Evaluation of the Million Hearts® Cardiovascular Disease Risk Reduction Model: Second Annual Report

November 2019

Lead authors:

Greg Peterson, Linda Barterian, Keith Kranker, Amanda Markovitz, Adam Rose*, Rumin Sarwar, Allison Steiner, Leslie Conwell, Jia Pu, Michael Barna, David Magid**, Kate Stewart, Laura Blue, Dan Kinber, Precious Ogbuefi, Nancy McCall

Contributing authors (in alphabetical order):

Nancy Clusen, Thomas Concannon*, Erick Geil***, Liisa Hiatt*, Michael Ho**, Elizabeth Holland, Holly Matulewicz, Andrew McGuirk, Sandi Nelson, Nabeel Qureshi*, Lei Rao, John Tyler***, Malcolm Williams*

*Author is from the RAND Corporation
**Author is from the University of Colorado
***Formerly with Mathematica

Submitted to:

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-1850
Contracting Officer's Representative: Patricia Markovich
Contract Number: HHSM-500-2014-00034I

Submitted by:

Mathematica Policy Research
1100 1st Street, NE
12th Floor
Washington, DC 20002-4221
Telephone: (202) 484-9220
Facsimile: (202) 863-1763
Project Director: Nancy McCall
Reference Number: 50496

This page has been left blank for double-sided copying.

ACKNOWLEDGMENTS

The authors gratefully acknowledge the guidance and contributions of our project officer, Patricia Markovich. In addition, we also gratefully acknowledge Randy Brown for his quality assurance reviews and John Kennedy and Colleen Fitts for carefully editing and producing this report. We also appreciate support from Erica Taylor and others on the CMS model implementation team, as well as from CMS's model implementation contractors. We are grateful to the individuals from the intervention organizations who shared their experiences with us.

This page has been left blank for double-sided copying.

CONTENTS

FIGURES

This page has been left blank for double-sided copying.

TABLES

LIST OF ACRONYMS

ABCS	Aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation
ACC/AHA	American College of Cardiology/American Heart Association
ACO	Accountable care organization
AMI	Acute myocardial infarction
ASCVD	Atherosclerotic cardiovascular disease
CAH	Critical access hospital
CCM	Chronic care management
CCN	CMS certification number
CCW	Chronic Conditions Data Warehouse
CDC	Centers for Disease Control and Prevention
CFIR	Consolidated Framework for Implementation Research
CI	Confidence interval
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CPC+	Comprehensive Primary Care Plus
CPT®	Current Procedural Terminology
CVD	Cardiovascular disease
D.O.	Doctor of osteopathic medicine
ED	Emergency department
EDB	Enrollment data base
EHR	Electronic health record
ESRD	End-stage renal disease
FFS	Fee-for-service
FQHC	Federally qualified health center
HCC	Hierarchical Condition Category
HCPCS	Healthcare common procedure coding system
HDL	High-density lipoprotein
HHS	U.S. Department of Health and Human Services
HIC	Health insurance claim number
IT	Information technology
LDL	Low-density lipoprotein
MBI	Medicare beneficiary identifier
mg/dL	Milligrams per deciliter
M.D.	Doctor of medicine
MIPS	Merit-based Incentive Payments System
mmHg	Millimeters of mercury

MSSP	Medicare Shared Savings Program
N.P.	Nurse practitioner
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
NQF	National Quality Forum
NSTEMI	Non-ST-elevation
P.A.	Physician assistant
PBPM	Per beneficiary per month
QA	Quality assurance
RHC	Rural health center
SBP	Systolic blood pressure
SDM	Shared decision making
STEMI	ST-elevation
TIA	Transient ischemic attack

EXECUTIVE SUMMARY

In January 2017, the Centers for Medicare & Medicaid Services (CMS) launched a rigorous five-year randomized trial of the Million Hearts® Cardiovascular Disease Risk Reduction Model (the Million Hearts Model). The model is designed to reduce heart attacks and strokes among Medicare fee-for-service (FFS) beneficiaries. The 516 organizations that joined the model include primary care and cardiology practices, outpatient hospital departments, and health centers located in urban and rural areas throughout the country. The Million Hearts Model encourages innovation by providing intervention organizations with the following incentives and supports:

- ***Payments*** for risk stratifying all eligible Medicare FFS beneficiaries and for providing cardiovascular care management for beneficiaries at high risk of a heart attack or stroke in the next 10 years, and—starting in the second model year—payments for reducing aggregate CVD risk among high-risk beneficiaries.
- ***Feedback reports*** describing organizations' performance in enrolling beneficiaries and reducing CVD risk for their high-risk beneficiaries.
- ***Learning systems*** focused on peers sharing best practices for implementing the model.
- ***Tools*** for calculating CVD risk, estimating the impact that different therapies would have on reducing risk, and reporting risk factors to CMS.

The 516 organizations were randomized to the intervention and control groups. The intervention organizations enroll eligible Medicare beneficiaries over time based on when they have a visit with a participating provider (physician, nurse practitioner, or physician assistant). Beneficiaries are eligible for the model if they are age 40 to 79, have not had a heart attack or stroke, and meet other criteria.[1] Providers at those organizations calculate beneficiaries' CVD risk at enrollment and annually thereafter using the American College of Cardiology/American Heart Association (ACC/AHA) risk calculator and a new longitudinal functionality designed specifically for this model. The risk calculator uses demographic and clinical data (including blood pressure and cholesterol levels) to estimate the likelihood that a person will have a heart attack or stroke within the next 10 years. The intervention organizations report these demographic and clinical data to CMS via the Million Hearts Data Registry, and the registry automatically calculates and reports the CVD risk scores back to the intervention organizations. Beneficaries are considered "high risk" if their risk is 30 percent or higher, "medium risk" if it is between 15 and 30 percent, and "low risk" if it is less than 15 percent.

To support the model's evaluation, CMS also pays control organizations to collect and report clinical data annually on their eligible Medicare FFS beneficiaries. CMS does not expect these

[1] Beneficiaries must be enrolled in Medicare Parts A and B, not have end-stage renal disease, and not be receiving hospice benefits.

organizations to calculate CVD risk scores or otherwise change their clinical care. Further, CMS does not supply risk information back to the control group organizations. Large control group organizations (those with more than 20 clinicians) had to select 20 of their clinicians and limit study enrollment to the patients of only those clinicians.

The overall goal of the evaluation is to assess whether, and through what mechanisms, the Million Hearts Model improves CVD care, reduces heart attacks and strokes, and lowers or maintains Medicare spending 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. The evaluation also seeks to identify early indicators of improvement in CVD preventive care, which includes increased provider awareness of their patients' CVD risk and increased use of the ABCS in the primary prevention of CVD—that is, aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation.

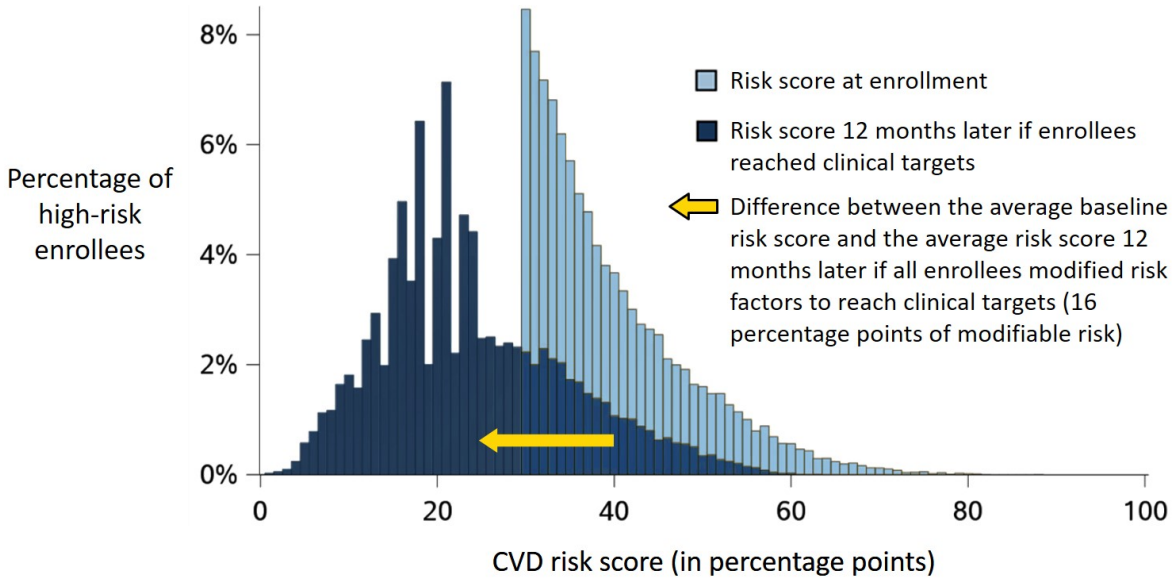
Model participation. At the beginning of the third Million Hearts Model year, 321 (62 percent) of the 516 randomized organizations remained in the model (152 in intervention and 169 in control), after CMS terminated some organizations for not meeting model requirements, and other organizations withdrew because of changes in priorities, challenges uploading required data elements, and financial incentives they did not view as commensurate with the work required.

The intervention organizations enrolled about 210,000 beneficiaries from January 1, 2017, through June 30, 2018, with new enrollment tapering off in the first half of 2018. This tapering was expected, given that the model specifies that organizations should enroll everyone eligible at first contact after the model launch—so new enrollees would be limited to new patients, those who visit the organization rarely, or beneficiaries with visits who were missed in the earlier periods. The control organizations enrolled about 115,000 beneficiaries through December 31, 2017. (More current data for the control group are not yet available, as control organizations are required to submit data only once per year, compared to every six months for the intervention organizations). In both the intervention and control groups, 18 percent of all enrollees in 2017 were high risk, 40 percent were medium risk, and 42 percent were low risk.

Baseline cardiovascular risk. Addressing modifiable risk factors through the ABCS of CVD risk management could reduce almost 40 percent of high-risk enrollees' estimated CVD risk at baseline. Most of this risk reduction could be achieved through lowering blood pressure—for example, by initiating or intensifying anti-hypertensive medications. The other risk factors contribute to modifiable risk in this order: elevated cholesterol, smoking, and not taking aspirin routinely. Stopping smoking reduces CVD risk substantially among those who smoke, but its potential contribution to population-wide CVD risk reduction is limited because only 12 percent of high-risk enrollees smoke. If all high-risk enrollees improved their CVD risk factors to evidence-based clinical targets, intervention organizations would see an almost 16 percentage

point average decrease in CVD risk scores one year after enrollment, from a mean of 40 to just under 25 (Figure ES.1) and 72 percent of the high-risk enrollees would no longer have a risk score greater than 30 percent (the threshold for high-risk enrollment).

Figure ES.1. Distribution of baseline CVD risk scores among 2017 high-risk enrollees in the intervention group and the distribution that would occur 12 months later if these enrollees reached evidence-based clinical targets



Source: Mathematica analysis of demographic and clinical data submitted to CMS through the Million Hearts Data Registry.

Note: The population includes 32,681 high-risk enrollees in the intervention group.

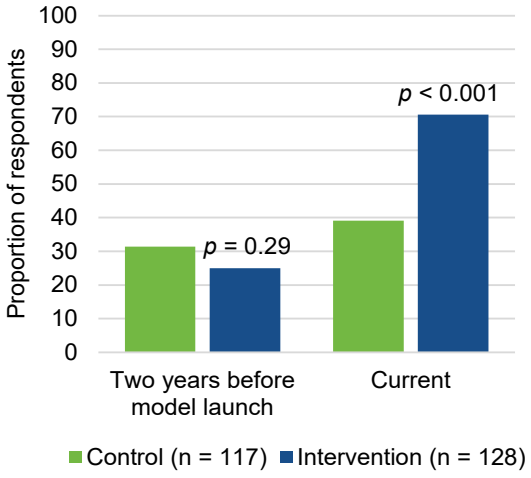
Model implementation in Year 3. Based on interviews with 14 participating organizations in spring 2019, organizations have continued to improve CVD care processes to implement the model:

- **Organizations shifted their emphasis** from enrolling beneficiaries in the first 18 months of the model to recalculating high-risk enrollees' risk scores during in-person anniversary visits and following up with patients biannually. The overall level of effort to implement the model remained consistent with previous years.
- More than half of the organizations participating in interviews **offered additional resources to help patients address their CVD risk factors**, either by making better use of existing resources or by procuring new ones.
- Respondents continued to report that **risk scores are a valuable tool** for engaging patients in lowering risk by taking medications or making lifestyle changes.

Leading indicators—Model impacts on CVD care processes. Data from a survey we administered to providers in fall 2018 and from Medicare Part D claims suggest that the Million Hearts Model has improved CVD care along the dimensions CMS envisioned:

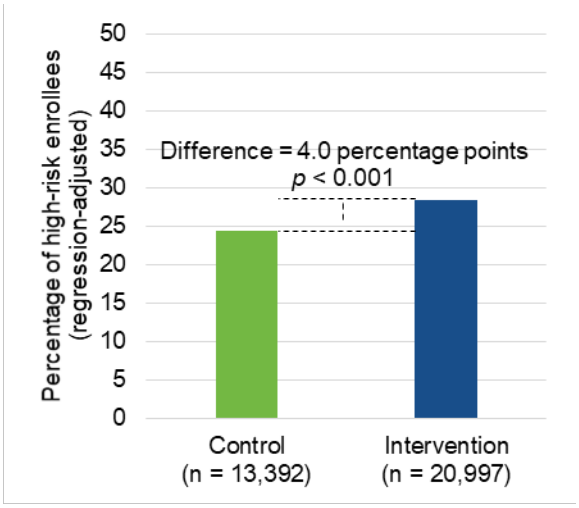
- **Intervention organizations appear to have substantially improved the delivery of CVD preventive care** in ways CMS envisioned. Relative to the control group, the model substantially increased the share of providers who reported they risk stratify at least half of their Medicare beneficiaries (71 percent in the intervention group versus 40 percent in the control group ($p < 0.001$) (Figure ES.2). Almost three-quarters of the intervention group providers said that risk stratification helped them identify beneficiaries at risk of CVD events and reported that the Million Hearts model prompted them to more systematically apply the current standard of CVD care to their Medicare beneficiaries.
- **Intervention organizations modestly increased the initiation or intensification of CVD-related medications.** Among the high-risk enrollees with Part D coverage, 90 percent had blood pressure or cholesterol levels above clinical targets and so met criteria for initiating or intensifying statins or antihypertensives. Among this group, the probability of initiating or intensifying statins or antihypertensives was 4 percentage points higher in the intervention than the control group (28 versus 24 percent, $p < 0.001$) (Figure ES.3).

Figure ES.2. Proportion of providers reporting they calculate CVD risk scores for at least half of their Medicare beneficiaries



Source: Mathematica's analysis of a provider survey administered in 2018.

Figure ES.3. Proportion of eligible high-risk enrollees with CVD medications initiated or intensified within 6 months of enrollment

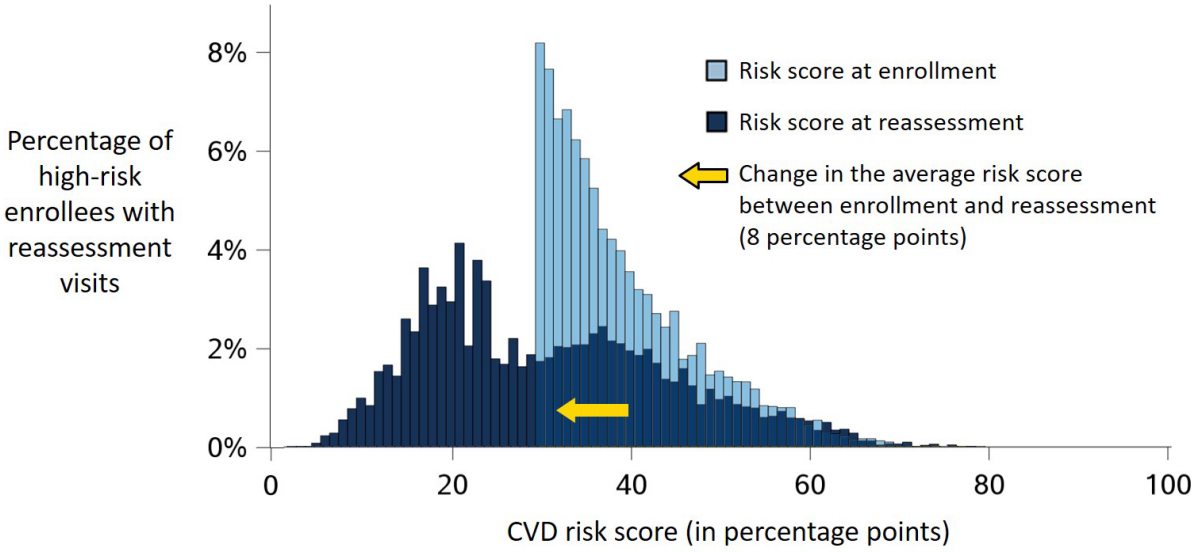


Source: Mathematica's analysis of Medicare Part D claims.
Note: CVD medications include statins and anti-hypertensive medications.

- **Among the half of high-risk enrollees with follow-up clinical data, CVD risk scores decreased by an average of 8 percentage points one year after enrollment** (Figure

ES.4). This represents a 20 percent average reduction in CVD risk scores from baseline levels (from 40 to 32 percent one year later). Improvements in blood pressure primarily drove the decrease in CVD risk scores, followed by greater aspirin use, improvements in cholesterol management, and to a much lesser extent smoking cessation. We cannot consider these reductions model impacts, because we currently lack follow-up clinical data from the control group, so we cannot know whether similar improvements would have occurred without the intervention. Nonetheless, these reductions are encouraging and provide early evidence of possible mechanisms through which the model *could* affect CVD risk scores.

Figure ES.4. Distribution of CVD risk scores at enrollment and reassessment visits about one year later



Source: Mathematica analysis of demographic and clinical data submitted to CMS through the Million Hearts Data Registry.

Note: The population includes 7,862 high-risk enrollees with a reassessment visit in the intervention group.

Early estimates of model impacts on heart attacks, strokes, survival, and spending. Using claims data with an average of 17 months of follow-up after beneficiaries enrolled in the model, we estimated the following model impacts:

- **The model did not measurably reduce the first-time incidence of heart attack, stroke, or transient ischemic attack (TIA)**. Beneficiaries in the intervention and control groups had very similar probabilities of having a heart attack, stroke, or TIA throughout the study period. For the medium and high-risk group combined, the ratio of the risk of a first-time CVD event between the intervention and control groups was 1.00 (p=0.90), with a 90 percent confidence interval of 0.93 to 1.06.

- **The model appears to have reduced the likelihood of dying among medium- and high-risk beneficiaries by about 7 percent**. The likelihood of dying was 7 percent lower in the intervention group than the control group throughout the study period (hazard ratio of 0.93, *p*=0.03, 90 percent confidence interval [CI]: [0.87, 0.98]). Although these early estimates are encouraging, they are surprising given the lack of measured effects on heart attacks and strokes, and it will be essential to assess whether the apparent mortality benefits persist over a longer time.
- **The model did not measurably reduce Part A and B spending and therefore did not generate savings to offset the roughly $5.6 million in model payments**. Among medium- and high-risk enrollees, the mean monthly Part A and B spending was similar between the intervention group ($863) and control group ($850) enrollees (*p*=0.44). Because the model did not measurably reduce Part A and B spending, there were no savings to offset the roughly $5.6 million in payments CMS made to the intervention organizations in the first 18 months of the intervention.
- **The model might have increased CVD hospitalizations among high-risk enrollees and increased Emergency Department (ED) visits among medium and high-risk enrollees combined.** Specifically, among high-risk enrollees, the CVD hospitalization rate was 13 percent higher in the intervention group than the control group (18 versus 16 hospitalizations per 1,000 beneficiaries per quarter, *p*=0.004). Among medium and high-risk enrollees combined, the outpatient ED visit rate[2] was 7 percent higher in the intervention than the control group (102 versus 95 visits per 1,000 beneficiaries per quarter, *p*=0.003). However, we did not find similar differences for CVD hospitalizations or ED visits in a key robustness check that defines the study population through claims-based attribution. This robustness check aims to limit potential for bias stemming from differences in the types of beneficiaries intervention versus control organizations enroll among their eligible patients. Because the findings differ, it is unclear whether the model truly increased CVD hospitalizations or outpatient ED visits.

Next steps. In the upcoming year, the evaluation team will conduct interviews with organizations that continue to participate, following organizations we interviewed earlier if they remain in the model. These interviews will focus on changes in overall implementation experience, in facilitators of and barriers to continued implementation, and to any changes in perceived impacts of the model on CVD for participating beneficiaries (including risk factors and sustainability of patients' adherence to statin or antihypertensive therapy and lifestyle changes). We will also extend the follow-up period for all study outcomes in the impact evaluation by a year, and will add select new outcomes measures (such as specific types of ED visits). We will assess the quality of the control group clinical data and, if sufficient, estimate impacts on CVD risk scores and their clinical components. Finally, we will continue to conduct robustness checks

[2] The outpatient ED visit rate includes stays in an observation unit that do not end in an inpatient admission.

for the main impact estimations, including using the attribution study population. We will assess whether any discrepancies in results persist and, if so, their likely sources and implications for drawing conclusions about model impacts.

Overall, the findings to date indicate that model has had positive impacts on CVD care processes along the lines CMS envisioned. Future implementation analyses will assess how model implementation continues to unfold, and future impact estimates will assess whether improvements in care processes ultimately reduce heart attacks, strokes, TIAs, and Medicare spending.

I. INTRODUCTION

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

Over the past 40 years, many risk factors for cardiovascular disease (CVD) have steadily improved in the United States, including reductions in blood pressure and cholesterol levels (Benjamin et al. 2019). However, progress on some risk factors has slowed recently (Wright et al. 2018). Further, national declines in deaths due to heart attacks, stroke, and other CVD events show signs of plateauing and have even reversed among certain groups (Mensah et al. 2017; Vaughan et al. 2017). The primary risk factors for CVD—high blood pressure, high cholesterol, smoking, type 2 diabetes, and obesity—can be treated effectively and inexpensively, though they might require behavioral changes that are difficult to make or sustain. If these risk factors were well controlled through behavioral modification or clinical treatment, the Centers for Disease Control and Prevention (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). With CVD costs resulting in an estimated $450 billion in health care spending and lost productivity each year (CDC 2012), reducing the number of heart attacks and strokes could result in significant financial savings.

In January 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts® Cardiovascular Disease Risk Reduction Model (the Million Hearts Model), designed to reduce heart attacks and strokes among Medicare fee-for-service (FFS) beneficiaries. The Million Hearts Model encourages innovation by offering organizations tools, 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 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 and patients' outcomes while reducing Medicare spending enough to offset the model payments, then CMS could expand the model to Medicare FFS beneficiaries more broadly. The model might also pave the way for other value-based payment approaches to prevent other chronic illnesses (Sanghavi and Conway 2015).

To test this core question, CMS is conducting a rigorous five-year randomized trial of 516 organizations across the country, with half assigned to the intervention group and half to a control group that receives usual care.[3] These organizations include primary care practices, specialty practices, hospitals, and federally qualified health centers (FQHCs), in both urban and rural locations. CMS expects intervention organizations to risk stratify all eligible Medicare FFS

[3] For more information about the Million Hearts Model, visit https://innovation.cms.gov/initiatives/Million-Hearts-CVDRRM/

beneficiaries,[4] provide cardiovascular care management to beneficiaries at high risk of a heart attack or stroke in the next 10 years, collect and report clinical data to CMS via the Million Hearts Data Registry, and participate in learning system activities. High risk is defined as a score of 30 percent or higher as calculated by the Million Hearts Longitudinal CVD Risk Assessment tool, based on the 2013 American College of Cardiology/American Heart Association (ACC/AHA) calculator (Goff et al. 2013).

CMS's trial of the Million Hearts Model comes 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 Model is one part) in 2012, 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 2017, HHS launched a second phase of the initiative, called Million Hearts 2022 (Wall et al. 2018), with a particular focus on decreasing sodium intake, increasing physical activity, and improving outcomes for populations with high rates of CVD events (especially African Americans and Hispanics ages 35 to 64).
- The AHA/ACC released new blood pressure guidelines in 2018 that lowered target blood pressures for many Americans, reflecting recent evidence that lowering blood pressure beyond previous targets can further reduce CVD events (Whelton et al. 2018). Further, both the new blood pressure and new cholesterol guidelines (Grundy et al. 2018) emphasize using CVD risk scores—which is a key component of the Million Hearts Model—to guide clinical decisions about when to initiate certain medications to reduce CVD risk.
- CMS and private payers encourage greater adoption of the ABCS within clinical care through quality measurement and value-based purchasing programs. For example, the National Quality Forum-endorsed measure, "Controlling High Blood Pressure" (NQF 0018), is a high-priority measure in the CMS Merit-based Incentive Payments System (MIPS). Further, the ABCS measures are mandatory for large group reporting via the MIPS web interface (Wright et al. 2018). Accountable care organizations and many commercial payers also use these measures in value-based arrangements.
- Finally, CMS has launched many other payment and delivery reform initiatives, such as the Medicare Shared Savings Program (MSSP), Comprehensive Primary Care Plus (CPC+), and Chronic Care Management (CCM) fees, to encourage better clinical care at lower costs.

The intervention organizations participating in the Million Hearts Model may also participate in these other initiatives. New supports, such as care management support provided through CPC+, could combine with the more modest Million Hearts Model incentives to spur improvements in care that neither would achieve alone. However, new initiatives might also offer the control

[4] Medicare beneficiaries are eligible if they are ages 40 to 79, have not had a heart attack or stroke, and they meet other inclusion criteria, such as being enrolled in Medicare Parts A and B, not having end-stage renal disease, and not receiving hospice benefits.

organizations new opportunities to improve their care, reducing the marginal impact of the Million Hearts Model incentives and supports relative to usual care.

B. Logic of how the Million Hearts Model is expected to improve outcomes

Figure I.B.1 illustrates the logic of how CMS expects the Million Hearts Model to achieve its intended outcomes. We have used this model to structure our data collection and analysis for the evaluation.

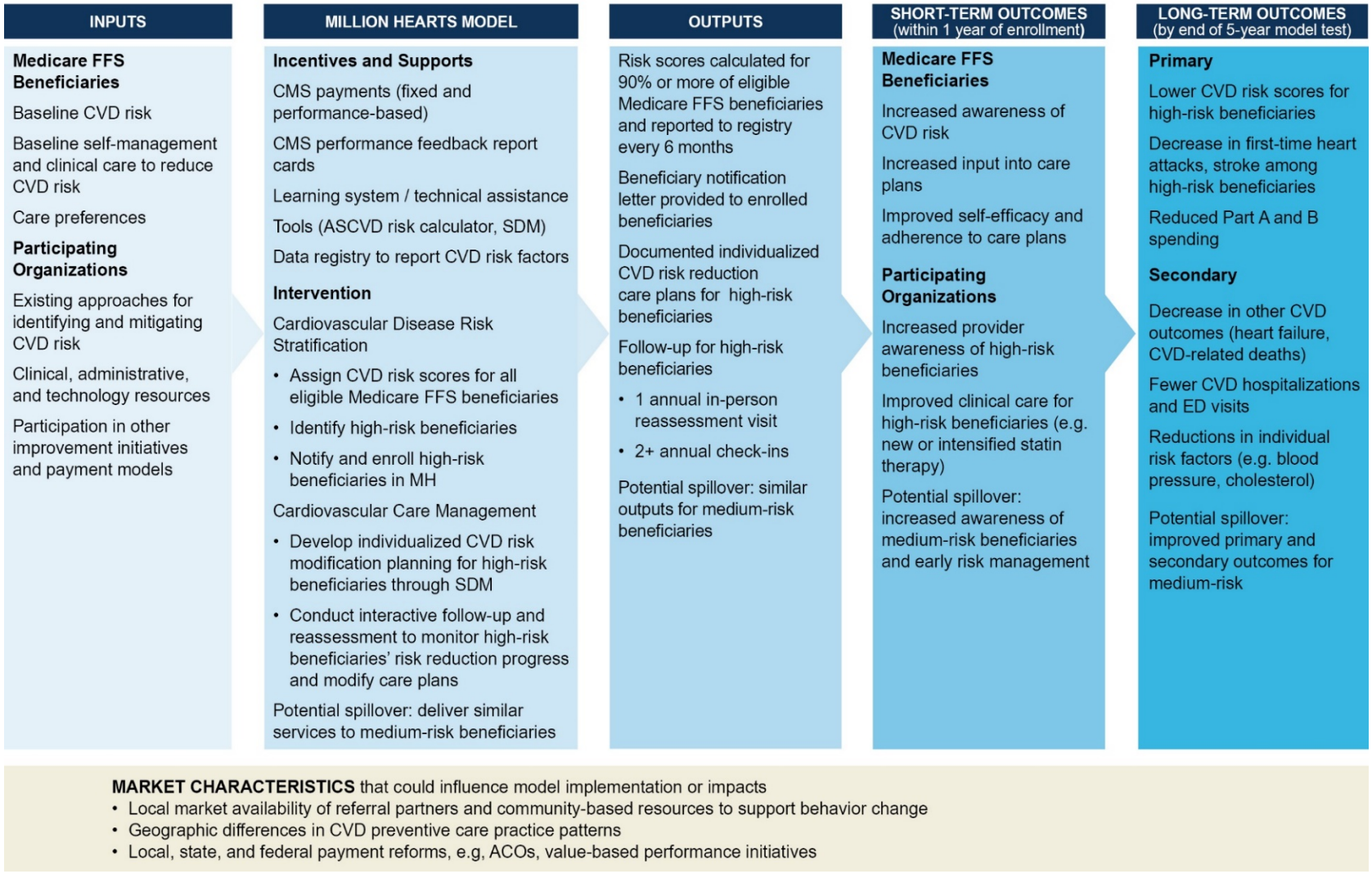
- **Inputs.** The inputs to the model include (1) intervention organizations' baseline approaches to identifying and mitigating CVD risks among their patients; and (2) Medicare beneficiaries' baseline CVD risk factors, self-care and clinical care (from all providers, not just the organization that enrolled them into the model), and care preferences.
- **Incentives and supports.** These incentives and supports CMS provides to intervention organizations to implement the model include (1) payments for risk stratifying all eligible 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.
- **Changes in CVD care processes to deliver the intervention.** The incentives and supports should prompt the intervention organizations to deliver the core elements of the model: 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 (such as phone calls) to assess and encourage progress on CVD risk reduction plans and to adjust those plans as needed.
- **Short-term outcomes.** The changes in CVD care are expected to lead to short-term outcomes (within weeks or months of beneficiaries enrolling), including improvement in (1) Medicare beneficiaries' awareness of their CVD risk factors and 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.
- **Long-term outcomes.** 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 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. Furthermore, the logic model recognizes CMS's expectation that organizations will vary significantly in how they approach the intervention, such as in how they structure their care teams. Some organizations, moreover, could have already risk stratified most of their patients or provided ongoing care management services at the start of the model testing period, whereas others might not have done so. The logic model will help us to identify such differences, as they could mean that some organizations appear more or less successful than others in reducing aggregate CVD risk for their high-risk beneficiaries given where they started.

CMS expects that most of the benefits will be for high-risk beneficiaries; however, there could also be positive spillover benefits to medium-risk beneficiaries if the act of risk stratifying all Medicare beneficiaries alone makes providers newly aware of important, modifiable CVD risk across their Medicare FFS panels, 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 low-density lipoprotein cholesterol exceeds 70 mg/dL; Grundy et al. 2018), 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 care management fees. Further, to the extent that participating organizations develop new processes to manage CVD risk for high-risk patients, such as offering group smoking cessation classes, the organizations might offer the same services for medium-risk beneficiaries as well.

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



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.

C. Evaluation objectives and focus of this report

1. Evaluation objectives

The overall goal of the evaluation is to assess whether, and through what mechanisms, the Million Hearts Model improves CVD care, reduces heart attacks and strokes, and lowers or maintains Medicare spending (including program costs) among Medicare FFS beneficiaries. CMS could 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. **Implementing the model.** The evaluation will describe how participating organizations change their care delivery to implement the core components of the Million Hearts 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 (participating organizations and beneficiaries) engage with the model, how readily organizations can incorporate its 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 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). Because the model could have positive spillover effects for medium-risk beneficiaries, it will assess these impacts for high-risk beneficiaries alone as well as for the medium- and high-risk groups combined. The impact evaluation will also assess whether the model improves secondary outcomes, such as reducing individual CVD risk factors or reducing CVD-related hospitalizations or emergency department (ED) visits, and 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 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. It will also identify 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. Focus and organization of this report

The focus of this report is to describe how organizations have implemented the Million Hearts Model during its first 2.5 years (January 2017 to April 2019) and to present early model impacts on short-term and long-term outcomes. The evaluation team used a mixed-methods approach to

conduct these analyses, drawing from key informant phone interviews, clinical data collected through the Million Hearts Data Registry, and Medicare claims.

Chapter II describes characteristics of the organizations and beneficiaries participating in the Million Hearts Model. We focus on changes in participation since the previous report, as well as new quantitative data about enrollees' baseline use of CVD-related medications and the extent to which their baseline CVD risk is modifiable. Chapter III describes the experiences of intervention organizations implementing the model in Year 3—focusing on key changes in implementation from Years 1 and 2 (the focus of the first annual report [Conwell et al. 2019]); changes in facilitators of and barriers to implementing the model; and changes in perceived impacts of the model on beneficiaries (including risk factors, adherence to statin or antihypertensive therapy, and lifestyle changes). This implementation analysis relies on telephone interviews conducted in February and March of 2019, many of which were with organizations visited last year.

In Chapter IV, we use claims and survey data to describe model impacts on (1) long-term outcomes, including first-time heart attack and stroke, spending, and mortality (Section A); and (2) short-term outcomes, including changes in CVD preventive care processes and CVD-medications (Section B). Based on prespecified hypotheses, we would expect to see changes in short-term outcomes in the period covered in this report, but not necessarily impacts on the long-term outcomes that could take up to five years to materialize. In Chapter V, we synthesize the qualitative and quantitative data collected to date to describe the mechanisms that could cause the impacts observed thus far and the prospects for future model impacts on CVD events. We also describe how the study's findings fit in the broader literature on the effects of using CVD risk scores and care management to reduce CVD events. Chapter VI briefly describes the next steps for the evaluation.

Throughout the report, we use the most current data available for the analyses. However, the specific period covered by the different analyses vary by data source.

- The implementation evaluation focuses on implementation at the time of the telephone interviews in spring 2019, almost 2.5 years into implementation—including changes made in implementation since the earlier site visits in spring 2018.
- The analysis of model participation includes data on (1) organizations that withdrew or stayed in the model through the end of 2018, and (2) the beneficiaries the participating organizations enrolled through June 2018. (These enrollment data are lagged because they are captured in the registry, which requires multiple steps to collect and validate the enrollment data.) Indeed, only intervention group data are available through June 2018; the most current control group data—because of less frequent reporting to the registry—are from December 2017.
- The analysis of model impacts on organizational-level CVD care processes relies on a provider survey administered about 22 months into model implementation.
- The analysis of model impacts on beneficiary outcomes relies on beneficiaries enrolled in 2017 with outcomes measured through October 2018, the latest claims available at the time

we analyzed the data. This means that the maximum length of beneficiary follow-up is 22 months (for someone enrolled in January 2017 and followed through October 2018). The mean follow-up length across all enrollees, given the rolling enrollment, was 17 months.

II. CHARACTERISTICS OF MILLION HEARTS MODEL PARTICIPANTS

Summary of findings

This chapter focuses on aspects of model participation that are new compared to last year's evaluation report (Conwell et al. 2019), which described participation through December 2017 in detail. In particular, we describe organizational participation through December 2018 and beneficiary enrollment through the most current data available. Among 2017 enrollees— the focus of last year's report and the impact evaluation described in Chapter IV—we describe additional baseline characteristics not covered in the previous report, including use of CVD medications and a measure of the extent to which beneficiaries' CVD risk is modifiable. Findings include:

- Of the 516 organizations originally randomized, 321 (62 percent) stayed in the model through the end of 2018. The rate of withdrawal slowed in the second half of 2018.
- The participating intervention organizations enrolled 210,433 Medicare beneficiaries during 2017 and the first half of 2018, with new enrollment tapering off in the first half of 2018. This tapering was expected because the model specifies that organizations should enroll everyone eligible at first contact—limiting new enrollees to new patients, those who visit the organization rarely, or beneficiaries with visits who were missed in the earlier periods. The control organizations enrolled 117,506 beneficiaries in 2017 (more current data not yet available).
- Enrollees had a high degree of CVD medication use at baseline. Among 2017 high-risk enrollees, 90 percent took antihypertensives and 69 percent took statins. Medium-risk beneficiaries also had fairly high rates of CVD medication use (80 percent for antihypertensives and 61 percent for statins). Consistent with a high degree of cardiovascular

Recap of previously reported findings for Model Year 1

- The **516 organizations that joined the model** included primary care and cardiology practices, health centers, and outpatient hospital departments located throughout the country.
- About **60 percent of organizations enrolled beneficiares in 2017 and remained in the model** by the end of the year. The intervention and control organizations that remained were similar in terms of location, size, and organizational type.
- About **5,000 providers participated in the model** in 2017. Most were primary care physicians, but participants included cardiologists, nurse practitioners, and physician assistants.
- The participating organizations enrolled about **300,000 Medicare beneficiaries** (about 180,000 in intervention and 120,000 in control groups). Almost one-fifth (18 percent) were high risk, 40 percent were medium risk, and 42 percent were low risk. The percentages in each risk category were nearly identical in the intervention and control groups.
- **Among high-risk enrollees, the mean estimated risk of having a CVD event in 10 years was 40 percent**. Age and other nonmodifiable risk factors drove some of this risk, but there is also important room for improvement—including reductions in blood pressure, low-density lipoprotein cholesterol, smoking cessation, and more routine use of aspirin.

Source: Conwell et al. 2019.

care at baseline, enrollees also had high baseline office visit rates, which provided opportunities to identify and address CVD risk factors.

- Even with high baseline medication use, significant room remains to improve CVD risk scores among high- and medium-risk enrollees. We estimated modifiable risk by applying the Million Hearts Longitudinal Atherosclerotic Risk Assessment Tool to determine a beneficiary's calculated risk a year later if the beneficiary reached ambitious but clinically attainable targets. Based on this calculation, we estimate that 39 percent of the risk (or 16 of 40 percentage points) was potentially modifiable for high-risk enrollees and 28 percent (or 6 of 21 percentage points) for medium-risk enrollees.
- Blood pressure reduction has the greatest potential to reduce predicted CVD risk. Bringing the 74 percent of people with systolic blood pressure of 130 mmHg or higher down to 129 mmHg alone would reduce population-level CVD risk by an estimated 13 percentage points. These reductions could occur through further intensifying blood pressure medications (for example, adding a new drug class), changing diet and exercise patterns, or both.

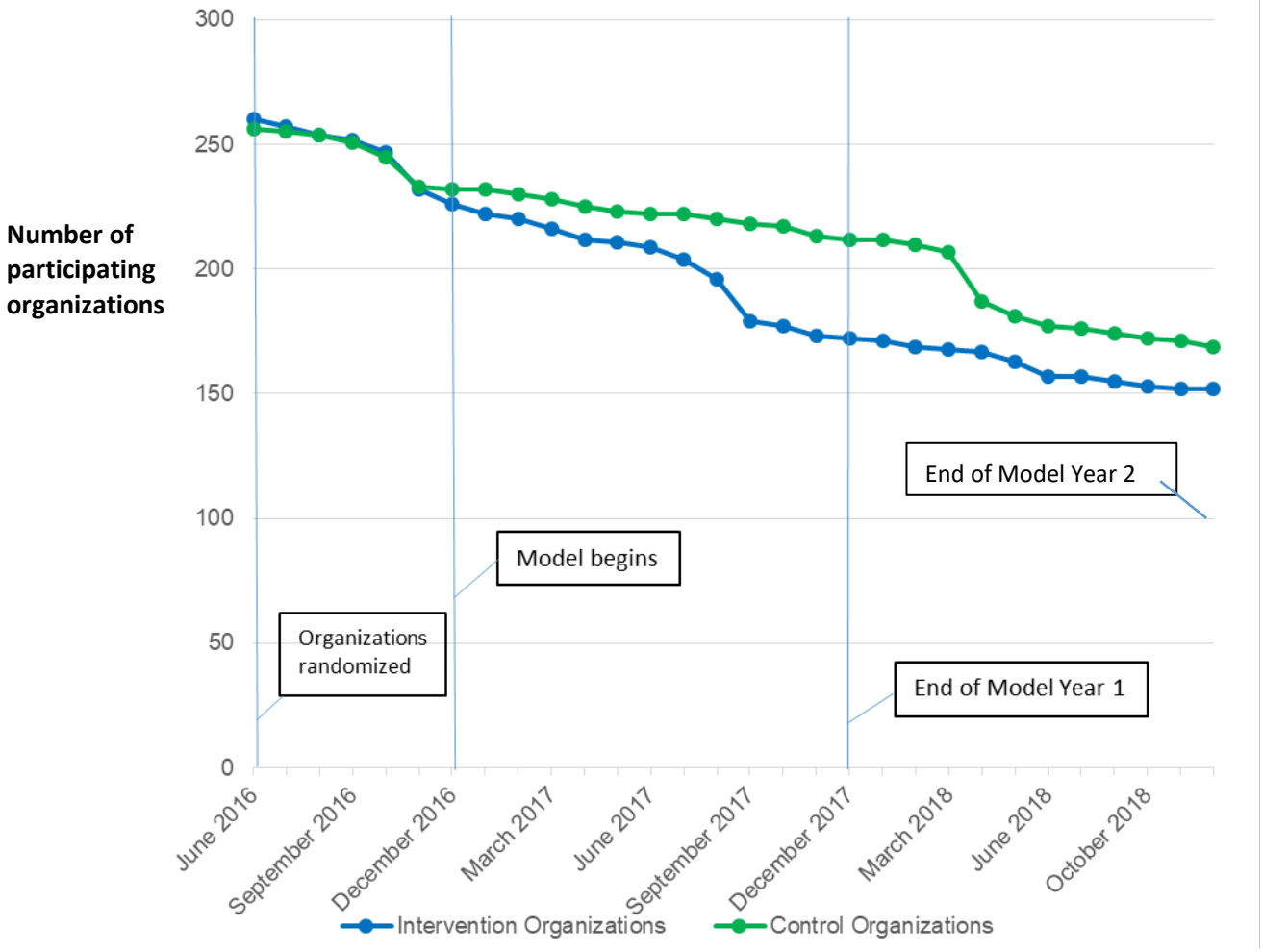
The analyses reported in this chapter rely on data from model applications, the Million Hearts Data Registry, Medicare claims including Part D data and enrollment files, CMS information on organizational participation and withdrawal, and the National Plan and Provider Enumeration System.

A. Participation by organizations in the Million Hearts Model over time

CMS originally enrolled 516 organizations into the model and, in June 2016, randomly assigned half to the intervention group and half to the usual care control group. Of these organizations, 321 (152 intervention and 169 control) remained in the model through the end of 2018, the most current data available (Figure II.A.1). Withdrawal from the model was highest in the first year and appears to have slowed in the latter half of 2018. The percentage of organizations remaining in the model through 2018 was somewhat lower for the intervention than the control group (58 and 66 percent, respectively).

Organizations that stayed in the model said they did so because they thought the model of care was right for patients and because they could fit the model's requirements into their workflow. In contrast, organizations that withdrew did so because of changes in organizational priorities, challenges uploading required data elements, and financial incentives that they did not view as commensurate with the work required (see Appendix E and Conwell et al. [2019] for more information about withdrawals). CMS also terminated some organizations for not meeting model requirements. Voluntary withdrawals and CMS terminations were particularly high shortly following the first required reporting period to the Million Hearts Data Registry (in July 2017 for intervention and January 2018 for control organizations), reflecting the challenges many organizations faced reporting to the registry.

Figure II.A.1. Number of organizations participating in the Million Hearts Model from June 2016 to December 2018, by intervention group



Source: Mathematica's analysis of CMS data on organizational participation and withdrawal.

Note: The intervention group had to report data to the Million Hearts Data Registry within six months after the model began, which explains the substantial decline in participation soon after July 2017. Control organizations did not have to report data to the registry until one year after the model began, which explains the substantial decline in participation soon after January 2018. This figure shows all organizations that had not withdrawn over time. However 71 of the 384 organizations identified as still participating by December 31, 2017 did not enroll any medium- or high-risk beneficiaries in 2017, so the impact results shown in Chapter IV do not include them.

B. Medicare beneficiaries enrolled in the Million Hearts Model over time

Participating organizations rapidly enrolled beneficiaries into the Million Hearts model in the first six months of 2017, with new enrollment tapering off over time. The intervention organizations enrolled 137,302 beneficiaries in the first half of 2017, another 45,742 in the second half of 2017, and another 27,389 in the first half of 2018 (see Appendix Figure A.1 for details). This tapering of enrollment over time was expected, because the model specifies that

organizations should enroll everyone eligible at first contact. New enrollees are limited to new patients, new Medicare beneficiaries, those who visit the organization rarely, or beneficiaries who visited the organization previously but were not enrolled in the Million Hearts Data Registry.

During calendar year 2017, when control group data are available, intervention organizations enrolled a total of 183,044 beneficiaries and control organizations enrolled 117,506 beneficiaries (Table II.B.1). Enrollment was lower in the control group than the intervention group because CMS instituted a cap of 20 providers that can enroll beneficiaries in control organizations, whereas intervention organizations can enroll beneficiaries for as many of their providers as they choose. High-risk[5] enrollees, who are the primary target population for the Million Hearts Model, made up 18 percent of enrollees in both intervention and control organizations. Medium-risk enrollees, for whom CMS expects the model to have positive spillover effects, make up 40 percent of enrollees. Beneficiaries newly enrolled in intervention organizations in the first half of 2018 tended to be modestly lower risk than enrollees in 2017 (46 versus 42 percent low risk in previous performance periods). This population could include a combination of younger individuals who aged into the Medicare population in 2018 and lower-risk beneficiaries who infrequently seek care.

Table II.B.1. Number of Medicare beneficiaries enrolled by intervention and control organizations from January 2017 to June 2018, overall and by CVD risk level

	Enrollment in 2017		Enrollment in first half of 2018, Intervention group
	Intervention group	Control group	
Number of enrolling organizations	170	158	136
Number of enrollees	183,044	117,506	27,389
Low risk	77,237 (42%)	49,700 (42%)	12,569 (46%)
Medium risk	72,502 (40%)	46,559 (40%)	10,534 (38%)
High risk	33,305 (18%)	21,247 (18%)	4,286 (16%)

Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Note: 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 Model. Control group enrollment after 2017 is not yet available.

This report's evaluation of the model impacts (Chapter IV) focuses on medium- and high-risk beneficiaries enrolled in calendar year 2017 in organizations that remained in the model through the end of 2017 (Model Year 1). The model impacts study population includes 104,214 medium- and high-risk beneficiaries enrolled by 161 intervention organizations and 66,948 beneficiaries

[5] We calculated baseline CVD risk scores using the 2013 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). 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.

enrolled by 152 control organizations. To be consistent with the impact evaluation, the remainder of this chapter describes newly constructed baseline characteristics for beneficiaries the 161 intervention organizations enrolled in 2017.

C. Cardiovascular care and use of CVD medications at baseline

Medium- and high-risk Medicare beneficiaries enrolled in intervention organizations in 2017 already received a significant amount of cardiovascular care at baseline, yet there is still room to reduce CVD risk. Among enrollees with a Part D plan (70 percent of all enrollees), most took medications—including blood pressure therapy, statins, or aspirin therapy—to reduce CVD risk factors at baseline (Table II.C.1). In particular, antihypertensive use was 90 percent among high-risk beneficiaries. Statin use was also common, with 69 percent of high-risk beneficiaries taking statins at baseline. Medium-risk enrollees also had high levels of medication use, with 80 percent taking antihypertensives at baseline and 61 percent taking statins. However, in spite of these high rates, many medium- and high-risk beneficiaries still had blood pressure and cholesterol levels well above clinical targets. For example, 74 percent of high-risk enrollees have systolic blood pressure levels of at least 130 mmHg, the threshold for recommending antihypertensive treatment among medium and high CVD risk individuals (Carey and Whelton 2018). In addition, 73 percent of high-risk enrollees had low-density lipoprotein (LDL) levels of at least 70 mg/dL, the threshold for discussing statin options with CVD patients at medium-and high- risk (Grundy et al. 2018).

Higher rates of statin use in the high-risk group compared to the medium- or low-risk group helps to explain one unexpected finding—that LDL cholesterol (an important predictor of risk) is *lower* in the high-risk group (mean of 93 mg/dL) than it is in the medium- (99 mg/dL) or low-risk group (104 mg/dL). The higher rate of statin use likely caused the drop in LDL levels in the high-risk group.

Among enrollees taking statins, we also examined drug intensity[6] at baseline to see if intensifying statins is a potential area of opportunity. Medium-intensity statins made up the majority of statin use, suggesting that there might be some opportunity to switch enrollees to high-intensity statins to reduce LDL levels if patients, with advice and guidance from their providers, determine that the benefits outweigh any risks.

The high medication rates suggest that medium- and high-risk enrollees already received a high level of cardiovascular care at baseline. Consistent with this, office visit rates in the year before enrollment were also high in this population, particularly office visits with Million Hearts providers (on average, high-risk enrollees had 3.3 office visits in the year before enrollment with the organization that enrolled them into the model). These high baseline visit rates provided plenty of opportunities to address patients' CVD risk factors, which helps to explain the high rates of CVD medication use at baseline.

[6] Low-intensity statins reduce LDL by approximately 30 percent or less on average, medium-intensity reduce LDL by approximately 30 to 49 percent, and high-intensity statins reduce LDL by approximately 50 percent or more (Grundy et al. 2018)

Table II.C.1. Baseline characteristics of Medicare beneficiaries enrolled by Million Hearts intervention organizations in 2017, by CVD risk level

	High risk (N = 32,831)	Medium risk (N = 71,383)	Low risk (N = 75,781)
Demographics			
Age, mean	74	71	64
% black	8	9	10
% male	65	54	25
CVD risk factors			
CVD risk score, mean (in %)	40	21	9
Diabetes, %	66	23	10
Total cholesterol, mean (in mg/dL)	169	177	186
HDL cholesterol, mean (in mg/dL)	47	52	57
LDL cholesterol, mean (in mg/dL)	93	99	104
% ≥ 70 mg/dL	73	80	85
Systolic blood pressure, mean (in mmHg)	140	131	124
% ≥ 130 mmHg	74	54	34
Current smoker, %	12	10	9
Medication use			
Aspirin use, %	51	43	29
Antihypertensive use in Part D,[a] %	90	80	60
Statin use in Part D,[a] %	69	61	49
Low intensity, %	7	6	6
Medium intensity, %	41	38	31
High intensity, %	21	17	12
Office visits in year before enrollment			
Office visits, mean (# per 1,000 beneficiaries)	9,888	8,990	9,254
Office visits with model-aligned providers, mean (# per 1,000 beneficiaries)	3,229	2,717	2,640

Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Note: 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 baseline visit date in the Million Hearts Model. The exception is cholesterol levels, which can be collected up to five years before or two months after enrollment. For all measures, means are calculated over nonmissing values.

[a] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 23,121 for high risk; N = 48,876 for medium risk; N = 50,396 for low risk).

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

D. Opportunities for reducing CVD risk

Despite high levels of cardiovascular care at baseline, we find that medium- and high-risk enrollees still have substantial room to improve CVD risk scores. To see how much an enrollee could potentially improve his or her CVD risk scores over time, we calculated what the risk scores would be a year later if the beneficiary reached ambitious but clinically attainable targets (clinical targets defined in Table II.D.1), using the Million Hearts Longitudinal Atherosclerotic CVD (ASCVD) Risk Assessment Tool (Lloyd-Jones et al. 2017) to calculate CVD risk scores. We define modifiable risk as the difference between the enrollee's baseline CVD risk score and this target score the enrollee could potentially achieve one year later. We assume that enrollees could achieve this target score through a combination of lifestyle changes and through the four ABCS of CVD risk management—aspirin therapy (when appropriate), blood pressure control, cholesterol management, and smoking cessation. Our calculation of modifiable risk takes into account that enrollees will age and aging will increase CVD risk scores, counteracting some of the reductions in risk scores enrollees could achieve by hitting clinical targets.

