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

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TABLE OF CONTENTS

ACKNOWLEDGMENTS ii

LIST OF ACRONYMS xi

EXECUTIVE SUMMARY xiii

A. Million Hearts Model design and participation in the model xiv
B. CMS incentives and supports xvi
C. Risk stratification xvii
D. Improvements in cardiovascular care xviii
E. Reductions in cardiovascular risk xix
F. Impacts on heart attacks and strokes, mortality, service use, and spending xxi
G. Consistency of the findings across outcomes xxii

I. INTRODUCTION 1

A. Model goals and design 1
B. Causal pathway: From incentives and supports to reductions in heart attack and strokes 3
C. Evaluation goals and methods 5

II. PARTICIPATING ORGANIZATIONS AND THE BENEFICIARIES THEY ENROLLED 8

A. Summary of participating organizations 8
B. Reasons organizations participate 10
C. Beneficiary enrollment through December 2018 13

III. MODEL INCENTIVES AND SUPPORTS 15

A. Model incentives 15
B. Participants' perceptions of model tools and supports 19

IV. RISK STRATIFICATION AND DEGREE TO WHICH BASELINE CVD RISK IS MODIFIABLE 23

A. Extent of risk stratification 23
B. Degree to which baseline CVD risk is modifiable 29
C. Providers' awareness of CVD risk 33

V. IMPROVEMENTS IN PREVENTIVE CARDIOVASCULAR CARE TO REDUCE MODIFIABLE RISK 35

A. Use of CVD risk scores to guide CVD preventive care 35
B. Initiation or intensification of medications to reduce CVD risk factors 38
C. Follow-up with beneficiaries over time to encourage and sustain risk reduction 42

VI. REDUCTIONS IN CARDIOVASCULAR RISK ONE YEAR AFTER ENROLLMENT 48

A. Reductions in risk over time, by treatment arm 48
B. Role of CVD medications in driving risk reduction 52

VII. MODEL IMPACTS ON HEART ATTACKS AND STROKES, MORTALITY, SERVICE USE, AND SPENDING 56

A. Heart attacks and strokes 56

B. Mortality 58

C. Service use 60

D. Medicare spending 62

VIII. CONCLUSION 65

A. Estimated impacts on mortality: Possible mechanisms 67

B. Estimated impacts on CVD risk scores: Implications for averting CVD events and possible mechanisms 68

C. The Million Hearts Model's vision of care and its role in driving impacts 68

D. Relevance to CVD primary prevention beyond the Million Hearts Model 70

E. Next steps for the evaluation 71

REFERENCES 72

APPENDIX A: DEFINING THE ENROLLED STUDY POPULATION A.1

1. Beneficiaries enrolled in the Million Hearts Model in 2017 and 2018 ..... A.2

2. Beneficiaries included in the impact analyses of CVD events and other, long-term claims-based outcomes A.3

3. Beneficiaries included in impact analyses of medication initiation and intensification (Part D-based outcomes) A.5

4. Beneficiaries used for estimating impacts on CVD risk scores and risk factors A.7

APPENDIX B: SUPPLEMENTAL ANALYSIS OF MILLION HEARTS MODEL PAYMENTS B.1

APPENDIX C: DEFINING THE ATTRIBUTED BENEFICIARY POPULATION C.1

1. Attributing Medicare beneficiaries to participating organizations C.3

2. Predicting CVD risk scores for the attribution-based study population C.7

3. Weighting the population of attributed beneficiaries to reflect high- and medium-risk beneficiaries C.12

APPENDIX D: CONSTRUCTING MEASURES OF COUNTY- AND ORGANIZATION-LEVEL POPULATION HEALTH AND USE D.1

1. County-level characteristics from the Medicare geographic variations database D.2

2. County-level data from the CDC D.3

3. Organization-level use and spending characteristics D.3

APPENDIX E: BASELINE CHARACTERISTICS OF THE INTERVENTION AND CONTROL GROUPS PARTICIPATING IN THE MILLION HEARTS MODEL E.1

1. Baseline characteristics of the population used to estimate impacts on CVD events and other long-term, claims-based outcomes E.2

2. Baseline characteristics of the population used to estimate impacts on medication initiation and intensification (Part D-based outcomes) E.9

3. Baseline characteristics of the population used to estimate impacts on CVD risk scores and risk factors E.14

4. Baseline characteristics of the attributed population used for robustness checks E.18

5. Selection of attributed beneficiaries into the intervention and control groups E.24

APPENDIX F: ESTIMATING IMPACTS ON BENEFICIARIES' OUTCOMES: DETAILED METHODS AND SUPPLEMENTAL RESULTS F.1

1. Methods for estimating impacts using claims data F.2

2. Methods for estimating impacts on CVD risk scores using registry data F.8

3. Unadjusted cumulative probabilities of CVD events and death F.9

4. Supplemental regression results F.11

FIGURES

ES.1 Causal pathway for the Million Hearts Model xiv

ES.2 Intervention group beneficiaries had higher rates of CVD medication use: Percentage of high- and medium-risk beneficiaries who initiated or intensified CVD medications within one year of model enrollment xix

ES.3 Beneficiaries' CVD risk scores improved modestly more in the intervention group than in the control group: Estimated impacts on CVD risk scores one year after enrollment, among high-risk beneficiaries with reassessment data in 2017 or 2018 xx

ES.4 Causal pathway for the Million Hearts Model, with key findings through 2019 xxiv

I.B.1 Causal pathway for the Million Hearts Model 3

II.B.1 Rates of effective participation were very similar between the intervention and control groups: Participation in the Million Hearts Model from model launch to November 2019, by intervention and control group 12

III.A.1 Model payments were concentrated in the first year: Median payment per organization (N = 96), by payment type 17

IV.A.1 The model appears to have increased the use of risk stratification substantially: Proportion of providers reporting they calculate CVD risk scores for at least half of their Medicare beneficiaries 24

IV.A.2 The intervention group organizations ranged considerably in their proportion of attributed beneficiaries risk stratified and enrolled: Distribution across intervention organizations in their percentage of attributed Medicare beneficiaries enrolled in the Million Hearts Model 26

IV.B.1 Addressing modifiable risk factors could substantially reduce overall cardiovascular risk: The distribution of ASCVD risk scores at baseline among high-risk beneficiaries, and the distribution that would occur 12 months later if these beneficiaries reached evidence-based clinical targets 32

IV.C.1 Proportion of intervention group providers who reported that risk calculation helped identify high- and medium-risk beneficiaries 34

V.A.1 Most providers said they notified their Medicare beneficiaries of CVD risk scores during regular office visits: How intervention organizations notified their patients of CVD risk, as reported by intervention group providers 37

V.A.2 Proportion of intervention group providers reporting the Million Hearts Model prompted their organization to provide standard of care more systematically 37

V.B.1 Many beneficiaries initiated or intensified CVD medications after enrollment, but rates were consistently higher in the intervention group than the control group: Probability of initiating or intensifying statins or antihypertensive medications among candidate high- and medium-risk beneficiaries 40

V.C.1 Overall, intervention organizations submitted risk reassessment data for 57 percent of their eligible high-risk Medicare beneficiaries, with wide variation across organizations: Distribution of rates of reassessment visits across intervention organizations 46

VI.B.1 Systolic blood pressure declined more for people who initiated or intensified antihypertensives than for those who did not—but declines were greater in the intervention group than in the control group regardless of medication 54

VI.B.2 Similarly, LDL cholesterol declined more for people who initiated or intensified statins than for those who did not—but declines were greater in the intervention group than in the control group regardless of medication 54

VII.D.1 Spending was similar between the intervention and control groups across quarters: Regression-adjusted mean Medicare Parts A and B spending (without model payments) for enrolled beneficiaries, by quarter and intervention group 64

VIII.1 Causal pathway for the Million Hearts Model, with key findings through 2019 66

A.1 Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for Medicare enrollment and claims-based outcomes A.4

A.2 Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for Medicare Part D outcomes A.6

A.3 Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for CVD risk score and risk factor outcomes A.8

B.1 Total CMS payments to intervention organizations B.2

C.1 Flow of organizations, providers, and beneficiaries from attribution to the final impact analysis population for robustness checks B.6

C.2 Receiver operating curves for assigning beneficiaries to the high- or medium-CVD risk groups: Results from the CVD risk group prediction model C.11

F.1 Cumulative probability of having a first-time heart attack, stroke, or TIA (composite measure), by quarter of enrollment and intervention group F.10

F.2 Cumulative probability of dying for any reason, by quarter of enrollment and intervention group F.10

TABLES

ES.1 The CVD risk profile of enrolled beneficiaries was almost identical between the intervention and control groups: Number of Medicare beneficiaries enrolled by intervention and control organizations from January 2017 to December 2018, overall and by CVD risk level xv

II.A.1 Organizations assigned to the control group were similar to the intervention group organizations: Characteristics of organizations that enrolled at least one beneficiary in the Million Hearts Model from January 3, 2017, to December 31, 2018 9

II.C.1 Enrollment was greater in 2017 than 2018, but, in both years, the risk profile was similar between the intervention and control groups: Number of Medicare beneficiaries enrolled by intervention and control organizations from January 2017 to December 2018, overall and by CVD risk level 14

IV.A.1 The enrolled beneficiaries were healthier and had more frequent visits with Million Hearts Model participants than beneficiaries who appeared eligible but were not enrolled: Characteristics of enrolled beneficiaries versus beneficiaries eligible but not enrolled, 2017 to 2018 28

IV.B.1 Beneficiaries enrolled in 2017 and 2018 had a combination of modifiable and nonmodifiable risk factors: Baseline characteristics of Medicare beneficiaries enrolled by Million Hearts intervention organizations in 2017 and 2018, by CVD risk level 30

IV.B.2 Clinical targets to define modifiable risk: ABCS strategies 31

V.B.1 The model increased intensification and initiation of both statins and antihypertensives: Estimated impacts on the initiation or intensification of CVD-related medications 41

V.C.1 The model prompted modest increases in the frequency of office visits: Estimated impacts on office visits after enrollment 44

VI.A.1 CVD risk scores decreased by more for the intervention group than the control group: Estimated impacts on CVD risk scores and risk factors one year after enrollment, among high-risk beneficiaries with reassessment data in 2017 or 2018 51

VII.A.1 The model had no impact on the incidence of first-time heart attack, stroke, or TIA: Estimated ratio of the hazard of a first-time heart attack, stroke, or TIA between intervention and control beneficiaries (regression-adjusted) 57

VII.B.1 High- and medium-risk beneficiaries in the intervention group had a lower death rate than those in the control group: Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries (regression-adjusted) 58

VII.C.1 Rates of all-cause service use were higher in the intervention group: Estimated impacts on the number of inpatient admissions and outpatient ED visits and observation stays (number per 1,000 beneficiaries per quarter) 61

VII.D.1 So far, the model has not reduced Medicare Parts A and B spending: Estimated impacts on Medicare spending (dollars per beneficiary per month) 63

A.1 CVD risk reduction population: Baseline characteristics of high-risk Medicare beneficiaries enrolled in Million Hearts intervention organizations with and without reassessment visits A.10

B.1 Percentage of intervention organizations earning risk reduction payment amounts, by performance period and overall (N = 96) B.3

C.1 Overlap between the populations of enrolled beneficiaries and attributed beneficiaries C.7

E.1 Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in 2017 and 2018: Intervention versus control group E.3

E.2 Baseline characteristics of high-risk Medicare beneficiaries enrolled in 2017 and 2018: Intervention versus control group E.7

E.3 Baseline characteristics of high- and medium-risk Medicare beneficiaries included in the Part D analyses: Intervention versus control group E.10

E.4 Baseline characteristics of high-risk Medicare beneficiaries included in the Part D analyses: Intervention versus control group E.12

E.5 Baseline characteristics of high-risk Medicare beneficiaries included in the CVD risk reduction analysis: Intervention versus control E.15

E.6 Baseline characteristics of high- and medium-risk (predicted) Medicare beneficiaries attributed to participating organizations: Intervention versus control E.19

E.7 Baseline characteristics of high-risk (predicted) Medicare beneficiaries attributed to participating organizations: Intervention versus control E.22

E.8 Characteristics of enrolled beneficiaries versus beneficiaries eligible but not enrolled, 2017 to 2018, by intervention arm E.26

F.1 Covariates included in the regression models used for estimating impacts on a beneficiary's outcomes F.4

F.2 Locations of different impact estimates in this report F.11

F.3 Sizes of the studies population used for different impact estimates F.17

F.4 Estimated ratio of the hazard of a first-time heart attack, stroke, or TIA between intervention and control beneficiaries: Sensitivity tests and exploratory analyses F.19

F.5 Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries: Sensitivity tests and exploratory analyses F.20

F.6 Estimated impacts on the number of inpatient admissions (number per 1,000 beneficiaries per quarter): Sensitivity tests and exploratory analyses F.21

F.7 Estimated impacts on the number of outpatient ED visits and observation stays (number per 1,000 beneficiaries per quarter): Sensitivity tests and exploratory analyses F.22

F.8 Estimated impacts on Medicare spending (dollars per beneficiary per quarter): Sensitivity tests and exploratory analyses F.23

F.9 Estimated impacts on office visits: Sensitivity tests and exploratory analyses F.24

F.10 Estimated impacts on binary measures of CVD events and mortality F.25

F.11 Estimated impacts on all-cause mortality for medium-risk beneficiaries F.26

F.12 Estimated impacts on the initiation or intensification of CVD medications: Sensitivity tests and exploratory analyses F.27

F.13 Estimated impacts on CVD risk scores among high-risk beneficiaries with reassessment data: Sensitivity tests and exploratory analyses F.28

F.14 Estimated impacts on CVD risk scores before and after controlling for medication initiation or intensification, among high-risk beneficiaries with reassessment data and enrolled in Part D F.28

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
CAH	Critical access hospital
CCN	CMS certification number
CCW	Chronic Conditions Data Warehouse
CDC	Centers for Disease Control and Prevention
CDC WONDER	CDC Wide-ranging ONline Data for Epidemiologic Research
CI	Confidence interval
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus disease 2019
CPC	Comprehensive Primary Care
CPC+	Comprehensive Primary Care Plus
CVD	Cardiovascular disease
ED	Emergency department
EHR	Electronic health record
ES	Executive summary
ESRD	End-stage renal disease
FFS	Fee-for-service
FQHC	Federally qualified health center
GVDB	Geographic variations database
HCC	Hierarchical Condition Category
HDL	High-density lipoprotein
IT	Information technology
LDL	Low-density lipoprotein
mg/dL	Milligrams per deciliter
mmHg	Millimeters of mercury
n.a.	Not applicable
NP	Nurse practitioner
NPI	National Provider Identifier
NPPES	National Plan and Provider Enumeration System
PA	Physician assistant
PP	Performance period

PBPM	Per beneficiary per month
RHC	Rural health center
SBP	Systolic blood pressure
TCPI	Transforming Clinical Practice Initiative
TIA	Transient ischemic attack
TIN	Taxpayer Identification Number

EXECUTIVE SUMMARY

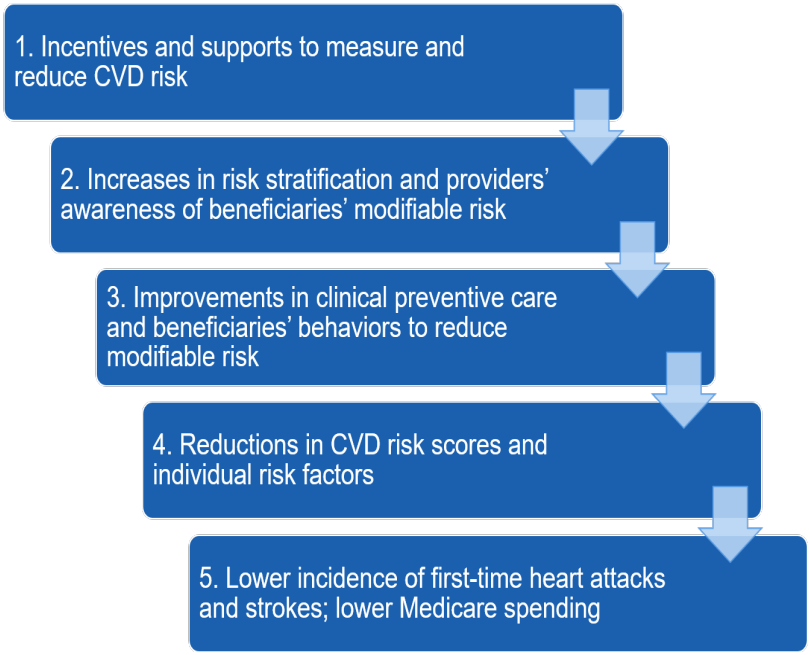
In 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts® Cardiovascular Disease (CVD) Risk Reduction Model. In this pay-for-prevention model, CMS pays participating organizations for (1) assessing each of their eligible Medicare fee-for-service (FFS) beneficiaries' risk of having a heart attack or stroke over 10 years, using a formal risk assessment tool; and (2) reducing risk among their high-risk beneficiaries, defined as those with a 30 percent or higher predicted risk. The goal is to reduce the incidence of heart attacks and strokes among Medicare beneficiaries ages 40 to 79 who have not previously had one of these events, without increasing Medicare spending. CMS is testing the model in a large, five-year randomized trial that includes primary care and cardiology practices, health centers, and hospitals throughout the United States.

In its first three years, the Million Hearts Model improved cardiovascular preventive care, but did not yet reduce observed heart attacks and strokes or lower Medicare spending. Providers in the Million Hearts Model were much more likely than control group providers to report measuring and being aware of their patients' cardiovascular risk. Beneficiaries enrolled by the intervention group were also modestly more likely than control group beneficiaries to initiate or intensify medications to lower blood pressure or cholesterol. As a result of improvements in CVD preventive care, high-risk beneficiaries in the intervention group had slightly larger average reductions in CVD risk scores (by 1.2 percentage points) than those in the control group. However, the model did not measurably reduce the incidence of first-time heart attacks or strokes through October 2019—the first two years and 10 months of the model—nor generate savings in Medicare spending that would offset model payments during that time.

Despite a lack of impacts on CVD events and spending, this report found notable impacts for some secondary outcomes. In particular, among high- and medium-risk beneficiaries (defined as beneficiaries with a 10-year predicted probability of heart attack or stroke of 15 percent or more) the death rate was 6 percent lower in the intervention group than in the control group. We further found increases of 3 to 4 percent in hospitalizations and emergency department (ED) visits among this same population. These findings were unexpected but consistently observed in a series of robustness checks.

This report follows each step of the model's anticipated causal pathway, which describes how the Million Hearts Model, if it works as intended, could reduce heart attacks and strokes and reduce Medicare spending enough to offset model payments (Figure ES.1). Section A of this executive summary describes the design of the Million Hearts Model and the organizations participating in it through 2019. Sections B through F then describe our findings for each step in the anticipated causal pathway (Figure ES.1) from CMS incentives and supports to reductions in first-time heart attacks and strokes. Section G describes the consistency of findings across outcomes.

Figure ES.1. Causal pathway for the Million Hearts Model



A. Million Hearts Model design and participation in the model

Million Hearts Model participants are diverse organizations, including primary care and cardiology practices, health centers, and hospitals throughout the United States. CMS randomly assigned 516 organizations to the Million Hearts Model intervention and control groups. The intervention organizations agreed to (1) assess the 10-year CVD risk of their eligible Medicare FFS beneficiaries (ages 40 to 79, without a previous heart attack or stroke, without end-stage renal disease, and not enrolled in hospice); and (2) provide cardiovascular care management services to reduce CVD risk among high-risk beneficiaries. Services included meeting with beneficiaries to discuss CVD risk, shared decision making to develop individualized plans for reducing risk, and following up regularly to assess and encourage beneficiaries' progress in reducing risk.

CMS paid intervention organizations for risk assessment among all eligible Medicare FFS beneficiaries and for reducing risk among high-risk beneficiaries. (CMS also paid control organizations to submit clinical data needed for the evaluation, but did not ask these organizations to calculate CVD risk or otherwise change their CVD preventive care.) Although CMS paid for risk reduction only among high-risk beneficiaries, CMS expected the model would also reduce CVD risk for medium-risk beneficiaries (those with a 15 to 30 percent predicted probability of a heart attack or stroke over 10 years). By encouraging risk stratification for all eligible patients, CMS expected the model to increase providers' awareness of CVD risk across the providers' entire patient panels, prompting improvements for medium- *and* high-risk beneficiaries. Indeed, CMS anticipated that this positive spillover to medium-risk beneficiaries would be necessary to make the model cost-neutral to Medicare. For this reason, we consider the

high- and medium-risk beneficiaries combined to be the primary target population for the evaluation.

Among the 516 organizations randomly assigned to the intervention and control groups, 345 went on to participate in the first two model years, meaning they enrolled at least one beneficiary in 2017 or 2018. Participating organizations varied in their location, size, organization type, and experience with CMS initiatives before the model launched. Together, the participants enrolled 388,001 Medicare FFS beneficiaries in 2017 and 2018, by providing CMS with clinical, demographic, and visit data needed to calculate a CVD risk score (see text box next page) and validate a beneficiary's visit with the organization. The intervention and control groups had very similar CVD risk profiles (Table ES.1). Intervention and control beneficiaries also looked similar on a wide range of beneficiary-level characteristics that we could observe, including CVD risk factors. However, some differences existed between the groups in regional characteristics and characteristics of their enrolling organizations—for example, with a higher proportion of intervention beneficiaries than control beneficiaries enrolled by organizations participating in other CMS initiatives (such as the Medicare Shared Savings Program) and by organizations in the South.

Table ES.1. The CVD risk profile of enrolled beneficiaries was almost identical between the intervention and control groups: Number of Medicare beneficiaries enrolled by intervention and control organizations from January 2017 to December 2018, overall and by CVD risk level

	Intervention group	Control group
Number of enrolling organizations	173	172
Number of beneficiaries	230,664	157,337
Low risk	99,117 (43%)	68,285 (43%)
Medium risk	90,797 (39%)	61,538 (39%)
High risk	40,750 (18%)	27,514 (18%)

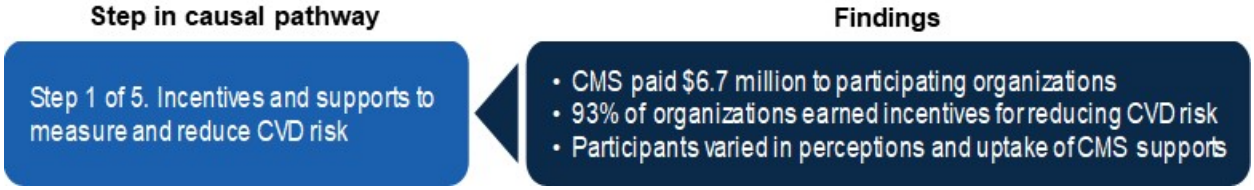
Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

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 to 30 percent. Low CVD risk is less than 15 percent. Risk is measured as of a beneficiary's enrollment date in the Million Hearts Model.

CVD = cardiovascular disease.

In interviews and a survey we fielded in 2018, organizations said they joined the Million Hearts Model primarily because they viewed CVD risk management as a priority and the model fit with their existing workflows and health information technology. CMS payment was also an important factor. Nevertheless, model participation declined considerably over time. By November 2019, 311 organizations (60 percent of those originally randomized) remained in the model, with roughly one-third of those no longer reporting data to CMS. For organizations that withdrew, the most common reasons for leaving included not perceiving incentives as commensurate with the work required, a lack of staff, and challenges sharing required data with CMS.

B. CMS incentives and supports



From January 2017 to June 2019, CMS paid $6.7 million to intervention organizations for participating in the Million Hearts Model. Among intervention organizations that were active in the model through June 2019, the median total payment over these 30 months was $23,303. Payments were highest in 2017 and declined thereafter, as performance-based payments—based on average CVD risk reduction at the organization—comprised a larger share of total payments. Almost all (93 percent) of the organizations active through June 2019 received some incentive payments for reducing risk among their high-risk beneficiaries. However, organizations typically did not reduce risk enough to earn the largest possible incentive payment of $10 per beneficiary per month.

CMS offered several tools and supports in addition to the incentive payments to help organizations implement the Million Hearts Model. When designing the model, CMS worked with leading cardiovascular epidemiologists to develop a novel, CVD longitudinal risk stratification tool—the Million Hearts Longitudinal Atherosclerotic Cardiovascular Disease

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. 2013):

- Demographics, including age, sex, and race
- Clinical factors, including blood pressure, 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). A person's initial risk score is calculated the same way as under the previously existing tool. But to calculate follow-up risk scores (an updated 10-year predicted probability of heart attack or stroke), the new tool incorporates additional information about aspirin use, time since quitting smoking, and changes since the initial assessment in blood pressure and cholesterol. Specifically, based on results from clinical trials, the new tool estimates—for an individual person—how much starting aspirin therapy, quitting smoking, and reducing blood pressure or cholesterol would change a person's CVD risk.

CMS uses the new calculator—the Million Hearts Longitudinal Atherosclerotic CVD Risk Assessment Tool—to estimate risk reduction, the basis of the model's risk reduction payments.

(ASCVD) Risk Assessment Tool—which estimates changes over time in a person's risk of heart attack or stroke (Lloyd-Jones et al. 2017). Under this tool, a person's initial risk score is the same as calculated under the previously existing American College of Cardiology (ACC)/American Heart Association (AHA) ASCVD Risk Estimator (Goff et al. 2013). However, the new tool can estimate risk *reduction* over time, based on changes in a person's risk factors. CMS therefore uses this tool when calculating Million Hearts Model risk reduction payments. CMS also developed a data registry model participants were required to use to share information with CMS and could choose to use to track enrolled beneficiaries' progress. (The novel risk stratification tool was built into the registry software and available as a web-based app.) Other model supports included a learning system to encourage care improvement and performance reports for organizations to assess improvement over time and benchmark their performance against their peers.

Participants' perceptions and uptake of these tools and supports varied. In interviews with 10 to 15 intervention group organizations per year, respondents reported their experiences with the Million Hearts Data Registry improved over the first three years of the model, although some still reported challenges sharing data in 2020. Respondents had mixed views of the usefulness of learning system events and performance feedback reports. Although respondents described using the ACC/AHA ASCVD Risk Estimator for both initial CVD risk assessments and annual reassessments, no respondents reported using the longitudinal functions of the novel risk calculator at the point of care.

C. Risk stratification

The Million Hearts Model substantially increased the rate of CVD risk stratification, but did not lead to universal risk stratification in the intervention group. Nearly all intervention organizations we interviewed had a CVD risk calculator available at the point of care—for example, using the ACC/AHA ASCVD Risk Estimator as a web- or phone-based app or built into the electronic health record. In a 2018 survey, 71 percent of intervention providers said they calculated CVD risk scores for at least half of their Medicare beneficiaries, compared with just 39 percent of control providers ($p < 0.001$). Despite this impact of the model, there was still room for intervention organizations to improve. In 2017 and 2018, the intervention organizations risk stratified and enrolled about half (52 percent) of those who appeared eligible for the Million Hearts Model in claims data. Although claims data cannot perfectly reflect all model eligibility criteria, organizations could have enrolled more beneficiaries than they did.

A combination of modifiable and nonmodifiable risk factors drove beneficiaries' CVD risk at enrollment. For example, among high-risk beneficiaries enrolled in 2017 or 2018, the mean age was 74 (a nonmodifiable risk factor) and about two-thirds of beneficiaries had diabetes (a risk

factor difficult to modify). However, nearly three-quarters had uncontrolled hypertension, which is potentially modifiable. Overall, we estimated that 39 percent of CVD risk at enrollment was potentially modifiable within one year of enrollment among high-risk beneficiaries. Among medium-risk beneficiaries, 28 percent was potentially modifiable.

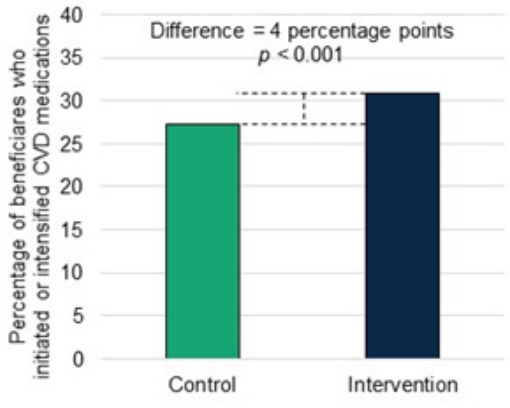
Across three years of interviews, providers said risk stratification made them more aware of beneficiaries' risk. These findings were consistent with findings from the 2018 provider survey, in which providers reported (1) reviewing CVD risk scores more consistently than before the model launch and (2) using risk scores helped them to identify high- and medium-risk beneficiaries they otherwise would not have identified.

D. Improvements in cardiovascular care

Providers reported using CVD risk scores to inform CVD preventive care for high- and medium-risk Medicare beneficiaries. In interviews and the 2018 provider survey, providers credited the Million Hearts Model with increasing the extent to which they used CVD risk scores to guide (1) discussions with beneficiaries about CVD risk and (2) treatment recommendations. Specifically, providers used the risk scores as a starting point for discussions with beneficiaries about overall risk, the factors driving it, and options for reducing risk. Providers viewed these discussions as increasing beneficiaries' awareness of risk and motivating people to consider lifestyle changes or medications that could reduce risk. Common treatment recommendations included smoking cessation and increased use of statin or antihypertensive therapy.

Among high- and medium-risk beneficiaries, CVD medication initiation and intensification increased during the first year of enrollment in both the intervention and control groups, but increases were modestly larger (by 4 percentage points, $p < 0.001$) in the intervention group

Figure ES.2. Intervention group beneficiaries had higher rates of CVD medication use: Percentage of high- and medium-risk beneficiaries who initiated or intensified CVD medications within one year of model enrollment



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

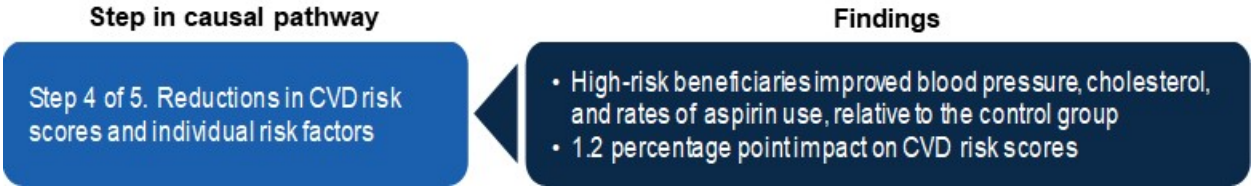
Note: CVD medications include statins and antihypertensive medications. Results are regression adjusted.

(Figure ES.2). The differences between the intervention and control groups in the first year of enrollment persisted for as long as we observed the beneficiary follow-up period for these outcomes, up to 2.5 years.

Under the Million Hearts Model, CMS required intervention organizations to follow up with their high-risk beneficiaries at least twice per year. This follow-up could be in person, by phone, or by email. During these contacts, providers or other clinical staff discussed and encouraged progress on reducing CVD risk. The Million Hearts Model appeared to have modestly increased follow-up, including office visits. For example, in the 2018 provider survey, 58 percent of intervention group providers reported following up with high-risk beneficiaries about CVD risk reduction plans at least once every three months, compared to 43 percent of control group providers ($p < 0.019$).

CMS also expected an annual, in-person risk reassessment for each high-risk beneficiary. However, the intervention organizations reported risk reassessment data for only 57 percent of eligible high-risk beneficiaries, on average, well short of CMS's initial goal of 95 percent.

E. Reductions in cardiovascular risk

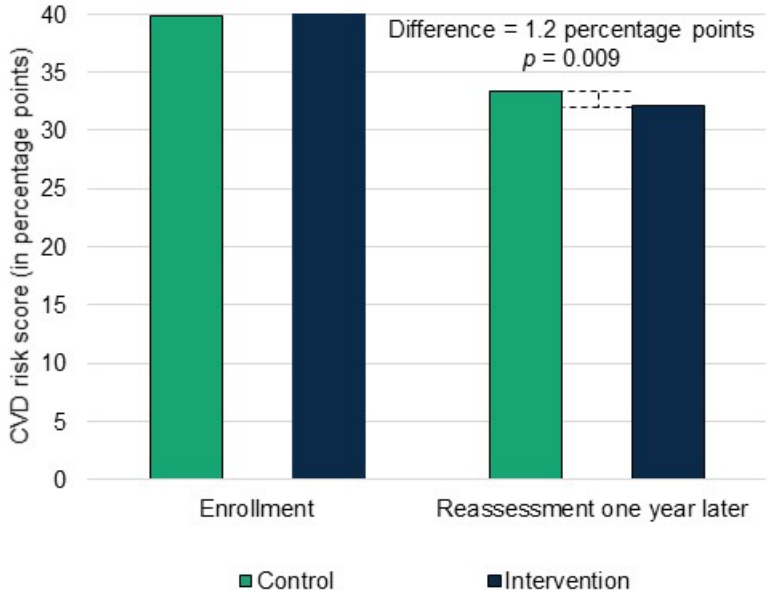


One year after enrollment, CVD risk scores had decreased for high-risk beneficiaries with reassessment data in both the intervention and control groups. (The change in risk score was calculated using the Million Hearts Longitudinal ASCVD Risk Assessment Tool.) These risk score declines occurred largely due to decreases in blood pressure, but also from decreases in low-density lipoprotein cholesterol, increases in aspirin use, and small decreases in smoking prevalence. However, CVD risk scores decreased modestly more in the intervention group (8 percentage points) than in the control group (7 percentage points). (For this analysis, unlike the others, we focused on high-risk beneficiaries only. Intervention organizations were not required to submit reassessment data for other beneficiaries.) After regression adjustment, the Million Hearts Model reduced high-risk beneficiaries' 10-year predicted risk of a heart attack or stroke

by 1.2 percentage points ($p = 0.009$; Figure ES.3). Contributing to this impact on average CVD risk scores, the Million Hearts Model achieved modest impacts on blood pressure and cholesterol levels, with reductions of about 1 percent for each, and a substantial impact (a 10 percentage-point increase) in the use of aspirin therapy.

On average, the beneficiaries who initiated or intensified antihypertensives or statins experienced larger reductions in risk scores than those who did not, and this was true in both the intervention and control groups. Nevertheless, the impact of the Million Hearts Model on these medications, as well as on aspirin use, likely explains some but not all of the observed difference between the intervention and control groups in blood pressure, cholesterol levels, or CVD risk scores. Other possible explanations for impacts on CVD risk scores and risk factors could include increased medication adherence, use of nonstatin medications to lower cholesterol, or lifestyle modification.

Figure ES.3. Beneficiaries' CVD risk scores improved modestly more in the intervention group than in the control group: Estimated impacts on CVD risk scores one year after enrollment, among high-risk beneficiaries with reassessment data in 2017 or 2018

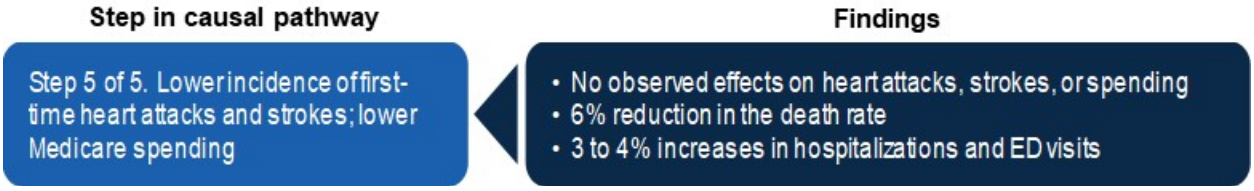


Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare claims and enrollment data.

Note: Mean values at enrollment are the actual means observed; the means at reassessment and differences are regression adjusted. The analytic population is limited to the roughly 50 percent of high-risk beneficiaries eligible for a reassessment visit by the end of 2018 who had reassessment data recorded in the Million Hearts Data Registry.

CVD = cardiovascular disease.

F. Impacts on heart attacks and strokes, mortality, service use, and spending



1. CVD events

From January 2017 to October 2019, the incidence of first-time heart attack, stroke, or transient ischemic attack (TIA) was similar for the intervention and control groups. Among the intervention group's high- and medium-risk beneficiaries, 2.7 percent had a first-time heart attack, stroke, or TIA within two years of enrollment, compared to 2.8 percent in the control group. In regression analyses, we estimated the hazard ratio—that is, the ratio in the risk of having a first-time CVD event in the intervention versus control groups. This estimate was 1.00, indicating no model effect (p = 0.90, 90 percent confidence interval of 0.95 to 1.04).

2. Mortality

Among high- and medium-risk beneficiaries, the death rate was 6 percent lower in the intervention group than in the control group (p = 0.007). Before regression adjustment, 3.9 percent of beneficiaries in the intervention group died within two years of enrollment, compared to 4.2 percent in the control group—a difference of about three deaths per 1,000 people over two years. This observed impact was surprising because the impacts on mortality occurred without a corresponding reduction in CVD events measured in Medicare claims data. We expected reductions in fatal hearts attacks or strokes would, at least partly, drive any impacts on survival. At least three potential explanations exist for these impacts on survival, and all three are consistent with the available evidence:

1. The model could have prompted beneficiaries to go to the hospital at early signs of a CVD event and this could have prevented some deaths. In that case, we would observe reductions in the death rate, as we have. We did not see corresponding reductions in CVD events (that is, heart attacks, strokes, and TIAs) as measured using Medicare claims data. However, events that go untreated do not generate claims. Thus, if the model prompted beneficiaries to go to the hospital earlier than they would have otherwise when experiencing a CVD event, we might observe claims for the intervention beneficiaries who went to the hospital quickly but not for control group beneficiaries who died outside the hospital.
2. There could be reductions in the death rate from other conditions due to improvement in exercise or diet, medication therapy, or mechanisms we did not anticipate at the beginning of the evaluation. One such mechanism could be that, because the model encouraged beneficiaries to have more office visits, providers might have been more likely to detect and address other health conditions.

3. Finally, the impact estimates could reflect systematic differences between the intervention and control groups and not true impacts. Our careful use of regression adjustment and robustness checks alleviates—but does not rule out—this concern. Differences between the intervention and control beneficiaries could have either existed at random assignment or been introduced during model implementation by organization- and provider-level attrition or by differences in the types of beneficiaries intervention and control organizations chose to enroll among their eligible beneficiaries.

