

REPORT

Evaluation of the Million Hearts[®] Cardiovascular Disease Risk Reduction Model: First Annual Report

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EXECUTIVE SUMMARY

In January 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts[®] Cardiovascular Disease Risk Reduction Model (the Million Hearts CVD Model), designed to reduce heart attacks and strokes among Medicare fee-for-service (FFS) beneficiaries. The overall goal of the evaluation is to assess whether, and through what mechanisms, the Million Hearts CVD Model improves CVD care, reduces first-time heart attacks and strokes, and reduces Medicare spending for Medicare FFS beneficiaries. If the model improves care quality and reduces Medicare spending enough to offset the model payments, then the evaluation will also assess the feasibility and likely benefit of scaling the model to Medicare FFS beneficiaries more broadly. CMS may use the findings from the evaluation to inform decisions about whether and how to scale the model to other Medicare beneficiaries. The model may also pave the way for value-based payment approaches to prevent other chronic illnesses (Sanghavi and Conway 2015).

CMS is testing the Million Hearts CVD Model in a rigorous five-year randomized trial of 516 organizations throughout the country, with half assigned to the intervention group and half to a control group that receives usual care. The intervention organizations are expected to:

- Risk stratify all eligible Medicare FFS beneficiaries using the 2013 American College of Cardiology/American Heart Association (ACC/AHA) calculator
- Provide cardiovascular care management to high-risk beneficiaries (those with a 30 percent or higher predicted risk of having a heart attack or stroke in the next 10 years), including developing a risk modification plan and contacting beneficiaries at least twice a year to assess progress and adjust plans as needed
- Follow up with high-risk beneficiaries in person once a year to reassess their CVD risk
- Collect and report clinical data to CMS via the Million Hearts Data Registry and participate in learning system activities to help organizations implement the model effectively

In exchange, CMS supports the intervention organizations with three types of payments. The CVD risk stratification payment is a one-time payment (\$10) for each beneficiary an organization assesses with the ACC/AHA risk calculator. In the first model year, CMS paid monthly cardiovascular disease care management (CVD CM) fees (\$10) for each beneficiary categorized as high risk in the initial assessment. In Model Years 2 to 5, CMS is making monthly risk reduction payments for each high-risk beneficiary, with the size of the payment ranging from \$0 to \$10 depending on an organization's performance in reducing the average 10-year predicted risk among all beneficiaries initially designated as high risk. CMS is calculating the change in each person's CVD risk using a new longitudinal tool designed specifically for this model (Lloyd-Jones et al. 2017). To support the model's evaluation, CMS also pays control organizations to collect and report clinical data on their eligible Medicare FFS beneficiaries.¹ These organizations are not required to calculate CVD risk scores or otherwise change their clinical care, and no information is fed back to the control group organizations.

¹ Specifically, CMS pays control organizations \$20 for each eligible beneficiary for whom they report data to the registry in each of the first three years of the model test (for a maximum of \$60 per beneficiary).

Although CMS has set guidelines for implementation, the model is not prescriptive. Indeed, CMS expects that organizations will vary significantly in how they approach the intervention—for example, in how they structure their care teams. Some organizations, moreover, could already be risk stratifying most of their patients or providing ongoing care management services, whereas others may not. These differences will likely mean that some organizations are more successful than others in reducing aggregate CVD risk for their high-risk beneficiaries.

The primary objective of this report is to describe how the Million Hearts CVD Model has been implemented during its first 16 months (January 2017 to April 2018), including the characteristics of the organizations, providers, and beneficiaries who are participating in the model. We also describe the degree of similarity between the intervention and control beneficiaries at enrollment and draw implications for the feasibility of a rigorous impact evaluation. The evaluation team used a mixed-methods approach, drawing from site visits, phone interviews, clinical data collected through the Million Hearts Data Registry, Medicare claims, and model application data.

Characteristics of the organizations, providers, and beneficiaries participating in the Million Hearts CVD Model

The 516 organizations that joined the model are primary care practices, specialty practices, federally qualified health centers, and hospitals located throughout the country in rural and urban areas. Organizations reported joining the model because it aligned with their goals to prevent CVD and because it would require only modest changes to their workflows.

Of the 516 randomized organizations, 319 (62 percent) actively participated in the first year, meaning they did not withdraw and they successfully reported at least one eligible beneficiary to the Million Hearts Data Registry. Compared with the organizations that withdrew from the model, those that stayed tended to be larger (in number of providers and sites), to be primary care practices (rather than specialty practices), and to have participated in other CMS payment and delivery reform models at baseline. Still, the 319 organizations that actively participated in 2017 reflected a similar diversity in size, location, and type as the initial set of 516 organizations that was randomized, and the rate of attrition was similar between the intervention and control groups during the first year. About 5,000 providers participated in the model in the first year. Two-thirds of these providers were physicians (mainly primary care); the remainder were nurse practitioners or physician assistants.

In the first year, the participating organizations enrolled nearly 300,000 Medicare FFS beneficiaries aged 40-79 who had not had a previous heart attack or stroke. (Table ES.1). Eighteen percent of these enrollees were high risk (with a 30 percent or higher predicted likelihood of having a heart attack or stroke in the next 10 years), 40 percent were medium risk (with a predicted risk of 15 to 30 percent), and 42 were low risk (with a predicted risk of less than 15 percent). The intervention organizations enrolled more beneficiaries than the control group because CMS capped the number of providers allowed to participate at 20 for control organizations but not for intervention organizations. Although the two groups enrolled different numbers of beneficiaries, the share of enrollees that fell into each of the three risk categories was almost identical for the intervention and control groups.

CVD risk group (predicted likelihood of a heart attack or stroke in 10 years)	Intervention	Control	All
Low (<15 percent)	75,924 (42%)	49,351 (42%)	124,275 (42%)
Medium (15–30 percent)	71,476 (40%)	46,311 (40%)	117,787 (40%)
High (> 30 percent)	32,875 (18%)	21,103 (18%)	53,978 (18%)
All	180,275	116,765	297,040

Table ES.1. Number of enrollees in 2017, by intervention/control group andrisk level

Source: Million Hearts Data Registry.

CVD = cardiovascular disease.

Beneficiaries who fell into the different risk categories varied in both their non-modifiable and modifiable CVD risk factors (Table ES.2). Beneficiaries in the high-risk group were older and much more likely to be male and to have diabetes, important non-modifiable risk factors. But they were also more likely to have high blood pressure and to be a smoker, key modifiable drivers of risk. Interestingly, the average total cholesterol level was lower in the high-risk group, suggesting that (a) some high-risk beneficiaries are already (at baseline) receiving statin therapy to lower cholesterol, and (b) there is room for improvement in CVD risk even among the medium and lower risk enrollees.

Table ES.2. Characteristics of the 2017 intervention group enrollees atbaseline, by risk level

Characteristic	Low risk	Medium risk	High risk
CVD risk score, mean	9	21	40
No	n-modifiable risk fac	ctors	
Age, mean	64	71	74
Male	25%	54%	65%
History of diabetes	10%	23%	66%
	Modifiable risk facto	rs	
Systolic blood pressure, mean (mm Hg)	124	131	140
Has elevated or high blood pressure (>130 mm Hg)	34%	54%	74%
Total cholesterol, mean (mg/dL)	186	177	169
LDL cholesterol > 70 mg/dL	85%	80%	73%
Hypertension: treatment or diagnosis	53%	76%	91%
Current smoker	9%	10%	12%

Source: Million Hearts Data Registry.

CVD = cardiovascular disease; LDL = low-density lipoprotein.

Meaningful room for improvement in CVD risk factors exists within the high-risk population— the model's primary target population—and the medium-risk population. For example, 74 percent of high-risk enrollees have high blood pressure and would benefit from medications or behavior changes to control blood pressure. Further, 73 percent of high-risk beneficiaries have low-density lipoprotein (LDL) cholesterol exceeding 70 mg/dL and might benefit from new or intensified medications to lower cholesterol. Finally, 12 percent of beneficiaries smoke, a major driver of CVD risk.

Randomization was largely successful in creating intervention and control groups that had had similar characteristics at baseline, despite the fact that some organizations left the model and others did not enroll all of their eligible beneficiaries. The intervention and control groups were very similar at baseline on beneficiary demographics, CVD risk factors, and Medicare service use and spending. This is true for the high-risk group—the primary target population—as well as for the medium and high-risk groups combined. But the intervention and control groups differed in the types of organizations that enrolled the beneficiaries. For example, intervention group beneficiaries were more likely to be enrolled by large organizations (those with more than 20 providers).

The similarity between the intervention and control groups on most baseline characteristics means that a rigorous evaluation of model impacts should be possible. Specifically, this baseline similarity increases our confidence that differences in outcomes between the intervention and control groups can be credibly interpreted as model impacts, and are not due to pre-existing differences between the groups. The observed differences in the types of organizations enrolling beneficiaries does pose some risk to the estimates. Therefore, we will test the sensitivity of the main findings to alternative definitions of the study populations that limit the potential for differences between the groups in the types of organizations that enroll them or other characteristics.

CVD preventive services provided by the intervention organizations at the launch of the Million Hearts CVD Model

Organizations offered a variety of approaches to support risk factor management; more than half the organizations offered patient education programs and patient reminders for elevated cholesterol and hypertension. Nearly three-quarters of the intervention organizations referred patients to quit lines (a toll-free smoking cessation help line available in each state), and nearly half the organizations offered individual smoking cessation programs. But 10 to 20 percent of the organizations offered no specific support services for patients with modifiable CVD risk factors.

Implementation of the Million Hearts CVD Model by intervention organizations

Findings from the first 16 months of implementing the Million Hearts CVD Model based on site visits and telephone interviews with 15 intervention organizations suggest that intervention organizations have made improvements in their CVD preventive care. Figure ES.1 summarizes how organizations are identifying eligible beneficiaries, calculating risk scores, identifying high-risk beneficiaries, and providing CVD preventive services. Implementation approaches for key components of the model varied across organizations. In addition, changes to CVD preventive care differed across providers, even within an organization. The emerging evidence included the following:

• Increased provider awareness of CVD risk among Medicare FFS beneficiaries. CVD risk scores helped providers more consistently identify high-risk beneficiaries as well as medium-risk beneficiaries, who could also benefit from interventions to reduce CVD risk.

- Improved provider-patient discussions of CVD risk factors and risk management. Sharing the risk score with beneficiaries helped motivate them to consider lifestyle changes and medication options. Discussion of CVD risk provided an opportunity to discuss the potential benefits of treatments, address beneficiaries' concerns with medication therapy, and tailor treatment plans to beneficiaries' needs and goals.
- Enhanced team-based care to reduce CVD risk. More than half the intervention organizations reported new roles for clinical staff to help identify high-risk beneficiaries and develop risk reduction care plans. Some organizations described new roles for medical assistants, nurses, and population health team members to increase follow-up of high-risk beneficiaries and reassessment of CVD risk.
- Increased provider consistency and intensity of treatment to reduce CVD risk. Increased attention to CVD risk calculation led providers to more often initiate or intensify medication therapy to address modifiable risk factors.

Figure ES.1. Summary of intervention organizations' efforts to implement key steps in the Million Hearts CVD Model



Control organizations' delivery of CVD preventive care

Control organizations receive payments to collect and report clinical data on their eligible Medicare FFS beneficiaries, but these organizations are not required to calculate CVD risk scores or otherwise change their clinical care. However, identifying how control organizations provide CVD preventive care—including any efforts they may make to risk stratify patients provides additional insight into whether changes in care delivery made by the intervention organizations are due to the Million Hearts CVD Model or to broader changes in the delivery of CVD care. Although CVD risk calculators are publicly available, efforts by providers in intervention organizations to implement the Model appear to have led to a change in practice patterns that differ from control organizations related to CVD risk stratification and reduction, including the following:

- Compared to the control organizations, intervention organizations more systematically riskstratified all eligible beneficiaries, routinely notified providers and beneficiaries of elevated risk scores, or used risk scores to drive care planning for beneficiaries with high CVD risk.
- Intervention organizations were required to, and routinely did, generate CVD care plans that included an electronic summary of the beneficiary's CVD risk score, individual cardiac risk factors, and plans to address the elevated risk. In contrast, control organizations often did not generate such CVD care plans.
- Intervention organizations appeared to be more systematic in arranging for follow-up of high-risk beneficiaries. None of the control organizations indicated using the CVD risk score to identify high-risk beneficiaries for follow-up beyond what they otherwise would have done.
- Control and intervention organizations appeared to use similar approaches to modify beneficiary CVD risk factors such as elevated cholesterol or hypertension. Likewise, neither intervention nor control organizations are adding new services as a result of participating in the model.

Experiences of Million Hearts CVD Model participants in using the tools and supports provided by CMS

Respondents from intervention and control organizations reported that meeting model reporting requirements was a substantial burden, and they had mixed reactions concerning the usefulness of tools and supports provided by CMS as part of the Million Hearts CVD Model.²

- **Risk calculator.** Respondents from intervention organizations liked the CVD risk calculator—especially the longitudinal features—but reported that it was not practical to use during in-person visits with beneficiaries. Respondents noted that the process for gaining access to and logging into the registry was burdensome for providers and prevented point-of-care risk stratification with the tool. Instead, providers who wanted access to a calculator during an office visit would use a built-in calculator within their electronic health record or other application.
- Million Hearts Data Registry. More than two-thirds of intervention and control organizations were manually uploading data to the registry, which respondents reported to be a time-consuming process.
- Learning system. The learning system to support intervention organizations generally received praise for early webinars on meeting the requirements of the model and using the Million Hearts Data Registry. But respondents had mixed reactions on the value of later webinars.

² For intervention organizations, the tools and supports included the Million Hearts Data Registry, CVD risk calculator, learning system, incentive payments, and performance reports.

- **Payment incentives.** The median payment incentives during the first year of the Million Hearts CVD Model were \$8,530 (mean of \$28,074) for intervention organizations and \$7,590 (mean of \$15,126) for control organizations. Most intervention organizations did not view the financial incentives as being adequate to cover their costs for data collection and reporting and CVD risk management. Nevertheless, respondents reported that they chose to stay in the model because the Million Hearts CVD Model supported other value-based purchasing efforts—and also because the care provided as part of the model was right for patients. Most control organizations generally thought the payments were adequate for what they were asked to do.
- **Performance reports.** Few respondents were aware of the performance reports CMS provided. But those who were aware of them recognized that the reports were a summary of the data that the organizations themselves had reported to the Million Hearts Data Registry, which provided limited additional value to support decision making.

Reasons why organizations withdrew from the Million Hearts CVD Model

About one-quarter of organizations were terminated for failing to respond to CMS's requests for information, including the requirement that organizations must sign the Model Participation Agreement or respond to a corrective action plan. Of the remaining organizations that withdrew, most did so because of challenges in meeting the model requirements. Some organizations withdrew because they lacked resources to collect and report the required data. Others reported difficulty with using the Million Hearts Data Registry and the specific data elements the model required organizations to report. Only a few respondents expressed concern about meeting the model's care delivery requirements, including follow-up contacts with high-risk beneficiaries.

Next steps

During the next year, we will continue to collect feedback from organizations on their experiences implementing the model. We will also estimate early impacts of the model on several outcomes, including:

- Incidence of first-time heart attack and stroke
- Medicare Part A and B spending, with and without model payments
- CVD-related hospitalizations and outpatient emergency department visits

Implementation evaluation. The evaluation team will use qualitative and quantitative data to assess how organizations are implementing the model. Using interview data from a group of intervention organizations, the team will continue to document implementation experiences, including any barriers and facilitators to implementation. The evaluation team also will interview staff from control organizations and organizations that withdrew from the model in 2018; these data will provide insight, respectively, into changes in cardiovascular preventive care management under care as usual and challenges to participating in the model. Using data from the Million Hearts Data Registry, the team will construct measures of model implementation, such as the percentage of eligible beneficiaries enrolled in the model and the percentage of high-risk beneficiaries who received reassessment visits. Additional quantitative data will come from the results of two surveys the evaluation team is fielding to intervention and control

organizations. These data will provide additional insight into how intervention organizations implement the model, the barriers and facilitators to implementing it, and how the model differs from usual care—as reflected by the control group responses.

Impact evaluation. For the next annual report, we will estimate early impacts of the model on several claims-based outcomes, including incidence of first-time heart attack and stroke; Medicare Part A and B spending, with and without model payments; and CVD-related hospitalizations and outpatient emergency department visits. In estimating these impacts, we will use the population of 2017 enrollees and measure all outcomes relative to a person's enrollment date—for example, estimating impacts in the first year following enrollment. We will estimate impacts for (1) the high-risk enrollees, the primary target population for the model, and (2) the medium- and high-risk enrollees combined, given the expectation the model could have positive spillover effects to medium-risk beneficiaries.

Further, we plan to estimate impacts on intermediate outcomes, anticipated by the Million Hearts CVD Model logic model. For the roughly 70 percent of medium- and high-risk beneficiaries covered by Medicare Part D, we plan to assess initiation or intensification of antihypertensive or statin medications (for people with elevated blood pressure or cholesterol at baseline, respectively). In addition, by comparing responses between the intervention and control organizations with questions on the surveys we are fielding, we plan to estimate impacts on (1) the extent to which organizations use CVD risk scores to guide their care (and the extent to which this has changed over the previous two years since the model began) and (2) the extent to which organizations proactively follow up with their high-risk patients to encourage and assess progress in reducing CVD risk. Finally, we will also assess completeness of the reassessmentvisit data in the Million Hearts Data Registry. This analysis will be a first step in assessing model impacts on a key study outcome—the reduction in 10-year CVD risk scores.

I. INTRODUCTION

A. Overview of the Million Hearts Cardiovascular Disease Risk Reduction Model

Despite significant reductions in key risk factors for cardiovascular disease (CVD) over the past 20 years, CVD remains the leading cause of death and disability in the United States. CVD costs an estimated \$450 billion in health care spending and lost productivity each year (Centers for Disease Control and Prevention [CDC] 2012). The primary risk factors for CVD—high blood pressure, high cholesterol, smoking, type 2 diabetes, and obesity—can be treated effectively and inexpensively. If these risk factors were well controlled through behavioral modification or treatment, CDC has estimated that the risk for death from heart attacks and strokes in the United States could fall by more than half (CDC 2012).

In January 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts[®] Cardiovascular Disease Risk Reduction Model (the Million Hearts CVD Model), designed to reduce heart attacks and strokes among Medicare fee-for-service (FFS) beneficiaries. Medicare's current FFS payment system does not reward providers for developing and implementing innovative approaches for preventing chronic illnesses such as CVD and their associated morbidity. The Million Hearts CVD Model encourages innovation by offering providers supports and financial incentives to assess and reduce the 10-year predicted risk of heart attack and stroke among their Medicare FFS beneficiaries.

Through this model, CMS is testing this core question: Do the supports and financial incentives offered to organizations in the Million Hearts CVD Model reduce 10-year predicted CVD risk, the number of first-time CVD events (heart attacks and strokes), and total cost of care for their Medicare FFS beneficiaries over the 5-year model period? If the model improves care quality while reducing Medicare spending enough to offset the model payments, then CMS may expand the model to Medicare FFS beneficiaries more broadly. The model may also pave the way for other value-based payment approaches to prevent other chronic illnesses (Sanghavi and Conway 2015).

CMS is testing the Million Hearts CVD Model in a rigorous five-year randomized trial of 516 organizations throughout the country, with half assigned to the intervention group and half to a control group that receives usual care. These organizations include primary care practices, specialty practices, hospitals, and federally qualified health centers (FQHCs), in both urban and rural locations. The intervention organizations are expected to do the following:

• **Risk stratify all eligible Medicare FFS beneficiaries.** Intervention organizations use the 2013 American College of Cardiology/American Heart Association (ACC/AHA) calculator to estimate each eligible beneficiary's risk of having a heart attack or stroke over the next 10 years (Goff et al. 2013). The inputs to this risk calculation are age, gender, race, cholesterol levels, blood pressure, smoking status, whether the beneficiary has diabetes, and whether the beneficiary is being treated for hypertension. Beneficiaries are eligible if they are ages 40 to

79, have not had a heart attack or stroke and they meet other inclusion criteria.³ Beneficiaries with a CVD risk score exceeding 30 percent are considered high risk. Those with a risk score from 15 percent to 30 percent are considered medium risk. All other scores are considered low risk.

- **Provide cardiovascular care management to high-risk beneficiaries.** This includes (1) shared decision making and individual risk modification planning—that is, helping beneficiaries understand their CVD risk and the benefits and drawbacks of different treatment options, then jointly deciding on a clinical approach to reduce risk that reflects the beneficiary's goals, values, and concerns; (2) annual, in-person risk reassessments to identify changes in each high-risk beneficiary's clinical risk and to update his or her care plan; and (3) a minimum of two interactive follow-up contacts (any mode) each year to assist the beneficiary in making progress on the care plan.
- Collect and report clinical data to CMS via the Million Hearts Data Registry. The organizations will submit eligible beneficiaries' initial risk scores and supporting clinical data, as well as risk score updates over time for high-risk beneficiaries. CMS will calculate changes in risk over time by using the Million Hearts Longitudinal CVD Risk Assessment tool. This tool, which was developed specifically for the Million Hearts CVD Model, translates a person's changes in cholesterol, blood pressure, smoking status, and aspirin use over time into a new 10-year risk score (Lloyd-Jones et al. 2017).
- **Participate in learning system activities.** These activities include webinars and videoconferences that are designed to spread effective strategies for implementing the model, particularly through peer-to-peer learning.

CMS supports the intervention organizations with three types of payments. The CVD risk stratification payment is a one-time payment (\$10) for each beneficiary an organization assesses with the ACC/AHA risk calculator. In the first model year, CMS paid monthly cardiovascular disease care management (CVD CM) fees (\$10) for each beneficiary categorized as high risk in the initial assessment. In Model Years 2 to 5, CMS is making monthly risk reduction payments for each high-risk beneficiary, with the size of the payment ranging from \$0 to \$10 depending on an organization's performance in reducing the average 10-year predicted risk among all beneficiaries initially designated as high risk. To support the model's evaluation, CMS is also paying control organizations to collect and report clinical data on their eligible Medicare FFS beneficiaries.⁴ These organizations are not required to calculate CVD risk scores (and do not have access to the risk calculator available through the data registry) or otherwise change their clinical care.

Although CMS has set guidelines for implementation, the model is not prescriptive. Indeed, CMS expects that organizations will vary significantly in how they approach the intervention—for example, in how they structure their care teams. Some organizations, moreover, could already be risk stratifying most of their patients or providing ongoing care management services,

³ The criteria include being enrolled in Medicare Part A and B, not having end-stage renal disease, and not receiving hospice benefits.

⁴ Specifically, CMS is paying control organizations \$20 for each eligible beneficiary for whom they report data to the registry in each of the first three years of the model test (for a maximum of \$60 per beneficiary).

whereas others might not. These differences will likely mean that some organizations are more successful than others in reducing aggregate CVD risk for their high-risk beneficiaries.

CMS is testing the Million Hearts CVD Model at a time of rapid change in the financing and delivery of health care services, including cardiovascular care. The U.S. Department of Health and Human Services (HHS) launched the broader Million Hearts initiative (of which the Million Hearts CVD Model is one part) in 2011, with the goal of preventing 1 million heart attacks and strokes within five years (CDC 2012). This campaign has included public health initiatives to increase awareness of CVD risks and clinical initiatives to increase the use of aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation (ABCS) in clinical care. In addition to the campaign, CMS payment and delivery reforms, such as the Medicare Shared Savings Program (MSSP), Comprehensive Primary Care Plus (CPC+), and Chronic Care Management (CCM) fees, encourage better care at lower costs.

The organizations participating in the Million Hearts CVD Model may also participate in these other initiatives—which could either help or hinder the model's effectiveness. New supports, such as CCM, could combine with the more modest Million Hearts CVD Model incentives to spur improvements in care that neither would alone. However, new initiatives might also offer the control organizations new opportunities to improve their care, reducing the marginal impact of the Million Hearts CVD Model incentives and supports relative to usual care.

B. Evaluation objectives and purpose of this report

1. Evaluation objectives

The overall goal of the evaluation is to assess whether, and through what mechanisms, the Million Hearts CVD Model improves CVD care, reduces heart attacks and strokes, and lowers or maintains Medicare spending (including program costs) among Medicare FFS beneficiaries. CMS may use the findings from the evaluation to inform decisions about whether and how to scale the model to Medicare beneficiaries more broadly.

To meet this overall goal, the evaluation has specific objectives that fall within three areas:

- 1. **Model implementation.** The evaluation will describe how participating organizations change their care delivery to implement the core components of the Million Hearts CVD Model and the factors that make it easier or harder to make such changes. This analysis will include (1) how organizations structure their CVD care teams; (2) the approaches they use to risk stratify beneficiaries, engage in shared decision making, and provide ongoing CVD care management to high-risk beneficiaries; and (3) the intensity and consistency with which they deliver these services. The evaluation will also describe how extensively stakeholders (practices and beneficiaries) engage with the model, how readily organizations can incorporate the model's provisions into their existing clinical workflows, and the degree to which organizations engage in and benefit from the model's learning activities.
- 2. **Model impacts.** The evaluation will assess whether the Million Hearts CVD Model reduces CVD risk (as measured by 10-year risk scores), reduces the incidence of first-time heart attacks and strokes, and does so while lowering or maintaining total Medicare FFS spending (including program costs). The primary analyses will assess impacts for high-risk beneficiaries given that CMS is paying intervention organizations to manage cardiovascular

risk for this group. But the evaluation will also estimate impacts for the medium- and highrisk groups combined because the model could have positive spillover effects for mediumrisk beneficiaries (as described in Chapter I, Section C). The impact evaluation will also assess whether the model (1) improves secondary outcomes, such as reducing individual CVD risk factors or reducing CVD-related hospitalizations or emergency department (ED) visits, and (2) has unintended consequences, such as side effects from aggressive treatment of CVD risk factors.

3. **Synthesis.** The evaluation will synthesize the implementation and impact findings to identify (1) the mechanisms that drive overall program impacts, including where along the expected causal pathway from model inputs to final outcomes the model did or did not work as expected, and (2) the factors that drive variation in organizations' individual performance in reducing CVD risk for their Medicare beneficiaries.

If the model shows favorable impacts, then the evaluation will also assess the feasibility and likely benefit of scaling the model to Medicare FFS beneficiaries more broadly.

2. Purpose of the first annual report

The primary purpose of this report is to describe how the Million Hearts CVD Model has been implemented during its first 16 months (January 2017 to April 2018). The evaluation team used a mixed-methods approach, drawing from site visits, phone interviews, clinical data collected through the Million Hearts Data Registry, Medicare claims, and model application data to describe the following:

- The characteristics of the organizations, providers, and beneficiaries who are participating in the model—including an assessment of how similar intervention and control participants were at the start of the model and the implications of this similarity for rigorously assessing the model's impacts.
- The reasons organizations joined the model and the reasons that some organizations withdrew
- How intervention organizations are implementing the model on the ground and factors that have helped and hindered implementation
- The extent to which the Million Hearts CVD Model has prompted changes in CVD care
- How control organizations deliver CVD preventive care—as a proxy for the type of care that intervention organizations might have delivered had they not been in the intervention—and how these organizations are meeting their reporting requirements to CMS
- The organizations' experiences with the tools and financial incentives that CMS provided to the intervention organizations to support model implementation and to the control organizations to support data reporting

In our future annual reports, we plan to estimate the impacts of the Million Hearts CVD Model on heart attacks and strokes, the 10-year CVD risk scores, Medicare spending, and other outcomes.

C. Logic model guiding the evaluation

1. Logic model

The evaluation team has developed a logic model (Figure I.1) to guide all aspects of the evaluation. This model may be read as a series of if-then statements that link the model inputs to reductions in the model's three long-term, primary outcomes: (1) CVD risk among high-risk beneficiaries, (2) first-time CVD events, and (3) Medicare expenditures.

Specifically, the model begins with inputs—including (1) the intervention organizations' baseline approaches to identifying and mitigating CVD risks among their patients, and (2) Medicare beneficiaries' baseline CVD risk factors; self-care and clinical care (from all providers, not just the organization that enrolled them into the model); and care preferences. Organizations will likely vary in the extent to which they are already using CVD risk scores to guide care and prompt discussions with beneficiaries. The Million Hearts CVD Model may have larger impacts for organizations that were not already, at baseline, routinely using risk scores to guide care.

The logic model then shows the incentives and supports that CMS provides to the intervention organizations to implement the Million Hearts CVD Model. These incentives and supports include (1) payments for risk stratifying all Medicare FFS beneficiaries, for providing cardiovascular care management for high-risk beneficiaries, and—starting in the second model year—payments for reducing aggregate CVD risk among high-risk beneficiaries; (2) learning systems focused on peers sharing best practices for implementing the model; and (3) tools for calculating CVD risk, estimating the impact that different therapies would have on reducing risk, and reporting risk factors to CMS. These incentives and supports are expected to prompt the intervention organizations to deliver the core elements of the model—including, beginning or strengthening processes to risk stratify their Medicare beneficiaries; developing individual care plans based on shared decision making for high-risk patients; and following up with patients in person at least once each year and twice through other means (for example, phone calls) to assess and encourage progress on CVD risk reduction plans and to adjust those plans as needed.

Once the participating organizations implement these core elements, the expected short-term outcomes (within weeks or months of a beneficiary enrolling) include improvement in (1) Medicare beneficiaries' awareness of their CVD risk factors as well as their motivation and actions to reduce these risks, such as improving diet or exercise patterns or adhering to statin or blood pressure therapy, and (2) the clinical CVD preventive care that participating organizations deliver—for example, initiating or intensifying statin therapy for beneficiaries with high cholesterol. Finally, these short-term outcomes should lead to the final outcomes expected by the end of the 5-year study period: lower 10-year CVD predicted risk; lower incidence of first-time heart attack and stroke; and lower overall Medicare spending, largely through reducing spending on acute CVD events.

The logic model also recognizes that the participating organizations operate in different markets and policy settings, which could influence the extent to which an organization can reduce CVD risk among its Medicare beneficiaries. For example, participating organizations will vary in the availability of referral partners such as cardiologists, hypertension clinics, and dieticians that could support an organization's efforts to reduce CVD risk.

Figure I.1. Logic of how the the Million Hearts CVD Model is intended to improve outcomes

INPUTS	MILLION HEARTS MODEL	OUTPUTS	SHORT-TERM OUTCOMES (within 1 year of enrollment)	LONG-TERM OUTCOMES (by end of 5-year model test)
Medicare FFS Beneficiaries Baseline CVD risk Baseline self-management and clinical care to reduce CVD risk Care preferences Participating Organizations Existing approaches for identifying and mitigating CVD risk Clinical, administrative, and technology resources Participation in other improvement initiatives and payment models	 Incentives and Supports CMS payments (fixed and performance-based) CMS performance feedback report cards Learning system / technical assistance Tools (ASCVD risk calculator, SDM) Data registry to report CVD risk factors Intervention Cardiovascular Disease Risk Stratification Assign CVD risk scores for all eligible Medicare FFS beneficiaries Identify high-risk beneficiaries Identify and enroll high-risk beneficiaries Notify and enroll high-risk beneficiaries in MH Cardiovascular Care Management Develop individualized CVD risk modification planning for high-risk beneficiaries through SDM Conduct interactive follow-up and reassessment to monitor high-risk beneficiaries' risk reduction progress and modify care plans Potential spillover: deliver similar services to medium-risk beneficiaries 	Risk scores calculated for 90% or more of eligible Medicare FFS beneficiaries and reported to registry every 6 months Beneficiary notification letter provided to enrolled beneficiaries Documented individualized CVD risk reduction care plans for high-risk beneficiaries Follow-up for high-risk beneficiaries • 1 annual in-person reassessment visit • 2+ annual check-ins Potential spillover: similar outputs for medium-risk beneficiaries	Medicare FFS Beneficiaries Increased awareness of CVD risk Increased input into care plans Improved self-efficacy and adherence to care plans Participating Organizations Increased provider awareness of high-risk beneficiaries Improved clinical care for high-risk beneficiaries (e.g. new or intensified statin therapy) Potential spillover: increased awareness of medium-risk beneficiaries and early risk management	Primary Lower CVD risk scores for high-risk beneficiaries Decrease in first-time heart attacks, stroke among high-risk beneficiaries Reduced Part A and B spending Secondary Decrease in other CVD outcomes (heart failure, CVD-related deaths) Fewer CVD hospitalizations and ED visits Reductions in individual risk factors (e.g. blood pressure, cholesterol) Potential spillover: improved primary and secondary outcomes for medium-risk
MARKET CHAP	ACTERISTICS that could influence model im	plementation or impacts		

- · Local market availability of referral partners and community-based resources to support behavior change
- Geographic differences in CVD preventive care practice patterns
- · Local, state, and federal payment reforms, e.g, ACOs, value-based performance initiatives

ACO = accountable care organization; ASCVD = atherosclerotic cardiovascular disease; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee for service; MH = Million Hearts; SDM = shared decision making.