Table II.D.1. Clinical targets to define modifiable risk

CVD risk management strategies	Clinical target
Aspirin therapy	Initiate aspirin therapy if age is between 40 and 70 years and baseline ASCVD risk score is 10% or higher
Blood pressure control	• Target an SBP level of less than 130 mmHg • Initiate antihypertensive treatment if: 1) ASCVD risk score is less than 10% and SBP is 140 or higher, or 2) ASCVD risk score is 10% or higher and SBP is 130 or higher
Cholesterol management	Target an LDL cholesterol level of less than 70 mg/dL
Smoking cessation	All smokers quit smoking

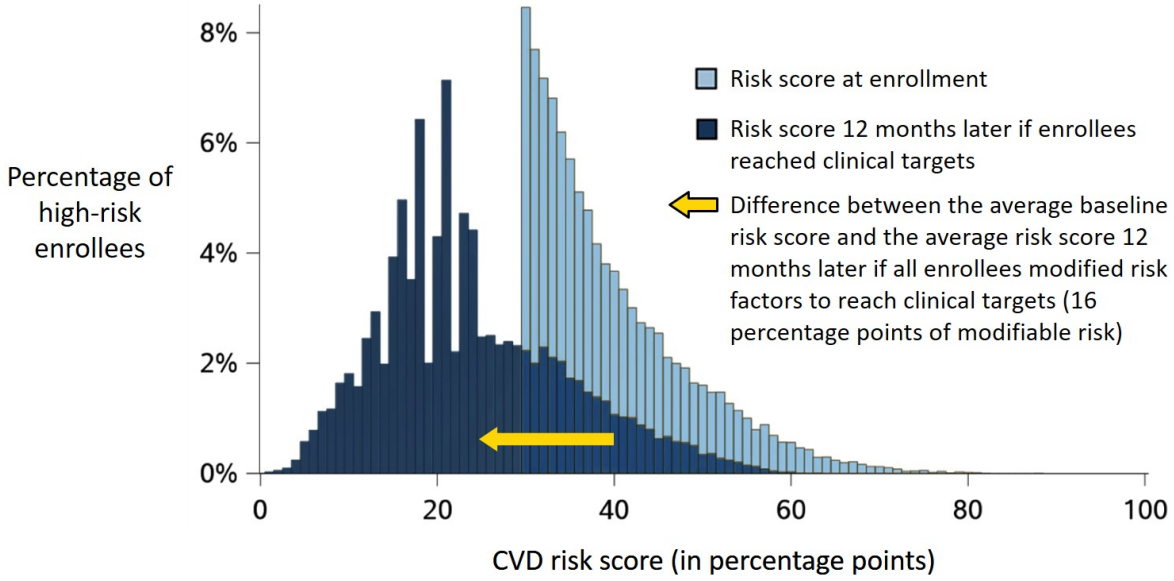
Note: Appendix C provides support from the research literature for the clinical targets we selected. We selected clinical targets only for those risk factors needed to calculate risk scores using the Million Hearts Longitudinal ASCVD Risk Assessment Tool. We assume that follow-up risk scores are calculated one year later and that enrollees age one year but all other risk factors besides those shown in Table II.D.1 remain unchanged.

ABCS = aspirin therapy in appropriate patients, blood pressure control, cholesterol management, and smoking cessation; ASCVD = atherosclerotic cardiovascular disease; CVD = cardiovascular disease; LDL = low-density lipoprotein; mg/dL = milligrams per deciliter; mmHg = millimeters of mercury; SBP = systolic blood pressure.

If all 32,831 high-risk enrollees in intervention organizations met these clinical targets through a combination of lifestyle changes and clinical treatment, we estimate that CVD risk scores in this population would decrease by an average of 16 percentage points one year after enrollment. For an average high-risk beneficiary with a CVD risk score of 40 percent, this means that an estimated 39 percent (16 percentage points divided by 40 percent) of the baseline risk score is potentially modifiable. Conversely, an estimated 61 percent of the beneficiaries' baseline risk score is nonmodifiable or difficult to modify. Figure II.D.1 illustrates how reaching these clinical targets could shift the overall CVD risk score distribution to lower average scores. After reaching

these targets, 72 percent of the high-risk enrollees would no longer have a risk score greater than 30 percent (the threshold for high-risk enrollment). The lowest risk score would be just over one percent—reflecting that for some people, especially younger women, large improvements in modifiable risk factors are projected to yield very low overall risk.

Figure II.D.1. The distribution of CVD risk scores at baseline among high-risk enrollees in 2017, and the distribution that would occur 12 months later if these enrollees reached evidence-based clinical targets



Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Notes: Figure includes 32,681 high-risk enrollees, excluding enrollees with an implausible LDL value, defined as less than 20 mg/dL (n = 150). Modifiable risk is defined as the difference between an enrollee's baseline CVD risk score and the risk score 12 months later if the enrollee reached ambitious but clinically attainable targets, with risk scores calculated using the Million Hearts Longitudinal ASCVD Risk Assessment Tool. Risk score changes 12 months later take into account aging since baseline. High CVD risk indicates enrollees with a 30 percent or higher predicted risk of having a heart attack or stroke in the next 10 years.

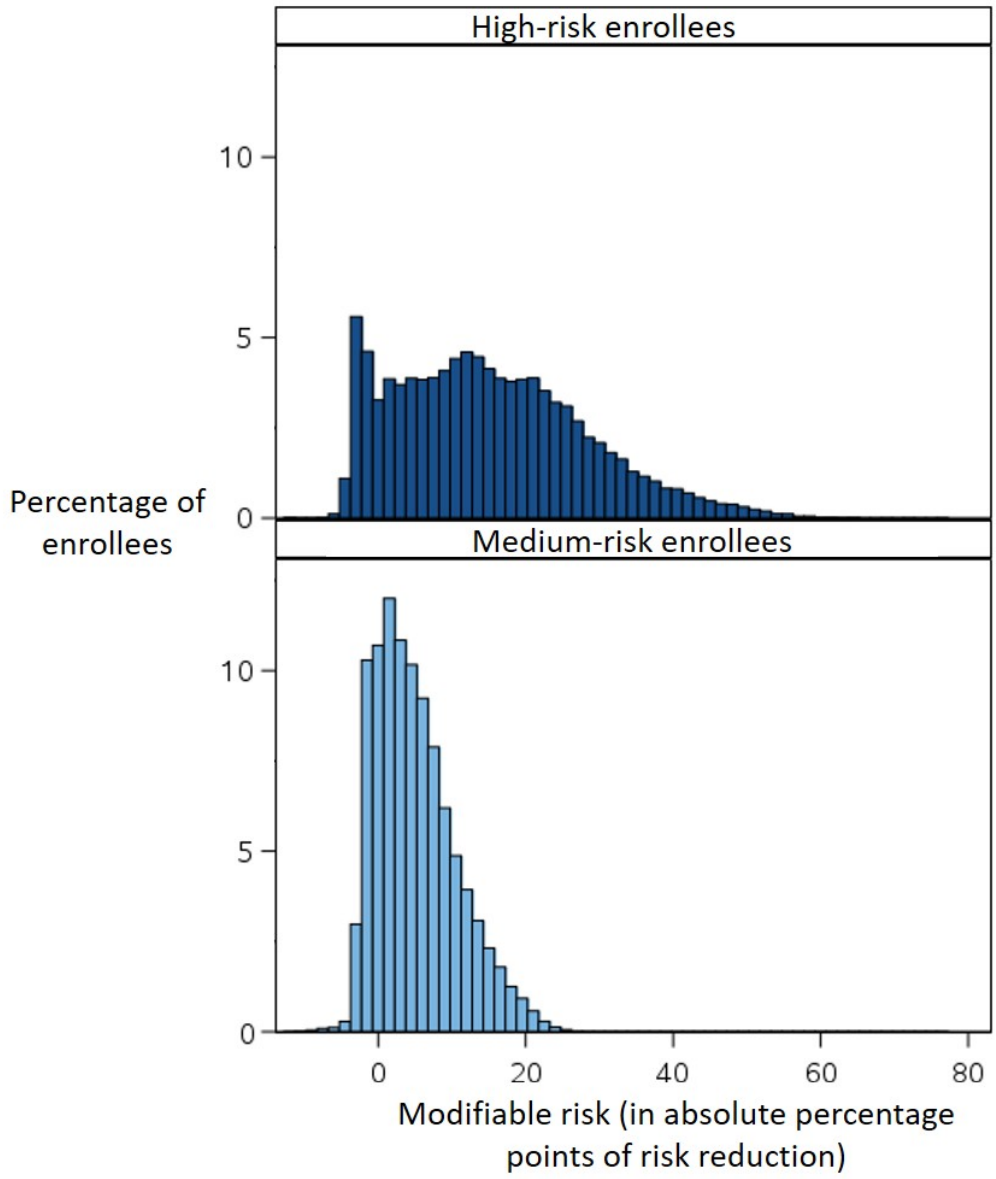
ABCS = aspirin therapy in appropriate patients, blood pressure control, cholesterol management, and smoking cessation; ASCVD = atherosclerotic cardiovascular disease; LDL = low-density lipoprotein

Figure II.D.2 compares the distribution of modifiable risk, calculated as the difference between baseline risk score and the risk score achievable 12 months later if enrollees met clinical targets, for medium- and high-risk enrollees. Medium-risk enrollees have less modifiable risk on average than high-risk enrollees but still have substantial room for improvement, with an estimated 6 percentage point average modifiable risk comprising 28 percent (6 percentage points divided by 21 percent) of their baseline risk score. Indeed, some medium-risk beneficiaries actually have higher modifiable risk than some high-risk beneficiaries. For example, about 5 percent of

medium-risk beneficiaries have modifiable risk above 16 percentage points, the average modifiable risk among high-risk beneficiaries.

The modifiable risk calculation, as described earlier, takes aging into account when calculating risk score 12 months after baseline. Because aging counteracts the reductions in risk due to hitting clinical targets, it is possible, in some rare instances, for an enrollee to have negative modifiable risk. This means that the risk score achievable 12 months after enrollment if the enrollee met clinical targets is *worse* than the baseline risk score, indicating that projected increases in risk over time due to aging surpass any reductions in risk scores due to managing risk factors. For example, a 78-year-old man with diabetes but well-controlled cholesterol and systolic blood pressure who does not smoke would be at high risk for CVD but have little room to modify his CVD risk score, leading to negative modifiable risk.

Figure II.D.2. Distribution of modifiable CVD risk among medium- and high-risk Medicare beneficiaries enrolled by Million Hearts intervention organizations in 2017



Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

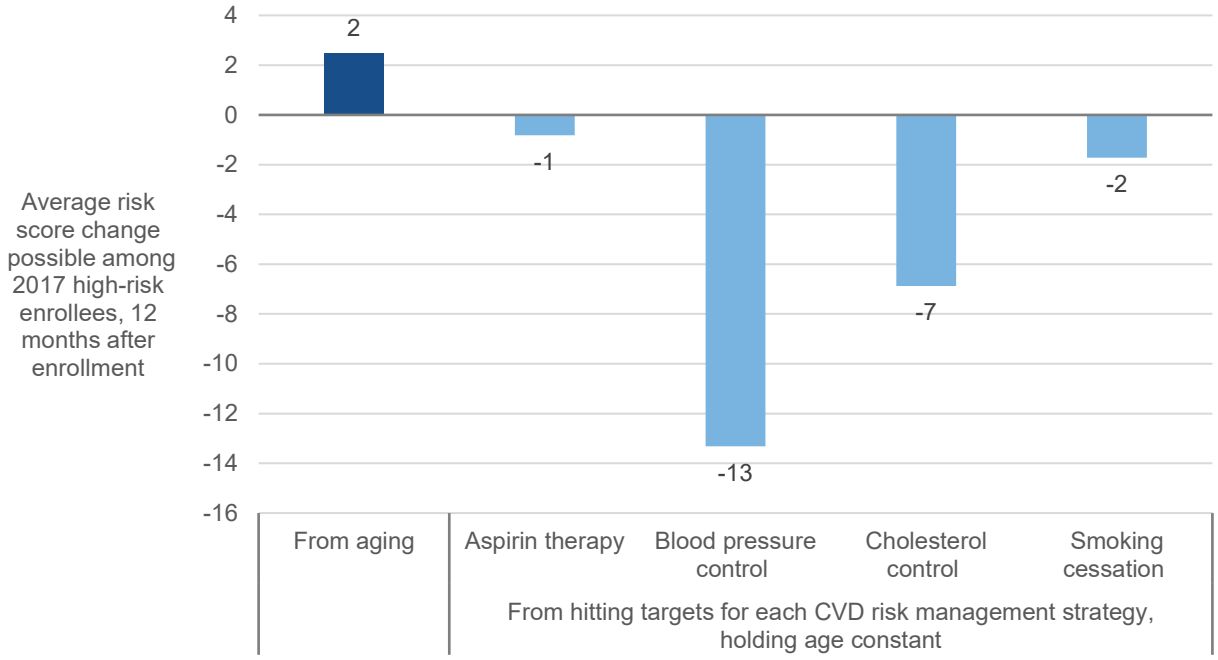
Note: Figure includes 32,681 high-risk and 71,182 medium-risk enrollees, excluding enrollees with implausible LDL values, defined as less than 20 mg/dL (n = 351). Modifiable risk is defined as the difference between an enrollee's baseline CVD risk score and the risk score 12 months later if the enrollee hit ambitious but clinically attainable targets, with risk scores calculated using the Million Hearts Longitudinal ASCVD Risk Assessment Tool. Risk score changes 12 months later take into account aging since baseline. High CVD risk indicates enrollees 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.

ABCS = aspirin therapy in appropriate patients, blood pressure control, cholesterol management, and smoking cessation; ASCVD = atherosclerotic cardiovascular disease; LDL = low-density lipoprotein.

Enrollees can use four primary CVD management strategies to modify their CVD risk scores—that is, the four ABCS of CVD risk management—aspirin therapy (when appropriate), blood pressure control, cholesterol management, and smoking cessation. To understand how much of the overall modifiable risk they could achieve through each of these strategies alone, using the Million Hearts Longitudinal ASCVD Risk Assessment Tool, we calculated the possible risk score change enrollees could achieve if they hit clinical targets for each of the CVD risk-management strategies. Figure II.D.3 shows the average CVD risk score change if all 2017 high-risk enrollees in intervention organizations hit clinical targets for each strategy, holding age constant. The figure also shows aging alone increases CVD risk scores by an average of 2 percentage points. Several findings emerged:

- **Blood pressure reduction** has the greatest potential to reduce CVD risk scores. If all high-risk enrollees with hypertension reduced systolic blood pressure to the clinical target of less than 130 mmHg, but did not change any other modifiable risk factors, it could lead to a 13 percentage point reduction in average CVD risk scores one year later, holding age constant. The large change in CVD risk scores is due to a combination of (1) the high prevalence of elevated blood pressure (74 percent with at least 130 mmHg) at enrollment and (2) the strong association between decreases in systolic blood pressure and decreases in CVD risk score using the Million Hearts Longitudinal ASCVD Risk Assessment Tool.
- **Cholesterol reduction** has the second greatest potential to reduce CVD risk scores. Elevated LDL cholesterol was common at enrollment, with 73 percent of high-risk enrollees having levels of 70 mg/dL or greater. If these enrollees reduced their LDL levels to the clinical target of less than 70 mg/dL, this alone could lead to a 7 percentage point reduction in average CVD risk scores one year later. This potential reduction in risk scores due to LDL is substantial, but smaller than potential reductions due to modifying systolic blood pressure (7 versus 13 percentage points). That is because, per unit of decrease, changes in systolic blood pressure result in much greater predicted ASCVD risk reductions than do changes in LDL cholesterol.
- **Smoking cessation** is important for smokers, but has a relatively small potential to affect average CVD risk scores across the entire high-risk population**.** Among smokers, quitting smoking would lead to a 14 percentage point average risk reduction. However, smokers made up only 12 percent of high-risk beneficiaries enrolled in the intervention group in 2017. When averaged across the entire population, smoking cessation would lead to an expected 2 percentage point average reduction in CVD risk scores.
- **Aspirin therapy** has a relatively small potential to reduce risk scores. Recent clinical guidelines do not recommend routine aspirin use for patient aged 70 years or older (Arnett et al. 2019), who account for over half of the high-risk enrollee population. If all high-risk 2017 enrollees under the age of 70 began aspirin therapy, we would expect only a 1 percentage point average reduction in CVD risk scores across the entire population of high-risk beneficiaries enrolled in the intervention group in 2017.

Figure II.D.3. Possible risk score change after 12 months among 2017 high-risk enrollees: Change due to aging and from hitting targets for each of the four primary CVD risk management strategies



Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Note: Figure includes 32,681 high-risk enrollees, excluding enrollees with an implausible LDL value, defined as less than 20 mg/dL (n = 150). For each CVD risk management strategy, these bars show the average change in risk score possible 12 months later if all high-risk enrollees met clinical targets, net of the average change in risk scores due to aging one year. The sum of changes in risk scores for modifying each ABCS risk factor individually does not add up to the overall modifiable risk presented in the text because the Million Hearts Longitudinal ASCVD Risk Assessment Tool is not additive.

ABCS = aspirin therapy in appropriate patients, blood pressure control, cholesterol management, and smoking cessation; ASCVD = atherosclerotic cardiovascular disease; CVD = cardiovascular disease

Given that we saw (1) a large room for improvement in reducing blood pressure and cholesterol and (2) already high rates of CVD medications at baseline, intensifying medication could be the greatest area of opportunity to reduce risk scores. Intensification could include escalating dosages of existing medications or adding new medications. Although medication rates were already high at baseline, some beneficiaries could lower their risk scores from starting medications—particularly for statins and aspirin. Patients and providers would have to decide to either initiate or intensify medications together, weighing the likely benefits and costs. Other areas of opportunity that we did not measure in this report include adhering to medications and modifying lifestyles. Low adherence is a major problem for both statins (Colantonio et al. 2019) and antihypertensives (Tajeu et al. 2016), and can lead to better-managed risk factor levels. There is also evidence that lifestyle modification—including adopting healthy diets, increasing physical activity, reducing sodium intake, and reducing stress—can lead to substantial reductions in CVD risk (Chu et al. 2016; Eckel et al. 2014).

III. IMPLEMENTING THE MILLION HEARTS MODEL: YEAR 3

Summary of findings

At the beginning of the third year of the Million Hearts Model, the participating intervention organizations are implementing the model as intended. This conclusion is based on findings from interviews with 14 organizations in early 2019, a survey sent to all participating intervention organizations (practice survey), and data from CMS and its implementation contractor. Emerging evidence from the third year of the model (2019) included the following:[7]

- Organizations have shifted their emphasis from enrolling beneficiaries to recalculating high-risk enrollees' risk scores during in-person anniversary visits, and following up with patients biannually. The overall level of effort to implement the model at the beginning of 2019 remained consistent with previous years.
- More than half of the organizations participating in interviews reported offering additional resources to help patients address their CVD risk factors. They did so by making better use of existing resources or by procuring new ones, such as providing patients with blood pressure cuffs to encourage home monitoring.
- All 14 of the intervention organizations interviewed improved the average CVD risk score for high-risk enrollees by at least 4 percentage points and qualified for risk-reduction incentive payments. In contrast, one-third of all participating intervention

Recap of previously reported implementation findings for Model Years 1 and 2*

- Providers reported that, under the model, they have more consistently assessed their patients' 10-year CVD risk. This helps them identify medium- and high-risk beneficiaries who could benefit from interventions to reduce or stabilize CVD risk.
- Sharing risk scores with beneficiaries helped motivate them to consider lifestyle changes and medication options.
- Organizations appeared well-equipped to provide CVD preventive care and did not change or add services as a result of participating in the model. Increased attention to calculating CVD risk led providers to more often initiate or intensify medication therapy to address uncontrolled risk factors.
- One-third of organizations used an electronic health record (EHR)-based risk calculator. About half of organizations used web-based or other applications to calculate CVD risk scores. No organizations used the risk calculator in the Million Hearts data registry at the point of care.
- Most organizations integrated model tasks into existing staff workflows. However, some organizations faced resource constraints and lack of provider buy-in that made it more difficult to implement all model requirements consistently.
- Most organizations were just beginning to focus on follow-up contacts and reassessment visits.

*The first annual report (Conwell et. al. 2019), covering the first 16 months of the model's implementation, described these findings.

[7] To ensure consistency in reporting the number of organizations that apply in this chapter, we use numerals to refer to one or two organizations, *several* to refer to three organizations, *about one-third* to refer to 4 or 5 organizations, *about one-half* to refer to 6 to 8 organizations, *about two-thirds* to refer to 9 or 10 organizations, *nearly all* to refer to 11 to 13 organizations, and *all* to refer to 14 organizations interviewed.

organizations failed to lower CVD risk scores by at least 2 percentage points. Therefore, they did not qualify for risk-reduction incentive payments.

- Respondents continue to report that risk scores are a valuable tool for engaging patients in risk-management planning and interventions.
- Meeting data reporting requirements, including submitting data to the registry, led at least five of the 172 intervention organizations participating at the end of 2017 to withdraw from the model in 2018.

A. Model implementation in Year 3

The 2019 interview findings suggest that intervention organizations continued to implement the model as intended. These organizations also achieved successes in reducing risk scores. In this chapter, we describe these findings that build upon the implementation analysis described in the first annual report, which detailed intervention organizations' efforts to implement the Million Hearts Model in the first 16 months following the model's launch (January 2017 to June 2018) (Conwell et al. 2019). We base these findings on telephone interviews conducted by the evaluation team in early 2019 with respondents from 14 participating intervention organizations. We interviewed 10 of these 14 organizations in 2018 for the first annual report. Another four organizations replaced organizations that had participated in interviews in 2018 but subsequently withdrew from the model, or remained in the model but declined to respond for the current report (see Appendix B). Interview respondents included clinical and administrative leads responsible for implementing the model at each organization and frontline providers, such as physi cians, nurse practitioners, or physician assistants. Such providers deliver care to model-eligible beneficiaries but do not manage the implementation of the model. We also present data on implementing the model, including examples of barriers and facilitators from a practice survey administered to participating organizations.[8] We sent this survey to the key staff who implement the model at each of the 152 intervention organizations that had remained in the model through 2018; 139 organizations responded to the survey (response rate was 91 percent).

Model requirement

Intervention organizations must update high-risk enrollees' 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 baseline enrollment visit.

Intervention organizations have focused their efforts on recalculating risk scores and completing annual anniversary reassessment visits within a 10- to 14-month window following the baseline enrollment visit. Often these reassessments happened during regularly scheduled office visits such as annual wellness visits. Respondents reported that most beneficiaries routinely have one or more regularly scheduled office visits per year. These visits are an opportunity to recalculate

[8] Although we use the term *practice survey*, some of the participating organizations receiving the survey were hospitals, FQHCs, or rural health centers.

high-risk enrollees' risk scores without further burdening beneficiaries or staff to coordinate an additional office visit solely for reassessments.

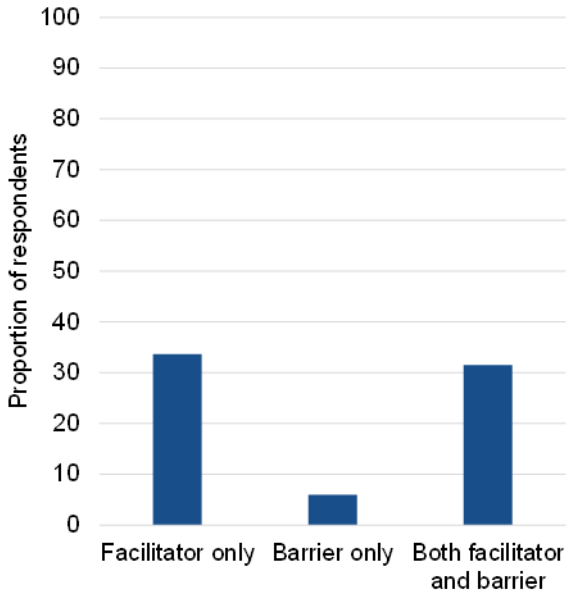
Participating organizations used various strategies to identify and monitor high-risk enrollees due for an anniversary visit. Common strategies included using patient registries maintained in a computer-based spreadsheet or running reports using data from the EHR. Several organizations had no system to track whether enrollees were due for an anniversary visit. Respondents from these organizations assumed that most high-risk enrollees met the anniversary visit requirement through regularly scheduled office visits. However, respondents also acknowledged that some enrollees were less consistent about scheduling or attending visits, and could therefore miss visits within the anniversary window.

The 14 organizations we interviewed conducted reassessment visits for 70 percent of eligible beneficiaries in the first six months of 2018 (the most recent period for which these data are available).[9] Some high-risk enrollees were lost to follow-up despite organizational efforts to engage and bring them in for anniversary office visits.

Providers and other clinical staff at nearly all organizations interviewed used risk scores to engage high-risk enrollees in treatment decisions. Risk scores helped patients understand and actively engage in health care decisions, according to respondents at two-thirds of the organizations. One care manager said that sharing and explaining the risk score helped patients conceptualize how their risk factors contributed to their overall health, making "a light bulb finally go off in their heads." Respondents also said that knowing their risk scores motivated patients to reduce their CVD risk because the patients could set quantifiable goals to reduce risk and see actual changes to their scores. Other respondents noted that understanding the risk factors that contributed to their risk scores helped patients better understand the reasons behind providers' treatment recommendations. For example, providers at several organizations reported that patients tend to be most resistant to statin therapy. Providers noted that the CVD risk score helped patients understand the need for a statin, whereas before they declined statin therapy because they did not think that their cholesterol levels were high enough to justify medication. These findings align with the results from the practice survey, in which almost two-thirds of respondents said that patients' receptivity facilitated implementing the model (Figure III.A.1).

[9] The implementation contractor provided these data based on data submitted by practices to the Million Hearts Data Registry.

Figure III.A.1. Perceptions of patients' receptivity as a facilitator of or barrier to model implementation among participating intervention organizations



Source: Mathematica's analysis of a practice survey administered in 2018 to key contacts at each intervention organization who interacted with CMS about the Million Hearts Model.

Only two organizations reported that providers did not routinely use the risk score to engage patients because they did not have time and/or did not find it helpful. They reported that the risk score was not available at the point of care and took too much time to calculate during the visit. Instead, providers at these organizations preferred to discuss CVD risk factors with patients rather than share risk scores. Some providers also felt that sharing the risk score was not helpful if the beneficiary already received the maximum therapy for modifiable risk factors.[10] Finally, one provider raised concerns that risk scores inaccurately classify beneficiaries as high or low risk, because the scores rely on blood pressure values that can fluctuate greatly due to "white coat hypertension."

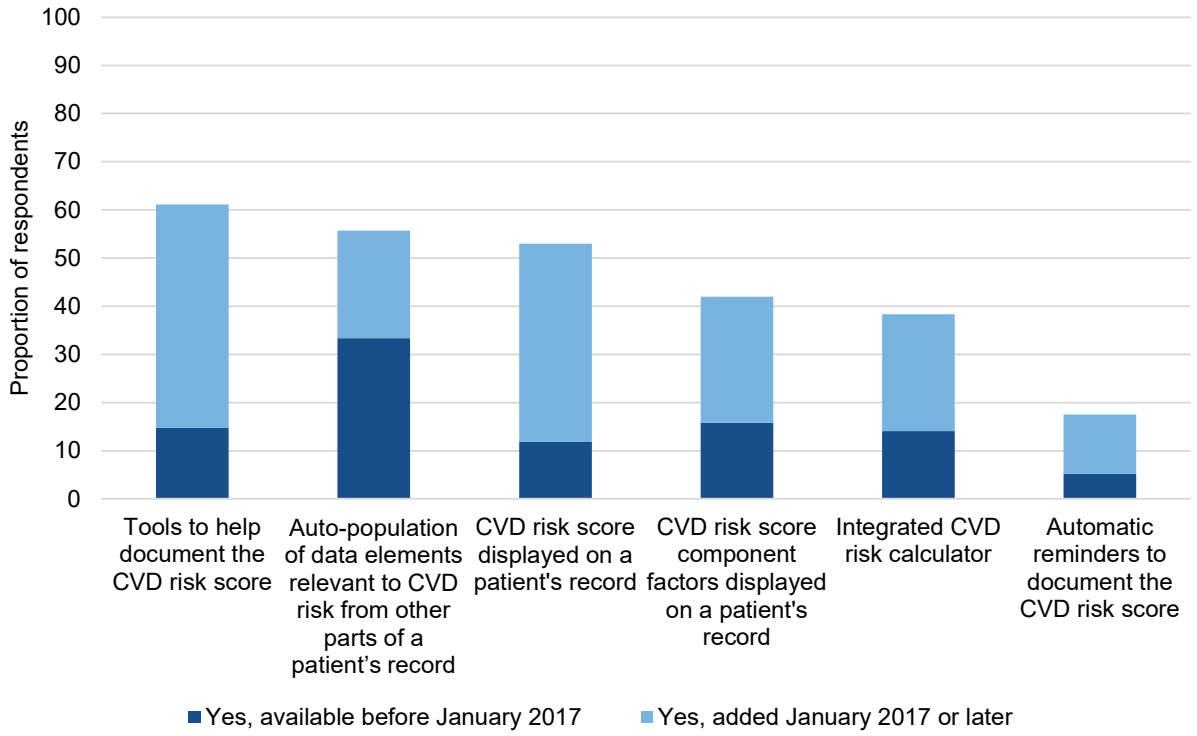
> "I don't need to tell you what white coat hypertension is. The literature is flushed with papers. I have identified a few patients that when they come here, their systolic blood pressure is super high. Not because they are hypertensive patients. But when they leave and they take their blood pressure at home, it's totally normal. My patient gets automatically a high-risk score, but then another day comes back with a blood pressure normal, [and the risk score] drops 15 points and it's just because of the blood pressure."
>
> *-Provider leader*

[10] As shown in Figure II.D.2, a sizeable share of high-risk enrollees had no or very low modifiable CVD risk.

All of the intervention organizations interviewed reduced the average risk scores of their enrollees by 4 percentage points or more (from the initial to reassessment risk score) in the first six months of 2018. Respondents most commonly attributed risk score reductions to providers becoming more aware of CVD risk within their patient panel and focusing more on CVD preventive care. Organizations tried to maintain awareness of risk scores by (1) having risk scores prominently displayed in EHRs, (2) staff giving the provider a written document with the patient's risk score before the visit, or (3) having providers calculate risk scores themselves during the visit. These reports are consistent with results from the practice survey. Those results show that practices newly implemented EHR and other health information technology (IT) tools that calculate, display, and alert providers of patients CVD risk since the launch of the model in January 2017 (Figure III.A.2).

> "[Knowing the risk score helps us] get away from the notion that your focus is on just treating a number, an LDL or a total cholesterol, and more like treating a whole patient, making decisions based on their total risk versus just not their LDL or the fact that they're a smoker or something like that."
>
> *-Frontline provider*

Figure III.A.2. Prevalence of health IT tools that support calculating and increasing awareness of risk scores among participating intervention organizations



Source: Mathematica's analysis of a practice survey administered in 2018 to key contacts at each intervention organization who interacted with CMS about the Million Hearts Model.

According to about one-half of providers we interviewed, seeing the risk score encouraged them to more aggressively and consistently address uncontrolled risk factors that contribute to high

CVD risk scores. These providers mentioned that the risk score helped them treat the whole patient instead of focusing on treating individual risk factors. Providers said they more frequently prescribed statin therapy to patients who could benefit as a result of knowing patients' risk scores. The providers also said they were more likely than they were before the launch of the model to intensify the regimen of blood pressure medications and to start aspirin among patients who could benefit.

Nearly every interviewed provider cited patients' nonadherence as the reason it is difficult to reduce some patients' risk scores. Almost 40 percent of respondents to the practice survey also identified patients' receptivity as a barrier to implementing the model (Figure III.A.1). However, about two-thirds of interviewed providers also said that sharing and explaining the risk score with patients likely reduced the frequency of nonadherence. Several providers also noted that it can be difficult to reduce risk scores for some patients because their risk is driven mainly by factors, like age and gender, which cannot be modified.

More than half of organizations reported offering additional resources to help patients address their CVD risk factors. They did so by making better use of existing resources or by procuring new ones. Existing resources included referrals to local health promotion programs, free or low-cost gym memberships, and smoking cessation programs. Patient uptake of most of these resources is unknown. The exception is smoking cessation in which respondents said at least a few patients enrolled. Organizations offered several types of new services. Some provided blood pressure cuffs to encourage home blood pressure monitoring. Others developed a new clinical pathway to promote smoking cessation. Still others started new partnerships with a local nonprofit organization that helps patients understand and manage various CVD risk factors through free classes and other resources. Intervention organizations funded these new resources and services through internal or external funding, the latter most commonly from community partnerships or grants.

Model requirement

Intervention organizations must engage high-risk Medicare FFS beneficiaries twice a year in interactive, two-way communications to assess the beneficiary's progress and update the care plan. Follow-up contacts can be conducted in person or remotely (such as via telephone, mobile device, or secure electronic patient portals.) 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.

Organizations largely re-assessed risk for high-risk patients during regularly office visits rather than scheduling separate visits for that purpose. Nearly all intervention organizations reported that they already saw high-risk enrollees every three or six months to monitor chronic conditions and review laboratory results. Respondents reported it was relatively easy to discuss a beneficiary's CVD risk during these visits. However, several providers noted that some patients had competing health demands that crowded out time available to discuss CVD risk. About half of the organizations tracked whether patients had come in for quarterly or biannual office visits and called to schedule visits for those patients who had not already done so. These tracking efforts typically existed before

implementing the Million Hearts Model and were also used for patients not enrolled in the model.

About half of the organizations followed up with patients by telephone at least twice a year to monitor adherence to CVD preventive care plans and to answer enrollees' questions. One organization sent text messages to model enrollees about CVD-relevant topics to supplement office visit contacts. Beneficiaries could respond to these texts, although the organization reported receiving only a few replies. One-third of organizations reported referring high-risk enrollees to existing care management programs that included monthly telephone calls to follow up with enrollees on their CVD risk factors and other conditions. Organizations offering these care management services to high-risk enrollees participated in other initiatives, such as CPC+ or patient-centered medical homes, for which the care management programs were developed.

Interestingly, the only cardiology practice in the 2019 sample found it challenging to follow up with patients—a challenge also shared by another cardiology practice that participated in the 2018 interviews.[11] Respondents in both organizations noted that their panels included a large number of consultative patients who return to their primary care provider for routine care. It is within the normal scope of practice for cardiologists to ask some patients to return on an annual basis. However, providers noted that it is professionally awkward to reach out to another provider's patient between visits.

Organizations focused on ensuring high-risk enrollees systematically received follow-up contacts. In our first annual report and in our 2019 interviews, respondents reported that the Million Hearts Model contributed to providers' awareness and treatment of uncontrolled CVD risk factors for medium-risk beneficiaries. This could produce spillover effects in terms of reducing risk for medium-risk beneficiaries. However, we did not see a spillover in the processes that organizations use to track high-risk enrollees. Specifically, about two-thirds of organizations had established systems to ensure a minimal follow-up frequency for high-risk beneficiaries. These same systems are not routinely applied to medium-risk beneficiaries, absent the presence of comorbid conditions that warrant such follow-up.

> "I think we will see some cumulative impact [on medium-risk patients], but I can't tell you that we've intentionally done more to focus on that next lower rung."
>
> *— Director of quality improvement*

Organizations are devoting a similar level of effort to implementing the model in 2019 as in the previous year. Respondents reported they focused less on enrolling new beneficiaries because they had successfully enrolled most eligible patients during the first model year. This is consistent with the tapering off of new enrollments we observed over time across all intervention organizations. Instead, organizational efforts focused on reassessing and following up with high-risk enrollees. About half of the organizations had minimally altered existing workflows to

[11] In the 2018 round of interviews, two organizations were staffed predominantly by cardiologists. One of these organizations subsequently dropped out, leaving one cardiology practice in our sample.

follow up with high-risk enrollees. The other half had added new workflows. An administrative or clinical support staff member identified patients due for a follow-up or reassessment based on a review of patient lists, registries, or gap reports and called them to schedule an appointment. Several medium and large organizations had hired new staff or significantly changed the responsibilities of existing staff to oversee this and other workflows related to the Million Hearts Model. In some organizations, staff were not dedicated solely to the model, but also helped implement other organizational initiatives.

The data were mixed on whether organizations were missing potentially new high-risk enrollees. Respondents from about one-third of organizations said that the reduced focus on enrollment made it more difficult to enroll new patients. This perhaps caused them to miss some newly eligible patients. In contrast, several other respondents reported that newly eligible patients often were new to the organization. This, in turn, made it easy to flag patients in need of checking for model eligibility, especially compared to the first model year when organizations checked all beneficiaries for eligibility.

B. Participants' perceptions of model supports

CMS provides intervention organizations in the Million Hearts Model with tools and supports to help implement the model requirements. Among those tools are the Million Hearts Longitudinal CVD Risk Assessment tool, data registry, payment incentives, learning systems, and performance reports. Similar to interviews conducted in 2018 for the first annual report, respondents reported mixed reactions to the tools and supports, which in general have not been as useful as CMS had hoped.

Nearly all intervention organizations use CVD risk scores to guide patient care, but they generally do not use the Million Hearts Longitudinal ASCVD Risk Assessment tool at the point of care. CMS provides intervention organizations with access to this risk assessment tool via the Million Hearts Data Registry; CMS also created a website with the baseline risk calculator. The tool, based on the ACC/AHA ASCVD Risk Estimator, calculates baseline risk and has additional functionalities for (1) simulating improvements in risk that would accompany different treatment plans and (2) calculating changes in risk over time based on changes in an individual's risk factors. Although CMS sponsored the development of these longitudinal functionalities specifically for the Million Hearts Model, the tool is now available publicly on the ACC/AHA website and as a smart phone application.[12,13] As reported in the first annual report, participating providers also use existing CVD risk calculators (for example, online or through the EHR or smart phone applications) to identify baseline risk and guide treatment plans. Of note, only the risk scores calculated within the CMS registry are acceptable for enrolling beneficiaries into the model and assessing change in risk scores.

[12] The calculator is available at http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/.

[13] More information on the Million Hearts CVD risk calculator, including the functionalities added for the Million Hearts CVD Model, is available in the first annual evaluation report at https://downloads.cms.gov/files/cmmi/mhcvdrrm-firstann-evalrpt.pdf.

None of the intervention organizations interviewed by the evaluation team used the Million Hearts Longitudinal ASCVD Risk Assessment tool at the point of care with patients, citing the burdensome process for logging into the registry.

- About one-fifth of organizations rely on other clinical or administrative staff—not the provider—to calculate the risk score using the Million Hearts Longitudinal ASCVD Risk Assessment tool after the office visit. They then send the risk score to the providers to review.
- About two-thirds of the organizations have either a CVD risk calculator integrated in the EHR, a link to a CVD risk calculator within the EHR, or their providers or clinical support staff calculate a CVD risk score using a website linked to the desktop or phone app.
- Only one organization reported using the publicly available ACC/AHA ASCVD Risk Estimator with the longitudinal functionality during the visit. Though this is the same calculator available through the Million Hearts Data Registry, the publicly available calculator does not allow providers to save patients' data. This risk estimator is likely to produce risk scores that differ from the Million Hearts Longitudinal ASCVD Risk Assessment tool if providers input baseline clinical risk factors that differ from the baseline data submitted to the Million Hearts Data Registry.
- Another organization noted that in addition to the static CVD risk calculator (that is, used to estimate baseline risk) built into the EHR, it also had a link to the longitudinal version. However, the respondent was unsure whether any providers calculated the risk score with the longitudinal version.
- One organization noted it hoped to upgrade to an EHR package that included a longitudinal CVD risk calculator, but for now it uses the static CVD risk calculator.

The Million Hearts Data Registry continues to be time-consuming to use. However, organizations reported fewer challenges than in the past as they became familiar with the system. CMS designed the Million Hearts Data Registry as a resource that organizations could use to record demographic, clinical, and encounter data for eligible beneficiaries, and to calculate and monitor CVD risk over time. At least twice a year, intervention organizations must report clinical data needed to calculate the CVD risk score for (1) new beneficiaries treated by participating providers and (2) the annual risk reassessment for existing high-risk beneficiaries.

> "Thinking back a year ago, we were ready to cave. We were ready to say I'm not sure we can continue on; it was just so burdensome. Now, it feels like that burden's lifted. We figured it out and we're moving forward...."
>
> *-Director of quality*

During the interviews conducted in 2018 for the first annual report, respondents from nearly all organizations reported frustrations with the Million Hearts Data Registry. During the 2019 interviews, respondents noted that the registry was still cumbersome and time-consuming, but they experienced fewer frustrations now than in the past for several reasons:

- They had entered most of their eligible beneficiaries into the registry during the first model year.
- Respondents had become more familiar with the registry.
- The Million Hearts Model team and its implementation contractor had improved the registry.
- The registry became better integrated into the organization's workflow.

Nevertheless, one organization noted that the burden of the registry made it wary to participate—or recommend participation to other organizations—in a future CMS model or program. Another organization interviewed in 2018 declined to participate in our interviews this year due to frustrations with the registry. Analysis by the evaluation team of data collected by CMS from organizations terminated from the model indicate that among the 20 intervention organizations that voluntarily withdrew during 2018, 5 reported a negative data entry experience (see Appendix B).[14]

> "As far as the goal of working with the patients, the risk score, the care coordination involved… it's a great program. The only reason I never want to do it again is because of the [Million Hearts data] registry."
>
> *-Million Hearts coordinator*

Intervention organizations reported continued challenges with the registry. The challenges included outages, lack of clear guidance about how to address locked records in the registry (such as those resulting from lost to follow-up status), and the labor-intensive process of reconciling beneficiaries' previous Medicare identifiers (health insurance claim [HIC] numbers) with the new Medicare beneficiary identifier (MBI).[15]

The payment incentives generally were not commensurate with the level of effort to participate, but this did not always deter organizations from continuing to participate. The Million Hearts Model payments seek to incentivize participating organizations to risk stratify eligible beneficiaries and to reduce CVD risk scores for high-risk enrollees. Intervention organizations receive $10 for each eligible beneficiary they risk stratify. Further, in the first two performance periods (January 1 to June 30, 2017, and July 1 to December 31, 2017), intervention organizations received a fixed $10 per beneficiary per month (PBPM) care management fee for each high-risk enrollee receiving care management services. Starting in the third performance period (January 1 to June 30, 2018), a risk-reduction payment scaled to the organization's performance in reducing CVD risk among its high-risk cohort has replaced the fixed care management fee. Organizations earn the full $10 PBPM if they reduce average CVD risk across

[14] In 2018, 20 intervention and 43 control organizations withdrew from the model. Of these 63 organizations, only 30 had submitted data to the Million Hearts Data Registry on at least one eligible medium- or high-risk beneficiary. As described in Chapter II, these 30 organizations remain in the analysis of impacts due to the intent-to-treat design of the evaluation.

[15] The transition from HIC numbers to MBIs was a Medicare requirement unrelated to the Million Hearts CVD Model that occurred in 2018. For more information, visit https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedicareCard-FactSheet-TextOnly-909365.pdf.

their panel by 10 percentage points or more. They receive $5 PBPM if they reduce risk by 2 to 10 percentage points, and $0 if they reduce CVD risk by less than 2 percentage points.

A total of 147 intervention organizations participated in the model through the end of the third performance period (June 30, 2018). Of those, 21 (14 percent) received the full $10 PBPM payment. Another 76 (52 percent) received the $5 PBPM payment, and 50 (34 percent) did not receive a risk-reduction payment.[16] Average payments received for the third performance period ($6,676) were less than what organizations received in the first two performance periods (Table III.B.1). Payments were lower in the third performance period because organizations did not enroll many new beneficiaries (and therefore did not receive the fixed risk stratification fee) and because few organizations earned the highest risk-reduction payment rate ($10 PBPM).

Table III.B.1. Incentives that CMS paid to intervention organizations during the first 3 performance periods (n = 147)

Performance period	Mean	Bottom quartile	Median	Top quartile
Performance period 1	$12,547	$1,350	$3,700	$9,720
Performance period 2	$15,561	$1,650	$4,580	$12,210
Performance period 3	$6,675	$140	$1,710	$5,445
Cumulative payment	$34,784	$ 4,470	$10,850	$25,975

Source: Mathematica's analysis of payment data received from the implementation contractor. The first performance period was January 1, 2017, to June 30, 2017; the second performance period was July 1, 2017, to December 31, 2017; and the third performance period was January 1, 2018, to June 30, 2018.

All 14 organizations interviewed received risk-reduction incentive payments. More than half of interview respondents responsible for administering or overseeing the model at their organization reported that the incentive payments did not cover the costs of participating in the model. One-quarter felt the payments covered that cost but the rest were unsure. Nearly all respondents assessed their cost of participation based on the staff time allocated to meeting the model requirements.

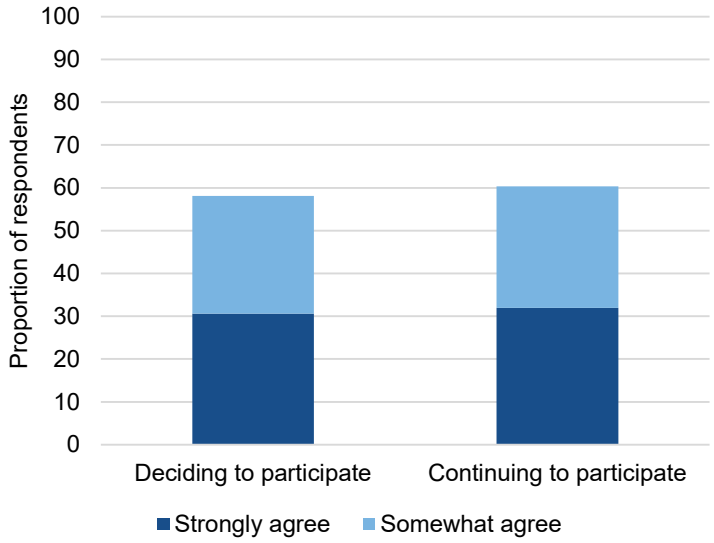
[16] The implementation contractor provided payment data. We excluded the 10 organizations that, although still participating at the end of third performance period, had not enrolled any medium- or high-risk beneficiaries in 2017. We made these exclusions to be consistent with the impact evaluation (reported in Chapter IV), which focuses on impacts for medium- and high-risk beneficiaries.

Despite their frustration with payments, respondents noted that this did not deter their participation. They noted they did not participate only for financial gain, but rather because this was the right thing to do for their patients. Two interview respondents volunteered that they did not plan to drop out of the model due to the insufficient payments. However, they claimed they would hesitate to participate in a similar model or program in the future for this reason.

> "We know our patients are appreciative of it … Our providers are appreciative of being able to see or utilize this risk scoring tool to see their patients in a different light … But … If I were to think of the actual cost it takes us to run the program versus what we receive back, it doesn't match. But it doesn't deter us from our participation…."
>
> *-Care manager*

Perceptions on the importance of financial incentives were similarly mixed in analyses of data from CMS on why organizations withdrew from the model and the practice survey. Seven of the 20 intervention organizations that withdrew from the model in 2018 reported to CMS that they did so because the level of effort was not commensurate with the incentives. Fewer than one-third of respondents (one from each organization) in the practice survey strongly agreed that the financial incentives were an important factor in either their organization's initial decision to participate in the model or to continue to participate (Figure III.B.1). We sent this survey only to organizations that remained in the model through 2018. It does not represent the views of organizations that withdrew.

Figure III.B.1. The importance of Million Hearts financial incentives for deciding to, or continuing to, participate in the model, among participating intervention organizations



Source: Mathematica's analysis of a practice survey administered in 2018 to key staff implementing the model within each organization. The number of respondents for these questions was 138.

The payments sought to incentivize providers to deliver higher-quality care to high-risk beneficiaries. But very few frontline providers—those who did not manage the implementation of the model—were aware of the payment amounts.

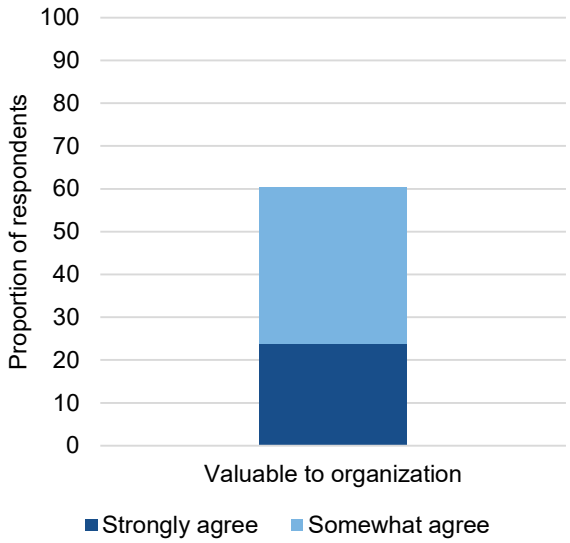
Learning system events received mixed reviews, and several respondents found the more operationally focused events to be the most useful. The Million Hearts Model learning system events aim to support intervention organizations' participation in the model. An individual from each intervention organization must attend one learning system event per quarter, either by attending a live webinar or by viewing the recording on demand. Nearly all organizations we interviewed reported that administrative or clinical support staff attended the webinars. Depending on the content, attendees might disseminate learnings to other staff. Providers typically did not attend the learning system events due to time constraints or inconvenient scheduling.

Similar to the findings reported in the first annual report, reactions to the learning system events were mixed. Respondents noted that events focused on model operations and requirements were most helpful. These included assistance with the data registry, model updates, and how to leverage EHRs to implement the model. Several respondents appreciated the peer learning opportunities and made changes to their practice based on what they learned. For example, one organization implemented a new EHR-based Million Hearts care plan and another adapted a sheet in the EHR for tracking risk scores, follow-up contacts, and any changes to the patient's plan for care.

Respondents typically found less beneficial the webinars focused on improving clinical care, such as how to change patients' behavior or better engage patients. Several respondents noted that these topics are repetitive of webinars of other models, such as CPC+ or the patient-centered medical home certification process. In addition, about one-third of respondents felt they had already implemented these best practices. However, some of these respondents also acknowledged that these topics might be useful to underperforming or resource-limited organizations. Despite mixed reactions to the learning system events, about one-half of respondents noted that they obtained some useful information. Ideas for improving learning system events included focusing on the needs of smaller, resource-constrained organizations; offering the events at more convenient times; offering multiple topics each quarter from which to choose; and having more time for questions and answers.

Results from the practice survey corroborate the mixed reactions to the learning system events. About one-quarter of respondents (24 percent) strongly agreed that the learning system events were valuable to improving CVD prevention for their organizations, and about one-third (37 percent) somewhat agreed (Figure III.B.2).

Figure III.B.2. Proportion of respondents agreeing that learning activities are valuable for improving CVD prevention among participating intervention organizations



Source: Mathematica's analysis of a practice survey administered in 2018 to key contacts at each intervention organization who interact with CMS about the Million Hearts Model. The number of respondents for these individual questions were 138 and 120, respectively.

Performance reports were not widely used, as nearly all respondents either had limited familiarity with them or did not find them useful. Twice a year, CMS sends intervention organizations performance reports. These reports include information on beneficiaries' enrollment and risk status, treatment therapies, payment history, and learning system attendance. They summarize data submitted by organizations to the Million Hearts Data Registry or maintained by the implementation contractor and are available six to eight months after the end of a performance period. Beginning with the third performance period, the reports included additional information on (1) beneficiary status (still enrolled versus lost to follow-up); (2) average change in risk scores for the organization and how it compared to the average change for all other intervention organizations; (3) changes in treatment regimen (such as aspirin use or statin therapy) from baseline; and (4) earning potential for risk-reduction payments, which show hypothetical payments if organizations achieve at least 10 percentage point aggregate risk reduction.[17]

Interview respondents designated as the intervention organization's CMS key contact for the Million Hearts Model had limited familiarity with the performance reports. Several respondents were not familiar with the performance reports, and others had vaguely recalled seeing them in the past but could not comment on them in detail. Two respondents familiar with the reports said they shared them at quality improvement meetings, but also said that for the most part they already knew the information that the reports contained. Respondents from two other

[17] Year 2, Period 1 performance reports were made available in February 2019, which was midway through primary data collection.

