



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

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Lead authors:

Greg Peterson, Alli Steiner, Rhea Powell, Julia Rollison*, Amanda Markovitz, Laura Blue, Kate Stewart, Dan Kinber, Rachel Kogan, Danielle Whicher, Rui Wang, Jia Pu, Keith Kranker, Malcolm Williams*, Nancy McCall

Contributing authors (in alphabetical order):

Alex Bryce, Liisa Hiatt*, Elizabeth Holland, Caroline Mack, David Magid**, Sandi Nelson, Precious Ogbuefi, Nabeel Qureshi*, Carol Razafindrakoto, Sarah Wagner, Laura Whitaker

* Author is from the RAND Corporation ** Author is from the University of Colorado

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Mathematica Inc. 1100 1st Street, NE 12th Floor Washington, DC 20002-4221 Telephone: (202) 484-9220 Project Director: Greg Peterson Reference Number: 50496

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List of Acronyms

ABCS	Aspirin when appropriate, blood pressure control
ACC	American College of Cardiology
ACO	Accountable care organization
AHA	American Heart Association
AMI	Acute myocardial infarction
ASCVD	Atherosclerotic cardiovascular disease
САН	Critical access hospital
CCN	CMS Certification Number
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus disease 2019
CPC	Comprehensive Primary Care
CPC+	Comprehensive Primary Care Plus
CPT	Current procedural terminology
CVD	Cardiovascular disease
ED	Emergency department
EHR	Electronic health record
ESRD	End-stage renal disease
FFS	Fee-for-service
FQHC	Federally qualified health center
HCC	Hierarchical Condition Category
HDL	High-density lipoprotein cholesterol
IT	Information technology
LDL	Low-density lipoprotein cholesterol
MA	Medical Assistant

MBSF	Medicare Beneficiary Summary File
mg/dL	Milligrams per deciliter
mmHg	Millimeters of mercury
NP	Nurse practitioner
n.a.	Not applicable
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
PA	Physician assistant
PBPM	Per beneficiary per month
PP	Performance period
RHC	Rural health center
SBP	Systolic blood pressure
ТСРІ	Transforming Clinical Practice Initiative
TIA	Transient ischemic attack
TIN	Tax Identification Number

Executive Summary

In 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts[®] Cardiovascular Disease (CVD) Risk Reduction Model. In this payfor-prevention model, CMS pays participating organizations (1) for assessing each of their eligible Medicare fee-for-service (FFS) beneficiary's risk of having a heart attack or stroke over the next 10 years and (2) for reducing CVD risk among high-risk beneficiaries. The goal of the model is to reduce the incidence of first-time heart attacks and strokes among Medicare FFS beneficiaries and to reduce Medicare spending enough to fully offset model payments. CMS is testing the model in a randomized controlled trial over five years among primary care practices, specialty practices, health centers, and hospital outpatient departments throughout the United States.

Over four years (2017 to 2020), the model has improved CVD preventive care, including risk assessment, but has not measurably reduced first-time heart attacks or strokes or reduced Medicare spending. The model has increased all-cause hospitalizations and outpatient emergency department visits and appears to have Over four years (2017 to 2020), the Million Hearts CVD Risk Reduction Model enrolled more than 250,000 Medicare beneficiaries throughout the United States who were at elevated risk of having a heart attack or stroke over 10 years. The model had the following effects on beneficiaries:

- Increased the initiation or intensification of statins and anti-hypertensive medications by 3.4 percentage points (31.3 percent in the intervention group and 27.9 percent in the control group) among those who were candidates for treatment.
- Decreased CVD risk factors—systolic blood pressure and low-density lipoprotein (LDL) cholesterol—by 1.3 percent each, relative to the control group (among the subset of enrollees with the highest CVD risk).
- Did not measurably reduce first-time heart attacks or strokes.
- Did not reduce Medicare Part A and B spending.
- Increased all-cause hospitalizations by 3.8 percent and outpatient emergency department visits by 2.9 percent, relative to the control group.
- Appears to have reduced all-cause mortality by 0.3 percentage points (with 6.6 percent of people dying within 3 years in the intervention group versus 6.9 percent in the control group).

modestly reduced all-cause mortality rates. Although the COVID-19 pandemic has created several challenges to implementing the model, and organizations have adapted their implementation strategies accordingly, the main findings are largely consistent with those we reported earlier covering the model's first three years (Blue et al. 2020). A future report will assess the model's impacts over its full five years.

This executive summary describes the design of the model (Section A) and how organizations have implemented it through early 2021, focusing on changes in implementation from earlier years—including changes due to COVID-19 (Sections B and C). The executive summary then describes changes in CVD risk scores among high-risk beneficiaries (Section D) and model

impacts on intermediate and long-term outcomes (Section E). It ends with a brief discussion of the findings and their relevance to other research on CVD prevention (Section F).

A. Model design

The Million Hearts Model has two major components.

- 1. Guidelines on CVD preventive care, which share several features with the American College of Cardiology's and American Heart Association's CVD prevention guidelines (Arnett et al. 2019). The organizations randomly assigned to the Million Hearts Model intervention group agreed to use a formal risk assessment tool (Goff et al. 2014; text box) to assess the risk of each of their eligible Medicare beneficiary's risk of a heart attack or stroke over 10 years; and provide cardiovascular care management services to high-risk Medicare beneficiaries (those with a calculated 10-year risk, or *risk score*, of 30 percent or higher). Medicare FFS beneficiaries are eligible for the Million Hearts Model if they are ages 40 to 79, have not previously had a heart attack or stroke, do not have end-stage renal disease, and are not enrolled in hospice. The required cardiovascular care management services include (1) discussing CVD risk with high-risk patients; (2) developing, in conjunction with patients, individualized care plans for reducing risk; (3) having an annual in-person reassessment visit, including recalculating 10-year CVD risk using a longitudinal calculator designed for this purpose (Lloyd-Jones et al. 2017); and (4) following up with high-risk patients at least twice more each year (by any mode) to monitor and encourage progress in CVD risk reduction.
- 2. Incentives and supports. CMS pays intervention organizations \$10 for each eligible beneficiary they risk stratify. Further, in 2017, CMS paid \$10 per beneficiary per month (PBPM) for cardiovascular care management services for high-risk beneficiaries and—starting in 2018—a monthly payment that ranges from \$0 to \$10 for each high-risk beneficiary reassessed. The size of the payment depends on the organization's performance in reducing average risk among all its high-risk patients. Organizations submit the clinical data needed to assess risk both initially and over time via the online Million Hearts Data Registry. CMS also provides regular webinars and peer-to-peer learning sessions and sends each organization semiannual reports on its progress enrolling beneficiaries and reducing CVD risk.

Although CMS provided broad guidelines for providing CVD preventive care and financial incentives for reducing CVD risk, CMS did not prescribe *how* organizations should reduce risk. For example, organizations and their providers could choose to use medications, encourage behavior changes, offer new services, or any combination of these options, depending on what the organization and its providers believed would most benefit their at-risk Medicare beneficiaries.

CMS paid organizations randomly assigned to the usual care control group for submitting clinical data needed to assess beneficiaries' CVD risk at baseline and annually thereafter through 2019.

CVD risk scores: A closer look

The CVD risk score represents a person's **predicted probability of having a heart attack or stroke within 10 years**, as calculated using a standardized tool. At a person's initial CVD risk assessment, the risk score is based on several factors (Goff et al. 2014):

- Demographics, including age, sex, and race
- Clinical factors, including blood pressure and cholesterol levels, and history of diabetes
- Patients' behaviors, including current smoking status and use of medications to control blood pressure

When designing the Million Hearts Model, CMS worked with leading cardiovascular epidemiologists to develop a **novel risk calculator that estimates changes over time in a person's risk of heart attack or stroke** (Lloyd-Jones et al. 2017). The new tool incorporates additional information about aspirin use, time since quitting smoking, and changes since the initial assessment in blood pressure and cholesterol.

B. Participating organizations and the Medicare beneficiaries they have enrolled

1. Participating organizations

CMS enrolled 516 organizations and randomly assigned half to the intervention group and half to a usual care control group. About two-thirds of these organizations (N = 345) participated in the model's first two years, which we defined as having enrolled at least one Medicare beneficiary during this time. These participating organizations included primary care and specialty practices, health centers, and hospital outpatient departments throughout the country. The organizations varied in size, location, and participation in other CMS initiatives. The intervention and control organizations were largely similar on these dimensions, though intervention organizations tended to have fewer providers.

Organizations steadily withdrew from the model over its first four years (2017 to 2020). Of the 173 intervention organizations that participated in 2017 or 2018, only 136 (or 79 percent) were still formally in the model as of December 2020, and only 78 (or 45 percent) still submitted clinical data to CMS in 2020. Organizations must continue to report clinical data to receive model payments. Control organizations withdrew at similar rates through December 2019, when control group participation in the model ended.

2. Beneficiaries enrolled

Despite the significant attrition, the participating organizations enrolled hundreds of thousands of Medicare FFS beneficiaries into the model. An organization enrolls a beneficiary by submitting the clinical data needed to calculate a beneficiary's CVD risk score, with the enrollment date the day of the clinical visit when the organization collected these data. From 2017 to 2020, the intervention group enrolled 273,730 beneficiaries and the control group enrolled 177,489 beneficiaries (Figure ES.1). Enrollment was lower in the control group largely because CMS

capped at 20 the number of control group providers per organization who could enroll beneficiaries, but did not apply this cap to the intervention group. In both the intervention and control groups, enrollment was highest in 2017 and declined in later years, as only beneficiaries who were newly eligible for the model (for example, new to Medicare)—or were missed in earlier years—could be enrolled each year.

Figure ES.1. More than half of the beneficiaries enrolled from 2017 to 2020 were high or medium risk: Number of Medicare beneficiaries enrolled by intervention and control organizations, by risk level

	Enrollment from 2017 to 2020		
CVD risk group at baseline (predicted probability of having a heart attack or stroke in 10 years)	Intervention	Control	
High (≥ 30%)	46,568 (17%)	30,119 (17%)	
Medium (15–29.9%)	106,844 (39%)	68,595 (39%)	
Low (< 15%)	120,318 (44%)	78,775 (44%)	
All	273,730	177,489	

Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data. Data for control organizations reflects enrollment from 2017 to 2019, after which control organizations stopped enrolling beneficiaries.

In both the intervention and control groups, about 56 percent of all enrollees were in either the high- or medium-risk group, the population included for most of the analyses. CMS anticipated the model would have impacts for (1) high-risk enrollees (those with a 30 percent or higher 10-year CVD risk), for whom CMS pays for measured risk reduction, and (2) medium-risk enrollees (those with a 15 to 30 percent risk score). Although CMS does not require cardiovascular care management or pay for risk reduction among this medium-risk group, CMS anticipated risk assessment would make providers newly aware of elevated risk in this group as well as among high-risk beneficiaries, prompting improvements in CVD care. In both the intervention and control groups, the high-risk group accounted for 17 percent of enrollees. The medium-risk group was more than twice as large, accounting for 39 percent of enrollees.

Within the population of high- and medium-risk beneficiaries, we estimate about one-third of the total CVD risk at baseline was due to modifiable risk factors. Specifically, among high- and medium-risk beneficiaries enrolled in 2017 or 2018, the average predicted risk of having a heart attack or stroke over 10 years was 27 percent. We estimate 9 percentage points (or 33 percent [9 of 27]) was due to modifiable risk factors, especially elevated systolic blood pressure and elevated cholesterol. The other 18 percentage points of total risk were due to nonmodifiable factors, such as age and sex, or factors that are difficult to modify, such as having diabetes.

C. Model implementation in 2020 and early 2021, and organization plans to sustain changes in CVD care beyond 2021

1. Model implementation

In 2020 and 2021, intervention group organizations faced several challenges related to the COVID-19 pandemic. The pandemic made it harder to see patients for office visits, especially during spring 2020; to obtain clinical data needed for CVD risk calculation; and to devote staff time to implementing the model. In an early 2021 survey, most organizations still participating in the model reported the Million Hearts Model had become less of a priority due to COVID-19.

Although the model became less of a priority overall, many organizations took advantage of design changes CMS made to ease model implementation during the pandemic. Starting in 2020, CMS allowed organizations to conduct assessment and reassessment visits via telehealth, whereas previously CMS had required these be in person. Further, CMS permitted organizations to collect blood pressure data from beneficiaries who self-reported blood pressure from a validated home monitoring device. In an early 2021 survey, all intervention organizations that responded reported increasing their use of telehealth during the pandemic, and 63 percent reported that greater use of telehealth enabled them to continue the model's risk-assessment activities.

In part due to these design flexibilities, by the time of the survey in early 2021, intervention organizations reported continuing risk assessment at rates well above pre-intervention levels, but below their peak in 2018 (Figure ES.2). The proportion of intervention organizations that reported calculating CVD risk scores for most of their Medicare beneficiaries decreased from 61 percent in 2018 to 46 percent in 2021. However, this percentage remained higher than the 14 percent of organizations that reported risk stratifying most of their Medicare beneficiaries before joining the model in 2016. In interviews, providers continued to report risk stratification helped make them more aware of their patients' CVD risk, and that they used risk scores to aid discussions of risk—and possible ways to reduce it—with their patients.

Figure ES.2. Organizations reported calculating CVD risk scores in 2021 at higher rates than they did before the intervention, but below their peak in 2018: Percentage of intervention organizations reporting they calculated CVD risk scores for at least half of their Medicare beneficiaries



Source: Surveys administered in 2018 (N = 88) and 2021 (N = 90) to key contacts at each intervention organization in the Million Hearts Model.

CVD = cardiovascular disease.

Except for changes they made due to COVID-19, intervention organizations reported continuing to use the same strategies they did in prior years to implement the model. For example, organizations continued to use (1) the electronic health record (EHR) or online apps to calculate risk scores when possible; and (2) tracking tools or registries, care managers, and automated scheduling to follow up with high-risk beneficiaries over time.

2. Model payments

Model payments declined in 2020 and most participating organizations reported payments were not an important factor in their continued participation in the model. The mean payments per organization in each of the two six-month performance periods in 2020 were \$3,700, well below the mean payments of about \$13,900 in the first two six-month periods in 2017. The declines occurred in large part because organizations generally did not continue to risk stratify new patients in 2020, and because the model was designed to shift from guaranteed payments for cardiovascular care management services in the first year to performance-based incentives in later years. In the 2021 survey, only 43 percent of organizations said the model payments were an important factor for their continued participation in the model, down from 61 percent reporting this in 2018.

3. Participants' overall perceptions of the model

The intervention organizations held mixed views of the model, crediting it with improving quality of CVD preventive care while expressing limited interest in participating in a similar model in the future. In the 2021 survey, 66 percent of organizations responding reported that participating in the Million Hearts Model helped their organization improve quality of care for

CVD prevention, and a similar percentage reported the model helped their organization improve their patients' CVD risk scores. However, only 45 percent of surveyed organizations agreed that, if offered, they would participate in the Million Hearts Model in the future.

This mixed assessment likely reflects different perceptions of different aspects of the model, which we heard in past interviews (Blue et al. 2020) and was affirmed again in interviews in early 2021. Participating organizations generally liked the vision of care the model encourages and see striving toward that vision as improving their CVD preventive care. But they view data reporting requirements of the model as burdensome, and payments as not commensurate with them.

4. Plans to sustain changes in CVD care beyond 2021

Overall, a little more than half of intervention organizations responding to the 2021 survey said the Million Hearts Model prompted changes in how they assessed and managed CVD risk *and* that they planned to sustain changes after the model ended. About one-third of the organizations said the model had not prompted care changes, and a small minority said the model had prompted changes but they did not plan to sustain them after 2021 (Figure ES.3).

Among organizations that said they planned to sustain changes beyond 2021, more than 90 percent said they were likely or somewhat likely to sustain changes made to systematically identify patients at high risk for CVD. Nearly three-quarters were likely or somewhat likely to sustain changes related to the role of care managers in CVD risk assessment and reassessment, and about two-thirds planned to sustain changes related to the use of an embedded EHR tool to assess CVD risk.

Figure ES.3. More than half of intervention organizations surveyed in 2021 reported they made changes to CVD care through their participation in Million Hearts Model that they plan to sustain after the model ends: Percentage of organizations reporting they made changes to CVD care and whether they plan to sustain those changes



Source: Surveys administered in 2021 to key contacts at each intervention organization in the Million Hearts Model (N=89).

CVD = cardiovascular disease.

D. Changes in risk scores among high-risk intervention group beneficiaries

1. Changes in risk scores among high-risk enrollees in the intervention group

For organizations participating in the Million Hearts Model, average risk score reduction among high-risk beneficiaries is a key measure of model performance. Among high-risk beneficiaries, the average CVD risk score fell by 8 percentage points between enrollment and the one-year reassessment—with the predicted probability of having a heart attack or stroke within 10 years falling from 40 percent at enrollment to 32 percent roughly one year later. However, average risk scores in the control group also declined by a large amount (7 percentage points) over this period. The large reduction in risk scores among both the intervention and control groups— compared to the relatively small difference in risk score reduction between the two groups— indicate factors that affect both the intervention and control groups (rather than the impact of the Million Hearts Model) explain most of the decline in risk scores. These other factors could include organizations addressing risk factors under usual care, or random fluctuations in blood pressure over time that lead to apparent declines when the population analyzed includes mostly people with particularly high blood pressure reading at enrollment.

2. Variation in CVD risk reduction across intervention organizations, and possible drivers of variation

Intervention organizations participating in the Million Hearts Model varied considerably in their average risk reduction achieved. Among 54 organizations that submitted enough reassessment data to generate a stable estimate of organizational-level risk reduction, the organization with the greatest documented reduction in average CVD risk scores had an average risk reduction of 13.4 percentage points. The reduction was 2.9 percentage points for the organization with the smallest

reduction. Average risk reduction was measured across all reassessment visits occurring from November 2017 to December 2019.

The single strongest predictor of an organization's risk reduction was whether the organization had a lot of room for improvement to begin with—meaning that beneficiaries' risk scores were driven largely by modifiable risk factors, such as elevated blood pressure and lipid levels and smoking, instead of nonmodifiable factors, such as age and sex. Specifically, the mean amount of modifiable risk at baseline at an organization accounted for 30 percent of the variation in risk score reduction across organizations.

To identify CVD preventive care approaches that might contribute to risk score reduction, we interviewed a sample of organizations with unusually high or low average risk score reduction but with similar organizational characteristics. Compared to the organizations with smaller reductions in the average CVD risk score, the organizations with large reductions (1) reported more proactive communication and/or wider use (across different types of providers) of the documented risk score in the EHR; and (2) tended to point to the important role of project champions and highly engaged staff in quality improvement efforts or innovative initiatives, such as the Million Hearts Model. On the other hand, organizations with small reductions in average CVD risk were more likely to mention patients' compliance as a barrier to success.

E. Model impacts on intermediate and long-term outcomes

1. Intermediate outcomes

The Million Hearts Model modestly improved some intermediate outcomes within one year of enrollment, the prespecified period for estimating impacts on these outcomes.

- Among the 90 percent of high- and medium-risk beneficiaries with blood pressure or cholesterol levels above thresholds for treatment at enrollment, the likelihood of initiating or intensifying CVD medications (statins or antihypertensives) was 3.4 percentage points higher in the intervention group (31.3 percent) than the control group (27.9 percent, p < 0.001; Figure ES.4). The impact estimate was only slightly larger (4.4 percentage points, p < 0.001) for the high-risk beneficiaries alone. This indicates the model had positive spillover to the much larger medium-risk group, as CMS hypothesized.
- Adherence to CVD medications was similar in the intervention and control groups among beneficiaries already taking these medications at enrollment. About 75 percent of high- and medium-risk beneficiaries were adherent to statins and 87 percent were adherent to antihypertensives in the year after enrollment. Following other studies, we considered beneficiaries adherent if their prescription fills indicated they had enough pills to cover at least 80 percent of the days in the year.
- CVD risk scores decreased for high-risk beneficiaries in both the intervention and control groups, but the decrease was 1.3 percentage points (3.8 percent) larger in the intervention group (p = 0.003). This modest impact was driven by small reductions relative to the control

group in systolic blood pressure (-1.3 percent, p = 0.002) and in LDL cholesterol (-1.3 percent, p = 0.04), and by a substantial (10 percentage point) increase in the use of aspirin, relative to the control group (p = 0.005). We did not observe any impacts on smoking rates, though smoking was uncommon (with 12 percent current smokers at enrollment) in both groups.

Figure ES.4. The Million Hearts Model modestly increased the use of statins and antihypertensive medications. Percentage of high- and medium-risk beneficiaries initiating or intensifying medications within a year of enrollment, by intervention group



Source: Medicare Part D claims. Limited to enrollees with Part D coverage and blood pressure or cholesterol at baseline above levels for treatment with medications.

*** = *p* < 0.001.

2. Long-term outcomes

No detectable impact on first-time heart attack or stroke. Over four years, the model did not measurably reduce the incidence of first-time heart attacks or strokes, one of the study's two primary long-term outcomes. That is, the incidence of first-time heart attacks, strokes, or transient ischemic attacks was similar for the intervention and control groups (Figure ES.5). The ratio of the risk (hazard ratio) of having a first-time heart attack and stroke in the intervention versus the control group was 0.97, and not statistically different from zero (p = 0.20, 90 percent confidence interval of [0.93, 1.01]).

Figure ES.5. The model had no detectable impact on the percentage of beneficiaries with first-time heart attacks, strokes, or TIAs within three years of enrollment: Percentage of high- and medium-risk beneficiaries with first-time heart attacks, strokes, or TIAs within 1, 2, or 3 years after enrollment (regression-adjusted)



Source: Regression-adjusted results based on Medicare claims. TIA = transient ischemic attack.

No detectable impact on Medicare spending. Average Medicare spending was very similar for intervention and control group beneficiaries during the entire study period, both before and after Million Hearts Model payments are included. Future analyses will estimate model impacts over the full five years, the time period CMS prespecified for the final assessment of model impacts.

Even though the model has not measurably improved the study's primary long-term outcomes, it has had some significant and unexpected effects on secondary outcomes.

- The model increased acute care use. Rates of all-cause hospitalizations and outpatient emergency department (ED) visits were modestly (3 to 4 percent) higher for the intervention group than the control group (*p*-values all less than 0.1). These increases were not concentrated in CVD-specific events, indicating the model modestly increased use of acute care of all kinds, not only CVD-specific care. This could occur, for example, if the model prompted patients to become more aware of their health risk overall, prompting greater use of health care services generally, including acute care.
- The model was associated with a modestly lower risk of death over three years. Among high- and medium-risk beneficiaries, the probability of dying within three years of enrollment was 0.3 percentage points (or 4 percent) lower in the intervention group (6.6 percent) than the control group (6.9 percent; p = 0.02). Among high-risk beneficiaries, the death rate was similar in the intervention and control groups—indicating the apparent mortality effect concentrated among medium-risk beneficiaries.

The finding of reduced mortality is surprising given that we did not observe any impacts on firsttime heart attacks and strokes, which is the main route through which we anticipated the model could improve survival. As noted in the <u>Third Annual Report</u> (Blue et al. 2020), there are at least three possible explanations for these results:

- 1. By measuring CVD events in hospital and ED claims data, we might have missed some true model impacts on fatal heart attacks or strokes for which patients were pronounced dead outside the hospital setting—leading us to observe an impact on the death rate, even as we miss a true impact on heart attacks and strokes. This could occur if the model prompted beneficiaries to go to the hospital at early signs of a CVD event that might otherwise prove fatal. Even more deaths outside a hospital setting could have been missed during the early months of the COVID-19 pandemic in 2020 when avoidance of care led to large (almost 50 percent) declines in hospitalizations for heart attacks and strokes (Solomon et al. 2020; Baum and Schwartz 2020; Stewart et al. 2021).
- 2. There could be reductions in the death rate from other conditions due to improvement in exercise or diet, medication therapy, or mechanisms we did not anticipate at the beginning of the evaluation. One such mechanism could be that, because the model encouraged beneficiaries to have more office visits, providers might have been more likely to detect and address other health conditions. This second mechanism would be consistent with the general increase in medical care we observed in the intervention group, as evidenced by increases in all-cause office visits (Blue et al. 2020), inpatient stays, and outpatient ED visits.
- **3.** Finally, the impact estimates could reflect systematic differences between the intervention and control groups and not true impacts. Our careful use of regression adjustment and robustness checks alleviates—but does not rule out—this concern. Differences between the intervention and control beneficiaries could either have existed at random assignment or been introduced during model implementation by organization- and provider-level attrition or by differences in the types of beneficiaries intervention and control organizations chose to enroll among their eligible beneficiaries.

F. Discussion

The findings from this study are consistent with those from similar studies. For example, like this evaluation, a 2017 Cochrane review of risk scoring for CVD primary prevention linked risk score use to an increased use of statins and antihypertensive medications and to small reductions in total cholesterol and systolic blood pressure (Karmali et al. 2017). However, the review found "little to no effect" on CVD events.

One difference between this evaluation and the previous research summarized by Karmali et al. (2017) is the Million Hearts Model tests a policy intervention—that is, incentives and supports to *encourage* use of CVD risk scores and other CVD preventive care. This model does not test the use of risk scores (or other care processes) directly, as in the studies summarized by the Cochrane review. As such, the findings from this evaluation also contribute meaningfully to the health policy research literature, including pay-for-performance programs. Our study finds modest incentives can improve CVD medication use and reduce CVD risk factors in varied clinical settings.

Our final evaluation report will estimate impacts over the full five-year model test, capitalizing on this large study population and five-year duration to see if the observed improvements in CVD care translate into reductions in CVD events and any notable changes in Medicare spending.

I. Introduction

Cardiovascular disease (CVD) is a leading cause of death, disability, and health care expenditures in the United States (Virani et al. 2021). Improvements in diet and exercise, smoking cessation, and appropriate use of preventive medications could substantially reduce the burden of CVD (Karmali et al. 2016; Yusuf et al. 2020). In 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts[®] Cardiovascular Disease Risk Reduction Model to reduce the incidence of first-time heart attacks and strokes among Medicare beneficiaries (Sanghavi and Conway 2015). In this model, CMS pays providers to assess each of their Medicare beneficiaries. CMS is testing the Million Hearts Model in a large, five-year randomized trial that includes primary care and cardiology practices, health centers, and hospital outpatient departments throughout the country.

The Million Hearts Model is part of the broader Million Hearts Initiative, which the U.S. Department of Health and Human Services launched in 2012 to prevent one million heart attacks and strokes within five years (Centers for Disease Control and Prevention [CDC] 2012; Wall et al. 2018). In its first five-year cycle (2012–2016), the broader initiative prevented an estimated 135,000 heart attacks, strokes, and related acute cardiovascular events and saved \$5.6 billion in direct medical costs (Ritchey et al. 2020). The benefits of this broader initiative were concentrated among those 75 or older, especially women.

The Million Hearts Model launched at the beginning of 2017 and will run through the end of 2021. This fourth annual evaluation report builds on prior reports (Conwell et al. 2019; Peterson et al. 2019; Blue et al. 2020), describing (1) how organizations implemented the Million Hearts Model during 2020 and early 2021; and (2) the impacts the model has had on heart attacks and strokes, Medicare spending, and intermediate outcomes over four of the planned five years of the model. The COVID-19 pandemic, which began in early 2020, has shaped how organizations have implemented the model during this period and the relative priority organizations have been able to place on the model. The pandemic has also led people to delay preventive care services, including CVD prevention (Lau and McAlister 2021), underscoring the importance of continuing to monitor and address CVD risk factors through initiatives such as the Million Hearts Model.

A. Model goals and design

The goals of the Million Hearts Model are to (1) decrease the incidence of first-time heart attacks and strokes among high- and medium-risk Medicare fee-for-service (FFS) beneficiaries over five years and (2) decrease Medicare Part A and B spending on CVD events enough to offset model payments. To help meet these goals, the model provides guidelines for CVD preventive care and targeted financial incentives and supports.

Guidelines on CVD preventive care. Intervention organizations agreed to do the following:

- Calculate each of their eligible Medicare FFS beneficiaries' risk of having a heart attack or stroke over 10 years, using a formal risk assessment tool. Beneficiaries are eligible for the Million Hearts Model if they are ages 40 to 79, have not had a previous heart attack or stroke, do not have end-stage renal disease, and are not enrolled in hospice. Beneficiaries are considered to be at high risk if their predicted 10-year CVD risk (referred to as the risk score) is at least 30 percent, at medium risk if their risk score is from 15 to 30 percent, and at low risk if it is less than 15 percent.
- **Provide cardiovascular care management services to high-risk patients.** These services include (1) meeting with beneficiaries to discuss their overall CVD risk and individual risk factors; (2) jointly developing individualized plans for reducing risk that reflect both the efficacy of different treatment options and beneficiaries' goals and priorities; (3) reassessing the beneficiary's risk each year, using a longitudinal tool designed specifically for the model (Lloyd-Jones et al. 2017); and (4) following up with the patient at least twice each year to gauge and encourage progress in reducing CVD risk.

These guidelines are consistent with the American College of Cardiology's (ACC) and American Heart Association's (AHA) guidelines that recommend providers calculate and use CVD risk scores to guide CVD preventive care (Arnett et al. 2019).

Incentives and supports. CMS provides organizations financial incentives and supports to assist them in assessing CVD risk for all eligible beneficiaries and providing CVD preventive care to their high-risk beneficiaries. Intervention organizations are eligible to receive three types of payments:

- \$10 for each eligible Medicare FFS beneficiary the organizations risk stratify
- \$10 per high-risk beneficiary per month for providing cardiovascular care management services (first model year only)
- \$0 to \$10 per high-risk beneficiary per month depending on how successful the organization is in reducing the average risk score for all of its high-risk beneficiaries assessed during the relevant period (starting in the second model year). Specifically, CMS pays \$10 per month if the average CVD risk score for high-risk beneficiaries declines from baseline by more than 10 percentage points; \$5 if the score declines by 2 to 10 percentage points; and \$0 if it declines by less than 2 percentage points.

In addition, from 2017 to 2019, CMS paid control organizations for sharing clinical data from model-eligible beneficiaries but did not ask those organizations to calculate risk scores or change their CVD preventive care. To limit model costs, CMS allowed up to 20 providers in each control organization to enroll beneficiaries but did not apply a similar cap to the intervention group.

CMS also offers intervention organizations several tools and supports to help them improve their CVD preventive care and meet reporting requirements:

- Semiannual reports describing their performance enrolling beneficiaries and reducing CVD risk
- Peer-to-peer learning sessions to encourage organizations to share strategies for implementing the model
- The Million Hearts Data Registry, a secure portal CMS created where intervention and control organizations are required to submit the clinical and demographic data needed to calculate a beneficiary's CVD risk
- The Million Hearts Longitudinal Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment Tool—a novel tool developed for the Million Hearts Model to track changes in CVD risk over time, based on evidence from clinical trials that link changes in heart attack and stroke rates to changes in CVD risk factors (Lloyd-Jones et al. 2017). Under this tool, a person's initial risk score is the same as calculated under the previously existing ACC/AHA ASCVD Risk Estimator (Goff et al. 2014). However, because the new tool can estimate risk change for a given individual over time, CMS uses this tool when estimating risk reduction, the basis of the Million Hearts Model risk reduction payments.

Although CMS provided broad guidelines for providing CVD preventive care and financial incentives for reducing CVD risk, CMS did not prescribe *how* organizations should reduce risk. For example, organizations and their providers could choose to use medications, encourage behavior changes, offer new services, or any combination of these options, depending on what the organization and its providers believed would most benefit their at-risk Medicare beneficiaries.

Although CMS paid organizations only for reducing CVD risk among high-risk beneficiaries, CMS anticipated some positive spillover to medium-risk beneficiaries as well. That is, the model (which paid for risk assessment for all eligible beneficiaries) could prompt providers to become more aware of CVD risk in their medium-risk population, and to improve CVD preventive care for these beneficiaries as well.

B. Previous findings

CMS contracted with Mathematica and RAND to evaluate whether the model is achieving its intended goals. As reported in the <u>Third Annual Report</u> (Blue et al. 2020), the Million Hearts Model improved CVD preventive care, but did not yet reduce first-time heart attacks and strokes or lower Medicare spending during its first three years (2017 to 2019). Figure I.B.1 summarizes findings through 2019 along a causal pathway we developed that describes the steps that could lead to the intended outcomes if each step works as intended.



Figure I.B.1. Causal pathway for the Million Hearts Model, with key findings through 2019

C. Research questions, data sources, and methods for this report

Research questions. This report explores new questions about the implementation and impact of the Million Hearts Model, particularly in light of the COVID-19 pandemic and the changes participating organizations made to continue implementing the model in this period. It also builds on the findings reported through 2019 by expanding the time frame for observing impacts on CVD events, spending, and other outcomes. The report addresses five key research questions:

- 1. How are intervention organizations implementing the model in 2020 and early 2021, focusing on changes compared to prior years and changes relating to the COVID-19 pandemic?
- **2.** To what extent, and how, do intervention organizations plan to sustain any changes they have made to CVD care after the model ends?
- **3.** How have risk scores changed for high-risk beneficiaries in the intervention group and what might be contributing to variation in performance across intervention organizations in reducing CVD risk for their high-risk beneficiaries?
- 4. What impact has the model had on intermediate outcomes—including use of CVD medications, CVD risk scores, and individual risk factors (such as blood pressure and cholesterol)?

5. What impact has the model had on first-time heart attacks and strokes, mortality, service use, and Medicare spending over four years (2017 to 2020)?

Data source and methods. To answer these research questions, we used a mix of data sources and methods:



Interviews with model participants. To understand model implementation in 2020 and early 2021, facilitators of and barriers to implementation, COVID-19's influence on model implementation and prioritization, and plans to sustain changes in care beyond the model, we conducted 22 interviews with providers and staff at 10

intervention organizations. These organizations are part of a cohort of organizations that have been interviewed each year of the model and were originally selected to represent a range of sizes, locations, and types (for example, primary care and cardiology practices). In addition, to understand strategies and approaches to CVD risk reduction, we conducted 20 interviews with providers and staff at three organizations with above-average CVD risk reduction and four organizations with below-average CVD risk reduction.



Practice survey. In 2021, we surveyed the person designated by each intervention organization as the lead for overseeing the model's implementation. This person might be a clinician, an office manager, or other administrative lead. The survey asked how the organization implemented the model, barriers to and facilitators of

implementation, and perceptions about the model's effects on CVD preventive care. The survey also asked about plans for sustaining changes in care and experiences related to the COVID-19 pandemic. The survey asked several questions that overlapped with a similar survey we administered in 2018; in those cases, we compared responses over time.



Registry. We used clinical and demographic data from the Million Hearts Data Registry to identify Medicare beneficiaries enrolled into the model by the intervention and control organizations in the first four years of the model (January 2017 through December 2020). These data include beneficiaries' characteristics at enrollment,

including age, sex, CVD risk factors, and CVD risk scores. Further, the registry includes similar data for patients with annual reassessment visits. We used the reassessment data to identify frequency of reassessment visits for high-risk patients, the change in CVD risk scores and risk factors by year of enrollment, and the impact of the Million Hearts Model on CVD risk scores and individual risk factors.



Payment data. These data indicate how much CMS paid the intervention organizations, how these payments varied over time, and the extent to which organizations earned available incentive payments for CVD risk reduction.



Medicare claims and enrollment data. By design, all beneficiaries enrolled in the Million Hearts Model are Medicare FFS beneficiaries with Part A and B coverage. About 70 percent also had Part D coverage. We used Medicare Part A and B claims and the Medicare Enrollment Database through December 2020 for several purposes:

- Define the study's main outcomes—first-time heart attacks and strokes and Medicare spending—and several secondary outcomes (for example, mortality and rates of ED visits and hospitalizations). We estimated model impacts as regression-adjusted differences in outcomes between the intervention and control groups.
- Define a beneficiary's characteristics when the beneficiary enrolled in the model (for example, presence of certain chronic conditions). We used these characteristics to describe the population the model served, assess the degree of similarity between the intervention and control groups, and as covariates in regression models estimating the impacts of the Million Hearts Model.
- To examine the number of visits that high-risk enrollees had with Million Hearts organizations before and during the COVID-19 pandemic, as context for factors facilitating or impeding model implementation.

We used Medicare Part D claims to assess whether the model increased the (1) initiation or intensification of statins to lower cholesterol or antihypertensive medications to lower blood pressure and (2) adherence to these medications within one year of enrollment.

Testing COVID-19 bias on impacts. COVID-19 could bias impact estimates if it drives differences in outcomes between the intervention and control groups that are unrelated to the model. Although COVID-19 substantially changed service use and spending patterns, changes were similar for both the intervention and control groups, suggesting little risk of bias due to COVID-19. A detailed description of our methods and findings is available in <u>Appendix A</u>.

Report organization. We start (<u>Chapter II</u>) by describing the organizations participating in the Million Hearts Model, how participation has changed over time, and the number of beneficiaries participating organizations enrolled from 2017 to 2020. <u>Chapter III</u> explores model implementation during 2020 and 2021, with a particular focus on the implications of the COVID-19 pandemic on model implementation and organizations' plans to sustain changes to CVD care after the model ends. <u>Chapter IV</u> summarizes changes in CVD risk scores and risk factors among intervention group enrollees, including factors that might contribute to variation across organizations in their success in reducing CVD risk. <u>Chapter V</u> updates estimates of model impacts on intermediate outcomes, service use, spending, first-time heart attacks and strokes, and mortality from 2017 to 2020. The average beneficiary follow-up period increased by 50 percent (from 27 to 40 months). Chapter V also includes a new set of outcome measures— adherence to CVD medications. In <u>Chapter VI</u>, we discuss overall findings from the report, including its contributions to the literature on interventions and policies for reducing CVD risk.

II. Participating Organizations and the Beneficiaries They Enrolled



Key findings

CMS randomly assigned 516 organizations to the intervention and control groups of the Million Hearts Model.

- Among them, 345 participated in the first two model years, meaning they enrolled at least one beneficiary in 2017 or 2018.
- These participating organizations included primary care practices, cardiology practices, health centers, and hospital outpatient departments located in rural and urban areas across the country.

As of December 2020, about 60 percent of the 516 randomized organizations formally remained in the model, meaning they had not withdrawn or CMS had not terminated them.

- Organizations withdrew largely because they did not think the financial incentives were commensurate with the work required or they did not have adequate staff to comply with the model requirements, particularly uploading data to the registry.
- After the model launched, the number of intervention organizations reporting visit data to the registry (a requirement to receive incentive payments) declined considerably over time, from 174 in the first six months of the model to 63 by last six months of 2020. This decline started before the COVID-19 pandemic and continued at a similar rate during it.
- Intervention organizations that continued to actively participate by formally remaining in the model and continuing to report data to the registry through December 2020 (78 organizations) tended to be larger and had enrolled more beneficiaries than organizations that did not (95 organizations).

During the first four years of the model (2017 to 2020), participating intervention and control organizations enrolled 451,219 Medicare FFS beneficiaries.

- Enrollment was highest in 2017 and decreased each year, partly because the number of beneficiaries still eligible for enrollment decreased over time.
- The CVD risk profile was very similar between intervention and control groups.

The population used for the impact evaluation is a subset of the total beneficiaries enrolled in the model namely, those who enrolled in 2017 or 2018 and were classified as high or medium risk.

- Among these beneficiaries, the average risk of having a heart attack over 10 years was 27 percent. Of this total risk, we estimate that 9 percent was due to modifiable factors such as high cholesterol or blood pressure, and the rest was to due age, diabetes, sex, and other nonmodifiable factors.
- We included beneficiaries in the impact evaluation even if the organization that enrolled them stopped participating in the model, following an intent-to-treat evaluation design.

A. Summary of participating organizations

Organizations were eligible for the Million Hearts Model if they had at least one physician, nurse practitioner, or physician assistant who billed Medicare and used an electronic health record (EHR). CMS accepted all 516 eligible organizations that applied to the model and signed a Model Participant Agreement agreeing to model requirements. CMS randomly assigned half of

the organizations to the intervention group and half to a control group, making sure organizations were similar in location and size.

Among the 516 organizations CMS accepted to the Million Hearts Model, about two-thirds (345) participated in the first two years of the model (2017 to 2018) by enrolling at least one Medicare beneficiary. Even though one-third of the randomized organizations did not participate, the number of participating organizations remained evenly split between the intervention and control groups, with half in the intervention group (173 organizations) and half in the control group (172 organizations).

As described in the <u>Third Annual Report</u> (Blue et al. 2020), the 345 participating organizations included primary care and cardiology practices, health centers, and hospital outpatient departments (Table II.A.1). Intervention and control organizations were similarly spread throughout the country and across urban and rural areas. About half of the organizations also participated in or had applied to at least one other CMS initiative when they applied for the model, mostly commonly the Medicare Shared Savings Program. Even after one-third of randomized organizations did not participate in the model, the remaining 172 control group organizations were similar to the 173 intervention group organizations across most of these characteristics (Table II.A.1). The biggest differences between the two groups were in the mean number of providers, which was greater among control organizations, and participation in the Medicare Shared Savings Program, which was greater among intervention organizations, as reported in organizations to the model.

Characteristic	Intervention organizations (N = 173)	Control organizations (N = 172)	Difference (in percentage points)
Size (from Million Hearts Model application)	((, , , , , , , , , , , , , , , , , , ,
Number of providers, mean	38	49	-11.3
1 to 5 providers (%)	35	31	3.9
6 to 19 providers (%)	28	32	-4.2
20 or more providers (%)	37	37	0.4
Number of sites, mean	8	7	0.7
1 site (%)	39	35	3.3
2 to 5 sites (%)	31	33	-1.3
6 or more sites (%)	30	32	-1.9

Table II.A.1. Organizations assigned to the control group were similar to the intervention grouporganizations: Characteristics of organizations that enrolled at least one beneficiary in the Million HeartsModel from January 3, 2017, to December 31, 2018
Characteristic	Intervention organizations (N = 173)	Control organizations (N = 172)	Difference (in percentage points)		
Location (from Million Hearts Model application)					
Rural (%)	46	47	-0.8		
Census region (%)					
Northeast	30	24	6.2		
Midwest	17	20	-3.6		
South	38	40	-2.0		
West	15	16	-1.3		
Organization type ^a					
Primary care (%)	52	55	-3.2		
Specialty or multispecialty (%)	23	20	2.2		
FQHC, RHC, or other health center (%)	15	15	0.5		
CAH or rural hospital (%)	3	5	-2.3		
Acute care hospital (%)	8	5	2.9		
Participating in other CMS models or programs when applied for the Million Hearts Model ^b					
In one or more model (or application pending at random assignment) (%)	51	49	2.0		
In Medicare Shared Savings Program (%)	29	22	8.0		
In Advance Payment ACO (%)	5	5	0.6		
Applied for ACO Investment Model (%)	8	12	-4.1		
In CPC Initiative (%)	3	7	-4.1		
In Bundled Payments for Care Improvement (%)	6	5	1.7		
Applied for TCPI (%)	4	5	-1.2		

Source: Organizations' self-reported data from the Million Hearts Model application data linked to the CMS National Plan and Provider Enumeration System.

^a The evaluation obtained organization type by merging (1) the NPI from participating organizations, which they provided when they applied to the Million Hearts Model; with (2) January 2018 data from the CMS NPPES. We then used primary taxonomy codes to categorize the organizations. "Other health centers" include Indian health and migrant health centers. We used Type 1 NPIs for sole practitioners without a Type 2 NPI. For the 13 organizations that did not have an organizational NPI that matched with NPPES, we reviewed their websites and the NPIs of the individual providers working in the organization to assign the organization to one of the organization types.

^b We coded organizations as not participating in other CMS models if they responded on the application that they did not know.

ACO = accountable care organization; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CPC = Comprehensive Primary Care; FQHC = federally qualified health center; NPI = National Provider Identifier; NPPES = National Plan and Provider Enumeration System; RHC = rural health center; TCPI = Transforming Clinical Practice Initiative.

B. Model retention through December 2020

1. Participation in the model over time

Of the 516 organizations randomly assigned to the intervention and control groups, 457 (225 intervention and 232 control) remained in the model as of the January 2017 launch date. In both the intervention and control groups, participation declined when the first Million Hearts registry data were due (summer 2017 and early 2018, respectively) (solid blue and green lines, Figure

II.B.1). After the first two model years (January 2017 through December 2018) the number of organizations that formally remained in the model, meaning they did not request to withdraw from the model nor did CMS terminate them for failing to meet model requirements, remained relatively stable. A total of 144 intervention organizations and 165 control organizations were still in the model through the end of 2019. Control group organizations received payment for submitting data for only the first three years of the model and thus control group participation in the model ended in December 2019. As of December 31, 2020, 136 intervention organizations remained in the model.



Figure II.B.1. Model participation declined over time in both the intervention and control groups: Participation in the Million Hearts Model from launch to December 2020, by intervention and control group

- ≠ - Organization reported at least one visit in the registry for the previous 6 months (Control)

- Source: Mathematica's analysis of CMS data on organizational participation and withdrawal and Million Hearts Data Registry.
- Note: The dotted lines indicate the number of organizations that participated in the model by having at least one visit that occurred in a given six-month performance period, as indicated by clinical indicators reported to the Million Hearts Registry.
- CMS = Centers for Medicare & Medicaid Services.



Some organizations did not formally withdraw from the model but did not actively participate in one key aspect of the model—reporting clinical data to the Million Hearts registry. Organizations must submit data to the registry to earn incentive payments for risk stratification and CVD risk reduction. Therefore, for each six-month performance period, we also looked at whether organizations reported clinical data

from at least one Million Hearts visit occurring in that time frame (dotted lines in Figure II.B.1).¹ The number of organizations that reported clinical data from at least one visit is very similar between the intervention and control groups through December 2019, which is the last period for which control groups had to report data to the registry. However, the number of organizations reporting clinical data from at least one visit declined considerably in both groups. Whereas 174 intervention organizations reported data from a visit that occurred during the first six-month performance period (January to June 2017), only one-third of that number (63) reported data from a visit that occurred during the eighth six-month performance period (July to December 2020).² The downward trend in the number of intervention organizations with a Million Hearts visit was similar in model Years 2, 3, and 4 (a decrease of about 30 organizations each year), suggesting this trend predated the COVID-19 pandemic. This decline has implications for future sustainability of the model. However, it is important to note that it is possible organizations continued to participate in some model requirements but no longer uploaded clinical data to the registry. For example, 32 percent of intervention organizations that had stopped reporting data to the registry said, in the 2021 practice survey, they were reassessing CVD risk for at least half of their high-risk beneficiaries.³

Lastly, with each model year, there was an increasing difference between the number of intervention organizations that formally remained in the model versus the number that continued to have Million Hearts visits (difference between solid blue and dotted blue lines). The divergence in the two lines can be explained in part because CMS stopped terminating organizations from the model midway through 2018. In the first 18 months of the model, CMS terminated organizations for not meeting certain requirements, such as uploading data to the registry. In later years of the model, CMS stopped terminating organizations and organizations in later years might be formally enrolled in the model, but no longer submitting data to the registry.

¹ This metric is based on when the enrollment or reassessment visit occurred, not when the organization uploaded data to the registry. Intervention organizations report a risk score and clinical indicators for each enrollment and reassessment visit. Control organizations report clinical indicators (but not a risk score) for visits with beneficiaries attributed to the model.

 $^{^{2}}$ The number of intervention organizations that submitted data to the registry in the first performance period (174) is greater than the number of intervention organizations that enrolled a beneficiary in the first two model years (173) because organizations submitted enrollment data that could not be validated and thus did not count as an enrollment.

³ We looked at the survey responses among the organizations that had not submitted registry data from July 2019 through June 2020.

2. Reasons for withdrawal

CMS gathers feedback from organizations that formally withdraw from the model. As reported previously (Blue et al. 2020), in the first three model years, organizations voluntarily left the model because they did not think the financial incentives were commensurate with the work required and they felt they did not have adequate staff to comply with the model requirements anymore. Other common reasons for withdrawing included changes in organizational priorities and—especially in the first model year—challenges uploading required data elements to the Million Hearts Data Registry. In the fourth model year, eight additional intervention organizations formally withdrew. Among the six organizations that provided reasons for withdrawing, reasons included staffing and leadership changes, or practice ownership changes that made it difficult to comply with the model requirements. Three of the organizations specifically mentioned challenges related to the COVID-19 pandemic.

3. Characteristics of organizations that continued actively participating in the model through December 2020

Given the decline in model participation over time and potential implications for sustainability, we compared the characteristics of organizations that continued actively participating in the model through December 2020 to those that did not (Table II.B.1). Specifically, we compared (1) the 78 organizations that formally remained in the model and continued submitting data to the registry through 2020 to the (2) 95 organizations that participated early in the model (that is, had enrolled at least one beneficiary in 2017 or 2018) but either formally withdrew or stopped submitting data to the registry by 2020. Organizations that still actively participated in the model in 2020 enrolled more beneficiaries in the first two years of the model on average, compared to organizations that did not (2,015 versus 754). Organizations that actively participated through 2020 also tended to be larger, based on the average number of providers reported in the organizations' Million Hearts Model application (52 versus 26). Organizations that actively participated were also less likely to be in a rural location (36 versus 54 percent), and more likely to be classified as a specialty or multispecialty practice (35 versus 13 percent).

Table II.B.1. Intervention organizations that actively participated in the model through 2020 tended to be larger and enroll more beneficiaries: Characteristics of organizations that actively participated in the model through December 2020 versus those that had enrolled at least one beneficiary in 2017 or 2018 but had stopped actively participating by December 2020

	Actively participating in 2020	Not actively participating in 2020	
Characteristic	(N = 78)	(N = 95)	Difference
Enrollment			
Number of beneficiaries enrolled in 2017 or 2018 (all risk levels) (mean)	2,015	754	1,261
Size (from Million Hearts Model application)			
Number of providers, mean	52	26	26.1
1 to 5 providers (%)	33	37	-3.5
6 to 19 providers (%)	21	34	-13.2
20 or more providers (%)	46	29	16.7
Number of sites, mean	10	6	4.3
1 site (%)	33	43	-9.8
2 to 5 sites (%)	27	35	-7.8
6 or more sites (%)	40	22	17.6
Location (from Million Hearts Model application)			
Rural (%)	36	54	-17.8
Census region (%)			
Northeast	24	35	-10.4
Midwest	17	17	-0.2
South	45	32	13.3
West	14	16	-1.7
Territories	0	1	-1.1
Organization typea			
Primary care (%)	49	55	-6.0
Specialty or multispecialty (%)	35	13	22.0
FQHC, RHC, or other health center (%)	12	18	-6.4
CAH or rural hospital (%)	0	5	-5.3
Acute care hospital (%)	5	9	-4.3
Participating in other CMS models or programs when a	applied for the Milli	on Hearts Model ^b	
In one or more model (or application pending at random assignment) (%)	51	51	0.8
In Medicare Shared Savings Program (%)	32	27	4.7
In Advance Payment ACO (%)	5	5	-0.1
Applied for ACO Investment Model (%)	6	9	-3.1
In CPC Initiative (%)	1	4	-2.9
In Bundled Payments for Care Improvement (%)	10	3	7.1
Applied for TCPI (%)	5	3	2.0

Source: Organizations' self-reported data from the Million Hearts Model application data linked to the CMS National Plan and Provider Enumeration System.

^a The evaluation obtained organization type by merging (1) the NPI from participating organizations, which they provided when they applied to the Million Hearts Model; with (2) January 2018 data from the CMS NPPES. We then used primary taxonomy codes to categorize the organizations. "Other health centers" include Indian health and migrant health centers. We used Type 1 NPIs for sole practitioners without a Type 2 NPI. For the 13 organizations that did not have an organizational NPI that matched with NPPES, we reviewed their websites and the NPIs of the individual providers working in the organization to assign the organization to one of the organization types.

^b We coded organizations as not participating in other CMS models if they responded on the application that they didn't know.

ACO = accountable care organization; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CPC = Comprehensive Primary Care; FQHC = federally qualified health center; NPI = National Provider Identifier; NPPES = National Plan and Provider Enumeration System; RHC = rural health center; TCPI = Transforming Clinical Practice Initiative.

4. Implications for estimating impacts

The steady decline in participation over the course of the model could make it challenging for the model to have its fully intended impacts on heart attacks and strokes. Following the intent-to-treat evaluation design for the impact evaluation (Chapter V), the impact evaluation includes beneficiaries whose enrolling organizations are no longer participating in the model. About 30 percent of the high- and medium-risk beneficiaries in the intervention group were enrolled by organizations that either formally withdrew as of December 2020 or no longer reported to the registry in 2020.⁴ If the organizations that withdrew or stopped reporting data to the registry also stopped following the CVD preventive care guidelines specified by the model, model impacts could be attenuated for these 30 percent of enrollees. Alternatively, if an organization stops reporting data to the registry, but maintains changes in CVD preventive care, we might still observe impacts for these enrollees.

C. Beneficiary enrollment through December 2020

Intervention and control organizations enroll beneficiaries by collecting required demographic and clinical data needed to calculate the beneficiary's CVD risk. The beneficiary is considered enrolled as of the date of the visit during which the organization collects the required clinical data elements to submit to the registry (which beginning in 2020, could also occur through telehealth).



During the first four model years, intervention and control organizations enrolled 451,219 Medicare beneficiaries: 273,730 in the intervention group and 177,489 in the control group (Figure II.C.1). Enrollment was substantially lower in the control group than the intervention group because of the 20-provider cap CMS placed on control

⁴ Although 55 percent (N = 95) of the 173 intervention organizations that enrolled at least one beneficiary either formally withdrew by December 2020 or no longer submitted data to the registry in 2020, such organizations enrolled only 30 percent of high- and medium-risk intervention group enrollees. This is because the organizations that remained in the model through 2020 tended to enroll more beneficiaries in the first two years of the model (Table II.B.1).

organizations, which did not apply to the intervention organizations. In addition, control organizations stopped enrolling beneficiaries at the end of the third model year as planned.

As expected, enrollment was greatest in 2017 and continued at lower rates in later years, as CMS expected organizations to enroll eligible Medicare FFS beneficiaries at first contact (Figure II.C.1). Enrollees in 2018, 2019, and 2020 are limited to those who are new to the organization or to Medicare FFS, those who infrequently visit the organization, or those who were missed during previous visits. Furthermore, fewer organizations enrolled new beneficiaries over time.

Figure II.C.1. Enrollment was greatest in 2017 and continued at lower rates in later years: Cumulative number of Medicare beneficiaries enrolled in the intervention and control groups from January 2017 to December 2020, by year (all CVD risk levels)



Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data. n.a. = not applicable (control organizations stopped enrolling beneficiaries in 2020).

The percentage of beneficiaries in each of the risk groups was very similar between intervention (2017 to 2020) and control organizations (2017 to 2019) (Figure II.C.2). In both the intervention and control groups, about 17 percent of enrollees were high-risk—that is, had a 10-year predicted probability of first-time heart attack or stroke of 30 percent or more— and another 39 precent were medium risk.

Figure II.C.2. The risk profile was very similar between the intervention and control groups:

Medicare beneficiaries enrolled by intervention and control organizations from January 2017 to December 2020, by CVD risk level

	Enrollment from 2017 to 2020		
CVD risk group at baseline (predicted probability of having a heart attack or stroke in 10 years)	Intervention	Control	
High (≥ 30%)	46,568 (17%)	30,119 (17%)	
Medium (15–29.9%)	106,844 (39%)	68,595 (39%)	
Low (< 15%)	120,318 (44%)	78,775 (44%)	
All	273,730	177,489	

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 first-time heart attack or stroke in the next 10 years. Medium CVD risk is 15 to 30 percent. Low CVD risk is less than 15 percent. Risk is measured as of a beneficiary's enrollment date in the Million Hearts Model. Data for control organizations reflects enrollment from 2017 to 2019, after which control organizations stopped enrolling beneficiaries.

CVD = cardiovascular disease.

As described in the <u>Third Annual Report</u>, we compared the characteristics of the beneficiaries intervention organization enrolled in the model to those who appeared to be eligible but did not enroll (Blue et al. 2020). We limited this analysis to attributed beneficiaries—that is, beneficiaries who, in 2017 or 2018, visited a provider participating in the Million Hearts Model, and who met model eligibility criteria we could replicate in claims. As shown in Table II.C.1., enrolled beneficiaries had more visits with the organization than those who were attributed to the organization but not enrolled. Enrolled beneficiaries also appeared to be modestly healthier than those not enrolled, with fewer chronic conditions, a lower likelihood of being eligible for Medicare due to disability, and lower hospitalization rates and Medicare spending in the year before a model-qualifying visit. The enrolled population was slightly older, slightly less likely to be Black than the non-enrolled population, and slightly less likely to also be enrolled in Medicaid.

Table II.C.1. The enrolled beneficiaries were healthier and had more frequent visits with MillionHearts Model participants than beneficiaries who appeared eligible but were not enrolled:Characteristics of enrolled beneficiaries versus beneficiaries eligible but not enrolled, 2017 to 2018

Characteristic	Enrolled in the model (N = 228,112)	Not enrolled in the model (N = 206,559)	Difference	Standardized difference ^a	p-value ^b
Demographic and Medicare enrollment characteristics					
Age	69	68	0.4	0.05	0.04
Black race, %	8	10	-1.2	-0.04	0.14
Dually enrolled in Medicare and Medicaid, %	14	16	-2.3	-0.06	0.04
Originally entitled to Medicare due to disability, %	23	26	-3.0	-0.07	< 0.01
Health and comorbid conditions					
HCC score	1.05	1.19	-0.1	-0.14	< 0.01
Count of chronic conditions	1.78	2.06	-0.3	-0.13	< 0.01
Medical service use and spending in year before attribution					
Total Medicare Parts A and B annualized expenditures (\$)	7,446	10,318	-2,872	-0.10	< 0.01
Hospital admissions (# per 1,000 beneficiaries)	182	274	-92	-0.06	< 0.01
Office visits with model-aligned providers ^c (# per 1,000 beneficiaries)	2,202	1,277	925	0.32	< 0.01

Sources: Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; and Medicare claims for health and comorbid conditions, medical service use and spending, and attribution.

Notes: We attributed beneficiaries using the approach described in Appendix C of the <u>Third Annual Report</u> (Blue et al. 2020). This attributed population is our best approximation of those eligible for the Million Hearts Model, based on Medicare claims and enrollment data. This population is slightly smaller than the 232,781 beneficiaries enrolled by intervention group organizations in 2017 and 2018. We excluded the few enrolled beneficiaries who (1) had enrollment visits in 2017 and 2018 validated only in the Million Hearts Data Registry after the fifth performance period, which ended in June 2019; (2) could not be attributed for the evaluation, due to lack of a qualifying visit with a Million Hearts Model provider in 2017 or 2018 (see Appendix C of the Third Annual Report); or (3) did not appear eligible for the model in Medicare claims and enrollment data.

^a The standardized difference is the difference between the means for attributed beneficiaries who were and were not enrolled in the model, divided by the standard deviation across attributed beneficiaries.

^b *p*-values are based on standard errors clustered at the level of the participating organization.

^c For this analysis, we define Million Hearts Model-aligned providers as those included on an organization's provider list to CMS at the time of random assignment.

CMS = Centers for Medicare & Medicaid Services; HCC = hierarchical condition category.

D. Study population

1. Definition of study population

The impact evaluation described in <u>Chapter V</u> focuses on a subset of the total enrolled beneficiaries during the first four years of the model. Specifically, the impact evaluation includes high- and medium-risk beneficiaries enrolled by intervention and control organizations during the first two years of the model, 2017 and 2018. It is limited to these two risk groups because the intervention is geared toward high-risk beneficiaries, but we expect some spillover to mediumrisk beneficiaries. We excluded 2019 intervention and control enrollees out of concerns that the substantial organization-level attrition at that point could create unobserved differences among the intervention and control group enrollees that would bias estimates of model impacts. Likewise, we excluded 2020 intervention enrollees due to attrition and because the control group stopped enrolling new beneficiaries in 2020, so there is no estimate of the counterfactual for the 2020 intervention group enrollees. In addition, the study population does not include the relatively few intervention and control beneficiaries (2,060 of 222,659 [0.9 percent] of all 2017 and 2018 high- and medium-risk enrollees⁵) enrolled in 2018 that were validated in the Million Hearts Data Registry after the fifth performance period, which ended in June 2019.

2. Characteristics of the study population



0

Claims

In both the intervention and control groups, the mean age of the enrollees was 72. A little more than half of enrollees were male (58 percent) and 8 percent of enrollees were Black. The mean Hierarchical Condition Category (HCC) score was 1.2, indicating slightly higher expected Medicare spending than the average Medicare FFS beneficiary (with a score of 1.0). Enrollees had, on average, about two chronic conditions, and had frequent office visits with medical providers (an average of 9 visits per person in the year before enrolling in the model) (Appendix F, Table F.1).