Although CMS is paying only for cardiovascular care management services for high-risk beneficiaries (those with a 10-year predicted risk of heart attack or stroke of at least 30 percent), the logic model anticipates that there may also be positive spillover to medium-risk beneficiaries (those with a 15 percent to 30 percent 10-year CVD risk). Specifically, the act of risk stratifying all Medicare beneficiaries alone could make providers newly aware of important, modifiable CVD risk across their Medicare FFS panel, not only among high-risk beneficiaries. Clinical guidelines recommend that providers consider initiating statin therapy for beneficiaries with a 10-year risk score as low as 7.5 percent (as long as LDL-C exceeds 70 mg/dL; Stone et al. 2014), well below the threshold for high-risk beneficiaries (and, in fact, below the threshold for medium-risk beneficiaries). Simply being newly aware of CVD risk could prompt changes in clinical care to reduce this risk, even if such efforts are not separately paid for through CVD CM fees. Further, to the extent that participating organizations develop new processes to manage CVD risk for high-risk patients, such as putting in alerts within electronic health records (EHRs), the organizations may use the same processes for medium-risk beneficiaries as well.

2. How the logic model guides the evaluation

The evaluation team is using the logic model to guide each of the three components of the evaluation—implementation, impact, and synthesis:

- 1. **Implementation.** The evaluation team is using the logic model to identify (1) specific incentives and supports that should be assessed in the implementation analysis—both the extent to which these supports were used and provider perceptions of them—and (2) core elements of the intervention.
- 2. **Impacts.** The evaluation team is using the logic model to identify the short-term and longterm outcomes that will be measured for the impact evaluation. This includes the primary long-term outcomes (for example, incidence of first-time heart attacks and strokes) but also short-term or intermediate outcomes such as increased provider initiation or intensification of statins or other medications. In addition, the logic model helps to identify the core study populations for the impact evaluation, which includes high-risk beneficiaries (given the model's explicit focus on these beneficiaries) and the high- and medium-risk beneficiaries combined (given anticipation of positive spillover for this group).
- 3. **Synthesis.** Once the evaluation team has collected evidence for both implementation effectiveness and outcomes, the team will use the logic model to help structure an analysis of what may have driven observed impacts. For example, if the model does not reduce CVD events, where along the causal pathway did the model appear to stop working? Did the model increase providers' awareness of CVD risk among their patient panels but not prompt changes in the types of clinical care that affect patient outcomes? The team will also use items identified under "market characteristics" and "inputs" to help develop testable hypotheses about which types of participating organizations would see greater success in reducing CVD risk.

Although the logic model is a useful tool to organize data collection, analysis, and presentation, important aspects of the evaluation may fall outside of the logic model because they are not anticipated mechanisms or outcomes of the intervention. For example, the evaluation team will also be assessing whether the Million Hearts CVD Model had any unintended consequences, such as complications from overtreatment of CVD risk factors or

increases in Medicare spending as beneficiaries seek new care and may even receive downstream interventions (for example, cardiac stress tests) as part of increased attention to CVD prevention.

D. Road map for the report

This report proceeds as follows. Chapter II describes the organizations and providers participating in the Million Hearts CVD Model and the characteristics of the roughly 300,000 Medicare beneficiaries the organizations enrolled in 2017. We also describe the similarity of beneficiaries between the intervention and control groups on a range of characteristics and why, in combination with planned sensitivity tests, the observed baseline balance indicates a rigorous assessment of the model's impacts should be feasible. Chapter III describes how intervention organizations implemented the model during its first 16 months (from January 2017 to April 2018). This chapter uses results from a survey to all intervention organizations (administered by CMS's model implementation contractor) to describe the CVD preventive services that organizations provided when the model began. Then, based on in-person and phone interviews with 15 organizations, we describe how intervention organizations implemented the model, the factors that helped and hindered implementation, and the extent to which the care they provided under the model differed from the care they provided before the model began.

Chapter IV presents the results of phone interviews with 10 control organizations to describe how CVD preventive care changed over the past two years at these organizations as a proxy for how intervention organizations might have changed CVD preventive care if they had not been assigned to the intervention. Chapter V discusses the supports and payments that organizations received to implement the model. We use CMS data to describe the supports provided to participating organizations, and we use interviews with respondents from participating organizations to describe their perceptions of the value of these supports in motivating or sustaining model implementation. Chapter VI discusses the reasons why many organizations left the model in 2017. Chapter VII briefly discusses our next steps for the evaluation.

II. CHARACTERISTICS OF THE ORGANIZATIONS, PROVIDERS, AND BENEFICIARIES PARTICIPATING IN THE MILLION HEARTS CVD MODEL

Chapter summary

A wide range of organizations are participating in the Million Hearts CVD Model. In the first model year, these organizations successfully enrolled about 170,000 medium- or high-risk Medicare FFS beneficiaries, many of whom could benefit from the types of improvements in CVD care that the model's logic envisions.

- The 516 organizations that joined the model are primary care practices, specialty practices, federally-qualified health centers, and hospitals located throughout the country in rural and urban areas.
- Organizations reported joining the model because it aligned with their goals to prevent CVD and because it would require only modest changes to their workflows.
- Of the 516 organizations, only 319 (62 percent) actively participated in the first year, meaning they did not withdraw and they successfully reported at least one eligible beneficiary to the Million Hearts Data Registry.
- About 5,000 providers participated in the model in the first year. Two-thirds of these providers were physicians (mainly primary care); the remainder were nurse practitioners or physician assistants.
- The participating organizations enrolled about 300,000 Medicare beneficiaries—18 percent were high risk, 40 percent were medium risk, and 42 percent were low risk.
- While much of the beneficiaries' baseline CVD risk was driven by age and other nonmodifiable factors, there is still meaningful room for improvement. For example, threequarters of high-risk beneficiaries would, according to AHA/ACC guidelines, qualify for therapy to bring their blood pressure under control.
- The intervention and control groups were very similar in their mean CVD risk scores, as well as in the individual components (e.g. age and cholesterol) of those scores. This similarity contributes to our overall assessment that a robust impact evaluation is feasible.

In this chapter, we describe the characteristics of the organizations, providers, and Medicare beneficiaries who participated in the model in its first year. The analyses rely on data from model applications, the Million Hearts Data Registry, Medicare claims and enrollment files, CMS information on organization participation and withdrawal, and the National Plan and Provider Enumeration System. We supplement these quantitative data sources with interviews with 15 intervention organizations and 10 control organizations about the reasons the organizations joined the model.

A. Characteristics of the organizations participating in the Million Hearts CVD Model

1. Characteristics of all 516 organizations that initially joined the model

CMS solicited requests for applications to participate in the Million Hearts CVD Model in May 2015 and April 2016. Organizations had to meet the following eligibility requirements (CMS 2015):

- The organization had at least one provider (medical doctor, doctor of osteopathic medicine, physician assistant, and nurse practitioner)
- Providers were enrolled in and eligible to bill for Medicare Part B
- The organization used an EHR system certified by the Office of the National Coordinator for Health Information Technology (ONC)
- Participating providers had met the criteria for the EHR Incentive Programs, also known as Meaningful Use, in performance year 2014

CMS received 762 applications. Of these, 246 organizations did not respond to requests for further information or withdrew from consideration before

Key findings:

- Organizations that applied and participated in the model were varied in location, size, type, and experience with other CMS initiatives.
- Almost all reported joining the model—at least in part—because it aligned with organizational goals to prevent CVD.
- Of the 516 organizations that were randomized, 319 actively participated in the first model year.

Data sources:

- Applications from model participants
- National Plan and Provider Enumeration System
- In-person and telephone interviews with 15 intervention and 10 control organizations

randomization. CMS randomly assigned the remaining 516 organizations to the intervention (N = 260) and usual-care control groups (N = 256). With the assistance of NORC, the Million Hearts application support contractor, CMS used an adaptive randomization procedure intended to make the intervention and control groups similar, on average, in size and location.

The 260 organizations randomized into the intervention group varied considerably in their size, location, type, and experience with other CMS payment or care delivery reforms (Table II.1).

- Roughly one-third of the organizations self-reported having 1 to 5 providers, one-third reported having 6 to 19 providers, and one-third reported having 20 or more providers.
- Similarly, about one-third of the organizations had only one practice location, another one-third had two to five locations, and the final one-third had six or more locations.
- The organizations were distributed across all 10 HHS regions and all 4 census regions (Figure II.1).
- Half of the organizations self-reported being located in a rural area.
- The organizations were primarily practices—either primary care practices (46 percent) or specialty practices (23 percent).

Characteristic	Intervention organizations (N = 260)	Control organizations (N = 256)	Difference
Size (from Million Hearts CVD Model application)			
Number of providers, mean	44	43	1.0
1 to 5 providers (%)	34	36	-1.7
6 to 19 providers (%)	30	30	-0.5
20 or more providers (%)	36	34	2.2
Number of sites, mean	7	7	0.7
1 site (%)	37	35	1.4
2 to 5 sites (%)	34	34	-0.1
6 or more sites (%)	29	30	-1.2
Location (from Million Hearts CVD Model application)			
Rural (%)	50	43	6.6†
Census region (%)			•
Northeast	27	26	0.4
Midwest	22	20	2.0
South	35	37	-1.7
West	16	16	-0.6
Territories	< 1	< 1	0.0
Organization type ^a			
Primary care (%)	46	48	-1.5
Specialty or multispecialty (%)	23	21	1.2
FQHC, RHC, or other health center (%)	14	14	-0.2
CAH or rural hospital (%)	7	6	0.7
Acute care hospital (%)	7	5	2.2
Participates in other CMS models or programs ^b			
In one or more model (or application pending at randomization) (%)	47	44	3.6
In Medicare Shared Savings Program (%)	27	19	7.8†
In Advance Payment ACO (%)	5	4	1.1
Applied for ACO Investment Model (%)	8	12	-4.4†
In CPC Initiative (%)	3	5	-2.8†
In Bundled Payments for Care Improvement (%)	6	4	2.3
Applied for TCPI (%)	4	4	-0.1

Table II.1. Characteristics of the 516 organizations that joined the Million Hearts CVD Model and were randomized to the intervention or control groups

Source: Self-reported Million Hearts CVD Model application data linked to the CMS National Plan and Provider Enumeration System.

Note: Daggers (†) denote differences between the two groups that are larger than 0.10 (†) standard deviations. A target of 0.25 standardized differences is an industry standard, but CMMI has recently expressed a preference for balance within 0.10 standardized differences--that is, a preference for better balance--for other CMMI evaluations.

^aOrganization type was obtained by merging (1) the NPI from participating organizations, which were provided at the time of application to the Million Hearts CVD Model, with (2) January 2018 data from the CMS National Plan and Provider Enumeration System. The primary taxonomy codes were then used to categorize the organizations. Other health centers include Indian health and migrant health centers. The few unknown cases are those for which we could not find an organizational NPI. We used Type 1 NPIs for sole practitioners without a Type 2 NPI. This table omits some organization type categories; for this reason, percentages sum to less than 100 percent.

^bFor the purpose of this table, organizations were coded as not participating in other CMS models if they responded on the application that they didn't know.

ACO = accountable care organization; CAH = critical access hospital; CMMI = Center for Medicare & Medicaid Innovation; CPC = Comprehensive Primary Care; FQHC = federally qualified health center; NPI = National Provider Identifier; RHC = rural health center; TCPI = Transforming Clinical Practice Initiative.





- Source: Self-reported model application data linked to (1) CMS data on organization withdrawals and (2) data from the Million Hearts Data Registry.
- Note: Organizations actively participated in the Million Hearts CVD Model in 2017 if the organization (1) had not withdrawn or requested a withdrawal before December 31, 2017, and (2) had successfully reported at least one eligible Medicare FFS beneficiary to the Million Hearts Data Registry with a visit date between January 3, 2017, and December 31, 2017.

- Twenty-one percent of organizations were an FQHC or a critical access hospital (CAH), while 7 percent were acute care hospitals (for example, an outpatient department of the hospital).
- At enrollment, about half of the organizations already participated in another CMS payment and delivery reform model, such as the Medicare Shared Savings Accountable Care Organization (ACO) Program.

As expected, due to random assignment, the 256 organizations assigned to the control group were similar to the 260 intervention group organizations in terms of their size, location, type, and experience with other CMS payment and delivery reform models (Table II.1). Notably, organizations assigned to the intervention and control groups had similar size distributions because the randomization procedure effectively stratified by the number of providers in the organizations. Most other characteristics were similar between the intervention and control organizations as well. One exception was that intervention organizations were more likely than control organizations to report being located in rural areas (50 percent versus 43 percent).

2. Why organizations joined the model

Based on interviews with representatives of 25 intervention and control organizations, organizations enrolled in the model because they found it compatible with their internal goals and workflows, thereby reducing the burdens of implementing the model. Almost all organizations reported that an organizational commitment to prevent CVD and generally improve quality of care contributed to their decision to participate in the model. One-third of intervention and control organizations reported already participating in quality improvement initiatives prior to joining the Million Hearts CVD Model, including those led by an ACO or CMS (for example, CPC+). Prior experience with quality improvement programs could mean that the organizations already had infrastructure to implement quality improvement initiatives (such as adequate staff or health information technology [IT]).

Two-thirds of the intervention organizations interviewed reported that they expected the model would require only minimal changes to their clinical workflows and health IT systems. For example, two-thirds of intervention organizations said that their providers already followed ACC/AHA treatment guidelines or already used a CVD risk calculator. In addition, a little more than a third of intervention organizations reported that their health IT and data management capabilities were well suited to meet the requirements of the Million Hearts CVD Model. For example, one organization had an existing partnership with an external management firm that was able to manage data (for example, collecting and submitting data to the Million Hearts Data Registry) and support general IT needs (for example, adding a risk calculator to computer desktops). Other organizations had existing EHR software or health IT staff that could support the model.

Nearly a third of organizations interviewed also reported joining because the model might benefit the large number of high-risk patients they served. Representatives of one cardiac specialty hospital that almost exclusively treated high-risk, cardiac patients thought the model was well-suited for the patients served in their facility. A few organizations believed that the Million Hearts CVD Model's requirements could help them monitor and improve the quality of care they delivered to high-risk patients.

Most intervention organizations did not cite payment incentives as a motivating factor to participate, although one-fourth of intervention organizations said that the payments were one of many factors. These organizations all cited other reasons for joining, such as the ones listed above, as well as the opportunity to prepare for future value-based purchasing efforts. Moreover, these organizations noted that it felt like a bonus to be reimbursed for services they already provided, even if the payments were not the primary motivating factor to participate.

3. Characteristics of organizations that actively participated in the first year of the model

Of 516 organizations that joined the model and were randomized, 129 organizations withdrew or were terminated by CMS and 68 organizations did not successfully report any model-eligible beneficiaries to the Million Hearts Data Registry by the end of 2017.⁵ As a result, only 319 organizations (62 percent) actively participated in the first year, which we defined as the organization (1) successfully reporting at least one Medicare FFS beneficiary in the Million Hearts Data Registry during 2017 and (2) not withdrawing by December 31, 2017. Chapter VI discusses the reasons why organizations withdrew, which can be best understood after highlighting some of the barriers to and facilitators of model implementation (in Chapters III through V).

The 319 organizations that actively participated in 2017 were broadly similar to the 197 organizations that did not, although there were some notable differences (Table II.2). Specifically, participation was higher among large organizations (those with 20 or more providers or with six or more sites), primary care practices (as opposed to specialty practices and other providers), and organizations that had participated in other CMS payment and delivery reform models. Nonetheless, the 319 organizations that actively participated in 2017 still reflected a similar diversity in size, location, and type as the initial set of 516 organizations that was randomized (Table II.3).

Although the intervention and control groups after attrition were similar on some characteristics, attrition did create some baseline differences between the two groups. After attrition, the intervention organizations had fewer providers on average than the control organizations (39 providers versus 53 providers), were less likely to be in a rural area (by 5 percentage points), were more often located in the Northeast, had a somewhat different mix of organizational types, and participated in different CMS models.

⁵ Among the organizations that withdrew, 58 organizations did so in the eight months after randomization but before the model went live in January 2017 and 71 withdrew or were terminated by CMS during 2017. Some of the organizations that did not successfully report any eligible beneficiaries to the registry in 2017 may enroll beneficiaries in the future.

Characteristic	Organizations that actively participated in 2017 (N = 319)	Organizations that were randomized but did <i>not</i> actively participate in 2017 (N = 197)	Difference
Size (from Million Hearts CVD Model application)			
Number of providers, mean	46	40	5.6
1 to 5 providers (%)	33	39	-5.7†
6 to 19 providers (%)	29	30	-1.0
20 or more providers (%)	38	31	6.7†
Number of sites, mean	8	6	1.6†
1 site (%)	37	34	3.8
2 to 5 sites (%)	30	41	-10.2†
6 or more sites (%)	32	26	6.4
Location (from Million Hearts CVD Model application)			
Rural (%)	46	48	-1.6
Census region (%)			
Northeast	28	24	4.0
Midwest	18	26	-8.0†
South	38	34	4.4
West	16	16	-0.3
Territories	< 1	< 1	-0.2
Organization type			
Primary care (%)	52	39	13.5 ±
Specialty or multispecialty (%)	20	25	-4.5†
FQHC, RHC, or other health center (%)	14	14	0.2
CAH or rural hospital (%)	4	10	-5.8†
Acute care hospital (%)	6	7	-1.5
Participates in other CMS models or programs			
In one or more model (or application pending at randomization) (%)	50	39	11.3†
In Medicare Shared Savings Program (%)	26	18	7.9†
In Advance Payment ACO (%)	5	5	-0.4
Applied for ACO Investment Model (%)	10	9	1.2
In CPC Initiative (%)	5	3	2.5†
In Bundled Payments for Care Improvement (%)	5	4	1.8
Applied for TCPI (%)	5	4	1.1

Table II.2. Characteristics of organizations that did and did not actively participate in the Million Hearts CVD Model in 2017

Source: Self-reported model application data linked to (1) CMS data on organization withdrawals, (2) data from the Million Hearts Data Registry, and (3) the CMS National Plan and Provider Enumeration System.

Notes: Organizations actively participated in the Million Hearts CVD Model in 2017 if the organization (1) had not withdrawn (including termination by CMS) or requested a withdrawal before December 31, 2017, and (2) had successfully reported at least one eligible Medicare FFS beneficiary to the Million Hearts Data Registry with a visit date between January 3, 2017, and December 31, 2017.

Daggers denote differences between the two groups that are larger than 0.10 (†) or 0.25 (‡) standard deviations. This table omits some organization type categories; for this reason, percentages sum to less than 100 percent.

ACO = accountable care organization; CAH = critical access hospital; CMMI = Center for Medicare & Medicaid Innovation; CPC = Comprehensive Primary Care; FFS = fee-for-service; FQHC = federally qualified health center; RHC = rural health center; TCPI = Transforming Clinical Practice Initiative.

Characteristic	Intervention organizations (N = 163)	Control organizations (N = 156)	Difference
Size (from Million Hearts CVD Model application)			
Number of providers, mean	39	53	-13.7
1 to 5 providers (%)	36	29	6.7
6 to 19 providers (%)	26	33	-6.3
20 or more providers (%)	37	38	-0.4
Number of sites, mean	8	7	0.7
1 site (%)	39	35	4.0
2 to 5 sites (%)	29	31	-2.0
6 or more sites (%)	31	33	-2.0
Location (from Million Hearts CVD Model application)			
Rural (%)	44	49	-5.2†
Census region (%)			
Northeast	31	25	5.7†
Midwest	17	19	-2.7
South	38	38	0.2
West	14	18	-3.8†
Territories	< 1	< 1	0.6†
Organization type			
Primary care (%)	51	53	-2.3
Specialty or multispecialty (%)	21	19	2.2
FQHC, RHC, or other health center (%)	14	15	-0.6
CAH or rural hospital (%)	3	6	-2.7†
Acute care hospital (%)	7	4	3.5†
Participates in other CMS models or programs			
In one or more model (or application pending at	51	49	2.2
randomization) (%)			
In Medicare Shared Savings Program (%)	30	21	8.9†
In Advance Payment ACO (%)	5	4	0.4
Applied for ACO Investment Model (%)	9	12	-3.6†
In CPC Initiative (%)	3	7	-4.0†
In Bundled Payments for Care Improvement (%)	7	4	2.9†
Applied for TCPI (%)	4	6	-2.1

Table II.3. Characteristics of intervention and control organizations that actively participated in the Million Hearts CVD Model in 2017

Source: Self-reported model application data linked to (1) CMS data on organization withdrawals, (2) data from the Million Hearts Data Registry, and (3) the CMS National Plan and Provider Enumeration System.

Notes: This table is limited to the 319 organizations that (1) had not withdrawn (including termination by CMS_ or requested a withdrawal before December 31, 2017, and (2) had successfully reported at least one eligible beneficiary to the Million Hearts Data Registry with a visit date between January 3, 2017, and December 31, 2017.

Daggers denote differences between the two groups that are larger than 0.10 (†) or 0.25 (‡) standard deviations. A target of 0.25 standardized differences is an industry standard, but CMMI has recently expressed a preference for balance within 0.10 standardized differences--that is, a preference for better balance--for other CMMI evaluations. This table omits some organization type categories; for this reason, percentages sum to less than 100 percent.

ACO = accountable care organization; CAH = critical access hospital; CMMI = Center for Medicare & Medicaid Innovation; CPC = Comprehensive Primary Care; FQHC = federally qualified health center; RHC = rural health center; TCPI = Transforming Clinical Practice Initiative.

B. Number and types of providers who participated in the model

1. Provider eligibility requirements

In each performance period during the intervention, CMS expects that organizations will submit clinical data to the Million Hearts Data Registry for all eligible Medicare beneficiaries seen by their participating providers. The organizations identify which of their providers are participating by uploading a list of provider identifiers (the National Provider Identifier [NPI] and associated Tax ID numbers) to the Million Hearts Data Registry. To be eligible, a provider must be a medical doctor, doctor of osteopathic medicine, physician assistant, or nurse practitioner. Although CMS allows—and indeed encourages—other types of clinical or nonclinical staff (including nurses, pharmacists, and social workers) to be part of the CVD

Key findings:

- A total 5,250 providers participated in the model in 2017.
- Over two-thirds of participating providers were physicians (mainly primary care); the remainder were nurse practitioners or physician assistants.
- Due to a cap of 20 providers per organization in the control group but not the intervention group, nearly twice as many providers participated in the intervention group than the control group.

Data sources:

- Million Hearts Data Registry
- National Plan and Provider Enumeration System

care team, these staff are not considered participating providers. To limit CMS's financial exposure, CMS capped the number of providers that could participate in control organizations at 20 providers, but did not place any similar cap on the intervention organizations.

2. Characteristics of participating providers

The 163 intervention organizations that participated in the first year successfully submitted data to the registry for Medicare FFS beneficiaries seen by 3,622 distinct providers in 2017 (Table II.4).⁶ The majority of these providers were physicians (72 percent)—mostly primary care physicians (48 percent of all providers) followed by cardiovascular specialists (14 percent) and other specialists (10 percent). Physician assistants (17 percent) and nurse practitioners (9 percent) accounted for most of the remaining providers. According to the National Plan and Provider Enumeration System (NPPES) data set, a small fraction (2 percent) of the providers were medical students or other provider types that were not eligible to participate, though this may be due to NPPES being outdated for some providers. On average, each organization submitted data for 51 beneficiaries per participating provider.

The intervention group included more participating providers than the control group (3,622 providers versus 1,628 providers; Table II.4). This difference was driven by the 20-provider cap imposed by CMS. Although the intervention and control groups have a similar proportion of large organizations (defined as those with 20 or more providers), the large intervention organizations can report beneficiaries for as many of their providers as they chose while the controls are capped at twenty. As a result, the intervention group includes organizations with as many as several hundred participating providers while the large control organizations remain at 20 participating providers.

⁶ The providers themselves may not have been the ones actually reporting the data to the registry. Rather, other office staff may have entered the data for the providers, as our site visits confirmed has occurred (see Chapter V).

	Providers who saw at least one model-eligible Medicare beneficiary successfully reported to the registry in 2017			
Characteristic	Intervention group (N = 3,622)	Control group (N = 1,628)	Difference	
Provider specialty type (%)				
Physicians	72	76	-4.3	
Primary care practitioners	48	57	-9.6†	
Internist	19	22	-2.3	
Other primary care	28	35	-7.4†	
Cardiovascular	14	16	-1.7	
Cardiologist	10	12	-1.3	
Interventionist	4	4	-0.5	
Other	< 1	< 1	0.2	
Other specialists	10	3	7.0‡	
Non-physicians	28	23	4.3	
Nurse practitioner	17	14	2.9	
Physician assistant	8	8	0.2	
Other ^a	3	2	-1.3	
Number of beneficiaries reported to the registry per provider				
Mean	50	72	-21.7	
25th percentile	6	16	n.a.	
50th percentile	27	47	n.a.	
75th percentile	74	111	n.a.	

Table II.4. Characteristics of providers who participated in the Million HeartsCVD Model in 2017, by intervention group

Source: Self-reported model application data linked to (1) CMS data on organization withdrawals, (2) data from the Million Hearts Data Registry, and (3) provider specialty taxonomy codes from NPPES as of January 2018.

Notes: This table includes providers who (1) worked in organizations that actively participated in the Million Hearts CVD Model in 2017 and (2) saw at least one eligible Medicare FFS beneficiary in 2017 who was successfully reported to the Million Hearts Data Registry.

Daggers denote differences between the two groups that are larger than 0.10 (†) or 0.25 (‡) standard deviations. A target of 0.25 standardized differences is an industry standard, but CMMI has recently expressed a preference for balance within 0.10 standardized differences--that is, a preference for better balance--for other CMMI evaluations.

^aOther includes providers coded as medical students and other providers. Although providers can be coded as medical students, the small proportion identified as such could be due to two reasons: (1) the NPPES data are out of date (providers are not required to update their taxonomy information after initially applying for an NPI), and (2) NPPES does not validate the selected taxonomy code for a given provider. The category also includes providers with specialties that, based on NPPES taxonomy codes, were not allowed to register beneficiaries. These providers did not have at least one health care provider taxonomy code listed in NPPES indicating that they were an allopathic or osteopathic physician, a nurse practitioner, or a physician assistant.

CVD = cardiovascular disease; FFS = fee for service; n.a. = not applicable; NPI = National Provider Identifier; NPPES = National Plan and Provider Enumeration System.
The specialties of participating providers differed somewhat between the intervention and control organizations (Table II.4). Fewer intervention group providers were primary care physicians (48 percent versus 57 percent of control group providers), more were other types of specialists (10 percent versus 3 percent), and more were non-physician providers (28 percent versus 23 percent). Some of these differences may be due to the 20-provider cap on control organizations; the larger control organizations appeared to have selectively chosen physician providers over other types. When we repeated the analyses with the subset of organizations with 19 or fewer providers (that is, the subset of organizations for which the 20-provider cap would not have been a consideration), the proportions of participating providers in each specialty type were more similar between the intervention and control groups. For example, the proportion of providers who were not physicians in the intervention group was nearly equivalent to the proportion in the control group (30 percent versus 29 percent; data not shown).

On average, the control organizations reported data for significantly more eligible Medicare beneficiaries per provider than the intervention organizations (72 average beneficiaries versus 51 average beneficiaries; Table II.4). Control organizations subject to a 20-provider cap appear to have selectively chosen providers who saw the largest volume of beneficiaries. In contrast, intervention organizations—not subject to the cap—reported data from low-volume as well as high-volume providers, drawing down the average per provider.

C. Characteristics of Medicare beneficiaries enrolled in the Million Hearts CVD Model

The intervention and control organizations successfully reported data to the registry for almost 300,000 model-eligible Medicare beneficiaries in 2017 (Table II.5). CMS considers these beneficiaries to be enrolled in the Million Hearts CVD Model because they passed a validation procedure as described next. But beneficiaries and providers in the control group might not know they are participating in the model (rather, someone in the control group organization might submit patients' clinical data to the registry on behalf of the organization's providers). For both intervention and control group enrollees, the enrollment date is the date that the beneficiary visited the organization as reported in the registry and validated by CMS.

Key findings:

- Together, intervention and control organizations enrolled 297,040 Medicare beneficiaries in 2017.
- Eighteen percent of the beneficiaries were in the high-risk group.
- Of these, roughly 65 percent had diabetes and three-quarters had blood pressure that was not well controlled.
- The intervention and control groups were well balanced at baseline on CVD risk factors, suggesting a rigorous evaluation of the model's impacts is feasible.

Data sources:

- Million Hearts Data Registry
- Medicare claims and enrollment data

1. Process for enrolling beneficiaries

The organizations follow a four-step process—enrollment, validation, alignment, adjudication (EVAA)—to enroll each beneficiary into the Million Hearts CVD Model:

• **Enrollment.** First, the organization provisionally enrolled a beneficiary by submitting to the Million Hearts Data Registry (1) information about a beneficiary's visit with the organization and (2) all of the demographic and clinical data required to calculate the

beneficiary's baseline CVD risk score and support calculation of follow-up risk scores in the future.

- Validation. The CMS implementation contractor validated this provisional enrollment by looking through Medicare claims and enrollment data to confirm that (1) the beneficiary did visit the organization and (2) the beneficiary was eligible for the model—for example, he or she was age 40 to 79 at the time of the visit with no history of a heart attack or stroke.
- Alignment. If two organizations provisionally enrolled the same beneficiary, then the implementation contractor aligned the beneficiary with the organization that the beneficiary visited most recently.
- Adjudication. Organizations could ask CMS to reconsider the validation or alignment status of a beneficiary, which CMS would then need to approve.

If beneficiaries passed the four-step EVAA process, they were officially enrolled, and CMS paid the organization for those enrollments. Although CMS's implementation contractor validated about 300,000 enrollees in 2017, organizations tried to enroll several thousand more beneficiaries, but these provisional enrollments could not be validated. This often occurred because the organization had not submitted the full list of providers' identifiers or Tax ID numbers required to verify that the beneficiary had a visit with the organization at or near the time indicated in the registry.⁷

In addition to validating beneficiaries whom organizations provisionally enrolled, the CMS implementation contractor also identified beneficiaries whom organizations most likely should have enrolled but did not. Specifically, the contractor used claims data to attribute beneficiaries to the organizations and then compared the list with beneficiaries whom organizations enrolled successfully. CMS informed the organizations about beneficiaries who were eligible but not enrolled. The organizations could then go through the process of enrolling these beneficiaries or report why a person should not be enrolled—for example, the beneficiary declined to participate or only visited the participating organization once. Data from the implementation contractor suggest that, by June 2018, the intervention organizations had enrolled two-thirds of their eligible beneficiaries with visits during the first half of 2017. Comparable data were not available for control beneficiaries or beneficiaries with visits in the second half of 2017.

2. Total enrollment, by risk group and intervention status

The participating intervention and control organizations enrolled 297,040 beneficiaries in 2017 who also met study inclusion criteria (Table II.5).⁸ Overall, enrollment was higher in the

⁷ As of May 2018, there were 17 organizations that had not had any of their provisionally enrolled beneficiaries validated. Only one of these organizations had formally withdrawn from the model by the end of 2017; the remaining 16 were not counted among the 319 organizations considered active participants in this report because they did not enroll any beneficiaries. Some of these organizations and their beneficiaries might be added to the evaluation population in the future when the identifiers required for validation are updated.

⁸ The 319 participating organizations successfully enrolled a total of 300,086 Medicare FFS beneficiaries in 2017. However, 3,046 of these beneficiaries did not meet one or more of the following study inclusion criteria: All of their clinical data had plausible values (see Appendix A for definitions of plausible values), they were observable in Medicare FFS claims at enrollment, and they were enrolled at least six months before the organization that enrolled

intervention group than the control group (180,275 beneficiaries versus 116,765 beneficiaries). As described previously, this is because CMS capped the number of providers who could participate in the model for the control group but not the intervention group. The median number of enrollees per organization, however, was similar between the intervention and control groups.

The CVD risk scores were extremely similar between enrolled beneficiaries in the intervention and control groups. Eighteen percent of beneficiaries in both the intervention and control groups were high risk as of their model enrollment date, meaning that their baseline CVD risk score was at least 30 percent. This high-risk group is the primary target population for the Million Hearts CVD Model. A further 40 percent of beneficiaries were medium risk at enrollment, meaning they had a baseline CVD risk score of 15 percent to 30 percent.

 Table II.5. Enrollment and CVD risk profiles for the intervention and control groups

	Intervention group (N = 163 organizations)			Control group (N = 156 organizations)		
	Sum across organizations	Average per organization	Median across organizations	Sum across organizations	Average per organization	Median across organizations
Number of beneficiaries enrolled by 12/31/2017	180,275	1,106	312	116,765	748	362
Low CVD risk	75,924 (42%)	466	132	49,351 (42%)	316	157
Medium CVD risk	71,476 (40%)	439	123	46,311 (40%)	297	135
High CVD risk	32,875 (18%)	202	60	21,103 (18%)	135	65

Sources: Analysis of data from the Million Hearts Data Registry and the Medicare Enrollment Database and claims data accessed through the Virtual Research Data Center at CMS.

