



Evaluation of the Million Hearts[®] Cardiovascular Disease Risk Reduction Model

Final Evaluation Report

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List of Acronyms

ABCS	aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation
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
CCW	Chronic Conditions Data Warehouse
CDC	Centers for Disease Control and Prevention
CHD	coronary heart disease
CI	confidence interval
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus disease 2019
CPC	Comprehensive Primary Care
CPC+	Comprehensive Primary Care Plus
СРТ	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
HCPCS	Healthcare Common Procedure Coding System

HDL	high-density lipoprotein
HHS	U.S. Department of Health and Human Services
ICD-10	International Classification of Diseases, 10th edition
IT	information technology
LDL	low-density lipoprotein
MA	medical assistant
MBSF	Medicare Beneficiary Summary File
mg/dL	milligrams per deciliter
mmHg	millimeters of mercury
NP	nurse practitioner
n.a.	not applicable
n.d.	no date
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
NSTEMI	non-ST elevation
PA	physician assistant
PBPM	per beneficiary per month
PP	performance period
RHC	rural health center
SBP	systolic blood pressure
STEMI	ST elevation
SVI	Social Vulnerability Index
ТСРІ	Transforming Clinical Practice Initiative
TIA	transient ischemic attack
TIN	Tax Identification Number

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Executive Summary

In 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts[®] Cardiovascular Disease (CVD) Risk Reduction Model. Under this model, CMS paid participating health care organizations to measure and reduce CVD risk, and organizations committed to following guideline-recommended care processes for the primary prevention of CVD. The model's goal was to reduce the incidence of heart attacks and strokes, including transient ischemic attacks (mini strokes), among Medicare beneficiaries ages 40 to 79 who had not previously had one. CMS hoped reduced spending on heart attacks and strokes would offset the model payments, making the Million Hearts Model cost-neutral to Medicare. CMS tested the model from 2017 to 2021 in a large, randomized trial, including hundreds of thousands of beneficiaries across the United States.

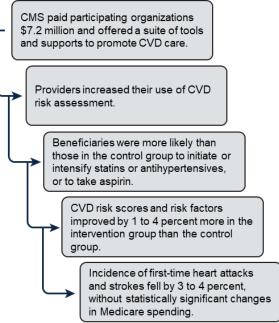
Over five years, the Million Hearts Model reduced the incidence of first-time heart attacks and strokes by 3 to 4 percent among beneficiaries at high or medium risk of these events but did not measurably affect Medicare spending. The reduction in heart attacks and strokes corresponds (depending on the outcome definition used) to roughly one prevented event over five years for every 250 to 400 high- and medium-risk beneficiaries enrolled. The evaluation did not detect savings in Medicare spending for the events. However, model payments were small, at an estimated \$1 per month of enrollment per high- and medium-risk beneficiary in the evaluation population. As a result, total Medicare spending, including Parts A and B and model payments, was similar between intervention and control group beneficiaries.

These findings for the study's primary outcome measures reflect the accumulation of changes along a hypothesized causal pathway (Figure ES.1). The reduction in first-time heart attacks and strokes was accompanied by a 4 percent reduction in all-cause mortality over five years among high- and medium-risk beneficiaries. Consistent with the model logic, the largest relative declines, by cause, were among deaths due to coronary heart disease (CHD) and cerebrovascular disease.

A. Model design

Under the Million Hearts Model, organizations randomly assigned to participate in the intervention group agreed to assess each of their eligible Medicare fee-forservice (FFS) beneficiaries' risk of a heart attack or stroke over 10 years. They further agreed to provide cardiovascular care

Figure ES.1. The model improved outcomes along a hypothesized causal pathway



management services to high-risk Medicare beneficiaries: that is, those with a calculated 10-year risk, or *risk score* (text box), of 30 percent or higher.¹ Medicare FFS beneficiaries were eligible for the Million Hearts Model if they were ages 40 to 79, had not previously had a heart attack or stroke, did not have end-stage renal disease, and were not enrolled in hospice. The model's recommended cardiovascular care management activities aligned with clinical guidelines about the primary prevention of CVD from the American College of Cardiology and the American Heart Association (Arnett et al. 2019). These activities included working with high-risk beneficiaries to develop care plans to reduce CVD risk, following up at least twice per year to monitor and encourage risk reduction, and a formal risk reassessment each year.

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). That tool incorporates additional information about aspirin use, time since quitting smoking, and changes since the initial assessment in blood pressure and cholesterol.

CMS offered the model participants a number of payments and supports to implement the model:

- **Payments.** Throughout the five-year model, CMS paid intervention group organizations to calculate CVD risk scores for eligible beneficiaries. In addition, during the first year of the model (2017), CMS paid a flat monthly fee (per high-risk beneficiary enrolled) for providing cardiovascular care management. Then, from 2018 to 2021, CMS paid the organizations for reducing risk among high-risk beneficiaries, with payment amounts depending on the average risk reduction achieved among the organization's enrolled high-risk population.
- Nonfinancial tools and supports. CMS created the online Million Hearts Data Registry for organizations to submit clinical data needed to assess CVD risk. The registry software included a novel risk calculator to track patients' changes in CVD risk over time, based on changes in risk factors. This calculator was the basis for the model's performance-based risk-

¹ The Million Hearts Model categories of high, medium, and low CVD risk (defined, respectively, as having CVD risk scores of \geq 30 percent, 15 to < 30 percent, and < 15 percent) do not correspond to recent categories used elsewhere for high (\geq 20 percent), intermediate (7.5 to < 20 percent), borderline (5 to < 7.5 percent) or low CVD risk (< 5 percent) (Lloyd-Jones et al. 2019).

reduction payments. CMS also hosted regular peer-to-peer learning sessions for the intervention organizations and sent each organization semiannual reports describing its progress enrolling beneficiaries and reducing CVD risk.

In addition to affecting outcomes among high-risk beneficiaries, CMS anticipated the model could improve outcomes for medium-risk beneficiaries: those with risk scores of at least 15 percent and less than 30 percent. CMS expected the model might reduce rates of heart attacks and strokes among both groups together—high- and medium-risk beneficiaries—to fully offset model payments.

Over the model's five years (2017–2021), CMS paid intervention organizations \$7.2 million equivalent to roughly \$1 per beneficiary per month (PBPM) on average—for the beneficiaries enrolled in 2017 and 2018 (the focus of this report). CMS also paid organizations randomly assigned to the control group for submitting clinical data needed to calculate CVD risk scores but did not provide the control organizations with calculated risk scores. CMS contracted with Mathematica and its partner, the RAND Corporation, to evaluate the Million Hearts Model.

B. Participation

CMS randomly assigned 516 organizations that volunteered for the model, with about half assigned to the intervention group and the remainder assigned to a usual-care control group. Of these, 345 organizations (173 in the intervention group and 172 in the control group) participated by enrolling at least one beneficiary in the model in 2017 or 2018. (This evaluation focuses on beneficiaries enrolled in 2017 and 2018 so that everyone in the evaluation population enrolled early enough to experience potential benefits of the model.) Participating organizations included primary care and cardiology practices, health centers, and hospitals throughout the country. Organization leaders said they joined, in part, because the model was consistent with their CVD prevention goals and because the organizations already assessed CVD risk for some of their patients—making it easier to implement the model.

However, many participating organizations withdrew over time, citing low payments and challenges reporting data to the Million Hearts Data Registry. By the end of the model, in December 2021, 45 of the 173 participating intervention organizations (26 percent) had formally withdrawn, and an additional 82 organizations (47 percent) had stopped reporting clinical data to the registry as required to receive model payments. Nevertheless, because the evaluation outcome measures are mostly from administrative data—Medicare claims and the National Death Index—we could and did track beneficiaries' outcomes, regardless of whether the enrolling organizations left the model.

Overall, the intervention organizations enrolled 130,578 high- and medium-risk beneficiaries in 2017 and 2018 and the control organizations enrolled 88,286. Together, these comprised the analytic population for the evaluation (Table ES.1). The intervention group was bigger than the control group because, to limit evaluation costs, CMS capped (at 20) the number of providers per control organization who could enroll beneficiaries. Organizations enrolled about half the beneficiaries who appeared eligible for the model based on Medicare claims and enrollment data.

Thus, to deal with potential bias in evaluation results due to incomplete enrollment, we conducted sensitivity tests using a population of attributed beneficiaries (that is, those who appeared eligible for the model in Medicare data). We found results generally consistent with the main results reported here.

Table ES.1. The Million Hearts Model enrolled more than 200,000 intervention group beneficiaries in its first two years

	Enrollment from 2017 to 2018			
CVD risk group at baseline (predicted probability of having a heart attack or stroke in 10 years)	Intervention	Control		
High (≥ 30%)	40,423 (18%)	27,277 (18%)		
Medium (15–29.9%)	90,155 (39%)	61,009 (39%)		
Low (< 15%)	98,135 (43%)	67,533 (43%)		
All	228,713	155,819		

CVD = cardiovascular disease.

The enrolled intervention and control beneficiaries had very similar CVD risk at enrollment (Table ES.2). Among high- and medium-risk beneficiaries in both groups, the mean age was 72 years, 58 to 59 percent were male, 6 to 7 percent were Black, and 38 to 39 percent had diabetes. Among enrolled beneficiaries with Medicare Part D coverage (for whom we could measure medication use), most were taking statins or antihypertensive medications at baseline, indicating they were receiving treatment for their CVD risk factors even before the model began. Still, opportunities remained to reduce CVD risk. We estimated more

Table ES.2. Intervention and control group beneficiaries had very similar CVD risk at enrollment

	Mean CVD risk score at baseline (predicted probability of having a heart attack or stroke in 10 years)	
Population	Intervention	Control
High- and medium-risk beneficiaries	27%	27%
High-risk beneficiaries	40%	40%

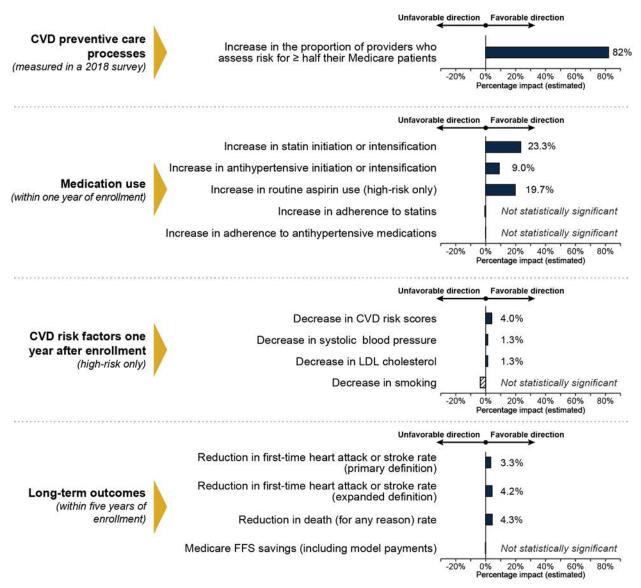
CVD = cardiovascular disease.

than one-quarter of the beneficiaries' average risk was due to modifiable risk factors such as high blood pressure, high cholesterol, or smoking.

C. Changes in CVD risk stratification and discussions of CVD risk

As intended, the Million Hearts Model substantially increased rates of CVD risk assessment among Medicare FFS beneficiaries. In a 2018 survey of 366 providers across intervention and control organizations (response rate: 71 percent), providers in the intervention group were nearly twice as likely as control group providers to report conducting CVD risk assessments for at least half of their Medicare patients. Almost three quarters (71 percent) of providers in the intervention group said they did, compared to 39 percent in the control group (an 82 percent difference). Figure ES.2 summarizes impacts of the Million Hearts Model across outcomes.

Figure ES.2. The Million Hearts Model had large, favorable effects on CVD risk assessment and medication use, with smaller effects on CVD risk factors and, ultimately, heart attacks and strokes



Notes: The primary definition of heart attacks and strokes uses only hospital claims (including outpatient claims) to identify first-time events. The expanded definition uses both hospital claims and National Death Index data. Unless otherwise specified, all reported impact estimates are statistically significant at least at a p < 0.10 threshold.

FFS = fee-for-service; CHD = coronary heart disease; CVD = cardiovascular disease; LDL = low-density lipoprotein.

In the same survey and in interviews, providers in the intervention group said they thought the model's focus on routine risk assessment made them more aware of beneficiaries' CVD risk generally. They also credited the model with increasing their use of risk scores to inform treatment decisions, such as recommending medications, and said they perceived the risk score to be useful for prompting discussions with beneficiaries about CVD risk and risk factors.

Also as intended, intervention organizations followed up frequently with high-risk beneficiaries. This was true for both the intervention and control groups, in which more than 80 percent of surveyed providers reported following up at least twice per year (which CMS requested from the intervention group). However, more intervention group providers reported following up with high-risk beneficiaries even *more frequently* than the model required—at least every three months—compared to control group providers (58 versus 43 percent, [p = 0.02]). Interviews with intervention group providers in 2019 and 2020 indicated many organizations used dedicated staff and tracking systems, such as electronic health record alerts and Microsoft Excel-based trackers, to ensure high-risk beneficiaries received follow-up recommended under the model. This follow-up most often occurred in person. Nevertheless, formal annual reassessment of CVD risk—with data reported to the Million Hearts Data Registry—fell well below CMS's model expectations from 2018 to 2021. Reassessment rates were especially low during the COVID-19 pandemic, but even before the pandemic, the number of reassessment visits each month was generally less than half the number anticipated, based on enrollment numbers.

D. Increases in CVD medication use

CMS let participating organizations choose how to reduce CVD risk and many providers reported focusing on medications. We found the model increased use of medications for CVD prevention within one year of enrollment:

- Among high- and medium-risk beneficiaries with room for improvement in cholesterol management at enrollment, the proportion initiating or intensifying statins in the first year after enrollment was 23 percent (or, in absolute terms, 3.5 percentage points) higher in the intervention group.
- Similarly, among those with elevated blood pressure at enrollment, the proportion who either initiated or intensified antihypertensive medications within one year of enrollment was 9 percent (2.4 percentage points) higher in the intervention group than the control group.
- Among high-risk beneficiaries only—for whom we have self-reported data on aspirin use via the Million Hearts Data Registry—the model increased the proportion taking aspirin one year post-enrollment by 20 percent (10.7 percentage points).
- There were no statistically significant changes in adherence to either statins or antihypertensives in the first year after enrollment.

For both statins and antihypertensives, the estimated impacts on initiation and intensification were only modestly smaller among the combined high- and medium-risk group than they were among the high-risk-only group. Given CMS made cardiovascular management payments and risk reduction payments only for high-risk beneficiaries, this finding suggests substantial spillover of model effects to medium-risk beneficiaries.

E. Decreases in CVD risk factors and risk scores

About half the beneficiaries who should have received an annual reassessment visit under the Million Hearts Model had one recorded in the Million Hearts Data Registry. Among these beneficiaries, who were all in the high-risk group, the model reduced CVD risk scores by 4 percent (absolute 1.3 percentage points) in the first year after enrollment. That is, one year after enrollment, risk scores in both the intervention *and* control groups were substantially lower than they had been at enrollment, but the decline was 4 percent greater, on average, in the intervention group.

Similarly, levels of systolic blood pressure and low-density lipoprotein cholesterol also fell, on average, in both the intervention and control groups, but with greater declines (about 1 percent larger) in the intervention group. These reductions largely drove the impacts on CVD risk scores overall, along with the previously mentioned increase in aspirin use.

We have no evidence the model prompted other changes in health-related behavior. There was no statistically significant impact on smoking one year after enrollment. Although we lack data on changes in diet or exercise, across dozens of provider interviews and roughly one dozen interviews with high-risk beneficiaries, the beneficiaries and providers said they did not perceive major changes in these areas.

F. Effects on service use

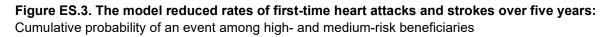
The evaluation hypothesized the Million Hearts Model could reduce rates of CVD-related hospitalizations and outpatient visits to the emergency department (ED). However, over a period of up to five years post-enrollment, the model did not measurably affect rates of CVD-related acute-care service use.

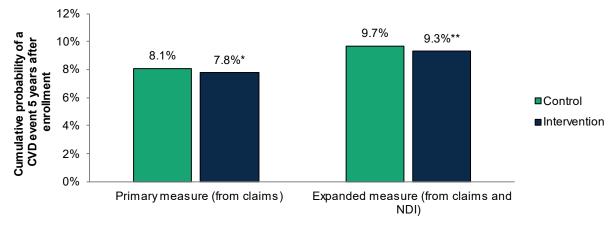
Over the same period, the model increased hospitalizations for all causes by about 4 percent among high- and medium-risk beneficiaries. This effect was unintended, and the cause is not clear. It is possible the model made providers and patients more aware of their health risks generally, prompting greater use of hospital services. Although the model increased hospitalization rates, it had no detectable impact on the frequency of ED visits or office visits generally among high- and medium-risk beneficiaries.

G. Effects on heart attacks and strokes, mortality, and Medicare spending

Over a follow-up period of up to five years post-enrollment, the Million Hearts Model reduced the incidence of first-time heart attacks and strokes by 3 to 4 percent (depending on the outcome measure used) among high- and medium-risk beneficiaries (Figure ES.2). This reduction was smaller than the 7 percent reduction originally anticipated by CMS, but still meaningful given the large number of beneficiaries affected. Specifically:

- When we measured events using Medicare claims data—that is, based on diagnosis codes associated with hospitalizations and ED visits—about 8 percent of beneficiaries experienced an event within five years of enrollment (Figure ES.3). The incidence of first-time heart attacks and strokes was an estimated 3.3 percent lower in the intervention group than the control group (from the figure, [8.1–7.8]/8.1 ≈ 0.033, with results not exact due to rounding). This estimate corresponds to one averted event over five years for every 391 high- and medium-risk beneficiaries enrolled.
- Because some heart attacks and strokes do not generate a Medicare claim—for example, if a beneficiary dies before reaching a hospital—we also assessed impacts on an expanded outcome measure, which included deaths due to CHD and cerebrovascular disease, identified in the National Death Index. Using this expanded measure of events in claims plus CHD and cerebrovascular deaths without a claim, 9 to 10 percent of beneficiaries experienced an event within five years of enrollment (Figure ES.3). The incidence of first-time heart attacks and strokes was an estimated 4.2 percent lower in the intervention group than in the control group ([9.7–9.3]/9.7 ≈ 0.042). This corresponds to one averted event over five years for every 267 high- and medium-risk beneficiaries enrolled.





Note: The primary definition uses only hospital claims (including outpatient claims) to identify first-time heart attacks and strokes, including transient ischemic attacks. The expanded definition uses both hospital claims and NDI data.

*/** Significantly different from zero at the 0.1/0.05 level, two-tailed test, respectively. CVD = cardiovascular disease; NDI = National Death Index.

Over the same period, the model reduced the all-cause death rate by 4.3 percent among high- and medium-risk beneficiaries. This estimate corresponds to one prevented death over five years for every 191 high- and medium-risk beneficiary enrolled in the model. Analyses by cause of death show the largest relative impact in deaths due to CHD and cerebrovascular disease—the category most plausibly affected by the model.

As with the impacts on medication use, the impacts on heart attacks and strokes and mortality did not concentrate among the high-risk beneficiaries for whom CMS made cardiovascular care management and risk reduction payments. Rather, across outcomes, our evaluation results suggest spillover of model effects to medium-risk beneficiaries, and potentially even larger effects for medium-risk beneficiaries. CVD risk scores might have been especially helpful for identifying elevated risk among medium-risk beneficiaries, whose risk factors might otherwise have been less obvious than risk factors among high-risk beneficiaries.

The model had no detectable effect on PBPM Medicare spending. Despite the reduction in firsttime heart attacks and strokes, Medicare spending for those events was not statistically significantly lower in the intervention group than the control group. At the same time, however, the unintended increase in hospitalizations did not measurably increase total Medicare spending, and model payments were low when averaged across all enrolled beneficiaries: roughly \$1 per high- and medium-risk beneficiary per month. Average monthly Medicare FFS spending, including model payments, was very similar between the intervention group and the control group (\$959 versus \$958 PBPM, respectively). Note that our estimates of effects on spending do not include (1) any possible increases in Medicare spending on medications (Part D) due to increases in statin or antihypertensive use; or (2) costs of implementing the model, such as building and maintaining the Million Hearts Data Registry and calculating semiannual performance.

H. Conclusion

In a large, randomized trial, the Million Hearts Model improved CVD preventive care and reduced first-time heart attacks and strokes, even in a population receiving considerable CVD care at baseline. The model did not measurably change Medicare FFS spending. Findings from the Million Hearts Model also indirectly support clinical guidelines underpinning the model's requirements, such as use of routine CVD risk assessment to encourage the primary prevention of CVD. This model is promising for CMS and other payers or health systems seeking to improve health outcomes for CVD, the leading cause of death in the United States and worldwide.

I. Introduction

Cardiovascular disease (CVD) is a leading cause of death, disability, and health care expenditures in the United States (Tsao et al. 2022). In addition, disparities in CVD burden are well documented, with African Americans experiencing higher rates of CVD-related morbidity and mortality than White populations (Carnethon et al. 2017). Improvements in clinical treatment of CVD risk factors, diet, exercise, and smoking cessation could substantially reduce the burden of CVD across populations (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 improve CVD preventive care and reduce the incidence of first-time heart attacks and strokes among Medicare beneficiaries (Sanghavi and Conway 2015). The five-year model paid providers to assess Medicare beneficiaries' risk of having a heart attack or stroke and for reducing that risk among their high-risk beneficiaries. CMS tested the model in a large, randomized trial that included primary care and cardiology practices, health centers, and hospital outpatient departments throughout the country.

The Million Hearts Model promoted the goals of the national 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). The U.S. Department of Health and Human Services has continued the Million Hearts[®] initiative, recently committing to preventing one million hearts attacks and strokes from 2022 to 2027 (CDC 2022). The advent of the COVID-19 pandemic three years into the Million Hearts Model led to delays in CVD preventive care services (Lau and McAlister 2021). These disruptions underscore the importance of continuing to monitor and address CVD risk factors through efforts such as the Million Hearts Model (Shiels et al. 2022).

This Final Evaluation Report describes the results of the five-year randomized trial.

A. Model goals and design

The goals of the Million Hearts Model were 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 Parts A and B spending on CVD events—that is, heart attacks and strokes—enough to offset model payments. To help meet these goals, the model provided guidelines for CVD preventive care and targeted financial incentives and supports, such as performance feedback and peer-to-peer learning.

Guidelines for CVD preventive care. CMS set broad guidelines for how organizations would provide CVD preventive care. These guidelines were consistent with clinical guidelines from the American Heart Association (AHA) and the American College of Cardiology (ACC). Organizations that joined the model agreed that, if they were randomly assigned to the intervention group, they would follow these guidelines:

- 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 were eligible for the Million Hearts Model if they were ages 40 to 79, had not had a previous heart attack or stroke, did not have end-stage renal disease (ESRD), and were not enrolled in hospice. Beneficiaries were considered to be at high risk if their predicted 10-year CVD risk (referred to as the risk score) was at least 30 percent, at medium risk if their risk score was from 15 to 30 percent, and at low risk if it was less than 15 percent. (The risk score thresholds for these categories differ from those of the high-, intermediate-, borderline-, and low-risk categories now commonly used elsewhere [Lloyd-Jones et al. 2019]).
- **Provide cardiovascular care management services to high-risk patients.** These services included (1) meeting with each high-risk beneficiary to discuss CVD risk and risk factors; (2) jointly developing an individualized plan for reducing risk that reflected both the efficacy of different treatment options and the beneficiary's 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 beneficiary at least twice each year to gauge and encourage progress in reducing CVD risk.

Within these broad guidelines, 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.

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

- 1. \$10 for each eligible Medicare FFS beneficiary for whom the organizations assessed risk.
- **2.** \$10 per high-risk beneficiary per month for providing cardiovascular care management services (first model year only, 2017).
- **3.** \$0 to \$10 per high-risk beneficiary per month depending on how successful the organization was in reducing the average risk score for all its high-risk beneficiaries assessed during the relevant period (starting in 2018, the second model year). Specifically, CMS paid \$10 per month if the average CVD risk score for high-risk beneficiaries declined from baseline by more than 10 percentage points, \$5 if the average score declined by 2 to 10 percentage points, and \$0 if it did not decline or declined by less than 2 percentage points.

In addition, from 2017 to 2019, CMS paid control group 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.

Over the five-year model, CMS paid \$7.9 million to 173 intervention organizations, of which we estimate \$7.2 million was for the beneficiaries enrolled in 2017 and 2018, who are the focus of this report. About one-third of the \$7.9 million (37 percent) was for risk stratification, another one-third (35 percent) was for cardiovascular care management services for high-risk beneficiaries in the first model year, and the remaining 28 percent was for successfully reducing risk in model Years 2 to 5. The share of payments going to risk reduction was relatively low, in part, because many organizations withdrew from the model or did not report data in later model years (Chapter II). On average, each organization staying in the model and still reporting data received \$2,723 to \$15,251 in each six-month model performance period, with the amounts generally declining over time as incentive payments shifted to depend largely on reducing risk among high-risk beneficiaries (Appendix A).

Tools and supports. CMS also provided several tools and supports to help intervention organizations improve their CVD preventive care and meet reporting requirements:

- Semiannual reports to each intervention organization described their performance enrolling beneficiaries and reducing CVD risk.
- Peer-to-peer learning sessions encouraged organizations to share strategies for implementing the model and reducing risk.
- A secure portal, the Million Hearts Data Registry, enabled intervention and control organizations to submit the required clinical and demographic data needed to calculate a beneficiary's CVD risk.

In addition, CMS supported the development of the Million Hearts Longitudinal Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment Tool, a novel tool that enabled the Million Hearts Model organizations to track changes in CVD risk over time, based on evidence from clinical trials that linked changes in CVD risk factors to changes in heart attack and stroke rates (Lloyd-Jones et al. 2017). Under this tool, a person's initial risk score was the same as calculated under the previously existing ACC/AHA ASCVD Risk Estimator (Goff et al. 2014). However, because the new tool could estimate risk change for a given individual over time, CMS used this tool when estimating risk reduction, the basis of the Million Hearts Model risk reduction payments. The tool also enabled clinicians to estimate how much different therapies (for example, statins) would reduce a patient's risk. This was intended to help guide treatment discussions and decisions.

B. Causal pathway for the Million Hearts Model

Working with CMS staff and written materials about the model, we developed a casual pathway that describes how the model, if it worked as intended, could reduce heart attacks and strokes, and reduce spending enough to offset model costs. We describe each step of the pathway in Figure I.B.1.

1. CMS provides incentives and supports for stratifying and reducing risk. Specifically, CMS pays organizations for each eligible Medicare FFS beneficiary they risk stratify, for providing cardiovascular care management for high-risk beneficiaries in the first model year, and subsequently for reducing risk among high-risk beneficiaries. The supports include peer-to-peer Figure I.B.1. Causal pathway for the Million Hearts Model Incentives and supports to measure and reduce 1 CVD risk Increases in risk stratification and providers' awareness of beneficiaries' modifiable risk Improvements in clinical preventive care and 3 beneficiaries' behaviors to reduce modifiable risk Reductions in CVD risk scores and 4 individual risk factors Lower incidence of first-time heart attacks and 5 strokes; lower Medicare spending

learning, feedback reports, and access to a tool that estimates how much different therapies would reduce risk for individual beneficiaries.

- 2. Providers risk stratify their Medicare beneficiaries and become more aware of their patients' cardiovascular risk. Motivated both by the model incentives and their organizations' agreement to follow the model's provisions, providers increase the extent to which they calculate risk scores for their Medicare FFS beneficiaries, review these scores, and assign beneficiaries to risk categories (high, medium, and low). This process makes providers more aware of their patients' CVD risk, including how much of this risk is modifiable. An underlying assumption in the model is that a meaningful share of beneficiaries' total CVD risk is due to modifiable factors, such as elevated blood pressure or cholesterol, that could be reduced through improvements in care.
- **3.** Providers work more closely and consistently with beneficiaries to reduce modifiable risk through improvements in clinical care and self-care. With greater awareness of patients' CVD risk, providers become more likely to meet with beneficiaries to discuss their risk, factors driving their risk, and options for reducing the risk. Subsequently, through a process of shared decision making, providers and beneficiaries develop individualized care plans that reflect beneficiaries' priorities and preferences. Options include initiating or intensifying preventive medications (statins, antihypertensives, and aspirin), increasing adherence to medications, quitting smoking, or changing diet or exercise patterns. Through discussions with their providers, beneficiaries become more aware of their risk and more willing to start new medications or change their behaviors in ways that reduce risk. As a



result, we expect to see increases in the use of CVD medications, adherence to medications, smoking cessation, or improvements in diet or exercise. Further, the model increases the extent to which providers follow up with high-risk beneficiaries to assess and encourage risk reduction over time, including through formal annual risk reassessments. We expect to see improvement in CVD preventive care for high-risk patients, given that the model explicitly incentivizes risk reduction in this group. However, we also expect improvements for medium-risk patients because, through greater use of risk stratification, providers become more aware of the elevated risk for this group.

- 4. These improvements in clinical care and self-care reduce overall cardiovascular risk, as well as individual risk factors. These improvements lead to lower CVD risk scores during the annual reassessment visits for high-risk beneficiaries. We also expect lower risk scores among medium-risk beneficiaries, although intervention group organizations did not submit the clinical data needed to assess whether these improvements occurred.
- 5. By the end of the five-year test, the reductions in CVD risk reduce the incidence of firsttime heart attacks and strokes and reduce Medicare spending. CMS projected the model would reduce first-time heart attacks and strokes among high- and medium-risk beneficiaries by 7 percent. Reductions of this size could lower Medicare spending on hospitalizations for CVD events and related post-acute care enough to fully offset the payments CMS makes to organizations for participating in the model.

Although the casual pathway outlines the mechanisms that might lead to reduced heart attacks and strokes, not *all* organizations would need to meet *all* model requirements to achieve these intended outcomes. For example, an organization may not reassess risk for all beneficiaries annually but may still make substantial improvements in risk stratification and risk reduction. Conversely, an organization may already have very high rates of risk stratification, in which case the model would not prompt additional behavior changes needed to result in reduced heart attack and stroke. The causal pathway is intended to be a framework for understanding the changes organizations made as a result of the model.

C. Goals of the evaluation, data sources, and evaluation methods

The evaluation assessed whether and how, over five years, the Million Hearts Model improved CVD preventive care, reduced first-time heart attacks and strokes, and lowered Medicare spending enough to offset model payments. We used a mix of data sources and methods to answer these questions.



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



Registry. We used clinical and demographic data from the Million Hearts Data Registry to identify Medicare beneficiaries enrolled into the model (January 2017 through December 2021). These data included beneficiaries' characteristics at enrollment, such as age, gender, CVD risk factors, and CVD risk scores. Further, the

registry included similar data for patients with annual reassessment visits. We used the reassessment data to identify the 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.



Provider survey. In 2018, we surveyed randomly selected providers in each of the intervention and control organizations enrolling beneficiaries. The survey asked about CVD preventive care, including how often providers risk stratified their patients. We estimated model impacts on self-reported CVD preventive care as the regression-

adjusted differences in providers' responses. We surveyed 366 providers, with a response rate of 71 percent.



Practice survey. In 2018 and 2021, we surveyed the person designated by each organization as the lead for overseeing the model's implementation. This person might be a clinician, an office manager, or an 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. For the 2018 survey, we surveyed 323 intervention and control group organizations, with a response rate of 89 percent. For the 2021 survey, we surveyed 132 intervention group organizations, with a response rate of 68 percent.



Interviews with model participants and enrolled beneficiaries. To understand model implementation, including facilitators of and barriers to implementation, we interviewed providers and staff from a cohort of 10 to 15 intervention organizations in 2018, 2019, 2020, and 2021. The evaluation team selected organizations to represent a

range of sizes, locations, and types (for example, primary care and cardiology practices). To understand beneficiaries' experiences with the Million Hearts Model, we interviewed 14 highrisk beneficiaries seen at a Million Hearts Model organization for a reassessment visit in 2021.



Medicare claims and enrollment data. We used Medicare Parts A and B claims and the Medicare Enrollment Database through December 2021 for several purposes:

- To 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 emergency department [ED] visits and hospitalizations). We estimated model impacts as regression-adjusted differences in outcomes between the intervention and control groups.
- To define a beneficiary's characteristics when the beneficiary enrolled in the model (for example, whether the individual had ischemic heart disease or was

originally entitled to Medicare due to disability). 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.

We used Medicare Part D claims to assess whether the model increased (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. By design, all beneficiaries enrolled in the Million Hearts Model were Medicare FFS beneficiaries with Parts A and B coverage. About 70 percent also had Part D coverage.



National Death Index (NDI). The NDI is a database of all deaths in the United States, including cause of death information from death certificates. To estimate impacts on heart attacks and strokes including fatal events that did not generate a hospital claim, and to understand model impacts on mortality by cause of death, we

obtained Medicare-linked NDI data for deceased Medicare FFS beneficiaries enrolled by intervention and control group organizations.

We provide additional details about these data sources, as relevant, throughout the report. Previous annual reports provided details on the methods we used to collect and analyze interview and survey data. For qualitative interview methods and analysis, see <u>Appendix B of the Second</u> <u>Annual Report</u> (Peterson et al. 2019). For 2018 provider and practice survey methods, see <u>Appendix E of the Second Annual Report</u>. For 2021 practice survey methods, see <u>Appendix C of</u> <u>the Fourth Annual Report</u> (Peterson et al. 2022).

Report organization. <u>Chapter II</u> describes the organizations participating in the Million Hearts Model, how participation changed over time, and the number of beneficiaries participating organizations enrolled over the five-year model. Chapters III through VII follow the causal pathway (<u>Section I.B</u>), estimating whether the model had intended effects on CVD care processes and short- and long-term outcomes. Specifically, <u>Chapter III</u> explores whether and how the model changed CVD risk stratification and discussions of CVD risk between the providers and beneficiaries. <u>Chapters IV</u>, <u>V</u>, and <u>VI</u> summarize changes in medication use, decreases in CVD risk factors and risk scores, and effects on service use, respectively. <u>Chapter VII</u> describes effects of the model on long-term model outcomes, including CVD events, mortality, and Medicare spending. <u>Chapter VIII</u> explores variations in model impacts by beneficiary subgroups. Finally, in <u>Chapter IX</u>, we discuss overall conclusions from the evaluation of the model, including drivers of model impacts, strengths and limitations of the evaluation, and contributions to CVD prevention research.

II. Whom the Model Served



- Of 516 organizations accepted to the Million Hearts Model, 345 participated, meaning they entered data for at least one beneficiary in 2017 or 2018 and CMS validated the data to enroll those beneficiaries.
 - Half of the participating organizations were in the intervention group (173) and half were in the control group (172).
 - Participating organizations were of different sizes and included primary care practices, specialty
 practices, and health centers located in rural and urban areas throughout the country.
 - Control group organizations were similar to the intervention group organizations across most of these organization-level characteristics.
- Model participation declined considerably over time in both the intervention and control groups.
 - By the end of the model period, only 46 intervention organizations still submitted data to the registry.
 - Organizations said they withdrew largely because they did not think the financial incentives were commensurate with the work required or they lacked adequate staff to comply with the model requirements, particularly uploading data to the registry.
 - Intervention organizations that continued to actively participate through 2021 by formally remaining in the model and submitting data were larger and more likely to be in urban areas than those that did not.
- During the five years of the model (2017 to 2021), intervention and control organizations enrolled 462,582 Medicare FFS beneficiaries.
 - Enrollment was highest in the first year and decreased each subsequent year, which was expected because the number of beneficiaries eligible for enrollment was supposed to decrease over time.
- The analytic population used for the impact evaluation includes 130,578 high- and medium-risk beneficiaries enrolled in 2017 and 2018, as these beneficiaries enrolled early enough and had high enough CVD risk to experience potential benefits of the model.
- Beneficiaries in the analytic population enrolled by intervention organizations received a substantial amount of cardiovascular care at baseline, yet there was still room to reduce CVD risk.
 - Among high-risk beneficiaries, about 40 percent of total CVD risk was due to modifiable risk factors and among medium-risk beneficiaries, about 29 percent was modifiable.
 - The main modifiable risk factors were blood pressure and low-density lipoprotein (LDL) cholesterol.
 - Age, gender, and diabetes status were important nonmodifiable risk factors.

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. Organization leaders said they joined, in part, because the model was consistent with their CVD prevention goals and because the organizations already assessed CVD risk for some of their patients, making it easier to implement the model.

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 and 2018) by enrolling at least one Medicare beneficiary. These participating organizations included primary care practices, specialty practices, and health centers located in rural and urban areas throughout the country (Table II.A.1). Enrollment per organization varied widely, with eight organizations enrolling only one beneficiary and one organization enrolling as many as 25,377 (interquartile range: 136–1,091).

The 172 control group organizations that enrolled beneficiaries were generally similar to the 173 participating intervention group organizations across most characteristics. For example, the intervention and control organizations had a similar regional distribution and specialty mix. The biggest differences between the two groups were in the mean number of providers, which was lower among intervention organizations (38 versus 49), and participation in the Medicare Shared Savings Program, which was greater among intervention organizations (29 versus 22 percent), as reported in organizations' applications to the model (Table II.A.1).

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
Number of sites, mean	8	7	0.7
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

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)	
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	

Source: Organizations' self-reported data from the Million Hearts Model application data linked to the CMS NPPES.

^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.

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

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

B. Model retention



Model participation declined over time for both intervention and control

organizations (Figure II.B.1). 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, the number of organizations that formally participated, meaning they did not request to withdraw from the model nor did CMS terminate them for failing to meet model requirements, declined around the time the first Million Hearts Data Registry data were due (September 2017 and March 2018, respectively) (solid blue and green lines). Control group organizations received payment for submitting data for the first three years of the model, and thus control group participation in the model ended in December 2019. As of December 31, 2021, 128 intervention organizations remained in the model. However, only 46 of these—about one-fifth of the formal participants as of the January 2017 launch date—still submitted data to the Million Hearts Data Registry during the final six-month performance period (July to December 2021). Only those organizations submitting data (dotted lines in Figure II.B.1) could earn model incentive payments for risk stratification and CVD risk reduction.

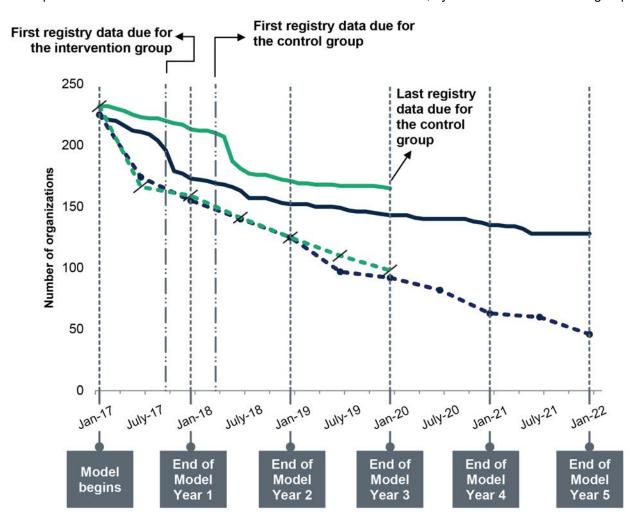


Figure II.B.1. Model participation declined over time in both the intervention and control groups: Participation in the Million Hearts Model from launch to December 2021, by intervention and control group

Not withdrawn or terminated (intervention)

- Not withdrawn or terminated (control)
- • Organization reported at least one visit in the registry for the previous 6 months (intervention)
- ✓ 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 reported to the Million Hearts Data Registry.
- CMS = Centers for Medicare & Medicaid Services.



Throughout the model, CMS gathered written feedback from organizations that formally withdrew. The evaluation team also conducted exit interviews in spring and summer 2018 with withdrawing organizations. Most organizations that voluntarily left the model within the first three model years said they did so because they found the financial incentives not commensurate with the work required. In particular, withdrawn participants often cited the model's requirements to submit data to the Million Hearts Data Registry or noted they lacked resources to implement the model, usually related to insufficient staff capacity or EHR capabilities. Among the seven organizations that provided a reason for withdrawing in 2020 or 2021, reasons included leadership and staffing changes, especially related to the COVID-19 pandemic.

Intervention organizations that continued to participate through 2021 were larger and more urban than those that did not. Fifty-nine intervention organizations formally remained in the model through 2021 and submitted data to the registry that year. These organizations enrolled more beneficiaries in the first two years of the model, on average, than the 114 organizations that enrolled at least one beneficiary in 2017–2018 but did not actively participate in 2021 (an average of 2,273 per organization versus 830; see <u>Appendix B, Table B.1</u>). The active participants in 2021 had, on average, a greater number of providers reported in the organizations' Million Hearts Model application (60 versus 26), were less likely to be in a rural location (32 versus 53 percent), and were more likely to be classified as a specialty or multispecialty practice (36 versus 16 percent).

C. Enrolled beneficiaries

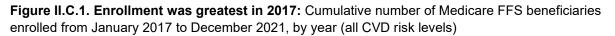
Intervention and control organizations enrolled Medicare FFS beneficiaries in the model by collecting demographic and clinical data needed to calculate the beneficiary's CVD risk score and submitting those data to CMS through the Million Hearts Data Registry. CMS validated each enrollment by comparing the beneficiary's demographic and visit information against CMS administrative data. The beneficiary was considered enrolled as of the date of the systolic blood pressure reading.

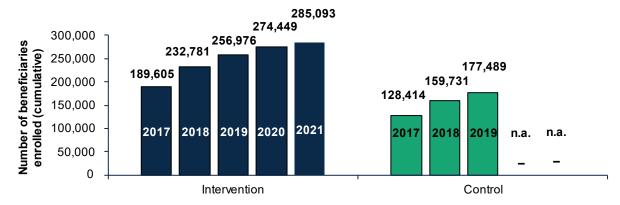


During the five years of the model (2017 to 2021), intervention and control organizations enrolled 462,582 Medicare FFS beneficiaries: 285,093 in the intervention group and 177,489 in the control group (Figure II.C.1). Enrollment was substantially lower in the control group than the intervention group because of the 20-

provider cap CMS placed on control organizations, which did not apply to the intervention organizations. In addition, control organizations stopped enrolling beneficiaries at the end of the third model year (2019) as planned.

As anticipated, enrollment was highest in 2017, as CMS expected organizations to enroll and assess CVD risk for all eligible Medicare FFS beneficiaries at first contact (Figure II.C.1). Enrollment decreased each subsequent year because only beneficiaries who were new to the organization or to Medicare FFS, those who infrequently visited the organization, or those who were missed during previous visits could be enrolled in later years.





CVD = cardiovascular disease; FFS = fee-for-service; n.a. = not applicable (control organizations stopped enrolling beneficiaries at the end of 2019).

Most of the analyses in this report are based on the high- and medium-risk Medicare beneficiaries enrolled by Million Hearts Model organizations in 2017 and 2018. We did not include beneficiaries enrolled in 2019 in the impact estimation due to concerns that organizational attrition by then could lead to unobserved differences between the intervention and control groups that could bias estimates. (We did not include beneficiaries enrolled in 2020 or 2021 because, by design, the control group had stopped enrolling beneficiaries by then.) In addition, estimating impacts for the high- and medium-risk population enrolled in 2017 and 2018 ensures that beneficiaries included in the analysis had enough time since enrollment and enough CVD risk to experience the potential benefits of the model.

We further limited the analytic population to 218,864 beneficiaries (130,578 in the intervention group and 88,286 in the control group) who met three additional criteria needed for analysis: (1) were not missing key clinical data; (2) were observable in Medicare claims at enrollment (alive, enrolled in Medicare Parts A and B with Medicare as the primary payer, and not covered under a managed care plan); and (3) met the Million Hearts Model claims-based enrollment criteria of being ages 40 to 79, with no evidence of a prior heart attack or stroke, with Medicare as their primary payer, without ESRD, and without hospice benefits.

Among the beneficiaries enrolled in 2017 and 2018, in both the intervention and the control groups, more than half were high or medium risk. In addition, those in the intervention group had a similar risk profile to those in the control group (Figure II.C.2). Beneficiaries enrolled in the Million Hearts Model intervention group (of any risk level) had largely similar demographic and health characteristics to the national Medicare FFS population ages 40 to 79 (see <u>Appendix B, Table B.2</u>). However, the enrolled beneficiaries were more likely to be White than the national average (83 versus 79 percent) and were more affluent, with lower scores, on average, on the Social Vulnerability Index (SVI)—that is, they resided in Census tracts with slightly lower average social vulnerability.

Figure II.C.2. More than half of the 2017–2018 enrolled beneficiaries were high or medium risk: Medicare beneficiaries enrolled by intervention and control organizations from January 2017 to December 2018, by CVD risk level

	Enrollment from 2017 to 2018			
CVD risk group at baseline (predicted probability of having a heart attack or stroke in 10 years)	Intervention	Control		
High (≥ 30%)	40,423 (18%)	27,277 (18%)		
Medium (15–29.9%)	90,155 (39%)	61,009 (39%)		
Low (< 15%)	98,135 (43%)	67,533 (43%)		
All	228,713	155,819		

CVD = cardiovascular disease.

The 40,423 high- and 90,155 medium-risk beneficiaries in the intervention group already received substantial cardiovascular care at baseline (Table II.C.1). Most took one or more medications—including blood pressure therapy, statins, and aspirin—to reduce CVD risk factors. For example, among high-risk beneficiaries with Part D enrollment, 90 percent used antihypertensives at enrollment and 69 percent used statins. (High statin use might also explain low cholesterol levels among high-risk beneficiaries relative to the low-risk beneficiaries.) Intervention group beneficiaries also tended to visit health care providers regularly. For example, high-risk beneficiaries had an average of nearly 10 office visits in the year before enrollment, including 3 with the organization that enrolled them. These visits could have created opportunities to address CVD risk before the beneficiaries enrolled in the Million Hearts Model.

Nevertheless, beneficiaries still had a substantial degree of modifiable risk at enrollment.

For example, about three-quarters of high-risk beneficiaries had high systolic blood pressure levels (of at least 130 mmHg). In addition, about three-quarters had LDL cholesterol levels of at least 70 mg/dL, the threshold given in clinical guidelines for discussing statin options with patients at high or medium risk of CVD (Grundy et al. 2018). Twelve percent smoked. Age, gender, and diabetes status were important nonmodifiable risk factors.

We calculated how much each enrolled beneficiary's CVD risk score might change if he or she met clinical targets for aspirin use, blood pressure control, cholesterol management, and smoking cessation². (Although diabetes is often preventable through lifestyle factors, we considered it nonmodifiable once it was present.) Among high-risk beneficiaries, about 40 percent of total CVD risk was due to modifiable risk factors (a mean of 16 percentage points out of a mean risk

² We calculated modifiable risk as the amount of CVD risk a person could reduce within one year of model enrollment, according to the Million Hearts Longitudinal ASCVD Risk Assessment Tool, if that person were to meet clinical targets for (1) aspirin use if appropriate (based on clinical guidelines as of 2018), (2) systolic blood pressure less than 130 mmHg, (3) LDL cholesterol less than 70 mg/dL, and (4) immediate smoking cessation. See <u>Appendix C of the Second Annual Report</u> for more details, including rationale for the clinical targets used.

score of 40 percent). Among medium-risk beneficiaries, about 29 percent was modifiable (6 percentage points out of a mean risk score of 21 percent). These levels of modifiable risk suggest ample opportunity to reduce CVD risk during the model, especially in the high-risk group.

Table II.C.1. Beneficiaries in the intervention group received a substantial amount of cardiovascular care at baseline, yet there was still room to reduce risk: Baseline characteristics of Medicare beneficiaries enrolled by Million Hearts Model intervention organizations in 2017 and 2018, by CVD risk level

	High risk (N = 40,423)	Medium risk (N = 90,155)	Low risk (N = 98,135)
Demographics			
Age, mean	74	71	64
% Black	7	8	8
% male	65	55	25
Neighborhood characteristics ^a			
SVI score, mean (1 to 100)	44	42	43
CVD risk factors			
CVD risk score, mean (in %)	40	21	9
CVD modifiable risk score, mean (in %)	16	6	2
Diabetes, %	65	23	10
Total cholesterol, mean (in mg/dL)	169	177	186
HDL cholesterol, mean (in mg/dL)	47	52	57
LDL cholesterol, mean (in mg/dL)	93	99	104
% ≥ 70 mg/dL	73	80	85
Systolic blood pressure, mean (in mmHg)	140	131	124
% ≥ 130 mmHg	74	54	34
Current smoker, %	12	10	9
Medication use			
Aspirin use, %	51	43	30
Antihypertensive use in Part D, ^b %	90	79	60
Statin use in Part D, ^b %	69	61	49
Low intensity, %	7	6	5
Medium intensity, %	41	37	31
High intensity, %	21	17	12

	High risk (N = 40,423)	Medium risk (N = 90,155)	Low risk (N = 98,135)
Office visits in year before enrollment			
Office visits, mean (# per 1,000 beneficiaries)	9,856	8,946	9,078
Office visits with model-aligned providers, mean (# per 1,000 beneficiaries)	2,979	2,490	2,381

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

Note: High CVD risk indicates beneficiaries with a 30 percent or higher predicted risk of having a heart attack or stroke in the next 10 years. Medium CVD risk is 15 percent to 30 percent. Low CVD risk is less than 15 percent. Characteristics were measured as of a beneficiary's enrollment in the Million Hearts Model. The exception was cholesterol levels, which could be collected up to five years before or two months after enrollment. For all measures, means were calculated over nonmissing values.

^a We measured vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status,
(2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 the highest level of social vulnerability.

^b Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment (N = 28,348 for high risk; N = 61,064 for medium risk; N = 62,916 for low risk).

CDC = Centers for Disease Control and Prevention; CVD = cardiovascular disease; FFS = fee-for-service; HDL = high-density lipoprotein; LDL = low-density lipoprotein; SVI = Social Vulnerability Index.

D. Implications of organizations' participation for estimating impacts of the Million Hearts Model

Unless otherwise noted, we estimated impacts among all beneficiaries in the analytic population (high- and medium-risk beneficiaries enrolled in 2017–2018) through the end of the Million Hearts Model in December 2021 for as long as those beneficiaries remained observable in Medicare claims data. Beneficiaries remained observable if they were alive, enrolled in Medicare Parts A and B with Medicare as the primary payer, and not covered under a managed care plan. We followed an intent-to-treat design; this means the analytic population included beneficiaries whose enrolling organization withdrew from the model or stopped actively participating (submitting data needed to earn model payments).

Because the analytic population included beneficiaries whose enrolling organizations stopped participating in the model, impacts could have been attenuated by organizations leaving the model. However, this attenuation is less concerning than it might appear from the steady decline in organizational participation because organizations with more enrolled beneficiaries were more likely to stay in the model. On average, for 78 percent of the follow-up days in our impact evaluation (that is, days from a beneficiary's date of enrollment to the date of censoring), the enrolling organization was still actively participating in the model. In addition, if the organizations that withdrew or stopped reporting data to the registry continued to follow the CVD preventive care guidelines specified by the model, we might still observe impacts for enrolled beneficiaries in those organizations even if the organizations no longer actively participated.

III. Changes in CVD Risk Stratification and Discussion of CVD Risk



Key findings

- The Million Hearts Model increased rates of CVD risk assessment among Medicare FFS beneficiaries.
 - In a 2018 survey, providers in the intervention group were nearly twice as likely as control group providers to report conducting CVD risk assessments for at least half of their Medicare patients (an 82 percent difference).
 - Rates of risk assessment declined in the final years of the model but remained above premodel levels.
- Providers in the intervention group believed the model increased their awareness of beneficiaries' CVD risk. They also perceived the risk score to be a valuable tool for engaging beneficiaries in managing their risk factors.
- Providers in the intervention group credited the model with increasing their use of risk scores to inform treatment decisions, such as recommending medications, and inform discussions with beneficiaries.
- Intervention organizations tended to follow up frequently with high-risk beneficiaries, but formal annual reassessment of risk fell well below model expectations.

The Million Hearts Model aimed to promote systematic CVD risk assessment for eligible Medicare FFS beneficiaries. As noted in <u>Chapter I</u>, participating organizations agreed to use a standardized tool to estimate the 10-year risk of heart attack and stroke for beneficiaries ages 40 to 79 without a history of these CVD events. For beneficiaries found to be at high CVD risk, the organizations then agreed to (1) discuss CVD risk and use shared decision making to develop individualized care plans, (2) contact high-risk beneficiaries at least twice a year to follow up, and (3) reassess CVD risk annually. This chapter describes the impact of the Million Hearts Model on rates of CVD risk assessment, relative to rates in the control group. The chapter then explores providers' perceptions of how the model changed their awareness of CVD risk and affected care for high-risk beneficiaries.

A. Changes in risk assessment under the Million Hearts Model

The Million Hearts Model required that intervention organizations assess CVD risk for all eligible Medicare FFS beneficiaries. This requirement aligns with ACC/AHA guidelines for CVD primary prevention which recommend routine calculation of CVD risk scores among adults ages 40 to 75 (Goff et al. 2014; Arnett et al. 2019). The model promoted existing clinical guidelines around

Model requirement

Intervention organizations agreed to assess CVD risk for all eligible Medicare FFS beneficiaries.

regularly assessing patients for CVD risk. However, our survey of Million Hearts Model

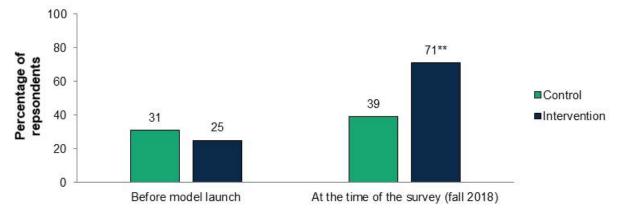
providers in 2018 suggested that, before model launch, substantial opportunity existed to improve adherence to these clinical guidelines (Figure III.A.1).



The Million Hearts Model substantially increased risk assessment of Medicare FFS beneficiaries and the frequency with which providers reviewed risk scores. In fall 2018, about 18 months after the model launch, 71 percent of intervention providers we surveyed reported they or someone

on their care team calculated CVD risk scores for at least half of their Medicare beneficiaries. This was an 82 percent difference from control group providers (p < 0.001), of whom 39 percent reported calculating CVD risk scores for at least half of their Medicare beneficiaries (Figure III.A.1). Similarly, 78 percent of intervention group providers reported reviewing CVD risk scores more consistently in 2018 than two years previously, before the model launch, compared to 52 percent of control group providers (p < 0.001) (Figure III.A.2). These findings suggest the model had its intended effect on the second step of the causal pathway (Chapter I), which was to increase CVD risk assessment of beneficiaries. In interviews from 2018 to 2020, many intervention group organizations described using web-based calculators, smart-phone applications, or EHR-based calculators to calculate risk score; at others, the clinical providers did the risk assessment themselves.

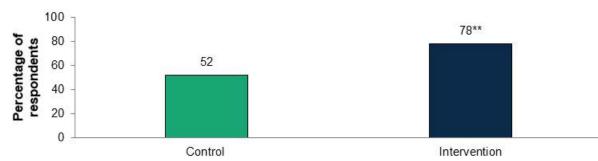
Figure III.A.1. By 2018, the Million Hearts Model had increased rates of CVD risk assessment: Proportion of surveyed providers reporting they calculated CVD risk scores for at least half of their Medicare beneficiaries



Source: Mathematica's analysis of a provider survey administered in 2018 to control (n = 117) and intervention (n = 128) group organizations.

** Significantly different from the control group percentage at the 0.05 level, two-tailed test.

Figure III.A.2. By 2018, the Million Hearts Model had increased the consistency with which providers reviewed risk scores: Proportion of providers in 2018 reporting they reviewed CVD risk scores more consistently than two years previously



Source: Mathematica's analysis of a provider survey administered in 2018 to control (n = 117) and intervention (n = 128) group organizations.

** = Significantly different from the control group percentage at the 0.05 level, two-tailed test.



Intervention group providers fell short of the requirement to risk assess all eligible Medicare FFS beneficiaries. Although the model appears to have prompted large increases in CVD risk assessment, intervention organizations enrolled and obtained risk scores for only about half

(52 percent) of those who appeared eligible for the model in 2017 and 2018, according to Medicare data. That is, the organizations enrolled about half of the Medicare FFS beneficiaries who (1) had an outpatient visit in 2017 and 2018 with a participating provider who enrolled beneficiaries; and (2) met model eligibility criteria we could observe in Medicare administrative data, such as ages 40 to 79 and no history of a heart attack or stroke. Organizations appear more likely to have assessed risk for beneficiaries who had existing relationships with the practice and fewer acute needs that might divert providers' attention from preventive care. Enrolled beneficiaries had more office visits to the enrolling organizations, on average, than those who appeared eligible but did not enroll (Appendix B, Table B.3). Enrolled beneficiaries also appeared to be modestly healthier than those not enrolled, with fewer chronic conditions and lower hospitalization rates and Medicare spending in the year before a model-qualifying visit.



Organizations we interviewed tended to have higher rates of risk assessment and enrollment than average, and our respondents typically perceived they assessed CVD risk routinely. However, interview respondents gave some reasons for not assessing risk more often. For example, risk assessment takes time, and one organization noted

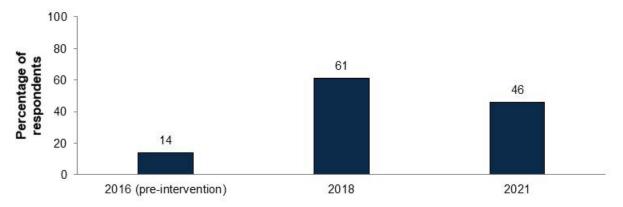
that, if the risk score was not calculated before the patient's visit, calculating it could take the doctor's time away from the patient. We also heard about lapses in uploading data to the Million Hearts Data Registry. That is, some beneficiaries had been risk assessed, but the organization did not take the time to enroll them in the model via the Million Hearts Data Registry.



Despite early increases, rates of risk assessment appeared to decline in later years of the model, but they remained higher than before the model launch. In addition to surveying model providers in 2018, in 2018 and 2021 we surveyed key staff who administered the Million Hearts Model at intervention organizations. At both time

points, we asked about the proportion of Medicare beneficiaries for whom the organization had calculated a CVD risk score. In 2018, respondents also answered a question about risk assessment before the model launched in 2017. A comparison of responses from intervention organizations that responded in 2021 suggests organizations continued risk assessing at rates more than three times pre-intervention levels, but rates in 2021 had fallen below the levels reported in 2018 (Figure III.A.3). In interviews, organization staff noted the model had become less of a priority by 2021 due to competing demands and staffing challenges during the COVID-19 pandemic.

Figure III.A.3. 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 and 2021 to key contacts at each intervention organization in the Million Hearts Model. We limited the analysis to respondents in 2021 (n = 90). We considered two organizations that responded to the survey in 2021 but not in 2018 missing from the 2018 responses.
- Note: Estimates for 2016 responses were reported in the 2018 survey; respondents were asked to recall their care delivery two years before the time of the survey (n = 87).

CVD = cardiovascular disease.

B. Changes in providers' awareness of beneficiaries' CVD risk



Intervention group providers reported the model increased their awareness of CVD risk. Specifically, among providers who said on the 2018 provider survey they reviewed CVD risk scores more consistently than before the model launch, about three-quarters reported that calculating risk

scores helped them identify Medicare beneficiaries with high or medium risk. The remaining intervention group providers who answered the question said reviewing the risk score more consistently merely confirmed CVD risk they had already recognized. Interviews with providers from 10 intervention group organizations in 2020 supported these findings. Respondents at nearly all organizations

"Obviously, knowing what the risk score is, it's had an impact on how we may approach [the patients]. There's some people that we might not have recognized were as highrisk as they are."

-Provider, 2020

interviewed said they believed providers' awareness of CVD risk increased as a result of participating in the model. Respondents offered several explanations for this perception. First, organizations calculated risk scores for a larger proportion of their patient panels, so more risk information was available for providers to see. Second, some organizations made the risk-score information, when available, more accessible to their providers. For example, some featured the risk score more prominently in each patient's record in the EHR or gave their providers a written document with the patient's risk score before a visit. In addition, in some cases, providers were themselves newly calculating the risk scores during the patient's visit.

C. Providers' use of risk scores to guide preventive care



CMS envisioned that as part of the cardiovascular care management provided to high-risk beneficiaries, participating organizations would document the beneficiary's risk score, changes in the risk score, and the care team's recommendation for preventive care services. Furthermore,

organizations would help beneficiaries understand their cardiovascular risk and treatment options. In this section, we discuss how intervention group providers used CVD risk scores to guide care. We also discuss **"I prioritize medications because lifestyle changes are so hard. Per**

beneficiaries' perceptions of risk discussions.

"I prioritize medications because lifestyle changes are so hard. People are ... not going to change very often."

-Provider, 2020

Providers credited the model with increasing their use of risk scores to guide treatment

recommendations. In 2018, three-quarters of intervention group providers surveyed said the model changed how they used CVD risk scores to inform clinical care. Interviews with intervention group providers from 2018 to 2021 supported these findings and provided context. For example, providers said seeing the risk score prompted them to address uncontrolled risk factors newly or more aggressively. Several providers noted they focused on medication and smoking cessation in particular because the risk score calculator showed these interventions

could reduce CVD risk substantially. Providers also reported recommending changes to diet and exercise, although they perceived beneficiaries faced challenges implementing or maintaining recommended diet and exercise changes.

Providers used risk scores to guide discussions with beneficiaries about CVD risk and managing risk factors. More than three-quarters of intervention group providers surveyed in 2018 noted the model changed the extent to which they used the risk scores to cue discussions with beneficiaries. Most (71 percent) also reported risk scores were valuable for engaging beneficiaries in managing their risk factors. In interviews from 2018 to 2021, providers gave examples of how they perceived these conversations increased beneficiaries' awareness of CVD risk and motivated beneficiaries to consider medication or lifestyle changes. For example, some beneficiaries who had resisted statins in the past agreed to start taking them. Nevertheless, several providers across the years of interviews noted that discussing the specific risk score could be overwhelming or difficult for some beneficiaries to understand or prioritize.

Largely consistent with providers' perceptions, high-risk beneficiaries recalled discussing CVD risk and how to reduce their individual risk factors. In 2021 we interviewed 14 highrisk beneficiaries enrolled in the Million Hearts Model, referred to the evaluation team by 10 intervention organizations (Appendix C). All of the beneficiaries interviewed recalled discussing CVD risk and risk factors with their Million Hearts Model providers. One beneficiary specifically recalled the provider calculating and discussing the risk score during a visit. Most beneficiaries described making changes to reduce CVD risk factors as recommended by their model providers, such as changing medication use and diet. More than half of beneficiaries said they felt involved in decisions about addressing their CVD risk. For example, they mentioned their providers communicated effectively and took their preferences or personal situations into account when recommending lifestyle or medication changes. These findings were generally consistent with model expectations that participating providers would discuss CVD risk with their enrolled high-risk beneficiaries and engage in a shared decision-making process to reduce risk. Beneficiaries recalled discussing ways to reduce their risk, and many also noted their providers had encouraged medications and changes to diet and exercise for a long time-making it unclear whether the model prompted these recommendations or if this was just usual care.

D. Trends in follow-up and annual risk reassessment

Model participants were supposed to provide ongoing care to high-risk beneficiaries with the goal of reducing their CVD risk (text box). This section discusses the extent to which the model promoted sustained engagement with high-risk beneficiaries.



The model appears to have modestly increased rates of follow-up with high-risk beneficiaries. As of 2018, both

intervention and control group providers reported frequent follow-ups with high-risk beneficiaries. More than 80 percent of intervention and control group providers reported following up (for example, through office visits, telephone calls, emails, or letters) at least every six months, as the model required. However, more intervention group providers reported following up with high-risk beneficiaries even *more frequently* than the model required—at least every three months—compared to control group providers (58 versus 43 percent, [p = 0.02]). Interviews with intervention group providers in 2019 and 2020 indicated many organizations used dedicated staff and tracking

Million Hearts Model requirements for high-risk beneficiaries

Intervention organizations had to update CVD risk scores annually with updated clinical data. The annual risk reassessment was supposed to happen in person each year within a 10- to 14-month window of the enrollment visit.