3. Service use

Among high- and medium-risk beneficiaries, CVD-related service use was similar between the intervention and control groups, but the intervention group had rates 3 to 4 percent higher than the control group's for all-cause hospitalizations and ED visits. For example, through October 2019, there were 14.0 CVD-related hospitalizations per 1,000 beneficiaries per quarter in the intervention group, compared to 13.7 in the control group (p = 0.29). But looking at hospitalizations for any cause, the intervention group rate of 64.5 per 1,000 beneficiaries per quarter was 4 percent higher than the control group rate of 62.2, a difference that was statistically significant (p = 0.009).

The finding that the Million Hearts Model increased acute care service use is counter to our hypotheses that the model might reduce acute care. This implies some other factor, which we did not hypothesize, explains why the model increased acute care use. For example, the model might have made people more engaged with the health care system generally, so that beneficiaries received care for a broader array of clinical issues than they otherwise would have. (As noted previously, this is also a potential explanation for the unexpected impacts on mortality.)

4. Medicare spending

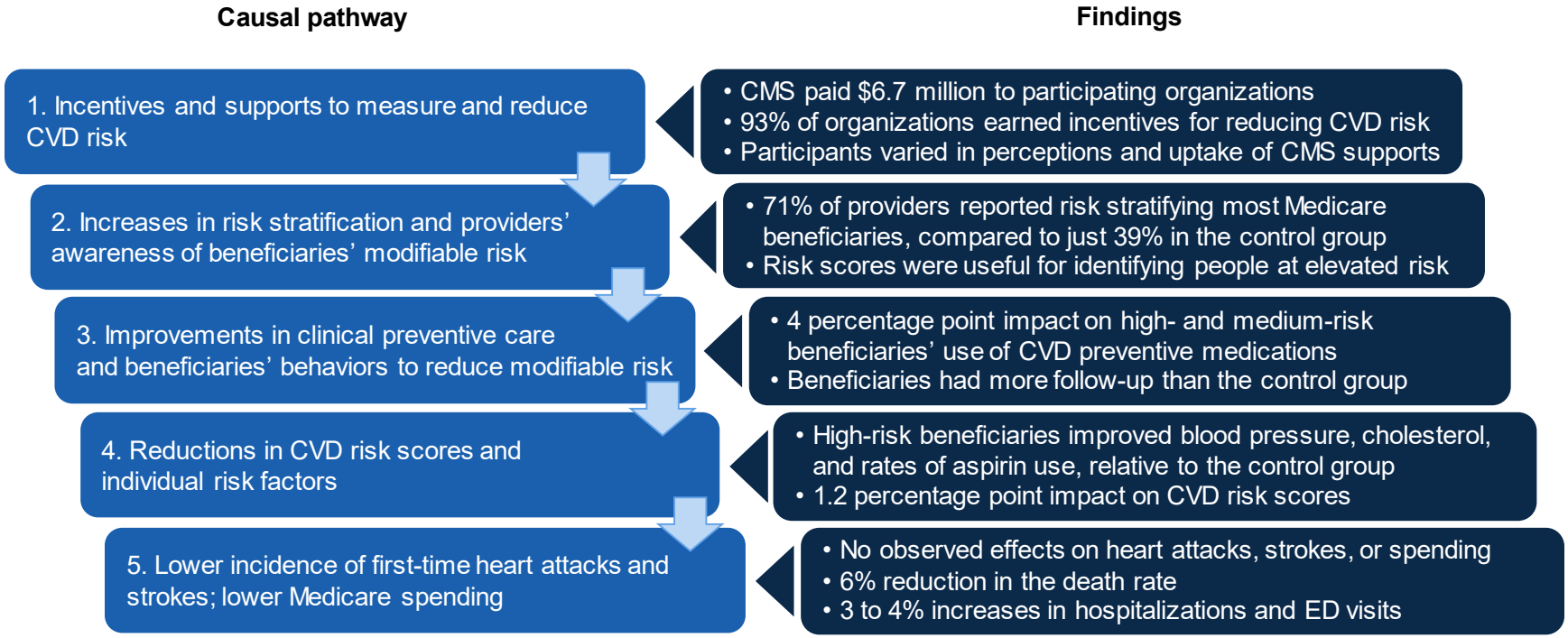
Medicare spending after enrollment was similar for intervention and control group beneficiaries through October 2019. The regression-adjusted mean spending among high- and medium-risk beneficiaries in the intervention group was $903 per beneficiary per month, compared to $898 per beneficiary per month in the control group. This difference was not statistically different from zero (p = 0.69). This finding is consistent with the lack of observed impacts on CVD events, the hypothesized mechanism for lower spending. Because the model did not reduce Medicare Parts A and B spending, it did not generate savings to offset model payments. (The small increases in spending we would expect from observed increases in hospitalizations are within the margin of error of our spending estimates.)

G. Consistency of the findings across outcomes

Together, these findings tell a consistent story: The Million Hearts Model achieved large impacts on rates of risk stratification, but the impacts grew smaller with each step along the causal pathway. Figure ES.4 summarizes the findings. These findings are also consistent with those from similar studies. For example, a 2017 Cochrane review found that using CVD risk scores for CVD primary prevention (1) increased use of statins and antihypertensive medications, (2) modestly reduced CVD risk scores and individual risk factors, and (3) had little to no effect on

CVD events (Karmali et al. 2017). Nonetheless, the studies included in that review had smaller sample sizes and typically shorter follow-up than planned for the Million Hearts Model. In future reports, we will estimate the impact of the Million Hearts Model over its full five years to assess whether observed improvements in CVD preventive care eventually translate into measurable reductions in CVD events.

Figure ES.4. Causal pathway for the Million Hearts Model, with key findings through 2019



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

I. INTRODUCTION

Although many risk factors for cardiovascular disease (CVD) have declined substantially in the past several decades, CVD remains a leading cause of death and disability in the United States (Virani et al. 2020). Improvements in diet and exercise, smoking cessation, and appropriate use of preventive medications could substantially reduce the burden of CVD (Karmali et al. 2016; Yusuf et al. 2020). In 2017, the Centers for Medicare & Medicaid Services (CMS) launched the Million Hearts® Cardiovascular Disease Risk Reduction Model to reduce the incidence of first-time heart attacks and strokes among Medicare beneficiaries (Sanghavi and Conway 2015). In this pay-for-prevention model, CMS pays providers (1) to assess each of their Medicare beneficiaries' risk of having a heart attack or stroke over 10 years, using a formal risk assessment tool (Goff et al. 2013); and (2) for reducing that risk among their high-risk beneficiaries (those with a 30 percent or higher predicted risk). CMS is testing the model in a large, five-year randomized trial that includes primary care and cardiology practices, health centers, and hospitals throughout the country. If the model successfully reduces CVD events—and reduces Medicare spending enough to offset model payments—CMS might expand the model, making it part of how Medicare funds primary prevention for CVD nationally.

The Million Hearts Model is part of the broader Million Hearts Initiative, which the U.S. Department of Health and Human Services launched in 2012 to prevent one million heart attacks and strokes within five years (Centers for Disease Control and Prevention [CDC] 2012; Wall et al. 2018). This campaign has included public health initiatives to increase awareness of CVD risk and clinical initiatives to increase the use of aspirin when appropriate, blood pressure control, cholesterol management, and smoking cessation (the ABCS of CVD prevention).

A. Model goals and design

The Million Hearts Model has two primary goals. The first is to decrease the incidence of first-time heart attacks and strokes among high- and medium-risk Medicare fee-for-service (FFS) beneficiaries over five years. The second goal is to decrease Medicare Part A and B spending on CVD events enough to fully offset model payments.

To meet these goals, CMS is providing both broad guidelines for how intervention organizations should provide CVD preventive care and targeted incentives and supports for organizations to reduce CVD risk.

Guidelines for CVD preventive care. When they joined the model, organizations agreed that—if they were randomly assigned to the intervention group—they would do the following (CMS 2016):

- **Calculate each of their eligible Medicare FFS beneficiaries' risk of having a heart attack or stroke over 10 years.** Beneficiaries are eligible for the Million Hearts Model if they are ages 40 to 79, have not already had a heart attack or stroke, do not have end-stage renal disease, and are not enrolled in hospice. Beneficiaries are considered to be at high risk if their predicted 10-year CVD risk (referred to as the *risk score*) is at least 30 percent, at

medium risk if their risk score is from 15 to 30 percent, and at low risk if it is less than 15 percent.

- **Provide cardiovascular care management services to high-risk patients.** These services include (1) meeting with beneficiaries to discuss their risk scores and risk factors driving the scores; (2) jointly developing individualized plans for reducing risk that reflect both the efficacy of different treatment options and beneficiaries' goals and priorities; (3) reassessing the beneficiary's risk each year, using a longitudinal tool designed specifically for the model (Lloyd-Jones et al. 2017); and (4) following up with the patient at least twice each year to gauge and encourage progress in reducing CVD risk.

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

Although CMS set broad guidelines for how intervention organizations would provide CVD preventive care, the model does not prescribe how organizations should reduce risk. For example, organizations might reduce risk through increasing the use of CVD preventive medications, or through encouraging changes in diet or exercise. Some organizations might choose to offer wholly new services—such as smoking cessation classes—if enough of their at-risk Medicare beneficiaries would benefit from them.

Incentives and supports. CMS pays organizations $10 for each eligible Medicare FFS beneficiary the organizations risk stratify. For the first year of the model, 2017, CMS also paid organizations $10 per high-risk beneficiary per month for providing cardiovascular care management services. Starting in 2018, CMS has paid $0 to $10 per high-risk beneficiary per month depending on how successful the organization is in reducing the average risk score for all of its high-risk beneficiaries assessed during the relevant period. Specifically, CMS pays $10 per month if the average CVD risk score for high-risk beneficiaries declines from baseline by more than 10 percentage points; $5 if the score declines by 2 to 10 percentage points; and $0 if it declines by less than 2 percentage points. CMS pays control organizations for sharing clinical data from model-eligible beneficiaries and did not ask those organizations to calculate risk scores or change their CVD preventive care. To limit its outlays, CMS allowed up to 20 providers in each control organization to enroll beneficiaries but did not apply a similar cap to the intervention group.

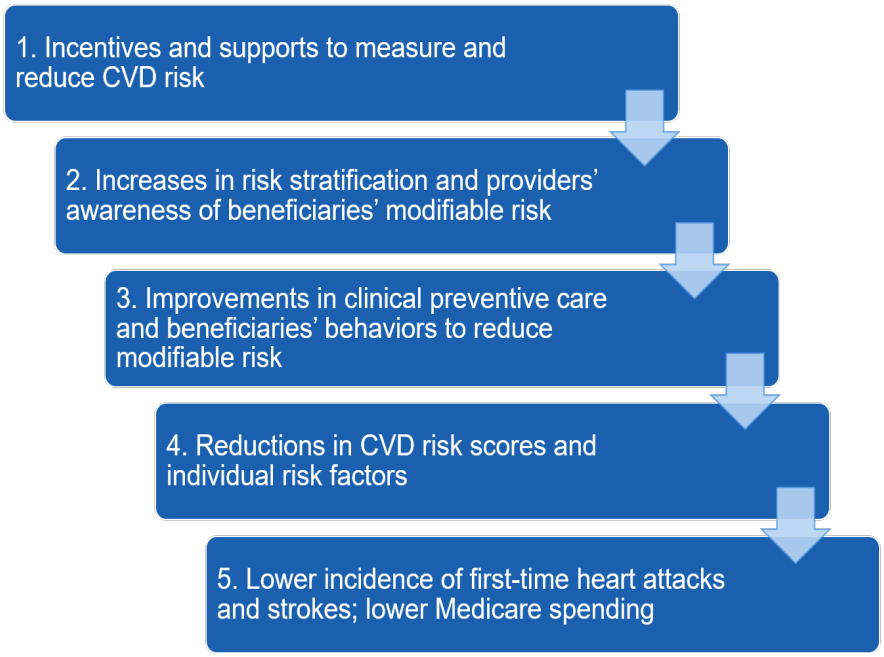
CMS also offers intervention organizations several tools and supports to help them improve their CVD preventive care and meet reporting requirements. CMS sends organizations semiannual reports describing their performance enrolling beneficiaries and reducing CVD risk. CMS also offers peer-to-peer learning sessions to encourage organizations to share strategies for implementing the model and expects organizations to attend these sessions at least once each quarter. In addition, CMS created the Million Hearts Data Registry, a secure portal where intervention and control organizations were required to submit the clinical and demographic data needed to calculate a beneficiary's CVD risk. Via the registry, intervention organizations have access to the Million Hearts Longitudinal Atherosclerotic Cardiovascular Disease (ASCVD)

Risk Assessment Tool—a novel tool developed for the Million Hearts Model to track changes in CVD risk over time, based on evidence from clinical trials that links changes in heart attack and stroke rates to changes in CVD risk factors (Lloyd-Jones et al. 2017). Under this tool, a person's initial risk score is the same as calculated under the previously existing ACC/AHA ASCVD Risk Estimator (Goff et al. 2013). However, because the new tool can estimate risk *change* for a given individual over time, CMS uses this tool when estimating risk reduction, the basis of the Million Hearts Model risk reduction payments.

B. Causal pathway: From incentives and supports to reductions in heart attack and strokes

Based on model documents and discussions with CMS staff, we developed a causal pathway (Figure I.B.1) that describes how the model, if it is working as intended, could reduce heart attacks and strokes and reduce Medicare spending enough to offset model payments. We describe each step of the causal pathway after the figure.

Figure I.B.1. Causal pathway for the Million Hearts Model



1. **CMS provides incentives and supports for risk stratification and risk reduction.** Specifically, CMS pays organizations for each eligible Medicare FFS beneficiary they risk stratify, for providing cardiovascular care management for high-risk beneficiaries (in 2017), and for reducing risk among high-risk beneficiaries (2018 to 2021). The supports include peer-to-peer learning, feedback reports, and access to a tool that estimates how much different therapies would reduce risk for individual beneficiaries.
2. **Providers are more likely to 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 should make 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, and so 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 their patients' CVD risk, providers become more likely to meet with beneficiaries to discuss their risk scores, the factors driving their risk, and options for reducing the risk. Further, through a process of shared decision making, providers and beneficiaries develop individualized care plans to reduce risk 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 these initial discussions with their providers, beneficiaries will become more aware of their risk, and more willing to start new medications or change their behavior in ways that reduce their risk. As a result, we would expect to see increases in the use of CVD medications, adherence to medications, smoking cessation, or improvements in diet or exercise. Further, the model should increase 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 would 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 would 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 should reduce overall cardiovascular risk, as well as individual risk factors.** These improvements should lead to lower CVD risk scores during the annual reassessment visits for high-risk beneficiaries. We would also expect lower risk scores among medium-risk beneficiaries, although intervention group organizations do not submit the clinical data needed to assess whether these improvements occur.
5. **The reductions in CVD risk should, by the end of the five-year test, reduce the incidence of first-time heart attacks and strokes and reduce Medicare spending.** Specifically, CMS anticipated the model would reduce first-time heart attacks and strokes among high- and medium-risk beneficiaries by at least 7 percent. Reductions of this size should 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.

For the Million Hearts Model to have its intended impacts on heart attacks and strokes, it is not necessary for all model participants to meet all model requirements. Instead, the causal pathway hinges on *changes* in care. An organization could miss one or more requirements (for example, a

requirement to risk stratify at least 90 percent of eligible beneficiaries) and still make substantial improvements in risk stratification and risk reductions that drive reductions in heart attacks and strokes. At the same time, however, an organization might meet the model requirements without making any changes described in the causal pathway. For example, it could have high rates of risk stratification without becoming *more likely* to risk stratify (Step 2 of the causal pathway) or working with beneficiaries *more closely and consistently* to reduce CVD risk (Step 3). In that case, the organization would not be making the changes needed to change rates of heart attack and stroke. Throughout this report, we focus on the changes organizations made as a result of the model.

Because CMS expected impacts among high- *and* medium-risk beneficiaries to make the model cost-neutral to Medicare, we consider the high- and medium-risk beneficiaries as the primary population for the evaluation for all outcomes, unless otherwise noted.

C. Evaluation goals and methods

The evaluation assesses whether and how the Million Hearts Model improves CVD preventive care, reduces first-time heart attacks and strokes, and lowers Medicare spending enough to offset model payments. To meet this goal, we used a mix of data sources and methods:

- **Interviews with model participants.** We conducted three rounds of interviews (in 2018, 2019, and 2020) with 10 to 15 intervention organizations per round. We selected organizations representing a range of sizes, locations, and types (for example, primary care and cardiology practices). Each round generally followed the same organizations so that we could track changes in model implementation over time; however, in later rounds, we replaced some organizations that withdrew from the model with organizations we had not interviewed before. During interviews, we asked about strategies participants used to implement the model, the ways (if any) the model differed from their standard care before model launch, barriers to and facilitators of change, and their perceptions of the model's effects on clinical care and patients' self-care.


Interviews

- **Provider survey.** In 2018, we surveyed randomly selected providers in each of the intervention and control organizations enrolling beneficiaries and asked questions about CVD preventive care: for example, how often they risk stratified their patients. More than two-thirds (70 percent) of surveyed providers responded to the survey, representing 90 percent of organizations. We estimated model impacts on self-reported CVD preventive care as the regression-adjusted differences in providers' responses. We also asked intervention group providers additional questions about their perceptions of the model and its effects. For methodological details about survey fielding and analysis, please see Appendix E of the second annual report (Peterson et al. 2019).


Provider survey

- **Practice survey.** In 2018, we also surveyed the person designated by each intervention organization as the lead for overseeing the model there. This person might be a clinician, an office manager, or other administrative lead. The survey asked about how the organization implemented the model, barriers to and facilitators of implementation, and perceptions about the model's effects on CVD preventive care. Almost all (91 percent) of the intervention organizations still participating in the model at the time of fielding responded to the survey.

- **Registry.** We used clinical and demographic data from the Million Hearts Data Registry to identify Medicare beneficiaries enrolled into the model by the intervention and control organizations in 2017 and 2018. These data include information on the beneficiaries' baseline characteristics (including their CVD risk scores and risk factors) to assess the degree to which risk was due to modifiable factors such as elevated blood pressure versus unmodifiable ones such as age. We also used reassessment data submitted to the registry in 2017 and 2018 to assess whether the model reduced CVD risk scores.

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

- **Medicare claims and enrollment data.** We used Medicare Parts A and B claims and the Medicare Enrollment Database 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 also used these data to define a beneficiary's characteristics when the beneficiary enrolled in the model (for example, age and the presence of certain chronic conditions). We used these characteristics to describe the population the model served, assess the degree of similarity between the intervention and control groups, and as covariates in regression models estimating the impacts of the Million Hearts Model. Finally, we used Medicare Part D claims to assess whether the model increased the initiation or intensification of statins to lower cholesterol or antihypertensive medications to lower blood pressure. By design, all beneficiaries enrolled in the Million Hearts Model were Medicare FFS beneficiaries with Part A and B coverage. About 70 percent also had Part D coverage.

This third annual report integrates the findings from these different data sources, and we have organized it around the causal pathway. After an initial chapter describing the participating organizations and their number of enrolled beneficiaries, each chapter of the report corresponds to a step in the pathway. The report is cumulative, presenting key findings from the first three years of the Million Hearts Model. The main new analyses in this report since the second annual report (Peterson et al. 2019) are as follows: (1) a third round of interviews (in 2020), (2) extending the period for assessing model participation and payments by one year (through 2019), (3) adding beneficiaries enrolled in 2018 into the population used for the impact evaluation, (4) estimating model impacts on CVD risk scores and CVD risk factors, (5) extending the analysis

of impacts on CVD preventive medications from six months to one year after enrollment, and (6) extending the outcome period for CVD events and all other Parts A and B claims-based outcomes by 12 months (from October 2018 to October 2019). The impact estimates on the final outcomes of CVD events and spending now cover almost three years of the full planned five years of the model test.

II. PARTICIPATING ORGANIZATIONS AND THE BENEFICIARIES THEY ENROLLED

A. Summary of participating organizations

Key findings

The Million Hearts Model randomly assigned 516 organizations. Among them, 345 participated in the first two model years, meaning they enrolled at least one beneficiary in 2017 or 2018. Participating organizations varied in their location, size, organization type, and experience with CMS initiatives before the model launched, but the intervention and control groups were similar, on average, across these characteristics.

In 2015 and 2016, CMS solicited applications from eligible organizations throughout the country. Organizations were eligible 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 also signed a Model Participant Agreement describing 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.

About two-thirds (345) of the 516 organizations that joined the Million Hearts Model participated in the first two years of the model by enrolling at least one Medicare beneficiary. Even though one-third of randomly assigned organizations did not participate, the number of participating organizations remained the same between the intervention and control groups, with half in the intervention group (173 organizations) and half in the control group (172 organizations). (Section B describes factors associated with participants' attrition.)

The participating intervention organizations included primary care practices, cardiology practices, health centers, and hospital outpatient departments throughout the country (Table II.A.1). About half of the organizations also participated in or had applied to at least one other CMS initiative when they applied for the model, mostly commonly the Medicare Shared Savings Program. Despite early attrition from the model, the 172 organizations assigned to the control group were similar to the intervention group organizations across most of these characteristics. The biggest difference between the two was in the mean number of providers. Another difference was that intervention organizations were more likely than control organizations to participate in the Medicare Shared Savings Program (29 versus 22 percent).

Table II.A.1. Organizations assigned to the control group were similar to the intervention group organizations: Characteristics of organizations that enrolled at least one beneficiary in the Million Hearts Model from January 3, 2017, to December 31, 2018

Characteristic	Intervention organizations (N 173)	Control organizations (N 172)	Difference (in percentage points)
Size (from Million Hearts Model application)			
Number of providers, mean	38	49	-11.3
1 to 5 providers (%)	35	31	3.9
6 to 19 providers (%)	28	32	-4.2
20 or more providers (%)	37	37	0.4
Number of sites, mean	8	7	0.7
1 site (%)	39	35	3.3
2 to 5 sites (%)	31	33	-1.3
6 or more sites (%)	30	32	-1.9
Location (from Million Hearts Model application)			
Rural (%)	46	47	-0.8
Census region (%)			
Northeast	30	24	6.2
Midwest	17	20	-3.6
South	38	40	-2.0
West	15	16	-1.3
Organization type[a]			
Primary care (%)	52	55	-3.2
Specialty or multispecialty (%)	23	20	2.2
FQHC, RHC, or other health center (%)	15	15	0.5
CAH or rural hospital (%)	3	5	-2.3
Acute care hospital (%)	8	5	2.9
Participating in other CMS models or programs when applied for the Million Hearts Model[b]			
In one or more model (or application pending at random assignment) (%)	51	49	2.0
In Medicare Shared Savings Program (%)	29	22	8.0
In Advance Payment ACO (%)	5	5	0.6
Applied for ACO Investment Model (%)	8	12	-4.1
In CPC Initiative (%)	3	7	-4.1
In Bundled Payments for Care Improvement (%)	6	5	1.7
Applied for TCPI (%)	4	5	-1.2

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

Note: The number of participating organizations (345) is greater than in thesecond annual report (Peterson et al. 2019) largely because the second annual report covered participation only through 2017. Some organizations enrolled beneficiaries for the first time only in 2018.

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

[b] For the purpose of this table, we coded organizations as not participating in other CMS models if they responded on the application that they didn't know.

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

B. Reasons organizations participate

Key findings

Organizations joined the Million Hearts Model primarily because they viewed CVD risk management as a priority and the model fit with existing workflows, clinical care approaches, and health information technology (IT) systems. CMS payment was also an important factor for many organizations. Nevertheless, model participation declined considerably over time. About 40 percent of the 516 organizations initially randomly assigned withdrew from the model by November 2019, with some of those remaining no longer reporting data to CMS. For organizations that withdrew, the most common reasons for leaving included not perceiving incentives as commensurate with the work required, a lack of staff, and challenges uploading required data to the Million Hearts Data Registry.

1. Reasons organizations joined the model


Interviews

Nearly all organizations we interviewed reported joining the model—at least in part—because the vision of care aligned with their existing organizational goals to prevent CVD and improve quality of care. For example, about two-thirds of intervention organizations said their providers already used a CVD risk calculator and provided care management services for some beneficiaries before joining the Million Hearts Model. The model required those organizations to implement services more systematically across all beneficiaries, but did not require major changes to software or staff training.

> "This Million Hearts [Model] ties in pretty nicely with our CPC+ initiatives that we do. And so it's all part of our quality program. If they had totally different goals, it would be much more difficult.…"
>
> *—Frontline provider*

As described in the first and second annual reports (Conwell et al. 2019; Peterson et al. 2019), about two-thirds of intervention organizations also reported joining the model because it was compatible with their existing workflows and clinical care approaches, and this made implementing the model easier. In particular, about one-third of intervention organizations reported that their health IT and data management capabilities were well suited to meet the model requirements. For example, organizations said their EHR software and health IT staff helped them to meet requirements related to sharing data with CMS through the Million Hearts Data Registry. About one-third of intervention and control organizations also participated in other quality improvement initiatives before or alongside the Million Hearts Model, including initiatives led by CMS, such as Comprehensive Primary Care Plus (CPC+). Prior experience with quality improvement programs helped organizations implement the model if they already had infrastructure in place, such as health IT and adequate staffing, needed to perform the clinical processes required by the model and to report progress to CMS.

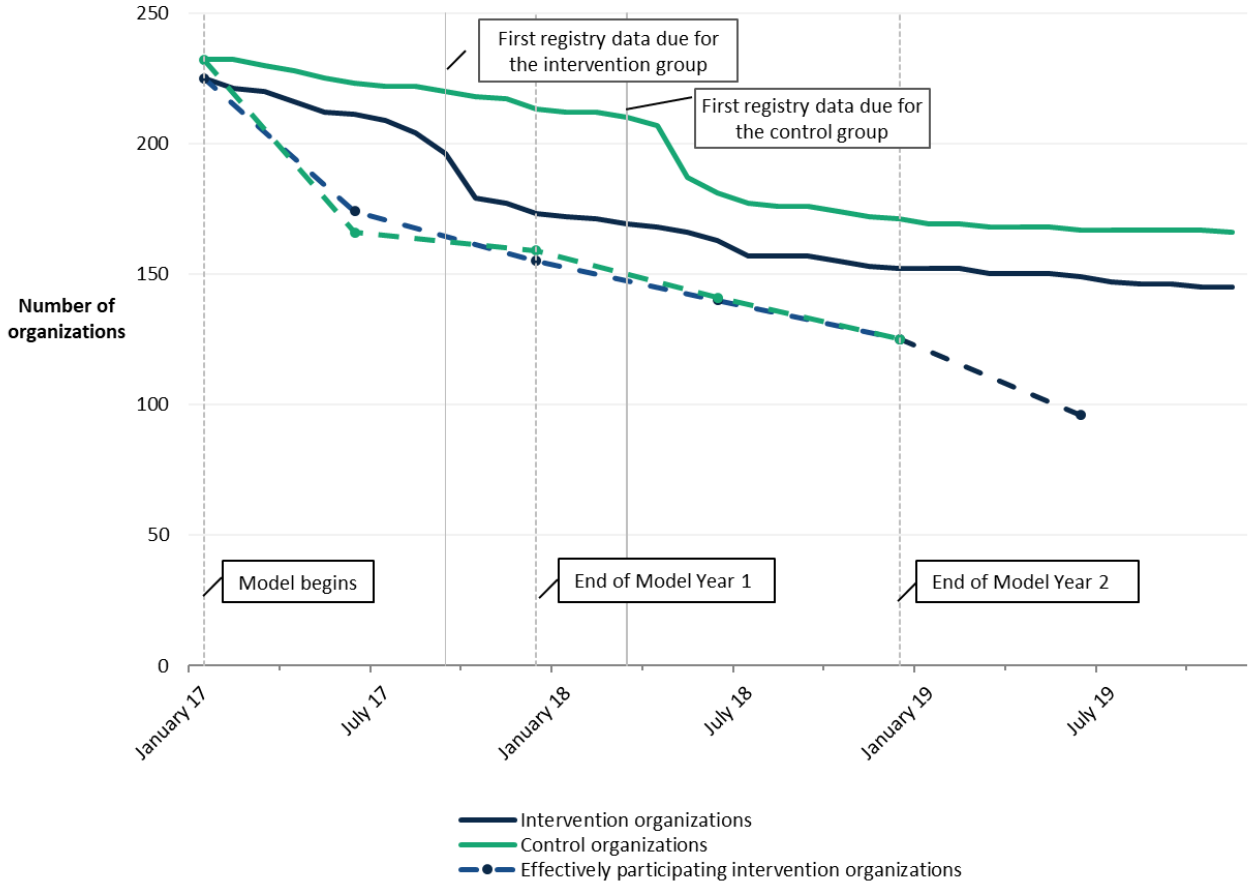
For many organizations, payment incentives contributed to the decision to participate in the Million Hearts Model, although organizations rarely mentioned payments as the primary motivating factor. Among respondents to the practice survey we fielded in 2018, 60 percent of organizations agreed that payments were important to the organization's decision to join the model, with about one-third strongly agreeing. At the same time, of the 14 organizations we interviewed in 2019, about half said that although financial incentives played a role in their decision, the incentives were not their primary motivation for joining the model. Rather, the goals of the model aligned with other organizational goals and staff felt it was the right thing to do for their patients. Chapter III further describes organizations' perceptions of incentive payments.

2. Model retention

Withdrawal from the Million Hearts Model was highest following the initial random assignment in 2016 and through the first model year (2017), leveling off after that (Figure II.B.1). Of the 516 organizations randomly assigned, 457 (89 percent) had not withdrawn by the model launch on January 3, 2017. Through November 2019, 311 remained in the model, meaning that CMS had not terminated them and they did not voluntarily withdraw. As shown in Figure II.B.1, participation in the intervention group (the solid blue line) dipped in the summer of 2017. That decline corresponded to the first time intervention-group organizations had to upload data to the Million Hearts Data Registry. The control group must provide data only once per year, although many participants in both groups chose to upload more frequently. As with the intervention group in mid-2017, control group participation (the solid green line) dipped in early 2018, the first time that that group had to upload data. By November 2019, the number of organizations remaining in the model was somewhat lower for the intervention group (145 organizations, or 56 percent of those randomly assigned) than the control group (166 organizations, or 65 percent).

Some organizations did not formally withdraw from the model and CMS did not terminate them, yet they no longer appeared to be active in the model as of late 2019. We therefore defined an organization as *effectively participating* in a performance period if the organization (1) had not withdrawn from the model or been terminated by CMS, and (2) uploaded data to the Million Hearts Data Registry for at least one visit that occurred in the performance period. As shown in Figure II.B.1, rates of effective participation (dotted lines) are very similar between the intervention and control groups through December 2018, even though formal withdrawals (solid lines) were more common in the intervention group than the control group. The figure shows effective participation in the intervention group through June of 2019 but only through December 2018 for the control group, because the control group has to provide data only once per year. Although CMS considers the model participants on a given date to be all organizations that had not withdrawn or been terminated by that date, for the purpose of this report, we consider participants to be the 345 organizations that effectively participated *at any time* in the first two model years—that is, enrolling at least one beneficiary in 2017 or 2018.

Figure II.B.1. Rates of effective participation were very similar between the intervention and control groups: Participation in the Million Hearts Model from model launch to November 2019, by intervention and control group



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

Note: We consider an organization to be *effectively participating* in a performance period if it submitted data for at least one visit occurring in the period. An organization could effectively participate in a period without effectively participating in the previous one. However, this was not common.

CMS = Centers for Medicare & Medicaid Services.

> "[We] agree with [the] approach to patient care but without the administrative oversight that is becoming a burden to the organization. [We] plan to continue with changes made to clinical care, dedicated to improving cardiovascular health."
>
> *—Written comment from withdrawing organization*

Interviews

As reported in the first and second annual reports (Conwell et al. 2019; Peterson et al. 2019), organizations that stayed in the model said they did so because they thought the model of care was right for their patients and because they could fit the model requirements into their existing workflows. These reasons are very similar to those given for joining the model in the first place, described previously. The reasons organizations voluntarily left the model were similar in all model years (2017–2019), mainly that organizations did not think the financial incentives were

commensurate with the work required[1] and they felt they did not have adequate staff to comply with the model requirements anymore. (In 2016, before the model launch, CMS also terminated several organizations that did not sign an update to the Model Participation Agreement.) Other common reasons for withdrawing included changes in organizational priorities and—especially in the first year of the model (Figure II.B.1)—challenges uploading required data elements to the Million Hearts Data Registry. Although several organizations have withdrawn, many recognize that the model has been helpful for the care of their patients. For example, two organizations that withdrew in 2019 volunteered that although they could not meet the administrative requirements of the model, they plan to continue risk stratifying their patients even after withdrawing.

C. Beneficiary enrollment through December 2018

Key findings

During the first two years of the model, participating intervention and control organizations enrolled 388,001 Medicare FFS beneficiaries, with 82 percent enrolled in 2017 and 18 percent in 2018. About one-sixth of beneficiaries enrolled by the intervention and control organizations were at high risk—that is, with a 10-year predicted probability of heart attack or stroke of 30 percent or more.

Organizations enroll beneficiaries during routine office visits. We describe the intervention organizations' efforts to risk stratify and enroll beneficiaries in Chapter IV (covering Step 2 of the causal pathway), but here we briefly describe enrollment numbers for both the intervention *and* control groups, as this provides context for all chapters that follow. To enroll beneficiaries, intervention and control organizations must collect the demographic and clinical data needed to calculate a beneficiary's CVD risk at the time of the visit. They report these data to CMS via the Million Hearts Data Registry, which shows CVD risk scores for intervention group beneficiaries but does not show them for control group beneficiaries. When CMS confirms that an organization has submitted all the required data, it considers the beneficiary enrolled in the model. A beneficiary's enrollment date is the date of his or her office visit.

During the first two years of the model, intervention and control organizations enrolled 388,001 Medicare beneficiaries (Table II.C.1): 230,664 in the intervention group and 157,337 in the control group. Enrollment was substantially lower in the control group than the intervention group because of the 20-provider cap that CMS placed on control organizations, which did not apply to the intervention organizations. High-risk beneficiaries—that is, those with a 10-year predicted probability of heart attack or stroke of 30 percent or more—comprised about one-sixth of the beneficiaries enrolled by the intervention and control organizations. The percentage of

[1] CMS expected organizations to risk stratify at least 90 percent of eligible Medicare FFS beneficiaries and to provide clinical, demographic, and visit data for these beneficiaries. CMS further expected organizations to provide annual reassessment data for at least 95 percent of high-risk beneficiaries enrolled.

beneficiaries in each of the risk groups was very similar between intervention and control organizations.

As expected, enrollment in 2018 was lower than in 2017 for both the intervention and control organizations (Table II.C.1) because the model specifies that organizations should enroll all eligible Medicare FFS beneficiaries at first contact. This limited enrollees in 2018 to beneficiaries new to the organization or new to FFS Medicare, those who visited the organization infrequently, or beneficiaries with visits in 2017 that might have been missed. Overall, across the intervention and control groups, 82 percent of beneficiaries had enrollment dates in 2017 and 18 percent had enrollment dates in 2018. Beneficiaries newly enrolled in the model in 2018 tended to be at slightly lower risk than those enrolled in 2017 in both the intervention and control organizations, in part because the population includes younger individuals who aged into the Medicare population in 2018.

Table II.C.1. Enrollment was greater in 2017 than 2018, but, in both years, the risk profile was similar between the intervention and control groups: Number of Medicare beneficiaries enrolled by intervention and control organizations from January 2017 to December 2018, overall and by CVD risk level

	Enrollment in 2017		Enrollment in 2018	
	Intervention group	Control group	Intervention group	Control group
Number of enrolling organizations	171	164	134	140
Number of beneficiaries	189,605	128,414	41,059	28,923
Low risk	80,216 (42%)	54,706 (43%)	18,901 (46%)	13,579 (47%)
Medium risk	75,022 (40%)	50,611 (39%)	15,775 (38%)	10,927 (38%)
High risk	34,367 (18%)	23,097 (18%)	6,383 (16%)	4,417 (15%)

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 to 30 percent. Low CVD risk is less than 15 percent. Risk is measured as of a beneficiary's enrollment date in the Million Hearts Model.

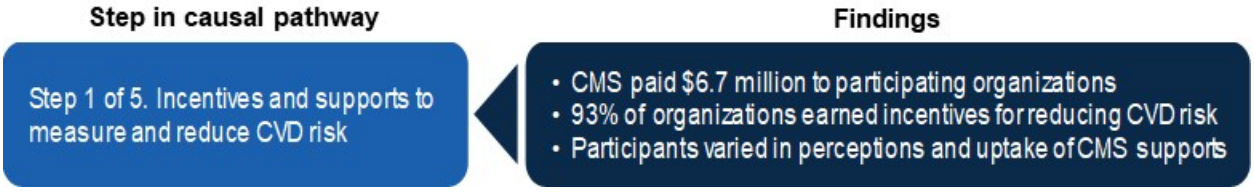
CVD = cardiovascular disease.

Appendix A describes our methods for defining the enrolled population in more detail, including how the full population (Table II.C.1) relates to the subset used to estimate impacts of the Million Hearts Model on beneficiaries' outcomes, including CVD risk factors, use of statins and antihypertensives, heart attack and stroke rates, and Medicare spending (Chapters V through VII). For the most part, the impact evaluation focuses on a subset of the population shown in Table II.C.1—high- and medium-risk beneficiaries only—as we expect that population to benefit most from the model. Following a few additional sample restrictions (described in Appendix A) that population includes 130,641 high- and medium-risk beneficiaries enrolled by 172 intervention organizations and 88,312 high- and medium-risk beneficiaries enrolled by 170 control organizations. The number of distinct organizations (342) is lower than the number in Table II.C.1 (345) because some organizations did not enroll any beneficiaries with high or medium risk at enrollment.