Notes: High CVD risk indicates beneficiaries with a 30 percent or higher predicted risk of having a heart attack or stroke in the next 10 years. Medium CVD risk is 15 percent to 30 percent. Low CVD risk is less than 15 percent. Risk is measured as of a beneficiary's enrollment date for the Million Hearts CVD Model. The total number of organizations (163 in the intervention group and 156 in the control group) is the number of active organizations that enrolled any beneficiaries. But not all organizations enrolled beneficiaries in all three risk categories (low, medium, and high). The averages and medians per organization are calculated over the full population of active organizations, including those with no enrollees in a given risk category.

CVD = cardiovascular disease.

3. Characteristics of the intervention group enrollees, by risk level

Table II.6 shows mean beneficiary characteristics among the intervention group enrollees, by risk level. For context, the table also shows national FFS averages for the beneficiary characteristics when available.

Demographics. High-risk beneficiaries were older than medium- and low-risk beneficiaries and a much higher proportion of the beneficiaries was male. This was expected given that older age and being male increase predicted CVD risk. Reflecting age differences across the groups,

them left the model (if applicable). Appendix A (Figure A.1) details how many of the beneficiaries, by intervention status, are removed from the study population because of each of these three conditions.

the low-risk beneficiaries were much more likely to be eligible for Medicare because of a disability rather than older age (65 or older). Low-risk beneficiaries were also more than twice as likely as high-risk beneficiaries to be dually enrolled in Medicare and Medicaid. This difference could be because low-risk beneficiaries are younger on average (mean age younger than 65) and are more likely to be entitled to Medicare because of disability. Because people who are entitled to Medicare because of disability typically live for some of their working years without employment income (Social Security Administration 2019), they may be poorer than average.

CVD risk factors. The average baseline risk score for high-risk beneficiaries was 40 percent, meaning that—on average—beneficiaries in this group were predicted to have a 40 percent chance of a heart attack or stroke in the next 10 years. Some of this CVD risk was due to factors that are not modifiable, such as age, sex, and history of diabetes; and some was due to factors amenable to either clinical therapy or behavior change, such as blood pressure levels or smoking status. Two beneficiaries with the same overall risk score could have very different proportions due to modifiable risk factors—and hence different opportunities for risk reduction.

As expected, most of the drivers of CVD risk were more common among high-risk beneficiaries than among beneficiaries with lower risk. For example, nearly two-thirds of highrisk beneficiaries had diabetes. This proportion is more than twice the national Medicare FFS average and much higher than the proportion for both the medium- and low-risk groups. Highrisk beneficiaries were also somewhat more likely to be smokers compared with medium- and low-risk beneficiaries, but only 12 percent of high-risk beneficiaries smoked.

Surprisingly, high-risk beneficiaries had lower total cholesterol and LDL cholesterol than medium- and low-risk beneficiaries, despite higher cholesterol leading to higher risk scores all else being equal. Indeed, more than one-quarter of high-risk beneficiaries (27 percent) had LDL cholesterol below 70, the cutoff the ACC/AHA guidelines use for recommending statin therapy to reduce cholesterol (Stone et al. 2014). A further 36 percent had LDL between 70 and 100. The lower cholesterol levels in the high-risk group (relative to the low- and medium-risk groups) could be because high-risk beneficiaries often have other risk factors, such as diabetes, that would have made them strong candidates for lipid-lowering statin therapy before the Million Hearts CVD Model began.⁹ As expected, high-density lipoprotein (HDL) cholesterol—the so-called good cholesterol—increases as we move from the high-risk to the medium- and low-risk groups.

The mean blood pressure among the high-risk group was 140 mm Hg. Seventy-four percent of the beneficiaries did not have their blood pressure well controlled, as indicated by systolic blood pressure values of 130 mm Hg or higher (Whelton et al. 2018). And some beneficiaries had very high systolic blood pressure (150 mm Hg or higher). The measured blood pressure levels indicate that, even if most beneficiaries were receiving some form of blood pressure medications at enrollment, these treatments were not sufficient to bring their blood pressure under control (systolic blood pressure of 129 mm Hg or lower).

⁹ Participating organizations provided information about beneficiaries' statin use. But because this information was current as of the time of data upload rather than as of the enrollment-qualifying visit, it is not clear whether statistics on statin use reflect baseline characteristics of the beneficiaries or effects of the model itself. In future reports, the evaluation team will use Medicare Part D data to assess statin use at enrollment among Medicare beneficiaries with Part D coverage.

Overall, the baseline CVD risk factors among the high-risk enrollees indicate that meaningful room for improvement exists in clinical- or self-care to reduce the likelihood of future CVD events. Seventy-four percent of the high-risk enrollees would-according to the ACC/AHA 2017 hypertension guidelines (Whelton et al. 2018)—qualify for blood pressure lowering medications because their systolic blood pressure is 130 or higher. A 2016 overview of systematic reviews (Karmali et al. 2016) found that such blood pressure-lowering therapy can reduce coronary heart disease events by 16 percent and strokes by 36 percent. Even among people who already receive blood pressure therapy, intensifying therapy (specifically, to target a systolic blood pressure value of less than 120 rather than 140) can reduce CVD events, including heart attack and stroke, by 25 percent (SPRINT Research Group 2015). Similarly, the 12 percent of high-risk beneficiaries who smoke at baseline could benefit greatly from quitting smoking. Studies suggest that quitting smoking can reduce CVD events by about 27 percent (Lloyd-Jones et al. 2017), with benefits varying by how long someone has stopped smoking. Finally, statin therapy reduces the risk of CVD events by an estimated 25 percent relative to no statin (Karmali et al. 2016), and using high-intensity statins lowers risk somewhat more than moderate-intensity statins (Stone et al. 2014). Seventy-three percent of the high-risk enrollees have LDL cholesterol of at least 70, which could indicate that initiating new statin therapy is appropriate. Because we do not yet have data on how many of the high-risk enrollees were already taking statins, it is unclear how much further CVD reduction could be achieved through new statin therapy for this group. We expect that at least some beneficiaries would benefit from starting or intensifying statin therapy.

The CVD risk factor data also indicate that meaningful room for improvement exists among medium-risk enrollees. As discussed in Chapter I, the medium-risk group is not the primary target population for the model, but there could be positive spillover effects among this group. Sixty-four percent of the medium-risk beneficiaries had elevated blood pressure, and 10 percent smoked. Further, 80 percent had LDL cholesterol of at least 70 and so could potentially benefit from statin therapy—though, as with high-risk beneficiaries, we do not yet know how many of these beneficiaries were already taking statins at baseline.

Chronic conditions and Medicare service use and expenditures. The high-risk beneficiaries were somewhat sicker overall than medium- and low-risk beneficiaries compared with national averages for the Medicare FFS population, as indicated by higher mean Hierarchical Condition Category (HCC) scores and counts of comorbid conditions.

The average of total annual Medicare expenditures was slightly higher in the high-risk group (\$8,183 per year for the intervention group) than in the low- and medium-risk groups (\$7,465 and \$7,629, respectively). But total expenditures, especially Part A expenditures, were much lower among Million Hearts CVD Model beneficiaries in all risk groups than the national Medicare FFS average. This is likely partially because the Medicare FFS average is based on all Medicare FFS beneficiaries during a year, including those who die, while the Million Hearts CVD Model population expenditures is measured in the 12 months before enrollment, which ensures that all beneficiaries were alive over the measurement period. Because end-of-life care can be very expensive, the restriction to beneficiaries who were alive at enrollment should yield lower-than-average annual expenditures. In addition, the Million Hearts CVD Model population has an age limit of 79 and is restricted to beneficiaries with no previous heart attack or stroke.

This likely further contributes to lower annual expenditures for the Million Hearts CVD Model's enrolled population.

The low-risk beneficiaries had a roughly 25 percent higher rate of outpatient ED visits than either the high- or medium-risk groups. This could be because beneficiaries in the CVD low-risk group, despite being younger than average, were on average more socioeconomically disadvantaged—as indicated by a higher proportion of beneficiaries with disabilities and dual eligibility—and had greater difficulty meeting care needs through regular primary care channels.

4. Comparison of beneficiaries at baseline for the intervention and control groups

The intervention and control groups were very similar at baseline on demographics, CVD risk factors, and Medicare service use and spending. This is true for the high-risk group (Table II.7)—the primary target population—and for the medium- and high-risk groups combined (Table II.8). Specifically, the intervention and control groups were similar in age; gender; CVD risk (overall score and its clinical components); Medicare spending and hospitalizations in the prior year; and HCC score, which predicts future spending. For example, among high-risk enrollees, both the intervention and control groups had a mean age of 74 and a mean CVD risk score of 40 percent. The mean HCC score for high-risk enrollees was 1.38 in the intervention group and 1.37 in the control group. As shown in Appendix B, the intervention and control groups were also well balanced in their use of specific CVD preventive services in their year before enrollment (for example, echocardiograms and cardiac stress tests) and the extent to which beneficiaries already had cardiovascular diseases (coronary artery disease or congestive heart failure).

The intervention and control groups differed in the types of organizations that enrolled them. Among high-risk enrollees, the intervention group beneficiaries were, on average, enrolled by organizations that had more providers (127 versus 91) and more sites (25 versus 14), that were more likely to participate in other CMS payment or delivery reforms at baseline (70 versus 55 percent), and that were less likely to be a primary care practice (42 versus 54 percent). In addition, intervention enrollees were more likely to live in the South (50 versus 34 percent) and to be enrolled in the first quarter of 2017 (47 versus 37 percent).

Some of these differences in the organizational characteristics of enrolled beneficiaries are attributable to the 20-provider cap. For example, because there is no cap for the intervention group, it makes sense that (1) the intervention group would enroll more beneficiaries overall and (2) a larger share of those beneficiaries would be enrolled by large organizations. If we trim the intervention group to mimic the 20-provider cap, we find that the intervention and control groups are much more similar in the size of the study population and the share of beneficiaries enrolled by large organizations (see Appendix C for details on how we trimmed the study population and the resulting baseline balance).¹⁰

¹⁰ We mimic the 20-provider cap in the large intervention group organizations by ranking their providers by number of beneficiaries they enrolled and then picking the top 20 providers and their beneficiaries (dropping beneficiaries enrolled by the other providers).

	High risk (N = 32,875)	Medium risk (N = 71,476)	Low risk (N = 75,924)	Medicare FFS average
Demographics				
Age mean	74	71	64	71 0 ^a
% black	8	9	10	9.5ª
% male	65	54	25	45.5 ^a
% dually enrolled in Medicare and Medicaid	9	10	21	19.9 ^a
% originally entitled to Medicare because of disability	12	15	36	26 1 ^b
% rural	27	24	23	NA
CVD risk factors				
CVD risk score mean (in %)	40	21	٥	ΝΔ
Diabatas %	40	21	10	28.10
Diaucies, 10 Total cholostorol, moon (in ma/dl.)	160	23	186	20.1 ⁻ NA
HDL cholesterol mean (in mg/dL)	109	52	57	
I DL cholesterol mean (in mg/dL)	47	90	104	NΔ
% < 70 ma/dl	27	20	15	NΔ
% 70-99 mg/dl	36	36	34	NA
% 100–129 mg/dl	22	27	31	NA
% ≥130 mg/dl	14	17	21	NA
Systolic blood pressure, mean (in mmHg)	140	131	124	NA
% <130 mmHa	26	46	66	NA
% 130-139 mmHg	28	28	21	NA
% 140–149 mmHg	21	15	9	NA
% ≥150 mmHg	25	10	4	NA
Treated for or diagnosed with hypertension, %	91	76	53	58.6 ^d
Current smoker, %	12	10	9	13.7 ^e
Chronic conditions				
HCC score mean	1.38	1.08	0.98	1 00
Count of conditions, mean	2.7	1.9	1.6	NA
Sorving use and enanding in year before anreliment		1.0		
Total Part A and P maan (\$ par person)	0 102	7 465	7 620	10 925f
Dart A moan (\$ por porson)	0,100	7,400	1,029	5 055Í
Fait A, mean (\$ per person)	2,400	2,190	Z,JIZ 5 210	5,055 [°]
Fait D, meall (\$ per person) Hogpital admissions, maan (# par 1,000)	3,111	0,∠07 170	0,010	0,700°
Outpatient ED visite mean (# per 1,000)	202	274	526	247° 416h
Office visits mean (# per 1,000)	9 895	8 992	9 258	NΔ

Table II.6. Baseline characteristics of intervention group enrollees in 2017, by CVD risk level

Source: Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Notes: High CVD risk indicates beneficiaries with a 30 percent or higher predicted risk of having a heart attack or stroke in the next 10 years. Medium CVD risk is 15 percent to 30 percent. Low CVD risk is less than 15 percent. Characteristics are measured as of a beneficiary's enrollment date in the Million Hearts

TABLE II.6 (CONTINUED)

CVD Model. The one exception is cholesterol levels, which might be collected up to five years before enrollment or two months after enrollment. For all measures, means are calculated over non-missing values.

^aAverage for 2015, from CMS.gov, Medicare Beneficiary Characteristics (2015).

^bAverage for 2014, from CMS.gov, Medicare Beneficiary Characteristics (2014) and Haile et al. (2017).

^cAverage for 2016, from Chronic Conditions Data Warehouse (2018).

^dAverage for 2016, from Chronic Conditions Data Warehouse (2018). This benchmark is for percentage of beneficiaries with hypertension, not whether treated for or diagnosed with hypertension.

eAverage for 2015, among All Medicare Beneficiaries (including Part C), from Medicare Current Beneficiary Survey (2015).

^fAverage for 2017, from Medicare Trustees Report (2018).

⁹Average for 2016, from Kaiser Family Foundation (2016).

^hAverage for 2012, from Gerhardt et al. (2014).

CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee for service; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

Table II.7. Baseline characteristics of high-risk enrollees, by intervention group

	Intervention	Control		Standardized
Characteristic	(N = 32,875)	$(N = 2^{1,103})$	Difference ^a	difference ^b
Clinical indicators of beneficiary's cardiovascu	ılar risk			
CVD risk score (percentage points)	40	40	0.1	0.01
Has diabetes (%)	66	64	1.6	0.03
Systolic blood pressure (mm Hg)	140	139	0.2	0.01
Total cholesterol (mg/dL)	169	169	0.1	0.00
HDL cholesterol (mg/dL)	47	48	-0.3	-0.02
LDL Cholesterol (mg/dL)	93	92	0.5	0.01
Is treated for or diagnosed with hypertension (%)	91	88 12	2.4 1 1	0.08
Lises aspirin (%)	51	50	-1.1	-0.03
Beneficiary demographic and Medicare enrolling	nent characteri	stics	0.0	0.02
Age	74	74	-0.2	-0.04
Black race (%)	8	6	17	0.04
Male (%)	65	65	-0.4	-0.01
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.6	-0.02
Originally entitled to Medicare because of	12	12	-0.1	0.00
disability (%)				
Beneficiary health and comorbid conditions				
HCC score	1.38	1.37	0.0	0.01
Count of chronic conditions	2.7	2.6	0.0	0.02
Beneficiary medical service use and spending	in year before I	model enrollme	nt	
Total Medicare Parts A and B annualized expenditures (\$)	8,183	8,010	172.2	0.01
Hospital admissions (per 1,000 beneficiaries)	202	200	1.3	0.00
Outpatient ED visits or observation stays	391	379	12.4	0.01
(per 1,000 beneficiaries)				
Office visits (per 1,000 beneficiaries)	9,895	9,451	444.4	0.06
Characteristics of organization enrolling the be	eneficiary			
Total number of practitioners	127	91	36.2	0.15
Total number of service sites	25	14	10.8	0.42
Organization type ^c (%)	10	= 4	10.1**	0.04
Primary care	42	54	-12.1**	-0.24
Organization was participating in or had	32 70	52 55	0.5	0.01
application pending for another model at	70	55	15.0	0.51
randomization (%)				
Characteristics of clinician enrolling the benef	iciarv			
Provider specialty ^c (%)	,			
Primary care physician	60	62	-1.5	-0.03
Cardiologist	25	26	-1.2	-0.03
Characteristics of beneficiary's region				
Rural (%)	27	28	-1.1	-0.03
Census region (%)				
Northeast	25	22	2.4	0.06
Midwest	19	29	-9.6	-0.23
South	50	34	15.9	0.33
West		15	-8.7	-0.28
Characteristics of beneficiary's Million Hearts			04.0**	0.00
Days between model launch (1/3/2017) and	110	141	-24.8	-0.26
Enrolled in the first guarter of the year (%)	47	37	9.1*	0.19

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk and characteristics of model enrollment; Medicare enrollment database for beneficiary demographic and Medicare enrollment

TABLE II.7 (CONTINUED)

characteristics; Medicare claims for health and comorbid conditions, and medical service use and spending; the organizations' applications to the Million Hearts CVD Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; and beneficiary zip codes from the Medicare enrollment database, linked to data from the Census Bureau, for regional characteristics.

Note: See Appendix A for details about variable construction.

^aAsterisks indicate statistically significant differences between the intervention and control groups at the p < .01 (**) and p < .05 (*) levels; *p*-values are based on standard errors clustered at the level of the participating organization. For binary variables, the *p*-values come from a t-test. For categorical variables, they come from an F-test and we report the same value across all categories.

^bThe standardized difference is the difference between the intervention and control group means, divided by the standard deviation across the intervention and control groups. A target of 0.25 standardized differences is an industry standard, but CMMI has recently expressed a preference for balance within 0.10 standardized differences--that is, a preference for better balance--for other CMMI evaluations.

^cThis table omits some organization type and provider specialty categories; percentages might add up to less than 100 percent.

CMMI = Center for Medicare & Medicaid Innovation; CVD = cardiovascular disease; ED = emergency department; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NPPES = Centers for Medicare & Medicaid Services' National Plan and Provider Enumeration System.

Table II.8. Baseline characteristics of medium- and high-risk enrollees combined, by intervention group

	Intervention group mean	Control group mean	D:#=====	Standardized
	(N = 104,351)	(N = 67,414)	Difference ^a	difference
Clinical indicators of beneficiary's cardiovascula	ar risk	~=		
CVD risk score (percentage points)	27	27	0.1	0.01
Has diabetes (%)	37	35	2.2	0.05
Systolic blood pressure (mm Hg)	134	134	-0.1	-0.00
lotal cholesterol (mg/dL)	1/4	173	1.2	0.03
HDL cholesterol (mg/dL)	50	51	-0.1	-0.01
LDL cholesterol (mg/dL)	97	95	1.3	0.04
Is treated for or diagnosed with hypertension (%)	81	75	5.2^	0.13
Is current smoker (%)	11	12	-0.8	-0.02
Uses aspirin (%)	45	43	1.7	0.03
		70	0.2	0.04
Aye Black race (%)	8	6	-0.2	-0.04
Malo (%)	57	50	2.0	0.08
Male (70) Dually oprolled in Medicare and Medicaid (%)	57	10	-1.5	-0.03
Originally entitled to Medicare because of	9 14	10	-0.3	-0.01
disability (%)	14	14	0.2	0.01
Beneficiary health and comorbid conditions				
HCC score	1 17	1 17	0	0.00
Count of chronic conditions	2.1	2.1	Õ	0.01
Beneficiary medical service use and spending in	vear before mo	del enrollment	-	
Total Medicare Parts A and B annualized	7,691	7,623	68.6	0.00
expenditures (\$)				
Hospital admissions (per 1,000 beneficiaries)	186	190	-4.8	-0.01
Outpatient ED visits or observation stays	380	364	15.2	0.01
(per 1,000 beneficiaries)				
Office visits (per 1,000 beneficiaries)	9,277	8,951	326.0	0.04
Characteristics of organization enrolling the ben	eficiary			
Total number of practitioners	123	96	27.5	0.12
Total number of service sites	25	14	10.8	0.43
Organization type ^c (%)				
Primary care	44	54	-9.5**	-0.19
Specialty or multispecialty	30	33	-3.3**	-0.07
Organization was participating in, or had	71	56	15.1	0.32
application pending for, another model at				
Characteristics of clinician enrolling the henefic	lon/			
Provider specialty (%)	lary			
Primary care physician	61	62	-15	-0.03
Cardiologist	24	25	-1.5	-0.03
Characteristics of beneficiary's region				0.00
Rural (%)	25	26	-1.5	-0.03
Census region (%)	-		-	
Northeast	26	22	3.7	0.09
Midwest	20	29	-9.5	-0.22
South	48	33	15.1	0.31
West	6	15	-9.4	-0.31
Characteristics of beneficiary's Million Hearts C	VD Model enrolln	nent		
Days between model launch (1/3/2017) and	122	143	-21.5**	-0.23
enrollment date				o 4-
Enrolled in the first quarter of the year (%)	44	36	1.5*	0.15

Sources: See Table II.7 for table sources and notes.

5. Implications of baseline balance for a rigorous impact evaluation

Overall, the baseline characteristics show that randomization succeeded in producing intervention and control groups that were similar in demographics, service use, and CVD risk factors—despite organization-level attrition from the model and incomplete data reporting to the Million Hearts Data Registry. This similarity increases our confidence that we will be able to rigorously estimate the model's impacts on CVD events and other outcomes in future reports. Specifically, we plan to estimate impacts as the difference in outcomes between intervention and control group enrollees. The baseline similarity increases the likelihood that any observed differences in outcomes are in fact attributable to model impacts—not pre-existing differences between the groups.

But the observed baseline differences in the characteristics of the organizations that enrolled the beneficiaries do pose some risk to generating credible impact estimates. If, for example, large organizations provide different types of CVD care than smaller organizations, the fact that a larger fraction of the intervention group is enrolled by large organizations could lead to differences in outcomes that are unrelated to model impacts. Further, organizational attrition, the 20-provider cap that applied only to the control group, and incomplete reporting make it possible that the intervention and control groups differ in ways that we have not observed but could confound the impact estimates. For example, intervention group organizations might selectively enroll beneficiaries they think are most likely to comply with clinical recommendations for CVD risk reduction. This could lead to better outcomes in the intervention group that are not attributable to model impacts.

We plan to address the risks to the impact estimates in two ways. First, we will use multivariate regressions that adjust for the characteristics of the organizations enrolling the beneficiaries in the impact estimates. Second, we will conduct two sensitivity tests (see Appendix C for details) that estimate impacts after we have redefined the study populations in the following ways that limit the potential differences between the intervention and control groups:

- **Trimming the intervention group to mimic the 20-provider cap**. This test will remove much of the potential risk of bias due to differences in the sizes of organizations enrolling beneficiaries.
- Attributing Medicare beneficiaries to participating organizations using claims data. Rather than defining the study population as actual enrollees, this test will define the population as everyone we attribute—using claims data—to participating organizations and who meet model eligibility criteria that we can observe in claims. This approach will remove the potential for biases attributable to (1) the 20-provider cap, because we will attribute using lists of providers that organizations submitted before randomization (and so before the cap came into effect), and (2) differences in the types of beneficiaries organizations chose to enroll via the registry, because we will include all eligible beneficiaries—whether or not they are enrolled.

Overall, we believe that a rigorous impact evaluation is possible, due both to the strong baseline balance on CVD risk factors and other beneficiary-level characteristics and the planned sensitivity tests. Further, given the actual number of enrollees in 2017, we project that the impact

estimates will have sufficient statistical precision to reliably detect the 7 percent impact on firsttime heart attacks and strokes that CMS originally anticipated when designing the model test (see Appendix D for the statistical power calculations). This page has been left blank for double-sided copying.

III. APPROACHES INTERVENTION ORGANIZATIONS USED TO DELIVER CVD PREVENTIVE CARE AND IMPLEMENT THE MILLION HEARTS CVD MODEL

Chapter summary

Findings from the first 16 months of implementation of the Million Hearts CVD Model suggest that intervention organizations have made improvements in their CVD preventive care. Implementation approaches for key components of the model varied across organizations. In addition, changes to CVD preventive care differed across providers, even within an organization. The emerging evidence included the following:

- Increased provider awareness of CVD risk among Medicare FFS beneficiaries. CVD risk scores helped providers more consistently identify high-risk beneficiaries as well as medium-risk beneficiaries, who could also benefit from interventions to reduce or stabilize CVD risk.
- Improved provider-patient discussions of CVD risk factors and risk management. Sharing the risk score with beneficiaries helped motivate them to consider lifestyle changes and medication options. Discussion of CVD risk provided an opportunity to discuss the potential benefits of treatments, address beneficiaries' concerns with medication therapy, and tailor treatment plans to beneficiaries' needs and goals.
- Enhanced team-based care to reduce CVD risk. More than one-half of the intervention organizations reported new roles for clinical staff to help identify high-risk beneficiaries and assist with development of risk reduction care plans. Some organizations described new roles for medical assistants, nurses, and population health team members to increase follow-up of high-risk beneficiaries and reassessment of CVD risk.
- Increased provider consistency and intensity of treatment to reduce CVD risk. Increased attention to CVD risk calculation led providers to more often initiate or intensify medication therapy to address uncontrolled risk factors.

This chapter first describes the CVD preventive services that intervention organizations provided in the early months of the model (defined as baseline), based on a survey of intervention organizations by the CMS implementation contactor (Appendix E describes the survey). Afterwards, the implementation experiences of 15 intervention organizations that participated in telephone or in-person interviews in early 2018 are described.

A. Baseline assessment of CVD preventive care

The evaluation team's analysis of results from a care delivery and monitoring survey in April 2017 found that the intervention organizations had the resources they needed to provide CVD preventive care when the Million Hearts CVD Model launched. The analysis was limited to 163 intervention organizations that actively participated in the Million Hearts CVD Model in 2017. The survey, which was administered by the implementation contractor, addressed service offerings apart from provider-recommended medication and behavioral therapies, including approaches for addressing elevated cholesterol, hypertension, and smoking. Other risk factors (such as diabetes) were not addressed in the survey.

Survey findings suggest that organizations offered a variety of approaches to support risk factor management.¹¹ The most common approaches for addressing high cholesterol and hypertension were patient education programs and patient reminders, each of which was used by just over one-half of the intervention organizations (Figures III.1 and III.2). For smoking cessation, the most common approach was referral to guit lines (a toll-free smoking cessation help line available in each state), which was offered by three-quarters of the intervention organizations (Figure III.3). Nearly one-half of the organizations offered individual smoking cessation programs. However, for each of these risk factors, between 10 percent and 20 percent of the organizations offered no specific support services for patients.

Key findings

- Just over one-half of intervention organizations offered patient education programs and patient reminders to manage cholesterol and hypertension in support of provider recommended medication and behavioral therapies.
- Three-quarters of intervention organizations offered referral to quit lines; one-half offered individual smoking cessation programs to support provider recommendations for reducing CVD risk associated with smoking.
- Between 10 and 20 percent of organizations offered no specific service offerings related to cholesterol, hypertension, and smoking risk factor management.

Data source:

• Implementation contractor survey to intervention organizations

Compared to small or medium organizations, a higher proportion of large organizations (twenty or more providers) had sophisticated strategies for helping providers address key CVD risk factors. Their key strategies included audits and feedback, provider education initiatives, and provider financial incentives.¹² For example, more than one-half of the large organizations provided audits and feedback for hypertension management, compared with roughly a third of medium and small organizations. In addition, urban organizations (which tend to be larger) were more likely to refer patients to specialty services offered by other providers or organizations. For example, around 40 percent of urban organizations had access to a cholesterol specialist compared with fewer than 20 percent of rural organizations. However, data were not available on how often beneficiaries received the services that organizations reported having.

¹¹ The survey did not define terms for risk factor management. Patient education programs may encompass interventions as minimal as providing handouts about a chronic condition. Patient reminders may encompass interventions as minimal as automated telephone calls to remind beneficiaries of upcoming appointments. Non-physician-led programs refer to programs in which a pharmacist or nurse manages a chronic condition, such as cholesterol or blood pressure, by using an algorithm until control is achieved. There is evidence spanning multiple decades for the effectiveness of such programs. Specialty referrals would be referrals to a specialist such as a cardiologist or endocrinologist or to a clinic dedicated to managing a specific condition.

¹² All differences described in this paragraph were statistically significant at the p < 0.05 level based on a chi-square test.

Figure III.1. Approaches to cholesterol management reported by intervention organizations as of April 2017



- Source: Mathematica Policy Research/RAND analysis of the Million Hearts Model Annual Survey on Care Delivery, which was fielded in April 2017 by CMS and its Million Hearts CVD Model implementation contractor.
- Note: Analysis was limited to 163 intervention organizations that participated in the model throughout 2017.

Figure III.2. Approaches to hypertension management reported by intervention organizations as of April 2017



- Source: Mathematica Policy Research/RAND analysis of the Million Hearts Model Annual Survey on Care Delivery, which was fielded in April 2017 by CMS and its Million Hearts CVD Model implementation contractor.
- Notes: Analysis was limited to 163 intervention organizations that participated in the model throughout 2017. Home telemonitoring refers to a program that allows transmission of blood pressure values to the managing provider or other clinical staff on a frequent (often daily) basis, as an aid to management. There is copious evidence for the effectiveness of such an approach.

*Other hypertension management program refers to a non-physician-led hypertension management program (e.g., nursing, pharmacist).

Figure III.3. Approaches to smoking cessation reported by intervention organizations as of April 2017



Source: Mathematica Policy Research/RAND analysis of the Million Hearts Model Annual Survey on Care Delivery, which was fielded in April 2017 by CMS and its Million Hearts CVD Model implementation contractor.

Notes: Analysis was limited to 163 intervention organizations that participated in the model throughout 2017. The survey response categories might mask differences between organizations that offer individual smoking cessation counseling sessions. For example, it is possible that one organization may have a psychologist who visits the site two afternoons per week and receives many referrals, while another organization may only occasionally refer selected beneficiaries to an outside psychologist.

B. Characteristics of intervention organizations selected for interviews

To understand implementation of the Million Hearts CVD Model at the organization level, the evaluation team selected a sample of 15 intervention organizations for in-person site visits (12 organizations) and telephone interviews (3 organizations).¹³ Interviews with organization leaders and frontline staff explored their strategies for implementing the model, how the model contributed to changes in CVD preventive care, and the barriers of and facilitators to implementation. The 15 organizations were selected to reflect the diversity across all intervention organizations in location;¹⁴ size; geographic setting (urban or rural); organizational characteristics; and participation in other CMS models or programs. The number of enrolled Medicare FFS beneficiaries for each organization at the time of the interviews ranged from fewer than 50 beneficiaries to more than 15,000 beneficiaries. Our methods for selecting the organizations, conducting the interviews, and analyzing the data are described in Appendix F.

C. Intervention organizations' Million Hearts CVD Model implementation experience

This section uses the evaluation framework (Figure III.4) to summarize how organizations implemented the Million Hearts CVD Model. The framework is aligned with the model components specified in the Model Participation Agreement—CVD risk stratification (Steps 1 to 4) and cardiovascular care management (Steps 5 to 7)—and includes the model implementation requirements described in the agreement that align with the steps in this evaluation framework (CMS 2016).

¹³ Telephone interviews were conducted with the smallest sites to reduce their burden.

¹⁴ The organizations were located in Arkansas, California, Colorado, Kentucky, Michigan, Missouri, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, South Carolina, Washington, and West Virginia.



Figure III.4. Framework for evaluating implementation of the Million Hearts CVD Model

1. Identify all eligible Medicare FFS beneficiaries

Of the 15 organizations interviewed, most created reports to run within their EHRs to identify beneficiaries who were eligible for the Million Hearts CVD Model. In some cases, these reports could not assess all eligibility criteria (for example, disqualifying conditions such as a prior heart attack or stroke). Therefore, some organizations supplemented these reports with a manual review for these characteristics. In a few cases, staff relied solely on a manual chart review to determine model eligibility. Respondents from a few organizations thought they had identified all eligible beneficiaries who had had an office

Model Eligibility

All Medicare FFS beneficiaries age 40 to 79 at the time of initial reporting who have Medicare Parts A and B are eligible for inclusion in the model, unless they meet one or more of the following exclusion criteria: a prior heart attack or stroke, endstage renal disease, a current election of the hospice care benefit (as defined in 42 CFR § 418.20), Medicare Advantage, or a primary payer other than Medicare.

visit. However, respondents from several other organizations acknowledged that they did not identify all eligible beneficiaries because of delays in setting up automated identification systems or because they relied on manual systems. One organization did not identify eligible beneficiaries; instead, staff uploaded data from all beneficiaries to the Million Hearts Data Registry, which allowed the Million Hearts algorithm to identify who was eligible for the model.

2. Assign CVD risk scores for eligible Medicare FFS beneficiaries

About one-third of the organizations interviewed used a risk calculator integrated in their EHR, while more than one-half used a separate application, such as a smartphone application, or they relied on the Million Hearts Data Registry. Sometimes, the approach varied across providers within an organization or multiple approaches were used.