In both the intervention and control groups, high- and medium-risk beneficiaries had an average CVD risk score of 27 percent, meaning the average beneficiary had a 27 percent predicted probability of a first-time heart attack or stroke within 10 years of enrollment. In both groups, about one-third of the risk was considered modifiable, meaning providers and patients had the opportunity to change these risk factors and therefore reduce overall CVD risk (Appendix F, Table F.1). The main modifiable risk factors were systolic blood pressure (60 percent had systolic blood pressure of at least 130 mm Hg, the threshold for high blood pressure) and low-density lipoprotein (LDL) cholesterol (78 percent had LDL of at least 70 mg/dL, the threshold for treatment intensification among those with a 10-year predicted CVD risk score of 7.5 percent or higher) (Grundy et al. 2018, Welton et al. 2017; Arnett et al. 2019). The remaining risk was

⁵ Includes 1,003 of 132,550 (0.8 percent) of intervention group 2017 and 2018 high- and medium-risk enrollees and 1,057 of 90,109 (1.2 percent) of control group 2017 and 2018 high- and medium-risk enrollees.

driven by nonmodifiable factors such as age or sex and difficult to modify factors such as diabetes.

Beneficiaries also had relatively high medication use and adherence at baseline. Four of five medium- and high-risk beneficiaries were already taking an antihypertensive medication when they enrolled in the Million Hearts Model and about two-thirds were already taking a statin medication. Among beneficiaries who used an antihypertensive medication in the 12 months before enrollment, 84 percent were adherent, defined as the proportion of days covered by the medication being greater than 80 percent in the baseline year (Chapter VI provides details on measuring adherence). Among beneficiaries who used a statin in the 12 months before enrollment, 70 percent were adherent. Even with this high medication use at baseline, a sizeable percentage of the medium- and high-risk enrollees still had blood pressure and cholesterol above levels indicated for intensifying treatment. These patterns suggest the greatest room for improvement related to medications might be for intensifying medications, with less—though still some—room to improve adherence or to start medications (especially statins) for the first time.

<u>Appendix E</u> further describes the study population and the methods for defining it.

III. Model Implementation in 2020 and Early 2021, and Organization Plans to Sustain Changes in CVD Care Beyond 2021



Key findings

- In 2020 and 2021, intervention organizations faced several challenges related to the COVID-19 pandemic, and many organizations reported the Million Hearts Model became less of a priority.
 - COVID-19 made it harder to see patients for office visits, especially during spring 2020; to obtain clinical data needed for CVD risk calculation; and to devote staff time to implement the model.
 - In response to these challenges, many intervention organizations used telehealth to perform enrollment or reassessment telehealth visits, and some organizations increased use of selfmeasured blood pressure.
- Organizations reported risk stratifying fewer Medicare FFS beneficiaries during the pandemic, but still more than they did before the model began.
 - The proportion of intervention organizations that reported calculating CVD risk scores for most of their Medicare beneficiaries decreased from 61 percent in 2018 to 46 percent in 2021.
 - However, this percentage remained higher than the 14 percent of organizations that reported risk stratifying most of their Medicare beneficiaries before joining the model in 2016.
 - In interviews, providers continued to report risk stratification helped make them more aware of their patients' CVD risk.
- Except for changes they made due to COVID-19, intervention organizations continued to use processes to implement the model they had put in place in earlier years. For example, organizations continued to use the following:
 - EHRs to calculate risk scores when possible
 - Tracking tools or registries, care managers, and automated scheduling to follow high-risk beneficiaries over time
- Nearly two-thirds of organizations surveyed in 2021 agreed that participating in the model helped improve quality of care or improved patients' CVD risk scores.
- In interviews, most organizations said model payments were too small to cover the costs of implementing the model. Payments declined over time, from a mean of \$15,251 in the second performance period (July to December 2017) to \$3,970 in the eighth performance period July to December 2020).
- More than half of organizations surveyed reported the Million Hearts Model prompted their
 organization to change care delivery related to assessing and managing CVD risk and that they plan
 to sustain those changes after participation in the model ends. These organizations report they plan to
 sustain changes made to (1) systematically identify patients at high risk for CVD, (2) the role of care
 managers in CVD risk assessment and reassessment, and (3) the use of an embedded EHR tool to
 assess CVD risk.

This chapter describes how intervention organizations implemented the model in 2020 and early 2021, focusing on changes from prior years and how COVID-19 has shaped implementation. We also describe the extent to which, and how, intervention organizations plan to sustain any changes they have made to CVD care after the model ends. This chapter draws on data collected during interviews with participating organizations, practice surveys collected in 2018 and 2021, visit and demographic data from the Million Hearts Data Registry, and Medicare claims. Appendices B and C provide more detail about the data sources.

A. COVID-19's influence on model design and prioritization

1. Model design changes in response to COVID-19

COVID-19 caused marked disruption in the health care system in 2020. Health care organizations and providers made changes to care for individuals with COVID-19 and reduce transmission of COVID-19 infection for community members and health care personnel. Broadly, providers across the United States adapted to provide care in different ways, in some cases delaying non-urgent care, while also facing staffing and revenue challenges brought on by the pandemic. During this time, CMS made regulatory and reimbursement changes to allow for using telehealth on a much wider scale (Hoffman 2020; Moore and Munroe 2021). For example, before COVID-19, reimbursement for telehealth was available only for providers administering telehealth visits from a physician's office or hospital, and for health professional shortage areas. In the setting of the COVID-19 pandemic, CMS removed these limitations on telehealth. Other changes to telehealth policies included reimbursing audio-only visits and allowing providers to evaluate new patients via telehealth. CMS also introduced flexibilities to payment and service delivery models it is testing to address needs of organizations participating in these models (Verma 2020).

CMS made some changes to the design of the Million Hearts Model to aid in implementation during the COVID-19 pandemic. Specifically, CMS permitted participating organizations to conduct enrollment and annual reassessment visits for the model via telehealth during the COVID-19 pandemic, starting March 6, 2020. Organizations could newly charge these telehealth visits to Medicare, taking advantage of CMS's expansion of telehealth during the pandemic. Participating organizations also had the option to use blood pressure measurements obtained outside of the office setting via ambulatory blood pressure monitoring or self-measured blood pressure⁶ for qualifying beneficiaries, if they collect readings using a device validated for clinical accuracy. The model team provided guidance that organizations should not submit a visit without blood pressure from a validated device, as the registry would not accept this incomplete visit. In addition, in spring 2020, CMS waived the requirement that model participants attend a minimum

⁶ Ambulatory blood pressure monitoring is an automated technique to assess blood pressure using a device that records daytime and nighttime blood pressure at regular intervals during routine activities throughout the course of a 24-hour period. After 24 hours, the ambulatory blood pressure monitor is returned to the provider's office and the blood pressure readings are recorded. Self-measured blood pressure monitoring involves an individual measuring blood pressure using a personal blood pressure monitor, typically at home (Shimbo et al. 2015).

of one learning system event per quarter during the pandemic and shortened the length of the learning system sessions to less than an hour to reduce burden on participating organizations.

In addition, some flexibilities CMS introduced to the Million Hearts Model before the pandemic became particularly important during it. In 2017, CMS waived requirements in the initial Million Hearts Model participation agreement stipulating that organizations report data to the registry for 90 percent of eligible beneficiaries and reassess and update data for 95 percent of their eligible high-risk beneficiaries. Rather, participating organizations could choose whether and how many beneficiaries to report to the registry, but receive payment only for those reported to registry. This flexibility was particularly important during COVID-19, because it meant organizations could stay in the model even if they found it particularly challenging to assess and reassess risk during the COVID-19 pandemic or report data to the registry.

2. Organizational adaptations in the context of the COVID-19 pandemic and flexibilities provided by CMS in response to the pandemic



Organizations increased use of telehealth during 2020 and 2021. Outpatient office visits for high-risk beneficiaries enrolled in the Million Hearts Model decreased in early 2020, coincident with the emergence of the COVID-19 pandemic (Figure III.A.1). About the same time, telehealth visits increased, providing a possible way for

organizations to follow up with high-risk patients on CVD risk reduction during COVID-19 (see <u>Appendix B</u>, Section 1 for additional details). Telehealth visits decreased after June 2020, but from July to November 2020, they still accounted for 15 percent of all high-risk beneficiary visits to the organizations. As such, telehealth could be an important mode for model implementation on an ongoing basis.



Figure III.A.1. In-person office visits to Million Hearts Model organizations decreased in early 2020 while telehealth visits increased for high-risk beneficiaries' visits

- Source: Mathematica's analysis of a Medicare FFS claims for high-risk beneficiaries enrolled in the Million Hearts Model. The figure reports the number of outpatient office or telehealth visits to a Million Hearts Model organization for each intervention group beneficiary in each intervention month.
- Note: Because intervention months are relative to the enrollment date in the Million Hearts Model, the start and end dates of each month vary across beneficiaries. To assign intervention months to calendar months, we identified the intervention month for each beneficiary that contained March 11, 2020, the start of the COVID-19 pandemic. We assigned that month to March 2020 and each relative month before and after its respective calendar month. <u>Appendix B</u>, Section 1 provides additional details on how we measured outpatient office and telehealth visits and how we assigned relative months to calendar months.

PBPM = per beneficiary per month.



Consistent with these changes identified in claims for outpatient office and telehealth visits, all organizations that responded to the 2021 practice survey reported having increased use of telehealth visits either a lot (84 percent) or some (16 percent) due to COVID-19 (Figure III.A.2). About two-thirds of survey respondents said increased use of telehealth visits enabled them to continue implementing the Million Hearts Model's risk assessment activities.



To what extent did your practice make the following changes due to COVID-19?



- Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention organization in the Million Hearts Model (N = 89).
- Note: We only asked organizations that reported they had increased use of home blood pressure monitoring the question about whether increased use of home blood pressure monitoring helped them implement the model. As a result, this question was not applicable for 36 percent of respondents.

Likewise, all organizations we interviewed reported they conducted at least some portion of reassessment visits via telehealth, and some organizations found use of telehealth as essential to continuing the model. During interviews, organizations shared how the proportion of visits conducted via telehealth changed over the course of the COVID-19 pandemic. Early on in spring 2020, several organizations noted most visits were via telehealth, whereas at the time of interviews in early 2021, organizations estimated the percentage of reassessments conducted via telehealth ranged from none to up to one-third of visits. Respondents from about one-third of organizations interviewed mentioned that conducting visits via telehealth was essential to continuing in the model in 2020.

Organizations increased use of self-measured blood pressure in 2020 and 2021. About twothirds of organizations increased use of home blood pressure monitoring either by a lot (13 percent) or some (51 percent). About half of organizations said they both increased use of blood pressuring and doing so enabled them to continue implementing Million Hearts Model riskassessment activities (Figure III.A.2). Half of the organizations we interviewed mentioned they asked patients to purchase blood pressure cuffs so they could take their own blood pressure during or shortly before the visit. About one-third of the organizations we interviewed mentioned recently starting blood pressure self-monitoring programs. These programs enable patients to transmit blood pressure readings taken at home to the EHR, where providers can view them.

Among organizations that encouraged self-measured blood pressure, the degree to which enrolled beneficiaries had access to a blood pressure cuff and could report self-measured blood pressure readings to organizations varied. One respondent interviewed in 2021 estimated about half of beneficiaries enrolled in the model by that organization had home blood pressure cuffs, but other respondents used more qualitative descriptors, saying "some" or "a lot" of beneficiaries could provide self-measured blood pressure readings. Physicians at a couple of organizations mentioned referring patients to the YMCA Blood Pressure Self-Monitoring Program, from which they would receive free blood pressure cuffs and education. One organization mentioned scheduling times for patients to stop by the office for bloodwork and blood pressure readings. In addition, a couple of organizations mentioned recommending their patients go to smaller blooddrawing facilities that took a lot of COVID-19 precautions and one organization "developed a drive-thru lab system for people who had critical labs that had to be done."

3. Barriers to implementing the model in the setting of COVID-19



Despite the flexibilities provided, intervention organizations described many barriers to implementation related to the COVID-19 pandemic. In responses to an open-ended survey question that asked about COVID-19's effect on model implementation, organizations cited challenges with staff limitations (15 respondents), difficulty implementing telehealth (14 respondents), and challenges scheduling inperson visits (11 respondents).

Although beneficiaries at some organizations provided self-measured blood pressure readings, most organizations we interviewed (7 of 10) mentioned challenges collecting blood pressure readings and updated lipid panels when patients were seen via telehealth, especially at

the beginning of the pandemic in early 2020. Interview respondents also noted challenges scheduling in-person visits, needing to devote resources to implement telehealth platforms, needing to institute new safety measures for staff and patients, and losing staff either because those staff were reassigned to assist with COVID-19 response efforts or because the organization underwent staffing reductions.

"Prior to COVID, our [risk score] numbers were coming down. I did notice a couple of our patients had creeped back up, but I really feel like it's the hypertension has kind of got the best of them during this time, whether it's with stress or just not following up with their medication."

-Director of Nursing

Half of the organizations interviewed also mentioned the negative impact of COVID-19 on reducing beneficiaries' CVD risk, noting some patients experienced increasing blood pressure as a result of the added stress from the pandemic, delayed or missed care, getting less exercise, and having fewer healthy take-out options available from restaurants.

4. Model prioritization among intervention organizations in the setting of COVID-19



nterviews

Implementing the model became less of a priority during the pandemic. Most organizations that responded to the survey reported implementing the model became a lower priority due to COVID-19 (Figure III.A.3). Similarly, most organizations we interviewed (7 of 10) also said implementing the model was less of a priority during 2020 and early 2021 because of competing priorities related to COVID-19. Two organizations interviewed reported that, although the priority of the model within the organization did not change, they experienced some delays in reassessment visits and data entry due to COVID-19.

Figure III.A.3. Implementation of the Million Hearts Model became a lower priority due to COVID-19 for more than half of organizations





Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention organization in the Million Hearts Model (N = 89).

The priority for most organizations in the model over the past year was to address issues related to the COVID-19 pandemic, but several interviewees mentioned the importance of continuing to monitor high-risk CVD patients, especially in the setting of COVID-19. These interviewees noted CVD and the clinical factors associated with increased risk of CVD (such as hypertension, diabetes, and obesity) are also factors associated with increased risk of more severe outcomes from COVID-19 (Bae et al. 2021; Zhou et al. 2020).

"During this past year with the pandemic we've been very focused on those people that have higher risk, especially high-risk for complications of COVID ... so we've been doing ongoing outreach to those patients that have high-risk cardiovascular disease."

-Provider

B. Measures of CVD risk assessment over time, including during COVID

CVD risk assessments and reassessments are key activities under the model. Intervention organizations agreed to assess CVD risk for all eligible Medicare FFS beneficiaries (when beneficiaries enroll in the model), and to reassess risk annually for all high-risk patients. In this section, we use varied data sources (surveys, registry, Medicare claims and enrollment data) to report on these activities throughout the model (2017 to 2020), including during COVID-19.

Overall, we found trends of decreasing enrollment over time (which is expected) but also decreasing reassessments for high-risk beneficiaries over time (which is not expected). These declines generally predated COVID-19, but were particularly pronounced early in the pandemic (spring 2020). Reassessment visits rebounded some in summer 2020, but resumed their overall general decline. These reassessment data point to challenges in consistently implementing the model as initially envisioned over a sustained period. Nonetheless, organizations still reported assessing CVD risk more in 2021 than they did before joining the model in 2016, indicating some organizations have been able to maintain changes in CVD care, including during COVID-19.

1. Enrollment visits



During 2020, enrollment visits declined, following the same trend as previous years of the model (Figure III.B.1). As reported in the first and second annual reports, some decline in enrollment is expected, because the model specifies organizations should enroll all eligible Medicare FFS beneficiaries at first contact. This limited

enrollees in later years of the model to beneficiaries new to the organization or new to Medicare FFS, those who visited the organization infrequently, or beneficiaries with visits earlier in the model that might have been missed.





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



Consistent with these expectations, organizations we interviewed reported they did not focus on enrolling new beneficiaries. However, most of the organizations we interviewed (6 of 10) reported they were continuing to enroll some beneficiaries in the model at the time of interviews in 2021. Although organizations can receive payments

for enrolling beneficiaries in all model years (2017–2021), other interviewees reported they had stopped enrolling beneficiaries. Organizations might have decreased their focus on enrollment due to a change in priorities in the setting of COVID-19 (as described earlier in Chapter III, Section A), and the perception that payments were not sufficient to support activities, noted in all years of interviews (Conwell et al. 2019; Peterson et al. 2019; Blue et al. 2020). Organizations that continued to enroll beneficiaries into the model described enrolling beneficiaries who were newly eligible for the model because of aging into Medicare, switching from Medicare Advantage to Medicare FFS, patients joining a practice, or because organizations participating in the model had merged with other practices, resulting in beneficiaries who were newly eligible for the model.

2. Reassessment visits for high-risk beneficiaries



Registry data

The number of reassessment visits for high-risk beneficiaries reported in the registry decreased over time in 2020, continuing a longer-term trend. The number of reassessment visits was lower than the number of anticipated reassessment visits if all enrolled beneficiaries in Figure III.B.1 who remained model-eligible received their annual reassessment visits (Figure III.B.2). Reassessment visits decreased particularly during the early COVID-19 period in spring 2020, followed by a rebound in reassessment visits and return to the prior trajectory mid-year in 2020. Because most

enrollment visits occurred in the first half of 2017 and peaked in March 2017 (Figure III.B.1.), and reassessment visits occur 10 to 14 months after the enrollment visit, anticipated reassessment visits are cyclical and peak each March in subsequent years of the model, as shown in Figure III.B.2. Of note, the decrease in office visits due to COVID-19 was most pronounced in spring 2020 (Figure III.A.1), about when we would have anticipated a potential peak in reassessment visits.





Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare enrollment data. Note: Anticipated reassessment visit counts are the number of reassessment visits that might have occurred if all eligible high-risk model enrollees had received annual reassessment visits within the four-month window of time around the anniversary of the beneficiary's enrollment in the model (the anniversary window). Appendix B, Section 2 provides details.

Just over half of organizations surveyed reported they recalculate risk annually for at least half of their high-risk Medicare beneficiaries. About one-quarter of organizations reported they recalculated CVD risk annually for 75 to 100 percent of their high-risk beneficiaries, and another one-quarter reported they recalculated risk for 50 to 75 percent of their high-risk beneficiaries (Figure III.B.3). These self-reported risk reassessment rates indicate organizations, on the whole, are partly implementing the risk reassessments as intended. When the model began, CMS expected organizations to reassess all of their high-risk beneficiaries annually (and to submit reassessment data to the registry for at least 95 percent of their enrollees). Many intervention organizations are, per the survey, falling well short of this initial target, but many still are risk reassessing at least half of their high-risk patients.

Figure III.B.3. Over half of organizations surveyed reported they recalculate risk annually for at least half of their high-risk Medicare beneficiaries



For Medicare beneficiaries identified as high risk for CVD, what percentage do you recalculate risk for about annually (or more frequently)?

Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention Source: organization in the Million Hearts Model (N = 72). The number of respondents for this question is lower than the full sample due to skip logic.

CVD = cardiovascular disease.



Consistent with declines in reassessment rates over time, the proportion of eligible high-risk patients who had a reassessment visit in the registry about one, two, and three years after enrollment also decreased with subsequent enrollment years (Table III.B.1).⁷ The decrease in reassessment visits over time might be partly due to the fact that these visits are more likely to be due during 2020 or 2021, when organizations have fewer visits generally due to COVID-19. During an earlier round of interviews



(before the COVID-19 pandemic), organizations also mentioned some decreases in reassessment visits can occur because beneficiaries transfer their care to other

practices if the beneficiary relocates out of the area where the Million Hearts Model organization is located, or because beneficiaries choose to find a new provider. During those earlier interviews, one organization mentioned changes in scheduling processes to an open access scheduling approach that made it harder to ensure reassessment visits occurred over time. Other factors that might contribute to decreases in reassessment visits over time could include general barriers to implementing the model (discussed in Section E), such as insufficient staff time and competing organizational priorities.

⁷ Figure III.B.2 presents changes in the number of reassessment visits in calendar time, but the data in Table III.B.1 are in enrollment time-that is, the proportion of people who received reassessment visits within one, two, and three years after their individual dates of enrollment. Because people enrolled in the model on different dates, the calendar period covered during each enrollment year varies by person.

Time after enrollment	Number of beneficiaries eligible for a reassessment visit ^a	Number of eligible beneficiaries with a reassessment visit ^ь	Percentage of eligible beneficiaries with a reassessment visit
One year	33,203	18,563	56
Two years	27,234	8,752	32
Three years	18,800	4,531	24

Table III.B.1. The proportion of eligible high-risk beneficiaries who had a reassessment visit in the registry about one, two, and three years after enrollment decreased with subsequent years

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

^a Eligible beneficiaries remained model-eligible and observable through the end of their reassessment visit anniversary window. Anniversary windows range from 10 to 14 months after enrollment for one-year reassessment visits, 22 to 26 months after enrollment for two-year reassessment visits, and 34 to 38 months after enrollment for three-year reassessment visits (see <u>Appendix B</u> for additional details).

^b Reassessment visits were defined as model-eligible visits that occurred 10 to 21 months post-enrollment (one-year visits), 22 to 33 months post-enrollment (two-year visits), or 34 to 45 months post-enrollment (three-year visits) (see <u>Appendix B</u> for details).

Characteristics of Medicare beneficiaries who had a reassessment visits at one, two, and three years were generally similar to those who were eligible but did not have reassessment visits at those time points, but differed in some dimensions (Appendix B). For example, beneficiaries who received a reassessment visit were similar in most clinical indicators of CVD risk (CVD risk scores, percentage of modifiable CVD risk, blood pressure and cholesterol measurements, and smoking rates), were similar in use of medications (including aspirin, statins, and antihypertensives), and had similar demographic characteristics. However, compared to beneficiaries who did not receive a reassessment visit, those who did were more likely to have diabetes (for example, 68 versus 61 percent for the one-year reassessment visit); to have been enrolled into the Million Hearts Model by a primary care provider (for example, 63 versus 50 percent the one-year reassessment visit); and to have had slightly more visits with Million Hearts Model providers. Some of these differences in reassessment visit rates could be related to beneficiaries with diabetes having office visits on a more regular basis, creating more opportunity for reassessment. Likewise, those beneficiaries enrolled by a primary care provider might see their enrolling provider more frequently than those enrolled by a specialty organization.

3. Overall CVD risk calculation for Medicare panel



Fewer organizations in 2021 reported calculating CVD risk scores for more than half of their Medicare beneficiaries compared to 2018; however, **organizations continue to report calculating CVD risk score for a higher proportion of their Medicare beneficiaries compared to 2016, before joining the model** (Figure III.B.4). This

pattern suggests organizations have been able to maintain some, though not all, of the changes they made in CVD risk assessment and reassessment, despite challenges posed by COVID-19. The decline in the proportion of organizations' Medicare beneficiaries who have had risk calculation is consistent with the decline in risk assessments over the course of the model.

Figure III.B.4. Organizations reported calculating CVD risk scores in 2021 at higher rates than they did before the intervention, but below their peak in 2018: Percentage of intervention organizations reporting they calculated CVD risk scores for at least half of their Medicare beneficiaries



Source: Mathematica's analysis of practice surveys administered in 2018 (N = 88) and 2021 (N = 90) to key contacts at each intervention organization in the Million Hearts Model.

Note: Estimates for 2016 responses were reported in the 2018 survey; respondents were asked to recall practices two year before the time of the survey (N = 87).

CVD = cardiovascular disease

C. Processes for implementing the model in 2020 and 2021



Having described the degree of risk assessment over time (a key measure of model implementation), we now turn to the processes organizations used to implement the model. Overall, we find that—aside from changes organizations made due to COVID-19—organizations largely used similar processes as they did in earlier years to implement the model.



1. Calculating and communicating CVD risk

Organizations continue to leverage EHR capabilities to calculate CVD risk

score when possible. In 2021, over 95 percent of organizations reported at least one EHR function that supported model implementation (Figure III.C.1). EHR functionality supporting risk calculation did not change from 2018 to 2021. In both 2018 and 2021, a little less than half of respondents had an integrated CVD risk calculator, and a little more than half had the CVD risk score displayed on the patients' record, and nearly twothirds had other tools in the EHR to help document CVD risk score. One exception is auto-population of data elements relevant to cardiovascular risk, which increased from being available for 59 percent of organizations in 2018 to 72 percent in 2021. Autopopulation of data elements relevant to cardiovascular risk was not discussed during interviews in 2021; however, during interviews in earlier years of the model, two interviewees described how the EHR automated the process for calculating and documenting the risk score in the EHR, and walked users through the components included in risk calculation.

Million Hearts Model requirements: Care management for high-risk beneficiaries

Intervention organizations must update CVD risk scores annually with updated clinical data. The annual reassessment of the CVD risk score should happen in person within 10 to 14 months after the enrollment visit (though CMS has permitted visits that fall outside this range).

Intervention organizations must also engage high-risk Medicare FFS beneficiaries twice a year with follow-up contacts 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.) The <u>first annual</u> <u>report</u> (Conwell et al. 2019) described the model requirements.



Figure III.C.1. Organizations report EHR functionality that supports model implementation





CVD = cardiovascular disease; EHR = electronic health record.

More than one-third of organizations interviewed (4 of 10) were in the process of integrating a CVD risk calculator into their EHRs or improving the current calculator available in their EHRs. Among those we interviewed, two who previously did not have a CVD risk calculator embedded in their EHRs mentioned they were in the process of building one into their EHRs.

In addition, a couple of organizations that already had static CVD risk calculators built into their EHR mentioned t they planned to build in more advanced longitudinal calculators (text box). However, these practices noted that COVID-19 had delayed the EHR builds.

The ability to estimate how initiating different evidence-based therapies would change CVD risk score was Note: asked only in the 2021 survey, thus it is not applicable (n.a.) for the 2018 survey.

CVD risk calculators

CMS provides intervention organizations with access to the Million Hearts ASCVD Risk Assessment Tool to calculate CVD risk scores via the Million Hearts Data Registry (Lloyd-Jones et al. 2017). The longitudinal tool 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 only risk scores calculated within the CMS registry are acceptable for enrolling beneficiaries into the model and assessing change in risk scores, participating providers also use "static" CVD risk calculators (for example, online or through the EHR or smart phone applications) to identify risk and guide treatment plans.

Respondents from most organizations interviewed (6 of 10) believed risk score calculation increased providers' awareness of CVD risk among high-risk beneficiaries, and often for medium-risk beneficiaries as well. However, respondents from a couple of organizations said they did not feel the model increased providers' awareness of CVD risk because providers were already aware of CVD risk before the implementation of the model, as we found in prior years (Blue et al. 2020; Peterson et al. 2019).

The most common method for notifying beneficiaries about their risk score reported in 2021 was by a provider during an in-person visit (88 percent), which is consistent with findings from the survey completed in 2018. Survey respondents could report more than one method the organizations used to notify beneficiaries of risk scores, if applicable. In the 2021 practice survey, organizations newly had the option to report if beneficiaries were notified of their risk score during video telehealth visits. Among survey respondents, 35 percent of organizations reported using telehealth visits with providers to notify beneficiaries of risk scores. Similar to prior years, a smaller proportion of organizations reported notifying beneficiaries of risk scores via written communication (18 percent), by other clinical staff during an in person visit (17 percent) or telehealth visit with other staff (11 percent), or by phone call from the provider (11 percent) or other staff (10 percent). Only 6 percent reported that they do not notify beneficiaries of their risk scores.

2. Managing risk for high-risk beneficiaries

As they did in 2018, organizations surveyed in 2021 reported using tracking tools or registries, care managers, and automated scheduling to ensure high-risk beneficiaries were not lost to follow-up (Figure III.C.2).

Figure III.C.2. Organizations continue to use tracking tools, care managers, and automated scheduling to follow up with beneficiaries



Source: Mathematica's analysis of practice surveys administered in 2018 and 2021 to key contacts at each intervention organization in the Million Hearts Model (N = 90).

CVD = cardiovascular disease.

Most organizations that participated in interviews (7 of 10) maintained a spreadsheet or tracker used by office staff, such as care managers, to identify beneficiaries who are due for a reassessment visit and practice staff will reach out to schedule. However, about one-third of organizations (3 of 10) mentioned they discontinued using their tracker or had a hard time maintaining it due to the challenges related to the COVID-19 pandemic.

Organizations varied in the frequency with which they followed up with beneficiaries. The model requires that, in addition to annual reassessment visits, organizations reach out to high-risk patients at least two more times per year (any mode) to monitor and encourage progress in risk reduction. In the 2021 practice survey, 73 percent of organizations reported they followed up with patients at least every six months, which would meet the model requirements, and another 25 percent indicated they followed up with patients "as needed." Only 1 percent of intervention organizations reported following up with high-risk patients annually, which would be less than the required frequency (Figure III.C.3). In interviews, several organizations noted they often have follow-up contacts with patients during regularly scheduled visits, rather than needing to make separate contacts specifically focused on CVD risk reduction. Indeed, about half of the organizations mentioned high-risk patients often have more frequent visits with their providers

than the model requires, and the organization counts those visits as fulfilling the follow-up requirements under the model.

Figure III.C.3. Organizations vary in the frequency with which they follow up with beneficiaries, but generally reported follow-up rates that exceeded the model requirement of twice per year

Once you have identified Medicare beneficiaries as having high CVD risk,





Source: Mathematica's analysis of practice surveys administered in 2018 (N = 70) and 2021 (N = 72) to key contacts at each intervention organization in the Million Hearts Model. The number of respondents for these questions is lower than the full sample due to skip logic. The survey did not ask this question to organization respondents who reported their organization did not calculate CVD risk score or respondents who reported they did not know if their organization calculated CVD risk score.

CVD = cardiovascular disease.

To reduce CVD risk for high-risk beneficiaries, providers we interviewed said they focused on use of medications, including statins and antihypertensives, as well as smoking cessation. In addition, most organizations we interviewed mentioned having various resources available that could help high-risk beneficiaries reduce their CVD risk, such as access to dieticians, nutritionists, or smoking cessation counselors. Other types of resources mentioned less frequently include diabetes educators, clinical pharmacists embedded in the practice, care managers to develop care plans and follow up with patients, educational materials, lists of community resources, and incentives to physicians who met certain CVD quality metrics.

When beneficiaries had several unaddressed CVD risk factors, respondents from nearly half (4 of 10) of the organizations interviewed discussed the need to personalize care by determining which changes a beneficiary was willing to make. Respondents from a couple of organizations discussed the need to find what motivates patients.

Respondents from almost all of the organizations we interviewed (8 of 10) stated at least a portion of beneficiaries seem motivated by seeing their CVD risk scores to make lifestyle or medication changes to reduce their overall risk. Several respondents commented beneficiaries seem particularly motivated when a provider shows them how much their risk could be, or has been, reduced by making certain changes, such as quitting smoking.

Respondents from most of the organizations we interviewed in 2021 felt the model helped to motivate change to reduce CVD risk for some patients. Respondents from a couple of organizations mentioned they have seen CVD risk scores continue to decrease over time, whereas respondents from a couple of other organizations noted CVD risk scores tend to plateau at some point for several reasons, including that some people seem less motivated over time, because physicians run out of options for making further care management changes, and beneficiaries' age continues to increase.

As in prior years, respondents from organizations we interviewed described a challenge related to negative patient perceptions of statins. About one-third of organizations (3 of 10) mentioned they are constantly trying to overcome the negative perceptions patients have of statins.

None of the interview respondents felt the model resulted in downsides or unintended consequences for Medicare beneficiaries. "I think that there are definitely at least some of our patients who have changed behaviors over the past few years. It can likely be linked to practices that we've adopted because of the Million Hearts Model."

-Quality improvement manager

D. Payments, model tools, and other supports for model implementation

1. Payment amounts, overall and by type



Organizations in the intervention group can receive payments for risk stratifying eligible Medicare beneficiaries (all model years), providing cardiovascular care management to beneficiaries at high risk of having a heart attack or stroke (first model year only), and reducing risk among beneficiaries at high risk (model Years 2 through

5). From January 2017 to December 2020, CMS paid \$7.6 million to intervention organizations participating in the Million Hearts Model. Total CMS payments to intervention organizations were highest in the second six-month performance period (July to December 2017). Payments then decreased in subsequent periods, partly because organizations withdrew from the model (Appendix B, Figure B1).

To understand the payment amounts, we calculated the mean payments in each performance period by payment type (risk stratification, cardiovascular care management, and risk reduction; Figure III.D.1). In each period, we limited to organizations that still participated in the model that period, as evidenced by still uploading data to the registry. We included organizations that either had a payment that period or could have received a payment because they submitted at least one reassessment visit. In general, the greatest mean payments were concentrated in the first year and tended to decline over time. Mean payments ranged from a high of \$15,251 in the second performance period to a low of \$3,478 in the seventh performance period (Figure III.D.1). Mean payments were three to four times higher than median payments, with medians ranging from a high of \$4,005 in the second performance period to a low of \$660 in the seventh performance period. These high ratios (of mean to median) indicate outlier organizations that received higher payment amounts than most skewed the distribution of payments.





Source: Mathematica's analysis of payment data received from the implementation contractor.

Note: The analysis calculated mean payments among organizations that had a non-zero payment or a reassessment visit in each payment period. Cardiovascular care management payments applied during PP1 and PP 2 only (although organizations might have received them during PP 3) and risk-reduction payments began in PP 3.

N = number of organizations; PP = performance period.

Most organizations received some payments for reducing risk for their high-enrollees, but these payments were generally modest. The mean risk-reduction payment for each six-month performance period ranged from \$5,086 to \$2,118 across the performance periods. The median

risk-reduction payment for each six-month performance period ranged from \$1,233 to only \$360 per organization. In performance periods 3 through 8, when organizations were eligible to receive risk-reduction payments, one-sixth to one-quarter of the organizations that reported

reassessment visits received the highest risk-reduction payment amount of \$10 per beneficiary per month (PBPM) (<u>Appendix B</u>, Table B.3). Slightly more than half of the organizations that ever submitted reassessment data achieved the maximum payment category in at least one performance period. And almost all (94 percent) organizations that ever submitted a reassessment visit obtained a risk-reduction payment either in the middle or highest payment tier in at least one of the performance periods.

The mean risk reduction across participating organizations decreased over time (from a 7.7 percentage point decline in performance period 3 to a 4.7 percentage point decline in performance period 8). Correspondingly, the proportion of organizations that submitted reassessment visits but earned no riskreduction payment increased over time (from 6 to 32 percent) (Appendix B, Table B.3). The change in risk reduction over time might be related to patients aging or developing diabetes, which increases the predicted risk score, making it difficult to sustain large reduction (from baseline) in CVD risk over many years. <u>Chapter IV</u> describes changes in risk reduction over time further.

Million Hearts Model incentive structure

- Model Year 1: Intervention organizations receive \$10 per eligible beneficiary who is risk stratified and \$10 PBPM in cardiovascular care management fees for each high-risk beneficiary.
- Model Years 2–5: Intervention organizations receive \$10 per eligible beneficiary who is risk stratified. They also receive riskreduction payments based on average change in risk score among high-risk beneficiaries (\$0 PBPM for average risk reduction less than 2 percentage points, \$5 PBPM for average risk reduction from 2 to 10 percentage points, and \$10 PBPM for average risk reduction greater than 10 percentage points).

2. Perceptions of payment



Only 43 percent of surveyed organizations reported financial incentives were an important factor for their continued participation in the model in 2021, compared to 61 percent in 2018.



Among the organizations we interviewed, most (8 of 10) said they did not track the costs associated with participating in the model. Although they did not explicitly track costs, respondents from about one-third of the organizations interviewed said their perception was that the incentive payments were insufficient to cover the costs

associated with participating and respondents from about half of the organizations were unsure. Only one large organization felt the incentive payments adequately covered the costs. Consistent with our prior interviews, respondents from a couple of organizations also noted the incentive payments were not the primary reason they participated in the Million Hearts Model. Rather, these organizations said they participated because they felt their patients would benefit.

3. Perceptions of other tools and supports

In the 2021 practice survey, more than half of organizations reported the learning activities were valuable to their efforts to improve CVD prevention. Further, the percentage of organizations that agreed the learning activities were valuable was similar in 2018 and 2021, about 60 percent. However, fewer organizations strongly agreed in 2021 (15 percent) than in 2018 (28 percent) (Figure III.D.2).

Figure III.D.2. Most organizations reported learning activities were valuable to their efforts to improve CVD prevention in 2021, as in 2018





Source: Mathematica's analysis of practice surveys administered in 2018 (N = 88) and 2021 (N = 89) to key contacts at each intervention organization in the Million Hearts Model.

Half of the organizations we interviewed in 2021 felt the Million Hearts Model registry was easier to use compared to prior years or that it provided useful information for implementing the model. However, about one-third of organizations continued to experience challenges with registry use, similar to findings reported previously (Blue et al. 2020).

E. Overall perceptions of the model

1. Perceptions of model effect on quality of care

	≣Ø	
Pra	actice survey	



Nearly two-thirds of organizations somewhat or strongly agreed that participating in the model helped improve quality of care (66 percent) or improved patients' CVD risk scores (64 percent) (Figure III.E.1). In interviews, respondents reported positive changes to quality of care related to improving superpass of CVD risk scores and improving consistency of use of CVD

awareness of CVD risk among providers and improving consistency of use of CVD risk scores. Half the organizations (5 of 10) said they monitored changes in risk scores over time among beneficiaries enrolled in the model using either CMS reports or other internal data sources. A couple of organizations noted risk scores seem to continue to

decrease over time for individual beneficiaries. Other organizations (2 of 10) noted risk scores seem to plateau at some point. Reasons provided by interviewees for why risk scores plateau included beneficiaries' continue to get older, some beneficiaries might be less motivated by the risk score over time, and providers can make only a limited number of care management changes to reduce CVD risk.

Figure III.E.1. Most organizations agreed that participating in the model helped improve quality of care or improved patients' CVD risk scores



Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention organization in the Million Hearts Model (N = 89).

CVD = cardiovascular disease.

The interviews from this and earlier years suggest two ways the model has improved quality of CVD preventive care. First, organizations reported the model increased their use of CVD risk scores, making them more aware of CVD risk in their patient panel. Providers could then use their standard set of therapeutic tools, such as initiating medications or counseling on lifestyle changes, to help bring down those risks. Second, the model increased the extent to which providers discussed CVD

"As a practice, we've always utilized preventative care and we've always been on top of seeing our patients regularly. But I think having this model has just brought it more into the forefront, more awareness. I think just seeing the [Million Hearts] that we flag for our patient charts, seeing that or having an alert sent to us by our staff has brought it more to the forefront for that.

– Provider

risk scores with patients. As described, some organizations said these conversations about risk helped to motivate patients to make lifestyle or medication changes to reduce their overall risk. Together, these two types of quality improvements could lead to improvement in risk scores over time.

2. Cross-cutting barriers and facilitators to implementation



Interviews

Although the surveys and interviews commonly reported barriers related to COVID-19 to implementing the model, organizations noted other barriers to implementation as well. Insufficient staff time and competing organizational priorities continued to be top barriers noted by organizations in the survey administered in 2021 (Figure III.E.2), similar to findings reported in the prior 2018 survey (Appendix C). Lack of patient engagement with CVD risk-reduction activities was another commonly cited barrier in the 2021 practice survey.

In interviews, several organizations remarked that staffing shortages and staff limitations were a barrier to implementing the model, and COVID-19 exacerbated them in the past year. In addition, one respondent reported organizational transitions such as mergers decreased the ability to focus on implementing the model.



Figure III.E.2. Factors organizations identified as barriers to implementing the model

■Considerable barrier ■Somewhat of a barrier □Not a barrier □Don't know

Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention organization in the Million Hearts Model. The number of respondents for individual questions ranged from 88 to 89 due to missing responses.

CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; EHR = electronic health record; IT = information technology

Organizations also reported in the two surveys factors that helped to implement the model. Organizational leadership support for the model, participation in other quality improvement initiatives, and staff time to implement the model were among the top factors identified as supporting implementation (Figure III.E.3). Respondents cited information technology support, staff buy-in, and staff time as important facilitators of model implementation slightly more frequently in 2021 compared to 2018 (<u>Appendix C</u>). Also, having a practice champion was a factor reported by nearly four-fifths of organizations in the survey administered in 2021 (prior surveys did not ask this question).

In interviews, several organizations (4 of 10) thought the model intersected nicely with other quality initiatives they participated in, such as the Comprehensive Primary Care Plus Model and Patient-Centered Medical Home initiatives, because they are already monitoring metrics related to CVD prevention such as blood pressure control as part of chronic disease prevention and management efforts for these other programs. One interview respondent noted participation in
another program enabled their organization to hire a dietician who could provide guidance on dietary changes in support of CVD risk reduction. A few organizations we interviewed also reported having staff dedicated to implementing the Million Hearts Model was beneficial.



Figure III.E.3. Factors organizations identified as helpful to implementing the model

e: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention

Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention organization in the Million Hearts Model. The number of respondents for individual questions ranged from 87 to 90 due to missing responses for some questions.

ACO = accountable care organization; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; IT = information technology; RR = risk reduction

3. Future participation in similar models

About 45 percent of the organizations that responded to the survey said they would participate in the model in the future, if offered (Figure III.E.4).

Figure III.E.4. Organizations had varying responses regarding potential future participation in a similar model

If offered, our organization would participate in the Million Hearts Model in the future.



Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention

To further facilitate the implementation of the Million Hearts Model or other similar models in the future, interview respondents suggested reducing administrative burden and adding additional supports, such as conducting direct outreach to beneficiaries about CVD risk from CMS or partner organizations such as the American Heart Association. A few interview respondents (3 of 10) also commented that better communication between CMS and participating organizations, especially with regard to being available to provide support when registry issues arise, or clearer guidelines would be helpful. Two practices mentioned that use of the registry was cumbersome and could be improved.

F. Plans to sustain changes in cardiovascular care after the model ends

1. Changes to CVD care and plans to sustain changes after the model ends



Interview

More than half of organizations surveyed reported both that they made changes to care delivery related to CVD risk assessment and management that they plan to sustain after participation in the Million Hearts Model ends. The remaining organizations indicated either they did not make changes to care delivery during the model (24 percent); they didn't know if they made care delivery changes during the model (11 percent); they made changes but did not plan to sustain those changes (3 percent); or they did not know if their organization will sustain changes it had made during the model (8 percent) (Appendix C).

Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each interventio organization in the Million Hearts Model (N = 89).

The survey asked organizations that said they planned to sustain changes related to care delivery to describe how likely the organization would be to continue to sustain specific changes (Figure III.F.1). Among those that said they planned to sustain changes made to care delivery during the model, more than 90 percent of the organizations were likely or somewhat likely to sustain changes made to systematically identify patients at high risk for CVD. Nearly three-quarters were likely or somewhat likely to sustain changes related to the role of care managers in CVD risk assessment and reassessment; about two-thirds planned to sustain changes related to the use of an embedded EHR tool to assess CVD risk.



Source: Mathematica's analysis of a practice survey administered in 2021 to key contacts at each intervention organization in the Million Hearts Model. The number of respondents for questions shown in the pie chart on the left side of the figure was 89. The number of respondents for individual questions shown in the dotted box on right side of the figure ranged from 50 to 51 due to skip logic and missing responses, as the survey asked these questions only of organizations that said they planned to sustain changes.

CVD = cardiovascular disease.

Similarly, nearly all (9 of 10) organizations interviewed said they planned to sustain some or all of the care management changes they made under the Million Hearts Model after the model ends. Most organizations characterized the primary changes they made to care management through the model as using a CVD risk calculator to calculate risk scores and then using the risk score to inform treatment decisions.

All organizations that discussed sustaining all or some components of the Million Hearts Model during interviews said they will continue to calculate CVD risk scores for their patients after the model ends. A few (3 of 10) mentioned they intend to maintain clinical decision support or care management tools they integrated into their EHRs under the model and, as previously mentioned, more than one-third of organizations are in the process of integrating CVD risk calculators or more advanced CVD risk calculators into their EHRs.

A couple of organizations mentioned during interviews they would discontinue their approach to follow-up contacts for high-risk individuals. In one case, the organization planned to integrate Million Hearts beneficiaries into other ongoing care management programs; in the other, the organization had followed up with Million Hearts beneficiaries via text message under the model and did not plan to continue the follow-up text messages but noted these individuals already see their providers more frequently.

2. Barriers to and facilitators of sustaining changes

The survey also asked organizations that indicated they planned to sustain changes about facilitators of (Figure III.F.2) and barriers to sustaining changes (Figure III.F.3). Having a practice champion, participation in other quality improvement initiatives, and information technology support were the three factors that stood out as being "very helpful" for more than half of the organizations.

Figure III.F.2. Factors that organizations identified as helpful in sustaining changes made during the model





Source: Mathematica's analysis of a practice survey administered in 2021 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 50 to 51 due to skip logic and missing responses. The survey asked these questions only of organizations that said they planned to sustain changes made during the model.

ACO = accountable care organization; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; IT = information technology.

Insufficient staff time stood out as one of the most considerable barriers for sustaining CVD risk assessment activities after the end of the model, followed by competing organizational priorities, lack of funding, and staff turnover. These reasons are consistent with implementation challenges during the model and reasons some organizations left the model.

Figure III.F.3. Factors organizations identified as a barrier in sustaining changes made during the model





■Considerable barrier ■Somewhat of a barrier □Not a barrier □Don't know

CVD = cardiovascular disease; EHR = electronic health record; IT = information technology.

Source: Mathematica's analysis of a practice survey administered in 2021 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 50 to 51 due to skip logic and missing responses. The survey asked these questions only of organizations that said they planned to sustain changes made during the model.

IV. Changes in CVD Risk Scores over Time Among Intervention Group Beneficiaries



- For organizations participating in the Million Hearts Model, average risk score reduction among enrolled high-risk beneficiaries is a key measure of model performance. Among high-risk beneficiaries with three reassessment visits by the end of 2020, the average CVD risk score fell by 8 percentage points between enrollment and the first-year reassessment. This means the predicted probability of a having heart attack or stroke within 10 years fell from 40 percent at enrollment to just 32 percent roughly one later. (The average risk score also declined by a large amount, 7 percentage points, in the control group within the first year of enrollment.) Average CVD risk scores rose again in subsequent years but remained 5 percentage points below the average at enrollment by the third reassessment visit.
 - Decreases in blood pressure and LDL cholesterol drove the decreases in the average CVD risk score, observed between enrollment and each annual reassessment visit.
 - An aging population, increased rates of diabetes, or a lack of persistence in treatment of CVD risk factors over time could have caused increases in the average CVD risk score, observed between the one-year reassessment visit and subsequent visits.
 - The decline in CVD risk scores in both the intervention and control groups indicates that, despite small impacts on risk scores (<u>Chapter V</u>), other factors that affect both the intervention and control groups—such as all organizations addressing risk factors or random fluctuations in blood pressure over time—explain the majority of the decline in risk scores.
 - Intervention organizations participating in the Million Hearts Model varied considerably in the average risk reduction they achieved. From 2017 to 2019, the highest-performing organization had a 13.4 percentage-point average risk reduction across its enrolled high-risk beneficiaries, whereas the lowest-performing organization had a 2.9 percentage-point risk reduction.
- The single strongest predictor of an organization's performance in reducing risk was whether the organization had room for improvement to begin with: that is, with a large fraction of the beneficiaries' risk scores at enrollment driven by modifiable risk factors, such as elevated blood pressure and lipid levels and smoking, as opposed to nonmodifiable risk factors like age.
- In interviews with organizations that had unusually high or low average risk score reduction, but with similar organizational characteristics, the high performers (1) appeared to report more proactive communication and/or wider use (across different types of providers) of the documented risk score in the EHR; and (2) tended to point to the important role of project champions and highly engaged staff in quality improvement efforts or innovative initiatives, such as the Million Hearts Model. At the same time, organizations with less risk reduction were more likely to mention patients' compliance as a barrier to success.

Average CVD risk score reduction across organizations' enrolled beneficiaries is a key measure of performance in the Million Hearts Model and is tied to the model's risk reduction payments, or incentive payments. This chapter begins by presenting information about changes in risk scores and risk factors for the high-risk beneficiaries (Section A.1). Because the Million Hearts Model makes incentive payments based on organizations' mean risk reduction, we then present variation in the organizations' model performance—that is, variation in the changes in risk scores across participating organizations (Section A.2). Finally, we explore organizational factors that might contribute to this variation in risk reduction across organizations (Section B). Understanding the characteristics and CVD risk-reduction strategies of successful organizations could help policymakers and clinicians target or focus their CVD risk-reduction efforts in the future.

A. Description of changes in beneficiaries' CVD risk scores

1. Change in CVD risk scores across all intervention organizations



In this section, we examine changes in CVD risk scores among high-risk beneficiaries across intervention organizations that reported reassessment information. We describe the average risk score reduction among high-risk beneficiaries enrolled by intervention organizations and seen for three annual reassessment visits by the end of

2020. We calculated changes in CVD risk scores using the Million Hearts Longitudinal ASCVD Risk Assessment Tool, a tool developed especially for the Million Hearts Model. These changes in risk scores, taken alone, are not necessarily a sign of model impacts—because some of these changes, and potentially many of them, could have occurred even without the model. However, to understand the experience of beneficiaries enrolled in the Million Hearts Model—as well as the experience of participating organizations paid for achieving risk reduction among those beneficiaries—it is valuable to assess the extent of risk score change over time. In addition to showing average CVD risk reduction in the intervention group in this section, we show CVD risk reduction among control group beneficiaries during follow-up visits one year after enrollment.⁸ This illustrates changes in CVD risk scores that might have occurred even without the model. Chapter V presents formal estimates of impacts on risk scores (relative to the control group experience).

⁸ The control group was required to submit data only on follow-up visits to the Million Hearts Data Registry through December 2019, so there is limited data on two- and three-year follow-up visits for the control group.

CVD risk scores: A closer look

The CVD risk score represents a person's **predicted probability of having a heart attack or stroke within 10 years**, as calculated using a standardized tool. At a person's initial CVD risk assessment, the risk score relies on several factors (Goff et al. 2014):

- Demographics, including age, sex, and race
- Clinical factors, including blood pressure and cholesterol levels, and history of diabetes
- Patients' behaviors, including current smoking status and use of medications to control blood pressure

When designing the Million Hearts Model, CMS worked with leading cardiovascular epidemiologists to develop a novel risk calculator that estimates changes over time in a person's risk of heart attack or stroke (Lloyd-Jones et al. 2017). It calculates a person's initial risk score the same way as the previously existing tool. But to calculate follow-up risk scores (an updated 10-year predicted probability of heart attack or stroke), the new tool incorporates additional information about aspirin use, time since quitting smoking, and changes in blood pressure and cholesterol since the initial assessment. Specifically, based on results from clinical trials, the new tool estimates—for an individual person—how much starting aspirin therapy, quitting smoking, and reducing blood pressure or cholesterol would change a person's CVD risk. CMS uses the new calculator—the Million Hearts Longitudinal Atherosclerotic CVD Risk Assessment Tool—to estimate risk reduction, the basis of the model's risk reduction payments.

In the first year after enrollment, CVD risk scores decreased by an average of 8 percentage points among the 2,978 high-risk intervention beneficiaries who received three annual reassessment visits (Figure IV.1). Specifically, at enrollment the average high-risk beneficiary had a CVD risk score of 40 percent—indicating a 40 percent predicted probability of having a heart attack or stroke in the subsequent 10 years. However, roughly one year after enrollment, the average CVD risk score among this population was just 32 percent, indicating a 32 percent predicted probability of 10-year heart attack or stroke (hence a reduction of 8 percentage points, on average—or, in other words, a predicted 8 heart attacks and strokes averted over 10 years for every 100 high-risk beneficiaries enrolled). In the first year after enrollment, CVD risk scores also decreased in the control group by an average of 7 percentage points, suggesting much of the change in average CVD risk scores would have occurred under care as usual, even without the model.

In this same population of beneficiaries (described in more detail in Appendix D), risk scores rose in subsequent visits but remained 5 percentage points lower than baseline during three-year reassessment visits. That is, the average risk score three years after enrollment (35 percent) was still 5 percentage points lower than the average at enrollment (40 percent). These results suggest the greatest risk reduction across intervention group beneficiaries occurred in the first year following enrollment, but beneficiaries maintained much of their risk reduction through the first three years after enrollment.





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

Note: The blue line represents 2,978 high-risk intervention group beneficiaries who received three reassessment visits by December 2020. For comparison, the green line includes 10,209 high-risk control group beneficiaries who received at least one follow-up visit by December 2019. (After December 2019, the control group was not required to submit data to the Million Hearts Data Registry.) One-year reassessment visits occurred 10 to 21 months after enrollment, two-year reassessment visits occurred 22 to 33 months after enrollment, and three-year reassessment visits occurred 34 to 45 months after enrollment. Appendix D describes full eligibility criteria for reassessment visits. Although the blue line presents patterns for the subset of intervention enrollees with reassessment visits in all three follow-up years, the patterns are similar when we expand to the larger populations followed for just one or two years (see Appendix D).

CVD = cardiovascular disease.

Decreases in CVD risk scores could be caused by (1) impacts of the Million Hearts Model; (2) improvements in risk factors under care as usual, which affect both the intervention and control groups; and (3) natural fluctuations in CVD risk factors, which create a statistical artifact known as regression to the mean. That is, for beneficiaries near the threshold for being categorized as high risk at enrollment, natural fluctuations in blood pressure or cholesterol readings could lead to defining a beneficiary as high risk one day and medium risk another. Such fluctuations are particularly common for blood pressure, which can vary between readings and day to day. Because organizations had to report reassessment data only for high-risk beneficiaries, when we calculate the change in CVD risk scores, we reflect the experience of many beneficiaries who fluctuated toward higher risk factor levels during the enrollment visit (and are likely to have better levels at reassessment) but reflect the experiences of fewer beneficiaries who fluctuated toward low risk factor levels at the enrollment visit (who are likely to have higher levels at reassessment). This regression to the mean could explain why both the intervention and control groups experienced large risk reductions in the first year, even though this reduction did not fully persist in later years for the intervention group. In Chapter V, we show that in both the intervention and control groups almost one-third of beneficiaries with uncontrolled blood

pressure or LDL cholesterol initiated or intensified CVD medications during the first year after enrollment, suggesting some of the decreases in CVD risk scores occurred through care as usual.

Decreases in systolic blood pressure and LDL cholesterol, which are both risk factors used to calculate the CVD risk score using the Million Hearts Longitudinal ASCVD Risk Assessment Tool, drove the decreases in the mean CVD risk score. Mean systolic blood pressure and mean LDL cholesterol both declined the most in the first year following enrollment. However, LDL cholesterol continued to decline across the three reassessment visits (Appendix D, Figures D.2 and D.3), reflecting either impacts of the intervention or improvements in cholesterol management under the standard of care (for example, increased statin use) during the three years. Increases in mean CVD risk scores, observed between the one-year reassessment visits and subsequent visits, is caused in part by an aging population and might also be caused by increased diabetes rates or a lack of persistence in treatment of CVD risk factors over time. Age and diabetes status are both risk factors that raise the CVD risk score in the Million Hearts Longitudinal ASCVD Risk Assessment Tool.

The analysis described here covers risk score reduction among the 2,978 high-risk intervention beneficiaries who received three annual reassessment visits (occurring 10 to 21 months after enrollment, 22 to 33 months after enrollment, and 34 to 45 months after enrollment, respectively.) This population is a small subset of the 18,347 high-risk intervention beneficiaries who had at least one reassessment visit (at any time), and an even smaller subset of the roughly 46,000 high-risk intervention beneficiaries enrolled in the model through 2020. However, beneficiaries who received one-year reassessments, or one- and two-year reassessments, but not all three reassessments had a similar trajectory of CVD risk score change over the period observed (Appendix D, Figure D.1). Also, the populations with one-, two-, and three-year reassessment visits were generally similar in terms of demographics, CVD risk factors, and other baseline characteristics to the full population eligible for reassessment but not reassessed (Chapter III).

2. Variation in risk score change across intervention organizations





Because the Million Hearts Model pays each participating organization based on its average risk reduction achieved across the organization's high-risk beneficiaries, it is valuable to examine the variation in organizational performance. That is, we analyzed how much the participating organizations varied in their average CVD risk score reduction. (In other words, instead of looking at average risk reduction across all beneficiaries with a certain number of reassessment visits, we looked at the average risk reduction across beneficiaries enrolled *by a given organization* and with a

reassessment visit.) For this analysis, we limited the set of participating organizations to include only those organizations with (1) an adequate number of beneficiary reassessments for us to get a stable measure of the organization's performance reducing CVD risk and (2) a large enough proportion of eligible beneficiaries reassessed that we expect the measured performance should reflect risk reduction for the organization's Medicare patients overall. Given these two

goals and the timing of the data available when we began analysis for this report, we set the following criteria for selecting organizations for the analysis:

- 1. Each organization enrolled at least 40 percent of its 2017–2018 beneficiaries who appeared eligible in claims for enrollment in the Million Hearts Model.
- **2.** Each organization conducted reassessment visits with at least 40 percent of its high-risk beneficiaries who were due for such a visit by the end of 2018.
- **3.** Each organization conducted no fewer than 22 reassessment visits used to calculate risk reduction payments by December 31, 2019.

These criteria yielded a set of organizations with diverse organizational characteristics (N = 54).⁹ They also guaranteed the selected organizations had robust model implementation–because we could not obtain a reasonable measure of model performance for organizations with minimal participation in the model. For example, the selection criteria avoided the possibility of us calculating an organization's risk-reduction performance based on just a handful of beneficiaries, for which a single beneficiary's unusual experience might unduly influence the average risk reduction. The criteria also avoided the possibility of us calculating risk-reduction performance for an organization that reported its data very selectively to try to increase its payments—say, reporting reassessment data only for beneficiaries who achieved a large risk reduction.

We defined each organization's performance as the average risk reduction across all reassessment visits occurring at the organization from November 2017 to December 2019 (used to calculate risk-reduction payments for the third through sixth Million Hearts Model performance periods). We calculated performance for each organization based on the data CMS used to calculate model risk reduction payments in 2018 and 2019. Each reassessment counted equally toward the measure of performance (the organization's average risk reduction).

This analysis of organizations' risk-reduction performance uses a different (shorter) time period than the analysis in Section IV.A.1 of beneficiaries' average risk reduction (that is, 2017–2019 instead of 2017–2020). We chose a shorter period for the organizational analysis because many organizations stopped reporting reassessment data over time, and we wanted to compare average risk reduction over roughly the same time period for all organizations, without removing organizations from the analysis unnecessarily. The analysis weights each organization equally.

Overall, performance varied substantially among the 54 organizations with robust model implementation eligible for this analysis (Figure IV.2). The average risk reduction among beneficiaries with reassessment visits occurring from November 2017 to December 2019 was 7.5 percentage points (standard deviation = 2.15). The highest-performing organization—that is, the organization with the greatest reduction in average CVD risk scores—had a 13.4 percentage-

⁹ Fifty-eight organizations met the three selection criteria listed. However, we dropped four additional organizations from the analysis because they had the same reassessment visits used to calculate payments in more than one performance period. This meant we could not calculate the average risk reduction across all reassessment visits without double-counting some visits. See Appendix D for details.

point risk reduction, and the lowest-performing organization had a 2.9 percentage-point risk reduction.





Source: Mathematica's analysis of Million Hearts Model 2018–2019 payment data.

Note: We defined *high performers* as organizations with an average risk reduction of at least 8.9 percentage points and *lower performers* as those with an average risk reduction of no more than 6.0 percentage points. These categories of high and lower performers correspond to roughly the top 20 and bottom 20 percent of the performance distribution.

CVD = cardiovascular disease.

Even the lowest-performing organization in this analysis achieved an average risk reduction of at least 2 percentage points, which is enough to earn risk-reduction payments. This strong performance likely reflects a combination of factors. First, on average, high-risk beneficiaries experienced substantial risk reduction in the first year after enrollment, even in the control group, as described previously in this chapter. Second, organizations with robust model implementation—a requirement to be included in this analysis—might have been more likely to achieve risk reduction than the excluded organizations, which failed to enroll and/or reassess a large number of beneficiaries in the Million Hearts Model.

B. Organizational factors as potential contributors to variation in risk reduction across organizations

After four years of the model, organizations have substantial experience implementing their CVD risk-stratification and care management strategies. In this section, we first examine baseline organizational features that might explain variation in performance across high- and lower-performing organizations. A more in-depth examination follows of a sample of the high- and lower-performing organizations to identify potential organizational-level strategies effective for reducing CVD risk scores.