Intervention organizations also had to engage high-risk Medicare FFS beneficiaries twice a year in interactive, two-way communications to assess the beneficiary's progress reducing CVD risk and update the care plan. Follow-up contacts could be conducted in person or remotely (such as by phone, mobile device, or secure electronic patient portal.)

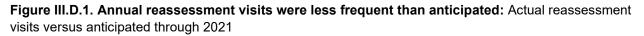
systems, such as EHR alerts and Excel-based trackers, to ensure high-risk beneficiaries received follow-up. Follow-up most often occurred in person, but providers also used phone calls and text or portal messages to conduct follow-up.

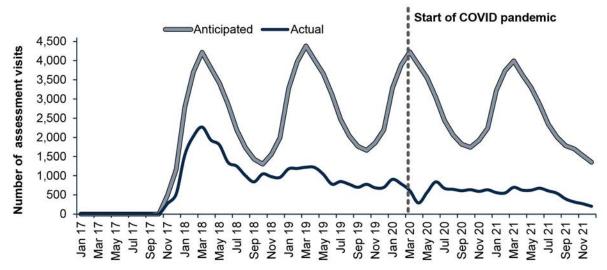


Intervention organizations reassessed risk but fell short of the model target of reassessing each high-risk beneficiary annually. The Million Hearts Model sought to incentivize providers to reassess high-risk beneficiaries' risk each year and reward organizations that reduced CVD risk

on average across their high-risk beneficiaries. However, the number of reassessment visits for high-risk beneficiaries reported in the registry fell below the anticipated level in 2018 and decreased over time (Figure III.D.1). Given that initial enrollment into the model was highest in the early months of 2017 (soon after the model launch) and that reassessment visits were supposed to occur in a 10- to 14-month window every year after enrollment, we would anticipate a large number of annual reassessment visits during the spring of each model year (grey line in Figure III.D.1). Actual reassessment visits reported to the registry did not follow this pattern closely (black line). Two factors could explain the observed pattern of organizations dropping out of the model: (1) organizations failing to upload data to the registry for reassessment visits that occurred; or (2) general challenges implementing the model's requirements related to conducting reassessments, such as competing priorities (especially during the COVID-19 pandemic) or difficulty tracking beneficiaries for follow-up.

Although it is possible organizations reassessed risk without reporting it to the registry, the survey of intervention organizations in 2021 also suggested reassessments occurred less often than specified by the model. In the survey, about one-quarter of intervention organizations reported recalculating risk annually for 75 to 100 percent of their high-risk beneficiaries. Another one-quarter said they recalculated risk annually for 50 to 75 percent of their high-risk beneficiaries. The remaining organizations said they reassessed risk for fewer than half of their beneficiaries or did not know.





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 beneficiaries 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 of the <u>Fourth Annual Report</u> provides details.



Annual reassessment of risk likely did not occur using the Million Hearts ASCVD Risk Assessment Tool, developed specifically for the model. CMS worked with leading cardiovascular epidemiologists to develop this novel longitudinal risk calculator and then used it to calculate the model's pay-for-performance incentive

payments. The tool calculates CVD risk at the initial assessment 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. CMS used the second of these features to calculate the model's risk reduction payments. Although

"I think having more of the longitudinal risk calculator available in an easier fashion, that would be way more helpful. That's always been frustrating to me ... going to an outside web portal."

– Provider, 2020

most intervention organizations interviewed had a risk calculator available at the point of care, interviews suggested intervention group providers were not, at the point of care, using the longitudinal version of the risk calculator developed for the model. Intervention organizations could access the longitudinal version in the Million Hearts Data Registry. However, providers noted it was too burdensome to access the tool within the registry during the patient's visit.

Because organizations lacked access to the tool during the visit, organization staff likely could not monitor progress on the risk-reduction measure CMS incentivized for payment during the visit. Use of the longitudinal calculator at the point of care does not appear to be a major driver of the observed impacts on beneficiaries' outcomes.

IV. Increases in CVD Medication Use One Year After Enrollment



Key findings

- Among beneficiaries who were candidates for statin therapy because their CVD risk at enrollment was high enough and their cholesterol was not well managed (LDL cholesterol was 70 mg/dL or higher), the Million Hearts Model increased the rate of initiating or intensifying statins by 3.5 percentage points (a 23 percent relative increase) within one year of enrollment.
 - 18.5 percent initiated or intensified statins within one year in the intervention group, compared to 15.0 percent in the control group (p < 0.001).
- Among beneficiaries with systolic blood pressure levels above the threshold for treatment at baseline, the Million Hearts Model increased the rate of initiating or intensifying antihypertensives by 2.4 percentage points (a 9 percent relative increase) within one year of enrollment.
 - 29.4 percent initiated or intensified antihypertensives within one year in the intervention group, compared to 27.0 percent in the control group, (p < 0.001).
- The model did not measurably increase adherence to statins or antihypertensives among beneficiaries who used these medications at baseline.
- The model increased aspirin use by 10.7 percentage points (a 20 percent relative increase) among high-risk beneficiaries by the time of their one-year reassessment visit.

This chapter describes our estimates of the Million Hearts Model's impacts on CVD medication use, including statins, antihypertensives, and aspirin, within one year of enrollment. The model did not prescribe how providers should reduce beneficiaries' CVD risk, and there were many options—such as improvements in diet, exercise, or smoking cessation, and/or medication use—one could pursue to lower CVD risk. However, we focus on CVD medication use as that is the approach for which we have the most reliable data, for both the intervention and control group. Moreover, we focus on the impacts over one year because we anticipated the model would have the greatest impact on these outcomes in the year after beneficiaries enrolled.

Because all high- and medium-risk beneficiaries had at least a 15 percent predicted risk at enrollment of a CVD event (the cutoff for the medium-risk group), many could have potentially benefited 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 LDL cholesterol of 70 mg/dL or higher consider statins if they have a CVD risk score over 7.5 percent or have diabetes, and that people with elevated systolic blood pressure (130 mmHg or higher) consider antihypertensive medications if their CVD risk score is over 10.0 percent (Grundy et al. 2018; Whelton et al. 2019; 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; U.S. Preventive Services Task Force 2022b).

Aspirin use can also reduce CVD events by about 12 percent (Dehmer 2022). More recent guidelines (2022) do not recommend aspirin use for primary prevention among adults 60 and older due to risks of bleeding (U.S. Preventive Services Task Force 2022a). However, during the period of the model (2017 through 2021) aspirin was recommended for people younger than 70 with elevated CVD risk (more than 10 percent) (Bibbins-Domingo 2016; Arnett et al. 2019).

The population in this chapter's analyses already used statins and antihypertensives at relatively high rates at baseline, as described in <u>Chapter II</u>. Most high- and medium-risk beneficiaries with Part D coverage used statins and antihypertensives at baseline (63 and 83 percent, respectively), and among high-risk beneficiaries (for whom data on aspirin use were available) close to 50 percent used aspirin. However, room for improvement remained. In particular, about 90 percent of high- or medium-risk beneficiaries were candidates to initiate or intensify statins or antihypertensives because they met clinical criteria for new or more intensive use of at least one.

We estimated impacts as the regressionadjusted differences in outcomes (text box) for high- and medium-risk beneficiaries enrolled by the intervention and control organizations in 2017 and 2018. Appendix D defines the analytic populations used for impact estimation for all outcomes in this report. Details on the balance (that is, the similarity in baseline characteristics) between the intervention and control groups used for analysis are available in Appendix E and definitions of outcomes are in Appendix F. The regression models adjusted for beneficiaries' characteristics at enrollment to increase the precision of the estimates and to account for observed differences between the groups. We consider an impact estimate to be statistically significant if the *p*-value was less than 0.10 using a two-tailed test. Appendix G provides details on the regression methods and Appendix H provides supplemental results.

Initiation or intensification outcome definitions

Initiation: Not taking a medication in the four months before enrollment, but taking one or more within the first year after enrollment

Intensification of statin therapy: Moving to a statin at a higher intensity or dosage within the first year after enrollment

Intensification of antihypertensive therapy: Adding a new antihypertensive medication or increasing the dosage of an existing one within the first year after enrollment

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 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; Tamargo et al. 2019), we consider a beneficiary to be adherent to a medication in the first year of enrollment if the proportion of days covered is 80 percent or higher.

A. Increases in statin use



We assessed whether the Million Hearts Model increased the initiation and intensification of statins or increased adherence to statins within the first year of enrollment. We defined the study population as high- and medium-risk beneficiaries enrolled in 2017 or 2018 who had Medicare Part D coverage, enabling us to observe medication use in claims, and who were (1) candidates for initiation or intensification

of statins because they had LDL cholesterol of 70 mg/dL or higher or (2) eligible to be tracked for medication adherence because they used statins at baseline. About 68 percent of all high- and medium-risk beneficiaries in the model had Part D coverage. Among these, 63 percent used a statin in the year before enrollment.

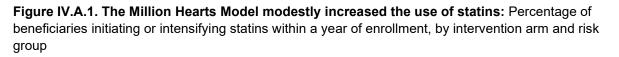
The model increased the initiation or intensification of statins by 3.5 percentage points (a 23 percent relative increase). Specifically, the regression-adjusted probability of initiating or intensifying statins within one year of enrollment was 18.5 percent in the intervention group and 15.0 percent in the control group (p < 0.001). Among beneficiaries with high CVD risk at baseline, we estimated the model increased rates of statin initiation or intensification by 4.9

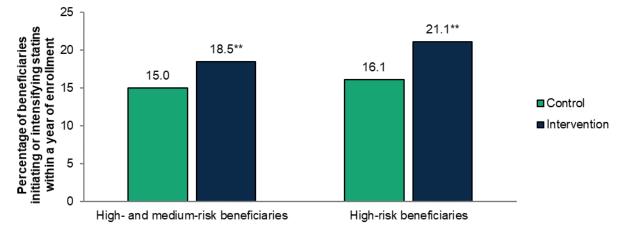
percentage points within one year of enrollment (21.1 percent in the intervention group and 16.1 percent in the control group, p < 0.001; Figure IV.A.1). CMS paid the participating organizations to reduce risk only among high-risk beneficiaries; however, the impact observed for high- and medium-risk beneficiaries combined is large enough to indicate spillover in CVD care to medium-risk beneficiaries. This positive spillover is important because the medium-risk group is much larger than (more than double) the high-risk group. Given the impact within the first year of enrollment, we also examined the model impact across the full follow-up period (through the end of 2021). The first-year difference in the percentage of beneficiaries who had initiated or intensified statins persisted up to five years (<u>Appendix H, Figure H.1</u>).

Study population

Analyses of statin initiation or intensification included **114,910 high- and medium-risk beneficiaries** enrolled by the intervention and control organizations in 2017 or 2018 who:

- Had Part D coverage
- Had LDL cholesterol of 70 mg/dL or higher





Sources: Mathematica's analysis of Medicare Part D claims linked to Medicare Parts A and B claims and enrollment data

Note: Analyses are limited to beneficiaries with Part D coverage and LDL cholesterol at enrollment of ≥ 70 mg/dL. We estimated regression-adjusted means using logistic regression models. <u>Appendix H, Table H.1</u> presents regression-adjusted means, impact estimates, sample sizes, and confidences intervals.

** Significantly different from the control group level at the 0.05 level, two-tailed test.

LDL = low-density lipoprotein.

The model did not measurably increase adherence to

statins. For high- and medium-risk beneficiaries who took statins at enrollment, the regression-adjusted percentage of beneficiaries with at least 80 percent of days covered by statins in the first year after enrollment was similar for the intervention and control groups (Figure IV.A.2). Moreover, the difference between the two groups did not differ statistically from zero (p = 0.31; <u>Appendix H, Table H.2</u>). Statin adherence at baseline was relatively high, with 70 percent of high- and medium-risk beneficiaries covered for at least 80 percent of days in the one year before enrollment. This level of baseline adherence left somewhat modest room for improvement (<u>Appendix E, Table E.1</u>).

Study population

Analyses of statin adherence included **89,970 high- and medium-risk beneficiaries** enrolled by the intervention and control organizations in 2017 or 2018 who:

- Had Part D coverage
- Filled a statin prescription in the one year before enrollment

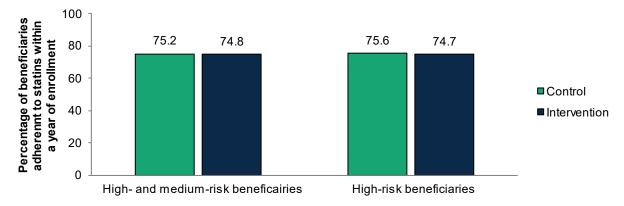


Figure IV.A.2. The Million Hearts Model did not affect adherence to statins: Percentage of high- and medium-risk beneficiaries adherent to statins in the first year after enrollment, by intervention arm

Sources: Mathematica's analysis of Medicare Part D claims linked to Medicare Parts A and B claims and enrollment data.

Note: Adherent beneficiaries are those who filled prescriptions to cover at least 80 percent of days in the followup year. Analyses are limited to beneficiaries with Part D coverage and statin use at enrollment. We estimated regression-adjusted means using logistic regression models. No differences between the intervention and control groups were statistically significant at the p < 0.10 level. <u>Appendix H, Table H.2</u> presents regression-adjusted means, impact estimates, sample sizes, and confidences intervals.

We conducted several analyses to assess the sensitivity of our results to possible data limitations and statistical assumptions. For the analyses of initiation and intensification of statins, results were consistent with findings from two sensitivity analyses, increasing our confidence in them. Specifically, impacts were similar when trimming the intervention group so that, like in the control group (as described in <u>Chapter I</u>), a maximum of 20 providers per organization could enroll beneficiaries. Similarly, the estimated impacts on adherence to statins were also largely consistent with findings from sensitivity analyses that (1) trimmed the intervention group to a maximum 20 providers; and (2) defined the intervention and control groups as beneficiaries attributed to the participating providers, whether or not those beneficiaries had enrolled in the model. This latter sensitivity analysis limited the possibility that intervention and control providers biased the impact estimates by differing in the types of beneficiaries enrolled among their eligible pool of beneficiaries. <u>Appendix H</u> describes the sensitivity analyses and results in more detail.

B. Increases in antihypertensive medication use



We assessed whether the Million Hearts Model increased the initiation and intensification of antihypertensives or increased adherence to antihypertensives within the first year after enrollment. Similar to the statin analyses, we defined the study population as high- and medium-risk beneficiaries enrolled in 2017 or 2018 who had Part D coverage, enabling us to observe medication use in claims, and who were

(1) candidates for initiation or intensification of antihypertensives because they had elevated systolic blood pressure (130 mmHg or higher) or (2) were eligible to be tracked for medication

adherence because they used antihypertensives at enrollment. Among high- and medium-risk beneficiaries with Part D coverage, 83 percent used an antihypertensive medication in the year before enrollment.

The model increased the initiation or intensification of antihypertensive medications by 2.4 percentage points

(a 9 percent relative increase). Specifically, the regression-adjusted probability of initiating or intensifying antihypertensives within one year of enrollment was 29.4 percent in the intervention group and 27.0 percent in the control group (p < 0.001). The estimated impact on initiating or intensifying antihypertensives was similar (also 2.4 percentage points) when we focused on the subset of beneficiaries with high CVD risk at baseline (Figure IV.B.1). When examining the model impact throughout the full follow-up period, we found differences in initiation and intensification between

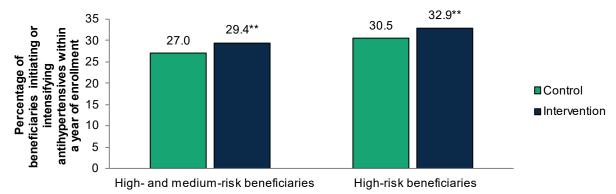
Study population

Analyses of antihypertensive initiation or intensification included **89,569 high- and medium-risk beneficiaries** enrolled by the intervention and control organizations in 2017 or 2018 who:

- Had Part D coverage
- Had elevated systolic blood pressure (130 mmHg or higher)

the two groups persisted up to five years (<u>Appendix H, Figure H.2</u>). As with analyses of statin use, results were consistent across sensitivity analyses. These included a sensitivity analysis 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.

Figure IV.B.1. The Million Hearts Model modestly increased the use of antihypertensives: Percentage of beneficiaries initiating or intensifying antihypertensives within a year of enrollment, by intervention arm and risk group



Sources: Mathematica's analysis of Medicare Part D claims linked to Medicare Parts A and B claims and enrollment data.

Note: Analyses are limited to beneficiaries with Part D coverage and systolic blood pressure at enrollment ≥ 130 mmHg. We estimated regression-adjusted means using logistic regression models. <u>Appendix H, Table H.4</u> presents regression-adjusted means, impact estimates, sample sizes, and confidences intervals.

** Significantly different from the control group level at the 0.05 level, two-tailed test.

The model did not measurably increase adherence

to antihypertensives. For high- and medium-risk beneficiaries who used antihypertensive medications at enrollment, the regression-adjusted percentage of beneficiaries with at least 80 percent of days covered by antihypertensives in the first year after enrollment was similar for the intervention and control groups (Figure IV.B.2) and the difference between the two groups was small and did not differ statistically from zero (p = 0.85; <u>Appendix H, Table H.5</u>). As with analyses of statin use, results were consistent across sensitivity analyses. Similar to statin adherence, given that 84 percent of beneficiaries taking

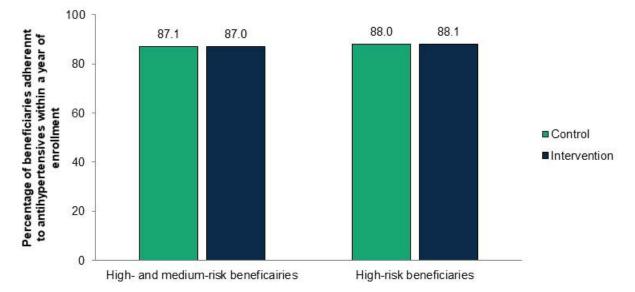
Study population

Analyses of antihypertensive adherence included **116,057 high and medium-risk beneficiaries** enrolled by the intervention and control organizations in 2017 or 2018 who:

- Had Part D coverage
- Filled an antihypertensive prescription in the one year before enrollment

antihypertensives already adhered for at least 80 percent of days in the one year before enrollment, the room for improvement in adherence after enrollment might have been limited (Appendix E, Table E.1).

Figure IV.B.2. The Million Hearts Model did not affect adherence to antihypertensives: Percentage of high- and medium-risk beneficiaries adherent to antihypertensives in the first year after enrollment, by intervention arm



Sources: Mathematica's analysis of Medicare Part D claims linked to Medicare Parts A and B claims and enrollment data.

Note: Adherent beneficiaries are those who filled prescriptions to cover at least 80 percent of days in the followup year. Analyses are limited to beneficiaries with Part D coverage and antihypertensive use at baseline. We estimated regression-adjusted means using logistic regression models. No differences between the intervention and control groups were statistically significant at the p < 0.10 level. <u>Appendix H, Table H.5</u> presents regression-adjusted means, impact estimates, sample sizes, and confidences intervals.

C. Increases in aspirin use



We estimated impacts on aspirin use one year after enrollment among highrisk beneficiaries who received an annual reassessment visit. Roughly half

of beneficiaries who could have received an inperson reassessment had at least one such visit recorded in the Million Hearts Data Registry.

Study population

Analyses of aspirin use included **28,343 high-risk beneficiaries** enrolled by the intervention and control organizations who received an annual reassessment visit recorded in the Million Hearts Data Registry.

The model increased aspirin use by 10.7 percentage points (a 20 percent relative increase) by the first annual reassessment. At the time of the one-year reassessment visits, intervention organizations reported that 65 percent of high-risk beneficiaries used aspirin compared to 54 percent of control-group high-risk beneficiaries, despite similar levels of aspirin use at enrollment (p = 0.002; Figure IV.C.1). Intervention organizations were required to submit reassessment data to the Million Hearts Data Registry only for their high-risk beneficiaries, so we cannot assess whether aspirin rates also increased for medium-risk beneficiaries. (Aspirin purchases are not observable in Medicare Part D claims because aspirin is an over-the-counter drug.)

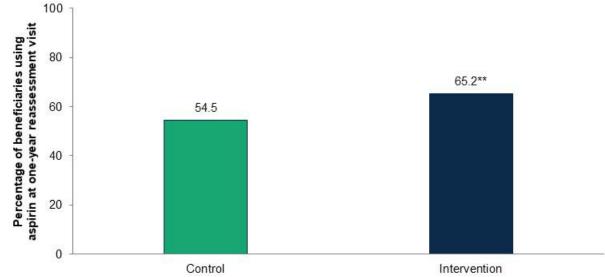


Figure IV.C.1. The Million Hearts Model increased aspirin use: Percentage of high-risk beneficiaries using aspirin therapy at one-year reassessment visits, by intervention arm

Sources: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare Parts A and B claims and enrollment data.

Note: Analyses are limited to beneficiaries who received an annual reassessment visit recorded in the Million Hearts Data Registry, including 18,101 beneficiaries enrolled in 125 intervention organizations and 10,242 beneficiaries enrolled in 110 control organizations. We estimated regression-adjusted means using logistic regression models. No differences between the intervention and control groups were statistically significant at the p < 0.10 level. Appendix H, Table H.7 presents impact estimates, and confidences intervals.

** Significantly different from the control group level at the 0.05 level, two-tailed test.

V. Decreases in CVD Risk Factors and Risk Scores One Year After Enrollment



- The Million Hearts Model reduced CVD risk scores by 4.0 percent for high-risk beneficiaries in the first year after enrollment.
 - CVD risk scores decreased for high-risk beneficiaries in both the intervention and control groups, but the decrease was 1.3 percentage points (4.0 percent) larger in the intervention group (*p* < 0.001).
- Reductions in CVD risk scores in the first year after enrollment were driven by 1.3 percent reductions relative to the control group in both systolic blood pressure and LDL cholesterol, as well as an increase in aspirin use described in <u>Chapter IV</u>.
 - Systolic blood pressure and LDL cholesterol decreased in both the intervention and control groups, but these risk factors decreased by more in the intervention group.
 - Modest (1.3 percent) reductions in systolic blood pressure and LDL cholesterol can drive larger (4 percent) reductions in CVD risk scores due to the outsized influence of some risk factors especially blood pressure—on the overall CVD risk score.
- We did not detect impacts on HDL cholesterol or smoking rates.

A. Reductions in overall CVD risk scores



About half of the beneficiaries who should have received an annual reassessment visit under the Million Hearts Model had one recorded in the

Million Hearts Data Registry. Among those with a recorded annual reassessment visit, we estimated impacts on CVD risk scores—as measured using the Million Hearts Longitudinal ASCVD Risk Assessment Tool—one year after enrollment.

Average CVD risk scores at reassessment were 1.3 percentage points (4.0 percent) lower in the intervention group than the control group

(Table V.A.1). CVD risk decreased between the initial assessment and the one-year reassessment in both the intervention and control groups, on average. However, these risk scores decreased by

Study population

Analyses of CVD risk scores and risk factors included **28,343 high-risk beneficiaries** enrolled by the intervention and control organizations who had the following characteristics:

- Received an annual reassessment visit recorded in the Million Hearts Data Registry by December 2019 (the last period of control group data submission)
- Enrolled by October 31, 2018, which was early enough that their anniversary window for a reassessment visit (10 to 14 months after baseline) occurred by December 2019

modestly more in the intervention group than the control group. Specifically, average risk scores in the intervention group fell from 40 percent at enrollment to 32 percent at reassessment (an 8 percentage-point decrease), while average risk scores in the control group fell from 40 to 33 percent (a 7 percentage-point decrease). After regression adjustment, the average CVD risk score at reassessment in the intervention group was 1.3 percentage points lower than in the control group (p < 0.001). The estimated impact of the intervention on CVD risk scores (text box) remained similar in sensitivity analyses 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, excluding beneficiaries with late reassessment visits (<u>Appendix H</u>).

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 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 (if applicable), 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 using aspirin therapy, quitting smoking, and reducing blood pressure or cholesterol would change a person's CVD risk. The tool then uses this information, along with updated data about age, diabetes status, and other factors used in calculating the initial risk score, to generate an updated risk score. CMS used 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.

Table V.A.1. CVD risk scores decreased more for the intervention group than for the controlgroup: Estimated impacts on CVD risk scores and risk factors one year after enrollment, among high-riskbeneficiaries with reassessment data in 2017 through 2019

			-				
				Regression-adjusted difference at reassessment			
	Visit	Intervention group mean	Control group mean	Difference	<i>p</i> - value	90% confidence interval	Percentage impact
CVD risk score							
CVD risk score (in percentage points)	Enrollment ^a	40	40				
	Reassessment	32	33	-1.3	<0.001	[-1.9, -0.8]	-4.0%
Individual risk fa	actors						
Systolic blood pressure (in mmHg)	Enrollment ^a	139	139				
	Reassessment	133	135	-1.7	<0.001	[-2.5, -1.0]	-1.3%
Total cholesterol (in mg/dL)	Enrollment ^a	167	169				
	Reassessment	162	163	-1.7	0.002	[-2.6, -0.8]	-1.1%
LDL cholesterol (in mg/dL)	Enrollment ^a	91	91				
	Reassessment	87	88	-1.1	0.04	[-2.0, -0.3]	-1.3%
HDL cholesterol (in mg/dL)	Enrollment ^a	47	48				
	Reassessment	47	47	-0.1	0.29	[-0.3, 0.1]	-0.3%
Probability of smoking ^b	Enrollment ^a	12	12				
	Reassessment	11	10	0.4	0.25	[-0.2, 0.9]	3.6%

Sources: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data. Note: This table covers 18,101 beneficiaries enrolled in 125 intervention organizations and 10,242 beneficiaries

enrolled in 110 control organizations. Control group 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 Enrollment means shown are unadjusted.

^b Smoking estimates exclude one control organization (n = 216 beneficiaries) with likely poor data quality. 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.

B. Improvements in individual CVD risk factors

Increases in aspirin use and reductions in systolic blood pressure and LDL cholesterol drove the overall reductions in CVD risk scores. Systolic blood pressure and LDL cholesterol declined in both the intervention and control groups in the year after enrollment, which drove reductions in CVD risk scores in both groups (Table V.A.1); however, the improvements in risk factors were greater in the intervention group than in the control group, which drove the difference in CVD risk scores at reassessment between the two groups. Specifically, systolic blood pressure decreased by 6 mmHg in the intervention group and 5 mmHg in the control group,³ with a regression-adjusted difference between the intervention and control groups at reassessment of 1.7 mmHg, or 1.3 percent (p < 0.001). LDL cholesterol decreased by 5 mg/dL in the intervention group⁴ and 3 mg/dL in the control group, with a regression-adjusted difference between the intervention and control groups of 1.1 mg/dL, or 1.3 percent (p = 0.04). Although improvements in systolic blood pressure and LDL cholesterol were only slightly greater in the intervention group than in the control group, these risk factors (particularly blood pressure) have outsized importance for CVD risk—so even very small impacts on them (of 1.3 percent) can explain most of the 4.0 percent impact we observed on overall CVD risk scores one year after enrollment. The impact on aspirin shown in Chapter IV also contributed. We found no evidence of an impact on HDL cholesterol or on smoking rates among the 12 percent of beneficiaries with reassessment visit data who smoked at enrollment.

We did not assess impacts on CVD risk scores and risk factors beyond one year after enrollment because the data were too incomplete for the second- and third-year reassessment visits to reliably estimate impacts. For a description of trends in CVD risk score and risk factors over three years after enrollment, see <u>Appendix I</u>.

The analyses in this chapter have several limitations:

First, we do not include medium-risk beneficiaries, and include only the subset of high-risk beneficiaries who had reassessment data recorded in the Million Hearts Data Registry. Although we see signs of spillover to the medium-risk population when we analyze medication use (Chapter IV), we cannot assess impacts on CVD risk scores or risk factors for that population because intervention organizations had to submit reassessment data in the Million Hearts Data Registry only for their high-risk beneficiaries. Within the high-risk population, our analyses include only those beneficiaries whose organization recorded an office visit in the Million Hearts Data Registry at least 10 months after enrollment, with appropriate clinical data needed to calculate an updated CVD risk score. As noted in Chapter II, a substantial number of organizations withdrew from the model or stopped submitting registry data by the end of 2019, so we do not have clinical data at reassessment for their

³ Unadjusted changes for the control group cannot be directly calculated from Table V.A.1, which shows unadjusted means at enrollment and adjusted control group means at reassessment.

⁴ This number is equal to the change between enrollment and reassessment presented in Table V.A.1 after rounding (91.498 mg/dL - 86.575 mg/dL = 5 mg/dL)

beneficiaries. Overall, reassessment rates were somewhat higher in the intervention group (51 percent) than the control group (43 percent). 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 E).

- 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. In addition, organizations were allowed to enter prior cholesterol readings (up to five years old) in the Million Hearts Data Registry, which might not have reflected current levels. These types of measurement error could lead to bias in the impact estimates if measurement error differs between the intervention and control groups. We have no evidence about measurement error for blood pressure. However, we found intervention beneficiaries were more likely to have updated cholesterol readings at reassessment than control beneficiaries (93 versus 76 percent, respectively).⁵ This suggests the completeness and quality of CVD risk factor data could be higher for the intervention group than the control group, potentially affecting our impact estimates.
- 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 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. In <u>Chapter VII</u>, we estimate impacts on the incidence of first-time CVD events directly.

⁵ 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—HDL, 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.

VI. Effects on Service Use



- Over five years, the Million Hearts Model did not measurably reduce rates of CVD-related hospitalizations and outpatient ED visits.
- The model *increased* all-cause hospitalizations by about 4 percent among high- and medium-risk beneficiaries
- The model had no detectable impact on the frequency of ED visits or office visits among high- and medium-risk beneficiaries, but increased all-cause ED visits among the high-risk-only group by about 3 percent.

We hypothesized the Million Hearts Model could reduce hospitalizations and outpatient ED visits for CVD-related reasons. These types of hospital visits or stays include acute care for heart attacks and strokes, as well as for other conditions such as angina. Better management of CVD risk factors might have reduced visits or stays for angina and other conditions even before the model had its impacts, if any, on heart attacks and strokes. In this chapter, we test this hypothesis by estimating impacts on (1) CVD-related hospitalizations and (2) CVD-related ED visits (including observation stays). In addition, we estimate impacts on (3) all-cause hospitalizations, (4) all-cause ED visits, and (5) ambulatory office visits as secondary outcomes. The model could have affected these secondary measures through effects on CVD-related service use and through other, unanticipated effects on non-CVD related service use. <u>Appendix F</u> describes the outcomes in more detail.

We estimated impacts on service use over up to five years. The study population included beneficiaries enrolled in 2017 or 2018 and who had high or medium CVD risk at enrollment (Appendix D). The analysis followed each beneficiary from the date they enrolled in the model through December 31, 2021, or until death or loss of observability in Medicare claims. Follow-up lengths ranged from one day to just under 60 months across beneficiaries, with a median of 51.6 months. Appendix E describes baseline characteristics of the intervention and control group beneficiaries and Appendix G describes the regression methods used in this analysis.

We assessed whether the COVID-19 pandemic might bias our impact estimates and found little risk that it would. In 2020 and 2021, the pandemic could have biased our impact estimates if it drove differences in outcomes between the intervention and control groups that were unrelated to the model. Although the COVID-19 pandemic substantially changed service use patterns, changes were similar in the areas where the intervention and control beneficiaries lived, suggesting little risk of bias due to the COVID-19 pandemic. <u>Appendix J</u> describes our methods and findings for assessing bias risk from COVID-19 in detail.

A. Impacts on hospitalizations and ED visits



CVD-related hospitalization and outpatient ED visit rates were similar between the intervention and control groups (Table VI.A.1). Through December 2021, there were 56.0 CVD-related hospitalizations per 1,000 high- and medium-risk beneficiaries per year in the intervention group, compared to a rate of 55.2 for the control group

(p = 0.48). The intervention and control groups had rates of 31.6 and 31.5 CVD-related ED visits per beneficiary per year, respectively, over the same period. Focusing on the high-risk group, rates of CVD-related hospitalization and outpatient ED visits were modestly (3.1 percent) higher in the intervention group than the control group, but these differences were not statistically significant (p = 0.21 and p = 0.41 for hospitalizations and ED visits, respectively). CVD-related admissions and ED visits accounted for 22 and 8 percent of all hospitalizations and ED visits, respectively, for the high- and medium-risk beneficiaries.

The model appears to have increased *all-cause* hospital admissions and, for high-risk beneficiaries, also increased all-cause outpatient ED visits (Table VI.A.1). Specifically, the rate of all-cause admissions among the intervention group was 3.7 percent greater for the high-and medium-risk beneficiaries combined (p = 0.005), and 4.1 percent greater for the high-risk beneficiaries (p = 0.02), relative to their respective control beneficiaries. The average number of all-cause outpatient ED visits increased by 2.9 percent for the high-risk beneficiaries (p = 0.09), relative to the control group. Differences in all-cause outpatient ED visits for high- and medium-risk beneficiaries in the intervention and control groups were smaller (2.2 percent) and not statistically significant (p = 0.15).

All the results in Table VI.A.1 were largely similar in the sensitivity analyses reported in <u>Appendix H</u>. These sensitivity analyses (1) trimmed the intervention group so that, as in the control group, a maximum of 20 providers per organization could enroll beneficiaries; (2) controlled for changes in the composition of beneficiaries over time since enrollment to account for any differences in beneficiaries who died or otherwise lost eligibility in the intervention and control groups (for example, due to differences in survival rates); and (3) estimated impacts using beneficiaries we attributed, using claims data, to the intervention and control providers that participated in the model, whether or not those beneficiaries enrolled in the model. This last check avoids the potential for bias stemming from intervention and control group providers differing in who they chose to enroll among their eligible beneficiaries.

The finding that the Million Hearts Model modestly increased acute care service use runs counter to our hypothesis that the model might reduce CVD-related acute care, which would by extension lead to small reductions in all-cause acute care. This finding implies some other factor, which we did not anticipate, explains why the model might have increased acute care use. In exploratory analyses (not presented here), we assessed whether ED visits increased for symptoms that beneficiaries might mistake as signs of a heart attack or stroke. However, we found all types of ED visits increased roughly equally—not only those we considered most plausibly related to CVD symptoms. We cannot rule out the possibility that the estimated impacts are spurious, meaning some factor other than the model made the intervention group systematically more likely than the control group to use acute care services. For example, the types of providers that chose to continue participating in the model after random assignment could have differed systematically. All impact estimates in this report are subject to similar limitations.

Table VI.A.1. Rates of all-cause acute care were higher in the intervention group: Estimated impacts on the number of inpatient admissions and outpatient ED visits including observation stays (number per 1,000 beneficiaries per year)

	Re (#/1		90%				
Outcome and risk group	Intervention group mean	Control group mean	Difference (%)	<i>p</i> -value	confidence interval		
Number of CVD-related	admissions						
High- and medium-risk beneficiaries	56.0	55.2	0.78 (1.4%)	0.48	[-1.0, 2.6]		
High-risk beneficiaries	75.6	73.3	2.30 (3.1%)	0.21	[-0.7, 5.3]		
Number of CVD-related	outpatient ED visi	ts and (observatio	n stays)				
High- and medium-risk beneficiaries	31.6	31.5	0.12 (0.4%)	0.91	[-1.7, 1.9]		
High-risk beneficiaries	38.4	37.2	1.16 (3.1%)	0.41	[-1.2, 3.5]		
Number of all-cause ad	missions						
High- and medium-risk beneficiaries	255.3	246.2	9.05 (3.7%)	0.005	[3.8, 14.3]		
High-risk beneficiaries	309.2	297.0	12.27 (4.1%)	0.02	[3.5, 21.1]		
Number of all-cause outpatient ED visits and observation stays							
High- and medium-risk beneficiaries	386.3	378.1	8.23 (2.2%)	0.15	[-1.1, 17.6]		
High-risk beneficiaries	422.7	410.8	11.92 (2.9%)	0.09	[0.2, 23.6]		

Source: Regression-adjusted results from Medicare claims data.

Note: Table covers 130,578 beneficiaries enrolled in 172 intervention organizations and 88,286 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,423 beneficiaries enrolled in 170 intervention organizations and 27,277 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. See <u>Appendix G</u> for more detail about the regression models.

CVD = cardiovascular disease; ED = emergency department.

B. Impacts on office visits

Intervention and control group beneficiaries had similar rates of ambulatory office visits, including telehealth visits (Table VI.B.1). Given the model's emphasis on follow-up for highrisk beneficiaries, we tested whether the Million Hearts Model changed the rate of outpatient office visits. An increase in office visits might also be consistent with the unanticipated effects observed for hospitalizations and ED visits: for example, if the model prompted providers to offer more intensive services generally to beneficiaries assessed as at high risk. We included telehealth visits in our measure of office visits because telehealth replaced many in-person visits during the COVID-19 public health emergency. However, through December 2021, there were 10,545 office visits per 1,000 high- and medium-risk beneficiaries per year in the intervention group (or just over 10 visits per beneficiary per year), which is similar to the rate of 10,444 visits in the control group. For high-risk beneficiaries, there were 11,312 office visits per 1,000 beneficiaries per year in the intervention group, compared to 11,174 for the control group. Intervention–control differences were not statistically significant for either population. Results were similar in robustness checks, detailed in <u>Appendix H</u>.

Taken together, the results in this chapter indicate a particular pattern of model impacts on service use that we did not anticipate. The Million Hearts Model increased all-cause hospitalizations and, for high-risk beneficiaries only, all-cause outpatient ED visits. These increases were not concentrated in hospital visits for cardiovascular care, or for visits for symptoms that might be easily mistaken for a heart attack or stroke. The model did not increase the frequency of office visits generally, though it might have increased frequency for specific types of visits we did not examine separately. One possible explanation for this pattern is that the model—though immediately focused on CVD risk—might have made providers and beneficiaries more aware of their health risks generally and more attuned to concerning symptoms, leading to longer patient evaluations and a greater chance of identifying something that requires additional care (particularly hospital-level care).

		gression-adjusted ,000 beneficiaries/		90%	
Outcome and risk group	Intervention group mean	Control group mean	Difference (%)	<i>p</i> -value	confidence interval
Office visits					
High- and medium-risk beneficiaries	10,545	10,444	101 (1.0%)	0.29	[-55, 258]
High-risk beneficiaries	11,312	11,174	138 (1.2%)	0.25	[-58, 334]

 Table VI.B.1. The model had no detectable impact on the frequency of office visits, including

 telehealth visits:
 Estimated impacts on office visits (per 1,000 beneficiaries per year)

Source: Regression-adjusted results from Medicare claims data.

Note: Table covers 130,578 beneficiaries enrolled in 172 intervention organizations and 88,286 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,423 beneficiaries enrolled in 170 intervention organizations and 27,277 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. Office visits include in-person and telehealth visits. See <u>Appendix H</u> for sample sizes and more detail about the regression models.

CMS = Centers for Medicare & Medicaid Services.

VII. Effects on Long-Term Outcomes: CVD Events, Mortality, and Medicare Spending



- The model reduced the incidence of first-time heart attacks and strokes among high- and medium-risk beneficiaries over five years.
 - The intervention group had a 3 percent lower risk of a first-time heart attack or stroke than the control group when we looked only at events observed in Medicare claims.
 - The intervention group had a 4 percent lower risk of a first-time heart attack or stroke when we
 used an expanded outcome definition, adding deaths due to coronary heart disease and
 cerebrovascular disease without a corresponding Medicare claim.
 - The findings suggest the model prevented one CVD event over five years for roughly every 250 to 400 high- and medium-risk beneficiaries enrolled, depending on the outcome definition used.
- The model reduced all-cause mortality among high- and medium-risk beneficiaries, with the greatest reductions in percentage terms in coronary heart disease (CHD) and cerebrovascular deaths.
 - The intervention group had a 4 percent lower risk of death from any cause than the control group over five years.
 - The intervention group had 11 percent fewer CHD or cerebrovascular deaths, measured over four years.
- The model had no detectable impact on Medicare spending per beneficiary per month (PBPM).
 - The model did not measurably reduce spending for first-time heart attacks and strokes.
 - Model payments were small: an estimated \$1 per high- and medium-risk beneficiary per month of enrollment.
 - Total Medicare spending PBPM, including model payments, was similar for intervention and control group beneficiaries.

The Million Hearts Model aimed to reduce the incidence of first-time heart attacks and strokes among high- and medium-risk beneficiaries. Further, it aimed to reduce Medicare spending on these events and related care enough to offset model payments. This chapter describes the model's estimated impacts over five years (2017 to 2021) on these two prespecified primary evaluation outcomes—CVD events and Medicare spending—as well as the secondary outcome of mortality, which we also hypothesized might decline.

Our planned analyses at the start of the evaluation included CVD events—that is, first-time heart attacks and strokes, including transient ischemic attacks (TIAs), also known as mini strokes and mortality measured using Medicare claims and enrollment data; however, in the final year of the evaluation, we obtained and incorporated cause-of-death information, based on death certificate data from the NDI (text box next page). Analyses with these additional data enhanced the evaluation in two ways:

1. NDI data enabled us to observe *fatal* CVD events that occurred without generating Medicare claims—for example, because they occurred outside the hospital. These fatal CVD events could represent a substantial number of events, especially in later years of the model during the COVID-19 pandemic. Using claims and NDI data in combination, we created an

Long-term outcomes

- 1. First-time CVD events
 - a. Claims only (prespecified primary outcome)
 - b. Expanded measure with NDI data
- 2. Mortality
 - a. All-cause mortality
 - b. Mortality by cause of death
- 3. Per capita Medicare Parts A and B spending
 - a. Spending on first-time CVD events
 - b. Total spending, without model payments (prespecified primary outcome)
 - c. Total spending, with model payments (prespecified primary outcome)

expanded measure of first-time heart attacks and strokes that includes both first-time CVD events as observed in claims and deaths due to CHD or cerebrovascular disease in the NDI. We defined deaths due to CHD or cerebrovascular disease as deaths with CHD or cerebrovascular disease recorded as the underlying cause of death.

2. NDI data enabled us to better understand model impacts on all-cause mortality by enabling a secondary analysis of model impacts on mortality by cause of death. We classified causes of death into CVD and non-CVD related, and further classified CVD-related deaths as CHD-related deaths, cerebrovascular disease-related deaths, or other CVD deaths based on the underlying cause of death codes obtained from the NDI.⁶ We hypothesized that the largest relative impacts of the model on mortality would concentrate in the CVD-related death categories (in the CHD and cerebrovascular death categories in particular). We restricted the cause-of-death analysis to beneficiaries enrolled early enough to follow up for at least four years to accommodate a statistical method commonly used to analyze causes of death, multinomial logistic regression (see <u>Appendix F, Section F.4</u>).

⁶ Additional details about these outcome variables and other measures used in this chapter are available in <u>Appendix F</u>. The non-CVD death category includes a few deaths of unknown cause that appeared in Medicare enrollment data but not in the NDI (N = 356, less than 2 percent of all deaths during the analysis period); because unknown causes of deaths were not numerous enough to model as a separate category in our regression models, we included them among non-CVD deaths.

National Death Index (NDI) data

- What is the NDI?
 - The NDI is a database of all deaths in the United States, including dates and causes of death, based on information recorded in death certificates.
- Value of NDI data
 - Using cause-of-death data, we can identify fatal heart attacks and strokes that did not generate a Medicare claim.
 - Previous studies suggest a substantial proportion of heart attacks and strokes for Medicare beneficiaries do not generate a claim—as many as one-third to one-half of all heart attacks (Psaty et al. 2016; Colantoni et al. 2018) and up to 70 percent of fatal heart attack and strokes (Xie et al. 2018). This proportion could have been even higher in 2020 and 2021 because, during the COVID-19 pandemic, people were less likely to go the hospital for any reason, including CVD events (Stewart et al. 2021).
 - Including deaths from CHD or cerebrovascular disease in an expanded measure of first-time heart attacks and strokes captured 2,513 additional intervention and control group beneficiaries who died from CHD or cerebrovascular disease by December 2021 but did not have a claim for a first-time CVD event (a 19 percent increase in the rate of the events).
- Limitations of NDI data
 - Diagnosis codes in NDI data contain less detail than those in claims (that is, they are truncated to the first four digits, in comparison to seven digits in the Medicare claims), making it more difficult to identify deaths due to first-time heart attacks and strokes specifically. Because of this, we included all CHD and cerebrovascular deaths, based on a definition widely used in NDI data analyses (Virani et al. 2021).
 - Due to lack of specificity in coding and because death certificates can contain errors, we anticipate our outcome measure based on NDI data will misclassify some non-CVD-related deaths as fatal CVD events (about 15 percent of non-CVD-related deaths) and misclassifies some fatal CVD events as non-CVD related (about 27 percent of true fatal CVD events [Olubowale et al. 2017]).

As in previous chapters, we estimated model 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 (<u>Appendix D</u>). The analysis followed each beneficiary from the date he or she enrolled in the model through December 31, 2021, or until one of the following occurred: (1) death, (2) loss of observability in Medicare claims (only when analyzing first-time CVD events and Medicare spending), or (3) a CVD event (only when analyzing first-time CVD events). Follow-up lengths ranged from one day to just under 60 months across beneficiaries, with a median of 51 to 54 months, depending on the outcome. <u>Appendix E</u> describes baseline characteristics of the intervention and control group beneficiaries and <u>Appendix G</u> describes the regression methods used in this analysis.

A. Effects on the incidence of heart attacks and strokes



The model reduced the incidence of first-time heart attacks and strokes by 3 to 4 percent among high- and medium-risk beneficiaries (Table VII.A.1). Using a claims-based measure of first-time heart attacks, strokes, and TIAs (a composite measure of CVD events), about 8 percent of

beneficiaries experienced an event within five years of enrollment (Figure VII.A.1). The hazard ratio indicating relative risk of first-time CVD events was 0.97—or 3.3 percent lower in the intervention group than in the control group (from Figure VII.A.1, [8.1–7.8]/8.1 \approx 0.033; the calculation is not exact due to rounding). This estimate suggests that one first-time CVD event was prevented over five years for every 391 high- and medium-risk beneficiaries enrolled in the model.

For the CVD-event outcome definition that adds deaths due to CHD and cerebrovascular disease (but which did not generate a claim), 9 to 10 percent experienced an event within five years of enrollment (Figure VII.A.2) the hazard ratio for high- and medium-risk beneficiaries was 0.96—suggesting a 4.2 percent lower risk of first-time CVD events among intervention beneficiaries ($[9.7-9.3]/9.7 \approx 0.042$). This corresponds to one event prevented over five years for every 267 high- and medium-beneficiaries beneficiaries enrolled. The estimated hazard ratio was further from 1.00 with the expanded measure (0.96) than with the claims-based measure (0.97), suggesting that including fatal CVD events that did not generate Medicare claims (in the expanded measure) was important for capturing the full impact of the Million Hearts Model.

For the high-risk group alone, the hazard ratio was close to 1.00 using both outcome definitions, indicating no detectable model effect. This finding might seem counterintuitive, given the model required follow-up only for the high-risk beneficiaries and made cardiovascular care management and risk reduction payments only for the high-risk population. There are two plausible explanations. First, it is possible the initial risk assessment was especially helpful for providers to identify beneficiaries with medium risk. In particular, if providers could recognize beneficiaries with high risk based on their risk factors alone, even without calculating a risk score, it is possible high-risk beneficiaries received CVD primary preventive care under care as usual in the control group. This would leave little room for the model to improve outcomes for the high-risk group. Second, it is possible the model did reduce incidence of first-time heart attacks and strokes among high-risk beneficiaries, but we lacked statistical power to detect model impacts. This explanation would be consistent with the impacts described earlier on intermediate outcomes of CVD medication use, risk scores, and risk factors.

	Projected probability of outcome within 5 years of enrollment ^a			Hazard ratio			
Outcome and risk group	Intervention mean	Control mean	Estimate	<i>p</i> -value	90% confidence interval		
First-time heart attacks, st	rokes, or TIAs (C	CVD events), ir	ו claims data alon	e ^b			
High- and medium-risk beneficiaries	7.8%	8.1%	0.97	0.09	[0.93, 1.00]		
High-risk beneficiaries	10.6%	10.7%	0.99	0.63	[0.94, 1.03]		
First-time heart attacks, in claims data alone							
High- and medium-risk beneficiaries	3.4%	3.5%	0.99	0.68	[0.93, 1.04]		
High-risk beneficiaries	4.7%	4.8%	0.99	0.89	[0.92, 1.07]		
First-time strokes or TIAs, in claims data alone							
High- and medium-risk beneficiaries	4.8%	5.0%	0.96	0.07	[0.92, 1.00]		
High-risk beneficiaries	6.4%	6.4%	1.00	0.98	[0.94, 1.06]		
First-time heart attack, stroke, or TIA or death due to CHD or cerebrovascular disease (expanded measure) ^c							
High- and medium-risk beneficiaries	9.3%	9.7%	0.96	0.02	[0.93, 0.99]		
High-risk beneficiaries	12.7%	12.9%	0.98	0.45	[0.94, 1.02]		

Table VII.A.1. The model reduced the incidence of first-time CVD events: Estimated ratio of the hazard of first-time CVD events between intervention and control beneficiaries (regression-adjusted)

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

Note: Table VII.A.1 covers 130,578 beneficiaries enrolled in 172 intervention organizations and 88,286 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,423 beneficiaries enrolled in 170 intervention organizations and 27,277 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores of 30 percent or higher.

^a The reported probability is defined as 1 minus the average Cox proportional-hazards model estimate of the survival function. The survival function gives the probability that a beneficiary did not die within 1,823 days after enrollment.

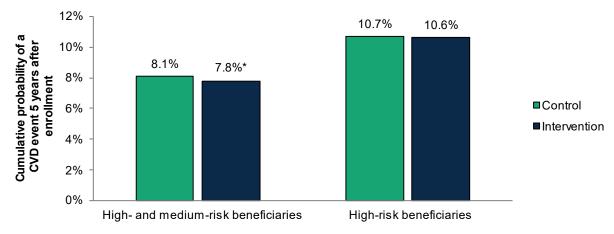
^b Heart attacks, strokes, TIAs, or stroke symptoms are identified as (1) a primary diagnosis on outpatient ED claim or inpatient claim or (2) a secondary diagnosis on an inpatient claim when the condition was listed as not present on admission. <u>Appendix F</u> describes the outcomes in detail. For heart attacks, we include all five types of acute myocardial infarctions described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

^c Beneficiaries with a first-time heart attack or stroke, including TIA, based on Medicare claims or who died due to CHD or cerebrovascular disease based on NDI data.

CHD = coronary heart disease; CVD = cardiovascular disease; ED = emergency department; NDI = National Death Index; TIA = transient ischemic attack.

In addition to estimating impacts on first-time heart attacks and strokes combined, we estimated impacts on first-time heart attacks separately from those on first-time strokes. The claims-based composite measure of all CVD events is composed of roughly 40 percent first-time time heart attacks and 60 percent first-time strokes, including TIAs. When examining those two components separately (Table VII.A.1), for high- and medium-risk beneficiaries, incidence of first-time strokes and TIAs was 4 percent lower in the intervention group than the control group. Meanwhile, incidence of heart attacks was similar for the high- and medium-risk intervention and control beneficiaries. When we focused on the high-risk beneficiaries alone, the intervention and control beneficiaries had similar rates of both first-time time heart attacks and first-time strokes or TIAs.

Figure VII.A.1. A lower risk of first-time CVD events among high- and medium-risk intervention beneficiaries than in the control group: Cumulative probability of having a first-time heart attack, stroke, or TIA five years after enrollment, as measured in Medicare claims, by intervention arm (regression-adjusted)



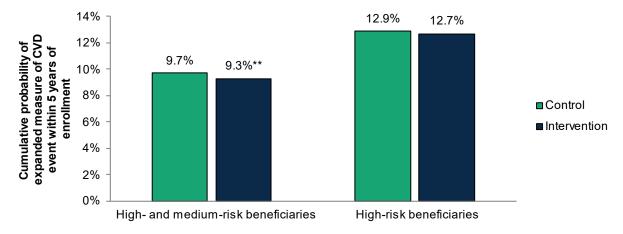
Source: Regression-adjusted results from Medicare claims.

Note: Percentages are the cumulative probability of a first-time CVD event over five years, defined as 1 minus the average Cox proportional-hazards model estimate of the survival function at 1,823 days (five years) after enrollment.

* Significantly different from the control group percentage at the 0.1 level, two-tailed test.

CVD = cardiovascular disease; TIA = transient ischemic attack.

Figure VII.A.2. A lower risk of first-time CVD events (using an expanded measure with NDI data) among high- and medium-risk intervention group beneficiaries than in the control group: Cumulative probability of having a first-time heart attack, stroke, or TIA, or dying from CHD or cerebrovascular disease five years after enrollment, by intervention arm (regression-adjusted)



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

Note: Percentages are the cumulative probability of a first-time CVD event (using an expanded measure with NDI data) over five years, defined as 1 minus the average Cox proportional-hazards model estimate of the survival function at 1,823 days (five years) after enrollment.

** = Significantly different from the control group percentage at the 0.05 level, two-tailed test.

CHD = coronary heart disease; CVD = cardiovascular disease; NDI = National Death Index; TIA = transient ischemic attack.

We conducted several analyses to assess the sensitivity of our results for first-time CVD events to possible data limitations and statistical assumptions. Results were consistent with findings from sensitivity analyses that (1) narrowed the outcome definition for the claims-based measure to include only strokes (not TIAs) and only heart attacks caused by reduced blood flow through arteries in the heart (Type 1);⁷ (2) trimmed the intervention group to a maximum of 20 providers; and (3) defined the intervention and control groups as beneficiaries attributed to the participating providers regardless of beneficiaries' model enrollment. This latter sensitivity analysis limited the possibility that intervention and control providers biased the impact estimates by differing in the types of beneficiaries enrolled among their eligible pool of beneficiaries. The consistency across sensitivity analyses increases our confidence in the results. Appendix H describes the sensitivity analyses and results in more detail. Regression adjustment materially altered the impact estimates, reflecting differences between the intervention and control groups that existed despite randomization (Appendix H, Tables H.12 and H.13). For example, intervention

⁷ This exclusion (1) limits to heart attacks most likely caused by blockages in the arteries supplying the heart (Thygesen et al. 2018) and that we might expect the intervention to influence most strongly (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.

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.

B. Effects on mortality



The model reduced all-cause mortality by 4.3 percent over five years among high- and medium-risk beneficiaries. In the intervention group, 13.8 percent of beneficiaries died within five years of enrollment in regression-adjusted analyses, compared to 14.3 percent for the control group,

translating to a hazard ratio of 0.96 (Table VII.B.1; Figure VII.B.1). This estimate suggests the model prevented one death over five years for every 191 high- and medium-risk beneficiary enrolled in the model.

Table VII.B.1. 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)

	Projected pro outcome within enrollm	n 5 years of	Hazard ratio			
Risk group	Intervention mean	Control mean	Estimate <i>p</i> -value		90% confidence interval	
Deaths (any reason)						
High- and medium-risk beneficiaries	13.8%	14.3%	0.96	0.01	[0.93, 0.98]	
High-risk beneficiaries	18.7%	18.8%	0.99	0.72	[0.95, 1.03]	

Source: Regression-adjusted results from Medicare enrollment data.

Note: We performed regression adjustment using survival analysis of mortality through December 2021. Table VII.B.1 covers 130,578 beneficiaries enrolled in 172 intervention organizations and 88,286 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,423 beneficiaries enrolled in 170 intervention organizations and 27,277 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores of 30 percent or higher.

^a The reported probability is defined as 1 minus the average Cox proportional-hazards model estimate of the survival function. The survival function gives the probability that a beneficiary did not die within 1,823 days after enrollment. CVD = cardiovascular disease.

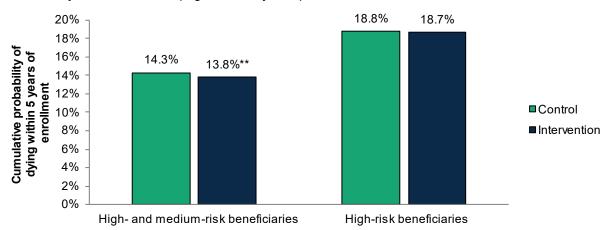


Figure VII.B.1. A lower risk of dying among high- and medium-risk intervention group

beneficiaries than in the control group: Cumulative probability of dying for any reason five years after enrollment, by intervention arm (regression-adjusted)

Source: Regression-adjusted results from Medicare claims.

Note: Percentages are the cumulative probability of dying over five years, defined as 1 minus the average Cox proportional-hazards model estimate of the survival function at 1,823 days (five years) after enrollment.

** = Significantly different from the control group percentage at the 0.05 level, two-tailed test.

The model reduced CHD and cerebrovascular deaths by 11 percent over four years among high- and medium-risk beneficiaries. As mentioned at the beginning of this chapter, we used newly available NDI data to better understand impacts on all-cause mortality by cause of death, focusing on the first four years after enrollment. We found the intervention group had 11 percent fewer CHD or cerebrovascular deaths than the control group (Table VII.B.2).

These cause-of-death analyses indicate the model's impact on all-cause mortality for high- and medium-risk beneficiaries resulted from a combination of hypothesized impacts on CVD-related deaths and impacts on non-CVD deaths we did not hypothesize. Impact estimates for CVD, CHD, and non-CVD deaths were all statistically significant, but the *percentage* reduction in CHD deaths (12 percent) was larger than the percentage reductions in other categories. For example, deaths due to non-CVD or unknown causes were lower by only 4 percent. By extension, the 11 percent model impact on CHD or cerebrovascular deaths combined—where we hypothesized impacts might concentrate—was larger than the model impact on all-cause mortality (first row in Table VII.B.2).

Among high-risk-only beneficiaries, rates of all-cause death were similar between the intervention and control groups (Table VII.B.1; Figure VII.B.1). However, the model reduced CHD-specific deaths by 0.32 percentage points (p = 0.03), translating to a 14 percent impact (Table VII.B.2). This 14 percent impact on CHD-specific deaths for the high-risk group is relatively similar to the estimated 12 percent impact we observed for the combined high- and medium-risk population.

	Percentage of people who died within 4 years after enrollment, by cause of death				
	Intervention group	Control group	Difference (%)	<i>p</i> -value	90% CI
High- and medium-risk bene	eficiaries				
All cause ^a	10.1	10.6	-0.48 (-5%)	0.009	[-0.77, -0.18]
CVD	2.8	3.0	-0.19 (-6%)	0.05	[-0.35, -0.03]
CHD or cerebrovascular	1.6	1.8	-0.19 (-11%)	0.009	[-0.32, -0.07]
CHD	1.3	1.5	-0.18 (-12%)	0.01	[-0.29, -0.06]
Cerebrovascular	0.3	0.3	-0.02 (-5%)	0.58	[-0.06, 0.03]
Other CVD	1.2	1.2	0.00 (0%)	0.95	[-0.09, 0.10]
Non-CVD or unknown cause	7.3	7.6	-0.29 (-4%)	0.06	[-0.53, -0.04]
High-risk beneficiaries					
All cause ^a	13.5	13.5	0.02 (0%)	0.95	[-0.51, 0.55]
CVD	3.9	4.2	-0.26 (-6%)	0.19	[-0.59, 0.07]
CHD or cerebrovascular	2.4	2.6	-0.24 (-9%)	0.14	[-0.50, 0.03]
CHD	1.9	2.2	-0.32 (-14%)	0.03	[-0.57, -0.07]
Cerebrovascular	0.5	0.4	0.08 (21%)	0.12	[-0.01, 0.17]
Other CVD	1.5	1.6	-0.03 (-2%)	0.82	[-0.21, 0.16]
Non-CVD or unknown cause	9.6	9.3	0.28 (3%)	0.29	[-0.16, 0.72]

Table VII.B.2. High- and medium-risk beneficiaries and high-risk-only beneficiaries in the intervention group had a lower risk of dying from CHD than those in the control group: Estimated impact on mortality by cause of death four years after enrollment (regression-adjusted)

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

Note: We performed regression adjustment using multinomial logistic regression models. The analysis was limited to beneficiaries enrolled early enough to be observed for at least four years by December 2021 (the date we pulled claims). Table covers 108,668 beneficiaries enrolled in 170 intervention organizations and 73,127 beneficiaries enrolled in 163 control organizations. Analyses of high-risk beneficiaries are limited to 34,131 beneficiaries enrolled in 168 intervention organizations and 22,901 beneficiaries enrolled in 157 control organizations with baseline CVD risk scores of 30 percent or higher.

^a All-cause mortality results presented in this table are from the same multinomial logistic regression model as the cause-specific results and will not exactly match the all-cause survival analysis results presented elsewhere in the report because of a different follow-up period (4 years instead of up to 5 years).

CHD = coronary heart disease; CI = confidence interval; CVD = cardiovascular disease; NDI = National Death Index.

We did not hypothesize the observed reduction in non-CVD deaths for high- and medium-risk beneficiaries. However, there might be model mechanisms that reduce both CVD events and deaths due to causes other than CVD. For example, statins are thought to have positive impacts on health beyond just their cholesterol-lowering effects (known as the pleiotropic effects of statins), including possibly reducing the growth of cancerous tumors (Ahmadi et al. 2020). The latest U.S. Preventive Services Task Force report on statin use for the primary prevention of CVD supports the idea of statins' benefits in reducing mortality from non-CVD causes (Chou et al. 2022). It is plausible the model's impacts on statin initiation and intensification reduced deaths due to causes other than CVD. However, it is noteworthy we did not observe similar reductions in non-CVD deaths among high-risk-only beneficiaries.

We cannot rule out the possibility that the estimated impacts on non-CVD deaths are spurious, meaning some factor other than the Million Hearts Model made the intervention group systematically less likely to die than the control group. For example, the types of providers that chose to continue participating in the model after random assignment could have differed systematically between the intervention and control groups. All impact estimates in this report are subject to similar limitations. Nonetheless, our estimates of the model's impacts on all-cause mortality were largely consistent with findings from three sensitivity analyses reported in Appendix H. 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) among beneficiaries we attributed, using claims data, to the intervention and control providers that participated in the model. For the impacts on mortality by cause of death, results were also consistent with findings when we set cause of death to unknown for beneficiaries with mismatched death dates in Medicare enrollment and the NDI.⁸

C. Effects on Medicare spending



The model had no detectable impact on Medicare spending. We analyzed spending both with and without the Million Hearts Model payments for high- and medium-risk beneficiaries,⁹ which totaled \$7.2 million or an average of \$1 PBPM of enrollment. CMS hypothesized the

model would reduce spending on CVD events and post-acute care, leading to a reduction in total Parts A and B Medicare spending. We found Medicare spending before accounting for model payments was similar for intervention and control group beneficiaries, both for the high- and medium-risk groups combined and for the high-risk group alone (Table VII.C.1; Figure VII.C.1). This was true despite increases in all-cause hospitalizations and ED visits reported in <u>Chapter VI</u>. Including the model payments, Medicare spending was still similar between the intervention and control groups (Table VII.C1), given that total model payments were small. Note our estimates of effects on spending do not include (1) any possible increases in Part D spending due to increases in statin or antihypertensive use; or (2) costs of implementing the model, such as building and maintaining the Million Hearts Data Registry and calculating semiannual performance.

⁸ Less than 3 percent of high- and medium-risk beneficiaries who died had mismatched death dates in Medicare enrollment and the NDI.

⁹ Model payments included (1) the risk stratification payments CMS paid for intervention group beneficiaries enrolled through December 2018 (all risk groups); (2) cardiovascular care management payments for intervention group high-risk beneficiaries, which CMS paid in 2017; and (3) risk reduction payments for intervention group high-risk beneficiaries, which CMS paid through the end of the model.