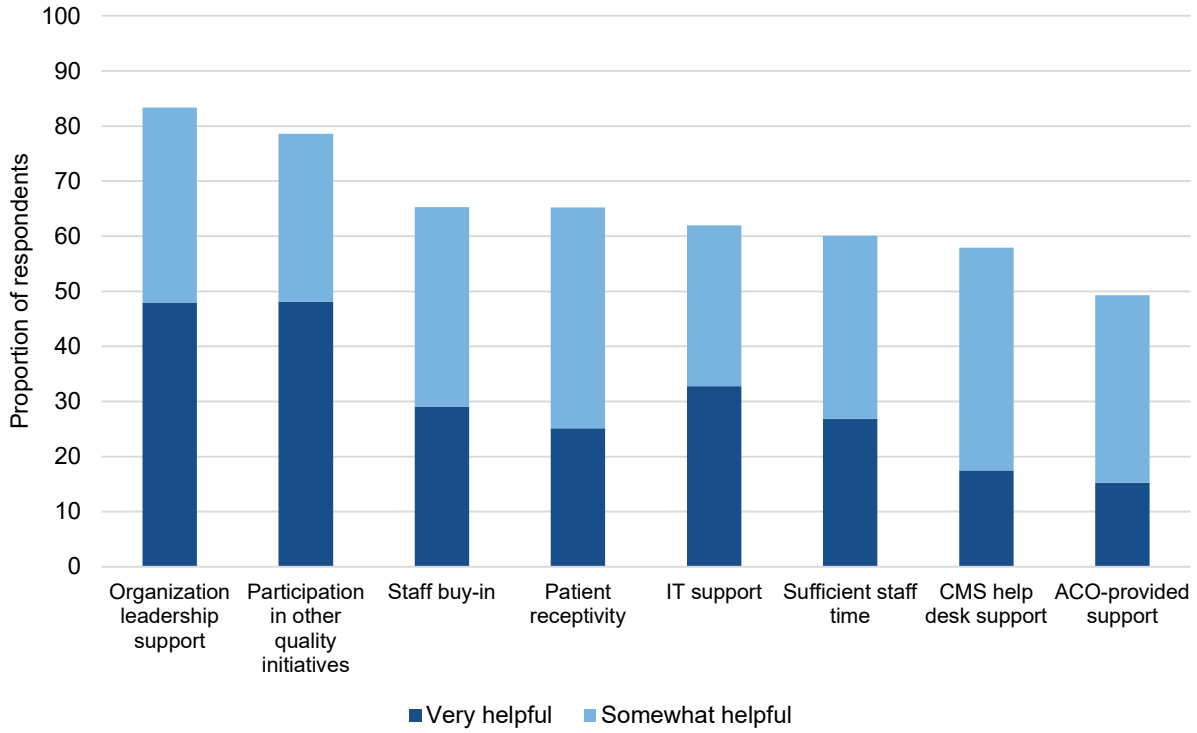
organizations expressed concerns about the accuracy of the data and the lag time for receiving the reports.

About one-third of the respondents expressed interest in receiving the performance reports more regularly and sooner after the end of the performance period. They stated that information on how their organization compared to the national cohort and having information about risk score changes stratified by beneficiaries' characteristics would be helpful. Beyond the performance reports, respondents expressed interest in receiving more feedback from CMS. In particular, they sought one-on-one feedback about whether they implemented the model correctly, whether the Million Hearts Model as a whole has been successful to date, and help identifying beneficiaries who could benefit from certain interventions based on their risk factors.

C. Barriers to, and facilitators of, implementing the Million Hearts Model

Based on interviews conducted in 2019 (early in the third year of implementing the model), a key facilitator of model implementation was to build on the processes and workflows established during the first two model years. The organizations that did this achieved greater consistency in risk stratification and heightened providers' awareness of risk scores. Respondents also mentioned organizational leadership support for the model, staff buy-in, and patient receptivity as facilitators, a finding that aligns with survey findings (Figure III.C.1). Respondents reported that available resources, aligned goals, and lessons learned from involvement with other initiatives—such as patient-centered medical homes, the MSSP, and CPC+—helped them implement the Million Hearts Model. More than half of the organizations reported participating in at least one of these initiatives. Specifically, participating in these initiatives helped staff to implement the care delivery changes required for the model. Among those changes were integrating the staff and workflows supporting these other initiatives with CVD risk score stratification and preventive care delivery.

Figure III.C.1. Perceptions of factors that have been helpful in implementing the Million Hearts Model among participating intervention organizations

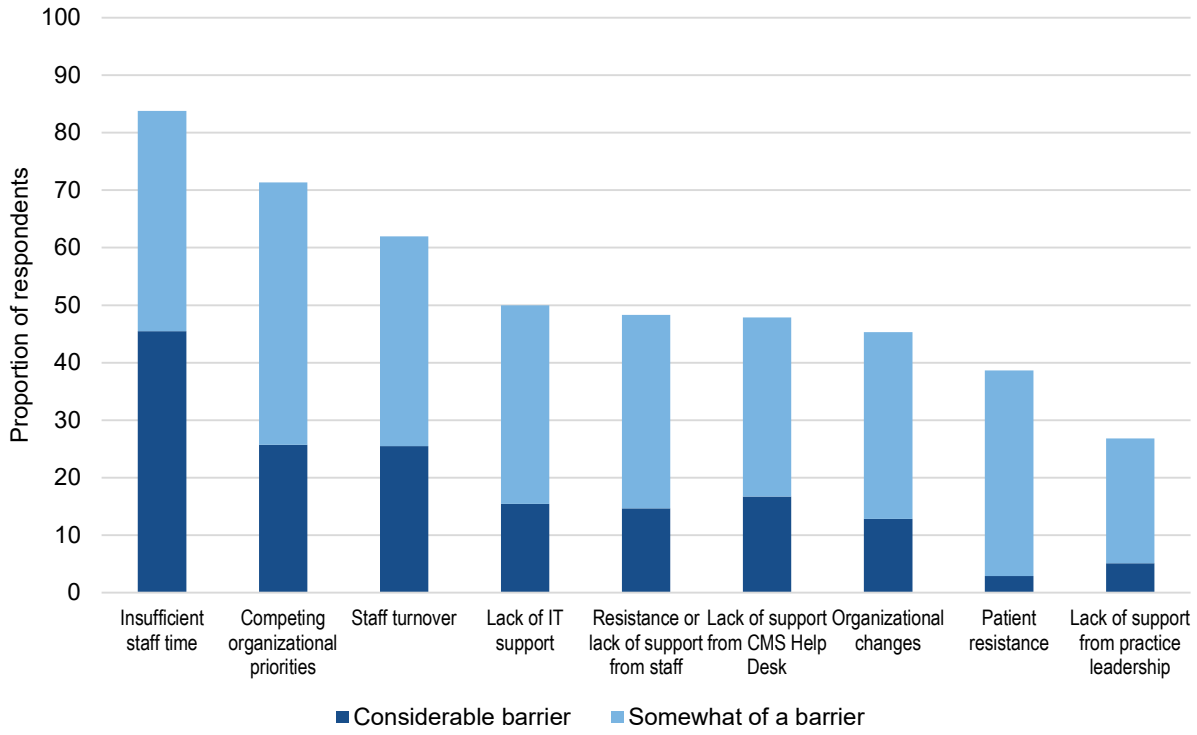


Source: Mathematica's analysis of a practice survey administered in 2018 to key contacts at each intervention organization who interact with CMS about the Million Hearts Model. The number of respondents for individual questions ranged from 135 to 138 due to missing responses.

ACO = accountable care organization.

In the 2019 interviews, respondents reported fewer barriers to implementing the model than respondents interviewed in 2018 had reported. The most commonly reported barriers were insufficient staff time, competing organizational priorities, and staff turnover. These were similar to the barriers reported in the practice survey (Figure III.C.2). In addition, data reported to CMS on factors that contributed to 20 intervention organizations withdrawing from the model in 2018 included insufficient staffing and other resources (9 organizations), a negative data entry experience (5 organizations), unattainable clinical requirements (3 organizations), and inadequate support from the CMS help desk (2 organizations).

Figure III.C.2. Perceptions of factors that have been a barrier in implementing the Million Hearts Model among participating intervention organizations



Source: Mathematica's analysis of a practice survey administered in 2018 to key contacts at each intervention organization who interact with CMS about the Million Hearts Model. The number of respondents for individual questions ranged from 137 to 138 due to missing responses.

D. Implications of the implementation findings

Results based on our interview sample probably do not represent all participating organizations. Organizations were not selected randomly, and some of those selected declined to be interviewed. In addition, the set of organizations we interviewed differs between 2018 and 2019, as 2 of the original 15 organizations had since dropped out of the model, another declined to participate due to frustrations with meeting the model requirements, and still another had experienced significant turnover and ended up not scheduling interviews with us. We replaced these organizations with four that had similar characteristics to retain targeted diversity of organizational characteristics in our intervention follow-up sample. Of these 4, 3 agreed to interviews and the fourth dropped out of the model soon after we contacted it.

Our final sample of organizations might have offered a more positive perspective on implementing the model than other intervention organizations, especially those that withdrew from the model. For instance, as reported earlier, the 70 percent rate of reassessment visits for the 14 organizations interviewed is considerably higher than the data presented in Chapter IV for all intervention organizations. Those data estimated that about half of high-risk enrollees eligible for an anniversary visit during the first six months of 2018 actually had one. Similarly, all of the

organizations we interviewed achieved CVD risk reduction that qualified them for risk-reduction payments. In contrast, 66 percent of all participating intervention organizations earned risk-reduction payments. These findings suggests that these organizations, as a whole, more successfully conducted reassessment visits than the overall intervention cohort, which could limit the generalizability of our findings to the rest of the cohort. Our general conclusions about CVD preventive care changes from the interviews are consistent with findings from the practice survey data.

Our assessment is that organizations appear to be implementing the Million Hearts Model as CMS intended. This is an important finding because it supports interpretation of impacts as attributable to the model rather than significantly affected by ineffective or incomplete implementation. Most respondents at the intervention organizations interviewed reported adapting their workflows to accommodate the model requirements. Their adaptations included stratifying risk at enrollment and anniversary visits, and ongoing CVD care management such as initiating or intensifying medication therapies and follow-up visits for high-risk beneficiaries.

Moreover, about one-third of organizations expressed a belief that they were doing better with reducing CVD risk than the data reported to the registry reflected. Specifically, some respondents noted their organizations' commitment to reducing CVD risk, but found the process of reporting data on all beneficiaries burdensome. In addition, some respondents noted that reassessment of risk sometimes occurs outside the 10- to 14-month window. If intervention organizations are doing a better job of improving CVD preventive care to reduce CVD risk over time than they are meeting the Million Hearts Model reporting requirements, then analysis of registry data might underestimate the model's impacts on risk scores. Claims-based analyses should detect the effects of the model on the targeted outcomes, namely the incidence of heart attack and stroke.

IV. MODEL IMPACTS ON CVD CARE PROCESSES AND BENEFICIARIES' OUTCOMES IN THE FIRST TWO YEARS

Summary of findings

When CMS designed the Million Hearts Model, it set two primary goals. The first was to reduce the first-time incidence of heart attacks, strokes, and TIAs among higher-risk Medicare beneficiaries over five years. The second goal was to reduce Medicare Part A and B spending enough to fully offset the costs of the model to CMS. In addition, CMS expected the model would improve the CVD care that intervention organizations provide, would reduce beneficiaries' CVD risk scores and individual risk factors, and could possibly improve other health outcomes.

In this report, we estimate impacts of the model by comparing outcomes for medium and high-risk beneficiaries enrolled by the intervention (N = 104,214) versus the control organizations (N = 66,984). We conducted separate analyses for high-risk, and the combined medium- and high-risk groups. For each beneficiary, we measured outcomes from the date of enrollment through October 2018 (or death or loss of observability in claims). The average follow-up period across all beneficiaries was 17 months. In addition, we estimated the model's impact on the CVD preventive care the organization provided roughly 22 months into implementation. We estimated this impact as the difference in self-reported approaches to CVD care between providers in intervention and control organizations on a survey we administered. We sent the survey to one randomly selected provider in each organization. The survey had a 71 percent response rate, with 128 respondents in the intervention group and 117 in the control group.

Overall, we found that the Million Hearts Model:

- **Did not show evidence of reducing the first-time incidence of heart attack, stroke, or TIA.** The intervention and control group beneficiaries had very similar probabilities of having a heart attack, stroke, or TIA throughout the study period. For high-risk enrollees, the ratio between the risk of an event in the treatment versus the control group (that is, the hazard ratio) was 1.03 (p=0.63, 90 percent CI: [0.93, 1.14]), indicating no discernible difference in risk. Similarly, for medium- and high-risk enrollees, the hazard ratio was 1.00 (p=0.90, 90 percent CI: [0.93, 1.06]).
- **Appears to have reduced the likelihood of dying among medium- and high-risk beneficiaries by about 7 percent.** The likelihood of dying was 7 percent lower in the intervention group than the control group throughout the study period (hazard ratio of 0.93, p=0.03, 90 percent CI: [0.87, 0.98]). For example, after 1.5 years of enrollment, the probability of dying was 2.7 percent in the intervention group and 3.0 percent in the control group. For high-risk enrollees alone, the impact estimate was similar, showing a 6 percent reduction in mortality. But this difference was not statistically significant (p=0.28), which might be due to the much smaller size, which decreases the precision of the estimates.

- **Did not measurably reduce Part A and B spending and therefore did not generate savings to offset the roughly $5.6 million in model payments.** Among medium- and high-risk enrollees, the mean monthly Part A and B spending was similar between the intervention group ($863) and control group ($850) enrollees (p=0.44). After accounting for model payments, the model appears to have increased Medicare spending by about $23 PBPM, or 3 percent.
- **Appears to have substantially improved the delivery of CVD preventive care along the lines CMS envisioned.** Relative to the control group, the model increased by 31 percentage points the share of providers reporting they risk stratify at least half of their Medicare beneficiaries (71 percent in the intervention group and 39 percent in the control, $p < 0.001$). Most intervention group providers (73 percent) said that risk stratification helped them identify beneficiaries at risk of CVD events, and most (71 percent) reported that the Million Hearts model prompted them to more systematically apply the current standard of CVD care to their Medicare beneficiaries.
- **Modestly increased the initiation or intensification of CVD-related medications.** Among the medium and high-risk enrollees with Part D coverage, 90 percent met criteria for being eligible to initiate or intensify statins or antihypertensives (defined as those with LDL baseline greater than 70 mg/dL, systolic blood pressure greater than 130 mm Hg, or both). Among this group, the probability of initiating or intensifying statins or antihypertensives was 4 percentage points higher in the intervention than the control group (28 versus 24 percent, $p < 0.001$).

In addition, among the roughly 50 percent of high-risk enrollees with follow-up clinical data, mean CVD risk scores declined by 8 percentage points (from 40 to 32 percent) one year after enrollment. Decreases in systolic blood pressure primarily drove this decline, but declines in cholesterol, increases in aspirin use, and a small decrease in smoking prevalence also contributed. These findings suggest the model *could* be reducing CVD risk but, without control group data yet, it is unclear whether similar improvements would have occurred without the intervention.

Finally, the CVD hospitalization rate among high-risk enrollees was 13 percent higher in the intervention group than the control group (18 versus 16 per 1,000 per quarter, p=0.004). This difference could signal that the model increased CVD hospitalization rates. However, we did not find similar effects in a key robustness check that defines the study population through claims-based attribution. This robustness check aims to limit potential for bias stemming from differences in the types of beneficiaries enrolled by intervention or control organizations among their eligible patients. Because the findings differ, it is unclear whether the model truly increased CVD hospitalizations. Future reports will investigate whether this discrepancy persists—and, if so, the reasons for it and implications for conclusions about model impacts.

In future analyses, we will extend the follow-up period to test whether the Million Hearts Model improved outcomes over the full five-year model period. These estimates will enable us to assess whether the large favorable impacts on CVD preventive care translate into improved final outcomes for beneficiaries and whether the apparent benefit for all-cause mortality persists.

A. Long-term outcomes for beneficiaries

In this chapter, we first describe the impact of the Million Hearts Model on key outcomes that CMS hypothesized would occur over the period of the model (five years) (Section A). Because the estimates in this report cover outcomes up to 22 months after enrollment, they cannot fully test these long-term hypotheses. However, the estimates provide an early look at impacts on core outcomes and we will update them in future reports. In Section B, we describe the model's impacts on outcomes that CMS expects to improve in the shorter term: (1) the CVD care that participating organizations provide; and (2) initiating or intensifying statins or antihypertensive medications for enrollees with elevated cholesterol, blood pressure, or both. In Section C, we describe some of the limitations in the methods, some of which we can address in future reports.

Hypotheses. When CMS designed the Million Hearts Model, it set two primary goals. The first was to reduce the first-time incidence of heart attacks, strokes, and TIAs among higher-risk Medicare beneficiaries over five years (Table IV.A.1). The second goal was to reduce Medicare Part A and B spending enough to fully offset the costs of the model to CMS. In addition, CMS expected the model could improve other final outcomes, including reducing CVD risk scores and individual risk factors, all-cause mortality, and CVD-related ED visits and hospital admissions.

CMS's calculations when designing the model also provide insight into the expected magnitude of impacts. CMS estimated that the model would have to reduce the incidence of first-time heart attack, stroke, and TIAs by 7 percent among medium- and high-risk enrollees to be cost neutral to Medicare. CMS projected that reductions of this size would generate enough savings in Medicare Part A and B spending to offset model payments. A 7 percent reduction translates into a relatively modest absolute reduction in risk. For example, if 14 percent of the control group beneficiaries had a heart attack or stroke after five years of enrollment, a 7 percent impact would mean that the intervention group rate would be 13 percent (or 1 percentage point lower).

Table IV.A.1. Hypotheses about the impacts of the Million Hearts Model on long-term outcomes for beneficiaries

Domain	Measure	Data source for measure	Beneficiaries included in hypothesis		Hypothesized direction (and timing) of effects
			High-risk	High- and medium-risk	
Final health outcomes	First-time incidence of heart attack, stroke, or transient ischemic attack	Medicare claims	✓	✓	↓ (5 years)
	All-cause mortality	Medicare enrollment data	✓	✓	↓ (5 years)
Medicare spending	Medicare Part A and B spending	Medicare claims	✓	✓	↓ (5 years)
	Medicare Part A and B spending with model payments	Medicare claims and CMS payments		✓[a]	No net increase (5 years)
CVD-related acute care	CVD-related hospitalizations	Medicare claims	✓	✓	↓ (5 years)
	CVD-related outpatient ED visits	Medicare claims	✓	✓	↓ (5 years)
CVD risk factors	Overall CVD risk scores	Million Hearts Data Registry	✓[b]		↓ (3 years)
	Individual components of the risk scores (blood pressure, cholesterol levels, and smoking)	Million Hearts Data Registry	✓[b]		↓ (3 years)

[a] Although CMS anticipated reductions in Medicare Part A and B spending among high-risk enrollees as well, it set the primary hypothesis about cost neutrality among medium- and high-risk beneficiaries combined. That is, CMS expected reductions in Part A and B spending among medium- and high-risk enrollees to offset the total model payments to intervention organizations.

[b] This hypothesis is limited to high-risk enrollees because, as initially planned, CMS collects follow-up CVD risk data only for high-risk enrollees.

CVD = cardiovascular disease.

In this report, we estimate model impacts as the regression-adjusted differences in outcomes for beneficiaries enrolled by the intervention and control organizations in 2017. The regression models adjusted for beneficiaries' characteristics at baseline to increase the precision and to adjust for observed differences between the groups. We estimate impacts for high-risk enrollees and for the medium- and high-risk enrollees combined (Table IV.A.2 provides the sizes of the study populations). As shown by the number of observations, the treatment group population is about 55 percent larger than the control group population. This differences occurs because CMS allowed up to 20 providers in control group organizations to enroll beneficiaries but did not apply a similar cap for intervention organizations. For each enrollee, we measured outcomes from the beneficiary's date of enrollment through October 2018 (or the date a person died or became unobservable in Medicare Part A and B claims). The mean follow-up period across all enrollees was 17 months, with a range from one day to 22 months.

The intervention and control groups were very similar at baseline on demographics, CVD risk factors, and recent service use and spending. (Appendix A provides detailed baseline characteristics.) This similarity increases our confidence that differences in outcomes for the intervention and control groups reflect model impacts, not other differences between the groups. The two groups did differ somewhat, however, at baseline in terms of geography and the type of organization enrolling the beneficiaries. These differences emphasize the importance of controlling for these factors in regression models.

We tailored the regression models to the type of outcome—using Cox proportional hazard models for event data (the primary outcome of heart attack, stroke, or TIA, and mortality) and linear models (with beneficiary-quarters as the unit of analysis) for the other outcomes. All models accounted for clustering of beneficiaries within organizations, which is needed to correctly estimate the statistical precision of the estimates. Appendix D provides details on the analysis methods.

Table IV.A.2. Size of study population used for primary impact estimates—Medicare FFS beneficiaries enrolled by participating organizations in 2017

	Number of organizations[a]		Number of beneficiaries		Mean follow-up (months)
CVD risk group	Intervention	Control	Intervention	Control	(Intervention and control)
High-risk	159[b]	147[b]	32,831	20,924	17
Medium- and high-risk combined	161	152	104,214	66,948	17

[a] Organizations are limited to those that enrolled at least one beneficiary in 2017 and had not withdrawn by the end of 2017.

[b] Two intervention organizations and five control organizations enrolled only medium-risk beneficiaries. The high-risk study population excludes these organizations.

We also ran two key robustness checks designed to identify potential biases in the impact estimates.

1. The first check removed beneficiaries enrolled by certain providers from the intervention group to mimic the 20 provider cap applied to the control group. Specifically, for large intervention group organizations, we excluded beneficiaries enrolled by providers who were not in the list of the top 20 providers enrolling the most beneficiaries for that organization. This trimming made the intervention and control groups much more similar in size (71,814 for intervention and 66,926 for control). It also improved the baseline balance at the beneficiary level on the types of organizations enrolling beneficiaries into the model (before trimming, a larger fraction of the intervention group was enrolled by large [more than 20 provider] organizations).
2. The second check used all beneficiaries we attributed to the intervention (N = 273,101) and control (N = 215,118) organizations and who, per characteristics observable in Medicare claims, met the model's eligibility requirements and were predicted to have medium or high

CVD risk. We attributed beneficiaries to the providers that organizations said, before they were randomized, they expected to participate in the model.[18] We designed this check to limit the potential for biases in the impact estimates that differences between the intervention and control groups could introduce in (1) the number and types of providers who actually participated in the model, including differences driven by the 20 provider cap; and (2) in the types of beneficiaries the participating providers chose to, or were able to, enroll among their eligible patients. We provide details about constructing this attribution-based population, including how we used claims data estimate an enrollee's baseline CVD risk, in Appendix A and the results in Appendix D.

Except for impacts on CVD-related ED visits and hospitalizations (discussed in Section IV.A.4) the robustness checks were generally consistent with, and therefore supported, the main findings.

1. First-time incidence of heart attack, stroke, or TIAs

Key finding

- The incidence of first-time heart attack, stroke, or TIA was similar for the intervention and control groups throughout the study period.

Data source

- Medicare claims

The model did not measurably reduce the incidence of first-time heart attack, stroke, or TIA (composite measure) throughout the follow-up period (mean of 17 months and maximum of 22 months). The probability of having a first-time heart attack, stroke, or TIA was very similar for the intervention and control group beneficiaries throughout the period, both for high-risk enrollees and for the medium- and high-risk enrollees combined. For example, 1.3 percent of the intervention group's high- and medium- risk beneficiaries had a first time heart attack, stroke, or TIA within 12 months of enrollment, which is the same rate found in the control group (Table IV.A.3; see Appendix D for details). In regression analyses, the ratio in the risk of having a first-time CVD event in the treatment versus control groups (also called the hazard ratio) was very close to 1, indicating no model effect on this risk. The confidence intervals around these estimates were small enough to suggest the model did not have substantively large effects on CVD events during the time period—not simply that the model might have had such effects, but they went undetected due to imprecision in the estimates. Specifically, the 90 percent confidence interval for the hazard ratio (0.93 to 1.06) does not span the 7 percent reduction target that CMS set for the model over the five-year test (Table IV.A.3).

[18] We removed listed providers who were either ineligible to participate (not a physician, nurse practitioner, or physician assistant) or had a specialty that did not—or was very unlikely to—enroll any beneficiaries during the intervention period.

Table IV.A.3. Estimated ratio of the hazard of a first time heart attack, stroke, or TIA between intervention and control beneficiaries (regression-adjusted)

	Percent (unadjusted) of beneficiaries with a CVD event within a year of enrollment[a]		Regression-adjusted hazard ratio		
Outcome and risk group	Intervention	Control	Ratio	p-value	90% confidence interval
First-time heart attack, stroke, or TIA (composite measure)[b]					
• High risk	1.7	1.8	1.03	0.63	[0.93, 1.14]
• Medium and high risk	1.3	1.3	1.00	0.90	[0.93, 1.06]
First-time heart attack					
• High risk	0.8	0.9	0.98	0.79	[0.84, 1.13]
• Medium and high risk	0.6	0.6	0.98	0.72	[0.87, 1.09]
First-time stroke or TIA					
• High risk	0.9	0.9	1.10	0.22	[0.97, 1.24]
• Medium and high risk	0.7	0.7	1.01	0.77	[0.94, 1.10]

Source: Unadjusted and regression-adjusted results from Medicare claims.

[a] Percentages calculated among beneficiaries who enrolled by October 31, 2017 so that we could follow them for at least a year before the end of the claims period on October 31, 2018.

[b] AMIs, strokes, TIAs, or stroke symptoms identified as a (1) primary diagnosis on outpatient ED claim or inpatient claim, or (2) a secondary diagnosis on an inpatient claim when the condition was listed as not present on admission. See Appendix C for detailed description of the outcomes. For acute myocardial infarctions (AMIs), we include all five types of AMI described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

TIA = transient ischemic attack

These primary estimates were largely consistent with the results from the following robustness checks (see Appendix D for detailed results), increasing our confidence in the primary results:

- Narrowing the outcome definition to include only Type 1 heart attacks and strokes. This exclusion (1) limits to heart attacks clearly caused by blockages in the arteries supplying the heart (Thygesen et al. 2018), and might be most expected to be influenced by the intervention (in contrast to other types of acute myocardial infarctions [AMIs], such as those that occur during surgeries, that might be less affected by primary CVD prevention), and (2) removes TIAs, which are less severe than strokes.
- Trimming the intervention group so that, like the control group organizations, a maximum of 20 providers could enroll beneficiaries.
- Estimating impacts using beneficiaries we attributed to the intervention and control organizations. These estimates were slightly more favorable, but were not statistically different from zero at the $p < .10$ level. For example, for the medium- and high-risk groups combined, the hazard ratio was 0.96, with a p-value of 0.20.

2. All-cause mortality

Key finding

- Among medium- and high-risk beneficiaries, the likelihood of dying for any reason was about 7 percent lower for the intervention group compared to the control group throughout the study period.

Data source

- Medicare enrollment data

The Million Hearts Model appears to have reduced the risk of dying (for any reason) during the follow-up period by about 7 percent. The risk of dying was lower in the intervention group than the control group throughout the study period—both for the high-risk beneficiaries alone and for the medium- and high-risk enrollees combined. For example, among medium and high-risk enrollees, the percentage of enrollees who died within a year of enrollment was 1.6 for the intervention group and 1.8 percent for the control group (Table IV.A.4). The regression analyses show that risk of death was about 6 percent (high-risk) or 7 percent (combined medium- and high-risk) lower in the intervention group than the control group. This difference was statistically significant at the $p < .10$ level for the combined medium- and high-risk groups (p=0.03) but not for the high-risk group alone (p=0.28, Table IV.A.4).

These primary results were consistent with the same set of robustness check described for CVD events. The impact estimate for the attribution-based study population was smaller, estimating a 4 percent reduction for the medium- and high-risk beneficiaries (hazard ratio of 0.96, p-value = 0.03). However, we would expect smaller impacts in the attribution population if the model's impacts act largely through beneficiaries actually enrolled in the model (given that only 37 percent of the attributed beneficiaries were enrolled in the model).[19]

Table IV.A.4. Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries (regression-adjusted)

	Percent (unadjusted) of beneficiaries who died within a year of enrollment[a]		Regression-adjusted hazard ratio		
Risk group	Intervention	Control	Hazard ratio	p-value	90% confidence interval
High risk	2.0	2.3	0.94	0.28	[0.87, 1.03]
Medium and high risk	1.6	1.8	0.93	0.03	[0.87, 0.98]

Source: Unadjusted and regression-adjusted results from Medicare enrollment data.

[a] Percentages calculated among beneficiaries who enrolled by October 31, 2017 so that we could follow them for at least a year before the end of the claims period on October 31, 2018.

[19] Although about 37 percent of the attribution population was enrolled through the registry, 71 percent were attributed to providers who participated in the model, defined as having enrolled at least one beneficiary in 2017.

3. Medicare Part A and B spending

The model did not measurably reduce Part A and B spending according to claims data available for this report (Table IV.A.5).

Key finding

- The model did not appear to generate any Medicare Part A and B savings to offset the roughly $5.6 million in model payments in the first 1.5 years of model implementation.

Data source

- Medicare claims data and CMS payments

- For medium- and high-risk beneficiaries combined, the evidence suggests little or no overall impact on Part A and B spending. The intervention group's mean spending was $12 per beneficiary per month (or 1 percent) higher than the control's groups mean, but this difference was not statistically different from zero (p=0.44).
- For high-risk enrollees, the evidence suggests the model may have increased Part A and B spending by about 3 percent. The intervention group's mean spending was $29 (or 3 percent) higher than the control group's mean, but the estimate was also not statistically significant (p=0.19) and had a wide confidence interval (ranging from $7 PBPM in savings to $66 PBPM in cost increases). Differences in mean spending between the intervention and control groups were fairly consistent across quarters, although the quarter-specific impact estimates were less precise (Figure IV.A.1).

Because the model did not measurably reduce Part A and B spending, it did not generate any savings to offset CMS's Million Hearts Model payments. CMS paid the intervention organizations roughly $5.6 million in the first 18 months of the intervention, or about $10 per beneficiary per month among the medium- and high-risk enrollees. When we factor these monthly payments into total Medicare spending, spending in the intervention group was about 3 percent higher (or $23 per beneficiary per month) than in the control group. This difference was estimated imprecisely and not statistically different from zero (p=0.16).

Table IV.A.5. Estimated impacts on Medicare spending (dollars per beneficiary per quarter)

	Regression-adjusted spending ($/beneficiary/month)				
	Intervention group mean	Control group mean	Difference	p-value	90% confidence interval
High-risk beneficiaries					
Parts A and B spending	$ 972	$ 943	$ 29	0.19	[-7, 66]
Inpatient spending	$ 347	$ 328	$ 19	0.16	[-3, 41]
Other spending	$ 625	$ 615	$ 10	0.36	[-8, 29]
High- and medium-risk beneficiaries					
Parts A and B spending	$ 863	$ 850	$ 12	0.44	[-14, 39]
Inpatient spending	$ 295	$ 285	$ 10	0.30	[-6, 26]

Table IV.A.5. (*Continued*)

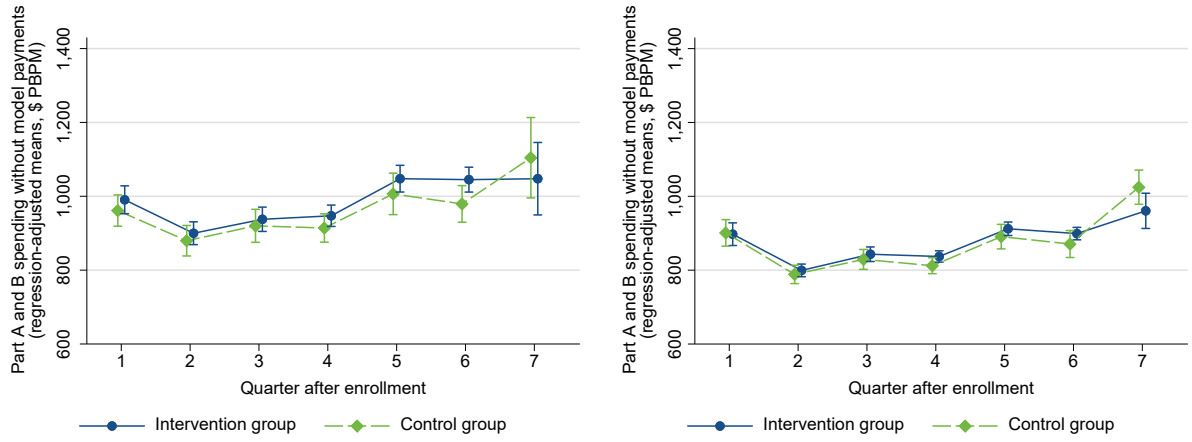
	Regression-adjusted spending ($/beneficiary/month)				
	Intervention group mean	Control group mean	Difference	p-value	90% confidence interval
Other spending	$ 567	$ 565	$ 2	0.76	[-11, 16]
Parts A and B spending plus model payments[a]	$ 873	$ 850	$ 23	0.16	[-4, 49]

Source: Regression-adjusted results from Medicare Part A and B claims data.

Note: Inpatient and other spending might not equal total spending because we calculated the impact estimates and regression-adjusted means from separate regression models. We estimated impacts separately by quarter since enrollment and then averaged the estimates across all quarters, weighting each quarterly estimate by the number of intervention group enrollees observed in that quarter.

[a] Total Million Hearts Model payments to intervention group organizations included in the impact evaluation for the first three performance periods were $5,563,915. We divided this amount by the number of beneficiary-quarters represented among the medium- and high-risk beneficiaries.

Figure IV.A.1. Regression-adjusted mean Medicare Parts A and B spending (without model payments) for enrolled beneficiaries, by quarter and intervention group



Source: Regression-adjusted results from Medicare Part A and B claims.

Note: The 90 percent confidence intervals displayed in this figure are the confidence intervals for each regression-adjusted mean.

4. CVD-related acute care

We hypothesized that the Million Hearts Model could reduce hospitalizations and outpatient ED visits (including observation stays) for CVD-related reasons. This includes acute care for heart attacks and strokes, but also for other conditions such as angina, that better management of CVD risk factors could also reduce. As shown in Table IV.A.6, CVD-related inpatient admissions and outpatient ED visits account for 21 and 8 percent of all hospitalizations and ED visits, respectively, for the medium- and high-risk beneficiaries enrolled in the model.

Key finding

- Rates of CVD-related ED visits and hospital admissions among high-risk enrollees were higher for the intervention group than they were for the control group.
- Results were not present in a key robustness check, raising questions about the accuracy of this result.

Data source

- Medicare claims data

Focusing first on CVD-related acute care, the model appears to have increased rates of CVD-related hospital admissions among high-risk enrollees. Specifically, over seven quarters of follow-up, the quarterly CVD-related hospitalization rate was 2 percentage points (or 13 percent) higher in the intervention group than the control group (p=0.004, Table IV.A.6). While surprising because it is opposite the hypothesized direction, this increase may be due to high-risk beneficiaries seeking CVD-related procedures such as stents. We will explore the specific types of CVD hospitalizations that increased in future reports. In contrast to the observed impacts for the high-risk group, we did not see any statistically significant effects on CVD-related hospitalizations for the medium and high-risk groups combined. Futher, the CVD-related ED visit rates were not statistically different between the intervention and control groups, either for the high-risk enrollees or the medium and high-risk enrollees combined.

Turning to model impacts on beneficiary use of acute care for any reason (not just CVD-related care), the model appears to have increased all-cause ED visits by about 9 percent for the high-risk group (p=0.003) and 7 percent for the medium and high-risk group combined (p=0.003). These unexpected increases may be due to the model increasing beneficiary awareness of their risk of heart attack or stroke, prompting more frequent trips to the ED for symptoms—like chest pain due to acid reflux—that are similar to a heart attack or stroke. All-cause hospitalization rates were also modestly higher in the intervention group than the control group, both for high-risk enrollees and for medium and high-risk enrollees combined.

In contrast to these findings using the primary study population, we did not find any statistically significant effects on CVD-related or all-cause acute care (ED visits or hospital admissions) using the attribution-based study population (Appendix D, Table D.5). We will further explore these differences in future reports, but for now, they lead to lower confidence in these findings.

Table IV.A.6. Estimated impacts on the number of inpatient admissions and outpatient ED visits and observation stays (number per 1,000 beneficiaries per quarter)

Population and utilization measure	Regression-adjusted rate (#/1,000 beneficiaries/quarter)				
	Intervention group mean	Control group mean	Difference	p-value	90% confidence interval
Number of CVD-related admissions					
High-risk beneficiaries	18	16	2.0	0.004	[0.9, 3.1]
High- and medium-risk beneficiaries	14	13	0.6	0.194	[-0.2, 1.4]
Number of CVD-related outpatient ED visits and observation stays					
High-risk beneficiaries	10	9	0.9	0.147	[-0.1, 1.9]
High- and medium-risk beneficiaries	8	8	0.4	0.350	[-0.3, 1.1]
Number of all-cause admissions					
High-risk beneficiaries	75	71	3.5	0.076	[0.3, 6.7]
High- and medium-risk beneficiaries	63	61	2.0	0.090	[0.1, 4.0]
Number of all-cause outpatient ED visits and observation stays					
High-risk beneficiaries	109	100	8.6	0.003	[3.9, 13.3]
High- and medium-risk beneficiaries	102	95	6.6	0.003	[3.0, 10.3]

Source: Regression-adjusted results from Medicare claims data.

5. CVD risk scores and individual CVD risk factors among beneficiaries in the intervention group

Among eligible enrollees in intervention organizations who received a reassessment visit by June 2018, CVD risk scores decreased by 8 percentage points on average. This represents a 20 percent average reduction in CVD risk scores from baseline levels (from 40 to 32 percent one year later). We cannot presume these reductions are due to the model because we currently lack control group data, and thus do not know whether similar improvements would have occurred without the intervention. Nonetheless, these reductions are encouraging and provide early evidence of possible mechanisms through which the model *could* affect CVD risk.

Key finding

- CVD risk scores decreased an average of 8 percentage points (from 40 to 32 percent) between enrollment and one year later for the half of beneficiaries with follow-up clinical data.
- Reductions in systolic blood pressure drove the overall decrease in CVD risk scores.
- Without control group data, these reductions cannot be interpreted as impacts—but they suggest the model *could* have impacts on CVD risk.

Data source

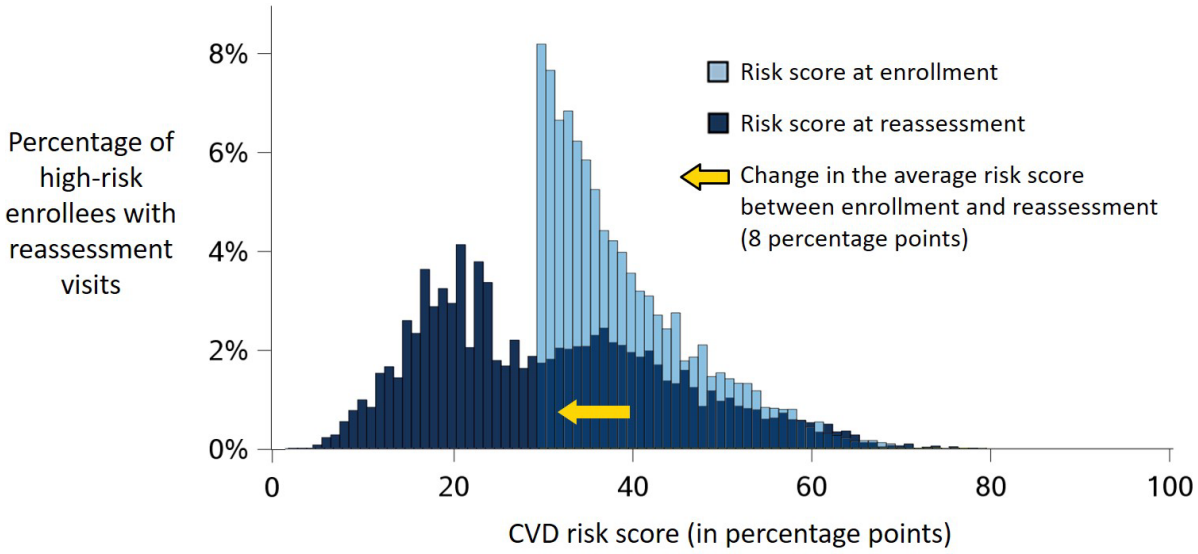
- Million Hearts Data Registry
- Medicare claims and enrollment data

Enrollees eligible for a reassessment visit included 16,551 high-risk enrollees whose baseline visit occurred early enough in 2017 that their anniversary window for a reassessment visit 10 to 14 months after baseline occurred by June 2018.[20] Among these eligible enrollees, about half had a reassessment visit for which the organization successfully reported follow-up clinical data in the registry. Enrollees with a reassessment visit were similar to everyone eligible with respect to CVD risk factors and many other baseline characteristics (see Appendix A)—but were somewhat more likely to have diabetes and to be enrolled by primary care providers (versus cardiologists or other specialists). To estimate changes in CVD risk scores that are representative of the full population of eligible enrollees, not just those who received a reassessment visit, we used inverse probability weights (so that those with a lower probability of having a reassessment visit get larger weight). Unweighted and weighted results were similar.

Owing to these risk score reductions, almost half of the enrollees classified as high risk at enrollment had risk scores below the high-risk threshold (30 percent probability of heart attack or stroke) at reassessment. Figure IV.A.2 shows how the CVD risk score distribution improved between enrollment and reassessment visits, among enrollees who were high risk at enrollment and received a reassessment visit. The average time between enrollment and reassessment visits was 12 months, so patients typically aged one year between enrollment and reassessment. If no risk factors had improved between enrollment and reassessment, we would have expected to see an increase in CVD risk scores due to aging rather than the reduction in scores observed.

[20] We excluded from our definition of eligible enrollees any beneficiary who died; had an acute myocardial infarction, stroke, or TIA; enrolled in Medicare Advantage; or lost Medicare as the primary payer within 14 months after the baseline visit because these beneficiaries were unlikely to have reassessment visits captured in the registry.

Figure IV.A.2. Distribution of CVD risk scores at enrollment and reassessment visits about one year later, among high-risk enrollees with reassessment visits



Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Note: CVD risk scores measured for the 7,862 enrollees with a reassessment visit, excluding enrollees with an implausible LDL value, which we defined as less than 20 mg/dL (n = 87) and beneficiaries not defined as high risk after adjusting baseline visit dates for the 6 percent of enrollees with earlier visits recorded in the registry (n = 68). Measures are weighted to represent the full population of enrollees eligible for a reassessment visit by June 30, 2018. High CVD risk indicates beneficiaries with a 30 percent or higher predicted risk at enrollment of having a heart attack or stroke in the next 10 years.

As expected, the largest reductions in risk scores were among enrollees who had more modifiable risk factors at enrollment, including high blood pressure, high cholesterol, and smoking. Enrollees with high modifiable risk, as defined in Chapter II, had an average 15 percentage point reduction in CVD risk scores and beneficiaries with low modifiable risk had only a 2 percentage point reduction.

Improvements in blood pressure, followed by aspirin use, improvements in cholesterol, and to a much lesser extent smoking cessation, primarily drove the decrease in CVD risk scores. As shown in Table IV.A.7, all modifiable CVD risk factors improved between baseline and reassessment, with notable mean reductions in systolic blood pressure and LDL of 6 mm Hg and 5 mg/dL, respectively. There was also an increase in CVD treatment, including a 15 percent increase in the use of aspirin. Table IV.A.8 uses these observed changes in risk factors to estimate the contributions to overall risk reduction attributable to each ABCS risk-reduction strategy. Several findings emerged:

- **Reductions in blood pressure** had by far the largest impact on CVD risk score reductions. We estimate that the observed 6 mm Hg reduction in systolic blood pressure alone could

have led to an 11 percentage point reduction in CVD risk scores at a population level. However, decreases in risk scores due to reductions in systolic blood pressure, as well as reductions in other risk factors described later, were partly offset by increases in risk scores due to aging. Aging increased risk scores by an estimated 3 percentage points on average. Thus, overall reductions in risk scores one year after enrollment were more modest.

- **Aspirin therapy** had a modest impact on CVD risk scores. With 66 percent of beneficiaries using aspirin at follow-up, we estimate that aspirin use alone could be associated with a 3 percentage point CVD risk score reduction. Although aspirin use was already high at baseline, in the Million Hearts Longitudinal ASCVD Risk Assessment Tool aspirin use at follow-up reduced CVD risk scores regardless of baseline use.
- **Reductions in cholesterol** also had a modest impact on CVD risk scores. We estimate that the observed 5 mg/dL reduction in LDL alone could have led to a 2 percentage point reduction in CVD risk scores.
- **Smoking cessation** had a large impact on risk scores for smokers (similar to the impact of blood pressure changes), but had a small average impact across the entire population of high-risk enrollees with a reassessment visit. This is because (1) the smoking prevalence was low at baseline (12 percent) and (2) a relatively modest number of smokers quit smoking (the number of smokers decreased from 11 percent at reassessment to 12 percent at enrollment).

Table IV.A.7. Average change in CVD risk factors between enrollment and reassessment visits, among high-risk enrollees with reassessment visits

	Mean value at enrollment	Mean value at reassessment	Change
CVD risk factors (higher is worse)			
Total cholesterol, mean (in mg/dL)	169	164	-5.5
HDL cholesterol, mean (in mg/dL)	48	48	0.5
LDL cholesterol, mean (in mg/dL)	93	88	-5.0
Systolic blood pressure, mean (in mmHg)	140	133	-6.3
Diabetes, %	67	69	2.0
Current smoker, %	12	11	-1.2
CVD treatment (should lower risk)			
Treated for or diagnosed with hypertension, %	91	95	3.9
Aspirin use, %	50	66	15.2

Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Notes: CVD risk scores measured for the 7,862 enrollees with a reassessment visit, excluding enrollees with an implausible LDL value, defined as less than 20 mg/dL (n = 87) and enrollees not defined as high risk after adjusting baseline visit dates for the 6 percent of enrollees with earlier visits recorded in the registry (n = 68). Measures are weighted to represent the full population of enrollees eligible for a reassessment visit by June 30, 2018. 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. For all measures, means are calculated over nonmissing values.

Table IV.A.7. (*Continued*)
CVD = cardiovascular disease; HDL = high-density lipoprotein; LDL = low-density lipoprotein.

Table IV.A.8. Change in CVD risk scores from enrollment to reassessment one year later attributable to improvements in each of the ABCS risk factors

CVD risk factor	Change in CVD risk factor between enrollment and reassessment	Estimate of population-level change in CVD risk score due to changes in this risk factor alone (average percentage point change in CVD risk score per high-risk enrollee)
Age (in years)	1	+3
Aspirin use, %	16	-3
Systolic blood pressure (in mmHg)	-6	-11
LDL cholesterol (in mg/dL)	-5	-2
Current smoker, %	-1	-0.1
All risk factor changes		-8

Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Notes: CVD risk scores measured for the 7,862 enrollees with a reassessment visit, excluding enrollees with an implausible LDL value, defined as less than 20 mg/dL (n = 87) and enrollees not defined as high risk after adjusting baseline visit dates for the 6 percent of enrollees with earlier visits recorded in the registry (n = 68). We estimated population-level changes in CVD risk score based on average characteristics for high-risk enrollees (see Appendix D for further details). The total change in CVD risk score is not the sum of the changes due to each risk factor alone because the Million Hearts Longitudinal ASCVD Risk Assessment Tool is not additive.

ABCS = aspirin therapy in appropriate patients, blood pressure control, cholesterol management, and smoking cessation; ASCVD = atherosclerotic cardiovascular disease; LDL = low-density lipoprotein

B. CVD preventive care and short-term outcomes

Hypotheses. Based on the logic of the Million Hearts Model (Figure I.B.1), we hypothesized that the model would (1) improve CVD care that organizations provide within one year of their participation in the model and (2) increase the use of CVD-related medications and follow-up office visits with Million Hearts providers within a year of when a beneficiary of enrolled. Table IV.B.1 lists the specific hypotheses, stratified by two key domains for the intervention: CVD risk stratification and cardiovascular care management for those with elevated CVD risk.

Table IV.B.1. Hypotheses about the impacts of the Million Hearts Model on CVD care processes and short-term outcomes for beneficiaries

Domain	Measure	Data source for measure	Populations included in hypothesis		Hypothesized direction (and timing) of effect
			Providers	Beneficiaries	
CVD risk stratification	Calculating CVD risk scores	Provider survey	✓		↑ (1 year[a])
	Reviewing CVD risk scores	Provider survey	✓		↑ (1 year[a])
	Provider awareness of CVD risk in patient panel	Provider survey	✓		↑ (1 year[a])
	Notification of high-risk beneficiaries of their CVD risk	Provider survey	✓		↑ (1 year[a])
Cardiovascular care management	Frequency of follow-up with high-risk beneficiaries	Provider survey	✓		↑ (1 year[a])
	Systematically following standard of care (self-report)	Provider survey	✓		↑ (1 year[a])
	Initiating or intensifying medications to lower blood pressure or cholesterol levels	Medicare claims (Part D)		✓ (medium and high risk)	↑ (6 months[b])
	Annual in-person visits with Million Hearts provider	Medicare claims (Part B)		✓ (high risk)	↑ (1 year[b])

[a] The hypothesis is that these outcomes would improve within a year of implementing the model (by the end of 2017) for the intervention organizations.

[b] The hypothesis is that these outcomes would improve within 6 months (for medications) or one year (for follow-up visits) of a beneficiary's date of enrollment. Because beneficiaries enrolled at different times, the calendar period covered by the hypothesis differs for each enrollee.

CVD = cardiovascular disease.

We tested these hypotheses using a combination of survey and Medicare claims data (see Appendix E for details on methods).

- **Survey analysis.** In fall 2018, we surveyed one randomly selected provider from each of the 283 organizations still participating in the model (and surveyed one randomly selected back-up if the first selected provider did not initially respond). We sent a total of 366 surveys, with an overall response rate of 71 percent (78 percent for intervention providers [N = 138/178] and 65 percent for control providers [N = 123/188]). We received at least one provider response from 87 percent of the organizations we surveyed (91 percent for intervention and

82 percent for control). We estimated impacts as the regression-adjusted differences in self-reported approaches to CVD preventive care between the intervention and control group respondents. We weighted the intervention respondents to account for the fact that some surveyed providers did not respond. We weighted the control respondents to resemble the intervention respondents on a range of provider characteristics, such as specialty and the type of organization in which they work. This weighting sought to ensure that control group respondents were a reliable counterfactual for the intervention group. However, because control respondents already largely resembled intervention group respondents before weighting, the weighting did not materially affect the results.

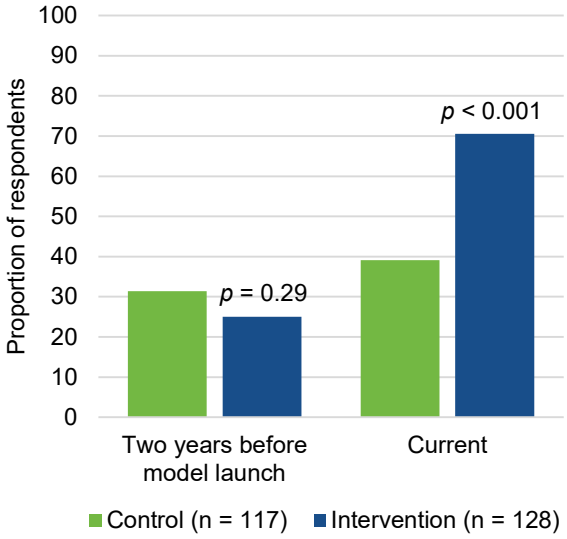
- **Claims-based analysis.** We identified CVD medication use in Part D claims and office visits with Million Hearts providers in Part B claims (see more details in Appendix C). We estimated impacts as regression-adjusted difference in outcomes for intervention and control group beneficiaries enrolled in 2017. For the medication analysis, we limited to the 70 percent of model enrollees who had Part D coverage for the full 12 months before enrollment and assessed medication use available in claims data for the six-month period following enrollment.