Risk calculator function within the EHR.

Approximately one-third of the organizations used a risk calculator built into their EHR, although the level of automated processing to assign a beneficiary a CVD risk score varied. Some EHR calculators automatically gathered EHR vital signs, laboratory values, and diagnosis codes to calculate a risk score and record it in the visit note—although, in some cases providers might have to navigate to a new tab in the EHR to see the risk score. Other EHRs required providers to manually input

Key findings

- At some organizations, medical assistants and other non-clinical staff played an important role in assisting with model implementation tasks, particularly risk stratification, which allowed providers to focus on risk reduction planning and patient care.
- EHR tools and functionalities, especially those related to CVD risk score calculation, facilitated model implementation for some organizations and hindered those who did not have this functionality.
- Organizations where providers calculated risk scores themselves were inconsistent in risk stratification.
- None of the 15 organizations had processes for documenting that beneficiaries actually were notified of their risk score.

Data source:

• Telephone and site visit interviews with 15 intervention organizations

components of the risk score. In practice, this meant that the provider or staff would need to navigate to the vital signs of the EHR to find the blood pressure value and then input that value into the calculator. Next, the provider or staff would navigate to the laboratory tab of the EHR to find cholesterol values and input those, and so on.

Model Requirements

Use of the model risk calculator in the Million Hearts Model ASCVD Registry to determine the 10-year CVD risk score for each eligible Medicare FFS beneficiary upon the beneficiary's first visit after the launch of the Million Hearts CVD Model.

Use of the risk scores to categorize eligible beneficiaries as high risk or as low or medium risk. A high-risk beneficiary is defined as an eligible beneficiary with a risk score greater than or equal to 30 percent. About one-quarter of organizations had a risk calculator available in their EHR before the launch of the Million Hearts CVD Model. Other organizations constructed a risk calculator function within their EHR specifically for the Million Hearts CVD Model. These functions were usually created by internal employees in charge of EHR customization and took between 9 and 12 months to build, depending upon the funding available and other information system priorities within an organization. One organization created a risk calculator with high functionality that was housed within the visit note section and pulled in

data automatically. However, the model launch at this organization was delayed for 11 months, until the EHR calculator was built. Interviewees at a few organizations mentioned that they had wanted to integrate the risk calculator into their EHR previously, but it was only through participation in the Million Hearts CVD Model that they were able to make the case and obtain the necessary resources for that change.

Web-based or smartphone application risk calculators. Staff at more than one-half of the interviewed organizations used web-based calculators or smartphone applications to calculate risk scores. Often, the provider calculates the risk score. For example, at one organization a medical assistant checks each day's appointments for eligible beneficiaries and uses an internally developed form to collect information on data elements needed to calculate the CVD risk score. The medical assistant then gives this information to the provider and the provider calculates the

risk score during the visit. In other cases, a nonprovider calculates the risk score prior to the visit and gives it to the provider, often on a piece of paper, at the time of the visit. Some organizations may have both providers and non-providers calculating risk scores.

"With the Million Hearts enrollees, more and more we're doing it [assigning CVD risk scores] at the first available opportunity when we interact with them in the office." — Physician

Although providers and staff at some organizations were familiar with risk calculators and used them at least some of the time prior to participation in the Million Hearts CVD Model, more than one-half of the organizations reported that participation in the model prompted adoption of a more routine process to assign CVD risk scores. For example, one medical assistant said of providers: "What has changed in their care that they deliver? I think they're more in tune with the calculator, using it more.... It's more [at the] forefront for them now." However, a few respondents noted difficulty in engaging some providers in calculating risk. Even among those providers who were engaged, there was still some inconsistency in use of the risk calculator. In particular, a small number of organizations reported that providers had to navigate out of the visit note section to access the risk calculator or they did not have a risk calculator in their EHR at all or in a way that facilitated its use—which seemed to contribute to the inconsistency in calculating risk scores.

Several respondents explicitly stated or implied that they expected the Million Hearts CVD Model implementation would place additional burden on providers in terms of documentation and follow-up care. This may have been more of a concern among organizations that required the provider to collect risk factor data and calculate the risk score. As a Million Hearts leader at one organization mentioned, "It takes time away from their care to be able to document this accurately." Some organizations addressed this challenge by involving non-provider staff (for example, medical assistants) in the process of initial CVD risk assessment and risk stratification. These staff took responsibility for gathering data to support risk score calculation, calculating CVD risk scores, and making sure that beneficiaries receive a new cholesterol panel if the latest one was not recent enough to be used to calculate risk scores. Some providers expressed appreciation for the staff assistance with these model implementation tasks, which allowed the providers to focus on risk reduction planning and patient care.

3. Ensure provider awareness of high-risk Medicare FFS beneficiaries

To achieve the goals of the Million Hearts CVD Model, organizations not only need to calculate CVD risk scores but also ensure that their providers are aware of the high-risk beneficiaries and their risk scores in order to review risk factors and recommend approaches to reduce CVD risk. For three-fourths of the 15 organizations that the evaluation team visited, providers had access to beneficiaries' risk scores at the time of their first visit to the provider after the Million Hearts CVD Model start-up, either in the EHR or pre-visit paperwork or by calculating it during the visit. However, in about one-quarter of the organizations the risk score

was calculated after the initial visit by non-provider staff. For example, one organization seemed to operate the Million Hearts CVD Model completely separately from direct care delivery activities. Non-provider staff identified eligible beneficiaries, calculated scores, and uploaded them to CMS. Respondents acknowledged that they did not have data available on whether providers actually were accessing the risk scores and discussing them with beneficiaries.

4. Notify and enroll high-risk Medicare FFS beneficiaries

Because most providers had access to the risk score at the initial visit, they were able to notify the majority of eligible patients of their CVD risk at that time. Among the one-quarter of organizations that notify patients of their score after the office visit, only one organization had a provider reach out to high-risk

Model Requirements

Notification of eligible beneficiaries identified as high-risk of their inclusion in the Million Hearts CVD Model using approved text provided by CMS.

beneficiaries to inform them of their score. At the other organizations, a non-provider staff member may call the beneficiaries to inform them of their score or the organization mails a letter to the beneficiary. In these cases, it is unclear when or if the provider sees the beneficiary's score. One organization had not yet developed a process to share the CVD risk scores with beneficiaries. None of the 15 organizations had processes for documenting that beneficiaries actually were notified of their risk score. In addition, organizations varied substantially in whether they thought the notification routinely happened for all beneficiaries.

5. Develop individualized CVD risk modification care plans using shared decision making

Nearly all organizations reported using shared decision making to engage beneficiaries in CVD risk modification planning prior to and after implementing the Million Hearts CVD Model, although their perceptions of what constituted shared decision making varied broadly. Almost all organizations described their shared decision making process as including one or more of the following: (1) a provider and beneficiary co-creating health goals and a plan to meet those goals. (2) a provider assessing the beneficiary's willingness to accept treatments and prioritizing the treatment plan accordingly, and (3) a provider reviewing the costs and benefits of treatments with the beneficiary. No organization had a mechanism for tracking and monitoring the frequency and quality of shared decision making. A few organizations specifically mentioned difficulties with documenting and monitoring use of shared decision making by providers. Organizations' shared decision making strategies included the following:

Key findings

- Providers faced challenges in shared decision making including time constraints and beneficiaries feeling overwhelmed by conversation about CVD prevention, particularly during visits for acute issues.
- Nevertheless, some providers reported that shared decision making helped engage beneficiaries in CVD risk management and gave providers more information to tailor beneficiary care plans to improve adherence.
- Most organizations relied on burdensome time-consuming manual processes to track high-risk beneficiaries due for follow-up contacts and CVD risk reassessments.
- Many organizations were just beginning to focus on beneficiary follow-up at the end of model year 1, and more than one-half lacked a systematic method to ensure they have completed follow-up contacts with beneficiaries twice a year.

• Use of the beneficiary's CVD risk score to initiate discussions. Nearly one-half of the organizations said that providers used the risk score as a starting point for shared decision making with beneficiaries about how to reduce CVD risk. These conversations sometimes included reviewing how individual risk factors contributed to the risk score and sometimes used the risk calculator to show how improving a risk factor could change the beneficiary's score going forward.

Model Requirement

Using a shared decision making process that involves a discussion between the provider and beneficiary regarding (1) the beneficiary's current level of CVD risk; (2) steps the beneficiary can take to reduce his or her risk; (3) the potential benefits and risks of different treatment options; and (4) the beneficiary's goals, values, and concerns (CMS 2016). Decision aids may be available on paper or through an electronic source such as a website or patient portal.

• Reliance on informal conversations rather than formal decision aids to guide risk modification discussions. Most organizations described using a shared decision making process that relied on informal conversations between the provider and beneficiary. About one-third of the organizations mentioned using decision

aids to guide risk management discussions, although it appeared that many respondents used the terms "decision aids" and "education materials" interchangeably. One organization did use an electronic decision aid for statin therapy, developed by the Mayo Clinic, which could be printed for beneficiaries to take home.



"[Discussing risk scores with beneficiaries]

• Use of patient education materials and resources to provide information on treatment options to beneficiaries. Three organizations developed in-house education materials that addressed the clinical benefits and potential side effects of treatment options (available in paper and electronic versions), which beneficiaries could read on their own and review with

their provider. In addition, one organization that was part of a larger health system reported referring beneficiaries to the system's lipid clinic, which helps beneficiaries through the shared decision making process for improving lipid profiles.

"[Documenting shared decision making] is one of the one thousand things providers have to do for each patient."

— Director of Quality Improvement

Engaging beneficiaries in shared decision making and documenting it presented a significant challenge for providers. More than one-half of the organizations reported that beneficiaries felt overwhelmed by conversations about CVD prevention, especially if the patient's visit was for another acute issue. Three organizations reported that newly hired providers struggled more with

shared decision making because they had not yet established relationships with beneficiaries. In addition, respondents reported that providers found it time-consuming to describe shared decision making activities in their notes. Two organizations attempted

"We want to know what is important to the patient because whatever is important to them is what they are more likely to work on, be driven to work on."

- Registered nurse

to overcome this barrier using "smart phrases"¹⁵ that allow providers to quickly document shared decision making activities. However, it is difficult to know how accurately the documentation reflects the shared decision making that occurred.

Despite the challenges of shared decision making, respondents reported that engaging beneficiaries in a discussion of their risk and potential approaches to reducing that risk was worthwhile. Respondents from two organizations credited the Million Hearts CVD Model with encouraging providers to carve out time for shared decision making during patient visits. These same two organizations and a third stated that shared decision making was valuable for improving patient outcomes because it engaged beneficiaries and therefore made them more likely to adhere to their treatment plan and because it gave providers more information to tailor the treatment plans.

Model Requirement

Creating an individualized risk modification plan (care plan) for each beneficiary that includes an electronic summary of the beneficiary's CVD risk score, the variables used to calculate the risk score, the preventive care services recommended by the provider, and medication reconciliation. CMS anticipates that developing the care plan (including the risk discussion with providers) will allow beneficiaries to leave the visit knowing their risk, how to reduce their risk, and the contents of the patientcentered care plan.

Almost all organizations reported using electronic care plans, although the content and process for creating a care plan varied across organizations and in some cases across providers in the same organization. More than one-third of the organizations created care plans by using free text notes in their EHR or after-visit summaries produced by their EHR as a previous Meaningful Use requirement. These care plans were unstructured and the type of information included in them varied by providers within an organization. Respondents at almost one-third of the organizations reported that care managers or population health department staff created care plans that included the risk score and the provider's notes. These staff share the care plan with beneficiaries in person, via mail, or through the patient portal after reviewing it with them during an in-person or phone visit. Providers were more likely to report feeling burdened by care plans at organizations where providers had sole responsibility for creating and maintaining them. Almost one-third of organizations used care plans created for other CMS models, including the CPC+ initiative. It was not always clear whether organizations adapted these care plans to meet the Million Hearts CVD Model requirements.

EHR tools partially relieved the burden of documenting care plans at three organizations; however, updating them continued to be a burden for providers because the tools did not transfer data within the care plans from one encounter to the next. Three organizations had EHR tools such as "dot phrases" or "smart text" that automatically import relevant patient data and details of the treatment plan in the visit note. Some organizations created or adapted dot phrases or smart text specifically to meet the Million Hearts CVD Model requirements, though other organizations already had this functionality. Respondents said that these tools lessened provider burden to document care plans and helped providers to more consistently document information when creating new care plans. However, these EHR tools did not necessarily offer smooth

¹⁵ Smart phrases are standard text available in the EHR for commonly documented issues, which providers can insert into their notes through a few clicks.

transfer of information across encounters, which remained a burden for providers who had to manually import patient information to new versions of the care plan.

6. Deliver CVD preventive care to high-risk Medicare FFS beneficiaries to reduce CVD risk

The Million Hearts CVD Model is not prescriptive with regard to how organizations deliver CVD preventive care. As part of this evaluation, the team assessed organizations' strategies for reducing CVD risk, including provider care delivery patterns, population-based interventions, and team-based care.

Provider care delivery patterns. Many providers said that they had not changed their practice due to the Million Hearts CVD Model. However, the evaluation team noted that some

Key findings

- More than one-half of organizations reported that participation in the model prompted adoption of a more routine process to assign CVD risk scores.
- Providers appeared to be more aware of beneficiary CVD risk and having more indepth discussions with patients about their risk factors and risk management options.
- Increased attention to CVD risk led some providers to more often initiate or intensify medication therapy to address uncontrolled risk factors.

providers had in fact made changes, especially in how aggressively they managed CVD risk factors. In some cases, providers appear to have extended these approaches to medium-risk beneficiaries (10-year risk, 15 percent to 29 percent). Findings included the following:

- Elevated cholesterol. Some providers reported using the CVD risk score as a starting point to engage high-risk beneficiaries in risk reduction planning discussions and to overcome patient reluctance to take statins. Providers reported that this led to initiating statin therapy with beneficiaries who were resistant to taking statin therapy or who had declined statins in the past. Providers also were more likely to intensify the statin dose for beneficiaries on statin drugs who were not at goal LDL cholesterol levels.
- **Hypertension.** To a limited extent, some providers described increased efforts to control blood pressure. However, most providers seemed to have already been putting forth maximal effort in this regard.
- **Smoking.** Providers found it challenging to help beneficiaries quit smoking. The Million Hearts CVD Model may have had the least impact on this risk factor.

Respondents from a number of organizations mentioned their involvement in programs to promote lifestyle changes among beneficiaries with diabetes, a risk factor for heart disease that is present for approximately two-thirds of the high-risk beneficiaries in the Million Hearts CVD Model (see Chapter II, Section C.3). Such programs, while intended to improve glycemic control, are also likely to have beneficial impacts on CVD risk. There was no evidence, however, that the model prompted initiation or expansion of these programs.

Population-based interventions. Respondents generally felt that they had good systems in place for managing CVD risk factors among their patient panels (see Chapter III, Section A). Therefore, they saw no need to change or add new services. None of the 15 interviewed organizations reported adding new population-based services for CVD risk management, such as a hypertension clinic, smoking cessation clinic, or lifestyle modification service, as a result of their participation in the Million Hearts CVD Model. However, respondents from many of the 15

organizations reported having added registries (separate from the Million Hearts Data Registry) or using population health departments or care managers to ensure adequate follow-up, prevent loss to follow-up, identify opportunities to improve a specific risk factor, or even suggest optimal management to the provider.

Respondents reported several barriers to adding new population-based programs to help providers address beneficiary CVD risk factors. First, some providers feel they should be responsible for these aspects of care management themselves. This especially applies to hypertension and hyperlipidemia. Second, providers find it challenging to address some risk factors, including smoking cessation and lifestyle improvements (such as increased exercise, improved diet, and weight loss). While respondents reported they could identify resources that may help beneficiaries address CVD risk factors (such as psychologists for smoking cessation, nutritionists for dietary improvements and weight loss, and exercise coaches for physical activity), providers frequently reported not referring beneficiaries to such services because of their perceptions that Medicare did not cover these services and beneficiaries could not afford to pay for them out of pocket.¹⁶

Team-based CVD preventive care delivery. Although many of the 15 intervention organizations interviewed involved non-provider clinical staff in CVD risk stratification activities, only a few reported involvement of non-provider clinical staff in the actual delivery of CVD preventive care. Most often, the role of the non-provider clinical staff to support CVD risk management for the Million Hearts CVD Model included reviewing the beneficiary's CVD risk score prior to the visit, identifying care gaps (such as a patient whose blood pressure remained uncontrolled), and reminding the provider to address the issue at the visit. However, we did not see any examples of still greater degrees of autonomy for staff to manage CVD risk factors. For example, despite clinical trials demonstrating the benefits of pharmacist- or nurse-managed CVD risk reduction programs, there was little evidence to suggest that intervention organizations expanded the use of these health professionals in the management of hypertension, elevated cholesterol, or smoking (Taylor et al. 2003; Denver et al. 2003; New et al. 2003; Wallymahmed et al. 2011). Finally, respondents reported no changes in their use of specialists to help with CVD prevention, such as endocrinologists who could help control hypertension.

Among the organizations that expanded staff roles, respondents attributed increases in teambased care directly to their participation in the Million Hearts CVD Model. That is, they stated that these changes would not have occurred without the impetus of the model. Non-provider staff usually took on new model-driven duties without additional time or resource support to perform these duties, although there were a few exceptions, particularly at the largest organizations. Notably, some respondents described increased professional satisfaction associated with these new responsibilities. A provider at one site explained, "In a sense it's brought somebody like [the medical assistant] more into the fold because … her role has typically been just bringing people

¹⁶ The following services are billable and payable under the Medicare physician fee schedule as separate services as of 2017: (a) G0445 - High intensity behavior health counseling, 30 minutes; (b) G0446 - Intensive behavior therapy for cardiovascular disease; (c) G0447 - Behavior counseling for obesity, 15 minutes; (d) G0108 - Diabetes management training per individual; (e) G0109 - Diabetes management training per individual; (f) 99406 - Behavior change for smoking, 3–10 minutes; and (g) 99407 - Behavior change for smoking > 10 minutes.

back, get them checked in, vitals.... I think this has given her a little bit something different to do and some ownership with something, too."

7. Follow up and reassess to monitor CVD risk reduction progress

Respondents from many organizations reported that during the first year of implementing the model their initial efforts focused on identifying eligible beneficiaries to enroll and calculating CVD risk scores. They later turned their attention to establishing follow-up and reassessment processes. In some cases, organizations were just starting to focus on systems for tracking follow-up contacts. Findings included the following:

 Most organizations relied on burdensome manual processes for tracking high-risk beneficiaries due for follow-up contacts and CVD risk

Model Requirement

Engaging high-risk Medicare FFS beneficiaries twice a year in interactive, twoway communications to assess the beneficiary's progress and update the care plan. Follow-up contacts may be conducted in person or remotely (such as via telephone, mobile device, or secure electronic patient portals) (CMS 2016). Intervention organizations must also update CVD risk scores annually with updated clinical data. The annual reassessment of the CVD risk score must happen in person within 10 to 14 months after the enrollment visit.

reassessments. Only one-third of the interviewed organizations used internal registries such as a health IT platform connected to the EHR or, more commonly, Excel spreadsheets or paper lists that staff manually updated. Staff at other organizations manually reviewed patient lists to determine who needed follow-up visits or reassessments. They noted that this manual review was time-consuming and burdensome for staff and that beneficiaries could fall through the cracks during busy times.

- More than one-half of organizations had no systematic way of ensuring that they had followup contacts with beneficiaries twice per year. Instead, they relied on existing workflows such as scheduling annual wellness visits; contacts for other initiatives (for example, CPC+); or other routine office visits—to meet the model's follow-up requirement. One-third of the organizations reported other strategies for following up with model enrollees. Three of these organizations reported using routine office visits for completing follow-up contacts as well, but also added alerts in the EHR to notify providers or nurses that a beneficiary was enrolled in the Million Hearts CVD Model and due for a follow-up visit. The remaining organizations communicated with beneficiaries via secure text messaging platforms. One did so as frequently as weekly using technology that existed prior to implementing the Million Hearts CVD Model; the other organization was implementing the text messaging platform as a part of model implementation.
- The majority of organizations lacked a systematic method to identify beneficiaries who required a reassessment. Similar to their approach for follow-up contacts, they relied on existing workflows that brought in beneficiaries for visits, such as annual wellness visits, CPC+ contacts, or other routine visits. Staff may flag which beneficiaries need a reassessment on the daily schedule or depend upon the nurse or provider to spot the need while looking at the patient chart during the visit.

D. Early beliefs and expectations of the effect of the Million Hearts CVD Model on CVD care and beneficiary outcomes

Respondents varied in how much they thought the Million Hearts CVD Model would impact clinical outcomes. Some respondents expressed great confidence that the increased attention to CVD prevention would result in improved outcomes, while others thought the impact would be minimal. Most fell between these extremes. Among those who predicted better outcomes, improved provider initiation and intensification of statins and higher beneficiary adherence to statins were viewed as the factors that would most likely lead to better outcomes. Improved

Key findings

- Some respondents expected the increased attention to CVD prevention would result in improved outcomes, while others thought the impact would be minimal. Most fell between these extremes.
- Potential barriers to improved clinical outcomes include other competing initiatives, insufficient resources to fully implement the model, and lack of buy-in from some providers.

blood pressure control and increased smoking cessation were also mentioned as potential mediators of improved outcomes, but much less often. Some respondents thought that the increased focus on these factors could lead to improved outcomes for both medium- and high-risk beneficiaries.

Barriers that could limit the Million Hearts CVD Model's impact on clinical outcomes include: (1) other competing initiatives or insufficient resources to fully implement the model and (2) lack of buy-in from some providers. First, the evaluation team's impression from interviews with the vast majority of respondents was that staff were doing their best to implement the model given available resources, competing priorities, and other demands. However, most organizations are involved with multiple initiatives—either internally or through another entity, including CMS. Although respondents expressed belief in the importance of the Million Hearts CVD Model and commitment to the goals, many also acknowledged that the model was not one of their organization's top priorities. In addition, for most intervention organizations, implementing the model required additional time and resources beyond the delivery of routine clinical care. The majority of intervention organizations were able to call on additional help from non-clinical office staff and IT staff to assist with model implementation. However, some organizations did not have additional resources to support implementation and struggled with implementation of the Million Hearts model. Second, while several respondents in intervention organizations described efforts to continually engage providers, a few respondents acknowledged that some providers were not on board with or focused on the model. So, even if there was room for improvement in their care, some providers within an organization might not have been making the necessary changes.

IV. APPROACHES CONTROL ORGANIZATIONS USED TO DELIVER CVD PREVENTIVE CARE

Chapter summary

Identifying how control organizations provide CVD preventive care—including any efforts to risk stratify patients—provides additional insight into whether changes in care delivery made by the intervention organizations (as described in Chapter III) are due to the Million Hearts CVD Model or broader changes in the delivery of CVD care. Control organizations receive payments to collect and report clinical data on their eligible Medicare FFS beneficiaries, but these organizations are not required to calculate CVD risk scores or otherwise change their clinical care. Interviews with 10

Key findings

- Providers at control organizations were not routinely risk stratifying patients or using risk scores to identify high-risk patients for follow up.
- Most control organizations had not made significant changes in their delivery of CVD preventive services since the launch of the Million Hearts CVD Model.

Data Source

 Telephone interviews with 10 control organizations

control organizations and 15 intervention organizations suggest that the Million Hearts CVD Model is leading to differences in how intervention and control organizations assess CVD risk and provide follow-up care. Specifically, although providers in both intervention and control organizations have access to publicly available CVD risk calculators—often predating the launch of the Million Hearts CVD Model—providers in the control organizations appear to be less systematic in risk stratifying beneficiaries, notifying high-risk beneficiaries of their heightened risk, and using risk scores to identify who needs follow up over time. Other notable similarities and differences between the control and intervention organizations interviewed are summarized in Table IV.1.

This chapter first describes the organizational characteristics of the 10 control organizations that participated in telephone interviews in July and August 2018, then discusses the organizations' approaches and changes to CVD preventive care.

Table IV.1. Similarities and differences in approaching CVD risk stratificationand follow-up care between a sample of intervention and controlorganizations

	Similarities	Differences
CVD risk stratification	A high proportion of both intervention and control organizations have EHR and/or web-based CVD risk calculators available for providers to use in the office.	The majority of control organizations left the decision to risk stratify beneficiaries to the discretion of the provider. In contrast, most intervention organizations attempted to systematically risk stratify all eligible beneficiaries and notify providers and beneficiaries of high-risk scores. At control organizations, risk stratification was generally done exclusively by providers. In contrast, at intervention organizations this was often done by nonclinical staff as well as providers.
Care planning based on beneficiary CVD risk score	No similarities identified.	Control organizations did not routinely generate CVD care plans that included an electronic summary of the beneficiary's CVD risk score, individual cardiac risk factors, and plans to address the elevated risk. In contrast, intervention organizations frequently did so, perhaps because it was a requirement of the model.
Follow-up based on CVD risk score	No similarities identified.	None of the control organizations indicated that they used the CVD risk score to identify high-risk beneficiaries for follow-up beyond what they otherwise would have provided. In contrast, intervention organizations appeared to be more systematic in arranging for follow-up of high-risk beneficiaries.

CVD = cardiovascular disease; EHR = electronic health record.

A. Characteristics of control organizations selected for interviews

To understand how control organizations delivered CVD preventive care, the evaluation team selected a sample of 10 organizations for telephone interviews. The process for selecting the control organizations for interviews was similar to that used to select the intervention organizations (see Appendix F). The control organizations interviewed represented a diverse group of organizations based on size, location, and organization type.¹⁷ Similar to intervention organizations, many control organizations interviewed also participated in other CMS models or programs.

We reached out to the individuals at control organizations who were CMS's primary contacts for communications about the model. This resulted in our speaking with individuals from a range of backgrounds and expertise, including providers, practice managers, health IT specialists, population health managers, and staff in other job roles. Although we aimed to identify the most appropriate person to provide detailed information about the organization's experience as a control organization in the model, often the knowledge about the model varied by type of respondent. For example, administrative staff were more knowledgeable about the organization's experience with uploading data to the data registry, while clinical staff knew more about clinical care activities. This range in respondent types and the limited number of interviews resulted in less information on some topics for the control organizations versus the intervention organizations.

¹⁷ Control organizations were located in California, Delaware, Florida, Georgia, Indiana, Minnesota, New York, Pennsylvania, and Texas.

B. Control organizations' approach to CVD preventive care

Unlike the intervention organizations, control organizations did not attempt to systematically risk stratify all eligible beneficiaries, routinely notify providers and beneficiaries of elevated risk scores, or use risk scores to drive care planning for beneficiaries with high CVD risk. This is a difference in practice patterns between intervention and control organizations that appears to be related to participation in the model. However, control and intervention organizations appeared to use similar approaches to manage beneficiary CVD risk factors such as elevated cholesterol or hypertension.

Model Requirement

Control organizations choose up to 20 providers to participate in the model and report clinical indicators for each eligible beneficiary attributed to these providers for the model by using the Million Hearts Data Registry. CMS pays control practices \$20 per eligible beneficiary for whom they report data to the registry in each of the first three years of the model test (for a maximum of \$60 per beneficiary). In contrast to intervention organizations, control organizations do not have access to the CVD Risk Calculator embedded in the Million Hearts Data Registry nor to the Million Hearts learning system events. Control organizations are not required to implement the CVD risk stratification and care management components of the model.

1. CVD risk stratification

The majority of control organization respondents we interviewed reported risk stratifying at least some patients. However, none of the respondents reported stratifying all eligible Medicare FFS beneficiaries for CVD risk or notifying providers and beneficiaries of high-risk scores, as the model requires intervention organizations to do. Almost all of the respondents at the control organizations stated either that not all providers risk stratified patients or they did so inconsistently. For example, at an organization in which all providers appeared to be risk stratifying patients at least some of the time, the respondent estimated that only about 40 percent of the organization's patients had been risk stratified.

Providers at control organizations typically risk stratify patients themselves during an office visit by using either a risk calculator built into the EHR or a web-based application. This is in contrast to intervention organizations, where risk stratification was often done by both providers and other clinical staff (such as nurses or medical assistants). Control organizations do not have access to the risk calculator in the Million Hearts Data Registry.

2. Care planning

Control organizations did not appear to be providing patients with CVD-specific care plans that included an electronic summary of the beneficiary's CVD risk score and data on the individual risk factors used to calculate the risk score, which was another difference from intervention organizations based on the Million Hearts CVD Model requirements. However, respondents at three control organizations indicated that their organizations utilized formal care plans or approaches that achieved some—but not all—of the same goals as a formal CVD care plan. For example, staff at one organization documented care plans and used this information to prompt a discussion of care options with patients; however, they did not provide patients with a copy of these visit notes. At another organization, the lead physician said he was probably the only one using care plans but that he did so prior to the launch of the Million Hearts CVD Model because the EHR had a place to document care plans to manage specific CVD risk factors, such as diabetes and obesity. This physician updated the care plans every time he saw patients and used patients' feedback to help develop goals. Thus, these care planning activities may occur with Million Hearts–eligible beneficiaries, but none of these activities were initiated based on a CVD risk score or completed by most providers.

These approaches to care planning contrast with intervention organizations, nearly all of which documented CVD risk modification plans in the EHR. Some intervention organizations reported that participation in the model led to more in-depth conversations with beneficiaries about CVD risk and treatment options than had occurred previously. This occurred to a greater degree than the evaluation team saw among control organizations. However, caution should be taken when interpreting these results because the respondents in three control practices were unable to comment on how their organization addressed care planning.

3. CVD preventive care

As noted in Chapter III, the Million Hearts CVD Model is not prescriptive in how organizations deliver CVD preventive care. Control organizations reported using a range of approaches to manage beneficiary CVD risk similar to those reported by intervention organizations. Some leave it to the discretion of the provider to counsel behavior change and prescribe medication and a few follow (or are setting up) a specific protocol for addressing blood pressure. Similar approaches were described for lipid management and smoking, with the provider assessing risk, prescribing medications, and providing counseling.

A minority of control organization respondents reported using a focused population health approach to CVD prevention. For example, one control organization has a well-developed patient-centered medical home (PCMH) model that includes care managers and all-or-nothing care bundle performance measures for a variety of conditions that affect CVD risk. Many aspects of CVD care relevant to the model are assessed by using this approach, including measurement of LDL and blood pressure control and documentation of lifestyle and smoking cessation advice.

4. Follow up with high-risk beneficiaries

In contrast to a majority of intervention organizations we interviewed, none of the control organizations interviewed were systematically using CVD risk scores to identify CVD beneficiaries for follow-up visits. Rather, in most of the control organizations providers used their clinical judgment to assess risk by using patient information such as a diagnosis of diabetes or high blood pressure; high risk was not defined solely by CVD risk. However, respondents at one-half of the control organizations reported following up with patients who providers deemed to be high risk two to four times per year; one organization contacts patients monthly. Respondents at a few other organizations stated that the frequency of follow up of high-risk patients varied, mainly based on provider discretion.

C. Changes in CVD preventive care at control organizations

Control organizations in the Million Hearts CVD Model are only required to report clinical data; they are not required to implement the CVD risk stratification and CVD care management components of the model. Nevertheless, it is possible that control organizations may change their approach to CVD preventive care over time—in some cases, control organizations may even make changes similar to the intervention organizations implementing the model. In fact, most control organizations applied to the model because they wanted to improve the quality of their

CVD prevention care. For example, the lead physician at one organization expressed a desire for the practice to stay on top of health care trends, specifically those that would help the practice better use data to inform care delivery.

Although several respondents noted that they are not encouraging changes to CVD preventive care delivery among providers, a respondent at one control organization reported that staff have started to intensify their approach to CVD prevention—which the respondent attributed to the decision to apply to the Million Hearts CVD Model. Signing up for the model required a lot of consensus building, the respondent said, so when the organization was assigned to the control group, there was strong support for continuing to try to meet the goal of improving CVD prevention despite the assignment. This organization made changes including (1) using weekly meetings to remind providers to risk stratify all patients (although, the organization has not yet started tracking the proportion of patients who are risk stratified); (2) starting a lipid referral clinic; and (3) designating a cardiologist to assist primary care providers in developing care plans to address elevated CVD risk. As a result, this organization is adopting activities that once fully implemented will make it look similar to an intervention organization.

The remaining nine organizations do not appear to be making major changes as a result of providing data to the Million Hearts Data Registry. Instead, the changes being made appear to be relatively minor and mainly to help organizations meet the reporting requirements. These changes included the following:

- Four organizations indicated that they more consistently ensure that patients have up-to-date lab values, such as lipid panels, because of the Million Hearts CVD Model reporting requirements for control organizations.
- One control organization planned to use data that it reports to the Million Hearts Data Registry to track gaps in care, although this had not been implemented at the time of the interview.
- One control organization enrolled in the Million Hearts Hypertension Control Challenge, a separate initiative focused on improving practice-level blood pressure control rates. This initiative, sponsored by CDC, is distinct from the Million Hearts CVD Model, though both fall under the umbrella of Million Hearts initiatives sponsored by HHS.
- One control organization began offering smoking cessation services and a fitness center but clarified that this was not due to the organization's decision to apply for the Million Hearts CVD Model.