III. MODEL INCENTIVES AND SUPPORTS

CMS provides intervention organizations with financial incentives and other tools to support implementation of the model requirements. In this chapter, we describe the payments made to intervention organizations through June 2019, organizations' perceptions of the payments, and organizations' perceptions of the other model tools and supports.

Chapter takeaway



A. Model incentives

Key findings

From January 2017 to June 2019, CMS paid $6.7 million to intervention organizations for participating in the Million Hearts Model. Among the 96 organizations that were active in the model through June 2019, the median total payment over these 30 months was $23,303. Ninety-three percent of those organizations earned risk reduction payments in at least one performance period when the payments were available.

Over three years of interviews, respondents responsible for overseeing model implementation consistently reported that CMS payments did not cover their costs of participation. Clinician providers and other frontline staff were generally unaware of the payment amounts their organizations had received, and individual providers were not paid directly for their performance related to Million Hearts Model requirements.

1. CMS payments to intervention organizations

The Million Hearts Model payments are designed to incentivize providers to (1) risk stratify eligible Medicare beneficiaries and (2) reduce CVD risk among model-enrolled beneficiaries at high risk of a heart attack or stroke (that is, those with at least a 30 percent predicted risk over 10 years). During the first model year, 2017, CMS paid intervention organizations for risk stratification and cardiovascular care management. During subsequent years, the payments shifted toward rewarding organizations for risk stratification and reducing beneficiaries' risk scores.

Million Hearts Model Incentive structure

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

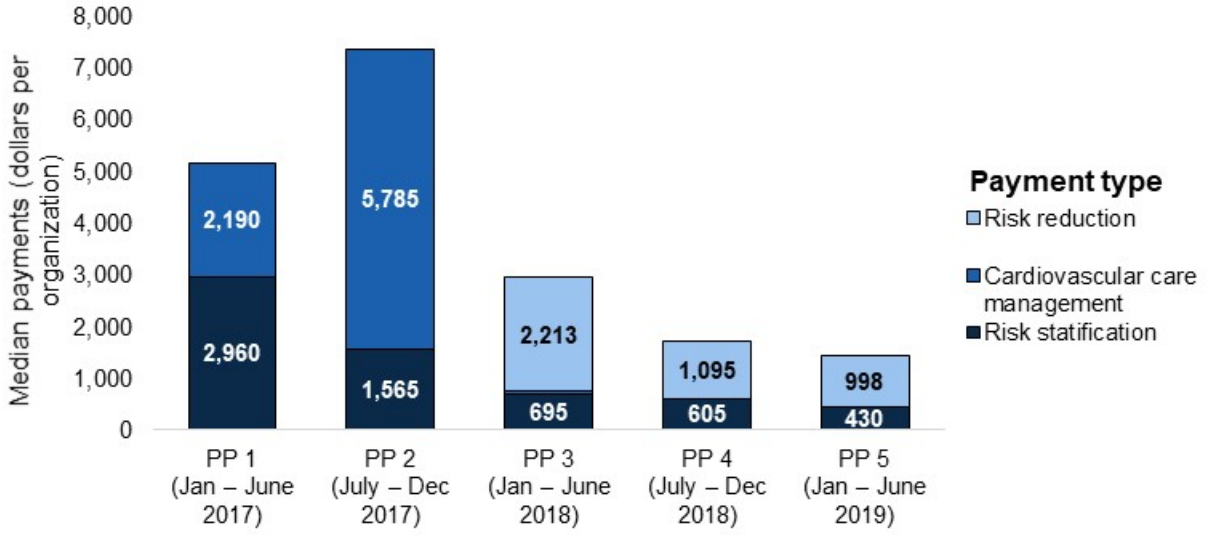
From January 2017 to June 2019, CMS paid $6.7 million to intervention organizations for participating in the Million Hearts Model. Total CMS payments to intervention organizations were highest in the second six-month performance period (July to December 2017). Payments then decreased in subsequent periods, partly because organizations withdrew from the model. (Appendix B shows results from supplemental analysis of model payments.) Among the 96 organizations that continued to participate and share data with CMS through June 2019, the median payment from January 2017 to June 2019 was $23,303.[2] Among these organizations, the median payment per performance period declined over time (Figure III.A.1) for two reasons:

1. They enrolled fewer new people in later periods (as there were fewer remaining eligible Medicare beneficiaries to enroll).
2. Payments for high-risk beneficiaries shifted from a uniform $10 per beneficiary per month (PBPM) in 2017 to a performance-based risk reduction payment with a maximum of $10 PBPM for high-risk beneficiaries.

Furthermore, the population for whom organizations receive the risk reduction payment can decline over time if beneficiaries are lost to follow-up (that is, if they fail to have an annual reassessment visit). A separate analysis of payments over time confirmed that nearly all organizations (93 percent) still participating through June 2019 received lower average payments per performance period after the first model year.

[2] Some organizations remained in the model but did not submit data to the Million Hearts Data Registry in every performance period.

Figure III.A.1. Model payments were concentrated in the first year: Median payment per organization (N = 96), by payment type



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

Note: The analysis calculated median payments among organizations that effectively participated in the model during the fifth performance period by uploading data for at least one enrollment or reassessment visit that occurred during that 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.

Among the 96 organizations that continued to effectively participate in the model through June 2019, 93 percent earned risk reduction payments in at least one of the three performance periods when these reduction payments were available. Fewer than half (41 percent) of organizations earned the top amount of $10 PBPM in at least one of three periods (Appendix B). The risk reduction payments across the three eligible periods were typically modest, with a median of $4,283 per organization and a range from $0 to more than $200,000. We also analyzed the potential risk reduction payments, had these organizations achieved the maximum risk reduction threshold for the beneficiaries included in their reassessment population. This analysis suggested that the median risk reduction payments over the three periods would have been about twice as high, increasing the median from $4,283 to just over $8,000.[3]

Overall, these modest payments suggest that the incentives were generally not large enough to cover major practice transformation, new services, or hiring of new staff. For example, the median payment of $23,303 over 30 months would not cover a full-time staff position. To implement the model, organizations might have had to allocate their work toward model requirements among existing administrative, clinical, or clinical support staff. Alternatively,

[3] The analysis calculated potential payments for intervention organizations that reported reassessment data but did not achieve more than 10 percentage points of average risk reduction. It calculated the potential risk reduction payment by applying the maximum $10 PBPM risk reduction fee to all high-risk beneficiaries who had a reassessment visit during a given performance period. The calculation assumes that each beneficiary was enrolled for 12 months between enrollment and reassessment.

organizations could have funded new staff and new clinical processes—if any—using combined money from the Million Hearts Model and other quality initiatives.

2. Participants' perceptions of model incentives


Interviews

Across three years of interviews with 10 to 15 organizations per year, respondents from nearly all interviewed organizations said they did not think the payments covered the costs of implementing the model requirements. Among the organizations we interviewed (all of which participated in the model at the time of the interviews), respondents offered various explanations of why this did not deter their participation: (1) financial incentives were important for signing up for the model, but over time, organization leaders were more motivated by the opportunity to improve patients' health outcomes; or (2) the model aligned with other quality incentive programs. Respondents from two organizations noted that although the payments were not substantial, the model did not require large changes to clinical workflows, and that administrative or clinical support staff could handle the more time-consuming requirements. In the second and third years of interviews (2019 and 2020), 2 of 10 organizations interviewed in both years were more critical of the payment amounts. One noted it would not participate in a similar model in the future because the model is "not affordable," and another noted the incentives did not "make it worthwhile to do [data entry] on a regular basis."

> "We knew going into Million Hearts that this wasn't going to be an incentive program that gave us significant dollar amounts. We weren't going to be able to do a huge transformation. But we were eager to enroll because it sounded like something that our patients could really benefit from."
>
> *—Care Coordinator*

Among the organizations interviewed over three years, there was no evidence that frontline providers received direct rewards for their individual performance reducing CVD risk. Nearly all the frontline providers interviewed were aware of the payment incentives generally but not of the specific payment amounts their organizations received. Around one-third of providers volunteered that they were not involved in their practice's finances and speculated that the financial incentives had little bearing on their provider colleagues' decisions. However, these providers also acknowledged that this sentiment might differ at a smaller practice whose clinicians were more involved in the administrative responsibilities and where the practice revenue depended more on these incentive payments.

B. Participants' perceptions of model tools and supports

Key findings

Across three years of interviews, none of the respondents reported using the Million Hearts Longitudinal ASCVD Risk Assessment Tool at the point of care. However, nearly all had another CVD risk calculator available at the point of care—for example, using the ACC/AHA ASCVD Risk Estimator as a web- or phone-based app or built into the EHR.

Perceptions and uptake of the other tools that CMS provided varied by respondent, organization type, and available resources. For example, whereas smaller organizations had grown more accustomed to the data entry process by 2020, larger organizations continued to express reporting issues. This might reflect their need to submit data for more beneficiaries.

Respondents found the learning system events most useful when the presentation topics were relevant for their organization type and available resources. Respondents initially did not use the model performance reports, but several found the reports to be useful after CMS added new types of information in 2019.

CMS offered intervention organizations a series of tools and supports to encourage implementing the requirements of the Million Hearts Model. Among these tools and supports were the Million Hearts Longitudinal ASCVD Risk Assessment Tool, a novel risk calculator that estimates changes over time in a person's risk of heart attack or stroke (Lloyd-Jones et al. 2017). Under this tool, a person's initial risk score is the same as calculated under the previously existing ACC/AHA ASCVD Risk Estimator (Goff et al. 2013). However, to calculate follow-up risk scores (an updated 10-year predicted probability of heart attack or stroke), the new tool incorporates additional information about aspirin use, time since quitting smoking, and changes since the initial assessment in blood pressure and cholesterol. CMS also provided model participants with (1) a data registry to share required information with CMS and to track enrolled beneficiaries' progress, (2) a learning system to encourage care improvement, and (3) performance reports to track progress and benchmark organizations against their peers.

Million Hearts Model tools and supports

- Million Hearts Longitudinal ASCVD Risk Assessment Tool
- Million Hearts Data Registry
- Learning system
- Performance reports

Organizations calculated risk scores for their Medicare beneficiaries, but generally did not use the Million Hearts Longitudinal ASCVD Risk Assessment Tool at the point of care. The novel CVD risk calculator provided by CMS expanded on the ACC/AHA ASCVD Risk Estimator (Goff et al. 2013). In addition to the functionalities in the existing calculator, the new calculator (1) simulated improvements in risk that would accompany different treatment plans and (2) calculated changes in risk over time based on changes in an

individual's risk factors.[4] However, over three years of interviews, we found little evidence that providers used this version of the calculator or took advantage of these expanded features at the point of care. Instead, organizations used EHR-based static calculators, web- or app-based versions of the ACC/AHA ASCVD Risk Estimator, or the Million Hearts Longitudinal ASCVD Risk Assessment Tool in the registry *after* the patient's visit. Around one-third of organizations reported using the web- or app-based ACC/AHA ASCVD Risk Estimator Plus tool, which includes the same expanded functionalities as the Million Hearts Longitudinal ASCVD Risk Assessment Tool. (The ACC/AHA ASCVD Risk Estimator *Plus* differs from the original ACC/AHA ASCVD Risk Estimator.) But organizations did not appear to take advantage of these functionalities, either because (1) the provider did not input baseline data when using the tools, or (2) clinical support staff calculated the risk score before or after the patient's visit, making it impractical to use the treatment simulation feature when discussing risk with patients.

> "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."
>
> *—Frontline Provider*

During the third round of interviews (2020), providers from about one-third of organizations indicated that they would be more likely to use the longitudinal risk assessment tool if it was integrated in the EHR. During the first year of our interviews (2018), three organizations expected that their EHR vendors would add the expanded longitudinal functionality. However, as of the third round of interviews, none of these organizations had dedicated the resources needed for this enhancement.

Experiences with the registry improved over time, but some larger organizations continued to report challenges. The Million Hearts Data Registry is a platform on which organizations record demographic, clinical, and visit data and calculate CVD risk scores using the Million Hearts Longitudinal ASCVD Risk Assessment Tool. As noted previously, intervention organizations are required to report data to CMS at least twice a year through the registry. During the first round of interviews, respondents from nearly all organizations reported frustration using the Million Hearts Data Registry. The following year, respondents expressed less frustration, noting they had become more accustomed to the system or no longer enrolled as many beneficiaries. During the most recent round of interviews in 2020, respondents from around one-third of interviewed organizations reported positive or neutral experiences with the registry. For example, two respondents noted that it was easy to use or that additional helpful features had been added over time, such as filtering features. Others noted that they had continued to become accustomed to the system and improved their processes over time. However, respondents from about one-third

> "I think the registry could be clearer about what each flag means and the action that should be taken. It's overwhelming when there are thousands of rows It's not clear which patients are closest in enrolling and which steps have to be performed.
>
> *—IT Coordinator*

[4] More information on the Million Hearts Longitudinal ASCVD Risk Assessment Tool, including the functionalities added for the Million Hearts Model, is available in the evaluation's first annual report (Conwell et al. 2019).

of organizations continued to express frustration, particularly at larger organizations using the bulk upload process to report data for many enrolled beneficiaries. For example, respondents responsible for the data upload described (1) substantial manual review required to resolve misalignment between the organizations' data system and the CMS system, (2) challenges identifying eligible beneficiaries using data provided by CMS, and (3) confusion about the flags in the registry and how to resolve them.

The usefulness of learning system events varied by topic; respondents consistently requested more options for completing model requirements related to attendance. CMS provides quarterly learning system events to help organizations implement the model. Topics varied from operationally focused events, such as how to comply with model requirements, to more clinically focused events, such as how to integrate team-based care. Individuals from each intervention organization must attend at least one event per quarter, either in real time or by watching a recording. Across three years of interviews, respondents reported that administrative or clinical support staff primarily attended these events, and then passed along relevant information to the care team. The more operationally focused events were the most helpful to respondents who appreciated hearing from organizations of similar type and size.

> "We're a small independent practice [and] we all kind of pulled together to do our own IT.… It's kind of frustrating to hear big hospital organizations talk about how they're doing things … that can't apply to us ever."
>
> *—Care Manager*

Respondents from about half of organizations expressed interest in having more options available to meet the requirement to attend one event per quarter. Over time, the number of learning system events per year decreased from 10 in 2017, to 6 in 2018, to 4 in 2019. Having more options would enable participants to select the most relevant events for their organization. In 2019 and 2020, respondents from about one-third of organizations interviewed felt that the information might be useful to other less advanced organizations, but that they had already implemented many of the recommendations. Several respondents noted learning systems events for other CMS initiatives they were a part of, such as CPC+, had already covered some topics.

Organizations became more familiar with performance reports over time; some features of the report were useful, but the lag time limited the utility of the reports. CMS sends intervention organizations performance reports twice a year, typically six to eight months after the end of a performance period. The first two performance reports included information on enrollment and risk status; treatment therapy (for example, proportion of high-risk beneficiaries who smoked or took statins at enrollment); Million Hearts Model payment history; and learning system attendance. During our first and second rounds of interviews in 2018 and 2019, respondents had little familiarity with the performance reports or said they did not find them useful because the reports summarized the same information the organization had entered in the registry. CMS made a third set of performance reports available partway through the second round of interviews in 2019 that included additional

> "I'm competitive, so I like to see what we are doing compared to everybody else."
>
> *—Clinician Leader and Model Champion*

information such as (1) beneficiaries' status over time (for example, enrolled, lost to follow-up, or ineligible); (2) average change in risk score among high-risk beneficiaries at the organization compared to at other organizations; (3) changes in treatment therapies since baseline; and (4) potential risk reduction payments, had the organizations achieved more than a 10-percentage-point average risk reduction. The third year of interviews (2020) found respondents evenly split among still having limited familiarity with the reports, finding the reports useful for quality improvement and benchmarking their performance, and not using the reports because the organization's internal systems were more up to date and therefore considered more useful.

IV. RISK STRATIFICATION AND DEGREE TO WHICH BASELINE CVD RISK IS MODIFIABLE

As part of the Million Hearts Model, participants were expected to risk stratify their Medicare FFS population. That meant using a standardized tool to estimate 10-year risk of heart attack and stroke for beneficiaries ages 40 to 79 without a history of these CVD events. Providers and beneficiaries could then act on the information to reduce CVD risk—as long as modifiable risk factors caused some of it. This chapter explores three closely related topics: the extent of risk stratification overall (Section A), the extent of modifiable risk among beneficiaries stratified as high or medium risk (Section B), and changes in providers' awareness of CVD risk as a result of risk stratification (Section C).

Chapter takeaway

A. Extent of risk stratification

Key findings

The Million Hearts Model substantially increased the rate of CVD risk stratification. Nearly all intervention organizations we interviewed had a risk calculator available at the point of care—for example, using the ACC/AHA ASCVD Risk Estimator as a web- or phone-based app or built into the EHR. In a 2018 survey, 71 percent of intervention providers said they calculated CVD risk scores for at least half of their Medicare beneficiaries, compared with just 39 percent of control providers. Despite this, there was still room to improve. The intervention organizations risk stratified and enrolled about half of those who appeared eligible for the Million Hearts Model in claims data.

1. How organizations risk stratified their Medicare beneficiaries

ACC/AHA guidelines for CVD primary prevention recommend routine calculation of CVD risk scores among adults ages 40 to 75 (Arnett et al. 2019), in line with the Million Hearts Model requirements. Indeed, many intervention organizations conducted these risk assessments before joining the Million Hearts Model. However, according to our 2018 provider survey, roughly one-quarter (23 percent) of organizations did not calculate risk for any patients before the model

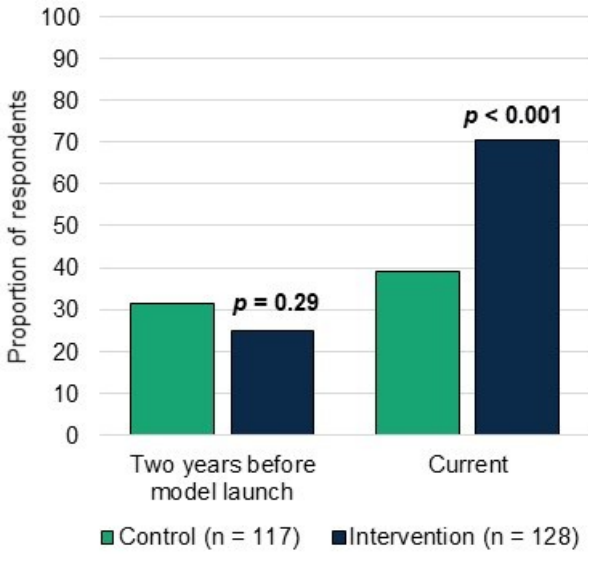
Model requirement

Intervention organizations use a model-approved risk calculator to determine the 10-year CVD risk score for each eligible Medicare FFS beneficiary. Using the risk scores, organizations then categorize eligible beneficiaries as high risk (score of at least 30 percent) or as low or medium risk.

started; an additional 50 percent said they did so for less than half of their Medicare beneficiaries or did not know how often the risk assessment occurred. To meet current clinical guidelines, therefore, and to comply with the model requirements to risk stratify all eligible Medicare beneficiaries, most organizations needed to update their health IT or clinical workflows, or to expand their existing risk-assessment approaches to more beneficiaries.

By our first round of interviews in early 2018, about one-half of the interviewed organizations used web-based calculators or smartphone applications to calculate risk scores (Conwell et al. 2019). Another one-third used a risk calculator built into the EHR. These EHR-based calculators varied in their level of automation, however. For example, some EHR calculators automatically gathered laboratory values and diagnosis codes from EHR fields to calculate a risk score and record it in the visit note. Other EHRs required providers to manually input components of the risk score. At some organizations, medical assistants and other nonclinical staff would conduct the risk stratification. At others, the clinical providers did the risk stratification themselves. All 10 of the organizations we interviewed in 2020 said they continued to perform risk stratification over time using the same approach they developed during the first year of the Million Hearts Model.

Figure IV.A.1. The model appears to have increased the use of risk stratification substantially: Proportion of providers reporting they calculate CVD risk scores for at least half of their Medicare beneficiaries



Source: Mathematica's analysis of a provider survey administered in 2018.
CVD = cardiovascular disease.

The model appears to have increased the use of risk stratification substantially. In the 2018 provider survey, 71 percent of intervention providers said they, or someone in their care team, calculated CVD risk scores for at least half of their Medicare beneficiaries. This compared to 39 percent of control providers—a 31 percentage point difference ($p < 0.001$; Figure IV.A.1). In both groups, one-quarter to one-third of providers were risk stratifying routinely before the model began in 2017, and providers in both groups reported increasing their use of risk scores since then. Still, the intervention providers reported substantially greater gains (25 to 71 percent) than control providers (31 to 39 percent). In other words, most Million Hearts Model participants were not

meeting current clinical guidelines for routine CVD risk assessment before the model began, but the model appears to have prompted large improvements.

> "It's so much a part of our workflow now. I would put it on the same priority level as any type of gap measure we might be helping our patients fill—like getting their colorectal cancer screenings done or breast cancer."
>
> *—Patient Navigator*

This increase in risk stratification is likely to continue in the future, now that the model has made risk stratification routine. In 2020, every intervention organization we interviewed said that it planned to continue risk stratification when the Million Hearts Model ends.

2. Number of beneficiaries risk stratified

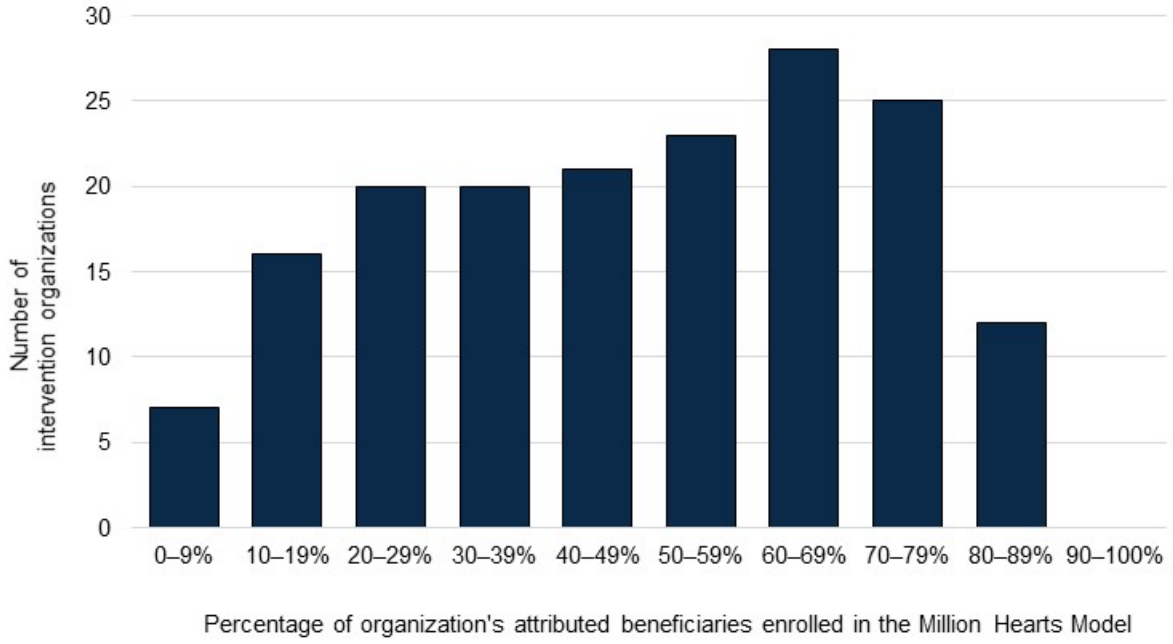
Model enrollment numbers are the best proxy for the number of beneficiaries risk stratified by organizations in the intervention group. To enroll a beneficiary into the Million Hearts Model, intervention organizations had to collect all clinical and demographic data needed to calculate a risk score and enter the data into the Million Hearts Data Registry. The registry software would then return the beneficiary's risk score, so that intervention group organizations received a risk score for every beneficiary enrolled—even if they had not had it at the time of the beneficiary's visit.

Overall, intervention organizations enrolled and obtained risk scores for 230,664 beneficiaries in 2017 and 2018. This represents 52 percent of those who appeared eligible for enrollment in the Million Hearts Model based on analysis of claims data—that is, 52 percent of beneficiaries who had an outpatient visit with a provider participating in the model and who met claims-based eligibility criteria for the model such as age from 40 to 79 and no history of heart attack or stroke. We call this population the *attributed population* (described in detail in Appendix C). This number (52 percent) likely underestimates the true proportion risk stratified because some beneficiaries who appear model eligible in claims are not, in fact, model eligible. For example, organizations could decline to enroll beneficiaries they expected were one-time visitors to their organization, a decision that could not be replicated in claims data. Beneficiaries, too, could decline to participate in the model, and we could not observe that either. Our inability to capture all of the model eligibility criteria in claims data likely explains some of the difference between the proportion enrolled (52 percent) and CMS's enrollment target of 90 percent, stated in the Model Participation Agreement.

However, some of the difference reflects room for improvement. That is, organizations could have enrolled more beneficiaries into the Million Hearts Model than they did. The intervention group organizations ranged considerably in their proportion of attributed beneficiaries risk stratified and enrolled: from a minimum of 4 percent to a maximum of 89 percent (Figure IV.A.2). We cannot say for certain why there was so much variation. Organizations at the low end are likely those that never fully engaged with the Million Hearts Model, faced many hurdles when trying to upload the data, or lacked resources to upload the data. Organizations at the high

end, in contrast, were likely those with highly systematized or automated methods for calculating risk scores and uploading them to the Million Hearts Data Registry.

Figure IV.A.2. The intervention group organizations ranged considerably in their proportion of attributed beneficiaries risk stratified and enrolled: Distribution across intervention organizations in their percentage of attributed Medicare beneficiaries enrolled in the Million Hearts Model



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

Note: Figure includes 172 intervention organizations that enrolled at least one beneficiary who met claims-based eligibility criteria in 2017 or 2018. We attributed beneficiaries to organizations using the approach described in Appendix B.

Organizations we interviewed tended to have higher rates of risk stratification and enrollment than average, and our respondents typically perceived that they risk stratified routinely. However, interview respondents did give some reasons for not risk stratifying more beneficiaries. For example, risk stratification 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. In our most recent round of interviews (2020), we also heard about lapses in uploading data to the Million Hearts Data Registry. That is, some beneficiaries had been risk stratified, but the organization did not take the time to enroll them in the model via the Million Hearts Data Registry.

3. Characteristics of beneficiaries enrolled versus those eligible but not enrolled

To determine whether the Million Hearts Model was more likely to serve some beneficiaries than others, we compared the characteristics of risk-stratified beneficiaries who were enrolled in the Million Hearts Model to those who appeared eligible for the model but were not enrolled. 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 that we could replicate in claims.

The enrolled beneficiaries differed in important respects from beneficiaries who appeared eligible but were not enrolled (Table IV.A.1). On average, enrolled beneficiaries had more visits with the organization than attributed, but not enrolled, beneficiaries in the 12 months leading up to a model-qualifying visit. Enrolled beneficiaries also appeared to be slightly 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. It is not surprising that frequent visitors to the organizations were more likely to be enrolled, as frequent visits would give the organizations more opportunities to collect the information needed to calculate a risk score—for example, ordering a lipid panel. For organizations that calculated risk scores during a patient's visit (as opposed to before or after the visit), more frequent visits would also present more opportunities for the risk calculation itself. The fact that enrolled beneficiaries were healthier, on average, could suggest that providers sometimes struggled to find time to risk stratify beneficiaries with more complex or acute medical needs.

Alternatively, the *types* of providers that beneficiaries visited might explain both findings—that enrolled beneficiaries on average were healthier, and had more visits with the enrolling organization. In particular, beneficiaries who visited primary care physicians were much more likely to enroll in the model than beneficiaries who visited cardiologists (Table IV.A.1). Cardiologists typically have less frequent visits with their patients, but might also see sicker patients, on average. The cardiology practices we interviewed in 2018 and 2019 said they frequently had one-time patients who came for consultations, with those patients returning to their primary care providers for follow-up (Peterson et al. 2019). Providers might have chosen not to enroll some beneficiaries who visited for one-time consultations.

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

Characteristic	Enrolled in the model (N = 228,112)	Not enrolled in the model (N 206,559)	Difference	Standardized difference[a]	*p* value[b]
Demographic and Medicare enrollment characteristics					
Age	69	68	0.4	0.05	0.04
Black race, %	8	10	-1.2	-0.04	0.14
Male, %	44	46	-1.9	-0.04	<0.01
Dually enrolled in Medicare and Medicaid, %	14	16	-2.3	-0.06	0.04
Originally entitled to Medicare due to disability, %	23	26	-3.0	-0.07	<0.01
Health and comorbid conditions					
HCC score	1.05	1.19	-0.1	-0.14	<0.01
Count of chronic conditions	1.78	2.06	-0.3	-0.13	<0.01
Medical service use and spending in year before attribution					
Total Medicare Parts A and B annualized expenditures ($)	7,446	10,318	-2,872	-0.10	<0.01
Hospital admissions (# per 1,000 beneficiaries)	182	274	-92	-0.06	<0.01
Outpatient ED visits or observation stays (# per 1,000 beneficiaries)	435	582	-147	-0.07	<0.01
Office visits with model-aligned providers[c] (# per 1,000 beneficiaries)	2,202	1,277	925	0.32	<0.01
Specialty of clinician who saw the beneficiary					
Primary care physician, %	63	44	18	0.38	<0.01
Cardiologist, %	23	40	-16	-0.36	<0.01

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

Notes: We attributed beneficiaries using the approach described in Appendix B. This attributed population is our best approximation of those eligible for the Million Hearts Model, based on Medicare claims and enrollment data.

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

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

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

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

B. Degree to which baseline CVD risk is modifiable

Key findings

A combination of modifiable and nonmodifiable risk factors drove beneficiaries' CVD risk. For example, among high-risk beneficiaries enrolled in 2017 or 2018, the mean age was 74 (nonmodifiable) and about two-thirds of beneficiaries had diabetes (difficult to modify). However, nearly three-quarters had uncontrolled hypertension, which is potentially modifiable.

Overall, we estimate that 39 percent of CVD risk at enrollment was potentially modifiable within one year of enrollment among high-risk beneficiaries. Among medium-risk beneficiaries, 28 percent was potentially modifiable.

Among high-risk beneficiaries enrolled in 2017 and 2018, the average CVD risk score was 40 percent (Table IV.B.1). This means, according to the risk calculator, the average high-risk beneficiary had a 40 percent chance of a heart attack or stroke within 10 years of model enrollment. This was nearly twice the average risk score of medium-risk beneficiaries and four times the average of low-risk beneficiaries.

For the Million Hearts Model to have its intended effects on heart attacks and strokes, however, it is not enough for providers merely to identify people at risk. Some risk must also be *modifiable*, meaning that patients and providers can act to reduce that risk—for example, through medication use or lifestyle changes. If the model is to succeed in reducing CVD events, the risk cannot be driven only by immutable risk factors such as age or sex.

At enrollment, high- and medium-risk beneficiaries enrolled in 2017 and 2018 typically had a combination of modifiable and nonmodifiable risk factors (Table IV.B.1). These findings are similar to those reported previously for beneficiaries enrolled in 2017 only (Conwell et al. 2019; Peterson et al. 2019):

- **Demographics.** Among high-risk beneficiaries, the mean age was 74 and roughly two-thirds were male. Among medium-risk beneficiaries, the mean age was 71 and more than half were male. Age and male sex both tend to increase CVD risk.
- **Diabetes.** About two-thirds of high-risk beneficiaries had diabetes—far more than among medium- or low-risk beneficiaries. Diabetes contributes strongly to the risk score calculation but is very difficult to modify. That is, even though Type II diabetes is largely preventable, remission is rare after the condition has developed (Karter et al. 2014).
- **Blood pressure.** Roughly three-quarters of high-risk beneficiaries and half of medium-risk beneficiaries had uncontrolled hypertension at enrollment, defined as systolic blood pressure of at least 130 mmHg. This was true even though most already took antihypertensive medications at enrollment. High blood pressure can be modifiable by starting new antihypertensive medications, titrating existing medications, or lifestyle modification.

- **Cholesterol.** Total cholesterol and low-density lipoprotein (LDL) cholesterol were *lower* at enrollment among high-risk beneficiaries than among medium- or low-risk beneficiaries, likely because the baseline rate of statin use was higher. Like blood pressure, total and LDL cholesterol can be modifiable through medication use or lifestyle modification. High-density lipoprotein (HDL) cholesterol is harder to modify (Grundy et al. 2018; Jellinger et al. 2017).
- **Smoking.** Higher-risk groups had higher smoking prevalence. Although tobacco is addictive and smoking cessation can be difficult, several therapies might help (Siu et al. 2015).

Table IV.B.1. Beneficiaries enrolled in 2017 and 2018 had a combination of modifiable and nonmodifiable risk factors: Baseline characteristics of Medicare beneficiaries enrolled by Million Hearts intervention organizations in 2017 and 2018, by CVD risk level

	High risk (N 40,446)	Medium risk (N 90,195)	Low risk (N 98,181)
Demographics			
Age, mean	74	71	64
Black race, %	8	8	9
Male, %	65	55	25
CVD risk factors			
CVD risk score, mean (in %)	40	21	9
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,[a] %	90	79	60
Statin use in Part D,[a] %	69	61	49
Low intensity, %	7	6	5
Medium intensity, %	41	37	31
High intensity, %	21	17	12

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

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

[a] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 28,391 for high risk; N = 61,132 for medium risk; N = 62,996 for low risk).

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

To assess the relative importance of modifiable and nonmodifiable risk factors to overall risk scores, we estimated the proportion of each beneficiary's CVD risk score at enrollment that was potentially modifiable through the ABCS strategies to reduce CVD risk: appropriate ***a***spirin therapy, ***b***lood pressure control, ***c***holesterol management, and ***s***moking cessation. Specifically, we applied the Million Hearts Longitudinal ASCVD Risk Assessment Tool to determine a beneficiary's CVD risk score one year after enrollment if the beneficiary reached ambitious but clinically grounded targets (Table IV.B.2).

Table IV.B.2. Clinical targets to define modifiable risk: ABCS strategies

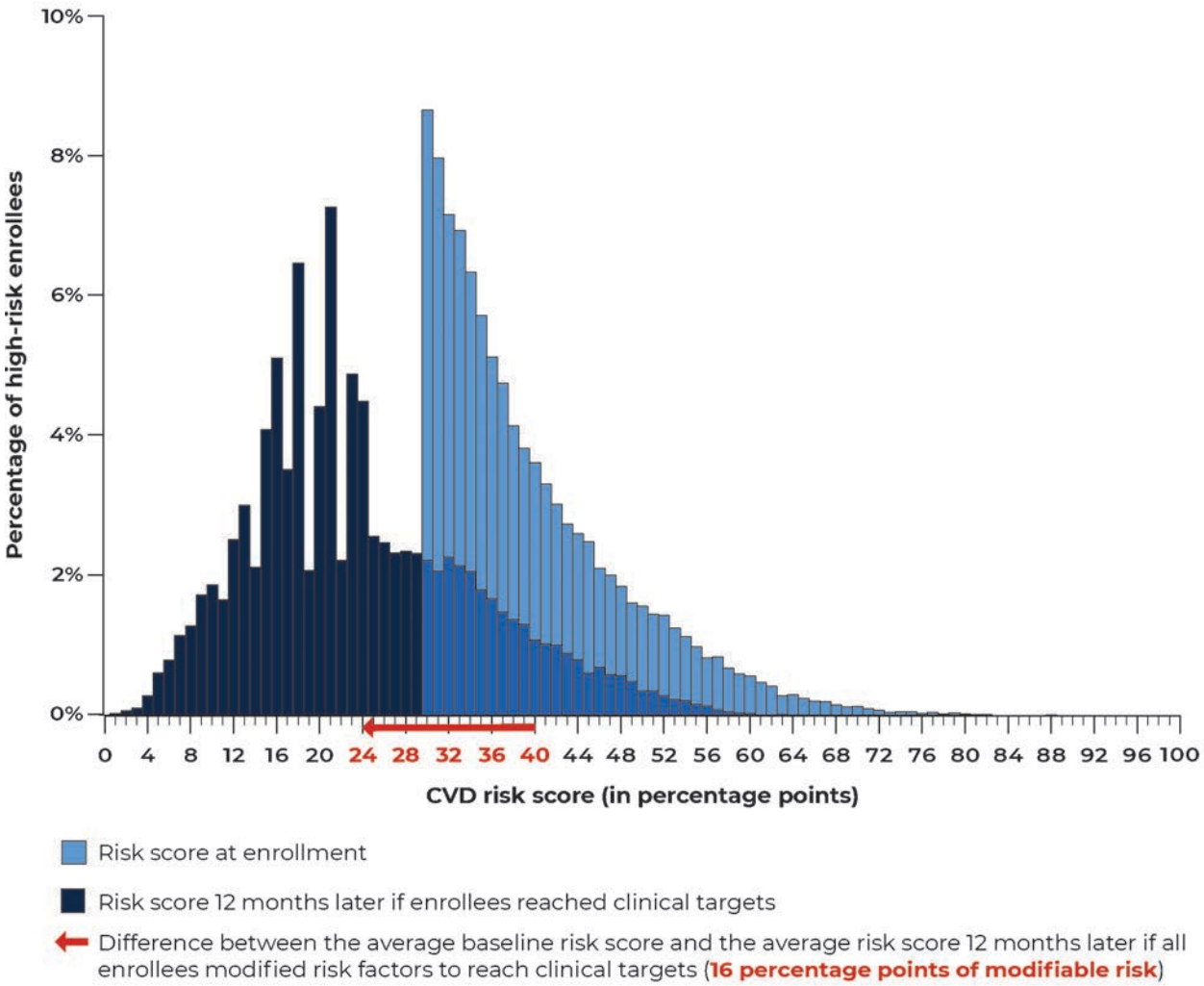
CVD risk management strategies	Clinical target
A: Aspirin therapy	Initiate aspirin therapy if age is 40 to 70 years and baseline ASCVD risk score is 10% or higher
B: Blood pressure control	• Target an SBP level of less than 130 mmHg • Initiate antihypertensive treatment if ASCVD risk score is 10% or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

Note: Clinical targets are based on the research literature, as described in thesecond annual report, Appendix C. We selected clinical targets only for those risk factors needed to calculate risk scores using the Million Hearts Longitudinal ASCVD Risk Assessment Tool. We assume that follow-up risk scores are calculated one year later and that beneficiaries age one year during that time, but all other risk factors besides those shown in Table IV.B.2 remain unchanged.