	Regree	ssion-adjusted s (dollars PBPM)			90% confidence interval
	Intervention group mean	Control group mean	Difference (%)	<i>p</i> -value	
High- and medium-risk be	eneficiaries				
Parts A and B spending	\$959	\$958	\$1 (0.1%)	0.94	[-18, 20]
Inpatient spending	\$324	\$317	\$7 (2.3%)	0.28	[-4, 18]
Other spending	\$635	\$641	\$-6 (-1.0%)	0.35	[-18, 5]
Parts A and B spending plus model payments ^a	\$960	\$958	\$ 2 (0.2%)	0.85	[-17, 21]
High-risk beneficiaries					
Parts A and B spending	\$1,104	\$1,095	\$10 (0.9%)	0.57	[-19, 38]
Inpatient spending	\$392	\$379	\$13 (3.3%)	0.24	[-5, 30]
Other spending	\$713	\$715	\$-3 (-0.4%)	0.78	[-19, 13]

 Table VII.C.1. The model had no detectable impact on Medicare Parts A and B spending: Estimated impacts on Medicare spending (dollars PBPM, regression adjusted)

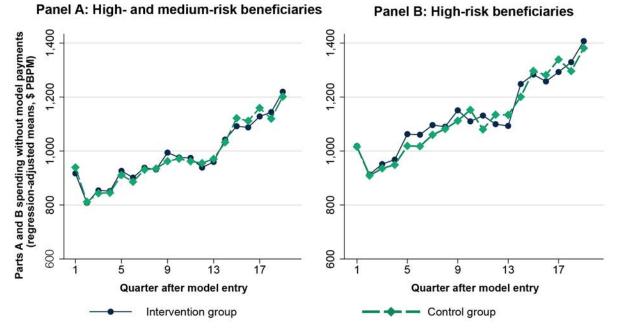
Source: Regression-adjusted results from Medicare Parts A and B claims data.

Note: Table VII.C.1 covers 130,578 beneficiaries enrolled in 172 intervention organizations and 88,286 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,423 beneficiaries enrolled in 170 intervention organizations and 27,277 beneficiaries enrolled in 165 control organizations with baseline cardiovascular disease 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 from 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 were an estimated \$7,264,803. To calculate PBPM spending, we divided this amount by the number of beneficiary-months represented among the highand medium-risk beneficiaries enrolled through December 2018.

PBPM = per beneficiary per month.

Figure VII.C.1. Spending was similar between the intervention and control groups across quarters: Medicare Parts A and B spending (without model payments) for enrolled beneficiaries, by quarter after enrollment and intervention group (regression-adjusted)



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

Note: Figure VII.C.1 covers 130,578 beneficiaries enrolled in 172 intervention organizations and 88,286 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,423 beneficiaries enrolled in 170 intervention organizations and 27,277 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores of 30 percent or higher.

CVD = cardiovascular disease; PBPM = per beneficiary per month.



The model did not measurably reduce Medicare spending for first-time CVD

events either. We estimated impacts on spending for CVD events alone because we and CMS expected the largest relative spending effects on spending for these outcomes. Our measure of CVD-event spending included spending for both acute and

post-acute care for first-time heart attacks and strokes. Specifically, we included spending for hospitalizations and ED visits, plus spending in the 90 days post-discharge (text box). We restricted this analysis to high- and medium-risk beneficiaries enrolled by August 31, 2017, and thus had enough follow-up time for us to observe them for four years for CVD events and 90 days of post-event spending before the end of the model on December 31, 2021. Beneficiaries in the intervention group had average spending for first-time CVD-events over this period that was similar to the control group's (Figure VII.C.2). Findings were similar in sensitivity analyses (Appendix H, Table H.21).

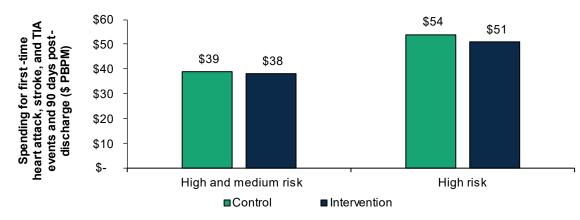
Medicare spending for first-time CVD events

Medicare Parts A and B spending averaged \$34,149 for each first-time CVD event (heart attacks and strokes, including TIAs) in the intervention group:

- \$18,185 (or 53 percent of spending for the episode) was incurred during the acute event: that is, the initial hospitalization or ED visit.
- \$15,964 (or 47 percent) occurred over the next 90 days post-discharge. We looked at spending
 over 90 days to capture post-acute care for CVD events, including stroke rehabilitation. Our
 outcome measure includes all spending during this period, due to challenges identifying spending
 specific to the CVD event.

Because only 5 percent of high- and medium- risk beneficiaries in the intervention group had a first-time CVD event in the four years included in this analysis, spending for first-time heart attacks and strokes averaged \$38 per beneficiary per month.

Figure VII.C.2. The intervention and control groups had similar levels of Medicare spending for first-time CVD events: Medicare Parts A and B spending within four years of enrollment for first-time heart attacks, strokes, and TIAs, including all care 90 days post-discharge, by intervention arm (regression-adjusted)



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

Note: The analysis was limited to beneficiaries enrolled early enough to be observed for at least four years by December 2021 (the date we pulled claims). Figure VII.C.2 covers 108,668 beneficiaries enrolled in 170 intervention organizations and 73,127 beneficiaries enrolled in 163 control organizations. Analyses of high-risk beneficiaries are limited to 34,131 beneficiaries enrolled in 168 intervention organizations and 22,901 beneficiaries enrolled in 157 control organizations with baseline CVD risk scores of 30 percent or higher. Appendix H, Table H.20 presents regression-adjusted means, impact estimates, and confidences intervals.

CVD = cardiovascular disease; PBPM = per beneficiary per month; TIA = transient ischemic attack.

VIII. Variation in Model Effects by Beneficiary Subgroup



Key findings

- The Million Hearts Model led to similarly sized relative decreases in the risk of first-time heart attack or stroke for beneficiaries with high versus low modifiable cardiovascular risk at enrollment.
- The model increased statin initiation or intensification more for those living in areas with high versus low social vulnerability.
- The model increased statin and antihypertensive initiation and intensification similarly for women and men, even though women had lower statin use and higher LDL cholesterol at baseline than men.

In Chapters IV and VII, we show the Million Hearts Model increased CVD medication initiation and intensification (defined in Chapter IV) and reduced the risk of first-time heart attacks and strokes across the enrolled high- and medium-risk population, on average. However, subpopulations-including women and those who are more socially vulnerable-might not share model impacts equally, given existing disparities in care and outcomes among these groups. For example, those who reside in more socially vulnerable communities are less likely to be screened or receive counseling for CVD risk factors (Shahu et al. 2020), and women are less likely to be prescribed or use statins (Virani et al. 2015). Thus, information about the impact of the model on these groups is important to the CMS Innovation Center's recent commitment to advancing health equity (Brooks-LaSure et al. 2021; CMS Innovation Center 2020; Joszt 2021). Further, subgroup estimates can help clarify the mechanisms through which the model achieved the average effects on first-time heart attacks and strokes. For example, did the model improve outcomes substantially just for the subset of beneficiaries with high modifiable cardiovascular risk at enrollment, or did it improve outcomes more evenly across the enrolled population? In this chapter, we focus on assessing model impacts for three subgroups, defined by high modifiable risk level, high social vulnerability, and gender.¹⁰

Although other subpopulations can experience differential impacts of the model, we limited the number of subgroup analyses to reduce the risk of chance findings, a risk that increases with each additional subgroup analysis (Wang et al. 2007). We chose combinations of subgroups and outcomes for which we thought there would be sufficient statistical power to identify clinically meaningful differences between the subgroups, because (1) subgroup categories were sufficiently large and (2) we expected there could be substantial differences in impacts between the subgroups. (The rationale for our expectations differed by subgroup and is described below). Based on those two criteria, we focused on incidence of heart attack and stroke for the analyses related to modifiable risk and focused on statin and antihypertensive medication initiation or intensification for analyses related to gender and social vulnerability. The number of racial and ethnic minority

¹⁰ For this report, we focus on gender rather than biological sex and we use the term *women* although reported data sometimes refer to *females*. This approach aligns with much of the literature in this field and speaks to likely nonbiological mechanisms for disparities in care.

beneficiaries was too low to produce meaningful subgroup estimates so we did not conduct analyses by race and ethnicity. Evaluations of future models might consider these as additional subgroups of interest.

A. Modifiable risk subgroup

We expected the Million Hearts Model to effect change by improving modifiable risk factors. Although enrolled beneficiaries on average had substantial modifiable risk at baseline-comprising about 40 percent of their baseline CVD risk for high-risk beneficiaries and 29 percent for medium-risk beneficiaries-there was considerable variation across the population (Chapter II). We assigned half of the high- and medium-risk beneficiaries to the high modifiable risk subgroup meaning a high degree of their overall CVD risk was due to modifiable risk factors, such as blood pressure, cholesterol, and smoking status. We assigned the other half to the low modifiable risk subgroup-meaning that, although the beneficiaries had high or medium CVD risk overall, only a small proportion of this risk was due to modifiable risk factors (the text box defines subgroups). On average, 51 percent of beneficiaries' total CVD risk was modifiable in the high modifiable risk group, and 9 percent was in the low modifiable risk group. Compared to beneficiaries in the low modifiable risk subgroup,

Modifiable risk

For each beneficiary, we calculated modifiable risk as the amount of CVD risk that could be reduced within one year of model enrollment, according to the Million Hearts Longitudinal ASCVD Risk Assessment Tool, assuming that person met clinical targets for (1) aspirin use if appropriate (based on clinical guidelines as of 2018), (2) systolic blood pressure less than 130 mmHg, (3) LDL cholesterol less than 70 mg/dL, and (4) immediate smoking cessation. Beneficiaries with at least 7.5 percentage points of modifiable CVD risk (the median value) were considered to have 'high' modifiable risk, and beneficiaries with less than 7.5 percentage points modifiable risk were considered to have 'low' modifiable risk.

beneficiaries with higher modifiable risk were younger; more likely to be non-Hispanic Black or Hispanic; more likely to be dually enrolled in Medicaid; and more likely to be in the high vulnerability category (that is, to live in a community with a high Social Vulnerability Index [SVI] score, which takes into account different aspects of disadvantage at the Census tract level, such as high rates of poverty, low educational attainment across populations, housing type, race and ethnicity, and access to transportation) (<u>Appendix E, Table E.10</u>).

We expected providers to perceive more opportunities to improve care among beneficiaries with greater modifiable risk and, thus, expected increases in medication use and other risk-reduction behaviors to be higher among beneficiaries with greater modifiable risk—particularly among those in the intervention group. Based on interviews with participating organizations, some providers reported there were often cases in which there was little room to lower CVD risk as risk scores were due to factors they could not control (for example, age). Thus, given the anticipated greater opportunity for improvement, we hypothesized that model impacts on CVD events would be larger for those with more modifiable risk.

We included high- and medium-risk beneficiaries enrolled in 2017 or 2018 in this analysis by modifiable risk group and assessed differential impacts on incidence of first-time CVD events, measured in Medicare claims.



The model had similarly sized impacts for first-time heart attacks or strokes among beneficiaries with high modifiable risk, compared to those with low modifiable risk. Specifically, the regression-adjusted hazard ratio, which captures the ratio of the risk of a first-time heart attack, stroke,

or TIA between the intervention and control groups, was 0.97 for beneficiaries with high modifiable risk, compared to 0.96 for beneficiaries with low modifiable risk (Table VIII.A.1). That is, the two subpopulations' impacts were similar, and the very small difference between these two impact estimates was not statistically significant (p = 0.96).¹¹

Table VIII.A.1. Point estimates suggest similar model effects on first-time CVD events for high and low modifiable risk subgroups, but estimates are not statistically significant for either group

				Regression	-adjusted
	Impact estimates for each subgroup			Regression-adjusted ratio of impacts comparing subgroup and reference group	
Subgroup (% of full population)	Projected probability of outcome within 5 years of enrollment, intervention group ^a	Projected probability of outcome within 5 years of enrollment, control group ^a	Regression- adjusted hazard ratio [90% Cl]	Ratio of impacts [90% CI]	p-valueª
First-time heart attac	k, stroke, or TIA, usi	ing a claims-based de	finition		
Low modifiable risk (<7.5 percentage points, 51%)	6.7	6.9	0.96 [0.92, 1.01]	[reference]	0.96
High modifiable risk (≥7.5 percentage points, 49%)	9.0	9.3	0.97 [0.92, 1.01]	1.00 [0.94, 1.06]	

Source: Unadjusted and regression-adjusted results from Medicare claims linked to clinical indicators of cardiovascular risk from the Million Hearts Data Registry.

Note: 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. The <u>Fourth Annual Report</u>, <u>Chapter VI</u> defines the clinical targets. Table covers 130,119 beneficiaries enrolled in 172 intervention organizations and 87,986 beneficiaries enrolled in 170 control organizations, excluding beneficiaries with missing modifiable risk score (459 intervention and 300 control beneficiaries).

^a The reported probability is defined as 1 minus the average Cox proportional-hazards model estimate of the survival function. The survival function gives the probability that a beneficiary did not die within 1,823 days after enrollment.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; CI = confidence interval; CVD = cardiovascular disease; TIA = transient ischemic attack.

¹¹ The impact estimates for each modifiable risk group were not themselves statistically different from 1 (indicating no effect), which is likely due to the decrease in the statistical precision of the estimates when we cut the study population roughly in half to define the subgroups. The point estimates for each subgroup were very similar to the estimate for the full population (hazard ratio = 0.97, as reported in <u>Chapter VII</u>), which was statistically significant.

One potential reason for this finding is the subpopulation with low modifiable risk still had a meaningful amount of modifiable risk at enrollment (9 percent; <u>Appendix E, Table E.10</u>)—enough room for the model to still improve outcomes for this group. In other words, if the model had eliminated *all* modifiable risk in the group with low modifiable risk, CVD events would be reduced even more than the 4 percent we found. Further, those in the group with high modifiable risk could have been identified as needing intervention and already receiving some care to address areas of modifiable risk before model participation, which could dampen the effects of the model (making effects for this group more like the effects for the group with low modifiable risk).

These subgroup findings suggest the model modestly improved outcomes broadly across the enrolled population, regardless of level of modifiable risk. The model reduced first-time heart attacks and strokes for the subset of beneficiaries with higher unmet medical needs by about 3 percent, as indicated by beneficiaries having high modifiable risk factors (such as high blood pressure) at baseline. However, it also reduced these events by similar amounts for beneficiaries with more subtle unmet needs, as captured by beneficiaries with relatively low modifiable risk. Therefore, the model appears to have helped providers and patients identify and address modifiable risk factors, whether the unmet need was large or modest at enrollment.

B. Socially vulnerable subgroup

The concept of social vulnerability encompasses vulnerability to poor outcomes related to residence in disadvantaged communities (Greer et al. 2016). The Centers for Disease Control and Prevention measures vulnerability at the community (Census tract) level with an index (the SVI) score. This score incorporates several different aspects of disadvantage, such as high rates of poverty, low educational attainment across populations, housing type, race and ethnicity, and access to transportation. There are important disparities in CVD care and outcomes among populations with high social vulnerability. These include a reduced likelihood for screening and counseling for risk factors related to CVD (Shahu et al. 2020), and an increased risk of dying from CVD (Wadhera et al. 2020; King et al. 2022). We categorized beneficiaries as residing in Census tracts with low, medium, or high vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population. Low-vulnerability beneficiaries were those residing in the bottom four SVI deciles of Census tracts, medium-vulnerability beneficiaries were those in the fifth to eight SVI deciles, and high-vulnerability beneficiaries were those in the top two SVI deciles.

Among high- and medium-risk beneficiaries, there were important differences between those with high and low social vulnerability. Socially vulnerable beneficiaries were more likely to be younger and have lower overall risk scores. However, they also had higher blood pressure, LDL cholesterol, and modifiable risk scores at baseline (<u>Appendix E, Table E.11</u>). As a result of these risks socially vulnerable beneficiaries were more likely to use antihypertensives and statins at baseline. So, although their overall CVD risk scores were lower on average than the non-vulnerable beneficiaries' (likely because of age), there was also a high degree of need within this population, some of which was unmet (<u>Appendix E, Table E.11</u>). Because of this high unmet

need, we hypothesized the model would have larger impacts on medication initiation or intensification for more socially vulnerable beneficiaries given the focus on universal risk assessment, which should uncover unmet need. This is turn would lead to greater impacts on the initiation or intensification of medication use to address the identified unmet need.

To evaluate this hypothesis, we used a variation of the medication analyses detailed in <u>Chapter</u> <u>IV</u>. For social vulnerability, we limited the analytic population to beneficiaries with Part D coverage. We then tested for differential impacts of the Million Hearts Model on CVD medication initiation or intensification for beneficiaries high in social vulnerability relative to those living in low- or medium-vulnerability tracts.



The model led to greater increases in statin initiation or intensification for highvulnerability beneficiaries versus lower-vulnerability beneficiaries. Specifically, the impact of the model was 4.9 percentage points among high-vulnerability beneficiaries (22.6 percent in the intervention group versus 17.7 percent in the control group; Table VIII.B.1). In comparison, the model increased rates of statin

intensification or intensification by just 3.4 percentage points in the low-vulnerability subgroup (16.9 versus 13.6 percent). That is, the impact estimate was 1.6 percentage points larger for the high-vulnerability group than it was for the low-vulnerability groups. However, the difference in impacts (between the different vulnerability groups) was smaller and not statistically significant for antihypertensive initiation or intensification (Table VIII.B.1).

	Impact es	stimates for each	subgroup	Difference in impacts relative to the reference group's impact estimate		
Subgroup (% of full population)	Regression- adjusted means, Intervention group	Regression- adjusted means, Control group	Intervention– control difference [90% Cl]	Estimate [90% Cl]	Joint <i>p</i> -valueª	
Statin initiation or ir (beneficiaries with L			nrollment			
Low vulnerability (40%)	16.9	13.6	3.4 [2.4, 4.4]	[reference]	0.07	
Medium vulnerability (40%)	18.2	15.2	3.0 [1.8, 4.2]	-0.4 [-1.4, 0.7]	_	
High vulnerability (19%)	22.6	17.7	4.9 [3.4, 6.4]	1.6 [0.1, 3.0]	_	

Table VIII.B.1. The Million Hearts Model increased statin use more for high- versus lowervulnerability categories among high- and medium-risk beneficiaries

	Impact es	stimates for each	subgroup	Difference in impacts relat to the reference group's impact estimate		
Subgroup (% of full population)	Regression- adjusted means, Intervention group	Regression- adjusted means, Control group	Intervention– control difference [90% Cl]	Estimate [90% Cl]	Joint <i>p</i> -value ^a	
Antihypertensive m (beneficiaries with S			n within 12 months	of enrollment		
Low vulnerability (39%)	27.5	25.4	2.1 [1.0, 3.2]	[reference]	0.51	
Medium vulnerability (40%)	29.5	27.2	2.2 [1.1, 3.4]	0.1 [-1.2, 1.4]	_	
High vulnerability (20%)	33.3	30.1	3.2 [1.6, 4.8]	1.1 [-0.6, 2.8]	_	

Sources: Regression-adjusted results from Medicare Part D claims linked to Medicare claims and enrollment data. Medicare enrollment database for beneficiaries' nine-digit zip codes to map to Census tracts; Centers for Disease Control and Prevention 2016 Census-tract-level SVI file for identifying beneficiaries in socially vulnerable Census tracts. Sample sizes are in <u>Table D.1 in Appendix D</u>.

Note: We estimated impacts using logistic regression models. Low vulnerability defined as deciles 1–4 of the Census tract summary SVI score, medium vulnerability defined as deciles 5–8, and high vulnerability defined as deciles 9 and 10.

^a We calculated joint *p*-values using a Wald test. The joint *p*-value tests the null hypothesis that the three subgroups have equal impact estimates.

CI = confidence interval; LDL = low-density lipoprotein; mg/dL = milligrams per deciliter; mm Hg = millimeters of mercury; SBP = systolic blood pressure; SVI = Social Vulnerability Index.

This difference in impacts on initiation or intensification of statins is clinically relevant for two key reasons. First, because beneficiaries living in more vulnerable areas had higher modifiable risk factors at baseline (such as high blood pressure, smoking rates, and LDL cholesterol), our findings suggest when providers become aware of CVD risk they might have otherwise overlooked through increases in risk assessment, they might be more likely to initiate or intensify medications to address that risk. Second, based on the efficacy of statins in lowering LDL cholesterol in clinical-trial populations (Karmali et al. 2016), this difference could be large enough to eliminate some of the disparity in LDL cholesterol in the high- versus low-vulnerability groups observed at enrollment.

C. Gender

There is evidence women receive less or suboptimal CVD preventive care than men (Shaw et al. 2017; Mosca et al. 2005), including fewer prescriptions for and use of statins, as well as less aggressive treatment for both primary and secondary prevention (Garcia et al. 2016; Virani et al. 2015). Women tend to have higher use of antihypertensive medications than men but are less likely to have achieved blood pressure control (Gu et al. 2008).

These same gender differences were present in the Million Hearts Model population. In examining characteristics between women and men at baseline (<u>Appendix E, Table E.16</u>), we found that, among high- and medium-risk beneficiaries, women had higher LDL cholesterol than men (in the intervention group, a mean of 106 mg/dL versus 97 mg/dL), higher systolic blood pressure (137 mmHg versus 134 mmHg), and were more likely to have a diabetes diagnosis (40 versus 36 percent). Women were less likely than men to use statins at baseline (58 versus 62 percent), less likely to use high-intensity statins (14 versus 19 percent), and less likely to adhere to statins when on them (65 versus 71 percent), despite more frequent care as evidenced by number of office visits (10 versus 9 per year). However, women were more likely to use antihypertensives than men (85 versus 80 percent).

We know from the literature that underestimation of CVD risk among women can hinder appropriate preventive care (Mosca et al. 2020; Shaw et al. 2017). For this subgroup analysis, we hypothesized the model would have larger impacts on medication initiation or intensification for women given the focus on universal CVD risk assessment. In theory, with universal assessment using the ASCVD risk calculator, women would be more likely to be newly identified as having high or medium CVD risk in the intervention group, which would, in turn, lead to increased medication use to address the identified risk.



The model increased medication use by similar amounts for men and women. The estimated impact of the model on statin initiation or intensification within one year of enrollment was very similar for women and men (3.5 percentage point impact for both groups; Table VIII.C.1). Likewise, we estimated the model had a slightly

larger impact on antihypertensive medication initiation or intensification for women (2.7 percentage points) than men (2.1 percentage points); however, this difference in impacts between the two subgroups was small and was not statistically significant (p = 0.16). Thus, the disparity in statin use between women and men was not reduced.

	Impact e	stimates for each	subgroup	Difference in in to the refere impact e	nce group's
Subgroup	Regression- adjusted means, Intervention group	Regression- adjusted means, Control group	Intervention– control difference [90% CI]	Estimate [90% Cl]	<i>p</i> -value ^a
	or intensification w th LDL cholesterol		fenrollment		
Men (53%)	18.6	15.1	3.5 [2.4, 4.6]	[reference]	0.96
Women (47%)	18.4	14.8	3.5 [2.6, 4.5]	0.03 [-0.81, 0.86]	

Table VIII.C.1. The Million Hearts Model increased medication use by similar amounts for men and women among high- and medium-risk beneficiaries

	Impact e	stimates for each	Difference in impacts relative to the reference group's impact estimate		
Subgroup	Regression- adjusted means, Intervention group	Regression- adjusted means, Control group	Intervention– control difference [90% Cl]	Estimate [90% Cl]	<i>p</i> -value ^a
	e medication initiat th SBP >= 130 mm		ion within 12 month	s of enrollment	
Men (53%)	28.5	26.4	2.1 [1.0, 3.1]	[reference]	0.16
Women (47%)	30.4	27.7	2.7 [1.8, 3.7]	0.7 [-0.1, 1.5]	

Source: Regression-adjusted results from Medicare Part D claims linked to Medicare claims and enrollment data. Note: We estimated impacts using logistic regression models. Sample sizes are in <u>Table D.1 in Appendix D</u>. CI = confidence interval; LDL = low-density lipoprotein; mg/dL = milligrams per deciliter; mm Hg = millimeters of mercury; SBP = systolic blood pressure

In other words, increases in risk assessment under the model did not appear to increase medication initiation and intensification more for women than it did for men, despite higher LDL cholesterol and higher systolic blood pressure for women at baseline and lower statin use at baseline. Use of antihypertensives among women was higher than among men at baseline.

These results suggest that disparities between women and men might not be a product of risk identification but rather decisions about care after identification. In a study of physicians' awareness and adoption of national CVD prevention guidelines, physicians perceived a lower CVD risk level for women compared to men—even in light of similar calculated risk scores (Mosca et al. 2005). Providers could also hesitate to initiate certain medications with women patients. In one study, researchers theorized that although recent meta-analyses of statin use have shown similar benefits between men and women, some providers could still perceive less of a benefit for women (Virani et al. 2015).

Further, the subgroup analysis did not examine subgroup impacts by gender on other outcomes (for example, cholesterol control) or consider potentially important subsegments of the population, such as women who have a diabetes diagnosis, as the risk for coronary heart disease is higher for women with diabetes than for men with the condition (Vogel et al. 2021). In an evidence review on health care gaps for women focused on cardiovascular medicine (Shaw et al. 2017), researchers found limited use of evidence-based therapies for both primary and secondary CVD prevention and that women with conditions like diabetes were less likely to meet goals for cholesterol control. These differences are not just in relation to medications. Research has also pointed to women being less likely to receive referrals to cardiac rehabilitation than men (Mosca et al. 2020; Garcia et al. 2016). These additional analyses might be valuable to explore in the future to better understand gender disparities and potential impacts on CVD prevention and care.

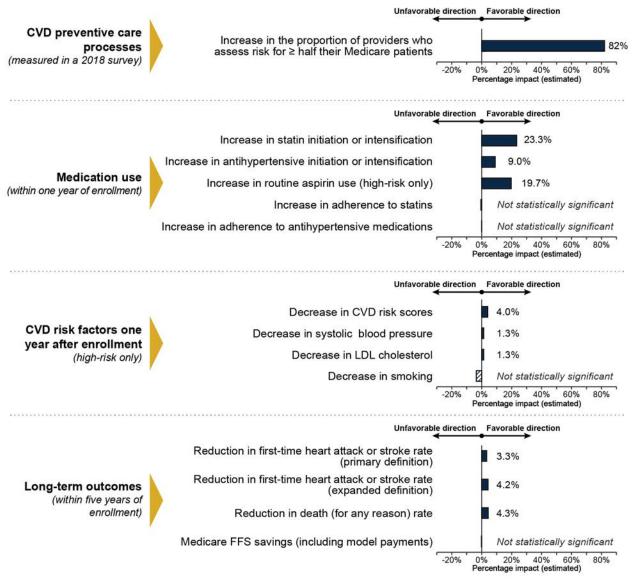
IX. Conclusions from the Million Hearts Model Evaluation

Over five years, the Million Hearts Model reduced the rate of first-time heart attacks and strokes by an estimated 3 to 4 percent among high- and medium-risk beneficiaries. The range in estimates reflects the two ways we defined first-time heart attacks and strokes, one using hospital claims only (showing a 3 percent impact) and the other using hospital claims and National Death Index (NDI) data (showing a 4 percent impact). These impact estimates imply roughly one prevented event over five years for every 250 to 400 high- and medium-risk beneficiaries enrolled. The impact estimates were not concentrated among just the high-risk beneficiaries, indicating positive spillover to medium-risk beneficiaries (for whom CMS paid for risk assessment but not cardiovascular care management services or risk reduction). The model did not measurably change total Medicare spending. In this chapter, we discuss what might have driven these results, strengths and limitations of the Million Hearts Model evaluation, the generalizability of its findings, and its contributions to the broader literature on preventive care for cardiovascular disease (CVD) and value-based care.

A. Potential drivers of model impacts on primary outcomes

We found model effects on CVD preventive care processes and intermediate outcomes that fit with the hypothesized causal pathway for the model (Figure IX.1). One likely driver of the model's impacts on heart attacks and strokes was providers' increased awareness of patients' CVD risk. Prompted by their commitments and the model's incentives and supports, intervention group providers were nearly twice as likely as control group providers to report they assessed CVD risk for at least half of their Medicare patients. Further, intervention group providers reported increasing their rates of risk assessment made them more aware of their patients' CVD risk and more likely to recommend CVD medications and other treatments. This, in turn, likely contributed to the observed increases in medication use (9 percent for antihypertensives, 23 percent for statins, and 20 percent for aspirin). In addition to providers focusing more on patients' risk, and therefore being more likely to recommend medications, providers in interviews also noted discussing CVD risk (though not necessarily risk scores) with their patients made some patients more interested in and willing to start or intensify medications. The increases in medications likely contributed to the observed 4 percent reduction in 10-year CVD risk scores (and smaller reductions in individual risk factors) among high-risk beneficiaries one year after enrollment. Reductions in CVD risk factors, in turn, likely led to the overall 3 to 4 percent reduction in rates of first-time heart attacks and strokes among high- and medium-risk beneficiaries.

Figure IX.1. The Million Hearts Model had large, favorable effects on CVD risk assessment and medication use, with smaller effects on CVD risk factors and, ultimately, heart attacks and strokes



Notes: The primary definition of heart attacks and strokes uses only hospital claims (including outpatient claims) to identify first-time events. The expanded definition uses both hospital claims and National Death Index data. Unless otherwise specified, all reported impact estimates are statistically significant at least at a *p* < 0.10 threshold.

FFS = fee-for-service; CHD = coronary heart disease; CVD = cardiovascular disease; LDL = low-density lipoprotein.

The finding that the model's impacts on CVD medications and heart attack and strokes were similar, or perhaps even larger, for medium-risk beneficiaries than high-risk beneficiaries supports the idea that risk assessment drove the impacts. CMS paid organizations for assessing CVD risk for all patients, but only paid for cardiovascular care management and risk reduction for high-risk beneficiaries. Through more systematic use of risk assessment, providers likely became more aware of risk for their medium-risk beneficiaries, prompting additional actions for that group. By definition, medium-risk beneficiaries had at least a 15 percent predicted risk of having a CVD event over 10 years, well above the 7.5 (Arnett et al. 2019) to 10 percent (Whelton et al. 2019) thresholds clinical guidelines use for recommending intensified treatment. Indeed, risk assessment might have been particularly helpful for identifying otherwise undetected and unaddressed risk among medium-risk beneficiaries. Compared to the high-risk population, the medium-risk beneficiaries more likely to be female, and less likely to have diabetes or hypertension—all factors that prior research has linked to providers underestimating true CVD risk (Morieri et al. 2022; Bairey Merz et al. 2017; Mosca et al. 2005).

Two factors help explain why the model reduced heart attacks and strokes even though 114 of the 173 intervention group organizations withdrew or stopped actively participating in the model by 2021. First, the 59 intervention organizations that actively participated at any time in 2021 were also those that enrolled a large share (almost 60 percent) of the total intervention group in 2017 and 2018. As a result, on average, 78 percent of a beneficiary's follow-up months occurred when their enrolling organization still participated actively in the model. Second, organizations might have continued some of their changes in CVD care processes even after they withdrew from the model. Organizations often cited challenges reporting data to the registry—not challenges with implementing key CVD care processes—as reasons for withdrawing. We found the model improved use of medications within the first year of model enrollment and these effects persisted, but did not grow, in later years post-enrollment.

One might expect the model would have measurably reduced Medicare spending because the model reduced first-time heart attacks and strokes. CMS hypothesized lower Medicare spending on hospital care and post-acute care for these events. In practice, however, there are at least three plausible explanations for why the model did not measurably reduce Parts A and B spending. First, spending on first-time CVD events is only a small fraction of total average Medicare spending, so even a large effect on CVD events—for example, the 7 percent reduction CMS initially hypothesized—would translate into a very small impact on total spending. Second, the actual reduction in CVD events of 3 to 4 percent, although meaningful, was less than the 7 percent initially projected, making it even harder to reliably detect effects on total spending. Even when we examined the model's effects just on spending for first-time CVD events, we found no statistically significant changes. Third, the model increased all-cause hospital admissions by an estimated 3.7 percent, so any savings on spending for CVD events were likely offset by other increases in inpatient spending.

B. Strengths and limitations of this study

1. Strengths

The Million Hearts Model was a large-scale randomized trial running for five years. The random assignment, which effectively stratified by region, was especially important in 2020 and 2021, when the COVID-19 pandemic changed care patterns (Stewart et al. 2021) and health outcomes (Xu et al. 2022) and did so unevenly across the country. Randomization meant the pandemic's influences on outcomes were similar in our intervention and control groups, limiting risk of bias to the estimates of model impacts (Appendix J). The long (five-year) model duration is especially important given that (1) the absolute benefits of statins (Yourman et al. 2020) and antihypertensive medications (Chen et al. 2022) are thought to increase over time and (2) the evaluation required long follow-up to observe a sufficient number of events to measure model effects on our primary outcomes with statistical precision.

The study had several additional strengths:

- CMS collected clinical data on CVD risk factors, which enabled us to estimate impacts on these factors and to include a richer set of covariates in all impact analysis regression models than would be possible using administrative data only.
- We incorporated the NDI data into the outcomes, capturing fatal out-of-hospital CVD events that we would have otherwise missed if we had used Medicare claims data alone.
- We used Medicare claims and enrollment and NDI data to measure long-term outcomes for beneficiaries, enabling us to track outcomes even after organizations that enrolled the beneficiaries withdrew.
- We collected primary data from surveys and interviews, enabling us to estimate impacts on organization-level care processes and understand providers' experiences.

2. Limitations

The primary limitation of the evaluation is that significant model attrition increased the risk of bias in our estimates of model impacts. Only 345 of the 516 organizations randomly assigned ever participated in the model, a number of clinicians at these organizations did not enroll any beneficiaries, and the providers who did enroll beneficiaries enrolled only about half the beneficiaries who appeared eligible in Medicare claims and enrollment data. If the intervention versus control groups differed in the types of organizations that remained in the model, or in the types of beneficiaries they chose to enroll, this could lead to differences in beneficiaries' outcomes unrelated to model impacts. We included a rich set of covariates to correct for any observed differences between the intervention and control group beneficiaries. We also conducted sensitivity tests using the population of all beneficiaries visiting the organizations and who appeared eligible for the model). These tests aimed to remove the effects on the impact estimates

of differences in whom organizations chose to enroll among their eligible population. Nonetheless, even with this adjustment and sensitivity tests, some risk of bias remains.

The study has several other limitations:

- The 20-provider cap for the control group meant the intervention group was larger than the control group, and the additional intervention group beneficiaries might have differed from control group beneficiaries in unobservable ways that biased impact estimates. The sensitivity analyses that trimmed the intervention group aimed to limit this risk of bias and showed similar estimates to the primary estimates.
- Because intervention organizations submitted follow-up clinical data for only high-risk beneficiaries, we could not estimate impacts on CVD risk factors or risk scores for the combined high- and medium-risk population.
- We did not measure whether the model led to any potential unintended consequences from intensifying treatment, such as the potential for internal bleeding from greater use of aspirin (Lloyd-Jones 2022).
- We had no data on beneficiaries' diet or exercise patterns, so we could not directly assess whether the model reduced heart attacks and strokes, in part, through improvements in diet or exercise.
- The control group might not have received usual care because CMS paid these organizations to report CVD risk factor data (but not risk scores) for all their eligible beneficiaries. Through this reporting, control group providers might have become more aware of CVD risk in their patient panels, leading to care improvements that attenuated the measured model impacts.

C. Generalizability of results to other organizations and beneficiaries

We anticipate the results from the Million Hearts Model evaluation will apply broadly to Medicare FFS beneficiaries ages 40 to 79, if they are served by organizations that join a similar model voluntarily and that have room for improvement in use of routine CVD risk assessment. The results should apply broadly because many types of organizations across the country participated in the model, as reflected in our impact estimates. However, the organizations that voluntarily participated in the model might have been those particularly eager to implement the model's vision of care. At other organizations, providers might have a range of perceptions of the value of risk scores, with some thinking risk scores are too time consuming to calculate and are redundant with other clinical data, such as systolic blood pressure, and so of limited value (Sposito et al. 2009). If organizations' staff are not intrinsically motivated to follow the Million Hearts Model's vision of care, those organizations likely would not respond to the model's incentives and supports in the same way. Finally, if organizations already have universal (or close to universal) CVD risk assessment, there would not be significant room for the model to improve care. Although this did not appear to be the case for the model participants—as evidenced by low absolute rates of risk assessment among the control group participants—risk

assessment might become more common over time, especially if new functions in electronic health records make it easier to calculate risk scores.

The subgroup impact estimates (Chapter VIII) support the idea that the model's estimated effects could apply to a range of beneficiaries. Specifically, the similar impact estimates for first-time CVD events for those in higher versus lower modifiable risk subgroups suggest the model's benefits are not confined to only those with substantial modifiable risk. The model's benefits extend to those with risk factors that are closer to, even though not at, optimal levels at baseline. Further, the similar estimated effects on CVD medications for men and women suggest the model's effects would generalize equally to both genders. Additional interventions might be needed to reduce disparities in CVD preventive care between women and men.

The SVI subgroup estimates suggest the model could have modestly larger effects on CVD care and outcomes for beneficiaries in higher vulnerability areas. The estimated effects on the use of CVD medications were somewhat larger for beneficiaries living in higher vulnerability areas, likely because the model's emphasis on universal risk assessment helped to raise providers' awareness of CVD risk they might otherwise have overlooked. For example, high-risk beneficiaries living in more vulnerable areas tended to be younger, which might have contributed to a misperception (Morieri et al. 2022)—before the model began—of lower CVD risk.

It is unclear whether the model's effects would generalize to other patient populations, including those who are younger or who receive less routine care, those who are older and have higher absolute risk of heart attacks and strokes due to age, or those with a substantially different racial or ethnic composition than the enrolled population. Patients who lack a usual source of care tend to have the highest modifiable risk factors, such as high blood pressure (Muntner et al. 2020), so a model like the Million Hearts Model could be particularly effective for this group. However, in interviews, model providers said they largely carried out model activities through routine visits with patients. That is, providers enrolled eligible beneficiaries when they came into the office and relied on regular office visits as a primary mechanism for following up with beneficiaries to assess and encourage progress on risk reduction plans. As a result, it is unclear whether the model could have similar effects for patients—regardless of payer—not already visiting the office regularly.

D. Contribution to literature on CVD preventive care and value-based care

1. CVD preventive care

The study's findings provide support for clinical guidelines for CVD prevention that recommend providers assess their patients' CVD risk and use those risk scores to guide care and treatment plans for individual patients (Arnett et al. 2019). The guidelines include this recommendation but note the evidence to support routine risk assessment is limited, mainly because trials of risk assessment have been too small and short to assess effects on long-term health outcomes (Lloyd-Jones et al. 2019). A 2017 meta-analysis found providing CVD risk scores to patients, clinicians, or both can increase initiating or intensifying antihypertensive medications and statins by about 5

percentage points and reduce systolic blood pressure level, total cholesterol level, and LDL cholesterol level by 3 mmHg, 4 mg/dL, and 1 mg/dL, respectively—all similar effect sizes to those we estimate among Million Hearts Model beneficiaries (Karmali et al. 2017). Further, given the large sample sizes and long follow-up period, the Million Hearts Model demonstrates these short-term improvements in intermediate outcomes did indeed translate, over five years, into lower rates of first-time heart attacks and strokes, as well as lower rates of coronary heart disease (CHD) and cerebrovascular deaths. As noted earlier, providers said risk assessment made them more aware of their patients' CVD risk. Further, some participating providers said the risk scores helped cue discussions with patients about risk, helping to convince patients of the value of treatment intensification, such as starting statins. If anything, the evaluation findings understate the value of risk assessment since some providers in the control group assessed risk for their patients as well—meaning that our estimates captured the effects of more consistent use of CVD risk scores, not consistent versus no use of CVD risk scores.

2. Value-based care

Responding to high and rising medical spending and inconsistent quality of care, CMS and other payers have experimented with ways to improve the value of medical care—including shared savings models, paying for performance on quality measures, and other alternatives or additions to fee-for-service care. These initiatives have had mixed effects on quality and cost outcomes, including for cardiovascular disease (MedPAC 2022; Sukul and Eagle 2020; Husaini and Joynt Maddox 2020).

This study contributes to the value-based care literature by demonstrating, in a rigorous randomized trial, one model with performance-based payments that was effective in improving long-term health outcomes without measurably affecting Medicare spending. The Million Hearts Model has several features that, together, define a unique position in the landscape of value-based care initiatives.

- *Embed performance-based payments into a broader initiative,* which includes organizations' commitment to CVD preventive care guidelines, feedback on performance, peer-to-peer learning, and payment both for care processes (risk assessment and care management) and performance (risk reduction). In contrast, some value-based care initiatives have focused primarily on paying for performance (Mendelson et al. 2017).
- *Focus on upstream prevention of disease,* whereas many value-based care initiatives focus on improving care for established conditions, including CVD (Sukul and Eagle 2020).
- *Focus on a single outcome*, whereas some other initiatives—like the national Merit-Based Incentive Payment System—reward performance on a wide range of performance measures, from which participants can choose (Joynt Maddox et al. 2017).

Some designers of the Million Hearts Model emphasized its performance-based payments (Sanghavi and Conway 2015), but these payments were a small part of the overall model. The performance-based payments accounted for only 28 percent of total payments (Appendix A). Most payments were instead either for risk assessment or cardiovascular care management services in 2017 (which were not tied to performance). The model's results reflect a test of all model components together, including not only performance-based payments, but also organizational commitment to CVD preventive care, payments for process, feedback, and peer-to-peer learning. It is unlikely a future test would succeed similarly solely by paying for measured risk reduction.

E. Conclusion

In this large, randomized trial, the Million Hearts Model improved CVD preventive care and reduced first-time heart attacks and strokes, even in a population already receiving considerable CVD care at baseline. The model did not measurably affect Medicare FFS spending. As a result, this model is a promising approach for CMS and other payers or health systems seeking to improve health outcomes for CVD, the leading cause of premature death and disability in the United States and worldwide (Sidney et al. 2019; World Health Organization 2020).

References

- Ahmedi, M., S. Amiri, S. Pecic, F. Machej, J. Rosik, et al. "Pleiotropic Effects of Statins: A Focus on Cancer." *Biochimica et Biophysica Acta (BBA) - Molecular Basis of Disease*, vol. 1866, no. 12, 2020.
- Arnett, D.K., R.S. Blumenthal, M.A. Albert, A.B. Buroker, Z.D. Goldberger, E.J. Hahn, C. Dennison Himmelfarb, et al. "2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines." *Journal of the American College of Cardiology*, vol. 74, no. 10, 2019, pp. e178–e232.
- Arnett, D.K., R.S. Blumenthal, M.A. Albert, A.B. Buroker, Z.D. Goldberger, E.J. Hahn, C.D. Himmelfarb, et al. "2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines." *Circulation*, vol. 140, no. 11, 2019, pp. e596–e646.
- Bairey Merz, C.N., H. Andersen, E. Sprague, A. Burns, M. Keida, M.N. Walsh, p. Greenberger, et al. "Knowledge, Attitudes, and Beliefs Regarding Cardiovascular Disease in Women: The Women's Heart Alliance." *Journal of the American College of Cardiology*, vol. 70, no. 2, 2017, pp. 123–132. doi: 10.1016/j.jacc.2017.05.024.
- Baum., A., and M.D. Schwartz. "Admissions to Veterans Affairs Hospitals for Emergency Conditions During the COVID-19 Pandemic." *JAMA*, vol. 324, no. 1, 2020, pp. 96–99.
- Bibbins-Domingo, K., for the U.S. Preventive Services Task Force. "Aspirin Use for the Primary Prevention of Cardiovascular Disease and Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement." *Annals of Internal Medicine*, vol. 164, no.12, 2016, pp. 836-845.
- Birkmeyer, J.D., A. Barnato, N. Birkmeyer, R. Bessler, and J. Skinner. "The Impact of the COVID-19 Pandemic on Hospital Admissions in the United States: Study Examines Trends in US Hospital Admissions During the COVID-19 Pandemic." *Health Affairs*, vol. 39, no. 11, 2020, pp. 2010–2017.
- Blecker, S., S.A. Jones, C.M. Petrilli, A.J. Admon, H. Weerahandi, F. Francois, et al. "Hospitalizations for Chronic Disease and Acute Conditions in the Time of COVID-19." *JAMA Internal Medicine*, 2020.
- Blue, L., G. Peterson, K. Kranker, T. Huffman, A. Steiner, A. Markovitz, M. Williams, et al. "Evaluation of the Million Hearts® Cardiovascular Disease Risk Reduction Model: Third Annual Report." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Mathematica, November 2020.
- Brooks-LaSure, C., E. Fowler, M. Seshamani, and D. Tsai. "Innovation at the Centers for Medicare & Medicaid Services: A Vision for the Next 10 Years." Health Affairs Blog, August 12, 2021.
- Cameron, A.C., and P.K. Trivedi. Microeconometrics: Methods and Applications. Cambridge, UK: Cambridge University Press, 2005. <u>https://doi.org/10.1017/CBO9780511811241</u>

- Carnethon, M., J. Pu, G. Howard, M. Albert, C. Anderson, A. Bertoni, M. Mujahid, et al.. "Cardiovascular Health in African Americans: A Scientific Statement from the American Heart Association." *Circulation*, vol. 136, no. 21, 2017, pp. e393–e423.
- Centers for Disease Control and Prevention. "About Million Hearts® 2027." 2022. Available at <u>https://millionhearts.hhs.gov/about-million-hearts/index.html</u>.
- Centers for Disease Control and Prevention. "CDC Grand Rounds: The Million Hearts Initiative." *Morbidity and Mortality Weekly Report*, vol. 61, no. 50, 2012, p. 1017.
- Centers for Medicare & Medicaid Services Innovation Center. "Innovation Center Strategy Refresh." Washington, DC: CMS, 2020. <u>https://innovation.cms.gov/strategic-direction-whitepaper</u>. Accessed September 9, 2022.
- Chen, T., F. Shao, K. Chen, Y. Wang, Z. Wu, Y.J. Wang, Y. Gao, V. Cornelius, et al. "Time to Clinical Benefit of Intensive Blood Pressure Lowering in Patients 60 Years and Older with Hypertension: A Secondary Analysis of Randomized Clinical Trials." *JAMA Internal Medicine*, vol. 182, no. 6, 2022, pp. 660–667. doi: 10.1001/jamainternmed.2022.1657.
- Chou, R, A. Cantor, T. Dana, J. Wagner, A.Y. Ahmed, et al. "Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force." *JAMA*, vol. 328, no. 8, 2022, pp. 754– 771.
- Chronic Conditions Data Warehouse. "CCW Chronic Conditions Algorithms." 2022. Available at <u>https://www2.ccwdata.org/web/guest/condition-categories-chronic</u>. Accessed November 18, 2022.
- Ciolino, Jody D., Hannah L. Palac, Amy Yang, Mireya Vaca, and Hayley M. Belli. "Ideal vs.
 Real: A Systematic Review on Handling Covariates in Randomized Controlled Trials." *BMC Medical Research Methodology*, vol. 19, no. 136, 2019. doi: 10.1186/s12874-019-0787-8.
- Cohen, J.T., P.J. Neumann, and M.C. Weinstein. "Does Preventive Care Save Money? Health Economics and the Presidential Candidates." *New England Journal of Medicine*, vol. 358, no. 7, 2008, pp. 661–663. doi: 10.1056/NEJMp0708558.
- Colantonio, L.D., E.B. Levitan, H. Yun, M.L. Kilgore, J.D. Rhodes, et al. "Use of Medicare Claims Data for the Identification of Myocardial Infarction: the REasons for Geographic And Racial Differences in Stroke (REGARDS) Study." *Medical Care*, vol. 56, no. 12, 2018, pp. 1051–1059.
- Conwell, L., L. Barterian, A. Rose, G. Peterson, K. Kranker, L. Blue, D. Magid, et al. "Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model®: First Annual Report." Prepared for the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Washington, DC: Mathematica, February 2019.
- Dehmer, S.P., L.R. O'Keefe, C.V. Evans, J.M. Guirguis-Blake, L.A. Perdue, M.V. Maciosek. "Aspirin Use to Prevent Cardiovascular Disease and Colorectal Cancer: Updated Modeling Study for the US Preventive Services Task Force." *Journal of the American Medical Association*, vol. 327, no.16, 2022, pp. 1598–1607.

- Eijkenaar, F., M. Emmert, M. Scheppach, and O. Schöffski. "Effects of Pay for Performance in Health Care: A Systematic Review of Systematic Reviews." *Health Policy*, vol. 110, nos. 2– 3, 2013, pp. 115–130. doi:10.1016/j.healthpol.2013.01.008.
- Garcia, M., S.L. Mulvagh, C.N. Merz, J.E. Buring, and J.E. Manson. "Cardiovascular Disease in Women: Clinical Perspectives." *Circulation Research*, vol. 118, no. 8, 2016, pp. 1273–1293. <u>https://doi.org/10.1161/CIRCRESAHA.116.307547</u>
- Goff, D.C., D.M. Lloyd-Jones, G. Bennett, S. Coady, R.B. D'Agostino Sr., R. Gibbons, P. Greenland, et al. "2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines." *Journal of the American College of Cardiology*, vol. 63, no. 25, Part B, 2014, pp. 2935–2959.
- Greer, S., L.J. Schieb, M. Ritchey, M. George, and M. Casper. "County Health Factors Associated with Avoidable Deaths from Cardiovascular Disease in the United States, 2006– 2010." *Public Health Reports*, vol. 131, no. 3, 2016, pp. 438–448. doi:10.1177/003335491613100310
- Grundy, S.M., N.J. Stone, A.L. Bailey, C. Beam, K.K. Birtcher, R.S. Blumenthal, L.T. Braun, et al. "2018 AHA/ACC/AACVPR /AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol." *Journal of the American College of Cardiology*, 2018. doi: 10.1016/j.jacc.2018.11.003.
- Gu, Q., V.L. Burt, R. Paulose-Ram, and C.F. Dillon. "Gender Differences in Hypertension Treatment, Drug Utilization Patterns, and Blood Pressure Control Among US Adults with Hypertension: Data from the National Health and Nutrition Examination Survey 1999– 2004." *American Journal of Hypertension*, vol. 21, 2008, pp. 789–798. [PubMed: 18451806]
- Haas, A., M.N. Elliott J.W. Dembosky, J.L. Adams, S.M. Wilson-Frederick, J.S. Mallett, et al. "Imputation of Race/Ethnicity to Enable Measurement of HEDIS Performance by Race/Ethnicity." *Health Services Research*, vol. 54, no. 1, 2019, pp. 13–23. Available at https://doi.org/10.1111/1475-6773.13099.
- Halanych, J.H., F. Shuaib, G. Parmar, R. Tanikella, V.J. Howard, et al. "Agreement on Cause of Death Between Proxies, Death Certificates, and Clinician Adjudicators in the Reasons for Geographic and Racial Differences in Stroke (REGARDS) Study." *American Journal of Epidemiology*, vol. 173, no. 11, 2011, pp. 1319–1326.
- Husaini, M., and K.E. Joynt Maddox. "Paying for Performance Improvement in Quality and Outcomes of Cardiovascular Care: Challenges and Prospects." *Methodist Debakey Cardiovascular Journal*, vol. 16, no. 3, 2020, pp. 225–231. doi: 10.14797/mdcj-16-3-225.
- Jones, A.M. "Health Econometrics" pp. 265–344. In Handbook of Health Economics, edited by J.C. Anthony and J.P. Newhouse. North-Holland, Amsterdam: 2000. https://www.sciencedirect.com/science/article/abs/pii/S1574006400801651

- Joszt, L. "CMMI Remains Dedicated to Value-Based Care Despite Pause to Some Models, Fowler Says." *The American Journal of Accountable Care*, July 15, 2021. Available at <u>https://www.ajmc.com/view/cmmi-remains-dedicated-to-value-based-care-despite-pause-to-some-models-fowler-says-ajac</u>.
- Joynt Maddox, K.E., A.P. Sen, L.W. Samson, R.B. Zuckerman, N. DeLew, and A.M. Epstein. "Elements of Program Design in Medicare's Value-Based and Alternative Payment Models: A Narrative Review." *General Internal Medicine*, vol. 32, no. 11, 2017, pp. 1249–1254. doi: 10.1007/s11606-017-4125-8.
- Karmali, K.N., D.M. Lloyd-Jones, M.A. Berendsen, D.C. Goff Jr., D.M. Sanghavi, N.C. Brown, L. Korenovska, et al. "Drugs for Primary Prevention of Atherosclerotic Cardiovascular Disease: An Overview of Systematic Reviews." *JAMA Cardiology*, vol. 1, no. 3, 2016, pp. 341–349. doi: 10.1001/jamacardio.2016.0218.
- Karmali, K.N., S.D. Persell, P. Perel, D.M. Lloyd-Jones, M.A. Berendsen, and M.D. Huffman. "Risk Scoring for the Primary Prevention of Cardiovascular Disease." *Cochrane Database of Systematic Reviews*, vol. 3, article no. CD006887, 2017. doi: 10.1002/14651858.CD006887.pub4.
- Katsoularis, I., O. Fonseca-Rodriguez, P. Farrington, K. Lindmark, and A. Fors Connolly. "Risk of Acute Myocardial Infarction and Ischaemic Stroke Following COVID-19 in Sweden: A Self-Controlled Case Series and Matched Cohort Study." *The Lancet*, published online July 29, 2021. doi:10.1016/S0140-6736(21)00896-5.
- Kim, N., S.M. Bernheim, L.S. Ott, L. Han, S.B. Spivack, X. Xu, M. Volpe, et al. "An Administrative Claims Measure of Payments Made for Medicare Patients for a 30-Day Episode of Care for Acute Myocardial Infarction." *Medical Care*, vol. 53, no. 6, June 2015. doi: 10.1097/MLR.00000000000361.
- King, J.B., L.C. Pinheiro, J. Bryan Ringel, A.P. Bress, D. Shimbo, P. Muntner, K. Reynolds, et al. "Multiple Social Vulnerabilities to Health Disparities and Hypertension and Death in the REGARDS Study." *Hypertension*, vol. 79, no. 1, 2022, pp. 196–206. doi: 10.1161/HYPERTENSIONAHA.120.15196.
- Lau, D., and F.A McAlister. "Implications of the COVID-19 Pandemic for Cardiovascular Disease and Risk-Factor Management." *Canadian Journal of Cardiology*, vol., 37, no. 5, 2021, pp. 722–732. doi: 10.1016/j.cjca.2020.11.001. Epub 2020 Nov 16. PMID: 33212203; PMCID: PMC7667463.
- Lloyd-Jones, D.M. "USPSTF Report on Aspirin for Primary Prevention." *JAMA Cardiology*, 2022, epub ahead of print.
- Lloyd-Jones, D.M., L.T. Braun, C.E. Ndumele, S.C. Smith Jr., L.S. Sperling, S.S. Virani, and R.S. Blumenthal. "Use of Risk Assessment Tools to Guide Decision-Making in the Primary Prevention of Atherosclerotic Cardiovascular Disease: A Special Report from the American Heart Association and American College of Cardiology." *Journal of the American College of Cardiology*, vol. 73, no 24, 2019, pp. 3153–3167. doi: 10.1016/j.jacc.2018.11.005.

- Lloyd-Jones, D.M., M.D. Huffman, K.N. Karmali, D.M. Sanghavi, J.S. Wright, C. Pelser, M. Gulati, et al. "Estimating Longitudinal Risks and Benefits from Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool: A Special Report from the American Heart Association and American College of Cardiology." *Journal of the American College of Cardiology*, vol. 69, no. 12, 2017, pp. 1617–1636. doi: 10.1016/j.jacc.2016.10.018.
- Martin, B., J. Jones, M. Miller, and R. Johnson-Koenke. "Health Care Professionals' Perceptions of Pay-for-Performance in Practice: A Qualitative Metasynthesis." *Inquiry*, vol. 57, 2020. doi: 10.1177/0046958020917491.
- Medicare Payment Advisory Commission. "Report to the Congress: Medicare Payment Policy. Washington, DC: MedPAC, 2022. <u>https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf</u>.
- Mendelson, A. K. Kondo, C. Damberg, A. Low, M. Motúapuaka, M. Freeman, M. O'Neil, et al.
 "The Effects of Pay-for-Performance Programs on Health, Health Care Use, and Processes of Care: A Systematic Review." *Annals of Internal Medicine*, vol. 166, no. 5, 2017, pp. 341–353. doi: 10.7326/M16-1881.
- Mihaylova, B., A. Briggs, A. O'Hagan, and S.G. Thompson. "Review of Statistical Methods for Analysing Healthcare Resources and Costs." *Health Economics*, vol. 20, no. 8, 2011, pp. 897–916. <u>http://dx.doi.org/10.1002/hec.1653</u>.
- Montgomery, J.R., A.H. Cain-Nielsen, P.C. Jenkins, S.E. Regenbogen, and M.R. Hemmila. "Prevalence and Payments for Traumatic Injury Compared with Common Acute Diseases by Episode of Care in Medicare Beneficiaries, 2008–2014." *JAMA*, vol. 321, no. 21, June 2019, pp. 2129–2131. doi: 10.1001/jama.2019.1146.
- Morieri, M.L., O. Lamacchia, E. Monzato, A. Giaccari, A. Avogaro, and the Lipid-Lowering Relevance Study Group. "Physicians' Misperceived Cardiovascular Risk and Therapeutic Inertia as Determinants of Low LDL-Cholesterol Targets Achievement in Diabetes." *Cardiovascular Diabetology*, vol. 21, no. 1, 2022. doi: 10.1186/s12933-022-01495-8.
- Mosca, L., A.H. Linfante, E.J. Benjamin, K. Berra, S.N. Hayes, B.W. Walsh, R.B. Fabunmi, et al. "National Study of Physician Awareness and Adherence to Cardiovascular Disease Prevention Guidelines." *Circulation*, vol. 111, no. 4, 2005, pp. 499–510. doi: 10.1161/01.CIR.0000154568.43333.82.
- Mosca, L., A.M. Navar, and N.K. Wenger. "Reducing Cardiovascular Disease Risk in Women Beyond Statin Therapy: New Insights 2020." *Journal of Women's Health*, 2020, pp. 1091– 1100. <u>http://doi.org/10.1089/jwh.2019.8189</u>.
- Muntner, P., S.T. Hardy, L.J. Fine, B.C. Jaeger, G. Wozniak, E.B. Levitan, and L.D. Colantonio. "Trends in Blood Pressure Control Among US Adults with Hypertension, 1999–2000 to 2017–2018." *Journal of the American Medical Association*, vol. 324, no. 12, 2020, pp. 1190– 1200. doi: 10.1001/jama.2020.14545.
- Nau, D. "Proportion of Days Covered (PDC) as Preferred Method of Measuring Medication Adherence." Springfield, VA: Pharmacy Quality Alliance, June 2011.

- NORC. "Quality Control Results CMS Million Hearts Randomization Results." Microsoft Excel file submitted to CMS. Bethesda, MD: NORC, 2016b.
- NORC. "The Million Hearts® Cardiovascular Risk Reduction Model: Develop Algorithm and Conduct Post Selection Randomization; Randomization Methodology Plan." Report submitted to CMS April 11, 2016. Bethesda, MD: NORC, 2016a.
- Olubowale, O.T., M.M. Safford, T.M. Brown, R.W. Durant, V.J. Howard, et al. "Comparison of Expert Adjudicated Coronary Heart Disease and Cardiovascular Disease Mortality with the National Death Index: Results from the REasons for Geographic And Racial Differences in Stroke (REGARDS) Study." *Journal of the American Heart Association*, vol. 6, no. 5, 2017, p. e004966.
- Peterson, G., A. Steiner, R. Powell, J. Rollison, A Markovitz, L. Blue, K. Stewart, et al. "Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model: Fourth Annual Report." Prepared for the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Washington, DC: Mathematica, February 2022.
- Peterson, G., L. Barterian, K. Kranker, A. Markovitz, A. Rose, R. Sarwar, A. Steiner, et al. "Evaluation of the Million Hearts Cardiovascular Disease Risk Reduction Model: Second Annual Report." Prepared for the U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. Washington, DC: Mathematica, November 2019.
- Psaty, B.M., J.A. Delaney, A.M. Arnold, L.H. Curtis, A.L. Fitzpatrick, et al. "Study of Cardiovascular Health Outcomes in the Era of Claims Data: The Cardiovascular Health Study." *Circulation*, vol. 133, no. 2, 2016, pp. 156–164.
- Salvado, E.Z., H.J. van Elten, and E.M. van Raaji. "The Linkages Between Reimbursement and Prevention: A Mixed-Methods Approach." Frontiers in Public Health, vol. 9, 2021. doi: 10.3389/fpubh.2021.750122.
- Sanghavi, D.M., and P.H. Conway. "Paying for Prevention: A Novel Test of Medicare Value-Based Payment for Cardiovascular Risk Reduction." *JAMA*, vol. 314, no. 2, 2015, pp. 123– 124. doi:10.1001/jama.2015.6681.
- Schochet, Peter. "Is Regression Adjustment Supported by the Neyman Model for Causal Inference?" *Journal of Statistical Planning and Inference*, vol. 140, no. 1, 2010, pp. 246– 259. doi:10.1016/j.jspi.2009.07.008. doi:10.1016/j.jspi.2009.07.008.
- Shahu, A., V. Okunrintemi, M. Tibuakuu, S.U. Khan, M. Gulati, F.A. Marvel, R.S. Blumenthal, and E.D. Michos. "Abstract 23: Income Disparity and Utilization of Cardiovascular Preventive Care Services in the Medical Expenditure Panel Survey (MEPS)." Originally published14 May 2020 https://doi.org/10.1161/hcq.13.suppl_1.23. Circulation: Cardiovascular Quality and Outcomes, vol. 13, 2020 p. A23.
- Shaw, L.J., C.J. Pepine, J. Xie, P.K. Mehta, A.A. Morris, N.W. Dickert, K.C. Ferdinand, et al. "Quality and Equitable Health Care Gaps for Women: Attributions to Sex Differences in Cardiovascular Medicine." *Journal of the American College of Cardiology*, vol. 70, no. 3, 2017, pp. 373–388. https://doi.org/10.1016/j.jacc.2017.05.051

- Shiels, M., A. Haque, A Berrington de Gonzalez, and N. Freedman. "Leading Causes of Death in the US During the COVID-19 Pandemic, March 2020 to October 2021." *JAMA Internal Medicine*, published online July 5, 2022. doi:10.1001/jamainternmed.2022.2476.
- Sidney, S., A.S. Go, M.G. Jaffe, M.D. Solomon, A.P. Ambrosy, and J.S. Rana. "Association Between Aging of the US Population and Heart Disease Mortality from 2011 to 2017." *JAMA Cardiology*, vol. 4, no. 12, 2019, pp. 1280–1286. doi: 10.1001/jamacardio.2019.4187.
- Sinha, S.S., N.M. Moloci, A.M. Ryan, A.A. Markovitz, C.H. Colla, V.A. Lewis, B.K. Hollenbeck, et al. "The Effect of Medicare Accountable Care Organizations on Early and Late Payments for Cardiovascular Disease Episodes." *Circulation: Cardiovascular Quality and Outcomes*, vol. 11, no. 8, 2018, p. e004495. doi: 10.1161/CIRCOUTCOMES.117.004495.
- Solomon, M.D., E.J. McNulty, J.S. Rana, T.K. Leong, C. Lee, S. Sung, et al. "The Covid-19 Pandemic and the Incidence of Acute Myocardial Infarction." New England Journal of Medicine, 2020. doi: 10.1056/NEJMc2015630.
- Solomon, M.D., M. Nguyen-Huynh, T.K. Leong, J. Alexander, J.S. Rana, J. Klingman, and A.S. Go. "Changes in Patterns of Hospital Visits for Acute Myocardial Infarction or Ischemic Stroke During COVID-19 Surgeries." *JAMA Internal Medicine*, June 2, 2021. doi:10.1001/jama.2021.8414.
- Sposito, A.C., J.A. Ramires, W. Jukema, J.C. Molina, P.M. da Silva, M.M. Chandafar, and P.W.F. Wilson. "Physicians' Attitudes and Adherence to Use of Risk Scores for Primary Prevention of Cardiovascular Disease: Cross-Sectional Survey in Three World Regions." *Current Medical Research and Opinion*, vol. 25, no. 5, 2009, pp. 1171–1178. DOI: 10.1185/03007990902846423.
- Stewart, K.A., L. Blue, K. Kranker, S. Nelson, N. McCall, P. Markovich, and G.G. Peterson. "Hospital Use for Myocardial Infarction and Stroke Among Medicare Beneficiaries from March to December 2020." *JAMA Cardiology*, vol. 6, no. 11, 2021, pp. 1340–1342. DOI: 10.1001/jamacardio.2021.2729.
- Sukul, D., and K.A. Eagle. "Value-Based Payment Reforms in Cardiovascular Care: Progress to Date and Next Steps." *Methodist Debakey Cardiovascular Journal*, vol. 16, no. 3, 2020. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7587316/pdf/i1947-6094-16-3-232.pdf.
- Sukul, D., M. Seth, J.M. Dupree, J.D. Syrjamaki, A.M. Ryan, B.K. Nallamothu, and H.S. Gurm. "Drivers of Variation in 90-Day Episode Payments After Percutaneous Coronary Intervention: Insights from Michigan Hospitals." *Circulation: Cardiovascular Interventions*, vol. 12, no. 1, 2019, p. e006928. doi: 10.1161/CIRCINTERVENTIONS.118.006928.
- Sun, C., S. Dyer, J. Salvia, L. Segal, and R. Levi. "Worse Cardiac Outcomes During the COVID-19 Pandemic in Boston Can Be Attributed to Patient Reluctance to Seek Care." *Health Affairs*, vol. 46, no. 6, May 2021. <u>https://doi.org/10.1377/hlthaff.2021.00250</u>.