Despite these individual changes, we found no evidence of widespread changes in risk stratification or care management at control organizations. None of the control organization respondents reported systematically risk stratifying all eligible beneficiaries or notifying providers and beneficiaries of the risk score—an important difference from most intervention organizations. Nor did any control organization report that it used risk scores to drive care planning and shared decision making among high-risk CVD beneficiaries. However, control organizations may change their approach to CVD preventive care over time—potentially making some changes similar to those made by intervention organizations, which are implementing the model's care delivery requirements. It is possible that some of these changes would have

occurred even if these organizations had not been collecting and reporting data for the Million Hearts CVD Model. The evaluation team will continue to monitor these sites over the course of the study to understand how their approach to CVD prevention evolves over time.

V. PARTICIPATING ORGANIZATIONS' EXPERIENCES USING THE TOOLS AND SUPPORTS PROVIDED BY CMS

Chapter summary

Respondents from intervention and control organizations reported that meeting the model reporting requirements posed a significant burden, and they had mixed reactions to the tools and supports provided by CMS as part of the Million Hearts CVD Model.¹⁸ Key findings included the following:

- **CVD risk calculator.** Respondents from intervention organizations liked the CVD risk calculator that was available through the registry—especially, the longitudinal features—but reported that it was not practical to use during in-person visits with beneficiaries. Instead, providers who wanted access to a calculator during an office visit would use a built-in calculator within their EHR or other application.
- Million Hearts Data Registry. The registry, which was used by both intervention and control organizations to report beneficiary demographic and clinical data, presented numerous challenges. Organizations reported spending a significant amount of time entering data into the registry—or, for bulk uploads, getting the data into the appropriate layout—and resolving data issues, such as not being able to identify in their EHR beneficiaries whom CMS attributed to them. In addition, respondents from both intervention and control organizations reported that CMS (or its contractor) was unresponsive to their requests for help in identifying and addressing errors in the upload process.
- Learning system. The learning system to support intervention organizations generally received praise for early webinars on meeting the requirements of the model and using the Million Hearts Data Registry; however, respondents had mixed reactions on the value of later webinars. Several smaller organizations, in particular, felt that some webinar content was not appropriate for their settings, such as model implementation strategies used by larger organizations with more resources. Many respondents reported that providers rarely attended the webinars, but instead delegated this task to nonclinical staff who were involved in implementing the model. Nearly 60 percent of organizations attended at least one event each quarter (the minimum requirement). However, attendance dropped off beginning in the second one-half of 2017 (first performance year).
- **Payment incentives.** The median payment incentives during the first year of the Million Hearts CVD Model were \$8,530 (mean of \$28,074) for intervention organizations and \$7,590 (mean of \$15,126) for control organizations. The majority of intervention organizations did not view the financial incentives as being adequate to cover their costs for data collection and reporting and CVD risk management. Nevertheless, respondents reported that they chose to stay in the model because the Million Hearts CVD Model supported other value-based purchasing efforts—and also because the care provided as part of the model was right for patients. Most control organizations generally thought the payments were adequate

¹⁸ For intervention organizations, the tools and supports included the Million Hearts Data Registry, CVD risk calculator, learning system, incentive payments, and performance reports. For control organizations, the only supports were the Million Hearts Data Registry and CVD risk stratification payments.

for what they were asked to do. However, respondents at 20 percent of control organizations reported that they had not received any payments (likely because of errors in the upload process).

• **Performance reports.** Very few respondents were aware of the performance reports provided by CMS. However, those who were aware of them recognized that the reports were a summary of the data that the organizations themselves had reported to the Million Hearts Data Registry, which provided limited value to support decision making.

This chapter addresses the feedback on the tools and supports provided by CMS based on interviews with 15 intervention and 10 control organizations. The team also supplemented the interview data with quantitative data from CMS on payments and learning system participation.

A. Million Hearts CVD Model risk calculator

An interactive atherosclerotic cardiovascular disease risk calculator, based on the ACC/AHA tool, is embedded in the Million Hearts Data Registry for intervention organizations. The calculator computes a patient's 10-year CVD risk score based on risk factors entered into the registry, which is a functionality long available in the publicly available ACC/AHA baseline CVD risk calculator. However, CMS also funded—in its preparations to launch the Million Hearts CVD Model—

Key findings

• The longitudinal features of the Million Hearts CVD risk calculator were well received but difficult for providers to integrate into clinical workflows.

Data Source

• Telephone and site visit interviews with 15 intervention organizations

two additions to this baseline risk calculator (Lloyd-Jones et al. 2017). First, building from a person's baseline CVD risk factors and therapies (for example, whether already taking statins), the new longitudinal version of the risk calculator simulates what a person's CVD risk would be if certain therapies were initiated (for example, started or intensified statins). CMS intended for this simulation to help guide clinical care and shared decision making by allowing both providers and beneficiaries to see quantitatively the likely impacts of different therapies on a beneficiary's individual CVD risk. The second new functionality is the calculation of a follow-up CVD risk score. This takes the observed changes in a person's risk factors (for example, changes in their LDL) and therapies (for example, new initiation of aspirin) between two visits to calculate the change in CVD risk between those two visits. CMS is using the longitudinal change in risk score to identify the extent to which organizations have reduced CVD risk for their high-risk beneficiaries, which is the basis for calculating the size of the performance-based payments under the Million Hearts CVD Model. Although CMS sponsored the development of the longitudinal CVD risk tool specifically for the Million Hearts CVD Model, the tool is now available publicly on the ACC/AHA website (http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/) and as a smartphone application. As a result, these two new functionalities are broadly available, including to control group organizations, though it is unclear how widely they are used. CMS anticipated that organizations would use the risk calculator for the purposes of baseline risk stratification, treatment planning, and reassessment of CVD risk; CMS also anticipated that organizations would use risk scores to inform shared decision making and care plan development (CMS 2015).

Participating providers can also use existing CVD risk calculators (for example, online or through the EHR or smart phone applications) to identify beneficiary risk and guide treatment
plans, though only the risk scores calculated within the CMS registry are acceptable for enrolling beneficiaries into the model. Control organizations are not required to calculate risk scores; however, they are required to submit the data that would be required to calculate a risk score. Although they do not have access to the risk calculator embedded within the Million Hearts Data Registry, the same risk calculator is available online (as described above). At the time of our interviews, risk calculators embedded within EHRs lacked the longitudinal functionality included in the calculator embedded in the Million Hearts Data Registry. However, respondents noted that several EHR vendors would be adding this functionality in the future.

None of the intervention organizations visited by the evaluation team used the calculator embedded in the Million Hearts Data Registry during the office visit. Several organizations noted that the process for gaining access to and logging into the registry prevented point-of-care risk stratification with the tool. Intervention organizations varied in their overall adoption of the risk calculator provided by CMS. Interviews with respondents from a sample of 15 intervention organizations indicated that approximately one-third have a risk calculator embedded in their EHR, which providers can access during the visit. About one-third of the organizations do not have a risk calculator in their EHR but have established processes for calculating an initial risk score by using an online or desktop calculator and entering it into the EHR (or adding a printed insert to a paper chart) before the visit. Most of these organizations then calculate the official Million Hearts CVD Model risk score in the registry after the visit by using data gathered by the

provider during the visit. The remaining one-third of the organizations reported calculating the risk score by using the registry tool after the office visit; however, some providers (but not all) at these organizations calculate the risk score online or by using a phone application during the visit.

B. Million Hearts Data Registry

CMS provided all participating organizations (intervention and control) with access to the Million Hearts Data Registry to record demographic, clinical, and visit data for eligible Medicare beneficiaries. Intervention organizations could also use this registry to calculate and monitor risk scores over time. All organizations are expected to report the beneficiary-level clinical indicators that are needed to calculate the 10-year CVD risk scores for eligible Medicare FFS beneficiaries. Twice per year throughout the 5-year model testing period, intervention organizations are required to report these data to CMS for (1) new beneficiaries treated

"Once you open it up and you're in there, it's easy ... and it's nice to have that predictive model. [However,] it is unrealistic for people to open it up during a visit with the amount of physicians we have. It's down a lot."

- Director of quality initiatives

Key findings

- Organizations spent significant time submitting data to the registry and resolving attribution issues.
- Organizations were critical of the help desk's lack of responsiveness to requests for help in addressing errors in the upload process.

Data Source

- Telephone and site visit interviews with 15 intervention organizations
- Telephone interviews with 10 control organizations

by the participating providers during a six-month period and (2) existing high-risk beneficiaries' annual risk assessment. Intervention organizations may choose to report more frequently. Control organizations are required to report at least once per year in Years 1, 2, and 3 for all eligible Medicare FFS beneficiaries.

Nearly all intervention and control organizations interviewed reported frustrations with the Million Hearts Data Registry. The majority of intervention and control organizations interviewed by the evaluation team were manually uploading the data to the registry—that is, entering data for one Medicare FFS beneficiary at a time via a web interface—while relatively few were using

the bulk upload options of entering data for multiple beneficiaries either by populating a Microsoft Excel template or by exporting data from an EHR. Respondents reported significant time burdens that included the processes for receiving access to the registry, logging into the registry, and entering the data. This was particularly true at the launch of the model, as organizations felt pressured to risk-stratify their eligible populations as quickly as possible. These frustrations were not limited to the manual uploads; respondents expressed frustrations that they

The workflow was substantial at the beginning because I was designing reports to pull the correct data.... At this point, it's not a lot of work. It's just kind of making sure we're staying on top of things and not letting anybody slip through the anniversary window without a visit, making sure their data is entered. So, it is not as labor-intensive now as it was a year ago."

- Data analyst

could not export data from the EHR into the registry, and the bulk upload Excel templates required organizations to update their programming. Despite these challenges, respondents from nearly one-third of the intervention organizations noted that the process for entering data into the registry had become less burdensome over time as staff figured out their work flow, gained a better understanding of the registry requirements, and had fewer beneficiaries to upload than at the beginning. Other respondents noted that, although they initially experienced some challenges, they were able to meet the requirements with the help of their internal resources (for example, an analytics department or IT resources).

C. Million Hearts CVD Model learning system

CMS and its implementation contractor designed the Million Hearts CVD Model learning system to support intervention organizations in their implementation of the model. Each intervention organization is required to attend a minimum of one learning system event per quarter; control organizations do not participate in the learning system. The learning system includes additional resources such as online materials and the Million Hearts Connect portal. Use of these other resources was not required as part of participation in the Million Hearts CVD Model. In addition to the learning system, CMS also provided introductory webinars to orient participating organizations to the Million Hearts CVD Model and its requirements.

During Model Year 1, the learning system contractor hosted 10 learning events focused on key

Key findings

- Organizations found early webinars focused on model requirements helpful in planning implementation activities.
- Events focused on larger organizations' implementation experiences were less helpful for smaller organizations that lacked resources to implement the featured activities.
- Providers had limited time to attend learning system events, so they delegated this to a staff person—who may or may not have shared the lessons with others within the organization.

Data Source

- Implementation contractor data
- Telephone and site visit interviews with 15 intervention organizations

topics related to Million Hearts CVD Model implementation, including CVD risk reduction strategies, shared decision making, and team-based care. Learning events were largely peer-to-peer driven, with the goal of sharing best practices among participating organizations.

Provider and staff perceptions of the Million Hearts CVD Model learning system included the following:

- Early webinars on model requirements were valuable, but later webinars received mixed reviews. Early webinars focused on meeting the requirements of the model and using the data registry, both of which organizations found helpful. Perceptions of the value of the content presented at later learning events varied, particularly by organization size. For example, a few respondents from large organizations found later webinars in which other organizations shared their implementation experiences useful for getting ideas they could adopt. However, respondents from some small organizations felt that the implementation experiences shared by large organizations with specialized staff roles and support resources (such as population health teams or data analysts) were less relevant to their own model implementation.
- Attendance was commonly assigned to a designated staff person involved in the Million Hearts CVD Model. Many organizations reported that providers had extremely limited time to attend learning system events and, therefore, they delegated participation in webinars to administrative or support staff. This presented several challenges. First, as one respondent described, some webinar content targeted to providers was not helpful for nonclinical attendees who were the designated learning system representative for the organization. Second, some respondents reported that lessons from learning system events were not widely shared with others at the organization, even when a designated staff member attended. In fact, many respondents were unaware of the learning system events. These findings may help explain why post-event survey feedback from staff who attended events was positive, but respondents at the organizations visited had more mixed reviews of the learning system.

D. Payment incentives

The Million Hearts CVD Model was designed to incentivize participating organizations to riskassess their patients, actively monitor them, and reduce CVD risk for high-risk beneficiaries through the use of financial payments. Organizations randomly assigned to the intervention group receive a onetime, \$10 risk assessment payment for each eligible Medicare FFS beneficiary assessed for CVD risk, regardless of the assigned risk category. After the initial risk stratification, intervention organizations are paid a monthly \$10 CVD care management payment for high-risk beneficiaries

Key findings

• Most participants said the payment incentives were not what motivated their participation but that they reduced the disincentive to participate.

Data Source

- CMS payment data
- Telephone and site visit interviews with 15 intervention organizations
- Telephone interviews with 10 control organizations

during the first year of the model. This payment is intended to help organizations establish care management services as specified by the model requirements. During the subsequent years of the model (Years 2 through 5), intervention organizations are paid up to \$10 monthly for high-risk beneficiaries, contingent on the organization's reduction of aggregate CVD risk for its high-risk beneficiaries. To receive ongoing care management payments, organizations must attest to providing at least one annual in-person reassessment of the risk score and a minimum of two annual follow-up contacts.

Organizations assigned to the control group receive a \$20 per beneficiary payment per reporting year for submission of required clinical and demographic data to CMS. Control organizations must report on all Medicare FFS beneficiaries. In addition, control organizations may submit data for a maximum of 20 providers, whereas intervention organizations have no limit to the number of providers who may enter beneficiary data into the registry. The payment model is summarized in Table V.1.

According to payment data provided by the implementation contractor, CMS paid nearly \$7 million in incentives to intervention and control organizations that enrolled at least one eligible beneficiary and were still participating in the model as of December 31, 2017 (319 organizations). Intervention organizations received a median of \$8,530 (mean of \$28,074) for the first model year. Control organizations received a median of \$7,590 (mean of \$15,126) in the first model year. The mean payments are notably higher than the medians (particularly for the intervention group), indicating that there are a small number of organizations in the upper range that are driving up the average across organizations.

Among intervention organizations, program leaders were more likely to be aware of payment incentives than frontline providers. At two-thirds of the organizations included in interviews, clinical and nonclinical staff that served as Million Hearts CVD Model leaders had seen the exact payment amounts. In contrast, at more than one-half of the

"I'm looking at [the financial incentives] as a primary care provider. I'm not looking at it as a businessperson. I think it's something that's good for quality of care for the patient. So from that point of view, to me, it's a win."

- Primary care provider

intervention organizations, frontline providers and other clinical staff (who were not model leaders) were aware that payment incentives existed but they were not aware of the specific amounts.

Year	Intervention	Control
1	\$10 per beneficiary risk assessment payment\$10 monthly care management payment for high-risk beneficiaries	\$20 per beneficiary data reporting payment
2–5	\$10 per beneficiary risk assessment payment Up to \$10 monthly care management payment based on aggregate absolute risk reduction for high-risk beneficiaries ^a	\$20 per beneficiary data reporting payment (Years 2 and 3 only)

Table V.1. Overview of Million Hearts CVD Model payment incentives, by model year and intervention status

Source: Million Hearts® Cardiovascular Disease Risk Reduction Model Participation Agreement, February 2016. ^aOrganizations receive the full \$10 care management payment per high-risk beneficiary if the aggregate risk reduction (among all high-risk beneficiaries) is greater than 10 percentage points. Organizations receive \$5 care management payments for aggregate risk reduction of 2 to 10 percentage points. They don't receive any care management payments for aggregate risk reduction of less than 2 percentage points.

Over half of intervention organizations and control organizations did not think that the payment incentives covered the costs of participating (such as submitting data). Nevertheless, most respondents reported that this did not negatively impact their continued participation in the model. Most of these respondents explained that they were not participating solely for the

money. Rather, the organizations were participating because they felt this was the right thing to do for their patients.

Organizations expected participation in the Million Hearts CVD Model would contribute to other financial benefits. Several organizations participate in other initiatives, such as the Medicare Shared Savings Program, other ACO models, and CPC+. They are hopeful that fewer heart attacks and strokes resulting from the

"I don't even know the amount. But it wasn't much at all. We are not doing this for the money, it's not that much money coming out of this program.... [But] why not reap the benefits of something that we already do?"

-Million Hearts program leader

Million Hearts CVD Model will lead to greater savings for these other programs as well. In other words, respondents felt they were already being paid to keep high-risk beneficaries out of the hospital through other value-based contracts, so they might as well reap the additional benefits through this model. Similarly, one respondent hoped that participation in the Million Hearts CVD Model would better position the organization for future CMS programs that may call for similar kinds of quality improvement and reporting.

In summary, although most organizations did not find the payment amounts well matched to the costs of participating, most organizations also did not apply to participate in the Million Hearts CVD Model solely for the financial benefit. Furthermore, organizations hoped the Million Hearts CVD Model would help them reap the benefits of other quality initiatives and prepare them for future CMS programs.

E. Performance reports

Twice a year, CMS provides performance reports to organizations in the intervention group. The report is intended to be used by organization leaders and staff to improve their performance and ultimately improve care provided to high-risk beneficiaries. The implementation contractor described the Year 1 performance reports as addressing issues such as beneficiaries' enrollment and risk status, treatment therapies (such as aspirin or statins) being used for high-risk beneficiaries,

Key findings

- Few respondents were aware of the CMS performance reports.
- Respondents who were aware of the reports thought they were of limited value to support decision making.

Data Source

• Telephone and site visit interviews with 15 intervention organizations

payment history, and learning system attendance. The Million Hearts CVD Model Request for Applications also noted that the performance report would provide longitudinal data, such as risk score changes from baseline, as well as benchmarks, such as state and national averages. Intervention organizations may access their performance reports through an online Million Hearts portal. These reports are available after every six-month performance period; the CMS model team and implementation contractor notify organizations when the reports are available. (CMS 2017)

Among respondents at the intervention organizations, awareness of performance reports was limited. At more than one-half of the intervention organizations, no respondents were aware of the performance reports, including individuals who were CMS's primary contact when

communicating about the Million Hearts CVD Model. At several other organizations, the primary contacts or data analysts had seen the performance report but the frontline staff had not.

Respondents who were familiar with the performance reports did not perceive them as providing new information; they described them as "vague" or containing "high-level stuff" that was already known. These respondents noted that the performance reports essentially regurgitated information that they had entered into the registry. Performance reports for the first model period did not include longitudinal risk score data or state or

"[Our internal report] has the risk scores listed, it has the date they got the beneficiary notice, it has the shared decision making.... So we did do some education with the practices to show them how to use that report ... and how to even drill it down to just see your practice's patients."

- Practice manager

national benchmarks. In addition, respondents from at least two organizations felt that the delay in receiving the performance reports diminished their utility.

VI. REASONS ORGANIZATIONS LEFT THE MODEL

Chapter summary

Understanding the reasons why organizations exited the model provides important insight into the facilitators and barriers of implementing the Million Hearts CVD Model. While many organizations left because of challenges in meeting the model requirements, others did so for reasons that had little to do with the model. The key findings include:

- About one-fourth were terminated by CMS for not meeting model requirements; others withdrew voluntarily. Organizations primarily withdrew due to difficulty with meeting the model's reporting requirements.
- Factors internal to the organization such as incompatible EHRs or insufficient staff capacity, as well as the perceived burden of the model design, affected the organizations' abilities to meet the reporting requirements. In particular, respondents reported difficulty with using the Million Hearts Data Registry and the specific data elements the model required organizations to report.
- While most respondents expressed concern about meeting the reporting requirements, only a few expressed concern about meeting the model's care delivery requirements, including follow-up contacts with high-risk beneficiaries.

This chapter first describes the characteristics of exiting organizations that were selected for interviews and then summarizes the reasons why organizations exited the model based on documentation provided by CMS and follow-up telephone interviews conducted with respondents from 17 organizations.

A. Characteristics of exiting organizations selected for interviews

The findings in this chapter were informed by documentation provided by CMS and findings from the 17 exit interviews that the evaluation team conducted in spring and summer 2018 with organizations that had withdrawn from the Million Hearts CVD Model. CMS provided a data set with a brief description of the reasons that 121 organizations withdrew as of fall 2017. The exit interviews that the evaluation team conducted included 15 intervention and 2 control group organizations. The team contacted 30 intervention and 14 control organizations for exit interviews (50 percent and 14 percent of these organizations, respectively, responded). The team interviewed

Key findings

- Many organizations withdrew due to concerns about meeting the reporting requirements; few had concerns about the care delivery requirements.
- Some organizations withdrew due to factors internal to the organization such as incompatible EHRs or insufficient staff capacity.

Data Source

- Reasons for withdrawing documented by CMS
- 17 interviews with intervention and control organizations that withdrew from the model

intervention organizations that represented the diverse characteristics of the total population of intervention group exiting organizations, including at least one organization in each category of organization size, location, and type (see Chapter II, Table II.2 for characteristics of the

organizations that did not actively participate in the model in 2017).¹⁹ The low response rate for control organizations limited the ability to interview organizations that represented the diverse characteristics of the total population of exiting control organizations. The findings focus on data collected from organizations that withdrew before December 31, 2017.

B. Summary of reasons for withdrawing previously reported to CMS

Using written documentation provided by CMS, the evaluation team conducted a thematic analysis on the reasons why 121 intervention and control organizations withdrew from the Million Hearts CVD Model through the fall of 2017. Organizations could have multiple reasons for withdrawing. Eleven organizations gave no reason for leaving the model. The findings from the analysis are summarized below:

- The most common reason for termination by CMS was for failing to respond to CMS's requests for information, including the requirement that organizations must sign the Model Participation Agreement or respond to a corrective action plan. For organizations that CMS terminated, the evaluation team did not always have data on the underlying reasons that an organization did not meet certain model requirements.
- Exiting organizations commonly cited the Million Hearts CVD Model's reporting requirements as reasons for withdrawing, especially related to difficulty with logging into the Million Hearts Data Registry, extracting EHR data in a format that was reportable to the data registry, or changing workflows to collect the required data elements.
- Other common challenges to participating in the model included: lacking necessary resources to implement the model (such as staff, money, or time); needing to focus on competing priorities; experiencing leadership changes (especially the departure of the person who had led the application to join the Million Hearts CVD Model); and lacking buy-in or engagement from organizational leaders, providers, or other staff.

C. Findings from interviews with exiting organizations

The interview findings with exiting organizations were consistent with the documentation provided by CMS and provided additional insight into the reasons why organizations withdrew from the model.

Nearly all exiting organizations perceived the Million Hearts Data Registry and reporting requirements to be burdensome. These challenges included logging into the data registry and obtaining the necessary data from their EHRs to report to the data registry. "The IT lift was the straw that broke the camel's back. If we could have done the data submittal without the extra work from IT, through existing queries or raw data, we may have stuck with it."

- Administrative lead

¹⁹ Exiting organizations were located in: Arizona, Illinois, Kansas, Louisiana, Michigan, Minnesota, Mississippi, New Jersey, New Mexico, Ohio, Oklahoma, Pennsylvania, South Carolina, and Texas.

Respondents lacked resources to collect and report the required data. Nearly threequarters of respondents cited inadequate staff capacity as a reason for withdrawing. Some noted that the financial support was not sufficient to cover the cost of reporting. Most of these

organizations had resorted to manual data entry methods after they faced challenges with extracting EHR data in a format that was compatible for reporting. Manual data entry was time-consuming and particularly burdensome for small organizations and FQHCs with limited staff, as well as for large organizations that had to upload data for thousands of beneficiaries.

"We thought there was crystal clear training. We loved the additional social connecting. We were intrigued by the access to peers. It just came down to [being part of] a brand-new Medicare ACO and new Medicaid ACO. Million Hearts was lower on the list."

- Administrative lead

Nearly one-half of respondents—typically those that withdrew after the model launched and especially those that withdrew in the second reporting period—said that their staff did not have time to submit data to the Million Hearts Data Registry because they were already too busy reporting for other initiatives, such as CPC+ or an ACO. These respondents reported feeling burdened by submitting data to yet another program. A few of these intervention organizations reported already receiving financial support and guidance to provide high quality care through other quality initiatives; they did not perceive an added benefit to also participating in the Million Hearts CVD Model.

More than one-third of respondents also reported concerns that collecting data for the Million Hearts CVD Model would burden their already busy providers. This was especially a concern for organizations that reported plans to have providers upload data to the registry during patient visits, a strategy that was not undertaken by

"Practices which have like 20 doctors and can afford a huge administrative staff, they can do it because that's what they are there for. [For small practices], you are forcing [providers to do] more administration, less medicine."

— Physician lead

any of the organizations that are described in Chapter III. Small organizations in particular reported that their providers already had too much to do. Moreover, respondents from 3 of the 15 organizations felt that asking providers to collect data for the Million Hearts CVD Model would overwhelm them, detract from their ability to focus on patient care, and make patient visits too long.

A few intervention organizations felt burdened by the care delivery requirements. In general, respondents reported that the care delivery requirements were not the reason they withdrew because the care delivery requirements aligned with how the organizations already delivered or strived to deliver CVD preventive care. Nevertheless, respondents from three organizations reported concerns about meeting the Million Hearts CVD Model's care delivery requirements. One organization withdrew because leaders thought that the model would require significant changes to their care delivery process—including performing more consistent follow-ups with high-risk beneficiaries and improving training for team-based care. Another organization cited the lack of EHR functionality to automatically risk stratify beneficiaries.

The level of payment deterred a few organizations from participating. Although the majority of respondents did not cite payment as a reason for withdrawing, it was mentioned as a reason by more than a quarter of respondents. Inadequate payment was never the only reason for

withdrawing; however, it typically amplified the reasons for withdrawing. The organizations that cited inadequate payment as a reason for withdrawing overwhelmingly withdrew in the second reporting period, presumably after attempting to implement the Million Hearts CVD Model but finding the level of effort to be greater than expected.²⁰ The majority of these organizations said that implementing the Million Hearts CVD Model had diverted resources from competing organizational priorities, such as participation in other quality improvement initiatives. Two organizations believed the Million Hearts CVD Model yielded inadequate returns on investment specifically because of the high cost of reporting—either because of staff time or health IT fees paid to automate data extraction and reporting.

²⁰ Organizations that withdrew before receiving payments from CMS, such as those who withdrew during the first reporting period, could estimate the potential payment based on number of beneficiaries who were risk stratified.

VII.NEXT STEPS FOR THE EVALUATION

During the next year, the evaluation team plans to continue documenting the implementation experiences of a group of intervention organizations and interview organizations assigned to the control group or that have withdrawn from the model in 2018. We will also use quantitative implementation metrics and survey data to describe how, and the extent to which, organizations have implemented the model—and the barriers and facilitators they have faced. In addition, the evaluation team will estimate early impacts of the model on CVD care, use of appropriate CVD medications, the incidence for first-time heart attack and stroke and Medicare spending. All of these analyses will be reported in the second annual report of the evaluation.

A. Implementation evaluation

The first year of the evaluation focused on describing organizations' implementation experiences during the first 16 months of implementing the Million Hearts CVD Model. During the second evaluation year, the evaluation team will follow up with the 15 intervention organizations interviewed during the first year so that we can describe changes they have made to model implementation, including changes in CVD preventive care. Findings in the second annual report will cover the following:

- Changes in overall implementation experience of the model
- Changes in facilitators and barriers to implementing the model
- Changes in perceived impact of the model on beneficiaries (including risk factors, adherence to statin or antihypertensive therapy, and lifestyle changes)

In addition, the evaluation team will interview respondents from a new sample of organizations assigned to the control group and a new sample of organizations that withdrew from the model in 2018. For the control organizations, our interviews and reported findings will focus on their experiences with the control group's reporting requirements and efforts to provide CVD preventive services—including their use of risk scores. This will supplement the material presented in the current annual report. For organizations that withdrew from the model, our interviews and reported findings will focus on why they left the model and any sustained efforts in cardiovascular care that resulted from the model.

The evaluation team also plans to use quantitative data to assess how organizations are implementing the model. Using data from the Million Hearts Data Registry, the team will construct measures such as the percentage of eligible beneficiaries enrolled and the percentage of high-risk beneficiaries who received reassessment visits. The team will analyze these data across all participating organizations and by selected characteristics, which could suggest possible barriers to implementing the model.

Additional quantitative data will come from the two surveys that we are fielding to intervention and control organizations. One survey was sent to the person at each intervention and control organization who is responsible for communicating with CMS about the Million Hearts CVD Model. A second survey was fielded to providers—specifically, one randomly selected provider per organization, selecting from among providers who had enrolled at least one

beneficiary into the model in 2017. Both surveys were fielded starting in the late summer and early fall of 2018. Although we will use survey data for the impact evaluation as well (see VII.B), from an implementation perspective, we will use the survey responses to assess the extent to which intervention organizations perform key activities expected by the model—for example, analyzing the providers' estimates of the percentage of Medicare beneficiaries for whom that provider has calculated a risk score. We also will use survey data to supplement interview data on barriers and facilitators to implementing the Million Hearts CVD Model—for example, analyzing responses to questions about the importance of the organization's EHR functionality, leadership buy-in, and so on.

B. Impact evaluation

For this first annual report, the impact evaluation focused on identifying the beneficiaries who enrolled in the model in 2017, their baseline characteristics, and the degree of similarity between the intervention and control groups in baseline characteristics. For the next annual report, we will estimate early impacts of the model on several outcomes:

- Incidence of first-time heart attack and stroke
- Medicare Part A and B spending, with and without model payments
- CVD-related hospitalizations and outpatient ED visits

In estimating these impacts, we will use the 2017 population of enrollees and measure all outcomes relative to a person's enrollment date—for example, estimating impacts in the first year of enrollment. Because beneficiaries were enrolled throughout 2017, the amount of time we can follow beneficiaries during the intervention period will vary by beneficiary. We expect to follow people for as many as 21 months (for someone enrolled in January 2017) and as few as 10 months (for someone enrolled in December 2017).²¹ We will estimate impacts both for (1) the high-risk enrollees, the primary target population for the model, and (2) the medium- and high-risk enrollees combined, given the expectation the model could have positive spillover effects to medium-risk beneficiaries (see Section I.C).

In addition to conducting these tests for the primary study population, we will also estimate impacts for two populations we are using for robustness checks: (1) the population resulting from trimming the intervention group in a way that mimics the 20-provider cap applied to the control group and (2) the claims-based attribution population. Appendix C describes these planned robustness analyses.

For the roughly 70 percent of medium- and high-risk model enrollees who are also enrolled in Medicare Part D, we will also assess model impacts on use of CVD-related medications. Specifically, after merging the 2017 enrollee data with Part D claims data, we will (1) assess the degree of balance at baseline between the intervention and control groups on use of statins to lower cholesterol and antihypertensive medications to lower blood pressure and (2) assess the

²¹ We anticipate pulling Medicare Part A and B claims in January 2019, meaning that beneficiaries would have complete claims data through October 2018 (allowing for the standard three-month runout from date of last service to when the service will appear in claims).

impact of the Million Hearts CVD Model on initiation or intensification of antihypertensive or statin medications (for people with elevated blood pressure or cholesterol at baseline, respectively). As described in the logic model (Section I.C), use of appropriate medications is one of the key pathways through which we and CMS expect the Million Hearts CVD Model can reduce the incidence of first-time heart attack and stroke.

We will also use the two surveys currently in the field to estimate impacts of the Million Hearts model on organizational-level CVD care. For example, by comparing responses between the intervention and control groups, we will estimate model impacts on (1) the extent to which organizations use CVD risk scores to guide their care (and the extent to which this has changed over the previous two years since the model began) and (2) the extent to which organizations proactively follow up with their high-risk patients to encourage and assess progress in reducing CVD risk.

Finally, we will also use the Million Hearts Data Registry to assess (1) the extent to which intervention group participants report follow-up clinical data for their high-risk beneficiaries and (2) the change in mean risk scores from baseline through one year of follow-up, overall and by organization. This analysis will be a first step in assessing model impacts on a key study outcome—the reduction in 10-year CVD risk scores. But because we will not have follow-up clinical data for the control group (given that they report these data less frequently than the intervention group; see Chapter V.B), we will not be able to formally estimate model impacts on CVD risk scores in the second annual report. We plan to estimate these in later reports, assuming sufficient data are available.