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

Despite high levels of cardiovascular medication use at baseline (Table IV.B.1), we found that high- and medium-risk beneficiaries still had substantial room to improve their CVD risk scores. On average, 39 percent of the risk (or 16 of the 40 percentage points at enrollment) was potentially modifiable for high-risk beneficiaries and 28 percent (or 6 of 21 percentage points, on average) was modifiable for medium-risk beneficiaries. These numbers for the beneficiaries enrolled in the model in 2017 and 2018 are almost identical to those reported in the second annual report for 2017 enrollees only (Peterson et al. 2019). Figure IV.B.1 illustrates how reaching the ABCS clinical targets could shift the overall CVD risk score distribution for high-risk beneficiaries to lower scores, on average.

Figure IV.B.1. Addressing modifiable risk factors could substantially reduce overall cardiovascular risk: The distribution of ASCVD risk scores at baseline among high-risk beneficiaries, and the distribution that would occur 12 months later if these beneficiaries reached evidence-based clinical targets



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

Note: Figure reflects findings for 40,254 high-risk beneficiaries enrolled in 2017 or 2018, excluding those with implausibly low LDL cholesterol values, less than 20 mg/dL (N = 192). Modifiable risk is defined as the difference between a beneficiary's baseline CVD risk score and the risk score 12 months later if the beneficiary reached ambitious but clinically attainable targets, with risk scores calculated using the Million Hearts Longitudinal ASCVD Risk Assessment Tool. Risk score changes 12 months later account for aging since baseline. High CVD risk indicates the beneficiary had a 30 percent or higher predicted risk of heart attack or stroke in the next 10 years.

ASCVD = atherosclerotic cardiovascular disease; LDL = low-density lipoprotein.

Among the ABCS strategies, blood pressure control had the greatest potential to reduce predicted CVD risk, followed by cholesterol management, smoking cessation, and increased use of aspirin (results not shown). For example, among high-risk beneficiaries, if everyone with a systolic blood pressure reading of greater than 129 mmHg at enrollment could reduce their systolic blood pressure to 129 mmHg, that change alone would reduce predicted CVD risk among the whole

high-risk population by an average of 13 percentage points.[5] Reducing LDL cholesterol from 70 mg/dL or higher to 69 mg/dL would, taken alone, reduce population-level CVD risk by an estimated 7 percentage points. These potential improvements (of 13 and 7 percentage points, respectively) sum to more than the total 16 percentage points of estimated risk reduction from addressing all ABCS strategies because the Million Hearts Longitudinal ASCVD Risk Assessment Tool is not additive. Stopping smoking would reduce CVD risk substantially among those who smoke, but its potential contribution to population-wide CVD risk reduction is limited because only 12 percent of high-risk beneficiaries and 10 percent of medium-risk beneficiaries smoked at enrollment. These findings, too, are similar to those reported previously for the 2017 enrollees only (Peterson et al. 2019).

C. Providers' awareness of CVD risk

Key findings

In interviews in 2020, providers continued to state that risk stratification made them more aware of beneficiaries' risk. This is consistent with findings from the 2018 survey, in which providers reported that (1) they reviewed CVD risk scores more consistently than before the model launch and (2) using risk scores helped them to identify high- and medium-risk beneficiaries they otherwise would not have identified.


Provider survey

The Million Hearts Model substantially increased the number of providers reviewing CVD risk scores consistently and having access to scores when meeting with Medicare beneficiaries. Specifically, in the 2018 provider survey, 78 percent of intervention-group providers reported they or their clinical team reviewed CVD risk scores somewhat or much more consistently than two years previously—that is, before the model launched—compared with 52 percent of control providers ($p < 0.001$). Further, among the intervention providers that calculated risk scores, 64 percent said they always or almost always had access to those scores when meeting with Medicare beneficiaries, compared to 49 percent of control providers ($p < 0.001$).


Interviews

These survey findings, which we reported previously (Peterson et al. 2019), correspond to data from the most recent round of interviews with participating organizations. Respondents at nearly all organizations said that providers' awareness of CVD risk had increased because of participation in the Million Hearts Model. They cited two reasons. First, about one-third of respondents stated that increased awareness among providers was a byproduct of more consistently calculating risk scores for high-risk Medicare beneficiaries. That is, providers became more aware of CVD risk because they or their staff calculated CVD risk scores for a larger proportion of their patients. Second, some organizations also used health IT tools to draw providers' attention to the CVD risk scores of beneficiaries identified as high risk. For example, one organization used best practice alerts

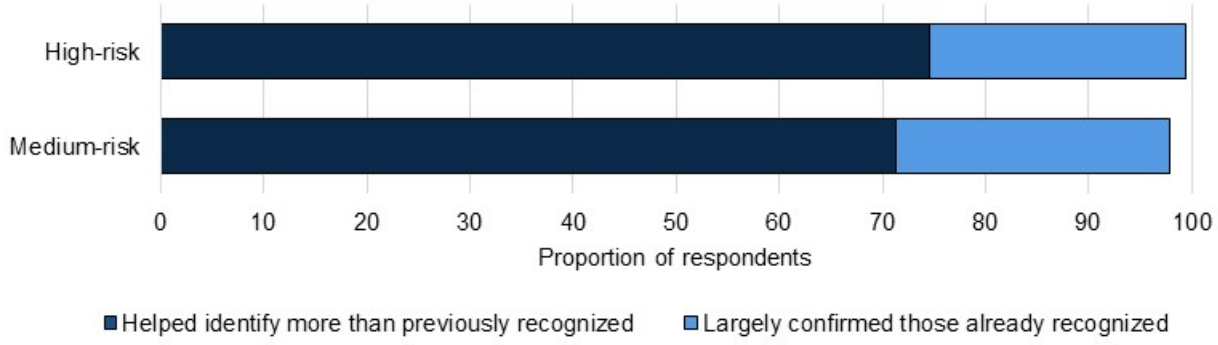
[5] The 13 percentage points represents the average change in risk score possible 12 months later if all high-risk beneficiaries met the blood pressure control clinical target, net of the average change in risk scores due to aging one year.

within the EHR; another had CVD risk scores over 30 go to the EHR landing page, so that it was front and center when a provider reviewed the patient's chart. Among organizations that did *not* perceive increases in providers' awareness as a result of the model, one said the providers did not typically know their patients' CVD risk scores. The other said its providers were aware of their beneficiaries' CVD risk, but already had been before joining the Million Hearts Model, so the model had not changed anything.

Providers also felt that risk scores helped them identify beneficiaries with elevated CVD risk that they might otherwise have missed. In the 2018 survey, among intervention providers that said they used risk scores more consistently than they had before the model, roughly three-quarters said risk stratification helped them to identify high-risk Medicare beneficiaries they had not previously recognized (Figure IV.C.1). The remaining one-quarter said risk calculation largely confirmed what they had recognized already—for example, based on the person's risk factors alone. Similar proportions said the model helped them to identify *medium*-risk beneficiaries, too. This makes it possible for the Million Hearts Model to improve care among the medium-risk population, even though CMS did not pay separately for cardiovascular care management or risk reduction among that group.

> "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 high-risk as they are."
>
> *—Provider*

Figure IV.C.1. Proportion of intervention group providers who reported that risk calculation helped identify high- and medium-risk beneficiaries



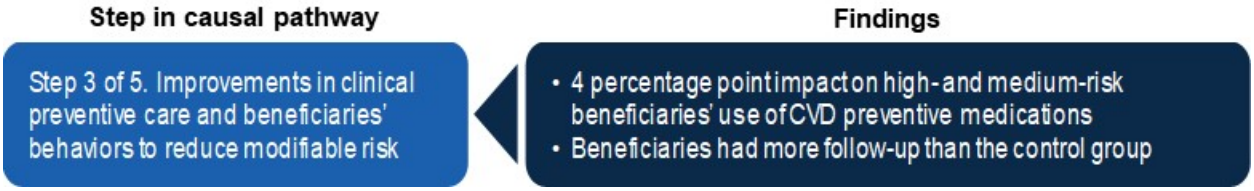
Source: Mathematica's analysis of a provider survey administered in 2018.

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

V. IMPROVEMENTS IN PREVENTIVE CARDIOVASCULAR CARE TO REDUCE MODIFIABLE RISK

We hypothesize that, once providers become more aware of their Medicare beneficiaries' cardiovascular risk, they will work with beneficiaries with elevated risk to develop and implement treatment plans to reduce it. In this chapter, we first (Section A) discuss the extent to which providers used CVD risk scores to guide discussions with Medicare beneficiaries and to inform treatment recommendations. Next, in Section B, we assess whether the model increased the initiation and intensification of statins and antihypertensive medications, one key potential pathway for reducing risk. Finally, in Section C, we describe the extent to which providers followed up with high-risk beneficiaries over time to monitor and encourage reduction in CVD risk.

Chapter takeaway



A. Use of CVD risk scores to guide CVD preventive care

Key findings

Providers used CVD risk scores to inform CVD preventive care for high- and medium-risk Medicare beneficiaries. In interviews and the 2018 provider survey, providers reported using risk scores as a starting point for talking with beneficiaries about CVD risk and options for reducing it. Providers also said that identifying high- and medium-risk beneficiaries encouraged them to recommend CVD-prevention strategies to them. Common recommendations included smoking cessation and increased use of statin or antihypertensive therapy. Providers credited the Million Hearts Model with increasing the extent to which they used CVD risk scores to guide their discussions with beneficiaries and their treatment recommendations.

Model requirement

Providers in intervention organizations meet with high-risk beneficiaries to discuss their CVD risk and options for reducing it. Through a shared-decision making process, providers and beneficiaries develop individualized plans for reducing CVD risk.

In the three round of interviews (2018, 2019, and 2020) and the 2018 provider survey, providers said they used CVD risk scores in two ways to guide CVD preventive care.

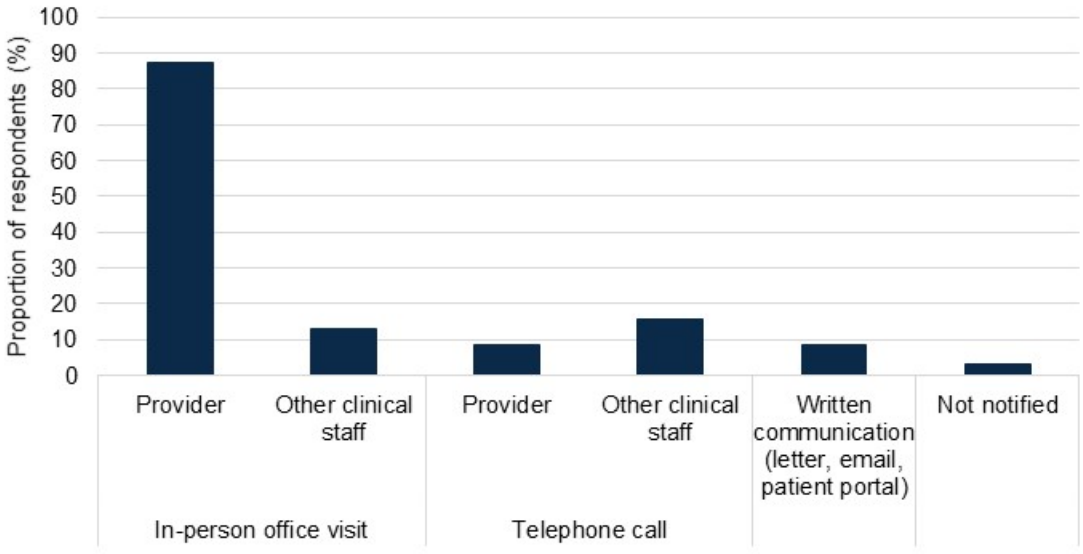
First, providers used risk scores to guide discussions with beneficiaries about their CVD risk and options for reducing it. In the 2018 survey, 87 percent of providers said they notified their Medicare beneficiaries of their CVD risk score during regular office visits (Figure V.A.1). Further, 69 percent reported that CVD risk scores were a valuable tool for engaging patients in understanding and managing their CVD risk. In interviews, providers said they used the risk scores as a starting point for discussions about a beneficiary's overall risk, the factors driving it, and the options they had for reducing CVD risk. Providers viewed these discussions as increasing beneficiaries' awareness of risk and motivating them to consider lifestyle changes or medications that could reduce risk. For example, several providers reported that some beneficiaries who had resisted taking statins in the past had decided to start taking them after learning their risk of a CVD event. Further, some providers thought that risk scores motivated beneficiaries because beneficiaries can set clear, numerical targets for reducing risk, much as they might set targets for reducing weight. Nevertheless, several providers in each of the rounds of interviews noted that discussing risk scores could be overwhelming for some beneficiaries, especially if CVD risk was not their most pressing medical concern.

"When the doctors actually share that score with the patients, I do think it hits home to a lot of patients. Do you realize that you have a 50 percent chance of having a heart attack in the next five years?"

—Practice administrator

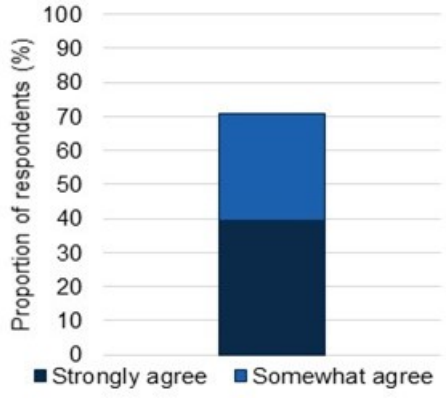
Second, providers' awareness of CVD risk informed treatment recommendations, sometimes prompting more aggressive treatment of risk factors. In each of the three rounds of interviews, some providers (around one-half in 2019 and 2020) reported that seeing the risk score encouraged them to address uncontrolled CVD risk factors. In the 2020 interviews, several providers said they focused on statins, smoking cessation, and use of antihypertensives in particular because the risk calculator showed that these therapies could cause the greatest declines in CVD risk. Providers also recommended changes to diet or exercise but noted that beneficiaries often had difficulty making or sustaining these lifestyle changes. Providers reported that risk scores informed clinical care for medium-risk Medicare beneficiaries as well as high-risk ones. None of the interviewed providers thought that using risk scores would have unintended consequences due to overly aggressive treatment of CVD risk factors.

Figure V.A.1. Most providers said they notified their Medicare beneficiaries of CVD risk scores during regular office visits: How intervention organizations notified their patients of CVD risk, as reported by intervention group providers



Source: Mathematica's analysis of a provider survey administered in 2018.
Note: Questions asked only of the 112 intervention group providers who reported currently calculating risk scores.

Figure V.A.2. Proportion of intervention group providers reporting the Million Hearts Model prompted their organization to provide standard of care more systematically



Source: Mathematica's analysis of a provider survey administered in 2018.
Note: Question asked of all 128 intervention group providers. Not all providers responded.

Providers credited the Million Hearts Model with increasing the extent to which they used risk scores to guide their discussions with patients and to inform their treatment recommendations. In the survey, the majority of intervention group providers said the model changed how they used CVD risk scores to (1) inform clinical care to reduce CVD risk among high- and medium-risk patients (76 percent of providers) and (2) cue discussions with patients about CVD risk with their patients (75 percent of providers). Based on the interviews, the specific change prompted by the model appears to be that providers used CVD risk scores more consistently to inform care and cue discussions. This more consistent use of risk scores, which the ACC and AHA recommend in clinical guidelines (Arnett et al. 2019), was likely a large part of why most providers (72 percent) reported that the Million Hearts Model prompted their organization to more consistently apply the current standard of CVD preventive care (Figure V.A.2).

However, participating providers have not used CVD risk scores fully in the ways the Million Hearts Model envisioned. As part of developing the Million Hearts Model, CMS funded the development of the Million Hearts ASCVD Longitudinal Risk Assessment Tool. This tool enables providers to estimate the likely risk reduction from different therapies, such as starting statins or quitting smoking (Lloyd Jones et al. 2017). However, providers reported challenges accessing this tool at the point of care (Chapter III). Instead, some providers estimated the likely impact of starting a new therapy by recalculating a hypothetical risk score, assuming the risk factor was addressed, using the standard baseline risk calculator, available within their EHRs or through web-based or smartphone applications. This approach tended to yield more pessimistic estimates of a person's room for improvement, relative to evidence from clinical trials about the impact of addressing CVD risk factors (Lloyd-Jones et al. 2017).

B. Initiation or intensification of medications to reduce CVD risk factors

Key findings

Among high- and medium-risk beneficiaries, CVD medication initiation and intensification increased during the first year of enrollment in both the intervention and control groups, but increases were modestly larger (by 4 percentage points, $p < 0.001$) in the intervention group. The impact estimates were slightly larger (5 percentage points, $p < 0.001$) among high-risk beneficiaries only, for whom CMS separately pays for risk reduction, than among high- and medium-risk beneficiaries combined. The intervention–control differences within the first year persisted for as long as we observed the beneficiary follow-up period, up to 2.5 years.

The Million Hearts Model is not prescriptive in how providers reduce risk, and there are many options—such as improvements in diet, exercise, or smoking cessation. However, initiating or intensifying CVD medications might be an effective strategy for many high- and medium-risk beneficiaries. Clinical guidelines recommend that people (ages 40 to 75) with elevated LDL (≥ 70 mg/dL) consider statins if they have a CVD risk score over 7.5 percent or have diabetes, and that people with elevated systolic blood pressure (≥ 130 mmHg) consider antihypertensive medications if their CVD risk score is over 10 percent（Grundy et al. 2018; Whelton et al. 2017; Arnett et al. 2019). Because high- and medium-risk beneficiaries all had at least a 15 percent predicted risk of a CVD event (the cutoff for the medium-risk group), many could potentially benefit from statins or antihypertensives if they also had elevated LDL cholesterol or blood pressure. Antihypertensives and statins, respectively, reduce blood pressure and LDL cholesterol by up to 25 percent on average (Karmali et al. 2016). As noted in Chapter IV, elevated blood pressure and LDL cholesterol are major drivers of modifiable risk within the Million Hearts Model population.

We used the randomized design to assess whether the Million Hearts Model increased the initiation or intensification of statins or anti-hypertensives among those with elevated risk factors at baseline. We defined the study population as high- and medium-risk beneficiaries enrolled in 2017 who (1) had Part D coverage, enabling us to see medication use in claims; and (2) were candidates for initiation or intensification of CVD medications because they had elevated systolic blood pressure, elevated LDL cholesterol, or both (text box). About 70 percent of all high- and medium-risk beneficiaries in the model had Part D coverage. Among this group, most took antihypertensives (82 percent) or statins (61 percent) at baseline. Nonetheless, 90 percent still had elevated cholesterol or blood pressure and so were candidates for initiation or intensification of CVD medications. We estimated impacts as the regression-adjusted differences between the intervention and control groups in the initiation or intensification within one year of enrollment. We adjusted for a range of baseline demographic, service use, and clinical, and geographic characteristics (Appendix D) to increase the precision of the estimates, and to account for the small differences between the groups at baseline. Even before any adjustments, the intervention and control groups were very similar at baseline on CVD risk factors, demographics, and medication use at baseline (Appendix E). In addition, the enrolled control group beneficiaries differed from the attributed but not enrolled control group beneficiaries in ways similar to the intervention group—that is, suggesting that selection into the analytic population was similar for the intervention and control groups (Appendix E). Both factors increase the confidence that differences during the intervention period reflect true model impacts. In addition to using regressions to formally estimate impacts within a year of enrollment (the pre-specified time period for this analysis), we describe the percentage of people initiating or intensifying medications throughout the full follow-up period, up to 2.5 years. This enables us to see when any intervention–control differences began and whether they persisted beyond a year.

Initiation or intensification

Candidates for medication initiation or intensification:

- For statin therapy: LDL cholesterol at enrollment ≥ 70 mg/dL
- For antihypertensives: Systolic blood pressure at enrollment ≥ 130 mm Hg

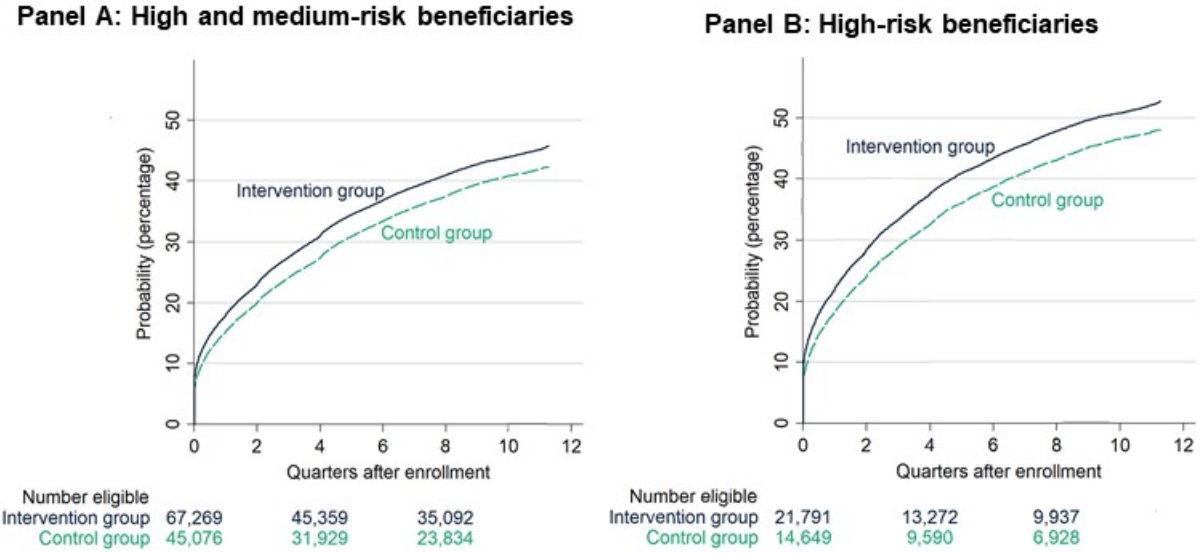
Initiation: Not taking a medication in the 4 months before enrollment, but taking one or more after enrollment

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

Intensification of antihypertensive therapy: Adding a new antihypertensive medication or increasing the dosage or strength of an existing one after enrollment.

The probability of initiating or intensifying these medications increased steadily in the first year after enrollment and continued more gradually afterwards (Figure V.B.1). The intervention group rate increased more quickly than the control group's in the first year and the differences between the two groups persisted through the maximum beneficiary follow-up observed.

Figure V.B.1. Many beneficiaries initiated or intensified CVD medications after enrollment, but rates were consistently higher in the intervention group than the control group: Probability of initiating or intensifying statins or antihypertensive medications among candidate high- and medium-risk beneficiaries



Source: Medicare Part D claims linked to enrollment data from the Million Hearts Registry.

The regression-adjusted probability of initiating or intensifying statins or antihypertensive medications within one year of enrollment was 4 percentage points higher in the intervention group than the control group: 31 percent in the intervention group and 27 percent in the control group ($p < 0.001$; Table V.B.1).

The impact estimates were modestly larger for high-risk beneficiaries (5 percentage points, 37 percent in the intervention group and 32 percent in the control group, $p < 0.001$) than for the high- and medium-risk groups combined. This larger impact for the high-risk group makes sense because the model required cardiovascular care management services only for the high-risk beneficiaries, and CMS pays for risk reduction among this group. However, the combined high- and medium-risk population was three times the size of the high-risk population by itself, so improvements among the high-risk group could not have been the only cause of the 4 percentage point impact in the combined population. CMS anticipated that care would improve for medium-risk beneficiaries as well as high-risk ones if providers became more aware of elevated risk among medium-risk beneficiaries as a result of systematic risk assessment.

The model increased both intensification and initiation for both statins and antihypertensives (Table V.B.1). Among high- and medium-risk beneficiaries, the impacts on initiation were similar to, or slightly larger than, impacts on intensification. However, because most (82 percent) of the high- and medium-risk beneficiaries already took antihypertensive medications at enrollment, many more people were candidates for antihypertensive intensification than were for initiating antihypertensives for the first time. Therefore, the population-wide increase in antihypertensive use was driven largely by intensification of medications rather than initiating new ones. In contrast, less than two-thirds (61 percent) of the high- and medium-risk

beneficiaries took statins at enrollment, so initiation and intensification contributed almost equally to the population-wide impacts on increase in statin use.

Table V.B.1. The model increased intensification and initiation of both statins and antihypertensives: Estimated impacts on the initiation or intensification of CVD-related medications

Outcome	Regression-adjusted mean		Adjusted difference (p value) [90% confidence interval]			Number of beneficiaries[a]
	Intervention group	Control group				
High and medium risk beneficiaries						
Statin or antihypertensive intensification or initiation	30.9	27.3	3.6	(p < 0.001)	[2.5, 4.7]	112,345
Antihypertensive intensification or initiation	28.9	26.5	2.5	(p < 0.001)	[1.5, 3.4]	74,711
Initiation	36.3	33.3	3.0	(p = 0.005)	[1.2, 4.7]	15,390
Intensification	27.0	24.7	2.3	(p < 0.001)	[1.3, 3.3]	59,321
Statin intensification or initiation	18.4	14.9	3.5	(p < 0.001)	[2.5, 4.6]	96,416
Initiation	26.7	22.7	4.0	(p < 0.001)	[2.6, 5.3]	48,344
Intensification	10.1	7.0	3.1	(p < 0.001)	[2.2, 4.1]	48,072
High risk beneficiaries						
Statin or antihypertensive intensification or initiation	37.3	32.4	4.8	(p < 0.001)	[3.3, 6.4]	36,440
Antihypertensive intensification or initiation	32.4	29.8	2.6	(p < 0.001)	[1.3, 3.9]	29,506
Initiation	48.8	44.1	4.6	(p = 0.01)	[1.6, 7.7]	4,235
Intensification	29.7	27.4	2.3	(p = 0.005)	[1.0, 3.6]	25,271
Statin intensification or initiation	21.1	15.7	5.4	(p < 0.001)	[3.9, 6.9]	28,922
Initiation	32.1	26.1	6.0	(p < 0.001)	[4.0, 8.0]	13,395
Intensification	11.8	6.8	4.9	(p < 0.001)	[3.5, 6.4]	15,527

Source: Analysis of Medicare Part D claims.

Notes: We estimated impacts using logistic regressions, with each beneficiary receiving the same weight and accounting for clustering of beneficiaries within organizations. The regressions adjusted for a range of baseline characteristics, including demographics, service use in the year before enrollment, CVD risk scores and risk factors, baseline medication use, and characteristics of the organization enrolling the beneficiary and of the region where the beneficiary lived.

[a] The number of beneficiaries varies across analyses because each analysis is limited to the beneficiaries who are candidates for that particular outcome. For example, when examining impacts on use of antihypertensives, we limited to beneficiaries with elevated systolic blood pressure (130 mm Hg or higher) at baseline.

CVD = cardiovascular disease.

These impact findings were consistent with findings from two robustness checks, increasing our confidence in them. Specifically, impacts were similar (1) among a trimmed population, in which we limited the intervention group to mimic the 20-provider cap CMS applied to the control group (by imposing a similar cap on the intervention group); and (2) when using a higher blood pressure threshold to define candidates for potential antihypertensive medication initiation or

intensification: systolic blood pressure greater than or equal to 140 mmHg instead of 130 mmHg. Detailed methods and results are in Appendix F.

C. Follow-up with beneficiaries over time to encourage and sustain risk reduction

Key findings

Most providers reported following up with high-risk beneficiaries in person, by phone, or email at least twice per year, the minimum frequency required by the Million Hearts Model. During these contacts, providers or other clinical staff discussed and encouraged progress on reducing CVD risk. The Million Hearts Model appeared to have modestly increased follow-up with high-risk beneficiaries, and—for some organizations—it focused follow-up contact more specifically on reducing CVD risk. However, overall, intervention organizations submitted risk reassessment data for 57 percent of their eligible high-risk beneficiaries, well below CMS's initial goal of 95 percent.

1. Follow-up with high-risk beneficiaries

Model requirement

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


Provider survey

Most intervention organizations followed up regularly with their high-risk Medicare beneficiaries to assess and encourage risk reduction, but room for improvement remained. In the 2018 survey, 84 percent of intervention-group providers reported they typically followed up with high-risk beneficiaries to monitor risk reduction plans at least twice a year, the minimum required by the model. Most (87 percent) also reported they used at least one of the following resources to help ensure high-risk Medicare beneficiaries were not lost to follow-up: care managers (54 percent), registries or tracking tools (34 percent), and automated scheduling with a minimum frequency (27 percent).


Interviews

Our three rounds of interviews provided additional insights into the strategies organizations used to follow up with high-risk Medicare beneficiaries. At the beginning of 2018, the organizations we interviewed had just begun focusing on follow-up. Most did not have formal processes in place to track follow-up for beneficiaries or used labor-intensive processes such as manually updating and reviewing paper lists (Conwell et al. 2019). By the beginning of 2019, in contrast, about two-thirds of the organizations had established follow-up systems as they shifted their focus from enrolling new beneficiaries.

Organizations used dedicated staff and systems to manage Million Hearts Model follow-up. By early 2019, about half of organizations reported formal systems—including building alerts into the EHR or creating separate Microsoft Excel-based tracking registries for administrative or clinical support staff to cross-reference with the Million Hearts Data Registry; the other half were less formal (Peterson et al. 2019). In addition, several medium-sized and large organizations hired new staff or significantly changed the responsibilities of existing staff to oversee beneficiary follow-up and other workflows related to the Million Hearts Model (Peterson et al. 2019). Nearly all organizations we interviewed continued these processes into early 2020, but one noted that the Million Hearts Model had become less of a priority, and the organization could not afford to use the same systematic processes it had previously used for tracking beneficiaries and ensuring follow up. Respondents cited certain staff positions (such as nurses or schedulers) as critical to ensuring the organizations scheduled beneficiaries for follow-up visits, and organizations that lost staff said they faced challenges securing follow-up visits.


Provider survey

Overall, the Million Hearts Model appears to have modestly increased the rates of follow-up with high-risk beneficiaries. In the 2018 survey, 58 percent of intervention group providers that calculated risk scores reported they followed up with high-risk Medicare beneficiaries at least once every three months through any mode (for example, office visits, telephone calls, emails or letters) to monitor plans to reduce risk. In contrast, among control group providers that calculated risk scores, 43 percent said they followed up with their high-risk Medicare beneficiaries at least once every three months, a 15 percentage point difference that was statistically significant ($p = 0.019$).


Interviews

Follow-up mostly occurred in person, but providers also used phone calls and text messages. In early 2018, about half of the organizations we interviewed relied on existing workflows, such as annual wellness visits or other routine office visits, to conduct follow-up. This approach made sense, in part, because high-risk beneficiaries tended to visit the Million Hearts Model organizations frequently. On average, enrolled beneficiaries had three to four visits with Million Hearts Model providers in the year after enrollment. Thus, providers could often meet the model's follow-up requirement through regular office visits—though this would not necessarily have been true for patients who visited less frequently than the average. Further, although organizations might not have needed to increase the *frequency* of visits with most high-risk beneficiaries to meet the model's follow-up requirements, those providers might have needed to change the *content* of the visits (to make sure they discussed CVD risk reduction plans and progress). Two organizations used secure text messaging to communicate with beneficiaries (Conwell et al. 2019). Similarly, in early 2019 and 2020, about two-thirds of the organizations we interviewed followed up with beneficiaries in routine office visits, but about half also relied on phone-based outreach and a few used text or email.


Claims

Using Medicare claims, we estimated the impact of the Million Hearts Model on the frequency of office visits. We found a modest (1 to 2 percent) increase in the frequency of office visits with any provider, including Million Hearts Model providers (Table V.C.1). This increase might be due to beneficiaries following up with their providers about their CVD risk factors. However, it could also be due to

the model increasing beneficiaries' contact with the health care system in general. For example, the model might have prompted beneficiaries' concerns about their CVD risk, causing them to come into the office more often, which in turn revealed other health conditions that would benefit from more regular provider attention.

Table V.C.1. The model prompted modest increases in the frequency of office visits: Estimated impacts on office visits after enrollment

	Regression adjusted number of office visits per quarter (#/beneficiary/quarter)				
	Intervention group mean	Control group mean	Difference (%)	*p* value	90% confidence interval
High and medium risk beneficiaries					
Number of office visits (per 1,000 beneficiaries per quarter)[a]	2,722	2,684	37.6 (1.4%)	0.06	[4.4, 70.8]
Cardiologist visits	571	575	-4.2 (-0.7%)	0.80	[-32.4, 23.9]
Visits with a Million Hearts Model provider	826	795	30.4 (3.8%)	0.26	[-13.8, 74.7]
Percentage with an office visit with a Million Hearts Model provider 10 to 15 months after enrollment[b]	73.4	70.3	3.1 (4.4%)	0.16	[-0.5, 6.7]
High risk beneficiaries					
Number of office visits (per 1,000 beneficiaries per quarter)[a]	2,922	2,871	50.4 (1.8%)	0.04	[9.5, 91.2]
Cardiologist visits	655	656	-1.0 (-0.2%)	0.96	[-38.5, 36.5]
Visits with a Million Hearts Model provider	921	883	38.4 (4.4%)	0.21	[-12.3, 89.1]
Percentage with an office visit with a Million Hearts Model provider 10 to 15 months after enrollment[b]	75.9	72.3	3.6 (4.9%)	0.13	[-0.3, 7.5]

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

Note: Table covers 130,641 beneficiaries enrolled in 172 intervention organizations and 88,312 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,446 beneficiaries enrolled in 170 intervention organizations and 27,287 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores 30 percent or higher. Percentage impacts are relative to the regression-adjusted control group mean. For this analysis, we define Million Hearts Model providers as those included on an organization's provider list to CMS at the time of randomization

[a] 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.

[b] Analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled in October 2019.

CMS= Centers for Medicare & Medicaid Services.

The content of follow-up visits focused primarily on monitoring and updating care or health management plans. This focus included changes to treatment, medication adherence, and answering beneficiaries' questions. In 2020, about half of the organizations we interviewed said they focused their follow-up contacts on monitoring progress toward care plans organizations developed specifically as part of their participation in the Million Hearts Model. For example, providers followed up with beneficiaries to check how they were tolerating a new statin or to ensure beneficiaries received necessary lab work to monitor cholesterol levels. However, about half of respondents said the content of their follow-up visits was not specific to the Million Hearts Model and did not change due to the model. Rather, these respondents noted that care managers or other staff followed up with all patients they considered high risk, including not just high CVD risk but also, for example, uncontrolled diabetes.

> "Whatever intervention we talked about or whatever goals we set from the first contact, that's usually what I focus on. The second contact is following up with those goals, reiterating the risk score—what it means and the things that we're trying to work on."
>
> *—Director of quality*

2. Annual reassessment visits

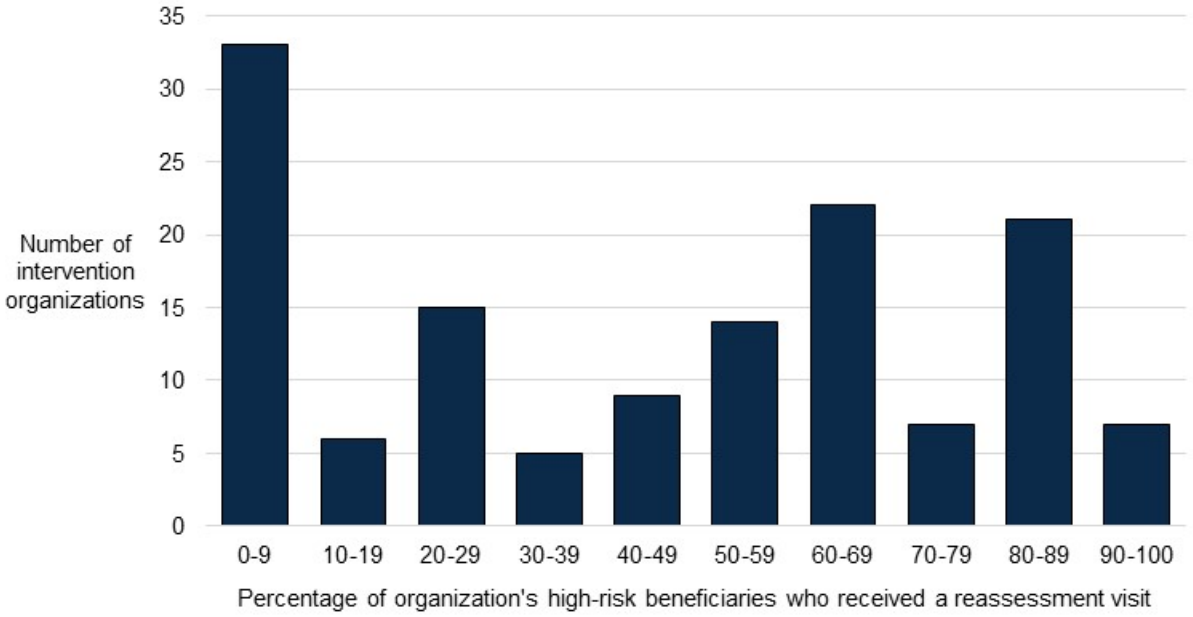
Model requirement

Intervention organizations update CVD risk scores annually with current clinical data. The first annual reassessment of the CVD risk score should happen in person, 10 to 14 months after the enrollment visit.