- Tamargo, C., K. Sando, Y. Prados, and K. Cowart. "Change in Proportion of Days Covered for Statins Following Implementation of a Pharmacy Student Adherence Outreach Program." *Journal of Managed Care & Specialty Pharmacy*, vol. 25, no. 5, 2019, pp.588–592. doi: 10.18553/jmcp.2019.25.5.588.
- Thygesen, K., J.S. Alpert, A.S. Jaffe, B.R. Chaitman, J.J. Bax, D.A. Morrow, H.D. White, and Executive Group on behalf of the Joint European Society of Cardiology (ESC)/American College of Cardiology (ACC)/American Heart Association (AHA)/World Heart Federation (WHF) Task Force for the Universal Definition of Myocardial Infarction. "Fourth Universal Definition of Myocardial Infarction (2018)." *Journal of the American College of Cardiology*, vol. 72, no. 18, October 2018. doi: 10.1016/j.jacc.2018.08.1038.
- Tsao, C.W., A.W. Aday, Z.I. Almarzooq, A. Alonso, A.Z. Beaton, M.S. Bittencourt, A.K. Boehme, et al. "Heart Disease and Stroke Statistics—2022 Update: A Report from the American Heart Association." *Circulation*, vol. 145, no. 8, 2022, pp. e153–e639. doi: https://doi.org/10.1161/CIR.000000000001052.
- U.S. Department of Health & Human Services. "HHS Regional Offices." Available at: <u>https://www.hhs.gov/about/agencies/iea/regional-offices/index.html</u>. Last accessed August 26, 2022.
- U.S. Preventive Services Task Force. "Aspirin Use to Prevent Cardiovascular Disease: US Preventive Services Task Force Recommendation Statement." *Journal of the American Medical Association*, vol. 327, no.16, 2022a, pp. 1577–1584.
- U.S. Preventive Services Task Force. "Statin Use for the Primary Prevention of Cardiovascular Disease in Adults US Preventive Services Task Force Recommendation Statement." *Journal of the American Medical Association*, vol. 328, no.8, 2022b, pp. 746–753.
- Virani, S.S., A. Alonso, H.J. Aparicio, E.J. Benjamin, M.S. Bittencourt, et al. "Heart Disease and Stroke Statistics—2021 Update: A Report from the American Heart Association." *Circulation*, vol. 143, no. 8, 2021, pp. e254–e743.
- Virani, S.S., L.D. Woodard, D.J. Ramsey, T.H. Urech, J.M. Akeroyd, T. Shah, A. Deswal, et al. "Gender Disparities in Evidence-Based Statin Therapy in Patients with Cardiovascular Disease." *American Journal of Cardiology*, vol. 115, 2015, pp. 21–26.
- Vogel, B., M. Acevedo, Y. Appelman, C.N. Bairey Merz, A. Chieffo, G.A. Figtree, M. Guerrero, et al. "The *Lancet* Women and Cardiovascular Disease Commission: Reducing the Global Burden by 2030." *The Lancet*, vol. 397, no. 10292, 2021, pp. 2385–2438.
- Wadhera, R.K., D.L. Bhatt, A.J.H. Kind, Y. Song, K.A. Williams, T.M. Maddox, R.W. Yeh, et al. "Association of Outpatient Practice-Level Socioeconomic Disadvantage with Quality of Care and Outcomes Among Older Adults with Coronary Artery Disease: Implications for Value-Based Payment." *Circulation: Cardiovascular Quality and Outcomes*, vol. 13, no, 2020, p. e005977. doi: 10.1161/CIRCOUTCOMES.119.005977.

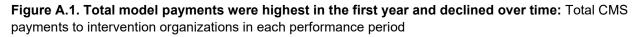
- Wall, H.K., M.D. Ritchey, C. Gillespie, J.D. Omura, A. Jamal, and M.G. George. "Vital Signs: Prevalence of Key Cardiovascular Disease Risk Factors for Million Hearts 2022—United States, 2011–2016." *Morbidity and Mortality Weekly*, vol. 67, no. 35, 2018, pp. 983–991. Available at <u>https://www.cdc.gov/mmwr/volumes/67/wr/mm6735a4.htm</u>.
- Wang, R., S.W. Lagakos, J.H. Ware, D.J. Hunter, and J.M. Drazen. "Statistics in Medicine— Reporting of Subgroup Analyses in Clinical Trials." *New England Journal of Medicine*, vol. 357, no. 21, 2007, pp. 2189–2194. doi: 10.1056/NEJMsr077003. PMID: 18032770.
- Whelton, P.K., R.M. Carey, W.S. Aronow, D.E. Casey Jr., K.J. Collins, C. Dennison Himmelfarb, S.M. DePalma, et al. "2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines." *Hypertension*, vol. 71, no. 6, 2019, pp. 1269–1324. Available at <u>https://doi.org/10.1161/HYP.000000000000066</u>.
- World Health Organization. "The Top 10 Causes of Death." WHO, 2020.
- Xie, F., L.D. Colantonio, J.R. Curtis, M.L. Kilgore, E.B. Levitan, et al. "Development of Algorithms for Identifying Fatal Cardiovascular Disease in Medicare Claims." *Pharmacoepidemiology and Drug Safety*, vol. 27, no. 7, 2018, pp. 740–750.
- Xu, J., S.L. Murphy, K.D. Kochanek, and E. Arias. "Mortality in the United States, 2021." NCHS Data Brief, No. 456, December 2022. https://www.cdc.gov/nchs/data/databriefs/db456.pdf.
- Yourman, L.C., I. Cenzer, J. Boscardin, B.T. Nguyen, A. Smith, M.A. Schonberg, N.L. Schoenborn, et al. "Evaluation of Time to Benefit of Statins for the Primary Prevention of Cardiovascular Events in Adults Aged 50 to 75 Years: A Meta-Analysis." *JAMA Internal Medicine*, vol. 181, no. 2, 2020. DOI:10.1001/jamainternmed.2020.6084.
- Yusuf, S., P. Joseph, S. Rangarajan, S. Islam, A. Mente, P. Hystad, M. Brauer, et al. "Modifiable Risk Factors, Cardiovascular Disease, and Mortality in 155,722 Individuals from 21 High-Income, Middle-Income, and Low-Income Countries (PURE): A Prospective Cohort Study." *Lancet*, vol. 395, no. 10226, 2020, pp. 795–808. doi: S0140-6736(19)32008-2.

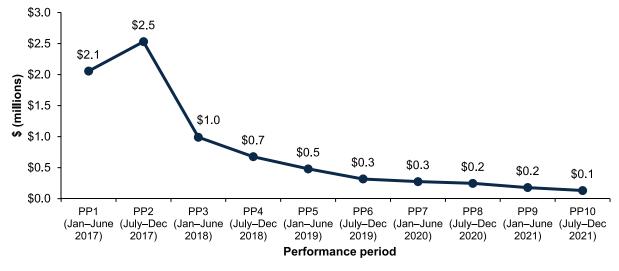
Appendix A

Model Payments through 2021

This appendix provides additional context about the model payments introduced in <u>Chapter I</u>. To understand the amounts the Centers for Medicare & Medicaid Services (CMS) paid organizations over the course of the model, we analyzed organization-level payment data provided by the implementation contractor.

Organizations in the intervention group could 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 (Year 1 only), and reducing risk among beneficiaries at high risk (model Years 2 through 5). From January 2017 to December 2021, CMS paid \$7.9 million to intervention organizations participating in the Million Hearts Model (Figure A.1). Payments to intervention organizations were highest in model Year 1 and declined over time. This trend reflects both (1) organizations dropping out the model over time and (2) average payments to those staying in the model decreasing as payments shifted from pay for process to pay for performance. Over the five-year model, 72 percent of the total payments to intervention organizations (\$5.7 million) was for processes (risk stratification and cardiovascular care management) and 28 percent (\$2.2 million) was for performance (risk reduction).





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.

We also calculated the mean payments in each performance period by payment type: risk stratification, cardiovascular care management, and risk reduction (Figure A.2). In each period, we limited the analysis 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. The greatest mean payments were concentrated in Year 1 and declined over

time as organizations enrolled fewer new beneficiaries and payments depended on reducing risk among high-risk beneficiaries. Most organizations received some payments for reducing risk for their high-risk beneficiaries, but these payments were generally modest. The mean risk-reduction payment for each six-month performance period ranged from \$5,086 to \$1,567 across the performance periods.

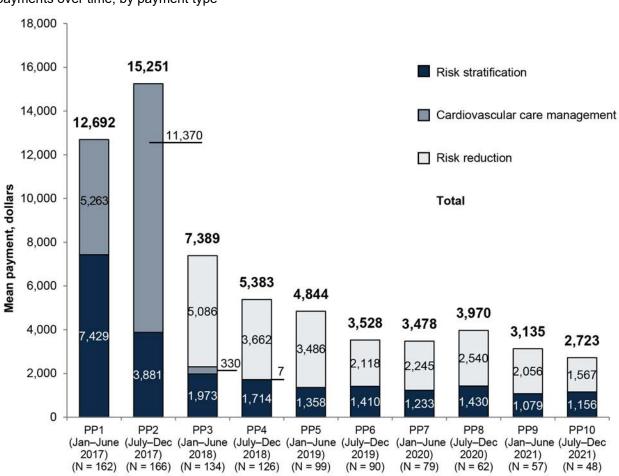


Figure A.2. Average payments to intervention organizations were concentrated in Year 1: Mean payments over time, by payment type



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 PP2 only (although organizations might have received them during PP3) and risk-reduction payments began in PP3.

N = number of organizations; PP = performance period.

Table A.1 shows the number of intervention organizations eligible for risk-reduction payments in performance periods 3 through 10 (January 2018 to December 2021) and the proportion of these organizations earning each risk-reduction payment category (\$0, \$5, or \$10 per beneficiary per month [PBPM]). Organizations received \$10 PBPM if the mean cardiovascular disease (CVD) risk score among the high-risk beneficiaries reported in that period was 10 or more percentage

points lower than these beneficiaries' CVD scores at model enrollment; \$5 PBPM if the mean risk reduction was from 2 to 10 percentage points; and \$0 if the mean risk reduction was less than 2 percentage points. For this analysis, in each period, we included organizations that 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 3rd performance period (the first period in which they were eligible to receive payments for risk reduction) to 38 in the 10th performance period. In each performance period, 8 to 26 percent of the organizations that submitted a reassessment visit met the criteria for the maximum riskreduction payment amount of \$10 PBPM—that is, they reduced the aggregate average risk among high-risk beneficiaries by more than 10 percentage points. The percentage of organizations that submitted reassessment visit data but did not qualify for any risk-reduction payments increased over time. One possible explanation for the decline in performance over time (that is, a smaller proportion of organizations achieving higher levels of mean risk reduction) is that CVD risk scores increase as people age. The aging of the high-risk population over the fiveyear trial likely offset some of the decrease in CVD risk observed for high-risk beneficiaries earlier in the trial.

_Performance period	Number of organizations	\$0 PBPM (%)	\$5 PBPM (%)	\$10 PBPM (%)
PP3 (Jan–June 2018)	109	6	72	22
PP4 (July–Dec 2018)	94	11	64	26
PP5 (Jan–June 2019)	91	16	65	19
PP6 (July–Dec 2019)	75	19	59	23
PP7 (Jan–June 2020)	68	22	53	25
PP8 (July–Dec 2020)	57	32	53	16
PP9 (Jan–June 2021)	49	41	51	8
PP10 (July–Dec 2021)	38	39	45	16
Total (any period) ^a	124	47	81	56

Table A.1. The number of organizations receiving risk reduction payments declined over time: 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 PP10 (Number of organizations 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.

PBPM = per beneficiary per month; PP = performance period

Appendix B

Characteristics of Participating Organizations and Enrolled Beneficiaries

This appendix provides supplemental information about the characteristics of participating organizations and their enrolled beneficiaries:

- Table B.1. Characteristics of (1) intervention group organizations that continued to actively participate in the model through December 2021 by formally remaining in the model and submitting data in that year versus (2) those that did not
- Table B.2. Characteristics of (1) beneficiaries in the Million Hearts Model intervention group, relative to (2) the national Medicare fee-for-service (FFS) population ages 40 to 79
- Table B.3: Characteristics of (1) the beneficiaries' intervention organization enrolled in the model versus (2) those who appeared to be eligible in claims data but did not enroll
- 1. Characteristics of intervention group organizations that continued to actively participate in the model through December 2021 versus those that did not

Based on the decline in model participation over time, Mathematica compared the characteristics of intervention organizations that continued to actively participate in the model through December 2021 to those that did not. Specifically, we compared (1) the 59 organizations that formally remained in the model through the end of 2021 and submitted data to the Million Hearts Data Registry at any time in that year; to (2) the 114 organizations that participated early in the model (that is, enrolled at least one beneficiary in 2017 or 2018) but either formally withdrew before the end of the model or stopped submitting data to the registry by 2021.

As shown in Table B.1, organizations that continued to actively participate in the model through 2021 were larger and more urban than those that did not. Organizations that actively participated in 2021 enrolled more beneficiaries in the first two years of the model on average (2,273 versus 830). They also had, on average, more providers reported in the organizations' Million Hearts Model application (60 versus 26). Organizations that actively participated were also less likely to be in a rural location (32 versus 53 percent), and more likely to be classified as a specialty or multispecialty practice at application (36 versus 16 percent).

The organizations that actively participated through 2021 accounted for a disproportionate share of total model enrollment in 2017 and 2018 and, therefore, their experiences in the model should have a disproportionate influence on model effects. Although the organizations that stayed active in the model through 2021 accounted for only 34 percent of the 173 organizations that participated (by enrolling any beneficiaries in 2017 or 2018), the organizations still active in 2021 had enrolled 59 percent of beneficiaries enrolled in 2017 and 2018. This pattern occurred because the organizations that stayed active in the model through 2021 were larger and, per organization, enrolled almost three times as many beneficiaries as the other organizations in the first two years of the model. Because we estimate impacts for enrolled beneficiaries, the organizations participating through 2021 contributed about 60 percent to the overall effect estimates.

Table B.1. Characteristics of organizations that actively participated in the model throughDecember 2021 versus those that enrolled at least one beneficiary in 2017 or 2018 but stoppedactively participating by December 2021

	Actively participating in 2021	Not actively participating in 2021	
Characteristic	(N = 59)	(N = 114)	Difference
Enrollment			
Number of beneficiaries enrolled in 2017 or 2018 (all risk levels) (mean)	2,273	830	1,443.5
Size (from Million Hearts Model application)			
Number of providers, mean	60	26	33.8
Number of sites, mean	10	7	3.3
Neighborhood characteristicsa			
Summary SVI score, mean (1 to 100)	46	50	-4.1
Location (from Million Hearts Model application)			
Rural (%)	32	53	-20.4
Census region (%)			
Northeast	25	32	-7.0
Midwest	19	16	2.9
South	42	35	7.3
West	14	16	-2.2
Organization type ^b			
Primary care (%)	47	54	-6.9
Specialty or multispecialty (%)	36	16	19.8
FQHC, RHC, or other health center (%)	12	17	-4.8
CAH or rural hospital (%)	0	4	-4.4
Acute care hospital (%)	5	9	-3.7
Participating in other CMS models or programs when a	applied for the Milli	on Hearts Model ^c	
In one or more model (or application pending at random assignment) (%)	54	49	5.1
In Medicare Shared Savings Program (%)	32	28	4.1

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

^a We measure vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability.

^b 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.

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

CAH = critical access hospital; CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare & Medicaid Services; FQHC = federally qualified health center; NPI = National Provider Identifier; NPPES = National Plan and Provider Enumeration System; RHC = rural health center; SVI = Social Vulnerability Index.

2. Characteristics of the Million Hearts Model intervention group and the national Medicare FFS population ages 40 to 79

To understand how well the Million Hearts Model population reflected the broader population that could have participated, we compared the model intervention group to the national Medicare FFS population of the same age (ages 40 to 79). These results could have implications for the generalizability of our evaluation findings beyond the study population. They also show how equitably the model reached Medicare FFS beneficiaries—that is, the extent to which the model over- or underrepresented certain demographic groups.

As shown in Table B.2, beneficiaries in Million Hearts Model intervention group were mostly similar to the national Medicare FFS beneficiaries ages 40 to 79. However, the enrolled beneficiaries in 2017 and 2018 were more likely to be White than the national average (83 versus 79 percent) and were more affluent, with lower Social Vulnerability Index (SVI) summary scores, on average. That is, they resided in Census tracts with slightly lower average social vulnerability. The analytic population (high- or medium-risk beneficiaries only) differed slightly from all enrolled beneficiaries in expected ways: being older on average with a higher proportion male. These demographic characteristics are strong predictors of higher cardiovascular disease risk.

	Million Hearts Mode	el intervention group			
Subgroup	All enrolled beneficiaries, 2017– 2018, with any risk level, % N = 228,713	Enrolled beneficiaries 2017– 2018, with high or medium risk only, % N = 130,578	Medicare FFS beneficiaries ages 40 to 79,ª % N = 21,349,183		
Demographics					
Age, mean	69	72	68		
Female, %	56	42	54		
Race and ethnicity, % ^b					
White, non-Hispanic	83	84	79		
Black, non-Hispanic	8	7	9		
Hispanic	5	4	6		
All other races and ethnicities	4	4	6		
Neighborhood characteristics ^c					
Summary SVI score, mean (1 to 100)	42.7	42.3	46.9		
HHS region, % ^d					
1: CT, ME, MA, NH, RI, and VT	4	3	6		
2: NY, NJ	15	15	8		
3: DC, DE, MD, PA, VA, and WV	20	21	11		
4: AL, FL, GA, KY, MS, NC, SC, and TN	23	23	22		
5: IL, IN, MI, MN, OH, and WI	9	8	16		

Table B.2. Characteristics of the Million Hearts Model intervention group and the nationalMedicare FFS population ages 40 to 79

	Million Hearts Mode			
Subgroup	All enrolled beneficiaries, 2017– 2018, with any risk level, % N = 228,713	Enrolled beneficiaries 2017– 2018, with high or medium risk only, % N = 130,578	Medicare FFS beneficiaries ages 40 to 79,ª % N = 21,349,183	
6: AR, LA, NM, OK, and TX	10	10	12	
7: IA, KS, MO, and NE	12	11	5	
8: CO, MT, ND, SD, UT, and WY	1	1	3	
9: AZ, CA, HI, and NV	5	6	12	
10: AK, ID, OR, and WA	1	1	4	
11: Missing, unknown, or out of USA	<1	<1	<1	

Sources: Medicare enrollment and claims data; Million Hearts Data Registry data; Centers for Disease Control and Prevention 2016 Census-tract-level SVI file for identifying beneficiaries in socially vulnerable Census tracts; and RAND race and ethnicity file.

Note: Characteristics of the Million Hearts Model evaluation intervention group population defined based on each beneficiary's enrollment date. Characteristics of the national, model-eligible Medicare FFS population defined on January 3, 2017.

^a We identified model-eligible beneficiaries as those who met the following model inclusion criteria: (1) did not have a prior heart attack or stroke; (2) did not have ESRD; (3) were not in hospice; and (4) were observable in Medicare claims and enrollment files during the prior year—that is, enrolled in Medicare Parts A and B FFS with Medicare as primary payer.

^b We used predicted probabilities of being in each category of race and ethnicity based on an algorithm developed by the RAND Corporation. Most but not all beneficiaries had predicted race and ethnicity probabilities available. The population sizes used for these analyses were N = 228,693 for the full Million Hearts Model intervention group, N = 130,569 for the high- and medium-risk intervention group, and N = 21,338,778 for the national, model-eligible population.

^c We measure vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability.

^d Region descriptions use standard abbreviations for U.S. states.

CDC = Centers for Disease Control and Prevention; ESRD = end-stage renal disease; FFS = fee-for-service; HHS = U.S. Department of Health and Human Services; SVI = Social Vulnerability Index.

3. Characteristics of beneficiaries enrolled in the model versus those who appeared to be eligible but did not enroll

Intervention group organizations enrolled about half of the beneficiaries who visited the organizations in 2017 and 2018 and appeared to be eligible for the Million Hearts Model, based on their age and clinical characteristics observed in Medicare claims data. To understand whether the organizations were more likely to serve certain types of beneficiaries than others, we compared the characteristics of the beneficiaries intervention group organization enrolled to those who appeared eligible but did not enroll. 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 Medicare claims and enrollment data.

As shown in Table B.3, enrolled beneficiaries had more visits with the enrolling organization than those 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 and slightly less likely to also be enrolled in Medicaid.

Characteristic	Enrolled in the model (N = 228,020)	Not enrolled in the model (N = 206,590)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Demographic and Medicare e					
Age, mean	69	68	0.4	0.05	0.04
Non-Hispanic Black ^c , %	8	9	-1.1	-0.04	0.17
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
Neighborhood characteristics	d				
Summary SVI score, mean (1 to 100)	43	44	-1.0	-0.04	0.57
Health and comorbid condition	ons				
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 spen	ding in year befor	re attribution			
Total Medicare Parts A and B annualized expenditures (\$)	7,447	10,314	-2,867	-0.10	<0.01
Hospital admissions (# per 1,000 beneficiaries)	181	273	-92	-0.06	<0.01
Office visits with model- aligned providers ^e (# per 1,000 beneficiaries)	2,202	1,277	925	0.32	<0.01

Table B.3. Characteristics of enrolled beneficiaries versus beneficiaries eligible but not enrolled,2017 to 2018

Sources: Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending, and attribution; Centers for Disease Control and Prevention 2016 Census-tract-level SVI file for identifying beneficiaries in socially vulnerable Census tracts; and RAND race and ethnicity file.

Notes: We attributed beneficiaries using the approach described in <u>Appendix C of the 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 <u>Appendix C of the Third Annual Report</u>); 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 The percentage of beneficiaries with non-Hispanic Black race is based on beneficiaries' predicted probabilities of falling into that category. The predicted probabilities were developed by the RAND Corporation from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^d We measured vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. ^e For this analysis, we defined Million Hearts Model-aligned providers as those included on an organization's provider list to CMS at the time of random assignment.

CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare & Medicaid Services; HCC = hierarchical condition category; MBSIG = Medicare Bayesian Improved Surname Geocoding; SVI = Social Vulnerability Index.

The control organizations also enrolled about half of their attributed beneficiaries, and the differences between those enrolled and not enrolled were similar to those found in the intervention group (see <u>Appendix E of the Third Annual Report</u>). This similarity is part of the reason the intervention and control groups are well balanced on pre-intervention characteristics (as shown in <u>Appendix E</u> of this report). That is, even though the intervention and control groups both enrolled beneficiaries who differed from their attributed beneficiaries in meaningful ways, they did so similarly—leading to enrolled populations that were also similar between the intervention and control groups.

Appendix C

Qualitative Data Collection and Methods for Beneficiary Interviews

Discussions between providers and patients about cardiovascular disease (CVD) risk are a core component of the Million Hearts CVD Risk Reduction Model. Model providers were to engage with high-risk beneficiaries in a shared decision-making process in which the beneficiary and provider jointly decide on an individualized plan to reduce CVD risk. In 2021, Mathematica interviewed beneficiaries enrolled in the model to address the following research questions:

- How did discussions with Million Hearts Model providers shape beneficiaries' knowledge about CVD risk scores and perceptions of their CVD risk?
- How did discussions about CVD risk with Million Hearts Model providers shaped beneficiaries' awareness about modifiable risk factors and engagement in behaviors that might reduce CVD risk?
- How did beneficiaries perceive their involvement in care planning and management to reduce CVD risk?

This appendix describes the qualitative data collection and analysis methods used for these beneficiary interviews.

1. Identifying and recruiting beneficiaries

We identified a convenience sample of high-risk beneficiaries seen at a Million Hearts Model organization for a reassessment visit in 2021. We contacted all 89 intervention organizations that responded to the 2021 practice survey and had not withdrawn from the model, asking each for contact information for five to seven high-risk beneficiaries who had a reassessment visit in 2021. Of the 89 organizations contacted, 18 provided information for a total of 104 beneficiaries. We attempted to contact each beneficiary by phone (up to five attempts).

If a beneficiary was interested in participating, we verbally reviewed a consent form and the beneficiary provided consent before we proceeded with the 30-minute interview. Beneficiaries who completed an interview received a \$50 check to thank them for their time. Of the 104 beneficiaries we called, 15 agreed to participate in interviews, 27 answered the phone but declined to participate, and 62 were nonresponsive (Table C.1).

Table C.1. Recruitment for beneficiary interviews

	Count (N)
Organization outreach	
Number of organizations contacted	89
Number of organizations declined or nonresponsive, ^a stopped outreach	71
Number of organizations that responded and provided beneficiaries' contact information	18
Beneficiary outreach	
Received contact information from practice	104
Sent mail outreach to beneficiary	103
Initiated phone outreach	104
Interviewee nonresponsive, ^b stopped outreach	62
Declined participation, stopped outreach	27
Scheduled interview	15
Completed interview	15

^a An organization was determined nonresponsive after five email or phone outreach attempts.

^b A beneficiary was determined nonresponsive after five phone outreach attempts.

2. Beneficiary sample

The final analytic sample included 14 beneficiaries enrolled by 10 different intervention group organizations.¹² The model organizations at which these beneficiaries received care were in all four U.S. Census regions (with nearly half in the South); most were primary care organizations. The average age of beneficiaries was 77 at the time of the interview, and nearly one-third were female. Most enrolled in the model in 2017 or 2018, and the average 10-year CVD risk score at the time of enrollment was 39.0 percent. Compared to all high-risk beneficiaries enrolled in the Million Hearts Model in 2017 and 2018, those we interviewed were of similar age and had a similar geographic distribution and mean CVD risk, but were more likely to be male.

3. Interview protocol

The beneficiary interview protocol included questions on the following topics:

- Beneficiaries' awareness of CVD risk, including if, how, and how often providers and other staff at the Million Hearts Model organization discussed CVD risk and CVD risk scores
- Factors that helped or made it harder for beneficiaries to understand CVD risk
- Beneficiaries' awareness of modifiable risk factors and actions taken to address those risk factors, including discussions of treatment options and behavior changes that could reduce CVD risk

¹² We interviewed 15 beneficiaries; however, the final analytic sample included 14 beneficiaries because we dropped one interview from the analysis because the registry data indicated the beneficiary was at low CVD risk.

- Factors motivating beneficiaries to make changes, how often providers or staff followed up about those changes, and any provider recommendations to reduce modifiable risk that were not made or sustained
- Beneficiaries' involvement in care planning and shared decision making, including whether and how providers and staff at model organizations involved beneficiaries in decisions about how to reduce CVD risk
- What beneficiaries liked about care planning discussions and what could be improved

Because most beneficiaries who participated in interviews first enrolled in the model in 2017 and 2018, we asked them to recall CVD risk discussions with their model providers over the past year, or even several years ago if providers discussed risk only at model enrollment and not during annual reassessment visits. Interviewers also asked about the relationship between the model provider and beneficiary, including how long the beneficiary had been seeing the provider and how frequently the beneficiary visited the provider each year.

We reviewed the interview protocol to ensure beneficiaries would understand the language and intent of the questions. We used the Microsoft Word readability function to estimate the grade level of the interview protocol; it measured the interview protocol to have language at an 8th-grade reading level. We also pilot tested the protocol with the first three beneficiaries who agreed to participate. Because those beneficiaries understood the language and did not express any concerns with the content of the questions, we made no additional changes based on those interviews. The RAND Institutional Review Board reviewed and approved the interview protocol.

4. Qualitative data analysis

To facilitate the analysis of the qualitative interview data, we created a code book with codes capturing the major topics discussed during the interviews and descriptions of when to apply those codes. We imported the codes and the interview transcripts into NVivo, a data analysis software. After discussing the code book as a team, each coder coded one transcript. A single team member then reviewed all the initial coded transcripts to check for consistency. Coders addressed any discrepancies and we updated the code book as needed. We then coded the remaining transcripts and analyzed the text related to each code to identify common themes in the data.

Appendix D

Study Population for Impact Evaluation

This appendix defines the population enrolled in the Million Hearts Model and subpopulations Mathematica used for the impact analyses in this report. The appendix has five sections:

- 1. Population enrolled in the Million Hearts Model in 2017 and 2018 (Section D.1)
- 2. Population included in impact analyses of cardiovascular disease (CVD) events and other long-term, claims-based outcomes (Section D.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 D.3)
- 4. Population used to estimate impacts on CVD risk scores and risk factors (Section D.4)
- **5.** Sample sizes of each of the populations used for impact analyses reported in Chapters IV through VIII and in <u>Appendix H</u>.

<u>Appendix C in the 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 to the registry data 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 388,057 beneficiaries enrolled by 173 intervention organizations and 172 control organizations (Figure D.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:

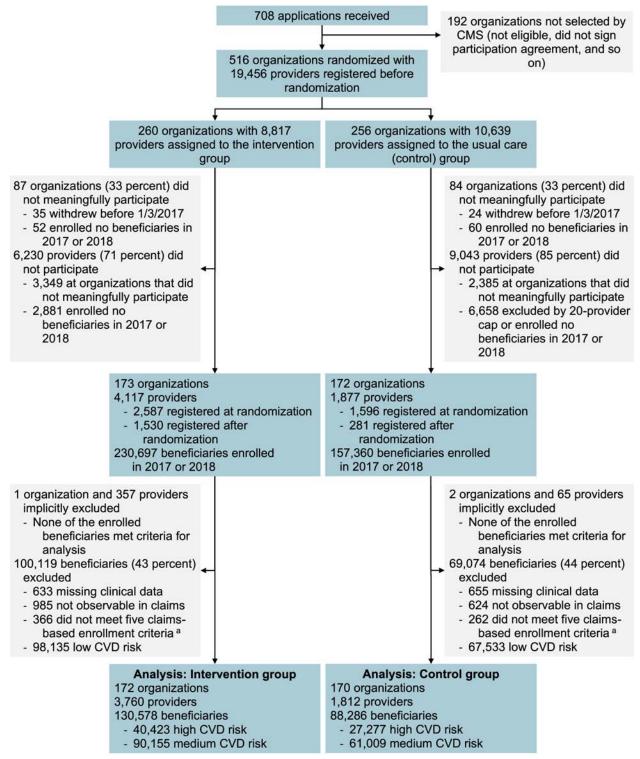
- Were not observable. These beneficiaries were not enrolled in Medicare Parts A and B FFS with Medicare as the primary payer during the month of enrollment and we could not construct study outcomes for them.
- **Did not meet claims-based model eligibility criteria.** These beneficiaries had evidence 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 1,984 beneficiaries from the intervention group and 1,541 beneficiaries from the control group (Figure D.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 218,864 beneficiaries (130,578 beneficiaries enrolled by 172 intervention organizations and 88,286 beneficiaries enrolled by 170 control organizations). Figure D.1 shows the flow of organizations (and their providers and beneficiaries), from random assignment and enrollment through the final study population.

Figure D.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)



Sources: Mathematica's analyses of Million Hearts' randomization files, registry data submitted by participating organizations, and Medicare enrollment and claims data.

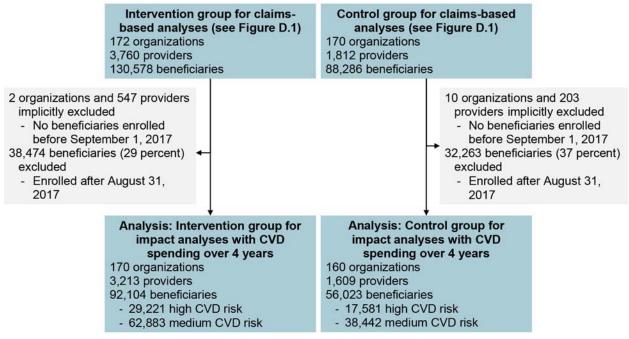
Note: Beneficiaries with high CVD risk were predicted to have, at enrollment, at least a 30 percent risk of a heart attack or stroke in the next 10 years; the predicted risk was 15 to 30 percent for medium-risk beneficiaries and less than 15 percent for low-risk beneficiaries.

^a 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.

For the analyses of impacts on Medicare spending on heart attacks and strokes, we restricted the study population (Figure D.1) to beneficiaries enrolled in Million Hearts on or before August 31, 2017. Among these beneficiaries we can observe spending during a one-month-long triggering event¹³ with 90-days follow-up for all CVD events happening within four years of enrollment. After applying this restriction, the study population comprised 148,127 beneficiaries: 92,104 beneficiaries enrolled by 170 intervention organizations and 56,023 beneficiaries enrolled by 160 control organizations. As shown in Figure D.2, this represents 71 percent of the intervention beneficiaries and 63 percent of control beneficiaries included in the population used for impact analysis of CVD events and other long-term, claims-based outcomes.

Figure D.2. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for analyses of Medicare spending for heart attacks and strokes



Sources: 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.

¹³ Among the first-time heart attacks and strokes included in this analysis, more than 95 percent had a hospital stay shorter than one month.

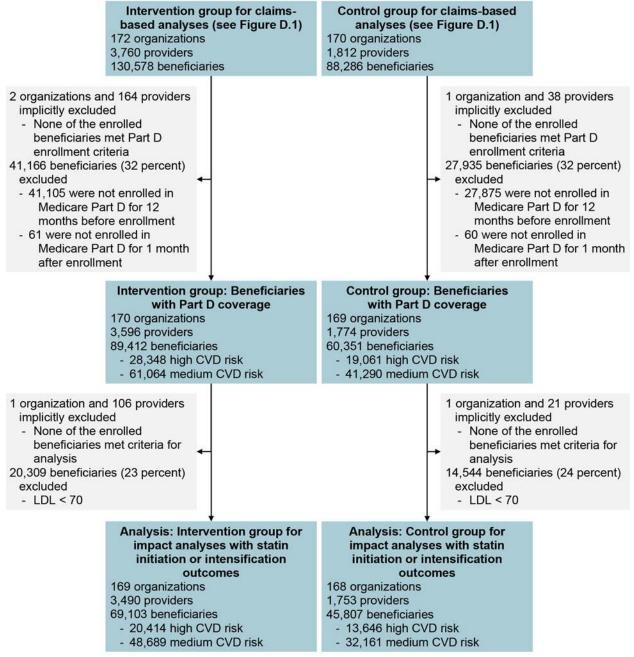
3. Beneficiaries included in impact analyses of medication initiation and intensification and adherence (outcome measures from Medicare Part D data)

For the analyses of impacts on medication use, we restricted the study population (Section D.2, Figure D.1) to beneficiaries enrolled in Medicare Part D for the 12 months before enrolling in the Million Hearts Model, enabling us to observe the beneficiaries' medication use (based on Part D data) for the full year before model enrollment. After applying this restriction, the study population with Part D coverage included 149,763 beneficiaries: 89,412 beneficiaries enrolled by 170 intervention organizations and 60,351 beneficiaries enrolled by 169 control organizations. As shown in Figure D.3, this represents about two-thirds (68 percent) of the beneficiaries included in the population used for impact analysis of CVD events and other long-term, claims-based outcomes.

From this population of beneficiaries with Medicare Part D coverage for the 12 months before enrolling in the Million Hearts Model, we further restricted the population for specific medication initiation and intensification and adherence outcomes as follows:

- 1. For the analyses of impacts on initiating and intensifying statin medication, we restricted the study population to beneficiaries who, at enrollment, had low-density lipoprotein (LDL) cholesterol levels at or above thresholds for treatment (70 md/dL). After applying this restriction, the study population included 69,103 beneficiaries enrolled by 169 intervention organizations and 45,807 beneficiaries enrolled by 168 control organizations, as shown in Figure D.3.
- 2. For the analyses of impacts on initiating and intensifying antihypertensive medication, we restricted the study population to beneficiaries who, at enrollment, had blood pressure levels at or above thresholds for treatment (130 mm Hg). After applying this restriction, the study population included 53,298 beneficiaries enrolled by 169 intervention organizations and 36,271 beneficiaries enrolled by 165 control organizations, as shown in Figure D.4.
- 3. For analyses of adherence to statin medications, we restricted the study population to beneficiaries who used statin therapy of any intensity level in the 12 months before enrollment. After applying this restriction, the study population included 90,017 beneficiaries: 53,550 beneficiaries enrolled by 168 intervention organizations and 36,420 beneficiaries enrolled by 165 control organizations, as shown in Figure D.5.
- 4. For analyses of adherence to antihypertensive medications, we restricted the study population to beneficiaries who used antihypertensive medications in the 12 months before enrollment. After applying this restriction, the study population included 69,450 beneficiaries enrolled by 169 intervention organizations and 46,607 beneficiaries enrolled by 166 control organizations, as shown in Figure D.6.

Figure D.3. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for analyses of statin initiation and intensification



Sources: 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).

Figure D.4. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for analyses of antihypertensive medication initiation and intensification

	Intervention group: Beneficiaries with Part D coverage (see Figure D.3) 170 organizations 3,596 providers 89,412 beneficiaries	Control group: Beneficiaries with Part D coverage (see Figure D.3) 169 organizations 1,774 providers 60,351 beneficiaries	
 1 organization and implicitly exclude None of the e beneficiaries analysis 36,114 beneficiari excluded SBP < 130 	ed enrolled met criteria for	4 organizations and implicitly exclude - None of the er beneficiaries n analysis 24,080 beneficiarie excluded - SBP < 130	d nrolled net criteria for
	Analysis: Intervention group for impact analyses with antihypertensive medication initiation or intensification outcomes 169 organizations 3,368 providers 53,298 beneficiaries - 20,886 high CVD risk - 32,412 medium CVD risk	Analysis: Control group for impact analyses with antihypertensive medication initiation or intensification outcomes 165 organizations 1,708 providers 36,271 beneficiaries - 14,119 high CVD risk - 22,152 medium CVD risk	

Sources: 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; SBP = systolic blood pressure (mm Hg).

Figure D.5. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for analyses of adherence to statins

	Intervention group: Beneficiaries with Part D coverage (see Figure D.3) 170 organizations 3,596 providers 89,412 beneficiaries		Control group with Part D (see Fig 169 organizations 1,774 providers 60,351 beneficiarie		
analysis 35,862 beneficiar excluded - 1,897 were n FFS Medicar as primary pa 12 months be or before tak used a statin - 33,965 did no	ed enrolled met criteria for ies (40 percent) iot enrolled in e Parts A and B ayer during the efore enrollment ing statins (if) ot use statin by intensity level	←		 analysis 23,931 beneficia excluded 1,439 were FFS Medica as primary p 12 months b or before tal used a statin 22,492 did r 	ded enrolled s met criteria for ries (40 percent) not enrolled in the Parts A and B bayer during the before enrollment king statins (if n) not use statin ny intensity level
		aries CVD risk	Analysis: Con adherence 165 organizations 1,685 providers 36,420 beneficiarie - 12,477 high CV - 23,943 medium	s D risk	

- Sources: 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 Excluding statins used only in an inpatient setting.

CVD = cardiovascular disease; FFS = fee-for-service.

	Intervention group: Beneficiaries with Part D coverage (see Figure D.4) 170 organizations 3,596 providers 89,412 beneficiaries		with Part I	: Beneficiaries D coverage jure D.4)
analysis 19,962 beneficiari excluded - 1,870 were no FFS Medicare as primary pa 12 months be or before taki antihypertens antihypertens - 18,092 did no	ed nrolled met criteria for es (22 percent) ot enrolled in e Parts A and B yer during the fore enrollment ng ive (if used an ive) ot use ive medications			 3 organizations and 36 providers implicitly excluded None of the enrolled beneficiaries met criteria for analysis 13,744 beneficiaries (23 percent) excluded 1,423 were not enrolled in FFS Medicare Parts A and B as primary payer during the 12 months before enrollment or before taking antihypertensive (if used a antihypertensive) 12,321 did not use antihypertensive medications in the 12 months before enrollment^a
	adherence to a	/D risk	adherence to a	/D risk

Figure D.6. Flow of organizations, providers, and beneficiaries from enrollment through analysis

- Sources: 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 Excluding antihypertensives used only in an inpatient setting.

CVD = cardiovascular disease; FFS = fee-for-service.

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 beneficiaries 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 incorporate flags for hospice and ESRD in our inclusion criteria, but analysis of pre-enrollment data suggests these affected 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 D.7 shows the flow of beneficiaries from the broader sample used for impacts analyses of CVD events and other long-term, claims-based outcomes (Figure D.1) to the population used for estimating impacts on CVD risk scores and risk factors. After applying the restrictions described, the study population included 28,343 high-risk beneficiaries: 18,101 high-risk beneficiaries enrolled by 125 intervention organizations and 10,242 high-risk beneficiaries enrolled by 110 control organizations.

Figure D.7. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for CVD risk score and risk factor outcomes

	Intervention group for claims- based analyses (see Figure D.1) 172 organizations 3,760 providers 130,578 beneficiaries	Control group for analyses (see 170 organizations 1,812 providers 88,286 beneficiaries		
having a reas 95,131 beneficiari excluded - 90,531 had me - 785 were enrol November 1, - 3,815 were not	ed nrolled met criteria for sessment visit es (73 percent) edium CVD risk ^a led on or after 2018 eligible for a tt visit through 14		 6 organizations and 211 provimplicitly excluded None of the enrolled beneficiaries met criteria having a reassessment 64,206 beneficiaries (73 percent) 64,206 beneficiaries (73 percent) 64,206 beneficiaries (73 percent) 64,206 beneficiaries (74 percent) 64,206 beneficiaries (75 percent) 64,206 beneficiaries (74 percent) 64,206 be	a for visit cent)) risk ^a ter a gh 14
	170 organizations 2,966 providers 35,447 beneficiaries (high CVD risk)	164 organizations 1,601 providers 24,080 beneficiaries	(high CVD risk)	
 45 organizations a providers implicit None of the e beneficiaries analysis 17,346 beneficiaries excluded 17,157 did not reassessmenter 189 missing ket 	tly excluded nrolled met criteria for es (49 percent) have a nt visit		 54 organizations and 640 providers implicitly exclude - None of the enrolled beneficiaries met criteria analysis 13,838 beneficiaries (57 pero excluded 13,716 did not have a reassessment visit 122 missing key clinical data 	i for cent)
	Analysis: Intervention group for impact analyses with longitudinal CVD risk score outcomes 125 organizations 1,802 providers 18,101 beneficiaries (high CVD risk)	Analysis: Control g analyses with lor risk score o 110 organizations 961 providers 10,242 beneficiaries	gitudinal CVD utcomes	

Sources: 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) described 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.

5. Sample sizes of different impact analyses

Table D.1 presents the corresponding sample sizes of each of the impact analyses reported in Chapters IV through VIII and in <u>Appendix H</u>. The intervention group for claims-based analyses (the first row of Table H.2) 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. As we described above, the analyses for medication initiation and intensification included about half the beneficiaries included in the first row, because the analyses were limited to beneficiaries enrolled in Part D who met the inclusion criteria for the medication use outcome measures. The analysis of impacts on Million Hearts Data Registry outcomes (CVD risk scores and risk factors) was limited to high-risk beneficiaries for whom organizations submitted reassessment data via the Million Hearts Data Registry.

Table D.1. Sizes of the studies population used for different impact estimates

	Analysis of medium benefic	n-risk iaries	Analysis of mediur benefic Number of b	n-risk iaries eneficiaries	Analysis of benefic	iaries	Analysis of benefic Number of be	iaries eneficiaries
Alternative outcome measure, population,	Number of or Intervention	Control	(sum of w Intervention	Control	Number of or Intervention	Control	(sum of w Intervention	Control
or model specification	group	group	group	group	group	group	group	group
Analysis of claims-based outcomes with the popula	ation of 2017 and	d 2018 enrolle	ed beneficiaries ⁱ)				
Main analysis	172	170	130,578	88,286	170	165	40,423	27,277
Followed at least three (or one or two) years	172	170	130,578	88,286	170	165	40,423	27,277
Followed at least four years	170	163	108,668	73,127	168	157	34,131	22,901
Attributed population ^c	172	171	434,316 (247,601)	292,790 (164,668)	172	171	434,316 (83,857)	292,790 (53,452)
Followed at least three (or one or two) years	172	171	434,316 (247,601)	292,790 (164,668)	172	171	434,316 (83,857)	292,790 (53,452)
Followed at least four years	169	163	355,074 (206,933)	239,520 (137,199)	169	163	355,074 (71,548)	239,520 (45,413)
Trim sample to 20 or fewer providers per organization	170	163	74,156	73,059	168	157	24,051	22,871
Not missing modifiable risk	172	170	130,119	87,986	n.a.	n.a.	n.a.	n.a.
Analysis of Part D outcomes with the population of	2017 and 2018	enrolled ben	eficiaries					
Antihypertensive medication intensification or initiation	169	165	53,298	36,271	165	160	20,886	14,119
Initiation	161	160	11,109	7,674	146	148	3,000	2,085
Intensification	168	164	42,189	28,597	163	159	17,886	12,034
Using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification	167	162	28,355	19,458	163	156	13,098	8,908
Not missing Social Vulnerability Index	169	165	53,280	36,261	n.a	n.a	n.a	n.a
Statin intensification or initiation	169	168	69,103	45,807	165	162	20,414	13,646
Initiation	168	164	34,857	23,111	160	160	9,431	6,454
Intensification	167	164	34,246	22,696	159	154	10,983	7,192
Not missing Social Vulnerability Index	169	168	69,077	45,796	n.a	n.a	n.a	n.a

	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
Antihypertensive medication adherence	169	166	69,450	46,607	166	161	24,308	16,230
Trim sample to 20 or fewer providers per organization	169	166	48,128	46,513	166	161	17,311	16,199
Attributed population ^c	172	170	183,345 (126,534)	123,202 (83,431)	172	170	183,345 (48,735)	123,202 (30,922)
Statin adherence	168	165	53,550	36,420	162	157	18,705	12,477
Trim sample to 20 or fewer providers per organization	168	165	37,194	36,340	162	157	13,352	12,451
Attributed population ^c	172	169	141,468 (96,475)	94,542 (63,308)	172	169	141,468 (37,181)	94,542 (23,484)
Any CVD medication use (all beneficiaries with Part D coverage)	170	169	89,412	60,351	166	162	28,348	19,061
Analysis of Million Hearts Data Registry outcomes	with the populat	ion of enrolle	ed beneficiaries					
Main analysis	n.a.	n.a.	n.a.	n.a.	125	110	18,101	10,242
Trim sample to 20 or fewer providers per organization	n.a.	n.a.	n.a.	n.a.	125	110	12,839	10,223
Beneficiaries who had reassessment data recorded 10 to 14 months after enrollment	n.a.	n.a.	n.a.	n.a.	123	104	14,652	7,795
CVD-event spending ^c								
Followed at least								
One or two years for events + four months to observe 90-day spending	172	170	130,578	88,286	170	165	40,423	27,277
Three years for events + four months to observe 90-day spending	172	167	124,601	85,149	170	164	38,678	26,437
Three years and eight months for events + four months to observe 90-day spending	170	163	108,668	73,127	168	157	34,131	22,901

	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
Four years for events + four months to observe 90- day spending	170	160	92,104	56,023	170	160	29,221	17,581
Trim sample to 20 or fewer providers per organization	170	160	62,601	55,957	167	153	20,479	17,551
Attributed population ^c	169	161	303,420 (178,754)	199,585 (115,700)	169	161	303,420 (62,959)	199,585 (39,090)
Four years for events + two months to observe 30- day spending	170	161	101,533	65,741	168	155	32,044	20,548

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 sensitivity analysis, we weighted the population to reflect high- and medium-risk beneficiaries or high-risk beneficiaries, as we described in <u>Appendix E of the 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.

^c We restricted to beneficiaries who enrolled in the Million Hearts Models early enough that—should a CVD event occur during the follow-up period—we could observe all spending during the event (including up to a month between admission and discharge should the event have yielded a long hospital stay) and for 90 days thereafter—for a total of four additional months to observe spending after the follow-up period for the event.

CVD = cardiovascular disease; ED = emergency department; n.a. = not applicable.

Appendix E

Baseline Characteristics

In this appendix, Mathematica provides detailed information on baseline characteristics of the beneficiaries in the intervention and control groups, across the four populations used for the impact analyses in <u>Chapters IV</u>, <u>V</u>, <u>VI</u>, and <u>VII</u>. In addition, we compare baseline characteristics of intervention and control beneficiaries within and across subgroups defined by modifiable risk, social vulnerability, and gender included in the subgroup analyses in <u>Chapter VIII</u>.

Sections E.1 through E.4 contain the baseline characteristics data for the four analysis populations in <u>Chapters IV</u>, <u>V</u>, <u>VI</u>, and <u>VII</u>, including the following:

- 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. For this population, we report baseline characteristics for both high- and medium-risk combined and high-risk only beneficiaries (Section E.1).
- Beneficiaries enrolled in 2017 and 2018 and who had Part D coverage and were included in analyses of Medicare Part D-related outcomes, including drug initiation or intensification as well as adherence to statins and antihypertensive medications. For brevity, we present baseline characteristics for a limited set of characteristics (Section E.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. This population includes high-risk beneficiaries only because the intervention group organizations did not have to submit reassessment data for other beneficiaries they enrolled (Section E.3).
- Beneficiaries enrolled on or before August 31, 2017, and included in analyses of spending for first-time heart attacks and strokes. For this population, we report baseline characteristics for both high- and medium-risk combined and high-risk only beneficiaries (Section E.4).

Sections E.5 through E.7 contain the baseline characteristics for the three subgroups:

- 1. Beneficiaries with high modifiable risk versus those with low modifiable risk (Section E.5). These subgroups came from the analysis population included in the analyses of CVD events and other long-term outcomes (Section E.1), and include high- and medium-risk (modifiable and nonmodifiable risk) beneficiaries combined.
- 2. Beneficiaries residing in U.S. Census tracts categorized as having low versus medium versus high social vulnerability (Section E.6). These subgroups came from the analysis population included in the analyses of Medicare Part D-related outcomes (Section E.2), and include high- and medium-risk beneficiaries combined.
- **3.** Men versus women (Section E.7). These subgroups also came from the analysis population included in the analyses of Medicare Part D-related outcomes (Section E.2), and include high- and medium-risk beneficiaries combined.

All baseline characteristics presented in the following sections reflect characteristics measured at enrollment. We generally considered differences between intervention and control group beneficiaries to be substantively important if they were either larger than 0.25 standardized differences or larger than 0.10 standardized differences and statistically significant at the 0.05 level.

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 E.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 15), 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). 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 (1) the intervention group would enroll more beneficiaries overall and (2) large organizations would enroll a larger share of those beneficiaries.

Based on U.S. Department of Health and Human Services (HHS)-defined regions (HHS n.d.), intervention group beneficiaries were less likely than control group beneficiaries to live in Region 5 (8 versus 17 percent).¹⁴ Intervention group beneficiaries were also less likely than control group beneficiaries to enroll in the Million Hearts Model in the fourth quarter of their enrollment year (12 versus 17 percent).

¹⁴ Region 5 includes Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

Characteristic	Intervention group mean (N = 130,578)	Control group mean (N = 88,286)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's card		(,,			
CVD risk score (%),	27	27	0.0	0.00	0.93
[standard deviation]	[10]	[10]			
Modifiable risk (%) ^c	9	9	0.1	0.01	0.75
Has diabetes (%)	39	38	0.2	0.00	0.85
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	0.82
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 with adherence 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	0.84
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	-0.6	-0.03	0.28
Proportion of beneficiaries with adherence to statins (%) ^{e, f}	70	71	-1.1	-0.03	0.25
Beneficiary's demographic and Medica	re enrollment ch	aracteristics			
Age	72	72	-0.1	-0.03	0.43
[standard deviation]	[5]	[5]			
Race and ethnicity (%) ^g					
Non-Hispanic Black	7	6	1.3	0.06	0.37
Non-Hispanic White	84	85	-1.4	-0.04	0.51
Hispanic	4	4	0.2	0.01	0.84
All other races and ethnicities	4	4	-0.1	-0.01	0.87
Men (%)	58	59	-1.0	-0.02	0.26

Table E.1. Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in2017 and 2018: Intervention versus control group

Characteristic	Intervention group mean (N = 130,578)	Control group mean (N = 88,286)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Dually enrolled in Medicare and Medicaid (%)	10	10	-0.5	-0.02	0.77
Originally entitled to Medicare because of disability (%)	13	14	-0.4	-0.01	0.74
Beneficiary's health and comorbid cond	litions				
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	0.79
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	0.1	0.01	0.80
Beneficiary's medical service use and s	pending in year	before model en	rollment		
Total Medicare Parts A and B annualized	7,824	7,658	166.2	0.01	0.60
expenditures (\$) [standard deviation]	[17,676]	[16,743]			
Hospital admissions (per 1,000 beneficiaries)	188	193	-5.0	-0.01	0.60
CVD-related hospital admissions (per 1,000 beneficiaries) ^h	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) ^h	29	28	1.4	0.01	0.69
Office visits (per 1,000 beneficiaries)	9,228	8,966	261.8	0.03	0.51
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,641	2,691	-49.4	-0.02	0.85
Cardiologist visits (per 1,000 beneficiaries)	1,851	1,805	45.9	0.01	0.82
Beneficiary's CVD-related procedures in	n year before mo	del enrollment			
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	0.94
Characteristics of organization enrollin	g the beneficiary	,			
Total number of practitioners	126	108	18.4	0.07	0.71
[standard deviation]	[178]	[300]			
Total number of service sites [standard	25	15	10.2	0.39	0.12
deviation]	[26]	[27]			
Organization type (%)					
Primary care	53	54	-0.2	0.00	0.47
Specialty or multispecialty	37	34	2.9	0.06	
FQHC, RHC, or other health center	5	5	-0.6	-0.03	

Characteristic	Intervention group mean (N = 130,578)	Control group mean (N = 88,286)	Difference	Standardized difference ^a	<i>p-</i> value ^b
CAH or rural hospital	1	2	-1.6	-0.14	praiae
Acute care hospital	5	5	-0.5	-0.02	
Organization was participating in or had application pending for another model at application (%)	70	55	14.3	0.30	0.13
Organizational-level mean Medicare spending and use ⁱ					
Parts A and B spending	7,666	7,648	17.9	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 the	e 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					
Rural (%)	24	26	-1.6	-0.04	0.73
HHS region (%)					
1: CT, ME, MA, NH, RI, and VT	3	3	-0.3	-0.02	0.47
2: NJ, NY, PR, and VI	15	12	3.1	0.09	
3: DC, DE, MD, PA, VA, and WV	21	15	6.2	0.16	
4: AL, FL, GA, KY, MS, NC, SC, and TN	23	17	5.7	0.14	
5: IL, IN, MI, MN, OH, and WI	8	17	-8.7	-0.27	
6: AR, LA, NM, OK, and TX	10	8	2.1	0.07	
7: IA, KS, MO, and NE	11	10	0.9	0.03	
8: CO, MT, ND, SD, UT, and WY	1	5	-3.7	-0.22	
9: AZ, CA, HI, and NV	6	8	-2.0	-0.08	
10: AK, ID, OR, and WA	1	4	-3.1	-0.18	
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	-30.2	-0.05	0.76
Per capita total Medicare Parts A and B spending in 2016	9,944	9,847	97.6	0.07	0.66

Characteristic	Intervention group mean (N = 130,578)	Control group mean (N = 88,286)	Difference	Standardized differenceª	<i>p-</i> value ^b
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
SVI (%) ^j					
Low vulnerability (deciles 1–4 of summary SVI score)	42	37	5.2	0.11	0.37
Medium vulnerability (deciles 5–8 of summary SVI score)	39	43	-3.8	-0.08	
High vulnerability (deciles 9 and 10 of summary SVI score)	19	20	-1.4	-0.04	
Characteristics of beneficiary's Million	Hearts Model en	rollment			
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	<0.01
Data submitted to the registry using bulk upload $(\%)^k$	50	49	0.8	0.02	0.93

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk (except diabetes status); Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBSIG 2.0 race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the CDC for 2016 Census-track-level summary SVI score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC 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 following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, diabetes, and ischemic heart disease. The following chronic conditions are defined by using HCC algorithms: 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 We defined modifiable risk 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. The Fourth Annual Report, Chapter VI 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 = 89,412 for the intervention group and n = 60,351 for the control group). This accounted for 68 percent of all beneficiaries enrolled in both the intervention and 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 the antihypertensive adherence measure, this included n = 69,450beneficiaries in the intervention group and n = 46,607 in the control group, accounting for 53 percent of all beneficiaries enrolled in each group. For the statin adherence measure, this included n = 53,550 beneficiaries in the intervention group and n = 36,420 in the control group, accounting for 41 percent of all beneficiaries enrolled in each group.

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

⁹ The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^h We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (Mathematica's <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.

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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

^j We measured social vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. We categorized beneficiaries as residing in Census tracts with low, medium, or high social vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population.

^k 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 varied 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; CDC = Centers for Disease Control and Prevention; 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; HHS = U.S Department of Health & Human Services; LDL = low-density lipoprotein; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dI = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center; SVI = Social Vulnerability Index.

Consistent with the combined high- and medium-risk population (Table E.1), the high-risk-only population enrolled in 2017 and 2018 balanced well on characteristics at enrollment such as age, sex, CVD risk score, recent service use, and Medicare spending (Table E.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), 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 less likely to live in Region 5 (8 versus 18 percent)¹⁵. High-risk beneficiaries in the intervention group were also less likely than those in the control group to have enrolled during the fourth quarter of their enrollment year (12 versus 17 percent).

Characteristic	Intervention group mean (N = 40,423)	Control group mean (N = 27,277)	Difference	Standardized differenceª	<i>p</i> -value ^b					
Clinical indicators of beneficiary's cardiovascular risk										
CVD risk score (%),	40	40	0.0	0.00	0.91					
[standard deviation]	[9]	[9]								
Modifiable risk (%) ^c	16	15	0.0	0.00	0.95					
Has diabetes (%)	64	62	1.4	0.03	0.31					
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	0.22					
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	0.43					
Proportion of beneficiaries with adherence to antihypertensives (%) ^{e, f}	85	86	-0.5	-0.01	0.45					
Uses statins based on Part D (%) ^d	69	68	0.9	0.02	0.50					
Intensity of statin use based on Part D (%) ^d										
Low intensity	7	7	0.1	0.00	0.89					

Table E.2. Baseline characteristics of high-risk Medicare beneficiaries enrolled in 2017 and 2018:Intervention versus control group

¹⁵ Region 5 includes Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

Characteristic	Intervention group mean (N = 40,423)	Control group mean (N = 27,277)	Difference	Standardized difference ^a	<i>p-</i> value ^b
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	0.22
Proportion of beneficiaries with adherence to statins (%) ^{e,f}	70	72	-1.6	-0.03	0.15
Beneficiary's demographic and Medic	are enrollment c	haracteristics			
Age	74	74	-0.1	-0.02	0.58
[standard deviation]	[4]	[4]			
Race and ethnicity (%) ^g					
Non-Hispanic Black	7	6	1.2	0.05	0.43
Non-Hispanic White	84	85	-1.3	-0.04	0.58
Hispanic	5	4	0.2	0.01	0.87
All other races and ethnicities	5	5	-0.1	-0.01	0.93
Men (%)	65	65	0.0	0.00	0.99
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.7	-0.02	0.68
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	0.59
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	0.0	0.00	0.96
Beneficiary's medical service use and	spending in yea	ar before model e	enrollment		
Total Medicare Parts A and B	8,337	8,058	279.0	0.02	0.38
annualized expenditures (\$)	[18,157]	[16,123]			
[standard deviation]					
Hospital admissions (per 1,000 beneficiaries)	204	201	3.1	0.00	0.75
CVD-related hospital admissions (per 1,000 beneficiaries) ^h	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) ^h	32	32	0.5	0.00	0.88
Office visits (per 1,000 beneficiaries)	9,856	9,517	338.6	0.04	0.39
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,979	2,992	-12.9	0.00	0.97

Characteristic	Intervention group mean (N = 40,423)	Control group mean (N = 27,277)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Cardiologist visits (per 1,000 beneficiaries)	2,074	2,038	35.8	0.01	0.86
Beneficiary's CVD-related procedures	in vear before n	nodel enrollment			
Received echocardiogram (%)	44	43	0.8	0.02	0.77
Received electrocardiogram (%)	74	74	0.4	0.01	0.90
Received cardiac stress test (%)	28	29	-0.1	0.00	0.97
Characteristics of organization enrolling	ng the beneficia				
Total number of practitioners	131	94	37.4	0.15	0.45
[standard deviation]	[204]	[280]			
Total number of service sites [standard	24	14	10.6	0.41	0.11
deviation]	[26]	[26]			
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 was participating 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 ⁱ					
Parts A and B spending	7,683	7,675	8.2	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	10.2	0.09	0.56
Characteristics of clinician enrolling the second s	ne beneficiary				
Provider specialty (%)					
Primary care physician	58	60	-2.6	-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	l .				
Rural (%)	26	27	-1.5	-0.03	0.77
HHS region (%)					
1: CT, ME, MA, NH, RI, and VT	3	3	-0.8	-0.04	0.54
2: NJ, NY, PR, and VI	15	12	2.5	0.07	
3: DC, DE, MD, PA, VA, and WV	21	15	6.7	0.18	
4: AL, FL, GA, KY, MS, NC, SC, and TN	24	18	5.4	0.13	
5: IL, IN, MI, MN, OH, and WI	8	18	-9.4	-0.28	
6: AR, LA, NM, OK, and TX	10	9	1.8	0.06	

Characteristic	Intervention group mean (N = 40,423)	Control group mean (N = 27,277)	Difference	Standardized difference ^a	<i>p-</i> value ^b
7: IA, KS, MO, and NE	10	9	1.4	0.05	
8: CO, MT, ND, SD, UT, and WY	1	4	-3.2	-0.20	
9: AZ, CA, HI, and NV	6	8	-1.6	-0.06	
10: AK, ID, OR, and WA	2	5	-3.0	-0.17	
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.8	-0.23	0.14
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	-43.7	-0.07	0.68
Per capita total Medicare Parts A and B spending in 2016	9,932	9,862	70.5	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	11.2	0.09	0.63
SVI (%) ^j					
Low vulnerability (deciles 1–4 of summary SVI score)	40	34	5.3	0.11	0.37
Medium vulnerability (deciles 5–8 of summary SVI score)	40	44	-3.6	-0.07	
High vulnerability (deciles 9 and 10 of summary SVI score)	20	21	-1.7	-0.04	
Characteristics of beneficiary's Million	n Hearts Model e	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	-2.1	-0.06	0.25
Fourth quarter of the year	12	17	-5.1	-0.15	<0.01
Data submitted to the registry using bulk upload (%) ^k	45	44	0.3	0.01	0.97

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk (except diabetes status); Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG 2.0 race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the CDC for 2016 Census-track-level summary SVI score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC 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 following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, diabetes, and ischemic heart disease. The following chronic conditions are defined by using HCC algorithms: 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI 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 = 28,348 for the intervention group and n = 19,061 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 and in the month of enrollment and with medication use at baseline. For the antihypertensive adherence measure, this included n = 24,308beneficiaries in the intervention group and n = 16,230 in the control group, accounting for 60 percent of all beneficiaries enrolled in each group. For analyses of statin adherence, this included n = 18,705 beneficiaries in the intervention group and n = 12,477 in the control group, accounting for 46 percent of all beneficiaries enrolled in each group.

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

⁹ The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^h We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (Mathematica's <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.

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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

^j We measured social vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. We categorized beneficiaries as residing in Census tracts with low, medium, or high social vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population.