1. Baseline organizational features



Payment data

Organizational features could explain some of the variance in performance across organizations. For instance, larger organizations might systematically perform better than smaller organizations on reducing CVD risk, if these larger organizations have greater resources to risk stratify beneficiaries (for example, capacity to add a CVD risk calculator to the EHR) or to perform cardiovascular care management (for example, offering smoking cessation classes, or using care managers to follow up oneon-one with high-risk beneficiaries). We tested a selected list of six baseline organizational features for their contribution to the variation in organizations'

performance reducing risk among high-risk beneficiaries: (1) rurality; (2) organization size, based on number of providers; (3) organization type (primary care, acute care hospital, federally qualified health center, rural health clinics, or other health center, and specialty or multispecialty); (4) participation in another CMS initiative; (5) geographic region (Northeast, Midwest, South, and West); and (6) mean amount of high-risk beneficiaries' risk scores due to modifiable risk factors.¹⁰

These six organizational features explained nearly half of the variance in performance among the 54 organizations with robust model implementation, described in Section A.2. Taken together (in a multivariate regression), the six organizational features explained 42.6 percent of the variance. Individually (in univariate regressions), two baseline organizational features explained more than 10 percent of the variance in risk reduction: (1) the mean amount of enrolled high-risk beneficiaries' risk score due to modifiable risk factors and (2) organization size based on the number of providers.

Of these, the mean amount of modifiable risk accounted for 30 percent of the variance in risk score reduction. In other words, the single strongest predictor of an organization's risk reduction was whether the organization had a lot of room for improvement to begin with—meaning modifiable risk factors, such as elevated blood pressure and lipid levels and smoking largely

¹⁰ We measured how much of each high-risk beneficiary's risk score at enrollment was potentially modifiable, if the beneficiary met clinical targets for blood pressure control, lipid management, and smoking cessation one year after enrollment. We regard this as a baseline feature for each organization. However, it was not measured based on each organization's start date in the Million Hearts Model, but rather as the mean at model enrollment among high-risk beneficiaries enrolled in 2017 or 2018.

drove beneficiaries' risk scores, instead of nonmodifiable factors, such as age and sex. For example, if we rank the organizations based on their mean amount of modifiable risk when the beneficiaries enrolled, organizations in the top half of the distribution (with modifiable risk greater than 14.9 percentage points) achieved a mean risk reduction from enrollment to reassessment of 8.5 percentage points, compared to a mean risk reduction of only 6.5 percentage points among organizations in the bottom half of the distribution (Figure IV.3).





Sources: Mathematica's analysis of Million Hearts Model payment data and data from the Million Hearts Data Registry.

In addition, organization size alone, measured by number of providers explained 17.6 percent of the variance in organizational performance. Specifically, larger organizations achieved greater risk reduction on average, with:

- Small organizations (1 to 5 providers) having a mean risk reduction of 6.5 percentage points
- Medium-sized organizations (6 to 19 providers) having a mean risk reduction of 8.0 percentage points
- Large organizations (20 or more providers) having a mean reduction of 8.4 percentage points

To sum up, six organizational features could explain a relatively high proportion of variance in risk reduction across organizations. From the perspectives of organizations, it might be difficult (if not impossible) in the short run to change their organizational features. However, from the perspective of policymakers, the high explanatory power of those six organizational features could suggest how to target CVD risk reduction incentive programs or supports in the future. For

example, if some organizations have already done a good job of addressing patients' modifiable risk factors before the risk-reduction initiative begins, it might be difficult for them to continue to achieve large reductions over time. Similarly, these findings suggest smaller organizations might need additional incentives or supports to aid in risk reduction, such as the focus of the Agency for Health Care Research and Quality EvidenceNOW initiative (Taylor et al. 2013; Meyers et al. 2018).

2. Organizations' strategies or approaches as potential drivers of CVD risk reduction



The evaluation team conducted targeted interviews with three high- and four lowerperforming organizations and analyzed the qualitative data to identify potential areas that might differentiate organizations that were unusually successful in reducing CVD risk among their high-risk beneficiaries from lower-performing organizations. We

defined *high performers* as organizations with an average risk reduction of at least 8.9 percentage points and *lower performers* as those with an average risk reduction of no more than 6.0 percentage points. These categories of high and lower performers correspond to roughly the top 20 and bottom 20 percent of the performance distribution shown in Figure IV.2. We aimed to interview high and lower performers that shared similar organizational characteristics, so we could better understand other drivers of performance not captured in the quantitative data—for example, the organizations' CVD risk-reduction strategies. Appendix D describes how we selected the sample of high- and lower-performing organizations to interview, as well as our qualitative methods. Three areas emerged as potential differentiators of performance.

High-performing sites seemed to have more proactive communication and/or wider use of the documented risk score in the EHR. All three of the high-performing sites mentioned transparent communication and use of the risk score outside the immediate care team of the physician or nurse. For example, one site used a unified chart model in which both the primary care physician and specialists such as endocrinologists have easy access to the patient's risk score in the EHR; another noted care coordinators and pharmacists can view information on the patient and document their

"The risk score gets entered ... as an alert in the patient's chart...Anyone that has a referral on this patient has access to our EMR [electronic medical record] ...so there's really good communication and continuity of care. The pharmacist also documents their notes, their conversations, their visits right into the EMR, so everyone can see that alert in the chart."

-Provider at high-performing site

own notes and conversations. Only one of the four lower-performing sites mentioned communication and use of risk scores outside the immediate care team. Specifically, the site mentioned sending the risk score to a cardiologist when referring a patient for needed follow-up, but staff at this organization also noted they did not understand why they would communicate a risk score to others outside the care team, such as pharmacists. In the <u>Third Annual Report</u> (Blue et al. 2020), we found model participants generally bought in to the Million Hearts Model's vision of care, which aligns with current ACC and AHA guidelines on CVD primary prevention

to include the routine use of CVD risk scores (Arnett et al. 2019). We also know providers generally found CVD risk scores to be a useful tool to inform CVD preventive care for high-risk beneficiaries (Blue et al. 2020). The finding that high-performing sites share their risk scores with a broader care team suggests there might be added value of stressing how the risk scores, when documented, are communicated for greater risk score reduction. Specifically, by sharing risk score information more broadly, other providers could become more aware of a patient's risk and take actions to help reduce risk. For example, an endocrinologist might prescribe a new medication, or a care manager could follow up specifically about CVD risk during a routine outreach to the patient to encourage greater adherence to a CVD risk reduction plan.

Lower-performing sites were more likely to mention patients' compliance as a barrier to

success. Although both high- and lowerperforming sites spoke to the importance of patients' compliance for risk reduction, only the lower-performing sites (three of four) reported patients' compliance as a barrier to achieving CVD risk reduction. None of the highperforming sites raised patient factors as barriers "Just patient compliance. I don't think on a provider end that there's anything holding us back from doing [an initiative like Million Hearts]. It's just whether we get our patients to do things."

-Nurse at lower-performing site

to risk reduction, but rather pointed to clinic-level factors such as competing initiatives or data management as challenges. This finding suggests education or training might be useful for clinic staff to discuss ways to better connect with their patients or otherwise improve patients' adherence to agreed-upon care plans.

High-performing sites noted the important role of project champions and engaged staff in the success of initiatives like the Million

Hearts Model. All three high-performing sites noted either a project champion or engaged and proactive staff (particularly those who embrace innovation) as key facilitators of the success of initiatives similar to the Million Hearts Model. One site referenced the tenacity of its Million Hearts Model champion for its initial and ongoing involvement with the model. The other two high-performing sites pointed to highly engaged staff who consistently support quality improvement initiatives or other innovative "We would not have been able to be affiliated with this initiative had it not been for [MANAGER NAME] and her background in research, her, again, tenacity. Her commitment to improving health care outcomes in the patient population is phenomenal. We would not have been able to even take this on had it not been for her being with our practice."

> -Practice administrator at highperforming site

programs. Only one lower-performing site mentioned the role of staff for the success of a CVD initiative and that mention was more in the context of staff background and capabilities of the team as opposed to staff motivation to improve CVD care. This finding is consistent with other studies examining characteristics that distinguish high- and lower-performing organizations. For example, Curry et al. (2011) found staff in high-performing hospitals for acute myocardial

infarction care reported the presence of champions, but physicians' presence in championing acute myocardial infarction quality improvement was minimal in lower-performing hospitals. Our finding from the Million Hearts Model high-performing participants reinforces the important role of champions or motivated staff who actively engage in supporting new initiatives or changes in practices or approaches.

Our interviews explored other potential CVD risk-reduction strategies and approaches, but no other themes appeared to be potential differentiators between the high- and lower-performing organizations. For example, when asked about patients' engagement, representatives from sites in both the high- and lower-performing groups mentioned the use of motivational interviewing or the need to individualize supports. When discussing approaches to medication, sites from both the high- and lower-performing groups noted the importance of medication as a major driver of risk reduction and mentioned how pharmacists can improve medication adherence. Representatives from both groups also said frequency of follow-up tends to vary based on a patient's risk and in-person visits can be useful to schedule subsequent follow-up visits while the patient is in the office. Although no clear distinctions or patterns emerged from these other areas of exploration in this sample of interviewees, specific approaches or strategies within these areas could serve as important differentiators we did not explore, or did not identify as differentiators given the organizations interviewed.

V. Model Impacts on Heart Attacks and Strokes, Service Use, Spending, and Mortality and Intermediate Outcomes over Four Years (2017 to 2020)



Key findings

- The Million Hearts Model modestly improved some intermediate outcomes within one year of enrollment, the prespecified period for estimating impacts on these measures:
 - Among beneficiaries with blood pressure or cholesterol levels above thresholds for treatment at baseline, the likelihood of initiating or intensifying CVD medications (statins or antihypertensives) was 3.4 percentage points higher in the intervention group (31.3 percent) than the control group (27.9 percent, *p* < 0.001).
 - Adherence to CVD medications was similar in the intervention and control groups.
 - CVD risk scores decreased for high-risk beneficiaries in both the intervention and control groups, but the decrease was 1.3 percentage points larger in the intervention group (p = 0.003).
- Over four years, the model did not measurably reduce the incidence of first-time heart attacks or strokes or reduce Medicare spending, the study's primary long-term outcomes.
 - The incidence of first-time heart attack, stroke, or transient ischemic attack (TIA) was similar for the intervention and control groups.
 - Medicare spending was also similar for intervention and control group beneficiaries. Because the model did not reduce Medicare Parts A and B spending, it did not generate savings to offset model payments.
 - Future analyses will examine outcomes over the full five-year test period.
- The model increased acute care use and was associated with lower all-cause mortality rates.
 - Rates of all-cause hospitalizations and outpatient ED visits were modestly (2.9 to 4.6 percent) higher for the intervention group (*p*-values all < 0.1).
 - Among high- and medium-risk beneficiaries, the death rate was about 5 percent lower in the intervention group than in the control group (*p* = 0.02). Over three years, this difference amounts to 2.8 fewer deaths per 1,000 people in the intervention group compared to the control group. Among high-risk beneficiaries, the death rate was similar in the intervention and control groups.

The Million Hearts Model aims to reduce the incidence of first-time heart attacks and strokes among medium- and high-risk enrollees over five years. Further, it aims to reduce Medicare spending on these events and related care enough to offset model payments. This chapter starts by describing the model's impacts on intermediate outcomes that could cause reductions in CVD events, including use of and adherence to CVD medications, reductions in CVD risk factors such as blood pressure and cholesterol, and reductions in CVD risk scores, all measured over roughly one year after enrollment. We estimated impacts over one year largely because we anticipated the model would have impacts on these intermediate measures by then. Further, for risk scores and risk factors, the data beyond one year were too incomplete to accurately estimate impacts. This chapter then describes our estimates of the model's impacts on long-term outcomes over roughly four years (2017 to 2020). Long-term outcomes include the evaluation's two prespecified primary outcomes (first-time CVD events and Medicare spending) and several secondary outcomes we hypothesized might decline (mortality and CVD-specific and overall service use [hospitalizations and ED visits]). In a future report, we will estimate impacts on long-term outcomes over the full five years of the model.

A. Intermediate outcomes



Registry data

We estimated impacts on intermediate outcomes as the regression-adjusted differences in outcomes between the intervention and control group beneficiaries one year after they enrolled in the model. We included in analyses high-risk or high- and mediumrisk beneficiaries enrolled by the intervention and control organizations in 2017 and 2018 (<u>Appendix E</u>). Even before any adjustments, the intervention and control groups appeared very similar at baseline on CVD risk factors, demographics, and medication use (<u>Appendix F</u>). However, we adjusted for a range of baseline demographic, service use, clinical, and geographic characteristics (<u>Appendix G</u>) to increase the precision of

the estimates, and to account for small observed differences between the groups at baseline. The methods we used in this report are similar to those we used in the <u>Third Annual Report</u> (Blue et al. 2020). Compared to the <u>Third Annual Report</u>, we increased the analytic sample to include beneficiaries enrolled in 2018 and added measures of medication adherence.

1. Use of CVD medications

The Million Hearts Model is not prescriptive in how providers reduce beneficiaries' CVD risk, and there are many options—such as improvements in diet, exercise, or smoking cessation. However, increasing CVD medication use, including initiation, intensification, and better adherence, might be effective strategies for many high- and medium-risk beneficiaries. Because high- and medium-risk beneficiaries all had at least a 15 percent predicted risk of a CVD event (the cutoff for the medium-risk group), many could potentially benefit from statins or antihypertensives if they also had elevated LDL cholesterol or systolic blood pressure. Clinical guidelines recommend that people (ages 40 to 75) with elevated LDL (\geq 70 mg/dL) consider statins if they have a CVD risk score over 7.5 percent or have diabetes, and that people with elevated systolic blood pressure (\geq 130 mmHg) consider antihypertensive medications if their CVD risk score is over 10 percent (Grundy et al. 2018; Whelton et al. 2018; Arnett et al. 2019). Antihypertensives and statins, respectively, reduce blood pressure and LDL cholesterol by up to 25 percent on average, and can reduce CVD events by 15 to 25 percent (Karmali et al. 2016).



We assessed whether the Million Hearts Model increased the initiation and intensification of statins or antihypertensives, or adherence to these medications. We defined the study population as high- and medium-risk beneficiaries enrolled in 2017 or 2018 who had Part D coverage, enabling us to see medication use in claims, and were either (1) candidates for initiation or intensification of CVD medications because

they had elevated (\geq 130 mmHg) systolic blood pressure, elevated (\geq 70 mg/dL) LDL cholesterol, or both; or (2) were candidates for adherence improvement because they used CVD medications at baseline. About 70 percent of all high- and medium-risk beneficiaries in the model had Part D coverage. Of those with Part D coverage, 90 percent were eligible for the initiation or intensification analysis because they had elevated systolic blood pressure, LDL, or both—despite high use of CVD medications at baseline. In addition, 60 percent were eligible for the statin adherence analysis and 77 percent were eligible for antihypertensive adherence analysis because they took statins or antihypertensives, respectively, at baseline.

Initiation or intensification of CVD medications

The regression-adjusted probability of initiating or intensifying statins or antihypertensive medications within one year of enrollment was 3.4 percentage points higher in the intervention group than the control group: 31.3 percent in the intervention group compared to 27.9 percent in the control group (p < 0.001; Figure V.A.1). The impact estimates were modestly larger for high-risk beneficiaries (4.4 percentage points, 37.7 percent in the intervention group and 33.3 percent in the control group, p < 0.001; Figure V.A.1) than for the high- and medium-risk groups combined. These estimates are largely consistent with impact estimates we reported in the <u>Third Annual Report</u> (Blue et al. 2020), which, unlike this report, did not include beneficiaries enrolled in 2018.

Initiation or intensification outcome definitions

Initiation: Not taking a medication in the 4 months before enrollment, but taking one or more after enrollment.

Intensification of statin therapy: Moving to a statin at a higher intensity or dosage after enrollment.

Intensification of antihypertensive therapy: Adding a new antihypertensive medication or increasing the dosage or strength of an existing one after enrollment. **Figure V.A.1. The Million Hearts Model modestly increased the use of statins and antihypertensive medications:** Percentage of high- and medium-risk beneficiaries initiating or intensifying medications within a year of enrollment, by intervention group



Panel A: High- and medium-risk beneficiaries





Source: Regression-adjusted results from Medicare Part D claims linked to Medicare claims and enrollment data.

Note: Limited to enrollees with Part D coverage and blood pressure or cholesterol at baseline above levels for treatment with medications. Regression-adjusted means estimated using logistic regression. <u>Appendix G</u>, Table G.4 presents regression-adjusted means, impact estimates, and confidences intervals. Sample sizes are in Table G.3.

*** = *p* < 0.001.

Participating organizations are incentivized to reduce risk only among high-risk beneficiaries; however, the impact observed for medium- and high-risk beneficiaries combined is large enough to suggest there was a positive spillover in CVD care for medium-risk beneficiaries, not just high-risk beneficiaries. This positive spillover is potentially important because the medium-risk group is much larger (more than double in size) than the high-risk group. Similarly, these were consistent with findings from two robustness checks, increasing our confidence in them. Specifically, impacts were similar when (1) trimming the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries; and (2) using a higher blood pressure threshold to define candidates for potential antihypertensive medication initiation or intensification: systolic blood pressure greater than or equal to 140 mmHg instead of 130 mmHg. Detailed methods and results are in <u>Appendix G</u>.

In addition to using regressions to estimate impacts within a year of enrollment (the prespecified period for this impact analysis), we also looked at percentage of beneficiaries who had initiated or intensified medications throughout the full follow-up period to see when any differences between the two groups began and whether they persisted beyond a year (Appendix G, Figure G.1). Differences between the two groups emerged during the first year and persisted up to four years.

Adherence to CVD medications

The model did not measurably increase adherence to CVD medications among the subset of beneficiaries who used statins or antihypertensives at baseline (Figure V.A.2). For high- and medium-risk beneficiaries combined, the regression-adjusted percentage of beneficiaries with 80 percent or more days covered by statins in the first year after enrollment was similar for the intervention and control groups and the difference between the two groups did not differ statistically from zero (p =0.68). The percentage of beneficiaries with 80 percent or more days covered by antihypertensives was also similar in both groups (p = 0.63). We also found no statistically significant impacts for high-risk beneficiaries alone, or for the proportion of days covered (Appendix G, Table G.4). Given the rates of adherence at baseline (68 percent for statins and 83

Adherence outcome definitions

Proportion of days covered: Ratio between the number of days covered by CVD medication and total number of observable days in the first year of enrollment. We can consider a day to be covered if the beneficiary had one or more statins or antihypertensive drugs for that day based on the prescription fill data and days of supply (Nau 2011).

Adherent: Following other studies (Nau 2011 and Tamargo et al. 2019), we consider a beneficiary to be adherent to a medication if the proportion of days covered is 80 percent or higher in the first year of enrollment.

percent for antihypertensives for high- and medium-risk beneficiaries), the room for improvement in medication adherence might have been modest, especially for antihypertensives (Appendix F, Table F.3).

Figure V.A.2. The Million Hearts Model did not affect adherence to CVD medications: Percentage of high- and medium-risk beneficiaries adherent to medications within a year of enrollment, by intervention group







Source: Regression-adjusted results from Medicare Part D claims linked to Medicare claims and enrollment data.

Notes: Limited to enrollees with Part D coverage and CVD medication use at baseline. Regression-adjusted means estimated using logistic regression. No differences between the intervention and comparison groups were statistically significant at the *p* < 0.10 level. Appendix G, Table G.4 presents regression-adjusted means, impact estimates, and confidences intervals. Sample sizes are in Table G.3.
 We consider a beneficiary to be adherent to a medication if the proportion of days covered with the medication is 80 percent or higher in the first year of enrollment.

CVD = cardiovascular disease.

These estimated impacts on medication adherence were also largely consistent with findings from two robustness checks reported in <u>Appendix G</u>, increasing our confidence in the results. Specifically, impacts were similar after (1) trimming the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries; and (2) estimating impacts using beneficiaries we attributed, using claims data, to the intervention and control providers that participated in the model. However, in a few cases, the results for the attributed population indicate very small (0.2 to 0.3 percentage point) increases in adherence. As a result, our main conclusion of no measurable impacts on adherence might be slightly conservative, but not to an extent that is clinically meaningful.

2. CVD risk scores and their components



We estimated impacts on CVD risk scores—as measured using the Million Hearts Longitudinal ASCVD Risk Assessment Tool—and individual risk factors contributing to the score, including blood pressure and cholesterol, among high-risk beneficiaries who received an annual follow-up visit. Although conceptually we would also like to

estimate model impacts on risk scores for medium-risk beneficiaries (given the potential for positive spillover of model impacts for this group), we cannot estimate these impacts because

follow-up clinical data for medium-risk beneficiaries are not available. CMS required intervention organizations to submit reassessment data only for high-risk beneficiaries, the group for whom CMS makes risk reduction payments. We used follow-up visit data through December 2019, the last period during which the control group had to submit data to the Million Hearts Data Registry. We restricted the population to beneficiaries enrolled by October 31, 2018. These beneficiaries enrolled early enough in

Study population

Analyses of CVD risk scores and risk factors included 28,357 high-risk beneficiaries enrolled by the intervention and control organizations in 2017 through October 31, 2018, who received an annual follow-up visit.

2018 so their anniversary window for a reassessment visit (10 to 14 months after baseline) occurred by the end of 2019. Among this population, 51 percent of eligible intervention beneficiaries and 43 percent of eligible control beneficiaries received a follow-up visit by the end of 2019. Most of these visits occurred within 10 to 14 months after enrollment but could occur up to 21 months after enrollment. <u>Appendix E</u> describes the population used in this analysis in more detail. The intervention beneficiaries who did have reassessment data remained very similar to the control beneficiaries with reassessment data on a wide range of baseline characteristics, including demographics, CVD risk factors at enrollment, and recent service use and Medicare spending (<u>Appendix F</u>). We did not estimate impacts on risk scores beyond one-year of enrollment because the data were too incomplete for the second- and third-year reassessment visits to reliably estimate impacts.

CVD risk scores decreased in both the intervention and control group, but risk scores decreased by modestly more in the intervention group (8 percentage points) than the control group (7 percentage points). After regression adjustment, the intervention group had a 1.3 percentage point greater decrease in CVD risk scores than the control group (p = 0.003) (Table V.A.1). These estimates were similar to those reported in the <u>Third Annual Report</u> (Blue et al. 2020). Compared to the <u>Third Annual Report</u>, we extended the timeline to identify reassessment visits for an additional year (through the end of 2019) which added 5,219 beneficiaries to the study population and increased the sample size by 23 percent. The estimated impact of the intervention on CVD risk scores also remained similar in sensitivity analyses (<u>Appendix G</u>) that trimmed the sample to 20 or fewer providers per organization and restricted to beneficiaries who had reassessment data 10 to 14 months after enrollment.

Table V.A.1. CVD risk scores decreased more for the intervention group than for the control

group: Estimated impacts on CVD risk scores and risk factors one year after enrollment, among high-risk beneficiaries with reassessment data in 2017 through 2019

				Regression-adjusted difference at reassessment			
	Visit	Intervention group meanª	Control group meanª	Difference	p-value	90% confidence interval	Percentage impact
CVD risk score							
CVD risk score (in percentage points)	Enrollment	40	40				
	Reassessment	32	33	-1.3	0.003	[-2.0, -0.6]	-3.8%
Continuous risk f	factors						
Systolic blood pressure (in mmHg)	Enrollment	139	139				
	Reassessment	133	134	-1.7	0.002	[-2.6, -0.8]	-1.3%
Total cholesterol (in mg/dL)	Enrollment	167	169				
	Reassessment	162	163	-1.7	0.002	[-2.6, -0.8]	-1.0%
LDL cholesterol (in mg/dL)	Enrollment	91	91				
	Reassessment	87	88	-1.1	0.04	[-2.0, -0.2]	-1.3%
HDL cholesterol (in mg/dL)	Enrollment	47	48				
	Reassessment	47	47	-0.1	0.36	[-0.3, 0.1]	-0.2%
Binary risk factor	s						
Probability of smoking ^b	Enrollment	12	12				
	Reassessment	11	11	0.3	0.29	[-0.2, 0.9]	3.2%
Probability of using aspirin	Enrollment	51	48				
	Reassessment	65	56	9.5	0.005	[3.9, 15,1]	17.1%

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

Note: Table covers 18,110 beneficiaries enrolled in 125 intervention organizations and 10,247 beneficiaries enrolled in 110 control organizations. Mean values at enrollment are the actual means observed, and the means at reassessment and differences are regression adjusted. See <u>Appendix G</u> for more detail about the regression models. Percentage impacts are relative to the regression-adjusted control group mean at reassessment.

^a Means shown are unadjusted.

^b Smoking estimates exclude one control organization (n = 216 beneficiaries) with possible data quality issues. Excluding this organization from other analyses did not change estimates materially, so all other analyses include this organization.

CVD = cardiovascular disease; HDL = high-density lipoprotein; LDL = low-density lipoprotein; mg/dL = milligrams per deciliter; mmHg = millimeters of mercury.

Contributing to the impact on CVD risk scores were impacts on several of the individual factors that contribute to overall risk. That is, systolic blood pressure and LDL cholesterol declined in both the intervention and control groups, which drove reductions in CVD risk scores in both groups; however, the improvement in risk factors was greater in the intervention group than in the control group, which drove the difference in CVD risk reduction between the two groups. Specifically, systolic blood pressure decreased by 6 mmHg in the intervention group and 5 mmHg in the control group, with a regression-adjusted difference between the intervention and control groups of 1.7 mmHg, or 1.3 percent (p = 0.002; Table V.A.1). LDL cholesterol decreased by 4 mg/dL in the intervention group and 3 mg/dL in the control group, with a regression-adjusted difference between the intervention (p = 0.04). The intervention group also reported 10 percentage point greater aspirin use at reassessment than the control group (p = 0.005). We found no evidence of an impact on smoking rates.

The impacts observed on systolic blood pressure and LDL cholesterol (each about 1 percent) might not seem clinically relevant for an individual patient, especially given random fluctuations across measurements. However, we detected this relatively small impact by measuring change in the average systolic blood pressure or LDL cholesterol over a large population—18,000 people—and a change in the average systolic blood pressure or LDL cholesterol of this magnitude could, potentially, have meaningful impacts on CVD event rates. Based on the Million Hearts Longitudinal ASCVD Risk Assessment Tool, the predicted risk of having a heart attack or stroke over the next 10 years is 1.3 percentage points (or 3.8 percent) lower in the intervention versus the control group. If this reduction in predicted risk from the tool translated into reductions in eventual events, the 1.3 percentage point reduction would correspond to preventing one heart attack or stroke over the next 10 years for every 78 high-risk beneficiaries enrolled. The following limitations apply to these findings:

• First, as noted, this analysis does not capture all high-risk beneficiaries enrolled in the model, only those who had reassessment data recorded in the Million Hearts Data Registry. A substantial number of organizations withdrew from the model or stopped effectively participating by the end of 2019, so we do not have clinical data at reassessment for their beneficiaries. In addition, even at organizations submitting data to the registry, only about half of eligible high-risk beneficiaries returned to the provider for an annual office visit. We cannot observe how the risk scores changed for beneficiaries without recorded reassessment data, and whether this differed for the intervention and control groups. However, we found no notable differences in baseline characteristics between the intervention and control group beneficiaries with reassessment visits (Appendix F)).

- Second, CVD risk scores are based on clinical data that are subject to measurement error. Blood pressure in particular can fluctuate, and a single blood pressure measurement might not accurately reflect a person's true or typical blood pressure—for example, if the patient feels anxious or the blood pressure cuff is positioned incorrectly. Measurement error could lead to bias in the impact estimates if measurement error differs between the intervention and control groups—for example, if the intervention group measured blood pressure more accurately than the control group or tended to have more recent cholesterol measurements in the medical record than the control group. We have no evidence about measurement error for blood pressure. However, we could estimate the proportion of beneficiaries with updated cholesterol readings at reassessment,¹¹ and found higher rates (93 percent) for intervention than control beneficiaries (76 percent). This suggests data quality could be higher for the intervention group than the control group.
- Third, we estimated impacts on predicted CVD risk using the Million Hearts Longitudinal ASCVD Risk Assessment Tool, but reductions in predicted risk might not translate into actual CVD events prevented. The Tool was built specifically for the Million Hearts Model and is used (1) at the point of care to assess beneficiaries' risk reduction and (2) to calculate model payments. The tool is based on evidence from randomized controlled trials about the effectiveness of CVD treatment and risk factor changes (Lloyd-Jones et al. 2017). However, any predictive tool relies on some assumptions. If the Million Hearts Model beneficiaries differ substantially from the clinical trial participants used to create the risk assessment tool, then the true effect on heart attacks and strokes could differ from the one event per 78 beneficiaries implied by the intervention–control group difference in the 10-year risk scores.. In the next section, we estimate impacts on the incidence of CVD events directly.

¹¹ We estimated the proportion of beneficiaries with updated cholesterol readings at reassessment as one minus the proportion of beneficiaries who had identical values in the Million Hearts Data Registry for all three measures of cholesterol—high-density lipoprotein, LDL, and total cholesterol— at enrollment and reassessment. The registry reports cholesterol values as whole numbers, so we cannot tell if values differed out to a decimal place.

B. Long-term outcomes



This section describes our estimates of the model impacts on long-term outcomes, including first-time CVD events, CVD-specific and overall service use (hospitalizations and ED visits), Medicare spending, and mortality, over about four years. We estimated impacts as the regression-adjusted differences in outcomes for

high- and medium-risk beneficiaries enrolled by the intervention and control organizations in 2017 and 2018. The regressions adjusted for beneficiaries' characteristics at enrollment to increase the precision of the estimates and to account for observed differences between the groups. The analysis followed each beneficiary from the date he or she enrolled in the model through December 31, 2020, or until death or loss of observability in Medicare claims. Follow-up lengths ranged from one day to just under 48 months across beneficiaries, with a median of 40.4 months. We did not include beneficiaries enrolled in 2019 or 2020 due to concerns that the significant additional attrition in 2019 and 2020 (Chapter II) could lead to unobserved differences between the intervention and control groups that could bias estimates of model impacts (further, the control group stopped enrolling beneficiaries at the end of 2019). Most intervention group beneficiaries enrolled in the model (85 percent) in 2017 and 2018. Appendices E, F, and G provide details on the methods and results for the impact estimates.

These methods for estimating impacts are the same as those used in the <u>Third Annual Report</u> (Blue et al. 2020), but with an extended outcome period. Compared to the <u>Third Annual Report</u>, we extended the outcome measurement period by 14 months (from October 31, 2019, to December 31, 2020),¹² so the evaluation now covers four years (2017 through 2020). The median follow-up length for CVD events for individual beneficiaries increased by 52 percent from 26.6 to 40.4 months. Extending the outcome period is critical because CMS initially hypothesized this model would take up to five years to have a 7 percent impact on firsttime heart attacks and strokes. Future analyses that cover five years will fully test this primary hypothesis.

Study population

Analyses of long-term outcomes included 218,929 high- and mediumrisk beneficiaries enrolled by the intervention and control organizations in 2017 and 2018, with more beneficiaries (N = 130,622) in the intervention group than the control group (N = 88,307) due mainly to the 20-provider cap that applied only to control organizations.

¹² In 2020, effects of COVID-19 could have led to bias in our impact estimates if COVID-19 drove differences in outcomes between the intervention and control groups that are unrelated to the model. Although COVID-19 substantially changed service use and spending patterns, changes were similar for both the intervention and control groups, suggesting little risk of bias due to COVID-19. <u>Appendix A</u> provides a detailed description of our methods and findings.

1. Heart attacks and strokes

The model did not measurably reduce the incidence of first-time heart attacks, strokes, or TIAs (a composite measure of CVD events) through December 2020. The probability of a CVD event was similar for the intervention and control group beneficiaries in regression analyses (Figure V.B.1). For example, in both the intervention and control groups, 4.0 percent of high- and medium-risk beneficiaries had a first-time heart attack, stroke, or TIA within three years of enrollment. Among the high-risk group only, 5.2 versus 5.4 percent of intervention and control group beneficiaries had a first-time CVD event within three years, a difference of less than two events per 1,000 people. In a different type of regression analysis that takes into account the time to a CVD event, the hazard ratio—that is, the ratio in the risk of having a first-time CVD event in the intervention group among high- and medium risk beneficiaries combined and among high-risk beneficiaries alone (Table V.B.1). However, this difference was not statistically significantly different from 1, indicating no detectable model effect on this outcome.

Figure V.B.1. The model had no detectable impact on the percentage of beneficiaries with firsttime heart attacks, strokes, or TIAs within 3 years of enrollment: Estimated percentage of intervention and control beneficiaries with first-time heart attacks, strokes, or TIAs within 1, 2, or 3 years after enrollment (regression-adjusted)



Source: Regression-adjusted results from Medicare claims.

Note: For each year, the analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled in December 2021. We performed regression adjustment using logistic regression models. No differences between the intervention and comparison groups were statistically significant at the p < 0.10 level. <u>Appendix G</u>, Table G.15 presents regression-adjusted means, impact estimates, and confidences intervals. Sample sizes are in Table G.3.

Before controlling for differences between the intervention and control groups in regression analyses, the unadjusted hazard ratio (0.92) suggested larger reductions in first-time CVD events for the intervention group (Table G.10). Although the participants in the intervention and control groups were randomly assigned, not all organizations actively participated by enrolling beneficiaries in the model during 2017 and 2018, leading to some differences between intervention and control group enrolled beneficiaries (<u>Chapter II</u>). For example, intervention beneficiaries included in the analysis were more likely than control group beneficiaries to live in the Eastern portion of the United States where rates of CVD events tend to be lower. Controlling for baseline characteristics (including but not limited to region and regional characteristics) led to adjusted estimates closer to no effect (a hazard ratio of 1.00). The difference between the unadjusted and adjusted impact estimates suggests intervention beneficiaries should have better outcomes than control beneficiaries even if the model had no effect, and the regression modeling is an important component of our analytic approach.

We found no statistically significant differences between the intervention and control groups for the individual components of the composite measure of CVD events: (first-time heart attacks and first-time strokes and TIAs (Table V.B.1). The estimates also are consistent with results from a series of robustness checks, reported in <u>Appendix G</u>: (1) narrowing the outcome definition to include only Type 1 heart attacks and strokes;¹³ (2) trimming the intervention group so that, as in the control group, a maximum of 20 providers per organization could enroll beneficiaries; and (3) estimating impacts using beneficiaries we attributed, using claims data, to the intervention and control providers that participated in the model. This consistency increases our confidence in the results.

¹³ This exclusion (1) limits to heart attacks most likely caused by blockages in the arteries supplying the heart (Thygesen et al. 2018), and which we might expect the intervention to most influence (in contrast to other types of acute myocardial infarctions, such as those that occur during surgeries, which primary CVD prevention might affect less); and (2) removes TIAs, which are less severe than strokes and less reliably identified using claims data.

Table V.B.1. The model had no detectable impact on the incidence of first-time heart attacks, strokes, or TIAs: Estimated ratio of the hazard of first-time heart attacks, strokes, or TIAs between intervention and control beneficiaries (regression-adjusted)

	Regression-adjusted hazard ratio					
Outcome and risk group	Ratio	<i>p</i> -value	90% confidence interval			
First-time heart attacks, strokes, or TIAs (composite measure) ^a						
High- and medium-risk beneficiaries	0.97	0.20	[0.93, 1.01]			
High-risk beneficiaries	0.97	0.37	[0.92, 1.02]			
First-time heart attacks						
High- and medium-risk beneficiaries	0.97	0.52	[0.91, 1.04]			
High-risk beneficiaries	0.98	0.64	[0.90, 1.06]			
First-time strokes or TIAs						
High- and medium-risk beneficiaries	0.97	0.27	[0.92, 1.02]			
High-risk beneficiaries	0.99	0.75	[0.92, 1.05]			

Source: Regression-adjusted results from Medicare claims.

Note: Table covers 130,622 beneficiaries enrolled in 172 intervention organizations and 88,307 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,442 beneficiaries enrolled in 170 intervention organizations and 27,283 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores of 30 percent or higher.

^a Heart attacks, 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. Appendix C of the <u>Second Annual Report</u> (Peterson et al. 2019) describes the outcomes in detail. For heart attacks, we include all five types of acute myocardial infarctions described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

CVD = cardiovascular disease; ED = emergency department; TIA = transient ischemic attack.

2. Hospitalizations and outpatient ED visits

We hypothesized 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, and for other conditions such as angina, which better management of CVD risk factors might also reduce. By extension, we hypothesized the model could reduce rates of all-cause hospitalizations and outpatient ED visits as well (as secondary outcomes). Counter to our hypothesis, our findings suggest higher rates of all-cause hospitalizations and outpatient ED visits in the intervention group, a finding we also reported in the <u>Third Annual Report</u> (Blue et al. 2020).

Focusing first on CVD-related acute care, the CVD-related hospitalization and outpatient ED visit rates for the combined high- and medium-risk groups was similar between the intervention and control groups (Table V.B.2). For example, through December 2020, there were 13.8 CVD-related hospitalizations per 1,000 beneficiaries per quarter in the intervention group, compared to a rate of 13.6 for the control group (p = 0.48). In the high-risk group, rates of CVD-related

hospitalization and outpatient ED visits were modestly (4.3 to 5.3 percent) higher in the intervention versus control groups, but these differences were not statistically significant (p = 0.11 and p = 0.22). CVD-related admissions and ED visits account for 22 and 8 percent of all hospitalizations and ED visits, respectively, for the high- and medium-risk beneficiaries.

Turning to model impacts on beneficiaries' use of acute care for any reason (not only CVDrelated care), the model appears to have increased all-cause admissions and ED visits, both for the high- and medium-risk beneficiaries combined and only the high-risk beneficiaries (Table V.B.2). Specifically, the average number of all-cause admissions increased among the intervention group by 3.8 percent for the high- and medium-risk beneficiaries combined and 4.6 percent for the high-risk beneficiaries, relative to their respective control beneficiaries. The average number of all-cause outpatient ED visits and observation stays increased by 2.9 percent for the high- and medium-risk beneficiaries combined and 4.2 percent for the high-risk beneficiaries, relative to the control group. All these differences in all-cause service use were statistically significant at the p < 0.05 level. Results were largely similar in the robustness checks using data trimmed to include no more than 20 providers per organization and using the population attributed to participating providers based on claims data.

In combination, the results for CVD-specific and all-cause acute care use indicate the model increased acute care that was not specific to CVD. The estimates for model impacts on all-cause acute care (inpatient stays and ED visits) were substantially larger in absolute terms than the intervention–control differences for CVD-specific acute care. The intervention-control differences for CVD-specific acute care were not statistically significant, though this might have been due to relatively low statistical power to detect effects. In relative terms, the percentage impact implied by the points estimates for CVD-specific acute care (also 4 to 5 percent). However, because CVD-specific acute care is only a small fraction of all acute care use in this population, the absolute impact estimates are much larger for all-cause acute care than CVD-specific acute care. For example, the model increased all-cause admissions for high-risk beneficiaries by an estimated 3.38 per 1,000 beneficiaries per year, more than four times the intervention–control difference for CVD-specific hospitalizations of 0.78.

The finding that the Million Hearts Model modestly increased acute care service use is counter to our hypotheses that the model might reduce acute care. This finding implies some other factor, which we did not hypothesize, explains why the model might have increased acute care use. For example, the model might have prompted beneficiaries to become more generally aware of their health risks, and more likely to seek medical care in the outpatient and inpatient settings. This would also be consistent with the finding from the <u>Third Annual Report</u> that the model increased the number of office visits with any type of provider by about 1 to 2 percent among medium- and high-risk beneficiaries (Blue et al. 2020). However, we cannot rule out the possibility that the estimated impacts are spurious, meaning some factor other than the Million Hearts Model made the intervention group systematically more likely than the control group to use acute care services.

Table V.B.2. Rates of all-cause service use were higher in the intervention group: Estimated impacts on the number of inpatient admissions and outpatient ED visits and observation stays (number per 1,000 beneficiaries per quarter)

	Re (#/1,0	gression-adjusted)00 beneficiaries/q		90%			
Outcome and risk group	Intervention group mean	Control group mean	Difference (%)	<i>p</i> -value	confidence interval		
Number of CVD-related							
High- and medium-risk beneficiaries	13.8	13.6	0.20 (1.5%)	0.48	[-0.3, 0.7]		
High-risk beneficiaries	18.7	17.9	0.78 (4.3%)	0.11	[-0.0, 1.6]		
Number of CVD-related outpatient ED visits and observation stays							
High- and medium-risk beneficiaries	8.0	7.8	0.11 (1.4%)	0.70	[-0.4, 0.6]		
High-risk beneficiaries	9.7	9.2	0.49 (5.3%)	0.22	[-0.2, 1.1]		
Number of all-cause admissions							
High- and medium-risk beneficiaries	63.5	61.2	2.32 (3.8%)	0.007	[0.9, 3.7]		
High-risk beneficiaries	76.4	73.0	3.38 (4.6%)	0.02	[1.0, 5.8]		
Number of all-cause outpatient ED visits and observation stays							
High- and medium-risk beneficiaries	97.7	94.9	2.80 (2.9%)	0.08	[0.2, 5.4]		
High-risk beneficiaries	106.6	102.3	4.27 (4.2%)	0.02	[1.2, 7.4]		

Source: Regression-adjusted results from Medicare claims data.

Note: The table covers 130,622 beneficiaries enrolled in 172 intervention organizations and 88,307 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,442 beneficiaries enrolled in 170 intervention organizations and 27,283 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores of 30 percent or higher. 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 beneficiaries observed in that quarter. Percentage impacts are relative to the regression-adjusted control group mean.

CVD = cardiovascular disease; ED = emergency department.

3. Medicare spending

The model did not measurably reduce Medicare Parts A and B spending (Table V.B.3). For highand medium-risk beneficiaries combined, the intervention group's regression-adjusted mean spending was similar to the control group's mean, and the difference between the two groups through December 2020 was not statistically different from zero (p = 0.81). Mean spending for high-risk beneficiaries in the intervention group was also similar to the mean spending observed for the control group, and the estimated difference was not statistically significant (p = 0.33). 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 V.B.2). Results from these analyses were largely similar to the results from our robustness checks (Appendix G), increasing our confidence in the findings.



Because the model did not measurably reduce Medicare Parts A and B spending, it did not generate any savings to offset CMS's Million Hearts Model payments. CMS paid the intervention organizations roughly \$7.1 million in the first four years for beneficiaries enrolled in 2017 and 2018, or about \$1.52 per beneficiary per month

among the intervention group's high- and medium-risk beneficiaries enrolled through December 2018. When we factor in these small average Medicare model payments (fourth row of Table V.B.3), there remains no statistically significant difference in spending between the intervention and control groups (p = 0.71).¹⁴

	Regree (\$	ssion-adjusted s i/beneficiary/mor		00%	
	Intervention group mean	Control group mean	Difference (%)	<i>p</i> -value	confidence interval
High- and medium-risk bene					
Parts A and B spending	\$ 921	\$ 918	\$ 3 (0.3%)	0.81	[-17, 22]
Inpatient spending	\$ 312	\$ 306	\$6 (2.1%)	0.36	[-5, 18]
Other spending	\$ 609	\$ 612	\$ -4 (-0.6%)	0.58	[-14, 7]
Parts A and B spending plus model payments ^a	\$922	\$918	\$4 (0.5%)	0.71	[-15, 24]
High-risk beneficiaries					
Parts A and B spending	\$ 1,057	\$ 1,040	\$ 17 (1.6%)	0.33	[-12, 46]
Inpatient spending	\$ 376	\$ 362	\$ 14 (3.8%)	0.20	[-4, 32]
Other spending	\$ 681	\$ 678	\$ 3 (0.4%)	0.75	[-13, 19]

 Table V.B.3. So far, the model has not reduced Medicare Parts A and B spending: Estimated impacts on Medicare spending (dollars per beneficiary per month)

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

Note: The table covers 130,622 beneficiaries enrolled in 172 intervention organizations and 88,307 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,442 beneficiaries enrolled in 170 intervention organizations and 27,283 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores of 30 percent or higher. The sum of 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 beneficiaries observed in that quarter. Percentage impacts are relative to the regression-adjusted control group mean.

^a Total Million Hearts Model payments to intervention group organizations included in the impact evaluation for the first eight performance periods were \$7,097,000. We divided this amount by the number of beneficiary-quarters represented among the medium- and high-risk beneficiaries enrolled through December 2018.

CVD = cardiovascular disease.

¹⁴ We assess the model's impact on net spending for high- and medium-risk beneficiaries combined, and not for the high-risk beneficiaries only, because CMS intended the Million Hearts Model to be cost-neutral only over the larger population.

Figure V.B.2. Spending was similar between the intervention and control groups across quarters: 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 Parts A and B claims.

PBPM = per beneficiary per month.

The finding that the Million Hearts Model did not decrease Medicare spending is counter to our original hypothesis that the model might reduce Medicare Parts A and B spending enough to fully offset model payments. These results are consistent with the lack of observed reductions in rates of CVD events or CVD-related hospitalizations, the hypothesized mechanisms for lower spending discussed previously. The small increases in spending we would expect from the modest increases in hospitalizations (discussed in the previous section) are well within the margin of error of our estimates of the model's overall effects on spending. The estimated impact on Medicare Parts A and B spending does not include the cost of Part D prescription drugs.

4. All-cause mortality

Fewer high- and medium-risk beneficiaries in the intervention group died than in the control group (Figure V.B.3). In the intervention group, 6.6 percent of beneficiaries died within three years of enrollment, compared to 6.9 percent for the control group—a difference of about 2.8 deaths per 1,000 people over three years (a 4.0 percent difference). The estimated hazard ratio was 0.95, a difference that is statistically significant (p = 0.02) (Table V.B.4). This finding is consistent with earlier findings and the results from several robustness checks (Appendix G).


Figure V.B.3. A smaller percentage of high- and medium-risk beneficiaries in the intervention group died within three years of enrollment: Estimated percentage of intervention and control who died within 1, 2, or 3 years after enrollment (regression-adjusted)

Source: Regression-adjusted results from Medicare claims and enrollment data.

Note: For each year, the analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled in December 2020. We performed regression adjustment using logistic regression models. For the high- and medium-risk groups combined, but not the high-risk groups (alone), the differences between the intervention and comparison groups were statistically significant at the p < 0.10 level. Appendix G, Table G.15 presents regression-adjusted means, impact estimates, and confidences intervals. Sample sizes are in Table G.3.

/* Significantly different from zero at the 0.05/0.01 levels, two-tailed test.

Medium-risk beneficiaries appear to drive the reduction in mortality. For high-risk beneficiaries, the rates of death were similar between the intervention and control groups (Figure V.B.3). The regression-adjusted percentage of beneficiaries who died within three years of enrollment was 8.8 for the intervention group and 8.7 percent for the control group. The estimated hazard ratio was 1.01 (Table V.B.4), indicating no measurable impact of the intervention on mortality for high-risk beneficiaries. This impact estimate, too, was consistent with a number of robustness checks, including trimming the population to no more than 20 providers per organization. Analyses of the medium-risk-only population suggest larger declines than for the high-risk-only population (Table V.B.4)—about 4.5 fewer deaths per 1,000 beneficiaries over three years (Table G.16).

Table V.B.4. High- and medium-risk beneficiaries in the intervention group had a lower death ratethan those in the control group:Estimated ratio of the hazard of dying (for any reason) betweenintervention and control beneficiaries (regression adjusted)

	Regression-adjusted hazard ratio of dying			
Risk group	Hazard ratio	<i>p</i> -value	90% confidence interval	
High- and medium-risk beneficiaries	0.95	0.02	[0.92, 0.99]	
High-risk beneficiaries	1.01	0.65	[0.97, 1.06]	
Medium-risk beneficiaries	0.91	<0.001	[0.87, 0.95]	

Source: Regression-adjusted results from Medicare enrollment data.

Note: The table covers 130,622 beneficiaries enrolled in 172 intervention organizations and 88,307 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,442 beneficiaries enrolled in 170 intervention organizations and 27,283 beneficiaries enrolled in 165 control organizations with baseline cardiovascular disease risk scores of 30 percent or higher. Analyses of medium-risk beneficiaries are limited to 90,180 beneficiaries enrolled in 169 intervention organizations and 61,024 beneficiaries enrolled in 167 control organizations with baseline CVD risk scores of at least 15 percent but less than 30 percent.

CVD = cardiovascular disease.

The observed impacts on all-cause mortality are surprising. The impacts occurred without a corresponding large reduction in CVD events, when we expected reductions in fatal heart attacks or strokes would, at least partly, drive any impacts on survival. At least two potential explanations for early impacts on survival 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 have missed some true model impacts on fatal heart attacks or strokes for which patients were pronounced dead outside the hospital setting.¹⁵ This could occur if the model prompted beneficiaries to go to the hospital at early signs of a CVD event that might otherwise prove fatal. Even more deaths outside a hospital setting could have been missed during the early months of the COVID-19 pandemic in 2020 when avoidance of care led to large (almost 50 percent) declines in hospitalizations for heart attacks and strokes (Solomon et al. 2020; Baum and Schwartz 2020). Second, there could be reductions in mortality from other conditions due to improvement in exercise or diet, medication therapy, medical treatment, or other mechanisms we did not anticipate at the beginning of the evaluation. This second mechanism would be consistent with the general increase in medical care we observed in the intervention group, as evidenced by increases in all-cause office visits (Blue et al. 2020), inpatient stays, and outpatient ED visits.

¹⁵ Record linkage in Sweden found three in four fatalities related to first-time major coronary events occurred out of the hospital, and the remaining one in four occurred in a hospital (Dudas et al. 2011). Similarly, a 2002 Centers for Disease Control and Prevention report found about half of fatal cardiac events in the United States occurred outside the hospital (Zheng et al. 2002). If this pattern is similar among Million Hearts Model beneficiaries, a substantial fraction of the fatal CVD events might not be coded as first-time heart attacks, strokes, or TIAs in claims data.

However, the impact estimates could also reflect bias and not true impacts. Our careful use of regression adjustment and our robustness checks alleviates—but does not rule out—concerns that differences between the intervention and control organizations potentially biased the impact estimates. Such differences could have either existed at random assignment or been introduced during model implementation by organization- and provider-level attrition or by differences in the types of beneficiaries who intervention and control organizations chose to enroll among their eligible beneficiaries. The robustness checks using the claims-based attribution population sought to limit the potential for this last source of bias; in that check, the hazard ratio for high-and medium-risk attributed beneficiaries fell between our main estimate of 0.95 (our main estimate) and 1.0 (no effect), with more statistical imprecision.

VI. Discussion

In its first four years, the Million Hearts Model improved cardiovascular preventive care, including risk assessment, and reduced CVD risk. However, the model did not measurably reduce the rate of first-time heart attacks and strokes. Although the COVID-19 pandemic caused substantial changes to model implementation in 2020 and early 2021, these findings about the model's overall impacts are largely consistent with those from the <u>Third Annual Report</u>, which covered results through the model's first three years (Blue et al. 2020).

Our evaluation has many strengths. The Million Hearts Model is a large-scale test, with a diverse set of health care provider organizations as participants, and hundreds of thousands of enrolled beneficiaries. Our mixed-methods approach provides rich data, both qualitative and quantitative, about the changes participating organizations made in response to the model, motivation for those changes, and effects on beneficiaries' outcomes. Use of Medicare claims data for most evaluation outcomes means we can observe outcomes of enrolled beneficiaries, even if the participating organizations exit the model. The randomized design helps to ensure unbiased impact estimates.

Nevertheless, our evaluation does have limitations. Chief among them is the high rate of attrition. This creates the possibility of systematic differences between the evaluation's intervention and control groups used to estimate impacts, despite the initial random assignment. Only about two-thirds of the organizations assigned to the intervention or control groups ever enrolled a beneficiary (345 of 516 organizations). Moreover, participating organizations enrolled only about half of the beneficiaries who appeared eligible for the model according to claims data (Blue et al. 2020), and provided annual reassessment data one year post-enrollment for only about half again of eligible high-risk beneficiaries. Incomplete data are particularly a problem for the analysis of impacts on changes in CVD risk scores and risk factors, which requires both enrollment and reassessment data. Nevertheless, for all analyses, we found the intervention and control group beneficiaries were similar to each other at enrollment on a range of demographic, clinical, and regional characteristics, despite the potential for differences to have emerged due to attrition and incomplete data reporting after random assignment. Some notable differences exist, however, with intervention group beneficiaries more likely than those in the control to be enrolled by larger organizations and by organizations in the South, for example (Appendix F). We attempted to guard against potential bias through regression adjustment. We also used a series of robustness checks to test the sensitivity of results to the definition of the study population, including by estimating impacts for claims-based outcomes among all beneficiaries attributed to Million Hearts Model organizations (that is, all beneficiaries who appeared eligible for the model, whether or not they enrolled; see Appendix G).

A. Incorporating current findings into the causal pathway of the Million Hearts Model evaluation

Figure VI.1 summarizes our understanding of the causal pathway for the Million Hearts Model as of early 2021, incorporating the new findings in this report with those from previous reports. We discuss the findings in detail after the figure.



Figure VI.1. Causal pathway for the Million Hearts Model, with key findings through early 2021

^a The 2018 rate is lower than reported in Chapter I (Figure I.B.1) because the Chapter I number represents results from a provider survey fielded in 2018, whereas the current numbers are from practice surveys in 2018 and 2021. The 2018 practice survey rate (61 percent) is lower than the 2018 provider survey rate (71 percent) in large part because a larger proportion of the practice survey respondents answered "Don't know" to the questions about risk assessment. In this chapter, we report numbers from the practice surveys rather than provider surveys because we did not field a provider survey in 2021.

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

Step 1: CMS provided financial incentives and a range of supports to encourage CVD risk assessment and risk reduction. As shown Figure VI.1 and reported in <u>Chapter III</u>, from January 2017 to December 2020, CMS paid \$7.6 million to intervention organizations participating in the Million Hearts Model. For these organizations, this represents a median payment per performance period (every six months) of \$660 to \$4,005. These payments are small relative to the cost of, say, hiring new staff, and suggest model participants largely relied on existing staff and processes to implement the model requirements—a finding supported by interviews.

The model payments include incentives to organizations that succeed in reducing their high-risk beneficiaries' average CVD risk scores—and most participating organizations earned these risk-reduction incentive payments. However, the proportion of organizations earning any incentive payments (either \$5 PBPM or \$10 PBPM, depending on risk reduction achieved) decreased over time: from 94 percent of organizations submitting reassessment data for performance period 3 (the first half of 2018) to 68 percent for performance period 8 (the second half of 2020). This decline in the proportion receiving incentive payments likely reflects that payments depend on beneficiaries' changes in risk score *since enrollment*. As time passes, the enrolled beneficiaries get older, and some might develop diabetes, so their risk scores rise even if other modifiable risk factors—such as blood pressure, lipid levels, and smoking—are well managed. Declines over time in incentive payments for risk reduction help to explain the overall decline in model payments over time.

CMS offered the Million Hearts Model participating organizations a number of tools and supports in addition to payments. As noted in earlier reports (Conwell et al. 2019; Peterson et al. 2019; Blue et al. 2020), participants varied in their perceptions and use of these tools and supports. The tools and supports include peer-to-peer learning opportunities, performance feedback reports, a data registry, and a novel risk calculator developed for the Million Hearts Model. Most participants we surveyed in 2021 said they found the Million Hearts Model learning events useful. Roughly one-third, however, reported challenges entering data into the Million Hearts Data Registry—although interviews suggest participants experienced less difficulty with the registry than in the early years of the model.

Step 2: Participating organizations substantially improved their rates of risk assessment, and reported greater awareness of CVD risk. Together, the CMS incentives, tools, and supports—along with model participants' commitment to the model's vision of care—seem to have prompted large gains in CVD risk assessment and awareness. For example, in our 2021 practice survey, respondents at 46 percent of intervention organizations reported risk stratifying most of their Medicare beneficiaries. This was lower than in 2018 (when 61 percent reported risk

stratifying most beneficiaries),¹⁶ and lower than CMS initially intended, when it set a model requirement of near-universal risk stratification. Nevertheless, risk stratification still appeared much more common among the intervention group organizations in 2021 than it had been before the model began; only 14 percent reported risk stratifying at least half their beneficiaries in 2016. As noted in the <u>Third Annual Report</u> (Blue et al. 2020), reported rates of risk stratification were also substantially higher in the intervention group than in the control group.

Starting in March of 2020, the COVID-19 pandemic posed a major barrier to CVD risk assessment, as providers and beneficiaries avoided face-to-face office visits, especially in the second quarter of 2020. Office visit rates largely rebounded by the end of the calendar year. By early 2021, 53 percent of the practice survey respondents at intervention group organizations reported they recalculated risk at least annually for at least half of their high-risk beneficiaries. This is consistent with model registry data for beneficiaries enrolled in 2017 or 2018, showing a 56 percent reassessment rate one year post-enrollment—that is, before the COVID-19 pandemic began. This, and other findings, suggest the pandemic exacerbated declines in risk assessment (including reassessment) from their peak in the early years in the model. However, even before the pandemic, rates of risk assessment declined as participating organizations cited insufficient staff time and competing organizational priorities as barriers to fulfilling the model requirements.

The causal pathway of our evaluation hypothesizes risk assessment will lead to greater awareness among providers of beneficiaries' CVD risk and, in turn, better preventive care. Although rates of risk assessment declined overall from 2018 to 2021, survey respondents and providers we interviewed in 2021 said CVD risk scores continued to help them identify patients at elevated risk of a heart attack or stroke. In addition, interviews with high-performing organizations (Chapter IV) suggest an increase in a *single* provider's awareness of beneficiaries' modifiable risk might not yield the greatest possible CVD risk reduction, on average, among that provider's patients. Instead, organizations that facilitate more proactive communication across providers and/or use the risk score information across a broader care team might achieve greater average risk reduction.

Step 3: Clinical care improved, especially use of CVD preventive medications. As noted in the <u>Third Annual Report</u> (Blue et al. 2020), providers credited the Million Hearts Model with increasing their use of CVD risk scores to guide discussions with beneficiaries and informing their treatment recommendations. The model also prompted moderate increases, according to a survey of model providers, in the frequency of follow-up with high-risk beneficiaries (through any mode) to monitor CVD risk, and small increases (of 1 to 2 percent) in the frequency of any type of office visits, relative to the control group (Blue et al. 2020). But perhaps the most notable

¹⁶ The 2018 rate is lower than reported in <u>Chapter I</u> (Figure I.B.1) because the Chapter I number represents results from a *provider* survey fielded in 2018, whereas the current numbers are from *practice* surveys in 2018 and 2021. The 2018 practice survey rate (61 percent) is lower than the 2018 provider survey rate (71 percent) in large part because a larger proportion of the practice survey respondents answered "Don't know" to the questions about risk assessment. In this chapter, we report numbers from the practice surveys rather than provider surveys because we did not field a provider survey in 2021.

improvement in clinical care, observed both this year and in previous reports (Peterson et al. 2019, Blue et al. 2020), was in use of CVD preventive medications. As shown in <u>Chapter V</u> of this report, across both the intervention and control groups, more than 25 percent of high- and medium-risk beneficiaries initiated or intensified statins or antihypertensives within 12 months of enrollment. However, these rates were higher in the intervention group (31 versus 28 percent), representing a roughly 3 percentage-point (or 12 percent) impact of the model. We found no meaningful impact on adherence to antihypertensives or statins among beneficiaries who took these medications before enrollment in the Million Hearts Model, but adherence to these medications was already fairly high at baseline.

It is striking we see effects on medication use not only among high-risk beneficiaries, but also among the much larger combined high- and medium-risk population. CMS did not pay intervention group organizations to provide cardiovascular care management to medium-risk beneficiaries and did not provide incentive payments for risk reduction among this group. Yet the estimated impact is only modestly smaller for the combined high- and medium-risk population (3.4 percentage points) than it is for the high-risk group alone (4.3 percentage points). This is true even though the combined population is more than three times the size of the highrisk population alone. This finding suggests substantial spillover of the Million Hearts Model from the high-risk beneficiaries targeted by the model requirements and incentives to the broader patient population.

Spillover of model impacts on medication use to the medium-risk population is likely the result of widespread CVD risk assessment—one model requirement that did apply to all Medicare FFS beneficiaries. The model encourages routine use of CVD risk scores, which represent people's predicted probability of experiencing a heart attack or stroke over 10 years. Although the cut-off for the high-risk group is 30 percent, someone with a risk score of 25 percent—considered medium risk under the Million Hearts Model—might still be more willing to act after hearing her risk. Providers, too, might be more willing to act. Clinical guidelines for cholesterol management (Grundy et al. 2018), blood pressure management (Carey and Whelton 2018), and aspirin use for CVD primary prevention (Arnett et al. 2019) all recommend considering therapy at CVD risk scores well below the threshold CMS used to define medium risk. As a result, some medium-risk beneficiaries would likely have received intensified therapy to reduce their CVD risk, after the score was calculated, even though they were not covered by many of the model requirements and payments, for high-risk beneficiaries only.