Taken together, these analyses should provide early insights into model impacts along the logic model described in Section I.C. This will include model impacts on (a) short-term outcomes—including improvements in organizational-level CVD care (measured in surveys) and initiation or intensification of CVD-related medications, and (b) longer-term outcomes, including the key outcomes of incidence of first-time heart attack and stroke and Medicare spending. Because the maximum follow-up period for the next annual report will be 21 months, we might expect to see larger impacts on the short-term outcomes than the longer-term outcomes. Future reports will continue to follow enrollees throughout the five-year model test.

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APPENDIX A

DEFINING THE BENEFICIARY STUDY POPULATION AND BENEFICIARY CHARACTERISTICS AT ENROLLMENT

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APPENDIX A: DEFINING THE BENEFICIARY STUDY POPULATION AND BENEFICIARY CHARACTERISTICS AT ENROLLMENT

1. Defining the beneficiary study population by using data from the Million Hearts Data Registry

We used data in the Million Hearts Data Registry to define the study population for the report. The study population includes all Medicare fee-for-service (FFS) beneficiaries whom the participating organizations enrolled during 2017. "Enrolled" means that the organization reported the beneficiary to the Million Hearts Data Registry and that CMS validated the beneficiary enrollment record (see Chapter II.C for a description of enrollment and validation). Specifically, the model implementation contractor provided five types of registry files that we linked together to define the study population:

- 1. Alignment files containing a unique identifier for each Medicare FFS beneficiary whom an organization enrolled, or tried to enroll, during 2017. The alignment files also indicate whether each beneficiary (1) passed all of the validation checks and so was successfully enrolled or (2) did not pass the validation checks, along with the reason for not passing—for example, the beneficiary had had a previous heart attack or stroke.
- 2. **Demographic files** that describe the demographic characteristics of each beneficiary an organization enrolled or tried to enroll. Demographic characteristics include date of birth, gender, and race/ethnicity.
- 3. Visit files that contain data on the baseline visit (and, if applicable, follow-up visits) that each beneficiary had with the participating organizations in 2017. The data for each visit include the visit date, the National Provider Identifier (NPI) for the provider the beneficiary visited, the Tax ID Number (TIN) for that NPI, the CVD risk score as of the visit, and the beneficiary's risk group (low, medium, and high) based on the CVD score during the baseline visit.
- 4. **Clinical files** that contain the individual clinical risk factors (for example, cholesterol levels, indicators of diabetes status) that underlie the baseline CVD risk calculation for each beneficiary.
- 5. **Practice files** that describe the characteristics—including the intervention status—of the organization that enrolled, or tried to enroll, the beneficiary.

We linked the alignment, demographic, visit, and clinical files together by using a unique beneficiary identifier common to all of these files. We then linked the combined files to the practice file via a unique identifier (called the LOI [Letter of Intent] number) for the organization that enrolled, or tried to enroll, each beneficiary. With these linked data, we were able to identify all of the beneficiaries the organizations successfully enrolled during 2017 as well as each enrollee's baseline visit date, his or her baseline risk score and risk group as of that date, the individual risk factors that supported that baseline risk score, and whether the participating organization that enrolled the beneficiary was assigned to the intervention or control group.

We limited the final study population to those with medium or high CVD risk at enrollment. This final study population of 2017 enrollees includes 171,765 beneficiaries (104,351 beneficiaries in the intervention group and 67,414 beneficiaries in the control group). These beneficiaries were enrolled by 315 organizations (162 in the intervention group and 153 in the control group).²² The number of organizations is smaller than the total 516 organizations originally randomized; some organizations withdrew from the model before the end of 2017, and others did not enroll any medium- or high-risk beneficiaries. In Figure A.1, we show the flow of organizations (and their providers and beneficiaries) from enrollment and randomization down to the final study population.

²² As described in Chapter II.A, 319 organizations (163 intervention and 156 control) actively participated in the first year of the model—meaning that the organization had not withdrawn by the end of the year and had successfully enrolled at least one Medicare beneficiary in 2017. However, four of these organizations (1 intervention and 3 control) only enrolled low-risk beneficiaries in 2017. Therefore, these four organizations drop out of the analytic population when we limit to medium- and high-risk beneficiaries. That explains why there are 315 organizations (162 intervention and 153 control) represented in the final analytic population rather than the 319 organizations we identified as participating in the first year. These four organizations will be included in future analytic populations if they enroll medium- or high-risk beneficiaries in later model years.

Figure A.1. Flow of organizations, providers, and beneficiaries from enrollment through analysis



CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease.

2. Cleaning clinical data from the Million Hearts Data Registry

A very small proportion of beneficiaries (0.2 percent of all enrollees) had clinically implausible values for one or more of the clinical variables in the registry data. We defined "implausible" as follows and reset the risk factor values to missing if the initial value was not plausible:

- Systolic blood pressure < 70 mm Hg
- Total cholesterol < 80 mg/dL or total cholesterol < high-density lipoprotein (HDL) cholesterol + low-density lipoprotein (LDL) cholesterol
- HDL cholesterol < 10 mg/dL or HDL cholesterol > total cholesterol LDL cholesterol
- LDL cholesterol < 20 mg/dL or LDL cholesterol > total cholesterol HDL cholesterol

We based these thresholds on (1) the clinical expertise of clinicians working on the evaluation project team and (2) the observed distributions of the blood pressure and cholesterol values.

We further set a beneficiary's overall CVD risk score to missing if any of the clinical input variables—that is, systolic blood pressure, total cholesterol, or HDL cholesterol—had been reset to missing. (LDL cholesterol is not an input into the baseline risk calculator.) This change affected 620 unique beneficiaries, who were dropped from the study population.

3. Adjusting the baseline visit dates for beneficiaries with several visits during the model period

We adjusted the baseline visit dates for 18,341 beneficiaries (6.1 percent of all enrollees) for whom, in the registry, there was an earlier visit date than the one selected as the baseline date for CMS payments and for whom the earlier visit was with a Million Hearts CVD Model provider. These beneficiaries could have received intervention services between their initial visit with a Million Hearts CVD Model provider and their official enrollment visit into the Million Hearts CVD Model. Therefore, adjusting the baseline date—and, when possible, using clinical values as of that date—was conceptually important. However, in practice, this adjustment affected only a small percentage of enrollees, and, among those affected, there was very little change in risk factors or CVD risk scores.

Specifically, when CMS planned the Million Hearts CVD Model, it expected organizations to upload beneficiary data to the registry at, or very soon after, each model-qualifying office visit. Therefore, when organizations uploaded their data to the registry by using one of the two bulk-upload options (as opposed to manually entering beneficiary data), the registry software was designed to select the date of the most recent systolic blood pressure reading as the baseline visit date. In practice, however, some organizations waited to upload their visits in batches rather than upload at or soon after each visit. As a result, the most recent visit at the time of an upload could potentially be several months after the true baseline visit. If the evaluation did not adjust accordingly, it could miss the impacts of any treatments delivered between the true baseline visit and the last visit before upload—for example, initiation of statin therapy or behavioral modification that occurred between these dates—thus underestimating the impacts of the model.

We revised the baseline visit dates whenever sufficient data were available to do so. Among the 154,270 beneficiaries who both (1) had data bulk-uploaded to the registry and (2) were enrolled, validated, and aligned by the Million Hearts implementation contractor based on a visit in 2017, 18,354 (11.9 percent) had at least one systolic blood pressure reading with a modelparticipating provider on or after the model's start date but before the baseline visit date selected by the registry software. Of these, 18,341 were also in the model-relevant age range (40 to 79 years) at the earlier visit. In these cases, we set the revised baseline date to the date of the earliest visit with a Million Hearts CVD Model provider after the model start date of January 2017. On average, the adjusted baseline visit date was 103 days before the baseline visit date selected by the registry software, and the adjusted baseline systolic blood pressure reading was 0.8 mm Hg higher than the originally selected value. Of the 18,354 beneficiaries, 13,280 (72 percent) also had cholesterol readings available for recalculating baseline risk scores as of the adjusted baseline date; that is, the cholesterol readings were taken within the model-prescribed five-year look-back or two-month look-forward window from the adjusted visit date. For the vast majority of patients (12,081 patients, or 91 percent of those with cholesterol readings as of the adjusted visit date), the adjusted cholesterol values were identical to those originally selected. (These frequent identical values were expected because most beneficiaries do not have frequent cholesterol tests; therefore, a lipid test that was within the five-year look-back of one visit date is likely still to be the most recent cholesterol reading at the next visit.) Age as of the adjusted baseline visit date was one year younger for 28 percent of affected beneficiaries and was unchanged for the remaining 72 percent.

To calculate the adjusted baseline CVD risk score for the 18,341 affected beneficiaries, we replaced the originally selected blood pressure, cholesterol, and age values with the adjusted values. If an adjusted cholesterol reading was not available as of the new baseline visit date, we retained the original one to calculate the adjusted baseline risk score. For all other risk factors used to calculate the baseline risk score (smoking status, diabetes, and hypertension treatment), we used the values based on the originally selected baseline visit date.

The adjusted baseline risk scores were on average 0.16 percentage points (1.86 percent) lower than the risk scores based on the originally selected visit dates. The lower average scores are likely attributable to the slightly younger age of the population that resulted from shifting baseline visit dates earlier. The baseline risk groups—that is, whether a beneficiary was identified as being at high, medium, or low risk of a heart attack or stroke in the next 10 years—changed for 3,154 of the 18,341 beneficiaries and remained unchanged for the remainder (Table A.1). For all analyses in this report using the primary study population—including assessments of baseline beneficiary-level characteristics—we used the adjusted baseline risk groupings.

Table A.1. Number of beneficiaries (and percentage of all model enrollees)
whose risk group changed when using the adjusted baseline visit date
instead of the originally selected date

Risk group change (original to adjusted)	Number of beneficiaries	Percentage of model enrollees in 2017 in this risk group, based on CVD score at the original baseline date
HIGH to LOW	**	**
HIGH to MEDIUM	698	1.28
MEDIUM to LOW	890	0.70
MEDIUM to HIGH	708	0.56
LOW to MEDIUM	833	0.70
LOW to HIGH	**	**
No change	15,120	5.03

Note: ** indicates numbers suppressed per CMS cell size suppression policy.

4. Development of beneficiary-level claims-based characteristics and geographic characteristics, calculated as of beneficiary enrollment date

We linked beneficiary information from the Million Hearts Data Registry to Medicare claims and enrollment data by using the CCW Beneficiary Identifier provided by the model implementation contractor. We further linked those beneficiary records to publicly available data about regional characteristics, making use of the beneficiary mailing address available in the Medicare Enrollment Database (EDB).

We defined all baseline characteristics as of a beneficiary's baseline visit date (or adjusted baseline visit date) used to enroll the person into either the intervention or control arm of the Million Hearts CVD Model. To do so, we used the EDB to identify time-invariant characteristics such as date of birth, original reason for Medicare entitlement, race, and gender. We categorized beneficiaries as dually eligible for Medicare and Medicaid based on their dual status on their enrollment date. We then created a beneficiary-month file that summarized time-varying characteristics, by month, for characteristics related to chronic conditions and for Medicare service use and expenditures. Given that the beneficiary-month data in the EDB were based on calendar month, we converted the file to beneficiary-enrollment-month level, with each month defined relative to each beneficiary's unique enrollment date. We then looked back over the relevant number of months to define particular baseline values—for example, looking back over the previous 12 months to summarize Medicare service use or spending in the year before enrollment. We processed all beneficiary-level data by using the Virtual Research Data Center at CMS.

a. Demographics and Medicare enrollment characteristics

We drew time-invariant demographic characteristics from the EDB. Then, for each month until 36 months before enrollment, we determined if the beneficiary was observable in Medicare claims data in the given month. (As we describe later in this appendix, the definitions of some baseline characteristics depend on the number of months observable.) A beneficiary was observable if he or she was alive, was enrolled in Medicare Parts A and B, was not enrolled in Medicare Advantage, and had Medicare as the primary payer of medical bills.

b. Chronic conditions

We created several types of chronic condition variables to (1) assess the similarity of the intervention and control groups on a wide range of traits and (2) aid in risk prediction for attributed beneficiaries (see Appendix C).

Conditions from the Master Beneficiary Summary File (MBSF). To confirm that beneficiaries enrolled in the model did not have a previous occurrence of a heart attack or stroke (and to remove those beneficiaries who had had a previous CVD event from the attribution-based population for sensitivity tests, as described in Appendix C), we used data on the first occurrence of heart attack or stroke, if any, as far back as 1999, drawn from the 2017 MBSF.²³ These first-occurrence dates identify the first time that the event or condition was observed for the person in Medicare FFS claims (as far back as 1999); it does not capture events or conditions before a person enrolled in FFS Medicare, during periods when a person may have been enrolled in a Medicare HMO, or before1999. The MBSF also provided dates of first occurrence since 1999, if applicable, of other common chronic conditions (Table A.2).

Chronic condition				
Acute myocardial infarction	Autism spectrum disorders			
Alzheimer's disease	Bipolar disorder			
Alzheimer's disease and related disorders of senile dementia	Traumatic brain injury and nonpsychotic mental disorders due to brain damage			
Atrial fibrillation	Cerebral palsy			
Cataracts	Cystic fibrosis and other metabolic developmental disorders			
Chronic kidney disease	Major depressive affective disorder			
Chronic obstructive pulmonary disease	Epilepsy			
Congestive heart failure	Fibromyalgia, chronic pain, and fatigue			
Diabetes	Sensory –deafness and hearing impairment			
Glaucoma	Viral hepatitis (general)			
Hip/pelvic fracture	HIV/AIDS			
Ischemic heart disease	Intellectual disabilities and related conditions			
Depression	Learning disabilities			
Osteoporosis	Leukemias and lymphomas			
Rheumatoid arthritis or osteoarthritis	Liver disease cirrhosis and other liver conditions (excluding hepatitis)			
Stroke or transient ischemic attack	Migraine and other chronic headache			
Breast cancer	Mobility impairments			
Colorectal cancer	Multiple sclerosis and transverse myelitis			
Prostate cancer	Muscular dystrophy			
Lung cancer	Obesity			

Table A.2	2. Chronic	conditions	with	first-occurrence	e variable	taken f	rom the
MBSF							

²³ For some beneficiaries, there was no record in the 2017 MBSF, so we used the 2016 MBSF record for them, if one was found.

TABLE A.2 (CONTINUED)

Chronic condition				
Endometrial cancer	Other developmental delays			
Anemia	Personality disorders			
Asthma	Post-traumatic stress disorder			
Hyperlipidemia	Peripheral vascular disease			
Benign prostatic hyperplasia	Schizophrenia			
Hypertension	Schizophrenia and other psychotic disorders			
Acquired hypothyroidism	Spina bifida and other congenital anomalies of the nervous system			
ADHD and other conduct disorders	Spinal cord injury			
Anxiety disorders	Sensory–blindness and visual impairment			

ADHD = attention deficit hyperactivity disorder; HIV/AIDS = human immunodeficiency virus/acquired immune deficiency syndrome.

Conditions from Chronic Condition Warehouse (CCW). We created variables by using Medicare claims data and publicly available technical specifications from the CCW (see CCW 2017 for specifications and code list) to indicate whether beneficiaries had any of 23 common chronic conditions²⁴ or 42 other chronic or potentially disabling conditions. The claims lookback period ranged from one to three years, depending on the condition category. These are the same conditions as reported in the MBSF files, described above. Although the MBSF indicates whether the beneficiary ever had the condition since 1999, these variables indicate which conditions were present and actively treated in the period before enrollment (up to 36 months before enrollment, depending on the condition).

Conditions based on hierarchical condition category (HCC). We created 87 chronic condition flags by using the Version 21 CMS-HCC risk-adjustment model (see CMS 2017), based on diagnosis codes from the International Classification of Diseases, 10th Revision (ICD-10), and by using Medicare claims in the year leading up to enrollment for each beneficiary. We also created an HCC score by using these same data based on the coefficients for the community and new enrollee regression models provided by CMS (CMS 2017). For beneficiaries who were observable in Medicare for at least 10 of the 12 baseline months, we set their HCC score by using the new enrollee model. For beneficiaries who were observable for fewer than 10 months, we set their HCC score by using the new enrollee model, based on demographic factors.

Model-relevant conditions using a code list from the model implementation contractor. The implementation contractor provided us with the same list of codes that it provided to modelparticipating organizations for uploading beneficiary clinical data to the Million Hearts Data Registry—for example, to identify data elements such as diabetes diagnosis, smoking status, hypertension treatment, and so on. We created a series of indicator variables—one for each risk factor—for whether any of the relevant codes was found in Medicare claims during the 12 months leading up to enrollment. These claims-based indicators cannot exactly replicate the registry data, however, because claims include diagnosis and procedure codes but not other code types used by participating organizations to populate the registry (for example, codes designed

²⁴ Although the CCW provides specifications for 27 common chronic conditions, we combined cancer-related variables into one, thus bringing the total number of conditions to 23.

for use in electronic health records, such as from the Systematized Nomenclature of Medicine– Clinical Terms [SNOMED CT] or RxNorm).

c. Procedures

To determine if a beneficiary in the Million Hearts CVD model had undergone various procedures within the 12 months before enrollment, we used publicly available technical specifications to classify procedure codes in claims data into Clinical Classifications Software (CCS) indicators (Agency for Healthcare Research and Quality 2017–2018). Relevant procedure codes include ICD-9 and ICD-10, Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS).

d. Medical service use

All-cause and CVD-related admissions. We calculated the total number of acute inpatient admissions and the number of CVD-related admissions occurring in the 12 months before enrollment into the Million Hearts CVD Model. The measure of CVD-related admissions covers more than 100 distinct diagnoses,²⁵ including those related to heart failure, hypertension, and angina, but excludes hospital stays with a principal diagnosis of acute myocardial infarction or stroke on any claim during the stay. This is because the study population is restricted to people without heart attack or stroke at enrollment.

Outpatient emergency department (ED) visits and CVD-related outpatient ED visits. We defined outpatient ED visits as ED visits or hospital observation stays that did not end in admission. We identified these visits by using revenue center and HCPCS codes. We used a similar set of diagnoses for the CVD-related outpatient visits as were used to flag the CVD-related admissions.²⁶ As with CVD-related admissions, CVD-related ED visits excluded visits

²⁵ We included 347 ICD-10 codes in our search for CVD-related admissions. Of those, the following were associated with admissions in our study population during the 12 months before enrollment: C380, D151, G9340, G9341, G9349, G9381, G9389, G939, I011, I050, I051, I052, I059, I060, I062, I071, I080, I081, I082, I083, I10, I110, I119, I130, I1310, I159, I160, I161, I169, I200, I201, I208, I209, I241, I248, I249, I2510, I25110, I25111, I25118, I25119, I255, I25700, I25708, I25709, I25710, I25719, I25720, I25790, I25810, I2589, I259, I270, I2781, I300, I301, I308, I309, I311, I312, I313, I319, I330, I340, I341, I342, I348, I350, I351, I352, I358, I361, I372, I38, I420, I421, I422, I426, I427, I428, I429, I440, I441, I442, I4430, I4439, I447, I4510, I452, I453, I455, I4581, I4589, I469, I470, I471, I472, I480, I481, I482, I483, I484, I4891, I4892, I4901, I4902, I491, I493, I495, I498, I499, I501, I5020, I5021, I5023, I5030, I5031, I5032, I5033, I5040, I5041, I5042, I5043, I509, I513, I514, I517, I5181, I5189, I6200, I6201, I6202, I6203, I6502, I6521, I6522, I6523, I6782, I6783, I700.

²⁶ Specifically, we included the same 347 ICD-10 codes in our search for CVD-related ED visits as for CVD-related admissions. Of the 347, the following were associated with outpatient ED visits in our study population during the 12 months before enrollment: A5201, B3322, C380, D151, G454, G9340, G9341, G9349, G9389, G939, G968, G969, G980, G988, I011, I018, I019, I050, I051, I052, I058, I059, I060, I061, I062, I068, I069, I071, I078, I079, I080, I081, I082, I083, I088, I089, I0981, I0989, I099, I10, I110, I119, I130, I1310, I132, I150, I151, I152, I158, I159, I160, I161, I169, I200, I201, I208, I209, I236, I240, I241, I248, I249, I2510, I25110, I25111, I25118, I25119, I252, I253, I2541, I255, I256, I25700, I25701, I25708, I25709, I25710, I25718, I25719, I25720, I25721, I25728, I25729, I25739, I25750, I25758, I25759, I25790, I25791, I25798, I25799, I25810, I25811, I25812, I2582, I2583, I2584, I2589, I259, I270, I271, I2720, I2721, I2781, I2789, I279, I281, I288, I289, I300, I301, I308, I309, I311, I312, I313, I314, I318, I319, I32, I330, I339, I340, I341, I342, I348, I349, I350, I351, I352, I358, I359, I360, I361, I362, I368, I369, I370, I371, I372, I379, I38, I39, I400, I401, I41, I420, I421, I422, I423, I425, I426, I427, I428, I429, I43, I440, I441, I442, I4430, I4439, I444, I447, I450, I4510, I4519, I452, I453, I454, I455, I456, I4581, I4589, I459, I462, I468, I469, I470, I471, I472, I479, I480, I481, I482, I483, I484, I4891, I4892, I4901, I4902, I491, I492, I493, I4940, I4940, I4949, I495, I498, I501, I5020, I5021, I5022, I5023, I5030, I5031, I5032, I5033, I5040, I5041,

with a primary diagnosis of acute myocardial infarction or stroke because beneficiaries with such events were excluded from the study population.

Office/clinic visits. We calculated the number of outpatient office visits in the 12 months before enrollment as well as the number of such visits with a Million Hearts CVD Model– aligned provider. We allowed one visit per beneficiary per day. To identify outpatient office visits, we flagged all claims in the carrier file with both (1) a specialty code indicating a claim from a physician assistant, nurse practitioner, or certified clinical nurse specialist (CMS 2017) and (2) a CPT or HCPCS code for evaluation and management services that indicated that the claim was for an outpatient office visit. By using the outpatient file, we further identified all outpatient visits to Federally Qualified Health Centers (FQHC), Rural Health Clinics (RHC), and Critical Access Hospitals (CAH). To identify the subset of those visits that were with Million Hearts CVD Model–aligned providers, we flagged NPI-TIN combinations and CMS Certification Number (CCN)-NPI combinations that were included in the list used in attribution (Appendix C) in the carrier and the outpatient files, respectively.

Cardiologist visits. To calculate the number of visits to a cardiologist during the 12 months before enrollment, we first limited the carrier claims file to claims from physicians. We then merged the carrier file to the publicly available CMS National Plan and Provider Enumeration System (NPPES) by NPI to obtain the primary taxonomy associated with each physician. Cardiologists were identified as those with a cardiology-related taxonomy code.

For all service use measures, we created both (1) a simple count over the previous year and (2) an annualized version that accounts for the fact that a person may not have been observable in Medicare FFS claims for all 12 months leading up to enrollment. This could result in counts understating true service use. The annualized versions summed the events over the observable months in the year before enrollment, divided by the number of observable months, and multiplied by 12. As indicated in the report, we used the annualized versions of the measures to describe baseline service use.

e. Medicare expenditures

We separately calculated Medicare expenditures over the 12 months before enrollment for claims from inpatient (separately for acute and nonacute care), carrier, outpatient, home health services, skilled nursing facility (SNF), hospice services, and durable medical equipment (DME). We summed these to create the measure of total Parts A and B Medicare expenditures. As with the annualized service use measures, we created an annualized expenditures variable that accounted for the fact that a beneficiary might not have been observable for all 12 months before enrollment. Specifically, we summed expenditures over the months observable during the year, divided by the number of observable months, and multiplied by 12.

f. Geographic characteristics

We constructed measures for characteristics of the local areas where beneficiaries reside, based on the ZIP code, state, and county FIPS code variables found in the Medicare EDB from

^{15042, 15043, 150810, 1509, 1510, 1511, 1513, 1515, 1517, 15181, 15189, 1519, 152, 16200, 16201, 16202, 16203, 1621, 1629, 16501, 16502, 16503, 16509, 1651, 16521, 16522, 16523, 16529, 1658, 1659, 1672, 16781, 16782, 1679, 1680, 1700.}

the month before the beneficiary's enrollment in the Million Hearts CVD Model. We used measures of these characteristics from two sources: the American Community Survey (ACS) 2016 five-year ZIP code estimates (Census Bureau 2017) and the 2016–2017 Area Health Resource Files (AHRF) (Health Resources and Service Administration 2017). In Table A.3, we present the included variables.

Table A.3. Beneficiary-level geographic variables

ACS variables (ZIP code level)	AHRF variables (county level)
State name	State name
Population in the ZIP code	County is Health Professionals Shortage Area (primary care) (2017)
Percentage of population white in the ZIP code	County is Health Professionals Shortage Area (mental health) (2017)
Percentage of population black in the ZIP code	County's Medicare Advantage penetration rate (2016)
Percentage Asian in the ZIP code	Total number hospitals in the county (2014)
Percentage American Indian or Alaska native in the ZIP code	Hospital beds in the county (2014)
Percentage native Hawaiians and other Pacific Islanders in the ZIP code	County population estimate (2016)
Percentage unknown race in the ZIP code	County population estimate (2016)
Percentage two or more races in the ZIP code	
Percentage Hispanic in the ZIP code	
Median household income in the ZIP code	
Percentage of persons in poverty in the ZIP code	
Percentage of persons with a high school degree or higher in the ZIP code	
Percentage of persons with a college degree or higher in the ZIP code	
Percentage of persons unemployed in the ZIP code	
Percentage of persons with no health insurance in the ZIP code	
Urban or rural area	

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APPENDIX B

DETAILED BASELINE CHARACTERISTICS FOR 2017 ENROLLEES

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APPENDIX B: DETAILED BASELINE CHARACTERISTICS FOR 2017 ENROLLEES

In this section, we provide additional detail on the baseline characteristics of the 2017 enrollees—both for the high-risk and medium-risk groups combined (Table B.1) and for the high-risk group only (Table B.2). Specifically, in addition to the variables shown in Tables II.7 and II.8 in Chapter II, we present in the detailed tables the prevalence of specific chronic conditions (including those indicating that a person had preexisting cardiovascular disease), the frequency with which beneficiaries received CVD-specific procedures in the year before enrollment (e.g., cardiac stress tests), standard deviations for key variables such as HCC score and Parts A and B spending in the year before enrollment, and *p* values for tests of whether the means in the intervention and the control groups are the same.

Characteristic	Intervention group mean (N = 104,351)	Control group mean (N = 67,414)	Difference	Standardized difference ^a	<i>p</i> -value ^b		
Clinical indicators of beneficiary's cardiovascular risk							
CVD risk score (%),	27	27	0.1	0.01	0.83		
[standard deviation]	[11]	[10]					
Has diabetes (%)	37	35	2.2	0.05	0.28		
Systolic blood pressure (mm Hg)	134	134	-0.1	-0.00	0.94		
Total cholesterol (mg/dL)	174	173	1.2	0.03	0.40		
HDL cholesterol (mg/dL)	50	51	-0.1	-0.01	0.89		
LDL cholesterol (mg/dL)	97	95	1.3	0.04	0.30		
Is treated for or diagnosed with hypertension (%)	81	75	5.2	0.13	0.04		
Is current smoker (%)	11	12	-0.8	-0.02	0.38		
Uses aspirin (%)	45	43	1.7	0.03	0.71		
Beneficiary demographic and Medica	are enrollment	characteristics	5				
Age	72	72	-0.2	-0.04	0.17		
[standard deviation]	[5]	[5]		0.00	0.00		
Black race (%)	8	6	2.0	0.08	0.23		
	57	59	-1.5	-0.03	0.11		
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.3	-0.01	0.84		
Originally entitled to Medicare because of disability (%)	14	14	0.2	0.01	0.85		
Beneficiary health and comorbid cor	nditions						
HCC score	1.17	1.17	0.00	0.00	0.97		
[standard deviation]	[1.00]	[1.00]	<u> </u>	0.04	0.04		
Count of chronic conditions	2.1	2.1	0.0	0.01	0.81		
Has chronic kidney disease (%)	25	25	0.2	0.00	0.87		
Has ischemic heart disease (%)	32	34	-2.2	-0.05	0.49		
Has congestive neart failure (%)	11	12	-0.6	-0.02	0.58		
Has atrial fibrillation (%)	12	12	-0.1	-0.00	0.94		
Has morbid obesity (%)	8 	(0.3	0.01	0.70		
Beneficiary medical service use and	spending in ye	ear before mod	lei enrollment	0.00	0.00		
i otal Medicare Parts A and B annualized expenditures (\$) [standard deviation]	7,691 [16,821]	7,623 [16,820]	68.6	0.00	0.82		
Hospital admissions (per 1,000 beneficiaries)	186	190	-4.8	-0.01	0.59		
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	380	364	15.2	0.01	0.40		
Office visits (per 1,000 beneficiaries)	9,277	8,951	326.0	0.04	0.41		
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,880	2,896	-16.2	-0.00	0.95		
Cardiologist visits (per 1,000 beneficiaries)	1,803	1,770	32.8	0.01	0.87		
Beneficiary CVD-related procedures	in year before	model enrollm	ent				
Received echocardiogram (%)	40	39	0.6	0.01	0.83		
Received electrocardiogram (%)	71	70	0.5	0.01	0.87		
Received cardiac stress test (%)	26	26	-0.5	-0.01	0.82		

Table B.1. Detailed baseline characteristics of 2017 medium- and high-riskenrollees combined, by intervention group
TABLE B.1 (CONTINUED)

	Intervention	Control		Standardized	
Characteristic	(N = 104,351)	(N = 67,414)	Difference	difference ^a	<i>p</i> -value ^b
Characteristics of organization enrol	lling the benefi	ciary			
Total number of practitioners	123	96	27.5	0.12	0.53
[standard deviation]	[160]	[274]			
Total number of service sites	25	14	10.8	0.43	0.10
[standard deviation]	[25]	[25]			
Organization type (%)					
Primary care	44	54	-9.5	-0.19	0.01
Specialty or multispecialty	30	33	-3.3	-0.07	
FQHC, RHC, or other health center	4	5	-1.1	-0.05	
CAH or rural hospital	1	3	-1.9	-0.15	
Acute care hospital	5	4	0.3	0.01	
Other	0	0	-0.2	-0.04	
Unknown typec	16	0	15.7	0.60	
Organization was participating in, or had application pending for	71	56	15.1	0.32	0.11
another model at randomization (%)					
Characteristics of clinician enrolling	the beneficiary	y			
Provider specialty (%)					
Primary care physician	61	62	-1.5	-0.03	0.85
Cardiologist	24	25	-1.5	-0.03	0.85
Physician with other specialty	3	1	1.9	0.14	0.15
Not a physician (for example, NP or	11	10	1.1	0.04	0.55
Characteristics of beneficiary's regio	on				
Rural (%)	25	26	-1.5	-0.03	0.76
Census region (%)	20	20	1.0	0.00	0.10
Northeast	26	22	37	0.09	0.07
Midwest	20	29	-9.5	-0.22	0.01
South	48	33	15.1	0.31	
West	6	15	-9.4	-0.31	
Characteristics of beneficiary's Millio	on Hearts CVD	Model enrollm	ent		
Days between model launch	122	143	-21.5	-0.23	<0.01
(1/3/2017) and enrollment date	[91]	[100]			
[standard deviation]					
Enrollment date is in (%)					
First quarter of the year	44	36	7.5	0.15	0.03
Second quarter of the year	33	30	2.5	0.05	0.20
Third quarter of the year	14	18	-3.6	-0.10	0.12
Fourth quarter of the year	9	16	-6.4	-0.19	<0.01
Data submitted to the registry using bulk upload (%)	49	49	-0.1	-0.00	0.99

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions (exception: atrial fibrillation, from the registry), medical service use and spending, and CVDrelated procedures; the organizations' applications to the Million Hearts CVD Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiary ZIP codes from the Medicare enrollment database, linked to data from the Census Bureau, for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: The following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: chronic kidney disease, ischemic heart disease. The following chronic conditions are defined by using HCC

TABLE B.1 (CONTINUED)

algorithms: congestive heart failure, morbid obesity. All procedures are defined by using Clinical Classifications Software indicators. See Appendix A.

^aThe standardized difference is the difference between the intervention and control group means, divided by the standard deviation across the intervention and control groups.

^b*p*-values are based on standard errors clustered at the level of the participating organization. For binary variables, the *p*-values come from a t-test. For categorical variables, they come from a single joint F-test of the equivalence of the intervention and control groups across all categories.

^c"Unknown" organizations are those without an organization type listed in NPPES—either because the organization had no organizational National Provider Identifier or because the organizational National Provider Identifier was not present in NPPES.

CAH = Critical Access Hospital; CVD = cardiovascular disease; FQHC = Federally Qualified Health Center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = Centers for Medicare & Medicaid Services' National Plan and Provider Enumeration System; PA = physician assistant; RHC = Rural Health Center.