^k 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 varied 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; CDC = Centers for Disease Control and Prevention; 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; HHS = U.S Department of Health & Human Services; LDL = low-density lipoprotein; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center; SVI = Social Vulnerability Index.

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/or adherence (Chapter IV). The tables in this section show additional information about blood pressure and cholesterol status at baseline compared to Tables E.1 and E.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 analyses of initiation or intensification of statins, the two groups were similar in terms of cholesterol levels and use of statins at baseline (Table E.3). They also were similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

	Intervention	Control group			
	group mean	mean	D	Standardized	
Characteristic	(N = 69,103)	(N = 45,807)	Difference	difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's					
CVD risk score (%),	27	27	-0.1	-0.01	0.84
[standard deviation]	[10]	[10]			
Modifiable risk (%) ^c	10	10	0.0	0.00	0.96
Has diabetes (%)	35	35	0.1	0.00	0.92
SBP (mm Hg)	134	134	-0.1	-0.01	0.86
Distribution of SBP (%)					
SBP < 130 mm Hg	39	38	0.7	0.01	0.67
SBP 130–139 mm Hg	28	28	-0.1	0.00	0.88
SBP 140–149 mm Hg	17	17	-0.3	-0.01	0.71
SPB ≥ 150 mm Hg	16	16	-0.2	-0.01	0.87
Total cholesterol (mg/dL)	186	186	0.2	0.01	0.82
HDL cholesterol (mg/dL)	52	52	-0.1	-0.01	0.86
LDL cholesterol (mg/dL)	108	108	0.5	0.02	0.50
Distribution of LDL cholesterol (%)					
LDL 70–99 mg/dL	47	47	-0.7	-0.01	0.50
LDL 100–129 mg/dL	33	32	0.2	0.00	0.64
LDL ≥ 130 mg/dL	21	20	0.5	0.01	0.49
Is current smoker (%)	11	12	-1.6	-0.05	0.13
Beneficiary's medication use					
Uses aspirin (%)	42	41	1.3	0.03	0.76
Uses antihypertensives based on Part D (%)	80	80	0.5	0.01	0.68

Table E.3. Baseline characteristics of high- and medium-risk Medicare beneficiaries included in the Part D analyses of statin initiation or intensification: Intervention versus control group

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 69,103)	(N = 45,807)	Difference	difference ^a	<i>p-</i> value ^b
Proportion of days covered by antihypertensives (%) ^d	89	89	-0.2	-0.01	0.62
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	82	83	-0.5	-0.01	0.40
Uses statins based on Part D (%)	56	56	0.0	0.00	0.99
Intensity of statin use based on Part D (%)					
Low intensity	7	7	-0.1	0.00	0.93
Medium intensity	35	35	0.3	0.01	
High intensity	15	15	-0.2	-0.01	
Proportion of days covered by any statins (%) ^d	79	79	-0.7	-0.02	0.32
Proportion of beneficiaries with adherence to statins (%) ^{d,e}	66	67	-1.2	-0.03	0.27
Beneficiary's demographic and Med	icare enrollment	characteristics			
Age	72	72	-0.1	-0.01	0.68
[standard deviation]	[5]	[5]			
Race and ethnicity (%) ^f					
Non-Hispanic Black	7	6	1.1	0.05	0.48
Non-Hispanic White	84	85	-1.4	-0.05	0.52
Hispanic	5	4	0.6	0.04	0.60
All other races and ethnicities	4	4	-0.3	-0.02	0.73
Men (%)	53	54	-1.0	-0.02	0.25
Dually enrolled in Medicare and Medicaid (%)	13	13	-0.8	-0.03	0.69
Originally entitled to Medicare because of disability (%)	14	15	-0.6	-0.02	0.65
Beneficiary's health and comorbid c	onditions				
HCC score	1.15	1.15	0.0	0.00	0.92
[standard deviation]	[0.99]	[0.99]			
Number of chronic conditions	2.0	2.0	0.0	0.01	0.86
Beneficiary's medical service use an	d spending in y	ear before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$) [standard deviation]	7,647 [16,360]	7,495 [15,640]	152.0	0.01	0.62
Hospital admissions (per 1,000 beneficiaries)	177	181	-3.5	-0.01	0.70
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	386	379	7.0	0.01	0.74
Office visits (per 1,000 beneficiaries)	9,288	8,938	349.8	0.05	0.40
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,674	2,699	-25.1	-0.01	0.93
Cardiologist visits (per 1,000 beneficiaries)	1,694	1,670	23.3	0.00	0.91

Characteristic	Intervention group mean (N = 69,103)	Control group mean (N = 45,807)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Characteristics of organization enro					p talle
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,629	7,638	-8.9	-0.01	0.98
Hospital admissions (per 1,000 beneficiaries)	181	191	-9.7	-0.25	0.22
Outpatient ED visits (per 1,000 beneficiaries)	375	367	8.4	0.08	0.64
Characteristics of clinician enrolling	the beneficiary				
Provider specialty (%)					
Primary care physician	59	62	-3.0	-0.06	0.69
Cardiologist	25	25	-0.1	0.00	0.99
Physician with other specialty	3	1	1.9	0.14	0.14
Not a physician (for example, NP or PA)	12	11	1.3	0.04	0.49
Characteristics of beneficiary's region	on				
Rural (%)	24	26	-2.4	-0.06	0.62
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	0.45
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,367	4,405	-38.6	-0.06	0.71
Per capita total Medicare Parts A and B spending in 2016	10,012	9,865	147.4	0.10	0.53
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	276	2.1	0.05	0.76
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	694	684	9.8	0.08	0.67

Note: For all measures, means are calculated over nonmissing values. 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 statins (LDL equal to 70

mg/dL or higher). This accounted for 53 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 52 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the antihypertensive adherence measure, this included n = 52,163 beneficiaries in the intervention group and n = 34,337 in the control group, accounting for 75 percent of all beneficiaries enrolled in each group included in analyses of initiation and intensification of statins. For the statin adherence measure, this included n = 36,881 beneficiaries in the intervention group and n = 24,480 in the control group, accounting for 53 percent of all beneficiaries enrolled in each group included in analyses of initiation and intensification of statins.

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

^f The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CDC = Centers for Disease Control and Prevention; 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dI = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

Among high-risk beneficiaries included in the analyses of initiation or intensification of statins, the two groups were similar in terms of cholesterol levels and use of statins at baseline (Table E.4). They also were similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

Characteristic	Intervention group mean (N = 20,414)	Control group mean (N = 13,646)	Difference	Standardized differenceª	<i>p-</i> value ^b
Clinical indicators of beneficiary's	cardiovascular ris	sk			
CVD risk score (%),	40	40	0.0	0.00	0.96
[standard deviation]	[9]	[9]			
Modifiable risk (%) ^c	17	17	0.0	0.00	0.95
Has diabetes (%)	60	59	1.1	0.02	0.50
SBP (mm Hg)	141	141	0.2	0.01	0.84
Distribution of SBP (%)					
SBP < 130 mm Hg	24	23	0.4	0.01	0.82
SBP 130–139 mm Hg	27	27	-0.3	-0.01	0.85
SBP 140–149 mm Hg	22	22	-0.5	-0.01	0.62
SPB ≥ 150 mm Hg	27	27	0.4	0.01	0.86
Total cholesterol (mg/dL)	183	184	-0.6	-0.02	0.45
HDL cholesterol (mg/dL)	49	49	-0.3	-0.02	0.61
LDL cholesterol (mg/dL)	106	106	-0.1	0.00	0.85
Distribution of LDL cholesterol (%)					
LDL 70–99 mg/dL	50	50	0.1	0.00	0.94
LDL 100–129 mg/dL	31	30	0.5	0.01	0.40
LDL ≥ 130 mg/dL	19	20	-0.6	-0.02	0.41
Is current smoker (%)	12	14	-2.1	-0.06	0.13
Beneficiary's medication use					
Uses aspirin (%)	47	46	1.0	0.02	0.80
Uses antihypertensives based on Part D (%)	89	88	0.9	0.03	0.26
Proportion of days covered by antihypertensives (%) ^d	90	90	-0.4	-0.02	0.40
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	84	84	-0.7	-0.02	0.36
Uses statins based on Part D (%)	61	60	1.2	0.03	0.36
Intensity of statin use based on Part D (%)					
Low intensity	7	7	0.0	0.00	0.83
Medium intensity	37	37	0.5	0.01	
High intensity	17	16	0.6	0.02	

Table E.4. Baseline characteristics of high-risk Medicare beneficiaries included in the Part D analyses of statin initiation or intensification: Intervention versus control group

Characteristic	Intervention group mean (N = 20,414)	Control group mean (N = 13,646)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Proportion of days covered by any statins (%) ^d	78	79	-0.8	-0.03	0.30
Proportion of beneficiaries with adherence to statins (%) ^{d,e}	65	67	-2.0	-0.04	0.12
Beneficiary's demographic and Med	icare enrollment	characteristics			
Age	74	74	0.0	-0.01	0.81
[standard deviation]	[4]	[4]			
Race and ethnicity (%) ^f					
Non-Hispanic Black	8	7	1.0	0.04	0.55
Non-Hispanic White	83	84	-1.4	-0.04	0.57
Hispanic	5	4	0.7	0.04	0.63
All other races and ethnicities	4	5	-0.2	-0.02	0.82
Men (%)	61	61	-0.1	0.00	0.89
Dually enrolled in Medicare and Medicaid (%)	12	14	-1.2	-0.04	0.59
Originally entitled to Medicare because of disability (%)	13	14	-1.1	-0.03	0.38
Beneficiary's health and comorbid c	onditions				
HCC score	1.34	1.34	0.0	0.01	0.85
[standard deviation]	[1.03]	[1.04]			
Number of chronic conditions	2.5	2.5	0.0	0.02	0.62
Beneficiary's medical service use an	nd spending in y	ear before model	enrollment		
Total Medicare Parts A and B	7,979	7,901	78.3	0.00	0.82
annualized expenditures (\$) [standard deviation]	[15,896]	[16,017]			
Hospital admissions (per 1,000 beneficiaries)	185	193	-7.9	-0.01	0.45
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	398	393	5.1	0.00	0.83
Office visits (per 1,000 beneficiaries)	9,789	9,343	445.9	0.06	0.29
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,985	2,977	8.0	0.00	0.98
Cardiologist visits (per 1,000 beneficiaries)	1,867	1,911	-43.9	-0.01	0.84
Characteristics of organization enro	lling t <u>he benefic</u>	iary			
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,635	7,674	-38.5	-0.02	0.89
Hospital admissions (per 1,000 beneficiaries)	182	192	-9.6	-0.24	0.23
Outpatient ED visits (per 1,000 beneficiaries)	379	373	5.9	0.05	0.74

	Intervention group mean	Control group mean	D://	Standardized	
Characteristic Characteristics of clinician enrolling	(N = 20,414)	(N = 13,646)	Difference	difference ^a	<i>p</i> -value ^b
Provider specialty (%)	The beneficiary				
Primary care physician	59	61	-2.1	-0.04	0.77
Cardiologist	25	26	-0.9	-0.02	0.91
Physician with other specialty	3	1	2.0	0.13	0.31
Not a physician (for example, NP or PA)	12	11	0.9	0.03	0.62
Characteristics of beneficiary's regi	on				
Rural (%)	26	28	-2.4	-0.05	0.67
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.8	-0.23	0.12
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.4	0.10	0.56
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,394	4,443	-49.1	-0.08	0.65
Per capita total Medicare Parts A and B spending in 2016	10,006	9,904	101.6	0.07	0.66
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	279	278	1.0	0.03	0.88
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	700	691	9.1	0.07	0.71

Note: For all measures, means are calculated over nonmissing values. The population for this table includes highrisk 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 statins (LDL equal to 70 mg/dL or higher). This accounted for 51 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 50 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the antihypertensive adherence measure, this included n = 17,218 beneficiaries in the intervention group and n = 11,414 in the control group, accounting for 84 percent of all beneficiaries enrolled in each group included in analyses of initiation and intensification of statins. For the statin adherence measure, this included n = 12,031 beneficiaries in the intervention group and n = 7,910 in the control group, accounting for 59 percent of all beneficiaries enrolled in the intervention group and 58 percent of all beneficiaries enrolled in the control group included in analyses of initiation and intensification of statins.

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

^f The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CDC = Centers for Disease Control and Prevention; 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; 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 the analyses of initiation or intensification of antihypertensive medications, the distribution of systolic blood pressure and rates of antihypertensive medication use were similar at enrollment between the groups (Table E.5). Further, they were similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

Table E.5. Baseline characteristics of high- and medium-risk Medicare beneficiaries included in the Part D analyses of initiation or intensification of antihypertensive medications: Intervention versus control group

Characteristic	Intervention group mean (N = 53,298)	Control group mean (N = 36,271)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Clinical indicators of beneficiary's					
CVD risk score (%),	29	29	0.1	0.01	0.72
[standard deviation]	[11]	[11]			
Modifiable risk (%) ^c	13	12	0.2	0.02	0.68
Has diabetes (%)	39	38	0.1	0.00	0.92
SBP (mm Hg)	143	143	0.0	0.00	0.99
Distribution of SBP (%)					
SBP 130–139 mm Hg	47	46	0.4	0.01	0.83
SBP 140–149 mm Hg	28	28	-0.4	-0.01	0.70
SPB ≥ 150 mm Hg	25	25	-0.1	0.00	0.97
Total cholesterol (mg/dL)	176	176	0.5	0.01	0.75
HDL cholesterol (mg/dL)	51	52	-0.3	-0.02	0.67
LDL cholesterol (mg/dL)	98	97	1.1	0.03	0.37
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	21	22	-1.2	-0.03	0.34
LDL 70–99 mg/dL	36	36	0.1	0.00	0.81
LDL 100–129 mg/dL	26	26	0.6	0.01	0.42
LDL ≥ 130 mg/dL	17	17	0.5	0.01	0.57
Is current smoker (%)	10	12	-1.8	-0.06	0.18
Beneficiary's medication use					
Uses aspirin (%)	45	42	3.4	0.07	0.41
Uses antihypertensives based on Part D (%)	83	83	0.4	0.01	0.76
Proportion of days covered by antihypertensives (%) ^d	89	90	-0.3	-0.01	0.48
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	83	84	-0.5	-0.01	0.44
Uses statins based on Part D (%)	62	62	0.0	0.00	0.98
Intensity of statin use based on Part D (%)					
Low intensity	6	6	-0.2	-0.01	0.50
Medium intensity	38	37	0.5	0.01	

Characteristic	Intervention group mean (N = 53,298)	Control group mean (N = 36,271)	Difference	Standardized difference ^a	<i>p-</i> value ^b
High intensity	18	18	-0.3	-0.01	p-value
Proportion of days covered by any statins (%)d	80	81	-0.7	-0.03	0.30
Proportion of beneficiaries with adherence to statins (%)d, e	68	70	-1.2	-0.03	0.27
Beneficiary's demographic and Med	icare enrollment	t characteristics			
Age	72	72	-0.1	-0.01	0.71
[standard deviation]	[5]	[5]			
Race and ethnicity (%)f					
Non-Hispanic Black	8	7	0.9	0.04	0.57
Non-Hispanic White	83	85	-1.1	-0.03	0.63
Hispanic	5	4	0.5	0.03	0.68
All other races and ethnicities	4	4	-0.3	-0.02	0.72
Men (%)	53	53	-0.8	-0.02	0.39
Dually enrolled in Medicare and Medicaid (%)	13	14	-1.0	-0.03	0.63
Originally entitled to Medicare because of disability (%)	15	16	-0.9	-0.02	0.53
Beneficiary's health and comorbid c	onditions				
HCC score	1.16	1.16	0.0	0.00	0.90
[standard deviation]	[0.98]	[0.97]			
Number of chronic conditions	2.1	2.0	0.0	0.01	0.71
Beneficiary's medical service use ar	nd spending in y	ear before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$)	7,474 [15,147]	7,319 [15,389]	154.1	0.01	0.63
[standard deviation]					
Hospital admissions (per 1,000 beneficiaries)	175	176	-1.2	0.00	0.90
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	387	382	4.5	0.00	0.83
Office visits (per 1,000 beneficiaries)	9,284	8,888	395.6	0.05	0.32
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,672	2,656	15.8	0.01	0.96
Cardiologist visits (per 1,000 beneficiaries)	1,704	1,645	59.7	0.01	0.75
Characteristics of organization enro	lling the benefic	iary			
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,724	7,634	90.6	0.06	0.76
Hospital admissions (per 1,000 beneficiaries)	184	192	-7.5	-0.19	0.36
Outpatient ED visits (per 1,000 beneficiaries)	380	367	12.9	0.12	0.47

	Intervention group mean	Control group mean	-	Standardized	
Characteristic	(N = 53,298)	(N = 36,271)	Difference	difference ^a	<i>p-</i> value ^b
Characteristics of clinician enrolling	the beneficiary				
Provider specialty (%)					
Primary care physician	57	61	-3.8	-0.08	0.63
Cardiologist	27	26	0.8	0.02	0.92
Physician with other specialty	3	1	2.1	0.15	0.11
Not a physician (for example, NP or PA)	11	11	0.8	0.03	0.65
Characteristics of beneficiary's regi	on				
Rural (%)	25	27	-2.0	-0.05	0.69
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.5	-0.16	0.26
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.5	0.11	0.49
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,381	4,421	-39.6	-0.06	0.70
Per capita total Medicare Parts A and B spending in 2016	10,002	9,878	124.9	0.08	0.59
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	277	1.3	0.03	0.85
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	696	685	10.9	0.09	0.64

Note: For all measures, means are calculated over nonmissing values. 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 (SPB equal to 130 mm Hg or higher). This accounted for 41 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 41 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the antihypertensive adherence measure, this included n = 41,522 beneficiaries in the intervention group and n = 28,153 in the control group, accounting for 78 percent of all beneficiaries enrolled in each group included in analyses of initiation and intensification of antihypertensive medications. For the statin adherence measure, this included n = 30,977 beneficiaries in the intervention group and n = 21,181 in the control group, accounting for 58 percent of all beneficiaries enrolled in each group included in analyses of initiation and intensification of antihypertensive medications.

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

^f The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CDC = Centers for Disease Control and Prevention; 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

Among high-risk beneficiaries included in the analyses of initiation or intensification of antihypertensive medications, the distribution of systolic blood pressure and rates of antihypertensive medication use were similar at enrollment between the groups (Table E.6). Further, they were similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

Table E.6. Baseline characteristics of high-risk Medicare beneficiaries included in the Part D analyses of initiation or intensification of antihypertensive medications: Intervention versus control group

Characteristic	Intervention group mean	Control group mean	Difformer	Standardized	n volueb
Characteristic Clinical indicators of beneficiary's o	(N = 20,886) ardiovascular ris	(N = 14,119)	Difference	difference ^a	<i>p-</i> value ^b
CVD risk score (%),	41	41	0.1	0.01	0.68
[standard deviation]	[9]	[9]	0.1	0.01	0.00
L Modifiable risk (%)⁰	19	19	0.1	0.01	0.86
Has diabetes (%)	59	58	1.1	0.02	0.45
SBP (mm Hg)	146	146	0.2	0.02	0.77
Distribution of SBP (%)					
SBP 130–139 mm Hg	37	37	0.4	0.01	0.86
SBP 140–149 mm Hg	28	29	-0.8	-0.02	0.45
SPB ≥ 150 mm Hg	34	34	0.4	0.01	0.84
Total cholesterol (mg/dL)	171	172	-0.6	-0.02	0.64
HDL cholesterol (mg/dL)	48	49	-0.4	-0.03	0.52
LDL cholesterol (mg/dL)	94	94	0.3	0.01	0.83
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	25	26	-0.5	-0.01	0.73
LDL 70–99 mg/dL	36	36	0.3	0.01	0.70
LDL 100–129 mg/dL	24	23	0.7	0.02	0.35
LDL ≥ 130 mg/dL	15	16	-0.5	-0.01	0.48
Is current smoker (%)	12	14	-2.4	-0.07	0.16
Beneficiary's medication use					
Uses aspirin (%)	50	48	2.3	0.05	0.56
Uses antihypertensives based on Part D (%)	90	89	0.9	0.03	0.24
Proportion of days covered by antihypertensives (%) ^d	90	91	-0.4	-0.02	0.34
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	85	86	-0.7	-0.02	0.35
Uses statins based on Part D (%)	66	66	0.6	0.01	0.62
Intensity of statin use based on Part D (%)					
Low intensity	7	7	-0.1	0.00	0.85
Medium intensity	40	39	0.6	0.01	

Characteristic	Intervention group mean (N = 20,886)	Control group mean (N = 14,119)	Difference	Standardized difference ^a	<i>p</i> -value ^b
High intensity	20	20	0.1	0.00	praiao
Proportion of days covered by any statins (%) ^d	81	82	-0.8	-0.03	0.25
Proportion of beneficiaries with adherence to statins (%) ^{d,e}	69	71	-1.6	-0.03	0.21
Beneficiary's demographic and Med	icare enrollment	t characteristics			
Age	74	74	0.0	-0.01	0.80
[standard deviation]	[4]	[4]			
Race and ethnicity (%) ^f					
Non-Hispanic Black	7	6	0.8	0.03	0.65
Non-Hispanic White	83	85	-1.3	-0.04	0.59
Hispanic	5	4	0.7	0.04	0.58
All other races and ethnicities	4	5	-0.1	-0.01	0.89
Men (%)	61	61	0.0	0.00	0.99
Dually enrolled in Medicare and Medicaid (%)	13	14	-1.0	-0.03	0.67
Originally entitled to Medicare because of disability (%)	13	14	-1.2	-0.04	0.36
Beneficiary's health and comorbid c	onditions				
HCC score	1.34	1.33	0.0	0.01	0.86
[standard deviation]	[1.02]	[1.02]			
Number of chronic conditions	2.5	2.5	0.0	0.02	0.63
Beneficiary's medical service use ar	nd spending in y	ear before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$)	7,844 [15,132]	7,849 [15;579]	-4.7	0.00	0.99
[standard deviation]					
Hospital admissions (per 1,000 beneficiaries)	185	191	-6.2	-0.01	0.55
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	390	391	-1.1	0.00	0.96
Office visits (per 1,000 beneficiaries)	9,818	9,375	442.6	0.06	0.28
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,942	2,906	36.0	0.01	0.91
Cardiologist visits (per 1,000 beneficiaries)	1,898	1,935	-36.8	-0.01	0.86
Characteristics of organization enro	lling the benefic	iary			
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,743	7,686	56.4	0.04	0.85
Hospital admissions (per 1,000 beneficiaries)	185	193	-8.0	-0.19	0.34
Outpatient ED visits (per 1,000 beneficiaries)	383	372	11.1	0.10	0.54

	Intervention group mean	Control group mean	_	Standardized	
Characteristic	(N = 20,886)	(N = 14,119)	Difference	difference ^a	<i>p-</i> value ^b
Characteristics of clinician enrolling	the beneficiary				
Provider specialty (%)					
Primary care physician	57	60	-2.8	-0.06	0.72
Cardiologist	28	28	0.0	0.00	1.00
Physician with other specialty	3	1	2.2	0.15	0.12
Not a physician (for example, NP or PA)	11	10	0.6	0.02	0.77
Characteristics of beneficiary's regi	on				
Rural (%)	26	28	-2.1	-0.05	0.71
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.8	-0.22	0.14
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.4	0.09	0.58
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,397	4,446	-48.9	-0.08	0.66
Per capita total Medicare Parts A and B spending in 2016	9,992	9,904	88.5	0.06	0.71
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	279	278	0.3	0.01	0.97
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	700	689	11.2	0.09	0.64

Note: For all measures, means are calculated over nonmissing values. The population for this table includes highrisk 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 (SPB equal to 130 mm Hg or higher). This accounted for 52 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 52 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the antihypertensive adherence measure, this included n = 17,833 beneficiaries in the intervention group and n = 11,971 in the control group, accounting for 85 percent of all beneficiaries enrolled in each group included in analyses of initiation and intensification of antihypertensive medications. For the statin adherence measure, this included n = 13,271 beneficiaries in the intervention group and n = 8,931 in the control group, accounting for 64 percent of beneficiaries enrolled in the intervention group and 63 percent of beneficiaries enrolled in the control group included in analyses of initiation and intensification of antihypertensive medications.

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

^f The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBISG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; 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 intervention and control groups were 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 (Table E.7). They were also similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

	Intervention	Control group	_		
Characteristic	group mean (N = 53,550)	mean (N = 36,420)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's c					
CVD risk score (%),	28	28	0.2	0.02	0.58
[standard deviation]	[11]	[11]			
Modifiable risk (%) ^c	8	8	0.1	0.01	0.75
Has diabetes (%)	47	47	0.5	0.01	0.64
SBP (mm Hg)	133	133	0.0	0.00	0.96
Distribution of SBP (%)					
SBP < 130 mm Hg	42	42	0.3	0.01	0.84
SBP 130–139 mm Hg	28	28	0.1	0.00	0.88
SBP 140–149 mm Hg	16	17	-0.5	-0.01	0.56
SPB ≥ 150 mm Hg	14	14	0.1	0.00	0.95
Total cholesterol (mg/dL)	163	162	0.8	0.02	0.47
HDL cholesterol (mg/dL)	50	50	0.0	0.00	0.94
LDL cholesterol (mg/dL)	86	85	1.3	0.04	0.20
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	0.21
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	0.43
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	86	87	-0.6	-0.02	0.24
Uses statins based on Part D (%) Intensity of statin use based on Part D (%)	99	99	0.1	0.01	0.54

Table E.7. Baseline characteristics of high- and medium-risk Medicare beneficiaries included in
the Part D analyses of adherence to statins: Intervention versus control group

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 53,550)	(N = 36,420)	Difference	difference ^a	<i>p</i> -value ^b
Low intensity	10	10	0.0	0.00	0.75
Medium intensity	60	59	0.9	0.02	
High intensity	28	29	-0.9	-0.02	
Proportion of days covered by any statins (%) ^d	81	82	-0.6	-0.03	0.28
Proportion of beneficiaries with adherence to statins (%) ^{d, e}	70	71	-1.1	-0.03	0.25
Beneficiary's demographic and Med	icare enrollment	characteristics			
Age	72	72	-0.1	-0.02	0.62
[standard deviation]	[5]	[5]			
Race and ethnicity (%) ^f					
Non-Hispanic Black	7	5	1.2	0.05	0.39
Non-Hispanic White	85	86	-1.5	-0.05	0.49
Hispanic	5	4	0.6	0.03	0.61
All other races and ethnicities	4	5	-0.2	-0.02	0.78
Men (%)	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 c	onditions				
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	0.95
Beneficiary's medical service use an	nd spending in y	ear before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$) [standard deviation]	8,431 [16,570]	8,312 [16,055]	118.9	0.01	0.71
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	381	8.7	0.01	0.66
Office visits (per 1,000 beneficiaries)	10,041	9,752	289.4	0.04	0.48
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,842	2,875	-32.9	-0.01	0.91
Cardiologist visits (per 1,000 beneficiaries)	2,156	2,115	41.3	0.01	0.85
Characteristics of organization enro	lling the benefic	iary			
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,828	7,793	34.8	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

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 53,550)	(N = 36,420)	Difference	difference ^a	<i>p</i> -value ^b
Characteristics of clinician enrolling	the 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 regi	on				
Rural (%)	23	25	-2.1	-0.05	0.64
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	0.11	0.48
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,351	4,401	-50.3	-0.08	0.62
Per capita total Medicare Parts A and B spending in 2016	10,036	9,931	104.2	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

Note: For all measures, means are calculated over nonmissing values. 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 analyses of statin adherence—that is, who used statin therapy of any intensity in the 12 months before enrollment. This accounted for 41 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 41 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the antihypertensive adherence measure, this included n = 47,703 beneficiaries in the intervention group and n = 32,207 in the control group, accounting for 89 percent of all beneficiaries enrolled in the intervention group included in analyses of initiation and intensification and 88 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 The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

Among high-risk beneficiaries included in analyses of adherence to statins, the intervention and control groups were well balanced on cholesterol- and statin-related measures, including mean values of total cholesterol, HDL cholesterol, and 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 (Table E.8). They were also similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 18,705)	(N = 12,477)	Difference	difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's	cardiovascular ris	sk			
CVD risk score (%),	40	40	0.0	0.00	0.93
[standard deviation]	[9]	[9]			
Modifiable risk (%) ^c	14	14	0.0	0.00	0.95
Has diabetes (%)	72	70	1.3	0.03	0.42
SBP (mm Hg)	138	138	0.1	0.00	0.95
Distribution of SBP (%)					
SBP < 130 mm Hg	29	28	0.6	0.01	0.72
SBP 130–139 mm Hg	28	28	0.1	0.00	0.95
SBP 140–149 mm Hg	20	21	-0.9	-0.02	0.39
SPB ≥ 150 mm Hg	23	23	0.2	0.00	0.92
Total cholesterol (mg/dL)	159	159	0.2	0.00	0.88
HDL cholesterol (mg/dL)	47	47	-0.3	-0.02	0.57
LDL cholesterol (mg/dL)	84	83	0.8	0.03	0.40
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	35	36	-0.9	-0.02	0.53
LDL 70–99 mg/dL	41	40	0.1	0.00	0.86
LDL 100–129 mg/dL	16	16	0.8	0.02	0.28
LDL ≥ 130 mg/dL	8	8	0.0	0.00	0.98
Is current smoker (%)	11	14	-2.6	-0.08	0.11
Beneficiary's medication use					
Uses aspirin (%)	56	54	2.2	0.04	0.63
Uses antihypertensives based on Part D (%)	94	93	0.8	0.03	0.12
Proportion of days covered by antihypertensives (%) ^d	92	92	-0.2	-0.01	0.47
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	88	88	-0.3	-0.01	0.63
Uses statins based on Part D (%)	99	99	0.1	0.01	0.49
Intensity of statin use based on Part D (%)					
Low intensity	10	10	0.0	0.00	0.92

Table E.8. Baseline characteristics of high-risk Medicare beneficiaries included in the Part D analyses of adherence to statins: Intervention versus control group

Characteristic	Intervention group mean (N = 18,705)	Control group mean (N = 12,477)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Medium intensity	59	59	-0.1	0.00	P
High intensity	30	29	0.1	0.00	
Proportion of days covered by any statins (%) ^d	81	82	-0.8	-0.03	0.22
Proportion of beneficiaries with adherence to statins (%) ^{d, e}	70	72	-1.6	-0.03	0.15
Beneficiary's demographic and Med	icare enrollment	t characteristics			
Age	74	74	0.0	-0.01	0.84
[standard deviation]	[4]	[4]			
Race and ethnicity (%) ^f					
Non-Hispanic Black	6	5	0.7	0.03	0.58
Non-Hispanic White	84	86	-1.2	-0.04	0.63
Hispanic	5	4	0.6	0.03	0.63
All other races and ethnicities	5	5	-0.2	-0.01	0.86
Men (%)	65	65	0.1	0.00	0.93
Dually enrolled in Medicare and Medicaid (%)	12	13	-1.6	-0.05	0.46
Originally entitled to Medicare because of disability (%)	12	14	-1.2	-0.04	0.33
Beneficiary's health and comorbid c	onditions				
HCC score	1.47	1.47	0.0	0.00	0.97
[standard deviation]	[1.10]	[1.10]			
Number of chronic conditions	2.9	2.9	0.0	0.01	0.77
Beneficiary's medical service use an	nd spending in y	ear before model	enrollment		
Total Medicare Parts A and B annualized expenditures (\$) [standard deviation]	8,808 [16,513]	8,570 [16,245]	237.5	0.01	0.50
Hospital admissions (per 1,000 beneficiaries)	208	209	-0.8	0.00	0.94
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	397	386	10.9	0.01	0.62
Office visits (per 1,000 beneficiaries)	10,468	10,092	375.2	0.05	0.37
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,105	3,126	-21.2	-0.01	0.95
Cardiologist visits (per 1,000 beneficiaries)	2,296	2,233	63.5	0.02	0.77
Characteristics of organization enro	lling the benefic	iary			
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,791	7,803	-12.1	-0.01	0.97
Hospital admissions (per 1,000 beneficiaries)	186	196	-10.0	-0.24	0.25
Outpatient ED visits (per 1,000 beneficiaries)	380	370	9.8	0.09	0.59

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 18,705)	(N = 12,477)	Difference	difference ^a	<i>p-</i> value ^b
Characteristics of clinician enrolling	the beneficiary				
Provider specialty (%)					
Primary care physician	55	57	-1.6	-0.03	0.85
Cardiologist	30	31	-1.2	-0.03	0.89
Physician with other specialty	3	1	2.1	0.14	0.18
Not a physician (for example, NP or PA)	10	10	0.4	0.01	0.83
Characteristics of beneficiary's regi	on				
Rural (%)	25	27	-2.4	-0.05	0.64
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.7	-0.21	0.16
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.4	0.09	0.56
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,372	4,428	-55.6	-0.09	0.60
Per capita total Medicare Parts A and B spending in 2016	10,011	9,951	60.5	0.04	0.80
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	279	-0.2	0.00	0.98
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	696	687	8.6	0.07	0.71

Note: For all measures, means are calculated over nonmissing values. The population for this table includes highrisk 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 analyses of statin adherence—that is, who used statin therapy of any intensity in the 12 months before enrollment. This accounted for 46 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 46 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the antihypertensive adherence measure, this included n = 17,627 beneficiaries in the intervention group and n = 11,666 in the control group, accounting for 94 percent of all beneficiaries enrolled in each group included in analyses of initiation and intensification.

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

^f The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities were developed by the from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; 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 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 E.9). 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.

Table E.9. Baseline characteristics of high- and medium-risk Medicare beneficiaries included in the Part D analyses of adherence to antihypertensive medications: Intervention versus control group

Characteristic	Intervention group mean (N = 69,450)	Control group mean (N = 46,607)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Clinical indicators of beneficiary's	cardiovascular ris				
CVD risk score (%),	28	28	0.0	0.00	0.93
[standard deviation]	[11]	[11]			
Modifiable risk (%) ^c	9	9	0.1	0.01	0.89
Has diabetes (%)	44	44	-0.3	-0.01	0.76
SBP (mm Hg)	134	134	-0.1	-0.01	0.86
Distribution of SBP (%)					
SBP < 130 mm Hg	40	40	0.6	0.01	0.68
SBP 130–139 mm Hg	28	28	0.0	0.00	0.98
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	0.55
HDL cholesterol (mg/dL)	50	50	0.0	0.00	1.00
LDL cholesterol (mg/dL)	94	92	1.2	0.04	0.25
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	25	26	-1.4	-0.03	0.25
LDL 70–99 mg/dL	37	37	0.2	0.00	0.77
LDL 100–129 mg/dL	24	23	0.7	0.02	0.29
LDL ≥ 130 mg/dL	14	13	0.6	0.02	0.43
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	0.17
Proportion of days covered by antihypertensives (%) ^d	90	90	-0.2	-0.01	0.56
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	84	84	-0.5	-0.01	0.42
Uses statins based on Part D (%)	68	68	-0.4	-0.01	0.76

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 69,450)	(N = 46,607)	Difference	difference ^a	<i>p</i> -value ^b
Intensity of statin use based on Part D (%)					
Low intensity	7	7	0.0	0.00	0.91
Medium intensity	41	41	0.3	0.01	
High intensity	20	21	-0.7	-0.02	
Proportion of days covered by any statins (%)d	82	82	-0.7	-0.03	0.23
Proportion of beneficiaries with adherence to statins (%) ^{d, e}	71	72	-1.4	-0.03	0.17
Beneficiary's demographic and Med	icare enrollment	characteristics			
Age	72	72	-0.1	-0.01	0.73
[standard deviation]	[5]	[5]			
Race and ethnicity (%) ^f					
Non-Hispanic Black	7	6	1.1	0.05	0.47
Non-Hispanic White	84	85	-1.4	-0.04	0.55
Hispanic	4	4	0.5	0.03	0.68
All other races and ethnicities	4	4	-0.2	-0.01	0.81
Men (%)	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 c	onditions				
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 ar	nd spending in y	ear before model	enrollment		
Total Medicare Parts A and B	8,556	8,369	187.1	0.01	0.56
annualized expenditures (\$) [standard deviation]	[16,832]	[16,311]			
Hospital admissions (per 1,000 beneficiaries)	205	210	-4.5	-0.01	0.64
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	407	403	3.8	0.00	0.85
Office visits (per 1,000 beneficiaries)	10,031	9,725	305.6	0.04	0.46
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,875	2,914	-39.2	-0.01	0.90
Cardiologist visits (per 1,000 beneficiaries)	2,109	2,073	35.4	0.01	0.87
Characteristics of organization enro	lling t <u>he benefic</u>	iary			
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,774	7,736	38.0	0.02	0.90
Hospital admissions (per 1,000 beneficiaries)	185	195	-9.6	-0.23	0.26

Characteristic	Intervention group mean (N = 69,450)	Control group mean (N = 46,607)	Difference	Standardized differenceª	<i>p-</i> value ^b
Outpatient ED visits (per 1,000 beneficiaries)	379	368	10.8	0.10	0.54
Characteristics of clinician enrolling	the beneficiary				
Provider specialty (%)					
Primary care physician	55	58	-2.7	-0.05	0.75
Cardiologist	30	30	0.0	0.00	1.00
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	0.62
Characteristics of beneficiary's regi	on				
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	-48.6	-0.08	0.64
Per capita total Medicare Parts A and B spending in 2016	9,997	9,905	91.6	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 FFS beneficiaries in 2016	694	687	6.7	0.05	0.77

Note: For all measures, means are calculated over nonmissing values. 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 analyses of adherence to antihypertensives—that is, who used antihypertensive medications in the 12 months before enrollment. This accounted for 53 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 53 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the statin adherence measure, this included n = 47,703 beneficiaries in the intervention group and n = 32,207 in the control group, accounting for 69 percent of all beneficiaries enrolled in the intervention group included in analyses of initiation and intensification of antihypertensive medications and 68 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 The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

Among high-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 E.10). 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.

Characteristic	Intervention group mean (N = 24,308)	Control group mean (N = 16,230)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Clinical indicators of beneficiary's o	ardiovascular ris	sk			
CVD risk score (%),	40	40	-0.1	-0.01	0.74
[standard deviation]	[9]	[9]			
Modifiable risk (%) ^c	15	15	-0.1	-0.01	0.84
Has diabetes (%)	67	66	0.7	0.02	0.64
SBP (mm Hg)	139	139	0.1	0.01	0.92
Distribution of SBP (%)					
SBP < 130 mm Hg	27	26	0.4	0.01	0.81
SBP 130–139 mm Hg	28	27	0.3	0.01	0.80
SBP 140–149 mm Hg	21	22	-0.9	-0.02	0.34
SPB ≥ 150 mm Hg	25	25	0.2	0.00	0.93
Total cholesterol (mg/dL)	167	167	-0.5	-0.01	0.71
HDL cholesterol (mg/dL)	47	48	-0.2	-0.01	0.72
LDL cholesterol (mg/dL)	91	90	0.3	0.01	0.80
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	29	29	-0.5	-0.01	0.72
LDL 70–99 mg/dL	37	37	0.4	0.01	0.56
LDL 100–129 mg/dL	21	21	0.6	0.02	0.40
LDL ≥ 130 mg/dL	12	13	-0.5	-0.02	0.45
Is current smoker (%)	11	14	-2.6	-0.08	0.11
Beneficiary's medication use					
Uses aspirin (%)	52	50	1.9	0.04	0.65
Uses antihypertensives based on Part D (%)	100	100	0.0	0.00	0.75
Proportion of days covered by antihypertensives (%) ^d	91	91	-0.3	-0.02	0.43
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	85	86	-0.5	-0.01	0.45
Uses statins based on Part D (%)	72	71	0.7	0.02	0.54

Table E.10. Baseline characteristics of high-risk Medicare beneficiaries included in the Part D analyses of adherence to antihypertensive medications: Intervention versus control group

Characteristic	Intervention group mean (N = 24,308)	Control group mean (N = 16,230)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Intensity of statin use based on Part D (%)	(,)	(praide
Low intensity	7	7	0.1	0.00	0.91
Medium intensity	43	42	0.3	0.01	
High intensity	22	22	0.3	0.01	
Proportion of days covered by any statins (%) ^d	82	83	-0.6	-0.03	0.32
Proportion of beneficiaries with adherence to statins (%) ^{d, e}	71	72	-1.4	-0.03	0.21
Age	74	74	0.0	-0.01	0.84
[standard deviation]	[4]	[4]			
Race and ethnicity (%) ^f					
Non-Hispanic Black	6	6	0.7	0.03	0.63
Non-Hispanic White	84	85	-1.3	-0.04	0.60
Hispanic	5	4	0.6	0.04	0.62
All other races and ethnicities	5	5	-0.1	0.00	0.95
Men (%)	63	63	0.1	0.00	0.96
Dually enrolled in Medicare and Medicaid (%)	12	13	-1.4	-0.04	0.53
Originally entitled to Medicare because of disability (%)	13	14	-1.1	-0.03	0.37
Beneficiary's health and comorbid c	onditions				
HCC score	1.45	1.45	0.0	0.01	0.87
[standard deviation]	[1.10]	[1.10]			
Number of chronic conditions	2.8	2.8	0.0	0.02	0.62
Beneficiary's medical service use ar	nd spending in y	ear before model	enrollment		
Total Medicare Parts A and B	8,740	8,471	269.2	0.02	0.45
annualized expenditures (\$) [standard deviation]	[16,681]	[16,262]			
Hospital admissions (per 1,000 beneficiaries)	210	209	1.1	0.00	0.92
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	405	403	1.6	0.00	0.94
Office visits (per 1,000 beneficiaries)	10,380	9,951	429.3	0.06	0.32
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,101	3,134	-33.0	-0.01	0.92
Cardiologist visits (per 1,000 beneficiaries)	2,189	2,152	37.2	0.01	0.87

Characteristic	Intervention group mean (N = 24,308)	Control group mean (N = 16,230)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Characteristics of organization enro	lling the benefic	iary			
Organizational-level mean Medicare spending and use ^g					
Parts A and B spending	7,749	7,742	7.1	0.00	0.98
Hospital admissions (per 1,000 beneficiaries)	185	195	-9.5	-0.23	0.27
Outpatient ED visits (per 1,000 beneficiaries)	381	372	9.3	0.08	0.61
Characteristics of clinician enrolling	the beneficiary				
Provider specialty (%)					
Primary care physician	56	58	-1.9	-0.04	0.81
Cardiologist	29	29	-0.7	-0.02	0.93
Physician with other specialty	3	1	2.0	0.13	0.18
Not a physician (for example, NP or PA)	11	10	0.6	0.02	0.75
Characteristics of beneficiary's regi	on				
Rural (%)	26	28	-2.3	-0.05	0.66
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.8	-0.24	0.12
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.4	0.09	0.59
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,391	4,448	-56.6	-0.09	0.60
Per capita total Medicare Parts A and B spending in 2016	9,986	9,908	77.9	0.05	0.74
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	279	278	0.1	0.00	0.98
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	698	689	9.1	0.07	0.70

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B claims for health and comorbid conditions, medical service use, and spending; registry data linked to NPPES for clinician-level characteristics; and 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.

Note: For all measures, means are calculated over nonmissing values. The population for this table includes highrisk 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 analyses of adherence to antihypertensives—that is, who used antihypertensive medications in the 12 months before enrollment. This accounted for 60 percent of all beneficiaries enrolled in the intervention group in 2017 and 2018 and, similarly, 60 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 the statin adherence measure, this included n = 17,627 beneficiaries in the intervention group and n = 11,666 in the control group, accounting for 73 percent of all beneficiaries enrolled in the intervention group included in analyses of initiation and intensification of antihypertensive medications and 72 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 The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

⁹ 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organization-level means included in this table are the variance-shrunken means for each 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

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, (Table E.11). 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, enrolled by organizations that had more sites on average (28 versus 17). Intervention group beneficiaries resided in counties with higher baseline rates of all-cause outpatient emergency department (ED) visits compared to control group beneficiaries to live in HHS Region 4 (26 versus 14 percent), ¹⁶ and less likely to live in Regions 5 (6 versus 18 percent), 8 (1 versus 6 percent), and 10 (1 versus 6 percent)¹⁷.

Characteristic	Intervention group mean (N = 18,101)	Control group mean (N = 10,242)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Clinical indicators of beneficiary's	cardiovascular	risk			
CVD risk score (%),	40	40	0.2	0.03	0.26
[standard deviation]	[9]	[9]			
Modifiable risk (%) ^c	15	15	-0.2	-0.01	0.82
Has diabetes (%)	66	63	2.7	0.06	0.16
Systolic blood pressure (mm Hg)	139	139	-0.4	-0.03	0.70
Systolic blood pressure is 130 mm Hg or higher (%)	73	75	-1.7	-0.04	0.38
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
LDL cholesterol is 70 mg/dL or higher (%)	72	72	0.8	0.02	0.64
Is current smoker (%) ^d	12	14	-2.5	-0.08	0.20

Table E.11. Baseline characteristics of high-risk Medicare beneficiaries included in the CVD risk reduction analysis: Intervention versus control

¹⁶ Region 4 includes Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee.

¹⁷ Region 5 includes Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin. Region 8 includes Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming. Region 10 includes Alaska, Idaho, Oregon, and Washington.

	Intervention group mean	Control group mean	D:#	Standardized	
Characteristic	(N = 18,101)	(N = 10,242)	Difference	difference ^a	<i>p-</i> value ^b
Beneficiary's medication use	54	40	0.7	0.05	0.00
Uses aspirin (%)	51	48	2.7	0.05	0.60
Uses antihypertensives based on Part D (%) ^e	90	90	0.4	0.01	0.69
Proportion of days covered by antihypertensives (%) ^f	91	92	-0.3	-0.01	0.61
Proportion of beneficiaries with adherence to antihypertensives (%) ^{f, g}	87	87	-0.6	-0.02	0.54
Uses statins based on Part D $(\%)^d$	70	70	0.8	0.02	0.66
Intensity of statin use based on Part D ^e (%)					
Low intensity	7	7	-0.2	-0.01	0.58
Medium intensity	43	42	1.2	0.02	
High intensity	21	21	-0.2	-0.01	
Proportion of days covered by any statins (%) ^f	82	83	-0.8	-0.03	0.32
Proportion of beneficiaries with adherence to statins (%) ^{f, g}	72	74	-2.2	-0.05	0.11
Beneficiary's demographic and Me	edicare enrollme	ent characteristic	s		
Age	74	74	0.0	0.00	0.94
[standard deviation]	[4]	[4]			
Race and ethnicity (%) ^h					
Non-Hispanic Black	7	6	0.7	0.03	0.72
Non-Hispanic White	85	86	-0.9	-0.03	0.76
Hispanic	4	4	0.4	0.03	0.75
All other races and ethnicities	4	4	-0.3	-0.02	0.76
Men (%)	65	67	-1.2	-0.03	0.34
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	conditions				
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	0.1	0.02	0.58
Has chronic kidney disease (%)	35	35	0.6	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	0.61
Has atrial fibrillation (%)	11	11	-0.1	0.00	0.96
Has morbid obesity (%)	9	9	0.0	0.00	0.99

Characteristic	Intervention group mean (N = 18,101)	Control group mean (N = 10,242)	Difference	Standardized difference ^a	p-value ^b
Beneficiary's medical service use a					p-value
Total Medicare Parts A and B	7,432	7,138	294.3	0.02	0.47
annualized expenditures (\$)	[15,405]	[14,495]			
[standard deviation]					
Hospital admissions (per 1,000 beneficiaries)	176	170	6.5	0.01	0.56
CVD-related hospital admissions (per 1,000 beneficiaries) ⁱ	40	37	2.9	0.01	0.61
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	343	328	15.1	0.02	0.39
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) ⁱ	26	27	-1.5	-0.01	0.67
Office visits (per 1,000 beneficiaries)	9,579	9,090	488.8	0.07	0.35
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,224	3,219	4.9	0.00	0.99
Cardiologist visits (per 1,000 beneficiaries)	1,969	1,970	-1.8	0.00	0.99
Beneficiary's CVD-related procedur	es in year befo	re model enrollm	nent		
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	0.91
Characteristics of organization enro	olling the benef	iciary			
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	-1.7	-0.09	
Organization was participating in, or had application pending for, another model at application (%)	69	61	7.9	0.17	0.50
Organizational-level mean Medicare spending and use ^j					
Parts A and B spending	7,437	7,481	-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

Characteristic	Intervention group mean (N = 18,101)	Control group mean (N = 10,242)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Characteristics of clinician enrollin					praiae
Provider specialty (%)	5	, ,			
Primary care physician	63	65	-1.5	-0.03	0.87
Cardiologist	24	24	-0.6	-0.01	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	0.05	0.54
Characteristics of beneficiary's reg	jion				
Rural (%)	28	24	3.1	0.07	0.63
HHS region (%)					
1: CT, ME, MA, NH, RI, and VT	2	4	-2.5	-0.14	<0.01
2: NJ, NY, PR, and VI	13	9	3.4	0.11	
3: DC, DE, MD, PA, VA, and WV	23	15	8.1	0.21	
4: AL, FL, GA, KY, MS, NC, SC, and TN	26	14	11.8	0.30	
5: IL, IN, MI, MN, OH, and WI	6	18	-11.7	-0.36	
6: AR, LA, NM, OK, and TX	8	8	-0.3	-0.01	
7: IA, KS, MO, and NE	16	12	3.2	0.09	
8: CO, MT, ND, SD, UT, and WY	1	6	-4.7	-0.27	
9: AZ, CA, HI, and NV	5	8	-2.8	-0.11	
10: AK, ID, OR, and WA	1	6	-4.6	-0.26	
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	70.4	0.12	0.57
Per capita total Medicare Parts A and B spending in 2016	9,799	9,733	65.8	0.05	0.80
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	282	276	6.1	0.14	0.49
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	711	676	34.3	0.27	0.21
SVI (%) ^k					
Low vulnerability (deciles 1–4 of summary SVI score)	41	39	2.1	0.04	0.45
Medium vulnerability (deciles 5–8 of summary SVI score)	40	43	-3.4	-0.07	

Characteristic	Intervention group mean (N = 18,101)	Control group mean (N = 10,242)	Difference	Standardized difference ^a	<i>p-</i> value ^b
High vulnerability (deciles 9 and 10 of summary SVI score)	19	18	1.3	0.03	
Characteristics of beneficiary's Mil	llion Hearts Mod	del enrollment			
Days between model launch (1/3/2017) and enrollment date [standard deviation]	146 [141]	162 [137]	-16.5	-0.12	0.24
Enrollment date is in (%)					
2017 (as opposed to 2018)	91	90	0.6	0.02	0.79
First quarter of the year	48	42	6.0	0.12	0.18
Second quarter of the year	31	30	0.9	0.02	0.73
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 (%) ^I	40	47	-6.7	-0.13	0.57

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk (except diabetes status); Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the Centers for Disease Control and Prevention (CDC) for 2016 Census-tracklevel summary Social Vulnerability Index score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC 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 following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, diabetes, and ischemic heart disease. The following chronic conditions are defined by using HCC algorithms: 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, defines the 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 = 12,623 for the intervention group and n = 7,167 for the control group). This accounted for 70 percent of all beneficiaries enrolled in each group and included in the analyses of CVD risk reduction.

^f 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 the antihypertensive adherence measure, this included n = 10,946

beneficiaries in the intervention group and n = 6,188 in the control group, accounting for 60 percent of all beneficiaries enrolled in each group included in analyses of CVD risk reduction. For the statin adherence measure, this included n = 8,569 beneficiaries in the intervention group and n = 4,818 in the control group, accounting for 47 percent of all beneficiaries enrolled in each group included in analyses of CVD risk reduction.

⁹ We defined adherence based on whether the beneficiary had 80 percent or more days covered by the medication.

^h The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

ⁱ We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes, including those related to heart failure, hypertension, and angina (Mathematica's <u>Second Annual Report</u>, Appendix C). This measure excludes heart attacks and strokes because the analytic population excludes beneficiaries who had these events before enrolling in the Million Hearts Model.

^j 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

^k We measured social vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. We categorized beneficiaries as residing in Census tracts with low, medium, or high social vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population.

¹ 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 varied 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; CDC = Centers for Disease Control and Prevention; 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; HHS = U.S Department of Health & Human Services; LDL = low-density lipoprotein; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center; SVI = Social Vulnerability Index.

4. Baseline characteristics of the population used to estimate impacts on CVD-event spending

The high- and medium-risk beneficiaries enrolled on or before August 31, 2017, and included in analyses of CVD-event spending were very similar at enrollment with respect to beneficiary-level characteristics, such as age, sex, CVD risk score, medication use, recent service use, and Medicare spending (Table E.12). However, intervention and control group beneficiaries differed somewhat in the types of organizations that enrolled them. Compared to those enrolled by control group organizations, high- and medium-risk beneficiaries in the intervention group were, on average, enrolled by organizations with more sites (25 versus 14), and more likely to participate in or to have applied to participate in another model when they applied to the Million Hearts Model (72 versus 57 percent). In addition, based on HHS-defined regions, intervention group beneficiaries were less likely to live in Region 5 (8 versus 19 percent).¹⁸

Characteristic	Intervention group mean (N = 92,104)	Control group mean (N = 56,023)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Clinical indicators of beneficiary's			Difference	amerence	<i>p</i> -value [⊥]
CVD risk score (%),	27	27	0.1	0.01	0.78
[standard deviation]	[11]	[11]			
Modifiable risk (%) ^c	9	9	0.3	0.03	0.47
Has diabetes (%)	40	39	1.1	0.02	0.36
Systolic blood pressure (mm Hg)	134	134	0.0	0.00	0.99
Systolic blood pressure is 130 mm Hg or higher (%)	60	60	-0.4	-0.01	0.79
Total cholesterol (mg/dL)	174	173	0.9	0.02	0.55
HDL cholesterol (mg/dL)	50	51	-0.3	-0.02	0.70
LDL cholesterol (mg/dL)	96	95	1.1	0.03	0.38
LDL cholesterol is 70 mg/dL or higher (%)	78	76	1.4	0.03	0.31
Is current smoker (%)	11	11	-0.3	-0.01	0.71
Beneficiary's medication use					
Uses aspirin (%)	45	43	2.3	0.05	0.60
Uses antihypertensives based on Part D (%) ^d	84	83	0.7	0.02	0.53
Proportion of days covered by antihypertensives (%) ^e	90	90	-0.3	-0.02	0.39
Proportion of beneficiaries with adherence to antihypertensives (%) ^{e, f}	84	85	-0.5	-0.01	0.48
Uses statins based on Part D (%) ^d	64	64	-0.2	0.00	0.92

 Table E.12. Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in

 2017 and 2018 and included in CVD-event spending analysis: Intervention versus control group

¹⁸ Region 5 includes Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

	Intervention group mean	Control group mean		Standardized	
Characteristic	(N = 92,104)	(N = 56,023)	Difference	difference ^a	<i>p</i> -value ^b
Intensity of statin use based on Part D (%) ^d					
Low intensity	7	7	-0.1	0.00	0.97
Medium intensity	39	39	0.2	0.00	
High intensity	18	19	-0.2	-0.01	
Proportion of days covered by any statins (%) ^e	81	82	-0.8	-0.03	0.24
Proportion of beneficiaries with adherence to statins (%) ^{e, f}	70	71	-1.4	-0.03	0.22
Beneficiary's demographic and Me	dicare enrollme	nt characteristics			
Age	72	72	-0.2	-0.04	0.16
[standard deviation]	[5]	[5]			
Race and ethnicity (%) ^g					
Non-Hispanic Black	8	6	1.6	0.07	0.33
Non-Hispanic White	84	85	-1.0	-0.03	0.65
Hispanic	4	4	-0.1	-0.01	0.89
All other races and ethnicities	4	4	-0.4	-0.03	0.58
Men (%)	57	58	-1.2	-0.02	0.25
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.4	-0.01	0.82
Originally entitled to Medicare because of disability (%)	14	13	0.5	0.02	0.64
Beneficiary's health and comorbid	conditions				
HCC score	1.18	1.16	0.0	0.01	0.66
[standard deviation]	[1.00]	[0.99]			
Number of chronic conditions	2.1	2.1	0.0	0.02	0.54
Has chronic kidney disease (%)	25	25	0.6	0.01	0.64
Has ischemic heart disease (%)	32	34	-1.6	-0.03	0.62
Has congestive heart failure (%)	11	12	-0.4	-0.01	0.75
Has atrial fibrillation (%)	10	10	0.0	0.00	0.97
Has morbid obesity (%)	8	7	0.4	0.02	0.57
Beneficiary's medical service use a	and spending in	year before mode	el enrollment		
Total Medicare Parts A and B	7,713	7,571	142.6	0.01	0.66
annualized expenditures (\$)	[16,747]	[16,219]			
[standard deviation]					
Hospital admissions (per 1,000 beneficiaries)	186	188	-2.1	0.00	0.83
CVD-related hospital admissions (per 1,000 beneficiaries) ^h	40	41	-0.9	0.00	0.85
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	383	359	23.3	0.02	0.22
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) ^h	28	26	1.7	0.01	0.60

Characteristic	Intervention group mean (N = 92,104)	Control group mean (N = 56,023)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Office visits (per 1,000 beneficiaries)	9,344	8,935	409.2	0.05	0.31
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,971	2,867	104.3	0.03	0.72
Cardiologist visits (per 1,000 beneficiaries)	1,826	1,817	8.5	0.00	0.97
Beneficiary's CVD-related procedur	es in year befo	re model enrollme	ent		
Received echocardiogram (%)	40	39	0.9	0.02	0.75
Received electrocardiogram (%)	71	70	0.8	0.02	0.79
Received cardiac stress test (%)	26	26	-0.3	-0.01	0.91
Characteristics of organization enro	olling the benef	iciary			
Total number of practitioners	118	108	10.1	0.04	0.84
[standard deviation]	[144]	[306]			
Total number of service sites	25	14	10.5	0.40	0.13
[standard deviation]	[25]	[27]			
Organization type (%)					
Primary care	54	56	-1.3	-0.03	0.53
Specialty or multispecialty	36	33	3.7	0.08	
FQHC, RHC, or other health center	4	5	-1.1	-0.05	
CAH or rural hospital	1	2	-1.4	-0.12	
Acute care hospital	4	4	0.1	0.01	
Organization was participating in, or had application pending for, another model at application (%)	72	57	14.6	0.31	0.12
Organizational-level mean Medicare spending and use ⁱ					
Parts A and B spending	7,600	7,570	30.6	0.02	0.92
Hospital admissions (per 1,000 beneficiaries)	183	189	-5.8	-0.15	0.48
Outpatient ED visits (per 1,000 beneficiaries)	380	360	19.6	0.18	0.26
Characteristics of clinician enrolling	g the beneficiar	у			
Provider specialty (%)	-	-			
Primary care physician	61	63	-2.4	-0.05	0.76
Cardiologist	23	25	-1.4	-0.03	0.86
Physician with other specialty	3	1	2.3	0.16	0.13
Not a physician (for example, NP or PA)	11	10	1.7	0.06	0.37
Characteristics of beneficiary's reg	ion				
Rural (%)	25	26	-0.6	-0.01	0.91
HHS region (%)					
1: CT, ME, MA, NH, RI, and VT	3	4	-0.6	-0.03	0.28
2: NJ, NY, PR, and VI	15	11	3.6	0.11	
3: DC, DE, MD, PA, VA, and WV	21	15	5.8	0.15	

Characteristic	Intervention group mean (N = 92,104)	Control group mean (N = 56,023)	Difference	Standardized difference ^a	<i>p-</i> value ^b
4: AL, FL, GA, KY, MS, NC, SC,	25	18	7.4	0.18	p rance
and TN	20			0.10	
5: IL, IN, MI, MN, OH, and WI	8	19	-10.7	-0.32	
6: AR, LA, NM, OK, and TX	11	9	2.2	0.07	
7: IA, KS, MO, and NE	12	9	3.1	0.10	
8: CO, MT, ND, SD, UT, and WY	1	5	-3.6	-0.22	
9: AZ, CA, HI, and NV	3	8	-4.5	-0.20	
10: AK, ID, OR, and WA	2	4	-2.6	-0.16	
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	11	-0.5	-0.15	0.33
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	24	23	0.7	0.17	0.29
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,412	4,415	-3.0	-0.01	0.98
Per capita total Medicare Parts A and B spending in 2016	9,920	9,861	58.2	0.04	0.80
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	280	276	4.2	0.11	0.53
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	701	681	20.6	0.17	0.37
SVI (%) ^j					
Low vulnerability (deciles 1–4 of summary SVI score)	42	37	4.8	0.10	0.45
Medium vulnerability (deciles 5–8 of summary SVI score)	39	43	-3.5	-0.07	
High vulnerability (deciles 9 and 10 of summary SVI score)	19	20	-1.4	-0.03	
Characteristics of beneficiary's Mill	ion Hearts Mod	el enrollment			
Days between model launch	96	103	-6.7	-0.10	0.18
(1/3/2017) and enrollment date	[64]	[67]			
[standard deviation]					
Enrollment date is in (%)					
First quarter of the year	50	46	4.5	0.09	0.18
Second quarter of the year	37	38	-1.0	-0.02	0.64
Third quarter of the year	13	16	-3.5	-0.10	0.08
Fourth quarter of the year	0	0	0.0		
Data submitted to the registry using bulk upload (%) ^k	49	49	0.1	0.00	0.99

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk (except diabetes status); Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment

database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the Centers for Disease Control and Prevention (CDC) for 2016 Census-track-level summary Social Vulnerability Index score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC 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 following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, diabetes, and ischemic heart disease. The following chronic conditions are defined by using HCC algorithms: 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 = 63,586 for the intervention group and n = 38,678 for the control group). This accounted for 69 percent of all beneficiaries enrolled in each 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 the antihypertensive adherence measure, this included n = 50,144beneficiaries in the intervention group and n = 30,189 in the control group, accounting for 54 percent of all beneficiaries enrolled in each group. For the statin adherence measure, this included n = 38,649 beneficiaries in the intervention group and n = 23,608 in the control group, accounting for 42 percent of all beneficiaries enrolled in each group.

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

⁹ The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^h We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes, including those related to heart failure, hypertension, and angina (Mathematica's <u>Second Annual Report</u>, Appendix C). 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

^j We measured social vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status,

(2)household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. We categorized beneficiaries as residing in Census tracts with low, medium, or high social vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population.

^k 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 varied 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; CDC = Centers for Disease Control and Prevention; 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; HHS = U.S Department of Health & Human Services; LDL = low-density lipoprotein; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center; SVI = Social Vulnerability Index.

Consistent with the combined high- and medium-risk population mentioned before, the highrisk-only population enrolled by August 31, 2017, was well balanced on characteristics at enrollment, such as age, sex, CVD risk score, medication use, recent service use, and Medicare spending (Table E.13). High-risk-only beneficiaries in the intervention group were, compared to control beneficiaries, enrolled by organizations that on average 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 (71 versus 57 percent). In addition, intervention group beneficiaries less likely to live in Region 5 (8 versus 19 percent).¹⁹ High-risk beneficiaries in the intervention group were also less likely to have enrolled during the third quarter of their enrollment year (11 versus 15 percent).