In our interviews with high- and lower-performing intervention group organizations in 2021, we found high performers were less likely to cite patients' compliance as a barrier to model performance reducing CVD risk than lower-performing organizations with similar organizational characteristics. This highlights the potential importance of providers' beliefs about their patients in improving clinical care. (For example, providers who think their patients will, or could be encouraged to, adhere to treatment recommendations might be more likely to recommend new treatments. Conversely, providers whose patients face persistent barriers to following a treatment

regimen might have fewer opportunities to improve CVD risk.) High-performing organizations were also more likely to report having a motivated and engaged champion for the model.

Step 4: CVD risk scores fell substantially one year after enrollment—but the improvement was only modestly better than observed in the control group. Among the roughly one-half of high-risk beneficiaries with reassessment data one year after enrollment, average CVD risk scores fell by 8 percentage points (20 percent) in the intervention group between enrollment and the one-year reassessment, and by 7 percentage points in the control group. When we compared the reduction in CVD risk scores between the intervention and control groups, the adjusted difference represented a 1.3-percentage-point (or 3.8 percent) impact of the Million Hearts Model. Small reductions, relative to the control group, in systolic blood pressure and LDL cholesterol (of about 1 percent each) and a large increase in aspirin use (of 9.5 percentage points, or 17 percent), relative to the control group, drove this modest impact on risk scores. We found no impact on smoking rates.

Effects of this magnitude are potentially meaningful at the population level. That is, an individual might not care too much about a 1 percent decline in blood pressure, or a 1 percentage point decline in the 10-year risk of a heart attack or stroke. But multiplied across the entire population of Million Hearts Model beneficiaries, even these small effects would imply a nontrivial reduction in CVD events overall.

We have estimated impacts on risk scores only through one year post-enrollment, mostly due to limited data for the control group beyond one year. However, we have information about typical risk-score trajectories over *three* years within the intervention group (Chapter IV). Based on these data, it seems the greatest CVD risk reduction usually occurred within roughly one year of a beneficiary's enrollment in the Million Hearts Model, with more limited or no improvements in risk factors or risk scores after that, on average. (With the data available, we cannot say whether these trends would differ among control group beneficiaries.) As noted previously, risk scores increase with age, which might explain the increase in average risk scores from one to two years post-enrollment and from two to three years post-enrollment. That is, all else equal, a person's CVD risk score will increase over time due to age, even if modifiable risk factors such as blood pressure remain well managed.

Through 2019, the intervention-group organizations with the greatest success in reducing average risk scores among their patient panels were those with a large amount of modifiable risk among beneficiaries at enrollment—that is, with the greatest room for improvement. This could have implications for targeting organizations to participate in similar interventions in the future. In particular, incentive payments based on absolute risk reduction, as in the Million Hearts Model, might be more powerful for organizations with worse-managed risk factors at baseline, given those organizations have greater opportunity to win performance-based payments. In contrast, organizations with little room for improvement at baseline might have more limited opportunity to win performance-based payments. Such organizations might still improve their

care under a CVD risk-reduction initiative like the Million Hearts Model, but the financial incentives for change would be weaker.

Step 5: We found no measurable impact on first-time heart attacks and strokes. This finding is in line with those for earlier steps of the causal pathway, which show impacts growing smaller as we move along the pathway from clinical processes that providers can mostly control, such as rates of risk assessment (Step 2) to beneficiaries' use of medication (Step 3) to beneficiaries' outcomes for CVD risk factors (Step 4). In addition, 30 percent of the study population was enrolled by an organization that had formally exited the model or no longer submitted visit data to CMS by the end of 2020. Unless these organizations continued to implement other provisions of the Million Hearts Model (such as follow-up with high-risk beneficiaries) after leaving the model, we would expect attenuated impacts for the model's longer-term outcomes among these 30 percent of beneficiaries. With no observed impacts on first-time heart attacks and strokes, it is not surprising we observed no reductions in Medicare spending, either, to offset the model payments.

We will continue to monitor impacts of the Million Hearts Model as planned through the end of 2021—the prespecified test period for the evaluation. Even during the period covered in this report (through 2020), it is possible some small effect on heart attacks and strokes could have gone undetected, given the uncertainty inherent in any statistical estimation. For example, the point estimate (hazard ratio) of 0.97 for the main outcome of first-time heart attacks and strokes is statistically indistinguishable from 1, meaning no effect—and yet a point estimate of 0.97 also implies a reduction in heart attack and stroke rates of 3 percent (that is, 1 - 0.97 = 0.03). A reduction of 3 percent would, in fact, be consistent with our estimated impact on CVD risk scores of 3.8 percent. But our evaluation does not have sufficient statistical power to detect an impact of that magnitude. Statistical power should improve, at least somewhat, with the additional follow-up through the end of 2021.

Despite a lack of impacts on CVD events and spending, this report found notable impacts for some secondary outcomes. The observed impact on mortality is surprising, and could be due to some mechanism not anticipated in the Million Hearts Model causal pathway (<u>Chapter V</u>). Similarly, increased rates of hospitalizations and ED visits were unexpected as well, but—like the mortality findings—were consistent with a series of robustness checks and findings from previous years (Blue et al. 2020). Increased service use could occur, perhaps, if risk assessment is more likely to make providers aware of health conditions that need treatment. However, to explain the findings, this heightened provider awareness would likely have had to extend beyond CVD prevention: As shown in <u>Chapter V</u>, we did not find large enough increases in the intervention group's rate of CVD-related stays to explain the higher rates of all-cause hospitalizations and ED visits, relative to the control group.

B. Relevance of the Million Hearts Model findings to past studies and other research literature

The findings from this study are consistent with those from similar studies. For example, like this evaluation, a 2017 Cochrane review of risk scoring for CVD primary prevention linked risk score use to an increased use of statins and antihypertensive medications and to small reductions in total cholesterol and systolic blood pressure (Karmali et al. 2017). It found mixed evidence for impacts on smoking. However, the review found "little to no effect" on CVD events.

One difference between this evaluation and the previous research summarized by Karmali et al. (2017) is the Million Hearts Model tests a policy intervention—that is, incentives and supports to *encourage* use of CVD risk scores and other CVD preventive care. This model does not test the use of risk scores (or other care processes) directly, as in the studies summarized by the Cochrane review. In other words, whereas other studies have tested the effects of changes in CVD care described in Step 2 of our evaluation's causal pathway (Figure VI.1), this evaluation tests the effects of incentives and supports in Step 1 to *prompt* the changes in Steps 2 and beyond. As such, the findings from this evaluation also contribute meaningfully to the health policy research literature, including pay-for-performance programs.

Our study finds that modest incentives can improve CVD medications and CVD risk factors in varied clinical settings. Like this evaluation, other studies of pay-for-performance programs have generally found improvements in incentivized care processes, but with the effects trailing off as outcomes became more distal. For example, Mendelson et al. (2017) reviewed 69 wide-ranging pay-for-performance programs through October 2016. They concluded that pay-for-performance "may be associated with improved processes of care in ambulatory settings, but consistently positive associations with improved health outcomes have not been demonstrated in any setting." We found no effects of the Million Hearts Model on medication adherence. Although other studies have demonstrated potentially effective interventions for adherence, such as text message nudges (Thakkar et al. 2016), the Million Hearts Model participants we interviewed did not say they planned to adopt such interventions.

Finally, we conducted an in-depth examination of differences between high- and lowerperforming organizations. Our findings, like those from other studies of performance variation, suggest organizations might achieve greater success if they have a strong champion for the intervention or otherwise have staff deeply engaged in the model (for example, Curry et al. 2011). In addition, we found high-performing sites might have more proactive communication of risk scores across the care team, or wider use of the documented risk score in their EHRs. This aligns with previous studies' findings that link intervention success to more effective and strong communication across disciplines (Krumholz et al. 2011; Anderson et al. 2020), as well as to integrated systems to provide coordinated care (Benjamin et al. 2018; Anderson et al. 2020).

C. Plans to sustain changes under the Million Hearts Model and implications for future interventions

More than half of the organizations still participating in the model in 2021 reported they planned to sustain changes made for the model after it ends: in particular, changes related to (1) systematically identifying patients at high-risk for CVD, including use of an embedded EHR tool to assess CVD risk; and (2) the role of care managers in CVD risk assessment and reassessment. The COVID-19 pandemic forced some adaptations in care delivery generally (for example, greater use of telehealth), and in the model specifically (for example, use of remote blood pressure monitoring). Organizations might sustain these changes, too—helping to continue Million Hearts Model activities through the end of the model test in December 2021, or to continue monitoring and managing CVD risk in the future.

In some ways, participants' interest in sustaining elements of the Million Hearts Model appears to pose a paradox. That is, plans to sustain changes suggest the model has engaged providers and they are willing to conduct model activities in the long term. Yet high attrition from the model suggests the opposite, and less than half (45 percent) of survey respondents still participating in early 2021 said they would be willing to participate in a similar model in the future. We can explain the apparent paradox, in part, by recognizing two distinct components to the model:

- 1. *Model payments.* As noted, Million Hearts Model payments have been modest and generally declined over time. In our interviews, staff at participating organizations said they perceived the payments as not commensurate with work required for the model, especially work needed to report data via the Million Hearts Data Registry. This perception might help to explain the very high rate of nonparticipation in data reporting among organizations that officially remained in the model through 2020—even though data reporting is necessary to receive payments, both for risk reduction and for enrolling new beneficiaries.
- 2. *A vision of care.* In contrast, many model participants felt committed to the Million Hearts Model's vision of care, which aligns with ACC/AHA guidelines on CVD primary prevention (Arnett et al. 2019). Most intervention group organizations we interviewed over the past four years had changed their workflows substantially to integrate the model into their care processes: for example, building a risk stratification tool into the EHR or developing tools for tracking high-risk beneficiaries for follow-up. Roughly two-thirds of survey respondents in 2021 said they perceived the model had improved their care, and interview respondents favorably noted the alignment between model requirements and current clinical guidelines.

Importantly, model participants say they plan to sustain core features of the Million Hearts Model related to the *vision of care*. This includes identifying patients with high CVD risk, who would benefit from additional preventive care, and these changes could continue to have impacts on new Medicare beneficiaries after the model ends. In contrast, because many participants felt model payments were not commensurate with the model's data reporting requirements, the organizations might not participate in future initiatives with similar requirements for external data reporting and with similarly modest payments.

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Appendix A

Assessment of the Potential for COVID-19 to Bias Estimates of Model Impacts on Heart Attacks and Strokes and Other Outcomes

1. Overview of potential pathways for COVID-19 to bias impact estimates and assessment that bias has been minimal

The 2019 Coronavirus (COVID-19) pandemic could introduce bias into our impact estimates of the impacts of the Million Hearts[®] Cardiovascular Disease (CVD) Risk Reduction Model on heart attacks and strokes and other outcomes. This bias would occur if the pandemic led to differences in outcomes between the intervention and control groups that are unrelated to model impacts. For example, people avoided hospital care, including for heart attack and stroke symptoms, early in the pandemic (Baum and Schwartz 2020; Birkmeyer et al. 2020; Blecker et al. 2020; Solomon et al. 2020; Stewart et al. 2021). Because we identify heart attacks and strokes for the Million Hearts Model evaluation using Medicare hospital claims, hospital avoidance will lead us to miss true events. If this missingness occurs more in the intervention versus control group, this would drive intervention–control differences that we might erroneously misinterpret as model impacts.

How COVID-19 could bias estimates of model impacts. In principle, COVID-19 could bias estimates of model impacts in two ways, either separately or combined:

- 1. **Direct effects.** The coronavirus could infect the intervention and control group beneficiaries at different rates, driving differences in outcomes, including total deaths and COVID-19-related hospitalizations and Medicare spending, that are not due to model impacts.
- 2. Indirect effects. Even among beneficiaries who do not contract the virus, COVID-19 could indirectly affect outcomes by making people less likely to seek medical care of all kinds (lowering Medicare spending) and hospital care, including all-cause inpatient admissions and outpatient emergency department (ED) visits as well as hospital care for heart attacks and strokes specifically (lowering observed rates of these events in claims). If these indirect effects differ for the intervention and control groups, they too could drive outcome differences not related to model impacts.

Overall assessment: COVID-19 is unlikely to bias estimates of model impacts. Based on data through December 2020, we estimate COVID-19 created little risk of bias for the Million Hearts Model evaluation outcomes examined in this appendix: first-time heart attacks and strokes, all-cause admissions, all-cause outpatient ED visits, Medicare spending, and the all-cause death rate. COVID-19 appears to have had large effects on most of the outcomes examined in this appendix, either in the outcome levels or in our ability to detect them in claims data. For example, hospital use and total Medicare spending both decreased dramatically in spring 2020, relative to 2018–2019 levels. However, these effects were similar for the intervention and control groups through

December 2020. Further, three of the five years of the planned model test fell before the pandemic, meaning roughly 60 percent of the full follow-up period—and 75 percent of the period covered in this report (2017–2020)—are protected from any biases from COVID-19. For both reasons, the COVID-19 pandemic through the end of 2020 does not appear to have created a meaningful risk of bias to the evaluation. That is, even though COVID-19 had a large effect on outcomes in 2020, the differences in these effects between the intervention and control groups appear to be too small and too short-lived to affect our impact estimates for the Million Hearts Model.

We did not examine the potential for bias in impact estimates for intermediate outcomes namely, outcomes of CVD medication use or changes in CVD risk scores and risk factors because the follow-up period for those intermediate outcomes is only about one year postenrollment, which for our evaluation population primarily occurs before the COVID-19 pandemic began.

Organization of this appendix. We use data through December 2020 to assess the potential for bias due to the direct and indirect effects of COVID-19 for each of the long-term outcomes listed in Chapter V of this report. Section A.2 of this appendix shows county-level outcomes for the intervention and control beneficiaries for all weeks of 2020 versus 2018–2019; we use these to assess the extent to which the regions where intervention and control group beneficiaries reside might have experienced the 2020 pandemic period differently. Then, in Section A.3, we use these county-level differences to estimate how much our impact estimates for the Million Hearts Model are changed (that is, biased) by the observed, differential effects of COVID-19 between the intervention and control groups.

2. Estimating changes in key outcomes due to COVID-19 in intervention and control group counties

This section assesses the county-level changes in outcome rates in 2020 versus the average rates in 2018–2019 among Medicare fee-for-service (FFS) beneficiaries ages 40 to 79, with each county weighted by the number of intervention or control group beneficiaries. We interpret changes in 2020 relative to the same weeks in 2018 and 2019 as the effect of COVID-19 on outcomes. For all outcomes considered, we see large effects of COVID-19 on outcome levels. For example, the rate of hospital use for heart attacks and strokes fell roughly 40 percent from its 2018–2019 baseline in spring 2020, similar to the declines seen among other populations nationally (Solomon et al. 2020; Solomon et al. 2021). Total Medicare spending similarly declined by 30 to 40 percent in spring 2020 and mortality increased up to 40 percent during spring 2020 and the final months of the year. Nevertheless, for all outcomes, the pattern was similar for intervention group beneficiaries' counties as for the control group beneficiaries' counties-meaning we do not observe large outcome differences between the intervention and control groups. In Section A.3, we use these differences, along with assumptions about how long the observed differences persist, to estimate how large a bias COVID-19 could create in the Million Hearts Model impact estimates (that is, how large a difference in evaluation outcomes the COVID-19 pandemic could create between the intervention and control groups.)

Rationale for assessing county-level changes. Because the distribution of intervention and control group beneficiaries across U.S. counties is not identical (Table A.1), regional differences in COVID-19 infection rates or responses to COVID-19 could lead to differences in outcomes between the intervention and control groups. To assess the potential for such differences in outcomes due to COVID-19 between the evaluation's intervention and control groups, we calculate the county-level differences in outcome rates in 2020 versus the average rates in 2018-2019 among Medicare FFS beneficiaries ages 40 to 79, with each *county* weighted by number of intervention or control group beneficiaries. The rationale for using weighted county-level rates is to approximate the likely effects of COVID-19 on outcomes for the actual intervention and control groups based on the counties where intervention and control beneficiaries live. In contrast, we avoid looking at changes experienced by the actual intervention and control groups because differences in outcomes between those intervention and control groups could reflect either differential effects of COVID-19 or model impacts, and we cannot disentangle the two. By using the county-level data instead, we have a proxy for the outcomes the intervention (or control) group beneficiaries might experience due to COVID-19. This enables us to assess the differential effects of COVID-19 for intervention versus control beneficiaries, without risk the model caused those differences. We consider the general FFS population ages 40 to 79 to be a good proxy for the Million Hearts Model analytic population because these groups have similar, though not identical, demographic and health characteristics (Table A.1). In addition, because the Million Hearts Model intervention group beneficiaries comprise, on average, about 1 percent of a county's Medicare FFS population (data not shown), we do not expect the model could meaningfully affect county-level outcomes among the full Medicare FFS population.

	Million Hearts and	All Medicare FFS	
Subgroup	Intervention, %	Control, %	beneficiaries ages 40 to 79, %
Ages 40 to 79	100	100	100
Gender			
Male	58	59	47
Female	42	41	53
Dual status			
Dually eligible	10	10	16
Not dually eligible	90	90	84
Race and ethnicity			
White, non-Hispanic	86	88	82
Black, non-Hispanic	8	7	9
All other races and ethnicities	6	5	9
Number of chronic conditions ^{a,b}			
0 or 1	9	9	15
2 to 5	41	41	34
6 or more	35	36	31
Excluded: not observable for prior 2 years ^c	15	15	20
Region			
Pacific	5	6	13
Mountain	3	9	7
North Central	19	29	22
South Central	23	16	18
South Atlantic	23	18	22
New England and Mid-Atlantic	27	22	17

Table A.1. Characteristics of the national Medicare FFS population ages 40 to 79 and Million Hearts high- and medium-risk analytic population

Sources: Mathematica's analyses of Medicare enrollment and claims data and Million Hearts registry population data.

Note: Characteristics of the Million Hearts Model evaluation high- and medium-risk analytic population defined based on each beneficiary's enrollment date. Characteristics of the national Medicare FFS population defined on January 1, 2020.

^a The condition count was based on the presence of chronic conditions warehouse condition categories, including 26 of the original chronic conditions and 36 of the other chronic and potentially disabling conditions.

^b The count of the number of chronic conditions among the Million Heart's intervention and control groups might be lower than the count for the national population because the Million Hearts' analytic file combined all cancers (breast, colorectal, endometrial, lung, and prostate) into one overall cancer category, whereas the analytic file for the national population contained separate variables for cancer, and the Million Heart's analytic file does not include categories for sickle cell disease or HIV/AIDS, which the analysis file for the national population includes.

^c The subgroup analyses included beneficiaries based on the number of chronic conditions only if they were observable during the two years before their enrollment date (Million Hearts beneficiaries) or January 1, 2020 (national sample). We limited the sample because the look-back period for most of the chronic conditions algorithms requires two years of claims data.

FFS = fee-for-service.

Methods for measuring weighted county-level rates. We used the Medicare Beneficiary Summary File (MBSF) A/B/C/D segment to identify the census of beneficiaries ever enrolled in Medicare FFS since 2018. We constructed a beneficiary-week-level file that contained demographic and enrollment characteristics, including whether the beneficiary was between the ages of 40 and 79 at the start of each week, and an indicator for whether beneficiaries were observable that week because they were alive and enrolled in Medicare Parts A and B FFS with Medicare as the primary payer at the start of the week. For each observable week, we used inpatient and outpatient claims to identify unduplicated all-cause hospitalizations and outpatient ED visits (including observation stays), as well as hospitalizations and ED visits for heart attack and stroke. We calculated death rates for each week among beneficiaries who were alive and observable on the first day of the week. To develop measures of total Medicare spending per beneficiary per week, we summed total Medicare payment amounts across all claim types (inpatient, skilled nursing facility, hospice, home health, outpatient, carrier, and durable medical equipment)¹⁷ based on each claim's "thru" date.

For each week, we calculated the number of unduplicated events—that is, deaths, hospitalizations, and outpatient ED visits (all-cause and for heart attack and stroke)—per 100,000 observable FFS beneficiaries ages 40 to 79. We also calculated total Medicare spending per beneficiary among this population. We graphically compared weekly rates in 2020 to the mean rates in the same weeks across 2018 and 2019. To develop the weighted county-level rates of events and spending, we started with these beneficiary-week files. We then implemented the following steps:

- 1. For each county and week, we summed total events observed and total Medicare spending among observable FFS beneficiaries ages 40 to 79.
- 2. We calculated the event rate per 100,000 observable beneficiaries ages 40 to 79 per county per week and spending per beneficiary per week.
- **3.** We weighted each county by the number of intervention group beneficiaries who resided in that county at the time of their model enrollment. This gave higher weight to counties with more Million Hearts Model intervention group beneficiaries and lower weight to counties with relatively fewer beneficiaries. Counties with no intervention group beneficiaries received a weight of zero and we effectively dropped them from this analysis.
- 4. We output weighted weekly graphs of events among all counties that contained at least one intervention group beneficiary.

¹⁷ For the outpatient file and all Part A claims except for inpatient claims, we used the claim-level Medicare payment amount. For inpatient claims, we measured Medicare payment as the claim-level Medicare payment amount plus the per diem amount multiplied by the number of covered days. For carrier and durable medical equipment files, we used the line-level Medicare payment amount.

5. We repeated Steps 3 and 4 for the control group. We included any counties that contained both intervention and control group beneficiaries in both intervention and control group weighted analyses with different weights, based on the number of intervention and control group beneficiaries, respectively.

a. Changes in weighted county-level rates of heart attacks and strokes due to COVID-19

Figure A.1 shows the change, by week, from 2018–2019 to 2020 in the rate of heart attacks and strokes, as identified in acute inpatient and outpatient ED (including observation stay) claims. We use the same set of diagnosis codes (found in any position) to identify heart attacks and strokes as used for the impact analyses presented in Chapter V. This variable reflects *all* heart attacks and strokes, not only first-time heart attacks and strokes—which is the evaluation outcome—due to feasibility challenges identifying first-time events for the full FFS population nationally. The rates in Panels A and B of Figure A.1 (intervention group and control group, respectively) are the weighted mean rates among beneficiaries ages 40 to 79 for every county in the United States. Panel C reports the percentage change in weighted rates between 2020 and the average rate for 2018 and 2019 for the same week for each group.

Figure A.1 shows that, although the rate of heart attacks and strokes appeared to fall by roughly 40 percent in some weeks during spring 2020 for beneficiaries ages 40 to 79, relative to the same weeks in previous years, the decline and partial recovery were very similar between the intervention and control group counties. Throughout the second half of 2020, event rates remained roughly 10 percent below 2018–2019 levels for both groups. We do not anticipate all, or even most, of the declines in observed heart attacks and strokes reflect a true reduction in events during this period. Rather, we expect the decline is largely due to people avoiding hospital care when a heart attack or stroke occurred, possibly receiving no medical care, receiving nonhospital care, or dying at home before making it to the hospital (Sun et al. 2021).



Figure A.1. Observed heart attacks and strokes declined similarly in 2020 in intervention group beneficiaries' counties as in control group beneficiaries' counties (beneficiaries ages 40 to 79)

Source: Mathematica's analyses of Medicare enrollment and claims data.

Note: For the rates in Panels A and B, the denominator in each week is the number of Medicare FFS beneficiaries in each county between the ages of 40 and 79 who were alive and enrolled in Medicare Parts A and B FFS with Medicare as primary payer at the start of that week. The numerator is the number (among the denominator population) of acute inpatient hospitalizations, outpatient ED visits, and outpatient observation stays for a new AMI or stroke, based on a relevant claim with an AMI or stroke diagnosis in any position. The rates in Panel A are weighted by the number of intervention group beneficiaries.) Similarly, the rates in Panel B are weighted by the number of control group beneficiaries in each county. (This figure effectively drops counties with no intervention group beneficiaries.) Similarly, the rates in Panel B are weighted by the number of creports the percentage change in weighted rates between 2020 and the average rate for 2018 and 2019 for the same week for each group.

AMI = acute myocardial infarction; ED = emergency department; FFS = fee-for-service.

b. Changes in weighted county-level rates of all-cause hospitalizations and outpatient ED visits due to COVID-19

Figures A.2 and A.3 show the changes in weighted rates between 2020 and 2018–2019 for all-cause hospitalizations and outpatient ED visits, respectively. In both figures, the rates in Panel A (intervention group) are the mean rates among beneficiaries ages 40 to 79 for every county in the United States, with each county-level value weighted by the number of intervention group beneficiaries residing in that county. Similarly, the rates in Panel B (control group) are weighted by the number of control group beneficiaries in each county. Panel C reports the percentage change in weighted rates between 2020 and the average rate for 2018 and 2019 for the same week for each group.

These figures show that, although the rates of all-cause hospitalizations and outpatient ED visits fell during the 2020 pandemic period, particularly in the early weeks of the pandemic, the decline and partial recovery for both types of service use were very similar between the intervention and control group counties. For both outcomes, event rates remained well below 2018–2019 levels (by about 10 to 25 percent, respectively) in the second half of 2020.





Source: Mathematica's analyses of Medicare enrollment and claims data.

Note: For the rates in Panels A and B, the denominator in each week is the number of Medicare FFS beneficiaries in each county between the ages of 40 and 79 who were alive and enrolled in Medicare Parts A and B FFS with Medicare as primary payer at the start of that week. The numerator is the number (among the denominator population) of acute inpatient hospitalizations. The rates in Panel A are weighted by the number of intervention group beneficiaries in each county. (This figure effectively drops counties with no intervention group beneficiaries.) Similarly, the rates in Panel B are weighted by the number of control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries.) Panel C reports the percentage change in weighted rates between 2020 and the average rate for 2018 and 2019 for the same week for each group.

FFS = fee-for-service.



Figure A.3. All-cause outpatient ED visits and observation stays declined similarly in intervention group beneficiaries' counties as in control group beneficiaries' counties (beneficiaries ages 40 to 79)

Source: Mathematica's analyses of Medicare enrollment and claims data.

- Note: For the rates in Panels A and B, the denominator in each week is the number of Medicare FFS beneficiaries in each county between the ages of 40 and 79 who were alive and enrolled in Medicare Parts A and B FFS with Medicare as primary payer at the start of that week. The numerator is the number (among the denominator population) of outpatient ED visits and observation stays. The rates in Panel A are weighted by the number of intervention group beneficiaries in each county. (This figure effectively drops counties with no intervention group beneficiaries.) Similarly, the rates in Panel B are weighted by the number of control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries.) Panel C reports the percentage change in weighted rates between 2020 and the average rate for 2018 and 2019 for the same week for each group.
- ED = emergency department; FFS = fee-for-service.

c. Changes in weighted county-level rates of total Medicare spending

Figure A.4 shows the percentage change in weighted rates between 2020 and 2018–2019 for Medicare spending among beneficiaries ages 40 to 79. Because we use the "thru" date on the claims, we bin spending for any services billed only once during a monthly period (such as skilled nursing care for those with stays lasting at least through the end of the month, and hospice for beneficiaries who are still alive) into the week containing the last day of the month. As a result, the line graphs of total spending per beneficiary per week in Panels A and B—that is, graphs for mean weighted, weekly spending per beneficiary in intervention and control counties, respectively—show spikes, or peaks, for the weeks that contain the last day of a month. In Panel C, however, when we measure the difference between weighted intervention and control county-level total spending per beneficiary per week, the spikes disappear because they occurred during the same weeks for both groups and cancel out.

Figure A.4. Total Medicare FFS Parts A and B spending per person per week declined similarly in intervention group beneficiaries' counties as in control group beneficiaries' counties (beneficiaries ages 40 to 79)



Source: Mathematica's analyses of Medicare enrollment and claims data.

Note: The figure reports the percentage change in weighted spending per person per week between 2020 and the average rate for 2018 and 2019 for the same week for each group. To calculate each county's perperson per-week spending, the denominator for each week is the number of Medicare FFS beneficiaries in each county between the ages of 40 and 79 who were alive and enrolled in Medicare Parts A and B FFS with Medicare as primary payer at the start of that week. The numerator is the total Medicare Parts A and B FFS spending during that week among the denominator population. Intervention group weekly spending rates are weighted by the number of intervention group beneficiaries in each county. (This figure effectively drops counties with no intervention group beneficiaries.) Similarly, control group weekly rates are weighted by the number of control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries.)

We binned spending by week based on the claim thru date, so claims paid monthly (for example, skilled nursing facility and hospice for beneficiaries using services all month) get binned on the last date of each month. This explains the monthly spikes in spending in Panels A and B of the figure.

^a The spike in Panel C in Week 40 is because 2020 was a leap year; Week 40 of 2020 starts on September 30, 2020, whereas Week 40 starts on October 1 in 2018–2019. Together, these two factors lead to an artificial reduction in spending in Week 39 in 2020, relative to 2018–2019, followed by an increase in spending in Week 40 relative to 2018–2019, as the end-of-month expenditures for September are counted in Week 40 in 2020 rather than Week 39. FFS = fee-for-service.

d. Changes in weighted county-level death rates due to COVID-19

Figure A.5 shows the percentage change in the weighted death rate between 2020 and 2018–2019, measured among beneficiaries ages 40 to 79. The rates in Panel A of Figure A.5 (intervention group) are the mean rates among beneficiaries ages 40 to 79 for every county in the United States, with each county-level value weighted by the number of intervention group beneficiaries residing in that county. Similarly, the rates in Panel B (control group) are weighted by the number of control group beneficiaries in each county. Panel C reports the percentage change in weighted rates between 2020 and the average rate for 2018 and 2019 for the same week for each group.

The figure shows that, although the death rate rose sharply in spring 2020 and again at the end of the year for beneficiaries ages 40 to 79 and that it generally stayed above the 2018–2019 average rate in between, the increase in death rates was similar between the intervention and control group counties. The one exception was in Weeks 13 through 15, when death rates were a bit higher in the intervention group counties.

Figure A.5. The death rate for beneficiaries ages 40 to 79 increased similarly in intervention group beneficiaries' counties as in control group beneficiaries' counties, although with a higher peak for intervention group beneficiaries in the spring of 2020



Source: Mathematica's analyses of Medicare enrollment data.

Note: The figure reports the percentage change in weighted rates between 2020 and the average rate for 2018 and 2019 for the same week for each group (intervention versus control). To calculate the death rate for each county, the denominator for each week is the number of Medicare FFS beneficiaries in the county between the ages of 40 and 79 who were alive and enrolled in Medicare Parts A and B FFS with Medicare as primary payer at the start of that week. The numerator is the number of beneficiaries who died during that week among the denominator population. Intervention group weekly rates are weighted by the number of intervention group beneficiaries.) Similarly, control group weekly rates are weighted by the number of control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries.)

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FFS = fee-for-service.
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3. Estimating potential COVID-19-related bias on impact estimates for key outcomes

The trends in key study outcomes shown in Section A.2 differ only slightly between the counties where the intervention and the control group beneficiaries live. Nevertheless, it is not obvious from the figures alone whether small differences observed might have meaningful effects on the Million Hearts Model impact estimates.

In this section, we use the observed intervention– control differences in weighted county-level rates from Section A.2, along with assumptions about how long those observed differences will persist, to estimate how

Definitions

Direct effects are changes in outcomes due to COVID-19 cases—for example, excess deaths due to COVID-19.

Indirect effects occur because of the pandemic, but without being linked to any specific COVID-19 case—for example, a decline in spending when beneficiaries avoid care.

large a bias COVID-19 could create (that is, how large a difference in evaluation outcomes the COVID-19 pandemic would create even if the model had no impact). Using this approach, we can project the influence of COVID-19 through the end of the model period in December 2021, assuming the 2020 intervention–control differences persist through 2021. We will update our assessment of potential bias for the fifth annual report using actual data from 2021, when available.

We assess the potential for bias due to direct and indirect effects of COVID-19, as described in Table A.2.

Outcome measures (long-term outcomes from Chapter V)	Type of COVID-19 effect examined	9 Rationale for examining potential bias due to direc versus indirect effects	
First-time heart attack and stroke	Indirect	We assume reductions in observed heart attacks and strokes are due to people avoiding hospital care for these events or, possibly, due to fewer events actually occurring while the public takes measures to curb the spread of COVID-19 (indirect effects of COVID-19). In contrast, we do not assume COVID-19 infection directly affects the probability of heart attacks and strokes (a direct effect). ^a We examine whether intervention–control differences in the indirect effects of COVID-19 could bias our impact estimates.	
All-cause hospitalizations	Direct and indirect (combined)	COVID-19 can affect the hospitalization rate directly (for example, through hospitalizations to treat COVID-19) or indirectly (for example, due to cancelled elective procedures). We assess the potential for intervention– control differences in COVID-19's direct and indirect effects, combined, to bias impact estimates.	

Table A.2. Direct and indirect effects of COVID-19 could theoretically produce bias in the impact estimates for multiple outcomes in the Million Hearts Model evaluation

Outcome measures (long-term outcomes from Chapter V)	Type of COVID-19 effect examined	Rationale for examining potential bias due to direct versus indirect effects
All-cause outpatient ED visits (including observation stays)	Direct and indirect (combined)	COVID-19 can affect the ED visit rate directly (for example, through outpatient ED visits to treat COVID-19) or indirectly (for example, if people avoid ED care due to fear of contracting COVID-19). We assess the potential for intervention–control differences in COVID-19's direct and indirect effects, combined, to bias impact estimates.
Total Medicare spending	Direct Direct and indirect (combined)	COVID-19 can affect medical spending directly (for example, through hospitalizations and ED visits to treat COVID-19) or indirectly (for example, through cancelled or averted care). We separately assess the potential for bias due to (1) intervention–control differences in COVID-19's direct effects and (2) intervention–control differences in COVID-19's direct and indirect effects, combined.
Death rate	Direct	We assume all intervention–control differences in county- level death rates are due to direct effects of COVID-19— that is, differences in the incidence or severity of COVID-19 cases. We assess the potential for these direct effects to bias impact estimates.

^a COVID-19 could either increase or decrease observed rates of heart attacks and strokes. On the one hand, contracting COVID-19 might put beneficiaries at higher risk of heart attacks or strokes (Katsoularis et al. 2021), thus raising the overall rate. On the other, the Million Hearts Model beneficiaries with the highest CVD risk scores might have been those most likely to die from COVID-19. Excess mortality among the highest-risk beneficiaries would limit opportunities for the model to reduce heart attacks and strokes among those with the highest expected rates of CVD events.

ED = emergency department.

In broad terms, the calculations include three major steps:

- 1. We calculate the difference in outcomes between the intervention and control group counties during the COVID pandemic in 2020 (March 11, 2020, through December 31, 2020), based on the data shown in Section A.2. For example, for the assessment of COVID-19's direct effect on the death rate, we take the county-level death rates among beneficiaries ages 40 to 79 and calculate the difference in county-level rates between the intervention and control groups (with county-level rates weighted, as in Section A.2, by the number of intervention or control group beneficiaries).
- 2. We use the observed intervention–control differences from Step 1 along with assumptions about how long those differences could persist to project differences between the intervention and control group that could occur over the five-year model period due to COVID-19. We tested two different assumptions, assuming observed differences in outcomes either (a) occur only during 2020 (from March through December) or (b) persist through the end of the model in December 2021.
- **3.** We take the projected differences in outcomes due to COVID-19 from Step 2 and add them to the observed impact estimates reported in the Million Hearts Model Evaluation Third Annual Report (Blue et al. 2020). This gives us the projected impact estimates when we include differences due to COVID-19, if the estimates through 2020 had changed for no

reason other than COVID-19. Of course, the estimates included in Chapter V of this report in fact use longer follow-up than the Third Annual Report, and the estimates might differ for many reasons other than COVID-19—for example, due to strengthening or weakening effects of the Million Hearts Model the longer a person is enrolled.

For all of these calculations, we assume (1) the differences in outcomes between 2020 and the same weeks in 2019–2020 in a county for Medicare FFS beneficiaries ages 40 to 79 reflect the impact of COVID-19 in that county for those beneficiaries and (2) the impact of COVID-19 for Million Hearts enrollees living in a county is the same as the impact of COVID for all Medicare FFS beneficiaries ages 40 to 79 in the county. Table A.3 summarizes the findings from these analyses—namely, any bias due to COVID-19 is unlikely to change our conclusions about model impacts over the full five-year test.

Table A.3. For all outcomes studied, COVID-19 should cause minimal bias when drawing conclusions about model impacts over the full five-year test

	Estimated average change in outcome due to COVID-19			Conclusions about	
Assumption about intervention versus control group differences in COVID-19 burden, by outcome	Intervention group	Control group	Intervention– control difference in change	model impacts, after accounting for potential bias from COVID-19	
Heart attacks and strokes per 100,00	00 beneficiaries p	er year			
Differences observed from March to December 2020 persist only through December 2020	-56	-58	2	No change	
Differences observed from March to December 2020 persist through December 2021	-125	-130	5	No change	
All-cause hospitalizations per 1,000	beneficiaries per	quarter			
Differences observed from March to December 2020 persist only through December 2020	-2	-2	-0.02	No change	
Differences observed from March to December 2020 persist through December 2021	-5	-5	-0.05	No change	
Outpatient ED visits and observatio	n stays per 1,000	beneficiaries per q	uarter		
Differences observed from March to December 2020 persist only through December 2020	-6	-6	-0.14	No change	
Differences observed from March to December 2020 persist through December 2021	-14	-13	-0.30	No change	
Medicare spending for COVID-19-related hospitalizations, ED visits and observation stays					
Differences observed from March to December 2020 persist only through December 2020	\$6.20	\$6.35	-\$0.15	No change ^a	
Differences observed from March to December 2020 persist through December 2021	\$13.87	\$14.21	-\$0.34	No change ^a	
	Estimated av	erage change in ou COVID-19	tcome due to	Conclusions about	
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Assumption about intervention versus control group differences in COVID-19 burden, by outcome	Intervention group	Control group	Intervention– control difference in change	model impacts, after accounting for potential bias from COVID-19	
Total Medicare spending per benefic	ciary per month				
Differences observed from March to December 2020 persist only through December 2020	-\$6.79	-\$5.91	-\$0.88	No change	
Differences observed from March to December 2020 persist through December 2021	-\$15.19	-\$13.21	-\$1.98	No change	
All-cause deaths per 100,000 benefi	ciaries per year				
Differences observed from March to December 2020 persist only through December 2020	93	88	5	No change	
Differences observed from March to December 2020 persist through December 2021	207	197	10	No change	

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

Note: Estimates are based on county-level data for the outcomes among Medicare FFS beneficiaries ages 40 to 79 residing in the same counties as the intervention and control group high- and medium-risk model enrollees. We estimate the change in outcomes due to COVID-19 as the difference between outcomes observed in March– December 2020 versus outcomes observed in those same months in 2018–2019. We then use those numbers along with assumptions about how long the difference might persist (either through 2020 only or through 2021) and beneficiaries' observability in 2021 to assess the change in five-year outcome levels (2017-2021) due to the estimated effects of COVID-19 in 2020.

a We do not estimate impacts of the Million Hearts Model on Medicare spending related to COVID-19. To assess the effects of differences in COVID-19-related spending on our conclusions about the Million Hearts Model, we added the difference in COVID-19-related spending between the intervention and control groups to our impact estimate of the difference in total Medicare spending.

ED = emergency department.

The following sections describe the details of the calculations and results for each of the outcomes shown in Tables A.2 and A.3.

a. Calculating possible bias from the indirect, differential effect of COVID-19 on firsttime heart attacks and strokes between intervention and control groups

To estimate the indirect effects of COVID-19 on first-time heart attacks and strokes, we assume observed declines in 2020 in the rate of heart attacks and strokes, shown in Section A.2, Figure A.1, are due to care avoidance rather than true declines in CVD events (that is, due to indirect rather than direct effects of COVID-19). We further assume the decline in *first-time* heart attacks and strokes is the same as the decline in all heart attacks and strokes. We then calculate differences in heart attacks and strokes (as measured from claims for hospitalizations and ED visits) between the intervention and control groups using county-level event rates. We assume beneficiaries enrolled in the Million Hearts Model experienced the same decrease in observed event rates from March 11, 2020, to December 31, 2020, relative to the same months in 2018–2019, as other Medicare beneficiaries ages 40 to 79 in their counties.

Even though COVID-19 appears to have caused substantial declines in the number of people visiting the hospital for heart attacks and strokes, this decline in observed heart attacks and strokes is unlikely to bias our model impact estimates (Table A.4) because the decline was extremely similar for the intervention and control groups. The calculation involved three steps:

Step 1: Calculating the difference between the intervention and control groups

To calculate the decline in observed heart attacks and strokes due to COVID-19, adjusted for season, for each week from March 11, 2020, through December 31, 2020, we calculated the difference between the observed rate of heart attacks and strokes for that week and the observed rate in the corresponding week in 2018 and 2019 (as described in Section A.2). We then took the average of these weekly declines across March 11 through December 31, 2020, and annualized to get an estimate of the yearly rate of missing or unobserved heart attacks and strokes. The intervention group had 276 fewer heart attacks and strokes observed per 100,000 beneficiaries ages 40 to 79 per year and the control group had 287 fewer heart attacks and strokes observed per 100,000 beneficiaries ages 40 to 79 per year. This suggests about 10 fewer heart attacks and strokes observed per 100,000 beneficiaries ages 40 to 79 per year in the intervention group versus the control group due to COVID-19 (-276 minus -287).

Step 2: Projecting differences over the five-year model period

We tested two different assumptions, assuming observed differences between the intervention and control groups in heart attacks and strokes calculated in Step 1: (1) occur only between March 11, 2020, and December 31, 2020; or (2) persist through the end of the model in December 2021. Because Million Hearts Model beneficiaries enrolled on different dates, most beneficiaries are not in the evaluation analytic population for the full five years of the model test. For example, a beneficiary enrolled on July 1, 2018, could contribute to the analytic population for at most 3.5 years (from July 1, 2018, to December 31, 2021.) Thus, to project the average difference in the rate of heart attacks and strokes due to COVID-19 during the five-year model period, we had to estimate the proportion of beneficiaries' total follow-up time during the fiveyear model period that will occur during the COVID-19 period versus outside that period. For this report, which includes analyses through December 2020, we observed an average of 40 months of follow-up time per medium- or high-risk beneficiary from the start of the model to December 2020. For each subsequent month after December 2020, we estimated beneficiaries contributed just slightly less than a month of follow-up time on average, accounting for 2.5 percent yearly mortality and 1.5 percent yearly rate of experiencing a first-time heart attack or stroke in our population. We further assumed these rates are both relatively constant over time. Using these estimates of follow-up time, if differences due to COVID-19 occur only during the period from March 11, 2020, through December 31, 2020, then they occur during 20 percent of the total five-year model period. If differences persist through the end of the model in December 2021, then we estimate they occur during 45 percent of the total five-year model period. These percentages differ slightly from the percentages of follow-up time used in other calculations for all-cause admissions, all-cause outpatient ED visits, total Medicare Parts A and B FFS spending, and mortality because we exclude follow-up time for beneficiaries after a heart attack or stroke

when evaluating the impact on first-time heart attacks and strokes, but not when evaluating the impact on these other outcomes. Table A.4 shows results from the calculations for COVID-19's indirect effects on heart attacks and strokes. If the 10 additional heart attacks and strokes observed per 100,000 beneficiaries per year in Step 1 persist through December 2021, 45 percent of the model period, then over the full model period this would translate to approximately 5 additional events observed per 100,000 beneficiaries per year in the intervention group (10 multiplied by 45 percent).

Step 3: Estimating impacts including differences due to COVID

To estimate how COVID-19 could change the hazard ratios for first-time heart attacks and strokes reported in the Third Annual Report, we converted the additional events observed in the intervention group due to COVID-19 over the five-year model period to a ratio scale by dividing the additional events by the overall rate of heart attacks and strokes observed in our analytic population (1.5 events per 100 beneficiaries per year or 1,500 events per 100,000 beneficiaries per year). If differences persist through December 2021, the additional heart attacks and strokes observed in the intervention group would translate to a 0.3 percent higher event rate in the intervention group than the control group (5 divided by 1,500). That is, if the model had no effect on heart attacks and strokes, we would expect the hazard ratio to be 1.00; however, given the additional observed events in the intervention group due to COVID-19, we would instead see a hazard ratio of 1.003 (1.00 + 0.003) if differences persist through December 2021. We added this ratio change to the hazard ratio from the Third Annual Report to estimate the hazard ratio incorporating differences due to COVID-19. Because the hazard ratio in the Third Annual Report was 1.00, the effect of COVID-19 would be negligible. We also recalculated the upper and lower bounds of the confidence interval around this new estimate assuming bias due to COVID-19 would have minimal impact on the standard error of the impact estimate (Table A.4).

Table A.4. Estimated differences between the intervention and control groups in heart attacks and strokes observed in claims: Indirect effects are unlikely to substantively affect model impact estimates

	Estimated change (CVD events per	in heart attacks and to COVID-19 100,000 beneficiari	d strokes due es per year)	Potential bias on impact estimates from COVID-19		
Assumption about intervention and control group differences in COVID-19 burden	Intervention group	Control group	Difference	Observed impact estimate in Third Annual Report [HR and 90% Cl]	Projected impact estimate, including bias due to COVID-19, if COVID-19 were the only reason our estimate differed from one in the Third Annual Report [hazard ratio and 90% CI]	
Differences persist through December 2020	-56	-58	2	1.00 [0.95, 1.04]	1.00 [0.95, 1.05]	
Differences persist through December 2021	-125	-130	5	1.00 [0.95, 1.04]	1.00 [0.95, 1.05]	

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

Note: Estimates are based on county-level rates of hospitalizations and ED visits (including observation stays) for heart attack, stroke, and TIA among Medicare FFS beneficiaries ages 40 to 79 residing in the same counties as the intervention and control group high- and medium-risk model enrollees.

CI = confidence interval; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; HR = hazard ratio; TIA = transient ischemic attack.

b. Calculating possible bias from the combined direct and indirect, differential effect of COVID-19 on all-cause hospitalizations and outpatient ED visits between intervention and control groups

To estimate the direct and indirect effects of COVID-19 on all-cause hospitalizations and outpatient ED visits, we assume changes between 2018–2019 and 2020 in rates of hospitalizations and outpatient ED visits due to COVID-19 reflect both the direct effect of COVID-19—that is, an increase in admissions or ED visits for this condition—as well as the indirect effects of COVID-19—that is, a reduction in the number of admissions and ED visits due to canceled procedures, patients avoiding care, and excess mortality that precluded future service use. We then calculate the potential bias in our impact estimates for hospitalizations and ED visits between the intervention and control groups using county-level event rates, as with the calculation for first time heart attacks and strokes. We do not attempt to disentangle the direct effects of COVID-19 from the indirect effects because hospitalizations and ED visits are both secondary outcomes of the evaluation, and the calculations in Section A.3.c.iii for total Medicare spending (a primary outcome) suggested the maximum possible bias due to COVID-19 would come from direct and indirect effects combined.

Even though COVID-19 appears to have caused substantial declines in the number of all-cause hospitalizations and outpatient ED visits during 2020, as with the declines in heart attacks and stroke, this decline is unlikely to bias our model impact estimates (Tables A.5 and A.6) because the decline was extremely similar for the intervention and control groups. Next, we describe the three steps involved in the calculations. The calculations are similar for both all-cause hospitalizations and all-cause outpatient ED visits. The steps here mirror the steps described previously for calculating the possible bias from the indirect, differential effect of COVID-19 on heart attacks and strokes (Section A.3.a), except we use input data about county-level hospitalization and ED visit rates (rather than heart attack and stroke rates), and we did not have to account for censoring due to a first-time heart attack and stroke when estimating follow-up time in 2021.

Step 1: Calculating the difference between the intervention and control groups

To calculate the change in observed all-cause hospitalizations and outpatient ED visits due to COVID-19, adjusted for season, for each week from March 11, 2020, through December 31, 2020, we calculated the difference between the observed rate for that week and the observed rate in the corresponding week in 2018 and 2019 (as described in Section A.2). We then took the average of these weekly declines across March 11 through December 31, 2020, annualized, scaled per 1,000 beneficiaries, and then divided by 3 to obtain the quarterly rate of change per 1,000 beneficiaries (consistent with the units of our impact estimates). The intervention and control groups had 10.87 and 10.74 fewer all-cause hospitalizations per 1,000 beneficiaries ages 40 to 79 per quarter, respectively. The groups also had 32.26 and 31.53 fewer all-cause outpatient ED visits, respectively. This suggests 0.13 and 0.72 fewer all-cause hospitalizations

and outpatient ED visits per 1,000 beneficiaries ages 40 to 79 per quarter, respectively, in the intervention group versus the control group due to COVID-19.

Step 2: Projecting differences over the five-year model period

As with the calculation for first time heart attacks and strokes, we tested two different assumptions, assuming observed differences between the intervention and control groups in allcause admissions and outpatient ED visits calculated in Step 1 (1) occur only from March 11 to December 31, 2020; or (2) persist through the end of the model in December 2021. Because Million Hearts Model beneficiaries enrolled on different dates, most beneficiaries are not in the evaluation analytic population for the full five years of the model test. For example, a beneficiary enrolled on July 1, 2018, could contribute to the analytic population for at most 3.5 years (from July 1, 2018, to December 31, 2021.) Thus, to project the average difference in death rate due to COVID-19 during the five-year model period, we had to estimate the proportion of beneficiaries' total follow-up time during the five-year model period that will occur during the COVID-19 period versus outside that period. For this report, which includes analyses through December 2020, we observed an average of 40 months of follow-up time per medium- or high-risk beneficiary between the start of the model and December 2020. For each subsequent month after December 2020, we estimated beneficiaries contributed just slightly less than a month of followup time on average, accounting for 2.5 percent yearly mortality in our population and assuming the death rate is relatively constant over time. Using these estimates of follow-up time, if differences due to COVID-19 occur only during 2020-that is, from March 11, 2020, through December 2020-then they occur during 19 percent of the total five-year model period. If differences persist through the end of the model in December 2021, then we estimate they occur during 42 percent of the five-year model period.

Tables A.5. and A.6 show results from the calculations for combined direct and indirect effects on all-cause hospitalizations and all-cause outpatient ED visits, respectively. As noted, all-cause hospitalization rates in the intervention group were 0.13 admissions per 1,000 beneficiaries per quarter lower than in the control group and ED visits were 0.72 visits per 1,000 beneficiaries per quarter lower from March 11 through December 31, 2020. Using the assumption that differences persist through December 2021 as an illustrative example, these differences would occur for 42 percent of the model period, so across the five-year model period, we would estimate 0.05 fewer all-cause hospitalizations per beneficiary per quarter and 0.30 fewer all-cause outpatient ED visits per beneficiary per quarter for the intervention group compared to control group due to COVID-19 (respectively, -0.13 multiplied by 42 percent and -0.72 multiplied by 42 percent).

Step 3: Estimating model impact estimates, incorporating differences due to COVID-19

To project possible impact estimates including differences due to direct and indirect effects of COVID-19 on all-cause hospitalizations and all-cause outpatient ED visits, we added the change in the number of events due to COVID-19 over the five-year model period estimated in Step 2 to the impact estimates for all-cause hospitalizations and outpatient ED visits reported in the Third Annual Report. We also recalculated the upper and lower bounds of the confidence intervals

around these new estimates, assuming bias due to COVID-19 would have minimal impact on the standard error of the impact estimates.

The bias is extremely unlikely to alter our conclusions about model impacts on all-cause hospitalizations and all-cause outpatient ED visits. Even if the differences observed through December 2020 persisted through the end of the Million Hearts Model in December 2021, our impact estimate and 90 percent confidence interval for all-cause hospitalizations would change from 2.35 (0.9, 3.8) from the Third Annual Report to 2.30 (0.8, 3.8) (Table A.5). Similarly, for all-cause outpatient ED visits, our impact estimate and 90 percent confidence interval would change from 3.56 (0.7, 6.4) from the Third Annual Report to 3.26 (0.4, 6.1) due to bias from COVID-19 (Table A.6). These changes would not substantively affect our conclusions about the model's impacts on these outcomes.

Table A.5. Estimated differences between the intervention and control groups in all-cause hospitalizations are unlikely to substantively affect model impact estimates

	Estimated cha due to CO ben	nge in all-cause he VID-19 (admissions eficiaries per quar	ospitalizations s per 1,000 rter)	Potential bias on impact estimates from COVID-19		
Assumption about intervention and control group differences in COVID-19 burden	Intervention group	Control group	Difference	Observed impact estimate in Third Annual Report [difference and 90% CI]	Projected impact estimate, including bias due to COVID-19, if COVID-19 were the only reason our estimate differed from one in the Third Annual Report [hazard ratio and 90% CI]	
Differences persist through December 2020	-2	-2	-0.02	2.35 [0.9, 3.8]	2.33 [0.85, 3.80]	
Differences persist through December 2021	-5	-5	-0.05	2.35 [0.9, 3.8]	2.30 [0.82, 3.78]	

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

Notes: Estimates are based on county-level rates of all-cause hospitalizations among Medicare FFS beneficiaries ages 40 to 79 residing in the same counties as the intervention and control group high- and medium-risk model enrollees.

CI = confidence interval; FFS = fee-for-service.

Table A.6. Estimated differences between the intervention and control groups in all-cause outpatient ED visits and observation stays are unlikely to substantively affect model impact estimates

	Estimated ch visits and obs (visits per 1	nange in all-cause c servation stays due I,000 beneficiaries	outpatient ED e to COVID-19 per quarter)	Potential bias on impact estimates from COVID-19		
Assumption about intervention and control group differences in COVID-19 burden	Intervention group	Control group	Difference	Observed impact estimate in Third Annual Report [difference and 90% CI]	Projected impact estimate, including bias due to COVID-19, if COVID-19 were the only reason our estimate differed from one in the Third Annual Report [hazard ratio and 90% CI]	
Differences persist through December 2020	-6	-6	-0.14	3.56 [0.7, 6.4]	3.42 [0.60, 6.25]	
Differences persist through December 2021	-14	-13	-0.30	3.56 [0.7, 6.4]	3.26 [0.43, 6.08]	

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

Notes: Estimates are based on county-level rates of all-cause outpatient ED visits and observation stays among Medicare FFS beneficiaries ages 40 to 79 residing in the same counties as the intervention and control group high- and medium-risk model enrollees.

CI = confidence interval; ED = emergency department; FFS = fee-for-service.

c. Calculating possible bias from the direct effects alone and the combined direct and indirect, differential effects of COVID-19 on Medicare spending between intervention and control groups

As noted in Table A.2, we separately assess the potential for bias in the Million Hearts Model impact estimates for Medicare spending due to (1) the direct effects of COVID-19 and (2) COVID-19's direct and indirect effects, combined.

In an ideal world, we would like to assess the potential for bias due to COVID-19's indirect effects separately from the bias due to its direct effects. This would enable us to explore the potential for bias in scenarios in which, for example, the direct effects lasted longer than the indirect effects, or vice versa. However, with the data available, it is not straightforward to estimate COVID-19's *indirect* effects on total Medicare spending by themselves. That is, observed changes in spending between 2018–2019 and 2020 reflect a combination of direct effects (that is, spending for COVID-19 care) and indirect effects (changes in spending due to changes in care-seeking behavior and availability of services during the pandemic). For this reason, we first calculate the potential bias due to the combined direct *and* indirect effects (Section A.3.c.ii). Finally, in Section A.3.c.iii, we use both sets of calculations to assess the extent of bias that could arise from indirect effects, by comparing the bias due to direct effects only to the bias due to indirect and direct effects combined.

i. Direct effect of COVID-19 on Medicare Parts A and B spending

To estimate the direct effect on spending, we assume severe cases of COVID-19 that require a hospitalization or ED visit mostly drive the differences in Medicare spending due to COVID-19 infections.¹⁸ We calculated the difference between intervention and control group beneficiaries in their rates of COVID-19 hospitalizations, outpatient ED visits, and observation stays from March 11 to December 31, 2020, among high and medium-risk beneficiaries who were alive and observable on March 11, 2020. Having calculated the difference in severe COVID-19 cases, we then used national estimates of Medicare FFS payments for each COVID-19 hospitalization and ED visit (Centers for Medicare & Medicaid Services [CMS] 2020; Fiedler and Song 2020) to estimate the differences in Medicare spending that would result from these observed differences in severe COVID-19 cases.

Relative to the width of our confidence interval for the impact estimate for spending (greater than \$30 per beneficiary per month [PBPM]), the projected difference in Medicare spending due to direct effects of COVID-19 between the intervention and control groups was very small and

¹⁸ We considered using other indicators for whether a person had COVID-19, such as whether the person had a COVID-19 diagnosis in an office visit. However, we decided against this for two reasons. First, we anticipate a good deal of variation in whether people have office visits with a COVID-19 diagnosis depends on how often people were tested for COVID-19. In contrast, we anticipate the people who had a severe enough case of COVID-19 to need hospitalization would have COVID-19 hospitalization claims, regardless of COVID-19 testing rates in a region or time period. Second, COVID-19 will have its largest effects on Medicare spending when it requires acute care.

extremely unlikely to alter our conclusions about model impacts on spending. Next, we describe the three steps involved in the calculation. **These steps differ from the steps described previously to calculate direct and indirect effects of COVID-19 (Sections A.3.a and A.3.b).** Rather than using county-level information about changes in outcomes from 2018–2019 (among all FFS beneficiaries ages 40 to 79), we calculate the difference in COVID-19-related hospitalizations and ED visits among our evaluation's intervention and control groups. We then calculate the differential effect on spending due to this extra acute care caused by COVID-19.

Step 1: Calculating the difference between the intervention and control groups

We first generated variables to reflect COVID-19 hospitalizations and outpatient ED visits or observation stays from March 11 to December 31, 2020 among high- and medium-risk beneficiaries enrolled in the intervention or control groups who were alive and observable on March 11, 2020. We identified COVID-19 hospitalizations and ED visits as claims with a primary or secondary diagnosis code of B97.29 (other coronavirus as the cause of diseases classified elsewhere) before April 1, 2020, and diagnosis code of U07.1 (disease diagnosis of COVID-19 confirmed by lab testing) from April 1, 2020, onward, based on the recommendations from Mathematica's COVID-19 Data Primer (Bohl and Roozeboom-Baker 2020) and consistent with the definition used by the CMS to define COVID-19 cases and hospitalizations (CMS 2020). From March 11 through December 31, 2020, COVID-19 hospitalization rates in the intervention group were 39 visits per 100,000 beneficiaries per year lower than in the control group and ED visits were 89 visits per 100,000 beneficiaries per year lower. We estimated each hospitalization cost \$23,558 using the national average payment for Medicare FFS beneficiaries hospitalized for COVID-19 from January 1 to November 21, 2020 (CMS 2020). We estimated each ED visit or observation stay cost \$582 based on prices calculated from the Medicare Hospital Outpatient Prospective Payment System rules (Fiedler and Song 2020).

Step 2: Projecting differences over the five-year model period

We used the same assumptions about beneficiaries' follow-up time during the Million Hearts Model as we did for the calculations of all-cause hospitalizations and all-cause outpatient ED visits (Section A.3.b of this appendix), which would account for any excess mortality during 2020. As with the all-cause hospitalizations and outpatient ED visits calculations, we estimated that if differences due to COVID-19 occur only during the period from March 11 through December 31, 2020, then they occur during 19 percent of the total five-year model period, given rolling enrollment of model beneficiaries. If differences persist through the end of the model in December 2021, then they occur during 42 percent of the total five-year model period.

Table A.7 shows results from the calculations for direct effects on spending. Assuming differences persist through December 2021 as an illustrative example, COVID-19 hospitalization rates in the intervention group would be 39 visits per 100,000 beneficiaries per year lower than in the control group and ED visits would be 89 visits per 100,000 beneficiaries per year lower from March 11, 2020, through the end of the model. Assuming each hospitalization costs

\$23,558 and each ED visit costs \$582, these additional visits in the control group cost \$0.81 PBPM (largely due to the cost of hospitalizations). These differences occur for 42 percent of the model period; summarized across the five-year model period, we estimate \$0.34 PBPM less spending for the intervention group compared to control group due to COVID-19 (-\$0.81 multiplied by 42 percent).