1. CVD risk stratification

a. Calculating CVD risk scores

The Million Hearts Model substantially increased the use of risk stratification. A total of 71 percent of intervention providers reported calculating CVD risk scores for at least half of their Medicare beneficiaries compared with 39 percent of control providers—a 31 percentage point difference that is highly statistically significant ($p < 0.001$) (Figure IV.B.1). Both intervention and control providers reported increasing their use of risk scores since the model began in 2017, but intervention providers reported substantially greater gains (25 to 71 percent) than control providers (31 to 39 percent).

Figure IV.B.1. Proportion of providers reporting they calculate CVD risk scores for at least half of their Medicare beneficiaries



Source: Mathematica's analysis of a provider survey administered in 2018.

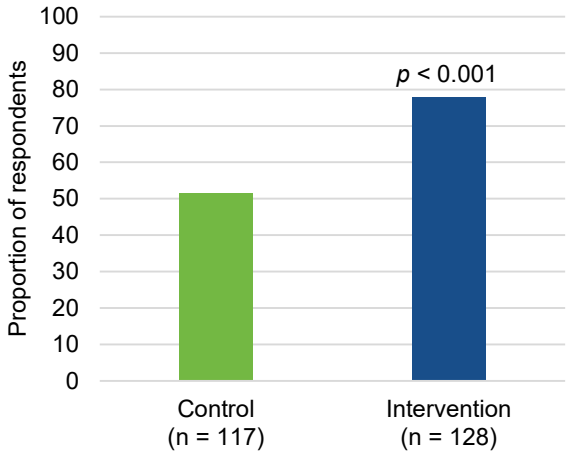
Although the model clearly increased risk stratification, it was not universal among intervention organizations. Nearly one-third of intervention providers reported that they did not currently calculate CVD risk scores for at least half of their Medicare beneficiaries or did not know how many beneficiaries they risk stratified. These providers might not risk stratify all of their eligible beneficiaries, perhaps due to capacity constraints or other priorities. Further,

some of their Medicare beneficiaries might not be eligible for the model (for example, older than 79) and so would not be expected to have been risk stratified for the model.

b. Reviewing CVD risk scores

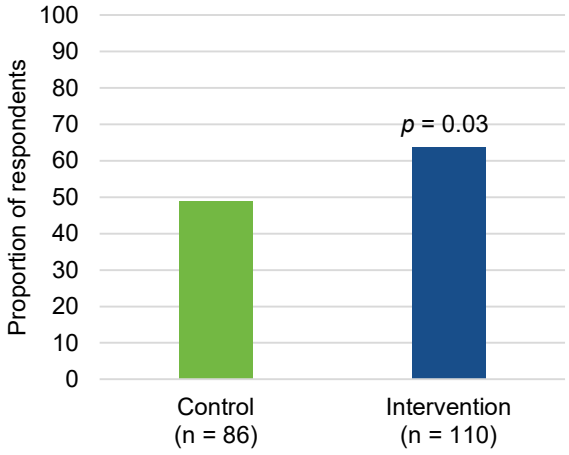
The results also indicate that the Million Hearts Model substantially increased providers' consistency in reviewing CVD risk scores and their access to scores when meeting with Medicare beneficiaries. Most intervention providers (78 percent) reported they or their clinical team review CVD risk scores somewhat or much more consistently than two years ago compared with 52 percent of control providers—a 26 percentage point difference ($p < 0.001$) (Figure IV.B.2). In addition, 64 percent of intervention providers who calculate CVD risk scores reported always or almost always having access to CVD risk scores when meeting with Medicare beneficiaries compared with 49 percent of control providers ($p < 0.001$) (Figure IV.B.3).

Figure IV.B.2. Proportion of providers reporting they review CVD risk scores more consistently than two years ago



Source: Mathematica's analysis of a provider survey administered in 2018.

Figure IV.B.3. Proportion of providers reporting they have access to risk scores while meeting with beneficiaries

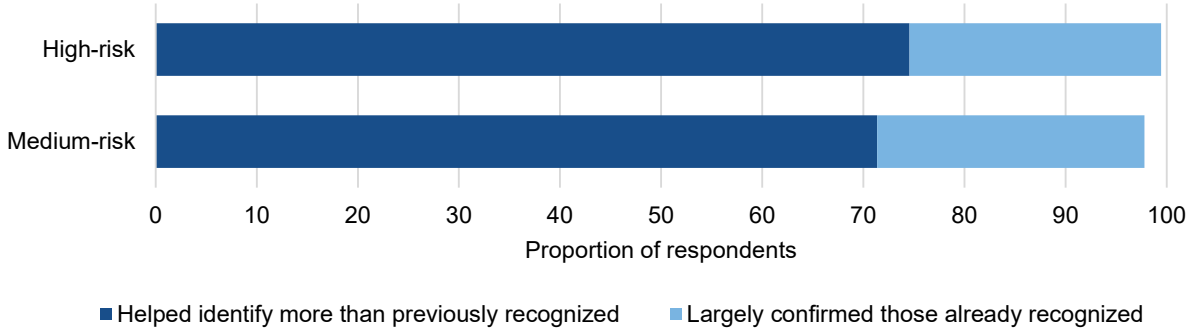


Source: Mathematica's analysis of a provider survey administered in 2018.
Note: Question asked only to providers who reported currently calculating risk scores.

c. Awareness of CVD risk in patient panel

Intervention group providers also reported that risk scores helped to identify beneficiaries with elevated CVD risk. Among intervention providers who reported reviewing risk scores more consistently now than they had two years ago, about three-fourths said that calculating risk scores has helped them identify Medicare beneficiaries with high or medium CVD risk that they had not previously recognized as high or medium risk. (Figure IV.B.4). The remaining intervention organization providers (about one-fourth) reported that risk calculation has largely confirmed Medicare beneficiaries already recognized with elevated CVD risk.

Figure IV.B.4. Proportion of intervention group providers who reported that risk calculation has helped identify high- and medium-risk beneficiaries



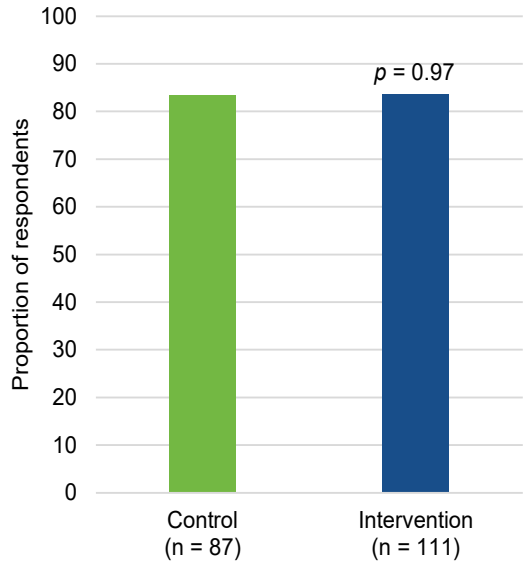
Source: Mathematica's analysis of a provider survey administered in 2018.

Note: Questions asked only of the 100 intervention group providers (of 128 total) who reported they review risk scores more consistently than two years ago.

d. Notifying high-risk beneficiaries

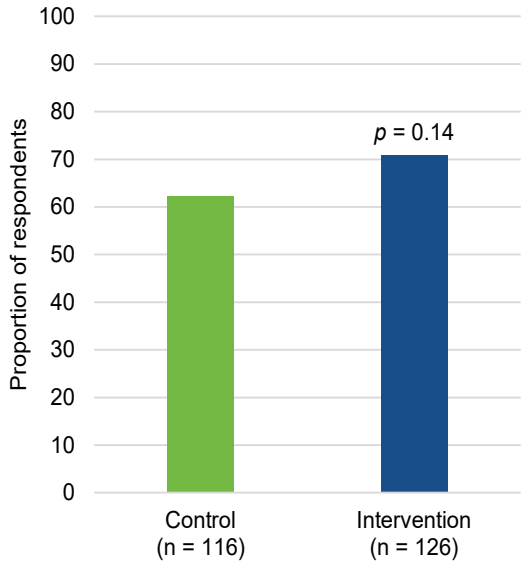
Model participation slightly increased the likelihood of notifying high-risk beneficiaries, but nearly all intervention and control providers who calculated risk scores reported notifying beneficiaries of their scores. Only 3 percent of intervention providers reported they did not notify beneficiaries of their risk scores compared with 9 percent of control providers (p=0.06). More than 80 percent of intervention and control organization providers who calculated risk scores reported they almost always engaged in follow-up discussions with high-risk beneficiaries about steps to take to reduce their risk (Figure IV.B.5). In addition, a majority of intervention and control organization providers (71 percent and 62 percent, respectively) considered risk scores a valuable tool for engaging beneficiaries in understanding and managing their risk factors (Figure IV.B.6). However, a small group of providers in both groups somewhat or strongly disagreed (14 percent of intervention providers and 14 percent of control providers).

Figure IV.B.5. Proportion of providers reporting they always or almost always engage in follow-up discussions with high-risk beneficiaries about steps to reduce CVD risk



Source: Mathematica's analysis of a provider survey administered in 2018.
Note: Question asked only of providers who reported they currently calculate risk scores. Not all providers responded to this question.

Figure IV.B.6. Proportion of providers reporting they believe risk scores are a valuable tool for engaging patients



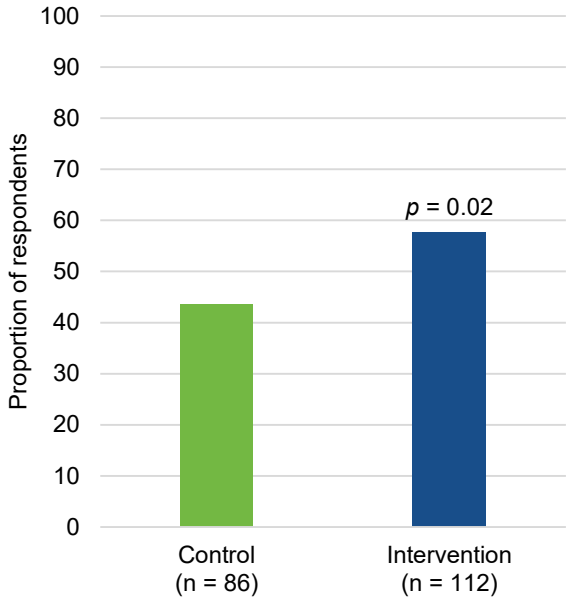
Source: Mathematica's analysis of a provider survey administered in 2018.
Note: Not all providers responded to this question.

2. Cardiovascular care management

a. Frequency of follow-up with high-risk beneficiaries

Compared to control group providers, providers from intervention organizations reported following up more frequently with high-risk beneficiaries. More than 80 percent of both intervention and control providers reported following up at least every six months with high-risk beneficiaries. However, 58 percent of intervention providers reported following up more frequently—at least every three months—compared with 43 percent of control providers (p=0.02) (Figure IV.B.7). Although frequency of follow-up does not necessarily imply differences in treatment to manage CVD risk factors, it does suggest the possibility of more active management. The survey question asked about follow up through any mode, which can include phone calls. Therefore, the impact on follow-up does not necessarily imply greater rates of in-person visits. (Indeed, as shown in Section IV.3.d, claims data indicate the model did not increase rates of in-person visits.)

Figure IV.B.7. Proportion of providers reporting follow-up with high-risk beneficiaries through any mode to monitor plans to reduce risk at least every three months



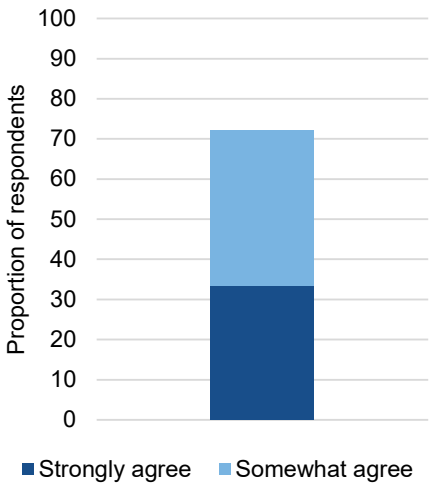
Source: Mathematica's analysis of a provider survey administered in 2018.

Note: Question asked only of providers who reported currently calculating risk scores. Not all providers responded to this question.

b. Provide standard of care for CVD risk reduction

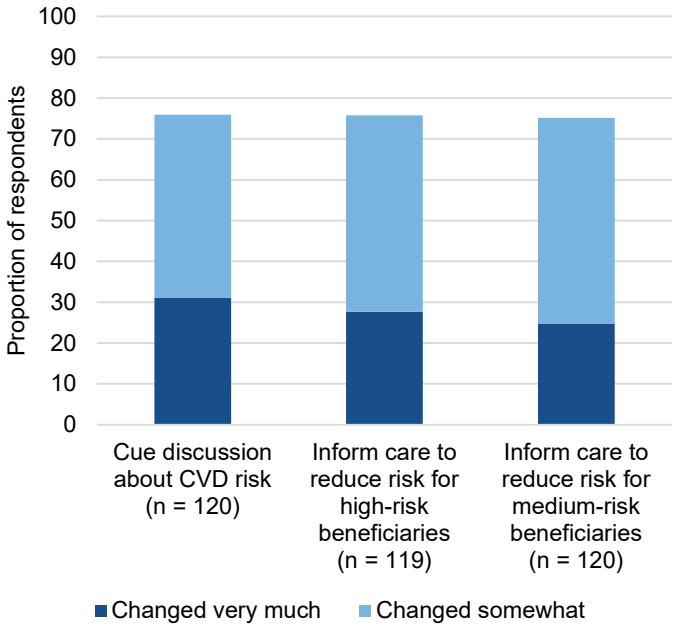
Most providers from intervention organizations reported that Million Hearts Model participation prompted changes to their standard of care for CVD risk reduction. Of the 96 percent of intervention providers who were aware of their organization's participation in the model, most (72 percent) somewhat or strongly agreed that the model has prompted their organization to provide more systematically what is considered the current standard of care (Figure IV.B.8).[21] In addition, three-fourths of intervention providers reported that participating in the model has changed how they use CVD risk scores to cue discussions about CVD risk with beneficiaries and inform clinical care to reduce risk in high- and medium-risk beneficiaries (Figure IV.B.9).

Figure IV.B.8. Proportion of intervention group providers reporting that Million Hearts prompted their organization to provide more systematic standard of care



Source: Mathematica's analysis of a provider survey administered in 2018.
Note: Question asked only of the 121 intervention group providers who knew of their organization's participation in Million Hearts.

Figure IV.B.9. Proportion of intervention group providers reporting that participating in Million Hearts changed their use of CVD risk scores



Source: Mathematica's analysis of a provider survey administered in 2018.
Note: Questions asked only of providers who knew of their organization's participation in Million Hearts. Not all providers responded.

Control providers' CVD preventive care changes. A total of 80 percent of control provider survey respondents were aware that their organization participated in the Million Hearts Model.

[21] The survey did not define what is considered the current standard of CVD preventive care.

Among these providers, 47 percent somewhat or strongly agreed that model participation had prompted their organization to provide more systematically what is considered the current standard of care in the field. More than half reported that they changed how they use CVD risk scores to cue discussions about CVD risk with beneficiaries and inform clinical care to reduce risk for both high- and medium-risk beneficiaries.

These changes could be considered contamination of the control group, because they may reflect changes in CVD care that control organizations made because of their participation in the model.[22] If so, this suggests that our estimated impacts on short- and long-term beneficiary outcomes might be somewhat smaller than the true impacts. True impacts would be best measured using a control group that did not make any improvements due to participating in the model (but that might very well make improvements for other reasons, such as staying current with evolving clinical guidelines for CVD care).

c. Initiating and intensifying CVD medication

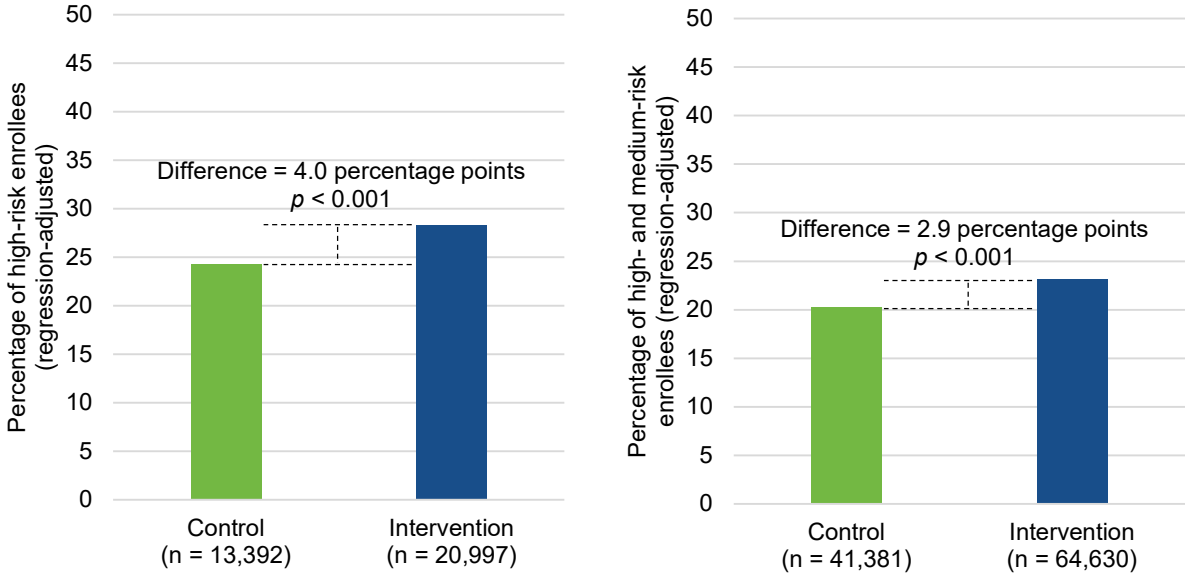
Overall, the evidence indicates that the Million Hearts Model modestly increased the initiation and intensification of medication interventions (statins and antihypertensives) to reduce CVD risk among high-risk enrollees, and among the high- and medium-risk groups combined (Table IV.B.2). Of the medium- and high-risk enrollees with Part D coverage, about 90 percent were candidates for CVD drug initiation or intensification (see text box for definitions). For this group, we found the following:

- Among **high-risk enrollees**, the regression-adjusted probability of having statins or antihypertensives initiated or intensified within six months of enrollment was 4 percentage points higher in the intervention group than the control group (28 percent in the intervention group and 24 percent in the control, $p < 0.001$).

[22] The control group could also have made improvements that are not due to participating in the model, but instead due to other quality improvement intiatives or due to general evolution in usual care. Those changes are not contamination.

- Among **medium and high-risk enrollees**, the regression-adjusted probability of initiating or intensifying statins or antihypertensive medications was 3 percentage points higher in the intervention group than the control group (23 percent in the intervention group and 20 percent in the control group, $p < 0.001$). Given that the number of beneficiaries in the combined high-and medium-risk group is three times that in the high-risk alone, but that the effect size is only slightly attenuated compared with results from the high-risk beneficiaries, these results suggest some positive spillover impacts to the medium-risk beneficiaries (Figure IV.B.10, Table IV.B.2).

Figure IV.B.10. Initiating and intensifying statins or antihypertensive medication among eligible high-risk enrollees (left panel) and combined high- and medium-risk enrollees (right panel) in the first six months after enrollment, by intervention group



Source: Mathematica's analysis of Medicare Part D claims.

Table IV.B.2. Estimated impacts on initiating or intensifying CVD-related medications (statins and antihypertensives)

Outcome measure	Regression-adjusted percentage		Difference (*p*-value) [90% confidence interval]			N
	Intervention group	Control group				
Panel A: Analyses with high-risk beneficiaries enrolled by participating organizations						
Statin or antihypertensive medication intensification or initiation	28.3	24.3	4.0	(*p* < .001)	[2.4, 5.6]	34,389
Antihypertensive medication intensification or initiation	24.1	22.0	2.1	(*p*=0.009)	[0.8, 3.5]	27,836
Initiation	40.2	35.9	4.3	(*p*=0.011)	[1.5, 7.1]	3,961
Intensification	21.5	19.6	1.9	(*p*=0.02)	[0.6, 3.3]	23,875
Statin intensification or initiation	15.5	11.5	4.0	(*p* < .001)	[2.7, 5.4]	27,297
Initiation	24.5	20.2	4.2	(*p* < .001)	[2.3, 6.2]	12,588
Intensification	8.0	4.2	3.7	(*p* < .001)	[2.5, 5.0]	14,709
Panel B: Analyses with medium- or high-risk beneficiaries enrolled by participating organizations						
Statin or antihypertensive medication intensification or initiation	23.1	20.2	2.9	(*p* < .001)	[1.8, 4.1]	106,011
Antihypertensive medication intensification or initiation	21.1	19.5	1.6	(*p*=0.01)	[0.5, 2.6]	70,487
Initiation	28.6	25.8	2.8	(*p*=0.02)	[0.9, 4.7]	14,372
Intensification	19.2	17.4	1.8	(*p*=0.003)	[0.8, 2.8]	56,115
Statin intensification or initiation	13.5	10.6	2.9	(*p* < .001)	[1.9, 3.9]	91,015
Initiation	20.4	17.1	3.3	(*p* < .001)	[2.0, 4.7]	45,465
Intensification	6.6	4.2	2.5	(*p* < .001)	[1.6, 3.3]	45,550

Source: Medicare Part D claims.

Note: Analysis included beneficiaries enrolled in Medicare Part D, who met eligibility criteria for statin initiation or intensification (those with LDL cholesterol at baseline of greater than 70 mg/dL) or for antihypertensive initiation or intensification (those with systolic blood pressure greater than 130 mm Hg).

Consistent with findings from the overall use of CVD medications, we found evidence of positive model impacts on initiating or intensifying statin therapy and antihypertensive medications individually (Table IV.B.2). Among high-risk enrollees, the impact estimates were modestly larger (4 percentage points) for statins than for antihypertensive medications (2 percentage points). Overall, beneficiaries (in either treatment or control) were more likely to initiate or intensify antihypertensive medications within six months of enrollment than they were to initiate or intensify statin therapy (Table IV.B.2).

For statins and antihypertensives, the model appears to have increased both intensification and initiation, which Table IV.B.2 reports separately. Most (83 percent) medium- and high-risk enrollees already took antihypertensive medications at enrollment, so the population-wide increase in antihypertensive medication is driven by intensification of medications for those already taking antihypertensive medications. In contrast, slightly more than one-third (36 percent) of the medium- and high-risk enrollees did not take statins at baseline, so initiation and intensification almost equally drove the population-wide impacts on increases in statin use.

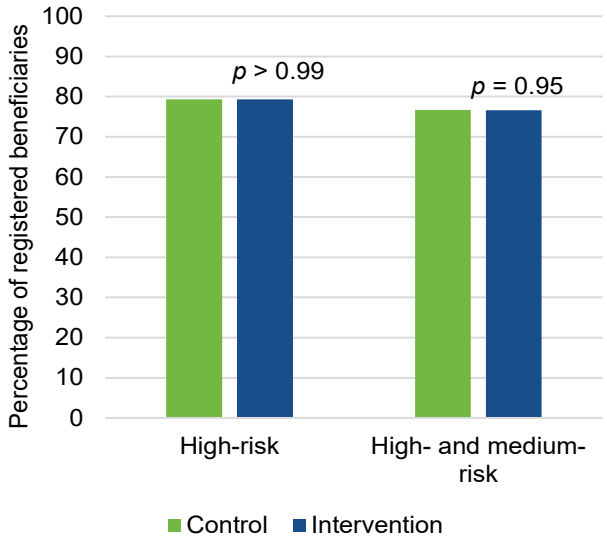
These impact findings were consistent with several robustness checks, increasing our confidence in them. We conducted a sensitivity analysis by implementing two additional regression models, one with the trimmed population and the other with a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification (systolic blood pressure greater than or equal to 140 mm Hg versus systolic blood pressure greater than or equal to 130 mm Hg in the major analysis). Both models provided results consistent with the findings from the major analysis (detailed results tables are available in Appendix D).

The analysis of initiating and intensifying CVD medication has several potential analytic limitations. First, we defined potential candidates for initiating and intensifying antihypertensive medication based on one systolic blood pressure reading at enrollment. This might not be sufficient to identify beneficiaries with persistently elevated blood pressure. For example, some enrollees with an elevated enrollment systolic blood pressure reading might have a normal blood pressure reading at a follow-up visit, and thus would not need to initiate or intensify antihypertensive medication. Second, we restricted this analysis to prescriptions billed under the Medicare Part D program and it might not include prescriptions filled at low-cost retail pharmacy programs with medication prices that are lower than Medicare Part D copayments or deductibles. Third, this analysis did not capture prescriptions that were written but not filled. However, all of these limitations are likely to affect both intervention and control groups, leaving us reasonably confident about our findings. Finally, we limited this analysis to initiating and intensifying medication during the first six months after enrollment and included only the registry population. For the future analysis, we will include results beyond the first six months and assess impacts on the attribution population.

d. High-risk beneficiaries with an annual in-person visit to a Million Hearts provider

The model had no measurable impact on the likelihood of having an office visit with a Million Hearts provider within 10 to 15[23] months of enrollment, for either high-risk beneficiaries ($p > 0.99$) or for both high- and medium-risk beneficiaries ($p=0.95$). This could be partly due to relatively high rates of office visits occurring for these beneficiaries: across both intervention and control organizations, nearly 80 percent of their registered beneficiaries had office visits with Million Hearts providers in their organization during this time window (Figure IV.B.11).

Figure IV.B.11. Percentage of registered beneficiaries with an office visit with a Million Hearts provider 10 to 15 months after enrollment



Source: Mathematica's analysis of claims data.

Note: Office visits with Million Hearts providers are identified using lists of providers that organizations submitted before

C. Limitations

In addition to limitations noted for specific outcomes, there are a four cross-cutting limitations for the impact estimates, some of which we plan to) address in future reports.

First, both the regsistry-based and the attribution-based impact estimates exclude almost 40 percent of the intervention and control organizations which were originally randomized for the model beause the organizations withdrew from the model before the end of the first year. Although the 60 percent of organizations that remained and are included in the impact evaluation were similar in type, location, size, and baseline participation in other initiatives, the attrition might have introduced unobserved differences between the remaining organizations that introduced some risk of bias to the estimates. In future reports, after a longer follow-up period, we can create metrics used in non-experimental studies that describe how large any unmeasured differences between the intervention and control groups would have to be to nullify any of the main impacts (Liu et al. 2013). This will help us identify how robust the main results are to potential confounders.

Second, the inconsistency between the registry- and attribution-based populations for some outcomes—especially CVD hospitalizations—raises the possibility that intervention and control organizations differ in the types of beneficiaries they can or chose to enroll among their eligible patients. This, too, could introduce bias in the main registry-based estimates. We will continue to investigate whether there are any discrepancies between the main estimates and registry-based

[23] Although the model requires a visit within 10 to 14 months after enrollment, we used a 10-to 15-month window because it aligned with the enrollment quarters that we use for other outcomes.

estimates, the possible causes for these differences, and how best to draw impact conclusions from the combined set of results.

Third, for the survey results, it is possible that intervention group providers reported what they thought they should report, rather than what they actually did. This could lead to apparent improvements in CVD preventive care that are not real. We designed the provider survey to mitigate this possibility—both by picking a randomly selected provider (rather than picking a model champion at the organization) and by asking questions in ways that limit the social desirability of certain responses. Further, the improvement in CVD medications observed in Part D claims independently corroborates the survey findings.

Finally, the provider survey results—as discussed in Section IV.B.2—suggest that that there has been some contamination of the control group. That is, control group providers self-report making some improvements in CVD care due to participating in the model that are beyond any improvements that they would have made from general improvements in usual care. This contamination would make impact estimates for study outcomes smaller than they would be if we compared to a true counterfactual that participating in the model did not influence. A simple calculation shows that the potential contamination could reduce the estimated effect of the model by about 30 percent.[24]

[24] Specifically, we could first assume that impacts in risk stratification drove the observed increase in CVD medication use. This would translate into a 0.13 percentage point impact in initiating or intensifying medication for each 1 percentage point impact on increases in risk stratification. We could then assume that, absent participation in the intervention (that is, absent contamination), the control group would not increase risk stratification at all. Instead control organizations would continue with risk stratification at the rate reported at baseline (this assumption, although unrealistic, aims to give an upper bound for the potential influence of contamination on the impact estimates). This would lead to an impact on risk stratification (relative to a true usual care counterfactual) of 41 percentage points, instead of the observed 31 percentage points. Using the scalar for converting increases in risk stratification to increases in medication use, this would translate to a 5.3 percentage increase in CVD medications. That is, under these assumptions, the contamination would cause the impact estimate to be about one-third smaller than the true impact (4.0 versus 5.3 percent impact on use of CVD medications).

This page has been left blank for double-sided copying.

V. POTENTIAL MECHANISMS FOR OBSERVED IMPACTS AND PROSPECTS FOR FUTURE IMPACTS

In this chapter, we describe potential mechanisms that might help explain observed impacts to date and then identify the implications for the model to achieve the goal of reducing CVD events. Finally, we consider how the observed impacts compare with other research on the use of CVD risk scores in clinical care on improvements and impacts on CVD events.

A. Potential mechanisms for observed impacts

This chapter synthesizes implementation and impact findings to accomplish two goals. The first is to explain the potential mechanisms driving the impact estimates we have observed thus far—that is, improvements in CVD care, improvements in use of CVD medications, and reductions in mortality of about 7 percent. The second goal is to describe the prospects for the model reducing first-time heart attacks, strokes, and TIAs over a longer follow-up period. We also describe how these study findings compare with, and contribute to, related studies in the broader cardiovascular literature.

1. Mechanisms for improvements in CVD care

The improvements in organizational-level CVD care processes appear to be due to a combination of (1) the incentives and supports from CMS, and (2) participating organizations committing to themselves and to CMS to follow through with the intervention described in the model. Incentive payments to intervention organizations were relatively modest (mean of $34,784 and median of $10,850 per organization in the first 18 months of the model). Among survey respondents, 60 percent of organizations agreed that payments were at least somewhat important to the organization's decision to join and stay in the model (without about one-third strongly agreeing and the other one-third somewhat agreeing). Interviews with providers and staff at 14 organizations revealed additional perspectives: half the organizations we interviewed said that, although financial incentives played a role in their decision, the goals of the model aligned with other organizational goals, and the financial incentives were not their primary motivation for implementing the model.

This finding has important implications for any potential future expansion of the model because it appears that the financial incentives the model currently offers would be insufficient, just by themselves, to generate the types of improvements in CVD care observed. Any expansion would likely have to be coupled with expectations (similar to those in the current model) about the specific care improvements organizations would make, and ways to emphasize the commitments that organizations are making to implement the model.

2. Mechanisms for increases in CVD-medications

From the surveys and interviews, it appears there are three drivers for the increased use of CVD medications. First, the act of *risk stratifying makes providers more aware of CVD risks* (and how they combine to create an overall CVD risk for the patients), helping providers to identify need

for CVD medications and other risk-reduction measures (such as diet and exercise) that might otherwise have been missed. As discussed earlier, most surveyed providers (75 percent) said that the model has increased their awareness of CVD risk among their patient panel.

Second, the model has *increased the extent to which providers focus on reducing CVD risk*—so, even when providers already knew about a patient's risk factors, they appear to have paid more attention to prescribing medications or recommending lifestyle changes that can reduce those risks. One way that organizations have continued to keep a patient's CVD risk in the forefront of providers' minds is to prominently display a patient's risk score on the patient's EHR record (52 percent of intervention organizations reported doing this, with 41 percent reporting newly doing so since they joined the Million Hearts Model).

Third, in interviews, providers noted that *discussing risk scores with patients*—and the factors driving those scores—helped make patients more receptive to taking medications. In particular, providers noted that patients are sometimes concerned about the side effects of statins, and seeing risk scores helps to convince patients that the benefits of taking statins outweigh the potential risks. This is consistent with our finding of larger impacts on initiating or intensifying statins (a 4.0 percentage point increase) than we did for blood pressure medications (a 2.1 percentage point increase).

The increases in medication use do not appear to be due to a general increase in the frequency of patients visiting with Million Hearts providers. On average, high-risk enrollees met in person with Million Hearts providers about three times in the year before enrollment and three times in the year after enrollment—well above the model requirement of one in-person visit each year. So, rather than increasing the frequency of in-person visits with Million Hearts providers, the model appears to change the content of those visits, adding a particular focus on CVD risk factors and ways to reduce them. This is consistent with our finding that providers reported they often could fit the requirements to discuss CVD risk at enrollment and annually thereafter into visits the patients already had planned with the practice.

3. Mechanisms for reductions in all-cause mortality rates

The observed impacts on all-cause survival are surprising in two ways: (1) they occurred quickly—within just 1.5 years of enrollment and (2) they occurred without any corresponding reduction in CVD events. We expect reductions in fatal hearts attacks or strokes would, at least partly, drive any impacts on survival. The estimates on survival are interim for now, given the relatively short duration of follow-up; it will be essential to assess whether any early impacts persist over the full five-year model test. Nonetheless, there are at least two potential explanations for early impacts on survival that do not operate through apparent reductions in heart attacks, strokes, or TIAs. The first is that, by measuring CVD events in hospital and ED claims data, we might miss some true model impacts on a particular type of CVD event—fatal heart attacks or strokes in which patients are pronounced dead outside of the hospital setting and are not transported to the hospital. Second, there could be reductions in mortality for other conditions, such as peripheral vascular disease, that could result from smoking cessation, improvement in exercise or diet, or medication therapy. In post hoc analyses, we identified that

improvements in CVD medications could at least partly mediate the impacts on survival, and we plan to explore this further for future reports.

4. Mechanisms for positive spillover to medium-risk beneficiaries

The model appears to have improved the use of CVD medications and improved all-cause survival for medium-risk beneficiaries in addition to the high-risk enrollees. CMS anticipated that such positive spillover might occur, and evidence from the baseline clinical data, the provider survey, and interviews provide insight into how that might happen. Specifically, baseline clinical data show that medium-risk beneficiaries have substantial modifiable CVD risk—on average, their CVD risk scores would decline by about 28 percent if, in a year, they met clinical targets for their modifiable risk factors. Second, the provider survey showed that the model has substantially increased risk stratification of *all* Medicare beneficiaries, and that risk stratification makes providers newly aware of CVD risk (high and medium risk) among their beneficiary population. In addition, providers we interviewed said the model has increased their awareness of CVD risk among their medium-risk beneficiaries as well, prompting more intensive therapies for this group. This, in turn, can drive the observed impacts on CVD medications and, potentially, on all-cause survival (though the impacts on survival must be confirmed over a longer time horizon).

B. Prospects for future impacts on CVD events

While we have not seen any impacts on CVD events yet, there are a few reasons to expect there could be impacts by the end of the fifth year, when we can fully test the prespecified primary hypothesis.

- First, there is significant modifiable CVD risk within the target populations. Specifically, modifiable risk factors (blood pressure, LDL levels, smoking, and aspirin use) account for almost 40 percent of estimated baseline CVD risk among high-risk enrollees, and almost 30 percent of baseline risk for medium-risk beneficiaries.
- Second, although substantial loss to follow-up limit the data for this assessment, CVD risk scores have improved substantially within the intervention group. Specifically, we see an average 7 percentage point reduction in CVD risk scores among high-risk enrollees a year after enrollment. Those reductions in risk have been driven primarily by improvements in blood pressure (a mean decrease of 6 mm Hg), followed by improvements in LDL cholesterol (mean decrease of 5 mL/dg), an increase in the percentage of people taking aspirin (from 50 to 66 percent), and a small reduction in the percentage of enrollees who smoke (from 12 to 11 percent). Once clinical data from the control group is available, we will have a better sense of whether or how much of this reduction is due to the model versus improvements that would have occurred without the intervention.
- Finally, the observed impact on CVD medications within 6 months of enrollment might translate into modest downstream reductions in events. The literature suggests that initiating or intensifying statins or blood pressure medications reduce CVD events on the order of 25 percent (Karmali et al. 2016, and Lloyd-Jones et al. 2017). The 2.1 percentage point increase in the use of anti-hypertensive medications (initiation or intensification) could therefore be

expected to reduce CVD events by about 0.5 percent (=2.1 percentage points*25 percent) among the 73 percent of enrollees with elevated blood pressure (or 0.4 percent for the full high-risk population). Similarly, the 4.0 percentage point increase in the use of statins could be expected to reduce CVD events by about 1 percent (=4.0 percent points*25 percent) among the 72 percent of enrollees with elevated cholesterol (or 0.7 percent for the full high-risk population). Combined, therefore, the observed impacts on both statin and anti-hypertensive medications could be anticipated to reduce CVD events for all high-risk enrollees by about 1 percent. This calculation suggests that to have the intended 7 percent reduction in CVD events overall, improvements in CVD risk factors would have to occur through more than just the medication impacts observed thus far. This could include improvements in adherence to medications (newly or already prescribed), changes in diet or exercise, or smoking cessation. Further, our medication analysis might not have captured all the ways providers could initiate or intensify medications, because we focus on a relatively short window (six months after enrollment) and because we have not included some recently developed medications that can also reduce CVD risk factors, such as PCSK9 inhibitors.

The model will have to overcome important challenges to reduce CVD events. The first is that some organizations have continued to withdraw from the model. Further attrition would reduce the active intervention provided to beneficiaries in the intervention group—though, if the reason an organization withdraws is largely due to challenges with meeting data reporting requirements (and not because it disliked the model's care delivery changes), we might expect any positive effects of the model on the organization's clinical CVD care could persist after withdrawal. Second, although CVD risk is modifiable for many people, it might not be for all. Indeed, some providers we interviewed did not discuss risk scores with patients whose risk was driven largely by factors that could not be modified. Third, as indicated by the high baseline office visit rates and high rates of medication use at baseline, these patients have already had their CVD risk factors managed to a fair degree—limiting the room for further improvement for some beneficiaries. Fourth, many providers noted that patients can choose not to adhere to any treatment recommendations to reduce CVD risk. Finally, as described in Section I.A, there have recently been many efforts to improve the ABCS in clinical care—including public and private payers providing bonuses to providers who perform well on, for example, blood pressure control for their patient panels. These efforts might generally improve CVD care in the intervention and control groups. Although clearly a benefit for population health overall, those improvements might make it more difficult for the Million Hearts Model to add value beyond improvements in usual care.

C. Comparison of findings with other studies

Several recent reviews have examined the impacts of using CVD risk scores in clinical care on improvements in CVD medications and subsequent reductions in CVD risk factors, global risk, and CVD events (Studziński et al. 2019; Collins et al. 2017; Karmali et al. 2017). The primary studies covered in these reviews assess impacts of providing CVD risk scores to providers, to patients, or both—and sometimes (as with the Million Hearts Model) couple risk scoring with other interventions (such as care management services) to reduce CVD risk factors. Overall, the evidence in support of using CVD risk scores to guide patient care is limited.

Studies examining the impacts of CVD risk scoring (compared to a usual care of not risk scoring or doing so only opportunistically) have significant limitations in design, including small sample sizes. However, the available evidence suggests the use of risk scores has increased use of CVD medications and modestly reduced follow-up risk scores and their individual clinical components. For example, Karmali et al. (2016) found that—across a dozen randomized trials conducted from 2003 to 2015—CVD risk scoring for the primary prevention of CVD increased initiation or intensification of CVD medications by an average of 47 percent, reduced systolic blood pressure by an average of 2.8 mm Hg, and reduced cholesterol by 1.2 mg/dL. The use of risk scoring has not been shown to reduce the frequency of CVD events, though most studies are either too underpowered or have too short a duration of follow-up to truly test impacts on CVD events. Studziński et al. (2019) concluded that some of the reasons risk scoring has not had larger effects might include that (1) many providers identify their patients' CVD risk factors, and initiate appropriate treatments, without formal risk scoring; and (2) risk scores can over- or under-estimate actual risk for some patients, leading to over- or under-treatment of risk factors. Risk scores could be poorly calibrated to actual risk given the limited number of variables entering the risk-scoring algorithms, the development of the algorithms from cohorts in the 1980s and 1990s when usual care for CVD risk factors was much different, and random fluctuations in blood pressure readings over time (a key driver of predicted risk).

Overall, our findings to date are consistent with these reviews, though they provide additional granularity about upstream CVD care processes, larger samples, and a focus on the Medicare FFS population (whereas the reviews focus on primary prevention in the general adult population). We too have found effects on CVD medications, and no effects in the short term on CVD events. However, we found large effects of the model on use of CVD risk scores, and that most providers report that using risk scores is valuable for identifying CVD risk which might have otherwise gone unnoticed.

Finally, unlike the primary studies cited in the reviews that are often small-scale clinical trials implemented in highly controlled settings, the Million Hearts Model is a pragmatic trial, including many different types of organizations throughout the country. Further, the model is most directly a test of incentives and supports from CMS to encourage adopting risk stratification and CVD care management strategies. It is not a direct test of CVD risk stratification itself, as was the case of the studies included in the reviews. As such, this study adds an important additional element to the literature—that incentives and supports from a major payer can lead to proximate improvements in CVD care processes in a wide range of organization types. It remains unclear in this study, due to the short period currently covered, whether these proximate improvements will ultimately reduce the incidence of first-time heart attacks, strokes, and TIAs.

VI. 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; we also will continue to review documentation on why organizations withdraw from the model in 2019 (if applicable). We will use quantitative implementation metrics to describe how, and the extent to which, organizations have implemented the model. In addition, the evaluation team will extend the outcome period for estimating impacts on all final beneficiary outcomes, will potentially add new outcome measures (such as adherence measures), and will continue to conduct robustness checks. The third annual report of the evaluation will report all of these analyses.

A. Implementation evaluation

The current annual report focuses on describing organizations' experiences as they entered their third year of implementing the Million Hearts Model. In the upcoming year, the evaluation team will interview organizations, some of which are in the current report and some that are new to the study, as necessary, if there is attrition within this sample. The upcoming interviews planned for early 2020 will cover the following topics:

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

In addition, the evaluation team will continue to review and categorize data provided by CMS on why organizations withdraw from the model in 2019; if the analysis requires additional clarification, we will conduct exit interviews with up to five organizations that withdraw from the model to better understand 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 implement the model. Using data from the Million Hearts Data Registry, the team will construct measures such as 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.

B. Impact evaluation

For next year's analyses, we will (1) extend the outcome period by one year for all long-term outcomes; (2) potentially add (in discussion with CMS) new claims-based outcome measures, including examining impacts on particular types of hospitalizations and ED visits to help explain the unexpected result that the model appears to have increased use of some acute care services; and (3) assess the quality of the control group clinical data. For these analyses, we will assess what share of relevant clinical metrics have missing values or biologically implausible values. If

the control group clinical data appear useable based on these assessments, we will estimate impacts on CVD risk scores and their clinical components. We will also continue to conduct robustness checks—including comparing primary estimates (based on model enrollees) to estimates that define the study population using claims-based attribution.

Finally, in collaboration with the implementation team, we will continue to monitor the participation rate of organizations. Further attrition from the model will not affect the study population for impact estimates (given our intent-to-treat analytic approach), but it will decrease the share of people in the treatment group who are enrolled by organizations continuing to participate in the model, which might—or might not—dilute overall impacts of the program.

Overall, the findings to date indicate that model has had positive impacts on CVD care processes along the lines CMS envisioned. Future implementation analyses will assess how implementation of the model continues to unfold, and future impact estimates will assess whether improvements in care processes ultimately reduce heart attacks, strokes, TIAs, and Medicare spending.

This page has been left blank for double-sided copying.

REFERENCES

Alexander, J.A., and L.R. Hearld. "Methods and Metrics Challenges of Delivery System Research." *Implementation Science*, vol. 7, no. 15, 2012, pp. 15–26.

Arnett, D.K., R.S. Blumenthal, M.A. Albert, A.B. Buroker, Z.D. Goldberger, E.J. Hahn, C.D. Himmelfarb, A. Khera, D. Lloyd-Jones, J.W. McEvoy, E.D. Michos, M.D. Miedema, D. Munoz, S.C. Smith Jr, S.S. Virani, K.A. Williams Sr, J. Yeboah, B. Ziaeian. "2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: Executive Summary." *Circulation,* 2019, doi: 10.1161/CIR.0000000000000677.

Benjamin, Emelia J., Paul Munter, Alvaro Alonso, Marcio S. Bittencourt, Clifton W. Callaway, April P. Carson, Alanna M. Chamberlain, et al. "Heart Disease and Stroke Statistics—2019 Update: A Report from the American Heart Association." *Circulation,* vol. 139, no. 10, 2019, pp. e56–e528. Available at https://www.ahajournals.org/doi/10.1161/CIR.0000000000000659.

Bibbins-Domingo, K., on behalf of the U.S. Preventive Services Task Force. "Aspirin Use for the Primary Prevention of Cardiovascular Disease and Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement." *Annals of Internal Medicine,* vol. 164, no. 12, 2016, pp. 836–845. doi: 10.7326/M16-0577.

Carey, R.M., and P.K. Whelton, for the 2017 ACC/AHA Hypertension Guideline Writing Committee. "Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Synopsis of the 2017 American College of Cardiology/American Heart Association Hypertension Guideline." *Annals of Internal Medicine,* vol. 168, no. 5, 2018, pp. 351–358. doi: 10.7326/M17-3203.

Centers for Disease Control and Prevention (CDC). "CDC Grand Rounds: The Million Hearts Initiative." *Morbidity and Mortality Weekly Report,* vol. 61, no. 50, 2012, p. 1017.

Centers for Medicare & Medicaid Services. "Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy." Baltimore, MD: Centers for Medicare & Medicaid Services, 2017. Available at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/TaxonomyCrosswalk.pdf. Accessed September 6, 2018.

Chronic Conditions Data Warehouse. "CCW Chronic Conditions Algorithms." 2017. Available at https://www.ccwdata.org/web/guest/condition-categories. Accessed November 2017.

Chu, P., A. Pandya, J.A. Salomon, S.J. Goldie, and M.G. Hunink. "Comparative Effectiveness of Personalized Lifestyle Management Strategies for Cardiovascular Disease Risk Reduction." *Journal of the American Heart Association,* vol. 5, no. 3, 2016, pp. 1–16. doi: 10.1161/JAHA.115.002737.

Colantonio, L.D., R.S. Rosenson, L. Deng, K.L. Monda, Y. Dai, M.E. Farkouh, M.M. Safford, K. Philip, K.E. Mues, and P. Muntner. "Adherence to Statin Therapy Among U.S. Adults Between 2007 and 2014." *Journal of the American Heart Association,* vol. 8, no. 1, 2019, pp. 1–20. doi: 10.1161/JAHA.118.010376.

Collins, D.R.J., A.C. Tompson, I.J. Onakpoya, N. Roberts, A.M. Ward, and C.J. Heneghan. "Global Cardiovascular Risk Assessment in the Primary Prevention of Cardiovascular Disease in Adults: Systematic Review of Systematic Reviews." *BMJ Open*, vol. 7, no. 3, March 2017, pp. 1–13. Available at https://bmjopen.bmj.com/content/7/3/e013650.

Conwell, L., L. Barterian, A. Rose, G. Peterson, K. Kranker, L. Blue, D. Magid, M. Williams, A. Steiner, R. Sarwar, J. Tyler, E. Brand, M. Barna, D. Kinber, N. Fu, T. Concannon, and N. McCall. "Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model: First Annual Report." Prepared for the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Princeton, NJ: Mathematica, February 2019.

Damschroder, L.J., D.C. Aron, R.E. Keith, S.R. Kirsh, J.A. Alexander, and J.C. Lowery. "Fostering Implementation of Health Services Research Findings into Practice: A Consolidated Framework for Advancing Implementation Science." *Implementation Science*, vol. 4, no. 50, 2009.

Eckel, R.H., J.M. Jakicic, J.D. Ard, J.M. de Jesus, N. Houston Miller, V.S. Hubbard, I.M. Lee, A.H. Lichtenstein, C.M. Loria, B.E. Millen, C.A. Nonas, F.M. Sacks, S.C. Smith Jr., L.P. Svetkey, T.A. Wadden, S.Z. Yanovski, K.A. Kendall, L.C. Morgan, M.G. Trisolini, G. Velasco, J. Wnek, J.L. Anderson, J.L. Halperin, N.M. Albert, B. Bozkurt, R.G. Brindis, L.H. Curtis, D. DeMets, J.S. Hochman, R.J. Kovacs, E.M. Ohman, S.J. Pressler, F.W. Sellke, W.K. Shen, S.C. Smith Jr., G.F. Tomaselli, and American College of Cardiology/American Heart Association Task Force on Practice Guidelines. "2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." *Circulation,* vol. 129, no. 25, 2014, pp. S76–S99. doi: 10.1161/01.cir.0000437740.48606.d1.

Goff, D.C., D.M. Lloyd-Jones, G. Bennett, S. Coady, R.B. D'Agostino Sr., R. Gibbons, et al. "2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." *Circulation,* vol. 129, suppl. 2, 2014, pp. S49–S73. doi: 10.1161/01.cir.0000437741.48606.98.

Grundy, S.M., N.J. Stone, A.L. Bailey, C. Beam, K.K. Birtcher, R.S. Blumenthal, L.T. Braun, S. de Ferranti, J. Faiella-Tommasino, D.E. Forman, R. Goldberg, P.A. Heidenreich, M.A. Hlatky, D.W. Jones, D. Lloyd-Jones, N. Lopez-Pajares, C.E. Ndumele, C.E. Orringer, C.A. Peralta, J.J. Saseen, S.C. Smith Jr, L. Sperling, S.S. Virani, and J. Yeboah. "2018 AHA/ACC/AACVPR /AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol." *Journal of the American College of Cardiology,* 2018. doi: 10.1016/j.jacc.2018.11.003.

Imai, K., and M. Ratkovic. "Covariate Balancing Propensity Score." *Journal of the Royal Statistical Society: Series B (Statistical Methodology)*, vol. 76, no. 1, 2014, pp. 243–263. doi:10.1111/rssb.12027.

Jellinger, P.S., Y. Handelsman, P.D. Rosenblit, Z.T. Bloomgarden, V.A. Fonseca, A.J. Garber, G. Grunberger, C.K. Guerin, D.S.H. Bell, J.I. Mechanick, R. Pessah-Pollack, K. Wyne, D. Smith, E.A. Brinton, S. Fazio, and M. Davidson. "American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease." *Endocrine Practice,* vol. 23, suppl. 2, 2017, pp. 1–87. doi: 10.4158/EP171764.APPGL.

Kaplan, E.L., and P. Meier. "Nonparametric Estimation from Incomplete Observations." *Journal of the American Statistical Association,* vol. 53, no. 282, 1958, pp. 457–481. doi:10.1080/01621459.1958.10501452.

Karter, A.J., S. Nundy, M.M. Parker, H.H. Moffet, and E.S. Huang. "Incidence of Remission in Adults with Type 2 Diabetes: The Diabetes and Aging Study." *Diabetes Care,* vol. 37, no. 12, 2014, pp. 3188–3195. doi: 10.2337/dc14-0874.

Karmali, K.N., D.M. Lloyd-Jones, and M.A. Berendsen. "Drugs for Primary Prevention of Atherosclerotic Cardiovascular Disease: An Overview of Systematic Reviews." *JAMA Cardiology,* vol. 1, no. 3, June 2016, pp. 341–349. Available https://jamanetwork.com/journals/jamacardiology/fullarticle/2517393.

Karmali, K.N., S.D. Persell, P. Perel, D.M. Lloyd-Jones, M.A. Berendsen, and M.D. Huffman. "Risk Scoring for the Primary Prevention of Cardiovascular Disease." *Cochrane Database of Systematic Reviews,* no. 3, 2017, pp. 1–155. Available at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006887.pub4/abstract.

Kass, G.V. "An Exploratory Technique for Investigating Large Quantities of Categorical Data." *Applied Statistics*, vol. 29, no. 2, 1980, pp. 119–127. doi:10.2307/2986296.