Characteristic	Intervention group mean (N = 29,221)	Control group mean (N = 17,581)	Difference	Standardized difference ^a	<i>p</i> -value ^b						
Clinical indicators of beneficiary's cardiovascular risk											
CVD risk score (%),	40	40	0.1	0.01	0.78						
[standard deviation]	[9]	[9]									
Modifiable risk (%) ^c	16	15	0.4	0.03	0.58						
Has diabetes (%)	66	63	2.5	0.05	0.13						
Systolic blood pressure (mm Hg)	139	139	0.4	0.02	0.69						
Systolic blood pressure is 130 mm Hg or higher (%)	74	74	0.1	0.00	0.96						
Total cholesterol (mg/dL)	169	169	0.1	0.00	0.95						
HDL cholesterol (mg/dL)	47	48	-0.6	-0.04	0.41						
LDL cholesterol (mg/dL)	92	92	0.5	0.02	0.68						
LDL cholesterol is 70 mg/dL or higher (%)	73	72	0.6	0.01	0.67						

Table E.13. Baseline characteristics of high-risk Medicare beneficiaries enrolled in 2017 and 2018 and included in the CVD-event spending analysis: Intervention versus control group

¹⁹ Region 5 includes Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

Characteristic	Intervention group mean (N = 29,221)	Control group mean (N = 17,581)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Is current smoker (%)	13	13	-0.4	-0.01	0.65
Beneficiary's medication use					
Uses aspirin (%)	51	50	0.9	0.02	0.83
Uses antihypertensives based on Part D (%) ^d	91	90	1.0	0.03	0.17
Proportion of days covered by antihypertensives (%) ^e	91	91	-0.4	-0.02	0.36
Proportion of beneficiaries with adherence to antihypertensives (%) ^{e, f}	86	86	-0.4	-0.01	0.55
Uses statins based on Part D (%) ^d	70	69	1.0	0.02	0.45
Intensity of statin use based on Part D (%) ^d					
Low intensity	7	7	0.1	0.00	0.89
Medium intensity	42	41	0.2	0.00	
High intensity	21	20	0.7	0.02	
Proportion of days covered by any statins (%) ^e	81	82	-1.0	-0.04	0.16
Proportion of beneficiaries with adherence to statins (%) ^{e, f}	70	72	-2.1	-0.05	0.10
Beneficiary's demographic and Me	dicare enrollme	nt characteristic	s		
Age	74	74	-0.2	-0.05	0.16
[standard deviation]	[4]	[4]			
Race and ethnicity (%) ^g					
Non-Hispanic Black	8	6	1.3	0.05	0.43
Non-Hispanic White	84	84	-0.3	-0.01	0.91
Hispanic	4	4	-0.3	-0.02	0.76
All other races and ethnicities	4	5	-0.7	-0.05	0.50
Men (%)	65	65	-0.3	-0.01	0.76
Dually enrolled in Medicare and Medicaid (%)	9	10	-0.6	-0.02	0.71
Originally entitled to Medicare because of disability (%)	12	12	0.2	0.01	0.85
Beneficiary's health and comorbid	conditions				
HCC score	1.38	1.36	0.0	0.02	0.55
[standard deviation]	[1.06]	[1.05]			
Number of chronic conditions	2.7	2.6	0.1	0.04	0.35
Has chronic kidney disease (%)	36	35	1.2	0.02	0.54
Has ischemic heart disease (%)	38	39	-1.1	-0.02	0.73
Has congestive heart failure (%)	14	14	-0.2	-0.01	0.88
Has atrial fibrillation (%)	11	11	0.1	0.00	0.94
Has morbid obesity (%)	9	8	0.5	0.02	0.66

Characteristic	Intervention group mean (N = 29,221)	Control group mean (N = 17,581)	Difference	Standardized difference ^a	<i>p</i> -value ^b
Beneficiary's medical service use a					
Total Medicare Parts A and B	8,194	7,909	285.0	0.02	0.40
annualized expenditures (\$)	[16,601]	[15,746]			
[standard deviation]					
Hospital admissions (per 1,000 beneficiaries)	201	197	3.6	0.01	0.73
CVD-related hospital admissions (per 1,000 beneficiaries) ^h	46	45	1.3	0.00	0.81
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	392	369	22.2	0.02	0.23
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries) ^h	30	28	1.6	0.01	0.64
Office visits (per 1,000 beneficiaries)	9,941	9,424	517.4	0.07	0.21
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,318	3,152	165.8	0.05	0.63
Cardiologist visits (per 1,000 beneficiaries)	2,016	2,004	12.5	0.00	0.95
Beneficiary's CVD-related procedur	es in year befor	e model enrolln	nent		
Received echocardiogram (%)	43	43	0.7	0.01	0.80
Received electrocardiogram (%)	74	74	0.4	0.01	0.89
Received cardiac stress test (%)	29	29	-0.3	-0.01	0.90
Characteristics of organization enro	olling the benefi	ciary			
Total number of practitioners	121	99	22.0	0.09	0.67
[standard deviation]	[165]	[300]			
Total number of service sites [standard deviation]	25 [26]	14 [28]	10.6	0.39	0.15
Organization type (%)					
Primary care	51	57	-5.6	-0.11	0.33
Specialty or multispecialty	39	31	8.6	0.18	
FQHC, RHC, or other health center	4	6	-1.6	-0.07	
CAH or rural hospital	1	2	-1.7	-0.14	
Acute care hospital	5	5	0.3	0.01	
Organization was participating in, or had application pending for, another model at application (%)	71	57	14.0	0.29	0.14
Organizational-level mean Medicare spending and use ⁱ					
Parts A and B spending	7,624	7,593	31.7	0.02	0.91
Hospital admissions (per 1,000 beneficiaries)	185	189	-4.4	-0.11	0.59
Outpatient ED visits (per 1,000 beneficiaries)	383	364	18.1	0.17	0.30

Characteristic	Intervention group mean (N = 29,221)	Control group mean (N = 17,581)	Difference	Standardized difference ^a	<i>p-</i> value ^b
Characteristics of clinician enrollin			Difference	difference	p-value
Provider specialty (%)	g the beneficial	y			
Primary care physician	61	62	-1.8	-0.04	0.81
Cardiologist	24	26	-1.7	-0.04	0.82
Physician with other specialty	3	1	2.2	0.15	0.02
Not a physician (for example, NP	11	10	1.4	0.05	0.13
or PA)		10	1.4	0.00	0.47
Characteristics of beneficiary's reg	ion				
Rural (%)	27	27	-0.3	-0.01	0.96
HHS region (%)					
1: CT, ME, MA, NH, RI, and VT	3	4	-1.4	-0.08	0.37
2: NJ, NY, PR, and VI	14	11	2.8	0.08	
3: DC, DE, MD, PA, VA, and WV	21	14	6.8	0.18	
4: AL, FL, GA, KY, MS, NC, SC, and TN	25	17	7.8	0.19	
5: IL, IN, MI, MN, OH, and WI	8	19	-11.0	-0.32	
6: AR, LA, NM, OK, and TX	11	9	1.8	0.06	
7: IA, KS, MO, and NE	11	7	3.9	0.13	
8: CO, MT, ND, SD, UT, and WY	1	4	-3.3	-0.21	
9: AZ, CA, HI, and NV	3	8	-4.6	-0.20	
10: AK, ID, OR, and WA	2	4	-2.6	-0.15	
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.7	-0.20	0.21
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	24	23	0.8	0.18	0.29
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,440	4,437	2.8	0.00	0.98
Per capita total Medicare Parts A and B spending in 2016	9,905	9,865	40.0	0.03	0.86
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	281	276	4.7	0.12	0.50
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	706	684	22.7	0.18	0.35
SVI (%) ^j					
Low vulnerability (deciles 1–4 of summary SVI score)	39	34	5.1	0.11	0.42
Medium vulnerability (deciles 5–8 of summary SVI score)	41	44	-3.7	-0.07	

	Intervention	Control			
Characteristic	group mean (N = 29,221)	group mean (N = 17,581)	Difference	Standardized difference ^a	<i>p</i> -value⁵
High vulnerability (deciles 9 and 10 of summary SVI score)	20	21	-1.4	-0.03	
Characteristics of beneficiary's Mil	lion Hearts Mod	el enrollment			
Days between model launch (1/3/2017) and enrollment date	92 [64]	100 [67]	-8.2	-0.13	0.11
[standard deviation] Enrollment date is in (%)					
First quarter of the year	53	47	5.8	0.12	0.10
Second quarter of the year	36	38	-2.0	-0.04	0.41
Third quarter of the year	11	15	-3.8	-0.11	0.03
Fourth quarter of the year	0	0	0.0		
Data submitted to the registry using bulk upload (%) ^k	43	44	-1.4	-0.03	0.88

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk (except diabetes status); Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the Centers for Disease Control and Prevention (CDC) for 2016 Census-tracklevel summary Social Vulnerability Index score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC 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 following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, diabetes, and ischemic heart disease. The following chronic conditions are defined by using HCC algorithms: 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, 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 = 20,495 for the intervention group and n = 12,364 for the control group). This accounted for 70 percent of all beneficiaries enrolled in each 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 the antihypertensive adherence measure, this included n = 17,745beneficiaries in the intervention group and n = 10,559 in the control group, accounting for 61 and 60 percent of beneficiaries enrolled in each group, respectively. For the statin adherence measure, this included n = 13,703 beneficiaries in the intervention group and n = 8,156 in the control group, accounting for 47 and 46 percent of beneficiaries enrolled in each group, respectively.

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

⁹ The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^h We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes, including those related to heart failure, hypertension, and angina (Mathematica's <u>Second Annual Report</u>, Appendix C). 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

^j We measured social vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. We categorized beneficiaries as residing in Census tracts with low, medium, or high social vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population.

^k 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 varied 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; CDC = Centers for Disease Control and Prevention; 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; HHS = U.S Department of Health & Human Services; LDL = low-density lipoprotein; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center; SVI = Social Vulnerability Index.

5. Baseline characteristics of the subgroups defined by modifiable risk score

Intervention and control group beneficiaries in both the high- and low-modifiable risk groups were well balanced on characteristics at enrollment such as age, sex, CVD risk score, medication use, recent service use, and Medicare spending. In both subgroups, organizations serving intervention group beneficiaries had more sites than control organizations (25 versus 14 and 25 versus 15 for the high- and low-modifiable risk subgroups, respectively), and intervention organizations were more likely than control organizations to participate in or to have applied to participate in another model when they applied to the Million Hearts Model (68 versus 56 percent and 71 versus 54 percent for the high- and low-modifiable risk subgroups, and similar to those described in Section E.1. In both subgroups, fewer intervention than control group beneficiaries resided in Region 5.²⁰ Fewer intervention than control group beneficiaries enrolled in the fourth quarter of their enrollment year (12 versus 17 percent for both subgroups) (Table E.14).

		High modifiable risk		Low modifiable risk		
Characteristic	Intervention group mean (N = 63,735)	Control group mean (N = 42,640)	Standardized difference ^a	Intervention group mean (N = 66,384)	Control group mean (N = 45,346)	Standardized difference ^a
Clinical indicators of beneficiary's c	ardiovascular risk					
CVD risk score (%),	31	31	-0.01	23	23	0.01
[standard deviation]	[11]	[11]		[8]	[8]	
Modifiable risk (%) ^b	16	16	0.01	2	2	0.02
Has diabetes (%)	41	41	0.00	36	35	0.01
Systolic blood pressure (mm Hg)	143	143	0.00	125	125	-0.03
Total cholesterol (mg/dL)	185	184	0.01	164	164	0.02
HDL cholesterol (mg/dL)	49	50	-0.03	52	51	0.01
LDL cholesterol (mg/dL)	107	105	0.04	87	87	0.02
Is current smoker (%)	20	22	-0.06	3	3	-0.03 *

Table E.14. Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in 2017 and 2018 included in subgroup
analyses defined by high and low modifiable risk: Intervention versus control group

²⁰ Region 5 includes Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

		High modifiable risk		Low modifiable risk			
Characteristic	Intervention group mean (N = 63,735)	Control group mean (N = 42,640)	Standardized difference ^a	Intervention group mean (N = 66,384)	Control group mean (N = 45,346)	Standardized difference ^a	
Beneficiary's medication use							
Uses aspirin (%)	45	43	0.04	46	43	0.06	
Uses antihypertensives based on Part D (%) ^c	86	86	0.02	79	79	0.01	
Proportion of days covered by antihypertensives (%) ^d	89	89	-0.02	91	91	0.00	
Proportion of beneficiaries with adherence to antihypertensives (%) ^{d, e}	82	83	-0.02	86	86	0.00	
Uses statins based on Part D (%) ^c	58	58	0.01	68	69	-0.02	
Intensity of statin use based on Part D (%) ^e							
Low intensity	6	6	0.00	6	7	0.00	
Medium intensity	35	35	0.00	42	41	0.01	
High intensity	17	17	0.01	19	21	-0.04	
Proportion of days covered by any statins (%) ^d	77	78	-0.04	84	84	-0.01	
Proportion of beneficiaries with adherence to statins (%) ^{d, e}	64	66	-0.04	75	75	-0.01	
Beneficiary's demographic and Medicare	e enrollment character	istics					
Age	71	71	-0.02	73	73	-0.03	
standard deviation]	[5]	[5]		[4]	[4]		
Race and ethnicity (%) ^f							
Non-Hispanic Black	10	8	0.05	5	4	0.06	
Non-Hispanic White	81	83	-0.05	87	88	-0.04	
Hispanic	5	4	0.02	4	4	0.01	
All other races and ethnicities	4	4	-0.01	4	4	-0.01	
/len (%)	56	56	-0.01	60	62	-0.03	
Dually enrolled in Medicare and Medicaid %)	12	13	-0.02	7	7	-0.02	
Originally entitled to Medicare because of disability (%)	17	17	-0.01	10	10	-0.01	

		High modifiable risk		Low modifiable risk			
Characteristic	Intervention group mean (N = 63,735)	Control group mean (N = 42,640)	Standardized difference ^a	Intervention group mean (N = 66,384)	Control group mean (N = 45,346)	Standardized difference ^a	
Beneficiary's health and comorbid conc	litions						
HCC score [standard deviation]	1.15 [0.98]	1.15 [0.98]	0.00	1.18 [1.02]	1.18 [1.03]	0.00	
Number of chronic conditions	2.1	2.1	0.00	2.1	2.1	0.00	
Has chronic kidney disease (%)	25	25	0.00	24	24	0.01	
las ischemic heart disease (%)	29	30	-0.02	35	37	-0.05	
las congestive heart failure (%)	10	11	-0.02	12	13	-0.02	
las atrial fibrillation (%)	8	8	0.01	12	12	0.00	
Has morbid obesity (%)	8	8	-0.01	7	7	0.02	
Beneficiary's medical service use and s	pending in year before	model enrollment					
Fotal Medicare Parts A and B annualized expenditures (\$) standard deviation]	7,344 [16,915]	7,188 [16,149]	0.01	8,272 [18,363]	8,085 [17,257]	0.01	
lospital admissions (per 1,000 peneficiaries)	182	183	0.00	192	201	-0.01	
CVD-related hospital admissions (per ,000 beneficiaries) ⁹	40	37	0.01	44	48	-0.01	
Outpatient ED visits or observation stays per 1,000 beneficiaries)	419	394	0.02	347	351	0.00	
CVD-related outpatient ED visits or observation stays (per 1,000 peneficiaries) ^g	32	29	0.01	26	27	0.00	
Office visits (per 1,000 beneficiaries)	8,900	8,646	0.03	9,531	9,256	0.04	
Office visits with model-aligned providers per 1,000 beneficiaries)	2,683	2,702	-0.01	2,601	2,673	-0.02	
ardiologist visits (per 1,000 eneficiaries)	1,644	1,596	0.01	2,044	2,001	0.01	
eneficiary's CVD-related procedures ir	n year before model enr	ollment					
Received echocardiogram (%)	37	36	0.02	42	42	0.01	
Received electrocardiogram (%)	68	68	0.01	73	72	0.01	
Received cardiac stress test (%)	24	24	0.00	28	28	-0.01	

		High modifiable risk		Low modifiable risk			
Characteristic	Intervention group mean (N = 63,735)	Control group mean (N = 42,640)	Standardized difference ^a	Intervention group mean (N = 66,384)	Control group mean (N = 45,346)	Standardized difference ^a	
Characteristics of organization enrolling	the beneficiary						
Total number of practitioners	127	96	0.13	125	118	0.03	
[standard deviation]	[185]	[280]		[171]	[317]		
Total number of service sites [standard	25	14	0.43	25	15	0.35	
deviation]	[26]	[25]		[25]	[28]		
Organization type (%)							
Primary care	50	55	-0.11	57	52	0.10	
Specialty or multispecialty	38	31	0.15	35	36	-0.03	
FQHC, RHC, or other health center	6	6	-0.01	3	4	-0.05	
CAH or rural hospital	1	3	-0.17	1	2	-0.10	
Acute care hospital	5	4	0.03	4	6	-0.07	
Organization was participating in, or had application pending for, another model at application (%)	68	56	0.25	71	54	0.35	
Organizational-level mean Medicare spending and use ^h							
Parts A and B spending	7,616	7,575	0.03	7,710	7,717	0.00	
Hospital admissions (per 1,000 beneficiaries)	185	191	-0.17	183	193	-0.26	
Outpatient ED visits (per 1,000 beneficiaries)	388	373	0.13	368	359	0.09	
Characteristics of clinician enrolling the	beneficiary						
Provider specialty (%)							
Primary care physician	59	62	-0.07	58	61	-0.06	
Cardiologist	25	24	0.01	28	28	-0.01	
Physician with other specialty	3	1	0.13	3	1	0.13	
Not a physician (for example, NP or PA)	13	12	0.02	10	8	0.06	
Characteristics of beneficiary's region							
Rural (%)	27	28	-0.04	22	23	-0.04	
HHS region (%)							
Region 1: CT, ME, MA, NH, RI, and VT	3	4	-0.03	3	3	0.00	
Region 2: NJ, NY, PR and VI	14	11	0.10	17	14	0.08	

		High modifiable risk		Low modifiable risk			
Characteristic	Intervention group mean (N = 63,735)	Control group mean (N = 42,640)	Standardized difference ^a	Intervention group mean (N = 66,384)	Control group mean (N = 45,346)	Standardized differenceª	
Region 3: DC, DE, MD, PA, VA, and WV	21	15	0.13	22	15	0.19	
Region 4: AL, FL, GA, KY, MS, NC, SC, and TN	25	19	0.15	21	16	0.14	
Region 5: IL, IN, MI, MN, OH, and WI	9	16	-0.24	8	18	-0.29	
Region 6: AR, LA, NM, OK, and TX	11	9	0.06	10	8	0.08	
Region 7: IA, KS, MO, and NE	10	10	0.00	12	10	0.06	
Region 8: CO, MT, ND, SD, UT, and WY	1	4	-0.20	1	6	-0.24	
Region 9: AZ, CA, HI, and NV	6	8	-0.07	5	7	-0.10	
Region 10: AK, ID, OR, and WA	1	5	-0.18	1	4	-0.19	
ounty-level health measures							
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.21	11	11	-0.10	
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	24	23	0.11	23	23	0.13	
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,425	4,455	-0.05	4,332	4,362	-0.05	
Per capita total Medicare Parts A and B spending in 2016	9,918	9,845	0.05	9,971	9,847	0.09	
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	279	278	0.02	277	275	0.04	
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	705	689	0.13	683	677	0.05	
VI (%) ⁱ							
Low vulnerability (deciles 1–4 of summary SVI score)	38	34	0.10	46	41	0.11	
Medium vulnerability (deciles 5–8 of summary SVI score)	40	44	-0.08	38	41	-0.08	
High vulnerability (deciles 9 and 10 of summary SVI score)	21	22	-0.03	16	18	-0.05	

		High modifiable risk		Low modifiable risk			
Characteristic	Intervention group mean (N = 63,735)	Control group mean (N = 42,640)	Standardized difference ^a	Intervention group mean (N = 66,384)	Control group mean (N = 45,346)	Standardized differenceª	
Characteristics of beneficiary's Million	Hearts Model enrollmer	nt					
Days between model launch (1/3/2017) and enrollment date [standard deviation]	192 [179]	210 [170]	-0.10	195 [176]	208 [166]	-0.07	
Enrollment date is in (%)							
2017 (as opposed to 2018)	83	82	0.03	83	84	-0.01	
First quarter of the year	42	37	0.09	39	34	0.10	
Second quarter of the year	30	28	0.04	32	30	0.04	
Third quarter of the year	16	18	-0.05	17	19	-0.06	
Fourth quarter of the year	12	17	-0.13 **	12	17	-0.13 **	
Data submitted to the registry using bulk upload (%) ^j	48	46	0.03	52	51	0.01	

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk (except diabetes status); Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the Centers for Disease Control and Prevention (CDC) for 2016 Census-track-level summary Social Vulnerability Index score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC 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. We calculated *p*-values 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.

The following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, diabetes, and ischemic heart disease. The following chronic conditions are defined by using HCC algorithms: 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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, defines the clinical targets.

^c Measured among beneficiaries who also had 12 months of Part D coverage before enrollment and in the month of enrollment. For the high modifiable risk subgroup, this included n = 42,693 intervention group and n = 28,766 control group beneficiaries, accounting for 67 percent of all beneficiaries enrolled in that subgroup in the intervention group and 67 percent in the control group. For the low modifiable risk subgroup, this included n = 46,406 intervention group and n = 31,381 control group beneficiaries, accounting for 70 percent of all beneficiaries enrolled in that subgroup in the intervention group and 69 percent in the control group.

^d 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 the antihypertensive adherence measure for the high modifiable risk subgroup, this included n = 34,353 beneficiaries in that subgroup in the intervention group and n = 23,009 in the control group, accounting for 54 percent of all beneficiaries in each subgroup. For the antihypertensive adherence measure for the low modifiable risk subgroup, this included n = 34,841

beneficiaries in that subgroup in the intervention group and n = 23,429 in the control group, accounting for 52 percent of all beneficiaries in each subgroup. For the statin adherence measure for the high modifiable risk subgroup, this included n = 23,507 beneficiaries in that subgroup in the intervention group and n = 15,798 in the control group, accounting for 37 percent of all beneficiaries in each subgroup. For the statin adherence measure for the low modifiable risk subgroup, this included n = 29,823 beneficiaries in that subgroup in the intervention group and n = 20,478 in the control group, accounting for 45 percent of all beneficiaries in each subgroup.

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

^f The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^g We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes, including those related to heart failure, hypertension, and angina (Mathematica's <u>Second Annual Report</u>, Appendix C). 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

¹We measured social vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. We categorized beneficiaries as residing in Census tracts with low, medium, or high social vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population.

^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.

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

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CAH = critical access hospital; CDC = Centers for Disease Control and Prevention; 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; HHS = U.S Department of Health & Human Services; LDL = low-density lipoprotein; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center; SVI = Social Vulnerability Index.

6. Baseline characteristics of the subgroups defined by social vulnerability

We divided the analysis population used for Part D medication-related analyses by low-, medium-, and high-social vulnerability for subgroup analyses of initiation or intensification of statins and antihypertensives. Within each subgroup (low, medium, and high vulnerability), the intervention and control groups were generally well balanced on measures of CVD risk, medication use, demographics and Medicare enrollment characteristics, and prior service use (Table E.15). However, in the high vulnerability subgroup, intervention group beneficiaries were more likely than control group beneficiaries to use aspirin at baseline (47 versus 38 percent) and were more likely to be enrolled in the model by a physician with other specialty (4 versus 1 percent). Further, the organizations that served intervention group beneficiaries had higher baseline outpatient ED visits than the organizations that served control group beneficiaries (428 versus 395 per 1,000 beneficiaries). In the medium-risk group, organizations that served intervention group beneficiaries than organizations that served control group beneficiaries (183 versus 194 per 1,000 beneficiaries).

		Low vulnerability			Medium vulnerability			High vulnerability		
Characteristic	Intervention group mean (N = 34,336)	Control group mean (N = 19,867)	Standardized difference ^a	Intervention group mean (N = 30,728)	Control group mean (N = 22,884)	Standardized difference ^a	Intervention group mean (N = 15,153)	Control group mean (N = 11,068)	Standardized differenceª	
Clinical indicators of benefici	ary's cardiovascul	ar risk								
CVD risk score (%),	27	27	0.01	28	28	0.00	28	28	0.00	
[standard deviation]	[10]	[10]		[11]	[11]		[11]	[11]		
Modifiable risk (%) ^b	9	9	0.00	10	10	0.02	12	11	0.05	
Has diabetes (%)	32	32	0.01	39	39	0.01	48	47	0.02	
SBP (mm Hg)	134	134	-0.01	135	136	-0.01	137	137	0.01	
Distribution of SBP (%)										
SBP < 130 mm Hg	35	34	0.02	33	32	0.02	31	30	0.02	
SBP 130–139 mm Hg	32	32	0.00	31	31	0.00	29	30	-0.02	
SBP 140–149 mm Hg	18	18	-0.01	19	20	-0.02	19	19	-0.01	
SPB ≥ 150 mm Hg	15	15	-0.01	17	17	0.00	20	20	0.01	
Total cholesterol (mg/dL)	179	178	0.03	179	178	0.02	179	179	0.00	
HDL cholesterol (mg/dL)	53	53	0.01	50	51	-0.02	49	50	-0.06	
LDL cholesterol (mg/dL)	100	99	0.03	101	100	0.04	102	101	0.03	

Table E.15. Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in 2017 and 2018 and included in subgroup analyses defined by the SVI summary score: Intervention versus control group

	Low vulnerability			Medium vulnerability			High vulnerability		
Characteristic	Intervention group mean (N = 34,336)	Control group mean (N = 19,867)	Standardized difference ^a	Intervention group mean (N = 30,728)	Control group mean (N = 22,884)	Standardized difference ^a	Intervention group mean (N = 15,153)	Control group mean (N = 11,068)	Standardizec differenceª
Distribution of LDL cholesterol (%)									
LDL < 70 mg/dL	14	15	-0.03	14	15	-0.03	14	15	-0.03
LDL 70–99 mg/dL	41	42	-0.01	40	40	0.00	39	39	0.01
LDL 100–129 mg/dL	28	27	0.02	28	28	0.01	28	28	0.00
LDL ≥ 130 mg/dL	17	17	0.01	18	17	0.03	19	18	0.02
s current smoker (%)	7	9	-0.07 *	12	13	-0.04	16	17	-0.03
Beneficiary's medication use									
Uses aspirin (%)	43	45	-0.03	43	42	0.03	47	38	0.19 *
Uses antihypertensives based on Part D (%)	80	78	0.04	82	83	-0.01	85	84	0.03
Proportion of days covered by antihypertensives (%)	90	90	0.01	89	90	-0.03	87	88	-0.04
Proportion of beneficiaries with adherence to antihypertensives %)°	85	85	0.01	83	84	-0.03	79	81	-0.05 *
Uses statins based on Part D (%)	61	61	0.00	60	61	-0.02	61	60	0.02
ntensity of statin use based on Part D (%)									
Low intensity	6	6	0.01	7	7	0.00	7	7	-0.01
Medium intensity	38	37	0.02	37	37	0.00	36	36	-0.01
High intensity	16	18	-0.04	17	17	-0.01	18	17	0.04
Proportion of days covered by any statins (%)	82	82	0.00	80	81	-0.05	76	78	-0.07 *
Proportion of beneficiaries with adherence to statins (%) ^c	72	72	-0.01	68	70	-0.05	61	64	-0.06 *
Beneficiary's demographic and N	ledicare enroll	ment characteri	stics						
Age	73	73	0.03	72	72	-0.03	71	71	-0.09 *
standard deviation]	[4]	[4]		[5]	[5]		[6]	[6]	
Race and ethnicity (%) ^d									
Non-Hispanic Black	2	3	-0.03	7	5	0.09	19	15	0.12
Non-Hispanic White	92	91	0.02	86	88	-0.06	63	71	-0.18
Hispanic	2	2	-0.01	3	3	0.00	13	9	0.14
All other races and ethnicities	4	4	0.01	4	4	-0.02	5	5	-0.04

	Low vulnerability			М	Medium vulnerability			High vulnerability		
Characteristic	Intervention group mean (N = 34,336)	Control group mean (N = 19,867)	Standardized differenceª	Intervention group mean (N = 30,728)	Control group mean (N = 22,884)	Standardized differenceª	Intervention group mean (N = 15,153)	Control group mean (N = 11,068)	Standardized difference ^a	
Men (%)	57	59	-0.03	53	54	-0.03	50	50	0.00	
Dually enrolled in Medicare and Medicaid (%)	4	6	-0.05	13	13	-0.03	31	28	0.07	
Originally entitled to Medicare because of disability (%)	8	9	-0.03	16	17	-0.02	27	24	0.07	
Beneficiary's health and comorbi	id conditions									
HCC score	1.10	1.10	0.00	1.21	1.20	0.00	1.34	1.31	0.02	
[standard deviation]	[0.95]	[0.94]		[1.03]	[1.02]		[1.07]	[1.07]		
Number of chronic conditions	1.9	1.9	0.01	2.2	2.1	0.02	2.4	2.3	0.02	
Beneficiary's medical service use	e and spending	g in year before	model enrollme	nt						
Total Medicare Parts A and B annualized expenditures (\$) [standard deviation]	7,638 [16,547]	7,424 [15,223]	0.01	7,898 [16,189]	7,776 [16,023]	0.01	8,269 [17,034]	7,982 [17,613]	0.02	
Hospital admissions (per 1,000 beneficiaries)	168	169	0.00	190	194	-0.01	207	201	0.01	
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	305	314	-0.01	398	380	0.02	565	511	0.04	
Office visits (per 1,000 beneficiaries)	9,204	8,983	0.03	9,475	9,063	0.06	9,909	9,410	0.06	
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,266	2,458	-0.07	2,920	2,744	0.05	3,219	3,180	0.01	
Cardiologist visits (per 1,000 beneficiaries)	1,870	1,740	0.04	1,753	1,726	0.01	1,613	1,780	-0.02	
Characteristics of organization e	nrolling the be	neficiary								
Organization-level mean Medicare spending and use ^e										
Parts A and B spending	7,837	7,730	0.07	7,577	7,660	-0.06	7,567	7,527	0.02	
Hospital admissions (per 1,000 beneficiaries)	182	191	-0.22	183	194	-0.29	184	189	-0.13	
Outpatient ED visits (per 1,000 beneficiaries)	353	339	0.15	379	377	0.02	428	395	0.26	

	Low vulnerability			М	edium vulnerab	ility		High vulnerabili	ty
Characteristic	Intervention group mean (N = 34,336)	Control group mean (N = 19,867)	Standardized difference ^a	Intervention group mean (N = 30,728)	Control group mean (N = 22,884)	Standardized difference ^a	Intervention group mean (N = 15,153)	Control group mean (N = 11,068)	Standardized differenceª
Characteristics of clinician enrol	ling the benefic	ciary							
Provider specialty (%)									
Primary care physician	58	63	-0.12	59	58	0.01	58	63	-0.11
Cardiologist	31	29	0.05	24	28	-0.09	20	19	0.03
Physician with other specialty	3	1	0.11	3	1	0.15	4	1	0.17 *
Not a physician (for example, NP or PA)	8	6	0.09	13	12	0.02	17	16	0.04
Characteristics of beneficiary's r	egion								
Rural (%)	13	15	-0.06	33	35	-0.05	30	28	0.06
County-level health measures									
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	11	0.03	11	12	-0.24	12	13	-0.24
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014– 2016	23	22	0.13	23	23	0.12	25	24	0.15
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,201	4,197	0.01	4,447	4,491	-0.07	4,581	4,626	-0.06
Per capita total Medicare Parts A and B spending in 2016	10,053	9,940	0.08	9,860	9,683	0.12	10,198	10,140	0.04
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	274	272	0.04	278	276	0.06	287	287	0.02
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	658	648	0.10	700	693	0.06	761	733	0.21

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the CDC for 2016 Census-track-level summary Social Vulnerability Index score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC 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. We calculated *p*-values 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.

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 (SPB equal to 130 mm Hg or higher or LDL equal to 70 mg/dL or higher). This accounted for 62 and 60 percent of all intervention and control beneficiaries in the low vulnerability subgroup, respectively, as well as 61 percent of all intervention and control group beneficiaries in the medium vulnerability subgroup, and 62 and 63 percent of all intervention and control group beneficiaries in the medium vulnerability subgroup, and 62 and 63 percent of all intervention and control group beneficiaries in the high vulnerability subgroup, respectively. We measured vulnerability using the CDC's summary SVI score. It is a percentile ranking of where each Census tract falls on the continuum of social vulnerability based on four broad domains: (1) socioeconomic status, (2) household composition and disability, (3) minority status and language, and (4) housing type and transportation. The score ranges from 0 to 100, with 0 reflecting the lowest and 100 reflecting the highest level of social vulnerability. We categorized beneficiaries as residing in Census tracts with low, medium, or high vulnerability based on the distribution of SVI scores among the Million Hearts Model enrolled population.

^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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, defines clinical targets.

^c 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 the antihypertensive adherence measure for the low vulnerability subgroup, this included n = 25,904 beneficiaries in that subgroup in the intervention group and n = 14,647 in the control group, accounting for 75 and 74 percent of beneficiaries in that subgroup, respectively. For the antihypertensive adherence measure for the medium vulnerability subgroup, this included n = 23,833 beneficiaries in that subgroup in the intervention group and n = 17,794 in the control group, accounting for 78 percent of all beneficiaries in each subgroup. For the antihypertensive adherence measure for the high vulnerability subgroup, this included n = 11,911 beneficiaries in that subgroup in the intervention group and n = 8,693 in the control group, accounting for 79 percent of all beneficiaries in each subgroup. For the statin adherence measure for the low vulnerability subgroup, this included n = 11,911 beneficiaries in each subgroup, this included n = 19,863 beneficiaries in that subgroup in the intervention group and n = 11,520 in the control group, accounting for 58 percent of all beneficiaries in each subgroup. For the medium vulnerability subgroup, this included n = 17,505 beneficiaries in that subgroup in the intervention group and n = 13,210 in the control group, accounting for 57 and 58 percent of beneficiaries in that subgroup, this included n = 8,522 beneficiaries in that subgroup in the intervention group and n = 6,232 in the control group, accounting for 56 percent of all beneficiaries in each subgroup.

^d The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^e 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

*/** Significantly different from zero at the .05/0.01 level, two-tailed test, respectively.

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CDC = Centers for Disease Control and Prevention; 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

7. Baseline characteristics of the subgroups defined by gender

We split the analysis population used for Part D medication-related analyses by gender for subgroup analyses of initiation or intensification of statins and antihypertensives. Within each subgroup (men and women), the intervention and control groups were well balanced on nearly all measures, including those of CVD risk, medication use, demographics and Medicare enrollment characteristics, and prior service use (Table E.16).

Table E.16. Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in
2017 and 2018 and included in subgroup analyses defined by gender: Intervention versus control
group

		Men		Women			
Characteristic	Intervention group mean (N = 43,462)	Control group mean (N = 29,699)	Standardized difference ^a	Intervention group mean (N = 36,784)	Control group mean (N = 24,134)	Standardized difference ^a	
Clinical indicators of beneficia	ry's cardiovasc	ular risk					
CVD risk score (%),	29	29	0.02	26	26	-0.02	
[standard deviation]	[11]	[11]		[10]	[10]		
Modifiable risk (%) ^b	10	10	0.02	10	10	-0.02	
Has diabetes (%)	36	36	0.00	40	40	0.00	
SBP (mm Hg)	134	134	-0.01	137	137	-0.02	
Distribution of SBP (%)							
SBP < 130 mm Hg	36	35	0.02	31	30	0.03	
SBP 130–139 mm Hg	32	32	-0.01	30	30	0.00	
SBP 140–149 mm Hg	18	19	-0.01	19	20	-0.02	
SPB ≥ 150 mm Hg	14	14	0.00	20	20	-0.02	
Total cholesterol (mg/dL)	169	169	0.01	190	190	0.01	
HDL cholesterol (mg/dL)	46	46	-0.01	57	57	-0.02	
LDL cholesterol (mg/dL)	97	96	0.03	106	105	0.03	
Distribution of LDL cholesterol (%)							
LDL < 70 mg/dL	16	17	-0.03	11	12	0.00	
LDL 70–99 mg/dL	43	43	0.00	37	37	0.01	
LDL 100–129 mg/dL	27	26	0.01	30	30	0.01	
LDL ≥ 130 mg/dL	14	14	0.02	22	22	-0.07	
Is current smoker (%)	11	12	-0.04	10	13	0.00	

		Men		Women				
a	Intervention group mean	Control group mean	Standardized	Intervention group mean	Control group mean	Standardized		
Characteristic	(N = 43,462)	(N = 29,699)	difference ^a	(N = 36,784)	(N = 24,134)	difference ^a		
Beneficiary's medication use-0			0.07	10	40	0.00		
Uses aspirin (%)	48	44	0.07	40	40	0.00		
Uses antihypertensives based on Part D (%)	80	79	0.01	85	84	0.02		
Proportion of days covered by antihypertensives (%)	89	89	-0.01	90	90	-0.01		
Proportion of beneficiaries with adherence to antihypertensives (%) ^c	83	84	-0.02	83	84	-0.01		
Uses statins based on Part D (%)	62	62	0.00	58	58	0.00		
Intensity of statin use based on Part D (%)								
Low intensity	6	6	0.00	7	8	-0.01		
Medium intensity	37	37	0.01	37	37	0.00		
High intensity	19	20	-0.02	14	14	0.00		
Proportion of days covered by any statins (%)	82	82	-0.02	78	79	-0.04		
Proportion of beneficiaries with adherence to statins (%)°	71	72	-0.02	65	67	-0.04		
Beneficiary's demographic and	I Medicare enro	Ilment characte	eristics					
Age	71	71	-0.02	73	73	-0.01		
[standard deviation]	[5]	[5]		[4]	[4]			
Race and ethnicity (%) ^d								
Non-Hispanic Black	6	5	0.05	9	8	0.04		
Non-Hispanic White	86	87	-0.06	82	83	-0.03		
Hispanic	4	4	0.04	5	4	0.03		
All other races and ethnicities	4	4	0.00	4	5	-0.04		
Dually enrolled in Medicare and Medicaid (%)	11	11	-0.01	15	17	-0.05		
Originally entitled to Medicare because of disability (%)	16	16	-0.02	13	14	-0.02		
Beneficiary's health and como	rbid conditions							
HCC score	1.18	1.18	0.00	1.18	1.19	-0.01		
[standard deviation]	[1.04]	[1.03]		[0.97]	[0.98]			
Number of chronic conditions	2.1	2.1	0.00	2.1	2.1	0.01		
Beneficiary's medical service ι	ise and spendir	ng in year befor	re model enrolln	nent				
Total Medicare Parts A and B annualized expenditures (\$) [standard deviation]	7,794 [16,631]	7,620 [16,548]	0.01	7,932 [16,375]	7,774 [15,483]	0.01		
Hospital admissions (per 1,000 beneficiaries)	177	180	0.00	191	195	-0.01		
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	359	348	0.01	427	426	0.00		
Office visits (per 1,000 beneficiaries)	8,974	8,680	0.04	9,992	9,628	0.05		

		Men			Women	
Characteristic	Intervention group mean (N = 43,462)	Control group mean (N = 29,699)	Standardized difference ^a	Intervention group mean (N = 36,784)	Control group mean (N = 24,134)	Standardized difference ^a
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,498	2,532	-0.01	2,930	2,969	-0.01
Cardiologist visits (per 1,000 beneficiaries)	1,881	1,875	0.00	1,653	1,580	0.02
Characteristics of organization	enrolling the b	eneficiary				
Organizational-level mean Medicare spending and use ^e						
Parts A and B spending	7,728	7,707	0.01	7,637	7,599	0.02
Hospital admissions (per 1,000 beneficiaries)	184	193	-0.24	181	190	-0.22
Outpatient ED visits (per 1,000 beneficiaries)	378	366	0.12	376	369	0.07
Characteristics of clinician enr	olling the bene	ficiary				
Provider specialty (%)						
Primary care physician	57	60	-0.04	59	63	-0.08
Cardiologist	29	29	-0.01	24	23	0.01
Physician with other specialty	3	1	0.12	3	1	0.16
Not a physician (for example, NP or PA)	10	9	0.03	13	12	0.04
Characteristics of beneficiary's	region					
Rural (%)	24	26	-0.07	24	26	-0.04
County-level health measures						
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014– 2016	11	11	-0.14	11	12	-0.20
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014– 2016	23	23	0.12	23	23	0.10
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,350	4,384	-0.06	4,388	4,442	-0.09
Per capita total Medicare Parts A and B spending in 2016	9,986	9,836	0.10	10,032	9,917	0.08
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	277	275	0.04	280	279	0.02
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	690	680	0.08	698	690	0.06

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Million Hearts Data Registry and Medicare Part D claims for beneficiaries' medication use; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; RAND MBISG race and ethnicity file for probabilities of being non-Hispanic Black, non-Hispanic White, Hispanic, or all other races and ethnicities; Medicare Parts A and B 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 and the CDC for 2016 Census-track-level summary SVI score, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the CDC and CMS's Medicare Geographic Variation Public Use File for regional characteristics; Million Hearts Data Registry for characteristics of model enrollment.

Note: For all measures, means are calculated over nonmissing values. We calculated *p*-values 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.

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 (SPB equal to 130 mm Hg or higher or LDL equal to 70 mg/dL or higher). This accounted for 57 and 57 percent of all intervention and control beneficiaries in the subgroup of men, respectively, as well as 67 percent and 67 percent of all intervention and control group beneficiaries in the subgroup of women, respectively.

^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 We defined modifiable risk 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. The <u>Fourth Annual Report</u>, Chapter VI, defines clinical targets.

^c 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 the antihypertensive adherence measure for the subgroup of men, this included n = 32,162 beneficiaries in that subgroup in the intervention group and n = 21,925 in the control group, accounting for 74 percent of all beneficiaries in each subgroup. For the antihypertensive adherence measure for the subgroup of women, this included n = 29,506 beneficiaries in that subgroup in the intervention group and n = 19,218 in the control group, accounting for 80 percent of all beneficiaries in each subgroup. For the statin adherence measure for the subgroup of men, this included n = 25,412 beneficiaries in that subgroup in the intervention group and n = 17,469 in the control group, accounting for 58 and 59 percent of beneficiaries in each subgroup, respectively. For the statin adherence measure for the subgroup of women, this included n = 20,491 beneficiaries in that subgroup in the intervention group and n = 13,501 in the control group, accounting for 56 percent of all beneficiaries in each subgroup in the intervention group and n = 13,501 in the control group, accounting for 56 percent of all beneficiaries in each subgroup.

^d The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The RAND Corporation developed the predicted probabilities from its MBSIG 2.0 algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

^e 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 most of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period generally spans the period before the intervention started and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organizational-level means included in this table are the variance-shrunken means for each organization.

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

ABCS = aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation; AMI = acute myocardial infarction; ASCVD = atherosclerotic cardiovascular disease; CDC = Centers for Disease Control and Prevention; 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; MBSIG 2.0 = Medicare Bayesian Improved Surname Geocoding; mg/dl = milligrams per deciliter; mmHg = millimeters of mercury; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

Appendix F

Impact Analysis Outcome Measures

1. Overview

The impact analyses described in Chapters IV through VII use outcome measures derived from Medicare administrative and Parts A, B, and D claims data, the Million Hearts Data Registry, and National Death Index (NDI) data. In previous reports, Mathematica described how we specified most of these outcome measures. In this appendix, we describe only updated or new outcome measures used in the current report. Table F.1 provides the location and links for outcome descriptions included in this appendix and in previous reports.

Outcome (Reported in which chapter of this report)	Description
Statin and antihypertensive initiation or intensification (<u>Chapter IV</u>)	Second Annual Report, Appendix C, Section 3
Statin and antihypertensive adherence (<u>Chapter IV</u>)	<u>Fourth Annual Report</u> , Chapter V, Section A.1 (page 67)
Aspirin use, CVD risk score, and CVD risk factors (<u>Chapter V</u>)	Sourced directly from the Million Hearts Data Registry
Hospitalizations, ED visits, and office visits (<u>Chapter VI</u>)	Second Annual Report, Appendix C, Section 2.d
First-time heart attack and stroke (<u>Chapter VII</u>)	Described in this appendix, <u>Section 2</u>
All-cause mortality (<u>Chapter VII</u>)	Sourced directly from the Medicare Enrollment Database
Cause-specific mortality (<u>Chapter VII</u>)	Described in this appendix, <u>Section 4</u>
Combined CVD event and mortality measure (Chapter VII)	Described in this appendix, <u>Section 4</u>
CVD-event spending (<u>Chapter VII</u>)	Described in this appendix, <u>Section 3</u>
Medicare Parts A and B spending (<u>Chapter VII</u>)	Second Annual Report, Appendix C, Section 2.d

Table F.1. Sources for definitions of outcome measures

The rest of this appendix defines updated or new measures. In <u>Section F.2</u>, we present our updated definition of first-time heart attack or stroke, which includes several newly added codes for stroke. <u>Section F.3</u> describes our new 90-day cardiovascular disease (CVD)-event spending measure. In <u>Section F.4</u>, we provide information on the National Death Index (NDI) outcome measures, including measures of cause-specific mortality and a composite measure to capture both claims-based first-time heart attacks or strokes and NDI-based deaths due to coronary heart disease (CHD) or cerebrovascular disease.

2. Claims-based definition of first-time heart attack or stroke (updated for stroke)

We measured heart attacks and strokes using inpatient hospital claims and outpatient emergency department (ED) or observation stay claims. Furthermore, we constructed two versions of the heart attack and stroke outcomes—one using a narrow definition of the event, the other a broader definition of the event. As Table F.2 describes, the narrow definition uses only the principal diagnosis on both inpatient and outpatient claims. In contrast, the broader definition looks at principal or secondary diagnoses on inpatient claims, as long as the secondary diagnosis was not present on admission. The "not present on admission" restriction sought to exclude events previously diagnosed or treated.

The diagnosis codes used to define the narrow and broad definitions of heart attack and stroke were based on the Chronic Conditions Data Warehouse (CCW) definitions of heart attack and stroke. As in previous analyses, the narrow definition of heart attack limited the diagnoses to those categorized as ST elevation (STEMI), non-ST elevation (NSTEMI), and unspecified heart attack (this corresponds to Type I heart attacks, as defined by the Fourth Universal Definition of Myocardial Infarction [Thygesen et al. 2018]). For the broad definition of heart attack, we included all five types of heart attacks in the Fourth Universal Definition of Myocardial Infarction. We excluded any diagnoses for complications following STEMI and NSTEMI, as well as diagnoses for subsequent heart attack from the outcome definition because the outcome aim to measure first heart attacks.

For stroke, we limited the diagnoses for the narrow definition to those categorized as ischemic and hemorrhagic stroke. For the broad definition of stroke, we included ischemic and hemorrhagic stroke, transient ischemic attack (TIA), and stroke syndromes. Compared to prior evaluation reports, we updated the list of diagnosis codes for stroke, consistent with updates the CCW made to the list of stroke codes in its 2022 updates (Chronic Conditions Data Warehouse 2022). (The 2022 CCW updates did not change the narrow or broad definition of heart attack.)

	Narrow definition	Broad definition
Diagnosis codes		
Heart attack	STEMI: I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3 NSTEMI: I21.4 Unspecified: I21.9	STEMI: I21.01, I21.02, I21.09, I21.11, I21.19, I21.21, I21.29, I21.3 NSTEMI: I21.4 Unspecified: I21.9 Type 2: I21.A1 Other types: I21.A9
Stroke ^a	Ischemic and hemorrhagic stroke, original codes: I60.00, I60.01, I60.02, I60.10, I60.11, I60.12, I60.2, I60.20, I60.21, I60.22, I60.30, I60.31, I60.32, I60.4, I60.50, I60.51, I60.52, I60.6, I60.7, I60.8, I60.9, I61.0, I61.1, I61.2, I61.3, I61.4, I61.5, I61.6, I61.8, I61.9, I63.00, I63.011, I63.012, I63.013, I63.019, I63.02, I63.031, I63.032, I63.033, I63.039, I63.09, I63.10, I63.111, I63.112, I63.113, I63.119, I63.12, I63.131, I63.22, I63.231, I63.212, I63.213, I63.20, I63.211, I63.212, I63.213, I63.20, I63.22, I63.231, I63.232, I63.233, I63.239, I63.29, I63.30, I63.311, I63.312, I63.313, I63.319, I63.321, I63.322, I63.323, I63.329, I63.331, I63.332, I63.333, I63.339, I63.341, I63.342, I63.431, I63.442, I63.443, I63.449, I63.441, I63.442, I63.443, I63.449, I63.441, I63.442, I63.443, I63.449, I63.441, I63.50, I63.511, I63.512, I63.533, I63.59, I63.511, I63.522, I63.533, I63.59, I63.541, I63.542, I63.533, I63.59, I63.541, I63.542, I63.543, I63.549, I63.59, I63.6, I63.81, I63.89, I63.9, I63.59, I63.641, I63.542, I63.543, I63.549, I63.59, I63.643, I63.542, I63.543, I63.549, I63.59, I63.541, I63.542, I63.543, I63.549, I63.59, I63.643, I63.542, I63.543, I63.549, I63.59, I63.642, I63.543, I63.549, I63.59, I63.64, I63.542, I63.543, I63.549, I63.59, I63.64, I63.841, I63.89, I63.9, Ischemic and hemorrhagic stroke codes newly included in this Fifth Annual Report: I62.00, I62.01, I62.02, I62.9	Ischemic and hemorrhagic stroke, original codes: I60.00, I60.01, I60.02, I60.10, I60.11, I60.12, I60.2, I60.20, I60.21, I60.22, I60.30, I60.31, I60.32, I60.4, I60.50, I60.51, I60.52, I60.6, I60.7, I60.8, I60.9, I61.0, I61.1, I61.2, I61.3, I61.4, I61.5, I61.6, I61.8, I61.9, I63.00, I63.011, I63.012, I63.013, I63.019, I63.02, I63.031, I63.032, I63.033, I63.039, I63.09, I63.10, I63.111, I63.112, I63.113, I63.119, I63.12, I63.131, I63.132, I63.213, I63.219, I63.22, I63.231, I63.232, I63.233, I63.239, I63.29, I63.30, I63.311, I63.312, I63.313, I63.319, I63.321, I63.322, I63.323, I63.329, I63.331, I63.332, I63.333, I63.339, I63.341, I63.342, I63.343, I63.349, I63.39, I63.40, I63.411, I63.412, I63.413, I63.419, I63.421, I63.422, I63.423, I63.429, I63.431, I63.432, I63.433, I63.439, I63.441, I63.442, I63.443, I63.449, I63.49, I63.50, I63.511, I63.512, I63.513, I63.519, I63.521, I63.522, I63.523, I63.529, I63.531, I63.532, I63.533, I63.539, I63.6, I63.81, I63.542, I63.543, I63.549, I63.59, I63.6, I63.81, I63.89, I63.9. Ischemic and hemorrhagic stroke codes newly included in this Fifth Annual Report: I62.00, I62.01, I62.02, I62.9 TIA: G45.0, G45.1, G45.2, G45.8, G45.9, I67.81, I67.82, I67.841, I67.848, I67.89 Other stroke syndromes: G46.0, G46.1, G46.2, G46.3, G46.4, G46.5, G46.6, G46.7, G46.8, G97.31, G97.32, I66.01, I66.02, I66.03, I66.09, I66.11, I66.12, I66.13, I66.19, I66.21, I66.22, I66.23, I66.29, I66.3, I66.8, I66.9, I97.810, I97.811, I97.820, I97.821
Stroke exclusions (in		

Table F.2. Claims-based definitions of acute myocardial infarction and stroke (ICD-10 codes only)

Stroke exclusions (in any position, unless otherwise noted)

	Narrow definition	Broad definition
Diagnosis fields		
Inpatient claims	Principal only	Principal and secondary, but only those secondary diagnoses not present on admission
Outpatient ED and observation stay claims	Principal only	Principal only

^a For both narrow and broad definitions of stroke, we applied the CCW stroke exclusions as originally defined in their 2018 specifications and added new exclusion codes from the 2022 updates. The stroke exclusion codes, including the original 2018 codes are S01.90XA, S02.0XXA, S02.0XXB, S02.10XA, S02.10XB, S02.101A, S02.101B, S02.102A, S02.102B, S02.109A, S02.109B, S02.11GA, S02.11GB, S02.11HA, S02.11HB, S02.110A, S02.111A, S02.112A, S02.113A, S02.110B, S02.111B, S02.112B, S02.113B, S02.118A, S02.118B, S02.119A, S02.119B, S02.19XA, S02.19XB, S02.2XXA, S02.2XXB, S02.3XXA, S02.30XA, S02.3XXB, S02.30XB, S02.31XA, S02.31XB, S02.32XA, S02.32XB, S02.40AA, S02.40AB, S02.40BA, S02.40BB, S02.40CA, S02.40CB, S02.40CA, S02.40DA, S02.40DB, S02.40EA, S02.40EB, S02.40FA, S02.40FB, S02.400A, S02.400B, S02.401A, S02.401B, S02.402A, S02.402B, S02.411A, S02.411B, S02.412A, S02.412B, S02.413A, S02.413B, S02.42XA, S02.42XB, S02.600A, S02.600B, S02.601A, S02.601B, S02.602A, S02.602B, S02.609A, S02.609B, S02.61XA, S02.610A, S02.610B, S02.611A, S02.611B, S02.612A, S02.612B, S02.62XA, S02.620A, S02.62XB, S02.620B, S02.621A, S02.621B, S02.622A, S02.622B, S02.63XA, S02.630A, S02.63XB, S02.630B, S02.631A, S02.631B, S02.632A, S02.632B, S02.64XA, S02.640A, S02.64XB, S02.640B, S02.641A, S02.641B, S02.642A, S02.642B, S02.65XA, S02.650A, S02.65XB, S02.650B, S02.651A, S02.651B, S02.652A, S02.652B, S02.66XA, S02.66XB, S02.67XA, S02.670A, S02.670B, S02.671A, S02.671B, S02.672A, S02.672B, S02.69XA, S02.61XB, S02.62XA, S02.63XA, S02.64XA, S02.65XA, S02.66XA, S02.67XB, S02.69XB, S02.8XXA, S02.80XA, S02.8XXB, S02.80XB, S02.81XA, S02.81XB, S02.82XA, S02.82XB, S02.91XA, S02.91XB, S02.92XA, S02.92XB, S06.0X0A, S06.0X1A, S06.0X2A, S06.0X3A, S06.0X4A, S06.0X5A, S06.0X6A, S06.0X7A, S06.0X8A, S06.0X9A, S06.1X0A, S06.1X1A, S06.1X2A, S06.1X3A, S06.1X4A, S06.1X5A, S06.1X6A, S06.1X7A, S06.1X8A, S06.1X9A, S06.2X0A, S06.2X1A, S06.2X2A, S06.2X3A, S06.2X4A, S06.2X5A, S06.2X6A, S06.2X7A, S06.2X8A, S06.2X9A, S06.2X0B, S06.2X1B, S06.2X2B, S06.2X3B, S06.2X4B, S06.2X5B, S06.2X6B, S06.2X7B, S06.2X8B, S06.2X9B, S06.300A, S06.301A, S06.302A, S06.303A, S06.304A, S06.305A, S06.306A, S06.307A, S06.308A, S06.309A, S06.310A, S06.311A, S06.312A, S06.313A, S06.314A, S06.315A, S06.316A, S06.317A, S06.318A, S06.319A, S06.320A, S06.321A, S06.322A, S06.323A, S06.324A, S06.325A, S06.326A, S06.327A, S06.328A, S06.329A, S06.330A, S06.331A, S06.332A, S06.333A, S06.334A, S06.335A, S06.336A, S06.337A, S06.338A, S06.339A, S06.340A, S06.341A, S06.342A, S06.343A, S06.344A, S06.345A, S06.346A, S06.347A, S06.348A, S06.349A, S06.350A, S06.351A, S06.352A, S06.353A, S06.354A, S06.355A, S06.356A, S06.357A, S06.358A, S06.359A, S06.360A, S06.361A, S06.362A, S06.363A, S06.364A, S06.365A, S06.366A, S06.367A, S06.368A, S06.369A, S06.370A, S06.371A, S06.372A, S06.373A, S06.374A, S06.375A, S06.376A, S06.377A, S06.378A, S06.379A, S06.380A, S06.381A, S06.382A, S06.383A, S06.384A, S06.385A, S06.386A, S06.387A, S06.388A, S06.389A, S06.4X0A, S06.4X1A, S06.4X2A, S06.4X3A, S06.4X4A, S06,4X5A, S06,4X6A, S06,4X7A, S06,4X8A, S06,4X9A, S06,5X0A, S06,5X1A, S06,5X2A, S06,5X3A, S06,5X4A, S06.5X5A, S06.5X6A, S06.5X7A, S06.5X8A, S06.5X9A, S06.6X0A, S06.6X1A, S06.6X2A, S06.6X3A, S06.6X4A, S06.6X5A, S06.6X6A, S06.6X7A, S06.6X8A, S06.6X9A, S06.810A, S06.811A, S06.812A, S06.813A, S06.814A, S06.815A, S06.816A, S06.817A, S06.818A, S06.819A, S06.820A, S06.821A, S06.822A, S06.823A, S06.824A, S06.825A, S06.826A, S06.827A, S06.828A, S06.829A, S06.890A, S06.891A, S06.892A, S06.893A, S06.894A, S06.895A, S06.896A, S06.897A, S06.898A, S06.899A, S06.9X0A, S06.9X1A, S06.9X2A, S06.9X3A, S06.9X4A, S06.9X5A, S06.9X6A, S06.9X7A, S06.9X8A, S06.9X9A, OR Z51.89 as the principal diagnosis code. Exclusion codes newly included in this Fifth Annual Report are S02.121A, S02.121B, S02.122A, S02.122B, S02.129A, S02.129B, S02.831A, S02.831B, S02.832A, S02.832B, S02.839A, S02.839B, S02.841A, S02.841B, S02.842A, S02.842B, S02.849A, S02.849B, S02.85XA, and S02.85XB.

ED = emergency department; CCW = Chronic Conditions Data Warehouse; ICD-10 = International Classification of Diseases, 10th edition; NSTEMI = Non-ST elevation; STEMI = ST elevation; TIA = transient ischemic attack.

3. Claims-based definition of CVD event spending

We constructed a measure of spending for first-time heart attacks or strokes (CVD events), including spending during the first-time heart attack or stroke (hereafter, the acute event) and 90 days following the event. This measure included all Medicare fee-for-service (FFS) payments made to hospitals for the acute event (an inpatient stay, an outpatient ED visit, or observation stay) as well as all payments made to individual providers for care provided during the acute event. Further, this measure included all Medicare payments made to all providers in the 90-days after discharge for all services delivered during this window, even if they were unrelated to the acute event. This included Medicare payments for services found in each of the FFS claims files: inpatient, skilled nursing facility, hospice, home health, outpatient, carrier (also called part B), and durable medical equipment. If a claim was partially contained within the 90-day window for example, an inpatient hospital claim spanning days 86 to 95 post-discharge-we calculated the average daily payment for the claim and estimated Medicare payments contained within the 90-day episode window by multiplying the average daily payment rate by the number of days that fell in the 90-day window. We did not measure 90-day episode spending for acute events if (1) the beneficiary was not observable for the full 90-day window for any reason other than death—for example, if they moved into Medicare Advantage during the 90-day window—(n = 217 events excluded); or (2) if the acute event occurred too late in the analysis period to measure 90-day spending—for example, an event whose 90-day window ended on or after January 1, 2022 (n = 6 events excluded). The n = 223 excluded events represent 3 percent of the CVD events included in the event spending analyses.

4. NDI outcome measures

We constructed measures of cause-specific mortality based on the underlying cause of death codes obtained from the NDI.²¹ The World Health Organization defines the underlying cause of death as "the disease or injury which initiated the train of morbid events leading directly to death, or the circumstances of the accident or violence which produced the fatal injury." As Table F.3 describes, we classified underlying causes of death into CVD-related deaths, and further classified CVD-related deaths as CHD or cerebrovascular disease-related deaths using the same International Classification of Diseases, 10th edition (ICD-10) diagnosis-based definitions used by the American Heart Association and the Reasons for Geographic and Racial Differences in Stroke (REGARDS) project. According to REGARDS,²² NDI-derived cause-specific mortality based on these definitions had good specificity and modest sensitivity (specificity: 85 percent for all CVD, 90 percent for CHD, and 99 percent for cerebrovascular deaths; sensitivity: 73 percent for all CVD, 54 percent for CHD, and 52 percent for cerebrovascular deaths [Halanych et al. 2011; Olubowale et al. 2017]). Table F.4 presents top ICD-10 diagnosis codes in each cause-of-death category under CVD. We extracted the date of death from the Medicare Enrollment Database (EDB). Among 26,403 beneficiaries who died by the end of 2021 based on

²¹ NDI final files were obtained for years 2017 through 2020 and early release files were obtained for year 2021.

²² To assess sensitivity and specificity, REGARDS compared mortality data derived from death certificate and NDI data to CVD deaths determined by expert adjudication.

EDB, 98.7 percent had a corresponding NDI record. For deceased beneficiaries without a corresponding NDI record, we coded their cause of death as unknown.

Building on the measures of cause-specific mortality, we constructed a composite measure to capture both claims-based first-time heart attacks or strokes, as described in Section F.2, and NDI-based deaths due to CHD or cerebrovascular disease. This composite measure adds fatal CHD or cerebrovascular events identified in NDI data without an associated claim for first-time heart attacks or strokes, capturing fatal CHD or cerebrovascular events occurring outside the hospital in addition to first-time heart attacks and strokes in claims.

Table F.3. NDI-based definitions of CHD, cerebrovascular disease, and CVD (ICD-10 codes only)

Cause of death	ICD-10 diagnosis codes
All CVD-related deaths	100–199
CHD or cerebrovascular deaths	CHD: I20–I25, I46, I49
	Cerebrovascular: I60 to I69
All other deaths	All other ICD-10 codes

CHD = coronary heart disease; CVD = cardiovascular disease; ICD-10 = International Classification of Diseases, 10th edition; NDI = National Death Index.

Cause of death	Top 5 ICD-10 diagnosis codes				
CHD deaths	I25.1, Atherosclerotic heart disease of native coronary artery				
	I21.9, Acute myocardial infarction, unspecified				
	I25.0, Atherosclerotic cardiovascular disease, so described				
	I46.9, Cardiac arrest, cause unspecified				
	I25.5, Ischemic cardiomyopathy				
Cerebrovascular	I64, Stroke, not specified as hemorrhage or infarction				
deaths	I61.9, Nontraumatic intracerebral hemorrhage, unspecified				
	I63.9, Cerebral infarction, unspecified				
	I62.9, Nontraumatic intracranial hemorrhage, unspecified				
	l67.9, Cerebrovascular disease, unspecified				
Other CVD deaths	I50.0, Congestive heart failure				
	I11.9, Hypertensive heart disease without heart failure				
	I48, Atrial fibrillation and flutter				
	I42.9, Cardiomyopathy, unspecified				
	I50.9, Heart failure, unspecified				

Table F.4. Top ICD-10 diagnosis codes, by cause-of-death category

CHD = coronary heart disease; CVD = cardiovascular disease; ICD-10 = International Classification of Diseases, 10th edition.

Appendix G

Regression Methods

In <u>Chapter VIII</u>, Mathematica reported estimates of the impacts of the Million Hearts Model on cardiovascular disease (CVD) medication use, CVD risk factors and risk scores, service use, first-time heart attacks and strokes, mortality, and Medicare spending, as well as variation in model impacts by beneficiary subgroup. This appendix details our methods for estimating impacts. <u>Appendix F</u> described the definitions of outcome variables used in impact analyses.

1. Empirical estimation design

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 high- and medium-risk beneficiaries combined and (2) the high-risk beneficiaries alone. We considered beneficiaries at 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 2021 (or the date a person died or became unobservable in Medicare claims).²³ The median follow-up period across all beneficiaries included in our analysis was 51.6 months, with a range from one day to just under 60.0 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 50.7 months. Analyses of death continued to follow beneficiaries after they became unobservable in Medicare claims because mortality data were available for all enrolled beneficiaries, leading to a longer follow-up time of 54.1 months. Given the date we pulled the claims data and the rolling enrollment, we observed each beneficiary from 1 to 19 quarters (or just under 60.0 months), 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).

²³ 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 three or six months needed to confirm intensification or adherence, respectively.

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 that 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 have been risk stratified or reported to the registry.

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 E) 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 in the model 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. We made a few modifications to the covariates used in the impact analyses in this report, compared to previous years. Specifically, we (1) switched data sources (from registry to claims) for a few variables (such as diabetes); (2) added some new covariates for select combinations of chronic conditions (for example, a covariate that indicated whether a beneficiary had heart failure *and* chronic kidney disease); (3) modeled CVD risk separately for small, medium, and large organizations. More details are available in Table G.1.