Registry data

Overall, intervention organizations submitted risk reassessment data for 57 percent of their eligible high-risk Medicare beneficiaries through December 2018, with wide variation across organizations (Figure V.C.1). For this analysis, we considered beneficiaries to be eligible for reassessment if they (1) enrolled early enough in 2017 that their anniversary window for a reassessment visit (10 to 14 months after enrolled) occurred by the end of 2018; (2) had a CVD risk score at enrollment greater than or equal to 30 percent, so that they were categorized as high-risk at enrollment; (3) did not die, have a CVD event, enroll in Medicare Advantage, or lose Medicare as the primary payer within 14 months of enrollment in the Million Hearts Model; and (4) were enrolled by an organization that remained in the model (that is, did not withdraw) through March 31, 2019, the date that performance data for 2018 was due. This 57-percent reassessment rate was well below the 95 percent that CMS required at start of the model, although CMS did not enforce this requirement. The wide variation across organizations in reassessment rates likely reflected (1) variation in strategies organizations used to track and encourage follow-up contacts, including reassessment visits; and (2) the fact that some organizations effectively disengaged in the model, not doing the annual risk reassessment, or doing the reassessment but not reporting data to the registry. The difference between survey responses and our calculated rates of risk reassessment could have arisen because (1) the survey asked about *all* modes of follow-up, not just in-person reassessment visits; (2) survey respondents might have overstated their true rates of follow-up; or (3) some organizations conducted routine CVD reassessments in person but did not submit all reassessment data to the registry.

Figure V.C.1. Overall, intervention organizations submitted risk reassessment data for 57 percent of their eligible high-risk Medicare beneficiaries, with wide variation across organizations: Distribution of rates of reassessment visits across intervention organizations



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

Note: The figure includes 139 intervention organizations that (1) enrolled at least one high-risk beneficiary who was eligible to receive a reassessment visit by the end of 2018 and(2) still participated in the Million Hearts model through the data submission period for 2018 registry data (March 31, 2019). Beneficiaries were eligible to receive a reassessment visit if they were (1) enrolled early enough in 2017 that their anniversary window for a reassessment visit (10 to 14 months after baseline) occurred by the end of 2018; (2) had a baseline risk score of at least 30 percent, so that they were categorized as high-risk at enrollment; and (3) did not die, have a CVD event, enroll in Medicare Advantage, or lose Medicare as the primary payer within 14 months of enrollment (because these events would make a beneficiary ineligible for a model reassessment visit).

CVD = cardiovascular disease.

The high-risk beneficiaries with submitted reassessment data were more likely than eligible beneficiaries without reassessment data submitted to have diabetes (69 versus 61 percent), to have been enrolled by a primary care provider (66 versus 50 percent), and to have had more visits with Million Hearts Model providers in the year before enrollment in the model (3.5 versus 2.8 visits; see Appendix A). One possible explanation for these differences is that all three of these factors tended to increase how often patients would visit the Million Hearts Model providers, thus increasing opportunities for reassessment visits. For example, beneficiaries with diabetes could be more likely to come into the office regularly to receive care for that condition, and beneficiaries might be more likely to visit their primary care provider routinely than to visit a cardiologist routinely. The result is that certain groups of beneficiaries—namely, those with more overall contact with Million Hearts Model providers—were more likely to receive and have data submitted to CMS for the annual CVD risk monitoring expected under the model.

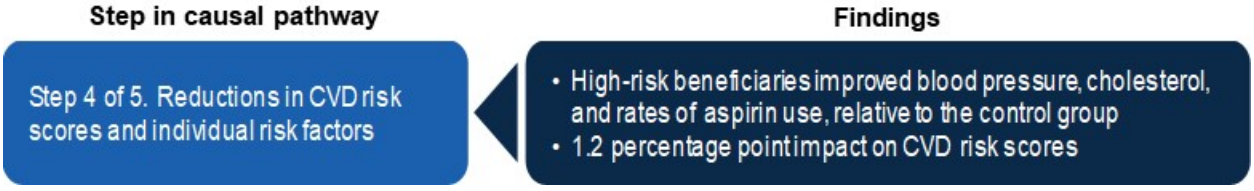
In addition to submitting the clinical data CMS used to calculate risk at reassessment, some organizations also recalculated risk scores themselves during or after the reassessment visits. However, when they did so, they used the same ASCVD Risk Estimator they had used to calculate the baseline risk score, rather than the novel longitudinal calculator developed for the model: the Million Hearts ASCVD Longitudinal Risk Assessment Tool. The newer tool generally estimates bigger changes in CVD risk due changes in blood pressure and other modifiable risk factors than the baseline calculator does. Therefore, organizations that recalculated risk themselves would have seen different changes in risk scores than CMS used to determine the incentive payments.

During the 2020 interviews, providers at one-third of the organizations interviewed expressed some concerns about tracking CVD risk over time due to the strong influence age has on risk calculations. As beneficiaries age, their estimated risk of a CVD event increases significantly, which can offset gains beneficiaries and providers make in reducing modifiable risk factors. Providers in these organizations said they could readily access CVD risk scores for beneficiaries over time because the scores were calculated and stored within beneficiaries' records in the EHR. However, providers preferred to monitor and track progress instead on modifiable risk factors, such as blood pressure and cholesterol.

VI. REDUCTIONS IN CARDIOVASCULAR RISK ONE YEAR AFTER ENROLLMENT

If the Million Hearts Model is working as intended, improvements in clinical care and patients' behaviors should lower CVD risk scores for high-risk beneficiaries at their annual reassessment visits. In Section A of this chapter, we describe reductions in cardiovascular risk scores—as measured using the Million Hearts Longitudinal ASCVD Risk Assessment Tool—and changes in risk factors one year after enrolling in the model. We further estimate the impact of the Million Hearts Model on reducing CVD risk. In Section B, we explore whether changes in CVD medications one year after model enrollment could explain the observed risk reductions.

Chapter takeaway



A. Reductions in risk over time, by treatment arm

Key findings

One year after enrollment, CVD risk scores decreased for high-risk beneficiaries in both the intervention and control groups. However, CVD risk scores decreased by modestly more in the intervention group (8 percentage points) than in the control group (7 percentage points). After regression adjustment, the Million Hearts Model appears to have reduced high-risk beneficiaries' 10-year predicted risk of a heart attack or stroke by 1.2 percentage points ($p = 0.009$). In addition to the impact on CVD risk scores, the Million Hearts Model achieved modest impacts on blood pressure and cholesterol levels of about 1 percent each, and a substantial impact (10 percentage points) in the use of aspirin therapy.

To describe changes in CVD risk scores and CVD risk factors—and to estimate the impact of the Million Hearts Model on these outcomes—we compared risk scores (as determined by the Million Hearts Longitudinal ASCVD Risk Assessment Tool) and risk factors among high-risk beneficiaries in the intervention versus control groups, one year after model enrollment. Although conceptually we would also like to estimate model impacts on risk scores for medium-risk beneficiaries (given the potential for positive spillover of model impacts for this group), we cannot estimate these impacts because follow-up clinical data for medium-risk beneficiaries are not available. CMS required intervention organizations to submit reassessment data only for high-risk beneficiaries, the group for whom CMS makes risk reduction payments.

Our analysis of risk reduction included 15,078 intervention and 8,060 control beneficiaries who (1) enrolled early enough in 2017 that their anniversary window for a reassessment visit (10 to 14 months after baseline) occurred by the end of 2018; (2) had a baseline risk score of at least 30 percent, so that they were categorized as high risk at enrollment; (3) did not die, have a CVD event, enroll in Medicare Advantage, or lose Medicare as the primary payer within 14 months of enrollment (because these events would make a beneficiary ineligible for a model reassessment visit); and (4) had reassessment data recorded in the Million Hearts Data Registry from a reassessment visit in 2017 or 2018 (at least 10 months after enrollment and no more than 23). This last condition—having reassessment data by the end of 2018—restricted the sample to 52 percent of intervention beneficiaries[6] and 44 percent of control beneficiaries who met the first three criteria. That is, roughly half of intervention group beneficiaries eligible for an annual reassessment visit actually had one recorded in the Million Hearts Data Registry; one-third to one-half of the control group beneficiaries had complete reassessment data in the registry. Appendix A describes the population for analysis in more detail. The intervention beneficiaries who did have reassessment data remained very similar to the control beneficiaries with reassessment data on a wide range of baseline characteristics, including demographics, CVD risk factors at enrollment, and recent service use and Medicare spending (Appendix E).

Among high-risk beneficiaries with reassessment data by the end of 2018, CVD risk scores decreased in the year between enrollment and reassessment in both the intervention and control groups (Table VI.A.1). Notably, these decreases in risk scores occurred *even though* beneficiaries aged and diabetes prevalence rose—both factors that would tend to make risk higher over time, not lower. Overall, the reduction in risk scores was driven by reductions in systolic blood pressure and LDL cholesterol—two risk factors that have a large influence on overall risk scores, as calculated using the Million Hearts Longitudinal ASCVD Risk Assessment Tool (Lloyd-Jones et al. 2017).

CVD risk scores decreased in both groups, but risk scores decreased by modestly more in the intervention group (8 percentage points) than the control group (7 percentage points). We used common statistical methods (linear regression, as described in Appendix F) to estimate impacts of the Million Hearts Model, adjusting the observed difference in risk reduction between the intervention and control groups to account for differences in (1) beneficiaries' baseline characteristics and (2) the time between their enrollment and reassessment measurements (ranging from 10 to 23 months). After this regression adjustment, the intervention group had a 1.2 percentage point greater decrease in CVD risk scores than the control group ($p = 0.009$). This estimated impact of the intervention on CVD risk scores remained similar in sensitivity analyses (Appendix F) 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.

[6] The 52 percent of intervention beneficiaries is lower than the 57 percent reassessment rate visit reported in Chapter V because the analysis in Chapter V was restricted to organizations that were still participating in the Million Hearts model through the data submission period for 2018 registry data (March 31, 2019).

Contributing to the impact on CVD risk scores were impacts on several of the individual risk factors that contribute to overall risk. That is, systolic blood pressure and LDL cholesterol declined in *both* the intervention and control groups, which drove reductions in CVD risk scores in both groups; however, the improvement in risk factors was greater in the intervention group than in the control group, which drove the difference in CVD risk reduction between the two groups Specifically, systolic blood pressure decreased by 6 mmHg in the intervention group and 5 mmHg in the control group, with a regression-adjusted difference between the intervention and control groups of 1.5 mmHg, or 1.1 percent ($p = 0.007$; Table VI.A.1). LDL cholesterol decreased by 4 mg/dL in the intervention group and 3 mg/dL in the control group, with a regression-adjusted difference between the intervention and control groups of 1.2 mg/dL, or 0.9 percent ($p = 0.04$). The intervention group also reported 10 percentage points greater aspirin use at reassessment than the control group ($p = 0.002$). We found no evidence for an impact of the model on smoking rates.

The impacts we observed on systolic blood pressure and LDL cholesterol (each about 1 percent) might not seem clinically relevant for an individual patient, especially given random fluctuations across measurements. However, a change in the *average* systolic blood pressure or LDL cholesterol of this magnitude—measured over several thousand people—is unlikely to be due to chance and could, potentially, have impacts on CVD event rates.

In particular, assuming the reductions in predicted risk—that is, CVD risk scores—translate into reductions in eventual CVD events, a 1.2 percentage point impact on the risk score suggests the model could prevent one heart attack or stroke[7] over the next 10 years for every 86 high-risk beneficiaries enrolled. This represents a 3.5 percent reduction in risk relative to the expected CVD risk score at reassessment. (That is, a 1.2 percentage-point reduction is 3.5 percent of the control group's estimated risk score at reassessment [1.2 / 33 = 0.035 with rounding].) Although a 3.5 percent impact might, again, seem modest for a given individual, it can have a meaningful impact over a large population.

[7] The CVD risk score as measured with the Million Hearts Longitudinal ASCVD Risk Assessment Tool is supposed to reflect a person's risk of first occurrence of nonfatal myocardial infarction, coronary heart disease death (including fatal myocardial infarction), or fatal or nonfatal stroke (Goff et al. 2014). Note that for the impact evaluation results presented in Chapter VII, our composite measure for the primary outcome of first-time heart attack or stroke also includes transient ischemic attacks.

Table VI.A.1. CVD risk scores decreased by more for the intervention group than the control group: Estimated impacts on CVD risk scores and risk factors one year after enrollment, among high-risk beneficiaries with reassessment data in 2017 or 2018

	Visit	Intervention group mean	Control group mean	Regression adjusted difference at reassessment (p value) [90% confidence interval]			Percentage impact
CVD risk score							
CVD risk score (in percentage points)	Enrollment	40	40				
	Reassessment	32	33	-1.2	(p = 0.009)	[-1.9, -0.4]	-3.5%
Continuous risk factors							
Systolic blood pressure (in mmHg)	Enrollment	139	139				
	Reassessment	133	134	-1.5	(p = 0.007)	[-2.3, -0.6]	-1.1%
Total cholesterol (in mg/dL)	Enrollment	167	168				
	Reassessment	162	163	-1.5	(p = 0.02)	[-2.5, -0.5]	-0.9%
LDL cholesterol (in mg/dL)	Enrollment	91	91				
	Reassessment	87	88	-1.2	(p = 0.04)	[-2.2, -0.2]	-1.4%
HDL cholesterol (in mg/dL)	Enrollment	47	48				
	Reassessment	47	47	-0.1	(p = 0.55)	[-0.3, 0.1]	-0.2%
Binary risk factors							
Probability of smoking	Enrollment	12	12				
	Reassessment	11	10	0.4	(p = 0.21)	[-0.1, 1.0]	4.1%
Probability of using aspirin	Enrollment	50	49				
	Reassessment	65	55	10.2	(p = 0.002)	[4.7, 15.7]	18.5%

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

Note: Table covers 15,078 beneficiaries enrolled in 124 intervention organizations and 8,060 beneficiaries enrolled in 99 control organizations. Mean values at enrollment are the actual means observed, and the means at reassessment and differences are regression adjusted. See Appendix F for more detail about the regression models. Percentage impacts are relative to the regression-adjusted control group mean at reassessment.

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

The following limitations apply to these findings:

- First, as noted previously, this analysis does not capture all high-risk beneficiaries enrolled in the model, only those who had reassessment data recorded in the Million Hearts Data Registry. A substantial number of organizations withdrew from the model or stopped effectively participating by the end of 2018 (Chapter II), so we do not have clinical data at reassessment for their beneficiaries. In addition, even at organizations submitting data to the registry, not all high-risk beneficiaries returned to the provider for an annual office visit. We

cannot observe how the risk scores changed for beneficiaries without recorded reassessment data, and whether this differed for the intervention and control groups. However, we found no notable differences in baseline characteristics between the intervention and control group beneficiaries with reassessment visits (Appendix 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—for example, if the patient feels anxious or the blood pressure cuff is positioned incorrectly. Measurement error could lead to bias in the impact estimates if measurement error differs between the intervention and control groups—for example, if the intervention group measured blood pressure more accurately than the control group or tended to have more recent cholesterol measurements on file than the control group. We have no evidence about measurement error for blood pressure. However, we could estimate the proportion of beneficiaries with updated cholesterol readings at reassessment, and found higher rates for intervention than control beneficiaries. This suggests data quality could be higher for the intervention group than the control group.
- Third, we estimated impacts on predicted CVD risk using the Million Hearts Longitudinal ASCVD Risk Assessment Tool, but reductions in predicted risk might not translate into actual CVD events prevented. The Million Hearts Longitudinal ASCVD Risk Assessment Tool is based on evidence from randomized controlled trials about the effectiveness of CVD treatment and risk factor changes (Lloyd-Jones et al. 2017). However, any predictive tool relies on some assumptions. If the Million Hearts Model beneficiaries differ substantially from the clinical trial participants used to create the risk assessment tool, for example, then the true effect on heart attacks and strokes could differ from the one event per 86 beneficiaries that we estimated here. In Chapter VII, we estimate impacts on CVD events directly—although at present we can do so only for the first couple of years of the model, through late 2019.

B. Role of CVD medications in driving risk reduction

Key findings

On average, beneficiaries who initiated or intensified antihypertensives or statins experienced larger reductions in risk scores than those who did not, and this was true in both the intervention and control groups. The fact that intervention beneficiaries were more likely than control beneficiaries to use these medications likely explains some, but not all, of the observed difference in CVD risk scores. Increases in aspirin use in the intervention group, relative to the control group, can also explain some, but not all, of the observed impacts on CVD risk scores.

Identifying the drivers of reduced CVD risk scores in the intervention and control groups can help us understand how the Million Hearts Model is achieving its impacts on risk scores. This

understanding could inform how to scale the model eventually or, alternatively, improve it so that it has greater impacts.

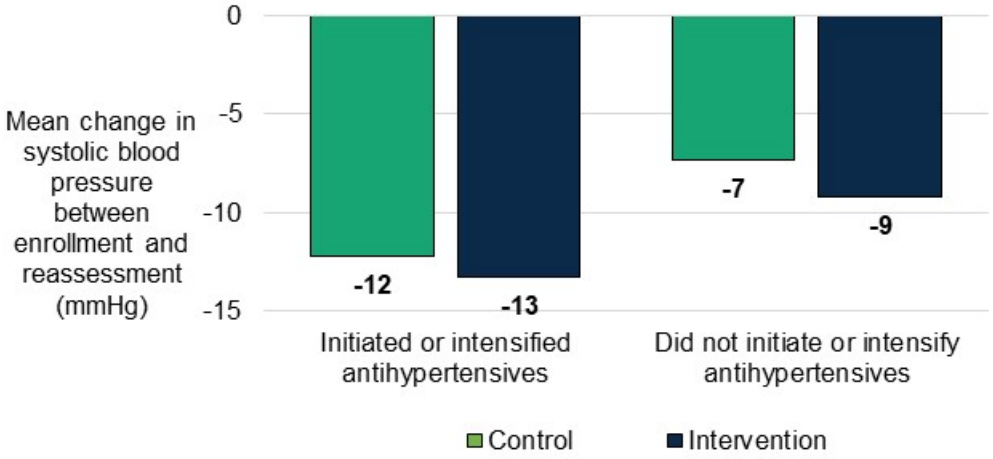
One plausible explanation for the observed CVD risk score reductions is an increase in use of antihypertensive and statin medications. That is, it is possible the observed impacts on initiation and intensification of antihypertensive and statin medications (described in Chapter V) led to impacts on blood pressure and LDL cholesterol (described in Section A), and this, in turn, explains the 1.2 percentage point impact on overall mean CVD risk score. This section explores that hypothesis.

Recap of Chapter V findings

- Among high-risk beneficiaries in the intervention group, **37 percent initiated or intensified statins or antihypertensive medications** within one year of enrollment
- This was **5 percentage points higher** than in the control group (32 percent)

Linking registry data with Part D claims data, we observed clinically meaningful decreases in systolic blood pressure among beneficiaries with uncontrolled hypertension who initiated antihypertensive medications within one year of enrollment (Figure VI.B.1). Similarly, we observed meaningful decreases in LDL cholesterol among beneficiaries with elevated LDL cholesterol who initiated statin therapy (Figure VI.B.2). Given data constraints, we limited this analysis to high-risk beneficiaries who (1) had reassessment data and were included in the analysis described in Section A and (2) were enrolled in Medicare Part D in the year before Million Hearts Model enrollment through the date of their first annual reassessment. Overall, not only did the intervention group contain more beneficiaries who initiated or intensified CVD preventive medications (Chapter V), improvements in blood pressure and LDL cholesterol were greater for the intervention group *even among* those initiating or intensifying the medications in question. Moreover, improvements were greater for the intervention group than the control group among high-risk beneficiaries who did *not* initiate or intensify medications. The fact that risk factors improved for beneficiaries (both intervention and control) who did not use medications) suggests other factors, such as a beneficiary's lifestyle change, also contributed to risk factor change beyond initiating or intensifying antihypertensives or statins.

Figure VI.B.1. Systolic blood pressure declined more for people who initiated or intensified antihypertensives than for those who did not—but declines were greater in the intervention group than in the control group regardless of medication

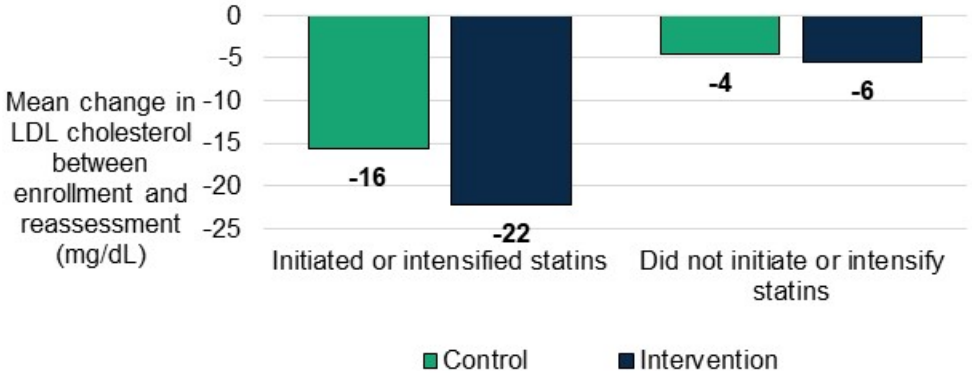


Source: Mathematica's analysis of Million Hearts Data Registry data linked to Medicare Part D claims and enrollment data.

Note: Figure shows mean change in systolic blood pressure between enrollment and first annual reassessment, by antihypertensive initiation or intensification over the same period, among high-risk beneficiaries with uncontrolled hypertension at enrollment and reassessment data recorded in 2017 or 2018. The analysis includes 7,621 high-risk intervention group beneficiaries and 4,163 high-risk control group beneficiaries who (1) met the criteria for inclusion in the analysis of risk reduction described in Section A of this chapter, (2) were enrolled in Medicare Part D in the year before model enrollment through the date of their first annual reassessment, and (3) and met the eligibility criteria described in Chapter V for antihypertensive initiation or intensification (that is, those with systolic blood pressure greater than 130 mmHg).

mmHg = millimeters of mercury.

Figure VI.B.2. Similarly, LDL cholesterol declined more for people who initiated or intensified statins than for those who did not—but declines were greater in the intervention group than in the control group regardless of medication



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

Note: Figure shows mean change in LDL cholesterol between enrollment and first annual reassessment, by statin initiation or intensification over the same period, among high-risk beneficiaries with elevated LDL at enrollment and reassessment data recorded in 2017 or 2018. The analysis includes 7,632 high-risk intervention group beneficiaries and 4,053 high-risk control groups beneficiaries who (1) met the criteria for inclusion in the analysis of risk reduction described in Section A of this chapter, (2) were enrolled in

Medicare Part D in the year before model enrollment through the date of their first annual reassessment, and (3) met the eligibility criteria for statin initiation or intensification described in Chapter V (those with LDL cholesterol at baseline of greater than 70 mg/dL).

LDL = low-density lipoprotein; mg/dL = milligrams per deciliter.

In exploratory analyses, we reestimated the model's impacts on CVD risk scores, but this time including control variables in the regression to remove the influence of model impacts on medications. If the model impacts on initiating or intensifying statins and antihypertensives had driven the reduction in CVD risk scores, we would expect that this reestimated impact on risk scores would be close to zero. We found, instead, that the reestimated impact was slightly smaller, but still meaningful (and statistically significant) after adding the new control variables (Appendix F). These findings suggest model impacts on medications can explain part of the impact on CVD risk scores, but other factors likely contributed as well. This finding is not surprising given the results in Figures VI.B.1 and VI.B.2.

> "I prioritize medications because lifestyle changes are so hard. People are … not going to change very often."
>
> *—Provider*

The model could reduce CVD risk through several possible other mechanisms. In interviews, a few providers volunteered that the model helped to motivate greater adherence to medications (not only initiating or intensifying medications). In registry data, we also observed impacts on aspirin use,[8] which could explain up to one-quarter of the impact on CVD risk scores. It is also possible that the model increased use of medications not included in our analysis, such as medications not covered in Part D (including those filled at low-cost retail pharmacies) or nonstatin cholesterol-lowering medications. Finally, it is possible that improvements in diet and exercise contributed to risk reductions. In interviews, a few providers volunteered that they did not see the model changing these behaviors, because the behaviors require difficult changes in long-standing habits. Nonetheless, even small improvements in diet or exercise—or larger improvement among a small fraction of all beneficiaries—could contribute to the modest population-level model impacts on CVD risk scores we observed. We have not interviewed or directly collected information from beneficiaries to assess whether they changed their diet or exercise habits.

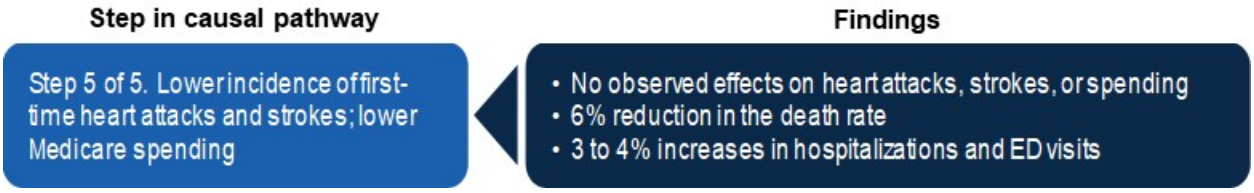
[8] New guidelines released in 2019 recommend using aspirin infrequently to prevent primary cardiovascular disease (Arnett et al. 2019); however, annual reassessments included in this analysis were from 2017 and 2018, when more widespread use of aspirin was the standard of care.

VII. MODEL IMPACTS ON HEART ATTACKS AND STROKES, MORTALITY, SERVICE USE, AND SPENDING

The Million Hearts Model aims to reduce the incidence of first-time heart attacks and strokes over five years. Further, it should reduce Medicare spending on these events and related care enough to offset model payments. This chapter describes our estimates of the model's impacts on first-time CVD events and Medicare spending over roughly three years. We also estimated impacts on mortality and service use (hospitalizations and ED visits), which we hypothesized might decline. In a future report, we will estimate impacts over the full five years of the model.

We estimated impacts as the regression-adjusted differences in outcomes for high- and medium-risk beneficiaries enrolled by the intervention and control organizations in 2017 and 2018. We constructed all outcomes from Medicare Parts A and B claims and enrollment data. For each beneficiary, we measured outcomes from the date he or she enrolled in the model through October 31, 2019, or until death or loss of observability in Medicare claims. The median length of follow-up was 26.6 months, with a range from one day to just under 34 months. The study population included 218,953 beneficiaries, with more beneficiaries (N = 130,641) in the intervention group than the control group (N = 88,312) due mainly to the 20-provider cap that applied only to control organizations. The regressions adjusted for beneficiaries' characteristics at enrollment to increase the precision of the estimates and to account for observed differences between the groups. The appendices (A–F) provide details on the methods and results for the impact estimates.

Chapter takeaway



A. Heart attacks and strokes

Key findings

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

The model did not measurably reduce the incidence of first-time heart attack, stroke, or TIA (a composite measure) through October 2019. The unadjusted probability of these events was very similar for the intervention and control group beneficiaries. For example, 2.7 percent of the intervention group's high- and medium-risk beneficiaries had a first-time heart attack, stroke, or TIA within 24 months of enrollment, compared to 2.8 percent in the control group (Table VII.A.1). In regression analyses, the hazard ratio—that is, the ratio in the risk of having a first-

time CVD event in the intervention versus control groups—was 1.00, indicating no model effect on this outcome for high- and medium-risk beneficiaries (Table VII.A.1). Given uncertainty in any statistical estimation, it is possible some small effect could have gone undetected. However, the 90 percent confidence interval around this estimate (0.95 to 1.04) indicates the analyses had good statistical power to detect the 7 percent reduction target that CMS set for the model over the five-year test, if the model had achieved such a large impact through October 2019. We also found no statistically significant impacts for high-risk beneficiaries alone, or for the individual components of the composite measure: (1) first-time heart attacks and (2) first-time strokes and TIAs.

Table VII.A.1. The model had no impact on the incidence of first-time heart attack, stroke, or TIA: Estimated ratio of the hazard of a first-time heart attack, stroke, or TIA between intervention and control beneficiaries (regression-adjusted)

Outcome and risk group	Percentage (unadjusted) of beneficiaries with a CVD event within two years of enrollment[a]		Regression adjusted hazard ratio		
	Intervention	Control	Ratio	*p* value	90% confidence interval
First time heart attack, stroke, or TIA (composite measure)[b]					
High- and medium-risk beneficiaries	2.7	2.8	1.00	0.90	[0.95, 1.04]
High-risk beneficiaries	3.6	3.8	1.01	0.84	[0.94, 1.08]
First time heart attack					
High- and medium-risk beneficiaries	1.2	1.3	1.02	0.69	[0.94, 1.10]
High-risk beneficiaries	1.7	1.8	1.01	0.81	[0.92, 1.12]
First time stroke or TIA					
High- and medium-risk beneficiaries	1.5	1.5	0.98	0.65	[0.93, 1.04]
High-risk beneficiaries	2.1	2.0	1.02	0.68	[0.94, 1.11]

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

Note: Table covers 130,641 beneficiaries enrolled in 172 intervention organizations and 88,312 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,446 beneficiaries enrolled in 170 intervention organizations and 27,287 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores 30 percent or higher. See Appendix F for more detail about the regression models.

[a] Percentages calculated among beneficiaries who enrolled by October 31, 2017, so that we could follow them for at least two years (or until death or loss of observability in Medicare Parts A and B claims) before the end of the claims period on October 31, 2019. We present unadjusted results in the first two columns because the Cox proportional hazards regression model framework does not produce adjusted estimates.

[b] AMIs, strokes, TIAs, or stroke symptoms identified as a (1) primary diagnosis on outpatient ED claim or inpatient claim or (2) a secondary diagnosis on an inpatient claim when the condition was listed as not present on admission. Appendix C of the second annual report (Peterson et al. 2019) describes the outcomes in detail. For AMIs, we include all five types of AMI described in the Fourth Universal Definition of Myocardial Infarction (Thygesen et al. 2018).

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

These estimates are largely consistent with impact estimates we reported in the second annual report (Peterson et al. 2019), following beneficiaries through October 2018. The estimates also are consistent with results from a series of robustness checks, reported in Appendix F: (1) narrowing the outcome definition to include only Type 1 heart attacks and strokes;[9] (2) trimming the intervention group so that, like in the control group, a maximum of 20 providers per organization could enroll beneficiaries; and (3) estimating impacts using beneficiaries we attributed, using claims data, to the intervention and control providers that participated in the model. This consistency increases our confidence in the results.

B. Mortality

Key findings

Among high- and medium-risk beneficiaries, the death rate was about 6 percent lower in the intervention group than in the control group—reflecting a difference of roughly three deaths per 1,000 people over two years. Among high-risk beneficiaries, the death rate was similar in the intervention and control groups.


Claims

The death rate was about 6 percent lower in the intervention group than in the control group among high- and medium-risk beneficiaries combined (Table VII.B.1); 3.9 percent of beneficiaries in the intervention group died within two years of enrollment, compared to 4.2 percent for the control group, or a difference of about three deaths per 1,000 people over two years. In regression-adjusted analyses, the estimated hazard ratio was 0.94, a difference that is statistically significant ($p = 0.007$). This is largely consistent with the results from the robustness checks (Appendix F) and is also similar to what we reported in the second annual report with a shorter time horizon (0.93). The estimates on survival are interim because we have not yet observed the full five-year model test; it will be essential to assess whether impacts persist.

Table VII.B.1. High- and medium-risk beneficiaries in the intervention group had a lower death rate than those in the control group: Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries (regression-adjusted)

	Percentage (unadjusted) of beneficiaries who died within two years of enrollment[a]		Regression adjusted hazard ratio		
Risk group	Intervention	Control	Hazard ratio	*p* value	90% confidence interval
High- and medium-risk beneficiaries	3.9	4.2	0.94	0.007	[0.90, 0.97]

[9] This exclusion (1) limits to heart attacks most likely caused by blockages in the arteries supplying the heart (Thygesen et al. 2018), and might be most expected to be influenced by the intervention (in contrast to other types of AMIs, such as those that occur during surgeries, which might be less affected by primary CVD prevention); and (2) removes TIAs, which are less severe than strokes and less reliably identified using claims data.

Risk group	Percentage (unadjusted) of beneficiaries who died within two years of enrollment[a]		Regression adjusted hazard ratio		
	Intervention	Control	Hazard ratio	*p* value	90% confidence interval
High-risk beneficiaries	5.1	5.3	0.98	0.65	[0.93, 1.04]

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

Note: Table covers 130,641 beneficiaries enrolled in 172 intervention organizations and 88,312 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,446 beneficiaries enrolled in 170 intervention organizations and 27,287 beneficiaries enrolled in 165 control organizations with baseline cardiovascular disease risk scores 30 percent or higher. See Appendix F for more detail about the regression models.

[a] Percentages calculated among beneficiaries who enrolled by October 31, 2017, so that we could follow them for at least two years (or until death) before the end of the claims and enrollment data period on October 31, 2019. We present unadjusted results in the first two columns because the Cox proportional hazards regression model framework does not produce adjusted estimates.

For high-risk beneficiaries, the death rate was similar in the intervention and control groups throughout the study period (Table VII.B.1). The unadjusted percentage of beneficiaries who died within two years of enrollment was 5.1 for the intervention group and 5.3 percent for the control group. In regression analysis, the estimated hazard ratio was 0.98—closer to 1—and not statistically significant ($p = 0.65$). This impact estimate, too, was consistent with a number of robustness checks, including trimming the population to no more than 20 providers per organization. This finding for high-risk beneficiaries, taken in combination with the impact estimate for high- and medium-risk beneficiaries combined, might suggest reductions in mortality for medium-risk beneficiaries, specifically, drive reductions in mortality among high- and medium-risk beneficiaries. However, in separate analyses assessing the overall *probability* of death over two years, the estimated impacts were very similar between the high-risk-only population and the larger combined population (Appendix F). This suggests the *relative* impact (in percentage terms) might have been greater for medium-risk beneficiaries, but high- and medium-risk beneficiaries experienced a similar decline in deaths in absolute terms—about three fewer deaths per 1,000 beneficiaries over two years.

The observed impacts on all-cause mortality are surprising. The impacts occurred without any corresponding reduction in CVD events, when we expected reductions in fatal hearts attacks or strokes would, at least partly, drive any impacts on survival. At least two potential explanations for early impacts on survival do not operate through apparent reductions in heart attacks, strokes, or TIAs. The first is that, by measuring CVD events in hospital and ED claims data, we might have missed some true model impacts on fatal heart attacks or strokes for which patients were pronounced dead outside of the hospital setting.[10] This could occur if the model prompted beneficiaries to go to the hospital at early signs of a CVD event that might otherwise prove fatal. Second, there could be reductions in mortality from other conditions due to improvement in

[10] Record linkage in Sweden found that 3 in 4 fatalities related to first-time major coronary events occurred out of the hospital, while the remaining 1 in 4 occurred in a hospital (Dudas et al. 2011). Similarly, a 2002 CDC report found that about half of fatal cardiac events in the United States occurred outside of the hospital (Zheng et al. 2002). If this pattern is similar among Million Hearts Model beneficiaries, a substantial fraction of the fatal CVD events might not be coded as first-time heart attacks, strokes, or TIAs in claims data.

exercise or diet, medication therapy, or other mechanisms we did not anticipate at the beginning of the evaluation. One such mechanism could be that, because the model encouraged beneficiaries to have more office visits (as demonstrated in Chapter V), providers might have been more likely to detect and address other health conditions.

However, the impact estimates could also reflect bias and not true impacts. Our careful use of regression adjustment and our robustness checks alleviates—but does not rule out—concerns that differences between the intervention and control organizations potentially biased the impact estimates. Such differences could have either existed at random assignment or could have been introduced during model implementation by organization- and provider-level attrition or by differences in the types of beneficiaries who intervention and control organizations chose to enroll among their eligible beneficiaries. The robustness checks using the claims-based attribution population sought to limit the potential for this last source of bias.

C. Service use

Key findings

Rates of all-cause hospitalizations and outpatient ED visits were modestly higher for the intervention group than the control group, both for high- and medium-risk beneficiaries (3 to 4 percent higher) and for high-risk beneficiaries alone (4 to 6 percent higher). The model was also associated with slightly increased rates of CVD-related hospital admissions among high-risk beneficiaries.

Claims

We hypothesized that the Million Hearts Model could reduce hospitalizations and outpatient ED visits (including observation stays) for CVD-related reasons. This includes acute care for heart attacks and strokes, but also for other conditions such as angina, which better management of CVD risk factors might also reduce. By extension, we hypothesized that the model could reduce rates of all-cause hospitalizations and outpatient ED visits as well (as secondary outcomes). As shown in Table VII.C.1, CVD-related admissions and ED visits account for 22 and 8 percent of all hospitalizations and ED visits, respectively, for the high- and medium-risk beneficiaries.

Focusing first on CVD-related acute care, the CVD-related hospitalization rate for the combined high- and medium-risk groups was similar between the intervention and control groups (Table VII.C.1). Specifically, through October 2019, there were 14.0 hospitalizations per 1,000 beneficiaries per quarter in the intervention group, compared to a rate of 13.7 for the control group. This relatively small (2.5 percent) difference in the rate of CVD-related hospitalizations was not statistically significant ($p = 0.29$). In contrast, the model appears to have increased rates of CVD-related hospital admissions among high-risk beneficiaries. There were 1.05 more hospitalizations per 1,000 beneficiaries per quarter (or 5.9 percent more) in the intervention group than the control group ($p = 0.08$). The rates of CVD-related ED visits and observation stays did not differ statistically between the intervention and control groups, either for the high-risk beneficiaries or the high- and medium-risk beneficiaries combined.

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

Outcome and risk group	Regression adjusted rate (#/1,000 beneficiaries/quarter)				
	Intervention group mean	Control group mean	Difference (%)	*p* value	90% confidence interval
Number of CVD related admissions					
High- and medium-risk beneficiaries	14.0	13.7	0.35 (2.5%)	0.286	[-0.2, 0.9]
High-risk beneficiaries	19.0	17.9	1.05 (5.9%)	0.084	[0.1, 2.0]
Number of CVD related outpatient ED visits and observation stays					
High- and medium-risk beneficiaries	8.2	8.1	0.13 (1.6%)	0.693	[-0.4, 0.7]
High-risk beneficiaries	9.9	9.5	0.36 (3.8%)	0.432	[-0.4, 1.1]
Number of all cause admissions					
High- and medium-risk beneficiaries	64.5	62.2	2.35 (3.8%)	0.009	[0.9, 3.8]
High-risk beneficiaries	77.2	73.6	3.63 (4.9%)	0.023	[1.0, 6.2]
Number of all cause outpatient ED visits and observation stays					
High- and medium-risk beneficiaries	102.3	98.7	3.56 (3.6%)	0.039	[0.7, 6.4]
High-risk beneficiaries	111.2	105.4	5.77 (5.5%)	0.004	[2.5, 9.0]

Source: Regression-adjusted results from Medicare claims data.