Step 3: Estimating model impact estimates, incorporating differences due to COVID-19

To project possible impact estimates, including differences due to COVID-19 for spending, we added the differential spending due to direct effects of COVID-19 over the five-year model period estimated in Step 2 to the impact estimate for spending reported in the Third Annual Report. We also recalculated the upper and lower bounds of the confidence interval around this new estimate assuming bias due to COVID-19 would have minimal impact on the standard error of the impact estimate. The true impact of the model might differ in later years from the period reported in the Third Annual Report; however, this exercise, demonstrating the magnitude of the bias from COVID-19 relative to the impact estimate from earlier reports, is useful for understanding how the bias might affect our conclusions about Million Hearts Model impacts (Table A.7). We find the bias is extremely unlikely to alter our conclusions about model impacts on Medicare spending. Even if the differences observed through December 2020 persisted through the end of the Million Hearts Model in December 2021, our impact estimate and 90 percent confidence interval for total Medicare PBPM spending would change from \$4.44 (-\$14, \$23) from the Third Annual Report to \$4.10 (-\$14, \$22) (Table A.7).

	No. hospi Marc De (visi benefic	No. of estimated COVID-19 hospitalizations from March 2020 through December 2021 (visits per 100,000 beneficiaries per year)a		No. of estimated COVID-19 ED visits from March 2020 through December 2021 (visits per 100,000 beneficiaries per year)		ed s from ugh 21 000 year)	Estin spe COVID year	nated addit ending due 1-19 over th r model per (PBPM)	ional to e five- riod	Potential bias on impact estimates from COVID-19	
Assumption about intervention and control group differences in COVID-19 burden	Intervention group	Control group	Difference	Intervention group	Control group	Difference	Intervention group	Control group	Difference	Observed impact estimate in Third Annual Report [difference and 90% CI]	Projected impact estimate, including bias due to COVID-19, if COVID-19 were the only reason our estimate differed from one in the Third Annual Report [difference and 90% CI]
Differences persist through December 2020	744	761	-18	358	397	-40	\$6.20	\$6.35	-\$0.15	\$4.44 [-14, 23]	\$4.29 [-14, 23]
Differences persist through December 2021	1,663	1,703	-39	800	888	-89	\$13.87	\$14.21	-\$0.34	\$4.44 [-14, 23]	\$4.10 [-14, 22]

Table A.7. Under two different assumptions, differences between the intervention and control groups in rates of severe COVID-19 are unlikely to substantively affect model impact estimates for total Medicare Parts A and B spending

Sources: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data and national Medicare FFS payments for COVID-19 hospitalizations and ED visits (CMS 2020; Fiedler and Song 2020).

Notes: Estimates include intervention (N = 40,443) and control (N = 27,282) high- and medium-risk beneficiaries who were alive and observable on March 11, 2020. To calculate additional spending, we assumed Medicare payments for each COVID-19 hospitalization were \$23,558 (CMS 2020) and Medicare payments for each COVID-19 ED visits or observation stay were \$582 (Fiedler and Song 2020).

^a According to CMS data, there were N = 691,077 COVID-10 hospitalizations among Medicare FFS beneficiaries in 2020 and early 2021 (based on inpatient claims from January 1, 2020, to March 20, 2021) (CMS 2021). With a FFS population of nearly 38 million in 2020 (Kaiser Family Foundation 2021), this works out to about 1,831 COVID-hospitalizations per 100,000 beneficiaries. In previous Mathematica analyses, we calculated an all-cause hospitalization rate of 23,953 per 100,000 FFS beneficiaries in 2020 (data not shown). Thus, COVID-19 hospitalizations reflected about 8 percent of all hospitalizations for Medicare FFS beneficiaries in 2020.

CI = confidence interval; CMS = Centers for Medicare & Medicaid Services; ED = emergency department; FFS = fee-for-service; PBPM = per beneficiary per month.

ii. Combined direct and indirect effects of COVID-19 on total Medicare spending

To estimate the combined direct and indirect effects on total Medicare spending, we assume differences in total spending between 2018–2019 and 2020 reflect both the direct effect of COVID-19—that is, an increase in spending for COVID-19-related inpatient admissions or ED visits—as well as the indirect effects of COVID-19—that is, changes in spending due to changes in care-seeking behavior and availability of services during the pandemic. We then calculate differences in total Medicare spending between the intervention and control groups using county-level PBPM spending estimates, similar to the calculations for all-cause hospitalizations and outpatient ED visits. We assume beneficiaries enrolled in the Million Hearts Model experience the same change in observed PBPM rates from March 11 to December 31, 2020, relative to the same months in 2018–2019, as other Medicare beneficiaries ages 40 to 79 in their counties.

COVID-19 appears to have caused temporary yet substantial declines in PBPM spending in spring 2020 (Figure A.4). However, this decline is unlikely to bias our model impact estimates because the decline was extremely similar for the intervention and control groups (Table A.8). Next, we describe the three steps involved in the calculations. The steps here mirror the steps described previously for calculating the possible bias from the combined direct and indirect effects of COVID-19 on hospitalizations and ED visits (Section A.3.b), except we use input data about county-level spending, rather than acute service use.

Step 1: Calculating the difference between the intervention and control groups

To calculate the change in total Medicare Parts A and B spending due to the direct and indirect effects of COVID-19, adjusted for season, for each week from March 11 through December 31, 2020, we calculated the difference between the observed per beneficiary per week spending for that week and the observed spending in the corresponding week in 2018 and 2019 (as described in Section A.2). We then took the average of these weekly changes across March 11 through December 31, 2020, annualized and divided by 12 to get an estimate of the PBPM change in spending. Total Medicare spending among Medicare beneficiaries ages 40 to 79 in intervention and control group counties declined by \$36.19 and \$31.48 PBPM, respectively, during the pandemic period compared to 2018–2019. This suggests \$4.71 lower PBPM spending in the intervention group versus the control group due to COVID-19.

Step 2: Projecting differences over the five-year model period

We used the same assumptions about beneficiaries' follow-up time during the Million Hearts Model as we did for the calculations of all-cause hospitalizations and outpatient ED visits (Section A.3.b of this appendix). As with the all-cause hospitalizations and outpatient ED visits calculations, we estimated that if differences due to COVID-19 occurred only during the period from March 11 through December 31, 2020, then they occurred during 19 percent of the total five-year model period, given rolling enrollment of model beneficiaries. If differences persisted through the end of the model in December 2021, then they occurred during 42 percent of the total five-year model period. Table A.8 shows results from the calculations for direct and indirect effects on total Medicare spending PBPM. As noted, PBPM spending for the intervention group was \$4.71 PBPM lower than PBPM spending in the control group from March 11 to December 31, 2020. Assuming that differences persist through December 2021 as an illustrative example, this difference occurs for 42 percent of the model period, so across the five-year model period we estimate \$1.98 PBPM lower spending for the intervention group compared to the control group due to COVID-19 (-\$4.71 multiplied by 42 percent).

Step 3: Estimating model impact estimates, incorporating differences due to COVID-19

To project possible impact estimates, including differences due to direct and indirect effects of COVID-19 on Medicare spending, we added the change in PBPM spending due to COVID-19 over the five-year model period estimated in Step 2 to the impact estimates for total Medicare spending reported in the Third Annual Report. We also recalculated the upper and lower bounds of the confidence intervals around these new estimates assuming bias due to COVID-19 would have minimal impact on the standard error of the impact estimates. The bias is extremely unlikely to alter our conclusions about model impacts on Medicare spending. Even if the differences observed through December 2020 persisted through the end of the Million Hearts Model in December 2021, our impact estimate and 90 percent confidence interval for total Medicare PBPM spending would change from \$4.44 (-\$14, \$23) from the Third Annual Report to \$2.46 (-\$16, \$21) (Table A.8).

Table A.8. Estimated differences between the intervention and control groups in mean spending per beneficiary per month are unlikely to substantively affect model impact estimates

	Estimated chai	nge in spending due (dollars PBPM)	to COVID-19	Potential bias on impact estimates from COVID-19			
Assumption about intervention and control group differences in COVID-19 burden	Intervention group	Control group	Difference	Observed impact estimate in Third Annual Report [difference and 90% Cl]	Projected impact estimate, including bias due to COVID-19, if COVID-19 were the only reason our estimate differed from one in the Third Annual Report [difference and 90% CI]		
Differences persist through December 2020	-\$6.79	-\$5.91	-\$0.88	\$4.44 [-14, 23]	\$3.55 [-\$15, \$22]		
Differences persist through December 2021	-\$15.19	-\$13.21	-\$1.98	\$4.44 [-14, 23]	\$2.46 [-\$16, \$21]		

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

Note: Estimates are based on county-level mean spending per beneficiary per month among Medicare FFS beneficiaries ages 40 to 79 residing in the same counties as the intervention and control group high- and medium-risk model enrollees.

CI = confidence interval; FFS = fee-for-service; PBPM = per beneficiary per month.

iii. Comparing direct versus combined direct and indirect effects of COVID-19 on total Medicare spending

The previous sections presented findings for the direct effects of COVID-19 on our impact estimates for total Medicare spending—that is, the potential bias due to increased spending for beneficiaries in the intervention and control groups who had ED visits and hospital admissions for COVID-19 (Section A.3.c.i). We also present findings of the combined direct and indirect effects of COVID-19 on total Medicare spending PBPM based on changes in spending (Section A.3.c.ii). Table A.9. summarizes those previous results, showing the direct effects of COVID-19 on spending account for about 17 percent of the total difference in spending (direct and indirect combined) between intervention and control groups, whether we assume these differences persist until the end of 2020 or the end of 2021. For example, the direct effect of COVID-19 on total Medicare spending through December 2020 was -\$0.15 relative to -\$0.88 for the combined direct and indirect and indirect effects.

The comparison of direct versus combined direct and indirect effects also shows the direct effects increase spending because Medicare pays for COVID-19 admissions and ED visits (and this excess spending is slightly higher for the control group because that group had slightly higher rates of COVID-19 inpatient admissions and ED visits). In contrast, the combined direct and indirect effects lower total Medicare spending, likely due to beneficiaries avoiding care, canceled procedures, and excess mortality that prevented future service use. The magnitudes of the effects imply the reduction in spending due to indirect effects is about twice as large as the increase in spending due to direct effects.

Nevertheless, the intervention–control *differences* in COVID-19 effects are all negative—that is, with the intervention group experiencing lower costs than the control group. Because the direction of the potential bias is negative for the direct effects and for the direct and indirect effects combined and because the combined effects are larger—that is, more negative—we can deduce that the indirect effects of COVID-19 must also produce a potential bias that is also negative in sign. (For example, in the first two rows of the table, an intervention–control difference of -0.15 PBPM due to the direct effects and an intervention–control difference of -0.88 PBPM due to the direct and indirect effects combined would suggest a difference due to indirect effects of -0.73 PBPM [-0.88 - 0.15 = -0.73]). Because the potential bias due to COVID-19's indirect effects operates in the same direction as the potential bias due to direct effects, we do not have to consider scenarios in which the direct effects last longer than the indirect effects, or vice versa. That is, those scenarios could not cause greater bias than we have already calculated for the direct and indirect effects combined—and we have already shown that, if those differences persist through the end of the model in 2021, they will not meaningfully alter the evaluation's conclusions.

	Estimated change in spending due to COVID-19 (dollars PBPM)					
	Intervention group	Control group	Difference			
Differences persist through December 2020						
Direct effects of COVID-19 ^a	\$6.20	\$6.35	-\$0.15			
Direct and indirect effects of COVID-19 ^b	-\$6.79	-\$5.91	-\$0.88			
Differences persist through December 2021						
Direct effects of COVID-19 ^a	\$13.87	\$14.21	-\$0.34			
Direct and indirect effects of COVID-19 ^b	-\$15.19	-\$13.21	-\$1.98			

Table A.9. Comparison of estimated changes in total Medicare spending PBPM due to direct effects only versus direct and indirect effects combined

Sources: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data and national Medicare FFS payments for COVID-19 hospitalizations and ED visits (CMS 2020; Fiedler and Song 2020).

^a Estimates for direct effects of COVID-19 include intervention (N = 40,443) and control (N = 27,282) high- and medium-risk beneficiaries who were alive and observable on March 11, 2020. To calculate additional spending, we assumed Medicare payments for each COVID-19 hospitalization were \$23,558 (CMS 2020) and Medicare payments for each COVID-19 ED visits or observation stay were \$582 (Fiedler and Song 2020).

^b Estimates for combined direct and indirect effects of COVID-19 are based on county-level mean spending PBPM among Medicare FFS beneficiaries ages 40 to 79 residing in the same counties as the intervention and control group high- and medium-risk model enrollees.

CMS = Centers for Medicare & Medicaid Services; ED = emergency department; FFS = fee-for-service; PBPM = per beneficiary per month.

iv. Calculating possible bias from the direct, differential effect of COVID-19 on death rates between intervention and control groups

To estimate the direct effect of COVID-19 on the death rate, we assume excess deaths from March 11 to December 31, 2020, relative to the same period in 2018–2019, are all COVID-19 deaths. We further assume beneficiaries in our intervention and control groups experience the same increase in the death rate as we observe in their counties among all beneficiaries ages 40 to 79 (Figure A.5). The intervention and control counties experienced similar changes in death rates during the 2020 pandemic period; because of this, the risk of bias from differential mortality on our impact estimates is low. Next, we describe the three steps involved in the calculation. The steps here mirror the steps described previously for calculating the possible bias from the combined direct and indirect effects of COVID-19 on all-cause hospitalizations and ED visits (Section A.3.b), except we use input data about county-level mortality, rather than other outcomes. We assume all excess deaths in a county during the relevant period are related to COVID-19.

Step 1: Calculating the difference between the intervention and control groups

To estimate excess deaths due to COVID-19, adjusted for season, for each week from March 11 through December 31, 2020, we calculated the difference in the death rate for that week and the death rate in the corresponding week in 2018 and 2019 (as described in Section A.2). We then took the average of the excess death rate due to COVID-19 from March 11 through December 31, 2020, and annualized it to get an estimate of the yearly rate of excess deaths. The intervention group had 495 excess deaths per 100,000 beneficiaries ages 40 to 79 per year and the control group had 470 excess deaths per 100,000 beneficiaries ages 40 to 79 per year. Based on these numbers, we calculated 25 additional deaths per 100,000 beneficiaries ages 40 to 79 per year.

Step 2: Projecting differences over the five-year model period

We used the same assumptions about beneficiaries' follow-up time during the Million Hearts Model as we did for the calculations of all-cause hospitalizations and outpatient ED visits (Section A.3.b). As with the all-cause hospitalizations and outpatient ED visits calculations, we estimated that if differences due to COVID-19 occurred only during the period from March 11 through December 31, 2020, then they occurred during 19 percent of the total five-year model period, given rolling enrollment of model beneficiaries. If differences persisted through the end of the model in December 2021, then they occurred during 42 percent of the total five-year model period. Table A.10 shows results from the calculations for the death rate. If the 25 additional deaths per 100,000 beneficiaries per year calculated in Step 1 persist through December 2021, 42 percent of the model period, then over the full model period this would translate to 10 additional deaths per 100,000 beneficiaries per year in the intervention group than in the control group (25 multiplied by 42 percent).

Step 3: Estimating impacts, incorporating the differences in outcomes due to COVID-19

To estimate how COVID-19 could change the hazard ratios for the death rate reported in the Third Annual Report—our last annual report before the COVID-19 period began—we converted the excess deaths due to COVID-19 over the five-year model period to a ratio scale by dividing the excess deaths by the overall death rate observed in our analysis population (2.5 deaths per 100 beneficiaries per year or 2,500 deaths per 100,000 beneficiaries per year). If differences persist through December 2021, the additional deaths in the intervention group relative to the control group would translate to a 0.4 percent higher death rate in the intervention group than the control group (10 divided by 2,500). That is, if the model had no effect on mortality, we would expect the hazard ratio to be 1.00; however, because of the additional deaths in the intervention group 4 to COVID-19, we would instead see a hazard ratio of 1.004 (1.00 + 0.004) if the differences observed from March to December 2020 persist through December 2021. We added this ratio change to the hazard ratio from the Third Annual Report to estimate the hazard ratio in the Third Annual Report was 0.94 (or 0.936 before rounding), the effect of COVID-19 would be to

increase the ratio slightly from 0.936 to 0.940 (0.936 + 0.004). We also recalculated the upper and lower bounds of the confidence interval around this new estimate assuming bias due to COVID-19 would have minimal impact on the standard error of the impact estimate (Table A.10).

Table A.10. Under two different assumptions, regional differences in COVID-19 deaths are unlikely to substantively affect our model impact estimates for the all-cause death rate

	Estimated exc	ess deaths due to Co five-year model peri er 100,000 beneficiar	OVID-19 over the od ies per year)	Potential bias on impact	estimates from COVID-19
Assumption about intervention and control group differences in COVID-19 burden	Intervention group	Control group	Difference	Observed impact estimate in Third Annual Report [hazard ratio and 90% Cl]	Projected impact estimate, including bias due to COVID-19, if COVID-19 were the only reason our estimate differed from one in the Third Annual Report [hazard ratio and 90% CI]
Differences persist through December 2020	93	88	5	0.94 [0.90, 0.97]	0.94 [0.90, 0.97]
Differences persist through December 2021	207	197	10	0.94 [0.90, 0.97]	0.94 [0.90, 0.98]

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

Note: Estimates are based on county-level death rates among Medicare FFS beneficiaries ages 40 to 79 residing in the same counties as the intervention and control groups' high- and medium-risk model beneficiaries.

CI = confidence interval; FFS = fee-for-service.

e. Supplemental detail about assumptions for the bias calculations

In Table A.11, we list the complete set of assumptions for each of the bias calculations.

Table A.11. Summary of assumptions for interpreting calculations as bias due to COVID-19

Assumptions for each step of the calculations

Step 1: Calculating the difference between the intervention and control groups

Indirect effect of COVID-19 on heart attacks and strokes

Model enrollees experience the same decrease in observed heart attacks and strokes as other Medicare beneficiaries ages 40 to 79 in their counties.

The Million Hearts Model did not affect county-level rates. This is a reasonable assumption because intervention group enrollees account for less than 5 percent of Medicare beneficiaries in most counties.

Declines in the county-level rates of all heart attacks and strokes, including first-time and repeat events, are the same, in relative terms, as declines in the rates of first-time heart attacks and strokes. First-time heart attacks and strokes are a primary outcome of interest for the evaluation.

No other secular trend aside from the effects of COVID-19 differentially affected rates of heart attacks and strokes in the intervention versus the control group from March through December 2020.

Combined direct and indirect effect of COVID-19 on all-cause hospitalizations and outpatient ED visits

Model enrollees experience the same change in all-cause hospitalizations and all-cause outpatient ED visits as other Medicare beneficiaries ages 40 to 79 in their counties.

The Million Hearts Model did not affect all-cause hospitalizations and all-cause outpatient ED visits. This is a reasonable assumption because intervention group enrollees account for less than 5 percent of Medicare beneficiaries in most counties.

No other secular trend aside from the direct and indirect effects of COVID-19 differentially affected all-cause hospitalizations and outpatient ED visits in the intervention versus the control group from March through December 2020.

Direct effect and combined direct and indirect effect of COVID-19 on Medicare Parts A and B spending

Assumptions to calculate direct effects of COVID-19 on Medicare Parts A and B spending

Differences in COVID-19 spending between intervention and control groups come primarily from severe COVID-19 cases that require a hospitalization or ED visit.

The diagnosis codes used (B97.29 and U07.1) capture most COVID-19 hospitalizations and ED visits. It is possible COVID-19 cases were coded with less specific diagnoses, particularly early in the pandemic.

Differences in COVID-19 spending between intervention and control groups come primarily from the cost of the COVID-19 hospitalization or ED visit, not including any additional Medicare spending incurred due to long-term consequences of COVID-19.

The average cost of COVID-19 hospitalizations and ED visits are similar between the full Medicare FFS population (including beneficiaries ages 80 and older) and among the high- and medium-risk beneficiaries enrolled in the Million Hearts Model. These average costs could differ if, for example, the model enrollees are less likely to have severe enough disease to be put on a ventilator.

The average cost of COVID-19 hospitalizations and ED visits does not change over the course of 2020 and 2021. Thus far, the average cost has changed little since the start of the pandemic and December 2020 (CMS 2020).

Assumptions for each step of the calculations

Assumptions to calculate combined direct and indirect effects of COVID-19 on Medicare Parts A and B spending

Model enrollees experience the same change in Medicare spending as other Medicare beneficiaries ages 40 to 79 in their counties.

The Million Hearts Model did not affect county-level spending. This is a reasonable assumption because intervention group enrollees account for less than 5 percent of Medicare beneficiaries in most counties.

No other secular trend aside from the direct and indirect effects of COVID-19 differentially affected Medicare spending in the intervention versus the control group from March through December 2020.

Direct effect of COVID-19 on death rates

Model enrollees experience the same increase in death rates as other Medicare beneficiaries ages 40 to 79 in their counties.

The Million Hearts Model did not affect county-level death rates. This is a reasonable assumption because intervention group enrollees account for less than 5 percent of Medicare beneficiaries in most counties.

No other secular trend aside from the effects of COVID-19 differentially affected the death rate in the intervention versus the control group counties from March through July 2020.

Step 2: Projecting differences over the five-year model period

Differences between intervention and control group beneficiaries (1) occur only during the period from March 11 to December 31, 2020; or (2) persist through the end of the model in December 2021. When we assume differences persist through the end of the model, we assume the differences do not get larger or smaller than they were from March 11 to December 31, 2020.

Step 3: Estimating impacts, incorporating the differences in outcomes due to COVID-19

Covariates used in impact models do not correct for most of the bias due to COVID-19. Our standard covariates can predict some of the differences due to COVID-19, leading to less bias due to COVID-19 in our covariate-adjusted impact models.

Bias due to COVID-19 will have minimal impact on the standard error of the impact estimate.

CMS = Centers for Medicare & Medicaid Services; ED = emergency department; FFS = fee-for-service.

4. Conclusions

We found little evidence to suggest intervention and control groups experienced substantively different changes in outcomes due to COVID-19. For all long-term evaluation outcomes, COVID-19 changed outcome levels in 2020, quite dramatically in some cases, but these changes were similar for both groups. Moreover, it is not possible for COVID-19 to have affected impact estimates for the evaluation's intermediate outcomes (related to medication use and changes in CVD risk) because we analyze these outcomes only through 12 months post-enrollment. The follow-up period for those outcomes therefore ends no later than December 2019 (for beneficiaries enrolled in December 2018)—before the COVID-19 pandemic began. We conclude COVID-19 is unlikely to bias estimates of the impact of the Million Hearts Model on any outcomes analyzed in this report.

Appendix B

Detailed Methods and Supplemental Results for Implementation Metrics from Registry, Claims, Enrollment, and Payment Data

This appendix describes the methods Mathematica used to develop the following implementation metrics included in <u>Chapter III</u>:

- Claims-based measures of the total number of in-person office and telehealth visits by calendar month (Section B.1)
- Registry-based measures of reassessment visit counts and rates, including actual and anticipated reassessment visit counts, and rates of one-, two-, and three-year reassessment visits (Section B.2); in this section, we also describe the characteristics of eligible high-risk beneficiaries in the intervention group who did and did not receive one-, two-, and three-year reassessment visits

In addition, this appendix extends the payment analysis presented in <u>Chapter III</u> (Section B.3) by describing Million Hearts Model payments to intervention organizations over time and by type of payment.

1. Claims-based measures of in-person office visits and telehealth visits, by calendar month

Using carrier and outpatient Medicare fee-for-service (FFS) claims, we counted the number of outpatient office or telehealth visits per beneficiary per intervention month for high-risk intervention group beneficiaries enrolled in the Million Hearts Model in 2017 and 2018. For the main impact evaluation, we defined intervention months relative to a beneficiary's enrollment date in the Million Hearts Model, so the calendar period covered by these months varies across beneficiaries. For example, a beneficiary who enrolled in the model on January 3, 2017, will have intervention month one defined as the period from January 3 to February 2, 2017, whereas a beneficiary who enrolled on March 15, 2018, will have intervention month one defined as the period from March 15 to April 14, 2018. To make an analysis of visits feasible, we reused the intervention month approach we developed for the impact evaluation. We flagged outpatient office and telehealth visits in each enrollment month based on current procedural terminology (CPT) or Healthcare Common Procedure Coding System codes for outpatient office¹⁹ or

¹⁹ Outpatient office or clinic codes include 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99487, 99489, 99495, 99496, 99304, 99305, 99306, 99307, 99308, 99309, 99310, 99315, 99316, 99324, 99325, 99326, 99327, 99328, 99334, 99335, 99336, 99337, 99339, 99340, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, 99318, 99490, 99497, G0402, G0438, G0439, G0181, 99492, 99493, 99494, 99484, G0502, G0503, G0504, G0507, 99354, 99355, 99358, 99359, 99406, 99407, 97802, 97803, 96152, 96153, 96154, 96160, G0101, G0102, G0108, G0109, G0270, G0271, G0442, G0443, G0444, G0445, G0446, G0447, 99401, 99402, 99403, 99404, 99408, 99409, 99411, 99412, 99420, 99429, 99381, 99382, 99383, 99384, 99385, 99386, 99387, 99391, 99392, 99393, 99394, 99395, 99396, 99397, G0473, G0466, G0467, G0468, G0469, G0470, G2064, G2065, G0076, G0077, G0078, G0079, G0080, G0081, G0082, G0083, G0084, G0085, G0086, G0087, G2011, G2076, G9987, G0296, G0396, G0397, Q0091, G0511, G0512, G0463, 99488, G0505, G0506, and 99483.

telehealth²⁰ visits. In addition, we flagged visits as telehealth if they were billed with an office visit code and either the code was associated with modifier GT, GQ, G0, or 95 or the claim indicated place of service equal to 'telehealth'. To avoid double-counting visits across outpatient and carrier claims-for example, for beneficiaries who had an office visit at a critical access hospital outpatient facility and for whom we would observe both an outpatient and carrier claim-we counted only one visit per beneficiary per day. If a beneficiary had claims for both an in-person office visit and a telehealth visit on the same date, we counted this as one office visit. Our measures of outpatient office and telehealth visits are limited to providers aligned with the Million Hearts Model. We identified these providers based on National Provider Identifier (NPI) and Tax Identification Number (TIN) combinations (carrier file) and Centers for Medicare & Medicaid Services (CMS) Certification Number (CCN) and NPI combinations (outpatient file) that ever participated in the model. To examine the pattern of visits over calendar time, we had to convert the visits observed in intervention months (which are relative to a beneficiary's enrollment date and so vary in calendar time across beneficiaries) to calendar months. To do so, we assigned each intervention month for each high-risk beneficiary to a calendar month as follows: the intervention month that contained March 11, 2020-the date when the World Health Organization declared coronavirus a global pandemic—was assigned to March 2020. The intervention month before that was assigned to February 2020 and the one before that to January 2020 and so forth. Similarly, the month after March 2020 was assigned to April 2020 and the following month to May 2020 and so forth. We then calculated the mean number of office visits, telehealth visits, and both types of visits per beneficiary per month to Million Hearts-aligned providers from January 2019 to November 2020. The denominator for each month is the number of observable high-risk beneficiaries in that month-that is, alive and enrolled in Medicare Parts A and B FFS with Medicare as primary payer.

2. Reassessment visit counts and rates

a. Reassessment visits counts: actual and anticipated

Trend graphs in <u>Chapter III</u> showing reassessment visit counts over calendar time include reassessment visits for all high-risk beneficiaries enrolled by intervention organizations from 2017 through 2020 (N = 46,613). We defined reassessment visits as validated visits with nonmissing cardiovascular risk scores submitted to the Million Hearts Data Registry 10 months or more after organizations enrolled the beneficiary in the model, provided that organizations attested to the accuracy of the visit record. Beneficiaries could have up to four annual reassessment visits by the end of December 2020, occurring at least 10 months apart. We included a total of 36,620 reassessment visits in the analysis of overall reassessment visit counts. In later sections of <u>Chapter III</u>, we focus on just one-, two-, and three-year reassessment visits because very few beneficiaries were eligible for a four-year reassessment visit by the end of December 2020.

²⁰ Telehealth-specific codes include 98966, 98967, 98968, 99441, 99442, 99443, 98969, 99444, 98970, 98971, 98972, 99421, 99422, 99423, 99453, 99454, 99457, 99474, G2010, G2012, G2061, G2062, G2063, G9978, G9979, G9980, G9981, G9982, G9983, G9984, G9985, G9986, and G0071.

We calculated the anticipated number of reassessment visits during each month through the end of December 2020. These are the number of reassessment visits that might have occurred during that month if all eligible high-risk beneficiaries enrolled in the model had received reassessment visits each year within the four-month window of time around the anniversary of their enrollment (the anniversary window). We took into account in the calculation that some beneficiaries would become ineligible for the model before their reassessment anniversaries. We made the following two assumptions:

- 1. Every month after enrollment, about 0.7 percent of beneficiaries became ineligible (due to either death, heart attack, stroke, transient ischemic attack, end-stage renal disease [ESRD], election of the hospice care benefit, enrollment in Medicare Advantage, or because Medicare was not the primary payer). The 0.7 percent estimate is based on the proportion of our analytic population who became ineligible for a one-year reassessment visit within 14 months of enrollment. We assumed this ineligibility rate is stable over time with 0.7 percent of the starting population leaving each month. For example, we assumed 8.4 percent became ineligible each year (0.7 percent * 12 months).
- 2. Of the remaining beneficiaries who did not become ineligible, we assumed 10 percent had a one-year reassessment at 10 months post-enrollment, 15 percent at 11 months, 35 percent at 12 months, 25 percent at 13 months, and 15 percent at 14 months. These numbers are based on the distribution of time between enrollment and one-year reassessment we observed in the population who received a one-year reassessment visit (described in the next section). We assumed the same distribution of time to two-, three-, and four-year reassessments (for example, 10 percent of beneficiaries have a two-year reassessment at 22 months).

Anticipated reassessment visits follow a cyclical trend, reflecting different rates of enrollment throughout the year. Almost one-third of the total enrollment from January 2017 to December 2020 occurred in the first three months of the model (January through March 2017). Due to this peak in enrollment at the beginning of the model, which also corresponded to the beginning of the calendar year, a much greater percentage of beneficiaries were due for annual reassessment visits at the beginning rather than the end of each year.

b. Reassessment visit rates: one-year, two-year, and three-years post-enrollment

In addition to calculating overall reassessment visit counts, we calculated one-, two-, and threeyear reassessment visit rates among high-risk beneficiaries²¹ in our analytic population who remained eligible for a reassessment visit throughout their anniversary windows. Anniversary

²¹ Beneficiaries were categorized as high, medium, or low risk based on their CVD risk score at enrollment. For the 6 percent of beneficiaries who had CVD risk factor information recorded in the registry before the baseline visit date used by CMS's implementation contractor to calculate payments (Conwell et al. 2019), we included the beneficiaries in the denominator for reassessment visit rates as long as they were classified as high risk at both dates. We required the beneficiary to be classified as high risk at the enrollment date used for payment, even though we consider the beneficiary's true baseline to be the earlier visit, because intervention group organizations had to provide reassessment data only for beneficiaries classified as high risk at the later date.

windows range from 10 to 14 months after enrollment²² for one-year reassessment visits, 22 to 26 months after enrollment for two-year reassessment visits, and 34 to 38 months after enrollment for three-year reassessment visits. We restricted the denominator of the reassessment visit rates based on three criteria:

- 1. To be included in the denominator of the reassessment visit rates, we had to ensure we could observe the beneficiary through the end of their anniversary window. All beneficiaries in our analytic population, enrolled in 2017 and 2018, had enough follow-up time to observe a one-year reassessment visit through the end of December 2020, but only beneficiaries enrolled by October 31, 2018, had 26 months of follow-up needed to observe a two-year reassessment visit and only beneficiaries enrolled by October 31, 2017, had 38 months of follow-up needed to observe a three-year reassessment visit.
- 2. We further restricted reassessment rate denominators to beneficiaries who remained eligible for the model through the end of their anniversary windows. Model ineligibility could be due to death, heart attack, stroke, transient ischemic attack, ESRD, election of the hospice care benefit, enrollment in Medicare Advantage, or because Medicare was not the primary payer. We did not have flags for hospice and ESRD readily available, so we did not include these two reasons for model ineligibility in our analysis, but anticipate relatively few people would be excluded based on these criteria alone.
- **3.** Finally, we restricted reassessment visit denominators to only beneficiaries enrolled in organizations that remained a model participant through the end of the beneficiary's anniversary window.

Beneficiaries could be included in the denominator for one-year reassessment visits but not twoor three-year reassessment visits, or included in the denominator for one- and two-year reassessment visits but not three-year reassessment visits.

The numerator of the reassessment visit rates included visits recorded in the Million Hearts Data Registry through December 2020 with nonmissing risk scores and where the organization attested to the accuracy of the record. Reassessment visits could occur after the anniversary window, and organizations could still receive payments for these later reassessment visits (prorated based on the amount of time between enrollment and reassessment). Because of this, we included in the numerator one-year reassessment visits that occurred up to 21 months post-enrollment, two-year reassessment visits up to 33 months post-enrollment, and three-year reassessment visits up to 45 months post-enrollment.

Table B.1. compares the characteristics of high-risk beneficiaries who had a one-, two-, or threeyear reassessment visit to those who were eligible but did not have reassessment visits during

²² For the 6 percent of beneficiaries who had CVD risk factor information recorded in the registry before the baseline visit date used by CMS's implementation contractor to calculate payments (Conwell et al. 2019), we defined numerator and denominator criteria for reassessment visit rates based on the date used by CMS's implementation contractor to calculate payments. This is the date used to flag whether beneficiaries are within their anniversary window in the Million Hearts Data Registry.

that reassessment window. As noted in <u>Chapter III</u>, compared to beneficiaries who did not receive a reassessment visit, those who did were more likely to have diabetes (68 versus 61 percent for the one-year reassessment visit, 69 versus 62 percent for the two-year, and 70 versus 63 percent for the three-year reassessment visit); to have been enrolled into the Million Hearts Model by a primary care provider (63 versus 50 percent, 66 versus 52 percent, and 68 versus 55 percent for the one-, two-, and three-year reassessments, respectively); and to have had slightly more visits with Million Hearts Model providers. Further, those with reassessment visits tended to be enrolled by larger organizations (measured both by number of providers and number of service sites listed at application) and by organizations that participated in other CMS models—a pattern particularly evident in reassessment Years 2 and 3. In contrasting those with and without reassessment visits, we focused on differences that were substantive as a percentage of the mean—especially those in which differences were consistent across years. We did not assess whether any differences were statistically significant, but included differences that were substantive in terms of standardized differences (marked with a $^{\circ}$ symbol in the table).

Characteristic	Beneficiaries with one-year reassessment visit (N = 18,563)	Beneficiaries without one-year reassessment visit (N = 14,640)	Beneficiaries with two-year reassessment visit (N = 8,752)	Beneficiaries without two-year reassessment visit (N = 18,482)	Beneficiaries with three-year reassessment visit (N = 4,531)	Beneficiaries without three-year reassessment visit (N = 14,269)
Clinical indicators of beneficiary's	cardiovascular risk					
CVD risk score (%),	40	40	40	40	40	40
[standard deviation]	[9]	[9]	[9]	[9]	[8]	[9]
Modifiable risk (%)ª	15	16	15	16	15	15
Has diabetes (%)	68	61	69	62	70	63
Systolic blood pressure (mm Hg)	139	141	139	140	138	140
Total cholesterol (mg/dL)	167	169	167	168	167	168
HDL cholesterol (mg/dL)	47	48	47	48	47	48
LDL cholesterol (mg/dL)	91	93	91	92	91	92
Is current smoker (%)	12	12	11	12	10	11
Beneficiary's medication use						
Uses aspirin (%)	51	51	48	55	44	55
Uses antihypertensives based on Part D (%) $^{\rm b}$	90	90	91	90	91	90
Proportion of days covered by antihypertensives (%) ^c	91	90	91	91	92	91
Proportion of beneficiaries adherent to antihypertensives (%) ^{c, d}	87	85	86	86	87	86
Uses statins based on Part D (%) ^c	71	68	70	69	70	70
Intensity of statin use based on Part D (%) ^c						
Low intensity	7	7	7	7	7	7
Medium intensity	43	39	43	41	44	42
High intensity	21	22	20	22	19	21
Proportion of days covered by any statins (%) ^c	82	81	82	82	84	82
Proportion of beneficiaries adherent to statins (%) ^{c, d}	72	70	72	71	74	70

 Table B.1. CVD risk reduction population: Baseline characteristics of high-risk Medicare beneficiaries enrolled by Million Hearts intervention organizations with and without one-, two-, or three-year reassessment visits

Characteristic	Beneficiaries with one-year reassessment visit (N = 18,563)	Beneficiaries without one-year reassessment visit (N = 14,640)	Beneficiaries with two-year reassessment visit (N = 8,752)	Beneficiaries without two-year reassessment visit (N = 18,482)	Beneficiaries with three-year reassessment visit (N = 4,531)	Beneficiaries without three-year reassessment visit (N = 14,269)
Beneficiary's demographic and Me	dicare enrollment cha	aracteristics				
Age	74	74	74	74	74	74
[standard deviation]	[4]	[4]	[4]	[4]	[4]	[4]
Black race (%)	7	6	6	6	5	7
Male (%)	66	66	66	65	67	65
Dually enrolled in Medicare and Medicaid (%)	8	9	7	8	5	7
Originally entitled to Medicare because of disability (%)	11	12	11	11	10	10
Beneficiary's health and comorbid	conditions					
HCC score	1.30	1.37	1.26	1.33	1.24	1.29
[standard deviation]	[0.97]	[1.05]	[0.90]	[1.00]	[0.88]	[0.94]
Number of chronic conditions	2.5	2.6	2.5	2.6	2.5	2.5
Has chronic kidney disease (%)	35	35	36	34	36	34
Has ischemic heart disease (%)	37	42	36	41	35	40
Has congestive heart failure (%)	12	14	11	13	11	13
Has atrial fibrillation (%)	11	12	10	12	11	12
Has morbid obesity (%)	9	8	9	8	10	7
Beneficiary's medical service use a	nd spending in year	before model enrollm	nent			
Total Medicare Parts A and B annualized expenditures (\$)	7,497	8,588	6,749	8,150	6,507	7,569
[standard deviation]	[15,583]	[19,412]	[13,535]	[16,256]	[15,309]	[14,296]
Hospital admissions (per 1,000 beneficiaries)	178	213	159	192	149	172
CVD-related hospital admissions (per 1,000 beneficiaries) ^g	41	53	35	47	35	39
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	344	410	326	378	303	352
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) ^e	26	37	25	33	22	28
Office visits (per 1,000 beneficiaries)	9,587	10,003	9,305	9,970	9,122	9,903

Characteristic	Beneficiaries with one-year reassessment visit (N = 18,563)	Beneficiaries without one-year reassessment visit (N = 14,640)	Beneficiaries with two-year reassessment visit (N = 8,752)	Beneficiaries without two-year reassessment visit (N = 18,482)	Beneficiaries with three-year reassessment visit (N = 4,531)	Beneficiaries without three-year reassessment visit (N = 14,269)
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,199	2,636	3,211	2,850	3,350	3,071
Cardiologist visits (per 1,000 beneficiaries)	1,985	2,229	1,942	2,151	1,816	2,040
Beneficiary CVD-related procedure	s in year before mode	el enrollment				
Received echocardiogram (%)	42	47	39	46	39	45
Received electrocardiogram (%)	72	76	69	76	68	76
Received cardiac stress test (%)	28	31	27	31	28	31
Characteristics of organization enr	olling the beneficiary					
Total number of practitioners	136	131	147	117	167	109∆
[standard deviation]	[207]	[225]	[191]	[221]	[195]	[186]
Total number of service sites	28	22	30	22 ^Δ	34	22 [∆]
[standard deviation]	[28]	[25]	[29]	[26]	[30]	[26]
Organization type (%)						
Primary care	53	41	57	42 ∆	59	47
Specialty or multispecialty	41	45	37	46	36	42
FQHC, RHC, or other health center	4	5	3	5	2	4
CAH or rural hospital	0	1	0	0	0	0
Acute care hospital	3	8	2	7	3	7
Organization was participating in, or had application pending for, another model at randomization (%)	69	64	73	61 ^Δ	80	61 [∆]
Organization-level mean Medicare spending and use ^f						
Parts A and B spending	7,462	8,080∆	7,297	8,009∆	7,151	7,958∆
Hospital admissions (per 1,000 beneficiaries)	184	192	184	191	182	190
Outpatient ED visits (per 1,000 beneficiaries)	380	387	390	385	390	386

Characteristic	Beneficiaries with one-year reassessment visit (N = 18,563)	Beneficiaries without one-year reassessment visit (N = 14,640)	Beneficiaries with two-year reassessment visit (N = 8,752)	Beneficiaries without two-year reassessment visit (N = 18,482)	Beneficiaries with three-year reassessment visit (N = 4,531)	Beneficiaries without three-year reassessment visit (N = 14,269)
Characteristics of clinician enrollin	g the beneficiary					
Provider specialty (%)						
Primary care physician	63	50^{Δ}	66	52 ^Δ	68	55^{Δ}
Cardiologist	24	36 ^Δ	21	34^{Δ}	17	31 [∆]
Physician with other specialty	2	2	1	2	1	2
Not a physician (for example, NP or PA)	11	11	11	10	13	10
Characteristics of beneficiary's reg	ion					
Rural (%)	27	25	30	26	32	27
U.S. Census region (%)						
Northeast	19	28	16	23	10	24 ^Δ
Midwest	22	15	32	15	38	17
South	52	44	47	50	48	50
West	7	12	5	12	4	8
County-level health measures						
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	11	12	11 ^Δ	12	11 ^Δ
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	24	23	24	23	24	24
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,472	4,388	4,561	4,409 ^Δ	4,606	4,468
Per capita total Medicare Parts A and B spending in 2016	9,796	9,929	9,730	9,958	9,669	9,943
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	282	275	289	276 ^Δ	292	280 ^Δ
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	710	687	734	693∆	744	702^

Characteristic	Beneficiaries with one-year reassessment visit (N = 18,563)	Beneficiaries without one-year reassessment visit (N = 14,640)	Beneficiaries with two-year reassessment visit (N = 8,752)	Beneficiaries without two-year reassessment visit (N = 18,482)	Beneficiaries with three-year reassessment visit (N = 4,531)	Beneficiaries without three-year reassessment visit (N = 14,269)
Characteristics of beneficiary's Mi	llion Hearts Model en	rollment				
Days between model launch (January 3, 2017) and enrollment date	154	217△	135	1864	89	111∆
[standard deviation]	[154]	[191]	[138]	[171]	[73]	[80]
Enrollment date is in (%)						
First quarter of the year	48	38	52	43	59	46^{Δ}
Second quarter of the year	31	31	29	31	29	35
Third quarter of the year	13	16	11	16	9	15
Fourth quarter of the year	9	15	8	10	3	5
Data submitted to the registry using bulk upload (%) ^g	40	43	48	38	52	38

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, 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; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiary county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: This table includes three subpopulations. The first two columns, middle two columns, and last two columns include beneficiaries eligible for a one-, two-, or three-year reassessment visit, respectively. Beneficiaries were eligible if they were observable through the end of their reassessment visit anniversary window: that is, they were alive, enrolled in Medicare FFS Parts A and B with Medicare as primary payer, and had not had an AMI, stroke, or transient ischemic attack, and their organization had not withdrawn from the model.

For all measures, means are calculated over nonmissing values. Definitions of the following chronic conditions use the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, and ischemic heart disease. Definitions of the following chronic conditions use HCC algorithms: congestive heart failure and morbid obesity. Definitions of all procedures use Clinical Classifications Software indicators.

^A Indicates the difference between those with and without reassessment visits for a given year is 0.25 standardized differences or larger. The standardized difference is the difference between the group means among beneficiaries with and without a reassessment, divided by the pooled standard deviation across the two groups.

^a Modifiable risk is defined as the difference between a beneficiary's CVD risk score at enrollment and his or her 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.

^b Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment (N = 12,942 for beneficiaries with a one-year reassessment visit and N = 10,175 for beneficiaries without a one-year reassessment visit; N = 6,168 for beneficiaries with a two-year reassessment visit and N = 12,832 for beneficiaries without a two-year reassessment visit; N = 3,219 for beneficiaries with a three-year reassessment visit and N = 9,950 for beneficiaries without a three-year reassessment visit). This accounted for 70 percent of all enrolled beneficiaries with and 70 percent without a one-year reassessment visit, 70 percent of all enrolled beneficiaries with and 69 percent without a two-year reassessment visit, and 71 percent of all enrolled beneficiaries with and 70 percent without a three-year reassessment visit.

^o Measured among beneficiaries who also had 12 months of Part D coverage before and in the month of enrollment and with medication use at baseline. For analyses of antihypertensive adherence, this included N = 11,215 beneficiaries with a one-year reassessment visit and N = 8,724 without a one-year reassessment visit, accounting for 60 percent

of all beneficiaries with a one-year reassessment visit and 60 percent without a one-year reassessment visit. This included N = 5,373 beneficiaries with a two-year reassessment visit and N = 11,070 without a two-year reassessment visit, accounting for 61 percent of all beneficiaries with a two-year reassessment visit and 60 percent without a two-year reassessment visit. This included N = 2,810 beneficiaries with a three-year reassessment visit and N = 8,639 without a three-year reassessment visit, accounting for 62 percent of all beneficiaries with a three-year reassessment visit and 61 percent of all beneficiaries with a three-year reassessment visit.

For analyses of statin adherence, this included N = 8,808 beneficiaries with a one-year reassessment visit and N = 6,610 without a one-year reassessment visit, accounting for 47 percent of all beneficiaries with a one-year reassessment visit and 45 percent without a one-year reassessment visit. This included N = 4,157 beneficiaries with a two-year reassessment visit, accounting for 47 percent of all beneficiaries with a two-year reassessment visit and 46 percent without a two-year reassessment visit. This included N = 8,559 without a two-year reassessment visit, accounting for 47 percent of all beneficiaries with a two-year reassessment visit and 46 percent without a two-year reassessment visit. This included N = 2,175 beneficiaries with a three-year reassessment visit and N = 6,688 without a three-year reassessment visit, accounting for 48 percent of all beneficiaries with a three-year reassessment visit and 47 percent without a three-year reassessment visit.

^d We defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

^e We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the <u>Second Annual Report</u>, Appendix C), including those related to heart failure, hypertension, and angina (Peterson et al. 2019). In the baseline period, this measure excludes heart attacks and strokes because the analysis sample excludes any beneficiaries who had these events before enrolling in the Million Hearts Model.

^f Mathematica's <u>Third Annual Report</u>, Appendix D provides details on measure construction (Blue et al. 2020). To estimate organizational-level mean Medicare spending and use per beneficiary, we used only baseline data from the 2017 enrollees. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for its Medicare populations. The organization-level means included in this table are the variance-shrunken means for each organization.

⁹ Participating organizations could upload data manually (that is, entering data for each beneficiary visit one by one, using a web interface), or in bulk, using one of two CMS-provided tools. We show the proportion who used a bulk-upload tool in case data quality varies by data submission mode.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

3. Payments to intervention organizations, over time and by type of payments

In <u>Chapter III</u>, we reported median payments to intervention organizations decreased over time and the proportion of organizations meeting the criteria for risk-reduction payments also decreased. In this section, we provide additional analyses to support these statements. Figure B.1 shows *total* payments to organizations in the intervention group, by performance period. This figure demonstrates payments were highest in the first year of the model (that is, performance periods 1 and 2, or calendar year 2017), and declined steadily thereafter to a low of \$246,180 in the second half of 2020. Total payments declined over time both because (1) fewer organizations participated in the later performance periods and (2) the median payment per intervention organization also decreased over this period.



Figure B.1. Total CMS payments to intervention organizations in each performance period

Source: Mathematica's analysis of payment data to all intervention organizations received from the implementation contractor.

CMS = Centers for Medicare & Medicaid Services; PP = performance period.

Table B.2 reports total CMS payments by type and the number of organizations that either received a payment of any type or were eligible to receive a payment for reporting reassessment data in a given period. In the first model year, intervention organizations could receive \$10 per eligible beneficiary who was enrolled and risk stratified (risk-stratification payment) and \$10 per beneficiary per month (PBPM) in cardiovascular care management fees for each high-risk beneficiary (cardiovascular care management payment). In the subsequent model years, intervention organizations continued to receive \$10 per eligible beneficiary who was risk stratified. They also received risk reduction payments based on average change in risk score among high-risk beneficiaries (\$0 PBPM for average risk reduction less than 2 percentage points, \$5 PBPM for average risk reduction from 2 to 10 percentage points, and \$10 PBPM for average risk reduction greater than 10 percentage points). Consistent with Figure B.1., total payments

declined in each performance period as payments shifted from a uniform \$10 PBPM in 2017 to a performance-based risk-reduction payment with a maximum of \$10 PBPM for high-risk beneficiaries. Furthermore, risk-reduction payments made up a greater share of total payments than other payment types after the first model year, as organizations enrolled fewer new beneficiaries and shifted their focus to reassessing those enrolled in the first year.

		Payment type					
Performance period	Number of organizations	Risk stratification (\$)	CVD care management (\$)	Risk reduction (\$)	Recoupment (\$)	Total payment (\$)	
PP1 (Jan–June 2017)	162	1,203,450	852,540	n.a.	n.a.	2,055,990	
PP2 (July–Dec 2017)	166	644,180	1,887,500	n.a.	n.a.	2,531,680	
PP3 (Jan–June 2018)	134	264,440	44,200	681,505	0	990,145	
PP4 (July–Dec 2018)	126	215,970	820	461,385	-2,090	676,085	
PP5 (Jan–June 2019)	99	134,440	0	345,095	0	479,535	
PP6 (July–Dec 2019)	90	126,900	0	190,645	0	317,545	
PP7 (Jan–June 2020)	79	97,410	0	177,325	0	274,735	
PP8 (July–Dec 2020)	62	88,690	0	157,490	0	246,180	
Total	173	2,775,480	2,785,060	2,013,445	-2,090	7,571,895	

Table B.2. Total CMS payments in each performance period, by payment type

Source: Mathematica's analysis of payment data to all intervention organizations received from the implementation contractor.

Note: Intervention organizations received a one-time risk-stratification payment for each eligible, risk-stratified beneficiary whose clinical data were entered in the registry, regardless of the risk level. In the first model year, intervention organizations received a cardiovascular care management payment for beneficiaries who were risk stratified as high risk and received cardiovascular care management, as attested in the registry. Although organizations were eligible to receive cardiovascular care management payments only for care provided in 2017, some organizations received these payments during the third and fourth performance periods depending on when data were submitted to the registry. In Years 2 through 5, intervention organizations received risk-reduction payments for reducing average risk among high-risk beneficiaries, as indicated by clinical data reported to the registry.

CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular; n.a. = not applicable; PP = performance period

Table B.3 shows the number of intervention organizations eligible for risk-reduction payments in performance periods 3 through 8 (January 2018 to December 2020) and the proportion of these organizations earning each risk-reduction payment category (\$0, \$5, or \$10 PBPM). Eligible organizations submitted at least one reassessment visit to the registry for a given six-month performance period. The number of organizations submitting reassessment visits declined from 109 in the third performance period (the first period in which they were eligible to receive payments for risk reduction) to 57 in the eighth performance period. In each performance period, 16 to 26 percent of the organizations that submitted a reassessment visit met the criteria for the maximum risk-reduction payment amount of \$10 PBPM—that is, reducing aggregate average risk among high-risk beneficiaries by more than 10 percentage points. Slightly more than half (56 percent) of the organizations that ever submitted a reassessment visit achieved the maximum

payment amount in at least one of six performance periods during which they were eligible to receive risk-reduction payments. The percentage of organizations that submitted reassessment visit data but did not qualify for any risk-reduction payments increased each performance period. Average risk reduction, calculated among organizations that submitted at least one reassessment visit, also generally decreased over time.

Table D.S. I dyments for tisk reduction among organizations with a reassessment visit							
Performance period	Number of organizations	Mean risk reduction (pp)	\$0 PBPM (%)	\$5 PBPM (%)	\$10 PBPM (%)		
PP3 (Jan–June 2018)	109	-7.7	6	72	22		
PP4 (July–Dec 2018)	94	-7.1	11	64	26		
PP5 (Jan–June 2019)	91	-6.5	16	65	19		
PP6 (July–Dec 2019)	75	-6.9	1	59	23		
PP7 (Jan–June 2020)	68	-5.9	22	53	25		
PP8 (July–Dec 2020)	57	-4.7	32	53	16		
Total (any period) ^a	124	-6.6	40	81	56		

Table B.3. Payments for risk reduction among organizations with a reassessment visit

Source: Mathematica's analysis of payment data to all intervention organizations received from the implementation contractor.

Note: The \$0, \$5, and \$10 PBPM risk-reduction payments correspond to less than 2 percentage point, 2–10 percentage point, and greater than 10 percentage point average risk reduction, respectively.

^a The total row reflects the number of organizations that had reassessments in any period from PP3 to PP8 (Number of organizations column), the average change in risk scores across performance periods (Mean risk reduction column), and the number of organizations that received a risk-reduction payment in a given PBPM category for *any* of the eligible periods (PBPM columns). The three PBPM columns sum to more than 100 percent in the total row because organizations can shift categories each performance period.

PP = performance period; p.p. = percentage point; PBPM = per beneficiary per month.
Appendix C

Survey Methods and Supplemental Results

As described in <u>Chapter III</u>, Mathematica fielded a Practice Survey in 2021 with the intervention organizations to learn about their experiences implementing the Million Hearts Model, facilitators of and barriers to implementation, and any plans to sustain changes in care delivery related to cardiovascular disease (CVD) risk assessment and management after the end of the model period. We conducted the Practice Survey for 12 weeks from January to April 2021, and sent it to all intervention organizations still participating in the model at that time. This appendix describes the methods we used to develop, field, and analyze the survey. It also includes supplemental results not covered in <u>Chapter III</u>. The survey instrument is available in <u>Appendix H</u>.

1. Survey development

The 2021 Practice Survey included several items from the 2018 Practice Survey (see <u>Second Annual Report</u>) assessing how model participants implemented the model and the barriers to and facilitators of implementation they encountered (Peterson et al. 2019). To compare change over time, we minimized wording changes from the 2018 Practice Survey. We added new survey items to assess how the COVID-19 public health emergency affected implementation, and plans organizations had to sustain changes in CVD care made after the Million Hearts Model ends. Before fielding, we pre-tested new items with Mathematica staff to (1) test the wording of newly added and modified items and (2) gather feedback from clinicians with similar backgrounds to our expected survey respondents. We did not test the overall flow of the survey, nor did we test items that did not change from the 2018 Practice Survey. Following the pre-test, we revised the survey to clarify the wording.

We offered respondents the option to complete the self-administered survey by web or paper; 100 percent of respondents completed the survey via web. We estimated the length of the survey to be about 10 to 15 minutes for participants to complete.

2. Survey frame and response rates

From January to April 2021, we administered surveys to a census of the intervention organizations that remained in the Million Hearts Model. We initially sent the survey to the 138 intervention organizations that, per the tracker used by the Centers for Medicare & Medicaid Services (CMS), were still participating in the Million Hearts Model at the end of 2020 (that is, organizations that had not formally withdrawn from the model or been terminated by CMS). However, we removed six organizations from the survey sample that notified us of their withdrawal from the model, resulting in a total of 132 intervention organizations in the survey sample frame. We received 90 survey responses (89 completed and one partially completed), for

a total response rate of 68.2 percent. In Figure C.1, we depict how we arrived at the final survey frame, the number of organizations that responded, and those included in the analysis.





CVD = cardiovascular disease; MH = Million Hearts.

We anticipated a lower survey response rate in 2021 than we achieved in 2018 (91 percent) for a few reasons. First, as we fielded the survey in early 2021, organizations were operating under the strain of the COVID-19 public health emergency and we expected organizations might find it difficult to respond to the survey in this context. In addition, organizations were beginning the final model year and we expected some organizations might have disengaged from the Million Hearts Model. To boost response rates, we sent reminder emails to nonresponding organizations; at Week 6 of the field period, we also began reminder calls to nonresponding organizations.

3. Survey analysis

We analyzed survey results to describe organizations' responses to the 2021 survey and, when possible, compare responses to the 2018 survey. For the purpose of comparing responses over time, we limited our analysis of 2018 survey responses to the 90 organizations that also

responded to the survey in 2021. We considered two organizations that responded to the survey in 2021 but not in 2018 missing from the 2018 responses.

So the responses from the 90 organizations that responded to the survey more closely reflect the 132 organizations in the full survey frame, we developed analytic weights based on each organization's probability of responding to the survey. We first used a logistic regression model to predict each organization's probability of responding to the survey based on a list of organizational covariates (Table C.1). Then, we calculated these inverse probability weights as 1/p(x) where p(x) is the predicted probability of responding to the survey. Lastly, we calibrated the weights so they sum to be the target number of organizations (132).

After creating the weights, we assessed covariate balance on key characteristics of interest for organizations that completed the survey before and after the weighting (Table C.1). For example, 64 percent of the 132 organizations submitted data to the registry for performance periods 6 or 7 (July 2019 through June 2020), compared to 77 percent of the 90 respondents. However, after weighting, this difference decreased from 13 to 1 percent. After weighting, all covariates were similar between the respondents and the full survey frame.

To ensure comparability in respondent populations over time, we applied the same weights we developed for the 2021 survey to the 2018 survey. For example, if an organization received a weight of 1.2 for the 2021 survey analysis, that organization also received a weight of 1.2 in the 2018 survey analysis. This approach ensures changes in responses over time between the 2018 and 2021 survey are not due to either changes in which organizations responded or the weights they received in the analysis. As a result, observed changes should reflect true changes in model implementation and experiences within organizations over time.

	Full sam <u>ple frame</u>	Organizations that responded to the 2021 survey (unweighted)	Organizations that responded to the 2021 survey (weighted)
Characteristic	(N = 132)	(N = 90)	(N = 132)
Number of providers (from Million Hea	arts Model application)		
1 to 5 providers (%)	35	38	35
6 to 19 providers (%)	11	10	11
20 or more providers (%)	54	52	54
Organization type			
Acute care hospital (%)	10	8	9
FQHC, RHC, or other health center, CAH or rural hospital (%)	10	8	9
Primary care (%)	48	52	50
Specialty or multispecialty (%)	27	27	26
Location (from Million Hearts Model a	pplication)		
Rural (%)	60	61	61
Census region (%)			
Northeast	30	27	30
Midwest	15	19	16
South (+1 Territory)	40	41	40
West	14	13	14
Data reporting			
Reported an enrollment or reassessment visit for the sixth or seventh performance period (%)	64	77	65

Table C.1. Characteristics of organizations that responded to the 2021 Practice Survey, before and after applying weights

Sources: Mathematica's analysis of a survey administered to intervention organizations in 2021, 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.

Note: This table presents unadjusted proportions of organizations that completed a survey, and those proportions with the analytic weights applied. These weights account for nonresponse among organizations.

CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; FQHC = federally qualified health center; NPPES = National Plan and Provider Enumeration System; RHC = rural health center.

4. Supplemental results

To supplement the survey figures presented in the main report, we provide a detailed table (Table C.2) showing weighted counts of 2021 survey responses per individual response category for each survey question not already included in a table or figure in <u>Chapter III</u> of the main report. When applicable, we also show the 2018 survey responses for overlapping questions.