Kranker, K., L. Blue, and L. Vollmer Forrow. "Improving Effect Estimates by Limiting the Variability in Inverse Propensity Score Weights." Washington DC: Mathematica, 2019. Journal manuscript under review.

Lloyd-Jones, D.M., M.D. Huffman, K.N. Karmali, D.M. Sanghavi, J.S. Wright, C. Pelser, M. Gulati, F.A. Masoudi, and D.C. Goff, Jr. "Estimating Longitudinal Risks and Benefits from Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A Special Report from the American Heart Association and American College of Cardiology." *Journal of the American College of Cardiology,* vol. 69, no. 12, 2017, pp. 1617–1636. doi: 10.1016/j.jacc.2016.10.018.

Liu, W., S. Kuramoto, and E. Stuart. "An Introduction to Sensitivity Analysis for Unobserved Confounding in Non-Experimental Prevention Research." *Prevention Research,* vol. 14(6), 2013, pp. 570-580. Do

Mensah, G.A., G.S. Wei, P.D. Sorlie, L.J. Fine, Y. Rosenberg, P.G. Kaufmann, M.E. Mussolino, L.L. Hsu, E. Addou, M.M. Engelgau, and D. Gordon. "Decline in Cardiovascular Mortality: Possible Causes and Implications." *Circulation Research,* vol. 120, no. 2, 2017, pp. 366380. doi: 10.1161/CIRCRESAHA.116.309115.

Midboe, A.M., M.A. Cucciare, J.A. Trafton, N. Ketroser, and J.F. Chardos. "Implementing Motivational Interviewing in Primary Care: The Role of Provider Characteristics." *Translational Behavioral Medicine*, vol. 1, no. 4, 2011, pp. 588–594.

National Committee for Quality Assurance. *HEDIS 2018, Volume 2.* Washington, DC: NCQA, October 18, 2017.

NORC. "The Million Hearts® Cardiovascular Risk Reduction Model: Develop Algorithm and Conduct Post Selection Randomization; Randomization Methodology Plan." Report submitted to CMS April 11, 2016. Bethesda, MD: NORC, 2016a.

NORC. "Quality Control Results – CMS Million Hearts Randomization Results." Excel file submitted to CMS. Bethesda, MD: NORC, 2016b.

Powell, B.J., J.C. McMillen, E.K. Proctor, C.R. Carpenter, R.T. Griffey, A.C. Bunger, J.E. Glass, and J.L. York. "A Compilation of Strategies for Implementing Clinical Innovations in Health and Mental Health." *Medical Care Research and Review*, vol. 69, no. 2, 2012, pp. 123–157.

Sanghavi, Darshak M., and Patrick H. Conway. "Paying for Prevention: A Novel Test of Medicare Value-Based Payment for Cardiovascular Risk Reduction." *JAMA,* vol. 314, no. 2, 2015, pp. 123–124. doi:10.1001/jama.2015.6681.

Siu, A.L., for the U.S. Preventive Services Task Force. "Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement." *Annals of Internal Medicine,* vol. 163, no. 8, 2015, pp. 622–634. doi: 10.7326/M15-2023.

Studziński, K., T. Tomasik, J. Krzysztoń, J. Jóźwiak, and A. Windak. "Effect of Using Cardiovascular Risk Scoring in Routine Risk Assessment in Primary Prevention of Cardiovascular Disease: An Overview of Systematic Reviews." *BMC Cardiovascular Disorders,* vol. 19, no. 11, 2019, pp. 1–16. Available at https://bmccardiovascdisord.biomedcentral.com/track/pdf/10.1186/s12872-018-0990-2.

Tajeu, G.S., S.T. Kent, I.M. Kronish, L. Huang, M. Krousel-Wood, A.P. Bress, D. Shimbo, and P. Muntner. "Trends in Antihypertensive Medication Discontinuation and Low Adherence Among Medicare Beneficiaries Initiating Treatment from 2007 to 2012." *Hypertension*, vol. 68, no. 3, 2016, pp. 565–575. doi: 10.1161/HYPERTENSIONAHA.116.07720.

The SPRINT Research Group. "A Randomized Trial of Intensive Versus Standard Blood-Pressure Control." *New England Journal of Medicine,* vol. 373, no. 22, 2015, pp. 2103–2116. doi: 10.1056/NEJMoa1511939.

Thygesen, K., J.S. Alpert, A.S. Jaffe, B.R. Chaitman, J.J. Bax, D.A. Morrow, H.D. White, and Executive Group on behalf of the Joint European Society of Cardiology (ESC)/American College of Cardiology (ACC)/American Heart Association (AHA)/World Heart Federation (WHF) Task Force for the Universal Definition of Myocardial Infarction. "Fourth Universal Definition of Myocardial Infarction (2018)." *Journal of the American College of Cardiology,* August 2018. Available at http://www.onlinejacc.org/content/early/2018/08/22/j.jacc.2018.08.1038?_ga=2.16360694.1985950073.1544817965-1186146721.1544817965. Accessed May 22, 2019. doi: 10.1016/j.jacc.2018.08.1038.

Vaughan, A.S., M.D. Ritchey, J. Hannan, M.R. Kramer, and M. Casper. "Widespread Recent Increases in County-Level Heart Disease Mortality Across Age Groups." *Annals of Epidemiology,* vol. 27, 2017, pp. 796–800.

Wall, H.K., M.D. Ritchey, C. Gillespie, J.D. Omura, A. Jamal, and M.G. George. "Vital Signs: Prevalence of Key Cardiovascular Disease Risk Factors for Million Hearts 2022—United States, 2011–2016." *Morbidity and Mortality Weekly,* vol. 67, no. 35, 2018, pp. 983–991. Available at https://www.cdc.gov/mmwr/volumes/67/wr/mm6735a4.htm.

What Works Clearinghouse. "Assessing Attrition Bias: Addendum." 2014. Available at https://ies.ed.gov/ncee/wwc/Docs/ReferenceResources/wwc_attrition_v3.0.pdf. Accessed May 7, 2019.

Whelton, P.K., R.M. Carey, W.S. Aronow, D.E. Casey Jr., K.J. Collins, C. Dennison Himmelfarb, S.M. DePalma, S. Gidding, K.A. Jamerson, D.W. Jones, E.J. MacLaughlin, P. Muntner, B. Ovbiagele, S.C. Smith Jr., C.C. Spencer, R.S. Stafford, S.J. Taler, R.J. Thomas, K.A. Williams Sr., J.D. Williamson, and J.T. Wright Jr. "2017 ACC/AHA/AAPA/ABC /ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines." *Journal of the American College of Cardiology,* vol. 71, no. 6, 2018, pp. 1269–1324.

Wright, J.S., H.K. Wall, and M. Ritchey. "Million Hearts 2022: Small Steps are Need for Cardiovascular Disease Prevention." *JAMA,* vol 320, no. 18, 2018, pp. 1857-1858.

This page has been left blank for double-sided copying

APPENDIX A

DEFINING THE BENEFICIARY STUDY POPULATION AND BENEFICIARY CHARACTERISTICS AT ENROLLMENT

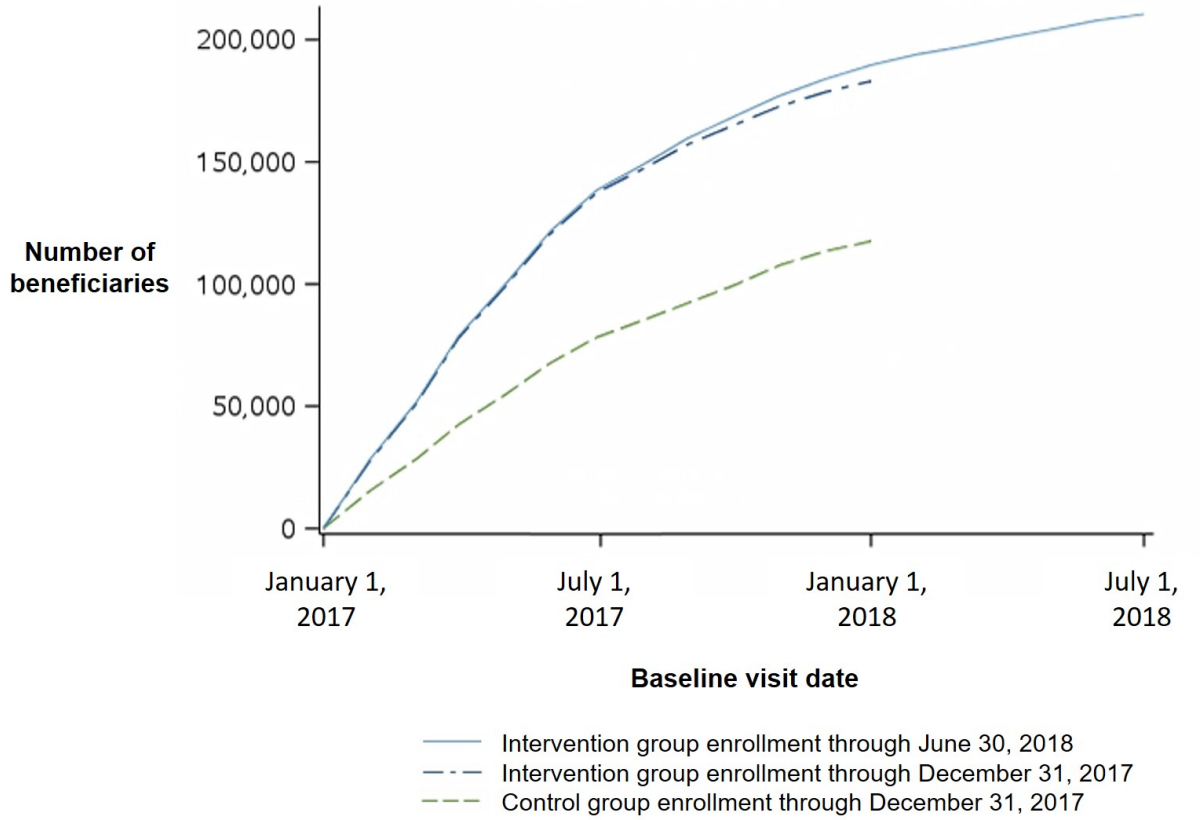
This page has been left blank for double-sided copying.

1. Defining the beneficiary study population

We used data from the Million Hearts Data Registry to define the study population for this report. The broad study population includes all Medicare fee-for-service (FFS) beneficiaries whom the participating organizations enrolled during the first three performance periods (January 2017 to June 2018). "Enrolled" means that the organization reported the beneficiary to the Million Hearts Data Registry and that CMS validated the beneficiary enrollment record. To enroll a beneficiary, an organization had to upload data to the registry on when the beneficiary had a baseline visit with the organization, as well as the demographic and clinical data needed to determine the beneficiary's baseline cardiovascular disease (CVD) risk. To validate each beneficiary's enrollment, the CMS implementation contractor used claims data to confirm that the beneficiary (1) did indeed have a visit with a provider from the organization near the time listed, and (2) met model eligibility criteria that could be replicated in claims. Medicare FFS beneficiaries met model eligibility criteria if they were ages 40 to 79, had no evidence of a prior heart attack or stroke, had Medicare as their primary payer, did not have end-stage renal disease (ESRD), and were not receiving hospice benefits.

As of the time of this report, intervention organizations reported enrollment through June 30, 2018, whereas control organizations reported enrollment only through the end of 2017. Figure A.1 shows enrollment over time. In 2017, intervention organizations enrolled a total of 183,044 beneficiaries and control organizations enrolled a total of 117,506 beneficiaries. In the first half of 2018, intervention organizations enrolled an additional 27,389 beneficiaries. Among beneficiaries newly enrolled during the first half of 2018, one-quarter had an office visit date in 2017 but the registry did not record them until after 2017. Figure A.1 shows modestly higher total enrollment in 2017 than we reported in the first annual report (Conwell et al. 2018). In that report, Table II.5 indicated that the intervention organizations enrolled 180,275 beneficiaries in 2017 and the control organizations enrolled 116,765 organizations. The reason for this difference is that, in the first annual report, we restricted to organizations that had not withdrawn by the end of 2017. By contrast, Figure A.1 in this report includes all organizations that enrolled any beneficiaries in 2017, including a few that withdrew by the end of 2017.

Figure A.1. Number of Medicare beneficiaries (any CVD risk level) enrolled into the model by intervention and control organizations from January 2017 to June 2018



Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare enrollment data.

Note: Beneficiaries newly enrolled by the intervention group after December 2017 (represented by the difference between the dashed dark blue line and the solid light blue line) include model-eligible beneficiaries with information validated for the first time in 2018, regardless of their baseline visit date.

Within this broader study population of everyone enrolled, we limited the final population used in the impact evaluation to those enrolled in 2017 and who had medium or high CVD risk at enrollment. We limited this population to 2017 enrollees because, at the time of analysis, enrollment data for the control group were current only through 2017. We limited the population to medium- and high-risk enrollees because, as the logic model (Figure I.B.1) indicates, CMS expects the model to improve outcomes for these beneficiaries. We also excluded beneficiaries who:

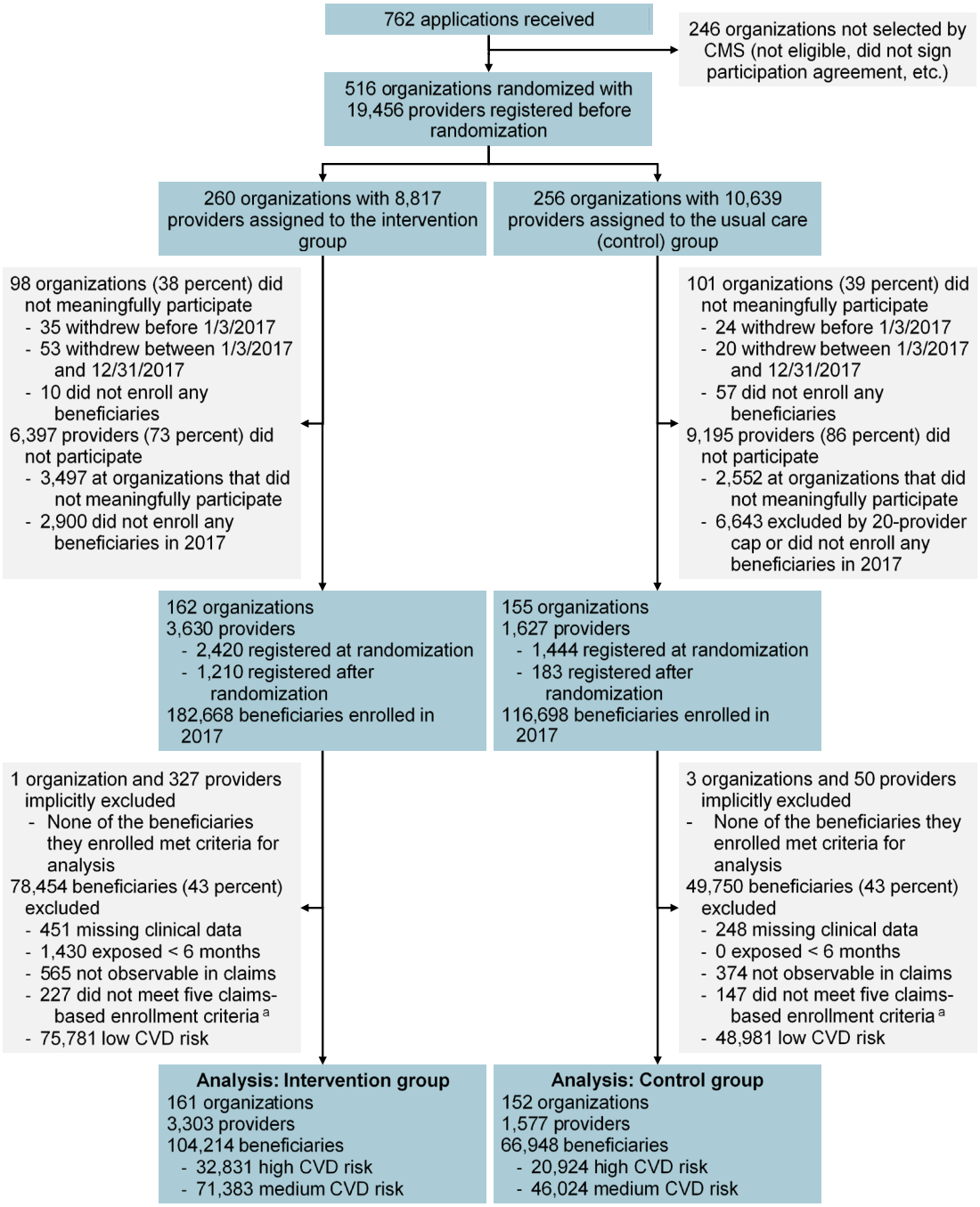
- Did not have substantial exposure to the intervention, which we defined as beneficiaries who (1) were enrolled by organizations that withdrew by the end of 2017, or (2) were enrolled by organizations that withdrew in the first half of 2018 and the difference between the person's enrollment date and the date the organization withdrew was fewer than six months.
- Were not observable in Medicare Part A and B claims during the month of enrollment, because so we could not construct study outcomes for them.

- Did not meet claims-based model eligibility criteria (for example, those who had evidence of a prior heart attack or stroke). CMS's implementation contractor only validated beneficiaries who met claims-based eligibility criteria. However, we found a very small number of enrollees who did not meet those criteria, likely due to differences in when we and the CMS implementation contractor pulled claims and Medicare enrollment data.

The final study population includes 171,162 beneficiaries (104,214 beneficiaries enrolled by 161 intervention organizations and 66,948 beneficiaries enrolled by 152 control organizations). In Figure A.2, we show the flow of organizations (and their providers and beneficiaries), from enrollment and randomization, down to the final study population.

This final study population differs slightly from the study population we reported in the first annual report (Conwell et al. 2017). In that report, we showed a similar flowchart that ended with a final study population of (1) 162 intervention organizations that enrolled 104,351 medium or high-risk beneficiaries, and (2) 153 control organizations that enrolled 67,414 medium or high-risk beneficiaries. The main reason for this difference is that we used updated data from CMS on the dates organizations withdrew from the model. That updated data showed two additional organizations withdrew in 2017 and so did not meet our study population inclusion criteria. In addition, updates in Medicare claims and enrollment data slightly changed the number of beneficiaries who met study inclusion criteria, such as being observable in Medicare claims.

Figure A.2. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation



[a]The criteria are FFS Medicare Parts A and B, ages 40–79, no prior AMI, no prior stroke, no ESRD, and no hospice.

AMI = acute myocardial infarction; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ESRD = end-stage renal disease; FFS = fee-for-service.

2. Baseline characteristics of the intervention and control groups

In this section, we provide detailed information on baseline characteristics for the 2017 enrollees—both for the high-risk and medium-risk groups combined (Table A.1) and for the high-risk group only (Table A.2). These characteristics were defined at enrollment, using the enrollee's baseline visit date to define the start of enrollment. We adjusted the baseline visit dates for 10,150 enrollees (6 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 Model provider. In these cases, we used the earliest recorded visit with a Million Hearts provider as the baseline date and, if available, updated CVD risk factor data so that they were measured on or before that date. In addition to reporting variable means or frequencies, the detailed tables report standard deviations for key variables such as hierarchical condition category (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.

The intervention and control groups were very similar at baseline with respect to beneficiary characteristics such as age, sex, predicted CVD risk, recent service use, and 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. Beneficiaries in the intervention and controls groups who were enrolled in Part D were also well balanced on medication use at baseline. For example, the number of high-risk enrollees taking high-intensity statins was 21 percent in the intervention group and 20 percent in the control group. There were some differences in the types of intervention and control organizations that enrolled beneficiaries. In particular, intervention group high-risk enrollees were, on average, enrolled by organizations that had more providers (128 versus 92) and more sites (25 versus 14) 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 33 percent) and to be enrolled in the first quarter of 2017 (47 versus 37 percent). Some of the differences in the organizational characteristics of enrolled beneficiaries are attributable to the 20-provider cap for the control organizations, which was a CMS requirement. 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.

Table A.1. Detailed baseline characteristics of medium- and high-risk Medicare beneficiaries enrolled in the Million Hearts Model in 2017, by intervention group

Characteristic	Intervention group mean (N = 104,214)	Control group mean (N = 66,948)	Difference	Standardized differencea	p-valueb
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	27 [11]	27 [10]	0.1	0.01	0.80
Modifiable risk (%)[c]	9	9	0.3	0.03	0.54
Has diabetes (%)	37	34	2.3	0.05	0.25
Systolic blood pressure (mm Hg)	134	134	-0.1	0.00	0.94
Total cholesterol (mg/dL)	174	173	1.3	0.03	0.36
HDL cholesterol (mg/dL)	50	51	-0.1	-0.01	0.88
LDL cholesterol (mg/dL)	97	95	1.4	0.04	0.27
Is current smoker (%)	11	12	-0.7	-0.02	0.41
Beneficiary medication use					
Uses aspirin (%)	45	43	1.7	0.04	0.70
Uses antihypertensives based on Part D[d] (%)	83	83	0.6	0.02	0.61
Uses statins based on Part D[d] (%)	64	64	-0.5	-0.01	0.73
Intensity of statin use based on Part D[d] (%)					
Low intensity	7	7	-0.1	0.00	0.95
Medium intensity	39	39	0.1	0.00	
High intensity	18	19	-0.5	-0.01	
Beneficiary demographic and Medicare enrollment characteristics					
Age [standard deviation]	72 [5]	72 [5]	-0.2	-0.05	0.15
Black race (%)	8	6	2.0	0.08	0.23
Male (%)	57	59	-1.6	-0.03	0.10
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.3	-0.01	0.86
Originally entitled to Medicare because of disability (%)	14	13	0.3	0.01	0.80
Beneficiary health and comorbid conditions					
HCC score [standard deviation]	1.17 [1.00]	1.17 [1.00]	0.0	0.00	0.96
Count of chronic conditions	2.1	2.1	0.0	0.01	0.80
Has chronic kidney disease (%)	25	25	0.2	0.00	0.86
Has ischemic heart disease (%)	32	34	-2.3	-0.05	0.48
Has congestive heart failure (%)	11	12	-0.6	-0.02	0.59
Has atrial fibrillation (%)	12	12	-0.1	0.00	0.94
Has morbid obesity (%)	8	7	0.3	0.01	0.69
Beneficiary medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	7,673 [16,764]	7,616 [16,826]	56.1	0.00	0.85
Hospital admissions (per 1,000 beneficiaries)	185	190	-4.6	-0.01	0.61
CVD-related hospital admissions (per 1,000 beneficiaries)[e]	35	35	-0.3	0.00	0.95
Outpatient ED visits or observation	379	363	16.3	0.01	0.37

Table A.1. (*Continued*)

Characteristic	Intervention group mean (N = 104,214)	Control group mean (N = 66,948)	Difference	Standardized differencea	p-valueb
stays (per 1,000 beneficiaries)					
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) [e]	28	27	1.2	0.01	0.71
Office visits (per 1,000 beneficiaries)	9,273	8,948	325.6	0.04	0.41
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,878	2,893	-14.3	0.00	0.96
Cardiologist visits (per 1,000 beneficiaries)	1,801	1,773	28.0	0.01	0.89
Beneficiary CVD-related procedures in year before model enrollment					
Received echocardiogram (%)	40	39	0.6	0.01	0.84
Received electrocardiogram (%)	71	70	0.5	0.01	0.88
Received cardiac stress test (%)	26	26	-0.6	-0.01	0.80
Characteristics of organization enrolling the beneficiary					
Total number of practitioners [standard deviation]	123 [160]	96 [274]	27.1	0.12	0.54
Total number of service sites [standard deviation]	25	14	10.7	0.42	0.11
Organization type (%)					
Primary care	44	53	-9.2	-0.19	0.01
Specialty or multispecialty	30	33	-3.5	-0.08	
FQHC, RHC, or other health center	4	5	-1.2	-0.05	
CAH or rural hospital	1	3	-1.9	-0.15	
Acute care hospital	5	4	0.2	0.01	
Other	0	0	-0.2	-0.04	
Unknown type [f]	16	0	15.7	0.60	
Organization was participating in, or had application pending for, another model at randomization (%)	71	56	15.4	0.32	0.10
Characteristics of clinician enrolling the beneficiary					
Provider specialty (%)					
Primary care physician	61	62	-1.5	-0.03	0.85
Cardiologist	24	26	-1.6	-0.04	0.84
Physician with other specialty	3	1	1.9	0.13	0.15
Not a physician (for example, N.P. or P.A.)	11	10	1.3	0.04	0.50
Characteristics of beneficiary's region					
Rural (%)	25	26	-1.4	-0.03	0.78
Census region (%)					
Northeast	26	23	3.6	0.08	0.07
Midwest	20	29	-9.7	-0.23	
South	48	33	15.5	0.32	
West	6	15	-9.5	-0.31	
Characteristics of beneficiary's Million Hearts Model enrollment					
Days between model launch (1/3/2017) and enrollment date [standard deviation]	122 [91]	143 [100]	-21.8	-0.23	0.00
Enrollment date is in (%)					
First quarter of the year	44	36	7.6	0.15	0.03

Table A.1. (*Continued*)

Characteristic	Intervention group mean (N = 104,214)	Control group mean (N = 66,948)	Difference	Standardized differencea	p-valueb
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	-0.20	0.00
Data submitted to the registry using bulk upload (%)	49	49	-0.3	-0.01	0.97

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 CVD-related procedures; the organizations' applications to the Million Hearts 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: For all measures, means are calculated over non-missing values. 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 algorithms: congestive heart failure, morbid obesity. All procedures are defined by using Clinical Classifications Software indicators.

[a]The 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]Modifiable risk is defined as the difference between a beneficiary's CVD risk score at enrollment and their possible risk score 12 months later if all ABCS risk factors were set to clinical targets, with risk scores calculated using the Million Hearts Longitudinal ASCVD Risk Assessment Tool.

[d]Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (n = 71,997 for intervention group and n = 46,430 for control group). This accounted for 69 percent of all beneficiaries enrolled in the treatment group and 69 percent in the control group.

[e]We defined CVD-related admissions and ED visits using 300-plus CVD-related diagnosis codes (listed in Appendix C), including those related to heart failure, hypertension, and angina. In the baseline period, this measure excludes heart attacks and strokes because any beneficiaries who had these events before enrollment in Million Hearts were excluded from the analysis sample.

[f]"Unknown" organizations are those without an organization type listed in NPPES—either because the organization had no organizational NPI or because the organizational NPI was not present in NPPES.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CVD = cardiovascular disease; ED = emergency department; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; N.P. = nurse practitioner; NPI = National Provider Identifier; NPPES = National Plan and Provider Enumeration System; P.A. = physician assistant; RHC = rural health center.

Table A.2. Detailed baseline characteristics of high-risk Medicare beneficiaries enrolled in the Million Hearts Model in 2017, by intervention group

Characteristic	Intervention group mean (N = 32,831)	Control group mean (N = 20,924)	Difference	Standardized difference[a]	*p*-value[b]
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	40 [9]	40 [9]	0.1	0.01	0.75
Modifiable risk (%)[c]	16	15	0.2	0.02	0.73
Has diabetes (%)	66	64	1.8	0.04	0.46
Systolic blood pressure (mm Hg)	140	139	0.2	0.01	0.88
Total cholesterol (mg/dL)	169	169	0.2	0.00	0.88
HDL cholesterol (mg/dL)	47	48	-0.3	-0.02	0.64
LDL cholesterol (mg/dL)	93	92	0.6	0.02	0.64
Is current smoker (%)	12	13	-1.0	-0.03	0.29
Beneficiary medication use					
Uses aspirin (%)	51	50	0.8	0.02	0.85
Uses antihypertensives based on Part D[d] (%)	90	90	0.7	0.02	0.35
Uses statins based on Part D[d] (%)	69	68	0.8	0.02	0.55
Intensity of statin use based on Part D[d] (%)					
Low intensity	7	7	0.0	0.00	0.94
Medium intensity	42	41	0.3	0.01	
High intensity	21	20	0.4	0.01	
Beneficiary demographic and Medicare enrollment characteristics					
Age [standard deviation]	74 [4]	74 [4]	-0.2	-0.04	0.23
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	0.94
Beneficiary health and comorbid conditions					
HCC score [standard deviation]	1.37 [1.06]	1.37 [1.06]	0.0	0.01	0.83
Count of chronic conditions	2.6	2.6	0.0	0.02	0.57
Has chronic kidney disease (%)	36	36	0.5	0.01	0.79
Has ischemic heart disease (%)	38	40	-1.6	-0.03	0.60
Has congestive heart failure (%)	14	14	-0.5	-0.02	0.63
Has atrial fibrillation (%)	14	14	-0.8	-0.02	0.73
Has morbid obesity (%)	9	8	0.2	0.01	0.87
Beneficiary medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	8,162 [16,502]	8,010 [16,029]	152.2	0.01	0.64
Hospital admissions (per 1,000 beneficiaries)	201	200	1.3	0.00	0.90
CVD-related hospital admissions (per 1,000 beneficiaries)[e]	41	39	1.3	0.00	0.78

Table A.2. (*Continued*)

Characteristic	Intervention group mean (N = 32,831)	Control group mean (N = 20,924)	Difference	Standardized difference[a]	*p*-value[b]
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	390	378	11.9	0.01	0.51
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[e]	31	30	0.4	0.00	0.91
Office visits (per 1,000 beneficiaries)	9,888	9,451	437.8	0.06	0.27
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,229	3,197	31.9	0.01	0.92
Cardiologist visits (per 1,000 beneficiaries)	2,010	1,954	56.7	0.01	0.78
Beneficiary CVD-related procedures in year before model enrollment					
Received echocardiogram (%)	43	43	0.4	0.01	0.88
Received electrocardiogram (%)	74	74	0.6	0.01	0.83
Received cardiac stress test (%)	28	29	-0.4	-0.01	0.87
Characteristics of organization enrolling the beneficiary					
Total number of practitioners [standard deviation]	128 [184]	92 [275]	35.6	0.15	0.45
Total number of service sites [standard deviation]	25	14	10.7	0.42	0.11
Organization type (%)					
Primary care	42	54	-11.8	-0.24	0.01
Specialty or multispecialty	32	32	0.3	0.01	
FQHC, RHC, or other health center	4	6	-1.7	-0.08	
CAH or rural hospital	1	3	-2.3	-0.17	
Acute care hospital	5	5	0.1	0.00	
Other	0	0	-0.1	-0.02	
Unknown type[f]	16	0	15.4	0.59	
Organization was participating in, or had application pending for, another model at randomization (%)	70	55	15.3	0.32	0.10
Characteristics of clinician enrolling the beneficiary					
Provider specialty (%)					
Primary care physician	60	62	-1.6	-0.03	0.84
Cardiologist	25	26	-1.4	-0.03	0.86
Physician with other specialty	3	1	1.8	0.12	0.19
Not a physician (for example, N.P. or P.A.)	11	10	1.2	0.04	0.53
Characteristics of beneficiary's region					
Rural (%)	27	28	-1.0	-0.02	0.86
Census region (%)					
Northeast	25	22	2.3	0.05	0.29
Midwest	19	29	-9.8	-0.23	
South	50	33	16.4	0.34	
West	6	15	-8.9	-0.29	
Characteristics of beneficiary's Million Hearts Model enrollment					
Days between model launch (1/3/2017) and enrollment date [standard deviation]	116 [90]	141 [101]	-25.1	-0.26	0.00
Enrollment date is in (%)					

Table A.2. (*Continued*)

Characteristic	Intervention group mean (N = 32,831)	Control group mean (N = 20,924)	Difference	Standardized difference[a]	*p*-value[b]
First quarter of the year	47	37	9.2	0.19	0.02
Second quarter of the year	32	30	1.8	0.04	0.40
Third quarter of the year	13	17	-3.6	-0.10	0.09
Fourth quarter of the year	8	16	-7.4	-0.23	0.00
Data submitted to the registry using bulk upload (%)	43	44	-1.1	-0.02	0.90

[d]Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (n = 23,121 for intervention group and n = 14,747 for control group). This accounted for 70% of all beneficiaries enrolled in the treatment group and 70% in the control group.

See Table A.1 for all other table notes and acronyms.

3. Defining the attribution-based study population for robustness tests

As described in Chapter IV, we used an attribution-based study population as one of the main robustness tests. We defined this population in three steps (Appendix C of Conwell et al. 2019 provides more details):

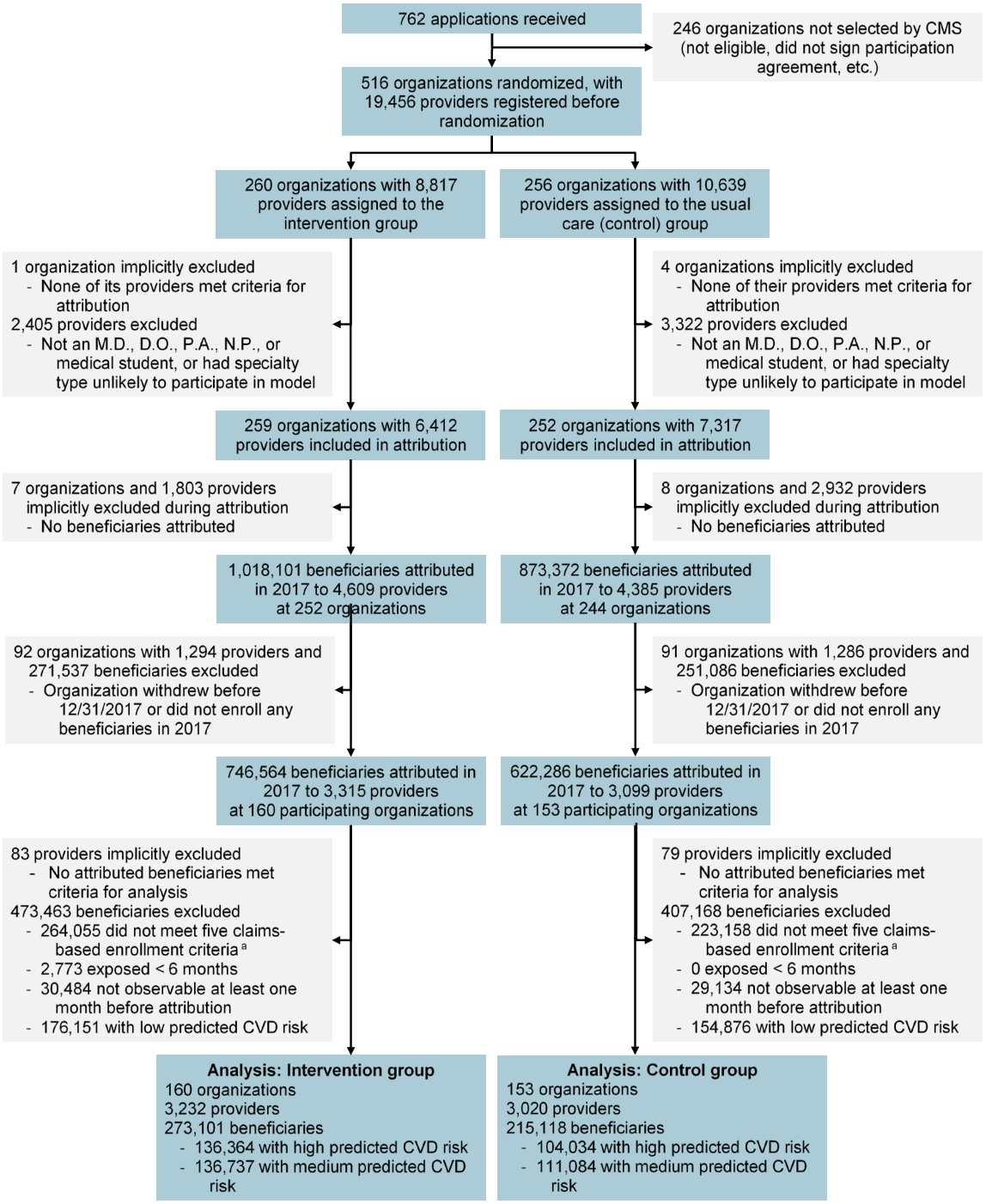
1. We used claims data to attribute Medicare FFS beneficiaries to participating organizations. Specifically, we identified providers working in each of the intervention and control organizations based on the list of National Provider Identifiers (NPIs) that each organization submitted to CMS before randomization and with specialties relevant to the model. This approach ensured that the list of providers was not affected by any additions or deletions to the list of participation providers that occurred after randomization, including deletions to meet the 20-provider cap applied only to the control group.
2. We attributed Medicare FFS beneficiaries to an organization when an NPI within that organization first had a visit in claims with that beneficiary between the model's launch in January 2017 and December 2017. A pseudo-enrollment date was assigned to each beneficiary. This was the date of the first qualifying claim, whether or not the beneficiary was enrolled in the Million Hearts Model and whatever his or her actual date of enrollment was.
3. We limited the population to observable beneficiaries who met the claims-based eligibility criteria (ages 40 to 79, with no previous heart attack or stroke, and no ESRD, and not in hospice). We also excluded organizations that withdrew before the end of 2017 and beneficiaries who were potentially exposed to the Million Hearts Model for fewer than 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, were not observable in Medicare claims data for at least one of the 12 months before attribution, or did not meet claims-based model eligibility criteria (for example, those who had evidence of a prior heart attack or stroke).
4. Using an algorithm we developed, we predicted a person's baseline CVD risk score from his or her claims-based characteristics at baseline. We needed to make these predictions because many beneficiaries in the attribution-based study population are not in the registry, so we

cannot observe their clinical data. We developed the risk prediction algorithm using the subset of 2017 enrollees for whom we had both clinical and claims data.

We limited the final population of attributed beneficiaries to those with medium or high predicted CVD risk. The final attribution study population includes 488,216 beneficiaries (273,101 beneficiaries in the intervention group and 215,115 beneficiaries in the control group) attributed to 213 organizations (160 intervention group and 153 control group). In Figure A.3, we show the flow of organizations (and their providers and beneficiaries), from enrollment and randomization, down to the final attribution-based study population.

The intervention and control groups are well balanced at baseline on claims-based beneficiary characteristics such as age, sex, predicted CVD risk, medication use, recent service use, and spending (Tables A.3 and A.4). 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. However, that intervention beneficiaries do still tend to be enrolled by larger organizations (mean size of 253 versus 179 practitioners in the intervention and control groups, respectively, for high-risk beneficiaries). 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, or were able, to enroll among their eligible Medicare patients. Therefore, 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.

Figure A.3. Flow of organizations, providers, and beneficiaries from attribution to the final impact analysis population for robustness checks



[a]The criteria are FFS Medicare Parts A and B, ages 40–79, no prior AMI, no prior stroke, no ESRD, and no hospice.

AMI = acute myocardial infarction; CVD = cardiovascular disease; D.O. = doctor of osteopathic medicine; ESRD = end-stage renal disease; FFS = fee-for-service; M.D. = doctor of medicine; N.P. = nurse practitioner; P.A. = physician assistant.

Table A.3. Characteristics of medium- and high-risk (predicted) Medicare beneficiaries attributed to actively participating intervention and control group organizations

Characteristic	Intervention group mean (N = 273,101)	Control group mean (N = 215,118)	Difference	Standardized difference[a]	*p*-value[b]
Clinical indicators of beneficiary's cardiovascular risk					
Predicted CVD risk score [standard deviation]	27 [9]	27 [9]	0.3	0.04	0.32
Diabetes with acute complications (%)	0	0	0.0	0.00	0.93
Diabetes with chronic complications (%)	22	23	-0.8	-0.02	0.52
Diabetes without complication (%)	15	16	-1.0	-0.03	0.21
Evidence of hypertension in claims over previous 12 months (%)	77	78	-0.5	-0.01	0.84
Evidence of hyperlipidemia in claims over previous 12 months (%)	52	53	-0.4	-0.01	0.86
Evidence of tobacco use in claims over previous 24 months (%)	8	9	-1.2	-0.04	0.12
Beneficiary medication use based on Part D[c]					
Uses antihypertensives (%)	80	81	-1.0	-0.02	0.64
Uses statins (%)	62	63	-0.5	-0.01	0.76
Intensity of statin use (%)					
Low intensity	6	6	0.1	0.00	0.29
Medium intensity	38	37	0.7	0.01	
High intensity	18	19	-1.3	-0.03	
Beneficiary demographic and Medicare enrollment characteristics					
Age [standard deviation]	72 [5]	72 [5]	0.0	0.00	0.98
Black race (%)	9	8	1.0	0.04	0.63
Male (%)	59	60	-0.8	-0.02	0.35
Dually enrolled in Medicare and Medicaid (%)	10	12	-2.2	-0.07	0.10
Originally entitled to Medicare due to disability (%)	14	15	-1.2	-0.03	0.39
Beneficiary health and comorbid conditions					
HCC score [standard deviation]	1.19 [1.07]	1.23 [1.10]	0.0	-0.03	0.37
Count of chronic conditions	2.1	2.2	-0.1	-0.03	0.51
Has chronic kidney disease (%)	24	25	-1.0	-0.02	0.42
Has ischemic heart disease (%)	34	35	-0.8	-0.02	0.80
Has congestive heart failure (%)	12	13	-0.9	-0.03	0.42
Evidence of atrial fibrillation in claims over previous 24 months (%)	10	10	0.1	0.00	0.90
Has morbid obesity (%)	7	7	-0.5	-0.02	0.45
Beneficiary medical service use and spending in year before attribution					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	8,582 [29,096]	8,446 [21,516]	136.0	0.01	0.65
Hospital admissions (per 1,000 beneficiaries)	210	220	-9.5	-0.01	0.46

Table A.3. (*Continued*)

Characteristic	Intervention group mean (N = 273,101)	Control group mean (N = 215,118)	Difference	Standardized difference[a]	*p*-value[b]
CVD-related hospital admissions (per 1,000 beneficiaries)[d]	42	45	-2.0	0.00	0.68
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	407	431	-24.2	-0.01	0.34
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[d]	34	36	-2.5	0.00	0.54
Office visits (per 1,000 beneficiaries)	9,104	8,659	445.3	0.06	0.22
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,179	2,118	60.8	0.02	0.74
Cardiologist visits (per 1,000 beneficiaries)	1,890	1,713	177.0	0.03	0.28
Beneficiary CVD-related procedures in year before attribution					
Received echocardiogram (%)	41	39	1.5	0.03	0.53
Received electrocardiogram (%)	70	69	0.6	0.01	0.82
Received cardiac stress test (%)	25	24	0.8	0.02	0.74
Characteristics of organization the beneficiary was attributed to					
Total number of practitioners [standard deviation]	233 [374]	182 [343]	51.0	0.14	0.69
Total number of service sites [standard deviation]	28	23	5.0	0.17	0.50
Organization type (%)					
Primary care	42	45	-2.9	-0.06	0.35
Specialty or multispecialty	38	31	6.8	0.14	
FQHC, RHC, or other health center	3	5	-1.8	-0.09	
CAH or rural hospital	1	2	-1.2	-0.11	
Acute care hospital	8	14	-6.7	-0.22	
Other	0	1	-0.5	-0.08	
Unknown[e]	8	2	6.2	0.28	
Organization was participating in, or had application pending for, another model at randomization (%)	59	56	2.8	0.06	0.81
Characteristics of clinician the beneficiary was attributed to					
Provider specialty (%)					
Primary care physician	58	56	2.2	0.04	0.75
Cardiologist	32	30	1.6	0.04	0.82
Physician with other specialty	3	3	0.2	0.01	0.86
Not a physician (for example, N.P. or P.A.)	8	12	-4.0	-0.14	0.05
Characteristics of beneficiary's region					
Rural (%)	22	27	-5.2	-0.12	0.26
Census region (%)					
Northeast	25	24	1.1	0.02	
Midwest	14	25	-10.4	-0.26	
South	44	33	10.5	0.22	
West	17	19	-1.2	-0.03	
Characteristics of beneficiary's attribution to participating organizations					

Table A.3. (*Continued*)

Characteristic	Intervention group mean (N = 273,101)	Control group mean (N = 215,118)	Difference	Standardized difference[a]	*p*-value[b]
Days between office visit used for attribution and January 3, 2017 [standard deviation]	109 [94]	111 [95]	-2.6	-0.03	0.43
Enrollment date is in (%)					
First quarter of the year	53	51	1.3	0.03	0.41
Second quarter of the year	26	27	-0.4	-0.01	0.60
Third quarter of the year	12	13	-0.4	-0.01	0.49
Fourth quarter of the year	9	10	-0.5	-0.02	0.39

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 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.

[a]The 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]Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (n = 187,136 for intervention group and n = 144,547 for control group). This accounted for 69 percent of all beneficiaries attributed to the treatment group and 67 percent in the control group.

[d]We defined CVD-related admissions and ED visits using 300-plus CVD-related diagnosis codes (listed in Appendix C), including those related to heart failure, hypertension, and angina. In the baseline period, this measure excludes heart attacks and strokes because any beneficiaries who had these events before enrollment in Million Hearts were excluded from the analysis sample.

[e]"Unknown" organizations are those without an organization type listed in NPPES—either because the organization had no organizational NPI or because the organizational NPI was not present in NPPES.

CAH = critical access hospital; CVD = cardiovascular disease; ED = emergency department; FQHC = federally qualified health center; HCC = hierarchical condition category; N.P. = nurse practitioner; NPI = National Provider Identifier; NPPES = National Plan and Provider Enumeration System; P.A. = physician assistant; RHC = rural health center.

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

Characteristic	Intervention group mean (N = 136,364)	Control group mean (N = 104,034)	Difference	Standardized difference[a]	*p*-value[b]
Clinical indicators of beneficiary's cardiovascular risk					
Predicted CVD risk score [standard deviation]	34 [8]	34 [7]	0.2	0.02	0.54
Diabetes with acute complications (%)	1	1	0.0	0.00	0.85
Diabetes with chronic complications (%)	33	34	-0.9	-0.02	0.67
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	0.76
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	0.18
Beneficiary medication use based on Part D[c]					
Uses antihypertensives (%)	86	87	-0.8	-0.02	0.63
Uses statins (%)	67	68	-0.5	-0.01	0.74
Intensity of statin use (%)					
Low intensity	7	7	0.0	0.00	0.44
Medium intensity	41	40	0.7	0.01	
High intensity	20	21	-1.2	-0.03	
Beneficiary demographic and Medicare enrollment characteristics					
Age [standard deviation]	74 [4]	74 [4]	-0.2	-0.04	0.39
Black race (%)	7	6	1.2	0.05	0.49
Male (%)	64	65	-0.6	-0.01	0.48
Dually enrolled in Medicare and Medicaid (%)	9	11	-1.8	-0.06	0.15
Originally entitled to Medicare due to disability (%)	12	13	-0.9	-0.03	0.47
Beneficiary health and comorbid conditions					
HCC score [standard deviation]	1.35 [1.12]	1.40 [1.15]	0.0	-0.04	0.36
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
Has congestive heart failure (%)	14	15	-1.2	-0.03	0.34
Evidence of atrial fibrillation in claims over previous 24 months (%)	12	12	0.0	0.00	1.00
Has morbid obesity (%)	7	8	-0.6	-0.02	0.42

Table A.4. (*Continued*)

Characteristic	Intervention group mean (N = 136,364)	Control group mean (N = 104,034)	Difference	Standardized difference[a]	*p*-value[b]
Beneficiary medical service use and spending in year before attribution					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	9,162 [34,507]	8,970 [20,889]	192.4	0.01	0.57
Hospital admissions (per 1,000 beneficiaries)	224	235	-11.4	-0.01	0.45
CVD-related hospital admissions (per 1,000 beneficiaries)[d]	48	50	-1.9	0.00	0.72
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	411	435	-23.9	-0.01	0.37
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[d]	38	39	-1.7	0.00	0.74
Office visits (per 1,000 beneficiaries)	9,714	9,222	492.7	0.06	0.21
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,417	2,329	88.6	0.03	0.69
Cardiologist visits (per 1,000 beneficiaries)	2,103	1,918	185.4	0.02	0.30
Beneficiary CVD-related procedures in year before attribution					
Received echocardiogram (%)	45	44	1.1	0.02	0.64
Received electrocardiogram (%)	74	74	-0.1	0.00	0.98
Received cardiac stress test (%)	28	27	0.6	0.01	0.83
Characteristics of organization the beneficiary was attributed to					
Total number of practitioners [standard deviation]	253 [394]	179 [342]	73.7	0.20	0.59
Total number of service sites [standard deviation]	28	23	5.3	0.18	0.50
Organization type (%)					
Primary care	40	44	-4.1	-0.08	0.29
Specialty or multispecialty	41	31	9.3	0.19	
FQHC, RHC, or other health center	2	4	-1.9	-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	
Unknowne	8	2	5.6	0.26	
Organization was participating in, or had application pending for, another model at randomization (%)	57	55	2.1	0.04	0.87
Characteristics of clinician the beneficiary was attributed to					
Provider specialty (%)					
Primary care physician	56	54	2.6	0.05	0.71
Cardiologist	33	32	0.9	0.02	0.91
Physician with other specialty	3	3	0.5	0.03	0.69

Table A.4. (*Continued*)

Characteristic	Intervention group mean (N = 136,364)	Control group mean (N = 104,034)	Difference	Standardized difference[a]	*p*-value[b]
Not a physician (for example, N.P. or P.A.)	7	11	-3.9	-0.14	0.06
Characteristics of beneficiary's region					
Rural (%)	23	28	-4.7	-0.11	0.38
Census region (%)					
Northeast	23	24	-0.5	-0.01	
Midwest	14	25	-10.9	-0.28	
South	44	33	11.1	0.23	
West	19	18	0.3	0.01	
Characteristics of beneficiary's attribution to participating organizations					
Days between office visit used for attribution and January 3, 2017 [standard deviation]	103 [92]	107 [93]	-3.1	-0.03	0.42
Enrollment date is in (%)					
First quarter of the year	55	53	1.6	0.03	0.40
Second quarter of the year	26	27	-0.7	-0.02	0.46
Third quarter of the year	11	12	-0.5	-0.02	0.52
Fourth quarter of the year	8	9	-0.5	-0.02	0.44

[c]Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (n = 96,187 for intervention group and n = 72,497 for control group). This accounted for 71% of all beneficiaries attributed to the treatment group and 70% in the control group.

See Table A.3 for all other table notes and acronyms.

4. Baseline characteristics of intervention group enrollees with annual reassessment visits

The Million Hearts Data Registry data available for this report included annual reassessment visits that occurred during or before June 2018 for high-risk enrollees in intervention organizations. Table A.5 compares baseline characteristics for enrollees who had a reassessment visit recorded in the registry and the full population of enrollees who were eligible to receive a reassessment visit by the end of June 2018. We identified enrollees who were eligible for a reassessment visit as high-risk enrollees with a baseline visit during or before April 2017. By the end of our available data in June 2018 (14 months after April 2017), these enrollees had all passed the 10- to 14-month anniversary window for an annual reassessment visit. We also excluded enrollees who died, had an acute myocardial infarction or stroke, enrolled in Medicare Advantage, or lost Medicare as their primary payer within 14 months after their baseline visit, because these beneficiaries were unlikely to have a reassessment visit recorded in the Million Hearts Data Registry.

Our goal is to understand changes in CVD risk scores and risk factors between baseline and reassessment among all beneficiaries enrolled by Million Hearts providers who were eligible for a reassessment visit, not just those who received a reassessment visit. To better represent this

larger population, we weighted enrollees based on their probability of receiving a reassessment visit. We calculated these inverse probability weights as p/p_x where p is the probability of having a reassessment visit among all eligible enrollees and p_x is each individual enrollee's predicted probability of having a reassessment visit. Predicted probabilities of having a reassessment visit were generated from a logistic regression model using covariates included in Table A.5.

Table A.5 shows the baseline characteristics of enrollees with a reassessment visit before and after weighting, compared to the full eligible population. Compared to all enrollees eligible for a reassessment visit, enrollees who received a reassessment visit were more likely to have diabetes (72 percent with visits versus 67 percent all eligible) and to have been enrolled by a primary care provider (70 percent with visits versus 62 percent all eligible). Those with reassessment visits also tended to be located more in the Midwest and South, have an earlier enrollment date in the model, and have their data submitted to the registry manually rather than by bulk upload. Demographic information (such as age and sex) and predicted CVD risk scores were similar for those who did and who did not receive a reassessment visit. After weighting enrollees with reassessment visits, all covariates considered were similar to the full population of eligible enrollees.