Note: Table covers 130,641 beneficiaries enrolled in 172 intervention organizations and 88,312 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,446 beneficiaries enrolled in 170 intervention organizations and 27,287 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores 30 percent or higher. We estimated impacts separately by quarter since enrollment and then averaged the estimates across all quarters, weighting each quarterly estimate by the number of intervention group beneficiaries observed in that quarter. Percentage impacts are relative to the regression-adjusted control group mean.

CVD = cardiovascular disease; ED = emergency department.

Turning to model impacts on beneficiaries' use of acute care for any reason (not only CVD-related care), the model appears to have increased all-cause admissions and ED visits, both for the high- and medium-risk beneficiaries combined and only the high-risk beneficiaries (Table VII.C.1). Specifically, the average number of all-cause admissions increased among the intervention group by 3.8 percent for the high- and medium-risk beneficiaries combined and 4.9 percent for the high-risk beneficiaries, relative to their respective control beneficiaries. The average number of all-cause outpatient ED visits and observation stays increased by about 3.6 percent for the high- and medium-risk beneficiaries combined and 5.5 percent for the high-risk beneficiaries, relative to the control group. All these differences in acute care use were statistically significant at the $p < 0.05$ level. These impacts were also larger (in absolute terms) than impacts on CVD-related acute care, suggesting increases in non-CVD-related acute care caused most of the difference. Results were largely similar in the robustness checks using data

trimmed to include no more than 20 providers per organization and using the population attributed to participating providers based on claims data.

The finding that the Million Hearts Model modestly increased acute care service use is counter to our hypotheses that the model might reduce acute care. This implies some other factor, which we did not hypothesize, explains why the model increased acute care use. For example, the model might have made people more engaged with the health care system generally, so that beneficiaries received care for a broader array of clinical issues they otherwise would not have. In exploratory analyses, not presented here, we assessed whether ED visits increased for symptoms that beneficiaries could mistake as signs of an impending heart attack or stroke. However, we found that all types of ED visits decreased roughly equally—not only those we considered most plausibly related to CVD symptoms.

As mentioned, we cannot rule out the possibility that the estimated impacts are spurious, meaning that some factor other than the Million Hearts Model made the intervention group systematically more likely than the control group to use acute care services. Although we have used regression models to adjust for observed differences—including adjusting for baseline differences between the intervention and control groups in county-, organization-, and beneficiary-level acute care service use—it remains possible that the beneficiaries in the intervention and control groups differed on unobserved factors.

D. Medicare spending

Key findings

Among high- and medium-risk beneficiaries, Medicare spending after enrollment was similar for intervention and control group beneficiaries. Because the model did not reduce Medicare Parts A and B spending, it did not generate savings to offset model payments.

The impact analyses suggest no reductions in Medicare Parts A and B spending (Table VII.D.1). For high- and medium-risk beneficiaries combined, the intervention group's regression-adjusted mean spending was similar to the control group's mean, and the difference between the two groups through October 2019 was not statistically different from zero ($p = 0.69$). Mean spending for high-risk beneficiaries in the intervention group was also similar to the mean spending observed for the control group, and the estimated difference was not statistically significant at the $p < 0.10$ level ($p = 0.14$). Differences in mean spending between the intervention and control groups were fairly consistent across quarters, although the quarter-specific impact estimates were less precise (Figure VII.D.1). Results from these analyses were largely similar to the results from our robustness checks (Appendix F), increasing our confidence in the findings.

Table VII.D.1. So far, the model has not reduced Medicare Parts A and B spending: Estimated impacts on Medicare spending (dollars per beneficiary per month)

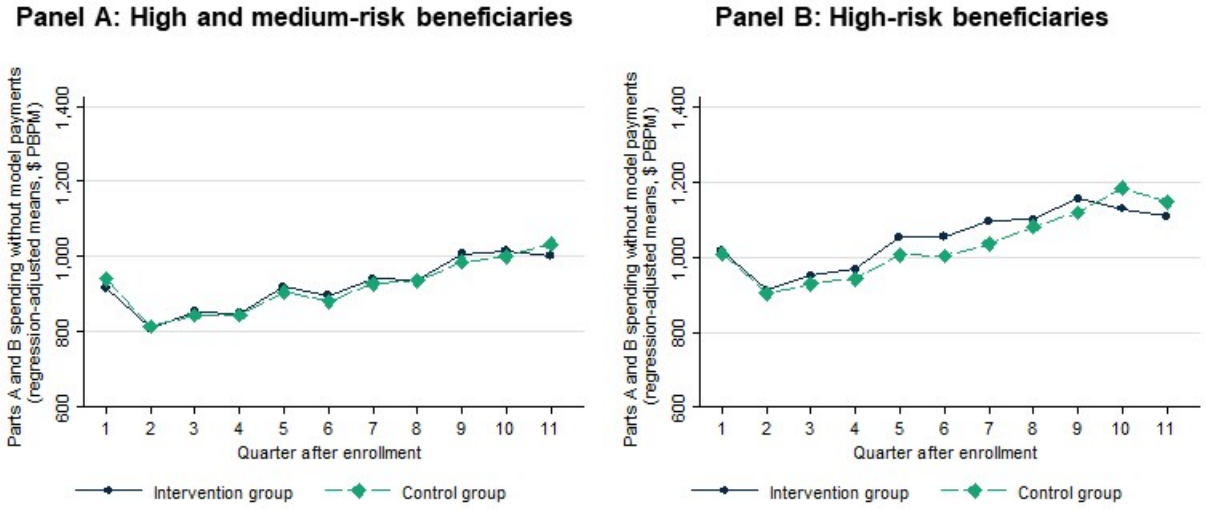
	Regression adjusted spending ($/beneficiary/month)				
	Intervention group mean	Control group mean	Difference (%)	*p* value	90% confidence interval
High and medium risk beneficiaries					
Parts A and B spending	$ 903	$ 898	$ 4 (0.5%)	0.69	[-14, 23]
Inpatient spending	$ 306	$ 301	$ 5 (1.6%)	0.51	[-7, 16]
Other spending	$ 597	$ 597	$ 0 (0.0%)	0.97	[-10, 9]
Parts A and B spending plus model payments [a]	$ 905	$ 898	$ 7 (0.7%)	0.56	[-12, 25]
High risk beneficiaries					
Parts A and B spending	$ 1,031	$ 1,006	$ 25 (2.4%)	0.14	[-3, 52]
Inpatient spending	$ 366	$ 351	$ 15 (4.2%)	0.18	[-3, 33]
Other spending	$ 665	$ 655	$ 10 (1.5%)	0.24	[-4, 24]

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

Note: Table covers 130,641 beneficiaries enrolled in 172 intervention organizations and 88,312 beneficiaries enrolled in 170 control organizations. Analyses of high-risk beneficiaries are limited to 40,446 beneficiaries enrolled in 170 intervention organizations and 27,287 beneficiaries enrolled in 165 control organizations with baseline CVD risk scores 30 percent or higher. The sum of inpatient and other spending might not equal total spending because we calculated the impact estimates and regression-adjusted means from separate regression models. We estimated impacts separately by quarter since enrollment and then averaged the estimates across all quarters, weighting each quarterly estimate by the number of intervention group beneficiaries observed in that quarter. Percentage impacts are relative to the regression-adjusted control group mean.

[a] Total Million Hearts Model payments to intervention group organizations included in the impact evaluation for the first five performance periods were $6,733,435. We divided this amount by the number of beneficiary-quarters represented among the medium- and high-risk beneficiaries enrolled through December 2018.

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



Source: Regression-adjusted results from Medicare Parts A and B claims.
PBPM = per beneficiary per month.

Because the model did not measurably reduce Medicare Parts A and B spending, it did not generate any savings to offset CMS's Million Hearts Model payments. CMS paid the intervention organizations roughly $6.7 million in the first 2.5 years, or about $2.13 per beneficiary per month among the intervention group's high- and medium-risk beneficiaries enrolled through December 2018. When we factor in these small average Medicare model payments (fourth row of Table VII.D.1), the slightly higher spending for intervention beneficiaries does not materially change the findings. That is, there is no statistically significant difference in spending between the intervention and control groups, even after accounting for model payments (p = 0.56). (We assess the model's impact on net spending for high- and medium-risk beneficiaries combined, and not for the high-risk beneficiaries only, because CMS intended the Million Hearts Model to be cost-neutral only over the larger population, as described in Chapter I.)

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

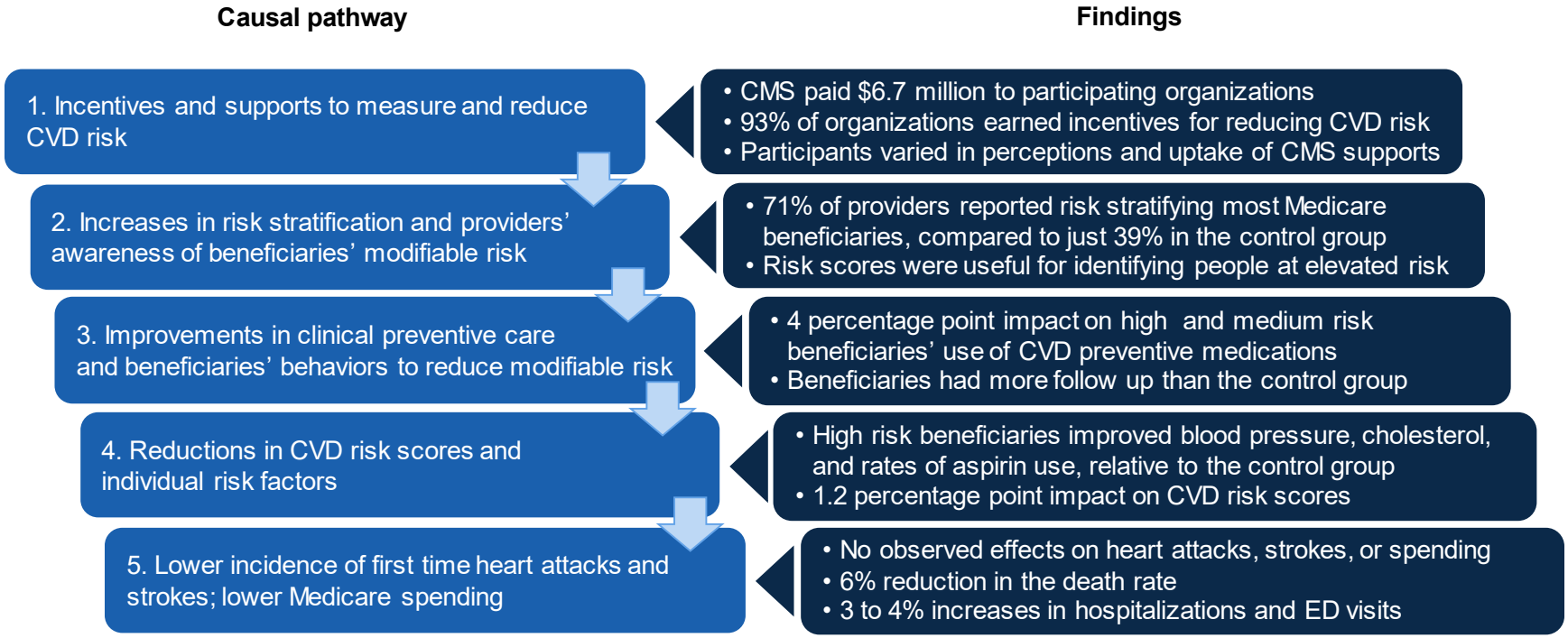
VIII. CONCLUSION

Over about three years, the Million Hearts Model improved cardiovascular preventive care but did not measurably reduce heart attacks and strokes or lower Medicare spending. Figure VIII.1 summarizes our findings across the report.

Together, these findings tell a consistent story: The Million Hearts Model achieved large impacts on rates of risk stratification, but the impacts grew smaller with each step along the causal pathway. These findings are also consistent with those from similar studies. For example, in their 2017 Cochrane review of risk scoring for CVD primary prevention, Karmali et al. synthesized results from 41 randomized controlled trials involving 194,035 participants. Like this report, that review found evidence to link CVD risk scoring to increased use of statins and antihypertensive medications and to small reductions in total cholesterol and systolic blood pressure. It found mixed evidence for impacts on smoking. However, the review found "little to no effect" on CVD events (Karmali et al. 2017). Studies of pay-for-performance programs generally have found improvements in incentivized care processes, but with effects trailing off as the outcomes became more distal. For example, Mendelson et al. (2017) reviewed 69 wide-ranging pay-for-performance programs through October 2016. They concluded that pay-for-performance "may be associated with improved processes of care in ambulatory settings, but consistently positive associations with improved health outcomes have not been demonstrated in any setting."

This trailing off of impacts could reflect several factors. Most likely, however, is that health care providers simply have greater control over clinical processes than any downstream effects of those processes. For example, Million Hearts Model participants could change their health IT and clinical workflows to make big gains in CVD risk stratification, but awareness of CVD risk will not always lead to reductions in risk. Some beneficiaries might have too few modifiable risk factors. Some might not tolerate medication intensification. For some, life events might make it difficult for the person to prioritize CVD prevention. The further we go along the causal pathway, the more outside factors—that is, factors beyond the providers' control—might influence a given outcome. In addition, some changes in upstream processes might take a long time, or sustained effort, to change a downstream outcome. For example, a person might need to try smoking cessation several times before succeeding. In those cases, we would expect to observe impacts on the upstream processes earlier than on downstream outcomes.

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



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

In fact, the findings from this report are more promising than those from other, related studies in two important respects. First, we found a reduction in the all-cause death rate (a secondary outcome), despite a lack of impact on first-time heart attacks and strokes. Second, unlike in previous studies, we could use the Million Hearts Longitudinal ASCVD Risk Assessment Tool to translate reductions in modifiable CVD risk factors into improvements in the 10-year *predicted* risk of CVD events. This enabled us to project effects on events over a longer period than we observed them. If the reductions in predicted risk (CVD risk scores) were to translate into reductions in CVD events, the findings suggest the model could avert 1 first-time heart attack or stroke over 10 years for every 86 high-risk beneficiaries enrolled.

In the rest of this chapter, we discuss possible drivers of our findings and the implications of these findings for CVD preventive care more broadly. Sections A and B cover possible mechanisms of observed decreases in mortality and CVD risk scores, respectively. Section C discusses the role of the Million Hearts Model's vision of care in driving impacts across outcomes. Section D discusses relevance of our findings to CVD primary prevention beyond the Million Hearts Model, and Section E describes next steps for the evaluation.

A. Estimated impacts on mortality: Possible mechanisms

We consider the 6 percent reduction in the death rate among high- and medium-risk beneficiaries to be suggestive, rather than definitive. Our evaluation did not specify the death rate as a primary endpoint of the study, and the link to the causal pathway is weaker for this outcome than for others. The finding is surprising given no discernible impacts on heart attacks and strokes.

We have three possible explanations for the apparent impact on the death rate:

1. The model could have prompted beneficiaries to go to the hospital at early signs of a CVD event, and this could have prevented some deaths. In that case, we would observe reductions in the death rate, as we have. We did not see corresponding reductions in CVD events (that is, heart attacks, strokes, and TIAs) as measured using Medicare claims data. However, events that go untreated do not generate claims. Thus, if the model prompted beneficiaries to go to the hospital earlier than they would have otherwise when experiencing a CVD event, we might observe claims for the intervention beneficiaries who went to the hospital quickly but not for control group beneficiaries who died outside the hospital.
2. There could be reductions in death rates from other conditions due to improvement in exercise or diet, medication therapy, or additional mechanisms we did not anticipate at the beginning of the evaluation. One such mechanism could be that, because the model encouraged beneficiaries to have more office visits, providers might have been more likely to detect and address other health conditions.
3. Finally, the impact estimates could reflect systematic differences between the intervention and control groups and not true impacts. Our careful use of regression adjustment and robustness checks alleviates this concern, but does not rule it out. As noted in Chapter VII, differences between the intervention and control beneficiaries could have either existed at random assignment or could have been introduced during model implementation by

organization- and provider-level attrition or by differences in the types of beneficiaries the intervention and control organizations chose to enroll among their eligible beneficiaries.

B. Estimated impacts on CVD risk scores: Implications for averting CVD events and possible mechanisms

Like the finding for mortality, we consider the impact on CVD risk scores to be suggestive rather than definitive, although for different reasons. CVD risk scores were a primary outcome of the model (Sanghavi and Conway 2015). However, because the participating organizations submitted incomplete reassessment data, we observed risk score changes for only about half of the eligible beneficiaries. This raises the possibility of selective reporting, especially given that intervention organizations received incentive payments based on the average risk reduction among the beneficiaries they reported. (We found no evidence of selective reporting but cannot rule it out.) Furthermore, reductions in predicted risk might not translate into actual CVD events prevented. The Million Hearts Longitudinal ASCVD Risk Assessment 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, no predictive tool is perfect.

Several possible mechanisms could explain the observed reductions in CVD risk. In this report, we have focused on (1) initiation or intensification of statin medication and antihypertensives and (2) aspirin use. We focused on these because we observed notable impacts on them, and because clinical trials have shown large benefits of such therapy. This is especially true for statins and antihypertensives (Williamson et al. 2016, Diao et al. 2012; Fretheim et al. 2012; Sundstrom et al. 2015; Bukkapatnam et al. 2010; Chen et al. 2012; Fulcher et al. 2015; Mihaylova et al. 2012; de Vries et al. 2012; Petretta et al. 2010; Ray et al. 2010; Taylor et al. 2013). We did not focus heavily on smoking cessation in this report because we did not observe impacts on smoking rates.

Other factors we have not measured might also contribute to reduced CVD risk. These factors could include, for example, improvements in diet or physical activity or other lifestyle improvements that affect blood pressure of cholesterol; use of nonstatin medications to reduce cholesterol; and improved medication adherence. Previous studies have not found strong evidence of CVD risk scores affecting medication adherence (Karmali et al. 2017). For diet and activity, it has been difficult to synthesize findings across past studies due to wide variation in measurement approaches. However, few previous studies have found meaningful effects on them (Usher-Smith et al. 2015; Karmali et al. 2017; Studziński et al. 2019). Moreover, within the Million Hearts Model, providers did not perceive that they succeeded in effecting lifestyle change.

C. The Million Hearts Model's vision of care and its role in driving impacts

When we first developed a logic model for the Million Hearts Model (Conwell et al. 2019), we hypothesized that CMS incentives and supports would lead to improvements in CVD care processes and outcomes at intervention organizations. This was consistent with earlier CMS descriptions of the model as "pay for prevention" (Sanghavi and Conway 2015). However, in

addition to the model's incentives and supports, CMS also laid out a vision of care developed in collaboration with provider organizations, including the AHA. At a high level, this vision had four components: (1) routine CVD risk stratification, (2) shared decision making to address CVD risk factors among those at high risk, (3) follow-up care for CVD primary prevention at specified intervals, and (4) a focus on reducing overall CVD risk scores, not just individual risk factors. (CMS was not prescriptive about how exactly organizations should reduce risk.) Thus, the model offered a combination of incentives and supports *and* a vision of care. Our evaluation tests the effect of this combination.

Over three years of interviews, we found that participants in the Million Hearts Model—at least those remaining after attrition—truly bought into the model's vision of care. This commitment is one reason organizations continued to participate in the model, even though payments were modest and often not perceived as covering the costs of implementing the model. Many providers said they carried out the model requirements because they found value in them. For example, participants felt that risk stratification was useful and helped them to identify and care for beneficiaries who would benefit from better CVD management.

> "Our lead clinical nurse went out and bought a satin heart costume that she wears to the clinics to remind people to calculate the 10-year ASCVD risk scores."
>
> *—Chief of Family Medicine*

Providers might support the vision of care in part because it aligns closely with current clinical guidelines. Specifically, the ACC/AHA guidelines on CVD primary prevention (Arnett et al. 2019) recommend routine use of CVD risk scores for people ages 40 to 75, and they provide guidance on how to calculate risk, in line with the Million Hearts Model requirements. Those guidelines further recommend using the risk scores, when calculated, as "the start of a conversation with the patient about risk-reducing strategies," with treatment decisions based on shared decision making. Overall then, by following the model's requirements for risk stratification and shared decision making, participating organizations delivered CVD preventive care that providers broadly recognized as a best practice. Nevertheless, most organizations did not seem to achieve this best practice without the Million Hearts Model. Our 2018 provider survey showed large improvements in risk stratification among the intervention group after joining the model, but not among the control group.

If the Million Hearts Model vision of care is a major driver of the model's impacts, it is worth considering how, exactly, this vision might lead to improvements in beneficiaries' CVD-related outcomes. The model encourages routine use of CVD risk scores, which represent people's predicted probability of experiencing a heart attack or stroke over some period. Expressing risk in this way—as opposed to simply as a list of risk factors—could make the risk more salient, or tangible, to both patients and providers, and might prompt greater action. For example, a patient might be more motivated to address his high blood pressure when he knows he has a 40 percent risk of a heart attack or stroke over 10 years than he would be knowing only that he has high blood pressure.

Importantly, this mechanism for reducing risk applies equally to medium- and high-risk beneficiaries. CMS did not pay intervention group organizations to provide cardiovascular care management to medium-risk beneficiaries and did not provide incentive payments for risk reduction among this group. However, someone with a risk score of 25 percent—considered medium risk under the Million Hearts Model—might still be more willing to act after hearing her risk of a heart attack or stroke. Clinical guidelines for cholesterol management (Grundy et al. 2018), blood pressure management (Carey and Whelton 2018), and aspirin use for CVD primary prevention (Arnett et al. 2019) all recommend considering therapy at CVD risk scores well below the threshold that CMS used to define medium risk. As a result, some medium-risk beneficiaries would likely have received intensified therapy to reduce their CVD risk, after the score was calculated, even though they were not covered by the model requirements and payments for high-risk beneficiaries only. This could help to explain the spillover of model impacts to medium-risk beneficiaries: for example, the impacts we observed for that group on medication use, and the apparent effects on survival, which were concentrated among medium-risk beneficiaries.

D. Relevance to CVD primary prevention beyond the Million Hearts Model

Our findings are relevant to CVD primary prevention efforts beyond the Million Hearts Model. Although the model's package of incentives, supports, and required care processes is unique, the care processes align with clinical guidelines broadly. As noted previously, ACC/AHA guidelines recommend routine CVD risk scoring (Arnett et al. 2019). Clinical guidelines in several other countries do as well (for example, Anderson et al. 2016; JBS3 Board 2014; Piepoli et al. 2016). As a result, findings from the Million Hearts Model could be relevant to a potentially large audience of health care providers aiming to increase use of CVD risk scores in line with these guidelines. Several key findings emerged with implications beyond the Million Hearts Model:

- In interviews and the 2018 provider survey, many of the Million Hearts Model providers said they found CVD risk scores to be useful, both for identifying patients who would benefit from greater CVD preventive care and for discussing risk with patients. This suggests organizations promoting guideline-based care could meet with support from their employee clinicians.
- Over three years of interviews, Million Hearts Model participants stated that easy availability of a risk scoring tool—for example, having the tool built into the EHR—was a major facilitator of implementing the model.
- Even among Medicare FFS beneficiaries—an aging population with comprehensive health care coverage—a substantial proportion of CVD risk was due to modifiable risk factors, especially high blood pressure. This suggests potential for improving CVD care, even in populations that already receive substantial health care services.
- Increased use of CVD risk scores and greater rates of follow-up visits might lead to reductions in CVD risk. However, they might also lead to higher rates of health care service use generally, possibly with some health benefits.

As with any study, it is unclear to what extent the findings from this model would generalize to other settings. That is, it is unclear whether other organizations would experience similar impacts if they implemented a similar model. The Million Hearts Model participants were diverse in their organization type, size, and location within the United States, and CMS imposed few formal eligibility criteria to participate. This would seem to make the findings relevant to a wide range of settings. Nevertheless, all participating organizations volunteered for the model. If CMS or others expanded or replicated the model in a different setting, participants might show a different level of enthusiasm for the model, and this could lead to different effects.

In addition, about half of Million Hearts Model participants already participated in or had applied to another CMS initiative when applying to this model. The Million Hearts Model incentives were modest—typically not large enough to fund new staff positions or major changes in care delivery—and many organizations drew on the resources they had acquired through other quality improvement initiatives to meet Million Hearts Model requirements. For example, organizations used care managers already hired using funding from accountable care organization programs or CPC+ to monitor and follow-up with beneficiaries designated as high risk under this model. For this reason, too, organizations might experience a different impact if they implemented a program like the Million Hearts Model in a different setting.

Among the current Million Hearts Model participants, however, many intend to continue with clinical changes they made for the model even after CMS ends its incentives and supports. Participants might not continue with all requirements in the same way that CMS specified for the model—for example, with reassessment visits occurring in a specified 10- to 14-month window. However, all organizations we interviewed in 2020 said they intend to continue CVD risk stratification after the model ends.

E. Next steps for the evaluation

We will continue to assess model implementation and impacts over the final two years of the Million Hearts Model. We have four major next steps:

1. Extend the outcome period through December 2021 to estimate impacts on CVD events, Medicare spending, and other secondary outcomes over the full five years of the model.
2. Consider adding new outcome measures, such as a measure of medication adherence, that could help CMS to better understand impacts on CVD risk and CVD events.
3. Interview organizations that have been most successful in reducing CVD risk among their high-risk beneficiaries, with the goal of identifying approaches that make these organizations so effective.

Continue to assess organizations' implementation of the Million Hearts Model in its final two years, based on interviews and a survey of intervention organizations; in particular, we aim to assess effects of the COVID-19 pandemic on routine cardiovascular preventive care, and organizations' plans to sustain any changes they made as a result of the Million Hearts Model after the model ends.

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APPENDIX A

DEFINING THE ENROLLED STUDY POPULATION

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

1. Population enrolled in the Million Hearts Model in 2017 and 2018
2. Population included in impact analyses of cardiovascular disease (CVD) events and other, long-term, claims-based outcomes
3. Population included in impact analyses of medication initiation and intensification (Part D claims-based outcomes)
4. Population used to estimate impacts on CVD risk scores and risk factors

For definition of the attributed population, please see Appendix C.

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 whom the participating organizations enrolled during the first four performance periods of the model (January 2017 to December 2018). *Enrolled* means that the organization reported the beneficiary to the Million Hearts Data Registry and that the Centers for Medicare & Medicaid Services (CMS) validated the beneficiary's enrollment record. To enroll a beneficiary, an organization had to upload data to the registry on when the beneficiary had a baseline visit with the organization, as well as 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 claims data to confirm that the beneficiary (1) did indeed have a visit with a provider from the organization near the time listed and (2) met model eligibility criteria that could be replicated in enrollment and claims data. Medicare FFS beneficiaries met model eligibility criteria if they were ages 40 to 79, had no evidence of a prior heart attack or stroke, had Medicare as their primary payer, did not have end-stage renal disease (ESRD), and were not receiving hospice benefits.

We 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 also excluded beneficiaries with the following characteristics:

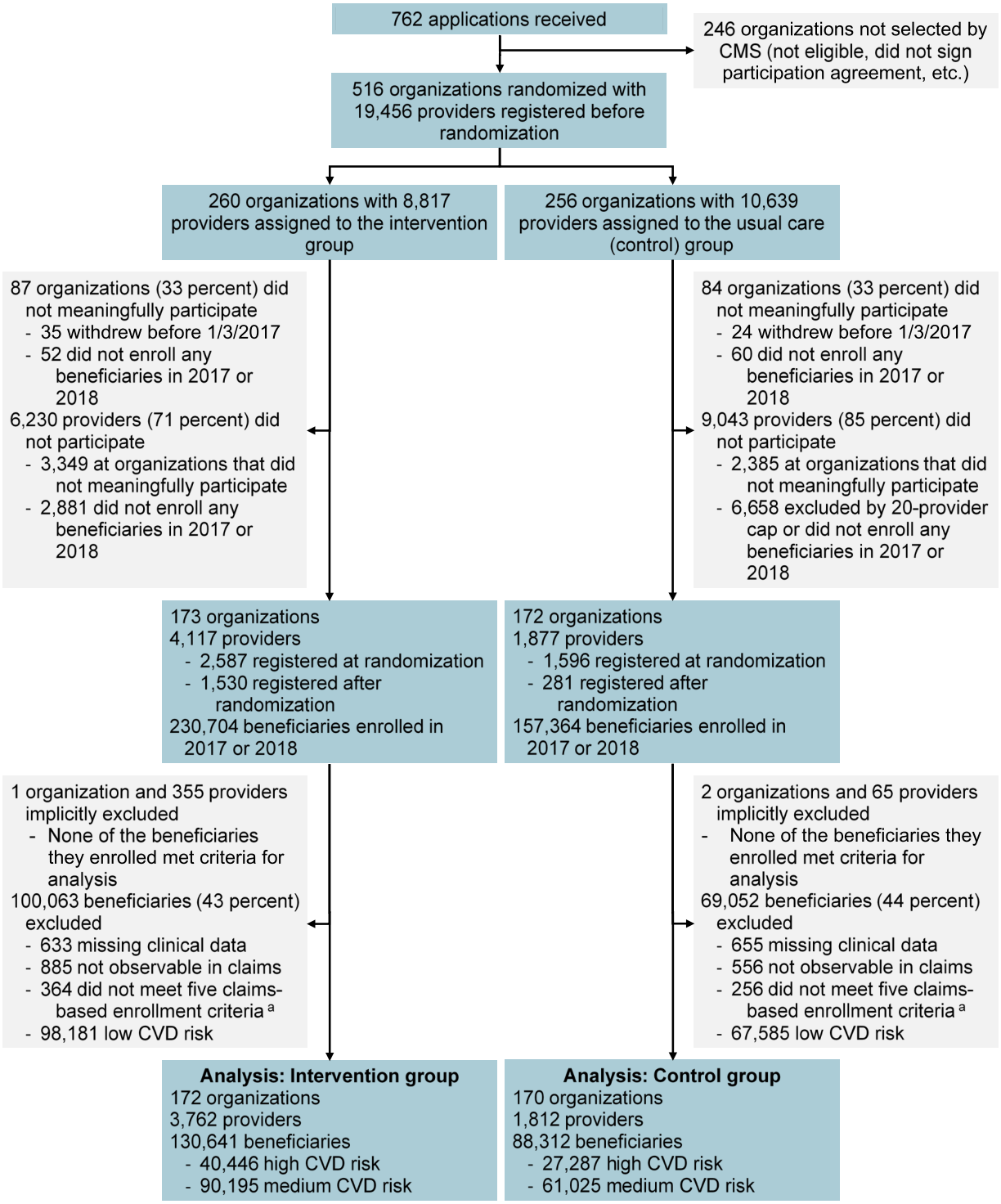
- Were not observable—that is, they were not enrolled in FFS Medicare Parts A and B with Medicare as the primary payer during the month of enrollment—because we could not construct study outcomes for them.
- Did not meet claims-based model eligibility criteria (for example, those who had evidence of a prior heart attack or stroke). CMS's implementation contractor 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.

The final study population included 388,001 beneficiaries enrolled by 173 intervention organizations and 172 control organizations).

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 218,953 beneficiaries (130,641 beneficiaries enrolled by 172 intervention organizations and 88,312 beneficiaries enrolled by 170 control organizations). Figure A.1 shows the flow of organizations (and their providers and beneficiaries), from random assignment and enrollment through the final study population.

Figure A.1. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for Medicare enrollment and claims-based outcomes



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

Notes: Beneficiaries with high CVD risk were predicted to have, at enrollment, at least a 30 percent risk of a heart attack or stroke in the next 10 years; the predicted risk was 15 to 30 percent for medium- risk beneficiaries and less than 15 percent for low-risk beneficiaries.
The total count of beneficiaries in this figure (388,068) is slightly higher than the count of enrolled beneficiaries reported in the main text of this report (388,001) because 67 enrolled beneficiaries had missing CVD risk scores at baseline. Figure A.1 includes these 67 as beneficiaries excluded due to "missing clinical data."

[a] The criteria are FFS Medicare Parts A and B, ages 40 to79, no prior acute myocardial infarction, no prior stroke, no ESRD, and no hospice.

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

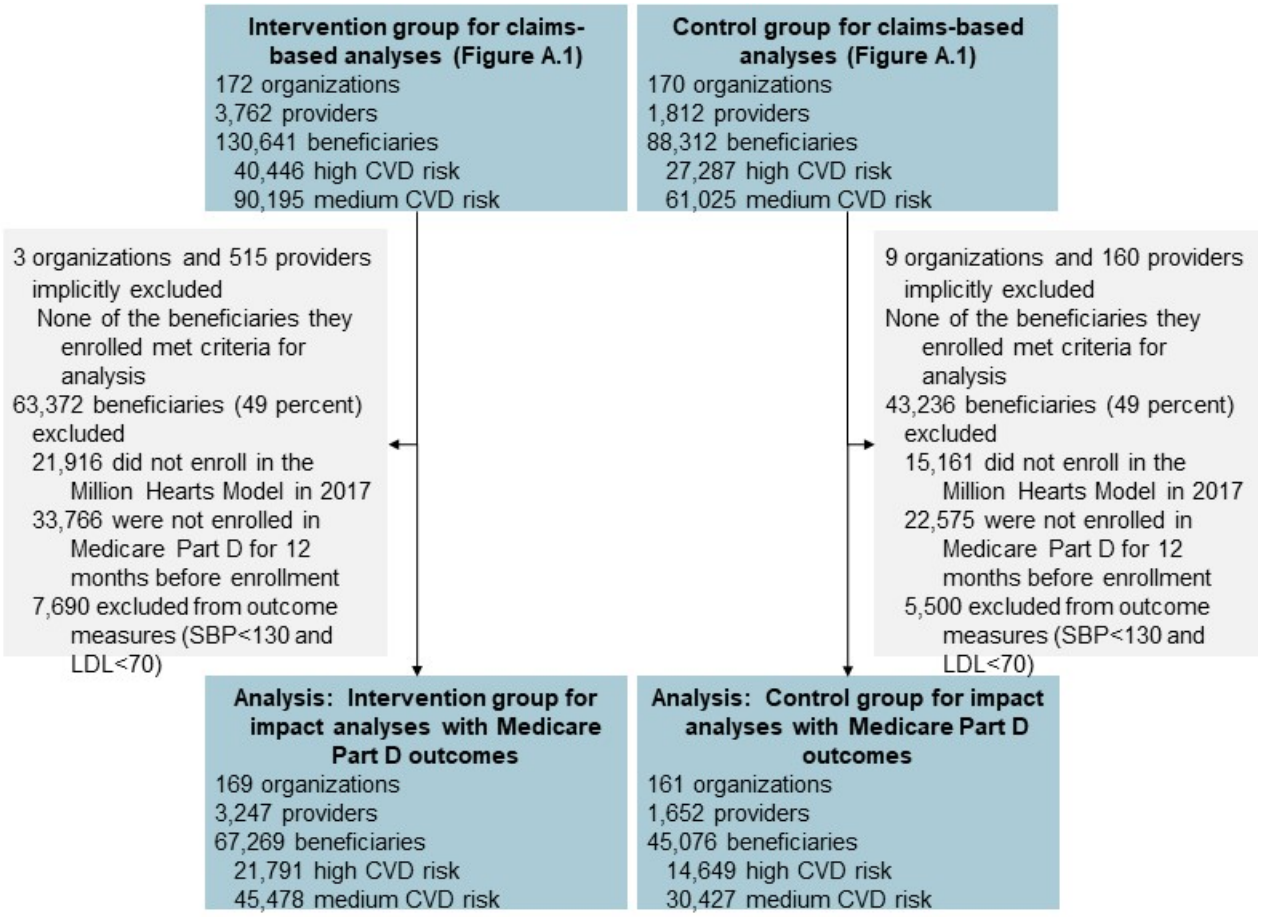
3. Beneficiaries included in impact analyses of medication initiation and intensification (Part D-based outcomes)

For the analyses of impacts on initiating and intensifying medication, we restricted the study population to beneficiaries who met three additional criteria:

1. The beneficiary was enrolled in Medicare Part D for the 12 months before enrolling in the Million Hearts Model.
2. The beneficiary had enrolled in the Million Hearts Model on or before December 31, 2017, so that we could observe each beneficiary for at least 15 months before the end of our claims-based follow-up period.
3. At enrollment, the beneficiary had either high blood pressure, defined as systolic blood pressure of 130 mm Hg or higher, or high cholesterol, defined as low-density lipoprotein (LDL) cholesterol of 70 mg/dL or higher.

After applying these restrictions, the study population included 112,345 beneficiaries: 67,269 beneficiaries enrolled by 169 intervention organizations and 45,076 beneficiaries enrolled by 161 control organizations. As shown in Figure A.2, this represents slightly more than half of the beneficiaries included in the population used for impact analysis of CVD events and other long-term, claims-based outcomes.

Figure A.2. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for Medicare Part D outcomes



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

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

CVD = cardiovascular disease; LDL = low-density lipoproteins cholesterol (mg/dL); SBP = systolic blood pressure (mm Hg).

