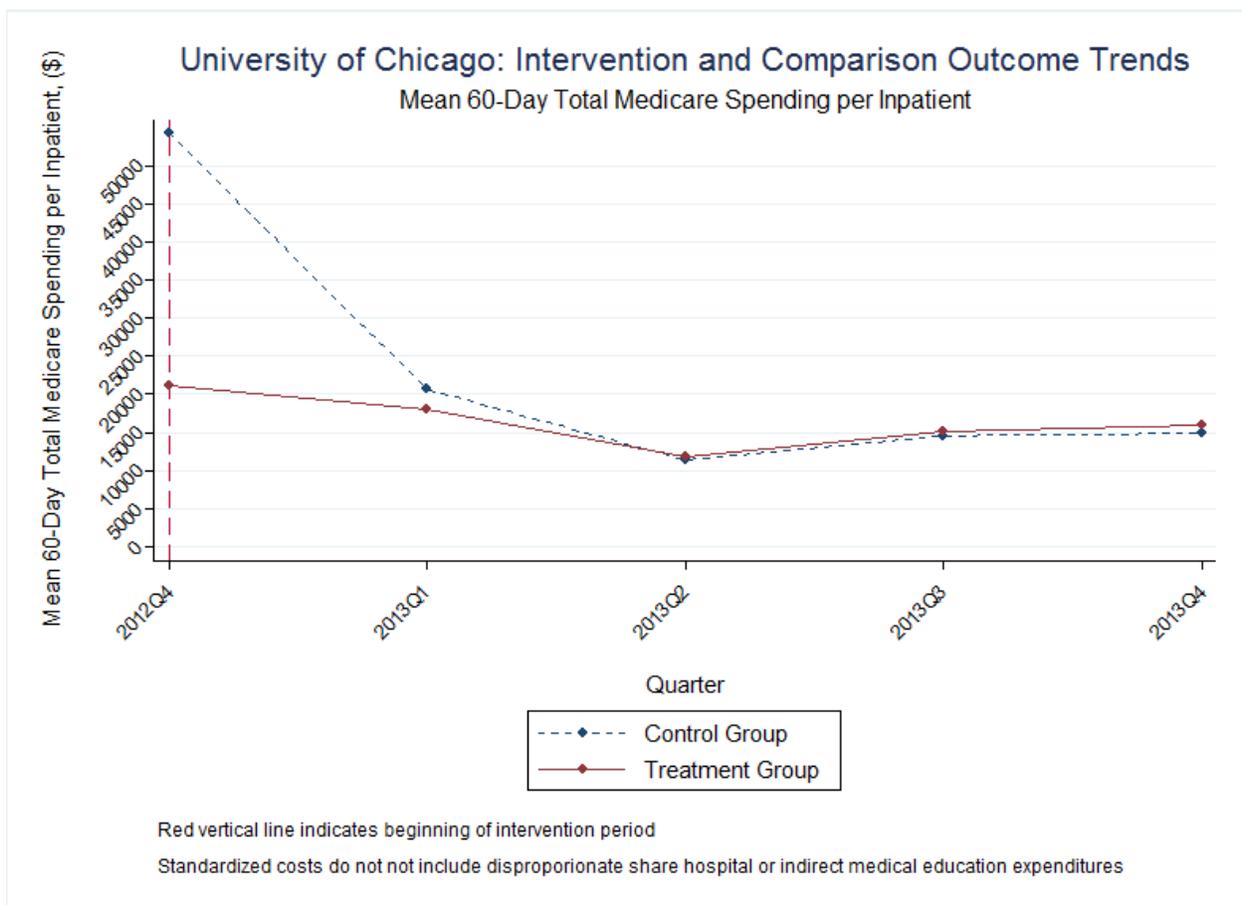
Exhibit 5: Average Quarterly ED Visits

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.5   Average Quarterly Medicare Spending

Exhibit 6 shows average Medicare spending per quarter for study participants. The very high rate in the first intervention quarter is an artifact: many individuals were recruited during an inpatient stay toward the end of this quarter and we prorated their quarterly costs (to accommodate rolling admissions). The higher costs in the early quarters may also reflect the fact that many of the early enrollees were in the hospital when enrolled—their enrollment began with a high-cost event—while in later quarters enrollment increased in the ED and community settings. In the first quarter of 2012 there were very few patients enrolled and these small numbers contributed to the difference between intervention and comparison groups in that quarter. The difference between the two groups overall is not significant at the .10 level.