Table A.5. Characteristics of high-risk Medicare beneficiaries enrolled in Million Hearts intervention organizations (enrollees) with and without reassessment visits

Characteristic	All enrollees eligible for a reassessment visit[a] (N = 16,551)	Enrollees with a reassessment visit[b] (N = 7,862)	Enrollees with a reassessment visit,[b] weighted to represent all eligible enrollees[c] (N = 7,862)
Clinical indicators of beneficiary's cardiovascular risk			
CVD risk score (%), [standard deviation]	40 [9]	40 [9]	40 [9]
Has diabetes (%)	67	72	67
Systolic blood pressure (mm Hg)	139	139	140
Total cholesterol (mg/dL)	169	168	169
HDL cholesterol (mg/dL)	48	47	47
LDL cholesterol (mg/dL)	92	92	93
Is treated for or diagnosed with hypertension (%)	91	93	91
Is current smoker (%)	12	12	12
Uses aspirin (%)	50	49	50
Beneficiary demographic and Medicare enrollment characteristics			
Age [standard deviation]	74 [4]	74 [4]	74 [4]
Black race (%)	8	8	8
Male (%)	64	64	64
Dually enrolled in Medicare and Medicaid (%)	8	8	8
Originally entitled to Medicare because of disability (%)	12	12	12

Table A.5. (Continued)

Characteristic	All enrollees eligible for a reassessment visit[a] (N = 16,551)	Enrollees with a reassessment visit[b] (N = 7,862)	Enrollees with a reassessment visit,[b] weighted to represent all eligible enrollees[c] (N = 7,862)
Beneficiary health and comorbid conditions			
HCC score	1.36	1.34	1.37
[standard deviation]	[1.02]	[1.00]	[1.04]
Count of chronic conditions	2.6	2.6	2.6
Has chronic kidney disease (%)	36	36	36
Has ischemic heart disease (%)	38	36	38
Has congestive heart failure (%)	13	13	13
Has atrial fibrillation (%)	13	12	14
Has morbid obesity (%)	9	10	9
Beneficiary medical service use and spending in year before model enrollment			
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	7,999 [15,789]	7,433 [14,794]	8,381 [17,258]
Hospital admissions (per 1,000 beneficiaries)	196	180	207
CVD-related hospital admissions (per 1,000 beneficiaries)[e]	39	35	42
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	371	357	370
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[e]	28	28	34
Office visits (per 1,000 beneficiaries)	10,099	9,802	10,207
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,587	3,847	3,588
Cardiologist visits (per 1,000 beneficiaries)	2,059	1,991	2,143
Beneficiary CVD-related procedures in year before model enrollment			
Received echocardiogram (%)	44	41	44
Received electrocardiogram (%)	75	71	75
Received cardiac stress test (%)	29	28	30
Characteristics of organization enrolling the beneficiary			
Total number of practitioners	120	127	118
[standard deviation]	[146]	[150]	[152]
Total number of service sites [standard deviation]	27 [27]	30 [28]	26 [28]
Organization type (%)			
Primary care	36	34	34
Specialty or multispecialty	35	27	37
FQHC, RHC, or other health center	3	4	3
CAH or rural hospital	1	0	1
Acute care hospital	5	4	4
Unknown type[f]	20	32	21
Organization was participating in, or had application pending for, another model at randomization (%)	74	74	74
Characteristics of clinician enrolling the beneficiary			
Provider specialty (%)			

Table A.5. (Continued)

Characteristic	All enrollees eligible for a reassessment visit[a] (N = 16,551)	Enrollees with a reassessment visit[b] (N = 7,862)	Enrollees with a reassessment visit,[b] weighted to represent all eligible enrollees[c] (N = 7,862)
Primary care physician	62	70	62
Cardiologist	22	16	23
Physician with other specialty	4	2	3
Not a physician (for example, N.P. or P.A.)	11	11	12
Characteristics of beneficiary's region			
Rural (%)	28	30	29
Census region (%)			
Northeast	22	12	21
Midwest	23	27	23
South	51	57	51
West	5	4	5
Characteristics of beneficiary's Million Hearts Model enrollment			
Days between model launch (1/3/2017) and enrollment date [standard deviation]	54 [34]	49 [33]	55 [34]
Enrollment date is in (%)			
First quarter of the year	80	84	79
Second quarter of the year	20	16	21
Data submitted to the registry using bulk upload (%)	39	35	39

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 CVD-related procedures; the organizations' applications to the Million Hearts 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: For all measures, means are calculated over non-missing values. 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 algorithms: congestive heart failure, morbid obesity. All procedures are defined by using Clinical Classifications Software indicators.

[a]Enrollees eligible for a reassessment visit were defined as high-risk enrollees whose baseline visit date was early enough in 2017 that their window for a reassessment visit 10 to 14 months after baseline occurred by June 2018. We also excluded from this definition any beneficiary who died, had an acute myocardial infarction or stroke, enrolled in Medicare Advantage, or lost Medicare as their primary payer within 14 months after their baseline visit. For the eligible enrollees definition, we used unadjusted baseline visit dates to reflect the date used for CMS payments.

[b]Excluding any enrollees with implausible values of continuous risk factors (n = 87) and enrollees not defined as high-risk using clinical data from the adjusted baseline visit date (n = 68)

[c]Weighted based on their probability of receiving a reassessment visit using inverse probability weights.

[d]Modifiable risk is defined as the difference between a beneficiary's CVD risk score at enrollment and their possible risk score 12 months later if all ABCS risk factors were set to clinical targets, with risk scores calculated using the Million Hearts Longitudinal ASCVD Risk Assessment Tool.

Table A.5. (Continued)

[e]We defined CVD-related admissions and ED visits using 300-plus CVD-related diagnosis codes (listed in Appendix C), including those related to heart failure, hypertension, and angina. In the baseline period, this measure excludes heart attacks and strokes because any beneficiaries who had these events before enrollment in Million Hearts were excluded from the analysis sample.

[f]"Unknown" organizations are those without an organization type listed in NPPES—either because the organization had no organizational NPI or because the organizational NPI was not present in NPPES.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CVD = cardiovascular disease; ED = emergency department; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; N.P. = nurse practitioner; NPI = National Provider Identifier; NPPES = National Plan and Provider Enumeration System; P.A. = physician assistant; RHC = rural health center.

This page has been left blank for double-sided copying.

APPENDIX B

QUALITATIVE DATA COLLECTION AND ANALYSIS

This page has been left blank for double-sided copying.

The implementation evaluation of the Million Hearts Model at the beginning of the third model year relies heavily on primary data collected from telephone interviews with intervention organizations. These are supplemented with a few interviews with organizations that withdrew from the model and analysis of documentation provided by CMS on why organizations withdrew. The evaluation also included analysis of findings from a practice survey administered in 2018 to key contacts at each intervention organization who interact with CMS concerning the Million Hearts CVD Risk Model; Appendix E describes this survey in detail. Finally, the evaluation also included analysis of payments to the organization; these data sources are described in the previous annual report (Conwell et al. 2019).

1. Telephone interviews with intervention participant organizations

a. Participant selection

The evaluation team conducted telephone interviews with respondents from 14 intervention organizations: 11 from the original 15 organizations selected to be followed longitudinally and 3 new organizations. Of the 15 original organizations, 2 withdrew from the Million Hearts Model in 2018 and participated in an exit interview instead. Two other previously interviewed organizations declined to participate in the interviews due to data entry challenges, according to one organization, and staff turnover, according to the other. We contacted four new organizations, of which one declined and withdrew from the model; the other three participated in interviews.

We describe our selection of the original sample of organizations in the first annual report. To maintain the diverse sample of interview participants reflecting all participating organizations, we selected replacement organizations that most closely resembled the original withdrawing organization in organization size (as defined by the number of providers), geographic region (defined by U.S. Department of Health and Human Services regions), and organization/specialty type (for example, primary care office, specialty, or federally qualified health center [FQHC]). The evaluation team also assessed such characteristics as rural versus urban location, participation in other CMS initiatives, and number of beneficiaries enrolled during the first program year. [25]

The 14 organizations interviewed represent:

- At least one organization from 9 of the 10 geographic regions, with up to three organizations in a region consistent with the distribution of all participating intervention organizations
- Six small (1 to 5 providers), four medium (6 to 19 providers), and four large (20 or more providers) organizations

[25] Intervention organizations for the first round of data collection were selected to meet targets for geographic region, organization size, and organization type criteria, as well as to achieve a diversity of organizations along the other characteristics considered. For more information on the analysis of organization characteristics and selection, refer to the first annual evaluation report at https://downloads.cms.gov/files/cmmi/mhcvdrrm-firstann-evalrpt.pdf.

- Seven primary care organizations, two specialty or multispecialty organizations, three hospitals (including one academic, one acute, and one large health system), and two FQHCs.

We did not select organizations that had withdrawn at the time of the analysis (early 2019).

We submitted the list of selected replacement organizations and their characteristics to CMS to review before we contacted those organizations to schedule interviews.

b. Development of interview protocols

We used semistructured protocols for each interview. These protocols were modified from the previous year's data collection to focus on reassessment visits, follow-up contacts, and changes in workflow. We customized topics for each respondent type to understand intervention organizations' approach to implementing the Million Hearts Model, changes in implementation from the first round of interviews (if applicable), and barriers and facilitators to successful implementation of the intervention. We identified types of respondents (for example, clinical model lead and information technology [IT]) and research questions, and a subset of constructs (Table B.1) from the Consolidated Framework for Implementation Research (CFIR) to draft the protocols. CFIR provides theory-based, prespecified constructs likely to influence implementation of complex programs and helps ensure a rigorous and methodical analysis of factors that facilitate or impede organizations' work on the Million Hearts 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 Model before collecting data to make our analyses more efficient. We revised the draft protocols based on the feedback from CMS before we collected data.

Table B.1. Interview respondents, research questions, and CFIR constructs for telephone interviews with Million Hearts Model intervention organizations

Examples of respondent types (two to five interviews per organization, depending on size)
Organization lead/champion of the Million Hearts Model
Physician/administrative lead
Key leadership figures (clinical IT director, clinical QA director)
Frontline clinicians (M.D., D.O., N.P., P.A.)
Clinical support staff (M.A., nurse, pharmacist, social worker)
Nonclinical support staff
Research questions
What changes have occurred over the past year in how organizations are implementing the model? What has facilitated or hindered implementation?
Has participation in the model led to changes in CVD preventive care among high- versus medium-risk beneficiaries? How does that differ from what has changed or not changed at control organizations?
What are respondents' perceptions of the model incentives and supports that have been provided to organizations?
What are organizations' expectations of how the model is affecting, or will affect, patient CVD care and outcomes?
Which organizations left the model and why?
Applied CFIR constructs
Perceived difficulty or complexity of implementing the model
Presence of external policy and incentives, including other quality initiatives
Communications within a participating organization regarding the model
Perceived priority or importance of the model within an organization
Perceived effect of leadership on model implementation
Performance feedback delivered to organizations

CFIR = Consolidated Framework for Implementation Research; CVD = cardiovascular disease; D.O. = doctor of osteopathic medicine; IT = information technology; M.A. = medical assistant; M.D. = doctor of medicine; N.P. = nurse practitioner; P.A. = physician assistant; QA = quality assurance.

c. Telephone interview process

A two-person team conducted telephone interviews using semistructured protocols described above. The principal investigators from Mathematica and RAND conducted the initial interviews with a single organization to ensure consistency in collecting data and to refine the protocols. Subsequent telephone interviews were conducted by two-member teams comprising senior and junior staff; these teams included members from both Mathematica and RAND when it was logistically feasible. Interview teams prepared for interviews by reviewing the organizations' performance data, such as enrollment, payment incentives, aggregate average risk reduction, and learning system attendance, that were in performance reports that the implementation contractor provided. For the 11 organizations from the longitudinal cohort, teams also reviewed interview notes from the first round of data collection. This information was used to tailor the interview protocols to reflect what was already known about the organization. This tailoring allowed the team to focus on changes to implementation and implementation of the Million Hearts Model requirements that were not yet relevant during the first round of data collection, such as the risk score reassessment process. Each interview lasted 30 to 60 minutes.

As in the first year of data collection, the number of interviews conducted with each organization varied, depending on the size of the organization, as well as the number and type of people involved in the Million Hearts Model at the organization. At a minimum, we met with each organization's model champion. We conducted two to five interviews per organization, depending on the size of the organization, to minimize burden on the smaller organizations. Often, interviews included more than one respondent at a time because the organization requested this. All interviews were audiorecorded and transcribed.

2. Intervention and control organizations that exited the model

a. Document review of reasons that organizations have withdrawn

For intervention and control organizations that withdrew from the model during 2018, CMS provided the evaluation team with data on reasons for withdrawal.[26] In some cases, organizations withdrew on their own; in others, CMS terminated their participation because they did not meet certain terms of model participation. 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. Some organizations cited more than one reason for withdrawing. The evaluation team considered each reason separately and allowed organizations to fall into as many categories as applied. Among 63 organizations that withdrew or were terminated by CMS in 2018, we assigned 49 organizations to one category, 10 organizations to two categories, 3 organizations to three categories, and 1 organization to four categories. The categories of reasons for withdrawing were as follows:

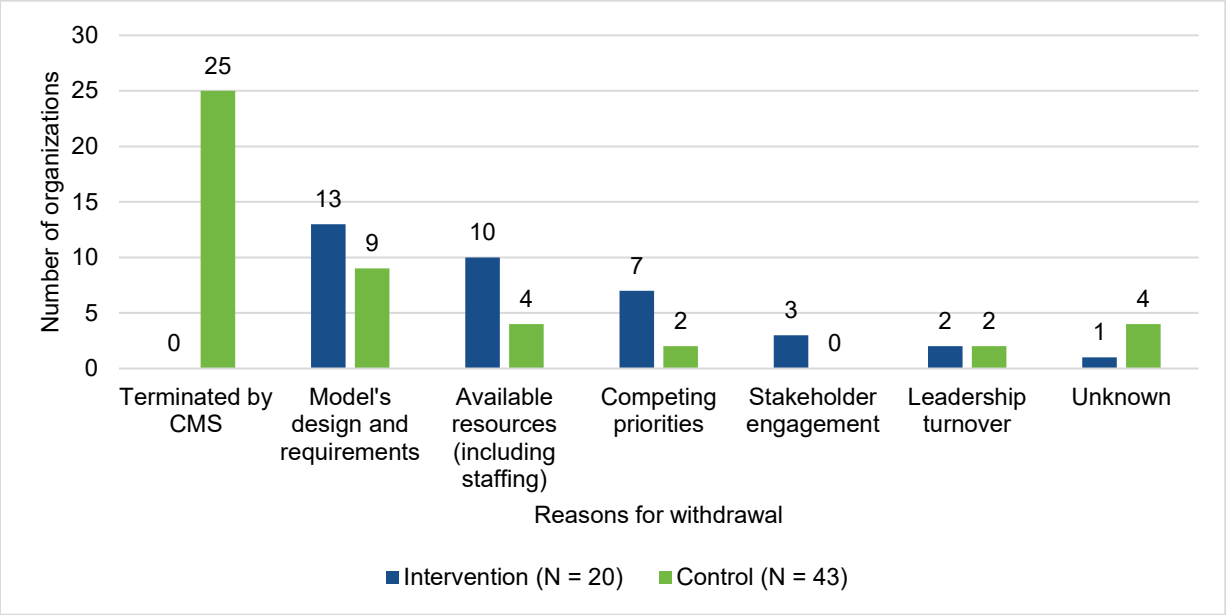
- Termination by CMS, usually after the organization did not respond to a corrective action plan
- An organization's perception that the model's design and requirements were too burdensome, especially requirements related to submitting data to the Million Hearts Data Registry, using the Million Hearts Connect portal, or using a CVD risk calculator
- An organization's lack of available resources to implement the Million Hearts Model, usually related to insufficient staff capacity or electronic health record capabilities
- An organization's need to focus on competing priorities
- A lack of buy-in or engagement from organizational leaders, providers, or other staff
- Changes in leadership at an organization

For five organizations, we did not have enough data to assess their reasons for leaving (unknown). The unknown factor was applied if there was not a reason given for withdrawing or if the reason was too vague to put it into one of the other categories previously discussed. The

[26] The date of withdrawal was identified as the date the organization requested to be withdrawn, if applicable; or (2) the date of actual withdrawal, if CMS terminated the organization.

unknown factor was mutually exclusive from other factors. Next, we present results from our analysis of the reasons the organizations exited the model during 2018 (Figure B.1).

Figure B.1. Analysis of reasons for withdrawal among organizations that exited the model in 2018 (N = 63)



Source: Mathematica analysis of data from CMS on reasons for withdrawal.

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

Participant selection. Using the data on reasons for withdrawal described above, we selected organizations that had withdrawn from the Million Hearts Model during 2018 for telephone interviews, including two organizations from the original longitudinal cohort. Data on why organizations withdrew helped the team identify the reasons for withdrawal and choose a group of withdrawing organizations to capture a diversity in factors cited as prompting the decision to withdraw. We did not include any organization that CMS had terminated. We also checked for diversity in organization type. Examples of respondents from these organizations include practice manager, clinical champion, or other designated people who made the decision to withdraw from the Million Hearts Model. In total, we contacted six organizations that withdrew from the model, of which two declined or did not respond and four were scheduled for an interview.

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 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

Telephone interview process. Using the interview protocol described above, we completed one telephone interview per organization with the four selected organizations that withdrew from the model. We scheduled interviews to occur during March 2019. A team member from Mathematica conducted each interview, and interviews took from 17 to 28 minutes. Each was recorded and transcribed.

3. Analysis of qualitative data

Qualitative data collected through interviews is a key data source for answering research questions related to changes in implementation of the model in the third model year, barriers and facilitators of implementation, changes in the delivery of CVD preventive care among beneficiaries, 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, key implementation components, and barriers and facilitators to implementing the Million Hearts Model and improving CVD care. After each set of interviews, the interview team summarized key implementation data on such topics as enrollment, risk stratification, and program supports, noting any changes since the first round of data collection, where applicable.

We imported transcribed interviews into the software NVivo to facilitate coding and analysis 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 research questions (Table B.1) and the logic model (Figure I.A.1 in the main report). To ensure inter-rater reliability, all members of the coding team coded the same first transcript 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 three transcripts and ensuring consistent coding, coders began independently coding transcripts, and coding was completed by late March 2019.

APPENDIX C

CONSTRUCTING ANALYSIS FILES AND BENEFICIARY MEASURES FROM MEDICARE CLAIMS AND REGISTRY DATA

This page has been left blank for double-sided copying.

This appendix describes how we constructed the impacts analysis files for the Million Hearts Model evaluation and how we constructed key covariates and outcomes variables. We refer readers to Appendix A of the first annual report (Conwell et al. 2019) for a description of all the baseline covariates contained in the analysis files, including demographic and Medicare enrollment-related characteristics at enrollment, as well as Hierarchical Condition Categories (HCC) scores, presence of diseases and conditions, and utilization and spending in the period before enrollment.

1. Structure of the analysis files

We constructed two types of analysis files. One file contains beneficiary-level observations that allow for analysis of "time-to-event" (or survival) outcomes, as well as analyses of Part D drug outcomes and changes in CVD risk scores for each beneficiary during the analysis period. This file contains one observation per beneficiary for all beneficiaries in the intervention and control groups, including all baseline covariates, as well as relevant covariates and outcomes variables, as described in Sections 2 through 4 of this chapter.

The second type of analysis file contains beneficiary-quarter observations during the intervention period to support analyses of changes over time in outcomes and analyses of average quarterly outcomes. We define the quarterly observations relative to each beneficiary's enrollment date. For example, quarter 1 for a beneficiary who enrolled on March 7, 2017, spans the period from March 7, 2017, through June 6, 2017, whereas quarter 1 for a beneficiary who enrolled on July 24, 2017, spans from July 24, 2017, through October 23, 2017. We sum total Medicare spending and utilization outcomes over each intervention quarter. We quarterize outcomes[27] for beneficiaries who were not observable for the full quarter and construct observability weights that reflect the amount of time that the beneficiary is observable in the quarter. Beneficiaries are observable if they were alive and enrolled in Medicare FFS Parts A and B with Medicare as their primary payer. Beneficiaries who are fully observable in any quarter receive an observability weight of one. Those who are observable for less than a quarter (for example, due to death or loss of Part A and B coverage) receive a weight that is the share of days in the quarter that the person was actually observed. For those beneficiaries who enrolled in the intervention at program start (January 3, 2017), the maximum number of quarters in the analysis file is seven. To make data checking easier, particularly to track which beneficiary-quarter observations should be excluded and for what reasons, we created a balanced data set such that each beneficiary had seven quarters of data and a variable that indicated whether each observation should be excluded and, if so, why. Furthermore, if a beneficiary did not actually enroll early enough to be observed in a given quarter (for example, quarter 7), the outcomes for that quarter were set to missing. Finally, we merged the baseline covariates onto each quarterly observation for each beneficiary so that each observation contained relevant quarterly outcomes and all baseline covariates.

[27] For example, if a beneficiary has one outpatient ED visit in the quarter but is observed for only 60 days out of the quarter, that beneficiary's quarterized outpatient ED visit rate would be (1 visits / 60 days observed)*90 days in quarter = 1.5 visits per quarter.

We constructed four analysis files: (1) the time-to-event file for the registry-based study population used for the primary impact analyses, (2) the time-to-event file for the attribution-based study population used for robustness checks, (3) the beneficiary-quarter file for the registry population, and (4) the beneficiary-quarter file for the attribution population. Appendix A describes, in detail, how we defined each of these populations.

2. Outcomes measures from Part A and B claims

a. Heart attacks and strokes

We measured heart attacks and strokes using inpatient hospital claims and outpatient emergency department (ED) or observation stay claims. Furthermore, we constructed two versions of the heart attack and stroke outcomes—one using a narrow definition of the event, the other a broader definition of the event. As Table C.1 describes, the narrow definition uses only the principal diagnosis on both inpatient and outpatient claims. In contrast, the broader definition looks at principal or secondary diagnoses on inpatient claims, as long as the secondary diagnosis was not present on admission. The "not present on admission" restriction was intended to exclude events previously diagnosed or treated.

The diagnosis codes used to define the narrow and broad definitions of heart attack and stroke were based on the Chronic Conditions Data Warehouse (CCW) definitions of heart attack and stroke (Chronic Conditions Data Warehouse 2017). For the narrow definition of heart attack, we limited the diagnoses to those categorized as ST elevation (STEMI), non-ST elevation (NSTEMI), and unspecified heart attack (this corresponds to Type I heart attacks, as defined by the Fourth Universal Definition of Myocardial Infarction [Thygesen et al. 2018]). For the broad definition of heart attack, we included all five types of heart attacks in the Fourth Universal Definition of Myocardial Infarction, excluding codes indicating that the heart attacks were subsequent to an earlier heart attack. We excluded any diagnoses for subsequent heart attack from the heart attack outcome definition because the outcome is intended to measure first heart attacks. For stroke, we limited the diagnoses for the narrow definition to those categorized as ischemic and hemorrhagic stroke. For the broad definition of stroke, we included ischemic and hemorrhagic stroke, transient ischemic attack (TIA), and stroke syndromes.

Table C.1. Claims-based definitions of acute myocardial infarction and stroke (ICD-10 codes only)

	Narrow definition	Broad definition
Diagnosis codes		
Heart attack	• STEMI: I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3 • NSTEMI: I21.4 • Unspecified: I21.9	• STEMI: I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3 • NSTEMI: I21.4 • Unspecified: I21.9 • Type 2: I21.A1 • Other types: I21.A9
Stroke	• Ischemic and hemorrhagic stroke: I60.00, I60.01, I60.02, I60.10, I60.11, I60.12, I60.2, I60.20, I60.21, I60.22, I60.30, I60.31, I60.32, I60.4, I60.50, I60.51, I60.52, I60.6, I60.7, I60.8, I60.9, I61.0, I61.1, I61.2, I61.3, I61.4, I61.5, I61.6, I61.8, I61.9, I63.00, I63.011, I63.012, I63.013, I63.019, I63.02, I63.031, I63.032, I63.033, I63.039, I63.09, I63.10, I63.111, I63.112, I63.113, I63.119, I63.12, I63.131, I63.132, I63.133, I63.139, I63.19, I63.20, I63.211, I63.212, I63.213, I63.219, I63.22, I63.231, I63.232, I63.233, I63.239, I63.29, I63.30, I63.311, I63.312, I63.313, I63.319, I63.321, I63.322, I63.323, I63.329, I63.331, I63.332, I63.333, I63.339, I63.341, I63.342, I63.343, I63.349, I63.39, I63.40, I63.411, I63.412, I63.413, I63.419, I63.421, I63.422, I63.423, I63.429, I63.431, I63.432, I63.433, I63.439, I63.441, I63.442, I63.443, I63.449, I63.49, I63.50, I63.511, I63.512, I63.513, I63.519, I63.521, I63.522, I63.523, I63.529, I63.531, I63.532, I63.533, I63.539, I63.541, I63.542, I63.543, I63.549, I63.59, I63.6, I63.81, I63.89, I63.9	• Ischemic and hemorrhagic stroke: I60.00, I60.01, I60.02, I60.10, I60.11, I60.12, I60.2, I60.20, I60.21, I60.22, I60.30, I60.31, I60.32, I60.4, I60.50, I60.51, I60.52, I60.6, I60.7, I60.8, I60.9, I61.0, I61.1, I61.2, I61.3, I61.4, I61.5, I61.6, I61.8, I61.9, I63.00, I63.011, I63.012, I63.013, I63.019, I63.02, I63.031, I63.032, I63.033, I63.039, I63.09, I63.10, I63.111, I63.112, I63.113, I63.119, I63.12, I63.131, I63.132, I63.133, I63.139, I63.19, I63.20, I63.211, I63.212, I63.213, I63.219, I63.22, I63.231, I63.232, I63.233, I63.239, I63.29, I63.30, I63.311, I63.312, I63.313, I63.319, I63.321, I63.322, I63.323, I63.329, I63.331, I63.332, I63.333, I63.339, I63.341, I63.342, I63.343, I63.349, I63.39, I63.40, I63.411, I63.412, I63.413, I63.419, I63.421, I63.422, I63.423, I63.429, I63.431, I63.432, I63.433, I63.439, I63.441, I63.442, I63.443, I63.449, I63.49, I63.50, I63.511, I63.512, I63.513, I63.519, I63.521, I63.522, I63.523, I63.529, I63.531, I63.532, I63.533, I63.539, I63.541, I63.542, I63.543, I63.549, I63.59, I63.6, I63.81, I63.89, I63.9 • TIA: G45.0, G45.1, G45.2, G45.8, G45.9, I67.81, I67.82, I67.841, I67.848, I67.89 • Other stroke syndromes: G46.0, G46.1, G46.2, G46.3, G46.4, G46.5, G46.6, G46.7, G46.8, G97.31, G97.32, I66.01, I66.02, I66.03, I66.09, I66.11, I66.12, I66.13, I66.19, I66.21, I66.22, I66.23, I66.29, I66.3, I66.8, I66.9, I97.810, I97.811, I97.820, I97.821
Diagnosis fields		
Inpatient claims	Principal only	Principal and secondary, but only those secondary diagnoses not present on admission
Outpatient ED and observation stay claims	Principal only	Principal only

ED = emergency department; NSTEMI = Non-ST elevation; STEMI = ST elevation; TIA = transient ischemic attack.

b. All other cardiovascular disease (CVD) events

To measure inpatient hospital stays or outpatient ED visits or observation stays for other cardiovascular conditions, we developed a list of more than 300 ICD-10 CVD-related diagnosis codes, including those related to heart failure, hypertension, and angina, but excluding any diagnoses for heart attack or stroke listed in Table C.1.[28] We then added diagnoses for subsequent heart attack (included in the CCW definition of heart attack)[29] to the definition of all other CVD events because we did not include these diagnoses in our definition of first-time heart attack, as described above. Consistent with our definitions of heart attack and stroke, we constructed two definitions of all other CVD events. Specifically, when we were using the narrow definition of heart attack and stroke, we categorized any diagnoses that were not used (for example, diagnoses for TIA and other stroke syndromes) as all other CVD. Whereas, when we were using the broad definition of heart attack and stroke, the all other CVD was defined using the original list of 300-plus diagnosis codes and subsequent heart attack diagnosis codes only.

c. Time-to-event outcomes: First-time heart attack, stroke, and all-cause mortality

For the survival analyses, we measured time to first heart attack and stroke based on the narrow and broad definitions described previously. We constructed time to a composite measure of heart attack or stroke, as well as measure of time to heart attack and a separate measure of time to stroke. We also measured time to death if a person died. In addition, we constructed a variable that measures time until the beneficiary is censored in the data set. This censoring date is defined differently, depending on the outcome. For heart attacks and strokes (the composite measure and its components), which require a person to be enrolled in Medicare Part A and B for us to observe the events in claims, the censor date is defined as the earlier of (1) the beneficiary death date, if non-missing; (2) the date the beneficiary is no longer observable in FFS Medicare;[30] or

[28] Of the ICD-10 diagnoses included in our list, the following were most frequently found on inpatient or outpatient claims during the baseline period in our study population: 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, I4901, I4902, I491, I493, I4949, I495, I498, I499, I501, I5020, I5021, I5022, I5023, I5030, I5031, I5032, I5033, I5040, I5041, I5042, I5043, I50810, I509, I510, I511, I513, I514, I515, I517, I5181, I5189, I519, I52, I6200, I6201, I6202, I6203, I621, I629, I6501, I6502, I6503, I6509, I651, I6521, I6522, I6523, I6529, I658, I659, I672, I6781, I6782, I6783, I679, I680, I700.

[29] These included: I220, I221, I222, I228, and I229.

[30] Beneficiaries are observable if they are alive, enrolled in Medicare FFS Parts A and B, and have Medicare as primary payer.

(3) the last date of the analysis period (October 31, 2018). For death, the censor date is October 31, 2018 (because Medicare records the date a person dies even if they disenroll in Part A and B and because death is the outcome for this analysis and not censoring). For sensitivity analyses, we constructed outcome variables for time to first heart attack, stroke, or death (whichever came first).[31] We also constructed outcome variables for time to first heart attack, stroke, death, or loss of Medicare observability (whichever came first).

d. Quarterly outcomes: Medicare spending, hospitalizations and ED visits, office visits

The outcomes measures analyzed at the beneficiary-quarter level include total Medicare Part A and B spending, hospitalizations (all-cause and CVD-related), outpatient ED visits and observation stays (all-cause and CVD-related), and total number of office visits and office visits with providers aligned with Million Hearts. We describe these briefly next. Additional details about these variables are in Appendix A of the first annual report (Conwell et al. 2019).

All-cause and CVD-related admissions. We calculated the total number of acute inpatient admissions and the number of CVD-related admissions that began during each quarter.

Outpatient 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 healthcare common procedure coding system (HCPCS) codes in the outpatient claims file. We only allowed for one ED visit per day so as not to count multiple claims from the same stay as multiple visits.

Office/clinic visits. 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, physician assistant, nurse practitioner, or certified clinical nurse specialist (Centers for Medicare & Medicaid Services 2017); and (2) a current procedural terminology (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, rural health centers, and critical access hospitals. To identify the subset of those visits that were with providers aligned with the Million Hearts Model, we flagged National Provider Identifier (NPI)-Tax Identification Number (TIN) combinations and CMS Certification Number (CCN)-NPI combinations that were included in the list used in attribution in the carrier and the outpatient files, respectively.

Medicare expenditures. We separately calculated Medicare expenditures for claims from inpatient (separately for acute and nonacute care), carrier, outpatient, home health services, skilled nursing facility, hospice services, and durable medical equipment. We summed these to create the measure of total Parts A and B Medicare expenditures.

[31] In this case, we set the censor date to the censor date used for analysis of impacts on heart attack and stroke.

3. Baseline characteristics and outcomes from Part D claims

Beneficiaries identified in the Million Hearts Data Registry are considered the registry population. For those who were also enrolled in Part D, we developed covariates and outcomes using Part D claims for relevant CVD medications (specifically, antihypertensive medications and statins). In this section, we describe these covariates and outcome measures, as well as the inclusion criteria for each outcome measure.

a. Use of CVD medications at baseline

For beneficiaries enrolled in Part D during all 12 months of the baseline period and on the day they enrolled in the Million Hearts Model, we constructed two variables for antihypertensive medication and statin use:

1. **Indicator variable for any use of antihypertensive medication.** This covariate indicates if the beneficiary had a Part D claim for at least one antihypertensive medication during the 12 months before enrollment.
2. **Categorical variable for intensity level of statin therapy.** This covariate indicates if a beneficiary had a Part D claim for at least one statin during the 12 months before the enrollment period. Statin users are further classified into low-, moderate-, or high-level statin therapy use based on the highest statin dose intensity level[32] during the baseline period.

To develop the list of antihypertensive medications and statins to be included for the Part D analysis, we reviewed lists of these medications compiled by quality improvement organizations (such as the National Committee for Quality Assurance), professional societies (such as the American Heart Association), and the formularies of health care systems (such as the Veterans Health Administration). From these information sources, we extracted drug names, national drug codes, and drug strengths. For statin therapy, we used medication and intensity level information from the HEDIS measure of statin therapy (National Committee for Quality Assurance 2017). For antihypertensive medications, we included five antihypertensive medication classes (angiotensin II receptor blockers, angiotensin converting enzyme inhibitors, beta blockers, calcium channel blockers, and thiazide diuretics).

[32] Low-intensity statins are expected to reduce LDL by 30 percent or less, medium-intensity statins are expected to reduce LDL by 30 to 49 percent, and high-intensity statins are expected to reduce LDL by 50 percent or more, relative to not taking statins (Grundy et al. 2018).

b. Initiation or intensification of CVD medications after enrollment

We constructed three outcome variables from the Part D data:

1. **Indicator variable for any antihypertensive medication initiation or intensification.** This variable indicates if a beneficiary (a) started antihypertensive medication use in the first six months after enrollment, among potential candidates for antihypertensive medication initiation; or (b) had any addition of a new antihypertensive medication, or any strength intensification of the baseline antihypertensive medications, in the first six months after enrollment, among potential candidates for antihypertensive medication intensification.
2. **Indicator variable for any statin therapy initiation or intensification.** This variable indicates if a beneficiary (a) started statin use in the first six months after enrollment, among potential candidates for statin therapy initiation; or (b) had a new statin at a higher intensity level (for example, from a medium- to high-intensity statin), or any dosage/strength increase of the statins they were taking at baseline, in the first six months after enrollment, among potential candidates for statin therapy intensification.
3. **Indicator variable for any antihypertensive medication or statin therapy initiation or intensification.** This variable indicates if the beneficiary met one or more of the criteria listed above for any antihypertensive medication or statin initiation or intensification.

The three outcomes variables were constructed only among those patients who met the inclusion criteria for initiation or intensification of each medication. In Table C.2, we present the inclusion criteria and sample sizes for each outcomes measure.

Table C.2. Eligibility criteria and sample sizes for outcomes constructed from the Part D claims

Outcome	Inclusion criteria	Sample sizes (and percentage of beneficiaries with Part D coverage in the risk group who met these criteria)
Antihypertensive medication initiation or intensification	• Had elevated blood pressure (defined as SBP 130 or higher) at enrollment. – Candidate for initiation if not taking any antihypertensive medications in the 120 days prior to the enrollment – Candidate for intensification if taking at least one antihypertensive medication in the 120 days prior to the enrollment	• High-risk group: – 16,964 treatment beneficiaries (73%) – 10,872 control beneficiaries (74%) • High- and medium-risk group combined: – 42,721 treatment beneficiaries – (59%) – 27,766 control beneficiaries – (60%)

Table C.2. (Continued)

Outcome	Inclusion criteria	Sample sizes (and percentage of beneficiaries with Part D coverage in the risk group who met these criteria)
Statin therapy initiation or intensification	• Had elevated LDL level (defined as LDL 70 or higher) at enrollment – Candidate for initiation if not taking any statins in the 120 days prior to the enrollment – Candidate for intensification if taking at least one statin in the 120 days prior to the enrollment	• High-risk group: – 16,698 treatment beneficiaries (72%) – 10,599 control beneficiaries (72%) • High- and medium-risk group combined: – 55,746 treatment beneficiaries (77%) – 35,269 control beneficiaries (76%)
Antihypertensive medication or statin therapy initiation or intensification	• Had elevated blood pressure (defined as SBP 130 or higher) or elevated LDL level (defined as LDL 70 or higher) at enrollment – Candidate for initiation if not taking any antihypertensive medications or statins in the 120 days prior to the enrollment – Candidate for intensification if taking at least one antihypertensive medication or statin in the 120 days prior to the enrollment	• High-risk group: – 20,997 treatment beneficiaries (91%) – 13,392 control beneficiaries (91%) • High- and medium-risk group combined: – 64,630 treatment beneficiaries (90%) 41,381 control beneficiaries (89%)

LDL = low-density lipoproteins; SBP = systolic blood pressure.

4. Baseline modifiable CVD risk from the Million Hearts Data Registry

We define modifiable risk as the difference between a beneficiary's CVD risk score at enrollment and a CVD risk score they could attain 12 months later if they hit a series of evidence-based clinical targets. For example, if a beneficiary had a baseline risk score of 32 percent and an attainable, or target, follow-up score of 20 percent one year later, the modifiable risk would be 12 percentage points (32 minus 20). We calculated baseline risk scores using the American College of Cardiology (ACC)/American Heart Association (AHA) Atherosclerotic Cardiovascular Disease (ASCVD) Risk Calculator. To reflect the same methods CMS uses to calculate risk scores at reassessment visits, we calculated target follow-up risk scores using the Million Hearts Longitudinal ASCVD Risk Assessment Tool. The Million Hearts Longitudinal ASCVD Risk Assessment Tool is designed to provide an updated CVD risk score at follow-up, taking into account baseline risk factor levels, as well as changes in risk factors in response to therapy, and was developed for use in the Million Hearts Model (Lloyd-Jones et al. 2017).

Our definition of modifiable risk aligns with the calculation that CMS uses for risk-reduction incentive payments, which also are calculated based on the changes in risk scores between

enrollment and annual follow-up visits among enrolled beneficiaries.[33] Consistent with CMS's calculations, we assume that beneficiaries age one year between enrollment and follow-up and take aging into account in calculations of follow-up risk scores. We also calculate modifiable risk for all enrolled beneficiaries, including beneficiaries who age out of the 40 to 79 age range that is eligible to first enroll in the model. This is consistent with current model implementation, which includes these beneficiaries in the calculations of risk-reduction incentive payments.

Table C.3 describes the clinical targets we use to define modifiable risk and justifies why they are chosen based on the research literature. We selected clinical targets only for those risk factors in the Million Hearts Longitudinal ASCVD Risk Assessment Tool. (Examples of risk factors not in the model are initiation of statin therapy and diastolic blood pressure.) We assume that some risk factors remain unchanged from enrollment—either because they are very difficult to modify, such as diabetes, or because there is no clear clinical target, such as for high-density lipoprotein (HDL) cholesterol. For beneficiaries with risk factor levels below the targets at enrollment—for example, a systolic blood pressure less than 130 mmHg—we assume that the risk factor remains below the target at follow-up. We calculated total cholesterol assuming that LDL cholesterol is modifiable but other lipid levels are not.

[33] Specifically, risk-reduction payments are calculated based on the average risk reduction among a participating organization's enrolled beneficiaries who were considered high risk—that is, with a risk score of at least 30 percent—at enrollment. For each eligible beneficiary, risk reduction is calculated as the baseline score minus the most recent (annual) follow-up risk score, one or more years later. If a beneficiary is not observed for the follow-up visit—because the beneficiary is lost to follow-up, dies, or becomes ineligible for the model—that beneficiary is excluded from the calculation.

Table C.3. Clinical targets used to define modifiable risk, and the evidence base for selecting them

Risk factors included in the Million Hearts Longitudinal ASCVD Risk Assessment Tool	Clinical target	Justification	References
Aspirin therapy	Initiate aspirin therapy if age between 40 and 70 and CVD risk score ≥ 10%	The U.S. Preventive Services Task Force recommends low-dose aspirin therapy for adults with CVD risk score ≥ 10%. The 2019 ACC/AHA guidelines for the prevention of CVD recommends against routine administration of low-dose aspirin for adult >70 years of age, but recommends considering low-dose aspirin for adults ages 40 to 70.	Bibbins-Domingo et al. 2016 Arnett et al. 2019
Systolic blood pressure	Target an SBP level of < 130 mmHg	The 2017 ACC/AHA hypertension guidelines recommends SBP <130 as a blood pressure goal. Therefore, we use this as the target even though there may be additional benefits to reducing SBP to <120 (The SPRINT Research Group 2015).	Carey and Whelton 2018 The SPRINT Research Group 2015
Antihypertensive treatment	- All individuals on antihypertensives at enrollment remain on antihypertensives - Initiate antihypertensive treatment if: 1) CVD risk score ≥ 10% and SBP ≥ 130 OR 2) 2) CVD risk score < 10% and SBP ≥ 140	The 2017 ACC/AHA hypertension guidelines recommend initiating drug treatment for adults with CVD risk score ≥ 10% and an average BP of 130/80 mmHg. For lower-risk adults, they recommend a BP threshold of 140/90 mmHg or higher for initiating drug treatment.	Carey and Whelton 2018
Smoking	All smokers quit smoking for the entire follow-up year	The U.S. Preventive Services Task Force recommends screening all adults for tobacco use and advising users to stop using tobacco.	Siu et al. 2015
LDL cholesterol	Target an LDL cholesterol level of < 70 mg/dL	Individuals with LDL < 70 are generally not treated with statins according to the 2018 ACC/AHA cholesterol guidelines. Although the guidelines recommend individual-specific goals (for example, reductions of 50% from pretreatment LDL levels), these require knowledge of pretreatment cholesterol, which we do not have for all patients.	Grundy et al. 2018
Total cholesterol	Calculated assuming LDL changes to the clinical target but that other lipid levels do not	Total cholesterol is a function of LDL, HDL, and triglycerides. There are no clear guidelines to support setting either HDL or triglyceride	Grundy et al. 2018

Table C.3. (Continued)

Risk factors included in the Million Hearts Longitudinal ASCVD Risk Assessment Tool	Clinical target	Justification	References
		goals. Statins have a much less pronounced effect on HDL and triglyceride (compared to LDL) levels.	
HDL cholesterol	No clinical target	There are no clear guidelines to support setting HDL goals. Statins have a much less pronounced effect on HDL (compared to LDL) levels and there is no consistent evidence that increasing HDL levels via drug therapy reduces cardiovascular risk. Because of this, clinicians are unlikely to set HDL goals when considering cholesterol management.	Grundy et al. 2018 Jellinger et al. 2017
Diabetes	No clinical target	Diabetes remission is very rare (fewer than 1 patient per 10,000 per year has a prolonged remission).	Karter et al. 2014

ACC = American College of Cardiology; AHA = American Heart Association; ASCVD = atherosclerotic cardiovascular disease; BP = blood pressure; CVD = cardiovascular disease; HDL = high-density lipoprotein; LDL = low-density lipoprotein; mg/dL = milligrams per deciliter; mmHg = millimeters of mercury; SBP = systolic blood pressure.

This page has been left blank for double-sided copying.

APPENDIX D

DETAILED METHODS AND RESULTS FOR ESTIMATING IMPACTS ON BENEFICIARY OUTCOMES

This page has been left blank for double-sided copying.

In Chapter IV, we present estimated impacts of the Million Hearts Model on beneficiary outcomes, measure changes in cardiovascular disease (CVD) risk and risk factors after enrollment, and report estimated impacts on the initiation or intensification of CVD medications, drawing on data from Medicare claims and the Million Hearts Registry. This appendix describes the methods for these analyses in detail and presents additional empirical results.

1. Methods for estimating impacts using claims data

The core design for estimating impacts used the cluster randomized trial, in which CMS randomly assigned 516 organizations (the clusters) to intervention and control groups. The 260 intervention organizations and the 256 control organizations were balanced on location (as defined by region), number of sites and practitioners, self-reported type of organization and self-reported number of Medicare beneficiaries (NORC 2016a, b). Although the unit of random assignment was the organization, the unit of analysis for most study outcomes is the beneficiary. That is, we estimate impacts as the regression-adjusted differences in outcomes between intervention and control *beneficiaries*. We estimated 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. Appendix A describes the populations of beneficiaries analyzed in this annual report and compares the beneficiaries in the intervention and control groups on a number of characteristics.

Because beneficiaries enrolled at different times, our follow-up data on beneficiary outcomes cover different calendar periods for each beneficiary. For each enrollee, we measured outcomes from the beneficiary's date of enrollment (in 2017) through October 2018 (or the date a person died or became unobservable in Medicare claims). The mean follow-up period across all enrollees was 17 months, with a range from one day to 22 months. We used an intent-to-treat design, following beneficiaries for all months after they enter the Million Hearts Model, whether or ns limits the possibility that differential attrition between the intervention and control groups could bias impact estimates. Nonetheless, this approach does not *guarantee* unbiased estimates, especially because some of the randomized organizations have dropped out of the study, more providers participated in the model at intervention organizations than at control organizations, and some eligible beneficiaries in the included organizations may not be risk stratified or reported to the registry.

a. Overview of types of regression models used for estimating impacts

Regression models are central to our framework for estimating impacts of the Million Hearts Model on beneficiaries' outcomes. The regression models adjust the impact estimates to account for differences in observed baseline characteristics of beneficiaries in the intervention and control groups (including the characteristics of the beneficiaries' organizations and providers at baseline). They also allow for statistical tests that determine whether the adjusted differences in outcomes between the intervention and control groups are likely due to chance. All models account for clustering of beneficiaries within organizations, which is needed to correctly estimate the statistical precision of the estimates.

We tailored the regression models to the type of outcome measure, with outcome measures falling into one of three types:

1. Impacts on time to the first of heart attack, stroke, or transient ischemic attack (TIA) and time to death were analyzed using Cox proportional hazard models at the beneficiary level.
2. Impacts on Medicare spending and utilization were estimated using linear regression models at the beneficiary-quarter level.
3. Impacts on the initiation or intensification of CVD medications were analyzed using logit regression models at the beneficiary level.

We describe the regression models for these three types of outcomes in the following subsections of this appendix.

b. Model for time to first of heart attack, stroke, or TIA and mortality

We used survival analysis techniques to estimate impacts of the Million Hearts Model on several outcomes:

- Time to first of heart attack, stroke, or TIA (a composite measure of CVD events)
- Time to first heart attack
- Time to first stroke or TIA
- Time to death (for any reason)

For these outcomes, our analyses used unweighted data at the beneficiary level (that is, one row per beneficiary, with each beneficiary receiving equal weight). We used two variables to describe each outcome: (1) a variable with the length of time (number of days) a beneficiary was in the sample and observed, and (2) an indicator variable that equaled one if the outcome occurred and equaled zero if the beneficiary's data were censored before the event occurred. For heart attacks, strokes, and TIAs, we could observe beneficiary outcomes up to October 2018 (the date claims data were pulled) as long as the beneficiary remained alive, enrolled in Medicare Parts A and B (not Medicare Advantage), and had Medicare as their primary payer. For mortality, we could observe outcomes for all beneficiaries through October 2018, regardless of their type of Medicare enrollment.

For each outcome, we produced tables and graphs with the unadjusted, cumulative probability of having the event as a function of time, separately for the intervention and control groups. The cumulative probability is defined as one minus the Kaplan-Meier (1958) estimate of the survival function. The survival function gives the probability that a beneficiary does not have an event within a specified amount of time.

Next, we used hazard modeling to estimate impacts on the risk of having these events throughout the study period. We used a Cox proportional hazard model. A hazard is the estimated probability of the event occurring at a certain time. Cox proportional hazard models are widely used in biostatistics and clinical trials to model impacts on event data. A major advantage of this

model is that it uses data for all beneficiaries—even those who do not have data for the full test period because they enrolled in the Million Hearts Model later in the intervention period, or because they died or otherwise became unobservable in FFS claims before experiencing a heart attack or stroke. The Cox proportional hazards model is expressed as:

$$h_i(t) = h_0(t)\ \exp(\delta\ MH_i + \beta\ x_i), \quad \text{(D.1)}$$

where $h_i(t)$ is the hazard (that is, the estimated probability the event occurs at time t) for beneficiary i, $h_0(t)$ is a baseline hazard (which does not need to be known for us to estimate the other model parameters), MH_i equals one for beneficiaries in the intervention group and equals zero for beneficiaries in the control group, and the remaining term is a set of baseline covariates (x_i). The Greek letters (δ and β) in Equation D.1 are parameters to be estimated.

The coefficient δ captures the effect of the Million Hearts Model on the time-to-event, adjusted for the remaining covariates in the model. We expressed δ as a hazard ratio for intervention versus control beneficiaries, along with its standard error and confidence interval. The hazard ratio is the ratio between the intervention and control groups in the risk of having a CVD event at each time point throughout the study period, with values less than 1 indicating that risk is lower in the intervention group than the control group. A key assumption behind the Cox model, known as the proportional hazards assumption, is that the ratio in risk remains constant throughout the study period. To account for the clustering of beneficiaries within organizations, we computed robust standard errors, clustered at the organization level. *P*-values and confidence intervals were computed from the cluster-robust standard errors.

The baseline covariates (x_i) and the vector are coefficients (β) were included to account for observed differences between the intervention and control groups at baseline and potentially improve the precision of the impact estimates. These covariates include beneficiary characteristics from claims and, for enrolled beneficiaries, data from the Million Hearts Data Registry. Among other things, the covariates accounted for the date of enrollment, beneficiary demographics, Medicare and Medicaid enrollment status, beneficiary health status, CVD risk factors at baseline, baseline outcomes measured in pre-enrollment claims data, characteristics of the organization and provider that enrolled the beneficiary, geographic region, and participation in other CMS initiatives at baseline. Because the covariates reduce the unexplained variation in the model, their inclusion could also tended to improve the statistical power of the models. Table D.1 provides a full list of covariates, with several of the specific covariates we used varying based on whether we defined the study population as beneficiaries enrolled through the registry versus those we attributed to organizations using Medicare claims data.