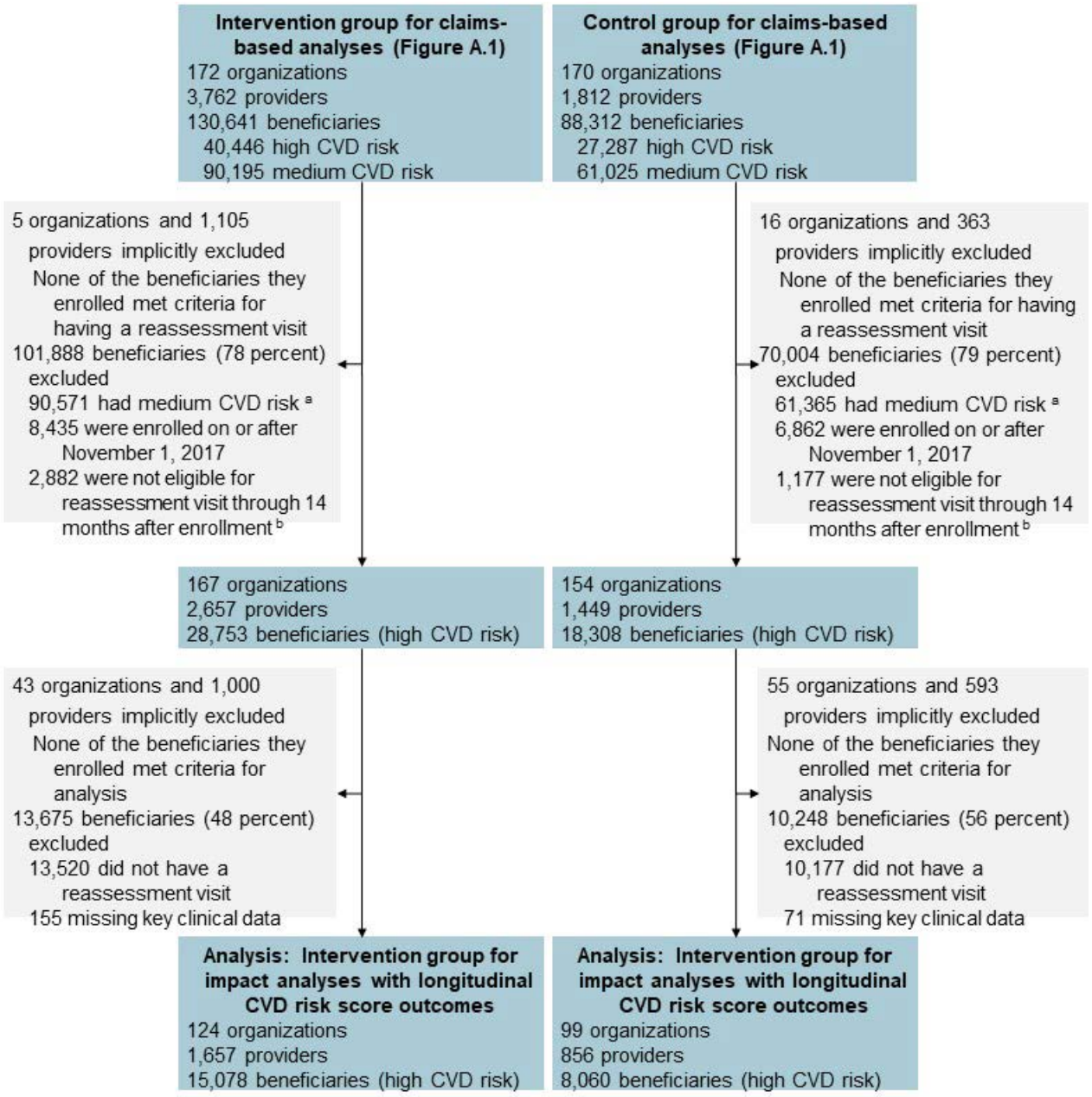
4. Beneficiaries used for estimating impacts on CVD risk scores and risk factors

To evaluate changes in CVD risk scores and risk factors, we analyzed outcomes among high-risk beneficiaries[11] who had a reassessment visit by the end of 2018. For this analysis, we limited the analytic population to high-risk beneficiaries who enrolled in the Million Hearts Model on or before October 31, 2017, 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 were not required to submit reassessment data for these beneficiaries. Model ineligibility could be due to death, acute myocardial infarction, stroke, transient ischemic attack, ESRD, election of the hospice care benefit, enrollment in Medicare Advantage, or because Medicare was not the primary payer. We did not have flags for hospice and ESRD readily available, so we did not include these two reasons for model ineligibility in our analysis, but analysis of pre-enrollment data suggests these affect only a small population.

Figure A.3 shows the flow of beneficiaries from the broader sample used for impacts analyses of CVD events and other, long-term, claims-based outcomes (Figure A.1) to the population used for estimating impacts on CVD risk scores and risk factors. After applying the restrictions described, the study population included 23,138 high-risk beneficiaries: 15,078 high-risk beneficiaries enrolled by 124 intervention organizations and 8,060 high-risk beneficiaries enrolled by 99 control organizations.

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

Figure A.3. Flow of organizations, providers, and beneficiaries from enrollment through analysis for the impact evaluation: Population used for CVD risk score and risk factor outcomes



Source: Mathematica 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 beneficiaries only if they were classified as high CVD risk at both dates. Conwell et al. (2019) describes our methods for adjusting the enrollment date used for evaluation to be the first date recorded in the registry with complete enrollment data.

[b] Restricts the sample to beneficiaries who remained alive; without acute myocardial infarction, stroke, or transient ischemic attack; and enrolled in Medicare FFS as their primary payer for 14 months after enrollment in the Million Hearts Model.

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

As noted in Chapter V, only 57 percent of intervention beneficiaries eligible for a reassessment visit had one. The intervention and control beneficiaries with reassessment data were very similar (see Appendix E). However, differences between beneficiaries who did and did not have a reassessment visit *within* the intervention and control groups could limit the generalizability of our analyses to the full population eligible for reassessment. Table A.1 shows the baseline characteristics of intervention group beneficiaries with a reassessment visit compared to beneficiaries enrolled by an intervention organization, were eligible for a reassessment visit, and yet did not have one. We limited this analysis to organizations that had not withdrawn before the deadline for submitting registry data for the fourth performance period (March 31, 2019).

Compared to all intervention-group beneficiaries who did not receive a reassessment visit, those who received a reassessment visit were more likely to have diabetes and to have been enrolled into the Million Hearts Model by a primary care provider. In the year before their initial model enrollment, those with reassessment visits also had lower mean total Medicare Parts A and B spending, lower rates of hospital admissions and outpatient emergency department (ED) visits, and more office visits with model-aligned providers. Beneficiaries with reassessment visits also tended to be located in the Midwest and South, in areas with higher county-level rates of all-cause admissions and outpatient ED visits, to have an earlier enrollment date in the model, and to have their data submitted to the registry manually rather than by bulk upload. Demographic information (such as age and sex) and CVD risk scores at enrollment were similar for those who did and who did not receive a reassessment visit.

Table A.1. CVD risk reduction population: Baseline characteristics of high-risk Medicare beneficiaries enrolled in Million Hearts intervention organizations with and without reassessment visits

Characteristic	Beneficiaries with a reassessment (N 14,956)	Beneficiaries without a reassessment (N = 11,068)	Difference	Standardized difference[a]	*p* value[b]
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	40 [9]	40 [9]	0.0	0.00	0.88
Modifiable risk (%)[c]	15	16	-0.5	-0.04	0.24
Has diabetes (%)	69	61	7.6	0.16	0.00
Systolic blood pressure (mm Hg)	139	140	-1.6	-0.10	0.01
Total cholesterol (mg/dL)	167	168	-0.7	-0.02	0.56
HDL cholesterol (mg/dL)	47	47	-0.2	-0.02	0.71
LDL cholesterol (mg/dL)	91	92	-0.7	-0.02	0.40
Is current smoker (%)	12	12	-0.6	-0.02	0.41
Beneficiary medication use					
Uses aspirin (%)	50	51	-1.1	-0.02	0.77
Uses antihypertensives based on Part D[d] (%)	90	91	-0.4	-0.01	0.64
Uses statins based on Part D[d] (%)	71	68	2.2	0.05	0.02
Intensity of statin use based on Part D[d] (%)					
Low intensity	7	7	0.1	0.00	0.00
Medium intensity	43	40	3.7	0.07	
High intensity	20	22	-1.6	-0.04	
Beneficiary demographic and Medicare enrollment characteristics					
Age [standard deviation]	74 [4]	74 [4]	-0.3	-0.07	0.05
Black race (%)	7	6	1.2	0.05	0.20
Male (%)	65	66	-0.7	-0.01	0.40
Dually enrolled in Medicare and Medicaid (%)	8	9	-1.1	-0.04	0.37
Originally entitled to Medicare because of disability (%)	11	12	-1.0	-0.03	0.28
Beneficiary health and comorbid conditions					
HCC score [standard deviation]	1.31 [0.98]	1.38 [1.04]	-0.1	-0.06	0.03
Number of chronic conditions	2.6	2.6	-0.1	-0.04	0.23
Has chronic kidney disease (%)	36	35	1.1	0.02	0.44
Has ischemic heart disease (%)	36	42	-6.0	-0.12	0.03
Has congestive heart failure (%)	12	14	-2.0	-0.06	0.05
Has atrial fibrillation (%)	11	13	-1.7	-0.05	0.14
Has morbid obesity (%)	9	8	0.9	0.03	0.35
Beneficiary medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	7,375 [14,682]	8,331 [16,999]	-955.7	-0.06	0.00
Hospital admissions (per 1,000 beneficiaries)	177	205	-28.1	-0.05	0.01

Characteristic	Beneficiaries with a reassessment (N 14,956)	Beneficiaries without a reassessment (N = 11,068)	Difference	Standardized difference[a]	*p* value[b]
CVD-related hospital admissions (per 1,000 beneficiaries)[e]	41	49	-8.1	-0.03	0.12
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	345	398	-53.1	-0.05	0.01
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[e]	25	34	-8.5	-0.04	0.07
Office visits (per 1,000 beneficiaries)	9,651	9,978	-327.1	-0.05	0.39
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,457	2,849	608.3	0.18	0.01
Cardiologist visits (per 1,000 beneficiaries)	1,956	2,111	-154.8	-0.04	0.34
Beneficiary CVD related procedures in year before model enrollment					
Received echocardiogram (%)	41	47	-6.0	-0.12	0.02
Received electrocardiogram (%)	72	77	-4.6	-0.11	0.07
Received cardiac stress test (%)	28	31	-2.9	-0.06	0.15
Characteristics of organization enrolling the beneficiary					
Total number of practitioners	128	127	0.4	0.00	0.99
[standard deviation]	[170]	[210]			
Total number of service sites	29	21	7.4	0.29	0.12
[standard deviation]	[28]	[24]			
Organization type (%)					
Primary care	54	40	14.2	0.29	0.02
Specialty or multispecialty	40	46	-5.9	-0.12	
FQHC, RHC, or other health center	3	5	-2.0	-0.10	
CAH or rural hospital	0	0	-0.4	-0.07	
Acute care hospital	3	8	-5.8	-0.26	
Organization was participating in, or had application pending for, another model at randomization (%)	71	65	6.8	0.15	0.35
Organization-level mean Medicare spending and use[f]					
Parts A and B spending	7,384	8,079	-695.0	-0.41	0.01
Hospital admissions (per 1,000 beneficiaries)	184	195	-11.0	-0.26	0.12
Outpatient ED visits (per 1,000 beneficiaries)	379	390	-11.3	-0.10	0.47
Characteristics of clinician enrolling the beneficiary					
Provider specialty (%)					
Primary care physician	66	50	15.6	0.32	0.01
Cardiologist	21	36	-14.8	-0.33	0.02
Physician with other specialty	2	2	-0.4	-0.03	0.60
Not a physician (for example, NP or PA)	11	10	0.3	0.01	0.80
Characteristics of beneficiary region					
Rural (%)	28	27	1.6	0.03	0.53
U.S. Census region (%)					
Northeast	17	28	-11.1	-0.27	0.01
Midwest	24	16	7.6	0.19	

Characteristic	Beneficiaries with a reassessment (N 14,956)	Beneficiaries without a reassessment (N = 11,068)	Difference	Standardized difference[a]	*p* value[b]
South	55	46	8.2	0.16	
West	5	9	-4.7	-0.18	
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	11	0.3	0.09	0.38
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	24	23	0.6	0.15	0.12
Age-adjusted mortality per 100,000 for residents ages 65and older in 2014–2016	4,509	4,417	92.3	0.16	0.13
Per capita total Medicare part A and B spending in 2016	9,761	9,865	-103.3	-0.09	0.37
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	284	277	7.1	0.19	0.03
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	714	694	20.0	0.16	0.07
Characteristics of beneficiary's Million Hearts Model enrollment					
Days between model launch (January 3, 2017) and enrollment date [standard deviation]	96 [74]	121 [83]	-24.3	-0.31	0.00
Enrollment date is in (%)					
First quarter of the year	54	41	13.4	0.27	0.00
Second quarter of the year	32	35	-3.2	-0.07	0.04
Third quarter of the year	11	18	-7.0	-0.20	0.00
Fourth quarter of the year	3	6	-3.2	-0.15	0.00
Data submitted to the registry using bulk upload (%)[g]	39	40	-1.2	-0.03	0.87

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiaries' demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending, and CVD-related procedures; the organizations' applications to the Million Hearts Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiary zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiary county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS' Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: The sample for this table includes beneficiaries eligible for a reassessment visit who were enrolled by organizations that had not withdrawn before the final date to submit registry data for the fourth performance period—specifically, by March 31, 2019. Eligible beneficiaries were defined as high-risk beneficiaries whose baseline visit date was on or before October 31, 2017. This is so that their window for a reassessment visit 10 to 14 months after baseline occurred by December 31, 2018. We also excluded from the definition any beneficiary who died, had an AMI or stroke, enrolled in Medicare Advantage, or lost Medicare as the primary payer within 14 months of the baseline visit. To define the eligible beneficiaries, we used unadjusted baseline visit dates to reflect the date used for CMS payments

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

[a] The standardized difference is the difference between the beneficiaries with and without a reassessment group means, divided by the standard deviation across the two groups.

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

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

[d] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 10,450 for beneficiaries with a reassessment visit and N = 7,709 for beneficiaries without a reassessment visit). This accounted for 70 percent of all enrolled beneficiaries with and 70 percent without a reassessment visit.

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

[f] See Appendix D for details on measure construction. To estimate organizational-level mean Medicare spending and use per beneficiary, we used only baseline data from the 2017 enrollees. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for its Medicare populations. The organization-level means included in this table are the variance-shrunken means for each organization.

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

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

APPENDIX B

SUPPLEMENTAL ANALYSIS OF MILLION HEARTS MODEL PAYMENTS

To support the findings in Chapter III, we conducted supplemental analyses of the Million Hearts Model payments. Figure B.1 shows total payments to organizations in the intervention group, by performance period. This figure demonstrates that payments were highest in the first year of the model (that is, performance periods 1 and 2, or calendar year 2017), and declined steadily thereafter. Total payments declined over time both because (1) fewer organizations participated in the later performance periods; and (2) the median payment *per intervention organization* also decreased over this period, as described in Chapter III. Table B.1 shows the proportion of intervention organizations earning risk reduction payments in performance periods 3 through 5 (January 2018 to June 2019), as measured among organizations that effectively participated in performance period 5 by submitting model data to the Centers for Medicare & Medicaid Services (CMS). Of these effective-participant practices, fewer than half (41 percent) earned the top amount of $10 per beneficiary per month (PBPM) in at least one of three periods.

Figure B.1. Total CMS payments to intervention organizations

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

PP = performance period.

Table B.1. Percentage of intervention organizations earning risk reduction payment amounts, by performance period and overall (N = 96)

Risk reduction payment category ($ PBPM)	Change in risk score (percentage points)	Performance period (percentages)			
		January June 2018	July December 2018	January June 2019	Any period[a]
$0	< 2	4.2	2.1	12.5	17.7
$5	2 – 10	65.6	59.4	61.5	86.5
$10	> 10	16.7	21.9	15.6	40.6
Did not submit reassessment data	Not applicable	13.5	16.7	10.4	25.0

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

Note: Analysis is limited to the 96 intervention organizations still participating in the model as of June 2019.

[a] If an organization received a risk reduction payment in this PBPM category in any of the three eligible periods. This column sums to more than 100 percent because each organization can shift categories in each performance period.

N = number of organizations; PBPM = per beneficiary per month.

APPENDIX C

DEFINING THE ATTRIBUTED BENEFICIARY POPULATION

To supplement our main analyses of beneficiaries enrolled in the Million Hearts Model through the Million Hearts Data Registry (described in Appendix A), we constructed a population of beneficiaries whom we attributed using claims data to participating intervention and control organizations. Attributed beneficiaries are those who (1) had a visit with a model-participating provider; and (2) per characteristics observable in Medicare claims, met the model's eligibility requirements. This attribution population serves two main goals in this report:

1. **To assess model implementation.** The attributed beneficiary population enables us to roughly estimate the percentage of beneficiaries eligible for enrollment who were actually enrolled. Further, we can assess how this percentage varies across organizations and how characteristics of beneficiaries enrolled differ from beneficiaries who were eligible (according to claims data) but were not enrolled. We present these analyses in Chapter IV.
2. **To support robustness checks of the impact estimates.** As a robustness check for all analyses of outcomes derived from Medicare enrollment and Parts A and B claims data, we reestimated the impact analysis regression models using the population of attributed beneficiaries. These checks support the analyses shown in Chapters V and VII, and we present detailed results in Appendix F. Using the attributed population to estimate impacts removes one potential source of bias—that intervention and control providers differed in the eligible beneficiaries they chose or were able to enroll. That is, if participating intervention and control providers selectively enrolled different types of beneficiaries among their eligible beneficiaries, it could bias the impact estimates obtained with the population of enrolled beneficiaries. The robustness check using attribution includes *all* beneficiaries who appeared model eligible and therefore should remove this type of bias. However, we emphasize the robustness check does not remove all potential forms of bias.[12]

In this appendix, we describe our method for defining the population of attributed beneficiaries. This method had three major components. First, we used claims data to attribute Medicare fee-for-service (FFS) beneficiaries to participating organizations based on visits to those organizations. We then limited the attributed population to beneficiaries who met Million Hearts Model eligibility criteria, to the extent those criteria could be replicated in Medicare claims or enrollment data (for example, ages 40 to 79, with no previous heart attack or stroke, no end-stage renal disease [ESRD], and not in hospice). Second, using an algorithm we developed, we used a person's claims-based characteristics at baseline to predict his or her (1) baseline cardiovascular disease (CVD) risk score; and (2) probabilities of being in the high-, medium-, and low-CVD risk groups. We made these predictions because many of the beneficiaries in the attribution-based study population had not submitted data to the Million Hearts Data Registry, so we could not observe clinical data to construct a true CVD risk score. We developed the risk prediction algorithm using data from the 2017 and 2018 enrolled beneficiaries, for whom we had both clinical and claims data. Third, for the impact analysis robustness checks and supporting descriptive statistics, we applied weights to the data for the attribution-based population to reflect

[12] For example, the robustness check does not remove potential bias from (1) differences between the intervention and control groups at random assignment, (2) differences that could have arisen due to differential attrition between the intervention and control organizations, or (3) differences across intervention and control organizations in in the types of providers enrolling beneficiaries—including differences driven by the 20-provider cap in the control group.

either high- and medium-risk or high-risk beneficiaries. The rest of this appendix describes these methods in more detail.

1. Attributing Medicare beneficiaries to participating organizations

Given the goals for attribution, we attributed beneficiaries only to providers who enrolled beneficiaries in the Million Hearts Model during 2017 and 2018, and only during the periods when these providers actively enrolled beneficiaries. For example, if a provider began enrolling beneficiaries in the model in July of 2018, we begin attributing beneficiaries to them beginning in that month as well. Note this approach differs from the one we used in the second annual report (Peterson et al. 2019) as we have refined the goals for the attribution-based population for this report.

Step 1. Identify providers to include in attribution

The first step in attributing beneficiaries was to construct a list of provider and organization identification numbers associated with each organization that participated in the Million Hearts Model. Providers were identified by their individual National Provider Identifiers (NPIs). Organizations were identified by their Tax ID Numbers (TINs), and, if applicable, the Centers for Medicare & Medicaid Services (CMS) Certification Numbers (CCNs).[13] Among all providers associated with each organization, we limited the list to 5,988 providers that enrolled at least one beneficiary in the Million Hearts Model in 2017 or 2018, using the definition described in Appendix A. The intervention group organizations had more providers per organization, on average, that the control group organizations; this partly resulted from CMS's decision to limit control group organizations to no more than 20 enrolling providers.

Changes to the attribution methods since the second annual report

The attribution methods described in this section differ from the methods used to attribute Medicare FFS beneficiaries to participating organizations in our earlier reports (Conwell et al. 2019; Peterson et al. 2019). Under the current approach, we attribute beneficiaries only to those providers actively participating in the model, rather than attributing beneficiaries to all providers listed on the organizations' applications. This means the attributed population better reflects the population that CMS expected organizations to enroll. However, it does not address the possibility of bias due to differences between the intervention and control groups in the types of organizations and providers participating.

[13] Organizations that bill outpatient and/or facility claims, such as critical access hospitals, federally qualified health centers, or rural health clinics, do so using their CCNs.

Step 2. Attribute beneficiaries to organizations

Next, we searched all Medicare FFS beneficiaries' carrier and outpatient claims for office or clinic visits from January 3, 2017, through December 31, 2018, billed (1) by one of the NPIs included in the provider list from Step 1 and (2) through one of the organization's TINs or CCNs. We then limited these claims to those with dates of service between the first and last dates each provider enrolled a beneficiary into the model. That is, we excluded claims from office or clinic visits that occurred before or after the period in which the provider participated in the model. For organizations that withdrew from the Million Hearts Model, we also required the date of service on the claim to be before the organization's withdrawal date.

We used procedure and revenue center codes to identify office and clinic visits in claims. Most of the codes we used were also used in CMS's Enrollment, Validation, Alignment and Adjudication process for defining the population used to determine Million Hearts Model payments. However, we added a few procedure and revenue center codes, mainly to help capture all visits at federally qualified health centers (FQHCs), rural health clinics, and critical access hospitals.[14]

Using the claims that met the criteria outlined earlier, we attributed Medicare FFS beneficiaries to an organization when the beneficiary first had a qualifying office or clinic visit between the model's launch in January 2017 and December 2018.[15] We assigned a pseudo-enrollment date to each beneficiary. This was the date of the first qualifying claim, irrespective of whether the beneficiary was enrolled in the Million Hearts Model and his or her actual date of enrollment. Likewise, we assigned each beneficiary to an NPI at the organization. These methods attributed slightly more than 1.2 million beneficiaries to the participating organizations and providers (Figure C.1).

Step 3. Use claims to remove ineligible beneficiaries

After we attributed beneficiaries to organizations, we used claims and other administrative data to construct baseline characteristics for each beneficiary. (The second annual report [Peterson et

[14] Specifically, we added procedure codes for primary care services that map to the FQHC new Prospective Payment System global visit codes (G0181, 99492-99494, 99484, G0502, G0503, G0504, G0507, 99354, 99355, 99358, 99359, 99406, 99407, 97802, 97803, 96152, 96153, 96154, 96160, G0101, G0102, G0108, G0109, G0270, G0271, G0442, G0443, G0444, G0445, G0446, G0447, and G0473); procedure codes for FQHCs under Medicare's prospective payment system (G0473, G0466, G0467, G0468, G0469, and G0470); two revenue center codes for FQHCs (0521 and 0522); and six codes recently added to the Comprehensive Primary Care Plus model (99488, 99491, 99483, G0505, G0506, and G0463). We also included procedure codes for counseling risk factor reduction and behavior change intervention (99401–99404, 99406–99409, and 99411–99412) and procedure codes for preventive services (99381–99387 and 99391–99397). Claims were limited by facility type and service type, as appropriate. We excluded all claims that occurred in an inpatient hospital emergency room setting.

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

al. 2019] describes this process.) We used these characteristics for a variety of purposes, including removing beneficiaries who were likely ineligible for the Million Hearts Model.

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

1. Enrolled in Medicare Parts A and B
2. Ages 40 to 79
3. No previous acute myocardial infarction or stroke (as observed in Medicare FFS claims dating back to 1999)
4. No ESRD
5. Not receiving hospice benefits
6. Observable in Medicare data for at least one of the 12 months before attribution; *observable* means the beneficiary was alive, enrolled in Medicare Parts A and B, had Medicare as the primary payer of medical bills, and was not enrolled in a Medicare Advantage plan

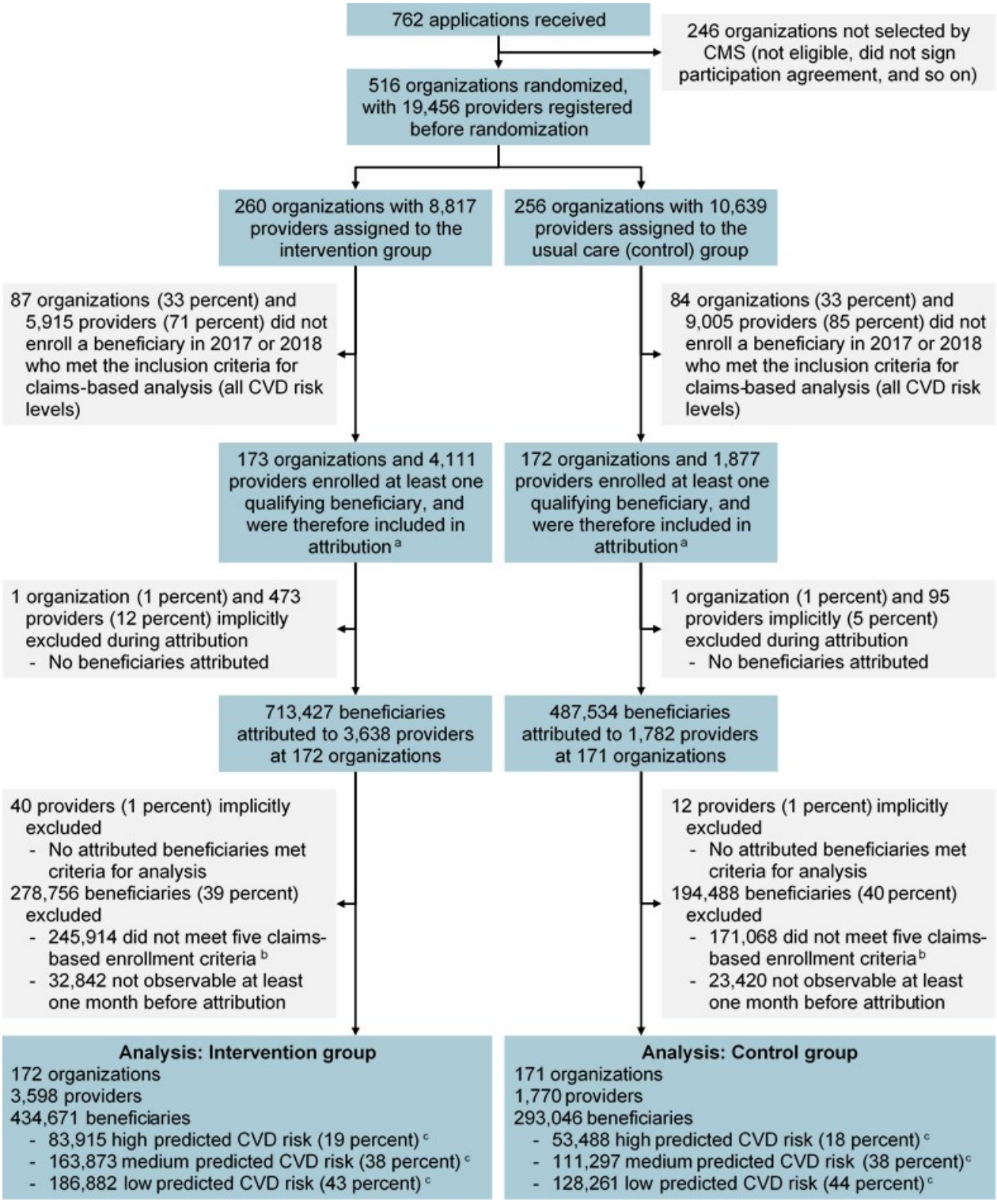
The first five criteria reflect the official Million Hearts Model enrollment criteria as best as they could be measured in Medicare data. We applied the last criterion for the purpose of the evaluation, to limit the population to beneficiaries who had nonmissing baseline characteristics.

After applying all study eligibility criteria, our analytic sample included 434,671 beneficiaries (of any CVD risk level) attributed to intervention organizations and 293,046 beneficiaries attributed to control organizations. The algorithm for attributing beneficiaries had high sensitivity, correctly including 98.9 percent of enrolled beneficiaries in the attribution population (Table C.1). Among the beneficiaries enrolled and attributed, 99.7 percent were attributed to the same organization that enrolled the beneficiary.

Figure C.1 shows the flow of organizations (and their providers and beneficiaries), from application and random assignment to the final attribution-based study population. About 52 percent of these beneficiaries were enrolled in the Million Hearts Model; the remaining 48 percent appeared eligible for the model in claims data but were not enrolled (Table C.1).[16] We note, however, that claims data cannot replicate all study inclusion and exclusion criteria, such as whether the beneficiary refused to participate in the model.

[16] The percentage of attributed beneficiaries meeting inclusion criteria who were enrolled in the model—52.3 percent—was stable across key subgroups of beneficiaries. Specifically, the percentage was 52.3 for the subgroups of beneficiaries in the intervention and control groups. Further, using the methods discussed later in this appendix, we found that 52.9, 53.0, and 51.4 percent of apparently eligible beneficiaries with high, medium and low predicted risk, respectively, were enrolled in the model.

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



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

[a] This includes 1,209 and 243 providers in the intervention and control groups, respectively, who were registered after randomization. In the control group, providers were in some cases excluded by a 20-provider cap.

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

[c] The number of beneficiaries with high, medium, and low predicted CVD risk is the sum of the weights for the respective analyses.

AMI = acute myocardial infarction; CVD = cardiovascular disease; ESRD = end-stage renal disease; FFS = fee-for-service.

Table C.1. Overlap between the populations of enrolled beneficiaries and attributed beneficiaries

	Not enrolled	Enrolled and met inclusion criteria	Enrolled but did not meet inclusion criteria	Total
Not attributed		2,443 (96.45%) [0.6%]	90 (3.55%) [2.7%]	2,533 [0.2%]
Attributed and met inclusion criteria	345,433 (47.5%) [42.4%]	380,564 (52.3%) [98.9%]	1,720 (0.24%) [51.4%]	727,717 [60.5%]
Attributed, but did not meet inclusion criteria	469,993 (99.3%) [57.6%]	1,712 (0.4%) [0.4%]	1,539 (0.3%) [49.0%]	473,244 [39.3%]
Total	815,426 (67.8%)	384,719 (32.0%)	3,349 (0.3%)	1,203,494

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

Note: Each cell contains the number of beneficiaries. Row percentages are in parentheses, and column percentages are in brackets. Percentages might not sum to 100 due to rounding. Inclusion criteria are FFS Medicare Parts A and B, ages 40–79, no prior acute myocardial infarction, no prior stroke, no end stage renal disease, no hospice, and observable at least one month before attribution. Inclusion criteria are calculated on the date of enrollment for the population of enrolled beneficiaries and calculated on the date of attribution for the population of enrolled beneficiaries.

FFS = fee-for-service.

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

Predicting CVD risk scores was critical in developing the attribution-based study population. Of the beneficiaries attributed to the participating organizations in 2017 and 2018 who appeared eligible in claims, about half were enrolled in the Million Hearts Model in 2017 and 2018. Therefore, we did not have clinical data from the Million Hearts Data Registry and had to compute risk scores for many attributed beneficiaries. However, our evaluation focused on beneficiaries with high and medium CVD risk for the impact analyses and related descriptive analyses (for example, for assessing balance between the intervention and control groups). Therefore, we needed a way to assign CVD risk scores to all beneficiaries in the attribution-based population, using available data.

To assign CVD risk scores within the attribution-based population, we developed algorithms to predict each person's CVD risk score or risk group based only on variables derived from Medicare claims and enrollment data. We developed these algorithms using data for a population

for which we had both detailed claims and clinical data: namely, beneficiaries enrolled in the Million Hearts Model in 2017 and 2018. Then we applied the algorithms to everyone in the attribution-based population, predicting two quantities from their claims-derived baseline characteristics: (1) their baseline CVD risk scores; and (2) their probabilities of belonging to the high, medium, and low CVD risk groups. The rest of this section describes the risk prediction model in more detail.

Changes to the risk prediction model since previous reports. The methods for predicting CVD risk scores are largely the same as the methods used in our first and second annual reports (Conwell et al. 2019; Peterson et al. 2019). There were four main changes to the model:

1. Previously we predicted CVD risk *scores* but did not predict CVD risk *group*. Now we predict both.
2. Using predicted CVD risk scores, we previously imposed cutoffs for the purpose of assigning beneficiaries to high-, medium-, and low-risk groups. This report uses a weighting approach instead (Section 3 of this appendix).
3. We now fit the prediction models using beneficiaries enrolled in either 2017 or 2018. Previously we included only the beneficiaries enrolled in 2017.
4. We added more predictor variables to the prediction model: (1) variables based on Part D data, including beneficiaries' antihypertensive medication and statin use in the year before attribution; and (2) all covariates used in the impact analysis regression models (listed in Appendix E) that the risk prediction models had not previously included.

The predictive performance of the model improved with these changes.

Developing the algorithm for predicting baseline CVD risk

Building on experience predicting baseline CVD risk in previous reports (Conwell et al. 2019; Peterson et al. 2019), we used machine learning techniques to estimate a beneficiary's 10-year CVD risk score (the response, or dependent variable) as a function of claims-based characteristics defined at the date of attribution (the predictors, or independent variables). We used the predicted baseline CVD risk scores as covariates in the impact analysis regression models for the attribution-based population and for related descriptive analyses.

We fit (estimated) prediction models using CVD risk scores for beneficiaries in the main (enrolled) study population—that is, using data for the subset of attributed beneficiaries enrolled in the Million Hearts Model in 2017 and 2018. After we fit the model, we used the results to compute CVD risk scores for all model-eligible beneficiaries in the attribution population. This required constructing claims-based predictor variables in an identical fashion in both the enrolled and attributed populations.[17] We used a single model to predict CVD risk scores for all

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

beneficiaries in the intervention and control groups to ensure we did not introduce bias by defining the risk groups differently for the intervention versus control group.

We repeated this process to develop a second model that could predict a beneficiary's CVD risk group. The process we used for predicting CVD risk *groups* was analogous to the methods for predicting CVD risk *scores*. However, the process required a few changes because the response variable was categorical rather than continuous. The model yielded the estimated probabilities that a beneficiary belonged to each of the three CVD risk groups—high, medium, and low. For each beneficiary, these probabilities summed to 1. We used the probabilities for weighting the population of attributed beneficiaries (as described in the next section of this appendix), as a covariate in the impact analysis regression models for the attribution-based population, and for our descriptive analyses using this population.

In the process of developing the two predictive models, we considered a range of candidate models. We fit the candidate models using a random 85 percent sample of the available data (the training data). We compared models based primarily on cross-validated mean squared errors (for risk scores) and classification accuracy (for risk groups). A model outperformed another one if it had a lower mean squared error or higher accuracy. We considered model performance on other metrics as well. Next, we report the performance of the model using the remaining 15 percent of the data (the testing data).[18] Candidate models varied in terms of the modeling approach, hyper-parameters, and response and predictor variables:

- **Modeling approaches.** We considered a range of modeling approaches for predicting CVD risk scores, including random forest regression; gradient boosted regression trees; multilayer perceptron neural networks; and elastic net, Lasso, and ordinary least squares regression models. For predicting CVD risk groups, we considered the random forest classifier, gradient boosting for classification, multinomial logistic regression with regularization, and multinomial logistic regression without regularization. See Hastie et al. (2009) for an overview of these methods. Models were fit using `Scikit-learn` in Python (Pedregosa et al. 2011).
- **Hyper-parameters.** Most of the modeling techniques required us to choose hyper-parameters (that is, parameters not directly estimated by the model but that affect the results). We generally tried a range of parameters and chose, through cross-validation, the ones with the best performance.
- **Response variables**. Based on our previous experience (Conwell et al. 2019), we used the CVD risk score minus a claim-based proxy of risk as the response variable for predicting

[18] After we selected the best candidate model, we refit the model using the entire data set. We used this final model to predict CVD risk scores for the attribution-based population.

CVD risk scores.[19,20] The beneficiaries' observed CVD risk groups were used as the response variable in the classification models.

- **Predictor variables.** The risk prediction models included all the variables we used as covariates in the impact analysis regression models (listed in Appendix F) and some additional claims-based variables that we learned predicted CVD risk in our first annual report (Conwell et al. 2019). We used Medicare Parts A, B, and D claims and enrollment data to construct a broad range of covariates to potentially include as predictor variables. These variables included demographic variables, reason for Medicare entitlement, hierarchical condition category (HCC) scores, chronic condition flags (measured by the Chronic Condition Warehouse [CCW] and HCC algorithms), years since the first occurrence of chronic conditions, service use and Medicare spending, receipt of cardiovascular-related procedures (measured using the CCW algorithm), beneficiaries' antihypertensive medication and statin use in the year before attribution, and direct proxies of CVD risk score inputs (such as flags for any indication of tobacco or aspirin use in claims).[21] We also constructed covariates based on the characteristics of the organizations and providers the beneficiary was attributed to and of the beneficiary's zip code (Appendix D).

Performance of the algorithm for predicting baseline CVD risk scores

Among all of the candidates, random forest regression performed the best. That is, it was most predictive of actual CVD risk in the testing data, as measured by the smallest mean squared error.[22] The R^2 in the testing data was 0.90, and the mean squared error was 15.0. This is notably better performance than we obtained in our first annual report with an R^2 of 0.82 and a mean squared error of 27.4. Including additional covariates from the Part D data, not available in the first report, appears to explain the improvement in part.

[19] We calculated this claims-based proxy using the Longitudinal Atherosclerosis Cardiovascular Disease (ASCVD) risk estimator formula; beneficiary inputs combined Medicare claims-based variables (such as age and presence of diabetes) supplemented by using the median value in the Million Hearts Model-enrolled population for the remaining variables (such as blood pressure and cholesterol), which could not be observed in Medicare data. This approach helped the risk prediction model deal with the nonlinear functional form of the ASCVD risk estimator.