Table C.2. Intervention organization responses to the 2021 and 2018 Practice Surveys

	2021 \$	2021 Survey		2018 Survey		
Response	Weighted number of respondents	Weighted proportion of respondents (%)	Weighted number of respondents	Weighted proportion of respondents (%)	Difference (%)	
What is your primary role in the Ce at your practice?	enters for Medicar	e & Medicaid Servi	ces (CMS) Million I	Hearts [®] Model imp	lementation	
Oversee the model but not responsible for day-to-day operations	44.3	33.5	48.1	38.1	-4.6	
Project manager / responsible for day-to-day operations	29.4	22.3	32.0	25.4	-3.1	
Clinical lead	30.4	23.0	22.9	18.2	4.9	
Health information technology/ entering data into model	14.7	11.1	15.7	12.4	-1.3	
Other role, not specified above	13.3	10.1	7.5	5.9	4.1	
Total	132.0		126.2			
About what proportion of Medicard calculator?	e beneficiaries has	s your practice cald	culated a CVD risk	score for, using a	ny risk	
We do not calculate CVD risk scores	2.6	2.0	5.0	3.9	-1.9	
1–24%	23.3	17.7	4.8	3.7	13.9	
25–49%	22.0	16.7	13.9	10.8	5.9	
50–74%	25.1	19.0	32.1	25.0	-6.0	
75–100%	35.3	26.7	46.3	36.0	-9.3	
Don't know	23.8	18.0	26.4	20.6	-2.6	
Total	132.0		128.5			
Thinking about the care your pract calculate CVD risk scores for? (20	tice provided 2 yea 18 survey questio	ars ago, what prop n)	ortion of Medicare	beneficiaries did y	our practice	
We do not calculate CVD risk scores	n.a.	n.a.	42.2	33.1	n.a.	
1–24%	n.a.	n.a.	28.5	22.4	n.a.	
25–49%	n.a.	n.a.	14.1	11.1	n.a.	
50–74%	n.a.	n.a.	11.2	8.8	n.a.	
75–100%	n.a.	n.a.	6.5	5.1	n.a.	
Don't know	n.a.	n.a.	24.9	19.5	n.a.	
Total	n.a.		127.2			
Once a risk score has been calcula beneficiaries in your practice? [lim	ated, how often an	e CVD risk scores a ons that reported th	available when pro hey calculate risk s	viders meet with N scores]	ledicare	
Always or almost always available when meeting with a Medicare beneficiary	74.8	70.8	66.5	68.5	2.3	

	2021 Survey		2018 :		
Response	Weighted number of respondents	Weighted proportion of respondents (%)	Weighted number of respondents	Weighted proportion of respondents (%)	Difference (%)
Sometimes available when meeting with a Medicare beneficiary	23.6	22.4	24.0	24.7	-2.3
Never available when meeting with a Medicare beneficiary	1.2	1.1	4.3	4.4	-3.3
Don't know	6.1	5.8	2.4	2.4	3.3
Total	105.6		97.1		
How are Medicare beneficiaries at organizations that reported they ca	your practice noti alculate risk score	fied of their CVD ri es]	sk score, if at all?	(check all that app	ly) [limited to
In person at office visit, by provider	93.0	88.1	78.9	81.2	6.8
In person at office visit, by other clinical staff	17.5	16.5	29.4	30.3	-13.8
Video telehealth visit, by provider	36.9	34.9	n.a.	n.a.	n.a.
Video telehealth visit, by other clinical staff	11.2	10.6	n.a.	n.a.	n.a.
Telephone call from provider	11.2	10.6	8.6	8.9	1.8
Telephone call from other clinical staff	10.8	10.2	16.6	17.1	-6.9
Written communication (for example, letter, email, patient portal)	18.7	17.7	18.6	19.1	-1.5
We do not notify Medicare beneficiaries of their risk score	6.3	6.0	5.4	5.6	0.4
Don't know	1.2	1.1	1.4	1.2	
Total	105.6		97.1		
To what extent have the following staff time to implement the model.	factors been help	ful in implementing	the CMS Million H	learts Model at yo	ur practice:
Not a factor helping implementation	25.3	19.7	40.6	32.4	-12.7
Very helpful	33.3	26.0	31.3	25.0	1.0
Somewhat helpful	67.2	52.4	44.4	35.4	17.0
Don't know	2.4	1.9	9.0	7.2	-5.3
Total	128.1		125.3		
To what extent have the following staff buy-in.	factors been help	ful in implementinç	g the CMS Million H	learts Model at yo	ur practice:
Not a factor helping implementation	25.5	19.7	33.5	26.1	-6.3
Very helpful	29.9	23.1	32.8	25.5	-2.4
Somewhat helpful	67.6	52.3	50.1	39.0	13.3
Don't know	6.3	4.9	12.1	9.4	-4.6
Total	129.4		128.5		
To what extent have the following patients' engagement with CVD ris	factors been help k reduction activi	ful in implementinç ties.	the CMS Million H	learts Model at yo	ur practice:
Not a factor helping implementation	24.3	18.6	n.a.	n.a.	n.a.
Very helpful	29.3	22.4	n.a.	n.a.	n.a.
Somewhat helpful	70.6	54.0	n.a.	n.a.	n.a.
Don't know	6.6	5.1	n.a.	n.a.	n.a.

	2021 Survey		2018 \$		
Response	Weighted number of respondents	Weighted proportion of respondents (%)	Weighted number of respondents	Weighted proportion of respondents (%)	Difference (%)
Total	130.8		n.a.		
To what extent have the followin organizational leadership suppo	g factors been help rt.	ful in implementing	the CMS Million F	learts Model at you	ur practice:
Not a factor helping implementation	14.6	11.1	13.0	10.1	1.0
Very helpful	58.5	44.7	68.6	53.4	-8.6
Somewhat helpful	56.5	43.2	41.5	32.3	10.9
Don't know	1.2	0.9	5.4	4.2	-3.3
Total	130.8		125.8		
To what extent have the followin practice champion for the Million the model and encourages colle	g factors been help n Hearts Model. (A p agues to implement	ful in implementing practice champion is the model.)	the CMS Million H s someone who ur	learts Model at younderstands the imp	ur practice: a portance of
Not a factor helping implementation	23.1	17.6	n.a.	n.a.	n.a.
Very helpful	50.6	38.7	n.a.	n.a.	n.a.
Somewhat helpful	50.7	38.8	n.a.	n.a.	n.a.
Don't know	6.4	4.9	n.a.	n.a.	n.a.
Total	130.8		n.a.		
To what extent have the followin participation in other quality imp	g factors been help provement initiatives	ful in implementing s.	the CMS Million H	learts Model at you	ur practice:
Not a factor helping implementation	12.3	9.4	17.8	14.1	-4.7
Very helpful	62.3	47.6	68.3	54.3	-6.7
Somewhat helpful	53.9	41.2	31.5	25.0	16.2
Don't know	2.4	1.8	8.3	6.6	-4.8
Total	130.8		125.8		
To what extent have the followin IT support (for example, electror	g factors been help nic health record [El	ful in implementing HR] functionality).	the CMS Million H	learts Model at you	ur practice:
Not a factor helping implementation	26.5	20.4	39.5	31.1	-10.7
Very helpful	49.3	38.0	44.5	35.0	3.0
Somewhat helpful	50.2	38.7	34.8	27.4	11.4
Don't know	3.7	2.8	8.3	6.5	-3.7
Total	129.6		127.0		
To what extent have the followin CMS help desk support.	g factors been help	ful in implementing	the CMS Million H	learts Model at you	ur practice:
Not a factor helping implementation	51.8	39.9	47.3	37.5	2.4
Very helpful	15.6	12.0	21.6	17.2	-5.2
Somewhat helpful	53.3	41.1	49.8	39.5	1.6
Don't know	9.0	7.0	7.3	5.8	1.2
Total	129.7		126.0		
To what extent have the followin accountable care organization (g factors been help ACO)-provided mate	ful in implementing rials, analytics, or o	the CMS Million H other support.	learts Model at you	ur practice:
Not a factor helping implementation	61.7	47.2	49.4	38.5	8.7
Very helpful	23.8	18.2	21.1	16.4	1.7

	2021	2021 Survey		2018 Survey		
Response	Weighted number of respondents	Weighted proportion of respondents (%)	Weighted number of respondents	Weighted proportion of respondents (%)	Difference (%)	
Somewhat helpful	30.4	23.3	42.3	32.9	-9.6	
Don't know	14.8	11.3	15.6	12.2	-0.8	
Total	130.8	11.0	128.5	12.2	0.0	
To what extent have the follo payment from CMS for telehe	wing factors been help ealth care.	ful in implementing	the CMS Million H	learts Model at you	ur practice:	
Not a factor helping implementation	37.3	28.5	n.a.	n.a.	n.a.	
Very helpful	45.4	34.7	n.a.	n.a.	n.a.	
Somewhat helpful	35.6	27.2	n.a.	n.a.	n.a.	
Don't know	12.5	9.6	n.a.	n.a.	n.a.	
Total	130.8		n.a.			
To what extent have the follo payments or financial incenti model or the Merit-based Inc	wing factors been help ives from other CMS ini entive Payment System	ful in implementing tiatives, such as th ı (MIPS).	the CMS Million H e Comprehensive	learts Model at you Primary Care Plus	ur practice: (CPC+)	
Not a factor helping implementation	32.6	24.9	n.a.	n.a.	n.a.	
Very helpful	38.7	29.6	n.a.	n.a.	n.a.	
Somewhat helpful	44.5	34.0	n.a.	n.a.	n.a.	
Don't know	15.0	11.5	n.a.	n.a.	n.a.	
Total	130.8		n.a.			
insufficient staff time for amo	ount of work.	rrier in implementi		i nearts model at y	our practice:	
Considerable barrier	66.8	51.0	58.0	45.1	5.9	
Somewhat of a barrier	44.1	33.7	43.9	34.2	-0.5	
Not a barrier	20.0	15.3	25.4	19.8	-4.5	
Don't know	0.0	0.0	1.1	0.9	-0.9	
Total	130.8		128.5			
To what extent have each of staff turnover.	the following been a ba	rrier in implementi	ng the CMS Million	ı Hearts Model at y	our practice:	
Considerable barrier	46.9	35.8	36.3	28.3	7.6	
Somewhat of a barrier	38.6	29.5	41.7	32.4	-2.9	
Not a barrier	44.2	33.8	49.4	38.4	-4.6	
Don't know	1.1	0.9	1.1	0.9	0.0	
Total	130.8		128.5			
To what extent have each of resistance or lack of support	the following been a ba from staff.	rrier in implementi	ng the CMS Million	Hearts Model at y	our practice:	
Considerable barrier	13.3	10.2	16.1	12.7	-2.5	
Somewhat of a barrier	63.7	48.7	52.8	41.8	6.9	
Not a barrier	52.6	40.2	56.5	44.6	-4.5	
Don't know	1.2	1.0	1.1	0.9	0.1	
Total	130.8		126.5			
To what extent have each of lack of patient engagement w	the following been a ba vith CVD risk-reduction	rrier in implementi activities.	ng the CMS Million	Hearts Model at y	our practice:	
Considerable barrier	15.8	12.3	n.a.	n.a.	n.a.	
Somewhat of a barrier	77.1	60.1	n.a.	n.a.	n.a.	
Not a barrier	30.4	23.7	na	na	na	

	2021 3	2021 Survey		2018 Survey		
Response	Weighted number of respondents	Weighted proportion of respondents (%)	Weighted number of respondents	Weighted proportion of respondents (%)	Difference (%)	
Don't know	5.0	3.9	n.a.	n.a.	n.a.	
Total	128.3		n.a.			
To what extent have each of t lack of support from practice	he following been a ba leadership.	rrier in implementi	ng the CMS Million	l Hearts Model at y	our practice:	
Considerable barrier	13.0	10.0	12.2	9.5	0.5	
Somewhat of a barrier	32.6	24.9	21.7	16.9	8.0	
Not a barrier	85.2	65.1	92.1	71.7	-6.5	
Don't know	0.0	0.0	2.6	2.0	-2.0	
Total	130.8		128.5			
To what extent have each of t lack of IT support, for example	he following been a ba e, EHR functionality.	rrier in implementi	ng the CMS Million	l Hearts Model at y	our practice:	
Considerable barrier	22.8	17.4	20.2	15.7	1.7	
Somewhat of a barrier	38.1	29.1	39.5	30.7	-1.6	
Not a barrier	67.4	51.6	62.4	48.5	3.0	
Don't know	2.5	1.9	6.5	5.0	-3.1	
Total	130.8		128.5			
To what extent have each of t lack of support from the CMS	he following been a ba help desk.	rrier in implementi	ng the CMS Million	l Hearts Model at y	our practice:	
Considerable barrier	22.1	16.9	18.6	14.4	2.4	
Somewhat of a barrier	18.0	13.8	46.1	35.8	-22.1	
Not a barrier	73.4	56.1	59.4	46.2	9.9	
Don't know	17.4	13.3	4.5	3.5	9.8	
Total	130.8		128.5			
To what extent have each of t organizational changes.	he following been a ba	rrier in implementi	ng the CMS Million	ı Hearts Model at y	our practice:	
Considerable barrier	17.2	13.3	20.8	16.2	-2.9	
Somewhat of a barrier	53.4	41.4	36.8	28.7	12.8	
Not a barrier	55.7	43.3	69.7	54.2	-11.0	
Don't know	2.6	2.0	1.1	0.9	1.1	
Total	128.8		128.5			
To what extent have each of t competing organizational or p	he following been a ba practice priorities.	rrier in implementi	ng the CMS Million	l Hearts Model at y	our practice:	
Considerable barrier	50.3	38.4	38.4	29.9	8.6	
Somewhat of a barrier	37.6	28.7	55.1	42.9	-14.1	
Not a barrier	40.4	30.9	30.4	23.6	7.3	
Don't know	2.5	1.9	4.6	3.6	-1.7	
Total	130.8		128.5			
To what extent have each of t challenges scheduling in-pers	he following been a ba son office visits.	rrier in implementi	ng the CMS Million	Hearts Model at y	our practice:	
Considerable barrier	32.2	24.6	n.a.	n.a.	n.a.	
Somewhat of a barrier	54.4	41.6	n.a.	n.a.	n.a.	
Not a barrier	44.2	33.8	n.a.	n.a.	n.a.	
Don't know	0.0	0.0	n.a.	n.a.	n.a.	
Total	130.8		n.a.			

	2021 \$	2021 Survey		urvey			
Response	Weighted number of respondents	Weighted proportion of respondents (%)	Weighted number of respondents	Weighted proportion of respondents (%)	Difference (%)		
Increased use of telehealth visits enduring the COVID-19 pandemic. [lin lot' due to COVID-19]	nabled us to cont nited to organizat	inue implementing ions that responde	Million Hearts Mod d they increased u	lel risk-assessme se of telehealth 's	nt activities ome' or 'a		
Not at all	48.1	36.8	n.a.	n.a.	n.a.		
Some	65.1	49.8	n.a.	n.a.	n.a.		
A lot	17.6	13.4	n.a.	n.a.	n.a.		
Total	130.8		n.a.				
Increased use of home blood pressure monitoring enabled us to continue implementing Million Hearts Model risk- assessment activities during the COVID-19 pandemic. [limited to organizations that responded they increased the use of home blood pressure monitoring 'some' or 'a lot' due to COVID-19]							
Not at all	21.0	25.1	n.a.	n.a.	n.a.		
Some	55.4	66.3	n.a.	n.a.	n.a.		
A lot	7.2	8.6	n.a.	n.a.	n.a.		
Total	83.6		n.a.				
Did your practice make changes to in the Million Hearts Model?	care delivery rela	ted to CVD risk as	sessment and man	agement through	participation		
Yes	85.6	65.4	n.a.	n.a.	n.a.		
No	30.9	23.6	n.a.	n.a.	n.a.		
Don't know	14.3	11.0	n.a.	n.a.	n.a.		
Total	130.8		n.a.				
Does your practice plan to sustain participation in the Million Hearts N delivery related to CVD risk assess	changes to care o lodel ends? [limit ment and manage	lelivery related to (ed to organizations ement]	CVD risk assessme s that responded th	nt and manageme at they made cha	ent after nges to care 		
Yes	72.0	84.2	n.a.	n.a.	n.a.		
No	3.4	4.0	n.a.	n.a.	n.a.		
Don't know	10.1	11.8	n.a.	n.a.	n.a.		
Total	85.6		n.a.				
Source: Mathematica's analysis of p	ractice survevs adr	ninistered in 2018 a	nd 2021.				

Notes: Survey respondents were weighted to account for nonresponse among intervention group organizations. The weighted number of respondents reported in this table differs from the unweighted number of responses reported in the main body of the report. The weighted totals do not always add to 132 because not all respondents might have been asked, or had answered, a particular question. Two organizations responded to the survey in 2021 but not in 2018, and therefore had a missing response for all items.

In this survey, providers include MDs, DOs, PAs, and NPs; other clinical staff includes LPNs, RNs, MAs, care managers and social workers.

CVD = cardiovascular disease; DO = doctor of osteopathy; IT = information technology; LPN = licensed practical nurse; MA = medical assistant; MD = medical doctor; n.a. = not applicable, question not included in survey in given year; NP = nurse practitioner; PA = physician assistant; RN = registered nurse.

Appendix D

Methods and Supplemental Results for Analysis of Risk Score Changes and Drivers of Variation in Performance in Reducing Cardiovascular Risk

This appendix describes (1) the methods for analyzing changes in risk scores over time for highrisk beneficiaries (including supplemental results from this analysis), (2) the process for calculating organizational performance in cardiovascular disease (CVD) risk reduction and identifying high- and lower-performing organizations, and (3) the process for collecting and analyzing supplemental qualitative data collection for a sample of high- and lower-performing organizations.

1. Changes in risk scores over time among intervention group beneficiaries

Mathematica calculated change in CVD risk scores over time among high-risk beneficiaries²³ in our analytic population using Million Hearts Data Registry data from 2017 through December 2020. We calculated CVD risk scores at reassessment visits using the Million Hearts Longitudinal Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment Tool. To be included in the analysis, beneficiaries had to be eligible for and receive a one-, two-, and three-year reassessment visit. Most of those visits occurred during the 4-month window of time around the anniversary of the beneficiary's enrollment in the model (the anniversary window),²⁴ which was 10 to 14 months after enrollment for the one-year reassessment, 22 to 26 months after enrollment for the two-year reassessment visits could occur after the anniversary window, and organizations could still receive payments for these later reassessment visits (pro-rated based on the amount of time between enrollment and reassessment). Because of this, we allowed one-year reassessment visits to occur up to 21 months post-enrollment, two-year reassessment visits up to 33 months post-enrollment, and three-year reassessment visits up to 45 months post-enrollment.

²³ Beneficiaries were categorized as high, medium, or low risk based on their CVD risk score at enrollment. For the 6 percent of beneficiaries who had CVD risk factor information recorded in the registry before the baseline visit date used by the Center for Medicare & Medicaid Services (CMS) implementation contractor to calculate payments (Conwell et al. 2019), we included the beneficiaries in the denominator for reassessment visit rates as long as they were classified as high risk at both dates. We required the beneficiary to be classified as high risk at the enrollment date used for payment, even though we consider the beneficiary's true baseline to be the earlier visit, because intervention group organizations had to provide reassessment data only for beneficiaries classified as high risk at the later date.

²⁴ For the 6 percent of beneficiaries who had CVD risk factor information recorded in the registry before the baseline visit date used by the CMS implementation contractor to calculate payments (Conwell et al. 2019), we defined numerator and denominator criteria for reassessment visit rates based on the date used by CMS's implementation contractor to calculate payments. This is the date used to flag whether beneficiaries are within their anniversary window in the Million Hearts Data Registry.

We included only visits with nonmissing risk scores and for which the organization attested to the accuracy of the visit information.

Beneficiaries were eligible for all three reassessment visits if they (1) were enrolled in the model on or before October 31, 2017, and thus had at least 38 months of follow-up to observe a threeyear reassessment visit within the three-year anniversary window through the end of 2020; (2) remained alive, without acute myocardial infarction or stroke or transient ischemic attack, and enrolled in Medicare fee-for-service with Medicare as their primary payer through the end of their three-year reassessment visit window 38 months post-enrollment; and (3) were enrolled in the Million Hearts Model by an organization that remained a model participant through the end of the beneficiary's reassessment visit window 38 months post-enrollment.

We compared the trends in CVD risk scores among intervention beneficiaries with all three reassessment visits to control group beneficiaries with a one-year follow-up visit (Figure IV.1). We calculated the control group trends using data through December 2019, which was the last time the control group was required (or permitted) to submit data to the Million Hearts Data Registry. Otherwise, one-year follow-up visits were defined the same way in the control group as one-year reassessment visits in the intervention group.

In Figures D.1 through D.3, we show trends in CVD risk scores and risk factors for beneficiaries who received all three reassessment visits, as well as for the larger population of beneficiaries who received a one-year reassessment visit, or a one- and two-year reassessment visit. Trends were generally similar for reassessment visits with overlapping data in these three nonmutually exclusive groups. However, beneficiaries with all three reassessment visits had somewhat lower systolic blood pressure and low-density lipoprotein (LDL) cholesterol levels at all visits, including the enrollment visit.





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

- Note: The blue solid line includes 2,978 high-risk intervention beneficiaries who received three reassessment visits by December 2020. The blue dashed line includes 8,361 high-risk intervention beneficiaries who received both one- and two-year reassessment visits by December 2020. The blue dotted line includes 18,347 high-risk intervention beneficiaries who received a one-year reassessment visit by December 2020. These three groups are not mutually exclusive. For comparison, the green line includes 10,209 control beneficiaries who received at least one follow-up visit by December 2019. (After December 2019, the control group was not required to submit data to the Million Hearts Data Registry.) One-year reassessment visits occurred 10 to 21 months after enrollment, two-year reassessment visits occurred 22 to 33 months after enrollment, and three-year reassessment visits occurred 34 to 45 months after enrollment.
- CVD = cardiovascular disease.

Figure D.2. Mean systolic blood pressure declined over the first two years post-enrollment, but then increased again slightly by the three-year reassessment: Change in systolic blood pressure between enrollment and annual reassessment visits through December 2020



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

Note: The blue solid line includes 2,978 high-risk intervention beneficiaries who received three reassessment visits by December 2020. The blue dashed line includes 8,361 high-risk intervention beneficiaries who received both one- and two-year reassessment visits by December 2020. The blue dotted line includes 18,347 high-risk intervention beneficiaries who received a one-year reassessment visit by December 2020. These three groups are not mutually exclusive. For comparison, the green line includes 10,209 control beneficiaries who received at least one follow-up visit by December 2019. (After December 2019, the control group was not required to submit data to the Million Hearts Data Registry.) One-year reassessment visits occurred 10 to 21 months after enrollment, two-year reassessment visits occurred 22 to 33 months after enrollment, and three-year reassessment visits occurred 34 to 45 months after enrollment.

mmHg = millimeters of mercury.



Figure D.3. Mean LDL cholesterol declined steadily over three years post-enrollment: Change in LDL cholesterol between enrollment and annual reassessment visits through December 2020

Note: The blue solid line includes 2,978 high-risk intervention beneficiaries who received three reassessment visits by December 2020. The blue dashed line includes 8,361 high-risk intervention beneficiaries who received both one- and two-year reassessment visits by December 2020. The blue dotted line includes 18,347 high-risk intervention beneficiaries who received a one-year reassessment visit by December 2020. These three groups are not mutually exclusive. For comparison, the green line includes 10,209 control beneficiaries who received at least one follow-up visit by December 2019. (After December 2019, the control group was not required to submit data to the Million Hearts Data Registry.) One-year reassessment visits occurred 10 to 21 months after enrollment, two-year reassessment visits occurred 22 to 33 months after enrollment, and three-year reassessment visits occurred 34 to 45 months after enrollment.

LDL = low-density lipoprotein; mg/dL = milligrams per deciliter.

2. Calculating organizational performance and identifying high- and lower-performing organizations

To identify high- and lower-performing organizations, we judged performance using the same performance measure used by the Centers for Medicare & Medicaid Services (CMS) to determine the model's incentive payments: the organization's average risk reduction among its high-risk beneficiaries with reassessment visits.

Organizations eligible for the quantitative analysis of variation in organizational

performance. For this analysis (Chapter IV, Section A.2), we limited the set of 108 intervention organizations still active in the model as of December 2019 to those that met three criteria, which we imposed to ensure a stable estimate of risk-reduction performance for each organization. Specifically, as noted in Chapter IV, organizations eligible for analysis had to have (1) enrolled at least 40 percent of their 2017–2018 beneficiaries who appeared eligible for the model in claims, (2) conducted reassessment visits with at least 40 percent of their high-risk beneficiaries

who were due for such a visit by the end of 2018, and (3) conducted no fewer than 22 reassessment visits used to calculate risk reduction payments for the period ending December 31, 2019. (We selected the threshold of 22 based on a Bayesian shrinkage model to estimate the reliability of each organization's performance score; results not shown.) Imposing these criteria left 58 organizations for which we calculated performance scores.

For each of the 58, we calculated the average risk reduction (performance) among high-risk beneficiaries with reassessment visits occurring from November 2017 to December 2019—the same period used to calculate risk reduction for the third through sixth performance periods—based on the data CMS used to calculate model risk reduction payments in 2018 and 2019. For each organization, we calculated the average risk reduction among high-risk beneficiaries, with risk reduction defined as the beneficiary's CVD risk score at enrollment (that is, the beneficiary's predicted probability at enrollment of having a heart attack or stroke within 10 years, measured as a percentage) minus the beneficiary's CVD risk score at reassessment (the 10-year predicted probability measured one year later). For example, a beneficiary with a risk score of 40 percent at enrollment and a risk score of 32 percent at reassessment would have a risk reduction of 8 percentage points. To calculate the organization's average risk reduction, we gave equal weight to all of the organization's reassessment visits from the relevant period, although this means some beneficiaries contributed to an organization's performance score more than once (for example, with both a first and a second reassessment visit).

We corrected the performance scores, when possible, among organizations with double-counted reassessment visits—that is, with visits included in the risk reduction payment calculation in more than one performance period. Double-counting was rare; it occurred only when an organization failed to earn a risk-reduction payment in one or more performance periods. Moreover, because the double-counting most often occurred in performance periods with very few observations, for several of the affected organizations we could identify the double-counted observations—and this enabled us to calculate a corrected performance score for the combined period from performance periods 3 through 6. When we could not identify the double-counted observations using available data, we dropped the organizations from the analysis, as we could not reliably ascertain these organizations' performance scores. This resulted in four organizations dropped, leaving a total of 54 organizations eligible for the analysis.

3. Interviewing a sample of high-and lower-performing organizations

To better understand potential drivers that might explain high performance, we interviewed staff from a sample of high- and lower-performing sites. This section details our approach to identifying the sample of organizations to interview and provides details on the development of the interview protocol, data collection, and subsequent analyses to identify potential drivers. **Identifying high- and lower-performing organizations to interview.** We interviewed select organizations to learn about the strategies they took to reduce CVD risk and their perceptions of the drivers of CVD risk reduction (<u>Chapter IV</u>, Section B.2). We aimed to interview a range of high- and lower-performing organizations. We defined high performers as those with an average risk reduction of at least 8.9 percentage points, and lower performers as those with an average risk reduction of no more than 6.0 percentage points. These categories of high and lower performers correspond to roughly the top 20 and bottom 20 percent of the performance distribution.

We removed organizations from the pool eligible for interviews if they withdrew from the Million Hearts Model in 2020, so we would interview only current model participants. This restriction removed four organizations from the set of 54 used for the quantitative analysis, including one high performer and one lower performer. This left 12 organizations eligible for interviews as high performers and 10 as lower performers.

We then aimed to interview high and lower performers that shared similar organizational characteristics, so we could better understand drivers of performance not captured in the quantitative data—for example, the organizations' CVD risk-reduction strategies. Table D.1 summarizes organizational characteristics of the seven organizations we interviewed.

	High performers	Lower performers
Characteristic	(N = 3)	(N = 4)
Mean risk score change (performance)	-9.40	-5.00
Number of organizations with 0 to 5 practitioners	1	3
Number of organizations with 6 to 19 practitioners	1	1
Number of organizations with 20 or more practitioners	1	0
Number located in rural areas	1	1
Number of primary care practices	2	2
Number of specialty or multispecialty practices	1	2
Number participating in other CMS initiatives when they applied for the model	2	3
Mean modifiable CVD risk (measured among 2017 and 2018 high-risk beneficiaries with reassessment visits by the end of 2019)	15.55	14.82

Table D.1. Characteristics of 3 high- and 4 lower-performing organizations we interviewed

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

Developing the interview protocol. We conducted a review of existing available organizational data (for example, interview transcripts and interviewer takeaways from previous rounds of interviews with intervention organizations) as well as a brief literature review to explore performance factors associated with improved CVD prevention care or health system performance for initiatives similar to the Million Hearts Model. The covered literature included relevant clinical guidelines or recommendation documents (for example, reports from the

American Heart Association) and publications about positive deviance studies and similar concepts. For example, in a mixed-methods positive deviance study by Krumholz et al. (2011) on survival after acute myocardial infarction, researchers found high- and low-performing hospitals differed on five domains of performance: (1) organizational values and goals, (2) senior management involvement, (3) broad staff presence and experience in acute myocardial infarction care, (4) communication and coordination among groups, and (5) problem solving and learning. In a more recent positive deviance study on veterans with chronic obstructive pulmonary disease, researchers found Veterans Affairs practice sites with low readmission rates had high quality working relationships and better communication among care teams compared to practices with high readmission rates (Anderson et al. 2020).

Based on the previous interviews and the literature review, we expected to see two categories of influencers or potential drivers of organizational performance for reducing CVD risk: (1) *features of the CVD risk reduction strategies and care processes* and (2) *features of the implementing organization*. The original logic model for the Million Hearts Model (Conwell et al. 2019) reflected these categories, as have other positive deviance studies (Bradley et al. 2012; Bates et al. 2019). We organized potential drivers from the literature into a table and met with five experts from the RAND Corporation and the University of Colorado School of Medicine to discuss their thoughts on the two categories of drivers and react to preliminary lists of potential performance drivers our evaluation team developed.

We then finalized a list of potential drivers and developed a semistructured interview protocol to attempt to obtain information about potential drivers across the two major categories. The protocol covered respondents' backgrounds and roles in delivering or coordinating cardiovascular care, their experiences with different risk-reduction approaches, reflections on factors associated with success in reducing risk, and experiences within their organizations.

Conducting interviews with high- and lower-performing organizations. The evaluation team conducted interviews, about one hour long, with 25 representatives (for example, providers, Million Hearts Model practice champions, and other care team members) of 9 intervention organizations (4 high-performing organizations and 5 lower-performing organizations) to identify approaches and strategies that might have led to improved CVD risk-reduction performance. Invited practices (N = 14) were not informed of their status as performance outliers, as that could have affected their responses. The team shared the overall intent of the study (that is, to learn from different organizations about their experiences and challenges improving cardiovascular care and outcomes for high-risk beneficiaries) and offered organizations \$50 for each person participating in the interviews and \$100 to the organization contact coordinating the interviews. Of the 14 organizations invited, 1 declined to participate and 4 were considered lost to follow-up upon receiving no response after 5 or more outreach attempts via phone and email. We excluded 2 additional organizations from the analysis (1 high performer and 1 lower performer) because we could not secure an interview with staff members involved in patient care at these organizations.

Following a team training to ensure consistency across interviewers, we conducted interviews via telephone to gather information about organizations' experiences. Key topics included organizations' processes for identifying cardiovascular risk, delivering CVD care management, and other service delivery strategies they had implemented. Interviews explored why organizations selected these strategies, why the respondents considered them effective (or ineffective), and factors that facilitated or hindered implementing these strategies to better understand the implementation context. We audio-recorded and transcribed all interviewers.

Analyzing data for potential differentiators between high- and lower-performing

organizations. Staff imported interview transcripts into NVivo and developed a codebook based on the interview protocol topics. Members of the team iteratively refined the codebook, beginning with coding the same transcript, suggesting modifications to codes or additions of codes for new topics. The team then met to discuss these modifications and arrive at consensus. We repeated this process with additional interview transcripts until we finalized the codebook by common assent. Analysts coded all data into 14 major areas within each of the two driver categories (that is, CVD strategies and approaches and health system or organizational factors). As noted, we removed from the analysis organizations that did not include a representative who provided or was involved in patients' care (N = 2). The final included sample for analysis included seven organizations (N = 7) representing 23 individuals from three high-performing and four lower-performing organizations. Team members analyzed coded data to compare and contrast the strategies of high-performing organizations to those of lower-performing organizations. We assigned specific constructs to analysts for rapid thematic analyses based on the coded data to allow for a deeper exploration into each construct. Data were blinded to the organization name as well as the organizations' measured performance (that is, high or lower). Analysts extracted themes by site, reapplied performance categories, and then reviewed them in groupings to see if themes emerged among high- and lower-performing organizations.

Appendix E

Study Population for Impact Evaluation

This appendix defines the population enrolled in the Million Hearts Model and subpopulations we used for the impact analyses in this report. The appendix has four sections:

- 1. Population enrolled in the Million Hearts Model in 2017 and 2018 (Section E.1)
- **2.** Population included in impact analyses of cardiovascular disease (CVD) events and other long-term, claims-based outcomes (Section E.2)
- **3.** Population included in impact analyses of Medicare Part D-related outcomes, including drug initiation or intensification as well as adherence to antihypertensive medications and statins (Section E.3)
- 4. Population used to estimate impacts on CVD risk scores and risk factors (Section E.4)

Appendix C in the <u>Third Annual Report</u> (Blue et al. 2020) defines the attributed population used in sensitivity analyses.

1. Beneficiaries enrolled in the Million Hearts Model in 2017 and 2018

Mathematica used data from the Million Hearts Data Registry to define the primary study population for this report. The study population includes all Medicare fee-for-service (FFS) beneficiaries enrolled by the participating organizations during the first four performance periods of the model (January 2017 to December 2018). Enrolled means the organization reported the beneficiary to the Million Hearts Data Registry and the Centers for Medicare & Medicaid Services (CMS) validated the beneficiary's 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, and provide the demographic and clinical data needed to determine the beneficiary's baseline CVD risk. To validate each beneficiary's enrollment, the CMS implementation contractor used Medicare claims data to confirm the beneficiary (1) did indeed have a visit with a provider from the organization near the time listed and (2) 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.

The study population included 388,065 beneficiaries enrolled by 173 intervention organizations and 172 control organizations (Figure E.1).

We further limited the population for this report to those who had complete and plausible clinical data needed to calculate a baseline CVD risk score (see Conwell et al. [2019] for details). We excluded beneficiaries with the following characteristics:

- Were not observable. These beneficiaries were not enrolled in Medicare Parts A and B FFS with Medicare as the primary payer during the month of enrollment and we could not construct study outcomes for them.
- **Did not meet claims-based model eligibility criteria.** These beneficiaries had evidence of a prior heart attack or stroke. CMS's implementation contractor validated only beneficiaries who met claims-based eligibility criteria. However, we found a very small proportion of beneficiaries who did not meet those criteria, likely due to differences in when we and the CMS implementation contractor pulled claims and Medicare enrollment data.

These further limitations removed 1,914 beneficiaries from the intervention group and 1,496 beneficiaries from the control group (Figure E.1).

2. Beneficiaries included in the impact analyses of CVD events and other, long-term claims-based outcomes

Within the broader population of beneficiaries enrolled in 2017 and 2018, we limited the population for most impact analyses to people with CVD risk scores at enrollment indicating high or medium CVD risk. We did this because CMS expected the model to improve outcomes for these beneficiaries, but not necessarily for beneficiaries with low CVD risk. With this restriction, the final study population for impact analyses of most claims-based outcomes included 218,929 beneficiaries (130,622 beneficiaries enrolled by 172 intervention organizations and 88,307 beneficiaries enrolled by 170 control organizations). Figure E.1 shows the flow of organizations (and their providers and beneficiaries), from random assignment and enrollment through the final study population.

Figure E.1. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for CVD events and other long-term claims-based outcomes (including high- and medium-risk beneficiaries)



- Source: Mathematica's analyses of Million Hearts' randomization files, registry data submitted by participating organizations, and Medicare enrollment and claims data.
- Note: Beneficiaries with high CVD risk were predicted to have, at enrollment, at least a 30 percent risk of a heart attack or stroke in the next 10 years; the predicted risk was 15 to 30 percent for medium-risk beneficiaries and less than 15 percent for low-risk beneficiaries. The count of beneficiaries enrolled in 2017 and 2018 shown in this table (230,701 + 157,264 = 388,605) differs from the count of beneficiaries enrolled in 2017 and 2018 shown in <u>Chapter II</u> Figure II.C.1.(392,512) for two reasons. The counts in this table include beneficiaries with missing risk scores, who were excluded from Figure II.C.1 (n = 64) and the counts in these tables do not include beneficiaries enrolled during a performance period after 2018 with an enrollment date in 2018 (n = 4,511).

^a The criteria are FFS Medicare Parts A and B, ages 40 to 79, no prior acute myocardial infarction, no prior stroke, no ESRD, and no hospice.

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

3. Beneficiaries included in impact analyses of medication initiation and intensification and adherence (Part D-based outcomes)

For the analyses of impacts on initiating and intensifying medication, we restricted the study population (Section E.2) to beneficiaries who met two additional criteria:

- 1. The beneficiary was enrolled in Medicare Part D for the 12 months before enrolling in the Million Hearts Model, enabling us to observe the beneficiary's medication use (based on Part D data) for the full year before model enrollment.
- 2. At enrollment, the beneficiary had either blood pressure or low-density lipoprotein (LDL) cholesterol levels at or above thresholds for treatment (130 mm Hg and 70 md/dL, respectively).

After applying these restrictions, the study population included 134,134 beneficiaries: 80,286 beneficiaries enrolled by 170 intervention organizations and 53,848 beneficiaries enrolled by 168 control organizations. As shown in Figure E.2, this represents more than half (61 percent) of the beneficiaries included in the population used for impact analysis of CVD events and other long-term, claims-based outcomes.

Intervention group for claims-Control group for claims-based based analyses (see Figure E.1) analyses (see Figure E.1) 172 organizations 170 organizations 3.760 providers 1.812 providers 130,622 beneficiaries 88,307 beneficiaries - 40,442 high CVD risk - 27,283 high CVD risk - 90,180 medium CVD risk - 61,024 medium CVD risk 2 organizations and 164 providers 1 organizations and 38 providers implicitly excluded implicitly excluded - None of the enrolled - None of the enrolled beneficiaries met Part D beneficiaries met Part D enrollment criteria enrollment criteria 27,937 beneficiaries (32 percent) 41,166 beneficiaries (32 percent) excluded excluded - 41,105 were not enrolled in - 27,877 were not enrolled in Medicare Part D for 12 Medicare Part D for 12 months before enrollment months before enrollment - 61 were not enrolled in - 60 were not enrolled in Medicare Part D for 1 month Medicare Part D for 1 month after enrollment after enrollment Intervention group: Beneficiaries **Control group: Beneficiaries with** with Part D coverage Part D coverage 170 organizations 169 organizations 3,596 providers 1,774 providers 89,456 beneficiaries 60.370 beneficiaries 1 organization and 10 providers 38 providers implicitly excluded implicitly excluded - None of the enrolled None of the enrolled beneficiaries met criteria for beneficiaries met criteria for analysis analvsis 9,170 beneficiaries (10 percent) 6,522 beneficiaries (11 percent) excluded from initiation and excluded from initiation and intensification outcome measures intensification outcome measures (SBP < 130 and LDL < 70) (SBP < 130 and LDL < 70) Analysis: Intervention group for Analysis: Control group for impact impact analyses with medication analyses with medication initiation or intensification initiation or intensification outcomes outcomes 170 organizations 168 organizations 3,558 providers 1.764 providers 80,286 beneficiaries 53.848 beneficiaries 25,760 high CVD risk - 17,320 high CVD risk - 54,526 medium CVD risk - 36,528 medium CVD risk

Figure E.2. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for analyses of medication initiation and intensification

Source: Mathematica's analyses of Million Hearts' randomization files, registry data submitted by participating organizations, and Medicare enrollment and claims data.

Note: Beneficiaries with high CVD risk were predicted to have, at enrollment, at least a 30 percent risk of a heart attack or stroke in the next 10 years; the predicted risk was 15 to 30 percent for medium- risk beneficiaries and less than 15 percent for low-risk beneficiaries.

CVD = cardiovascular disease; LDL = low-density lipoproteins cholesterol (mg/dL); SBP = systolic blood pressure (mm Hg).

For analyses of adherence to statin medications, we restricted the study population (Section E.2) to beneficiaries based on two criteria:

- 1. The beneficiary was enrolled in Medicare Part D for the 12 months before enrolling in the Million Hearts Model.
- 2. The beneficiary used statin therapy of any intensity level in the 12 months before enrollment.

After applying these restrictions, the study population included 90,017 beneficiaries: 53,583 beneficiaries enrolled by 168 intervention organizations and 36,434 beneficiaries enrolled by 165 control organizations, as shown in Figure E.3. There was considerable overlap between this population and the population used for analyses of medication initiation and intensification, with 89 percent of the population used for analyses of adherence to statins also eligible for analyses of medication initiation and intensification.

Figure E.3. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for analyses of adherence to statins



- Source: Mathematica's analyses of Million Hearts' randomization files, registry data submitted by participating organizations, and Medicare enrollment and claims data.
- Note: Beneficiaries with high CVD risk were predicted to have, at enrollment, at least a 30 percent risk of a heart attack or stroke in the next 10 years; the predicted risk was 15 to 30 percent for medium- risk beneficiaries and less than 15 percent for low-risk beneficiaries.

CVD = cardiovascular disease.

For analyses of adherence to antihypertensive medications, we restricted the study population to beneficiaries who met two additional criteria:

- 1. The beneficiary was enrolled in Medicare Part D for the 12 months before enrolling in the Million Hearts Model.
- 2. The beneficiary used antihypertensive medications in the 12 months before enrollment.

After applying these restrictions, the study population included 116,099 beneficiaries: 69,478 beneficiaries enrolled by 169 intervention organizations and 46,621 beneficiaries enrolled by 166 control organizations, as shown in Figure E.4. There was considerable overlap between this population and the population used for analyses of medication initiation and intensification, with 89 percent of the population used for analyses of adherence to antihypertensive medication also eligible for analyses of medication initiation and intensification.

Figure E.4. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for analyses of adherence to antihypertensive medication



- Source: Mathematica's analyses of Million Hearts' randomization files, registry data submitted by participating organizations, and Medicare enrollment and claims data.
- Note: Beneficiaries with high CVD risk were predicted to have, at enrollment, at least a 30 percent risk of a heart attack or stroke in the next 10 years; the predicted risk was 15 to 30 percent for medium- risk beneficiaries and less than 15 percent for low-risk beneficiaries.

CVD = cardiovascular disease.

4. Beneficiaries used for estimating impacts on CVD risk scores and risk factors

To evaluate changes in CVD risk scores and risk factors, we analyzed outcomes among high-risk beneficiaries²⁵ who had a one-year reassessment visit by the end of 2019. For this analysis, we limited the analytic population to high-risk beneficiaries who enrolled in the Million Hearts Model on or before October 31, 2018, because they were supposed to have a reassessment visit 10 to 14 months after enrollment, and this restriction ensured we could observe each beneficiary for 14 months before the end of our observation window on December 31, 2018. We further excluded beneficiaries who became ineligible for the model within 14 months of their enrollment visit because organizations did not have to submit reassessment data for them. Model ineligibility could be due to death, acute myocardial infarction, stroke, transient ischemic attack, ESRD, election of the hospice care benefit, enrollment in Medicare Advantage, or because Medicare was not the primary payer. We did not have flags for hospice and ESRD readily available, so we did not include these two reasons for model ineligibility in our analysis, but analysis of pre-enrollment data suggests these affect only a small population. We restricted reassessment visits to those occurring within 22 months of enrollment to capture one-year reassessment visits only, and excluded any reassessment visits with missing data on variables included in the CVD risk score.

Figure E.5 shows the flow of beneficiaries from the broader sample used for impacts analyses of CVD events and other long-term, claims-based outcomes (Figure E.1) to the population used for estimating impacts on CVD risk scores and risk factors. After applying the restrictions described, the study population included 28,357 high-risk beneficiaries: 18,110 high-risk beneficiaries enrolled by 125 intervention organizations and 10,247 high-risk beneficiaries enrolled by 110 control organizations.

²⁵ The model characterized beneficiaries as high, medium, or low risk based on their CVD risk score at enrollment. For the 6 percent of beneficiaries who had CVD risk factor information recorded in the registry before the baseline visit date used by CMS's implementation contractor to calculate payments (Conwell et al. 2019), we included the beneficiaries in the analysis of risk score impacts as long as they were classified as high risk at both dates. We required the beneficiary to be classified as high risk at the enrollment date used for payment, even though we consider the beneficiary's true baseline to be the earlier visit, because intervention group organizations had to provide reassessment data only for beneficiaries classified as high risk at the later date.

Figure E.5. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for CVD risk score and risk factor outcomes



- Source: Mathematica's analyses of Million Hearts' randomization files, registry data submitted by participating organizations, and Medicare enrollment and claims data.
- Note: Beneficiaries with high CVD risk were predicted to have, at enrollment, at least a 30 percent risk of a heart attack or stroke in the next 10 years; the predicted risk was 15 to 30 percent for medium- risk beneficiaries and less than 15 percent for low-risk beneficiaries.

^a For the 6 percent of beneficiaries with a visit recorded in the Million Hearts Data Registry before the enrollment date used for model payment, we included only beneficiaries classified as high CVD risk at both dates. Conwell et al. (2019) describes our methods for adjusting the enrollment date used for evaluation to be the first date recorded in the registry with complete enrollment data.

^b Restricts the sample to beneficiaries who remained alive; without acute myocardial infarction, stroke, or transient ischemic attack; and enrolled in Medicare FFS as their primary payer for 14 months after enrollment in the Million Hearts Model.

CVD = cardiovascular disease; FFS = fee-for-service.

Appendix F

Baseline Characteristics

In this appendix, Mathematica provides detailed information on baseline characteristics of the beneficiaries in the intervention and control groups, across three subpopulations used for the impact analyses in this report:

- Beneficiaries enrolled in 2017 and 2018 and included in analyses of cardiovascular disease (CVD) events and other long-term outcomes based on Medicare Parts A and B claims and Medicare enrollment data (Section F.1)
- Beneficiaries enrolled in 2017 and 2018 and included in analyses of Medicare Part D-related outcomes, including drug initiation or intensification as well as adherence to antihypertensive medications and statins (Section F.2)
- Beneficiaries enrolled by October 31, 2018, with reassessment data by December 31, 2019, and included in analyses of CVD risk factors and risk reduction (Section F.3)

In Section F.1, we present tables with baseline characteristics—that is, characteristics measured at enrollment—for both the high- and medium-risk populations combined as well as the high-risk-only population. For brevity, in Section F.2., we present tables with baseline characteristics for only the high- and medium-risk populations combined, though we find similar levels of balance in the high-risk populations alone (not reported). For the population included in the analysis of CVD risk factors and risk reduction (Section F.3), we present tables with baseline characteristics for the high-risk beneficiaries only because the intervention group organizations did not have to submit reassessment data for other beneficiaries they enrolled.

1. Baseline characteristics of the population used to estimate impacts on CVD events and other long-term, claims-based outcomes

The high- and medium-risk beneficiaries enrolled in 2017 and 2018 were very similar at enrollment with respect to beneficiary-level characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending (Table F.1). Within this population, beneficiaries in the intervention and control groups enrolled in Part D were well balanced at enrollment on medication use, including adherence. However, intervention and control group beneficiaries differed somewhat in the types of organizations that enrolled them. In particular, compared to those enrolled by control group organizations, high- and medium-risk beneficiaries in the intervention group were, on average, enrolled by organizations that had more providers (126 versus 108), had more sites (25 versus 14), and were more likely to participate in or to have applied to participate in another model when they applied to the Million Hearts Model (70 versus 55 percent). In addition, intervention group beneficiaries were more likely to live in the South (46 versus 34 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 Centers for Medicare & Medicaid Services (CMS) requirement. For example, because there is no cap for the intervention group, we assume that (1) the intervention group would enroll more beneficiaries overall and (2) large organizations would enroll a larger share of those beneficiaries.

	Intervention	Control group		Standardizod	
Characteristic	(N = 130,622)	(N = 88,307)	Difference	differ <u>ence^a</u>	<i>p</i> -value ^b
Clinical indicators of beneficiary's ca	rdiovascular risl	k			
CVD risk score (%),	27	27	0.0	0.00	0.92
[standard deviation]	[10]	[10]			
Modifiable risk (%) ^c	9	9	0.1	0.01	0.75
Has diabetes (%)	36	35	1.3	0.03	0.51
Systolic blood pressure (mm Hg)	134	134	0.0	0.00	0.95
Systolic blood pressure is 130 mm Hg or higher (%)	60	61	-0.4	-0.01	0.80
Total cholesterol (mg/dL)	174	174	0.6	0.02	0.65
HDL cholesterol (mg/dL)	50	51	-0.1	-0.01	0.83
LDL cholesterol (mg/dL)	97	96	1.1	0.03	0.33
LDL cholesterol is 70 mg/dL or higher (%)	78	77	1.2	0.03	0.33
Is current smoker (%)	11	12	-1.4	-0.04	0.24
Beneficiary's medication use					
Uses aspirin (%)	46	43	2.6	0.05	0.54
Uses antihypertensives based on Part D^{d} (%)	83	82	0.6	0.02	0.62
Proportion of days covered by antihypertensives (%) ^e	90	90	-0.2	-0.01	0.56
Proportion of beneficiaries adherent to antihypertensives (%) ^{e, f}	84	84	-0.5	-0.01	0.42
Uses statins based on Part D ^d (%)	63	64	-0.3	-0.01	0.86
Intensity of statin use based on Part D ^d (%)					
Low intensity	6	6	-0.1	0.00	0.83
Medium intensity	39	38	0.4	0.01	
High intensity	18	19	-0.6	-0.01	
Proportion of days covered by any statins (%) ^e	81	82	-0.7	-0.03	0.27
Proportion of beneficiaries adherent to statins $(\%)^{e, f}$	70	71	-1.2	-0.03	0.24
Beneficiary's demographic and Medic	are enrollment	characteristics			
Age	72	72	-0.1	-0.03	0.43
[standard deviation]	[5]	[5]			

 Table F.1. Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in

 2017 and 2018: Intervention versus control group

	Intervention	Control group			
Obere eteriotia	group mean	mean	Difference	Standardized	n velveb
	(N = 130,622)	(N = 00, 307)	Difference	difference.	<i>p</i> -value [®]
	0	7	1.0	0.08	0.30
Male (70)	56	59	-1.0	-0.02	0.20
Medicaid (%)	10	10	-0.5	-0.02	0.76
Originally entitled to Medicare					
because of disability (%)	13	14	-0.4	-0.01	0.75
Beneficiary's health and comorbid cor	nditions				
HCC score	1.16	1.17	0.0	0.00	0.89
[standard deviation]	[1.00]	[1.01]			
Number of chronic conditions	2.1	2.1	0.0	0.00	0.91
Has chronic kidney disease (%)	25	24	0.3	0.01	0.78
Has ischemic heart disease (%)	32	34	-1.7	-0.04	0.58
Has congestive heart failure (%)	11	12	-0.7	-0.02	0.54
Has atrial fibrillation (%)	10	10	0.1	0.00	0.93
Has morbid obesity (%)	7	7	0.2	0.01	0.80
Beneficiary's medical service use and	spending in ye	ar before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$)	7,824	7,658	166.0	0.01	0.60
[standard deviation]	[17,674]	[16,742]			
Hospital admissions (per 1,000 beneficiaries)	188	193	-5.1	-0.01	0.60
CVD-related hospital admissions (per 1,000 beneficiaries) ^g	42	43	-0.7	0.00	0.90
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	383	372	10.6	0.01	0.57
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) ^g	29	28	1.3	0.01	0.70
Office visits (per 1,000 beneficiaries)	9,228	8,967	261.1	0.03	0.51
Office visits with model-aligned providers (per 1.000 beneficiaries)	2,641	2,690	-49.4	-0.02	0.85
Cardiologist visits (per 1,000	1,851	1,805	45.6	0.01	0.83
Beneficiary's CVD-related procedures	in vear before	model enrollment	1		
Received echocardiogram (%)	40	39	0.8	0.02	0.80
Received electrocardiogram (%)	70	70	0.6	0.01	0.86
Received cardiac stress test (%)	26	26	-0.2	0.00	0.93
Characteristics of organization enrolli	ng the beneficia	arv		0.00	
Total number of practitioners	126	108	18.4	0.07	0 71
[standard deviation]	[178]	[300]		0.01	0.11
Total number of service sites	25	[000]	10.2	0.30	0.12
[standard deviation]	20 [26]	14 [27]	10.2	0.55	0.12
Organization type (%)	الحما	[27]			
Primary care	53	54	-0.1	0.00	0.47

	Intervention	Control group			
Characteristic	group mean (N = 130,622)	mean (N = 88,307)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Specialty or multispecialty	37	34	2.9	0.06	
FQHC, RHC, or other health center	5	5	-0.6	-0.03	
CAH or rural hospital	1	2	-1.6	-0.14	
Acute care hospital	5	5	-0.5	-0.02	
Organization participated in, or had application pending for, another model at application (%)	70	55	14.3	0.30	0.13
Organization-level mean Medicare spending and use ^h					
Parts A and B spending	7,666	7,649	17.7	0.01	0.95
Hospital admissions (per 1,000 beneficiaries)	184	192	-8.5	-0.21	0.30
Outpatient ED visits (per 1,000 beneficiaries)	378	366	12.0	0.11	0.49
Characteristics of clinician enrolling t	he beneficiary				
Provider specialty (%)					
Primary care physician	58	61	-3.1	-0.06	0.68
Cardiologist	27	26	0.2	0.00	0.98
Physician with other specialty	3	1	1.8	0.13	0.14
Not a physician (for example, NP or PA)	11	10	1.2	0.04	0.52
Characteristics of beneficiary's region	า				
Rural (%)	24	26	-1.6	-0.04	0.73
Census region (%)					
Northeast	27	22	4.6	0.11	0.09
Midwest	19	29	-9.8	-0.23	
South	46	34	12.3	0.25	
West	8	15	-7.0	-0.22	
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.5	-0.16	0.28
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.5	0.12	0.44
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,378	4,408	-30.3	-0.05	0.76
Per capita total Medicare Part A and B spending in 2016	9,945	9,847	98.2	0.07	0.66
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	277	1.4	0.03	0.84
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	694	683	11.1	0.09	0.62

Characteristic	Intervention group mean (N = 130,622)	Control group mean (N = 88,307)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Characteristics of beneficiary's Milli	on Hearts Model	enrollment			
Days between model launch (1/3/2017) and enrollment date [standard deviation]	194 [178]	209 [168]	-15.4	-0.09	0.18
Enrollment date is in (%)					
2017 (as opposed to 2018)	83	83	0.4	0.01	0.85
First quarter of the year	40	36	4.6	0.09	0.12
Second quarter of the year	31	29	1.8	0.04	0.24
Third quarter of the year	16	18	-2.0	-0.05	0.27
Fourth quarter of the year	12	17	-4.4	-0.13	0.00
Data submitted to the registry using bulk upload (%) ⁱ	50	49	0.9	0.02	0.93

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, 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; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Note: For all measures, means are calculated over nonmissing values. The Chronic Condition Warehouse algorithms defined the following chronic conditions: atrial fibrillation, chronic kidney disease, and ischemic heart disease. HCC algorithms defined the following chronic conditions: congestive heart failure and morbid obesity. All procedures are defined by using Clinical Classifications Software indicators. See the <u>Second</u> <u>Annual Report</u> (Peterson et al. 2019) for details on variable construction.

^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 his or her 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. Chapter VI of the <u>Third Annual Report</u> (Blue et al. 2020) defines the clinical targets.

^d Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment (N = 89,456 for the intervention group and N = 60,370 for the control group). This accounted for 68 percent of all beneficiaries enrolled in the intervention group and 68 percent in the control group.

^e Measured among beneficiaries who also had 12 months of Part D coverage before and in the month of enrollment and with medication use at baseline. For analyses of antihypertensive adherence, this included N = 69,478 beneficiaries in the intervention group and N = 46,621 in the control group, accounting for 53 percent of all beneficiaries enrolled in each group. For analyses of statin adherence, this included N = 53,583 beneficiaries in the intervention group and N = 36,434 in the control group, accounting for 41 percent of all beneficiaries enrolled in each group.

^fWe defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

⁹ We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the <u>Second Annual Report</u>, Appendix C), including those related to heart failure, hypertension, and angina. This measure

excludes heart attacks and strokes because the analytic population excludes beneficiaries who had these events before enrolling in the Million Hearts Model.

^h Mathematica's <u>Third Annual Report</u>, Appendix D, provides details on how we constructed organizational-level measures of spending and use (Blue et al. 2020). Briefly, to estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. We calculated the variance-shrunken means for each organization and merged these variables to the beneficiary-level analysis file by organization.

ⁱ Participating organizations could upload data manually (that is, entering data for each beneficiary visit one by one, using a web interface), or in bulk, using one of two CMS-provided tools. We show the proportion that used a bulkupload tool in case data quality varies by data submission mode.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

Consistent with the combined high- and medium-risk population, the high-risk-only population enrolled in 2017 and 2018 was well balanced on characteristics at enrollment such as age, sex, CVD risk score, recent service use, and Medicare spending (Table F.2). Also consistent with the larger population, high-risk-only beneficiaries in the intervention group were, compared to control beneficiaries, enrolled by organizations that on average had more providers (131 versus 94), had more sites (24 versus 14), were specialty or multispecialty organizations (39 versus 32 percent), and were more likely to participate in or to have applied to participate in another model when they applied to the Million Hearts Model (68 versus 56 percent). In addition, intervention group beneficiaries were more likely to live in the South (48 versus 35 percent). High-risk beneficiaries in the intervention group were also more likely to have enrolled during the first quarter of 2017 (43 versus 37 percent).

Table F.2. Baseline characteristics of high-risk Medicare beneficiaries enrolled in 2017 and 20	018:
Intervention versus control group	

	Intervention group mean	Control group mean		Standardized					
Characteristic	(N = 40,442)	(N = 27,283)	Difference	difference ^a	<i>p</i> -value ^D				
Clinical indicators of beneficiary's cardiovascular risk									
CVD risk score (%),	40	40	0.0	0.00	0.92				
[standard deviation]	[9]	[9]							
Modifiable risk (%) ^c	16	15	0.0	0.00	0.95				
Has diabetes (%)	65	64	0.8	0.02	0.74				
Systolic blood pressure (mm Hg)	140	140	0.2	0.01	0.87				
Systolic blood pressure is 130 mm Hg or higher (%)	74	74	-0.2	-0.00	0.90				
Total cholesterol (mg/dL)	169	169	-0.3	-0.01	0.82				
HDL cholesterol (mg/dL)	47	48	-0.3	-0.02	0.63				
LDL cholesterol (mg/dL)	93	92	0.5	0.01	0.67				
LDL cholesterol is 70 mg/dL or higher (%)	73	72	0.5	0.01	0.71				
Is current smoker (%)	12	14	-2.0	-0.06	0.21				
Beneficiary's medication use									
Uses aspirin (%)	51	49	1.6	0.03	0.69				
Uses antihypertensives based on Part D^{d} (%)	90	89	0.9	0.03	0.20				
Proportion of days covered by antihypertensives (%) ^e	91	91	-0.3	-0.02	0.44				
Proportion of beneficiaries adherent to antihypertensives (%) ^{e, f}	85	86	-0.5	-0.01	0.48				
Uses statins based on Part D^d (%)	69	68	0.9	0.02	0.50				

	Intervention	Control group		Stop doveling of	
Characteristic	group mean (N = 4 <u>0,442)</u>	(N = 2 <u>7,283)</u>	Difference	differ <u>ence^a</u>	<i>p</i> -value ^b
Intensity of statin use based on Part D ^d (%)					
Low intensity	7	7	0.1	0.00	0.90
Medium intensity	41	41	0.4	0.01	
High intensity	21	20	0.4	0.01	
Proportion of days covered by any statins (%) ^e	81	82	-0.8	-0.03	0.20
Proportion of beneficiaries adherent to statins (%) ^{e, f}	70	72	-1.6	-0.03	0.15
Beneficiary's demographic and Medic	are enrollment	characteristics			
Age	74	74	-0.1	-0.02	0.58
[standard deviation]	[4]	[4]			
Black race (%)	8	6	1.3	0.05	0.43
Male (%)	65	65	0.0	0.00	0.97
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.7	-0.02	0.67
Originally entitled to Medicare because of disability (%)	12	13	-0.8	-0.02	0.48
Beneficiary's health and comorbid cor	nditions				
HCC score	1.37	1.36	0.0	0.01	0.82
[standard deviation]	[1.06]	[1.06]			
Number of chronic conditions	2.6	2.6	0.0	0.02	0.58
Has chronic kidney disease (%)	36	35	0.8	0.02	0.58
Has ischemic heart disease (%)	38	39	-1.2	-0.03	0.67
Has congestive heart failure (%)	13	14	-0.5	-0.01	0.66
Has atrial fibrillation (%)	11	11	0.3	0.01	0.78
Has morbid obesity (%)	8	8	0.1	0.00	0.95
Beneficiary's medical service use and	spending in ye	ar before model	enrollment		
Total Medicare Parts A and B	0 227	9.057	280.3	0.02	0.38
Istandard deviation	0,337 [18 155]	0,037 [16 122]	200.5	0.02	0.00
Hospital admissions (per 1 000	204	201	3 1	0.00	0.76
beneficiaries)	204	201	0.1	0.00	0.70
CVD-related hospital admissions (per 1,000 beneficiaries) ⁹	49	45	3.9	0.01	0.45
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	395	383	11.4	0.01	0.54
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) ^g	32	32	0.5	0.00	0.89
Office visits (per 1,000 beneficiaries)	9,856	9,517	338.5	0.04	0.39
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,979	2,992	-12.9	0.00	0.97
Cardiologist visits (per 1,000 beneficiaries)	2,074	2,038	36.1	0.01	0.86
	Intervention group mean	Control group mean		Standardized	
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Characteristic	(N = 40,442)	(N = 27,283)	Difference	difference ^a	<i>p</i> -value ^b
Beneficiary's CVD-related procedures	in year before	model enrollment			
Received echocardiogram (%)	44	43	0.8	0.02	0.77
Received electrocardiogram (%)	74	74	0.4	0.01	0.89
Received cardiac stress test (%)	28	28	-0.1	0.00	0.97
Characteristics of organization enrolling	ing the beneficia	ary			
Total number of practitioners	131	94	37.3	0.15	0.45
[standard deviation]	[204]	[280]			
Total number of service sites [standard deviation]	24 [26]	14 [26]	10.6	0.41	0.11
Organization type (%)					
Primary care	50	55	-4.5	-0.09	0.35
Specialty or multispecialty	39	32	7.5	0.16	
FQHC, RHC, or other health center	5	6	-0.8	-0.04	
CAH or rural hospital	1	3	-2.0	-0.16	
Acute care hospital	5	5	-0.2	-0.01	
Organization participated in, or had application pending for, another model at application (%)	68	56	12.2	0.25	0.20
Organizational-level mean Medicare spending and use ^h					
Parts A and B spending	7,684	7,676	8.0	0.01	0.98
Hospital admissions (per 1,000 beneficiaries)	185	193	-8.1	-0.20	0.33
Outpatient ED visits (per 1,000 beneficiaries)	381	371	10.1	0.09	0.57
Characteristics of clinician enrolling t	he beneficiary				
Provider specialty (%)					
Primary care physician	58	60	-2.5	-0.05	0.74
Cardiologist	27	27	-0.3	-0.01	0.97
Physician with other specialty	3	1	1.7	0.12	0.19
Not a physician (for example, NP or PA)	11	10	1.0	0.03	0.59
Characteristics of beneficiary's region	า				
Rural (%)	26	27	-1.5	-0.03	0.77
Census region (%)					
Northeast	25	22	3.1	0.07	0.39
Midwest	19	28	-9.8	-0.23	
South	48	35	12.7	0.26	
West	9	15	-6.0	-0.19	
County-level health measures	2		0.0	5.10	
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.8	-0.23	0.14

	Intervention group mean	Control group mean	5."	Standardized	
Characteristic	(N = 40,442)	(N = 27,283)	Difference	difference	<i>p</i> -value [®]
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.4	0.10	0.55
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,401	4,445	-43.9	-0.07	0.68
Per capita total Medicare Part A and B spending in 2016	9,933	9,862	71.1	0.05	0.75
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	278	0.5	0.01	0.94
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	699	687	11.1	0.09	0.63
Characteristics of beneficiary's Million	n Hearts Model	enrollment			
Days between model launch (1/3/2017)	184	202	-17.7	-0.10	0.17
and enrollment date	[176]	[165]			
[standard deviation]					
Enrollment date is in (%)					
2017 (as opposed to 2018)	84	84	0.5	0.01	0.83
First quarter of the year	43	37	5.3	0.11	0.12
Second quarter of the year	30	29	1.8	0.04	0.30
Third quarter of the year	15	17	-2.0	-0.06	0.25
Fourth quarter of the year	12	17	-5.1	-0.15	0.00
Data submitted to the registry using bulk upload (%) ⁱ	45	44	0.3	0.01	0.97

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, 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; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: For all measures, means are calculated over nonmissing values. The Chronic Condition Warehouse algorithms defined the following chronic conditions: atrial fibrillation, chronic kidney disease, and ischemic heart disease. The HCC algorithms defined the following chronic conditions: congestive heart failure and morbid obesity. All procedures are defined by using Clinical Classifications Software indicators. See the <u>Second Annual Report</u> (Peterson et al. 2019) for details on variable construction.