Table D.1. Covariates included in the regression models used for estimating impacts on beneficiary outcomes

Baseline covariate	Included in models with the population of: Enrolled beneficiaries	Attributed beneficiaries
Clinical indicators of beneficiary's cardiovascular risk		
CVD risk score [a, b]	■	
Predicted CVD risk score [b]		■
Modifiable risk [a, b, c]	■	
Claims-based CVD risk score (assuming optimal values for clinical values)		■
Has diabetes (yes/no)[a]	■	
Evidence of diabetes in claims (yes/no)		■
Systolic blood pressure (mm Hg) [a]	■	
Evidence of hypertension in claims over previous 24 months (yes/no)		■
Total cholesterol (mg/dL) [a]	■	
HDL cholesterol (mg/dL) [a]	■	
LDL cholesterol (mg/dL) [a, c]	■	
Evidence of hyperlipidemia in claims over previous 12 months (yes/no)		■
Is treated for or diagnosed with hypertension (yes/no)[a]	■	
Is current smoker (yes/no)[a]	■	
Evidence of tobacco use in claims over previous 24 months (yes/no)		■
Uses aspirin (yes/no)[a]	■	
Evidence of aspirin use in claims over previous 24 months (yes/no)		■
Beneficiary demographic and Medicare enrollment characteristics		
Age (separately by age group) [b, d]	■	■
Black race (yes/no)	■	■
Male (yes/no)	■	■
Dually enrolled in Medicare and Medicaid (yes/no)	■	■
Originally entitled to Medicare due to disability (yes/no)	■	■
Beneficiary health and comorbid conditions		
HCC score [b]	■	■
Count of chronic conditions	■	■
Has chronic kidney disease (yes/no)	■	■
Has ischemic heart disease (yes/no)	■	■
Evidence of heart failure in claims over previous 24 months (yes/no)	■	■
Has atrial fibrillation (yes/no) [a]	■	
Evidence of atrial fibrillation in claims over previous 24 months (yes/no)		■
Has morbid obesity (yes/no)	■	■
Has dementia (yes/no)	■	■
Has diabetes with complications (yes/no)	■	■

Table D.1. *(Continued)*

	Included in models with the population of:	
Has dialysis status/acute renal failure/stage 5 chronic kidney disease (yes/no)	■	■
Has cancer (yes/no)	■	■
Has unstable angina (yes/no)	■	■
Has chronic obstructive pulmonary disease (yes/no)	■	■
Has vascular disease with complications (yes/no)	■	■
Has drug/alcohol dependence (yes/no)	■	■
Beneficiary medical service use and spending in year before model enrollment [e]		
Total Medicare Parts A and B annualized expenditures [b, f]	■	■
Total inpatient annualized expenditures [f]	■	■
Number of hospital admissions [f]	■	■
Number of CVD-related hospital admissions [f]	■	■
Number of outpatient ED visits or observation stays [f]	■	■
Number of CVD-related ED visits or observation stays [f]	■	■
Number of office visits [f]	■	■
Number of office visits with model-aligned providers [f]	■	■
Number of cardiologist office visits [f]	■	■
Beneficiary CVD-related procedures in year before model enrollment [e]		
Received echocardiogram (yes/no)	■	■
Received electrocardiogram (yes/no)	■	■
Received cardiac stress test (yes/no)	■	■
Received prophylactic vaccination/inoculation (yes/no)	■	■
Received colonoscopy/biopsy (yes/no)	■	■
Beneficiary CVD-related medication utilization before model enrollment [e, g]		
Antihypertensive medications in baseline year (yes/no/without Part D enrollment)	■	■
Statins in baseline year (no/low/moderate/high/without Part D enrollment)	■	■
Characteristics of organization enrolling the beneficiary [h]		
Total number of practitioners: (1 to 5/6 to 19/ 20 or more)	■	■
Total number of service sites: (1/2 to 5/6 or more)	■	■
Organization type: (primary care/specialty or multispecialty/FQHC, RHC, or other health center/ CAH, rural hospital, acute care hospital, other, or unknown)	■	■
Organization was participating in, or had application pending for, another model at randomization (yes/no)	■	■
Characteristics of clinician enrolling the beneficiary [h]		
Provider specialty (cardiovascular-related physician/primary care physician [non-cardiovascular]/other physician/other provider type[non-physician])	■	■
Characteristics of beneficiary's region		
Rural (yes/no)	■	■

Table D.1. *(Continued)*

	Included in models with the population of:	
Census region (midwest/south/west/other)	■	■
Characteristics of beneficiary's Million Hearts Model enrollment [e]		
Days between enrollment and January 3, 2017 [f]	■	■
Quarter of year enrollment date is in (first/second/third/fourth)	■	■
Less than 12 months observable in year before enrollment (yes/no)	■	■
Data submitted to the registry using bulk upload (yes/no)[a]	■	

[a] This variable was constructed using data from the Million Hearts registry.

[b] We also included an interaction term between this variable and the high-risk group indicator in models that included both medium- and high-risk beneficiaries.

[c] To account for missing values, this variable was interacted with indicator for missing data.

[d] We adjusted by age (a continuous variable) separately for four separate age groups: 40 to 64 years, 65 to 69 years, 70 to 74 years, and 75 to 79 years.

[e] For the population of attributed beneficiaries, these variables were defined according to the date of the visit that led to the beneficiary being attributed to the participating organization (in place of the date of enrollment).

[f] These variables were standardized before being included in the regression models.

[g] When estimating impacts of the Million Hearts Model on initiation or intensification of CVD medications, we measured CVD-related medication utilization in the 120 days before model enrollment. When estimating impacts on the remaining outcomes, we measured CVD-related medication utilization in the year before model enrollment.

[h] For the population of attributed beneficiaries, these variables were defined according to characteristics of the organization or provider that the beneficiary was attributed to (in place of the organization or provider that *enrolled* the beneficiary).

CVD = cardiovascular disease; ED = emergency department.

As noted earlier, Cox proportional hazard models require a proportional-hazards assumption, which means that the survival functions for the intervention and control groups have hazard functions that are proportional over time, which may not hold. (That is, Cox proportional hazards models assume that the hazard ratio is constant over time—but this might not be true.) Because the Cox model, by definition, is constrained to follow this assumption, it is important to evaluate its validity. For the primary outcome measures, we performed three tests to evaluate the validity of the model. We (1) conducted a hypothesis test for proportional hazards by intervention arm on the basis of Schoenfeld residuals, (2) examined a log-log plot of survival by intervention arm, and (3) compared the adjusted survival function to the (unadjusted) Kaplan-Meier survival function, separately by intervention arm. These tests did not suggest a failure of the proportional hazard assumption for any of the primary outcome measures.

c. Model for Medicare spending and other quarterly outcomes

For a number of claims-based outcome measures, we estimated impacts using linear regression models estimated at the beneficiary-quarter level. (That is, the data for the regression model included one row per beneficiary per quarter.) Quarters are three-month periods, defined relative to when the beneficiary was enrolled in the model. (For the population of attributed beneficiaries,

quarters are three-month periods defined relative to when the beneficiary was attributed to a participating organization.) The outcomes analyzed with this approach included:

- Medicare spending (with and without model payments, overall and by type of service)
- CVD-related and all-cause hospitalizations and outpatient ED visits and observation stays

We used an intent-to-treat design, following beneficiaries in the population for all quarters after they entered the Million Hearts Model, whether or not they continued to receive care from the intervention or control organizations. To be included in the analysis for a particular quarter, the beneficiary had to be observable in the quarter. Observability was based on several factors. First, the beneficiary needed to have been enrolled early enough (in calendar time) to be observed in the last day of the quarter (given the last date covered by our claims data—October 2018). Second, beneficiaries needed to be alive on the first day of the quarter. Third, beneficiaries needed to be observable in Medicare FFS claims. To be observable, beneficiaries had to be enrolled in Medicare Parts A and B (not Medicare Advantage) and have Medicare as the primary payer on the first day of the quarter. To account for beneficiaries who became unobservable during the quarter, we then reweighted beneficiaries using the fraction of days in the quarter they were observable and quarterized their outcomes.[34]

We used a longitudinal, linear regression model to compare regression-adjusted outcomes for the intervention and control beneficiaries during each follow-up quarter. The specific regression model was:

$$y_{it} = \sum_{\tau=1}^{T} 1(t = \tau) * (\alpha_\tau + \delta_\tau \, MH_i) + \beta \, x_i + \varepsilon_{it}, \qquad \text{(D.2)}$$

where y_{it} is the outcome measured for beneficiary i in follow-up quarter t. In this equation, τ indexes the quarters (1 for follow-up quarter 1, and 2 for follow-up quarter 2, and so on), T is the maximum number of quarters available for the outcome measure at the time of the report (that is, $T = 7$), the function "$1(t = \tau)$" is an indicator function that is used to allow the regression coefficients to vary by quarter, and MH_i equals one for beneficiaries in intervention organizations and equals zero for beneficiaries in control organizations. The coefficient α_t captures the secular effect of patient-time in quarter t. For example, average spending might increase as a patient ages, all else equal. As was the case before, the remaining covariates in Equation D.2, x_i are included to account for trends in the control group, potentially improve the precision of the impact estimates, account for features of the randomization process, and net out effects of any observed differences in characteristics between the intervention and control groups that arose by chance despite randomization. Because the sample changes as beneficiaries exit it, the covariates also help control for differential shifts in beneficiary characteristics over time that are unrelated to the model that, if unaccounted for, might have led to spurious conclusions. The

[34] For example, if someone had two hospitalizations and spent $100,000 before dying on the 60th day of the quarter, they were included in the analysis for that quarter, with a weight of ".667" (= 60/90), and their outcomes were recoded as "3" (= 2 / .667) and "$150,000" (= $100,000 / .667). In most beneficiary-quarter observations, beneficiaries were observed for the full quarter, so the observation received a weight of "1" and the outcomes were unmodified.

Greek letters (α, δ, and β) in Equation D.2 are parameters to be estimated, and the models are estimated by weighted least squares. To account for the clustering of beneficiaries within organizations, we report *p*-values and confidence intervals based on robust standard errors, clustered at the organization level.

The coefficients δ_t are our parameters of interest—they capture the impact of exposure to the Million Hearts Model in each quarter t. Because this is a linear regression model, this coefficient can be directly interpreted as the impact of the model in quarter t—the regression-adjusted average difference in outcomes in quarter t between intervention and control beneficiaries. By estimating separate impacts for each quarter, the regression models could capture whether impacts changed over time—that is, as beneficiaries were enrolled in the Million Hearts Model longer.

In this report, we mainly report estimates of the *average* impacts of the Million Hearts Model. To do this, we computed a weighted average of impacts and regression-adjusted means across the follow-up quarters:

$$\bar{\delta} = \frac{1}{T}\sum_{\tau=1}^{T} w_\tau \delta_\tau, \quad \text{(D.3)}$$

where w_τ is the share of intervention group observations (weighted) observed in quarter t.

d. Model for initiation or intensification of CVD medications

To estimate impacts of the Million Hearts Model on initiation or intensification of CVD medications within six months of enrollment in the model, we estimated impacts using logit regression models estimated at the beneficiary level. (That is, the data for the regression model included one row per beneficiary.)[35] To be included in the analysis, beneficiaries had to be alive, continuously enrolled in a Medicare Part D plan in the 12 months before enrollment, enrolled in Medicare Part D at enrollment, have non-missing baseline data for LDL cholesterol and systolic blood pressure, and be identified as a potential candidate for medication initiation or intensification. Potential candidates for statin therapy initiation or intensification needed to have LDL cholesterol levels at baseline greater than 70 mg/dL, and potential candidates for antihypertensive medication therapy initiation or intensification needed to have systolic blood pressure greater than 130 mm Hg at baseline.

We used a cross-sectional logit regression model to compare regression-adjusted outcomes for the intervention and control beneficiaries. The specific regression model was:

$$\Pr(y_i = 1) = \mathrm{F}(\alpha + \delta\, MH_i + \beta\, x_i), \quad \text{(D.4)}$$

where y_i is the outcome measured for beneficiary i, $F(u) = \exp(u)\,/(1 - \exp(u))$, MH_i equals one for beneficiaries in intervention organizations and equals zero for beneficiaries in control

[35] We also used logit regression models for sensitivity tests, discussed below, that estimated impacts on CVD events and mortality. Those regression models were nearly identical to the regression models for initiation or intensification of CVD medications described here.

organizations, and x_i is a set of baseline covariates. The Greek letters (α, δ, and β) in Equation D.4 are parameters to be estimated, and the model was estimated by maximum likelihood, with each beneficiary receiving equal weight. To account for the clustering of beneficiaries within organizations, we report *p*-values and confidence intervals based on robust standard errors, clustered at the organization level.

The coefficient δ is our parameter of interest—it captures the impact of exposure to the model on the probability of the outcome occurring. Because this is a nonlinear model, we calculated averaged marginal effects that expressed impacts as percentage point differences in the probability of the outcome occurring. Specifically, for each intervention group beneficiary, we used the model and the estimated parameters to calculate what that beneficiary's outcome would be if they were in the intervention group or the control group, and the difference in those two potential outcomes. We then calculated the average model impact as the average of these differences across all intervention group enrollees. As was the case above, the vector of coefficients, β, account for observed differences between the intervention and control groups in baseline covariates (x_i) and potentially improve the precision of the impact estimates.

2. Changes in CVD risk and risk factors after enrollment

In Chapter IV, Section A.6, we estimated the average change in CVD risk scores and CVD risk factors between (1) enrollment, and (2) reassessment visits occurring an average of one year after enrollment among beneficiaries in the intervention group with high (more than 30 percent) CVD risk at baseline. For these beneficiaries, we also estimated changes in the overall CVD risk score that were attributable to each of the four ABCS of CVD risk management: **a**spirin therapy, **b**lood pressure reduction, **c**holesterol reduction, and **s**moking cessation. To identify the changes in CVD risk score attributable to each ABCS risk factor, we calculated the expected change in CVD risk scores if average high-risk enrollees had experienced the average changes in ABCS risk factors observed in our population. Specifically, we calculated these population-level benefits by (1) calculating CVD risk scores for beneficiaries who had average levels of the risk factor of interest at baseline (for example, systolic blood pressure of 140 mm Hg) or, for binary risk factors, had the risk factor of interest at baseline (for example, they were smokers) and had average levels of all other risk factors; and (2) holding all other risk factors at their means, calculating the risk score reduction assuming that beneficiaries who had the risk factor (that is, were smokers) at baseline experienced the average change in the risk factor. The following examples illustrate this approach:

- **Systolic blood pressure.** We first calculated the CVD risk score for a beneficiary with the mean systolic blood pressure of 140 mm Hg and the average (or, for binary risk factors, the modal) value for all other risk factors. We then used the longitudinal risk calculator to identify the change in CVD risk score that would accompany the observed mean decline in systolic blood pressure (6 mm Hg) for this average high-risk enrollee. The decline turned out to by 11 percentage points. We considered this 11 percentage point reduction as the population-wide decline in CVD risk that could be attributed to improvements in blood pressure.

- **Smoking.** We first calculated the CVD risk score for a beneficiary who smoked at baseline and had the mean (or, for binary risk factors, the modal) value of all other baseline CVD risk factors. We then calculated the drop in CVD risk that the longitudinal model predicts one year later if this average high-risk enrollee who smoked had stopped smoking right after model enrollment (which was 11 percentage points). We then multiplied that reduction by the percentage of people who were observed to quit smoking after enrollment (which equals 11 percentage points multiplied by 1 percent) to get the population-wide decline in CVD risk score (0.1 percentage points) that could be attributed to smoking cessation.

3. Supplementary results

Figures D.1 and D.2 present unadjusted (Kaplan-Meyer) estimates of the cumulative probability of having a first-time heart attack, stroke or TIA (composite measure) or of dying by quarter of enrollment for the intervention and control groups, respectively. The cumulative probability is defined as 1 minus the Kaplan-Meier estimate of the survival function. The survival function is a function that gives the probability that a beneficiary does not have the event (for exaple, dying) within a specified time. The results present additional details and context to support the regression-adjusted results reported in the chapter.

In addition to estimating impacts for the primary study population of high-risk and medium- and high-risk enrolled beneficiaries, we estimated impacts for two populations for robustness checks:

1. **Trim sample to ≤20 providers per organization.** The first robustness check re-estimated impacts for the model enrollees, but trimmed the intervention group in a way that attempted to mimic the 20-provider cap applied to the control group. 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 (Conwell et al. 2019). That is, it appears the control organizations were strategically selecting the providers in their organization who could enroll the most beneficiaries. We replicated this rule in the intervention group by (1) identifying each provider who enrolled a beneficiary when working at a large intervention organization (with large organizations defined as those with more than 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. In the end, the analyses with our "trimmed" sample included 23,395 intervention group beneficiaries and 20,918 control group beneficiaries in the high-risk group, and 71,814 intervention group beneficiaries and 66,926 control group beneficiaries in the medium- and high-risk groups (combined). In our first annual report (Conwell et al. 2019), we showed this trimming makes the intervention and control groups more similar in both overall size and in the proportion of beneficiaries enrolled by large organizations. Therefore, it helps address the limitation that, even though the 2017 enrollees in the intervention and control groups are well balanced on a range of beneficiary-level characteristics, intervention-group beneficiaries are more likely to be enrolled by large organizations—which could potentially confound the impact estimates if size of the enrolling organization is correlated with the outcome.

2. **Analyses with attributed beneficiaries.** The second robustness check re-estimated 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. The methods for defining this population and predicting risk scores are discussed in Appendix A.

In Tables D.2 through D.8, we present results from our impact analyses of these populations, along with the results from our impact analyses of the primary study population of all enrolled medium- and high-risk beneficiaries (labeled "main analysis").[36] The main difference—which we discussed in Chapter IV—was that estimated impacts on hospitalizations and outpatient ED visits and outpatient stays are noticeably different for the two populations (Table D.5). For the rest of the outcome measures, the impact estimates for the registry population mostly align with the impact results for the main analyses.

In addition to the results with these robustness populations, the remaining tables in this appendix present the following supplementary results:

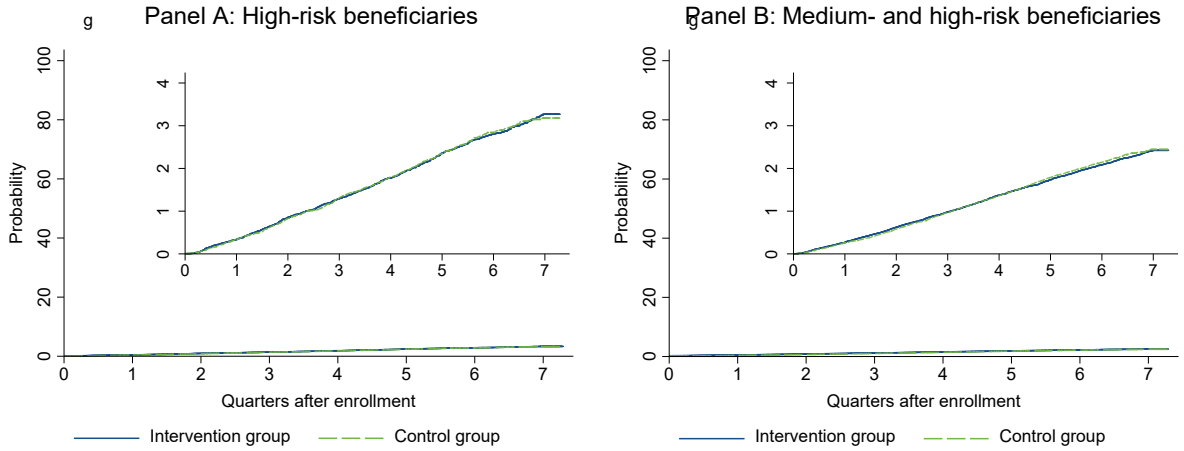
- **Unadjusted impact estimates.** These impact estimates are based on regression models similar to those discussed above but do not include the vector of baseline covariates (x_i). Discrepancies between the adjusted and unadjusted impact estimates, when present, suggest that the regression models are adjusting for differences in baseline characteristics between the intervention and control groups on variables related to outcomes.
- **Subgroups of enrolled beneficiaries.** For the primary outcome measures of CVD events and spending, we estimated impacts for subgroups defined by the proportion of beneficiaries' total 10-year CVD risk that is due to modifiable risk factors. For this analysis, we calculated the median percentage point level of modifiable risk (among high-risk intervention and control beneficiaries). We then estimated impacts separately for beneficiaries with modifiable risk above the median and beneficiaries with modifiable risk below the median. This subgroup analysis was predefined based on the hypothesized expectation that model impacts could be larger for beneficiaries for whom most of their CVD risk is modifiable. However, impact estimates are not statistically significant for either subgroup for either outcome measure (Tables D.2 and D.4).
- **Alternative outcomes measures.** In Table D.2, we present impact estimates with our composite measure of CVD events redefined using a narrower definition, excluding TIAs and stroke symptoms and certain acute myocardial infarctions (AMIs) from being considered CVD events. (See Appendix C for definitions of the outcome measures.) Table D.5 also

[36] We do not estimate impacts of the Million Hearts Model on initiation or intensification of CVD medications within six months of enrollment in the model with the population of attributed beneficiaries. This is because we do not observe baseline cholesterol or blood pressure for all these beneficiaries, which makes it difficult to identify candidates for initiation or intensification of CVD medication therapy.

presents results when we measure the impacts on the number of office visits using alternative outcome measures. Results are not notably different from the results in the main analyses.

- **Extra control variables.** In Table D.2, we present impact estimates for the population of attributed beneficiaries, where, in addition to controlling for the list of covariates in Table D.1, we control for the place of service for the visit that led to the beneficiary being attributed. We noticed there is imbalance in this variable between the intervention and control groups, but we had not included it in the main regression models. Impact estimates are somewhat smaller after adding this covariate.
- **Mechanisms of impacts on mortality.** In post-hoc analyses, shown in Table D.3, we explored whether impacts on mortality may have been mediated, in part, by increases in the initiation and intensification of CVD medication therapy. We found that, for medium- and high-risk enrollees eligible for the Part D analysis, the overall impacts on survival are attenuated and no longer statistically significant when we control for impacts on post-enrollment medication use (the hazard ratio changed from 0.90 [p=0.03] to 0.94 [p=0.36]).
- **Subgroups of attributed beneficiaries.** At the bottom of Table D.4, we explore why the estimated impacts of the model on Medicare spending are slightly smaller for attributed beneficiaries than they were for enrolled beneficiaries (the main analyses). We find that impact estimates for the high-predicted-risk attributed beneficiaries who were enrolled in the model are larger than the impact estimates for the remaining attributed beneficiaries who were not enrolled. However, the pattern is reversed for medium- and high-risk attributed beneficiaries.
- **Binary measures of CVD events and mortality.** We used a beneficiary-level logit regression model to estimate the effects of the Million Hearts Model on the proportion of beneficiaries with a first-time heart attack, stroke, or TIA during a specified period, using the subset of beneficiaries who enrolled early enough to be observed for the full period.[35] For example, we estimated effects on the proportion of beneficiaries who had a first-time heart attack, stroke, or TIA within one year of enrollment for the beneficiaries who enrolled early enough to be followed for one year in available claims data. (Some beneficiaries were dropped under this alternative modeling approach.) As with the Cox Proportional Hazard Models, the impact estimates are small and not statistically significant (Table D.6). When the process was repeated for death (for any reason), the results for medium- and high-risk beneficiaries indicate a statistically significant decrease in the probability of death (Table D.6), again confirming results with the main modeling approach.
- **Dropping some potential candidates for antihypertensive medication.** We conducted a sensitivity analysis by re-defining "potential candidates" for antihypertensive medication initiation or intensification as those with systolic blood pressures at baseline ≥ 140 mm Hg (as opposed to ≥ 130 mm Hg). The models are consistent with the findings from the main analysis (Table D.7).

Figure D.1. Cumulative probability of having a first-time heart attack, stroke or TIA (composite measure), by quarter of enrollment and intervention group

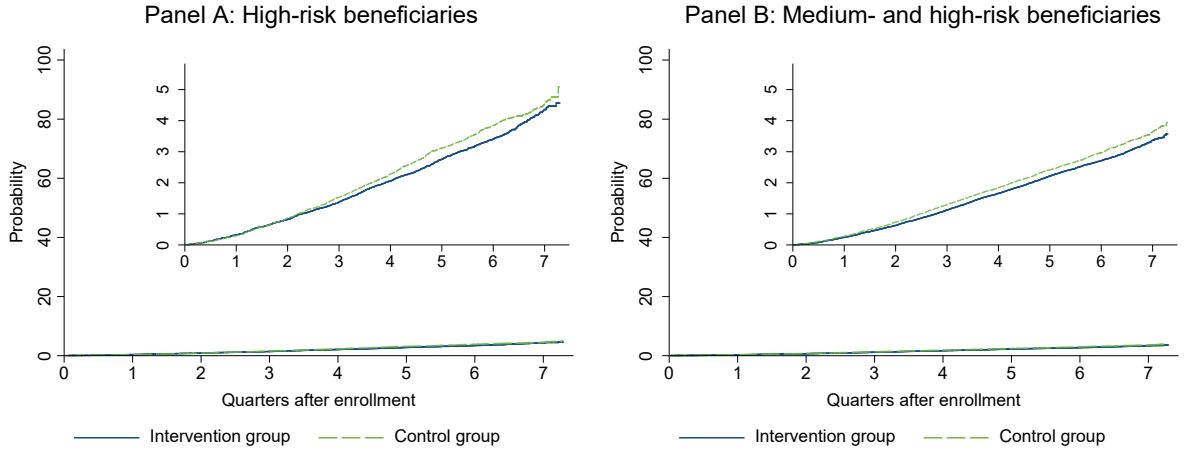


Source: Unadjusted results from Medicare claims.

Note: The cumulative probability is defined as 1 minus the Kaplan-Meier estimate of the survival function. The survival function is a function that gives the probability that a beneficiary does not have a heart attack, stroke, or TIA within a specified time. The inset in each panel shows the same data on an enlarged vertical axis.

TIA = transient ischemic attack

Figure D.2. Cumulative probability of dying for any reason, by quarter of enrollment and intervention group



Source: Unadjusted results from Medicare enrollment data.

Note: The cumulative probability is defined as 1 minus the Kaplan-Meier estimate of the survival function. The survival function is a function that gives the probability that a beneficiary does not die within a specified time. The inset in each panel shows the same data on an enlarged vertical axis.

Table D.2. Estimated ratio of the hazard of a first-time heart attack, stroke, or transient ischemic attack TIA between intervention and control beneficiaries: Sensitivity and exploratory analyses

Alternative outcome measure, population, or model specification	Hazard ratio (*p*-value) [90 percent confidence interval]	
	High-risk beneficiaries	Medium- and high-risk beneficiaries
Analyses with enrolled beneficiaries		
First-time heart attack, stroke, or TIA (main analysis)[a]	1.03 (*p*=0.63) [0.93, 1.14]	1.00 (*p*=0.90) [0.93, 1.06]
First-time heart attack or stroke using narrower definition [b]	1.03 (*p*=0.70) [0.92, 1.14]	0.99 (*p*=0.83) [0.92, 1.07]
First-time heart attack or stroke using narrowest definition [c]	1.02 (*p*=0.77) [0.92, 1.13]	0.99 (*p*=0.91) [0.92, 1.08]
Trim sample to ≤20 providers per organization	1.04 (*p*=0.54) [0.94, 1.15]	1.01 (*p*=0.76) [0.95, 1.08]
Unadjusted impact estimates	1.00 (*p*=0.97) [0.91, 1.10]	0.98 (*p*=0.68) [0.91, 1.06]
Subgroups of enrolled beneficiaries		
Beneficiaries with higher modifiable risk	1.07 (*p*=0.42) [0.93, 1.22]	0.99 (*p*=0.84) [0.91, 1.08]
Beneficiaries with lower modifiable risk	0.98 (*p*=0.82) [0.85, 1.13]	0.99 (*p*=0.92) [0.90, 1.09]
Analyses with attributed beneficiaries		
First-time heart attack, stroke, or TIA[a]	0.98 (*p*=0.49) [0.94, 1.03]	0.96 (*p*=0.20) [0.92, 1.01]
First-time heart attack or stroke using narrower definition [b]	0.98 (*p*=0.50) [0.93, 1.03]	0.96 (*p*=0.19) [0.91, 1.01]
First-time heart attack or stroke using narrowest definition [c]	0.98 (*p*=0.53) [0.93, 1.03]	0.96 (*p*=0.19) [0.91, 1.01]
Unadjusted impact estimates	0.94 (*p*=0.29) [0.86, 1.03]	0.93 (*p*=0.25) [0.85, 1.03]
Control for place of service at attribution [d]	0.99 (*p*=0.67) [0.95, 1.03]	0.97 (*p*=0.27) [0.93, 1.01]

Source: Regression-based impact estimates using Medicare claims.

[a]AMIs, strokes, TIAs, or stroke symptoms, using primary diagnoses on outpatient ED claims or primary and secondary diagnoses on inpatient claims. For AMIs, we include all five types of AMI described in the Fourth Universal Definition of Myocardial Infarction (2018).

Table D.2. (Continued)

[b]AMIs and strokes only (excludes TIAs or stroke syndromes), using primary diagnoses on outpatient ED claims or primary and secondary diagnoses on inpatient claims. For AMIs, we include only the first type of AMI described in the Fourth Universal Definition of Myocardial Infarction (2018).

[c]AMIs and strokes only (excludes TIAs or stroke syndromes) listed as primary diagnosis on ED or inpatient claim. For AMIs, we include only the first type of AMI described in the Fourth Universal Definition of Myocardial Infarction (2018).

[d]In addition to controlling for the list of covariates in Table D.1, we control for the place of service for the visit that led to the beneficiary being attributed. We noticed there is imbalance in this variable between the intervention and control groups, but we had not included it in the main regression models.

AMI = acute myocardial infarction; ED = emergency department; TIA = transient ischemic attack.

Table D.3. Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries: Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	Hazard ratio (*p*-value) [90 percent confidence interval]	
	High-risk beneficiaries	Medium- and high-risk beneficiaries
Analyses with enrolled beneficiaries		
Main analysis	0.94 (*p*=0.28) [0.87, 1.03]	0.93 (*p*=0.03) [0.87, 0.98]
Trim sample to ≤20 providers per organization	0.94 (*p*=0.30) [0.86, 1.03]	0.94 (*p*=0.08) [0.88, 1.00]
Unadjusted impact estimates	0.91 (*p*=0.10) [0.83, 1.00]	0.91 (*p*=0.08) [0.83, 1.00]
Enrolled beneficiaries who were candidates for drug therapy		
Main regression model specification	0.91 (*p*=0.12) [0.81, 1.01]	0.90 (*p*=0.02) [0.84, 0.97]
Over-control for initiation or intensification of statin therapy or antihypertensive therapy	0.91 (*p*=0.26) [0.78, 1.05]	0.94 (*p*=0.36) [0.84, 1.05]
Analyses with attributed beneficiaries		
Main regression model specification	0.96 (*p*=0.14) [0.92, 1.01]	0.95 (*p*=0.04) [0.92, 0.99]
Unadjusted impact estimates	0.91 (*p*=0.18) [0.82, 1.02]	0.91 (*p*=0.13) [0.82, 1.01]

Source: Regression-based impact estimates using Medicare enrollment data.

Table D.4. Estimated impacts on Medicare spending (dollars per beneficiary per quarter): Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	High-risk beneficiaries				Medium- and high-risk beneficiaries			
	Intervention group mean	Control group mean	Difference [90 percent CI]		Intervention group mean	Control group mean	Difference [90 percent CI]	
Analyses with enrolled beneficiaries								
Main analysis: Parts A and B spending	$ 972	$ 943	$ 29	[-7, 66]	$ 863	$ 850	$ 12	[-14, 39]
Inpatient spending only	$ 347	$ 328	$ 19	[-3, 41]	$ 295	$ 285	$ 10	[-6, 26]
Non-inpatient spending only	$ 625	$ 615	$ 10	[-8, 29]	$ 567	$ 565	$ 2	[-11, 16]
Parts A and B spending plus average model payments[a]	$ 1,004	$ 943	$ 61	[25, 98]	$ 873	$ 850	$ 23	[-4, 49]
Trim sample to ≤20 providers per organization	$ 981	$ 949	$ 32	[-5, 69]	$ 875	$ 859	$ 16	[-11, 42]
Allow beneficiaries to re-enter sample	$ 982	$ 949	$ 33	[-4, 71]	$ 875	$ 859	$ 16	[-11, 42]
Unadjusted impact estimates	$ 972	$ 950	$ 22	[-35, 80]	$ 863	$ 855	$ 7	[-45, 60]
Subgroups of enrolled beneficiaries								
Beneficiaries with higher modifiable risk	$ 971	$ 923	$ 47	[10, 85]	$ 870	$ 864	$ 6	[-23, 35]
Beneficiaries with lower modifiable risk	$ 972	$ 964	$ 8	[-42, 57]	$ 852	$ 834	$ 18	[-12, 47]
Analyses with attributed beneficiaries								
Parts A and B spending	$ 1,073	$ 1,062	$ 11	[-16, 38]	$ 985	$ 973	$ 12	[-13, 36]
Inpatient spending only	$ 387	$ 390	$ -2	[-18, 14]	$ 349	$ 348	$ 0	[-14, 15]
Non-inpatient spending only	$ 686	$ 673	$ 13	[-1, 28]	$ 636	$ 625	$ 11	[-2, 24]
Parts A and B spending plus average model payments[a]	$ 1,081	$ 1,062	$ 18	[-8, 45]	$ 989	$ 973	$ 15	[-9, 40]
Unadjusted impact estimates	$ 1,073	$ 1,064	$ 9	[-45, 63]	$ 985	$ 974	$ 11	[-38, 59]
Subgroups of attributed beneficiaries								
Beneficiaries enrolled and high risk	$ 979	$ 953	$ 27	[-10, 63]	$ 874	$ 870	$ 4	[-21, 29]
Beneficiaries not enrolled or not high risk	$ 1,099	$ 1,088	$ 11	[-17, 40]	$ 1,042	$ 1,021	$ 20	[-8, 48]

Source: Regression-based impact estimates using Medicare claims.

Table D.3. (Continued)

Note: We estimated impacts separately by quarter since enrollment and then averaged the estimates across all quarters, weighting each quarterly estimate by the number of intervention group enrollees observed in that quarter. Inpatient and other spending may not equal total spending because the impact estimates and regression-adjusted means were calculated from separate regression models.

[a]Total Million Hearts Model payments paid to intervention group organizations included in the impact evaluation for the first three performance periods were $5,563,915. This amount was divided by the number of beneficiary-quarters in the respective analysis to calculate the average cost per quarter per intervention group beneficiary, and then added to the intervention group beneficiaries' spending in each quarter. The number of beneficiary-quarters was calculate for each analysis, so the average Model cost per beneficiary per quarter varies across analyses.

CI = confidence interval.

Table D.5. Estimated impacts on the number of inpatient admissions and outpatient ED visits and observation stays (number per 1,000 beneficiaries per quarter): Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	High-risk beneficiaries				Medium- and high-risk beneficiaries			
	Intervention group mean	Control group mean	Difference [90 percent CI]		Intervention group mean	Control group mean	Difference [90 percent CI]	
Analyses with enrolled beneficiaries								
Number of inpatient admissions								
CVD-related	18	16	2.0	[0.9, 3.1]	14	13	0.6	[-0.2, 1.4]
All-cause	75	71	3.5	[0.3, 6.7]	63	61	2.0	[0.1, 4.0]
Number of outpatient ED visits and observation stays								
CVD-related	10	9	0.9	[-0.1, 1.9]	8	8	0.4	[-0.3, 1.1]
All-cause	109	100	8.6	[3.9, 13.3]	102	95	6.6	[3.0, 10.3]
Analyses with attributed beneficiaries								
Number of inpatient admissions								
CVD-related	19	19	0.1	[-0.6, 0.9]	16	16	-0.1	[-0.7, 0.5]
All-cause	80	81	-1.0	[-3.2, 1.2]	71	72	-0.3	[-2.0, 1.5]
Number of outpatient ED visits and observation stays								
CVD-related	11	11	-0.3	[-1.1, 0.5]	10	10	-0.2	[-0.9, 0.5]
All-cause	114	116	-1.8	[-6.3, 2.8]	110	111	-1.3	[-5.5, 3.0]

Source: Regression-adjusted results from Medicare claims data.

Note: We estimated impacts separately by quarter since enrollment and then averaged the estimates across all quarters, weighting each quarterly estimate by the number of intervention group enrollees observed in that quarter.

Table D.6. Estimated impacts on select secondary outcome measures

Outcome	High-risk beneficiaries				Medium- and high-risk beneficiaries			
	Intervention group mean	Control group mean	Difference [90 percent CI]		Intervention group mean	Control group mean	Difference [90 percent CI]	
Analyses with enrolled beneficiaries								
Percentage with a first-time heart attack, stroke, or TIA								
Within 6 months of enrollment[a]	0.85	0.77	0.08	[-0.07, 0.22]	0.62	0.55	0.07	[0.00, 0.15]
Within 12 months of enrollment[a]	1.74	1.71	0.03	[-0.19, 0.24]	1.33	1.33	0.01	[-0.11, 0.12]
Within 18 months of enrollment[a]	2.7	2.6	0.12	[-0.22, 0.47]	1.99	2.05	-0.06	[-0.25, 0.12]
Percentage who died								
Within 6 months of enrollment[a]	0.82	0.85	-0.02	[-0.17, 0.12]	0.63	0.71	-0.09	[-0.16, -0.01]
Within 12 months of enrollment[a]	2.02	2.24	-0.22	[-0.44, -0.00]	1.64	1.81	-0.16	[-0.27, -0.05]
Within 18 months of enrollment[a]	3.4	3.5	-0.09	[-0.48, 0.31]	2.8	2.9	-0.11	[-0.31, 0.10]
Number of office visits per 1,000 beneficiaries per quarter	2,947	2,883	63.8	[14.1, 113.4]	2,755	2,699	55.7	[12.8, 98.5]
Cardiologist visits	650	649	0.8	[-39.7, 41.3]	571	575	-4.1	[-35.8, 27.6]
Office visits with a Million Hearts provider	1,049	1,028	21.1	[-25.0, 67.3]	943	932	11.1	[-32.3, 54.5]
Percentage with an office visit with a Million Hearts provider between 10 and 15 months after enrollment	79.3	79.3	0.00	[-2.53, 2.54]	76.6	76.7	-0.10	[-2.72, 2.52]
Analyses with attributed beneficiaries								
Percentage with a first-time heart attack, stroke, or TIA								
Within 6 months of enrollment[a]	0.98	1.04	-0.06	[-0.13, 0.01]	0.84	0.88	-0.04	[-0.10, 0.02]
Within 12 months of enrollment[a]	1.86	1.95	-0.09	[-0.19, 0.01]	1.58	1.65	-0.07	[-0.15, 0.01]
Within 18 months of enrollment[a]	2.8	2.9	-0.12	[-0.26, 0.03]	2.4	2.5	-0.12	[-0.24, -0.00]
Percentage who died								
Within 6 months of enrollment[a]	1.20	1.32	-0.12	[-0.20, -0.04]	1.01	1.08	-0.08	[-0.13, -0.02]
Within 12 months of enrollment[a]	2.7	2.9	-0.18	[-0.32, -0.05]	2.25	2.38	-0.13	[-0.22, -0.04]
Within 18 months of enrollment[a]	4.4	4.7	-0.25	[-0.46, -0.04]	3.7	3.9	-0.21	[-0.35, -0.06]
Number of office visits per 1,000 beneficiaries per quarter[b]	3,009	2,979	30.4	[-15.2, 76.0]	2,855	2,824	31.3	[-9.0, 71.6]

Table D.6. (Continued)

	High-risk beneficiaries				Medium- and high-risk beneficiaries			
Cardiologist visits[b]	727	719	8.3	[-29.2, 45.9]	657	646	10.9	[-21.9, 43.6]
Office visits with a Million Hearts provider[b]	982	969	12.6	[-22.9, 48.1]	927	918	9.9	[-23.2, 43.0]
Percentage with an office visit with a Million Hearts provider between 10 and 15 months after enrollment[b]	77.3	75.5	1.8	[-0.3, 3.9]	75.5	73.7	1.8	[-0.3, 3.9]

Source: Regression-based impact estimates using Medicare claims.

[a] Analysis was limited to beneficiaries enrolled early enough to be observed at least the requested number of months, because claims were pulled in October 2018.

[b]These regression models included an additional control variable: place of service category for the office visit that led to the beneficiary being attributed.

CI = confidence interval; TIA = transient ischemic attack.

Table D.7. Estimated impacts on the initiation or intensification of CVD-related medications (statins, antihypertensives): Sensitivity tests and exploratory analyses

Outcome	High-risk beneficiaries				Medium- and high-risk beneficiaries			
	Intervention group percentage	Control group percentage	Difference [90 percent CI]		Intervention group mean	Control group mean	Difference [90 percent CI]	
Main analyses								
Antihypertensive medication intensification or initiation	24.1	22.0	2.1	[0.8, 3.5]	21.1	19.5	1.6	[0.5, 2.6]
Statin intensification or initiation	15.5	11.5	4.0	[2.7, 5.4]	13.5	10.6	2.9	[1.9, 3.9]
Statin or antihypertensive medication intensification or initiation	28.3	24.3	4.0	[2.4, 5.6]	23.1	20.2	2.9	[1.8, 4.1]
Trim sample to ≤20 providers per organization								
Antihypertensive medication intensification or initiation	23.9	21.8	2.1	[0.6, 3.5]	20.9	19.4	1.4	[0.3, 2.5]
Statin intensification or initiation	14.7	11.3	3.4	[2.0, 4.8]	13.2	10.7	2.5	[1.5, 3.6]
Statin or antihypertensive medication intensification or initiation	27.6	24.1	3.5	[1.8, 5.1]	22.8	20.2	2.6	[1.4, 3.8]
Sensitivity analysis using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification (SBP ≥ 140 mm Hg vs. SBP ≥ 130 mm Hg in the major analysis)								
Antihypertensive medication intensification or initiation	28.9	26.1	2.8	[1.0, 4.6]	26.9	24.7	2.2	[0.7, 3.7]
Unadjusted impact estimates								
Antihypertensive medication intensification or initiation	24.1	21.7	2.4	[0.6, 4.1]	21.1	19.2	1.9	[0.4, 3.4]
Statin intensification or initiation	15.5	11.6	3.9	[2.5, 5.3]	13.5	10.6	3.0	[1.8, 4.1]
Statin or antihypertensive medication intensification or initiation	28.3	24.1	4.2	[2.1, 6.2]	23.1	20.0	3.2	[1.5, 4.8]

Source: Regression-based impact estimates using Medicare Part D claims.

CI = confidence interval.

This page has been left blank for double-sided copying.

Appendix E

Survey Collection and Analysis

This page has been left blank for double-sided copying.

To estimate the impacts of the Million Hearts Model on processes of care, we developed and administered two separate survey instruments in the fall and winter of 2018 to participating intervention and control providers (the "provider survey") and organizations (the "practice survey"). These surveys included questions on how providers and organizations approach cardiovascular disease (CVD) preventive care along dimensions we expect the Million Hearts Model to influence, such as CVD risk stratification. We also calculated descriptive statistics about provider perceptions of model effects on CVD preventive care and about intervention group organizations' implementation experiences.

In this appendix, we describe how we developed the survey instruments and fielded the surveys to providers and organizations. We also present survey response rates and describe the methods we used to weight and analyze survey responses to estimate impacts and calculate descriptive statistics. At the end of the appendix, we present tables for the impact and descriptive estimates from these surveys. The tables cover the same topics we discussed in Chapters III and IV, but in more detail.

1. Development

We developed the provider and practice surveys to support formal estimation of impacts of the Million Hearts Model on approaches organizations and providers use to assess and mitigate CVD risk among Medicare beneficiaries. We surveyed both intervention and control providers and organizations to compare and contrast the delivery of CVD preventive care. If intervention providers and organizations implemented the requirements of the Million Hearts Model, but the care they delivered under the model is similar to the care they would have provided absent the intervention (as proxied by the control group), the model would have little to no impact on CVD care.

We designed the surveys to capture insights on model implementation from both the provider perspective and the organizational perspective. We used implementation findings from site visits in 2018 to inform the development of survey questions. For example, site visit findings revealed that intervention organizations started risk stratifying beneficiaries more consistently after they joined the model, but that there was variation across and within organizations in whether and how those risk scores were available to providers at the point of care or used to engage patients in their care.

To assess whether these experiences were shared more broadly by intervention and control providers and organizations participating in the Million Hearts Model, we included survey questions about changes in the use of risk scores compared to before the model, provider access to risk scores, provider use of risk scores in clinical care, and provider perception of the value of risk scores to engage patients. Appendix F contains the provider and practice survey instruments.

We developed the provider survey instrument to focus on the dimensions of the model that providers at participating organizations would likely have hands-on knowledge of, including:

- Calculating and reviewing CVD risk scores for their Medicare patients

- Awareness of CVD risk in their patient panels
- Notification of and follow-up with high-risk beneficiaries
- New services added to address CVD risk factors
- Value of learning system activities

For the practice survey, we included questions for the same dimensions as the provider survey[37] and added questions about organizational resources and model perspectives that primary contacts at participating organizations could answer based on their implementation experience, including:

- Facilitators and barriers to implementing the model
- Electronic health record (EHR) functionalities to support model implementation
- Perception of the role of financial incentives in model participation

2. Survey frame and response rates

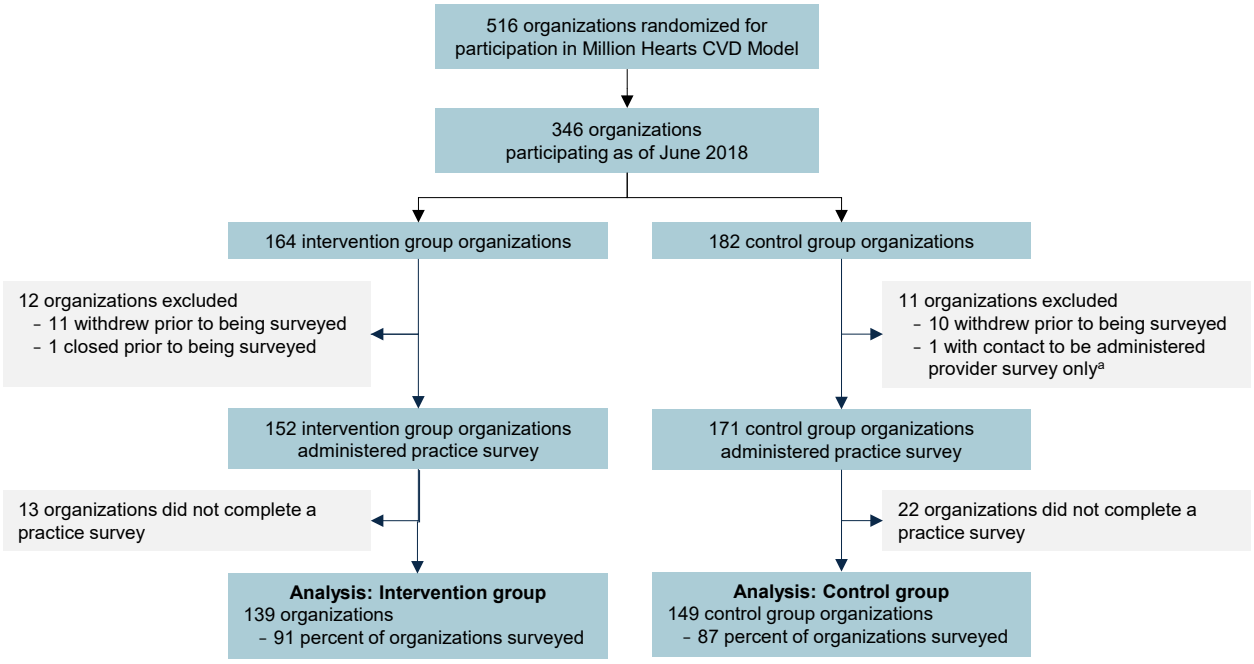
a. Practice survey

From September through November 2018, we administered practice surveys to 323 participating organizations (including 152 intervention group organizations and 171 control group organizations; Figure E.1). Of those surveyed, 288 organizations completed a practice survey, a response rate of 89 percent. By intervention status, 139 intervention organizations (91 percent) and 149 control group organizations (87 percent) completed a practice survey.

We designed the survey to be a census and not a sample—that is, we surveyed every organization that was still participating in the model when the survey was fielded. Specifically, the target survey frame included all 346 organizations indicated as participating in the Million Hearts Model as of June 2018, for which CMS provided a list of primary contacts (and secondary contacts, where available). However, we found that 11 intervention group and 10 control group organizations had withdrawn from the model before being surveyed, so they were removed from the practice survey population. In addition, one intervention group organization had closed, so that organization was also removed. For one control group organization, the primary contact provided also was the randomly selected provider for the provider survey (sampling detail in the next section); because the practice had no secondary contact on its application, we removed the organization from the practice survey population.

[37] We asked provider survey respondents about care processes for Medicare beneficiaries in their patient panel. For the practice survey, when we asked respondents questions covering the same topics, we asked about care processes for the organization's full panel of Medicare beneficiaries.

Figure E.1. Flow from organizations initially randomized down to those who responded and were included in analysis



Source: Mathematica analysis of data on organizations enrolled in the Million Hearts Model, their eligibility for the practice survey, and the number of organizations that responded to the survey.

[a] Through our sampling process for the provider survey, for this single organization, we randomly selected the provider who was identified as the primary contact for the organization. We preferred to have the contact complete the provider survey only. Because the organization had no secondary contact, we removed it from the survey sample.

b. Provider survey

We surveyed 366 providers from 283 organizations (including 178 providers from 140 intervention group organizations and 188 providers from 143 control group organizations) from the participating organizations that had at least one provider enroll a beneficiary into the Million Hearts Model (Figure E.2). Of the providers surveyed, 261 completed a provider survey (a response rate of 71 percent): 138 providers from intervention group organizations (78 percent) and 123 from control group organizations (65 percent). Those who completed a provider survey were from 128 intervention group organizations (91 percent of those with at least one provider surveyed) and 117 control group organizations (82 percent).

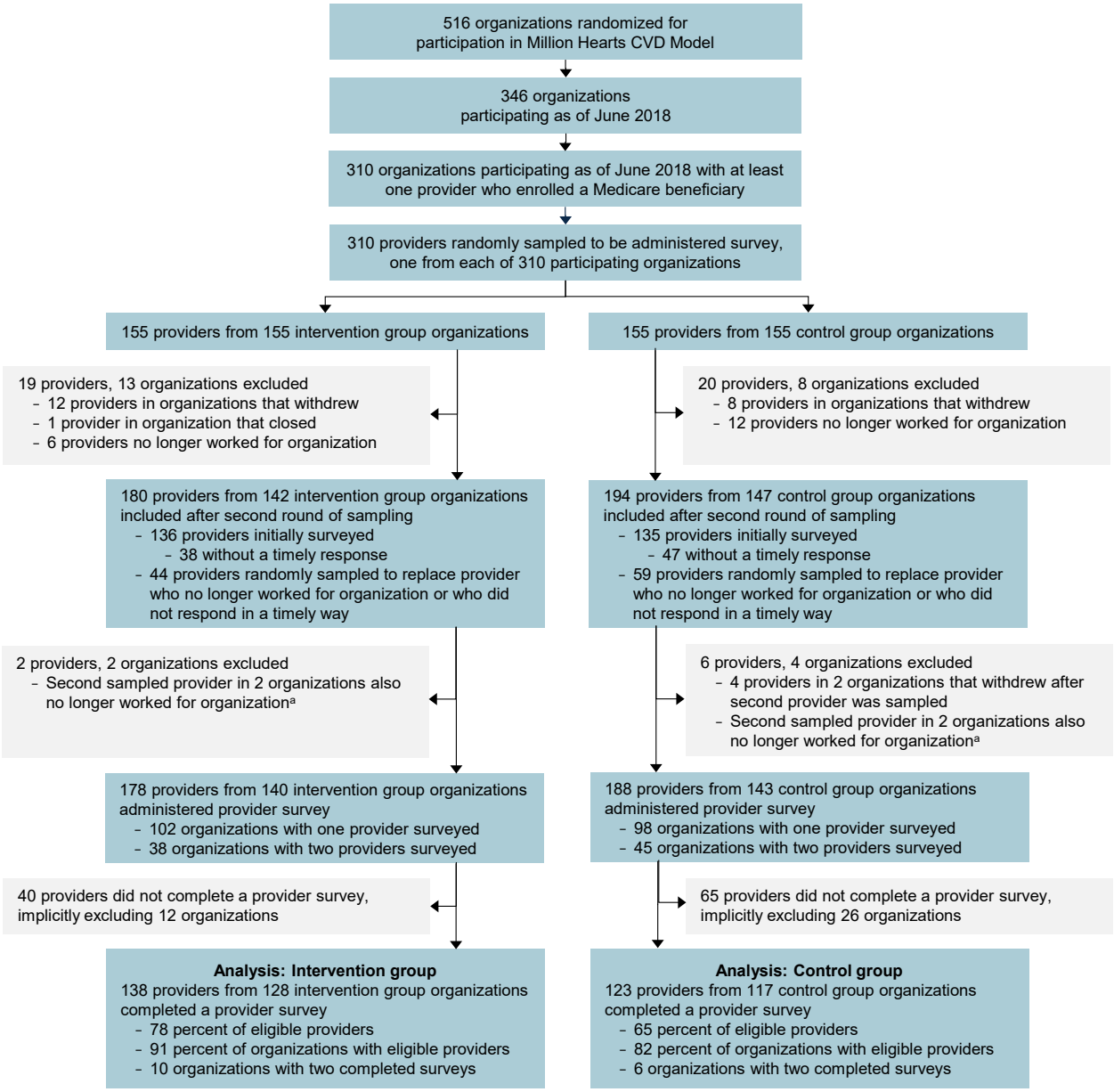
The target population for the provider survey included providers (physicians, nurse practitioners, or physician assistants) who enrolled at least one beneficiary during the first program year at each participating organization as of June 2018. We designed our sampling strategy to obtain one provider response from each participating organization so that (1) we would cover all organizations, and (2) each intervention organization would receive the same weight in the analyses. This sampling and weighting approach (see below) means that intervention

organizations with many providers receive the same weight as those with a few or just a single provider.