Table G.1. Covariates included in the regression models used for estimating impacts on a beneficiary's outcomes

	Included in regression models with the population of:			
	Enrolled	Attributed		
Covariate, measured at date of enrollment or attribution	beneficiaries	beneficiaries		
Clinical indicators of beneficiary's cardiovascular risk				
CVD risk score ^{a, b, c}	-			
Predicted CVD risk score		•		
Predicted probabilities of belonging to the high- or medium-, high-, medium-, and low-CVD risk groups (four variables) $^{\rm c}$		•		
Estimated modifiable risk ^{a, b, c, d}	-			
Claims-based CVD risk score (assuming optimal values for clinical values)		•		
Evidence of diabetes in claims (yes/no)	-	•		
Systolic blood pressure (mm Hg) ^a	-			
Evidence of hypertension in claims over previous 24 months (yes/no)	-	•		
Total cholesterol (mg/dL) ^a	-			
HDL cholesterol (mg/dL) ^a	-			
LDL cholesterol (mg/dL) ^{a, c}	-			
Evidence of hyperlipidemia in claims over previous 12 months (yes/no)	-	•		
Is current smoker (yes/no) ^{a,e}	•			
Evidence of tobacco use in claims over previous 24 months (yes/no)		•		
Uses aspirin (yes/no) ^{a,e}	-			
Evidence of aspirin use in claims over previous 24 months (yes/no)		•		
Beneficiary's medication use before model enrollment ^{f, g}				
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 categorical age group) ^b	•	•		
Race and ethnicity predicted probabilities: non-Hispanic Black, non-Hispanic White, Hispanic (3 variables) ^h	•	•		
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)	-	-		
Has atrial fibrillation (yes/no)	-	-		
Has morbid obesity (yes/no)	-			

	Included in regression models with the population of:			
Covariate, measured at date of enrollment or attribution	Enrolled beneficiaries	Attributed beneficiaries		
	beneficiaries	beneficiaries		
Has dementia (yes/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)	•	•		
Has heart failure <u>and</u> diabetes (yes/no)	•	•		
Has heart failure <u>and</u> chronic kidney disease (yes/no)	•	•		
Has heart failure <u>and</u> atrial fibrillation (yes/no)	-	-		
Has heart failure <u>and</u> ischemic heart disease (yes/no)	-	-		
Has ischemic heart disease <u>and</u> chronic kidney disease (yes/no)	•	-		
Has ischemic heart disease <u>and</u> diabetes (yes/no)	•	-		
Has ischemic heart disease <u>and</u> chronic obstructive pulmonary disease (yes/no)	•	•		
Beneficiary's medical service use and spending in year before model enrollment ^f				
Total Medicare Parts A and B annualized expenditures ^{b, i}	-	-		
Total inpatient annualized expenditures ⁱ	-	-		
Number of hospital admissions ⁱ	-	-		
Number of CVD-related hospital admissions ⁱ	-	-		
Number of outpatient ED visits or observation stays ⁱ	-	-		
Number of CVD-related ED visits or observation stays				
Number of office visits ⁱ				
Number of office visits with model-aligned providers ⁱ	•	-		
Number of cardiologist office visits ⁱ		-		
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 ^j				
Total number of practitioners (1 to 5, 6 to 19, or 20 or more) °	-	-		
Total number of service sites (1, 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 CMS model at random assignment (yes/no)	•	•		
Organizational-level mean Parts A and B Medicare spending ^{i, k}	-	-		

	Included in regression models with the population of:			
Covariate, measured at date of enrollment or attribution	Enrolled beneficiaries	Attributed beneficiaries		
Organizational-level mean hospital admissions (per 1,000 beneficiaries) ^{i, k}	•			
Organizational-level mean outpatient ED visits or observation stays (per 1,000 beneficiaries) ^{i, k}	•	•		
Characteristics of clinician enrolling the beneficiary ⁱ				
Provider specialty (cardiovascular-related physician/primary care physician [noncardiovascular]/other physician/other provider type [nonphysician])	•	•		
Characteristics of beneficiary's region				
Rural (yes/no)				
HHS Region (1: CT, ME, MA, NH, RI, and VT, 2: NY, NJ, PR, and VI, 3: DC, DE, MD, PA, VA, and WV, 4: AL, FL, GA, KY, MS, NC, SC, and TN, 5: IL, IN, MI, MN, OH, and WI, 6: AR, LA, NM, OK, and TX, 7: IA, KS, MO, and NE, 8: CO, MT, ND, SD, UT, and WY, 9: AZ, CA, HI, and NV, or 10: AK, ID, OR, and WA)	•	•		
Social Vulnerability Index (low vulnerability [summary SVI score deciles 1–4 or SVI unknown], medium vulnerability [summary SVI score deciles 5–8], or high vulnerability [summary SVI score deciles 9 and 10])	•	•		
County-level AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016 ⁱ	•	•		
County-level stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016 ⁱ	•	•		
County-level age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016 ⁱ	•	•		
County-level per capital total Medicare Parts A and B spending in 2016 ⁱ	•	•		
County-level hospital admissions per 1,000 Medicare FFS beneficiaries in 2016 ⁱ	•	•		
County-level outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016 ⁱ	•			
Characteristics of beneficiary's Million Hearts Model enrollment ^f				
Calendar month of the enrollment/attribution date (24 variables, each corresponding to 1 of the 24 months 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 options (yes/no) ^{a, d}	•			

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 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 Data Registry.

^b For the enrolled population, we included an interaction term between this variable and the high-risk group indicator, in addition to the high-risk indicator itself, in models that included both high- and medium-risk beneficiaries. For the attributed population, we interacted this variable with the probability of belonging to the high-risk group.

^c For the enrolled population, we interacted CVD risk group and modifiable CVD risk by three organization size categories: 1 to 5 practitioners, 6 to 19 practitioners, or 20 or more practitioners. For the attributed population, we interacted predicted CVD risk by organization size using the three organization size categories.

^d To account for missing values, we included an indicator for missing data in the regression model.

^e 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.

^f For the population of attributed beneficiaries, we defined these variables 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).

^g 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.

^h The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of falling into each category. The RAND Corporation developed the predicted probabilities from its Medicare Bayesian Improved Surname Geocoding (MBSIG 2.0) algorithm (Haas et al. 2019), which used information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

ⁱBefore including these variables in the regression models, we standardized each variable to have mean 0 and standard deviation 1.

^j For the population of attributed beneficiaries, we defined these variables according to characteristics of the organization or provider the beneficiary was attributed to (in place of the organization or provider that *enrolled* the beneficiary).

^k See <u>Appendix C of the 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.

AMI = acute myocardial infarction; CAH = critical access hospital; CVD = cardiovascular disease; ED = emergency department; FFS = fee-for-service; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL= high-density lipoprotein; HHS = U.S. Department of Health and Human Services; LDL = low-density lipoprotein; RHC = rural health center; mg/dL = milligrams per deciliter; mmHg = millimeters of mercury; SVI = Social Vulnerability Index.

2. Types of regression models used for estimating impacts

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 2021). 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.²⁴ 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 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 such as 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 and second assuming the beneficiary was in the control 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.
- 5. We used multinomial logistic regression models to analyze impacts on mortality by cause of death, defined by the underlying cause of death code in the National Death Index data. The

²⁴ We also computed regression-adjusted mean failure curves based on the Cox proportional hazard models. To construct these curves, we calculated a predicted failure curve for each intervention group beneficiary for each time (t) using (1) the baseline survival curve, (2) the Cox proportional hazard model coefficients, and (3) the beneficiary's characteristics (control variables). Each of these estimates represents, for each observation, the predicted probability of having the event within t days. Then we averaged these estimates across all intervention group observations for each t. We then repeated this calculation as if the beneficiary had belonged to the control group. We calculated standard errors using the delta method, treating the baseline survival curve as fixed.

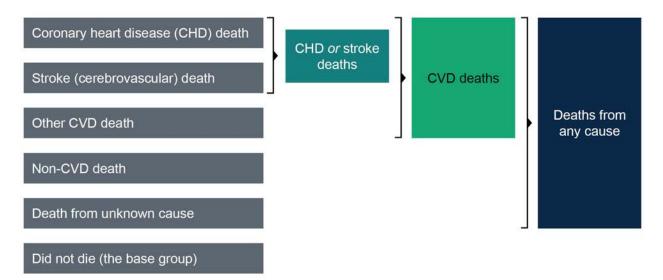
dependent variable was an unordered categorical variable indicating the cause-of-death, with a category reserved for beneficiaries who did not die.

6. We used two-part regression models to estimate the impact on CVD-event spending. These models are similar to the linear regression models (#4). Because most beneficiaries did not have a CVD event, and therefore had \$0 in CVD-event spending by definition—we estimated separate models for the intensive and extensive response margins. That is, we estimated (1) a logit model for the probability of a CVD event and (2) a linear model for the CVD-event spending conditional on having a CVD event. This allowed us to model the event rates and the outcome using separate processes (Cameron and Trivedi 2005; Jones 2000; Mihaylova et al. 2011).

All models accounted for clustering of beneficiaries within organizations, which is needed to correctly estimate standard errors, *p*-values, and confidence intervals. We described the first three types of regression models in more detail in <u>Appendix D of our Second Annual Report</u> (Peterson et al. 2019) and the fourth type of models is described in <u>Appendix F of our Third Annual Report</u> (Blue et al. 2020). The following subsections of this appendix describe the method for the fifth and sixth types of models in detail.

a. Models for cause of death

We used a multinomial logistic regression model, with one observation per beneficiary, to measure impacts on mortality by underlying cause-of-death outcome category:



Multinomial logistic regression models generate the predicted probability of each beneficiary falling into an outcome category—like our logistic regression models (Approach 3 mentioned above). Logistic regression models are restricted to binary outcome measures, but multinomial logistic regression models extend the approach for outcome measures with three or more categories.

Multinomial logistic regressions offer two key advantages over estimating one standard logistic regressions for each outcome category: (1) they permit assessments, with a single test statistic and *p*-value, of whether the distribution in responses across all response categories differs between the intervention and control groups (while also providing test statistics and *p*-values for the individual response options); and (2) they ensure the sum of the probabilities across all possible response categories totals to 1 for each beneficiary. All but one possible outcome category is modeled separately relative to a "base" response. That is, if the question has K + 1 possible responses, the multinomial logistic regression will include *K* logistic regressions for each response relative to an (arbitrarily chosen) base response. (Without loss of generality, we label the base response K = 0.) The regression model took the following form:

$$\frac{\Pr(y_i = 1)}{\Pr(y_i = 0)} = \exp(\alpha_1 + \delta_1 M H_i + \beta_1 x_i)$$

$$\frac{\Pr(y_i = 2)}{\Pr(y_i = 0)} = \exp(\alpha_2 + \delta_2 M H_i + \beta_2 x_i)$$

$$\dots$$

$$\frac{\Pr(y_i = K)}{\Pr(y_i = 0)} = \exp(\alpha_K + \delta_K M H_i + \beta_K x_i)$$
(G.1)

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

In Equation (G.1), y_i is the outcome for beneficiary *i*, MH_i equals one for intervention group organizations and zero for control group organizations; x_i are baseline covariates; and α_k , δ_k , and β_k are parameters to be estimated. We estimated the multinomial logit regression model by weighted maximum likelihood with beneficiary-level data.²⁵ In this model, each beneficiary has one, and only one, possible death outcome (that is, they either did not die or died and had one cause of death). The coefficients δ_k are our parameters of interest—they capture the impact of exposure to the Million Hearts Model on the probability of having each outcome *k*. The vectors of coefficients β_k account for observed differences between the intervention and control groups in beneficiary-, provider-, and organization-level baseline covariates (x_i) and potentially improve the precision of the impact estimates. Section A of this appendix describes the covariates that contributed to the analysis.

Because this is a nonlinear model, we calculated average marginal effects that expresses impacts as percentage point differences in the regression-adjusted probability of each outcome. Specifically, after estimating the model, we produced the estimated probability of each outcome

²⁵ Attribution population beneficiaries received weights based on the probability that they had high- or medium-CVD risk. See <u>Appendices C</u> and <u>F</u> of our <u>Third Annual Report</u> (Blue et al. 2020) for details.

category (k) for each intervention group beneficiary (i) twice—first assuming the beneficiary was in the intervention group, and second assuming the beneficiary was in the control group. For each beneficiary, we calculated the difference in predicted probability of death under these two conditions, and then estimated the model impact as the mean of these differences across all beneficiaries in the intervention group. We repeated this procedure for each outcome category (k). We also used this method to produce regression-adjusted means and impacts for combinations of outcome categories—for example, the probability of a CVD-related death was the sum of the probability of having a CHD death, the probability of having a stroke (cerebrovascular) death, and the probability of having other types of CVD-related deaths. To account for the clustering of providers within organizations, we reported *p*-values and confidence intervals based on robust standard errors, clustered at the organization level.

b. Model for CVD-event spending

We used a two-part model to estimate regression-adjusted impacts of the Million Hearts Model on Medicare spending for first-time heart attacks, strokes, and TIAs, including spending during and 90 days following the event. A combination of those two quantities models the expected CVD-event spending for each beneficiary in the analysis population. Our analyses used data at the beneficiary level (that is, one row per beneficiary), including weights as needed (footnote 25).

Our two-part regression models took the following form:

$$\mathbf{E}\left(y_{i}\left|MH_{i}, x_{i}\right) = \Pr\left(y_{i} > 0\left|MH_{i}, x_{i}\right) \times \mathbf{E}\left(y_{i}\left|y_{i} > 0, MH_{i}, x_{i}\right)\right), \quad (G.2)$$

where y_i is CVD-event spending measured for beneficiary *i* and the other variables are defined the same as they were in Equation (G.1). To reduce the risk of chance high-cost events in either the intervention or control group driving impact estimates, we Winsorized CVD-event spending. We set the CVD-event spending measure to \$150,000 when the actual value was greater than \$150,000 (which is around the 98th percentile). We used actual, rather than Winsorized spending measures in sensitivity analyses.

The specific regression model used to estimate the first part of Equation G.2 was the following logit regression model:

$$\Pr(y_i > 0 | MH_i, x_i) \times F(\alpha_i + \delta_1 MH_i + \beta_1 x_i), \qquad (G.3)$$

where $F(u) = \exp(u)/(1 - \exp(u))$. The specific regression model used to estimate the second part of Equation (G.2) was the following linear regression model, estimated among beneficiaries with a non-zero outcome (that is, with a first-time CVD event):

$$y_i = \alpha_2 + \delta_2 M H_i + \beta_2 x_i + \varepsilon_i \circ | \circ y_i > 0, \qquad (G.4)$$

In Equations (G.3) and (G.4), $\alpha_1, \delta_1, \beta_1, \alpha_2, \delta_2$, and β_2 are parameters to be estimated. The coefficients δ_k are our parameters of interest—they capture the impact of exposure to the Million Hearts CVD Model on expected CVD-event spending. The vectors of coefficients β_k account for observed differences between the intervention and control groups in beneficiary-, provider-, and organization-level baseline covariates (x_i) and improved the precision of the impact estimates.

These models generated the expected CVD-event spending for beneficiaries in the intervention group by multiplying predictions from the two parts (Equations [G.3] and [G.4]). As with other outcomes, we estimated model impacts as the mean difference between predicted CVD-event spending for intervention beneficiaries assuming they were in the intervention group, and assuming they were in the control group. To account for the clustering of providers within organizations, we reported p-values and confidence intervals based on robust standard errors, clustered at the organization level.

c. Estimating variation in impacts by subgroup

For subgroups based on modifiable risk score, Social Vulnerability Index (SVI), and gender, we first checked the balance within each subgroup. Then we estimated (1) impacts of the Million Hearts Model for each subgroup and (2) a test for differences in impact estimates between subgroups. We used the same regression models described earlier in this appendix but added variables to indicate the beneficiaries' subgroup category plus an interaction term (or terms) between the subgroup category and the intervention arm (intervention versus control group). We used separate models for each subgroup analysis. (For example, the SVI subgroup analysis did not also contain interactions between gender subgroups and intervention arm.)

We calculated regression-adjusted means and average treatment effects on the treated for each subgroup, using the values of all covariates observed among that subgroup's beneficiaries. That is, we allowed the distribution of covariates to vary between the modifiable risk, SVI, or gender categories. Specifically, for each beneficiary in the intervention group, we used the results of the regression model to generate (a) the predicted outcome based on his or her individual covariates and subgroup category (with the intervention group indicator turned "on" ["1"] to reflect that they are intervention group beneficiaries); (b) the predicted outcome assuming the individual was in the control group (that is, the predicted outcome produced by the model if the intervention group indicator was temporarily assigned to the control group ["0"]); and (c) the beneficiary-specific impact, which is the difference between predicted values (a) and (b). We then took the average of the three values across all intervention group beneficiaries within each subgroup to generate regression-adjusted intervention and control means and average impacts for (the intervention group in) that category. Then, we compared differences in average model effects across subgroups, using the estimated average treatment effects for each subgroup.

Appendix H

Supplemental Results

This appendix contains additional results to support the findings presented in Chapters IV through VIII. These results include sensitivity analyses to assess the robustness of the impact analysis results to alternative methodologies and exploratory analyses. Appendices <u>D</u> through <u>G</u> contain more details about the analysis methods. Specifically, <u>Appendix D</u> describes the beneficiaries included in these impact analyses, <u>Appendix E</u> displays characteristics of beneficiaries in the intervention and control groups before they enrolled in the model, <u>Appendix F</u> defines the outcomes used in the impact analyses, and <u>Appendix G</u> describes the regression methods used in the impact analyses.

Tables H.1 through H.22 present results from several analyses Mathematica conducted to (1) assess the sensitivity of the impact analysis results to alternative methodologies; and (2) explore other patterns in the data (for example, trends in impact estimates over time). We organized the results largely around the type of outcome measure (<u>Appendix D</u>). For comparative purposes, the tables include the results from our impact analyses of the primary study population of enrolled high- and medium-risk beneficiaries from Chapters IV through VIII (labeled main analysis). Sensitivity and exploratory analyses presented for most or all of the outcomes include the following:

Trimmed study population. We reestimated impacts for the beneficiaries enrolled in the model but trimmed the intervention group in a way that attempted to mimic the 20-provider cap applied to the control group. The enrollment patterns in the control group suggest 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 and 2018, (3) selecting the top 20 providers, and (4) removing from the study population any beneficiaries enrolled in 2017 and 2018 by providers at large organizations not ranked in the top 20. In our First Annual Report (Conwell et al. 2019), we showed this trimming made the intervention and control groups more similar in both overall size and in the proportion of beneficiaries enrolled by large organizations. Therefore, it helped address the limitation that large intervention organizations were more likely to enroll beneficiaries-which could potentially confound the impact estimates if the size of the enrolling organization correlated with the outcomes.

Analyses with attributed beneficiaries. We reestimated impacts on claims-based outcomes in a population we defined by attributing Medicare fee-for-service beneficiaries to the participating organizations using Medicare claims data.²⁶ 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) discussed the methods and rationale for defining this population and predicting risk scores for the beneficiaries, and it explained how we used weights to make the population resemble high- and medium-risk beneficiaries. To compare 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 attribution-based intervention group were enrolled in the model. For example, in Table H.22, we estimated the model increased Medicare spending by \$3 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 \$6 (\$3.21 / 0.56), assuming the model had no spillover effects to beneficiaries attributed to the organization but not enrolled into the model. Although we used the attributionbased 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 E</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 often affected our impact estimates. This could have happened 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) we measured some covariates at the organization level; (2) beneficiary-level covariates corresponded to the organizational characteristics (for example, U.S. Census region correlated with beneficiaries' race or ethnicity); or (3) many beneficiaries in the analysis population concentrated in a relatively small proportion of the organizations.

²⁶ We cannot analyze impacts on some outcomes—initiation or intensification of 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.

- 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.

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. Next, we discuss the effects of regression adjustment on our various outcomes.

1. Cardiovascular disease medication use

As noted in Chapter IV, the main findings for the impact of the Million Hearts Model on statin and antihypertension medication use were consistent across a series of sensitivity analyses (Tables H.1 through H.6), including after trimming the sample to 20 or fewer providers per organization, using the population of attributed beneficiaries, using a higher blood pressure threshold to define candidates for potential antihypertensive medication initiation or intensification, and in unadjusted analyses. When we used the trimmed study population, the estimated impact on initiating or intensifying statins decreased slightly from our main impact estimate of 3.5 percentage points to a new estimate of 3.0 percentage points for high- and medium-risk beneficiaries and decreased from 4.9 to 4.4 percentage points for high-risk beneficiaries but remained statistically significant. Estimates were also slightly lower than the main estimates in unadjusted analyses (3.2 and 4.6 for high- and medium-risk and high-risk beneficiaries, respectively, Table H.1). Similarly, the estimated impact on initiating or intensifying antihypertensive medication decreased slightly in trimmed analyses from 2.4 to 2.1 (for both high- and medium-risk beneficiaries, and high-risk alone, Table H.4). Unadjusted estimates for antihypertensives were similar to the main estimates, at 2.3 and 2.6 for high- and medium-risk and high-risk beneficiaries, respectively. Identifying beneficiaries eligible for initiation or intensification requires cardiovascular disease (CVD) risk factor data available only in the Million Hearts Data Registry, so we could not test the sensitivity to using a population of attributed beneficiaries.

Consistent with the main adherence results, sensitivity checks for adherence were all very close to zero, ranging from estimates of 1.0 percentage point lower to 0.3 percentage points greater adherence to statins and from estimates of 0.2 percentage points lower to 0.1 percentage points greater adherence to antihypertensives in the intervention group, indicating little to no effect of the model on adherence (Tables H.2 and H.5).

Aspirin use findings were also similar in adjusted and unadjusted analyses, and after trimming the sample to 20 or fewer providers per organization (Table H.7). The finding of 10.7 percentage point greater aspirin use in the intervention group was slightly larger after trimming the sample

(11.1 percentage points, Table H.7). The point estimate was attenuated in unadjusted analyses (8.5 percentage points) but remained statistically significant (p = 0.03). We could not assess sensitivity to using the population of attributed beneficiaries because aspirin use data were available only for the enrolled population, with data submitted to the Million Hearts Data Registry.

Additional sensitivity and exploratory analyses specific to statin and antihypertensive use included the following:

Breaking out initiation from intensification. We estimated impacts of the Million Hearts Model on initiating statins and antihypertensives, defined as receiving one or more statins or antihypertensives in the year after enrollment among beneficiaries who did not receive a statin or antihypertensive in the four months before enrollment. We also estimated impacts on intensifying statins and antihypertensives, defined as adding a new antihypertensive medication or increasing the intensity or dosage of statins or antihypertensives. We found the model increased both initiation and intensification of these CVD medications by a roughly similar magnitude as the combined initiation and intensification results (Tables H.1 and H.4).

Impacts on initiating or intensifying antihypertensive medication of dropping some potential candidates. We conducted a sensitivity analysis by redefining *potential candidates* for initiating or intensifying antihypertensive medication 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 H.4).

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 statin or antihypertensive use and proportion of days with any statin or antihypertensive use. We did this to understand the model's impact on overall statin or antihypertensive use among all beneficiaries with Part D coverage, regardless of baseline use of CVD medications. The proportion of beneficiaries with any statin use was 1.7 percent points higher in the intervention group than in the control group among high- and medium-risk beneficiaries combined (Table H.3), a statistically significant difference (p < 0.001), and the impact estimate was 2.1 percentage points when we focused on high-risk beneficiaries alone (p < 0.001, Table H.3). We observed a similar increase in the proportion of beneficiaries with any high-intensity statin use. The model did not increase the proportion of days with any statin use for high- and medium-risk beneficiaries (0.1 percentage points, p < 0.68, Table H.3) or for high-risk beneficiaries only (0.4 percentage points, p = 0.34, Table H.3). The model also did not increase the proportion of days with any high-intensity statin use for high- and medium-risk beneficiaries, but it did increase the proportion of days with any high-intensity statin use for high-risk beneficiaries alone (1.0 percentage point, p < 0.001, Table H.3). The model increased the proportion of beneficiaries using any antihypertensives in the first year after enrollment (high- and medium-risk beneficiaries combined: 0.5 percentage points, p =0.007; high-risk beneficiaries: 0.6 percentage points, p = 0.01, Table H.6), but did not affect the

proportion of days with any antihypertensive use for either high- and medium-risk combined beneficiaries or high-risk beneficiaries alone over the same period (Table H.6).

Trends in medication use over time since enrollment. Figures H.1 and H.2 present unadjusted (Kaplan-Meier) estimates of the cumulative probability of initiating and intensifying statins or antihypertensives, respectively.²⁷ In both the intervention and control groups, about 40 percent of eligible beneficiaries initiated or intensified statins (Figure H.1), and more than half of the eligible beneficiaries initiated or intensified antihypertensives (Figure H.2) over the follow-up period (almost five years in some cases). Many of these beneficiaries initiated or intensified medications in the first year after enrollment, with rates of statin and antihypertensive initiation and intensification increasing more gradually after one year. The intervention group's rate of initiating or intensifying statins and antihypertensives increased faster than the control group's rate in the first year and the differences between the two groups persisted up to five years. These figures do not adjust for observed differences in baseline covariates between the intervention and comparison groups; however, unadjusted and adjusted estimates of the impact on initiating or intensifying CVD medication were similar (Tables H.1 and H.4).

²⁷ 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 did not have the outcome (in this case, did not initiate or intensify CVD medications) within a specified time.

Table H.1. Estimated impacts on initiating or intensifying statins: Sensitivity analyses

	Regression	-adjusted					
	mea	an	Regres	Regression-adjusted difference			
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a	
High- and medium-risk beneficiaries							
Main analysis (among beneficiaries with LDL cholesterol >= 70 mg/dL)	18.5	15.0	3.5	<0.001	[2.6, 4.4]	114,910	
Initiation (among beneficiaries without statin use at baseline)	26.7	22.7	4.1	<0.001	[2.8, 5.3]	57,968	
Intensification (among beneficiaries with statin use at baseline)	10.1	7.2	2.9	<0.001	[2.1, 3.8]	56,942	
Trim sample to 20 or fewer providers per organization ^b	18.1	15.1	3.0	<0.001	[2.1, 4.0]	92,679	
Unadjusted impact estimates	18.5	15.3	3.2	<0.001	[1.8, 4.6]	114,910	
High-risk beneficiaries ^b							
Main analysis (among beneficiaries with LDL cholesterol >= 70 mg/dL)	21.1	16.1	4.9	<0.001	[3.6, 6.3]	34,060	
Initiation (among beneficiaries without statin use at baseline)	32.0	26.6	5.4	<0.001	[3.5, 7.2]	15,885	
Intensification (among beneficiaries with statin use at baseline)	11.7	7.1	4.5	<0.001	[3.2, 5.9]	18,175	
Trim sample to 20 or fewer providers per organization ^b	20.3	16.0	4.4	<0.001	[3.0, 5.7]	27,932	
Unadjusted impact estimates	21.1	16.5	4.6	<0.001	[2.9, 6.2]	34,060	

Sources: Mathematica's analysis of Medicare Parts A, B, and D claims and enrollment data.

Note: We estimated impacts using logistic regression for binary outcomes (initiating and intensifying CVD medication). Analyses of high-risk beneficiaries are limited to beneficiaries with baseline CVD risk scores of 30 percent or higher.

^a The number of beneficiaries varied 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 D</u> for details. The number reported in the table includes both intervention and control group beneficiaries.

^b This analysis population trimmed the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries.

CVD = cardiovascular disease; LDL = low-density lipoprotein; mg/dL = milligrams per deciliter.

Table H.2. Estimated impacts on adherence to statins: Sensitivity analyses

	Regression	-adjusted				
	mea	mean		Regression-adjusted difference		
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a
High- and medium-risk beneficiaries						
Main analysis (proportion of days covered by any statins)	83.0	83.1	-0.1	0.58	[-0.5, 0.2]	89,970
Trim sample to 20 or fewer providers per organization ^b	83.3	83.4	-0.1	0.70	[-0.5, 0.3]	73,534
Unadjusted impact estimates	83.0	83.2	-0.2	0.75	[-1.2, 0.8]	89,970
Attributed population	83.0	83.0	0.1	0.73	[-0.3, 0.4]	236,010
Implied effect for enrolled beneficiaries ^c			0.1	0.73	[-0.5, 0.8]	
Main analysis (proportion of beneficiaries adherent to statins)	74.8	75.2	-0.4	0.31	[-1.0, 0.2]	89,970
Trim sample to 20 or fewer providers per organization ^b	75.3	75.5	-0.2	0.53	[-0.8, 0.4]	73,534
Unadjusted impact estimates	74.8	75.5	-0.6	0.48	[-2.2, 0.9]	89,970
Attributed population	74.8	74.9	-0.1	0.83	[-0.6, 0.5]	236,010
Implied effect for enrolled beneficiaries ^c			-0.2	0.80	[-1.2, 0.9]	
High-risk beneficiaries ^b						
Main analysis (proportion of days covered by any statins)	83.1	83.3	-0.2	0.58	[-0.7, 0.4]	31,182
Trim sample to 20 or fewer providers per organization ^b	83.4	83.6	-0.2	0.59	[-0.7, 0.4]	25,803
Unadjusted impact estimates	83.1	83.5	-0.4	0.52	[-1.4, 0.6]	31,182
Attributed population	83.5	83.4	0.2	0.48	[-0.2, 0.5]	236,010
Implied effect for enrolled beneficiaries ^c			0.3	0.48	[-0.4, 1.0]	
Main analysis (proportion of beneficiaries adherent to statins)	74.7	75.6	-0.9	0.09	[-1.7, 0]	31,182
Trim sample to 20 or fewer providers per organization ^b	75.2	76.0	-0.8	0.14	[-1.7, 0.1]	25,803
Unadjusted impact estimates	74.7	75.8	-1.0	0.27	[-2.6, 0.5]	31,182
Attributed population	75.5	75.4	0.2	0.69	[-0.5, 0.8]	236,010
Implied effect for enrolled beneficiaries ^c			0.3	0.71	[-0.9, 1.5]	

Sources: Mathematica's analysis of Medicare Parts A, B, and D claims and enrollment data.

Note: We estimated impacts using logistic regression for binary outcomes (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 of 30 percent or higher.

^a The number of beneficiaries varied 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 D</u> for details. The number reported in the table includes both intervention and control group beneficiaries.

^b This analysis population trimmed the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries.

[°] 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 enrolled beneficiaries.

CVD = cardiovascular disease.

Table H.3. Estimated impacts on overall statin use among all beneficiaries with Part D coverage, regardless of baseline use of statin: Exploratory analyses

	Regression-adj	Regression-adjusted difference			
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval
High- and medium-risk beneficiaries					
Statin use among all beneficiaries, regardless of baseline use of medication					
Any statin use in the follow-up year	67.6	65.9	1.7	<0.001	[1.1, 2.3]
Any high-intensity statin use in the follow-up year	21.8	20.7	1.1	0.002	[0.5, 1.7]
Proportion of days with statin use in the follow-up year					
Proportion of days with any statin use	52.7	52.6	0.1	0.68	[-0.4, 0.7]
Proportion of days with any high-intensity statin use	15.6	15.4	0.3	0.11	[0, 0.6]
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	[1.3, 2.8]
Any high-intensity statin use in the follow-up year	25.1	23.0	2.0	<0.001	[1.2, 2.9]
Days covered in the follow-up year					
Proportion of days with any statin use	58.0	57.5	0.4	0.34	[-0.3, 1.2]
Proportion of days with any high-intensity statin use	18.2	17.2	1.0	<0.001	[0.5, 1.4]

Source: Mathematica's analysis of Medicare Parts A, B, and D 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). Sample sizes are in <u>Appendix D</u>, <u>Table D.1</u>.

	Regression-adjusted mean Regression-adjusted difference				difference	
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a
High- and medium-risk beneficiaries						
Main analysis (among beneficiaries with SBP >= 130 mm Hg)	29.4	27.0	2.4	<0.001	[1.5, 3.3]	89,569
Initiation (among beneficiaries without antihypertensive use at baseline)	36.7	33.3	3.4	<0.001	[1.9, 5.0]	18,783
Intensification (among beneficiaries with antihypertensive use at baseline)	27.5	25.3	2.2	<0.001	[1.2, 3.1]	70,786
Trim sample to 20 or fewer providers per organization ^b	29.3	27.1	2.1	<0.001	[1.1, 3.1]	73,104
Unadjusted impact estimates	29.4	27.1	2.3	0.03	[0.5, 4.1]	89,569
Using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification ^c	35.7	32.8	2.9	<0.001	[1.6, 4.1]	47,813
High-risk beneficiaries ^b						
Main analysis (beneficiaries with SBP >= 130 mm Hg)	32.9	30.5	2.4	0.002	[1.1, 3.6]	35,005
Initiation (among beneficiaries without antihypertensive use at baseline)	49.5	45.1	4.3	0.01	[1.6, 7.1]	5,085
Intensification (among beneficiaries with antihypertensive use at baseline)	30.1	28.1	2.0	0.01	[0.7, 3.3]	29,920
Trim sample to 20 or fewer providers per organization ^b	32.7	30.6	2.1	0.01	[0.8, 3.4]	22,006
Unadjusted impact estimates	32.9	30.3	2.6	0.04	[0.5, 4.7]	35,005
Using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification ^c	37.9	34.8	3.1	0.002	[1.5, 4.6]	28,991

Table H.4. Estimated impacts on initiation or intensification of antihypertensives: Sensitivity analyses

Sources: Mathematica's analysis of Medicare Parts A, B, and D claims and enrollment data.

Note: We estimated impacts using logistic regression for binary outcomes (CVD medication initiation and intensification). Analyses of high-risk beneficiaries are limited to beneficiaries with baseline CVD risk scores of 30 percent or higher.

^a The number of beneficiaries varied 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 D</u> for details. The number reported in the table includes both intervention and control group beneficiaries.

^b This analysis population trimmed the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries.

^c This analysis limited 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.

CVD = cardiovascular disease; mmHg = millimeters of mercury; SBP = systolic blood pressure.

Table H.5. Estimated impacts on adherence to antihypertensives: Sensitivity analyses

	Regression-adjusted mean			Regression-adjusted difference		
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a
High- and medium-risk beneficiaries						
Main analysis (proportion of days covered by any antihypertensives)	91.1	91.1	<0.05	0.86	[-0.2, 0.3]	116,057
Trim sample to 20 or fewer providers per organization ^b	91.2	91.2	0.1	0.75	[-0.2, 0.3]	94,641
Unadjusted impact estimates	91.1	91.2	<0.05	0.88	[-0.6, 0.5]	116,057
Attributed population	90.7	90.6	0.1	0.62	[-0.2, 0.3]	306,547
Implied effect for enrolled beneficiaries ^c			0.1	0.62	[-0.3, 0.6]	
Main analysis (proportion of beneficiaries adherent to antihypertensives)	87.0	87.1	<0.05	0.85	[-0.5, 0.4]	116,057
Trim sample to 20 or fewer providers per organization ^b	87.2	87.1	-0.2	0.99	[-0.5, 0.5]	94,641
Unadjusted impact estimates	87.0	87.2	-0.1	0.80	[-1.0, 0.8]	116,057
Attributed population	86.4	86.3	<0.05	0.91	[-0.4, 0.4]	306,547
Implied effect for enrolled beneficiaries ^c			<0.05	0.92	[-0.7, 0.8]	
High-risk beneficiaries ^b						
Main analysis (proportion of days covered by any antihypertensives)	92.0	91.9	0.1	0.70	[-0.2, 0.4]	40,538
Trim sample to 20 or fewer providers per organization ^b	92.1	92.0	0.1	0.65	[-0.2, 0.4]	33,510
Unadjusted impact estimates	92.0	92.1	-0.1	0.71	[-0.6, 0.4]	40,538
Attributed population	91.3	91.2	0.1	0.64	[-0.2, 0.4]	306,547
Implied effect for enrolled beneficiaries ^c			0.1	0.63	[-0.4, 0.7]	

Outcome	Regression-adjusted mean		Regression-adjusted difference			
	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	Number of beneficiaries ^a
Main analysis (proportion of beneficiaries adherent to antihypertensives)	88.1	88.0	0.1	0.71	[-0.4, 0.6]	40,538
Trim sample to 20 or fewer providers per organization ^b	88.1	88.2	0.1	0.81	[-0.5, 0.7]	33,510
Unadjusted impact estimates	88.1	88.3	-0.1	0.84	[-1.0, 0.8]	40,538
Attributed population	87.3	87.3	<0.05	0.96	[-0.5, 0.4]	306,547
Implied effect for enrolled beneficiaries ^c			<0.05	0.95	[-0.9, 0.8]	

Sources: Mathematica's analysis of Medicare Parts A, B, and D claims and enrollment data.

Notes: We estimated impacts using logistic regression for binary outcomes (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 of 30 percent or higher.< 0.05 refers to absolute values (that is, < 0.05 or > -0.05).

^a The number of beneficiaries varied 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 D</u> for details. The number reported in the table includes both intervention and control group beneficiaries.

^b This analysis population trimmed the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries.

^c 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 enrolled beneficiaries.

CVD = cardiovascular disease

Table H.6. Estimated impact on overall use of antihypertensives among all beneficiaries with Part D coverage, regardless of baseline use of antihypertensives: Exploratory analyses

	Regression-a	adjusted mean	Regre	fference	
Outcome	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval
High- and medium-risk beneficiaries					
Antihypertensive use among all beneficiaries, regardless of baseline use of medication					
Any antihypertensive use in the follow-up year	84.5	84.1	0.5	0.007	[0.2, 0.8]
Proportion of days with any antihypertensive use in the follow-up year	72.3	72.7	-0.4	0.30	[-1.1, 0.2]
High-risk beneficiaries					
Antihypertensive use among all beneficiaries, regardless of baseline use of medication					
Any antihypertensive use in the follow-up year	91.7	91.1	0.6	0.01	[0.2, 1.0]
Proportion of days with any antihypertensive use in the follow-up year	80.2	80.7	-0.4	0.40	[-1.2, 0.4]

Sources: Mathematica's analysis of Medicare Parts A, B, and D 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). Sample sizes are in <u>Appendix D, Table D.1</u>.

Alternative outcome measure, population, or model specification	Regression-adjusted mean at reassessment		Regression-adjusted difference in aspirin use between intervention and control groups at reassessment		
	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval
Main analysis	65	54	10.7	0.002	[4.9, 16.5]
Trim sample to 20 or fewer providers per organization	65	55	11.1	0.001	[5.4, 16.7]
Unadjusted impact estimates	65	57	8.5	0.03	[2.2, 14.9]

Table H.7. Estimated impacts on aspirin use among high-risk beneficiaries with reassessment data: Exploratory analyses

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

Note: Sample sizes are in <u>Appendix D, Table D.1</u>.

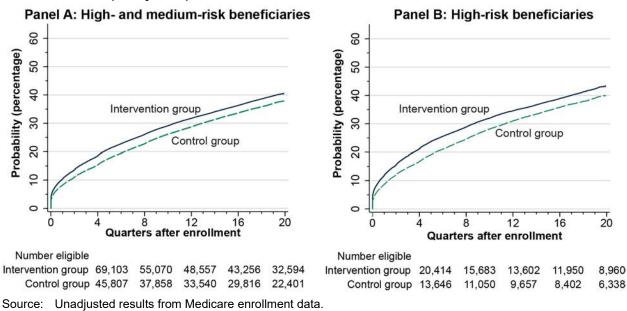
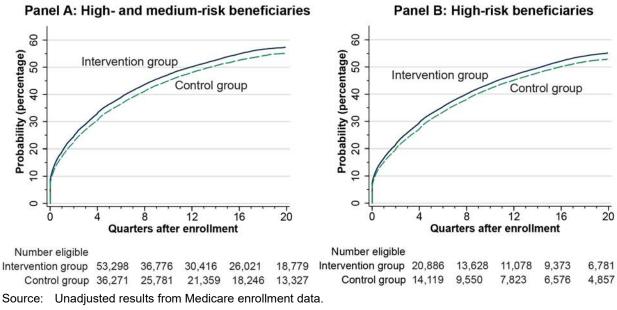


Figure H.1. Cumulative probability of initiating or intensifying statins, by quarter of enrollment and intervention arm (unadjusted)

Note: We defined the cumulative probability 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 a statin within a specified time.

Figure H.2. Cumulative probability of initiating or intensifying antihypertensives, by quarter of enrollment and intervention arm (unadjusted)



Note: We defined the cumulative probability 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 an antihypertensive within a specified time.

2. CVD risk scores

The main findings for the impact of the Million Hearts Model on CVD risk scores (Chapter V) were consistent after trimming the sample to 20 or fewer providers per organization and were present, though attenuated, in unadjusted analyses (Table H.8). The main finding that the model decreased CVD risk scores at reassessment by 1.3 percentage points (p < 0.001) was similar after trimming the sample (with the point estimate decreasing only slightly from 1.3 to 1.2). In unadjusted analyses, the impact estimate attenuated to 0.9 percentage points but remained statistically significant (p = 0.05). We could not assess sensitivity to using the population of attributed beneficiaries because CVD risk score data were available only for the enrolled population. We also conducted the following sensitivity analyses for CVD risk scores:

Impacts on CVD risk scores restricting to reassessment data collected 10 to 14 months after enrollment. The Centers for Medicare & Medicaid Services 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 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 sensitivity analysis, 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 H.8). Although we controlled for time between enrollment and reassessment visits, this sensitivity analysis addressed the limitation that impacts for reassessment visits could differ within the recommended time frame. Estimates from this sensitivity analysis were similar to impact results for the main analysis (-1.3 compared to -1.4 percentage points).

	Regression mean CVD ri reasses (percer	sk score at sment	Regression-adjusted difference in CVD risk scores between intervention and control groups at reassessment (percentage points)			
Alternative outcome measure, population, or model specification	Intervention group	Control group	Difference	<i>p</i> -value	90% confidence interval	
Main analysis	32	33	-1.3	<0.001	[-1.9, -0.8]	
Trim sample to 20 or fewer providers per organization	32	33	-1.2	<0.001	[-1.8, -0.6]	
Restrict to beneficiaries with reassessment data 10 to 14 months after enrollment	32	33	-1.4	<0.001	[-2.0, -0.8]	
Unadjusted impact estimates	32	33	-0.9	0.05	[-1.6, -0.2]	

Table H.8. Estimated impacts on CVD risk scores among high-risk beneficiaries with reassessment data: Sensitivity tests and exploratory analyses

Sources: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.Note:Sample sizes are in Appendix D, Table D.1.

CVD = cardiovascular disease.

3. Service use

The main findings for the impacts of the Million Hearts model on CVD-related and all-cause inpatient admission, CVD-related and all-cause emergency department (ED) visits (including observation stays), and office visits (reported in <u>Chapter VI</u>) were consistent across analyses that trimmed the sample to 20 or fewer providers per organization and used the population of attributed beneficiaries.²⁸ Impacts on rates of all-cause and CVD-related acute care were smaller, and not statistically significant, in unadjusted analyses.

For CVD-related inpatient admissions, the main impact estimates of 0.78 and 2.30 greater admissions per 1,000 beneficiaries per year for high- and medium-risk and high-risk intervention beneficiaries, respectively, were slightly attenuated in trimmed analyses to 0.68 and 2.26 and remained not statistically significant (Table H.9). In analyses of the population of attributed beneficiaries, estimates were slightly larger than the main analysis, with an implied effect for enrolled beneficiaries of 2.44 and 4.37 for the high- and medium-risk and high-risk intervention groups, respectively. The estimate for the high-risk group was statistically significant (p = 0.06), but the point estimates for the attribution population and the main analytic population were well within each other's margin of error. In unadjusted analyses of the main and attributed populations, estimates were smaller (either closer to zero or negative) with unadjusted estimates

²⁸ Our <u>Second Annual Report</u> (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 ED visits.

of -1.08 and 0.06 for high-and medium-risk and high-risk beneficiaries in the main analytic population.

For all-cause inpatient admissions, the main impact estimate of 9.05 greater admissions per 1,000 beneficiaries per year for high- and medium-risk beneficiaries increased slightly to 9.09 among the trimmed population and 12.24 for the population of attributed beneficiaries and remained statistically significant (Table H.9). For the high-risk population, the main impact estimate of 12.27 greater admissions per 1,000 beneficiaries per year decreased slightly to 12.21 for the trimmed population and 11.79 for the attributed population. The estimate for the attributed population was not statistically significant; however, the magnitude of the estimate impact was similar to the main analysis and the standard errors for the attributed population were larger, making it more difficult to detect significant effects compared to the main analysis. Unadjusted analyses of the main and attributed populations yielded smaller, statistically insignificant estimates (either closer to zero or negative) with unadjusted estimates of 3.42 and 6.82 for high-and medium-risk and high-risk beneficiaries in the main analytic population, respectively.

For CVD-related outpatient ED visits, the main impact estimates of 0.12 and 1.16 greater visits per 1,000 beneficiaries per year for high- and medium-risk and high-risk intervention beneficiaries, respectively, were slightly larger in trimmed analyses (0.47 and 1.23, respectively) but remained not statistically significant (Table H.10). As for CVD-related inpatient admissions, estimates were slightly larger among the population of attributed beneficiaries, with an implied effect for enrolled beneficiaries of 2.84 and 4.40 for the high- and medium-risk and high-risk intervention groups, respectively. The estimate for the high-risk group was statistically significant (p = 0.08), but the point estimate for the main analytic population was within the confidence interval of the estimate for the attributed population. In unadjusted analyses of the main and attributed populations, estimates were all negative (that is, showing fewer CVD-related ED visits for intervention beneficiaries) with unadjusted estimates of -1.38 and -0.90 for high- and medium-risk and high-risk beneficiaries in the main analytic population, respectively.

For all-cause ED visits, the main impact estimates of 8.23 and 11.92 greater visits per 1,000 beneficiaries per year for high- and medium-risk and high-risk intervention beneficiaries, respectively, were slightly higher the impact estimates for the trimmed population (8.35 and 14.60), and both sets of estimates were statistically significant only for the high-risk population (Table H.10). Estimates from the population of attributed beneficiaries were somewhat higher for the high- and medium-risk population (15.24 visits per 1,000 beneficiaries per year) and slightly attenuated for the high-risk population (11.89 visits per 1,000 beneficiaries per year), and neither were statistically significant. Unadjusted analyses of the main and attributed populations yielded smaller, statistically insignificant estimates (either closer to zero or negative) with unadjusted estimates of 3.50 and 6.51 for high-and medium-risk and high-risk beneficiaries in the main analytic population, respectively.

For office visits, the main impact estimate of 147 greater visits per 1,000 beneficiaries per year for high- and medium-risk intervention beneficiaries was similar after trimming the sample (173 visits per 1,000 beneficiaries per year) and decreased to 79 greater visits when we used the population of attributed beneficiaries and estimated the implied effect for enrolled beneficiaries. For the high-risk population, the main impact estimate of 170 greater visits per 1,000 beneficiaries per year among intervention beneficiaries increased slightly to 185 after trimming the sample and decreased to 70 greater visits in the population of attributed beneficiaries (after estimating the implied effect for enrolled beneficiaries). Results were not statistically significant in either the main or sensitivity analyses. Unadjusted results using the main and attributed populations were both larger than the corresponding regression-adjusted results but remained not statistically significant.

Adjusting for changes in composition of beneficiaries over time. The demographic composition of beneficiaries included in the models for service use (which are at the beneficiaryquarter level) change across quarters since enrollment as beneficiaries die or otherwise lose observability in Medicare claims. For example, beneficiaries with more chronic conditions at baseline are more likely to die, leaving a population in later quarters who were healthier at baseline. If these changes in beneficiary composition occurred differently for the intervention and control groups, for example due to differences in survival rates, it could lead to bias in our main impact estimates. To account for these potential intervention-control group differences in beneficiary composition in later quarters, we interacted beneficiaries' baseline characteristics with the quarter since enrollment. Beneficiaries' characteristics were key predictors of the study outcomes and included age, gender, CVD risk score, modifiable risk score, diabetes status, lowdensity lipoprotein (LDL) cholesterol, systolic blood pressure, statin use, antihypertensive use, hierarchical condition category (HCC) score, disability status, Social Vulnerability Index for region, receipt of low-income subsidy, and enrollment in the model by a primary care physician (versus a cardiologist or other specialist). For CVD-related and all-cause inpatient admissions, CVD-related and all-cause ED visits, and office visits, results from this sensitivity analysis were identical to the main impact results out to a decimal place.

Table H.9. Estimated impacts on the number of inpatient admissions (number per 1,000 beneficiaries per year): Sensitivity tests and exploratory analyses

	High- a	and medium	ı-risk benefici	aries		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 admis	ssions							
Main analysis	56.0	55.2	0.78	[-1.0, 2.6]	75.6	73.3	2.30	[-0.7, 5.3]
Trim sample to 20 or fewer providers per organization	57.2	56.5	0.68	[-1.2, 2.5]	76.4	74.1	2.26	[-0.9, 5.4]
Adjusting for changes in beneficiary composition over time since enrollment	56.0	55.2	0.78	[-1.0, 2.6]	75.6	73.3	2.30	[-0.7, 5.3]
Unadjusted impact estimates	56.0	57.0	-1.08	[-7.1, 5.0]	75.6	75.6	0.06	[-6.5, 6.6]
Main regression model specification, using the population of attributed beneficiaries	63.9	62.6	1.36	[-0.2, 2.9]	81.2	78.7	2.44*	[0.3, 4.6]
Implied effect for enrolled beneficiaries ^a			2.44	[-0.3, 5.2]			4.37*	[0.6, 8.2]
Unadjusted impact estimates, using the population of attributed beneficiaries	63.9	64.3	-0.41	[-6.9, 6.1]	81.2	81.9	-0.71	[-7.9, 6.5]
Implied effect for enrolled beneficiaries ^a			-0.74	[-12.3, 10.8]			-1.27	[-14.2, 11.6]

	High- a	and medium	-risk benefici	aries		High-risk I	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 all-cause inpatient admissi	ons							
Main analysis	255.3	246.2	9.05**	[3.8, 14.3]	309.2	297.0	12.27**	[3.5, 21.1]
Trim sample to 20 or fewer providers per organization	256.8	247.8	9.09**	[3.7, 14.5]	309.2	297.0	12.21**	[3.1, 21.3]
Adjusting for changes in beneficiary composition over time since enrollment	255.3	246.2	9.05**	[3.8, 14.3]	309.2	297.0	12.27**	[3.5, 21.1]
Unadjusted impact estimates	255.3	251.9	3.42	[-12.2, 19.1]	309.2	302.4	6.82	[-10.4, 24.1]
Main regression model specification, using the population of attributed beneficiaries	284.6	277.8	6.83**	[1.7, 12.0]	333.0	326.4	6.59	[-0.6, 13.8]
Implied effect for enrolled beneficiaries ^a			12.24**	[3.1, 21.4]			11.79	[-1.0, 24.6]
Unadjusted impact estimates, using the population of attributed beneficiaries	284.6	281.8	2.78	[-13.6, 19.2]	333.0	333.2	-0.14	[-18.5, 18.2]
Implied effect for enrolled beneficiaries ^a			4.98	[-24.4, 34.3]			-0.25	[-33.0, 32.5]

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 <u>Appendix D, Table D.1</u>.

^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 enrolled beneficiaries.

*/** Significantly different from zero at the 0.1/0.05 levels, two-tailed test.

 Table H.10. Estimated impacts on the number of outpatient ED visits and observation stays (number per 1,000 beneficiaries per year):

 Sensitivity tests and exploratory analyses

	High-	and medium-ris	sk beneficiaı	ies		High-risk be	neficiaries	
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	31.6	31.5	0.12	[-1.7, 1.9]	38.4	37.2	1.16	[-1.2, 3.5]
Trim sample to 20 or fewer providers per organization	33.7	33.2	0.47	[-1.4, 2.3]	40.4	39.1	1.23	[-1.3, 3.7]
Adjusting for changes in beneficiary composition over time since enrollment	31.6	31.5	0.12	[-1.7, 1.9]	38.4	37.2	1.16	[-1.2, 3.5]
Unadjusted impact estimates	31.6	33.0	-1.38	[-5.4, 2.6]	38.4	39.3	-0.90	[-5.7, 3.9]
Main regression model specification, using the population of attributed beneficiaries	36.0	34.4	1.59	[-0.3, 3.5]	41.1	38.7	2.46*	[0.1, 4.8]
Implied effect for enrolled beneficiaries ^a			2.84	[-0.5, 6.2]			4.40*	[0.2, 8.6]
Unadjusted impact estimates, using the population of attributed beneficiaries	36.0	36.7	-0.74	[-5.2, 3.7]	41.1	41.7	-0.62	[-5.6, 4.4]
Implied effect for enrolled beneficiaries ^a			-1.32	[-9.3, 6.6]			-1.11	[-10.0, 7.8]
Number of all-cause outpatient ED visits a	and observation	stays						
Main analysis	386.3	378.1	8.23	[-1.1, 17.6]	422.7	410.8	11.92*	[0.2, 23.6]
Trim sample to 20 or fewer providers per organization	393.1	384.7	8.35	[-1.4, 18.1]	430.3	415.7	14.60**	[2.5, 26.8]
Adjusting for changes in beneficiary composition over time since enrollment	386.3	378.1	8.23	[-1.1, 17.6]	422.7	410.8	11.92*	[0.2, 23.6]
Unadjusted impact estimates	386.3	382.8	3.50	[-24.6, 31.6]	422.7	416.2	6.51	[-24.8, 37.8]

	High-	and medium-ris	ies	High-risk beneficiaries				
Alternative outcome measure, population, or model specification	Intervention group mean	Control group mean	Difference		Intervention group mean	Control group mean	Difference	90% confidence interval
Main regression model specification, using the population of attributed beneficiaries	423.2	414.7	8.50	[-0.9, 17.9]	454.6	447.9	6.64	[-4.0, 17.3]
Implied effect for enrolled beneficiaries ^a			15.24	[-1.5, 32.0]			11.89	[-7.1, 30.9]
Unadjusted impact estimates, using the population of attributed beneficiaries	423.2	430.5	-7.35	[-36.2, 21.5]	454.6	464.6	-10.03	[-40.8, 20.8]
Implied effect for enrolled beneficiaries ^a			-13.18	[-64.8, 38.4]			-17.96	[-73.0, 37.1]

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 <u>Appendix D, Table D.1</u>.

^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 enrolled beneficiaries.

*/** Significantly different from zero at the 0.1/0.05 levels, two-tailed test.

CVD = cardiovascular disease; ED = emergency department.

Table H.11. Estimated impacts on the number of office visits (number per 1,000 beneficiaries per year): Sensitivity tests and exploratory analyses

	High-	and medium-ri	sk beneficiaı	ries		High-risk be	neficiaries	
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 office visits								
Main analysis	2,752	2,605	147	[-44, 339]	3,082	2,912	170	[-50, 391]
Trim sample to 20 or fewer providers per organization	2,771	2,598	173	[-29, 376]	3,066	2,881	185	[-45, 414]
Adjusting for changes in beneficiary composition over time since enrollment	2,752	2,605	147	[-44, 339]	3,082	2,912	170	[-50, 391]
Unadjusted impact estimates	2,752	2,610	143	[-254, 539]	3,082	2,867	215	[-276, 706]
Main regression model specification, using the population of attributed beneficiaries	2,443	2,399	44	[-116, 204]	2,775	2,736	39	[-136, 214]
Implied effect for enrolled beneficiaries ^a			79	[-208, 365]			70	[-242, 383]
Unadjusted impact estimates, using the population of attributed beneficiaries	2,443	2,482	-40	[-362, 283]	2,775	2,733	43	[-425, 510]
Implied effect for enrolled beneficiaries ^a			-71	[-648, 506]			76	[-758, 911]

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 <u>Appendix D, Table D.1.</u>

^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 enrolled beneficiaries.

*/** Significantly different from zero at the 0.1/0.05 levels, two-tailed test.

4. CVD events

Chapter VII reported that the Million Hearts Model reduced the incidence of first-time CVD events-defined as a first-time heart attacks, stroke, or transient ischemic attack (TIA)-by 3.3 percent for high- and medium-risk beneficiaries using a claims-based definition, with a regression-adjusted hazard ratio of 0.97 (p = 0.09). Figure H.3 shows adjusted survival curves illustrating the cumulative incidence of CVD events in the intervention and control groups over time. These results were generally consistent across a series of sensitivity analyses, including after (1) trimming the sample to 20 providers or fewer per organization, (2) using the population of attributed beneficiaries, (3) controlling for changes in beneficiary composition over time since enrollment, and (4) some additional analyses specific to this outcome (Table H.12). Not all sensitivity analyses found statistically significant impacts on CVD events for high- and mediumrisk beneficiaries. However, the regression-adjusted estimated reductions in events were all similar (ranging from hazard ratios of 0.96 when using a narrower definition of CVD events to an implied hazard ratio of 0.98 for enrolled beneficiaries when using beneficiaries we attributed through claims data to the intervention and control providers). For the high-risk population, our main approach estimated the hazard ratio to be 0.99 (p = 0.63) and all sensitivity analysis results were also fairly close to 1.00 (ranging from 0.98 to 0.99), with none statistically different from 1.00, indicating no detectable impact on first-time CVD events for the high-risk group. Chapter VII also reported that the model reduced the risk of first-time CVD events using an expanded measure of CVD events, including events captured in National Death Index (NDI) data, by 4.2 percent for high- and medium-risk beneficiaries, with a hazard ratio of 0.96 (p = 0.02). Figure H.4 shows adjusted survival curves illustrating the cumulative incidence of the expanded measure of CVD events in the intervention and control groups over time. These results remained similar after trimming the sample to 20 or fewer providers per organization (Table H.13). Estimated impacts for the population of attributed high- and medium-risk beneficiaries were not statistically significant, but the implied hazard ratio of 0.98 for enrolled beneficiaries calculated from the attribution population was similar in magnitude to the main estimate, given the margin of error for these estimates. For the high-risk population, our main approach estimated the hazard ratio to be 0.98 (p = 0.45) and results were similar for the sensitivity checks (0.97 for the trimmed population and 0.98 implied effect for enrolled beneficiaries based on the attribution population).

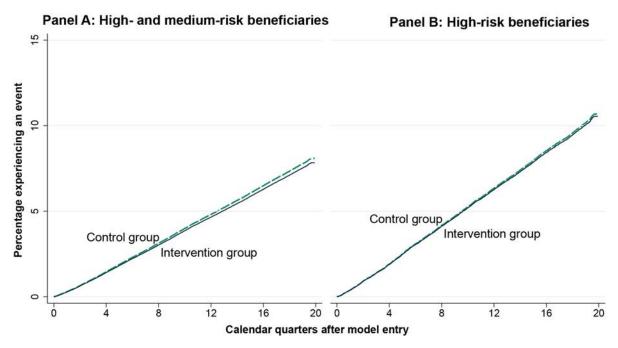
Unadjusted analyses found an 8 percent reduction in the incidence of first-time CVD events for high- and medium-risk beneficiaries in the intervention group using both the claims-based and expanded definitions (Tables H.12 and H.13), compared to the 3 to 4 percent reduction in adjusted analyses. The difference in these estimates suggests regression adjustment materially affected our estimate of the model impacts, and suggests the treatment group would have experienced lower rates of CVD events than the control group even if the model had no effect (given differences in baseline covariates). The 3 and 4 percent reductions in first-time CVD events reported in <u>Chapter VII</u> suggests intervention–control group differences in the likelihood of having a CVD event were smaller but still present after adjusting for baseline differences between the two groups. Unadjusted analyses for the high-risk group found a 6 percent reduction

in the incidence of first-time CVD events for the claims-based and expanded definitions; however, after regression adjustment we found no detectable difference between the intervention and control groups.

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 <u>Appendix F</u> for detailed definitions of the outcome measures. The impact estimates (hazard ratios) for these narrower and narrowest definitions of the CVD events were similar to the estimates with the primary definition (0.96 versus 0.97). That is, all definitions used indicate the model modestly reduced the incidence of first-time heart attacks and strokes for high- and medium-risk beneficiaries.

Binary measure of CVD events. 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 four-year period. Similar to the main findings, these binary models found a 4 percent reduction in incidence of first-time CVD events in Medicare claims for the high- and medium-risk beneficiaries over four years (Table H.14) (compared to 3 percent for the Cox proportional hazards model). For the expanded measure of CVD events, we found a 5 percent reduction in incidence of CVD events for the high- and medium-risk beneficiaries over four years using binary models (Table H.15)—similar to the 4 percent reduction estimated by the Cox proportional hazard model. Reductions for the high-risk group were larger in the binary models for the claims-based measure (4 percent over four years versus 1 percent for the Cox proportional hazards models) but were not statistically significant with either type of model. For the expanded definition of CVD events, estimated reductions in events for the high-risk group from the binary models were both larger (6 percent over four years versus 2 percent for the Cox proportional hazards models and statistically significant [Table. H.15]). Differences between the binary and Cox proportional hazards model that could explain these discrepant findings include (1) the binary models include a subset of the full population enrolled earlier in the model, (2) the binary models include less follow-up time, and (3) the models use different modeling assumptions that can yield somewhat disparate results.

Figure H.3. A 3.3 percent lower risk of first-time CVD events among high- and medium-risk intervention beneficiaries than in the control group: Cumulative probability of having a first-time heart attack, stroke, or TIA over five years after enrollment, as measured in Medicare claims, by intervention arm (regression-adjusted)



Source: Regression-adjusted results from Medicare claims.

Note: The cumulative probability (vertical horizontal axis) is defined as 1 minus the average Cox proportionalhazards model estimate of the survival function. The survival function gives the probability that a beneficiary did not experience an event within a given length of time after enrollment (the horizontal axis).

CVD = cardiovascular disease; TIA = transient ischemic attack.

Table H.12. Estimated ratio of the hazard of first-time heart attacks, strokes, or TIAs in Medicare claims between intervention and control beneficiaries within 5 years of enrollment: Sensitivity tests and exploratory analyses

	High- and medium-risk beneficiaries			High-risk beneficiaries			
Alternative outcome measure, population, or model specification	Estimated hazard ratio	<i>p</i> -value	90% CI	Estimated hazard ratio	<i>p</i> -value	90% CI	
Analyses with enrolled beneficiaries							
First-time heart attacks, strokes, or TIAs (main analysis) ^a	0.97	0.09	[0.93, 1.00]	0.99	0.63	[0.94, 1.03]	
First-time heart attacks or strokes using narrower definition ^b	0.96	0.07	[0.93, 1.00]	0.99	0.72	[0.94, 1.04]	
First-time heart attacks or strokes using narrowest definition ^c	0.96	0.12	[0.93, 1.00]	0.99	0.73	[0.94, 1.04]	
Trim sample to 20 or fewer providers per organization	0.97	0.10	[0.93, 1.00]	0.98	0.56	[0.93, 1.03]	
Adjusting for beneficiary composition over time since enrollment	0.97	0.09	[0.93, 1.00]	0.99	0.62	[0.94, 1.03]	
Unadjusted impact estimates	0.92	0.02	[0.87, 0.98]	0.94	0.10	[0.88, 1.00]	
Analyses with attributed beneficiaries							
First-time heart attacks, strokes, or TIAs ^a	0.99	0.53	[0.96, 1.02]	0.99	0.70	[0.96, 1.03]	
Implied effect for enrolled beneficiaries ^d	0.98		[0.93, 1.03]	0.99		[0.92, 1.05]	
Unadjusted impact estimates	0.95	0.17	[0.90, 1.01]	0.95	0.09	[0.89, 1.00]	
Implied effect for enrolled beneficiaries ^d	0.92		[0.83, 1.02]	0.90		[0.81, 1.00]	

Source: Regression-based impact estimates using Medicare claims.

Note: Sample sizes are in <u>Appendix D, Table D.1.</u>

^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 AMIs described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

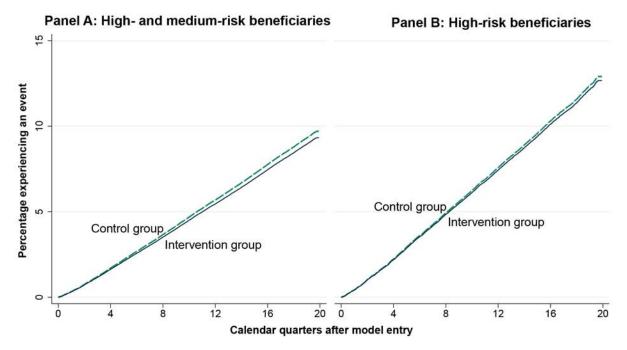
^b Heart attacks and strokes only (excludes TIAs or stroke syndromes), using primary diagnoses on outpatient ED claims or primary and secondary diagnoses on inpatient claims. For heart attacks, we include only the first type of AMIs described in the Fourth Universal Definition of Myocardial Infarction (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 AMIs 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 enrolled beneficiaries, then expressing this scaled regression coefficient as a hazard ratio.