^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 his or her 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. Chapter VI of the <u>Third Annual Report</u> (Blue et al. 2020) defines the clinical targets.

^d Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment (N = 28,366 for the intervention group and N = 19,066 for the control group). This accounted for 70 percent of all beneficiaries enrolled in the intervention group and 70 percent in the control group.

^e Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment and with medication use at baseline. For analyses of antihypertensive adherence, this included N = 24,322 beneficiaries in the intervention group and N = 16,233 in the control group, accounting for 60 percent of all beneficiaries enrolled in the intervention group and 59 percent in the control group. For analyses of statin adherence, this included N = 18,719 beneficiaries in the intervention group and N = 12,480 in the control group, accounting for 46 percent of all beneficiaries enrolled in each group.

^fWe defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

⁹ We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the <u>Second Annual Report</u>, Appendix C), including those related to heart failure, hypertension, and angina. This measure excludes heart attacks and strokes because the analytic population excludes beneficiaries who had these events before enrolling in the Million Hearts Model.

^h Mathematica's <u>Third Annual Report</u>, Appendix D, provides details on how we constructed organizational-level measures of spending and use (Blue et al. 2020). Briefly, to estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. We calculated the variance-shrunken means for each organization and merged these variables to the beneficiary-level analysis file by organization.

ⁱ Participating organizations could upload data manually (that is, entering data for each beneficiary visit one by one, using a web interface), or in bulk, using one of two CMS-provided tools. We show the proportion that used a bulkupload tool in case data quality varies by data submission mode.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

2. Baseline characteristics of the population used to estimate impacts on medication initiation and intensification and adherence (Part D-based outcomes)

This section describes baseline characteristics of beneficiaries who enrolled in the Million Hearts Model in 2017 and 2018, were also enrolled in Medicare Part D during the year before model enrollment and in their enrollment month, and were included in analyses of medication initiation, intensification, and adherence (<u>Chapter V</u>). The tables in this section show additional information about blood pressure and cholesterol status at baseline compared to Tables F.1 and F.2 and, for brevity, fewer details on organizational and geographic characteristics, which did not differ substantively between this population and the population described previously.

Among high- and medium-risk beneficiaries included in the initiation and intensification analyses, the distribution of systolic blood pressure and rates of antihypertensive medication use were similar at enrollment between the groups (Table F.3). The two groups were also similar in terms of cholesterol levels and use of statins at baseline. Further, they were similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

Characteristic	Intervention group mean (N = 80,28 <u>6)</u>	Control group mean (N = 53,84 <u>8)</u>	Difference	Standardized difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's ca	ardiovascular ris	k į			
CVD risk score (%),	28	28	0.0	0.00	0.96
[standard deviation]	[11]	[11]			
Modifiable risk (%) ^c	10	10	0.0	0.00	0.92
Has diabetes (%)	34	33	0.8	0.02	0.69
SBP (mm Hg)	135	135	-0.2	-0.01	0.78
Distribution of SBP (%)					
SBP < 130 mm Hg	34	33	0.9	0.02	0.52
SBP 130–139 mm Hg	31	31	-0.1	0.00	0.86
SBP 140–149 mm Hg	19	19	-0.5	-0.01	0.56
SPB ≥ 150 mm Hg	17	17	-0.3	-0.01	0.84
Total cholesterol (mg/dL)	179	178	0.7	0.02	0.60
HDL cholesterol (mg/dL)	51	51	-0.1	-0.01	0.88
LDL cholesterol (mg/dL)	101	100	1.0	0.03	0.31
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	14	15	-1.0	-0.03	0.29
LDL 70–99 mg/dL	40	40	-0.2	0.00	0.83
LDL 100–129 mg/dL	28	28	0.5	0.01	0.43
LDL ≥ 130 mg/dL	18	17	0.6	0.02	0.41
Is current smoker (%)	11	12	-1.8	-0.06	0.15

Table F.3. Baseline characteristics of high- and medium-risk Medicare beneficiaries include	ed in
the Part D analyses of initiation and intensification: Intervention versus control group	

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 80,286)	(N = 53,848)	Difference	difference ^a	<i>p</i> -value ^b
Beneficiary's medication use					
Uses aspirin (%)	44	42	2.0	0.04	0.64
Uses antihypertensives based on Part D (%)	82	81	0.5	0.01	0.71
Proportion of days covered by antihypertensives (%) ^d	89	90	-0.2	-0.01	0.52
Proportion of beneficiaries adherent to antihypertensives (%) ^{d, e}	83	84	-0.5	-0.01	0.39
Uses statins based on Part D (%)	60	61	-0.2	0.00	0.90
Intensity of statin use based on Part D (%)					
Low intensity	7	7	0.0	0.00	0.90
Medium intensity	37	37	0.3	0.01	
High intensity	17	17	-0.4	-0.01	
Proportion of days covered by any statins (%) ^d	80	81	-0.7	-0.03	0.23
Proportion of beneficiaries adherent to statins (%) ^{d, e}	68	69	-1.3	-0.03	0.21
Beneficiary's demographic and Medic	are enrollment	characteristics			
Age	72	72	-0.1	-0.01	0.74
[standard deviation]	[5]	[5]			
Black race (%)	8	7	1.2	0.05	0.46
Male (%)	54	55	-1.0	-0.02	0.27
Dually enrolled in Medicare and Medicaid (%)	13	14	-0.9	-0.03	0.65
Originally entitled to Medicare because of disability (%)	15	15	-0.7	-0.02	0.58
Beneficiary's health and comorbid cor	nditions				
HCC score	1.18	1.19	0.0	0.00	0.93
[standard deviation]	[1.01]	[1.01]			
Number of chronic conditions	2.1	2.1	0.0	0.01	0.87
Beneficiary's medical service use and	spending in ye	ar before model	enrollment		
Total Medicare Parts A and B					
annualized expenditures (\$)	7,856	7,689	167.5	0.01	0.60
[standard deviation]	[16,511]	[16,078]			
Hospital admissions (per 1,000 beneficiaries)	184	186	-2.8	0.00	0.77
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	390	383	6.9	0.01	0.74
Office visits (per 1,000 beneficiaries)	9,440	9,105	335.0	0.04	0.42
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,696	2,728	-31.7	-0.01	0.91
Cardiologist visits (per 1,000 beneficiaries)	1,776	1,743	33.2	0.01	0.87

Characteristic	Intervention group mean (N = 80,286)	Control group mean (N = <u>53,848)</u>	Difference	Standardized difference ^a	<i>p</i> -value ^b
Characteristics of organization enroll	ing the benefici	ary			<i>p</i> = 1.1.1.2
Organizational-level mean Medicare spending and use ^f					
Parts A and B spending	7,687	7,659	27.5	0.02	0.93
Hospital admissions (per 1,000 beneficiaries)	183	192	-9.3	-0.23	0.26
Outpatient ED visits (per 1,000 beneficiaries)	377	367	10.4	0.09	0.56
Characteristics of clinician enrolling t	he beneficiary				
Provider specialty (%)					
Primary care physician	58	61	-3.0	-0.06	0.70
Cardiologist	26	26	0.0	0.00	1.00
Physician with other specialty	3	1	2.0	0.14	0.13
Not a physician (for example, NP or PA)	12	10	1.1	0.03	0.57
Characteristics of beneficiary's region	า				
Rural (%)	24	26	-2.4	-0.06	0.61
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.6	-0.16	0.26
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.5	0.11	0.47
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,367	4,410	-42.9	-0.07	0.68
Per capita total Medicare Part A and B spending in 2016	10,008	9,872	135.4	0.09	0.56
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	277	1.4	0.03	0.84
Outpatient ED visits per 1,000 Medicare EES beneficiaries in 2016	694	684	9.2	0.07	0.69

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending; registry data linked to NPPES for clinician-level characteristics; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics.

Notes: For all measures, means are calculated over nonmissing values. See the <u>Second Annual Report</u> (Peterson et al. 2019) for details on variable construction.

The population for this table includes beneficiaries who enrolled in 2017 and 2018, had 12 months of Part D coverage before enrollment and in the month of enrollment, and met inclusion criteria for initiation or intensification of antihypertensives or statins (SBP equal to 130 mm Hg or higher or LDL equal to 70 mg/dL or higher). This accounted for 61 percent of all beneficiaries enrolled in the intervention group and, similarly, 61 percent in the control group.

^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 the difference between a beneficiary's CVD risk score at enrollment and his or her 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. Chapter VI of the <u>Third Annual Report</u> (Blue et al. 2020) defines clinical targets.

^d Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment and with medication use at baseline. For analyses of antihypertensive adherence, this included N = 61,695 beneficiaries in the intervention group and N = 41,153 in the control group, accounting for 77 percent of all beneficiaries enrolled in the intervention group included in analyses of initiation and intensification and 76 percent in the control group included in similar analyses. For analyses of statin adherence, this included N = 45,933 beneficiaries in the intervention group and N = 30,981 in the control group, accounting for 57 percent of all beneficiaries enrolled in analyses of initiation and intensification and 58 percent in the control group included in similar analyses.

^e We defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

^f Mathematica's <u>Third Annual Report</u>, Appendix D provides details on how we constructed organizational-level measures of spending and use (Blue et al. 2020). Briefly, to estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. We calculated the variance-shrunken means for each organization and merged these variables to the beneficiary-level analysis file by organization.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for service; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

Among high- and medium-risk beneficiaries included in analyses of adherence to statins, the distribution of systolic blood pressure and rates of antihypertensive medication use were similar at enrollment between the groups (Table F.4). The intervention and control groups were also well-balanced on cholesterol- and statin-related measures, including mean values of total cholesterol, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol, the distribution of LDL, intensity of statin use at enrollment, the proportion of days covered by statins, and the proportion of beneficiaries adherent to statins. They were also similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

	Intervention	Control group		o	
Characteristic	group mean $(N = 53, 583)$	(N = 36 434)	Difference	Standardized	n-value ^b
Clinical indicators of beneficiary's car	diovascular risl	(((00,+0+)	Billerence	anterence	p value
CVD risk score (%).	28	28	0.2	0.02	0.57
[standard deviation]	[11]	[11]			
Modifiable risk (%) ^c	8	8	0.1	0.01	0.75
Has diabetes (%)	41	40	1.5	0.03	0.53
SBP (mm Hg)	133	133	0.0	0.00	0.95
Distribution of SBP (%)					
SBP < 130 mm Hg	42	42	0.3	0.01	0.85
SBP 130–139 mm Hg	28	28	0.1	0.00	0.88
SBP 140–149 mm Hg	16	17	-0.5	-0.01	0.57
SPB ≥ 150 mm Hg	14	14	0.1	0.00	0.95
Total cholesterol (mg/dL)	163	162	0.9	0.02	0.46
HDL cholesterol (mg/dL)	50	50	-0.1	0.00	0.94
LDL cholesterol (mg/dL)	86	85	1.3	0.04	0.19
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	31	33	-1.7	-0.04	0.22
LDL 70–99 mg/dL	42	42	0.5	0.01	0.45
LDL 100–129 mg/dL	18	18	0.9	0.02	0.20
LDL ≥ 130 mg/dL	9	8	0.3	0.01	0.55
Is current smoker (%)	10	12	-1.9	-0.06	0.12
Beneficiary's medication use					
Uses aspirin (%)	53	49	3.6	0.07	0.45
Uses antihypertensives based on Part D (%)	89	88	0.6	0.02	0.44
Proportion of days covered by antihypertensives (%) ^d	91	92	-0.2	-0.01	0.41
Proportion of beneficiaries adherent to antihypertensives (%) ^{d, e}	86	87	-0.7	-0.02	0.23
Uses statins based on Part D (%)	99	99	0.1	0.00	0.58
Intensity of statin use based on Part D (%)					
Low intensity	10	10	0.0	0.00	0.76
Medium intensity	60	59	1.0	0.02	
High intensity	28	29	-0.9	-0.02	
Proportion of days covered by any statins (%)	81	82	-0.7	-0.03	0.27
Proportion of beneficiaries adherent to statins (%) ^e	70	71	-1.2	-0.03	0.24

 Table F.4. Baseline characteristics of high- and medium-risk Medicare beneficiaries included in

 the Part D analyses of adherence to statins:
 Intervention versus control group

	Intervention	Control group		Standardia	
Characteristic	group mean (N = 53,583)	mean (N = 36,434)	Difference	difference ^a	<i>p</i> -value ^b
Beneficiary's demographic and Medic	are enrollment	characteristics			
Age	72	72	-0.1	-0.02	0.63
[standard deviation]	[5]	[5]			
Black race (%)	7	6	1.3	0.05	0.37
Male (%)	57	58	-1.0	-0.02	0.43
Dually enrolled in Medicare and Medicaid (%)	12	13	-1.0	-0.03	0.64
Originally entitled to Medicare because of disability (%)	15	15	-0.6	-0.02	0.66
Beneficiary's health and comorbid co	nditions				
HCC score	1.29	1.30	0.0	-0.01	0.74
[standard deviation]	[1.06]	[1.06]			
Number of chronic conditions	2.4	2.4	0.0	0.00	0.94
Beneficiary's medical service use and	l spending in ye	ar before model	enrollment		
Total Medicare Parts A and B					
annualized expenditures (\$)	8,429	8,310	119.3	0.01	0.71
[standard deviation]	[16,567]	[16,052]			
Hospital admissions (per 1,000 beneficiaries)	198	204	-6.2	-0.01	0.53
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	389	380	8.9	0.01	0.66
Office visits (per 1,000 beneficiaries)	10,040	9,753	287.4	0.04	0.48
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,841	2,874	-32.9	-0.01	0.91
Cardiologist visits (per 1,000 beneficiaries)	2,156	2,115	40.9	0.01	0.85
Characteristics of organization enroll	ing the beneficia	ary			
Organizational-level mean Medicare spending and use ^f					
Parts A and B spending	7,828	7,794	34.4	0.02	0.91
Hospital admissions (per 1,000 beneficiaries)	185	196	-10.3	-0.25	0.24
Outpatient ED visits (per 1,000 beneficiaries)	377	367	10.3	0.10	0.57
Characteristics of clinician enrolling t	he beneficiary				
Provider specialty (%)					
Primary care physician	54	57	-2.7	-0.05	0.75
Cardiologist	31	32	-0.2	0.00	0.99
Physician with other specialty	3	1	2.0	0.14	0.14
Not a physician (for example, NP or PA)	10	10	0.7	0.02	0.69
Characteristics of beneficiary's region	n				
Rural (%)	23	25	-2.1	-0.05	0.64
County-level health measures					

Characteristic	Intervention group mean (N = 53,583)	Control group mean (N = 36,434)	Difference	Standardized difference ^a	<i>p</i> -value [⊳]
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.5	-0.16	0.28
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.5	0.11	0.48
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,350	4,401	-50.5	-0.08	0.62
Per capita total Medicare Part A and B spending in 2016	10,036	9,931	104.9	0.07	0.66
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	278	0.2	0.00	0.98
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	690	685	5.6	0.05	0.80

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, 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; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: The population for this table includes beneficiaries who enrolled in 2017 and 2018, had 12 months of Part D coverage before enrollment and in the month of enrollment, and met inclusion criteria for adherence to statins. This accounted for 41 percent of all beneficiaries enrolled in the intervention group and, similarly, 41 percent in the control group.

For all measures, means are calculated over nonmissing values. The Chronic Condition Warehouse algorithms define the following chronic conditions: atrial fibrillation, chronic kidney disease, and ischemic heart disease. The HCC algorithms define the following chronic conditions: congestive heart failure and morbid obesity. All procedures are defined by using Clinical Classifications Software indicators. See the <u>Second Annual Report</u> (Peterson et al. 2019) for details on variable construction.

^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 the difference between a beneficiary's CVD risk score at enrollment and his or her 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. Chapter VI of the <u>Third Annual Report</u> (Blue et al. 2020) defines the clinical targets.

^d Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment and with antihypertensive use at baseline. This included N = 47,729 beneficiaries in the intervention group and N = 32,218 in the control group, accounting for 89 percent of all beneficiaries enrolled in the intervention group included in the analysis of statin adherence and 88 percent in the control group included in the analysis of statin adherence.

^e Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment and with medication use at baseline. For analyses of antihypertensive adherence, this included N = 69,478 beneficiaries in the intervention group and N = 46,621 in the control group, accounting for 53 percent of all

beneficiaries enrolled in each group. For analyses of statin adherence, this included N = 53,583 beneficiaries in the intervention group and N = 36,434 in the control group, accounting for 41 percent of all beneficiaries enrolled in each group.

^fWe defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

⁹ We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the <u>Second Annual Report</u>, Appendix C), including those related to heart failure, hypertension, and angina. This measure excludes heart attacks and strokes because the analytic population excludes beneficiaries who had these events before enrolling in the Million Hearts Model.

^h Mathematica's <u>Third Annual Report</u>, Appendix D provides details on how we constructed organizational-level measures of spending and use (Blue et al. 2020). Briefly, to estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. We calculated the variance-shrunken means for each organization and merged these variables to the beneficiary-level analysis file by organization.

ⁱ Participating organizations could upload data manually (that is, entering data for each beneficiary visit one by one, using a web interface), or in bulk, using one of two CMS-provided tools. We show the proportion that used a bulk-upload tool in case data quality varies by data submission mode.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

Among high- and medium-risk beneficiaries included in the analyses of adherence to antihypertensive medications, the distribution of systolic blood pressure and rates of antihypertensive medication use were similar at enrollment between the groups (Table F.5). The intervention and control groups were also well balanced on the proportion of days covered by antihypertensives, and the proportion of beneficiaries adherent to antihypertensives. They were also similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

	Intervention	Control group		Ctonderdized	
Characteristic	(N = 69,478)	(N = 46,621)	Difference	difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's ca	rdiovascular ris	k			
CVD risk score (%),	28	28	0.0	0.00	0.92
[standard deviation]	[11]	[11]			
Modifiable risk (%) ^c	9	9	0.1	0.01	0.89
Has diabetes (%)	38	37	0.8	0.02	0.71
SBP (mm Hg)	134	134	-0.1	-0.01	0.86
Distribution of SBP (%)					
SBP < 130 mm Hg	40	40	0.6	0.01	0.69
SBP 130–139 mm Hg	28	28	0.0	0.00	0.97
SBP 140–149 mm Hg	17	17	-0.4	-0.01	0.60
SPB ≥ 150 mm Hg	15	15	-0.2	-0.01	0.86
Total cholesterol (mg/dL)	171	170	0.8	0.02	0.54
HDL cholesterol (mg/dL)	50	50	0.0	0.00	1.00
LDL cholesterol (mg/dL)	94	92	1.3	0.04	0.25
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	25	26	-1.5	-0.03	0.25
LDL 70–99 mg/dL	37	37	0.2	0.00	0.75
LDL 100–129 mg/dL	24	23	0.7	0.02	0.29
LDL ≥ 130 mg/dL	14	13	0.6	0.02	0.44
Is current smoker (%)	10	12	-1.9	-0.06	0.13
Beneficiary's medication use					
Uses aspirin (%)	48	45	3.1	0.06	0.49
Uses antihypertensives based on Part D (%)	99	100	-0.1	-0.01	0.19
Proportion of days covered by antihypertensives (%)	90	90	-0.2	-0.01	0.56
Proportion of beneficiaries adherent to antihypertensives (%) ^e	84	84	-0.5	-0.01	0.42
Uses statins based on Part D (%)	68	68	-0.4	-0.01	0.76
Intensity of statin use based on Part D (%)					

Table F.5. Baseline characteristics of high- and medium-risk Medicare beneficiaries included in the Part D analyses of adherence to antihypertensive medications: Intervention versus control group

	Intervention	Control group			
Characteristic	group mean	mean	Difference	Standardized	n velue ^b
	(N = 69,478)	(N = 46, 621)	Dimerence	amerence.	<i>p</i> -value ²
Low intensity	1	1	0.0	0.00	0.90
	41	41	0.3	0.01	
High intensity	20	21	-0.7	-0.02	0.00
statins (%) ^d	82	82	-0.7	-0.03	0.22
Proportion of beneficiaries adherent to statins (%) ^{d, e}	71	72	-1.4	-0.03	0.16
Beneficiary's demographic and Medica	are enrollment	characteristics			
Age	72	72	-0.1	-0.01	0.74
[standard deviation]	[5]	[5]			
Black race (%)	8	7	1.2	0.05	0.46
Male (%)	54	55	-1.0	-0.02	0.34
Dually enrolled in Medicare and Medicaid (%)	13	14	-1.2	-0.03	0.57
Originally entitled to Medicare because of disability (%)	15	16	-0.8	-0.02	0.55
Beneficiary's health and comorbid cor	nditions				
HCC score	1.29	1.30	0.0	-0.01	0.66
[standard deviation]	[1.07]	[1.08]			
Number of chronic conditions	2.4	2.4	0.0	0.00	0.91
Beneficiary's medical service use and	spending in ve	ar before model	enrollment		
Total Medicare Parts A and B					
annualized expenditures (\$)	8,556	8,368	187.7	0.01	0.56
[standard deviation]	[16,830]	[16,309]			
Hospital admissions (per 1,000 beneficiaries)	205	210	-4.5	-0.01	0.64
Outpatient ED visits or observation stavs (per 1.000 beneficiaries)	407	403	3.8	0.00	0.85
Office visits (per 1,000 beneficiaries)	10,030	9,726	304.0	0.04	0.46
Office visits with model-aligned	2,875	2,914	-38.9	-0.01	0.90
Cardiologist visits (per 1,000	2 100	2 074	35.0	0.01	0.87
beneficiaries)	2,103	2,074	00.0	0.01	0.07
Characteristics of organization enrolli	na the benefici	arv			
Organizational-level mean Medicare					
Parts A and B sponding	7 775	7 727	27.7	0.02	0.00
Hospital admissions (par 1 000	195	105	57.7	0.02	0.90
beneficiaries)	185	195	-9.0	-0.24	0.26
Outpatient ED visits (per 1,000 beneficiaries)	379	368	10.8	0.10	0.54
Characteristics of clinician enrolling the	ne beneficiary				
Provider specialty (%)					
Primary care physician	55	58	-2.7	-0.05	0.75
Cardiologist	30	30	0.0	0.00	1.00

	Intervention	Control group		Standardized	
Characteristic	(N = 69,478)	(N = 46,621)	Difference	difference ^a	<i>p</i> -value ^b
Physician with other specialty	3	1	1.8	0.13	0.14
Not a physician (for example, NP or PA)	11	10	0.9	0.03	0.63
Characteristics of beneficiary's region	า				
Rural (%)	24	26	-2.2	-0.05	0.65
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.6	-0.18	0.23
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.5	0.10	0.51
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,374	4,423	-48.8	-0.08	0.63
Per capita total Medicare Part A and B spending in 2016	9,997	9,905	92.2	0.06	0.69
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	278	0.2	0.01	0.97
Outpatient ED visits per 1,000 Medicare FES beneficiaries in 2016	694	687	6.7	0.05	0.77

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, 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; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: The population for this table includes beneficiaries who enrolled in 2017 and 2018, had 12 months of Part D coverage before enrollment and in the month of enrollment, and met inclusion criteria for adherence to antihypertensives. This accounted for 53 percent of all beneficiaries enrolled in each group.

For all measures, means are calculated over nonmissing values. The Chronic Condition Warehouse algorithms define the following chronic conditions: atrial fibrillation, chronic kidney disease, and ischemic heart disease. The HCC algorithms define the following chronic conditions: congestive heart failure and morbid obesity. All procedures are defined by using Clinical Classifications Software indicators. See the <u>Second Annual Report</u> (Peterson et al. 2019) for details on variable construction.

^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 the difference between a beneficiary's CVD risk score at enrollment and his or her 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. Chapter VI of the <u>Third Annual Report</u> (Blue et al. 2020) defines the clinical targets.

^d Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment and with statin use at baseline. This included N = 47,729 beneficiaries in the intervention group and N =

32,218 in the control group, accounting for 69 percent of all beneficiaries enrolled in the intervention group included in the analysis of antihypertensive adherence and 69 percent in the control group included in similar analysis.

^e Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment and with medication use at baseline. For analyses of antihypertensive adherence, this included N = 69,478 beneficiaries in the intervention group and N = 46,621 in the control group, accounting for 53 percent of all beneficiaries enrolled in each group. For analyses of statin adherence, this included N = 53,583 beneficiaries in the intervention group, accounting for 41 percent of all beneficiaries enrolled in each group.

^fWe defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

⁹ We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the <u>Second Annual Report</u>, Appendix C), including those related to heart failure, hypertension, and angina. This measure excludes heart attacks and strokes because the analytic population excludes beneficiaries who had these events before enrolling in the Million Hearts Model.

^h Mathematica's <u>Third Annual Report</u>, Appendix D provides details on how we constructed organizational-level measures of spending and use (Blue et al. 2020). Briefly, to estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. We calculated the variance-shrunken means for each organization and merged these variables to the beneficiary-level analysis file by organization.

ⁱ Participating organizations could upload data manually (that is, entering data for each beneficiary visit one by one, using a web interface), or in bulk, using one of two CMS-provided tools. We show the proportion that used a bulkupload tool in case data quality varies by data submission mode.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

3. Baseline characteristics of the population used to estimate impacts on CVD risk scores and risk factors

The intervention and control groups used for analyses of changes in CVD risk scores and risk factors were very similar at enrollment with respect to clinical indicators of cardiovascular risk, although more intervention group beneficiaries had diabetes (68 versus 65 percent; Table F.6). The two groups also had very similar rates of medication use at enrollment, and appeared balanced on characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending. Consistent with the populations and tables shown previously, intervention and control group beneficiaries differed somewhat in the types of organizations that enrolled them. Intervention group beneficiaries included in the CVD risk reduction analyses were, compared to control group beneficiaries, enrolled by organizations that had more sites on average (28 versus 17) and more practitioners (137 versus 112), and were more likely to participate in or have applied to participate in another model when they applied to the Million Hearts Model (69 versus 61 percent). In addition, intervention group beneficiaries were more likely to be enrolled by specialty or multispecialty practices (41 versus 31 percent) rather than primary care practices (53 versus 59 percent). The organizations that enrolled intervention group beneficiaries had lower rates of all-cause hospital admissions compared to the organizations that enrolled control group beneficiaries (184 versus 192 admissions per 1,000 beneficiaries), though they had higher rates of all-cause outpatient ED visits (379 versus 359 per 1,000 beneficiaries). Intervention group beneficiaries in this population were also more likely than control group beneficiaries to live in rural areas (28 versus 24 percent), the South (52 versus 31 percent), and were more likely to have enrolled in the first quarter of 2017 (48 versus 42 percent).

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 18,110)	(N = 10,247)	Difference	difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's o	cardiovascular ris	k			
CVD risk score (%),	40	40	0.3	0.03	0.25
[standard deviation]	[9]	[9]			
Modifiable risk (%) ^c	15	15	-0.2	-0.01	0.83
Has diabetes (%)	68	65	2.7	0.06	0.33
Systolic blood pressure (mm Hg)	139	139	-0.4	-0.02	0.71
Total cholesterol (mg/dL)	167	169	-1.2	-0.03	0.44
HDL cholesterol (mg/dL)	47	48	-0.8	-0.06	0.28
LDL cholesterol (mg/dL)	91	91	0.2	0.01	0.88
Is current smoker (%) ^d	12	12	-0.7	-0.02	0.41
Beneficiary's medication use					
Uses aspirin (%)	51	48	2.7	0.05	0.60
Uses antihypertensives based on Part D ^e (%)	90	90	0.3	0.01	0.71

Table F.6. Baseline characteristics of high-risk Medicare beneficiaries included in the CVD risk reduction analysis: Intervention versus control

	Intervention	Control group		o	
Characteristic	group mean (N = 18,110)	mean (N = 1 <u>0,247)</u>	Difference	Standardized differ <u>ence</u> ª	p-value ^b
Proportion of days covered by	91	92	-0.2	-0.01	0.64
antihypertensives (%) ^f					
Proportion of beneficiaries adherent to antihypertensives $(\%)^{f, g}$	87	87	-0.5	-0.01	0.58
Uses statins based on Part D ^e (%)	70	70	0.8	0.02	0.67
Intensity of statin use based on Part D ^e (%)					
Low intensity	7	7	-0.2	-0.01	0.57
Medium intensity	43	42	1.2	0.02	
High intensity	20	21	-0.2	-0.01	
Proportion of days covered by any statins (%) ^f	82	83	-0.8	-0.03	0.31
Proportion of beneficiaries adherent to statins (%) ^{f, g}	72	74	-2.3	-0.05	0.09
Beneficiary's demographic and Medica	are enrollment o	characteristics			
Age	74	74	0.0	0.00	0.94
[standard deviation]	[4]	[4]			
Black race (%)	7	6	0.7	0.03	0.74
Male (%)	65	67	-1.2	-0.03	0.35
Dually enrolled in Medicare and Medicaid (%)	8	8	0.0	0.00	0.99
Originally entitled to Medicare because of disability (%)	11	11	-0.4	-0.01	0.78
Beneficiary's health and comorbid cor	nditions				
HCC score	1.30	1.29	0.0	0.01	0.75
[standard deviation]	[0.97]	[0.97]			
Number of chronic conditions	2.5	2.5	0.0	0.02	0.58
Has chronic kidney disease (%)	35	35	0.7	0.01	0.77
Has ischemic heart disease (%)	37	38	-1.2	-0.02	0.76
Has congestive heart failure (%)	12	13	-0.7	-0.02	0.62
Has atrial fibrillation (%)	11	11	-0.1	0.00	0.96
Has morbid obesity (%)	9	9	0.0	0.00	1.00
Beneficiary's medical service use and	spending in ye	ar before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$)	7,435	7,137	298.0	0.02	0.47
[standard deviation]	[15,407]	[14,492]			
Hospital admissions (per 1,000 beneficiaries)	176	170	6.5	0.01	0.56
CVD-related hospital admissions (per 1,000 beneficiaries) ^h	40	37	2.9	0.01	0.61
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	343	328	15.0	0.02	0.39
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) ^h	26	27	-1.5	-0.01	0.67

	Intervention	Control group		Standardized	
Characteristic	(N = 18, 110)	(N = 10,247)	Difference	difference ^a	p-value ^b
Office visits (per 1,000 beneficiaries)	9,578	9,092	485.5	0.07	0.35
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,223	3,218	4.8	0.00	0.99
Cardiologist visits (per 1,000 beneficiaries)	1,969	1,970	-1.1	0.00	1.00
Beneficiary's CVD-related procedures	in year before	model enrollmen	t		
Received echocardiogram (%)	42	40	1.4	0.03	0.69
Received electrocardiogram (%)	72	72	-0.2	-0.01	0.95
Received cardiac stress test (%)	28	28	0.3	0.01	0.90
Characteristics of organization enrolling	ng the beneficia	ary			
Total number of practitioners	137	112	24.6	0.09	0.68
[standard deviation]	[207]	[315]			
Total number of service sites [standard deviation]	28 [28]	17 [29]	11.2	0.39	0.20
Organization type (%)					
Primary care	53	59	-5.7	-0.12	0.06
Specialty or multispecialty	41	31	9.5	0.20	
FQHC, RHC, or other health center	4	5	-0.8	-0.04	
CAH or rural hospital	0	1	-1.3	-0.15	
Acute care hospital	3	4	-1.6	-0.09	
Organization participated in, or had application pending for, another model at application (%)	69	61	7.9	0.17	0.50
Organization-level mean Medicare spending and use ⁱ					
Parts A and B spending	7,437	7,482	-44.3	-0.03	0.89
Hospital admissions (per 1,000 beneficiaries)	184	192	-8.5	-0.22	0.38
Outpatient ED visits (per 1,000 beneficiaries)	379	359	19.6	0.20	0.32
Characteristics of clinician enrolling the	ne beneficiary				
Provider specialty (%)					
Primary care physician	63	65	-1.5	-0.03	0.87
Cardiologist	24	24	-0.6	-0.02	0.95
Physician with other specialty	2	1	1.3	0.12	0.16
Not a physician (for example, NP or PA)	11	9	1.3	0.04	0.54
Characteristics of beneficiary's region	I				
Rural (%)	28	24	3.1	0.07	0.63
Census region (%)					
Northeast	19	20	-1.2	-0.03	0.19
Midwest	22	33	-10.8	-0.24	
South	52	31	21.7	0.45	

Characteristic	Intervention group mean (N = 18,110)	Control group mean (N = 10,247)	Difference	Standardized difference ^a	<i>p</i> -value ^b
West	7	17	-9.8	-0.31	
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.4	-0.11	0.59
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	24	23	1.1	0.23	0.25
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,474	4,403	70.5	0.12	0.57
Per capita total Medicare Part A and B spending in 2016	9,799	9,733	65.9	0.05	0.80
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	282	276	6.0	0.14	0.49
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	711	676	34.3	0.27	0.21
Characteristics of beneficiary's Million	n Hearts Model	enrollment			
Days between model launch (1/3/2017)					
and enrollment date	146	162	-16.4	-0.12	0.24
[standard deviation]	[142]	[137]			
Enrollment date is in (%)					
First quarter of the year	48	42	5.9	0.12	0.18
Second quarter of the year	31	30	0.9	0.02	0.72
Third quarter of the year	13	16	-3.8	-0.11	0.09
Fourth quarter of the year	8	11	-3.0	-0.10	0.05
Data submitted to the registry using bulk upload (%) ^j	40	47	-6.7	-0.13	0.57

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, 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; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: This population in this table is limited to high-risk beneficiaries who were eligible for and received a reassessment visit by December 31, 2019. We defined the population eligible for a reassessment visit as high-risk beneficiaries whose enrollment date was on or before October 31, 2018. This is so their window for a reassessment visit 10 to 14 months after enrollment occurred by December 31, 2019. We excluded from the definition of eligible beneficiaries any beneficiary who died, had an AMI or stroke, enrolled in Medicare Advantage, or lost Medicare as the primary payer within 14 months of the enrollment date. We determined eligibility based on the enrollment date used for CMS payments, rather than the adjusted date used for the evaluation. However, baseline characteristics in this table reflect characteristics as of the adjusted date—that is, the first date after model launch that a beneficiary visited the enrolling organization and for which we have complete data needed to calculate a baseline risk score. See Conwell et al. 2019 for details of this baseline date adjustment.

For all measures, means are calculated over nonmissing values. The Chronic Condition Warehouse algorithms define the following chronic conditions: atrial fibrillation, chronic kidney disease, and ischemic heart disease. The HCC algorithms define the following chronic conditions: congestive heart failure and morbid obesity. All procedures are defined by using Clinical Classifications Software indicators. See the <u>Second Annual Report</u> (Peterson et al. 2019) for details on variable construction.

^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 the difference between a beneficiary's CVD risk score at enrollment and his or her 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. Chapter VI of the <u>Third Annual Report</u> (Blue et al. 2020) defines clinical targets.

^d Smoking percentages exclude one control organization (n = 216 beneficiaries) with possible data quality issues.

^e Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment (N = 12,631 for the intervention group and N = 7,170 for the control group). This accounted for 70 percent of all beneficiaries enrolled in each group included in analyses of CVD risk reduction.

^f Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment and with medication use at baseline. For analyses of antihypertensive adherence, this included N = 10,949 beneficiaries in the intervention group and N = 6,190 in the control group, accounting for 60 percent of all beneficiaries enrolled in each group included in analyses of CVD risk reduction. For analyses of statin adherence, this included N = 8,574 beneficiaries in the intervention group and N = 4,821 in the control group, accounting for 47 percent of all beneficiaries enrolled in each group included in analyses of CVD risk reduction.

^gWe defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

^h We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the <u>Second Annual Report</u> [Peterson et al. 2019], Appendix C), including those related to heart failure, hypertension, and angina. This measure excludes heart attacks and strokes because the analytic population excludes beneficiaries who had these events before enrolling in the Million Hearts Model.

ⁱ Mathematica's <u>Third Annual Report</u>, Appendix D provides details on how we constructed organizational-level measures of spending and use (Blue et al. 2020). Briefly, to estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. We calculated the variance-shrunken means for each organization and merged these variables to the beneficiary-level analysis file by organization.

^j Participating organizations could upload data manually (that is, entering data for each beneficiary visit one by one, using a web interface), or in bulk, using one of two CMS-provided tools. We show the proportion that used a bulk-upload tool in case data quality varies by data submission mode.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CMS = Centers for Medicare & Medicaid Services; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL = high-density lipoprotein; LDL = low-density lipoprotein; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

Appendix G

Estimating Impacts on Beneficiaries' Outcomes: Detailed Methods and Supplemental Results

In <u>Chapter V</u>, Mathematica reported estimates of the impacts of the Million Hearts Model on the initiation or intensification of cardiovascular disease (CVD) medications, CVD medication adherence, CVD risk scores, first-time heart attacks and strokes, Medicare spending, and other outcomes. This appendix details our methods for estimating impacts and presents additional results. <u>Appendices E</u> and <u>F</u> described the beneficiaries included in the impact analyses and characteristics of beneficiaries in the intervention and control groups before they enrolled in the model.

1. Methods for estimating impacts using claims data

The core design for estimating impacts used the cluster randomized trial, in which the Centers for Medicare & Medicaid Services (CMS) randomly assigned 516 organizations (the clusters) to intervention and control groups. CMS assigned organizations to the two groups in a way that ensured, on average, the 260 intervention organizations and the 256 control organizations were similar in their locations (as defined by 10 U.S. Department of Health and Human Services regions), number of service sites, number of practitioners, 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 was the beneficiary. That is, we estimated impacts as the regression-adjusted differences in outcomes between intervention and control *beneficiaries*. We estimated impacts for (1) the medium- and high-risk beneficiaries combined and (2) the high-risk beneficiaries alone. Beneficiaries were considered high risk if, at the time of enrollment, their estimated 10-year risk of first-time heart attack and stroke was 30 percent or higher, medium risk if it was 15 percent or higher and less than 30 percent, and low risk if it was less than 15 percent.

Because beneficiaries enrolled at different times, our follow-up data on their outcomes cover different calendar periods for each beneficiary. For each beneficiary, we measured claims-based outcomes from the beneficiary's date of enrollment (in 2017 or 2018) through December 2020

(or the date a person died or became unobservable in Medicare claims).²⁶ The median follow-up period across all beneficiaries included in these analysis was 42.5 months, with a range from one day to just under 48 months. We measured spending and acute care use at the beneficiary-quarter level. Analyses of first-time CVD events stopped following beneficiaries after they had a CVD event, for a shorter median follow-up time of 40.4 months. Given the date we pulled the claims data and the rolling enrollment, we observed each beneficiary from 1 to 15 quarters, depending on how early in 2017 or 2018 the beneficiary enrolled in the model (and whether he or she was still alive and observable in claims at the start of the quarter). We used an intent-to-treat design, following beneficiaries for all months after they entered the Million Hearts Model, whether they continued to receive any active intervention from the participating organizations. This approach limited the possibility differential attrition between the intervention and control groups could bias impact estimates-that is, lead to differences in mean outcomes between the intervention and control groups that were not due to model impacts. 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 might not be risk stratified or reported to the registry.

We estimated model impacts as the regression-adjusted differences in claims-based outcomes for beneficiaries enrolled by the intervention and control organizations in 2017 and 2018—the first two years of the Million Hearts Model. We tailored the regression models to the type of outcome:

- 1. We used Cox proportional hazard models to measure impacts on first-time incidence of heart attacks, strokes, or transient ischemic attacks (TIAs) and death, with one observation per beneficiary. Each observation measured the time from enrollment to the event (heart attack or stroke, or death) or to the date of censoring in the data (from reaching the end of the observed claims period, December 2020). The models generated hazard ratios, which equal 1.00 if the risk of having an event over time is the same in the intervention and control groups. If the hypothesis that the model reduced first-time incidence of heart-attack or stroke is correct, we would expect a hazard ratio less than 1.00.
- 2. We used linear regression models to measure impacts on Medicare spending and service use, with one observation per beneficiary per quarter. The models generated differences in mean

²⁶ The antihypertensive medication and statin intensification, initiation, and adherence outcome measures cover the first year after beneficiaries were enrolled. These analyses relied on Part D claims data through June 2020. This time period enabled us to identify medication initiation, intensification, and adherence within the first year of enrollment for every beneficiary in the study population, along with an additional 3 months needed to confirm intensification and an additional 3 months needed to confirm adherence, for a total of 18 months post-enrollment. Because our analysis included beneficiaries enrolled through December 2018, this 18-month period extended through June 2020. We required 3 additional months for intensification measures because we considered a beneficiary to intensify antihypertensive therapy if he or she took a new antihypertensive medication within a year of enrollment, and still took his or her old medications at least once within the 3 months after starting a new medication. We required 6 additional months (that is, a total of 18 months) for adherence measures because we wanted to identify any prescriptions that started within one year of enrollment and ended up to 6 months after enrollment.

outcomes for each quarter. We averaged these quarterly impact estimates across all quarters, weighting the quarters by the number of beneficiaries observed each quarter.

- **3.** We used logistic regressions with one observation per beneficiary to analyze impacts on binary outcomes, including initiation, intensification, and proportion of beneficiaries adherent to CVD medication within one year of enrollment; binary cardiovascular risk factors smoking and aspirin use; and the incidence of CVD events and mortality within one, two, and three years of enrollment. These models generated the predicted probability of initiating or intensifying CVD medications within one year of enrollment for each intervention group beneficiary twice—first assuming the beneficiary was in the intervention group. For each beneficiary, we calculated the difference in predicted probability under these two conditions, and then estimated model impacts as the mean of these differences across all beneficiaries in the intervention group.
- 4. We used linear regression models, with one observation per beneficiary, to measure impacts on changes in continuous CVD risk factors, including systolic blood pressure, total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol, and measures of proportion of days covered by CVD medications.

We described the first three types of regression models in more detail in Appendix D of our <u>Second Annual Report</u> (Peterson et al. 2019) and the last type of models is described in Appendix F of our <u>Third Annual Report</u> (Blue et al. 2020). All models accounted for clustering of beneficiaries within organizations, which is needed to correctly estimate standard errors, *p*-values, and confidence intervals.

The regression models adjusted for beneficiaries' characteristics at baseline to increase the precision and to adjust for observed differences between the groups. Regression adjustment is appropriate because CMS used a relatively sophisticated method for assigning organizations to the intervention and control groups rather than simple random assignment (Ciolino et al. 2019). Further, even though the intervention and control groups were similar at baseline on many demographics, there were some relatively large standardized differences between the two groups (see Appendix F) and some smaller differences between the two groups in covariates that were highly related to the outcome, which made it important to control for these factors in regression models (Schochet 2010). Table G.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 (described in the Third Annual Report, Appendix C [Blue et al. 2020]). For beneficiaries identified through claims-based attribution, we had to use claims-based proxies for clinical values, such as blood pressure, collected in the registry. For models analyzing impacts on adherence, we also adjusted for baseline adherence levels. For models analyzing impacts on cardiovascular risk scores or risk factors, we adjusted for the time between baseline and followup visits at which cardiovascular risks were measured.

Table G.1. Covariates included in the regression models used for estimating impacts on a beneficiary's outcomes

	Included in models with t o	regression he population f:
	Enrolled	Attributed
Baseline covariate	beneficiaries	beneficiaries
Bradietad CVD risk scoro ^b	•	_
Predicted CVD lisk score		-
low-CVD risk groups (four variables)		•
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)		
Evidence of hypertension in claims since 1999 (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,d}	•	
Evidence of tobacco use in claims over previous 24 months (yes/no)		•
Uses aspirin (yes/no) ^{a,d}	•	
Evidence of aspirin use in claims over previous 24 months (yes/no)		•
Beneficiary's medication use before model enrollment ^{f, i}		
Antihypertensive medications in baseline year (yes/no/without Part D enrollment)	•	•
Statins in baseline year (no/low/moderate/high/without Part D enrollment)	•	•
Beneficiary's demographic and Medicare enrollment characteristics		
Age (separately by age group) ^ь	•	•
Black race (yes/no)	•	•
Male (yes/no)	•	•
Dually enrolled in Medicare and Medicaid (yes/no)	•	•
Originally entitled to Medicare due to disability (yes/no)	•	•
Received Part D low-income subsidy for at least one month over previous year	•	•
Beneficiary's health and comorbid conditions from claims		
HCC score ^b	•	•
Count of chronic conditions	•	•
Has chronic kidney disease (yes/no)	•	•
Has ischemic heart disease (yes/no)	•	•
Has heart failure (yes/no)	•	•

	Included in models with t o	regression he population f:
Baseline covariate	Enrolled beneficiaries	Attributed beneficiaries
Has atrial fibrillation (ves/no)		
Has morbid obesity (ves/no)	-	-
Has dementia (ves/no)		
Has diabetes with complications (yes/no)		
Has dialysis status, acute renal failure, or 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 or alcohol dependence (yes/no)		
Beneficiary's medical service use and spending in year before model enrollment ^f		
Total Medicare Parts A and B annualized expenditures ^{b, e}		•
Total inpatient annualized expenditures ^e	•	•
Number of hospital admissions ^e	•	•
Number of CVD-related hospital admissions ^e	•	•
Number of outpatient ED visits or observation stays ^e	-	•
Number of CVD-related ED visits or observation stays ^e	•	•
Number of office visits ^e	-	•
Number of office visits with model-aligned providers ^e	•	•
Number of cardiologist office visits ^e	•	•
Beneficiary's CVD-related procedures in year before model enrollment ^f		
Received echocardiogram (yes/no)	•	•
Received electrocardiogram (yes/no)	•	•
Received cardiac stress test (yes/no)	•	•
Received prophylactic vaccination or inoculation (yes/no)	•	•
Received colonoscopy or biopsy (yes/no)	•	•
Characteristics of organization enrolling the beneficiary ⁹		
Total number of practitioners (1 to 5 or 6 to 19 or 20 or more)	•	•
Total number of service sites (1 or 2 to 5 or 6 or more)	•	•
Organization type: (primary care, specialty or multispecialty, FQHC, RHC, or other health center, CAH, rural hospital, acute care hospital, or other)	•	•
Organization participated in, or had application pending for, another model at random assignment (yes/no)	•	•
Organizational-level mean Parts A and B Medicare spending ^{e, h}	•	•
Organizational-level mean hospital admissions (per 1,000 beneficiaries) ^{e, h}	•	-
Organizational-level mean outpatient ED visits or observation stays (per 1,000 beneficiaries) ^{e, h}	•	•

	Included in models with t o	regression ne population f:	
Baseline covariate	Enrolled beneficiaries	Attributed beneficiaries	
Characteristics of clinician enrolling the beneficiary ^g			
Provider specialty (cardiovascular-related physician/primary care physician [noncardiovascular]/other physician/other provider type [nonphysician])	•	•	
Rural (yes/no)	-	-	
Characteristics of beneficiary's region			
Census region (Midwest, South, West, or other)	-	-	
County-level AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016 ^e	•	•	
County-level stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016 ^e	•	•	
County-level age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016 ^e	•	•	
County-level per capital total Medicare Parts A and B spending in 2016 ^e	-	•	
County-level hospital admissions per 1,000 Medicare FFS beneficiaries in 2016 ^e	-	•	
County-level outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016 ^e	-	-	
Characteristics of beneficiary's Million Hearts Model enrollment ^f			
Days between enrollment and January 3, 2017 ^e	-	-	
Calendar quarter the enrollment date is in (one of eight quarters in 2017 and 2018)	•	•	
Fewer than 12 months observable in Medicare claims in the year before enrollment (yes/no)	•	•	
Data submitted to the registry using bulk upload (yes/no) ^{a, c}			

Notes: For estimating impacts of the model on the antihypertensive medication and statin intensification composite measures, all the variables in this table entered the regression models multiple times depending on eligibility for the underlying outcome. For example, the covariates entered the model once for beneficiaries eligible for initiation and once for beneficiaries eligible for intensification when we estimated impacts on statin initiation or intensification. In practice, this meant interacting a person's baseline covariates with a dummy variable for whether the person was eligible for initiation or intensification or intensification of a particular model.

For estimating impacts on follow-up CVD risk scores and risk factors, we added second-order polynomial terms for the number of months between enrollment and follow-up and the beneficiary's baseline CVD risk score and systolic blood pressure at enrollment.

^a We constructed this variable using data from the Million Hearts registry.

^b We included an interaction term between this variable and the high-risk group indicator in models that included both medium- and high-risk enrolled beneficiaries. We interreacted this variable with the probability of belonging to the high-risk CVD group for analyses of attributed beneficiaries.

° To account for missing values, we interacted this variable with an indicator for missing data.

^d To estimate the impacts of the model on the probability of smoking at reassessment, we adjusted for smoking status at enrollment. However, we did not control for aspirin use at enrollment. In the Million Hearts Data Registry, when a beneficiary is recorded as using aspirin daily at a visit, that will remain the status at later visits, including any annual reassessment visits. Because beneficiaries' aspirin status cannot change from daily user to nonuser between enrollment and reassessment visits, we cannot estimate a logit model that controls for aspirin use at enrollment. (There is no variation in aspirin use at reassessment among beneficiaries who used aspirin at enrollment, so this variable predicts the outcome perfectly. In a logit model, the coefficient for baseline aspirin would equal infinity, preventing convergence during maximum likelihood estimation.) Aspirin use was similar between intervention and control beneficiaries at enrollment, so we expect removing this variable from the model had minimal impact on the impact estimates.

^e Before including these variables in the regression models, we standardized each variable to have mean 0 and standard deviation 1.

^f 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).

⁹ 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).

^h See Appendix C of the <u>Second Annual Report</u> (Peterson et al. 2019) for details on measure construction. To estimate organizational-level mean Medicare spending and use per beneficiary, we used only baseline data from the beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention started and, importantly, before the model might have affected the use and expenditures for the Medicare beneficiaries associated with organizations participating in the model. The organization-level means included in the regression models are the variance-shrunken means for each organization.

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

AMI = acute myocardial infarction; 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; RHC = rural health center.

2. Unadjusted cumulative probabilities of medication initiation and intensification, CVD events, and death

Figures G.1 through G.3 present unadjusted (Kaplan-Meier) estimates of the cumulative probability of initiating or intensifying statins or antihypertensives, having a first-time heart attack, stroke or TIA (composite measure), or dying for each day following 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 gives the probability that a beneficiary does not have the event (for example, dying) within a specified time.

In both the intervention and control groups, more than half of eligible beneficiaries initiated or intensified CVD medications over the follow-up period (almost four years in some cases) (Figure G.1). Most of these beneficiaries initiated or intensified medications in the first year after enrollment, with rates of initiation and intensification increasing more gradually after one year. The intervention group's rate of medication initiation or intensification increased faster than the control group's rate in the first year and the differences between the two groups persisted up to four years. The curves showing the cumulative probabilities of CVD events for the intervention and control groups were initially similar but began to diverge after about a year (Figure G.2). These unadjusted estimates suggest the incidence of first-time CVD events was lower in the intervention group than the control group. However, regression-adjusted analyses, presented in Chapter V, indicate CVD events rates were similar for the intervention and control groups after we controlled for differences in baseline characteristics between the intervention and control groups. (Section G.3 of this appendix discusses this topic further.) In both panels of the figure, the cumulative probabilities of first-time CVD events at a fairly constant rate.

Figure G.3 depicts lower cumulative probability of dying (for any reason) among high- and medium-risk beneficiaries in the intervention group compared to the control group (Panel A). Further, this difference grew steadily over time. There was little difference in the cumulative probability of dying among high-risk beneficiaries (Panel B).

Figure G.1. Many beneficiaries initiated or intensified CVD medications after enrollment, but rates were consistently higher in the intervention group than the control group: Unadjusted cumulative probability of initiating or intensifying statins or antihypertensive medications among candidate high- and medium-risk beneficiaries



Source: Unadjusted results from Medicare Part D claims linked to Medicare claims and enrollment data.

Note: The cumulative probability is defined as 1 minus the Kaplan-Meier estimate of the survival function. The survival function gives the probability that a beneficiary does not initiate or intensify statins or antihypertensives within a specified time.

CVD = cardiovascular disease.





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 gives the probability that a beneficiary does not have a heart attack, stroke, or TIA within a specified time.

TIA = transient ischemic attack.

Figure G.3. 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 gives the probability that a beneficiary does not die within a specified time.

3. Supplemental regression results

Table G.2 describes where this report presents various impact analyses and Table G.3 presents the corresponding sample sizes. Appendix E defines the population for the analyses, and Appendix F compares the intervention and control groups on baseline characteristics. In the claims-based analyses (the first row), the intervention group in this population is about 48 percent larger than the control group. A major reason for this difference is that CMS allowed up to 20 providers in control organizations to enroll beneficiaries but did not apply a similar cap for intervention organizations. The analyses for medication initiation and intensification included about half the beneficiaries included from the first row, because the analyses were limited to beneficiaries enrolled in the model in 2017, enrolled in Part D, and meeting the inclusion criteria for the outcome measures. The analysis of follow-up CVD risk scores was limited to high-risk beneficiaries for whom organizations submitted reassessment data via the Million Hearts Data Registry.

Table G.4 presents the full set of results for the impact analysis of medication use. Tables G.5 through G.15 present results from several robustness checks we conducted to assess the sensitivity of the impact analysis results to alternative methodologies and exploratory analyses. The results are largely organized around the type of outcome measure (Table G.2). For comparative purposes, the tables also include the results from our impact analyses of the primary study population of enrolled high- and medium-risk beneficiaries (labeled "main analysis").

Table G.2. Locations of different impact estimates in this report

Main or alternative analysis	CVD medications: initiation and intensification	CVD medications: adherence	CVD risk scores	CVD events	Inpatient admissions	ED visits	Medicare spending	Mortality
Main analysis	Figure V.A.1 and Tables G.4 and G.5	Figure V.A.2 and Table G.4	Tables V.A.2 and G.9	Figure V.B.1 and Tables V.B.1 and G.10	Tables V.B.2 and G.11	Tables V.B.2 and G.12	Tables V.B.3 and G.13	Figure V.B.3 and Tables V.B.4 and G.14
Trimmed study population	Table G.5	Table G.6	Table G.9	Table G.10	Table G.11	Table G.12	Table G.13	Table G.14
Population of attributed beneficiaries	n.a.	Table G.7	n.a.	Table G.10	Table G.11	Table G.12	Table G.13	Table G.14
Unadjusted impact estimates	Figure G.1	n.a.	Table G.9	Table G.10 and Figure G.2	Table G.11	Table G.12	Table G.13	Table G.14 and Figure G.3
Drop potential candidates for antihypertensive medication if they have systolic blood pressure <140 mmHg	Table G.5	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Any CVD medication use among all beneficiaries with Part D coverage	n.a.	Table G.8	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Restrict to reassessment data collected 10 to 14 months after enrollment	n.a.	n.a.	Table G.9	n.a.	n.a.	n.a.	n.a.	n.a.
Narrower definitions of CVD events	n.a.	n.a.	n.a.	Table G.10	n.a.	n.a.	n.a.	n.a.
Binary outcome measures	n.a.	n.a.	n.a.	Table G.15	n.a.	n.a.	n.a.	Table G.15
Medium-risk beneficiaries	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	Table G.16

CVD = cardiovascular disease; ED = emergency department; n.a. = not applicable.