Of the 346 organizations indicated as still in the model as of June 2018, we found that 36 did not have at least one provider who enrolled a beneficiary in 2017. Therefore, we randomly sampled up to five providers from the remaining 310 organizations and obtained contact information for these providers from their organization's primary contacts.

We chose one of those providers as the initial provider to be administered the survey. However, if the initially selected provider was found to be ineligible for the survey—for instance, if the provider had left the organization—or did not respond to the survey, we chose a second provider from the organization (for those with more than one provider). This occurred for 44 intervention group organizations and 59 control group organizations. Because of follow-up efforts by email and telephone, for 10 intervention and 6 control group organizations, we received completed surveys from both providers that were eligible to be surveyed.

Figure E.2. Flow from organizations initially randomized down to the organizations and providers who responded to the provider survey



Source: Mathematica analysis of organization enrollment in the Million Hearts Model, provider selection and eligibility for the survey, and number of providers who responded to the survey.

[a] We did not release a survey to a third provider for these organizations, due to timing and resource constraints on the survey, as well as to avoid additional burden on the organizations.

3. Analytic methods

We analyzed the completed responses to the provider and practice surveys in two ways. First, we assessed impacts of the Million Hearts Model using differences between the intervention and control groups in their responses to a number of questions from the provider survey that aligned with our dimensions of interest (as presented in Chapter IV of the main report). Second, we used responses to both the provider and practice surveys to descriptively examine providers' perceptions of model impacts (in Chapter IV) and organizations' experiences implementing the model (in Chapter III).

a. Impact analysis

Outcomes. We focused on data from the provider survey to generate outcomes for estimating impacts of the Million Hearts Model. We compared the weighted distribution of responses to corresponding questions between the provider and practice surveys, and, in general, found consistent results.[38] In addition, we found fewer "don't know" responses to questions by providers than by organizations, potentially indicating that the providers were better attuned to their organization's experiences with the Million Hearts Model for the domains on which we wanted to assess impacts. We also found that, in the practice survey, the distribution of responses for a number of questions for which we intended to assess impacts[39] would have had a relatively high risk of bias due to "differential attrition," as defined by the What Works Clearinghouse (2014). This differential attrition occurs because the questions were asked only of organizations that met certain criteria (for example, use CVD risk scores), and the intervention and control groups differed in the extent to which they met these criteria.

The provider survey often contained many response options for a single question (see Table E.2 for the response options). In some cases, we collapsed certain categories before completing the impact analyses. We did this to simplify presentation and to make sure the categories had enough respondents. Chapter IV shows the collapsed categories, and Section D of this appendix provides more details.

Reweighting provider survey respondents. When we analyzed the provider survey data, there were two potential ways that simple averages of the responses might not reflect the intended target of inference:

[38] However, when examining the corresponding questions regarding new services to address CVD risk and resources used to ensure follow-up, we found inconsistencies between the two surveys (differences in responses between intervention and control group providers were in the opposite direction of those for organizations). Because we could not determine which survey's distribution was accurate, we chose to not assess either set of responses.

[39] Specifically, these questions were skipped for a disproportionately higher number of control group organizations than intervention group organizations. These questions were skipped because they were relevant only to organizations that responded they currently calculate CVD risk scores for their beneficiaries.

1. Because not all intervention group providers responded to the survey, those who responded might differ from those who did not in ways that affect their survey responses (nonresponse bias).
2. The providers in the control group who responded to the survey might differ—due to nonresponse, differences in organization attrition, or which providers were randomly drawn to be surveyed—in meaningful ways from the treatment respondents. Without correcting for these differences, the responses for the control group might not approximate the counterfactual for the treatment group, meaning that simple mean differences in responses could be a biased estimate of model impacts.

To limit these potential biases in the estimates, we developed analytic weights[40] for the intervention and control groups in a manner that, when applied: (1) baseline characteristics of intervention group respondents were more similar to those of all eligible intervention group providers, and (2) baseline characteristics of control group providers completing the survey were similar to those of the (reweighted) intervention group respondents that completed the survey. By weighting the control respondents to have baseline characteristics similar to those of the intervention group respondents, we increased the plausibility of the control group's survey responses representing the counterfactual for the intervention group responses.

To calculate the weights for the intervention group to account for nonresponse, we used the chi-squared automatic interaction detection (CHAID) method (Kass 1980). This method determines which characteristics are significant in predicting response, in order to form weighting classes for nonresponse adjustment. The weights are equivalent to the inverse of the observed response rate among intervention group providers in each class. We considered the following characteristics: number of providers, organization type, census region, rural indicator, and provider taxonomy category. From the CHAID analysis, we found that being in the Midwest Census region was the most significant in predicting response for the provider survey, thus produced one weight for providers in the Midwest and another for providers not in the Midwest.

To calculate the weights for the control group, we used a penalized version of the covariate balancing propensity score (CBPS) method (Imai and Ratkovic 2014). The (unpenalized) CBPS method uses an estimation procedure that calculates a set of weights which, when applied to the control group respondents, minimizes imbalance on provider and organization characteristics between the intervention and control groups. However, to achieve this balance, we found that the weights assigned to the control group respondents varied substantially, with some respondents receiving many (up to 50) times the weight of other respondents. We expected this variability of the weights would significantly reduce the statistical power of our impact analyses. To address this concern—that is, to more appropriately balance the competing priorities of having adequate balance and adequate statistical power—we implemented a penalized CBPS approach. This approach effectively imposed a constraint on the distribution of the weights when trying to

[40] For the 10 intervention and 6 control group organizations where two different providers both completed a provider survey, we started by assigning a weight of 0.5 to each provider. This weighted each of the two providers equally, such that their responses would represent their organization in total the same way as a provider's responses in another organization with only that single provider who completed a provider survey.

minimize imbalances between the intervention and control groups (Kranker et al. 2019). We fit the CBPS model iteratively with successively tighter constraints, until we identified the constraint that yielded the smallest variation of weights where the balance between the intervention and control groups met our predetermined standard of no absolute difference greater than 0.25 standard deviations.

After these weights were calculated, we assessed balance on key characteristics of interest for organizations with at least one provider who completed a provider survey (Table E.1). Before weighting, the intervention group providers came from larger, less rural, less primary care organizations that were less often participating in other CMS models. After applying the analytic weights, we found few differences in these characteristics, as expected; we controlled for the residual differences in our impact analysis regression models, which we describe next.

Table E.1. Characteristics of organizations that had at least one provider who completed a provider survey, before and after applying weights

Characteristic	Organizations with a provider who completed a survey (unweighted)			Organizations with a provider who completed a survey (weighted)		
	Intervention (N = 128)	Control (N = 117)	Difference	Intervention (N = 128)	Control (N = 117)	Difference
Size (from Million Hearts Model application)						
Number of providers						
1 to 5 providers (%)	35	31	4.4	37	35	1.9
6 to 19 providers (%)	24	34	-10.0†	24	27	-3.2
20 or more providers (%)	41	35	5.6†	39	37	1.3
Number of sites						
1 site (%)	36	38	-2.5	38	39	-0.5
2 to 5 sites (%)	30	32	-1.9	29	30	-0.8
6 or more sites (%)	34	30	4.5	33	32	1.4
Location (from Million Hearts Model application)						
Rural (%)	42	50	-7.4†	44	47	-3.0
Census region (%)						
Northeast	29	22	6.7†	30	27	3.1
Midwest	16	23	-7.5†	17	19	-2.0
South	39	36	3.2	38	37	0.7
West	16	19	-2.4	16	17	-1.7
Territories	0	0	0.0	0	0	0.0
Organization type						
Primary care (%)	50	57	-7.3†	50	54	-3.5
Specialty or multispecialty (%)	22	19	3.1	21	20	0.9
FQHC, RHC, or other health center (%)	16	15	1.0	17	17	0.3
CAH or rural hospital (%)	2	5	-3.6†	2	3	-1.1
Acute care hospital (%)	7	2	5.3‡	6	4	2.5†
Participates in other CMS models or programs						
In one or more model (or application pending at randomization) (%)	58	64	-6.4†	53	52	1.4

Sources: Mathematica analysis of a provider survey administered in 2018, with self-reported model application data linked to (1) CMS data on organization withdrawals, (2) data from the Million Hearts Data Registry, and (3) NPPES.

Table E.1. (Continued)

Notes: Presented are unadjusted proportions of organizations with at least one provider who completed a survey, and those proportions with the analytic weights applied. These weights account for nonresponse among intervention group providers, as well as to make comparison group providers more similar to the surveyed intervention group providers.

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

CAH = critical access hospital; CMMI = Center for Medicare & Medicaid Innovation; CVD = cardiovascular disease; FQHC = federally qualified health center; NPPES = National Plan and Provider Enumeration System; RHC = rural health center.

Regression model. To estimate impacts from the provider survey, we used multinomial logistic regression models. Multinomial logisitic regressions offer two key advantages over standard logistic regressions: (1) they permit assessments, with a single test statistic and *p*-value, of whether the distribution in responses across all response categories differences between the intervention and control groups (while also providing test statistics and *p*-values for the individual response options); and (2) they ensure that the sum of the probabilities across all possible response categories, within each intervention arm, is 1. For each survey question of interest, each possible response category is modeled separately relative to a "base" response. That is, if the question has K+1 possible responses, the multinomial logistic regression will include K logistic regressions for each response relative to an (arbitrarily chosen) base response. (Without loss of generality, we label the base response K = 0.) The regression model took the following form:

$$\frac{\Pr(y_{jp}=1)}{\Pr(y_{jp}=0)} = \exp(\alpha_1 + \delta_1 MH_p + \gamma_1 w_j + \theta_1 z_p)$$

$$\frac{\Pr(y_{jp}=2)}{\Pr(y_{jp}=0)} = \exp(\alpha_2 + \delta_2 MH_p + \gamma_2 w_j + \theta_2 z_p) \quad \text{(E.1)}$$

...

$$\frac{\Pr(y_{jp}=K)}{\Pr(y_{jp}=0)} = \exp(\alpha_K + \delta_K MH_p + \gamma_K w_j + \theta_K z_p)$$

subject to the constraint: $1 = \sum_{k=0}^{K} \Pr(y_{jp}=k)$

In Equation E.1, y_{jp} is the survey outcome measured for provider j in organization p, MH_p equals one for intervention group organizations and zero for control group organizations, w_j and z_p are baseline covariates, and the Greek letters (α_k, δ_k, γ_k, and θ_k) are parameters to be estimated. The multinomial logit regression model was estimated by weighted maximum likelihood. In this model, each provider can choose one, and only one, possible response per survey outcome.

The coefficients δ_k are our parameters of interest—they capture the impact of exposure to the Million Hearts Model on the probability of responding with response k. Because this is a

nonlinear model, we calculated average marginal effects that expressed impacts as percentage point differences in the regression-adjusted probability of each response. To account for the clustering of providers within organizations, we report *p*-values and confidence intervals based on robust standard errors, clustered at the organization level. Table E.2 reports these estimates, as well as more detail about the outcomes and response categories analyzed.

The vectors of coefficients γ_k and θ_k account for observed differences between the intervention and control groups in provider- and organization-level baseline covariates (w_j and z_p, respectively) and potentially improve the precision of the impact estimates. Specifically, w_j is a vector of indicator (yes/no) variables capturing the provider's specialty taxonomy categories (cardiologists and other cardiovascular specialists, other physicians, or nonphysicians) and z_p is a vector of organization-level covariates measured at baseline for organization *p*, including organization type (primary care clinic, specialty/multispecialty clinic, health center, or other type of organization); number of providers from the Million Hearts Model application (1 to 5, 6 to 19, 20 or more); number of sites from the Million Hearts Model application (1, 2 to 5, 6 or more); located in a rural region; census region (Northeast, Midwest, South, West); and participation in other CMS models or programs.[41]

We calculated two types of *p*-values for each survey question we used in the impact analysis. First, we calculated the single *p*-value for the joint test of the difference of distributions between the intervention and control providers across all response options for the question (using a two-tailed test). Second, we calculated separate *p*-values testing whether the difference between the proportions of intervention and control groups for each response option for the question was statistically different (also using a two-tailed test). In Chapter IV.B of the report, we highlight four questions where the intervention group responses were different from the control group responses. For all but one question, both types of *p*-values were statistically significant—that is, the joint test of the difference of distributions of responses was significant ($p < 0.10$), and the differences in individual response options we focus on in the text were also significant ($p < 0.10$). The one exception was for question Q12, corresponding to Figure IV.B.7. For that question, the joint test was not significant ($p=0.17$). However, the treatment and control groups were statistically different ($p=0.02$) for the key response option from which we draw inferences—the proportion of providers reporting that they followed up with their high-risk beneficiaries at least once every three months.

b. Descriptive analyses

In addition to the impacts analyses, we examined the weighted distribution of responses to some questions in the provider and practice surveys. For most of these questions, we focused on

[41] One provider survey question (Q3: "What proportion of Medicare beneficiaries in your panel have you or your clinical team calculated a cardiovascular risk score for, using any risk calculator?") was phrased in a different way from most other impact questions of interest, where respondents were asked to directly compare their current practice/status to two years prior. Therefore, in the impacts regression model, we added a covariate to account for their status two years prior, controlling for their response to Q4 ("Thinking about the care you provided 2 years ago, what fraction of Medicare beneficiaries in your panel then did you or your clinical team calculate CVD risk scores for?").

descriptive results for the intervention group providers or organizations only, and used the nonresponse weights (described earlier, calculated similarly for organizations as well) to calculate weighted mean responses. For a couple of questions on how providers in control organizations reported that they changed their care based on their participation in the Million Hearts Model, we used the CBPS weights designed to make the control group respondents look like intervention group respondents. Tables E.3 and E.4 show the specific survey questions we included in the descriptive analyses.

4. Analysis tables

To supplement the survey figures presented in Chapters III and IV of the main report, we provide detailed tables showing (weighted) counts of intervention and/or control group providers (or organizations, where applicable) per individual response category for each survey question of interest. We also show the percentage of respondents that selected each category, and 90 percent confidence interval bounds of the percentages for each response category.

- Table E.2 provides impact estimates, and two sets of *p*-values per question. The first *p*-value corresponds to the significance of the regression-adjusted difference in response rates between intervention and control group respondents for an individual response category, and the second corresponds to the joint significance of the differences across response categories.
- Table E.3 provides descriptive statistics of the distribution of intervention group responses to provider survey questions where impacts were not appropriate to estimate, but rather to examine intervention group providers' perceptions of impacts. The table also shows distributions of responses to practice survey questions to examine the intervention group organizations' implementation experiences.
- Table E.4 provides descriptive statistics of the distribution of control group responses to questions in the provider survey used to assess potential spillover effects of the Million Hearts Model.

Table E.2. Estimates of the impacts of the Million Hearts Model on CVD care processes, based on intervention and control group responses to the provider survey

Response	Weighted number of intervention group respondents	Weighted number of control group respondents	Regression-adjusted proportion of intervention group respondents	Regression-adjusted proportion of control group respondents	Regression-adjusted impact (90 percent CI)	*p*-value within response category	*p*-value across response categories
Q3: What proportion of Medicare beneficiaries in your panel have you or your clinical team calculated a cardiovascular risk score for, using any risk calculator?							
Less than 50%	24.8	55.1	19.3	47.1	-27.8 (-35.8, -19.8)	<0.001	<0.001
At least 50%	90.3	45.7	70.6	39.1	31.5 (23.7, 39.2)	<0.001	
Don't know	12.9	16.1	10.1	13.8	-3.7 (-8.8, 1.5)	0.24	
Total	*128.0*	*117.0*					
Q4: Thinking about the care you provided 2 years ago, what fraction of Medicare beneficiaries in your panel then did you or your clinical team calculate CVD risk scores for?							
Less than 50%	81.2	71.0	63.4	60.7	2.7 (-7.6, 13.0)	0.66	0.41
At least 50%	32.0	36.7	25.0	31.4	-6.4 (-16.2, 3.5)	0.29	
Don't know	14.8	9.3	11.6	7.9	3.6 (-2.3, 9.6)	0.31	
Total	*128.0*	*117.0*					
Q5: Are you, or is your clinical team, reviewing CVD risk scores for Medicare beneficiaries in your panel more consistently now than you were 2 years ago?							
No change from before	8.8	24.5	6.9	20.9	-14.0 (-21.0, -7.1)	<0.001	<0.001
Much more or somewhat more consistently	99.4	60.3	77.7	51.6	26.1 (16.8, 35.4)	<0.001	
Do not calculate risk scores	15.7	30.4	12.3	26.0	-13.7 (-21.6, -5.9)	0.004	
Don't know	4.0	1.7	3.1	1.5	1.7 (-1.0, 4.3)	0.31	
Total	*128.0*	*117.0*					
Q8: Once a risk score has been calculated, how often are CVD risk scores available when you meet with Medicare beneficiaries in your panel?							

Table E.2.. (Continued)

Response	Weighted number of intervention group respondents	Weighted number of control group respondents	Regression-adjusted proportion of intervention group respondents	Regression-adjusted proportion of control group respondents	Regression-adjusted impact (90 percent CI)	*p*-value within response category	*p*-value across response categories
Always or almost always available when meeting with a Medicare beneficiary	70.2	42.1	63.7	48.9	14.8 (3.8, 25.8)	0.03	<0.001
Sometimes available when meeting with a Medicare beneficiary	36.3	34.4	32.9	39.9	-7.0 (-17.4, 3.4)	0.27	
Never available when meeting with a Medicare beneficiary	3.2	4.3	2.9	4.9	-2.1 (-6.6, 2.5)	0.46	
Don't know	0.5	5.4	0.5	6.2	-5.8 (-8.4, -3.2)	<0.001	
Total	*110.1*	*86.1*					
Q11: After you identify Medicare beneficiaries in your panel with elevated CVD risk, do you engage in a follow-up discussion about specific steps patients can take to reduce their CVD risk?							
Almost always	92.8	72.9	83.6	83.4	0.2 (-8.5, 8.8)	0.97	0.97
Sometimes or never	18.3	14.5	16.4	16.6	-0.2 (-8.8, 8.5)	0.97	
Total	*111.1*	*87.4*					
Q14: How much do you agree or disagree with the following statement: CVD risk scores are a valuable tool for engaging patients in understanding and managing their CVD risk factors.							
Strongly or somewhat agree	89.1	71.9	70.9	62.2	8.7 (-1.0, 18.3)	0.14	0.14
Neutral, somewhat disagree, or strongly disagree	36.7	43.8	29.1	37.8	-8.7 (-18.3, 1.0)	0.14	
Total	*125.8*	*115.7*					
Q12: Once you have identified Medicare beneficiaries as having high CVD risk, how often does your practice follow up with them through any mode (e.g., office visits, telephone calls, emails, or letters) to monitor plans to reduce risk?							
At least every 3 months	64.7	37.4	57.7	43.5	14.2 (3.8, 24.6)	0.02	0.17
Every 6 months or annually	34.6	34.6	30.8	40.2	-9.4 (-19.4, 0.6)	0.12	

Table E.2.. (Continued)

Response	Weighted number of intervention group respondents	Weighted number of control group respondents	Regression-adjusted proportion of intervention group respondents	Regression-adjusted proportion of control group respondents	Regression-adjusted impact (90 percent CI)	*p*-value within response category	*p*-value across response categories
As needed	9.8	11.2	8.7	13.0	-4.3 (-12.4, 3.8)	0.38	
Don't know	3.2	2.9	2.8	3.4	-0.5 (-3.7, 2.7)	0.79	
Total	*112.3*	*86.1*					

Source: Mathematica analysis of a provider survey administered in 2018.

Note: Impact regressions were weighted to account for nonresponse among intervention group providers, as well as to make comparison group providers more similar to the surveyed intervention group providers. Because not all survey respondents may have been asked, or had answered, a particular question, weighted sample sizes can sum to non-integer values.

Standard errors were clustered to account for multiple providers per organization completing the provider survey.

We present *p*-values for two statistical tests for each question. The first *p*-value, "within response category," indicates the statistical significance of the difference between regression-adjusted intervention and control group response rates for each response category individually. The second, "across response categories," indicates the joint significance of the differences in regression-adjusted means across all response categories.

Table E.3. Descriptive analysis of intervention group respondents from provider and practice surveys

Response	Weighted number of intervention group respondents	Weighted proportion of intervention group respondents
Provider survey		
Q6: Is calculating CVD risk scores helping you identify Medicare beneficiaries in your panel as high risk who you did not previously recognize as being "high risk"?		
Yes, risk calculation has helped identify more high-risk Medicare beneficiaries in my panel than I had previously recognized	74.1	74.6
No, risk calculation has largely confirmed Medicare beneficiaries in my panel that I have already recognized as high risk	24.8	24.9
Don't know	0.5	0.5
Total	*99.4*	
Q7: Is calculating CVD risk scores helping you identify Medicare beneficiaries in your panel as medium risk who you did not previously recognize as being "medium risk"?		
Yes, risk calculation has helped identify more medium-risk Medicare beneficiaries in my panel than I had previously recognized	70.9	71.4
No, risk calculation has largely confirmed Medicare beneficiaries in my panel that I have already recognized as medium risk	26.3	26.4
Don't know	2.2	2.2
Total	*99.4*	
Q17.a: Has your participation in the CMS Million Hearts CVD Risk Reduction Model changed how you use CVD risk scores to: Cue discussions about CVD risk with your patients?		
Changed very much	37.3	31.1
Changed somewhat	53.7	44.8
Not changed	28.8	24.0
Total	*119.7*	
Q17.b: Has your participation in the CMS Million Hearts CVD Risk Reduction Model changed how you use CVD risk scores to: Inform clinical care to reduce CVD risk among high-risk Medicare beneficiaries?		
Changed very much	33.0	27.7
Changed somewhat	57.3	48.1
Not changed	28.9	24.2
Total	*119.2*	
Q17.c: Has your participation in the CMS Million Hearts CVD Risk Reduction Model changed how you use CVD risk scores to: Inform clinical care to reduce CVD risk among medium-risk Medicare beneficiaries?		
Changed very much	29.8	24.8
Changed somewhat	60.5	50.4
Not changed	29.9	24.9
Total	*120.2*	

Table E.3. (Continued)

Response	Weighted number of intervention group respondents	Weighted proportion of intervention group respondents
Q19.b: How much do you agree or disagree with the following statement? Participation in the CMS Million Hearts CVD Risk Reduction Model has prompted our practice to provide more systematically what is considered the current standard of care in this field.		
Strongly agree	40.4	33.3
Somewhat agree	47.0	38.8
Neutral	21.8	17.9
Somewhat disagree	6.1	5.0
Strongly disagree	6.0	4.9
Total	*121.3*	
Practice survey		
A12.a: Does your practice's EHR have any of the following functionalities: Integrated CVD risk calculator		
Yes, available before January 2017	19.2	14.0
Yes, added January 2017 or later	33.2	24.3
No	66.7	48.7
Don't know	17.8	13.0
Total	*136.9*	
A12.b: Does your practice's EHR have any of the following functionalities: CVD risk score displayed on patient record		
Yes, available before January 2017	16.1	11.8
Yes, added January 2017 or later	56.0	41.2
No	49.9	36.7
Don't know	14.0	10.3
Total	*136.0*	
A12.c: Does your practice's EHR have any of the following functionalities: CVD risk score component factors displayed on patient record		
Yes, available before January 2017	21.2	15.8
Yes, added January 2017 or later	35.1	26.2
No	65.8	49.1
Don't know	11.9	8.9
Total	*134.0*	
A12.d: Does your practice's EHR have any of the following functionalities: Automatic reminders to document the CVD risk score		
Yes, available before January 2017	7.1	5.2
Yes, added January 2017 or later	16.8	12.4
No	95.3	70.1
Don't know	16.8	12.4
Total	*136.0*	
A12.e: Does your practice's EHR have any of the following functionalities: Tools (such as pre-built phrases, templates, or drop down menus) to help document the CVD risk score		
Yes, available before January 2017	19.7	14.7
Yes, added January 2017 or later	62.2	46.4
No	39.3	29.3
Don't know	12.8	9.5

Table E.3. (Continued)

Response	Weighted number of intervention group respondents	Weighted proportion of intervention group respondents
Total	*134.0*	
A12.f: Does your practice's EHR have any of the following functionalities: Auto-population of data elements relevant to cardiovascular risk from other parts of a patient's record (such as blood pressure values)		
Yes, available before January 2017	45.0	33.4
Yes, added January 2017 or later	30.2	22.4
No	44.1	32.6
Don't know	15.7	11.6
Total	*135.0*	
B3.a: How much do you agree or disagree with the following statement? The financial incentives were an important factor for our organization in deciding to participate in the model.		
Strongly agree	42.2	30.6
Somewhat agree	38.0	27.5
Neutral	34.8	25.2
Somewhat disagree	9.9	7.1
Strongly disagree	13.1	9.5
Total	*138.0*	
B3.b: How much do you agree or disagree with the following statement? The financial incentives are an important factor for our organization in continuing to participate in the model.		
Strongly agree	44.1	31.9
Somewhat agree	39.2	28.4
Neutral	35.8	25.9
Somewhat disagree	9.9	7.1
Strongly disagree	9.1	6.6
Total	*138.0*	
B3.c: How much do you agree or disagree with the following statement? The learning activities offered by Million Hearts were valuable to our practice's efforts to improve cardiovascular disease prevention.		
Strongly agree	32.9	23.8
Somewhat agree	50.4	36.5
Neutral	39.9	28.9
Somewhat disagree	9.9	7.1
Strongly disagree	5.0	3.6
Total	*138.0*	
B4.a: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: Sufficient staff time to implement the model		
Not a factor in helping implementation	46.0	34.1
Very helpful	36.3	26.9
Somewhat helpful	44.9	33.2
Don't know	7.9	5.9
Total	*135.1*	
B4.b: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: Staff buy-in		
Not a factor in helping implementation	35.8	25.9
Very helpful	40.0	29.0

Table E.3. (Continued)

Response	Weighted number of intervention group respondents	Weighted proportion of intervention group respondents
Somewhat helpful	50.0	36.2
Don't know	12.2	8.8
Total	*138.0*	
B4.c: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: Patient receptivity		
Not a factor in helping implementation	39.7	28.9
Very helpful	34.5	25.1
Somewhat helpful	54.9	40.1
Don't know	8.0	5.9
Total	*137.1*	
B4.d: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: Organizational leadership support		
Not a factor in helping implementation	19.1	13.8
Very helpful	66.2	48.0
Somewhat helpful	48.8	35.4
Don't know	3.9	2.8
Total	*138.0*	
B4.e: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: Participation in other quality improvement initiatives		
Not a factor in helping implementation	22.2	16.3
Very helpful	65.5	48.1
Somewhat helpful	41.5	30.5
Don't know	6.9	5.1
Total	*136.1*	
B4.f: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: IT support (e.g., EHR functionality)		
Not a factor in helping implementation	45.0	32.9
Very helpful	44.9	32.8
Somewhat helpful	40.0	29.2
Don't know	7.1	5.2
Total	*137.1*	
B4.g: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: CMS Help Desk support		
Not a factor in helping implementation	49.5	36.1
Very helpful	24.0	17.5
Somewhat helpful	55.4	40.4
Don't know	8.2	6.0
Total	*137.1*	
B4.h: To what extent have the following factors been helpful in implementing the CMS Million Hearts model at your practice: ACO provided materials, analytics, or other support		
Not a factor in helping implementation	56.0	40.6
Very helpful	21.1	15.3
Somewhat helpful	47.0	34.0

Table E.3. (Continued)

Response	Weighted number of intervention group respondents	Weighted proportion of intervention group respondents
Don't know	14.0	10.1
Total	*138.0*	
B5.a: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Insufficient staff time for amount of work		
Not a barrier	21.4	15.5
Considerable barrier	62.8	45.5
Somewhat of a barrier	52.8	38.3
Don't know	1.0	0.7
Total	*138.0*	
B5.b: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Staff turnover		
Not a barrier	51.1	37.3
Considerable barrier	34.9	25.5
Somewhat of a barrier	50.0	36.5
Don't know	1.0	0.7
Total	*137.1*	
B5.c: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Resistance or lack of support from staff		
Not a barrier	69.9	51.0
Considerable barrier	20.1	14.7
Somewhat of a barrier	46.1	33.7
Don't know	1.0	0.7
Total	*137.1*	
B5.d: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Patient resistance		
Not a barrier	81.8	59.3
Considerable barrier	4.0	2.9
Somewhat of a barrier	49.3	35.7
Don't know	2.9	2.1
Total	*138.0*	
B5.e: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Lack of support from practice leadership		
Not a barrier	99.1	71.8
Considerable barrier	7.1	5.1
Somewhat of a barrier	29.9	21.7
Don't know	1.9	1.4
Total	*138.0*	
B5.f: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Lack of IT support, e.g., EHR functionality		
Not a barrier	63.9	46.3
Considerable barrier	21.3	15.4
Somewhat of a barrier	47.7	34.6
Don't know	5.1	3.7

Table E.3. (Continued)

Response	Weighted number of intervention group respondents	Weighted proportion of intervention group respondents
Total	*138.0*	
B5.g: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Lack of support from the CMS Help Desk		
Not a barrier	66.1	47.9
Considerable barrier	23.1	16.8
Somewhat of a barrier	43.0	31.1
Don't know	5.8	4.2
Total	*138.0*	
B5.h: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Organizational changes		
Not a barrier	74.5	54.0
Considerable barrier	17.8	12.9
Somewhat of a barrier	44.8	32.4
Don't know	1.0	0.7
Total	*138.0*	
B5.i: To what extent have each of the following been a barrier in implementing the CMS Million Hearts model at your practice: Competing organizational priorities		
Not a barrier	35.6	25.8
Considerable barrier	35.5	25.7
Somewhat of a barrier	62.9	45.6
Don't know	4.0	2.9
Total	*138.0*	

Source: Mathematica analysis of provider and practice surveys administered in 2018.

Note: Survey respondents were weighted to account for nonresponse among intervention group providers. Because not all respondents may have been asked, or had answered, a particular question, weighted sample sizes can sum to non-integer values.

Table E.4. Descriptive analysis of control group respondents from provider survey

Response	Weighted number of control group respondents	Weighted proportion of control group respondents
Q17.a: Has your participation in the CMS Million Hearts CVD Risk Reduction Model changed how you use CVD risk scores to: Cue discussions about CVD risk with your patients?		
Changed very much	13.9	15.8
Changed somewhat	36.8	41.6
Not changed	37.7	42.6
Total	*88.5*	
Q17.b: Has your participation in the CMS Million Hearts CVD Risk Reduction Model changed how you use CVD risk scores to: Inform clinical care to reduce CVD risk among high-risk Medicare beneficiaries?		
Changed very much	14.9	16.8
Changed somewhat	36.4	40.8
Not changed	37.8	42.4
Total	*89.1*	
Q17.c: Has your participation in the CMS Million Hearts CVD Risk Reduction Model changed how you use CVD risk scores to: Inform clinical care to reduce CVD risk among medium-risk Medicare beneficiaries?		
Changed very much	15.3	17.1
Changed somewhat	32.4	36.2
Not changed	41.8	46.7
Total	*89.5*	
Q19.b: How much do you agree or disagree with the following statement? Participation in the CMS Million Hearts CVD Risk Reduction Model has prompted our practice to provide more systematically what is considered the current standard of care in this field.		
Strongly agree	15.0	16.4
Somewhat agree	28.2	30.9
Neutral	24.2	26.5
Somewhat disagree	18.3	20.1
Strongly disagree	5.6	6.1
Total	*91.4*	

Source: Mathematica analysis of a provider survey administered in 2018.

Note: Survey respondents were weighted to make comparison group providers more similar to the surveyed intervention group providers on provider and organization characteristics. Because not all respondents may have been asked, or had answered, a particular question, weighted sample sizes can sum to non-integer values.

This page has been left blank for double-sided copying.

Appendix F

Survey instruments

This page has been left blank for double-sided copying.

This appendix contains the two survey instruments we developed and administered in the fall and winter of 2018 to intervention group providers (the "provider survey") and organizations (the "practice survey"). We administered separate versions of these two instruments to control group to providers and organizations, respectively. The control group versions had the same questions, but excluded several questions about experiences with implementing the Million Hearts Model that were relevant only to the intervention group. In the following survey instruments, we have marked the questions only included in the intervention group surveys with the following text in red font: "(ASKED ONLY TO INTERVENTION GROUP PROVIDERS)" for the provider survey, and "(ASKED ONLY TO INTERVENTION GROUP PRACTICES)" for the practice survey. Appendix E contains information about how we developed and fielded the surveys and about how we analyzed the survey responses.

Mathematica Ref. No. 50496

MATHEMATICA
Policy Research

CMS Million Hearts CVD Risk Reduction Model Provider Survey

This survey is to be completed by: [PROVIDER FNAME L NAME]

At practice organization: [PRACTICE ORG NAME] - [FILL MH-ID]

After answering each question, continue to the next question unless otherwise specified. If you have any questions, call 877-812-2551 or email the study team at MillionHearts@mathematica-mpr.com.

BEGIN HERE:

Q1. Are you, [PROV FNAME L NAME], currently providing clinical services at [PRACTICE]?

- ❍ Yes – I provide clinical services at that practice
- ❍ No – I am no longer providing clinical services there → **GO TO TERM**

TERM. Thanks for this information. Please return this form in the posted paid envelope provided.

Q2. When did you start providing clinical services at [PRACTICE]?

MARK ONE ONLY

- ❍ Before January 2017
- ❍ After January 2017

CARDIOVASCULAR (CVD) CARE

In this survey, providers include MDs, DOs, PAs, and NPs.

The next set of questions ask about the use of a risk calculator to predict a patient's 10-year risk of a cardiovascular event (heart attack or stroke). Examples of how a risk score may be calculated include—but are not limited to-- an online application, an application on a smartphone, or a calculator in the EHR.

Q3. What proportion of Medicare beneficiaries in your panel have you or your clinical team calculated cardiovascular risk score for, using any risk calculator?

MARK ONE ONLY

- ❍ 0% - We do not calculate CVD risk scores
- ❍ 1–24%
- ❍ 25–49%
- ❍ 50–74%
- ❍ 75–100%
- ❍ Don't know

Q4. Thinking about the care you provided 2 years ago, what fraction of Medicare beneficiaries in your panel then did you or your clinical team calculate CVD risk scores for?

MARK ONE ONLY

- ❍ 0% - We did not calculate CVD risk scores 2 years ago
- ❍ 1–24%
- ❍ 25–49%
- ❍ 50–74%
- ❍ 75–100%
- ❍ Don't know

IF YOU CALCULATE CVD RISK SCORES, CONTINUE TO Q5. IF NOT, GO TO Q13.

Q5. Are you, or is your clinical team, reviewing CVD risk scores for Medicare beneficiaries in your panel more consistently now than you were 2 years ago?

MARK ONE ONLY

- ❍ No change from before → **GO TO Q8**
- ❍ Yes, somewhat more consistently
- ❍ Yes, much more consistently
- ❍ Don't know → **GO TO Q8**

Q6. Is calculating CVD risk scores helping you identify Medicare beneficiaries in your panel as high risk who you did not previously recognize as being "high risk"?

The CMS Million Hearts Model defines high risk scores as greater than or equal to 30 percent chance of a CVD event over 10 years

MARK ONE ONLY

- ❍ Yes, risk calculation has helped identify more high-risk Medicare beneficiaries in my panel than I had previously recognized.
- ❍ No, risk calculation has largely confirmed Medicare beneficiaries in my panel that I already recognized as high risk.
- ❍ Don't know

Q7. Is calculating CVD risk scores helping you identify Medicare beneficiaries in your panel as medium risk who you did not previously recognize as being "medium risk"?

The CMS Million Hearts Model defines medium risk scores as between 15 and 29 percent chance of a CVD event over 10 years.

MARK ONE ONLY

- ❍ Yes, risk calculation has helped identify more medium-risk Medicare beneficiaries in my panel than I had previously recognized.
- ❍ No, risk calculation has largely confirmed Medicare beneficiaries in my panel that I already recognized as medium risk.
- ❍ Don't know

Q8. Once a risk score has been calculated, how often are CVD risk scores available when you meet with Medicare beneficiaries in your panel?

MARK ONE ONLY

- ❍ Always or almost always available when meeting with a Medicare beneficiary
- ❍ Sometimes available when meeting with a Medicare beneficiary
- ❍ Never available when meeting with a Medicare beneficiary
- ❍ Don't know

Q9. If you are able to access a Medicare beneficiary's CVD risk score, how do you access it at this practice?

MARK ONE ONLY

- ❍ It's prominently displayed on the patient's chart in the EHR
- ❍ It's available in the patient's chart in the EHR but I have to search for it or calculate it.
- ❍ It's not available in the EHR but is accessible to me in pre-visit paperwork.
- ❍ Other kind of access – not listed above
- ❍ It's not available in the EHR or the pre-visit paperwork
- ❍ Don't know

Q10. How are Medicare beneficiaries in your panel notified of their CVD risk score, if at all?

MARK ALL THAT APPLY

- ☐ In person at office visit, by provider
- ☐ In person at office visit, by other clinical staff
- ☐ Telephone call from provider
- ☐ Telephone call from other clinical staff
- ☐ Written communication (e.g., letter, email, patient portal)
- ❍ Medicare beneficiaries in my care at this practice are not notified of their CVD risk score
- ❍ Don't know

Q11. After you identify Medicare beneficiaries in your panel with elevated CVD risk, do you engage in a follow-up discussion about specific steps they can take to reduce their CVD risk . . .

MARK ONE ONLY

- ❍ Yes - almost always
- ❍ Yes - sometimes
- ❍ No - never

Q12. Once you have identified Medicare beneficiaries as having high CVD risk, how often does your practice follow up with them through any mode (e.g., office visits, telephone calls, emails, or letters) to monitor plans to reduce risk?

MARK ONE ONLY

- ❍ Monthly or more often than monthly
- ❍ Every 3 months
- ❍ Every 6 months
- ❍ Annually
- ❍ As needed
- ❍ Don't know

Q13. Do you use any of the following resources to help ensure that your Medicare beneficiaries with high CVD risk are not lost to follow-up?

MARK ALL THAT APPLY

- ☐ Care managers
- ☐ Registries or tracking tools
- ☐ Automated scheduling of follow-up visits with a minimum frequency
- ☐ None of the above
- ☐ Don't know

Q14. How much do you agree or disagree with the following statement: CVD risk scores are a valuable tool for engaging patients in understanding and managing their CVD risk factors.

MARK ONE ONLY

- ❍ Strongly agree
- ❍ Somewhat agree
- ❍ Neutral
- ❍ Somewhat disagree
- ❍ Strongly disagree

Q15. In the past two years, has your practice added any <u>new</u> programs or services to address the following CVD risk factors in your practice's patient population? These can be internal or external to your practice.

SELECT ONE PER ROW

	Yes	NO	DON'T KNOW
a. Blood pressure control	❍	❍	❍
b. Cholesterol management	❍	❍	❍
c. Smoking cessation	❍	❍	❍
d. Medication adherence	❍	❍	❍
e. Changes in lifestyle, including weight loss and exercise	❍	❍	❍

INVOLVEMENT IN THE MILLION HEARTS MODEL

Q16. Are you aware that your practice is participating in the Million Hearts CVD model, either as an intervention or control participant?

MARK ONE ONLY

❍ Yes, I'm aware of this practice's participation in the Million Hearts model

❍ No, I'm not aware of this practice's participation in the Million Hearts model → **GO TO Q21**

Q17. Has your participation in the Million Hearts model changed how you use CVD risk scores to:

SELECT ONE PER ROW

	Changed very much	Changed somewhat	Not changed
a. Cue discussions about CVD risk with your patients?	❍	❍	❍
b. Inform clinical care to reduce CVD risk among high-risk Medicare beneficiaries?	❍	❍	❍
c. Inform clinical care to reduce CVD risk among medium-risk Medicare beneficiaries?	❍	❍	❍

Q18. How much do you agree or disagree with the following statement[i]:

The learning activities offered by Million Hearts were valuable to my efforts to improve cardiovascular disease prevention.

MARK ONE ONLY

- ❍ Strongly agree
- ❍ Somewhat agree
- ❍ Neutral
- ❍ Somewhat disagree
- ❍ Strongly disagree
- ❍ Did not attend any of the learning system events

Q19. How much do you agree or disagree with the following statements:

SELECT ONE PER ROW

	Strongly Agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree
a. The cardiovascular preventive care our practice provides now is significantly different than the cardiovascular preventive care we provided before the model began (January 2017).	❍	❍	❍	❍	❍
b. Participation in the Million Hearts model has prompted our practice to provide more systematically what is considered the current standard of care in this field.	❍	❍	❍	❍	❍

Q20. How easy or challenging did you find it to implement the Million Hearts model at this practice?[ii]

MARK ONE ONLY

- ❍ Very challenging
- ❍ Somewhat challenging
- ❍ Somewhat easy
- ❍ Very easy
- ❍ Don't know

Q21. Please provide your contact information below:

Practice Address:_____
Street

_____
City, State, Zip Code

Phone: |___|___|___| - |___|___|___| - |___|___|___|___| **Email**:_____

That is the end of the survey - thank you for completing it! Your efforts will help make the evaluation of the Million Hearts demonstration a success. If you have any questions, please call 877-812-2551 or email MillionHearts@mathematica-mpr.com.

[i] Asked only to intervention group practices.
[ii] Asked only to intervention group practices.

Mathematica Ref. No. 50496-INTV

MATHEMATICA
Policy Research

The CMS Million Hearts CVD Risk Reduction Model Million Hearts Practice Survey

Practice Name: [PRACTICE ORG NAME] [[MH-ID]]

Please complete by November 5, 2018

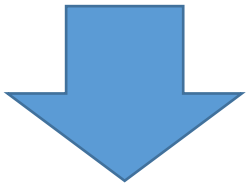
For more information about this survey, please call 877-812-2551 or email the study team at MillionHearts@mathematica-mpr.com.

SECTION A. CARDIOVASCULAR (CVD) CARE IN YOUR PRACTICE

In this survey, providers include MDs, DOs, PAs, and NPs.

The first set of questions ask about the use of a risk calculator to predict a patient's 10-year risk of a cardiovascular event (heart attack or stroke) in your practice. Examples of how a risk score may be calculated include—but are not limited to-- an online application, an application on a smartphone, or a calculator in the EHR.

BEGIN HERE:



A1. What is your primary role in the CMS Million Hearts model implementation at your practice?

MARK ONE ONLY

- ❍ Oversee the model but not responsible for day-to-day operations
- ❍ Project manager / responsible for day-to-day operations
- ❍ Clinical lead
- ❍ Health IT/ entering data into model
- ❍ Other role, not specified above

A2. What proportion of Medicare beneficiaries has your practice calculated a CVD risk score for, using any risk calculator?

MARK ONE ONLY

- ❍ 0% - we do not calculate CVD risk scores
- ❍ 1–24%
- ❍ 25–49%
- ❍ 50–74%
- ❍ 75–100%
- ❍ Don't know

A3. Thinking about the care your practice provided 2 years ago, what fraction of Medicare beneficiaries did your practice calculate CVD risk scores for at that time?

MARK ONE ONLY

- ❍ 0% - we did not calculate CVD risk 2 years ago
- ❍ 1–24%
- ❍ 25–49%
- ❍ 50–74%
- ❍ 75–100%
- ❍ Don't know

IF YOUR PRACTICE CALCULATES CVD RISK SCORES FOR MEDICARE BENEFICIARIES, (A2=1-100%) CONTINUE TO A4.

IF NOT, GO TO A10.

A4. Is your practice reviewing CVD risk scores for Medicare beneficiaries more consistently now than you were 2 years ago?

MARK ONE ONLY

- ❍ No change from before → **GO TO A7**
- ❍ Yes, somewhat more consistently
- ❍ Yes, much more consistently
- ❍ Don't know → **GO TO A7**

A5. Is calculating CVD risk scores helping your practice identify Medicare beneficiaries as high risk whom you did not previously recognize as being "high risk"?

The Million Hearts Model defines high risk scores as greater than or equal to 30 percent chance of a CVD event over 10 years.

MARK ONE ONLY

- ❍ Yes, risk calculation has helped identify more high-risk Medicare beneficiaries than we had previously recognized.
- ❍ No, risk calculation has largely confirmed Medicare beneficiaries we already recognized as high risk
- ❍ Don't know

A6. Is calculating CVD risk scores helping your practice identify Medicare beneficiaries as medium risk whom you did not previously recognize as being "medium risk"?

The Million Hearts Model defines medium risk scores as between 15-29 percent.

MARK ONE ONLY

- ❍ Yes, risk calculation has helped identify more medium-risk Medicare beneficiaries than we had previously recognized
- ❍ No, risk calculation has largely confirmed Medicare beneficiaries we already recognized as medium risk.
- ❍ Don't know

A7. Once a risk score has been calculated, how often are CVD risk scores available when providers meet with Medicare beneficiaries in your practice?

MARK ONE ONLY

- ❍ Always or almost always available when meeting with a Medicare beneficiary
- ❍ Sometimes available when meeting with a Medicare beneficiary
- ❍ Never available when meeting with a Medicare beneficiary
- ❍ Don't know

A8. How are Medicare beneficiaries at your practice notified of their CVD risk score, if at all?

MARK ALL THAT APPLY

- ☐ In person at office visit, by provider
- ☐ In person at office visit, by other clinical staff
- ☐ Telephone call from provider
- ☐ Telephone call from other clinical staff
- ☐ Written communication (e.g., letter, email, patient portal)
- ☐ We do not notify Medicare beneficiaries of their risk score
- ☐ Don't know

A9. Once you have identified Medicare beneficiaries as having high CVD risk, how often does your practice follow up with them through any mode (e.g., office visits, telephone calls, emails, or letters) to monitor plans to reduce risk?

MARK ONE ONLY

- ❍ Monthly or more often than monthly
- ❍ Every 3 months
- ❍ Every 6 months
- ❍ Annually
- ❍ As needed
- ❍ Don't know

ALL CONTINUE HERE:

A10. Does your practice use any of the following resources to ensure that Medicare beneficiaries with high CVD risk are not lost to follow-up?

MARK ALL THAT APPLY

- ☐ Care managers
- ☐ Registries or tracking tools
- ☐ Automated scheduling of follow-up visits with a minimum frequency
- ☐ None of the above

A11. In the past two years, has your practice added any <u>new</u> programs or services to address the following CVD risk factors in your practice's patient population?

These can be internal or external to your practice.

Select one per row

	YES	NO	DON'T KNOW
a. Blood pressure control	❍	❍	❍
b. Cholesterol management	❍	❍	❍
c. Smoking cessation	❍	❍	❍
d. Medication adherence	❍	❍	❍
e. Changes in lifestyle, including weight loss and exercise	❍	❍	❍

A12. Does your practice's EHR have any of the following functionalities? If so, please indicate whether it was available <u>before</u> or <u>after</u> January of 2017.

Select one per row

	Yes, available before Jan 2017	Yes, added Jan 2017 or later	No	Don't Know
a. Integrated CVD risk calculator	❍	❍	❍	❍
b. CVD risk score displayed on patient record	❍	❍	❍	❍
c. CVD risk score component factors displayed on patient record	❍	❍	❍	❍
d. Automatic reminders to document the CVD risk score	❍	❍	❍	❍
e. Tools (such as pre-built phrases, templates, or drop down menus) to help document the CVD risk score	❍	❍	❍	❍
f. Auto-population of data elements relevant to cardiovascular risk from other parts of a patient's record (such as blood pressure values)	❍	❍	❍	❍

SECTION B. INVOLVEMENT IN THE MILLION HEARTS MODEL

B1. How much do you agree or disagree with the following statements:

Select one per row

	Strongly Agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree
a. The cardiovascular preventive care our practice provides now is significantly different than the cardiovascular preventive care we provided before the model began (January 2017).	❍	❍	❍	❍	❍
b. Participation in the Million Hearts model has prompted our practice to provide more systematically what is considered the current standard of care in this field.	❍	❍	❍	❍	❍

B2. Million Hearts focuses only on Medicare fee-for-service beneficiaries at highest risk (more than 30 percent ten year risk based on the ACC/AHA ASCVD risk calculator). Considering Medicare beneficiaries with intermediate cardiac risk (15-29 percent ten year risk), has your management of these patients changed as a result of Million Hearts?[i]

MARK ONE ONLY

- ❍ No
- ❍ Yes, somewhat different
- ❍ Yes, very different
- ❍ Don't know

B3. Million Hearts provides financial incentives for risk stratification and for reductions in risk and offers support to practices through a learning system. How much do you agree or disagree with the following statements:

Select one per row

	Strongly Agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree
a. The financial incentives were an important factor for our organization in deciding to participate in the model.	❍	❍	❍	❍	❍
b. The financial incentives are an important factor for our organization in continuing to participate in the model.	❍	❍	❍	❍	❍
c. The learning activities offered by Million Hearts were valuable to our practice's efforts to improve cardiovascular disease prevention.[ii]	❍	❍	❍	❍	❍

The next set of questions ask about factors that were facilitators and / or barriers to implementing the Million Hearts Model at your practice.

B.4. To what extent have the following factors been <u>helpful</u> in implementing the Million Hearts model at your practice[iii]:

Select one per row

	Very helpful	Somewhat helpful	Not a factor helping implementation	Don't Know
a. Sufficient staff time to implement the model	❍	❍	❍	❍
b. Staff buy-in	❍	❍	❍	❍
c. Patient receptivity	❍	❍	❍	❍
d. Organizational leadership support	❍	❍	❍	❍
e. Participation in other quality improvement initiatives	❍	❍	❍	❍
f. IT support (e.g., EHR functionality)	❍	❍	❍	❍
g. CMS help desk support	❍	❍	❍	❍
h. ACO provided materials, analytics, or other support	❍	❍	❍	❍
i. Other factor that helped implementation of Million Hearts Model – not listed above (SPECIFY) _____	❍	❍	❍	❍

B5. To what extent have each of the following been a <u>barrier</u> in implementing the Million Hearts model at your practice[iv]:

Select one per row

	Considerable barrier	Somewhat of a barrier	Not a barrier	Don't Know
a. Insufficient staff time for amount of work	❍	❍	❍	❍
b. Staff turnover	❍	❍	❍	❍
c. Resistance or lack of support from staff	❍	❍	❍	❍
d. Patient resistance	❍	❍	❍	❍
e. Lack of support from practice leadership	❍	❍	❍	❍
f. Lack of IT support, e.g., EHR functionality	❍	❍	❍	❍
g. Lack of support from the CMS helpdesk	❍	❍	❍	❍
h. Organizational changes	❍	❍	❍	❍
i. Competing organizational priorities	❍	❍	❍	❍
j. Other barrier – not listed above (SPECIFY) _____	❍	❍	❍	❍

B6. How easy or challenging did your practice find it to implement the Million Hearts model at this practice?

MARK ONE ONLY

- ❍ Very challenging
- ❍ Somewhat challenging
- ❍ Somewhat easy
- ❍ Very easy
- ❍ Don't know

B7. Is your practice part of an accountable care organization (ACO) (Medicare, Medicaid, or commercial insurance)?

- ❍ Yes
- ❍ No
- ❍ Don't know

SECTION C. CLOSING

C1. Please confirm who completed this survey. Are you [PRIMARY CONTACT FNAME LNAME]?

- ❍ Yes
- ❍ No – update below:

Please provide your name and email address, as the person completing the survey:

_____
First name Last name

_____
Email address

C2. When did you start working at this practice?

- ❍ Before January 2017
- ❍ After January 2017

Thank you for completing this survey. Your efforts will help make the evaluation a success.

Please return this form to:

Mathematica Policy Research
P.O. Box 2393
Princeton, NJ 08543-2393

We have enclosed a postage-paid envelope for your convenience. If you have any questions, please call us at 877-812-2551 or email us at MillionHearts@mathematica-mpr.com.

[i] Asked only to intervention group practices.
[ii] Asked only to intervention group practices.
[iii] Asked only to intervention group practices.
[iv] Asked only to intervention group practices.

Mathematica

Princeton, NJ • Ann Arbor, MI • Cambridge, MA
Chicago, IL • Oakland, CA • Seattle, WA
Tucson, AZ • Woodlawn, MD • Washington, DC

EDI Global, a Mathematica Company

Bukoba, Tanzania • High Wycombe, United Kingdom

mathematica-mpr.com