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

Figure H.4. A 4.2 percent lower risk of first-time CVD events (using an expanded measure with NDI data) among high- and medium-risk intervention group beneficiaries than in the control group: Cumulative probability of having a first-time heart attack, stroke, or TIA, or dying from CHD or cerebrovascular disease over five years after enrollment, by intervention arm (regression-adjusted)



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

Note: The cumulative probability is defined as 1 minus the Cox proportional-hazards model estimate of the survival function. The survival function gives the probability that a beneficiary did not experience an event within a given length of time after enrollment (the horizontal axis).

CHD = coronary heart disease; CVD = cardiovascular disease; NDI = National Death Index; TIA = transient ischemic attack.

Table H.13. Estimated ratio of the hazard of first-time heart attacks, strokes, or TIAs or deaths from coronary heart disease or cerebrovascular disease between intervention and control beneficiaries (expanded measure with NDI data) within 5 years of enrollment: Sensitivity analyses

	High- and m	nedium-risk b	eneficiaries	High-risk beneficiaries		
Alternative population or model specification	Estimated hazard ratio	<i>p</i> -value	90% CI	Estimated hazard ratio	<i>p</i> -value	90% CI
Analyses with enrolled beneficiaries						
Main analysis ^a	0.96	0.02	[0.93, 0.99]	0.98	0.45	[0.94, 1.02]
Trim sample to 20 or fewer providers per organization	0.95	0.02	[0.92, 0.98]	0.97	0.28	[0.92, 1.02]
Unadjusted impact estimates	0.92	0.02	[0.87, 0.98]	0.94	0.11	[0.88, 1.00]
Analyses with attributed beneficiaries						
Main analysis ^a	0.99	0.44	[0.96, 1.02]	0.99	0.58	[0.96, 1.02]
Implied effect for enrolled beneficiaries ^b	0.98		[0.92, 1.03]	0.98		[0.92, 1.04]
Unadjusted impact estimates	0.96	0.23	[0.91, 1.02]	0.95	0.14	[0.90, 1.01]
Implied effect for enrolled beneficiaries ^b	0.92		[0.83, 1.03]	0.91		[0.83, 1.01]

Source: Regression-based impact estimates using Medicare claims and linked NDI data.

Note: Sample sizes are in Appendix D, Table D.1.

^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 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 enrolled beneficiaries, then expressing this scaled regression coefficient as a hazard ratio.

CI = confidence interval; ED = emergency department; NDI = National Death Index; TIA = transient ischemic attack.

	High	n- and medium	-risk beneficia	ries		High-risk be	eneficiaries	
Outcomeª	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 Th	As						
Within one year of enrollment	1.4	1.4	<0.05 (2%)	[-0.1, 0.1]	1.9	1.8	0.1 (6%)	[-0.1, 0.3]
Within two years of enrollment	2.8	2.8	<0.05 (0%)	[-0.1, 0.1]	3.8	3.8	<0.05 (-1%)	[-0.3, 0.2]
Within three years of enrollment	4.1	4.2	-0.1 (-2%)	[-0.3, 0.1]	5.5	5.6	-0.1 (-2%)	[-0.4, 0.2]
Within four years of enrollment	5.3	5.6	-0.2* (-4%)	[-0.4, 0]	7.0	7.2	-0.3 (-4%)	[-0.7, 0.1]
Analyses with enrolled beneficiaries	and sample trimm	ned to 20 or fe	wer providers	per organizat	ion			
Percentage with first-time heart attac	ks, strokes, or Th	As						
Within one year of enrollment	1.4	1.4	<0.05 (1%)	[-0.1, 0.1]	1.9	1.8	<0.05 (2%)	[-0.1, 0.2]
Within two years of enrollment	2.9	2.9	<0.05 (-1%)	[-0.2, 0.1]	3.9	3.9	<0.05 (-1%)	[-0.3, 0.3]
Within three years of enrollment	4.2	4.3	-0.1 (-2%)	[-0.3, 0.1]	5.6	5.7	-0.2 (-3%)	[-0.5, 0.2]
Within four years of enrollment	5.5	5.7	-0.2 (-4%)	[-0.4, 0]	7.0	7.4	-0.3 (-4%)	[-0.7, 0.1]
Analyses with attributed beneficiaries	S							
Percentage with first-time heart attac	ks, strokes, or Th	4						
Within one year of enrollment	1.7	1.7	<0.05 (-1%)	[-0.1, 0.1]	2.1	2.2	<0.05 (-2%)	[-0.2, 0.1]
Implied effect for enrolled beneficiaries ^b			<0.05	[-0.2, 0.1]			-0.1	[-0.3, 0.1]
Within two years of enrollment	3.3	3.3	<0.05 (0%)	[-0.1, 0.1]	4.0	4.0	<0.05 (1%)	[-0.1, 0.2]
Implied effect for enrolled beneficiaries ^b			<0.05	[-0.2, 0.2]			0.1	[-0.2, 0.4]
Within three years of enrollment	4.6	4.7	-0.1 (-1%)	[-0.2, 0.1]	5.7	5.8	<0.05 (-1%)	[-0.3, 0.2]
Implied effect for enrolled beneficiaries ^b			-0.1	[-0.4, 0.2]			-0.1	[-0.5, 0.3]

	High	n- and medium	-risk beneficia	iries	High-risk beneficiaries				
Outcomeª	Intervention group mean	Control group mean	Difference (%)	90% confidence interval	Intervention group mean	Control group mean	Difference (%)	90% confidence interval	
Within four years of enrollment	5.9	6.0	-0.1 (-2%)	[-0.3, 0.1]	7.1	7.4	-0.3 (-3%)	[-0.5, 0]	
Implied effect for enrolled beneficiaries ^b			-0.2	[-0.6, 0.1]			-0.4	[-0.9 , 0]	

Source: Regression-adjusted results using Medicare claims.

Notes: We preformed regression adjustment using logistic regression models. Sample sizes are in <u>Appendix D, Table D.1</u>.

< 0.05 refers to absolute values (that is, < 0.05 or > -0.05).

^a Analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled through December 31, 2021.

^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 enrolled beneficiaries.

*/** Significantly different from zero at the 0.1/0.05 levels, two-tailed test.

CVD = cardiovascular disease; TIA = transient ischemic attack.

Table H.15. Estimated impacts on binary measures of first-time heart attacks, strokes, or deaths from CHD or deaths due to CHD or cerebrovascular disease (expanded measure with NDI data; regression-adjusted)

Percentage with first-time heart attack, stroke, or TIA or death due	Regression mea		Regression-adjusted difference			
to CHD or cerebrovascular disease (composite measure) ^a	Intervention group	Control group	Difference (%)	<i>p</i> -value	90% CI	
High- and medium-risk beneficiarie	S					
Within one year of enrollment	1.6	1.6	-0.02 (-1%)	0.80	[-0.1, 0.1]	
Within two years of enrollment	3.3	3.4	-0.05 (-2%)	0.57	[-0.2, 0.1]	
Within three years of enrollment	5.0	5.1	-0.13 (-3%)	0.23	[-0.3, 0.0]	
Within four years of enrollment	6.5	6.9	-0.37 (-5%)	0.01	[-0.6, -0.1]	
High-risk beneficiaries						
Within one year of enrollment	2.2	2.1	0.07 (3%)	0.57	[-0.1, 0.3]	
Within two years of enrollment	4.6	4.6	-0.03 (-1%)	0.87	[-0.3, 0.2]	
Within three years of enrollment	6.7	6.8	-0.15 (-2%)	0.44	[-0.5, 0.2]	
Within four years of enrollment	8.6	9.1	-0.51 (-6)	0.04	[-0.9, -0.1]	

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

Note: We limited analyses to beneficiaries enrolled early enough to observe for at least four years by December 2021 (the date we pulled claims). See <u>Appendix G</u> for more detail about the regression models. Sample sizes are in <u>Appendix D</u>, <u>Table D.1</u>.

^a Beneficiaries with a first-time heart attack, stroke, or TIA based on Medicare claims or who died due to CHD or cerebrovascular disease based on NDI data

CHD = coronary heart disease; NDI = National Death Index; TIA = transient ischemic attack.

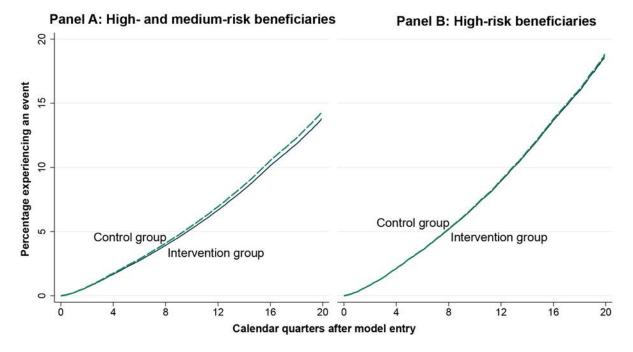
5. Impacts on mortality

Chapter VII reported a 4.3 percent reduction in all-cause mortality among high- and medium-risk beneficiaries, with hazard ratios of 0.96 (p = 0.01) for high- and medium-risk beneficiaries and 0.99 (p = 0.72) for high-risk beneficiaries. Figure H.5 shows adjusted survival curves illustrating the cumulative death rate in the intervention and control groups over time. These main findings remained the same after trimming the sample to 20 or fewer providers per organization and after controlling for changes in beneficiary composition over time since enrollment (Table H.16). Estimated impacts for the population of attributed high- and medium-risk beneficiaries were not statistically significant, but were similar in magnitude to the main estimates, with an implied hazard ratio of 0.97 for enrolled beneficiaries calculated from the attribution population compared to the main estimate of 0.96. For high-risk beneficiaries, the implied effect for enrolled beneficiaries calculated from the attribution population was 0.96, compared to 0.99 for enrolled beneficiaries, which falls within the margin of error for estimates of mortality. Unadjusted analyses found somewhat greater reductions in all-cause mortality, of 0.94 for high- and medium-risk beneficiaries and 0.97 for high-risk beneficiaries (although neither were statistically significant, reflecting the lower statistical power of the unadjusted analyses relative to adjusted analyses). Differences in our unadjusted and adjusted results indicates the presence of imbalances in covariates between the intervention and control groups and regression adjustment was an important aspect of our analytic approach. Using a binary measure of mortality and logit regression models (Table H.17), we estimated all-cause mortality was 4.2 percent lower for highand medium-risk intervention beneficiaries than control beneficiaries over four years and found no measurable effect on mortality for the high-risk group alone-qualitatively similar findings to those that used our main analysis approach.

Our main estimates indicate the model reduced CHD-specific deaths by 0.18 percentage points (p = 0.01, a 12 percent impact) for high- and medium-risk beneficiaries and by 0.32 percentage points (p = 0.03, a 14 percent impact) for high-risk beneficiaries. These findings were generally consistent with results after trimming the sample to 20 providers or fewer per organization and unadjusted analyses (Table H.19), and our impact estimates remained statistically significant for both high- and medium-risk beneficiaries and high-risk beneficiaries. For the population of attributed beneficiaries, implied effects for the enrolled population were 0.13 percentage points for high- and medium-risk beneficiaries and 0.24 percentage points for high-risk beneficiaries— similar to our main results within the margin of error for estimates of impacts by cause of death.

Cause of death set to unknown for mismatched death dates in Medicare enrollment and NDI. Less than 3 percent of high- and medium-risk beneficiaries had mismatched death dates in Medicare enrollment and NDI data. For these beneficiaries, we excluded the underlying cause of death codes obtained from NDI and set the cause of death to unknown in this sensitivity analysis. After setting the cause of death to unknown for beneficiaries with mismatched death dates in Medicare enrollment and NDI data, the estimates of model impacts were substantively unchanged (compared to those produced using the main outcome definition in our main analysis).

Figure H.5. A 4.3 percent lower risk of dying among high- and medium-risk intervention group beneficiaries than in the control group: Cumulative probability of dying for any reason over five years after enrollment, by intervention arm (regression-adjusted)



Source: Regression-adjusted results from Medicare enrollment data.

Note: The cumulative probability is defined as 1 minus the Cox proportional-hazards model estimate of the survival function. The survival function gives the probability that a beneficiary did not die within a given length of time after enrollment (the horizontal axis).

 Table H.16. Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries within 5 years of enrollment:

 Sensitivity tests and exploratory analyses

Alternative outcome measure,	High-and r	nedium-risk be	eneficiaries	High-risk beneficiaries			
population, or model specification	Estimated hazard ratio	<i>p-</i> value	90% confidence interval	Estimated hazard ratio	<i>p-</i> value	90% confidence interval	
Analyses with enrolled beneficia	ries						
Main analysis	0.96	0.01	[0.93, 0.98]	0.99	0.72	[0.95, 1.03]	
Trim sample to 20 or fewer providers per organization	0.96	0.03	[0.93, 0.99]	0.99	0.84	[0.95, 1.04]	
Adjusting for beneficiary composition over time since enrollment	0.96	0.01	[0.93, 0.98]	0.99	0.72	[0.95, 1.03]	
Unadjusted impact estimates	0.94	0.11	[0.88, 1.00]	0.97	0.38	[0.92, 1.03]	
Analyses with attributed benefici	aries						
Main regression model specification	0.98	0.30	[0.96, 1.01]	0.98	0.19	[0.95, 1.01]	
Implied effect for enrolled beneficiaries ^a	0.97		[0.93, 1.02]	0.96		[0.91, 1.01]	
Unadjusted impact estimates	0.97	0.33	[0.91, 1.02]	0.96	0.20	[0.91, 1.01]	
Implied effect for enrolled beneficiaries ^a	0.94		[0.84, 1.05]	0.93		[0.84, 1.02]	

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

Note: Sample sizes are in Appendix D, Table D.1.

^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 enrolled beneficiaries, then expressing this scaled regression coefficient as a hazard ratio.

Table H.17. Estimated impacts on binary measures of all-cause mortality (regression-adjusted)

	High- and medium-risk beneficiaries					High-risk b	eneficiaries	
Outcomeª	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 who died								
Within one year of enrollment	1.7	1.8	-0.2** (-8%)	[-0.3, 0]	2.1	2.2	-0.1 (-4%)	[-0.3, 0.1]
Within two years of enrollment	3.9	4.2	-0.2** (-5%)	[-0.4, -0.1]	5.2	5.2	<0.05 (0%)	[-0.3, 0.3]
Within three years of enrollment	6.7	6.9	-0.2* (-4%)	[-0.5, 0]	8.9	8.9	0.1 (1%)	[-0.3, 0.5]
Within four years of enrollment	10.1	10.6	-0.5** (-4%)	[-0.8, -0.2]	13.5	13.4	0.1 (0%)	[-0.5, 0.6]
Analyses with enrolled beneficiaries an	nd sample trimn	ned to 20 or fe	wer providers	per organizat	tion			
Percentage who died								
Within one year of enrollment	1.7	1.9	-0.2** (-10%)	[-0.3, -0.1]	2.1	2.2	-0.1 (-6%)	[-0.3, 0.1]
Within two years of enrollment	4.0	4.2	-0.2** (-5%)	[-0.4, -0.1]	5.2	5.2	<0.05 (-1%)	[-0.3, 0.3]
Within three years of enrollment	6.9	7.0	-0.2 (-3%)	[-0.4, 0]	9.1	9.0	0.1 (1%)	[-0.3, 0.5]
Within four years of enrollment	10.3	10.7	-0.4** (-4%)	[-0.7, -0.1]	13.7	13.6	0.1 (1%)	[-0.4, 0.7]
Analyses with attributed beneficiaries								
Percentage who died								
Within one year of enrollment	2.3	2.4	<0.05 (-2%)	[-0.1, 0]	2.9	3.0	-0.1 (-3%)	[-0.2, 0]
Implied effect for enrolled beneficiaries ^b			-0.1	[-0.2, 0.1]			-0.2	[-0.4, 0.1]
Within two years of enrollment	5.0	5.1	-0.1 (-1%)	[-0.2, 0.1]	6.4	6.5	-0.2 (-3%)	[-0.4, 0]
Implied effect for enrolled beneficiaries ^b			-0.1	[-0.4, 0.1]			-0.3	[-0.7, 0.1]
Within three years of enrollment	8.1	8.3	-0.1 (-1%)	[-0.3, 0.1]	10.4	10.5	-0.2 (-2%)	[-0.5, 0.1]
Implied effect for enrolled beneficiaries ^b			-0.2	[-0.6, 0.2]			-0.4	[-0.9, 0.2]

High- and medium-risk beneficiaries						High-risk beneficiaries				
Outcomeª	Intervention group mean	Control group mean	Difference	90% confidence interval	Intervention group mean	Control group mean	Difference	90% confidence interval		
Within four years of enrollment	11.8	12.0	-0.2 (-2%)	[-0.5, 0.1]	15.1	15.4	-0.3 (-2%)	[-0.7, 0]		
Implied effect for enrolled beneficiaries ^b			-0.3	[-0.8, 0.1]			-0.6	[-1.2, 0.1]		

Source: Regression-adjusted results from Medicare enrollment data.

Notes: We performed regression adjustment using logistic regression models. Sample sizes are in Appendix D, Table D.1.

< 0.05 refers to absolute values that is, < 0.05 or > -0.05).

^a Analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled through December 31, 2021.

^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 enrolled beneficiaries.

*/** Significantly different from zero at the 0.1/0.05 levels, two-tailed test.

Table H.18. Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries within 5 years of enrollment: Sensitivity tests and exploratory analyses

Alternative outcome measure,	High-and r	nedium-risk be	eneficiaries	High-risk beneficiaries			
population, or model specification	Estimated hazard ratio	<i>p</i> -value	90% confidence interval	Estimated hazard ratio	<i>p</i> -value	90% confidence interval	
Analyses with enrolled beneficia	ries						
Main analysis	0.96	0.01	[0.93, 0.98]	0.99	0.72	[0.95, 1.03]	
Trim sample to 20 or fewer providers per organization	0.96	0.03	[0.93, 0.99]	0.99	0.84	[0.95, 1.04]	
Adjusting for beneficiary composition over time	0.96	0.01	[0.93, 0.98]	0.99	0.72	[0.95, 1.03]	
Unadjusted impact estimates	0.94	0.11	[0.88, 1.00]	0.97	0.38	[0.92, 1.03]	
Analyses with attributed benefic	aries						
Main regression model specification	0.98	0.30	[0.96, 1.01]	0.98	0.19	[0.95, 1.01]	
Implied effect for enrolled beneficiaries ^a	0.97		[0.93, 1.02]	0.96		[0.91, 1.01]	
Unadjusted impact estimates	0.97	0.33	[0.91, 1.02]	0.96	0.20	[0.91, 1.01]	
Implied effect for enrolled beneficiaries ^a	0.94		[0.84, 1.05]	0.93		[0.84, 1.02]	

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

Note: Sample sizes are in <u>Appendix D, Table D.1</u>.

^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 enrolled beneficiaries, then expressing this scaled regression coefficient as a hazard ratio.

A 14	Regression mea		Regression-adjusted difference			
Alternative outcome measure, population, or model specification	Intervention group	Control group	Difference	<i>p</i> -value	90% CI	
High- and medium-risk beneficiarie	es					
Main analysis	1.3	1.5	-0.18 (-12%)	0.01	[-0.29, -0.06]	
Trim sample to 20 or fewer providers per organization	1.3	1.5	-0.20 (-13%)	0.007	[-0.32, -0.08]	
Unadjusted impact estimates	1.3	1.5	-0.18 (-12%)	0.06	[-0.34, -0.02]	
Cause of death set to unknown for mismatched death dates in Medicare enrollment and NDI	1.3	1.5	-0.18 (-12%)	0.01	[-0.30, -0.06]	
Main regression model specification, using the population of attributed beneficiaries	1.6	1.7	-0.08 (-4%)	0.21	[-0.17, 0.02]	
Implied effect for enrolled beneficiaries ^a			-0.13		[-0.30, 0.04]	
Unadjusted impact estimates, using the population of attributed beneficiaries	1.6	1.7	-0.06 (-4%)	0.53	[-0.23, 0.10]	
Implied effect for enrolled beneficiaries ^a			-0.11 (.%)	0.53	[-0.39, 0.17]	
High-risk beneficiaries						
Main analysis	1.9	2.2	-0.32 (-14%)	0.03	[-0.57, -0.07]	
Trim sample to 20 or fewer providers per organization	1.9	2.2	-0.39 (-17%)	0.01	[-0.65, -0.13]	
Unadjusted impact estimates	1.9	2.2	-0.27 (-12%)	0.09	[-0.53, -0.01]	
Cause of death set to unknown for mismatched death dates in Medicare enrollment and NDI	1.9	2.2	-0.32 (-14%)	0.04	[-0.57, -0.07]	
Main regression model specification, using the population of attributed beneficiaries	2.2	2.4	-0.14 (-6%)	0.17	[-0.30, 0.03]	
Implied effect for enrolled beneficiaries ^a			-0.24		[-0.52, 0.05]	
Unadjusted impact estimates, using the population of attributed beneficiaries	2.2	2.3	-0.10 (-5%)	0.41	[-0.31, 0.10]	
Implied effect for enrolled beneficiaries ^a			-0.18		[-0.54, 0.18]	

Table H.19. Estimated impacts on CHD mortality within four years after enrollment: Sensitivity tests

Sources: Regression-adjusted results from Medicare enrollment data and linked NDI data.

Note: We performed regression adjustment using multinomial logistic regression models. Analyses were limited to beneficiaries enrolled early enough to be observed for at least four years by December 2021 (the date we pulled claims) and include beneficiaries with a baseline cardiovascular disease risk score of at least 15 percent. Sample sizes are in <u>Appendix D, Table D.1</u>. The sensitivity analysis focused on the deaths due to CHD or cerebrovascular disease.

^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 enrolled beneficiaries, then expressing this scaled regression coefficient as a hazard ratio. CHD = coronary heart disease; NDI = National Death Index.

6. Medicare Parts A and B spending

Across a series of sensitivity and exploratory analyses, we found no detectable impacts of the Million Hearts Model on reducing Medicare spending for first-time heart attacks and strokes (henceforth, CVD event spending), which is consistent with the result from our main analysis in Chapter VII. We used two-part regression models to estimate the impact on CVD event spending, estimating (1) the probability of a CVD event and (2) CVD event spending conditional on having a CVD event. The estimated intervention-control difference in CVD event spending within four years of enrollment reported in Chapter VII was 5 percent for high- and medium-risk beneficiaries and 6 percent for high-risk beneficiaries alone. Although these differences were not precisely estimated and were not statistically significant, they were similar in magnitude to the 6 percent (0.3 percentage point) impact on the probability of having first-time CVD events over the same period (this first part of the two-part regression model).²⁹ Estimated impacts on CVD event spending were identical (after rounding to a whole number) when we trimmed the sample to 20 or fewer providers per organization and when we used the population of attributed beneficiaries—with \$2 reductions in spending for high- and medium-risk intervention beneficiaries and \$3 reductions for the high-risk group (using implied effects for enrolled beneficiaries in the attribution analysis). Unadjusted impacts showed slightly larger, but not statistically significant, reductions of -\$3 and -\$5 for high- and medium-risk intervention beneficiaries and high-risk beneficiaries, respectively. We also conducted the following sensitivity and exploratory analyses:

Varying time to identify CVD events. The main findings for CVD event spending used a subset of the analytic population (68 percent) who enrolled early enough to allow for sufficient follow-up time to identify spending. We conducted additional analyses shortening the time to identify CVD events, enabling us to include a greater proportion of the full analytic population. These included analyses to identify CVD events that occurred within one or two years of enrollment, which included the full analytic population enrolled in 2017 or 2018, and analyses of CVD events that occurred within three years and eight months of enrollment, which included all beneficiaries enrolled in 2017. Over these shorter time periods, we saw no statistically significant reductions in CVD event rates (consistent with the results in Table H.14) or average spending on first-time CVD events (Table H.20).

²⁹ This impact estimate of 0.3 percentage points was somewhat larger than, but within a margin of error of, the estimate for CVD events over four years we had obtained in Table H.14 (0.2 percentage points). The reason for the difference is that Table H.20 includes only about 85 percent of the beneficiaries included in Table H.14. For the high-risk group alone, the estimated impact on CVD events for the subset of the population enrolled in the model early enough to include in the CVD-event spending measure was 0.4 percentage points (6 percent) and reached statistical significance, but was also within a margin of error of the estimates for the larger population in Table H.14 (0.3 percentage points).

Using spending 30 days post-discharge. Researchers have measured CVD event episode spending over either 30 days (Kim et al. 2015) or 90 days (Montgomery et al. 2019; Sukul et al. 2019; Sinha et al. 2018) after an event. By measuring CVD event spending 90 days postdischarge (chosen a priori), the main CVD event spending outcome captured more of the longterm care after an event, including extended stroke rehabilitation. However, the 90-day postdischarge spending measure also contained more variability than a 30-day measure would have by including time after the end of follow-up care for most CVD events. Analyses of CVD event spending using a 30-day follow-up could have allowed a slightly larger subset of the analytic population (compared to a 90-day follow-up) because the measure required less follow-up time to observe spending, but we limited these analyses with 30- and 90-day follow up to beneficiaries enrolled by the end of October 2017 for comparability (76 percent of the high- and medium-risk analytic population). In analyses including only 30 days post-discharge, impacts of the model on CVD-event spending were statistically significant, suggesting a \$2 (6 percent) reduction in CVD-event spending for high- and medium-risk beneficiaries and a \$4 (8 percent) reduction for high-risk beneficiaries alone. These estimates were similar in magnitude to the estimates for spending measured 90 days post-discharge in absolute terms (-\$2 and -\$3, respectively) and larger in percentage terms (-5 and -6 percent, respectively). However, the analysis with 30-day post-discharge follow-up period had a smaller margin of error (that is, smaller standard errors and *p*-values).

Without Winsorizing spending. To reduce the risk of chance high-cost events in either the intervention or control group driving impact estimates, we Winsorized CVD event spending by setting the CVD event spending measure to \$150,000 when the actual value was greater than \$150,000 (which is around the 98th percentile). Findings were similar in sensitivity analyses in which we did not Winsorize spending (Table H.21), suggesting intervention–control group differences in high-cost events did not drive impact estimates (after regression adjustment).

There were also no statistically significant impacts of the Million Hearts Model on Parts A and B Medicare spending, with or without including model payments, across a series of sensitivity and exploratory analyses (Table H.22). The main estimates without model payments of \$1 per beneficiary per month for high- and medium-risk beneficiaries and \$10 for high-risk beneficiaries were slightly higher after trimming the sample to 20 or fewer providers per organization at \$4 and \$14 for high- and medium-risk and high-risk beneficiaries, respectively. The estimates were nearly identical after controlling for changes in the beneficiary composition over time since enrollment. For the population of attributed beneficiaries, implied effects for the enrolled population were \$6 for high- and medium-risk and \$1 for high-risk beneficiaries similar to our main results within the margin of error for spending estimates. Unadjusted impact estimates for the main analytic population and the attribution population were larger than the adjusted results, but also similar within the margin of error for spending measures, with unadjusted impact estimates of \$4 and \$16 for high- and medium-risk and high-risk beneficiaries, respectively; neither of these impact estimates were statistically significant because the unadjusted estimates were estimated imprecisely. Table H.20. Estimated impacts on spending during first-time heart attacks, strokes, and TIA events and 90 days post-discharge within 1, 2, 3, or 4 years after enrollment (regression-adjusted)

		npact on the eneficiaries with entage points)	Regression-adjusted spending for first-time heart attack, stroke or TIA events and 90 days post-discharge (\$ PBPM)				
Outcome	Difference (%)	90% confidence interval	Intervention group mean	Control group mean	Difference (%)	90% confidence interval	
High- and medium-risk beneficiaries							
First-time heart attacks, strokes, and TIAs ^a							
Within one year of enrollment	<0.05 (2%)	[-0.1, 0.1]	\$ 38	\$ 38	\$ 0 (1%)	[-3, 4]	
Within two years of enrollment	<-0.05 (-1%)	[-0.1, 0.1]	\$ 39	\$ 38	\$ 1 (3%)	[-1, 3]	
Within three years of enrollment	-0.1 (-2%)	[-0.3, 0.1]	\$ 39	\$ 39	\$ -1 (-1%)	[-3, 2]	
Within three years and eight months of enrollment ^b	-0.2 (-3%)	[-0.4, 0]	\$ 37	\$ 38	\$ -0 (-1%)	[-2, 2]	
Within four years of enrollment	-0.3** (-6%)	[-0.6, -0.1]	\$ 38	\$ 39	\$ -2 (-5%)	[-4, 0]	
High-risk beneficiaries							
First-time heart attacks, strokes, and TIAs ^a							
Within one year of enrollment	0.1 (6%)	[-0.1, 0.3]	\$ 54	\$ 50	\$ 4 (8%)	[-3, 11]	
Within two years of enrollment	<-0.05 (-1%)	[-0.3, 0.2]	\$ 55	\$ 54	\$ 1 (2%)	[-4, 6]	
Within three years of enrollment	-0.1 (-3%)	[-0.4, 0.2]	\$ 53	\$ 54	\$ -1 (-2%)	[-5, 3]	
Within three years and eight months of enrollment ^b	-0.2 (-4%)	[-0.6, 0.1]	\$ 50	\$ 51	\$ -1 (-2%)	[-5, 3]	
Within four years of enrollment	-0.4* (-6%)	[-0.8, 0]	\$ 51	\$ 54	\$ -3 (-6%)	[-7, 1]	

Source: Mathematica's analysis of Medicare Part D claims linked to Medicare claims and enrollment data.

Notes: Findings in this table are based on a two-part model, which separately estimates the probability a beneficiary has a first-time heart attack, stroke, or TIA (that is, has greater than zero spending for first-time heart attacks, strokes, or TIAs) using a logistic regression model, and then, conditional on having had an event, models the spending for the event using ordinary least squares. Multiplying the two parts will generate combined results. The two-part model can account for cases in which there are many zero values for the outcome variable better than ordinary least squares models that do not separately model the first part. Spending is Winsorized, or limited, to \$150,000 to reduce the influence of outlier values.

< 0.05 refers to absolute values (that is < 0.05 or > -0.05).

^a The number of beneficiaries varied across analyses to provide sufficient follow-up time between enrollment and the end of 2021 (the end of the claims period for this analysis) to observe 90-day post-discharge spending for first-time heart attacks, strokes, or TIAs that occurred over the observation period. For example, models of first-time heart attacks, strokes, and TIAs within four years of enrollment include beneficiaries enrolled on or before the beginning of August 2017 to allow for four years of follow-up time post-enrollment to observe a first-time heart attack, stroke, or TIA, at least a month to observe spending between admission and discharge for the event, and 90 days post-discharge. Sample sizes are in <u>Appendix D, Table D.1</u>.

^b Analysis includes beneficiaries enrolled by December 31, 2017, which is the same population used in Table H.14 to calculate the percentage of beneficiaries who had a first-time heart attack, stroke, or TIA within four years of enrollment.

*/** Significantly different from zero at the 0.1/0.05 levels, two-tailed test.

PBPM = per beneficiary per month; TIA = transient ischemic attack.

Table H.21. Estimated impacts on spending during first-time heart attacks, strokes, and TIA events and 90 days post-discharge within four years after enrollment: Sensitivity tests and exploratory analyses

Alternative outcome measure,	of beneficiar	ct on the percentage ies with an event itage point)	Regression-adjusted spending for first-time heart attack, stroke, or TIA events and 90 days post-discharge (\$ PBPM)					
population, or model specification	Difference (%)	90% confidence interval	Intervention group mean	Control group mean	Difference (%)	90% confidence interval		
High- and medium-risk beneficiar	ies							
Main analysis	-0.3** (6%)	[-0.6, -0.1]	\$ 38	\$ 39	\$ -2 (-5%)	[-4, 0]		
Trim sample to 20 or fewer providers per organization	-0.3** (-6%)	[-0.6, -0.1]	\$ 39	\$ 40	\$ -2 (-4%)	[-4, 1]		
Unadjusted impact estimates	-0.4** (-6%)	[-0.6, -0.1]	\$ 38	\$ 41	\$ -3 (-8%)	[-7, 0]		
Using spending 30 days post- discharge	-0.3** (-6%)	[-0.5, -0.1]	\$ 31	\$ 33	\$ -2* (-6%)	[-4, -0]		
Without Winsorizing spending	-0.3** (-6%)	[-0.6, -0.1]	\$ 39	\$ 41	\$ -2 (-5%)	[-5, 0]		
Main regression model specification, using the population of attributed beneficiaries	-0.1 (-2%)	[-0.3, 0.1]	\$ 35	\$ 35	\$ -1 (-2%)	[-2, 1]		
Implied effect for enrolled beneficiaries ^a	-0.2	[-0.6, 0.1]			\$ -2	[-5, 2]		
Unadjusted impact estimates, using the population of attributed beneficiaries	-0.1 (-2%)	[-0.3, 0]	\$ 42	\$ 43	\$ -1 (-3%)	[-4, 2]		
Implied effect for enrolled beneficiaries ^a	-0.5	[-1.1, 0.0]			\$ -2	[-7, 3]		
High-risk beneficiaries								
Main analysis	-0.4* (-6%)	[-0.8, 0]	\$ 51	\$ 54	\$ -3 (-6%)	[-7, 1]		
Trim sample to 20 or fewer providers per organization	-0.4 (-6%)	[-0.9, 0]	\$ 51	\$ 54	\$ -3 (-6%)	[-8, 2]		
Unadjusted impact estimates	-0.4* (-6%)	[-0.8, 0]	\$ 51	\$ 56	\$ -5 (-9%)	[-11, 1]		
Using spending 30 days post- discharge	-0.4* (-6%)	[-0.8, 0]	\$ 41	\$ 44	\$ -4* (-8%)	[-7, -0]		
Without Winsorizing spending	-0.4* (-6%)	[-0.8, 0]	\$ 53	\$ 56	\$ -3 (-5%)	[-7, 2]		

Alternative outcome measure, population, or model specification	Estimated impact on the percentage of beneficiaries with an event (percentage point)		Regression-adjusted spending for first-time heart attack, stroke, or TIA events and 90 days post-discharge (\$ PBPM)					
	Difference (%)	90% confidence interval	Intervention group mean	Control group mean	Difference (%)	90% confidence interval		
Main regression model specification, using the population of attributed beneficiaries	-0.3 (-4%)	[-0.6, 0]	\$ 36	\$ 38	\$ -1 (-4%)	[-3, 0]		
Implied effect for enrolled beneficiaries ^a	-0.5	[-0.9, 0]			\$-3	[-9, 2]		
Unadjusted impact estimates, using the population of attributed beneficiaries	-0.3 (-4%)	[-0.6, 0]	\$ 52	\$ 55	\$ -4 (-7%)	[-8, 1]		
Implied effect for enrolled beneficiaries ^a	-0.9**	[-1.6, -0.2]			\$ -6	[-14, 1]		

Source: Mathematica's analysis of Medicare Part D claims linked to Medicare claims and enrollment data.

Note: Findings in this table are based on a two-part model, which separately estimates the probability a beneficiary has a first-time heart attack, stroke, or TIA (that is, has greater than zero spending for first-time heart attacks, strokes, or TIAs) using a logistic regression model, and then, conditional on having had an event, models the spending for the event using ordinary least squares. The two parts are multiplied to generate combined results. The two-part model can account for cases in which there are many zero values for the outcome variable better than ordinary least squares models that do not separately model the first part. Spending is Winsorized, or limited, to \$150,000 to reduce the influence of outlier values except in the sensitivity analysis without Winsorizing spending. Sample sizes are in <u>Appendix D, Table D.1</u>.

^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 enrolled beneficiaries.

*/** Significantly different from zero at the 0.1/0.05 levels, two-tailed test.

PBPM = per beneficiary per month; TIA = transient ischemic attack.

	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	\$959	\$958	\$1	[-18, 20]	\$1,104	\$1,095	\$10	[-19, 38]
Parts A and B spending plus average model payments ^a	\$960	\$958	\$2	[-17, 21]	n.a.	n.a.	n.a.	n.a.
Trim sample to 20 or fewer providers per organization	\$972	\$969	\$4	[-15, 23]	\$1,112	\$1,098	\$14	[-16, 43]
Adjusting for changes in beneficiary composition over time since enrollment	\$959	\$958	\$1	[-18, 20]	\$1,104	\$1,095	\$10	[-19, 38]
Unadjusted impact estimates	\$959	\$955	\$4	[-46, 53]	\$1,104	\$1,088	\$16	[-38, 70]
Analyses with attributed beneficiaries								
Parts A and B spending	\$1,056	\$ 1,053	\$3	[-17, 23]	\$1,178	\$1,178	\$0	[-24, 25]
Implied effect for enrolled beneficiaries ^b			\$6	[-30, 41]			\$1	[-44, 45]
Unadjusted impact estimates	\$1,056	1,030	\$26	[-26, 78]	\$1,178	\$1,159	\$19	[-38, 75]
Implied effect for enrolled beneficiaries ^b			\$47	[-46, 140]			\$33	[-68, 135]

Table H.22. 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 <u>Appendix D, Table D.1</u>. 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 \$7,264,803. We divided this amount 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. We calculated the number of beneficiary-quarters for each analysis, so the average model cost per beneficiary per quarter varied 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. We obtained this estimate by dividing the overall impact estimate by the percentage of enrolled beneficiaries. CI = confidence interval; n.a.= not applicable.

Appendix I

Trends in CVD Risk Scores and Risk Factors

This appendix describes the average change in cardiovascular disease (CVD) risk scores and individual risk factors for high-risk beneficiaries in the intervention group during one-, two-, and three-year reassessment visits using Million Hearts Data Registry data from 2017 through December 2020. Mathematica calculated CVD risk scores at reassessment visits using the Million Hearts Longitudinal Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment Tool. Changes in risk scores and risk factors shown in this appendix, 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, they are shown here to describe the experiences of beneficiaries enrolled in the Million Hearts Model—as well as the experiences of participating organizations paid for achieving risk reduction among those beneficiaries. To illustrate changes that might have occurred even without the model, we show CVD risk reduction among control group beneficiaries during visits one year after enrollment.³⁰

1. Population included in trend analyses

The analyses in this appendix include high-risk beneficiaries who were eligible for and received one-, two-, and three-year reassessment visits. 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), which was 10 to 14 months after enrollment for the one-year reassessment, 22 to 26 months after enrollment for the two-year reassessment, and 34 to 38 months after enrollment for the three-year reassessment. However, reassessment visits could occur after the anniversary window, and organizations could still receive payments for these later reassessment visits (pro-rated based on the length of time between enrollment and reassessment). Because of this, for the analysis, we allowed one-year reassessment visits to occur 10 to 21 months post-enrollment, two-year reassessment visits 22 to 33 months post-enrollment, and three-year reassessment visits 34 to 45 months post-enrollment. 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 our analysis of 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 followup to observe a three-year reassessment visit within the three-year anniversary window through the end of 2020; (2) remained alive, without acute myocardial infarction, 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 postenrollment.

We compared the trends in CVD risk scores among intervention beneficiaries with one-, two-, and/or three- year follow-up visits to control group beneficiaries with a one-year follow-up visit. We calculated the control group trends using data through December 2019, which was the last

³⁰ The control group had to submit data to the Million Hearts Data Registry only through December 2019, so there are limited data on visits for the control group two or three years after enrollment.

time the control group was required (or permitted) to submit data to the Million Hearts Data Registry. Otherwise, we defined one-year follow-up visits in the control group the same way as one-year reassessment visits in the intervention group.

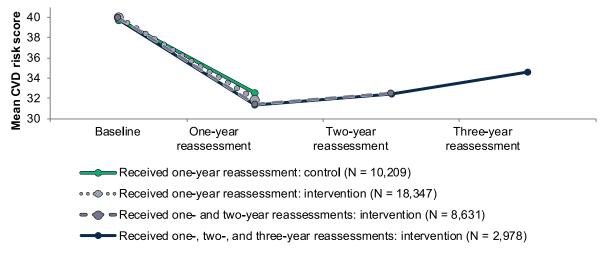
2. Trend analyses

In Figures I.1 through I.3, we show trends in CVD risk scores, systolic blood pressure, and lowdensity lipoprotein (LDL) cholesterol 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 LDL cholesterol levels at all visits, including the enrollment visit.

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 I.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 heart attack or stroke within 10 years (hence a reduction of 8 percentage points, on average). 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, 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. We discuss likely reasons for these observed trends next.

Figure I.1. Intervention beneficiaries who received one, two, and three annual reassessment visits had similar (mostly overlapping) changes in CVD risk scores: Change in risk scores between enrollment and annual reassessment visits through December 2020



Sources: 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 gray dashed line includes 8,361 high-risk intervention beneficiaries who received both one- and two-year reassessment visits by December 2020. The gray 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.

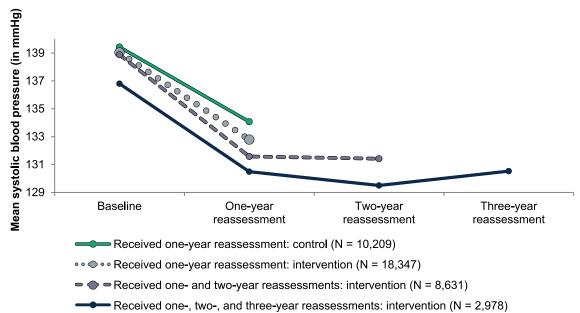
Decreases in CVD risk scores in the first year could be caused by (1) impacts of the Million Hearts Model; (2) improvements in risk factors under care as usual, which affected both the intervention and control groups; and (3) natural fluctuations in CVD risk factors, which created a statistical artifact 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 highrisk 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.

CVD = cardiovascular disease.

Decreases in systolic blood pressure, decreases in LDL cholesterol, and increases in aspirin use—which are all 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 (Figures I.2 and I.3). However, LDL cholesterol continued to decline across the three reassessment visits, 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, are caused in part by an aging population and possibly 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 raised the CVD risk score in the Million Hearts Longitudinal ASCVD Risk Assessment Tool.

Figure I.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



Sources: 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 gray dashed line includes 8,361 high-risk intervention beneficiaries who received both one- and two-year reassessment visits by December 2020. The gray 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.

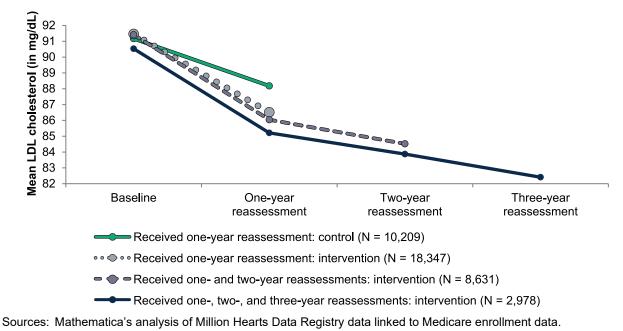


Figure I.3. Mean LDL cholesterol declined steadily over three years post-enrollment: Change in LDL cholesterol between enrollment and annual reassessment visits through December 2020

- Note: The blue solid line includes 2,978 high-risk intervention beneficiaries who received three reassessment visits by December 2020. The gray dashed line includes 8,361 high-risk intervention beneficiaries who received both one- and two-year reassessment visits by December 2020. The gray 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.

Appendix J

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 Mathematica's 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 have infected 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 did not contract the virus during the model test, COVID-19 could indirectly affect outcomes if it made 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 the end of the model period, December 2021, we estimated 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, the effects of COVID-19 on outcomes in 2020 and 2021 were similar for the intervention and control groups. Further, three of the five years of the model test occurred before the pandemic, meaning roughly 60 percent of the follow-up period is protected from any potential biases from COVID-19. For both reasons, the COVID-19 pandemic through the end of 2021 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 and 2021, the differences in these effects between the intervention and control groups appear to be too small 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.

Implications of COVID-19 for the generalizability of findings. The analyses in this appendix focus solely on the potential bias to our impact estimates caused by differences between intervention and control group beneficiaries' COVID-19 experiences. In other words, we assess whether differences in the direct and indirect effects of COVID-19 on key outcomes between the intervention and control groups might lead to inaccurate estimates of the Million Hearts Model's impacts *during the study period, 2017 to 2021*. However, COVID-19 also changed the clinical context of the intervention, and might have changed how organizations delivered the intervention. (For example, beneficiaries were less likely to make office visits in 2020 and providers might therefore have missed opportunities to adjust care for modifiable risk factors.) As a result, COVID-19 could affect the generalizability of the study findings—that is, the extent to which we would see similar impacts to those of the Million Hearts Model *if a similar model were repeated in a different period*. We discuss generalizability in <u>Chapter IX</u>.

Organization of this appendix. We assess the potential for bias due to the direct and indirect effects of COVID-19 for service use and long-term outcomes listed in Chapters <u>VI</u> and <u>VII</u>, respectively, of this report. Section J.2 of this appendix shows county-level outcomes for the intervention and control beneficiaries for all weeks of 2020 and 2021 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 2020–2021 pandemic period differently. Then, in Section J.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 and 2021 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 and 2021 relative to the same weeks in 2018 and 2019 as the effect of COVID-19 on outcomes, and we look at county-level changes—rather than changes among the evaluation's actual intervention and control groups—to distinguish differences between the intervention and control group caused by COVID-19 from differences between the groups

caused by the Million Hearts Model. For all outcomes considered, we see large effects of COVID-19 on outcome levels, especially in spring 2020. 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, winter 2020–2021, and fall 2021. 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 due to COVID-19 between the intervention and control groups. In Section J.3, we use these differences 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 J.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 calculated the *county-level* differences in outcome rates in each week in 2020 and 2021 versus the average rates for the same week in 2018–2019 among Medicare FFS beneficiaries ages 40 to 79, with each *county* weighted by the 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 avoided 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 enabled us to assess the differential effects of COVID-19 for intervention versus control beneficiaries, without risk the model caused those differences. We considered 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 J.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 did not expect the model could meaningfully affect county-level outcomes among the full Medicare FFS population.

	Million Hearts Model	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	19	
Not dually eligible	90	90	81	
Race and ethnicity ^a				
White, non-Hispanic	84	85	78	
Black, non-Hispanic	7	6	9	
Hispanic	4	4	7	
All other races and ethnicities	4	4	6	
Number of chronic conditions ^{b,c}				
0 or 1	9	9	16	
2 to 5	41	41	34	
6 or more	35	36	27	
Excluded: not observable for prior 2 years ^d	15	15	22	
HHS Region				
1: CT, ME, MA, NH, RI, and VT	3	3	6	
2: NY, NJ, PR, and VI	15	12	8	
3: DC, DE, MD, PA, VA, and WV	21	15	11	
4: AL, FL, GA, KY, MS, NC, SC, and TN	23	17	22	
5: IL, IN, MI, MN, OH, and WI	8	17	16	
6: AR, LA, NM, OK, and TX	10	8	12	
7: IA, KS, MO, and NE	11	10	5	
8: CO, MT, ND, SD, UT, and WY	1	5	3	
9: AZ, CA, HI, and NV	6	8	12	
10: AK, ID, OR, and WA	1	4	4	

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

Sources: Mathematica's analyses of Medicare enrollment and claims data and Million Hearts Data Registry 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 3, 2017.

^a The distribution of beneficiaries by race and ethnicity is based on their predicted probabilities of being in each category. The predicted probabilities were developed by the RAND Corporation from its Medicare Bayesian Improved Surname Geocoding (MBSIG 2.0) algorithm (Haas et al. 2019), which uses information from CMS administrative data and beneficiaries' names and characteristics of their Census blocks to assign each beneficiary probabilities of being non-Hispanic White, non-Hispanic Black, Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and multiracial.

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

^c The count of the number of chronic conditions among the Million Hearts Model intervention and control groups might be lower than the count for the national population because the Million Hearts Model evaluation 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 Hearts Model evaluation analytic file does not include categories for sickle cell disease or HIV/AIDS, which the analysis file for the national population includes.

^d The analyses of chronic conditions included beneficiaries only if they were observable during the two years before their enrollment date (Million Hearts Model beneficiaries) or January 3, 2017 (national sample). We limited the sample because the look-back period for most of the chronic conditions algorithms requires two years of claims data.

CMS = Centers for Medicare & Medicaid Services; FFS = fee-for-service; HHS = U.S. Department of Health and Human Services.

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)³¹ 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 and 2021 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

³¹ 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.

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.

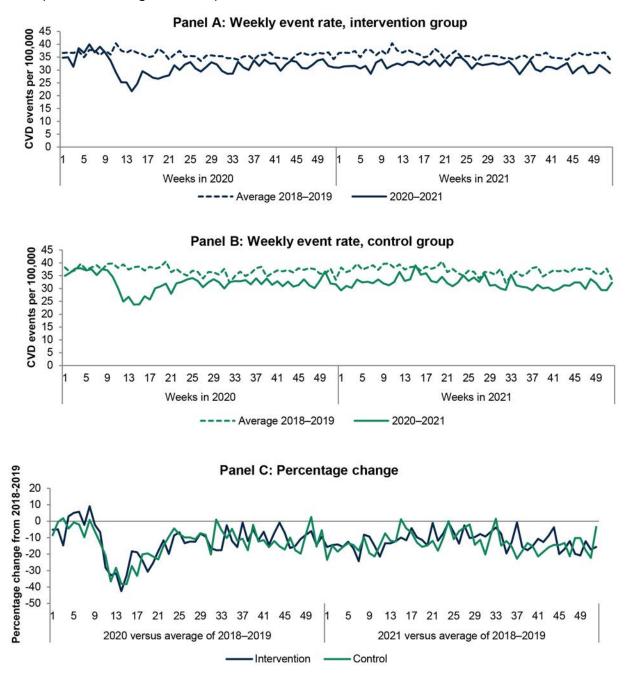
- 4. We produced weighted weekly graphs of events among all counties that contained at least one intervention group beneficiary.
- 5. We repeated Steps 3 and 4 for the control group. We included any counties that contained both intervention and control group beneficiaries in both intervention and control 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 J.1 shows the change, by week, in 2020 and 2021 relative to 2018–2019 in the rate of heart attacks and strokes, as identified in acute inpatient and outpatient ED (including observation stay) claims. We used the same set of diagnosis codes (found in any position) to identify heart attacks and strokes as used for the impact analyses presented in <u>Chapter VII</u>. 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 J.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 each week in 2020 and 2021 versus the average rate for 2018 and 2019 for the same week for each group.

Figure J.1 shows that, although the rate of heart attacks and strokes appeared to fall by roughly 40 percent in the early weeks of the pandemic in spring 2020 relative to the same weeks in previous years, the decline and subsequent partial recovery were very similar between the intervention and control group counties. Throughout the second half of 2020 and 2021, event rates remained lower than rates in 2018–2019 for both groups. We do not anticipate all, or even most, of the large decline in observed heart attacks and strokes in early 2020 reflected a true reduction in events during this period. Rather, we expect the decline was 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). The persistently lower rates in the second half of 2020 and throughout 2021 compared to 2018–2019 might reflect a combination of hospital avoidance as well as competing risk from mortality. That is, some Medicare beneficiaries died from pandemic-related circumstances before a heart attack or stroke could occur.

Figure J.1. Rates of observed heart attacks and strokes declined similarly in 2020–2021 in intervention and control group beneficiaries' counties relative to the average rates in 2018 and 2019 (beneficiaries ages 40 to 79)



Sources: 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 in each

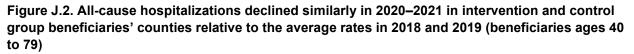
county. (This figure effectively drops counties with no intervention group beneficiaries.) Similarly, the rates in Panel B are weighted by the number of control group beneficiaries in each county. (This figure effectively drops counties with no control group beneficiaries.) Panel C reports the percentage change in weighted rates for each week in 2020 and 2021 versus the average rate for 2018 and 2019 for the same week for each group.

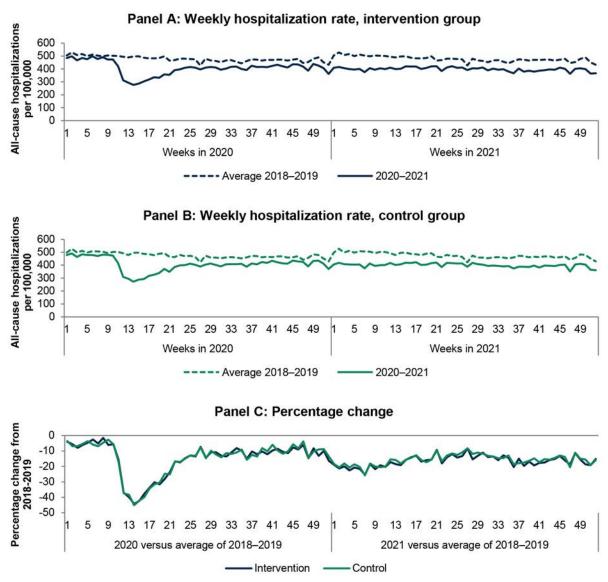
AMI = acute myocardial infarction; ED = emergency department; FFS = fee-for-service.

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

Figures J.2 and J.3 show the changes in weighted rates 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 in 2020 and 2021 versus 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 2020 and 2021, 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. The one exception was outpatient ED visits and observation stays; for this outcome, control group counties had a consistently smaller percentage change in weekly rates in the last 20 weeks of 2021 versus 2018–2019 compared to intervention group counties, though the differences were small. For both outcomes, event rates remained well below 2018–2019 levels (by about 10 to 25 percent, respectively) in the second half of 2020 and through all of 2021.



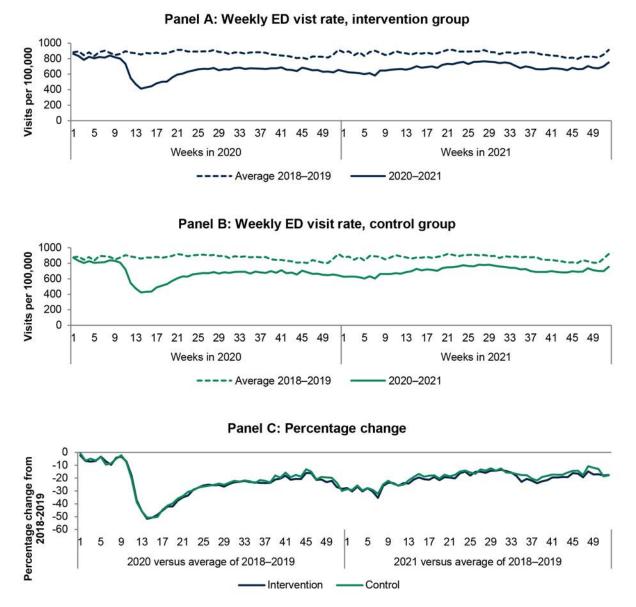


Sources: Mathematica's analyses of Medicare enrollment and claims data.

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 for each week in 2020 and 2021 versus the average rate for 2018 and 2019 for the same week for each group.

FFS = fee-for-service.

Figure J.3. All-cause outpatient ED visits and observation stays declined similarly in 2020–2021 in intervention and control group beneficiaries' counties relative to average rates in 2018 and 2019, although small differences began to appear in the second half of 2021 (beneficiaries ages 40 to 79)



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

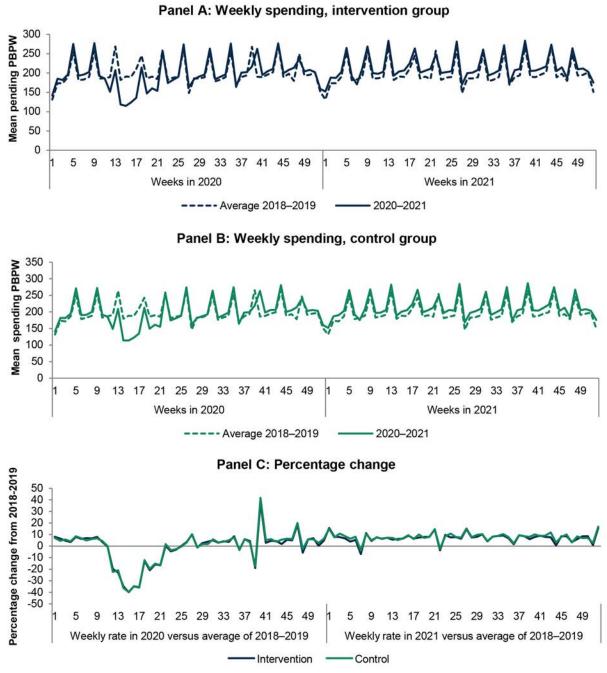
Note: For the rates in Panels A and B, the denominator in each week is the number of Medicare FFS beneficiaries in each county between the ages of 40 and 79 who were alive and enrolled in Medicare Parts A and B FFS with Medicare as primary payer at the start of that week. The numerator is the number (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.) Panel C reports the percentage change in weighted rates for each week in 2020 and 2021 versus 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 J.4 shows the percentage change in weighted rates 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 J.4. Total Medicare FFS Parts A and B spending per person per week changed similarly in intervention and control group beneficiaries' counties in 2020–2021 relative to the average in 2018 and 2019 (beneficiaries ages 40 to 79)



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

Notes: The figure reports the percentage change in weighted spending per person per week in 2020 and 2021 versus the average rate for 2018 and 2019 for the same week for each group. To calculate each county's per-person 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.)

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 of 2020 occurs 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 in 2020 relative to 2018–2019, as the end-of-month expenditures for September are counted in Week 40 in 2020 rather than Week 39.

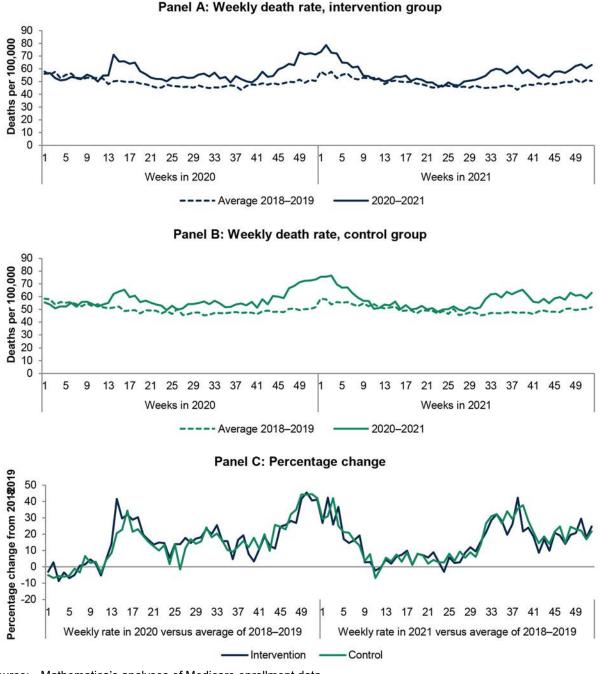
FFS = fee-for-service; PBPW = per beneficiary per week.

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

Figure J.5 shows the percentage change in the weighted death rate in 2020 and 2021 versus 2018–2019, measured among beneficiaries ages 40 to 79. The rates in Panel A of Figure J.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 in 2020 and 2021 versus the average rate for 2018 and 2019 for the same week for each group.

The figure shows that, although the death rate rose in spring 2020, winter 2020–2021, and fall 2021 for beneficiaries ages 40 to 79 and that it generally stayed above the 2018–2019 average rate between those surges, the increases in death rates were similar between the intervention and control group counties. The one exception was in Weeks 13 through 15 in 2020, when death rates were a bit higher in the intervention group counties.

Figure J.5. The death rate for beneficiaries ages 40 to 79 increased similarly in 2020–2021 relative to the average weekly rates in 2018 and 2019 in intervention 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 in 2020 and 2021 versus 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 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.)

FFS = fee-for-service.

3. Estimating potential COVID-19-related bias on impact estimates for key outcomes

The trends in key study outcomes shown in Section J.2 differ only slightly between the counties where the intervention and the control group beneficiaries lived. 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 used the observed intervention– control differences in weighted county-level rates from Section J.2 to estimate how large a bias COVID-19 could create (that is, how large a difference in

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.

evaluation outcomes the COVID-19 pandemic would create even if the model had no impact).

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

Table J.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	Type of COVID-19 effect examined	Rationale for examining potential bias due to direct 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 took measures to curb the spread of COVID-19 (indirect effects of COVID-19). In contrast, we do not assume COVID-19 infection directly affected the probability of heart attacks and strokes (a direct effect).a We examined 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 assessed the potential for intervention– control differences in COVID-19's direct and indirect effects, combined, to bias impact estimates.
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 assessed the potential for intervention–control differences in COVID-19's direct and indirect effects, combined, to bias impact estimates.
Total Medicare spending	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).
Death rate	Direct	We assumed all intervention–control differences in county- level death rates were due to direct effects of COVID-19— that is, differences in the incidence or severity of COVID-19 cases. We assessed 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.

CVD = cardiovascular disease; ED = emergency department.

In broad terms, the calculations include three major steps:

- We calculated the difference in outcomes between the intervention and control group counties during the COVID-19 pandemic in 2020 and 2021 (March 11, 2020, through December 31, 2021), based on the data shown in Section J.2. For example, for the assessment of COVID-19's direct effect on the death rate, we took the county-level death rates among beneficiaries ages 40 to 79 and calculated the difference in county-level rates between the intervention and control groups (with county-level rates weighted, as in Section J.2, by the number of intervention or control group beneficiaries).
- 2. We used the observed intervention–control differences from Step 1 to calculate differences in outcomes between the intervention and control group that could occur over the five-year model period due to COVID-19.
- 3. We took the differences in outcomes due to COVID-19 from Step 2 and added them to the observed impact estimates reported in the Million Hearts Model Evaluation Third Annual Report (Blue et al. 2020). This gave us the projected impact estimates when we included differences due to COVID-19, if the estimates through 2021 had changed for no reason other than COVID-19. Of course, the estimates included in Chapters <u>VI</u> and <u>VII</u> 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 assumed (1) the differences in outcomes in 2020 and 2021 versus the same weeks in 2019–2020 in a county for Medicare FFS beneficiaries ages 40 to 79 reflected the impact of COVID-19 in that county for those beneficiaries and (2) the impact of COVID-19 for Million Hearts Model beneficiaries living in a county was the same as the impact of COVID-19 for all Medicare FFS beneficiaries ages 40 to 79 in the county. Additional details about each calculation for each outcome are available in <u>Appendix A of the Fourth Annual</u> Report (Peterson et al. 2022). Table J.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.

	Estimated change in outcome due to COVID-19		Potential bias on impact estimates from COVID-19						
Outcomes	Intervention group	Control group	Difference	Observed impact estimate in Third Annual Report [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 [90% CI]	Conclusions about model impacts, after accounting for potential bias from COVID-19			
Outcomes analyzed in a	Outcomes analyzed in a survival model framework								
First-time heart attacks and strokes (events per 100,000 beneficiaries per year)	-124	-133	9	1.00 [0.95, 1.04]	1.00 [0.96, 1.05]	No change			
Death (events per 100,000 beneficiaries per year	189	191	-2	0.94 [0.90, 0.97]	0.94 [0.90, 0.97]	No change			
Outcomes analyzed at the	he beneficiary-qua	rter-level using	g linear regressi	ons					
All-cause hospitalizations (admissions per 1,000 beneficiaries per quarter)	-4.5	-4.4	-0.17	2.35 [0.9, 3.8]	2.18 [0.70, 3.66]	No change			
Outpatient ED visits and observation stays (visits per 1,000 beneficiaries per quarter)	-12	-11	-0.57	3.56 [0.7, 6.4]	2.99 [0.17, 5.81]	No change			
Total Medicare Parts A and B spending (spending per beneficiary per month)	\$7.87	\$10.56	-\$2.70	\$4.44 [-14, 23]	\$1.74 [-\$16, \$20]	No change			

Sources: 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 beneficiaries. We estimate the change in outcomes due to COVID-19 as the difference between outcomes observed between March 11, 2020, and December 31, 2021, versus outcomes observed in those same weeks in 2018–2019. We then use those numbers and beneficiaries' observability through the end of 2021 to assess the change in five-year outcome levels (2017–2021) due to the estimated effects of COVID-19.

CI = confidence interval; 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 service use and long-term evaluation outcomes considered in this appendix, COVID-19 changed outcome levels in 2020 and 2021, quite dramatically in the early weeks of the pandemic in some cases, but these changes were similar for both groups. Moreover, it was 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 analyzed 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 was unlikely to bias estimates of the impact of the Million Hearts Model on the outcomes analyzed in this report.

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