			•					
	Analysis of high- and medium-risk beneficiaries, number of organizations		Analysis of high- and medium-risk beneficiaries, number of beneficiaries (sum of weightsª)		Analysis of high-risk beneficiaries, number of organizations		Analysis of high-risk beneficiaries, number of beneficiaries (sum of weightsª)	
Alternative outcome measure, population, or model specification	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Analysis of claims-based outco	omes with the po	opulation of 2	2017 and 2018 en	rolled benefic	iaries ^b			
Main analysis	172	170	130,622	88,307	170	165	40,442	27,283
Followed at least one year	172	170	130,622	88,307	170	165	40,442	27,283
Followed at least two years	172	170	130,622	88,307	170	165	40,442	27,283
Followed at least three years	170	163	108,711	73,149	168	157	34,148	22,907
Trim sample to 20 or fewer providers per organization	172	170	90,046	88,120	170	165	28,770	27,223
Analysis of claims-based outco	omes with the po	opulation of a	ttributed benefic	iaries ^b				
Attribution	172	171	434,465 (247,691)	292,893 (164,721)	172	171	434,465 (83,884)	292,893 (53,467)
Followed at least one year	172	171	434,465 (247,691)	292,893 (164,721)	172	171	434,465 (83,884)	292,893 (53,467)
Followed at least two years	172	171	434,465 (247,691)	292,893 (164,721)	172	171	434,465 (83,884)	292,893 (53,467)
Followed at least three years	169	163	355,228 (207,019)	239,605 (137,244)	169	163	355,228 (71,575)	239,605 (45,426)
Antihypertensive adherence	172	170	183,417 (126,584)	123,238 (83,454)	172	170	183,417 (48,755)	123,238 (30,930)
Statin adherence	172	169	141,532 (96,503)	94,579 (63,332)	172	169	141,532 (37,200)	94,579 (23,491)

Table G.3. Sizes of the study populations used for different impact estimates

	Analysis of high- and Medium-riskAnalysis of high- and medium-riskbeneficiaries, number of organizationsof beneficiaries (sum of weightsª)		Analysis of beneficiarie of organi	high-risk s, number zations	Analysis of high-risk beneficiaries, number of beneficiaries (sum of weightsª)			
Alternative outcome measure, population, or model specification	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Analysis of Part D outcomes w	vith the populatio	on of 2017 ar	nd 2018 enrolled b	peneficiaries				
Composite measure: Statin or antihypertensive medication intensification or initiation	170	168	80,286	53,848	166	162	25,760	17,320
Trim sample to 20 or fewer providers per organization	170	168	55,107	53,734	166	162	18,298	17,283
Antihypertensive medication intensification or initiation	169	165	53,332	36,281	165	160	20,903	14,123
Initiation	161	160	11,121	7,677	146	148	3,004	2,085
Intensification	168	164	42,211	28,604	163	159	17,899	12,038
Using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification	167	162	28,375	19,462	163	156	13,109	8,910
Statin intensification or initiation	169	168	69,140	45,820	165	162	20,430	13,649
Initiation	168	164	34,873	23,113	160	160	9,437	6,455
Intensification	164	167	34,267	22,707	159	154	10,993	7,194
Antihypertensive medication adherence	169	166	69,478	46,621	166	161	24,322	16,233
Trim sample to 20 or fewer providers per organization	169	166	48,144	46,527	166	161	17,320	16,202
Statin adherence	168	165	53,583	36,434	162	157	18,719	12,480
Trim sample to 20 or fewer providers per organization	168	165	37,214	36,354	162	157	13,362	12,454

	Analysis of high- and medium-risk beneficiaries, number of organizations		Analysis of high- and medium-risk beneficiaries, number of beneficiaries (sum of weightsª)		Analysis of high-risk beneficiaries, number of organizations		Analysis of high-risk beneficiaries, number of beneficiaries (sum of weightsª)	
Alternative outcome measure, population, or model specification	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Any CVD medication use among all beneficiaries with Part D coverage	170	169	89,456	60,370	166	162	28,366	19,066
Analysis of follow-up risk scor	res and risk facto	rs with the po	pulation of enro	lled beneficia	ries			
Main analysis	n.a.	n.a.	n.a.	n.a.	125	110	18,110	10,247
Trim sample to 20 or fewer providers per organization	n.a.	n.a.	n.a.	n.a.	125	110	12,848	10,228
Beneficiaries who had reassessment data recorded 10 to 14 months after enrollment	n.a.	n.a.	n.a.	n.a.	123	104	14,660	7,799

Sources: Mathematica's analysis of Million Hearts Data Registry, Medicare claims, and enrollment data.

a The population of attributed beneficiaries includes beneficiaries of any risk level. For the robustness check impact analyses, we weighted the population to reflect high- and medium-risk beneficiaries or high-risk beneficiaries, as we described in Appendix E of the <u>Third Annual Report</u> (Blue et al. 2020). The sum of the weights is the effective sample size for the analyses.

b Claims-based outcomes include CVD events, death, Medicare spending, CVD-related and all-cause hospitalizations, CVD-related and all-cause outpatient ED visits and observation stays, and office visits.

CVD = cardiovascular disease; ED = emergency department; n.a. = not applicable.

Trimmed study population. We reestimated impacts for the beneficiaries enrolled in the model but trimming 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 the control organizations—faced with the 20-provider cap—largely selected their 20 model-participating providers using a rule we can replicate for the intervention group (Conwell et al. 2019). That is, it appears many control organizations strategically selected the providers in their organization who could enroll the most beneficiaries. We aimed to replicate this rule in the intervention group by (1) identifying each provider who enrolled a beneficiary when working at a large organization (with large organizations defined as having 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 study population any beneficiaries enrolled in 2017 by providers at large organizations not ranked in the top 20. 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 large organizations were more likely to enroll intervention group beneficiaries-which could potentially confound the impact estimates if the size of the enrolling organization correlated with the outcome. As noted in Chapter V, the impact estimates for the trimmed population mostly aligned with the impact results for the main analyses.

Analyses with attributed beneficiaries. We reestimated impacts on claims-based outcomes in a population we defined by attributing Medicare fee-for-service (FFS) beneficiaries to the participating organizations using Medicare claims data.²⁷ This approach limited potential biases in impact estimates that could stem from differences in the types of beneficiaries organizations chose to enroll, because the population included all eligible beneficiaries (to the extent we could replicate eligibility in claims)-whether or not they actually enrolled. Appendix C of the Third Annual Report (Blue et al. 2020) discusses the methods and rationale for defining this population and predicting risk scores for the beneficiaries, and it explains how we used weights to make the population resemble high- and medium-risk beneficiaries. For the purpose of comparing the impact estimates with the attributed beneficiaries to the main analysis, in the tables, we adjusted the regression model output to account for the fact that not all beneficiaries in the attributionbased intervention group were enrolled in the model. For example, in Table G.13, we estimated the model increased Medicare spending by \$6 for attributed beneficiaries with high- and medium-predicted risk, but only 56 percent of the beneficiaries in this regression model were actually enrolled, suggesting an impact of \$11 (\$6.20 / 0.56), assuming the model had no spillover effects to beneficiaries attributed to the organization but not enrolled into the model. As

²⁷ We cannot analyze impacts on some outcomes—initiation or intensification statins and antihypertensive medications or follow-up risk scores using the population of attributed beneficiaries. Those outcomes rely on registry data to define the study population, which are not available for the non-enrolled attributed beneficiaries.

noted in <u>Chapter V</u>, these results mostly align with the impact results for the main analyses²⁸ with the exception of some medication adherence results in which conclusions about statistical significance of estimates differed, but estimated differences were not clinically meaningful. Although we used the attribution-based results primarily as a check for the main registry-based results, some might be interested in the attribution-based results in their own right. These estimates reflected our best estimate of the impact of the model among all Medicare beneficiaries eligible for the model who had office or clinic visits with participating providers, regardless of whether the providers' organization enrolled them.

Unadjusted impact estimates. The unadjusted impact estimates relied on the regression models used for the main analyses, except we did not include baseline covariates. Differences between the adjusted and unadjusted impact estimates, when present, suggest the regression models adjusted for differences in baseline characteristics between the intervention and control groups on variables related to outcomes. One might not necessarily expect covariate adjustment to substantively change the impact estimated, given that the balance tables in <u>Appendix F</u> show the intervention and control groups were fairly similar (for example, absolute standardized differences in means below 0.10) on many covariates. However, covariate adjustment could affect our impact estimates for several reasons:

- In a clustered randomized trial such as this, it is possible some covariates differed between intervention and control organizations (clusters). This was more likely to happen when (1) some covariates were measured at the organization level; (2) beneficiary-level covariates were associated with the organizational characteristics (for example, U.S. Census region correlated with beneficiaries' race or ethnicity); or (3) many beneficiaries in the analysis population were concentrated in a relatively small proportion of the organizations.
- Even small differences in the means between the intervention and control groups could have undue effects on the impact estimate if the covariates were strongly associated with outcomes.
- Small differences in means between the intervention and control groups could add up to have a large *cumulative* effect on the impact estimates if they tended to work in the same direction.

Take for example our estimate of the impact of the Million Hearts Model on CVD events in Table G.10. The hazard ratio was substantially smaller before regression adjustment than after (0.92 versus 0.97), indicating regression adjustment materially affected our estimate of the model impacts. Specifically, the difference in these estimates suggests the treatment group would have experienced lower rates of CVD events than the control group if the model had no effects, given differences in baseline covariates. After we adjusted for those differences, we found similar rates of CVD events for the intervention and control groups. In exploratory analyses (not shown), we found several variables drove this difference between the adjusted and unadjusted impact

²⁸ Our Second Annual Report (Peterson et al. 2019) used a different algorithm for attributing beneficiaries to participating organizations. Impact analyses with this alternative definition of the attribution population did not support the main findings for inpatient admissions and outpatient emergency department visits.
estimates, including the rate of hospitalizations for heart attacks among those 65 and older in the region where the beneficiaries lived (which tended to be lower for intervention group beneficiaries than control group beneficiaries, and also strongly predicted CVD events in our study population). Given these differences between unadjusted and adjusted impact estimates, intervention beneficiaries would be expected to have better outcomes than control beneficiaries even if the model had no effect. The regression modeling is an important component of our analytic approach to account for these differences. Regression adjustment similarly affected the impact estimates for a few other outcomes (for example, all-cause emergency department [ED] visits and observation stays), but did not affect impact estimates for other outcomes to the same degree (for example, Medicare spending). Regression adjustment also affected impact estimates for the population of attributed beneficiaries for some outcomes (for example, CVD events and proportion of days covered by CVD medications).

In every case, regression adjustment significantly improved the precision of the impact estimates as we intended. That is, impact regression models that included baseline covariates resulted in smaller standard errors and *p*-values and narrower confidence intervals compared to the corresponding regression model without covariates.

Impacts on antihypertensive medication intensification or initiation of dropping some potential candidates. We conducted a sensitivity analysis by redefining *potential candidates* for antihypertensive medication initiation or intensification as those with systolic blood pressures at baseline of 140 mmHg or higher (as opposed to 130 mmHg or higher). The models with this smaller sample were consistent with the findings from the main analysis (Table G.5).

Overall medication use among all beneficiaries with Part D coverage. We estimated impacts of the Million Hearts Model on the proportion of beneficiaries with any CVD medication use and proportion of days with any CVD medication use. We did this to understand the Model's impact on overall CVD medication use among all beneficiaries with Part D coverage, regardless of baseline use of CVD medications. The proportion of beneficiaries with any statin use was about 1.6 percent higher in the intervention group than in the control group among high- and mediumrisk beneficiaries combined (Table G.8), a difference that is statistically significant (p < 0.001). This impact was larger for the high-risk beneficiaries only (2.1 percentage points, p < 0.001, Table G.8). The model also increased proportion of days with any statin use (0.8 percentage points, p < 0.001, Table G.8), with a slightly larger impact for the high-risk beneficiaries only (1.0 percentage points, p = 0.001, Table G.8). Similarly, the model increased the proportion of beneficiaries with any high-intensity statin use and proportion of days with any high-intensity statin use, for both high- and medium-risk beneficiaries combined and high-risk beneficiaries only (Table G.8). The model did not affect overall use of antihypertensives, but this analysis did not take into account the intensity of antihypertensives. As reported in Chapter V, the model did increase the initiation or intensification of antihypertensives, driven mainly by intensification that is, beneficiaries moving to higher intensity of antihypertensives.

Impacts on CVD risk scores restricting to reassessment data collected 10 to 14 months after enrollment. CMS expected organizations would submit risk reassessment data for high-risk beneficiaries within 10 to 14 months after they enrolled in the model. In practice, some organizations submitted data beyond the 14-month window or submitted just a two-year reassessment visits without submitting a one-year visit. We classified one-year reassessment visits as occurring within 22 months of enrollment, and more than 75 percent of one-year reassessment visits occurred within the recommended window. We included all visits outside the 10- to 14-month window, up to 22 months post-enrollment, to maximize the size of the study population and the share of eligible high-risk beneficiaries with reassessment data. However, as a robustness check, we also reestimated impacts on CVD risk scores one year after enrollment, restricting the sample to only beneficiaries who had reassessment data recorded 10 to 14 months after enrollment (Table G.9). Although we controlled for time between enrollment and reassessment visits, this robustness check addressed the limitation that impacts for reassessment visits could differ within the recommended time frame. Estimates from this robustness check aligned with the impact results for the main analyses.

Narrower definitions of CVD events. We calculated impact estimates with our composite measure of CVD events redefined using two narrower definitions, excluding TIAs and stroke symptoms and certain acute myocardial infarctions (AMIs)—specifically AMIs that are not Type 1 AMIs—from being considered CVD events. See Appendix C of the <u>Second Annual Report</u> (Peterson et al. 2019) for detailed definitions of the outcome measures. The impact estimates (hazard ratios) for this narrower definition of the CVD events were similar to the estimates with the primary definition. Specifically, the estimates do not indicate the model reduced the first-time incidence of heart attacks or strokes.

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 observe for the full period. For example, we estimated effects on the proportion of beneficiaries who had a first-time heart attack, stroke, or TIA within three years of enrollment, limiting the analysis to the subset of beneficiaries who enrolled early enough to follow for three full years in available claims data. As with the Cox proportional hazard models, the impact estimates were small and not statistically significant. When we repeated the process for death (for any reason), the results for medium- and high-risk beneficiaries indicated a statistically significant decrease in the probability of death, again supporting the results from the main modeling approach, namely that mortality rates were lower in the intervention group than the control group.

Medium-risk beneficiaries. We estimated impacts of the Million Hearts Model on mortality among only beneficiaries with medium CVD risk. We did this to understand how much the impacts among medium-risk beneficiaries drove impacts for the full sample of high- and medium-risk beneficiaries. The death rate was about 9 percent lower in the intervention group than in the control group among medium-risk beneficiaries (Table G.16, row 1), a difference that

is statistically significant (p < 0.001). This is a larger impact on the ratio of the hazard of dying than we found for either high- and medium-risk beneficiaries combined or for high-risk beneficiaries alone (Table G.14, row 1). The estimated impact on three-year probability of death was also larger for the medium-risk group (Table G.16, row 4) than the high-risk group (Table G.15, row 6). There was a 0.5 percentage point estimated impact on the probability of dying within three years for the medium-risk group compared to a 0.1 percentage point estimated impact for the high-risk group, which led to a combined average of 0.3 percentage point estimated impact in the medium- and high-risk groups combined. Table G.4. The model increased initiation and intensification of CVD medications but did not affect adherence: Estimated impacts on use of statins and antihypertensives

	Regression-adjusted mean Regression-adjusted		sion-adjusted	difference		
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a
High- and medium-risk beneficiaries						
Statin or antihypertensive initiation or intensification (beneficiaries with LDL cholesterol >=70 mg/dL or SBP >=130 mm Hg)	31.3	27.9	3.4	< 0.001	[2.3, 4.4]	134,134
Statin use						
Statin initiation or intensification (beneficiaries with LDL cholesterol >=70 mg/dL)	18.5	15.3	3.2	< 0.001	[2.2, 4.2]	114,960
Initiation (beneficiaries without statin use at baseline)	26.7	23.1	3.6	< 0.001	[2.3, 4.9]	57,986
Intensification (beneficiaries with statin use at baseline)	10.1	7.3	2.8	< 0.001	[1.9, 3.7]	56,974
Adherence (beneficiaries with statin use at baseline)						
Proportion of days covered by any statins	83.0	82.9	0.1	0.69	[-0.2, 0.4]	90,017
Proportion of beneficiaries adherent to statins	74.8	74.9	-0.1	0.68	[-0.7, 0.4]	90,017
Antihypertensive use						
Antihypertensive intensification or initiation (beneficiaries with SBP >=130 mm Hg)	29.4	27.1	2.3	<0.001	[1.3, 3.2]	89,613
Initiation (beneficiaries without antihypertensive use at baseline)	36.7	33.5	3.2	0.002	[1.5, 4.9]	18,798
Intensification (beneficiaries with antihypertensive use at baseline)	27.5	25.5	2.0	0.001	[1.1, 3.0]	70,815

	Regression-adjusted mean		Regres	sion-adjusted	difference	
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a
Adherence (beneficiaries with antihypertensive use at baseline)						
Proportion of days covered by any antihypertensives	91.2	91.3	-0.1	0.36	[-0.4, 0.1]	116,099
Proportion of beneficiaries adherent to antihypertensives	87.0	87.2	-0.1	0.63	[-0.5, 0.3]	116,099
High-risk beneficiaries ^b						
Statin or antihypertensive initiation or intensification (beneficiaries with LDL cholesterol >= 70 mg/dL or SBP >= 130 mm Hg)	37.7	33.3	4.4	< 0.001	[2.8, 5.9]	43,080
Statin use						
Statin intensification or initiation beneficiaries with LDL cholesterol >= 70 mg/dL)	21.1	16.3	4.8	< 0.001	[3.4, 6.1]	34,079
Initiation (beneficiaries without statin use at baseline)	32.0	26.7	5.3	< 0.001	[3.4, 7.1]	15,892
Intensification (beneficiaries with statin use at baseline)	11.7	7.3	4.3	< 0.001	[3.0, 5.7]	18,187
Adherence (beneficiaries with statin use at baseline)						
Proportion of days covered by any statins	83.1	83.1	0.0	0.92	[-0.5, 0.4]	31,199
Proportion of beneficiaries adherent to statins	74.7	75.3	-0.6	0.25	[-1.4, 0.2]	31,199
Antihypertensive use						
Antihypertensive intensification or initiation (beneficiaries with SBP >= 130 mm Hg)	32.9	30.5	2.4	0.002	[1.1, 3.6]	35,026
Initiation (beneficiaries without antihypertensive use at baseline)	49.4	44.7	4.7	0.006	[1.9, 7.5]	5,089
Intensification (beneficiaries with antihypertensive use at baseline)	30.1	28.1	2.0	0.013	[0.7, 3.3]	29,937
Adherence (beneficiaries with antihypertensive use at baseline)						

	Regression-adjusted mean		Regres			
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a
Proportion of days covered by any antihypertensives	92.0	92.0	0.0	0.90	-0.2, 0.3]	40,555
Proportion of beneficiaries adherent to antihypertensives	88.2	88.0	0.2	0.54	-0.3, 0.7]	40,555

Source: Mathematica's analysis of Medicare Part D claims linked to Medicare claims and enrollment data.

Note: We estimated impacts using logistic regression for binary outcomes (CVD medication initiation and intensification and proportion of beneficiaries adherent to CVD medication) and using linear regression for continuous outcomes (for the remaining outcomes). Analyses of high-risk beneficiaries are limited to beneficiaries with baseline CVD risk scores 30 percent or higher.

^a The number of beneficiaries varies across analyses, with some analyses assessing CVD medication use among all beneficiaries with Part D coverage and other analyses limited to those with CVD medication use or elevated risk factors at baseline. See <u>Appendix E</u> for details. The number reported in the table includes both intervention and control group beneficiaries.

CVD = cardiovascular disease; LDL = low-density lipoprotein; mg/dL = milligrams per deciliter; mmHg = millimeters of mercury; SBP = systolic blood pressure.

Alternative	High- a	nd mediun	n-risk benefi	ciaries	H	ligh-risk b	peneficiaries	
outcome measure, population, or model specification	Interventio n group mean	Control group mean	Difference	90% confidence interval	Intervention group mean	Control group mean	Difference	90% confidence interval
Statin or antihyp	ertensive med	dication inf	ensification	or initiation				
Main analysis	31.3	27.9	3.4***	[2.3, 4.4]	37.7	33.3	4.4***	[2.8, 5.9]
Trim sample to 20 or fewer providers per organization ^a	31.0	28.0	3.0***	[1.9, 4.1]	37.2	33.2	4.0***	[2.4, 5.6]
Antihypertensive	e medication i	ntensificat	ion or initiati	on				
Main analysis	29.4	27.1	2.3***	[1.3, 3.2]	32.9	30.5	2.4***	[1.1, 3.6]
Using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification ^b	35.7	32.9	2.8***	[1.5, 4.1]	37.9	34.7	3.2***	[1.6, 4.8]

Table G.5. Estimated impacts on the initiation or intensification of CVD medications: Sensitivity tests

Source: Regression-based impact estimates using Medicare claims.

Note: Sample sizes are in Table G.3.

^a This analysis population trimmed the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries enrollment.

^b This analysis limits the sample to beneficiaries with SBP of at least 140 mmHg at enrollment. The main analysis was limited to beneficiaries with SBP of 130 mmHg or higher.

*** Significantly different from zero at the 0.01 level, two-tailed test.

CI = confidence interval; CVD = cardiovascular disease; SBP = systolic blood pressure.

	Regression mea	-adjusted in	Re	usted	
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval
High- and medium-risk beneficiari	es				
Statin adherence (among beneficiaries with statin use at baseline)					
Proportion of days covered by any statins	83.3	83.3	0.0	0.97	[-0.3, 0.3]
Proportion of beneficiaries adherent to statins	75.3	75.4	-0.1	0.68	[-0.7, 0.4]
Antihypertensive adherence (beneficiaries with antihypertensive use at baseline)					
Proportion of days covered by any antihypertensives	91.2	91.3	-0.1	0.46	[-0.4, 0.1]
Proportion of beneficiaries adherent to antihypertensives	87.2	87.3	-0.2	0.51	[-0.6, 0.2]
High-risk beneficiaries					
Statin adherence (among beneficiaries with statin use at baseline)					
Proportion of days covered by any statins	83.4	83.5	-0.1	0.81	[-0.5, 0.4]
Proportion of beneficiaries adherent to statins	75.2	75.8	-0.6	0.23	[-1.4, 2.2]
Antihypertensive adherence (beneficiaries with antihypertensive use at baseline)					
Proportion of days covered by any antihypertensives	92.1	92.0	0.1	0.74	[-0.2, 0.3]
Proportion of beneficiaries adherent to antihypertensives	88.3	88.2	0.1	0.86	[-0.4, 0.6]

Table G.6. Impacts on CVD medication adherence, after trimming the intervention group to mimic the 20-provider cap in the control group: Sensitivity tests

Source: Mathematica's analysis of Medicare Part D claims linked to Medicare claims and enrollment data.

Note: We estimated impacts using logistic regressions for binary outcomes (proportion of beneficiaries adherent to statins and proportion of beneficiaries adherent to antihypertensives) and using linear regressions for continuous outcomes (all other outcomes in the table). Each beneficiary received the same weight and the regression models accounted for clustering of beneficiaries within organizations. The regressions adjusted for a range of baseline characteristics, including demographics, service use in the year before enrollment, CVD risk scores and risk factors, baseline medication use, and characteristics of the organization enrolling the beneficiary and of the region where the beneficiary lived. Sample sizes are in Table G.3.

CVD = cardiovascular disease.

Table G.7 Estimated impacts on CVD medication adherence among attributed beneficiaries: Sensitivity tests

	Regression	-adjusted				
	mea	an	Regressi	on-adjusted o	lifference	
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	
High- and medium-risk beneficiari	es					
Statin adherence (among beneficiaries with statin use at baseline)						
Proportion of days covered by any statins	83.0	82.8	0.3	0.06	[0.0, 0.5]	
Implied effect for enrolled beneficiaries ^a			0.5		[0.1, 0.9]	
Proportion of beneficiaries adherent to statins	74.8	74.6	0.2	0.48	[-0.2, 0.6]	
Implied effect for enrolled beneficiaries ^a			0.3		[-0.4, 1.1]	
Antihypertensive adherence (beneficiaries with antihypertensive use at baseline)						
Proportion of days covered by any antihypertensives	90.7	90.4	0.2	0.02	[0.1, 0.4]	
Implied effect for enrolled beneficiaries ^a			0.5		[0.1, 0.7]	
Proportion of beneficiaries adherent to antihypertensives	86.4	86.1	0.2	0.14	[-0.1, 0.5]	
Implied effect for enrolled beneficiaries ^a			0.4		[-0.1, 0.9]	
High-risk beneficiaries						
Statin adherence (among beneficiaries with statin use at baseline)						
Proportion of days covered by any statins	83.5	83.2	0.3	0.04	[0.1, 0.6]	
Implied effect for enrolled beneficiaries ^a			0.6		[0.1, 1.1]	
Proportion of beneficiaries adherent to statins	75.5	75.2	0.4	0.24	[-0.1, 0.9	
Implied effect for enrolled beneficiaries ^a			0.7		[-0.3, 1.6]	

	Regression mea	-adjusted an	Regressi	on-adjusted o	difference
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval
Antihypertensive adherence (beneficiaries with antihypertensive use at baseline)					
Proportion of days covered by any antihypertensives	91.3	91.0	0.3	0.01	[0.1, 0.4]
Implied effect for enrolled beneficiaries ^a			0.5		[0.2, 0.8]
Proportion of beneficiaries adherent to antihypertensives	87.3	87.0	0.2	0.25	[-0.1, 0.5]
Implied effect for enrolled beneficiaries ^a			0.4		[-0.2, 1.0]

Source: Mathematica's analysis of Medicare Part D claims linked to Medicare claims and enrollment data.

Note: We estimated impacts using logistic regressions for binary outcomes (proportion of beneficiaries adherent to statins and proportion of beneficiaries adherent to antihypertensives) and using linear regressions for continuous outcomes (all other outcomes in the table). Each beneficiary received the same weight and the regression models accounted for clustering of beneficiaries within organizations. The regressions adjusted for a range of baseline characteristics, including demographics, service use in the year before enrollment, CVD risk scores and risk factors, baseline medication use, and characteristics of the organization enrolling the beneficiary and of the region where the beneficiary lived. The number of beneficiaries varies across analyses, with statin analyses assessing statin use among beneficiaries with baseline statin use and antihypertensive analyses limited to those with antihypertensive use at baseline. Sample sizes are in Table G.3

^a This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.

CVD = cardiovascular disease.

	Regression	-adjusted					
	mea	an	Regression-adjusted difference				
Outcome	Intervention	Control	Difforence	n-valuo	90% confidence interval		
High- and medium-risk beneficiaries	group	group	Difference	p-value	interval		
Statin use among all beneficiaries, regardless of baseline use of medication							
Any statin use in the follow-up year	67.6	65.9	1.6	<0.001	[1.1, 2.2]		
Any high-intensity statin use in the follow-up year	21.8	20.8	1.1	0.005	[0.4, 1.7]		
Proportion of days with statin use in the follow-up year							
Proportion of days with any statin use	52.7	51.9	0.8	<0.001	[0.4, 1.1]		
Proportion of days with any high-intensity statin use	15.6	15.2	0.4	0.02	[0.1, 0.7]		
Antihypertensive use among all beneficiaries, regardless of baseline use of medication							
Any antihypertensive use in the follow-up year	84.5	84.7	-0.2	0.62	[-0.7, 0.4]		
Proportion of days with any antihypertensive use in the follow- up year	72.3	72.4	-0.1	0.55	[-0.5, 0.2]		
High-risk beneficiaries							
Statin use among all beneficiaries, regardless of baseline use of medication							
Any statin use in the follow-up year	73.2	71.1	2.1	<0.001	[1.4, 2.8]		
Any high-intensity statin use in the follow-up year	25.1	23.1	2.0	<0.001	[1.1, 2.8]		
Days covered in the follow-up year							
Proportion of days with any statin use	58.0	57.0	1.0	0.001	[0.5, 1.5]		
Proportion of days with any high-intensity statin use	18.2	17.1	1.1	<0.001	[0.6, 1.5]		

Table G.8. The model increased overall statin use among all beneficiaries with Part D coverage, regardless of baseline use of CVD medication: Exploratory analyses

	Regression mea	-adjusted an	Regressi	ssion-adjusted difference			
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval		
Antihypertensive use among all beneficiaries, regardless of baseline use of medication							
Any antihypertensive use in the follow-up year	91.7	91.3	0.4	0.15	[-0.1, 0.9]		
Proportion of days with any antihypertensive use in the follow-up year	80.3	80.3	0.0	0.89	[-0.5, 0.4]		

Source: Mathematica's analysis of Medicare Part D claims linked to Medicare claims and enrollment data.

Note: We estimated impacts using logistic regressions for binary outcomes (proportion of beneficiaries adherent to statins and proportion of beneficiaries adherent to antihypertensives) and using linear regressions for continuous outcomes (all other outcomes in the table). Each beneficiary received the same weight and the regression models accounted for clustering of beneficiaries within organizations. The regressions adjusted for a range of baseline characteristics, including demographics, service use in the year before enrollment, CVD risk scores and risk factors, baseline medication use, and characteristics of the organization enrolling the beneficiary and of the region where the beneficiary lived. Sample sizes are in Table G.3.

CVD = cardiovascular disease.

	Regression-adj between inte	usted difference ervention and cor reassessment	in CVD risk score ntrol groups at
Alternative outcome measure, population, or model specification	Difference	<i>p</i> -value	90% confidence interval
Main analysis	-1.3	0.003	[-2.0, -0.6]
Trim sample to 20 or fewer providers per organization	-1.2	0.006	[-1.8, -0.5]
Restrict to beneficiaries with reassessment data 10 to 14 months after enrollment	-1.4	0.001	[-2.1, -0.7]
Unadjusted impact estimates	-0.9	0.05	[-1.6, -0.2]

Table G.9. Estimated impacts on CVD risk scores among high-risk beneficiaries with reassessment data: Sensitivity tests and exploratory analyses

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

Note: Sample sizes are in Table G.3

CVD = cardiovascular disease.

Table G.10. Estimated ratio of the hazard of first-time heart attacks, strokes, or TIAs between intervention and control beneficiaries: Sensitivity tests and exploratory analyses

	High	High- and medium-risk beneficiaries			High-risk beneficiaries		
Alternative outcome measure, population, or model specification	Hazard ration	<i>p</i> -value	90% CI	Hazard ration	<i>p</i> -value	90% CI	
Analyses with enrolled beneficiaries							
First-time heart attacks, strokes, or TIAs (main analysis) ^a	0.97	0.20	[0.93, 1.01]	0.97	0.37	[0.92, 1.02]	
First-time heart attacks or strokes using narrower definition ^b	0.96	0.14	[0.92, 1.00]	0.98	0.49	[0.92, 1.03]	
First-time heart attacks or strokes using narrowest definition ^c	0.96	0.18	[0.92, 1.01]	0.98	0.46	[0.92, 1.03]	
Trim sample to 20 or fewer providers per organization	0.96	0.14	[0.92, 1.00]	0.96	0.31	[0.90, 1.02]	
Unadjusted impact estimates	0.92	0.04	[0.86, 0.98]	0.92	0.05	[0.86, 0.99]	
Analyses with attributed beneficiaries	;						
First-time heart attacks, strokes, or TIAsª	0.98	0.33	[0.95, 1.01]	0.98	0.39	[0.94, 1.02]	
Implied effect for enrolled beneficiaries ^d		0.97	[0.91, 1.02]		0.96	[0.90, 1.03]	
Unadjusted impact estimates	0.95	0.13	[0.89, 1.01]	0.94	0.06	[0.88, 0.99]	
Implied effect for enrolled beneficiaries ^d		0.90	[0.81, 1.01]		0.88	[0.79, 0.98]	

Source: Regression-based impact estimates using Medicare claims.

Note: Sample sizes are in Table G.3.

^a Heart attacks, strokes, TIAs, or stroke symptoms, using primary diagnoses on outpatient ED claims or primary and secondary diagnoses on inpatient claims. For heart attacks, we include all five types of acute myocardial infarctions described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

^b Heart attacks and strokes only (excludes TIAs or stroke syndromes), using primary diagnoses on outpatient ED claims or primary and secondary diagnoses on inpatient claims. For heart attacks, we include only the first type of acute myocardial infarctions described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

^c Heart attacks and strokes only (excludes TIAs or stroke syndromes) listed as primary diagnosis on ED or inpatient claim. For heart attacks, we include only the first type of acute myocardial infarctions described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

^d This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. We obtained this estimate by dividing the regression model coefficient corresponding to the impact estimate by the percentage of beneficiaries who were enrolled, then expressing this scaled regression coefficient as a hazard ratio.

CI = confidence interval; ED = emergency department; TIA = transient ischemic attack.

Table G.11. Estimated impacts on the number of inpatient admissions (number per 1,000 beneficiaries per quarter): Sensitivity tests and exploratory analyses

	High-	and medium-ri	sk beneficia	ries		High-risk beneficiaries			
Alternative outcome measure, population, or model specification	Intervention group mean	Control group mean	Difference	90% confidence interval	Intervention group mean	Control group mean	Difference	90% confidence interval	
Number of CVD-related inpatient admissions									
Main analysis	13.8	13.6	0.20	[-0.3, 0.7]	18.7	17.9	0.78*	[-0.0, 1.6]	
Trim sample to 20 or fewer providers per organization	14.1	13.9	0.18	[-0.3, 0.7]	18.8	18.1	0.74*	[-0.1, 1.6]	
Unadjusted impact estimates	13.8	14.0	-0.27	[-1.9, 1.3]	18.7	18.4	0.26	[-1.5, 2.0]	
Main regression model specification, using the population of attributed beneficiaries	16.0	15.6	0.35*	[-0.1, 0.8]	20.2	19.6	0.64***	[0.1, 1.2]	
Implied effect for enrolled beneficiaries ^a			0.62*	[-0.1, 1.4]			1.13***	[0.2, 2.1]	
Unadjusted impact estimates, using the population of attributed beneficiaries	16.0	16.1	-0.10	[-1.8, 1.6]	20.2	20.3	-0.13	[-2.0, 1.7]	
Implied effect for enrolled beneficiaries ^a			-0.17	[-3.2, 2.8]			-0.24	[-3.6, 3.1]	
Number of all-cause inpatient admissions									
Main analysis	63.5	61.2	2.32***	[0.9, 3.7]	76.4	73.0	3.38***	[1.0, 5.8]	
Trim sample to 20 or fewer providers per organization	63.9	61.5	2.37***	[0.9, 3.8]	76.4	72.9	3.49***	[1.0, 5.9]	
Unadjusted impact estimates (registry population)	63.5	62.4	1.06	[-3.0, 5.1]	76.4	74.4	2.00	[-2.5, 6.5]	
Main regression model specification, using the population of attributed beneficiaries	71.6	69.8	1.87***	[0.6, 3.2]	83.2	81.4	1.88**	[0.1, 3.6]	
Implied effect for enrolled beneficiaries ^a			3.34***	[1.1, 5.6]			3.35**	[0.2, 6.5]	
Unadjusted impact estimates, using the population of attributed beneficiaries	71.6	70.7	0.89	[-3.3, 5.1]	83.2	82.9	0.31	[-4.3, 4.9]	
Implied effect for enrolled beneficiaries ^a			1.59	[-5.8, 9.0]			0.55	[-7.6, 8.7]	

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 beneficiaries observed in that quarter. Sample sizes are in Table G.3.

^a This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. We obtained this estimate dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.

*/**/*** Significantly different from zero at the 0.1/0.05/0.01 levels, two-tailed test.

CVD = cardiovascular disease.

Table G.12. Estimated impacts on the number of outpatient ED visits and observation stays (number per 1,000 beneficiaries per quarter): Sensitivity tests and exploratory analyses

	High- and medium-risk beneficiaries			High-risk beneficiaries				
Alternative outcome measure, population, or model specification	Intervention group mean	Control group mean	Difference	90% confidence interval	Intervention group mean	Control group mean	Difference	90% confidence interval
Number of CVD-related outpatient ED visi	ts and observat	ion stays						
Main analysis	8.0	7.8	0.11	[-0.4, 0.6]	9.7	9.2	0.49	[-0.2, 1.1]
Trim sample to 20 or fewer providers per organization	8.5	8.3	0.15	[-0.4, 0.7]	10.2	9.7	0.47	[-0.2, 1.2]
Unadjusted impact estimates	8.0	8.2	-0.24	[-1.3, 0.8]	9.7	9.7	0.00	[-1.2, 1.2]
Main regression model specification, using the population of attributed beneficiaries	9.2	8.7	0.47*	[-0.1, 1.0]	10.5	9.8	0.64*	[-0.0, 1.3]
Implied effect for enrolled beneficiaries ^a			0.84*	[-0.1, 1.8]			1.14*	[-0.0, 2.3]
Unadjusted impact estimates, using the population of attributed beneficiaries	9.2	9.3	-0.13	[-1.3, 1.0]	10.5	10.6	-0.11	[-1.4, 1.2]
Implied effect for enrolled beneficiaries ^a			-0.22	[-2.3, 1.8]			-0.19	[-2.5, 2.1]
Number of all-cause outpatient ED visits a	and observation	stays						
Main analysis	97.7	94.9	2.80**	[0.2, 5.4]	106.6	102.3	4.27***	[1.2, 7.4]
Trim sample to 20 or fewer providers per organization	99.1	96.9	2.20*	[-0.5, 4.9]	108.0	103.7	4.31***	[0.9, 7.7]
Unadjusted impact estimates	97.7	95.6	2.09	[-5.1, 9.3]	106.6	103.2	3.40	[-4.6, 11.4]
Main regression model specification, using the population of attributed beneficiaries	107.7	105.0	2.74**	[0.1, 5.4]	115.1	112.7	2.38*	[-0.5, 5.3]
Implied effect for enrolled beneficiaries ^a			4.88**	[0.2, 9.5]			4.24*	[-1.0, 9.4]
Unadjusted impact estimates, using the population of attributed beneficiaries	107.7	108.8	-1.07	[-8.5, 6.4]	115.1	116.6	-1.52	[-9.4, 6.3]
Implied effect for enrolled beneficiaries ^a			-1.90	[-15.1, 11.3]			-2.70	[-16.7, 11.2]

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 beneficiaries observed in that quarter. Sample sizes are in Table G.3.

^a This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. We obtained this estimate by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.

*/**/*** Significantly different from zero at the 0.1/0.05/0.01 levels, two-tailed test.

CVD = cardiovascular disease; ED = emergency department.

	High- and medium-risk beneficiaries			High-risk beneficiaries				
Alternative outcome measure, population, or model specification	Intervention group mean	Control group mean	Difference	90% CI	Intervention group mean	Control group mean	Difference	90% CI
Analyses with enrolled beneficiaries								
Main analysis: Parts A and B spending	\$ 921	\$ 918	\$ 3	[-17, 22]	\$ 1,057	\$ 1,040	\$ 17	[-12, 46]
Parts A and B spending plus average model payments ^a	\$922	\$918	\$4	[-15, 24]	n.a.	n.a.	n.a.	n.a.
Trim sample to 20 or fewer providers per organization	\$ 934	\$ 929	\$ 5	[-14, 25]	\$ 1,063	\$ 1,044	\$ 20	[-9, 48]
Unadjusted impact estimates	\$ 921	\$ 914	\$ 7	[-42, 56]	\$ 1,057	\$ 1,036	\$ 21	[-32, 74]
Analyses with attributed beneficiaries								
Parts A and B spending	\$ 1,026	\$ 1,020	\$ 6	[-13, 26]	\$ 1,139	\$ 1,135	\$4	[-20, 28]
Implied effect for enrolled beneficiaries ^b			\$ 11	[-24, 46]			\$ 7	[-36, 50]
Unadjusted impact estimates	\$ 1,026	\$ 997	\$ 30	[-22, 81]	\$ 1,139	\$ 1,117	\$ 22	[-34, 79]
Implied effect for enrolled beneficiaries ^b			\$ 53	[-38, 144]			\$ 40	[-60, 140]

Table G.13. Estimated impacts on Medicare spending (dollars per beneficiary per month): Sensitivity tests and exploratory analyses

Source: Regression-based impact estimates using Medicare claims.

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 beneficiaries observed in that quarter. Sample sizes are in Table G.3. None of the estimates are significantly different from zero at the 0.1 level.

^a Total Million Hearts Model payments paid to intervention group organizations included in the impact evaluation for the first five performance periods were \$7,097,000. 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 calculated for each analysis, so the average model cost per beneficiary per quarter varies across analyses. (For analyses with the population of attributed beneficiaries, we accounted for the weights assigned to each beneficiary-quarter in these calculations.)

^b This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.

CI = confidence interval; n.a.= not applicable.

	High-and medium-risk beneficiaries			High-risk beneficiaries			
Alternative outcome measure, population, or model specification	Hazard ratio	<i>p</i> -value	90% confidence interval	Hazard ratio	<i>p</i> -value	90% confidence interval	
Analyses with enrolled b	eneficiaries						
Main analysis	0.95	0.02	[0.92, 0.99]	1.01	0.65	[0.97, 1.06]	
Trim sample to 20 or fewer providers per organization	0.96	0.06	[0.92, 0.99]	1.02	0.62	[0.97, 1.07]	
Unadjusted impact estimates	0.94	0.11	[0.88, 1.00]	0.98	p = 0.62	[0.92, 1.05]	
Analyses with attributed	beneficiaries						
Main regression model specification	0.98	0.33	[0.96, 1.01]	0.98	0.22	[0.95, 1.01]	
Implied effect for enrolled beneficiariesª		0.97	[0.92, 1.02]		0.96	[0.90, 1.01]	
Unadjusted impact estimates	0.97	0.41	[0.91, 1.03]	0.96	0.24	[0.91, 1.02]	
Implied effect for enrolled beneficiariesª		0.94	[0.84, 1.06]		0.93	[0.84, 1.03]	

Table G.14. Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries: Sensitivity tests and exploratory analyses

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

Note: Sample sizes are in Table G.3.

^a This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. We obtained this estimate by dividing the regression model coefficient corresponding to the impact estimate by the percentage of beneficiaries who were enrolled, then expressing this scaled regression coefficient as a hazard ratio.

·	High	n- and medium	-risk benefici	aries	-	High-risk be	eneficiaries	
Outcome ^a	Intervention group mean	Control group mean	Difference	90% confidence interval	Intervention group mean	Control group mean	Difference	90% confidence interval
Analyses with enrolled beneficiaries								
Percentage with first-time heart attac	ks, strokes, or Tl	As						
Within 12 months of enrollment	1.3	1.3	0.0	[-0.1, 0.1]	1.8	1.7	0.1	[-0.1, 0.3]
Within 24 months of enrollment	2.7	2.7	-0.0	[-0.1, 0.1]	3.6	3.7	-0.0	[-0.3, 0.2]
Within 36 months of enrollment	4.0	4.0	-0.1	[-0.2, 0.1]	5.2	5.4	-0.2	[-0.5, 0.1]
Percentage who died								
Within 12 months of enrollment	1.7	1.8	-0.2***	[-0.3, -0.0]	2.1	2.2	-0.1	[-0.3, 0.1]
Within 24 months of enrollment	3.9	4.2	-0.2***	[-0.4, -0.1]	5.2	5.2	-0.0	[-0.3, 0.3]
Within 36 months of enrollment	6.6	6.9	-0.3**	[-0.5, -0.0]	8.8	8.7	0.1	[-0.4, 0.5]
Analyses with enrolled beneficiaries	and sample trimn	ned to 20 or fe	wer providers	per organizat	tion			
Percentage with first-time heart attac	ks, strokes, or Tl	As						
Within 12 months of enrollment	1.4	1.3	0.0	[-0.1, 0.1]	1.8	1.8	0.0	[-0.1, 0.2]
Within 24 months of enrollment	2.7	2.7	-0.0	[-0.2, 0.1]	3.7	3.7	-0.0	[-0.3, 0.3]
Within 36 months of enrollment	4.1	4.1	-0.1	[-0.3, 0.1]	5.2	5.5	-0.2	[-0.6, 0.1]
Percentage who died								
Within 12 months of enrollment	1.7	1.9	-0.2***	[-0.3, -0.1]	2.1	2.2	-0.2*	[-0.4, 0.0]
Within 24 months of enrollment	4.0	4.2	-0.2***	[-0.4, -0.1]	5.2	5.3	-0.1	[-0.4, 0.3]
Within 36 months of enrollment	6.8	7.0	-0.2	[-0.4, 0.1]	9.1	8.9	0.2	[-0.3, 0.6]

Table G.15. Estimated impacts on binary measures of CVD events and mortality (regression-adjusted)

	High	- and medium	-risk benefici	aries		High-risk be	eneficiaries	
Outcome ^a	Intervention group mean	Control group mean	Difference	90% confidence interval	Intervention group mean	Control group mean	Difference	90% confidence interval
Analyses with attributed beneficiaries	;							
Percentage with first-time heart attack	ks, strokes, or Tl	٩						
Within 12 months of enrollment	1.6	1.7	-0.0	[-0.1, 0.0]	2.0	2.1	-0.1	[-0.2, 0.0]
Implied effect for enrolled beneficiaries ^b			-0.0	[-0.2, 0.1]			-0.1	[-0.3, 0.1]
Within 24 months of enrollment	3.1	3.1	-0.0	[-0.1, 0.1]	3.8	3.8	0.0	[-0.1, 0.2]
Implied effect for enrolled beneficiaries ^b			-0.0	[-0.2, 0.2]			0.0	[-0.3, 0.3]
Within 36 months of enrollment	4.4	4.5	-0.0	[-0.2, 0.1]	5.5	5.6	-0.1	[-0.3, 0.1]
Implied effect for enrolled beneficiaries ^b			-0.1	[-0.3, 0.2]			-0.2	[-0.6, 0.2]
Percentage who died								
Within 12 months of enrollment	2.3	2.4	0.0	[-0.1, 0.0]	2.9	3.0	-0.1	[-0.2, 0.0]
Implied effect for enrolled beneficiaries ^b			-0.1	[-0.3, 0.1]			-0.2	[-0.4, 0.1]
Within 24 months of enrollment	5.0	5.1	-0.1	[-0.2, 0.1]	6.4	6.6	-0.2*	[-0.4, 0.0]
Implied effect for enrolled beneficiaries ^b			-0.1	[-0.3, 0.1]			-0.4*	[-0.8, 0.1]
Within 36 months of enrollment	8.0	8.2	-0.2*	[-0.4, 0.0]	10.2	10.5	-0.3*	[-0.6, 0.0]
Implied effect for enrolled beneficiaries ^b			-0.3*	[-0.7, 0.0]			-0.5*	[-1.1, 0.0]

Source: Regression-based impact estimates using Medicare claims.

Note: Regression adjustment was performed using logistic regression models. Sample sizes are in Table G.3.

^a Analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled in December 2020. ^b This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. We obtained this estimate by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled. */**/*** Significantly different from zero at the 0.1/0.05/0.01 levels, two-tailed test.

CVD = cardiovascular disease; TIA = transient ischemic attack.

			Regressior	i-adjusted impa	act estimate	Number of (organizatior) the ar	beneficiaries is) included in nalysis
Alternative analysis	Intervention group mean	Control group mean (adjusted)	Estimate	<i>p</i> -value	90% confidence interval	Intervention group	Control group
Regression-adjusted ratio of hazard of dying (for any reason) between intervention and control beneficiaries	n.a.	n.a.	0.91	<0.001	[0.87, 0.95]	90,180 (169)	61,024 (167)
Regression-adjusted difference in the percentage of beneficiaries who died within one year of enrollment	1.5	1.6	-0.2	0.02	[-0.3, -0.1]	90,180 (169)	61,024 (167)
Regression-adjusted difference in the percentage of beneficiaries who died within two years of enrollment	3.4	3.7	-0.3	0.002	[-0.5, -0.1]	90,180 (169)	61,024 (167)
Regression-adjusted difference in the percentage of beneficiaries who died within three years of enrollment	5.6	6.1	-0.5	0.002	[-0.7, -0.2]	74,563 ª (168)	50,242 ª (160)

Table G.16. Estimated impacts on all-cause mortality for medium-risk beneficiaries

Source: Regression-adjusted results from Medicare enrollment data.

Note: These analyses include beneficiaries with baseline cardiovascular disease risk scores of at least 15 percent but less than 30 percent.

^a Percentages calculated among beneficiaries who enrolled by December 31, 2017, so we could follow them for at least three years (or until death) before the end of the claims and enrollment data period on December 31, 2020.

Appendix H

Practice Survey

Welcome to the CMS Million Hearts® CVD Model

Practice Survey!



CMS Million Hearts® CVD Model Practice Survey, January 2021

If you have any questions about the survey, we are here to help.

Please call 877-812-2551 (toll free) or email the study team at MillionHearts@mathematica-mpr.com.

Thank you for participating in the Centers for Medicare & Medicaid Services (CMS) Million Hearts[®] Cardiovascular Disease (CVD) Risk Reduction Model. CMS has hired Mathematica to evaluate the model. The evaluation will inform understanding of participating organizations' experiences with the model and assess the effects of the Million Hearts Model on health care quality, service use, and costs. As part of this effort, Mathematica is conducting a survey of organizations participating in the Million Hearts Model.

The questions concern cardiovascular care and your organization's involvement in the model. Completing the practice survey should take 10 to 15 minutes and you may skip any question you do not wish to answer. By sharing your experiences and lessons learned from working with the model, you will provide us valuable information for assessing the model's impacts and identifying opportunities for improvement.

Participation in the survey is voluntary but your input is very important. We will keep your responses confidential and use them only for research purposes. We will also combine your responses and report them with all other responses in aggregate; we will not report individual names or responses.

Thank you for taking the time to complete this survey!

Section A. Cardiovascular Disease (CVD) Care in Your Practice

This set of questions refer to 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 to calculate a risk score include—but are not limited to—an online application, an application on a smartphone, or a calculator in the electronic health record (EHR).

A1. What is **your** primary role in the Centers for Medicare & Medicaid Services (CMS) Million Hearts[®] Model implementation at your practice?

Select one only

- O Oversee the model but not responsible for day-to-day operations 1
- O Project manager / responsible for day-to-day operations2
- O Health information technology/ entering data into model4
- **A2.** About what proportion of Medicare beneficiaries has your practice calculated a CVD risk score for, using any risk calculator?

Select one only

О	0%we do not calculate CVD risk scores1	GO TO A7
0	1–24%2	GO TO A3
0	25–49%3	GO TO A3
0	50–74%	GO TO A3
0	75–100%5	GO TO A3
0	Don't knowD	GO TO A7

A3. Once a risk score has been calculated, how often are CVD risk scores available when providers meet with Medicare beneficiaries in your practice?

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

Select one only

0	Always or almost always available when meeting with a Medicare beneficiary1
0	Sometimes available when meeting with a Medicare beneficiary2
0	Never available when meeting with a Medicare beneficiary $\ldots 3$
0	Don't knowD

A4. How are Medicare beneficiaries at your practice notified of their CVD risk scores, if at all?

In this survey, **providers** include MDs, DOs, PAs, and NPs; **other clinical staff** includes LPNs, RNs, MAs, care managers and social workers.

Select all that apply

	In person at office visit, by provider	. A4_	_1
	In person at office visit, by other clinical staff	. A4_	_2
	Video telehealth visit, by provider	. A4_	_3
	Video telehealth visit, by other clinical staff	. A4_	_4
	Telephone call from provider	. A4_	_5
	Telephone call from other clinical staff	. A4_	_6
	Written communication (for example, letter, email, patient portal)	A4_	_7
О	We do not notify Medicare beneficiaries of their risk scores	. A4_	_8
О	Don't know	. A4_	_D
	NO RESPONSE	A4	М

A5. Once you have identified Medicare beneficiaries as having high CVD risk, how often does your practice follow up with them through any mode (for example, office visits, telehealth visits, telephone calls, SMS/text messages, emails, or letters) to monitor plans to reduce risk?

Select one only

nthly or more often than monthly	1
ery 3 months	2
ery 6 months	3
nually	4
needed	5
ı't knowI	C
	nthly or more often than monthly ery 3 months

A6. For Medicare beneficiaries identified as high risk for CVD, what percentage do you recalculate risk for about annually (or more frequently)? Your best estimate is fine.

Select one only

0	1–24%	2
0	25–49%	3
0	50–74%	4
0	75–100%	5
0	Don't know	D

A7. Does your practice use any of the following resources to ensure that Medicare beneficiaries with high CVD risk are not lost to follow-up?

Select all that apply

	Care managers	A7_1
	Registries or tracking tools	A7_2
	Automated scheduling of follow-up visits with a minimum frequency	A7_3
0	None of the above	A7_4

A8.	Does your practice's electronic health record	(EHR) have any	of the following	functionalities?
			Select one	per row

		Yes	No	Don't know	MISSING
a.	Integrated CVD risk calculator	1 O	0 0	DO	М
b.	CVD risk score displayed on patient's record	1 Q	0 0	DQ	М
C.	CVD risk score component factors displayed on patient's record	1 Q	O 0	DO	М
d.	Automatic reminders to document the CVD risk score	1 Q	\mathbf{O} 0	DO	М
e.	Tools (such as pre-built phrases, templates, or drop-down menus) to help document the CVD risk score	1 O	O 0	DQ	М
f.	Auto-population of data elements relevant to cardiovascular risk from other parts of a patient's record (such as blood pressure values)	1 Q	O 0	DQ	М
g.	The ability to estimate how initiating different evidence-based therapies would change CVD risk score	1 O	0 0	DQ	М

Section B. Involvement in the Million Hearts Model

The next set of questions asks about factors that are facilitators of and barriers to implementing the Million Hearts Model at your practice.

B1. To what extent have the following factors been **helpful** in implementing the Million Hearts Model at your practice:

		Select one per row						
		Very helpful	Somewhat helpful	Not a factor helping implementation	Don't know	MISSING		
a.	Staff time to implement the model	1 0	2 🔾	O O	DO	М		
b.	Staff buy-in	1 0	2 🔾	0 0	DO	М		
C.	Patients' engagement with CVD risk reduction activities	1 0	2 🔾	O 0	DO	М		
d.	Organizational leadership support	1 🔾	2 O	O O	DO	М		
e.	A practice champion for the Million Hearts Model (a practice champion is someone who understands the importance of the model and encourages colleagues to implement the model)	1 Q	2 🔾	C 0	DO	М		
f.	Participation in other quality improvement initiatives	1 O	2 O	O O	DO	М		
g.	IT support (for example, electronic health record (EHR) functionality)	1 O	2 🔾	O 0	DO	М		
h.	CMS help desk support	1 🔾	2 O	O O	DO	М		
i.	Accountable care organization (ACO)-provided materials, analytics, or other support	1 O	2 🔾	O 0	DO	М		
j.	Payment from CMS for telehealth care	1 🔾	2 O	O O	DO	М		
k.	Payments/financial incentives from other CMS initiatives, such as the Comprehensive Primary Care Plus (CPC+) model or the Merit-based Incentive Payment System (MIPS)	1 Q	2 🔾	C 0	DO	М		
Ι.	Other factor(s) that helped implementation of the Million Hearts Model – not listed above (Specify)	10	2 🔾					

B2. To what extent have each of the following been a **barrier** to implementing the Million Hearts Model at your practice:

		Select one per row						
		Considerable barrier	Somewhat of a barrier	Not a barrier	Don't know	MISSING		
a.	Insufficient staff time for amount of work	1 O	2 Q	0 0	DQ	М		
b.	Staff turnover	1 O	2 Q	0 0	$\mathbf{O} \; \mathbf{O}$	М		
C.	Resistance or lack of support from staff	1 O	2 Q	0 0	$\mathbf{O} \; \mathbf{O}$	М		
d.	Lack of patient engagement with CVD risk reduction activities	1 Q	2 Q	0 0	DO	М		
e.	Lack of support from practice leadership	1 O	2 Q	0 0	DO	М		
f.	Lack of IT support, for example, EHR functionality	1 Q	2 Q	0 0	DO	М		

		Considerable barrier	Somewhat of a barrier	Not a barrier	Don't know	MISSING
g.	Lack of support from the CMS help desk	1 O	2 Q	O 0	DO	М
h.	Organizational changes	1 O	2 Q	0 0	$\mathbf{O} \; \mathbf{O}$	М
i.	Competing organizational or practice priorities	1 O	2 Q	0 0	DO	М
j.	Challenges scheduling in-person office visits	1 O	2 Q	0 0	$\mathbf{O} \; \mathbf{O}$	М
k.	Other barrier(s) – not listed above (Specify)	1 O	2 Q			

B3. How much do you agree or disagree with the following statements regarding your impression of the Million Hearts Model:

		Select one per row					
		Strongly agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree	MISSING
a.	Participating in the Million Hearts Model helped our organization improve our patients' CVD risk scores .	1 O	2 Q	з О	4 Q	5 O	М
b.	Participating in the Million Hearts Model helped our organization improve quality of care for CVD prevention.	1 Q	2 Q	з О	4 Q	5 O	М
C.	The financial incentives were an important factor for our organization in continuing to participate in the Million Hearts Model.	1 Q	2 Q	з О	4 Q	5 O	М
d.	The learning activities offered by the Million Hearts Model were valuable to our organization's efforts to improve CVD prevention.	1 Q	2 Q	з О	4 Q	5 O	М
e.	If offered, our organization would participate in the Million Hearts Model in the future.	1 Q	2 Q	3 О	4 O	5 Q	М

The next set of questions relate to the impact of the coronavirus disease 2019 (COVID-19) public health emergency on implementing the Million Hearts Model.

		Not at all	Some	A lot	MISSING
a.	Our practice increased the use of telehealth visits	1 Q	2 🔾	3 О	М
b.	Increased use of telehealth visits enabled us to continue implementing Million Hearts Model risk assessment activities during the COVID-19 pandemic	1 Q	2 🔾	Οε	Μ
C.	Our practice increased the use of home blood pressure monitoring	1 Q	2 🔾	3 О	М
d.	Increased use of home blood pressure monitoring enabled us to continue implementing Million Hearts Model risk assessment activities during the COVID-19 pandemic	1 O	2 O	3 O £	М

B4. To what extent did your practice make the following change due to COVID-19: Select one per row

B5. Has implementing the Million Hearts Model at your organization changed as a priority due to COVID-19?

Select one only

\mathbf{O}	Implementing became a higher priority for our organization 1
•	implementing became a higher phonty for our organization T
О	Implementing became a lower priority for our organization2
0	No change in priority for our organization3
0	Don't know d

B6. Has COVID-19 had another effect on your organization's ability to implement the Million Hearts Model?

.....

Section C. Sustainability

The final set of questions are about continuing with Million Hearts Model CVD risk assessment activities after the model ends.

C1. Did your practice make changes to care delivery related to CVD risk assessment and management through participation in the Million Hearts Model?

0	Yes	.1 GO TO C2
0	No	.0 GO TO CLOSING SCREEN
0	Don't know	. D GO TO CLOSING SCREEN
_		

C2. Does your practice plan to sustain changes to care delivery related to CVD risk assessment and management after participation in the Million Hearts Model ends?

0	Yes1	GO TO C3
0	No0	GO TO C2a
0	Don't knowD	GO TO C2a

C2a. Please tell us why your organization may not sustain changes made during the Million Hearts Model

SCREEN

NO RESPONSE M GO TO CLOSING

C3. How likely or unlikely is your organization to continue with the following changes related to Million Hearts Model risk assessment activities after the model ends: Select one per row

		Very	Somewhat	Somewhat	Very	Don't	Not applicable – we did not make this type of change during the	
		likely	likely	unlikely	unlikely	know	model	MISSING
a.	The changes we made to how systematically we identify patients who are at high-risk for CVD.	1 Q	2 Q	3 Q	4 Q	DQ	N/A 🔾	М
b.	The changes we made related to the role of care managers in CVD risk assessment and reassessment.	1 Q	2 Q	з О	4 Q	DO	N/A O	М
C.	The changes we made related to use of an embedded electronic health record (EHR) tool to assess CVD risk.	1 Q	2 🔾	з О	4 O	DO	N/A O	М

C3_d. Please describe the types of changes that your practice plans to continue after the Million Hearts Model ends.



C4. Thinking about the changes made during the Million Hearts Model, how helpful or unhelpful do you think each of the following factors will be in sustaining those changes after the model ends: Select one per row

		-		-		
		Very helpful	Somewhat helpful	Unhelpful	Don't Know	MISSING
a.	Staff buy-in and engagement in activities	1 Q	2 Q	з О	DO	М
b.	A practice champion focused on CVD risk management					
(a	practice champion is someone who understands the importance of the model and encourages colleagues to implement the model.)	1 O	2 🔾	3 Q	D Q	Μ
c.	Patient receptivity to CVD risk evaluation	1 Q	2 O	з О	DO	М
d. qu	Participation in other ality improvement initiatives	1 O	2 Q	з О	DO	М
e.	IT support (e.g., EHR functionality)	1 Q	2 O	з О	DO	М
f.	ACO provided materials or analytics	1 O	2 O	3 О	DO	М
g.	Payments or incentives from ACO, other CMS initiatives, or other programs	1 Q	2 Q	з О	DQ	Μ
h.	Care managers or other staff supported by ACO, other CMS initiatives, or other programs	1 Q	2 Q	3 O	DQ	Μ
i.	Other helpful factor(s) not listed above (Specify)	1 Q	2 🔾			М
C5. To what extent do you think each of the following is a **barrier** to sustaining CVD risk assessment activities after the Million Hearts Model ends:

		Select one per row				
		Considerable barrier	Somewhat of a barrier	Not a barrier	Don't know	MISSING
a.	Insufficient staff time for amount of work	1 Q	2 O	3 О	DO	М
b.	Staff turnover	1 O	2 Q	3 О	\mathbf{O} D	М
C.	Resistance or lack of support from staff	1 Q	2 Q	3 О	\mathbf{O} D	М
d.	Lack of patient engagement	1 Q	2 Q	3 О	\mathbf{O} d	М
e.	Lack of support from practice leadership	1 Q	2 Q	3 О	\mathbf{O} D	М
f.	Lack of IT support, e.g., EHR functionality	1 O	2 Q	3 О	\mathbf{O} D	М
g.	Organizational changes	1 O	2 O	з О	\mathbf{O} D	М
h.	Competing organizational priorities	1 O	2 O	3 О	DQ	М
i.	Challenges scheduling in-person office visits	1 O	2 O	з О	\mathbf{O} D	М
j	Lack of funding	1 O	2 Q	3 О	DO	М
k.	Other barrier(s) – not listed above (Specify)	1 Q	2 Q			Μ

Thank you very much for completing the Million Hearts Model Evaluation Survey!



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