Table B.2. Detailed baseline characteristics of 2017 high-risk enrollees, byintervention group

Characteristic	Intervention group mean (N = 32,875)	Control group mean (N = 21,103)	Difference	Standardized difference ^a	<i>p</i> - value⁵
Clinical indicators of beneficiary's c	ardiovascular ris	sk			
CVD risk score (%),	40	40	0.1	0.01	0.77
[standard deviation]	[9]	[9]			
Has diabetes (%)	66	64	1.6	0.03	0.50
Systolic blood pressure (mm Hg)	140	139	0.2	0.01	0.85
Total cholesterol (mg/dL)	169	169	0.1	0.00	0.97
HDL cholesterol (mg/dL)	47	48	-0.3	-0.02	0.65
LDL cholesterol (mg/dL)	93	92	0.5	0.01	0.71
Is treated for or diagnosed with hypertension (%)	91	88	2.4	0.08	0.07
Is current smoker (%)	12	13	-1.1	-0.03	0.26
Uses aspirin (%)	51	50	0.8	0.02	0.85
Beneficiary demographic and Medic	are enrollment c	haracteristics			
Age	74	74	-0.2	-0.04	0.26
[standard deviation]	[4]	[4]			
Black race (%)	8	6	1.7	0.06	0.32
Male (%)	65	65	-0.4	-0.01	0.68
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.6	-0.02	0.71
Originally entitled to Medicare because of disability (%)	12	12	-0.1	-0.00	0.88
Beneficiary health and comorbid co	nditions				
HCC score	1.38	1.37	0.01	0.01	0.79
[standard deviation]	[1.06]	[1.07]			
Count of chronic conditions	2.7	2.6	0.0	0.02	0.55
Has chronic kidney disease (%)	36	36	0.5	0.01	0.77
Has ischemic heart disease (%)	38	39	-1.5	-0.03	0.63
Has congestive heart failure (%)	14	14	-0.5	-0.01	0.65
Has atrial fibrillation (%)	14	14	-0.7	-0.02	0.74
Has morbid obesity (%)	9	8	0.1	0.00	0.89
Beneficiary medical service use and	l spending in yea	r before model e	nrollment		
Total Medicare Parts A and B	8,183	8,010	172.2	0.01	0.59
annualized expenditures (\$) [standard deviation]	[16,544]	[16,032]			
Hospital admissions (per 1,000 beneficiaries)	202	200	1.3	0.00	0.89
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	391	379	12.4	0.01	0.49
Office visits (per 1,000 beneficiaries)	9,895	9,451	444.4	0.06	0.27
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,232	3,199	33.1	0.01	0.92
Cardiologist visits (per 1,000 beneficiaries)	2,011	1,947	64.4	0.02	0.75
Beneficiary CVD-related procedures	in year before m	nodel enrollment			
Received echocardiogram (%)	43	43	0.5	0.01	0.85
Received electrocardiogram (%)	74	74	0.7	0.02	0.81
Received cardiac stress test (%)	28	29	-0.3	-0.01	0.89

TABLE B.2 (CONTINUED)

Characteristic	Intervention group mean (N = 32 875)	Control group mean (N = 21 103)	Difference	Standardized	<i>p</i> - value ^b
Characteristics of organization onro	lling the bonefic	(N - 21,100)	Billerence	uniciciice	Value
Total number of practitioners	127	01	36.2	0.15	0.44
[standard deviation]	[184]	[274]	00.2	0.10	0.44
Total number of service sites	25	14	10.8	0.42	0.11
[standard deviation]	[26]	[26]	10.0	0.12	0.11
Organization type (%)					
Primary care	42	54	-12.1	-0.24	0.01
Specialty or multispecialty	32	32	0.5	0.01	
FQHC, RHC, or other health center	4	6	-1.7	-0.08	
CAH or rural hospital	1	3	-2.2	-0.17	
Acute care hospital	5	5	0.1	0.01	
Other	0	0	-0.1	-0.02	
Unknown typec	16	0	15.4	0.59	
Organization was participating in, or had application pending for, another model at randomization	70	55	15.0	0.31	0.11
(%)					
Characteristics of clinician enrolling	the beneficiary				
Provider specialty (%)					
Primary care physician	60	62	-1.5	-0.03	0.84
Cardiologist	25	26	-1.2	-0.03	0.87
Physician with other specialty	3	1	1.8	0.12	0.19
Not a physician (for example, NP or PA)	11	10	0.9	0.03	0.61
Characteristics of beneficiary's regi	on				
Rural (%)	27	28	-1.1	-0.03	0.84
Census region (%)					
Northeast	25	22	2.4	0.06	0.31
Midwest	19	29	-9.6	-0.23	
South	50	34	15.9	0.33	
West	7	15	-8.7	-0.28	
Characteristics of beneficiary's Milli	on Hearts CVD M	lodel enrollment			
Days between model launch	116	141	-24.8	-0.26	<0.01
(1/3/2017) and enrollment date	[90]	[101]			
[standard deviation]					
Enrollment date is in (%)			• •		
First quarter of the year	47	37	9.1	0.19	0.02
Second quarter of the year	32	30	1.8	0.04	0.41
Third quarter of the year	13	17	-3.6	-0.10	0.10
Fourth quarter of the year	8	16	-7.3	-0.23	<0.01
Data submitted to the registry using bulk upload (%)	43	44	-0.8	-0.02	0.93

See Table B.1 for table notes and acronyms.

APPENDIX C

PLANNED ROBUSTNESS CHECKS FOR THE IMPACT EVALUATION

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APPENDIX C: PLANNED ROBUSTNESS CHECKS FOR THE IMPACT EVALUATION

As described in Chapter II, we plan to conduct two main robustness checks to address potential limitations in the primary impact analyses. This appendix provides details about the robustness checks.

The first robustness check will re-estimate impacts for the model enrollees, but will trim the intervention group in a way that mimics the 20-provider cap applied to the control group. As we describe below, this trimming makes the intervention and control groups more similar in both overall size and in the proportion of beneficiaries enrolled by large organizations. It thereby helps address the limitation that, even though the 2017 enrollees in the intervention and control groups are well balanced on a wide range of beneficiary-level characteristics, intervention-group beneficiaries are more likely to be enrolled by large organizations—which could potentially confound the impact estimates.

The second robustness check will re-estimate impacts in a population we define by attributing Medicare FFS beneficiaries to the participating organizations using Medicare claims data. This approach prevents potential biases in impact estimates that could stem from (1) the 20-provider cap, because attribution is based on provider lists supplied before randomization (and so before the provider cap was applied), and (2) differences in the types of beneficiaries that organizations chose to enroll, given that the population will include all eligible beneficiaries (to the extent eligibility can be replicated in claims)—whether or not they actually enrolled.

For each of these two robustness populations, this appendix describes (1) the methods we used to construct the 2017 analytic population, and (2) the characteristics of the intervention and control groups at baseline. We show these baseline characteristics to confirm whether balance improved as expected relative to the primary population on variables like organization size, without creating large new imbalances that would limit the value of the robustness checks. In future reports, we will show the results of the robustness checks along with the main impact findings. If we find the results are consistent across the populations, this will increase our confidence in the main findings. If the results are not consistent, we will investigate the source of the discrepancy and determine which estimates are most credible and why.

Although these robustness analyses will be useful checks for the main impact estimates, they have their own limitations, which is why we are not planning to use them for the main estimates (unless we find major discrepancies in the main results and determine that the results of these robustness checks are more accurate). Specifically, the trimmed intervention group unnecessarily restricts the group's size, decreasing statistical power for the estimates by a small amount and making the resulting impact estimates less generalizable to the full population of enrollees. The attribution-based study population contains many beneficiaries who were not actually enrolled by the organizations, and so the analysis will have modest statistical power to detect effects unless there is significant positive spillover of model impacts from enrollees to those not enrolled. Such spillover could occur, for example, if a provider improved the way that he or she provided CVD care to all Medicare FFS beneficiaries, not only those enrolled in the model.

1. First robustness check: Trimming the intervention group to mimic the 20provider cap

a. Method for defining the trimmed study population

The enrollment patterns in the control group suggest that the control organizations-faced with the 20-provider cap—largely selected their 20 model-participating providers using a rule that we can replicate for the intervention group. Specifically, as shown in Table II.4 (Chapter II of the main report), the mean number of beneficiaries that each participating provider enrolled in the control group (72 beneficiaries in 2017) was much higher than the mean per provider in the intervention group (50 beneficiaries). Therefore, it appears that the large control group organizations selected their 20 providers by choosing those who could potentially enroll the largest number of Medicare beneficiaries. We replicated this rule in the intervention group by (1) identifying each provider who enrolled a beneficiary while working at a large intervention organization (with large organizations defined as those with over 20 providers enrolling beneficiaries), (2) ranking those providers by the number of beneficiaries they enrolled in 2017, (3) selecting the top 20 providers, and (4) removing from the intervention group any beneficiaries enrolled in 2017 by providers at large organizations that were not ranked in the top 20. For consistency, we applied the same rule to the control organizations—which dropped the control group population by 10 beneficiaries, because one control organization had more than 20 providers enrolling beneficiaries in 2017 (potentially because some providers left and were replaced by others in 2017).

b. Baseline balance for the trimmed population

Trimming the intervention group resulted in a group that was similar in size to the control group (23,268 high-risk beneficiaries in the intervention group versus 21,093 in the control group). These numbers are much closer than in the untrimmed high-risk populations (32,875 in the intervention group and 21,103 in the control).

In addition to making the two groups much more similar in size, trimming the intervention group also substantially decreased the difference in the proportion of beneficiaries who were enrolled by large organizations. For example, in the trimmed population, the mean size of the organization that enrolled beneficiaries was 96 providers in the intervention group versus 91 in the control group (Table C.1)—compared to 127 versus 91 in the untrimmed population. Further, as shown in Table C.1, the intervention and control groups for the trimmed population continued to be well balanced on a wide range of beneficiary-level factors, including demographics, CVD risk factors, and overall CVD risk scores (with a mean score of 40 for high-risk beneficiaries in both the intervention and control groups).

Table C.1. Balance between the intervention and control groups for high-risk enrollees, with the intervention group trimmed to mimic the 20-provider cap applied to the control group

Characteristic	Intervention group mean (n = 23,268)	Control group mean (n = 21,093)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's ca	rdiovascular ri	sk			
CVD risk score (%)	40	40	0.1	0.02	0.49
[standard deviation]	[9]	[9]			
Has diabetes (%)	66	64	1.3	0.03	0.58
Systolic blood pressure (mm Hg)	140	139	0.3	0.02	0.69
Total cholesterol (mg/dL)	168	169	-0.5	-0.01	0.69
HDL cholesterol (mg/dL)	47	48	-0.3	-0.02	0.62
LDL cholesterol (mg/dL)	92	92	-0.1	0.00	0.96
Is treated for or diagnosed with hypertension (%)	91	88	2.7	0.09	0.03
Is current smoker (%)	12	13	-1.2	-0.04	0.24
Uses aspirin (%)	54	50	3.8	0.08	0.24
Beneficiary demographic and Medica	are enrollment o	characteristics			
Age	74	74	-0.2	-0.04	0.30
[standard deviation]	[4]	[4]			
Black race (%)	7	6	1.1	0.04	0.51
Male (%)	66	65	0.5	0.01	0.59
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.3	-0.01	0.84
Originally entitled to Medicare due to disability (%)	12	12	-0.1	0.00	0.88
Beneficiary health and comorbid con	ditions				
HCC score	1.38	1.37	0.0	0.01	0.83
[standard deviation]	[1.06]	[1.07]			
Count of chronic conditions	2.6	2.6	0.0	0.02	0.66
Has chronic kidney disease (%)	35	36	-0.3	-0.01	0.85
Has ischemic heart disease (%)	39	39	-0.3	-0.01	0.93
Has congestive heart failure (%)	14	14	-0.2	-0.01	0.86
Has atrial fibrillation (%)	14	14	0.0	0.00	0.98
Has morbid obesity (%)	8	8	-0.5	-0.02	0.42
Beneficiary medical service use and	spending in ye	ar before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$)	8,312 [16,826]	8,010 [16,034]	302.0	0.02	0.34
Hospital admissions (per 1,000	204	200	3.6	0.01	0.74
Outpatient ED visits or observation stays (per 1 000 beneficiaries)	393	378	14.8	0.01	0.45
Office visits (per 1,000 beneficiaries)	10.018	9.449	569.3	0.07	0.08
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,206	3,197	8.3	0.00	0.98
Cardiologist visits (per 1,000 beneficiaries)	2,068	1,947	120.7	0.03	0.57
Beneficiary CVD-related procedures	in year before ı	nodel enrollmen	t		
Received echocardiogram (%)	44	43	1.6	0.03	0.58
Received electrocardiogram (%)	75	74	1.7	0.04	0.50

TABLE C.1 (CONTINUED)

Characteristic	Intervention group mean	Control group mean (n = 21 093)	Difference	Standardized	n-value ^b
Boosived earlies stress test (%)	(11 – 23,200)	(11 – 21,093)	Difference 0.5		<i>p</i> -value
Received cardiac stress test (%)	29	29	0.5	0.01	0.02
Characteristics of organization enrol	ling the benefic	ciary	F 4	0.00	0.04
I otal number of practitioners	96	91	5.1	0.02	0.91
Total number of convice sites	17	[274]	3.0	0.13	0.52
[standard deviation]	17	14	5.2	0.15	0.52
Organization type (%)					
Primary care	44	54	-10.5	-0.21	0.04
Specialty or multispecialty	34	32	2.1	0.04	
FQHC, RHC, or other health center	5	6	-0.6	-0.02	
CAH or rural hospital	1	3	-1.9	-0.14	
Acute care hospital	7	5	2.1	0.09	
Other	0	0	0.0	-0.01	
Unknown type ^c	9	0	8.9	0.42	
Organization was participating in, or had application pending for, another model at randomization (%)	64	55	8.6	0.18	0.35
Characteristics of clinician enrolling	the beneficiary	1			
Provider specialty (%)		•			
Primary care physician	60	62	-1.7	-0.04	0.82
Cardiologist	28	26	2.3	0.05	0.77
Physician with other specialty	2		0.6	0.05	0.53
Not a physician (for example, N.P. or P.A.)	9	10	-1.4	-0.05	0.49
Characteristics of beneficiary's regio	'n				
Rural (%)	26	28	-1.8	-0.04	0.67
Census region (%)					
Northeast	24	22	2.2	0.05	0.00
Midwest	15	29	-14.0	-0.34	
South	52	34	18.7	0.38	
West	8	15	-6.9	-0.22	
Characteristics of beneficiary's Millio	on Hearts CVD	Model enrollmen	t	-	
Days between model launch	119	141	-22.1	-0.23	0.00
(1/3/2017) and enrollment date	[90]	[101]		0.20	0100
[standard deviation]					
Enrollment date is in (%)					
First quarter of the year	45	37	7.6	0.15	0.02
Second quarter of the year	33	30	2.8	0.06	0.19
Third quarter of the year	13	17	-3.7	-0.10	0.03
Fourth quarter of the year	9	16	-6.6	-0.20	0.00
Data submitted to the registry using bulk upload (%)	33	44	-11.0	-0.23	0.18

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions (exception: atrial fibrillation, whose source was the registry), medical service use and spending, and CVD-related procedures; the organizations' applications to the Million Hearts CVD Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiary zip codes from the Medicare enrollment database, linked to data from the Census Bureau, for regional characteristics; Million Hearts Data Registry for characteristics of model enrollment.

TABLE C.1 (CONTINUED)

Notes: For large intervention organizations (those with over 20 providers enrolling beneficiaries), we trimmed the intervention group by including only beneficiaries enrolled by the 20 providers who enrolled the most beneficiaries for the organization. The following chronic conditions are defined using the Chronic Condition Warehouse algorithms: chronic kidney disease, and ischemic heart disease. The following chronic conditions are defined using HCC algorithms: congestive heart failure, and morbid obesity. All procedures are defined using Clinical Classifications Software indicators.

^aThe standardized difference is the difference between the intervention and control group means, divided by the standard deviation across the intervention and control groups.

^b*p*-values are based on standard errors clustered at the level of the participating organization. For binary variables, the *p*-values come from a t-test. For categorical variables, they come from a single joint F-test of the equivalence of the intervention and control groups across all categories.

^c"Unknown" organizations are those without an organization type listed in NPPES—either because the organization had no organizational National Provider Identifier or because the organizational National Provider Identifier was not present in NPPES.

CAH = Critical Access Hospital; CVD = cardiovascular disease; FQHC = Federally Qualified Health Center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; N.P. = nurse practitioner; NPPES = Centers for Medicare & Medicaid Services' National Plan and Provider Enumeration System; P.A. = physician assistant; RHC = Rural Health Center.

2. Second robustness check: Using claims to attribute Medicare beneficiaries to participating organizations

a. Method for defining the attribution-based study population

We defined this population in three steps. First, we used claims data to attribute Medicare FFS beneficiaries to participating organizations. Second, we limited the population to beneficiaries who met eligibility criteria, to the extent those criteria could be replicated in claims data (for example, ages 40 to 79, with no previous heart attack or stroke, and no ESRD, and not in hospice). Third, using an algorithm we developed, we predicted a person's baseline CVD risk score from his or her claims-based characteristics at baseline.²⁷ We needed to make these predictions because many of the beneficiaries in the attribution-based study population are not in the registry, and so we cannot observe their clinical data. We developed the risk prediction algorithm using the 2017 enrollees, for whom we had both clinical and claims data.

In this section, we first describe the method we used to attribute beneficiaries to participating organizations and to limit the population to those who met the Million Hearts CVD Model eligibility criteria observable in claims. We then describe how we developed the risk prediction algorithm and applied it to the full attribution-based study population.

i. Attributing Medicare beneficiaries to participating organizations

Step 1. Identify providers to include in attribution

The first step in attributing beneficiaries was to construct a list of provider and organization identification numbers associated with each organization that participated in the Million Hearts CVD Model. Providers were identified by their individual National Provider Identifier (NPI). Organizations were identified by their Tax ID Numbers (TINs), and, if applicable, the CMS' Certification Number (CCN).²⁸ Organizations supplied CMS with these identifiers at three points

²⁷ We developed the algorithm using the 2017 enrollees, for whom we have both clinical and claims data. For these beneficiaries, we could relate claims-based characteristics to actual CVD risk scores.

²⁸ Organizations that bill outpatient and/or facility claims, such as CAHs, FQHCs, or RHCs, do so using their CCN.

in time: (1) when they first applied to the model (organizations uploaded their lists to the Salesforce database that housed the applications); (2) between the time when they were accepted to the model and Go-Live in January 2017 (organizations revised their lists in Salesforce, which CMS then migrated into the Million Hearts Data Registry just before Go-Live); and (3) during the intervention period, when approved representatives at each participating organization could update their lists within the registry. We used this information from organizations' applications, the Million Hearts Salesforce database (extracted in January 2018), and the Million Hearts Data Registry to identify all NPIs, TINs, and CCNs that were associated with each organization at any time between application and the end of the first model year.

We then limited this master list of providers to a final set of providers that we used for attribution. Specifically, we limited it to providers who met the following three criteria:

- 1. The provider needed to have been listed in the organization's Million Hearts CVD Model application or added to CMS's Million Hearts Salesforce database as of June 8, 2016, when CMS randomized practices to the intervention and control groups. This restriction prevented providers from being included in attribution if they were added to the Million Hearts Salesforce database or the registry after randomization. (Given the model's rules, adding providers after randomization happened more often in the intervention group than in the control group, and therefore could have introduced bias.)
- 2. The provider's specialty taxonomy codes had to indicate that the provider was allowed to register beneficiaries in the Million Hearts Data Registry. The following provider types were included: medical doctors, doctors of osteopathic medicine, physician assistants, nurse practitioners, and medical students. Provider taxonomy codes were based on the January 2018 extract of the National Plan and Provider Enumeration System (NPPES) NPI Registry.²⁹ Providers could have up to 15 taxonomy codes in NPPES; to be included in the provider list for attribution, at least one of these codes needed to indicate a provider type that was allowed to register.
- 3. The provider's specialty type needed to be one that made the provider likely to participate in the intervention. This criterion was necessary because some organizations listed many or all of their providers in their Million Hearts CVD Model applications, including providers whose specialties made them unlikely to participate in the model. Provider specialties were ranked by the percentage of providers with the given primary specialty who enrolled at least one medium- or high-risk beneficiary in the Million Hearts CVD Model in 2017. Then, we removed providers whose primary specialty was one of those considered most unlikely to participate. In this step, about one-third of providers were removed from the provider list for attribution. For example, this criterion removed optometrists, anesthesiologists, orthopedic surgeons, radiologists, and obstetrician-gynecologists.

 $^{^{29}}$ A small number of providers (n = 57) were not in the January 2018 NPPES extract (and were not assigned a specialty type) because their NPIs were deactivated (usually because the providers had retired or died).

At the 516 organizations that were randomized, there were 13,729 providers who met the three criteria (Figure C.1). Of these, 9,576 providers (4,213 intervention and 5,363 control) were from the 319 organizations that participated actively in the model in 2017.³⁰

³⁰ Attribution included providers from all 516 organizations that were randomized. This ensured that beneficiaries were attributed to only one organization, regardless of whether the organization stayed in or withdrew from the Million Hearts CVD Model. After attribution, the population of beneficiaries was limited to those who were attributed to one of the 319 organizations that participated actively in the Million Hearts CVD Model in 2017 (Criterion 6 in Step 3).



Figure C.1. Flow of organizations, providers, and beneficiaries from attribution to the final analysis population

^aThe criteria are FFS Medicare, age 40–79, no prior AMI, no prior stroke, no end-stage renal disease, and no hospice.

AMI = acute myocardial infarction; CVD = cardiovascular disease; D.O. = doctor of osteopathic medicine; FFS = feefor-service; M.D. = medical doctor; N.P. = nurse practitioner; P.A.. = physician assistant.

Step 2. Attribute beneficiaries to organizations

Next, we searched for all Medicare FFS beneficiaries' carrier and outpatient claims for office or clinic visits from January 3, 2017, through December 31, 2017, billed (1) by one of the NPIs included in the final provider list and (2) through one of the organization's TINs or CCNs. We then identified the claim corresponding to the first qualifying office or clinic visit for each beneficiary, and attributed the beneficiary to the associated organization and provider (NPI).³¹ A pseudo-enrollment date was assigned to each beneficiary, which was the date of the first qualifying claim regardless of whether the beneficiary was enrolled in the Million Hearts CVD Model and whatever his or her actual date of enrollment. We also recorded the provider (NPI) who billed Medicare for the office or clinic visit and constructed an indicator variable for whether the beneficiaries saw any active providers on their pseudo-enrollment dates (that is, saw a provider who enrolled at least one beneficiary in the model in 2017).

We used procedure and revenue center codes to identify office and clinic visits in claims. Most codes were also used in CMS's Enrollment, Validation, Alignment and Adjudication (EVAA) process, and the codes were based on codes used by the Comprehensive Primary Care Plus (CPC+) model. However, we added a few procedure and revenue center codes, mainly to help capture all visits at FQHCs, Rural Health Clinics, and Critical Access Hospitals.³²

The algorithm for attributing beneficiaries had high sensitivity. When attribution was rerun using a list of providers who enrolled at least one beneficiary in the model in 2017, the attribution algorithm correctly included 99.6 percent of enrolled beneficiaries in the population. Among the beneficiaries enrolled and attributed, over 99 percent were attributed to the same organization that enrolled the beneficiary.

Step 3. Use claims to remove ineligible beneficiaries

After we attributed beneficiaries to organizations, we used claims and other administrative data sources to construct covariates for each beneficiary (as described in Appendix A). These covariates were used for a variety of purposes, including removing beneficiaries who were likely ineligible for the intervention.

Beneficiaries were included in our analytic sample if they met the following eight criteria as of their pseudo-enrollment date:

³¹ Rarely, a beneficiary was attributed to two different organizations on the same date. We attributed the beneficiary to a single organization as follows: We first chose the organization that had more visits with the beneficiary over the two years before the attribution date. If there was still a tie, we selected the organization that had last seen the beneficiary before the attribution date. Then, if there was still a tie, we randomly chose a single organization.

³² We added procedure codes for primary care services that map to the FQHC new Prospective Payment System global visit codes (G0181, 99492-99494, 99484, G0502, G0503, G0504, G0507, 99354, 99355, 99358, 99359, 99406, 99407, 97802, 97803, 96152, 96153, 96154, 96160, G0101, G0102, G0108, G0109, G0270, G0271, G0442, G0443, G0444, G0445, G0446, G0447, and G0473), procedure codes for FQHCs under Medicare's prospective payment system (G0473, G0466, G0467, G0468, G0469, and G0470), and two revenue center codes for FQHCs (0521 and 0522). Claims were limited by facility type and service type, as appropriate. We also included procedure codes for counseling risk factor reduction and behavior change intervention (99401-99404, 99406-99409, 99411-99412) and procedure codes for preventive services (99381-99387, 99391-99397).

- 1. Enrolled in Medicare Parts A and B
- 2. Ages from 40 to 79
- 3. No previous acute myocardial infarction or stroke (as observed in Medicare FFS claims dating back to 1999)
- 4. Did not have end-stage renal disease
- 5. Were not receiving hospice benefits
- 6. Attributed to an organization that was considered to be participating actively in 2017 which, as noted in Chapter II, we defined as an organization that (1) did not withdraw from the Million Hearts CVD Model (including termination by CMS) or request a withdrawal by December 31, 2017, and (2) enrolled at least one beneficiary in 2017
- 7. Potentially exposed to the intervention for at least six months—that is, the organization to which they were attributed did not withdraw from the model for at least six months following the beneficiary's pseudo-enrollment date
- 8. Observable in Medicare data for at least one month out of the 12 months before attribution; "observable" means that the beneficiary was alive, enrolled in Medicare Parts A and B, had Medicare as the primary payer of medical bills, and was not enrolled in a Medicare Advantage plan

The first five criteria reflect the official Million Hearts CVD Model enrollment criteria as best as they could be measured in Medicare data. The last three criteria were applied for the purpose of the evaluation, to limit the population to beneficiaries who had nonmissing covariates and could reasonably have been exposed to the intervention if they were randomized to the intervention arm.

After all study eligibility criteria were applied, our final analytic sample included a total of 449,281 beneficiaries (of any CVD risk level) attributed to intervention organizations and 370,702 beneficiaries attributed to control organizations (Figure C.1).

ii. Predicting CVD risk scores for the attribution-based study population

Predicting CVD risk scores was a key step in developing the attribution-based study population. The majority of beneficiaries who were attributed to the participating organizations in 2017 (and who appeared eligible in claims) were not enrolled in the Million Hearts CVD Model in 2017. Therefore, the clinical data from the Million Hearts Data Registry, which we needed to compute risk scores, were unavailable for many attributed beneficiaries. Meanwhile, our evaluation requires CVD risk scores in order to separate the population into high-, medium-, and low-risk subgroups and to assess balance between the intervention and control groups. In future reports, we also plan to use CVD risk scores as a covariate (control variable) in the impact analyses and for other purposes. Therefore, we needed a way to assign CVD risk scores to all beneficiaries in the attribution-based population by using available data.

Our overall approach to assigning CVD risk scores to everyone in the attribution population was to (1) use the registry-based population of 2017 enrollees, for whom both detailed claims and clinical data at baseline were available, to develop an algorithm that predicts a person's true baseline CVD score based on variables derived from claims data only, and then (2) apply that

algorithm to everyone in the attribution-based population, predicting their baseline CVD risk scores from their claims-derived baseline characteristics.

Developing the algorithm for predicting baseline CVD risk

Methods. We used machine learning techniques to develop the predictive model of CVD risk scores (the response, or dependent variable) using a broad array of claims-based covariates and other available data (the predictors, or independent variables). That is, the risk prediction algorithm estimates a beneficiary's 10-year CVD risk score as a function of claims-based characteristics defined at the date of attribution. The prediction models were fit (estimated) using CVD risk scores for beneficiaries in the registry-based study population—that is, with data for the subset of attributed beneficiaries enrolled in the Million Hearts CVD Model in 2017. After we fit the model, we used the results to compute CVD risk scores for all model-eligible beneficiaries in the attribution. This required us to construct claims-based predictor variables in an identical fashion in both the enrolled and attributed populations.³³ We used a single model to predict CVD risk scores for all beneficiaries in the intervention and control group in order to ensure that we did not introduce bias by defining the risk groups differently for intervention versus control.

In the process of developing the predictive model, we considered a range of candidate models. We fit the candidate models using a random 85 percent sample of the available data (the training data). Models were primarily compared based on cross-validated mean squared errors, although we considered model performance on other metrics as well. A model outperformed another one if it had a lower mean squared error. Below, we report the performance of the model using the remaining 15 percent of the data (the testing data).³⁴ Candidate models varied in terms of the modeling approach, hyper-parameters, and response and predictor variables:

- **Modeling approaches.** We considered a range of modeling approaches, including gradient boosted regression trees (GBRT); random forest regression; multilayer perceptron neural networks; and elastic net, Lasso, and ordinary least squares regression models. (See Hastie et al. [2009] for an overview of these methods.) Models were fit using Scikit-learn in Python (Pedregosa et al. 2011).
- **Hyper-parameters.** Most of the modeling techniques required us to choose hyperparameters (parameters that are not directly estimated by the model but affect the results). We generally tried a range of parameters and chose the ones with the best performance (through cross-validation).

³³ In the data from the Million Hearts Data Registry that we used to train and test the model, the covariates were calculated as of the date the beneficiary was enrolled in the Million Hearts CVD Model. Covariates for imputing CVD risk scores for the attribution-based study population were based on the date a beneficiary was attributed.

³⁴ After we selected the best candidate model, we refit the model using the entire data set. This final model was used to predict CVD risk scores for the attribution-based population.

- **Response variables**. Most candidate models used beneficiaries' observed CVD risk scores as the response variable. Our best model, however, was based on using the CVD risk score minus a claim-based proxy of risk as the response variable.^{35,36}
- **Predictor variables.** We used Medicare Parts A and B claims and enrollment data to construct a broad range of claims-based covariates for potential inclusion as predictor variables.³⁷ As described in Appendix A, these variables included demographic variables, Medicare enrollment categories, HCC scores, chronic condition flags (measured by the CCW and HCC algorithms), years since the first occurrence of chronic conditions, service use and Medicare spending, receipt of cardiovascular-related procedures (measured using the CCS algorithm), and direct proxies of CVD risk score inputs (such as flags for any indication of tobacco or aspirin use in claims). We also constructed covariates based on the characteristics of the organizations and providers the beneficiary was attributed to and the beneficiary's zip code.

Results. Among all of the candidates, the GBRT model performed the best—that is, it was most predictive of actual CVD risk, as measured by the smallest mean squared error.³⁸ Further, the model performed best if we set the response variable to the actual CVD risk score minus the claims-based proxy. The GBRT model was fairly successful at predicting risk scores and risk categories in the testing data (that is, in the 15 percent of the sample that was not used to fit the model). The R² in the testing data was 0.82, and the mean squared error was 27.4.

The receiver operating curves (Figure C.2) summarize the results of the model by illustrating the trade-offs between false positives (saying that a person was medium or high risk when, in fact, they were not) and true positives (saying that a person was medium or high risk when, in fact, they were). The ideal curve would ramp up immediately, indicating that the model perfectly predicts who is and is not, in fact, medium or high risk (100 percent true positives and 0 percent false positives). The area under the receiver curve (the AUC, also called the c-statistic) for a model with perfect prediction would be 1. In contrast, a model that was no better than chance would have a diagonal line, with an AUC less than or equal to 0.50.

³⁵ This claims-based proxy was calculated using the ASCVD risk estimator formula; inputs were a combination of claims-based variables (such as age and presence of diabetes) supplemented by using the median value in the registry-based study population for the remaining variables (such as blood pressure and cholesterol). This approach helped the model deal with the nonlinear functional form of the ASCVD risk estimator.

³⁶ We also considered developing separate risk prediction models for each clinical input to the ASCVD risk estimator. Despite the rich array of claims-based covariates and the use of state-of-the-art machine learning methods, we could not successfully predict key modifiable risk factors such as blood pressure or cholesterol. We did better at predicting overall CVD risk because many of the most important determinants of risk scores are observable in claims.

³⁷ There are reasons to believe we could improve the prediction model by incorporating predictors constructed with Medicare Part D data, such as use of statins and other CVD-related medications. We will explore this option over the next year.

³⁸ Our final GBRT model used 15,000 boosting stages, a least squares loss function with an alpha of 0.9 and a learning rate of 0.1, and trees with 50 percent of the predictors with a maximum depth of 3 and at least 5 observations per leaf. (See the Scikit-learn documentation for a description of what these hyper-parameters mean.)

For the final GBRT, the area under the receiver operating characteristic curve for the predicted model was 0.953 for determining membership in the high CVD risk group and 0.953 for determining membership in the (combined) high or medium CVD risk groups (Figure C.2). These statistics illustrate that the model does a good job of predicting CVD risk.