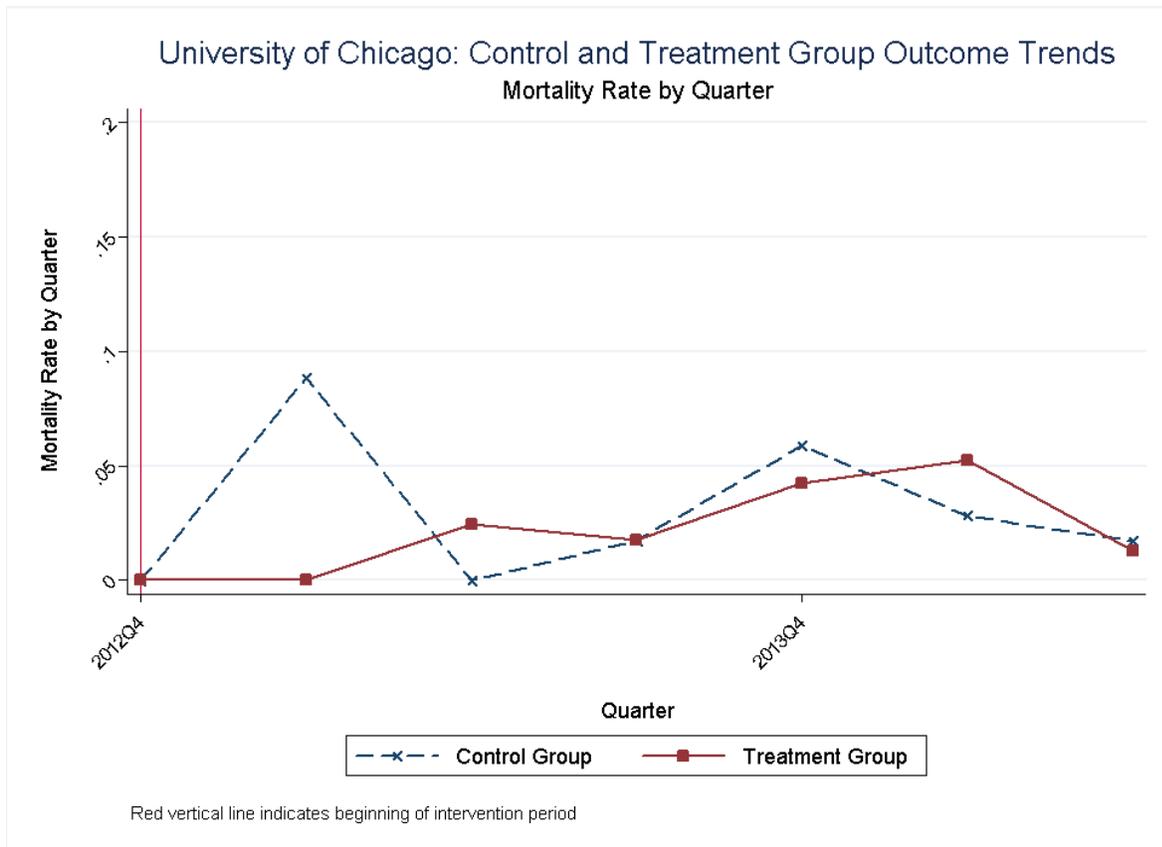**Exhibit 6: Average Quarterly Medicare Spending**

University of Chicago: Intervention and Comparison Outcome Trends
Mean 60-Day Total Medicare Spending per Inpatient

Red vertical line indicates beginning of intervention period

Standardized costs do not not include disproporionate share hospital or indirect medical education expenditures

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

2.2.6   Mortality

Although this program is very small, and few deaths would be expected, we examined mortality in the two groups.

Exhibit 7 shows the mortality rate by quarter in the intervention and comparison groups. Due to small numbers we draw no conclusions from this graph, but note that there does not appear to be a consistent difference between the two groups.

Exhibit 7: Mortality

University of Chicago: Control and Treatment Group Outcome Trends
Mortality Rate by Quarter

Red vertical line indicates beginning of intervention period

Source: Abt Associates analysis of Registry and Medicare Claims, completed in September 2014.

For all the exhibits above, we can make no inference about a statistical difference between the two groups, or about whether the intervention is causing this difference to change. In a future annual report we will aggregate data across the entire intervention period and use regression techniques to try to control for systematic differences in the two groups, although we caution that small numbers may not support such analyses.

Conclusions

- The earliest intervention and comparison groups differed in costs and mortality – probably due to very small numbers, rather than imperfect randomization.

- In later quarters, after more patients entered each group, differences between the groups were minimal.

- With enrollment continuing, it is difficult to identify an intervention effect because each patient is enrolled for differing lengths of time. A future report may take a 'days of exposure' approach and weight each participant's length of program enrollment.