Figure C.2. Receiver operating curves for assigning beneficiaries to the high or medium CVD risk groups: results from the CVD risk score prediction model





AUC = area under the ROC curve; CVD = cardiovascular disease; ROC = receiver operating characteristic.

Using the algorithm to assign CVD risk scores to all attributed and eligible beneficiaries

After we developed the algorithm, we assigned a predicted risk score for each eligible beneficiary in the attribution population. We did this by (1) calculating a claims-based version of the risk score, using just the person's demographics and assuming that his or her clinical values were at the median, and (2) adding an increment (moving that score up or down) based on the predicted increment from the algorithm.

The last step involved assigning beneficiaries to high-, medium-, and low-risk groups based on their predicted CVD risk scores. There is an inherent trade-off between sensitivity (classifying all the high- or medium-risk beneficiaries as "high or medium risk") and specificity (classifying all the low-risk beneficiaries as "low risk") in this process. We can increase the true positive rate by using a lower threshold to assign beneficiaries to groups, but this comes at the expense of a higher false positive rate (Figure C.2). For this report, we chose a threshold that yielded a true positive rate of 90 percent in the testing data. That is, with these thresholds, 90 percent of the beneficiaries who actually have high (>30 percent) CVD risk are assigned to the "high risk" group using the predicted CVD risk scores. Likewise, 90 percent of the beneficiaries who actually have high (>30 percent) or medium (15 to 30 percent) CVD risk are assigned to the "high risk" or "medium risk" groups by using the predicted CVD risk scores. With these thresholds, the false positive rate was 13.7 percent for the high-risk group and 14.4 percent for the high- and medium-risk groups combined (Table C.2).

Table C.2. I	Number of b	peneficiaries i	in the testing	data, by	actual risk	group
and by the	ris <mark>k group</mark> f	they were ass	igned to usin	g predict	ed risk sco	res

	Risk group assigned on the basis of predicted CVD risk scores					
Actual CVD risk group	Low	Medium	High			
Low	16,113	2,593	122			
	(86%)	(14%)	(<1%)			
	[86%]	[19%]	[<1%]			
Medium	2,552	10,285	4,895			
	(14%)	(58%)	(28%)			
	[14%]	[75%]	[40%]			
High	37	779	7,325			
	(<1%)	(10%)	(90%)			
	[<1%]	[6%]	[60%]			

Note: Each cell contains the number of beneficiaries in the testing data. Row percentages are in parentheses, and column percentages are in brackets. Percentages may not sum to 100 due to rounding.

CVD = cardiovascular disease.

After the analytic sample was limited to beneficiaries with predicted high and medium CVD risk, our final analytic sample included a total of 273,133 beneficiaries attributed to intervention organizations and 215,476 beneficiaries attributed to control organizations (Figure C.1).

Table C.3 compares the final analytic sample of attributed beneficiaries with those enrolled through the registry (in the main study population). (Similar results were found for control organizations; for brevity, we do not present those results.) Approximately 16 percent of high- or medium-risk enrollees in the model are not in the attribution-based population. This occurs mainly because (1) the provider list for attribution did not include any providers registered by organizations after randomization (1,210 and 191 providers in the intervention and control groups, respectively), and (2) the risk prediction model classified some high- and medium-risk beneficiaries as low risk.

Table C.3. Number of medium- or high-risk beneficiaries enrolled by or attributed to a participating intervention group organization

Attributed to a participating intervention group organization	Enrolled by a participating intervention group organization and medium or high CVD risk				
and medium or high predicted CVD risk	Yes	No	Total		
Yes	87,460 (32%) [84%]	185,673 (68%)	273,133 [94%]		
Νο	16,891 [16%]	Not applicable	16,891 [6%]		
Total	104,351 (36%)	185,673 (64%)	290,024		

Note: Each cell contains the number of beneficiaries. Row percentages are in parentheses and column percentages are in brackets. Percentages may not sum to 100 due to rounding.

CVD = cardiovascular disease.

b. Baseline balance for the attribution-based study population

The intervention and control groups are well balanced on claims-based beneficiary characteristics such as age, gender, predicted CVD risk, recent service use and spending (see Table C.4, which shows baseline balance for the beneficiaries predicted to be high risk when they were attributed to the organization). The two groups are also fairly similar on organizational characteristics that differed substantially in the main study population of 2017 enrollees— including number of sites, participation in other CMS initiatives at baseline, and likelihood of being a primary care practice. Note, however, that intervention beneficiaries do still tend to be enrolled by larger organizations (mean size of 252 versus 178 practitioners in the intervention and control groups, respectively). Finally, the intervention and control groups cannot have differences in unmeasured characteristics that might, in the primary study population, arise due to the 20-provider cap or to differences in the type of beneficiaries that organizations chose to enroll. As a result, this study population is protected against some potential biases (those stemming from both measured and possibly unmeasured baseline differences) that the primary study population is not, making it a good population for robustness checks.

Characteristic	Intervention group mean (n = 136,393)	Control group mean (n = 104,261)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's cardiov	/ascular risk				
Predicted CVD risk score [standard deviation]	34 [8]	34 [7]	0.2	0.02	0.55
Diabetes with acute complications (%)	1	1	0.0	0.00	0.87
Diabetes with chronic complications (%)	33	34	-0.9	-0.02	0.65
Diabetes without complication (%)	20	22	-1.7	-0.04	0.14
Evidence of hypertension in claims over previous 12 months (%)	85	86	-0.7	-0.02	0.77
Evidence of hyperlipidemia in claims over previous 12 months (%)	59	60	-0.9	-0.02	0.75
Evidence of tobacco use in claims over previous 24 months (%)	8	9	-1.1	-0.04	0.17
Beneficiary demographic and Medicare er	nrollment chara	cteristics			
Age	74	74	-0.2	-0.04	0.40
[standard deviation]	[4]	[4]			
Black race (%)	7	6	1.2	0.05	0.49
Male (%)	64	65	-0.6	-0.01	0.49
Dually enrolled in Medicare and Medicaid (%)	9	11	-1.9	-0.06	0.15
Originally entitled to Medicare due to disability (%)	12	13	-1.0	-0.03	0.46
Beneficiary health and comorbid conditio	ns				
HCC score [standard deviation]	1.35 [1.12]	1.40 [1.15]	-0.05	-0.04	0.37
Count of chronic conditions	2.5	2.6	-0.1	-0.04	0.49
Has chronic kidney disease (%)	32	34	-1.2	-0.02	0.48
Has ischemic heart disease (%)	40	41	-1.1	-0.02	0.75

Table C.4. Characteristics of high-risk (predicted) beneficiaries attributed to actively participating intervention and control group organizations

TABLE C.4 (CONTINUED)

Characteristic	Intervention group mean (n = 136,393)	Control group mean (n = 104,261)	Difference	Standardized difference ^a	p-value ^b	
Has congestive heart failure (%)	14	15	-1.2	-0.03	0.35	
Evidence of atrial fibrillation in claims over	12	12	0.0	0.00	0.98	
Has morbid obesity (%)	7	8	-0.6	-0.02	0.41	
Beneficiary medical service use and spen	ding in year be	fore attribut	ion			
Total Medicare Parts A and B annualized	9,172	8,942	230.3	0.01	0.49	
Hospital admissions (per 1,000 beneficiaries)	224	235	-11.1	-0.01	0.46	
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	411	435	-24.2	-0.01	0.36	
Office visits (per 1,000 beneficiaries)	9,716	9,216	499.7	0.06	0.20	
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,419	2,330	89.2	0.03	0.69	
Cardiologist visits (per 1,000 beneficiaries)	2,103	1,915	187.6	0.02	0.29	
Beneficiary CVD-related procedures in year	ar before attrib	ution				
Received echocardiogram (%)	45	44	1.2	0.02	0.63	
Received electrocardiogram (%)	74	74	-0.0	-0.00	0.99	
Received cardiac stress test (%)	28	27	0.6	0.01	0.82	
Characteristics of organization the benefic	ciary was attrib	uted to				
Total number of practitioners [standard deviation]	252 [394]	178 [341]	73.9	0.20	0.59	
Total number of service sites [standard deviation]	28 [26]	23 [32]	5.3	0.18	0.49	
Organization type (%)						
Primary care	40	45	-4.1	-0.08	0.29	
Specialty or multispecialty	41	31	9.3	0.20		
FQHC, RHC, or other health center	2	4	-1.8	-0.10		
CAH or rural hospital	1	2	-1.3	-0.12		
Acute care hospital	8	15	-7.2	-0.23		
Other	0	1	-0.5	-0.08		
Unknown ^c	8	2	5.6	0.26		
organization was participating in, or had application pending for, another model at randomization (%)	57	55	1.9	0.04	0.88	
Characteristics of clinician the beneficiary was attributed to						
Provider specialty (%)						
Primary care physician	56	54	2.5	0.05	0.72	
Cardiologist	33	32	0.9	0.02	0.90	
Physician with other specialty	3	3	0.5	0.03	0.69	
Not a physician (for example, N.P. or P.A.)	7	11	-3.9	-0.14	0.07	
Characteristics of beneficiary's region						
Rural (%)	23	28	-4.7	-0.11	0.38	
Census region (%)						
Northeast	23	24	-0.5	-0.01	0.73	
Midwest	14	24	-10.8	-0.28		
South	44	34	10.9	0.22		

TABLE C.4 (CONTINUED)

Characteristic	Intervention group mean (n = 136,393)	Control group mean (n = 104,261)	Difference	Standardized difference ^a	<i>p</i> -value ^b			
West	19	18	0.4	0.01				
Characteristics of beneficiary's attribution	Characteristics of beneficiary's attribution to participating organizations							
Days between office visit used for attribution and January 3, 2017 [standard deviation]	103 [92]	106 [93]	-3.1	-0.03	0.43			
Enrollment date is in (%)								
First quarter of the year	55	53	1.6	0.03	0.41			
Second quarter of the year	26	27	-0.7	-0.01	0.47			
Third quarter of the year	11	12	-0.5	-0.01	0.53			
Fourth quarter of the year	8	9	-0.5	-0.02	0.46			

Sources: Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending, CVD-related procedures, and attribution; the organizations' applications to the Million Hearts CVD Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiary zip codes from the Medicare enrollment database, linked to data from the Census Bureau, for regional characteristics.

Notes: We attributed beneficiaries and predicted their risk scores using the approach described in this appendix. The following chronic conditions and risk factors are defined using the Chronic Condition Warehouse algorithms: hyperlipidemia, tobacco use, chronic kidney disease, ischemic heart disease, congestive heart failure, and atrial fibrillation. The following chronic conditions are defined using HCC algorithms: diabetes (with and without complications), congestive heart failure, morbid obesity, and the count of chronic conditions. All procedures are defined using Clinical Classifications Software indicators. Hypertension was identified using procedure and diagnosis claims followed the algorithms developed by the Million Hearts implementation contractor; results were similar with the CCW and HCC algorithms. See Appendix A.

^aThe standardized difference is the difference between the intervention and control group means, divided by the standard deviation across the intervention and control groups.

^b*p*-values are based on standard errors clustered at the level of the participating organization. For binary variables, the *p*-values come from a Student's t-test. For categorical variables, they come from a single joint F-test of the equivalence of the intervention and control groups across all categories.

^c"Unknown" organizations are those without an organization type listed in NPPES—either because the organization had no organizational National Provider Identifier or because the organizational National Provider Identifier was not present in NPPES.

CAH = Critical Access Hospital; CVD = cardiovascular disease; FQHC = Federally Qualified Health Center; HCC = hierarchical condition category; N.P. = nurse practitioner; NPPES = Centers for Medicare & Medicaid Services' National Plan and Provider Enumeration System; P.A. = physician assistant; RHC = Rural Health Center.

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APPENDIX D.

ESTIMATING STATISTICAL POWER TO DETECT MODEL IMPACTS

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APPENDIX D: ESTIMATING STATISTICAL POWER TO DETECT MODEL IMPACTS

In this section, we describe how we estimated the statistical power to detect program impacts for the main registry-based study population (2017 enrollees) and the attribution-based study population described in Appendix C. We describe the methods and key assumptions behind the power calculations and present some additional results. These power calculations take into account the fact that randomization was at the organizational (not beneficiary) level, and that the organizations (clusters) are of widely varying sizes.

1. Methods and key assumptions

We estimated the statistical power to detect program impacts in the registry-based study population, using the actual number of actively participating organizations (N = 319) and the number of medium- and high-risk beneficiaries each organization actually enrolled during the first model year. For the attribution-based study population, we used the number of beneficiaries attributed in the first model year who had high or medium predicted CVD risk scores.

Our power calculations consider the threshold for policy relevance to be a 7 percent reduction in a composite measure of heart attack or stroke across the Medicare FFS beneficiaries who have high or medium baseline CVD risk scores. We base this threshold on CMS's deliberations when designing the Million Hearts CVD Model. CMS anticipated that, if successful, the Million Hearts CVD Model could potentially reduce CVD events by this amount and, if this occurred, lower Medicare spending on CVD events might fully offset program costs. Accordingly, CMS sought to enroll enough practices to yield a minimum detectable effect of 7 percent (or smaller) among medium- and high-risk Medicare FFS beneficiaries. We also examined statistical power under alternative effect sizes.

All power calculations assumed a 1-tailed test and p < 0.10 cutoff for statistical significance. These criteria are tailored for CMS evaluations, reflecting CMS's interest in avoiding false negatives (that is, erroneously failing to conclude that the program had favorable effects) as well as false positives. They are less stringent than the traditional criteria of two-tailed tests with p < 0.05 cutoffs, which limit false positives to a greater extent. We also made the following assumptions: (1) the incidence of the composite measure of heart attack or stroke is 20 percent for the high-risk group and 12 percent for the medium-risk group; (2) an intraclass correlation coefficient (ICC) for clustering between practices is 0.014; and (3) the covariates can explain 30 percent of the variation in outcomes at the patient level ($R^2 = 0.30$) and 20 percent at the organization level ($R^2 = 0.20$). To compute power, we constructed 2,000 simulated data sets with the assumed properties, estimated impacts with each simulated data set, and then calculated the percentage of data sets where we failed to reject the null hypothesis of no impacts.

2. Statistical power for the registry-based study population

Our power calculations indicate that the impact evaluation has an 80 percent chance of concluding that the model reduced the incidence of first-time heart attacks and strokes among medium- and high-risk beneficiaries in the registry-based study population if, in fact, the model

has its intended effect of reducing these events by 7 percent. This power meets the traditional standard of 80 percent.

In addition, the evaluation is similarly powered (80 percent) to detect impacts for the subgroup of high-risk beneficiaries. This is important because model impacts might be largest for the high-risk group, given that (1) their absolute risk is higher and so there is more room for improvement, and (2) they might receive more intensive services. CMS is paying organizations to provide longitudinal care management services for their high-risk beneficiaries but not for those at medium risk. The study is less well powered (71 percent) to detect impacts for the subgroup of medium-risk beneficiaries.

Figure D.1 presents statistical power under alternative effect sizes. The assumed 7 percent effect size, discussed above, is on a fairly steep portion of the curve, suggesting that statistical power could be well below 80 percent if the model has an effect less than 7 percent, but that power could be well higher than 80 percent if impacts are larger than 7 percent.

In additional power calculations (not shown), we found power may also be more limited if the event rate in the control group turns out to be less than the assumed rate of 20 percent (for high-risk beneficiaries) or 12 percent (for medium-risk beneficiaries). We also found our estimates of statistical power to be fairly insensitive to the number of beneficiaries at each organization. Specifically, the statistical power is not much higher when we multiplied the number of beneficiaries at each organization by, say, 150 percent or 200 percent (to account for sample addition in future program years), and not much lower when we multiplied the number of beneficiaries by, say, 90 percent (to account for potential loss-to-follow-up).



Figure D.1. Estimated power to detect an effect on the incidence of first-time heart attacks and strokes in the registry-based study population

Note: Statistical power is the probability of concluding that the program had any effect (using a one-tailed test with a p<0.10 cutoff for statistical significance) given the assumption that the true effect is a certain size. See the text for the assumptions underlying these calculations.

3. Statistical power for the attribution-based study population

Our power calculations indicate that the impact evaluation has an 85 percent chance of concluding that the model reduced the incidence of first-time heart attacks and strokes among medium- and high-risk beneficiaries in the attribution-based study population from 2017 if, in fact, the model reduces these events by 7 percent on average. Power is slightly higher (86 percent) for the subgroup of high-risk beneficiaries and slightly lower (82 percent) for the subgroup of medium-risk beneficiaries. All these power calculations exceed the traditional standard of 80 percent. However, there is a concern that average effects could be less than 7 percent in the full attribution-based population because not all of the beneficiaries in this population were enrolled in the model, and thus some beneficiaries statistical power could be substantially lower than 80 percent if the model only affects the subgroup of beneficiaries who were attributed to participating providers, if the model only affects the subset of intervention beneficiaries who were enrolled in the model, or (more generally) if average effects are less than 7 percent.



Figure D.2. Estimated power to detect an effect on the incidence of first-time heart attacks and strokes in the attribution-based study population

Average effect on the incidence of first-time heart attacks and strokes

Note: Statistical power is the probability of concluding that the program had any effect (using a one-tailed test with a p < 0.10 cutoff for statistical significance) given the assumption that the true effect is a certain size. See the text for the assumptions underlying these calculations. The first set of columns assumes a favorable 7 percent average effect on all beneficiaries in the study population; the second set of columns assumes an average effect of 7 percent times ≈ 0.71 , and the third set of columns assumes an average effect of 7 percent times ≈ 0.37 .

CVD = cardiovascular disease.

APPENDIX E

ANALYZING MODEL IMPLEMENTATION DATA FROM CMS AND THE IMPLEMENTATION CONTRACTOR

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APPENDIX E: ANALYZING MODEL IMPLEMENTATION DATA FROM CMS AND THE IMPLEMENTATION CONTRACTOR

Secondary data provided by CMS and the implementation contractor supported Mathematica's model implementation evaluation, including survey results, official documentation on practices' reasons for exiting the model, payment data, and data from the model's learning systems.

1. Survey results from the implementation contractor

In April 2017, the implementation contractor fielded the first Annual Million Hearts Survey on Care Delivery to intervention organizations; completion of this survey is required of intervention organizations as stated in the Model Participant Agreement. The survey captured data on cardiovascular care delivery early in the model period. Survey data were provided to the evaluation team, who then linked the data to an organization-level file that contained model application data (for example, number of practitioners at the organization, participation in other CMS initiatives) and organization taxonomy type from the NPPES—an online registry of clinicians National Provider Identifiers (NPIs). Analyses of survey data were limited to intervention organizations that had (1) enrolled at least one beneficiary between January 3, 2017, and December 31, 2017, and (2) not formally withdrawn (including termination by CMS) or requested a withdrawal from the model as of December 31, 2017 (n = 163 organizations).

2. CMS documentation on reasons that organizations have withdrawn

For participating organizations that withdrew from the model through fall 2017, CMS provided the evaluation team with data on reasons for withdrawal. These data included written communications from organizations to CMS, as well as notes that summarized CMS's exit interviews with organizations and/or CMS's reasons for terminating the organizations' participation.

After reviewing these data, we created seven categories for withdrawal and identified several themes in organizations' stated reasons for withdrawing. In some instances, organizations cited multiple reasons for withdrawing. The evaluation team considered each reason separately and allowed organizations to fall into as many categories as applied. Among the 121 withdrawing organizations, we assigned 93 organizations' reasons to one category, 24 organizations' reasons to two categories, and 4 organizations' reasons to three categories. The categories of reasons for withdrawing were as follows:

- Termination by CMS, usually after the organization failed to return a signed model participation agreement or did not respond to a corrective action plan
- An organization's lack of available resources to implement the Million Hearts CVD Model, usually related to insufficient staff capacity or electronic health record capabilities
- An organization's need to focus on competing priorities
- An organization's perception that the model's design and requirements were too burdensome, especially requirements related to submitting data to the Million Hearts Data Registry, using the Million Hearts Connect portal, or using a CVD risk calculator

- A lack of buy-in or engagement from organizational leaders, providers, or other staff
- Changes in leadership at an organization

For 21 organizations, we did not have sufficient data to assess their reasons for leaving (unknown). The unknown factor was applied either if there was not a reason given for withdrawing or if the reason was too vague to categorize it into one of the other categories previously discussed. The unknown factor was mutually exclusive with other factors.

3. Analysis of data from the Million Hearts CVD Model learning system

We obtained data from the CMS implementation contractor on (1) whether each intervention organization met the requirements of attending at least one learning activity per quarter and (2) attendee perceptions of the learning activities. The implementation contractor also provided data on participation in specific learning events, which we linked to data from the organizations' applications to join the Million Hearts CVD Model and findings from the site visits to assess whether the level of engagement varied across organizational characteristics. For the 15 intervention sites that we visited, we also assessed qualitatively whether there was a relationship between attendance of learning events and organizations' implementation experience. The analysis was limited to organizations that had actively participated in the first year of the model—that is, organizations that had enrolled at least one beneficiary between January 3 and December 31, 2017, and had not withdrawn from the model as of December 31, 2017 (n = 163).

4. Analysis of CMS payment data

We collected data from CMS, via the implementation contractor, on the actual amount CMS paid to each of the organizations (intervention and control) for participating in the model. These payments included risk stratification payments (for both intervention and control organizations) and cardiovascular care management payments (for intervention organizations only). We analyzed these payment data to calculate mean, median, and total payments paid to intervention and control organizations. The payment data analysis was limited to the same 163 organizations.

APPENDIX F

PRIMARY DATA COLLECTION AND ANALYSIS

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APPENDIX F: PRIMARY DATA COLLECTION AND ANALYSIS

The evaluation of the implementation of the Million Hearts Model relied mainly on primary data collected from site visits to intervention organizations, as well as telephone interviews with control organizations and organizations from both groups that withdrew from the model.

1. Site visits and virtual site visits with intervention participant organizations

a. Participant selection

The evaluation team conducted site visits with respondents from 15 intervention organizations, including in-person site visits to 12 organizations and virtual site visits via telephone interviews with three small organizations (that is, with five or fewer providers). Virtual site visits reduced the burden on small provider organizations that could arise from an in-person visit while still ensuring we gained their perspective on the model.

To ensure a diverse sample of site visit participants reflective of all participating organizations, we first analyzed the distribution of intervention organizations across organization size (as defined by the number of providers), geographic region (defined by Department of Health and Human Services regions), and organization/specialty type (for example, primary care office, cardiology office, or hospital outpatient department). Using these distributions, the evaluation team developed targets for the number of intervention organizations, the research team assessed characteristics such as rural versus urban location, participation in other CMS initiatives, and implementation readiness as indicated in the baseline implementation contractor survey (April 2017). To capture a range of implementation progress and experiences, the team also considered application responses about team-based care and shared decision-making and the number of provisionally enrolled beneficiaries. To supplement organizational characteristics provided in application and enrollment data, the evaluation team also reviewed organizations' websites (when available).

The research team then selected a set of site visit participants to meet targets we had set for the region, organization size, and organization type criteria, and to achieve a diversity of organizations along the other characteristics considered. For the 15 site visits, we targeted (1) at least one organization from each of the 10 geographic regions, with up to three organizations in a region depending on the distribution of all participating intervention organizations; (2) five small (1–5 providers), five medium (6–19 providers), and five large (20 or more providers) organizations; and (3) at least seven primary care organizations—at least three specialty or multispecialty organizations, at least three hospitals (including one academic, one rural, and one large health system), and at least one FQHC. We did not select organizations that had withdrawn at the time of the analysis (early 2018), although one organization later withdrew, after the site visit in March 2018. We also looked at organizations' responses to the implementation contractor's Annual Survey on Care Delivery to ensure that the overall sample represented a range of readiness to implement the model.³⁹ We submitted the list of selected organizations

³⁹ Respondents were asked to rate on a scale of 1 to 10, "To what extent do you think the staff in your health system/organization are ready to implement the Million Hearts® Model?"

(indicating whether these were planned as in-person or virtual site visits) and their characteristics to CMS to review before we contacted sites to schedule interviews.

For each selected organization, we also identified up to two additional organizations that are within the same CMS region and have similar characteristics (such as organization size or specialty). During our initial contact with the individual who was CMS's primary contact for communications about the model, we confirmed whether the organization was affiliated with another organization already included in our sample. If affiliations were identified, we planned to proceed with the second-choice organization, but this issue did not arise. This list of second- and third-choice organizations was also used to replace a chosen organization if the organization's contact declined or they had recently dropped out of the model. In total, we contacted 20 intervention organizations, of which five declined due to staff capacity or did not respond, and 15 were scheduled.

b. Development of interview protocols

We used semistructured protocols for each interview in the site visits and customized topics for each respondent type to understand intervention organizations' approach to implementing the Million Hearts CVD Model, as well as the barriers and facilitators to successful implementation of the intervention. We identified types of respondents (for example, clinical model lead and IT), research questions, and a subset of constructs (Table F.1) from the Consolidated Framework for Implementation Research (CFIR) to draft the protocols. CFIR provides theory-based, prespecified constructs that are likely to influence implementation of complex programs, and helps to ensure a rigorous and methodical analysis of factors that facilitate or impede organizations' work on the Million Hearts CVD Model (Damschroder et al. 2009; Alexander and Hearld 2012; Powell et al. 2012; Midboe et al. 2011). We did not ask informants about each of these CFIR constructs directly, but identified the constructs most relevant for the Million Hearts CVD Model before collecting data to make our analyses more efficient. The draft protocols were revised based on the feedback from CMS before we collected data.

Table F.1. Interview respondents, research questions, and CFIR constructs for site visits at Million Hearts CVD Model intervention organizations

Respondent types

Organization lead/champion of the Million Hearts CVD Model Physician/administrative lead Key leadership figures (clinical IT director, clinical QA director) Front-line clinicians (MD, DO, NP, PA) Clinical support staff (MA, nurse, pharmacist, social worker) Nonclinical support staff Key referral partners (for example, dieticians, pharmacists)

Research questions

Which organizations joined the model and why? Which organizations left the model and why? Among the participating organizations, how many and which types of providers participated in the model? How many Medicare beneficiaries did the participating organizations enroll, and what where these beneficiaries' characteristics at baseline? How much of patients' baseline CVD risk was driven by modifiable vs. not modifiable factors?

How did a sample of control organizations deliver CVD preventive care and participate in the Million Hearts Model?

How did participating organizations implement the model? What facilitated or hindered implementation? What types of CVD preventive services did the intervention practices offer at the launch of the MH Model? What are respondents' perceptions of the model incentives and supports that have been provided to participating organizations?

What are participants' early expectations of how the model is affecting, or will affect, patient CVD care and outcomes?

Applied CFIR constructs

Perceived advantages of the Million Hearts Model over prior CVD preventive care Planning for implementation within an organization Perceived difficulty or complexity of implementing the model Presence of external policy and incentives, including regulations, guidelines, and other quality initiatives Communications within a participating organization regarding the model Organizational culture (for example, norms and values) that affects model implementation Perceived priority or importance of the model within an organization Perceived effect of leadership on model implementation Performance feedback delivered to organizations

Definitions: CFIR = consolidated framework for implementation research; CVD = cardiovascular disease; DO = doctor of osteopathic medicine; IT = information technology; MA = medical assistant; MD = doctor of medicine; NP = nurse practitioner; PA = physician assistant; QA = quality assurance.

c. Site visit process

A two-person team conducted one-day, in-person site visits using semistructured protocols described above. The initial site visit was conducted by the principal investigators (PIs) from Mathematica and RAND to ensure consistency in collecting data and to refine the protocols. Subsequent site visits were conducted by two-member teams comprising senior and junior staff; many of these teams included members from both Mathematica and RAND when it was logistically feasible. Site-visit teams prepared for interviews by reviewing the organizations' applications and responses to the implementation contractor's annual survey and other relevant data. Each interview lasted 30 to 60 minutes.

The number of interviews conducted during each site visit varied depending on the size of the organization, as well as the number and type of people involved in the Million Hearts CVD

Model at the site. At a minimum we met with each organization's model champion. For larger organizations, we conducted three to seven interviews during each site visit. For some multisite geographically dispersed organizations, we conducted face-to-face interviews at two locations in order to capture the experience of key providers; sometimes, the organization arranged for respondents from satellite sites to meet the evaluation team at their main location where the majority of interviews were occurring. For three small organizations, we conducted virtual site visits, as noted above, including telephone interviews with one to three respondents to minimize burden on the organization. Often, interviews included more than one respondent at a time by request of the organization. All interviews were audio recorded and transcribed.

2. Telephone interviews with control group participants

a. Participant selection

We identified 10 control organizations for telephone interviews using the same process we used to select the intervention group participants for site visits. Because we were conducting interviews with fewer organizations, we aimed for the overall control sample to match the key characteristics of the overall intervention sample and did not match control organizations one-to-one with intervention organizations. For example, we chose a large hospital-based organization in HHS region 2 as a site visit participant and a large hospital-based control organization in HHS region 5 as a control organization. All 10 control organizations that we contacted participated in the interviews.

b. Development of interview protocol

We developed a semistructured protocol to conduct a single interview per organization with the primary or secondary contact at the control organizations; often, these respondents were practice managers, clinical champions, or staff involved in Million Hearts CVD Model data entry. Protocols covered the following topics:

- Motivation to participate in the Million Hearts CVD Model
- Experience with the Million Hearts Data Registry and reporting for the Million Hearts CVD Model
- Approach to CVD care and prevention, including recent changes
- Use of CVD risk stratification

c. Telephone interview process

We conducted telephone interviews with respondents from the 10 selected control organizations. For six organizations, one interview with a single person, such as a nurse or practice manager familiar with the delivery of CVD care and data entry into the Million Hearts Data Registry, was sufficient to answer all research questions. For the remaining four sites, multiple respondents participated in the interview at the organization's request, including at least one respondent focused on CVD care within the practice (for example, with a lead physician) and another focused on data entry (for example, with an administrative assistant).

The telephone interviews were divided between Mathematica and RAND staff on the team and were completed in late July and early August 2018. Interviews ranged from 15 to 50 minutes. All audio was recorded and transcribed.

3. Telephone interviews with intervention and control organizations that exited the model

a. Participant selection

We conducted telephone interviews with 16 intervention and three control organizations that withdrew from the Million Hearts CVD Model. We selected organizations whose characteristics (size, location, and organization type) represented the total population of organizations that withdrew from the model. We also chose organizations that withdrew at different time points: after randomization but before model launch, after model launch but before the end of the first performance period for the intervention organizations, and during the second performance period for the intervention. In addition, we reviewed data collected by CMS (see Appendix E) through interviews and written documentation on why organizations withdrew; these data helped the team to identify the range of reasons for withdrawal and chose a group of withdrawing organizations to capture a diversity in factors cited as prompting the decision to withdraw. (See Chapter VI in the main report for reasons practices withdrew.) Examples of respondents from these organizations included practice manager, clinical champion, or other designated people who made the decision to withdraw from the Million Hearts CVD Model. In total, we contacted 46 organizations that withdrew from the model, of which 27 declined or did not respond and 19 were scheduled for an interview.

b. Development of interview protocol

Interviews with these organizations aimed to complement the data CMS collected in its exit interviews, and protocols covered the following topics:

- Organizations' current approach to CVD care and how it compares with care recommended under the Million Hearts CVD Model
- Organizations' original motivation to participate in the model
- Factors influencing the decision to withdraw
- Perceptions of what aspects of the model presented implementation challenges
- Any changes to the model that could have encouraged them to continue to participate

c. Telephone interview process

Using the interview protocol described above, we completed one telephone interview per organization with the 20 selected organizations that withdrew from the model. We scheduled interviews to occur during March and July 2018. A team member from RAND or Mathematica conducted each interview, and interviews varied in length from 5 to 30 minutes, which reflected the respondents' willingness to speak with the team. Each was recorded and transcribed.

4. Analysis of qualitative data

Qualitative data collected through site visits and interviews is the key data source for answering research questions related to changes to the service delivery model, experiences in reporting data to the registry, learning system involvement and perceived usefulness, and response to payment incentives. To support these analyses, we organized analysis and reporting of qualitative data using this evaluation's specific research questions and a limited set of CFIR constructs tailored to the likely barriers and facilitators to implementing the Million Hearts CVD Model and improving CVD care.

We imported transcribed interviews into the software NVivo to facilitate coding of data and collaboration within our team. Members of the team jointly developed and iteratively refined a codebook, consisting of codes and their definitions. We began by developing a set of codes based on the key questions from CMS's request for proposals to evaluate the Million Hearts CVD Model, the logic model (Figure I.1 in the main report), and selected CFIR constructs (Table F.1). To ensure inter-rater reliability, members of the coding team all coded the same first eight transcripts and met to compare codes. During these meetings, we suggested modifications to the codebooks by changing the definition or adding new codes to facilitate consistent coding across coders. After coding the first eight transcripts, coders began independently coding transcripts, but met weekly to code a transcript together as a group in order to maintain inter-rater reliability and reduce researcher bias. Coding was completed by mid-July 2018.

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