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

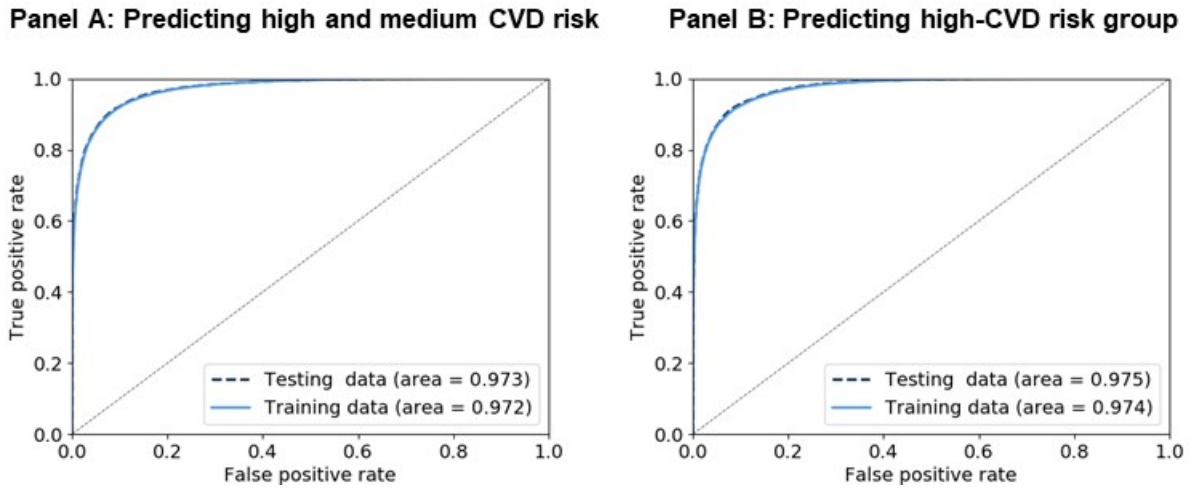
[21] The second annual report (Peterson et al. 2019) defines these variables.

[22] Our final random forest regression model used trees with half the predictors, at least 10 observations per split, and 5 observations per leaf. (See the `Scikit-learn` documentation for a description of these hyper-parameters.)

Performance of the algorithm for predicting baseline CVD risk groups

For predicting CVD risk groups, the gradient boosting classifier produced the highest cross-validated accuracy across candidate models (0.63).[23] The receiver operating curves (Figure C.2) summarize the results of the model by illustrating the trade-offs between false positives (saying a person was at high or medium risk when, in fact, he or she was not) and true positives (correctly saying a person was at high or medium risk). The ideal curve would ramp up immediately, indicating the model perfectly predicts who is and is not, in fact, at high or medium risk (100 percent true positives and 0 percent false positives). The area under the receiver curve (the AUC, also called the c-statistic) for a model with perfect prediction would be 1. In contrast, a model that performed as well as chance would have a diagonal line, with an AUC equal to 0.50. For the final model, the area under the receiver operating characteristic curve for the predicted model was 0.97, both for determining membership in the combined high- and medium-risk groups and the high-risk groups (Figure C.2). These statistics illustrate that the model predicts CVD risk well.

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



Note: The receiver operating curve is created by plotting the true positive rate against the false positive rate at various thresholds for classifying a beneficiary as at high or medium risk. Panel A shows the true and false positive rates when using the predicted CVD risk score to assign beneficiaries to the high- or medium-risk groups, and Panel B shows these rates when using the predicted risk scores to assign beneficiaries to the high-risk group. The true and false positive rates vary as a function of the threshold used to assign beneficiaries to groups. We calculated the curves by applying the CVD risk score prediction model to the testing and training data.

CVD = cardiovascular disease.

[23] Our final gradient boosting classifier model used 20 boosting stages, at least 50 observations per split, and 5 observations per leaf, trees with 80 percent of the predictors, maximum depth of 3, at least 5 observations per leaf, a deviance loss function, and a learning rate of 0.1. (See the `Scikit-learn` documentation for a description of these hyper-parameters.)

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

After we developed the two risk prediction models for CVD risk scores and CVD risk groups, we used the models to assign each eligible beneficiary in the attribution population a predicted risk score and probabilities of belonging to the high-, medium-, and low-risk groups, respectively. For the CVD risk scores, we did this by (1) calculating a claims-based version of the risk score, using just the beneficiary's demographics and assuming that his or her clinical values were at the median, and (2) adding an increment (moving that score up or down) based on the predicted increment from the algorithm. For CVD risk groups, we produced the probabilities directly from the model.

3. Weighting the population of attributed beneficiaries to reflect high- and medium-risk beneficiaries

The population of attributed beneficiaries includes beneficiaries of any risk level. For the robustness check impact analyses and accompanying descriptive analyses (such as comparing the baseline characteristics of intervention and control group beneficiaries in Appendix E), we weighted the population to reflect high- and medium-risk beneficiaries or high-risk beneficiaries, as appropriate.

- For estimating impacts among high- and medium-risk beneficiaries, each beneficiary's weight equaled the estimated probability of belonging to the high-risk group plus the probability of belonging to the medium-risk group.
- For estimating impacts among high-risk beneficiaries, each beneficiary's weight equaled the estimated probability of belonging to the high-risk group.

Using these weights, we calculated weighted linear, logistic, and Cox proportional hazard regression models and weighted sample statistics (in place of the unweighted regression models or unweighted sample statistics we used for the population of enrolled beneficiaries).[24]

The weighting scheme yields an effective sample of 83,915 high, 163,873 medium, and 186,882 low predicted CVD risk beneficiaries in the intervention group and another 53,488 high, 111,297 medium, and 128,261 low predicted CVD risk beneficiaries in the control group (Figure C.1).

[24] We estimated impacts on Medicare spending and service use using linear regression models, with one observation per beneficiary per quarter. To account for beneficiaries who became unobservable during the quarter, we then reweighted beneficiaries using the percentage of days in the quarter they were observable. With the attribution sample, the final weight for a beneficiary-quarter observation equaled the observability weight multiplied by the probability of belonging to the high- or medium-risk group.

APPENDIX D

CONSTRUCTING MEASURES OF COUNTY- AND ORGANIZATION-LEVEL POPULATION HEALTH AND USE

In the second annual report, Mathematica reported that the number of cardiovascular disease (CVD)-related admissions was 12.5 percent higher for high-risk intervention group beneficiaries compared to the control group during the model period (18 versus 16 per 1,000 beneficiaries per quarter; $p = 0.004$). We also reported that the number of outpatient ED visits was 7 percent higher for the medium- and high-risk intervention group compared to the control group (102 versus 95 per 1,000 beneficiaries per quarter; $p = 0.003$). However, the high-risk intervention group had a CVD-related admission rate about 5 percent higher at baseline (41 versus 39 per 1,000 beneficiaries per year) and the medium- and high-risk intervention group had an outpatient emergency department (ED) rate about 4 percent higher at baseline (379 versus 363 per 1,000 beneficiaries per year) (Blue et al. 2019; Peterson et al. 2019). Other studies have concluded that local factors that are unrelated to patients' health status have in part driven geographic variations in Medicare use and expenditures (Finkelstein et al. 2016; Zuckerman et al. 2010). We hypothesized that local area characteristics that differed between intervention and control groups might have partially confounded the impact findings—even though we had regression adjusted for *individuals'* recent use of hospital or ED services. For example, intervention beneficiaries residing in geographic areas with higher rates of hospital admissions or outpatient ED use in the baseline period might have been more likely to be hospitalized or have an outpatient ED visit in the intervention period compared to control beneficiaries with similar health status in areas with lower baseline use rates.

To address this potential confounding, we developed several geographic variables from different sources to use as control variables in our regression models. Section D.1 describes three area-level control variables we developed from the publicly available Medicare geographic variations database (GVDB). Section D.2 describes county-level control variables for acute myocardial infarction (AMI) hospitalizations, stroke hospitalizations, and age-adjusted mortality rates for the population ages 65 and older that we downloaded from publicly available data on the Centers for Disease Control and Prevention (CDC) website. Section D.3 concludes with a description of organization-level Medicare fee-for-service (FFS) spending and use characteristics we developed for each participating organization from pre-enrollment data among 2017 enrollees.

1. County-level characteristics from the Medicare geographic variations database

The GVDB public use files contain summary data on the Medicare population at the state and county levels.[25] These data include demographics and enrollment characteristics as well as use and spending among the FFS population. We selected the following variables at the county level for 2016, the year before the start of the Million Hearts Model:

- Medicare per capita spending in 2016[26]

[25] These files are available on the Medicare geographic variations database web page: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Geographic-Variation/GV_PUF. Accessed May 1, 2020.

[26] This is the nonstandardized, nonrisk-adjusted Medicare spending variable: that is, actual spending, from the GVDB file.

- Number of inpatient hospital stays per 1,000 beneficiaries in 2016
- Number of outpatient ED visits per 1,000 beneficiaries in 2016

We added these GVDB variables to the analysis file for the evaluation based on the county associated with each beneficiary's mailing address, as reported in the Medicare Enrollment Database. Appendix E provides information about balance between the intervention and control groups on these characteristics. Standardized differences of the mean values of these variables between intervention and control groups were small across all registry-based analysis samples, though the means were consistently higher for the intervention group.

2. County-level data from the CDC

The CDC has an Interactive Atlas of Heart Disease and Stroke page on its website.[27] In the Atlas, the CDC calculates annual hospitalization rates among the Medicare FFS population ages 65 and older for various categories of heart disease and stroke, and then pools and smooths the rates over calendar years 2014 to 2016. From the Atlas, we obtained the following variables at the county level:

- Total AMI hospitalizations, 2014 to 2016
- Total stroke hospitalizations, 2014 to 2016

The CDC website also houses CDC Wide-ranging ONline Data for Epidemiologic Research (CDC WONDER), which contains data from numerous sources, including vital statistics (births and deaths) as well as data on various public health measures.[28] From this database, we extracted county-level data on age-adjusted mortality rates among the general population ages 65 and older.

Similar to the GVDB variables, we added the variables from the CDC data sources to the analysis file for the evaluation by a beneficiary's county, and we report balance on these characteristics for each analysis population in Appendix E. Standardized differences of the mean values of these variables between intervention and control groups were small across all registry-based analysis samples; directionally, rates of AMI hospitalizations were slightly lower and stroke hospitalizations slightly higher for the intervention versus the control group. Age-adjusted mortality rates were slightly lower for the intervention group across most analysis samples.

3. Organization-level use and spending characteristics

We also constructed variables that reflect patterns of hospitalization, outpatient ED use, and Medicare Parts A and B FFS expenditures among 2017 enrollees at participating organizations in the baseline period. To the extent that beneficiaries enrolled in the intervention group had

[27] The atlas is available at https://www.cdc.gov/dhdsp/maps/atlas/index.htm. Accessed May 1, 2020.

[28] The CDC WONDER data are available at https://wonder.cdc.gov/. Accessed May 1, 2020.

different levels of use and expenditures from similar beneficiaries in the control group before the model, we would want to adjust for these baseline differences in our impact estimates.

Specifically, we developed a series of variables to measure the mean pre-intervention value at each participating organization (intervention and control) for three outcomes: hospitalizations, outpatient ED visits, and Medicare spending. To develop these variables, we limited the sample to 2017 enrollees. Because many of the 2017 intervention group beneficiaries were enrolled within the first few months of the year, their baseline period is more likely than the 2018 enrollees' to span the period before the Million Hearts Model began and, importantly, before the model might have affected organizations' use and spending for their Medicare population. We then calculated, for each organization, variance-shrunken rates of hospitalization and outpatient ED use and mean total Medicare spending using baseline annualized values of these variables for all 2017 enrollees included in the impacts analyses. The variance-shrunken means adjust organization means toward the grand mean, with more shrinkage for organizations with large variances. We applied this approach to address outlier mean organization-level values for small organizations. Appendix E provides information balance between intervention and control groups on these characteristics. Among the registry-based analysis samples, standardized differences of the mean values of these variables were small between intervention and control groups; directionally, Medicare spending and rates of outpatient ED visits were mostly higher, but all-cause hospitalization rates were lower for the intervention versus control group.

APPENDIX E

BASELINE CHARACTERISTICS OF THE INTERVENTION AND CONTROL GROUPS PARTICIPATING IN THE MILLION HEARTS MODEL

In this appendix, we provide detailed information on baseline characteristics of the beneficiaries in the intervention and control groups, across four subpopulations used for the analyses in this report:

- Beneficiaries enrolled in 2017 and 2018 and included in analyses of cardiovascular disease (CVD) events and other long-term outcomes based on Medicare Parts A and B claims and Medicare enrollment data (Section E.1)
- Beneficiaries enrolled in 2017 and included in analyses of drug initiation and intensification based on Medicare Part D data (Section E.2)
- Beneficiaries enrolled by October 31, 2017, with reassessment data by December 31, 2018, and included in analyses of CVD risk factors and risk reduction (Section E.3)
- Beneficiaries attributed to the Million Hearts Model organizations in 2017 and 2018 and included in the attribution population used for robustness checks (Section E.4)

In addition, for the main population described in Section E.1, this appendix compares enrolled beneficiaries to attributed beneficiaries, separately for the intervention and control groups (Section E.5).

Within each section, we present tables with baseline characteristics—that is, characteristics measured at enrollment or attribution, as appropriate—for both the high- and medium-risk populations combined as well as the high-risk-only population. The one exception to this is for the population included in the analysis of CVD risk factors and risk reduction; this analytic population is limited to high-risk beneficiaries because the intervention group organizations did not have to submit reassessment data for other beneficiaries they enrolled.

1. Baseline characteristics of the population used to estimate impacts on CVD events and other long-term, claims-based outcomes

The high- and medium-risk beneficiaries enrolled in 2017 and 2018 were very similar at enrollment with respect to beneficiary-level characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending (Table E.1). Within this population, beneficiaries in the intervention and controls groups enrolled in Part D were also well balanced on medication use at enrollment. However, intervention and control group beneficiaries differed somewhat in the types of organization 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 107), had more sites (25 versus 14), and were more likely to participate in or to have applied to participate in another model when they applied to the Million Hearts model (70 versus 55 percent). In addition, intervention group beneficiaries were more likely to live in the South (46 versus 34 percent). Some of the differences in the organizational characteristics of enrolled beneficiaries are attributable to the 20-provider cap for the control organizations, which was a Centers for Medicare & Medicaid Services (CMS) requirement. For example, because there is no cap for the

intervention group, it makes sense that (1) the intervention group would enroll more beneficiaries overall and (2) large organizations would enroll a larger share of those beneficiaries.

Table E.1. Baseline characteristics of high- and medium-risk Medicare beneficiaries enrolled in 2017 and 2018: Intervention versus control group

Characteristic	Intervention group mean (N 130,641)	Control group mean (N 88,312)	Difference	Standardized difference[a]	*p* value[b]
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	27 [10]	27 [10]	0.0	0.00	0.93
Modifiable risk (%)[c]	9	9	0.1	0.01	0.75
Has diabetes (%)	36	35	1.3	0.03	0.51
Systolic blood pressure (mm Hg)	134	134	0.0	0.00	0.95
Total cholesterol (mg/dL)	174	174	0.6	0.02	0.65
HDL cholesterol (mg/dL)	50	51	-0.1	-0.01	0.83
LDL cholesterol (mg/dL)	97	96	1.1	0.03	0.33
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	0.63
Uses statins based on Part D[d] (%)	63	64	-0.2	-0.01	0.87
Intensity of statin use based on Part D[d] (%)					
Low intensity	6	6	-0.1	0.00	0.83
Medium intensity	39	38	0.4	0.01	
High intensity	18	19	-0.6	-0.01	
Beneficiary's demographic and Medicare enrollment characteristics					
Age [standard deviation]	72 [5]	72 [5]	-0.1	-0.03	0.43
Black race (%)	8	7	1.5	0.06	0.36
Male (%)	58	59	-1.0	-0.02	0.26
Dually enrolled in Medicare and Medicaid (%)	10	10	-0.5	-0.02	0.76
Originally entitled to Medicare because of disability (%)	13	14	-0.4	-0.01	0.75
Beneficiary's health and comorbid conditions					
HCC score [standard deviation]	1.16 [1.00]	1.17 [1.01]	0.0	0.00	0.89
Number of chronic conditions	2.1	2.1	0.0	0.00	0.91
Has chronic kidney disease (%)	25	24	0.3	0.01	0.78
Has ischemic heart disease (%)	32	34	-1.7	-0.04	0.58
Has congestive heart failure (%)	11	12	-0.7	-0.02	0.54
Has atrial fibrillation (%)	10	10	0.1	0.00	0.93
Has morbid obesity (%)	7	7	0.1	0.01	0.80
Beneficiary's medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	7,824 [17,673]	7,661 [16,746]	163.0	0.01	0.61

Characteristic	Intervention group mean (N 130,641)	Control group mean (N 88,312)	Difference	Standardized difference[a]	*p* value[b]
Hospital admissions (per 1,000 beneficiaries)	188	193	-5.3	-0.01	0.58
CVD-related hospital admissions (per 1,000 beneficiaries)[e]	42	43	-0.8	0.00	0.88
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	382	372	10.4	0.01	0.58
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[e]	29	28	1.2	0.01	0.72
Office visits (per 1,000 beneficiaries)	9,222	8,963	259.1	0.03	0.52
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,639	2,689	-49.7	-0.02	0.85
Cardiologist visits (per 1,000 beneficiaries)	1,849	1,806	43.8	0.01	0.83
Beneficiary's CVD related procedures in year before model 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 enrolling the beneficiary					
Total number of practitioners	126	107	18.5	0.08	0.71
[standard deviation]	[178]	[299]			
Total number of service sites	25	14	10.2	0.39	0.12
[standard 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	
CAH or rural hospital	1	2	-1.6	-0.14	
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
Organization-level mean Medicare spending and use[f]					
Parts A and B spending	7,666	7,649	17.8	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 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
Census region (%)					
Northeast	27	22	4.6	0.11	0.09

Characteristic	Intervention group mean (N 130,641)	Control group mean (N 88,312)	Difference	Standardized difference[a]	*p* value[b]
Midwest	19	29	-9.8	-0.23	
South	46	34	12.3	0.25	
West	8	15	-7.0	-0.22	
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.5	-0.16	0.28
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.5	0.12	0.44
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,378	4,408	-30.3	-0.05	0.76
Per capita total Medicare Part A and B spending in 2016	9,945	9,847	98.2	0.07	0.66
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	277	1.4	0.03	0.84
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	694	683	11.1	0.09	0.62
Characteristics of beneficiary's Million Hearts Model enrollment					
Days between model launch (1/3/2017) and enrollment date [standard deviation]	194 [178]	209 [168]	-15.4	-0.09	0.18
Enrollment date is in (%)					
2017 (as opposed to 2018)	83	83	0.4	0.01	0.85
First quarter of the year	40	36	4.6	0.09	0.12
Second quarter of the year	31	29	1.8	0.04	0.23
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 (%)[g]	50	49	0.9	0.02	0.93

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending, and CVD-related procedures; the organizations' applications to the Million Hearts Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: For all measures, means are calculated over nonmissing values. The following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, 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 second annual report (Peterson et al. 2019) for details on variable construction.

[a] The standardized difference is the difference between the intervention and control group means, divided by the standard deviation across the intervention and control groups.

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

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

[d] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 89,523 for the intervention group and N = 60,433 for the control group). This accounted for 69 percent of all beneficiaries enrolled in the intervention group and 68 percent in the control group.

[e] We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the second annual report, 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.

[f] See Appendix D for details on measure construction. To estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organization-level means included in this table are the variance-shrunken means for each organization.

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

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

Consistent with the combined high- and medium-risk population, the high-risk-only population enrolled in 2017 and 2018 was well balanced on characteristics at enrollment such as age, sex, CVD risk score, recent service use, and Medicare spending (Table 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). High-risk beneficiaries in the intervention group were more likely than those in the control group to be enrolled by specialty or multispecialty organizations (39 versus 32 percent). In addition, intervention group beneficiaries were more likely to live in the South (48 versus 35 percent) or Northeast (25 versus 22 percent). High-risk beneficiaries in the intervention group were also more likely to have enrolled during the first quarter of 2017 (43 versus 37 percent).

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

Characteristic	Intervention group mean (N 40,446)	Control group mean (N 27,287)	Difference	Standardized difference[a]	*p* value[b]
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	40 [9]	40 [9]	0.0	0.00	0.91
Modifiable risk (%)[c]	16	15	0.0	0.00	0.95
Has diabetes (%)	65	64	0.8	0.02	0.74
Systolic blood pressure (mm Hg)	140	140	0.2	0.01	0.87
Total cholesterol (mg/dL)	169	169	-0.3	-0.01	0.81
HDL cholesterol (mg/dL)	47	48	-0.3	-0.02	0.63
LDL cholesterol (mg/dL)	93	92	0.5	0.01	0.67
Is current smoker (%)	12	14	-2.0	-0.06	0.21
Beneficiary's medication use					
Uses aspirin (%)	51	49	1.5	0.03	0.70
Uses antihypertensives based on Part D[d] (%)	90	89	0.9	0.03	0.20
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
Medium intensity	41	41	0.4	0.01	
High intensity	21	20	0.4	0.01	
Beneficiary's demographic and Medicare enrollment characteristics					
Age [standard deviation]	74 [4]	74 [4]	-0.1	-0.02	0.59
Black race (%)	8	6	1.3	0.05	0.43
Male (%)	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	0.49
Beneficiary's health and comorbid conditions					
HCC score [standard deviation]	1.37 [1.06]	1.36 [1.06]	0.0	0.01	0.81
Number of chronic conditions	2.6	2.6	0.0	0.02	0.59
Has chronic kidney disease (%)	36	35	0.8	0.02	0.58
Has ischemic heart disease (%)	38	39	-1.2	-0.03	0.67
Has congestive heart failure (%)	13	14	-0.5	-0.01	0.66
Has atrial fibrillation (%)	11	11	0.3	0.01	0.79
Has morbid obesity (%)	8	8	0.1	0.00	0.95
Beneficiary's medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	8,337 [18,154]	8,061 [16,128]	275.9	0.02	0.39
Hospital admissions (per 1,000 beneficiaries)	204	202	2.5	0.00	0.80
CVD-related hospital admissions (per 1,000 beneficiaries)[e]	49	46	3.6	0.01	0.49
Outpatient ED visits or observation	395	383	11.6	0.01	0.54

Characteristic	Intervention group mean (N 40,446)	Control group mean (N 27,287)	Difference	Standardized difference[a]	*p* value[b]
stays (per 1,000 beneficiaries)					
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[e]	32	32	0.5	0.00	0.88
Office visits (per 1,000 beneficiaries)	9,847	9,515	332.7	0.04	0.40
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,977	2,990	-12.8	0.00	0.97
Cardiologist visits (per 1,000 beneficiaries)	2,074	2,038	35.9	0.01	0.86
Beneficiary's CVD related procedures in year before model enrollment					
Received echocardiogram (%)	44	43	0.8	0.02	0.77
Received electrocardiogram (%)	74	74	0.4	0.01	0.89
Received cardiac stress test (%)	28	28	-0.1	0.00	0.98
Characteristics of organization enrolling the beneficiary					
Total number of practitioners [standard deviation]	131 [204]	94 [280]	37.5	0.15	0.45
Total number of service sites [standard deviation]	24 [26]	14 [26]	10.6	0.41	0.11
Organization type (%)					
Primary care	50	55	-4.5	-0.09	0.35
Specialty or multispecialty	39	32	7.5	0.16	
FQHC, RHC, or other health center	5	6	-0.8	-0.04	
CAH or rural hospital	1	3	-2.0	-0.16	
Acute care hospital	5	5	-0.2	-0.01	
Organization was participating in, or had application pending for, another model at application (%)	68	56	12.2	0.25	0.20
Organization-level mean Medicare spending and use[f]					
Parts A and B spending	7,684	7,675	8.4	0.01	0.98
Hospital admissions (per 1,000 beneficiaries)	185	193	-8.1	-0.20	0.33
Outpatient ED visits (per 1,000 beneficiaries)	381	371	10.1	0.09	0.57
Characteristics of clinician enrolling the 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					
Rural (%)	26	27	-1.5	-0.03	0.77
Census region (%)					
Northeast	25	22	3.1	0.07	0.39
Midwest	19	28	-9.8	-0.23	
South	48	35	12.7	0.26	
West	9	15	-6.0	-0.19	
County-level health measures					
AMI hospitalizations per 1,000	11	12	-0.8	-0.23	0.14

Characteristic	Intervention group mean (N 40,446)	Control group mean (N 27,287)	Difference	Standardized difference[a]	*p* value[b]
Medicare beneficiaries ages 65 and older in 2014–2016					
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.4	0.10	0.55
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,401	4,445	-43.9	-0.07	0.68
Per capita total Medicare Part A and B spending in 2016	9,933	9,861	71.2	0.05	0.75
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	278	0.5	0.01	0.94
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	699	687	11.1	0.09	0.63
Characteristics of beneficiary's Million Hearts Model enrollment					
Days between model launch (1/3/2017) and enrollment date [standard deviation]	184 [176]	202 [165]	-17.6	-0.10	0.17
Enrollment date is in (%)					
2017 (as opposed to 2018)	84	84	0.5	0.01	0.84
First quarter of the year	43	37	5.3	0.11	0.12
Second quarter of the year	30	29	1.8	0.04	0.30
Third quarter of the year	15	17	-2.0	-0.06	0.25
Fourth quarter of the year	12	17	-5.1	-0.15	<0.01
Data submitted to the registry using bulk upload (%)[g]	45	44	0.3	0.01	0.97

See Table E.1 for all table notes and acronyms, other than table note d.

[d] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 28,391 for the intervention group and N = 19,091 for the control group). This accounted for 70 percent of all beneficiaries enrolled in the intervention group and 70 percent in the control group.

2. Baseline characteristics of the population used to estimate impacts on medication initiation and intensification (Part D-based outcomes)

This section describes baseline characteristics of beneficiaries who enrolled in the Million Hearts Model in 2017, were also enrolled in Medicare Part D during the year before enrollment, and were included in analyses of medication initiation and intensification (Chapter V). 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, those in the intervention group had higher rates of hypertension at enrollment (80 versus 75 percent) than beneficiaries in the control group (Table E.3). Nevertheless, the distribution of systolic blood pressure and rates of antihypertensive medication use were similar at enrollment between the groups. The two groups were also similar in terms of cholesterol levels and use of statins at baseline. Further, they were similar with respect to characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending.

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

Characteristic	Intervention group mean (N 67,269)	Control group mean (N 45,076)	Difference	Standardized difference[a]	*p* value[b]
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	28 [11]	28 [11]	0.0	0.00	0.96
Modifiable risk (%)[c]	10	10	0.2	0.02	0.70
Has diabetes (%)	34	33	1.1	0.02	0.58
Is treated for or diagnosed with hypertension (%)	80	75	4.8	0.11	0.05
SBP (mm Hg)	135	135	-0.2	-0.01	0.82
Distribution of SBP (%)					
SBP < 130 mm Hg	34	33	1.0	0.02	0.51
SBP 130–139 mm Hg	31	31	-0.2	0.00	0.87
SBP 140–149 mm Hg	19	19	-0.7	-0.02	0.48
SPB ≥ 150 mm Hg	16	17	-0.2	0.00	0.90
Total cholesterol (mg/dL)	179	178	1.1	0.03	0.38
HDL cholesterol (mg/dL)	51	51	-0.1	-0.01	0.86
LDL cholesterol (mg/dL)	101	100	1.2	0.04	0.28
Distribution of LDL cholesterol (%)					
LDL < 70 mg/dL	14	15	-1.1	-0.03	0.28
LDL 70–99 mg/dL	40	41	-0.4	-0.01	0.56
LDL 100–-129 mg/dL	28	28	0.7	0.01	0.36
LDL ≥ 130 mg/dL	18	17	0.8	0.02	0.29
Is current smoker (%)	11	12	-0.9	-0.03	0.30
Beneficiary's medication use					
Uses aspirin (%)	44	42	1.6	0.03	0.73
Uses antihypertensives based on Part D (%)	82	82	0.5	0.01	0.68
Uses statins based on Part D (%)	61	61	-0.4	-0.01	0.79
Intensity of statin use based on Part D (%)					
Low intensity	7	7	0.0	0.00	0.98
Medium intensity	37	37	0.0	0.00	
High intensity	17	17	-0.4	-0.01	
Beneficiary's demographic and Medicare enrollment characteristics					
Age [standard deviation]	72 [5]	72 [5]	-0.2	-0.03	0.32
Black race (%)	8	7	1.4	0.06	0.38
Male (%)	54	55	-1.1	-0.02	0.23
Dually enrolled in Medicare and Medicaid (%)	13	13	-0.5	-0.01	0.82
Originally entitled to Medicare because of disability (%)	15	15	-0.1	0.00	0.96
Beneficiary's health and comorbid conditions					
HCC score [standard deviation]	1.18 [1.00]	1.18 [1.00]	0.0	0.00	0.96
Number of chronic conditions	2.1	2.1	0.0	0.01	0.78

Characteristic	Intervention group mean (N 67,269)	Control group mean (N 45,076)	Difference	Standardized difference[a]	*p* value[b]
Beneficiary's medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	7,706 [16,258]	7,605 [15,873]	101.0	0.01	0.74
Hospital admissions (per 1,000 beneficiaries)	182	184	-1.6	0.00	0.86
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	385	371	14.6	0.01	0.46
Office visits (per 1,000 beneficiaries)	9,408	9,064	343.7	0.05	0.41
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,877	2,844	33.6	0.01	0.91
Cardiologist visits (per 1,000 beneficiaries)	1,712	1,743	-31.1	-0.01	0.87
Characteristics of organization enrolling the beneficiary					
Organization-level mean Medicare spending and use[d]					
Parts A and B spending	7,622	7,610	12.4	0.01	0.97
Hospital admissions (per 1,000 beneficiaries)	182	190	-7.5	-0.19	0.36
Outpatient ED visits (per 1,000 beneficiaries)	378	365	13.2	0.12	0.46
Characteristics of clinician enrolling the beneficiary					
Provider specialty (%)					
Primary care physician	60	63	-2.1	-0.04	0.78
Cardiologist	24	25	-1.3	-0.03	0.87
Physician with other specialty	3	1	2.2	0.15	0.13
Not a physician (for example, NP or PA)	12	10	1.4	0.04	0.46
Characteristics of beneficiary's region					
Rural (%)	25	26	-1.7	-0.04	0.74
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11	12	-0.5	-0.16	0.29
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23	23	0.7	0.15	0.35
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,393	4,415	-21.3	-0.04	0.84
Per capita total Medicare Part A and B spending in 2016	9,983	9,865	118.4	0.08	0.61
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	280	276	3.7	0.09	0.58
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	698	685	13.7	0.11	0.55

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending; registry data linked to NPPES for clinician-level characteristics; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked

separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics.

Notes: For all measures, means are calculated over nonmissing values. See the second annual report (Peterson et al. 2019) for details on variable construction.

The population for this table includes beneficiaries who enrolled in 2017, had 12 months of Part D coverage before 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 percent of all beneficiaries enrolled in the intervention group in 2017 and, similarly, 62 percent in the control group.

[a] The standardized difference is the difference between the intervention and control group means, divided by the standard deviation across the intervention and control groups.

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

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

[d] See Appendix D for details on measure construction. To estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. 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; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; SBP = systolic blood pressure.

The high-risk intervention and control group beneficiaries included in analyses of medication initiation and intensification were very similar at enrollment on all characteristics shown in Table E.4.

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

Characteristic	Intervention group mean (N 21,791)	Control group mean (N 14,649)	Difference	Standardized difference[a]	*p* value[b]
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	40 [9]	40 [9]	0.0	0.00	0.89
Modifiable risk (%)[c]	17	17	0.2	0.02	0.75
Has diabetes (%)	63	62	0.8	0.02	0.77
Is treated for or diagnosed with hypertension (%)	91	89	2.0	0.07	0.13
SBP (mm Hg)	141	141	0.3	0.02	0.79
Distribution of SBP (%)					
SBP < 130 mm Hg	19	19	0.2	0.01	0.87
SBP 130–139 mm Hg	31	30	0.2	0.01	0.88
SBP 140–149 mm Hg	23	24	-1.0	-0.02	0.37
SPB ≥ 150 mm Hg	27	27	0.5	0.01	0.82
Total cholesterol (mg/dL)	173	173	-0.1	0.00	0.96
HDL cholesterol (mg/dL)	48	48	-0.5	-0.03	0.49
LDL cholesterol (mg/dL)	96	95	0.3	0.01	0.80
Distribution of LDL cholesterol (%)					

Characteristic	Intervention group mean (N 21,791)	Control group mean (N 14,649)	Difference	Standardized difference[a]	*p* value[b]
LDL < 70 mg/dL	20	21	-0.4	-0.01	0.73
LDL 70–99 mg/dL	40	40	0.3	0.01	0.73
LDL 100–129 mg/dL	24	24	0.3	0.01	0.67
LDL ≥ 130 mg/dL	15	15	-0.2	-0.01	0.80
Is current smoker (%)	12	13	-1.2	-0.04	0.22
Beneficiary's medication use					
Uses aspirin (%)	49	48	0.9	0.02	0.83
Uses antihypertensives based on Part D (%)	90	89	0.7	0.02	0.31
Uses statins based on Part D (%)	67	66	0.7	0.02	0.58
Intensity of statin use based on Part D (%)					
Low intensity	7	7	0.2	0.01	0.86
Medium intensity	40	40	0.2	0.00	
High intensity	20	19	0.3	0.01	
Beneficiary's demographic and Medicare enrollment characteristics					
Age	74	74	-0.1	-0.03	0.45
[standard deviation]	[4]	[4]			
Black race (%)	8	7	1.1	0.04	0.53
Male (%)	62	62	-0.3	-0.01	0.79
Dually enrolled in Medicare and Medicaid (%)	12	13	-0.7	-0.02	0.73
Originally entitled to Medicare because of disability (%)	13	13	-0.4	-0.01	0.73
Beneficiary's health and comorbid conditions					
HCC score	1.38	1.37	0.0	0.01	0.72
[standard deviation]	[1.04]	[1.05]			
Number of chronic conditions	2.6	2.6	0.1	0.03	0.47
Beneficiary's medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	8,055 [15,747]	7,943 [15,890]	112.7	0.01	0.74
Hospital admissions (per 1,000 beneficiaries)	193	192	1.3	0.00	0.89
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	394	385	8.1	0.01	0.70
Office visits (per 1,000 beneficiaries)	9,920	9,468	452.5	0.06	0.29
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,194	3,103	91.1	0.03	0.79
Cardiologist visits (per 1,000 beneficiaries)	1,914	1,987	-73.9	-0.01	0.72
Characteristics of organization enrolling the beneficiary					
Organization-level mean Medicare spending and use[d]					
Parts A and B spending	7,656	7,652	4.5	0.00	0.99
Hospital admissions (per 1,000 beneficiaries)	184	191	-6.5	-0.16	0.43
Outpatient ED visits (per 1,000 beneficiaries)	381	371	10.6	0.09	0.56

Characteristic	Intervention group mean (N 21,791)	Control group mean (N 14,649)	Difference	Standardized difference[a]	*p* value[b]
Characteristics of clinician enrolling the beneficiary					
Provider specialty (%)					
Primary care physician	60	61	-1.7	-0.04	0.82
Cardiologist	25	26	-1.5	-0.03	0.85
Physician with other specialty	4	1	2.3	0.15	0.14
Not a physician (for example, NP or PA)	11	10	1.0	0.03	0.59
Characteristics of beneficiary's region					
Rural (%)	26	28	-1.3	-0.03	0.81
County-level health measures					
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016[d]	11	12	-0.7	-0.21	0.16
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016[d]	24	23	0.6	0.13	0.40
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,419	4,442	-23.6	-0.04	0.83
Per capita total Medicare Part A and B spending in 2016	9,965	9,900	65.7	0.04	0.78
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	281	277	3.0	0.07	0.65
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	703	690	13.3	0.11	0.58

See Table E.3 for all table notes and acronyms.

3. Baseline characteristics of the population used to estimate impacts on CVD risk scores and risk factors

The intervention and control groups used for analyses of changes in CVD risk scores and risk factors were very similar at enrollment with respect to clinical indicators of cardiovascular risk, although more intervention group beneficiaries had diabetes (69 versus 65 percent; Table E.5). The two groups also had very similar rates of medication use at enrollment, and appeared balanced on characteristics such as age, sex, CVD risk score, recent service use, and Medicare spending. Consistent with the populations and tables shown previously, intervention and control group beneficiaries differed somewhat in the types of organizations that enrolled them. Intervention group beneficiaries included in the CVD risk reduction analyses were, compared to control group beneficiaries, enrolled by organizations that had more sites on average (29 versus 18), and were more likely to participate in or have applied to participate in another model when they applied to the Million Hearts Model (71 versus 60 percent). In addition, intervention group beneficiaries were more likely to be enrolled by specialty or multispecialty practices (40 versus 31). Intervention group beneficiaries in this population were also more likely than control group beneficiaries to live in the South (54 versus 29 percent), and were more likely to have enrolled in the first quarter of 2017 (54 versus 46 percent).

Table E.5. Baseline characteristics of high-risk Medicare beneficiaries included in the CVD risk reduction analysis: Intervention versus control

Characteristic	Intervention group mean (N 15,078)	Control group mean (N 8,060)	Difference	Standardized difference[a]	*p* value[b]
Clinical indicators of beneficiary's cardiovascular risk					
CVD risk score (%), [standard deviation]	40 [9]	40 [9]	0.4	0.04	0.15
Modifiable risk (%)[c]	15	15	0.2	0.02	0.76
Has diabetes (%)	69	65	3.6	0.08	0.25
Systolic blood pressure (mm Hg)	139	139	-0.2	-0.01	0.90
Total cholesterol (mg/dL)	167	168	-0.8	-0.02	0.62
HDL cholesterol (mg/dL)	47	48	-1.0	-0.07	0.21
LDL cholesterol (mg/dL)	91	91	0.2	0.01	0.88
Is current smoker (%)	12	12	-0.8	-0.02	0.41
Beneficiary's medication use					
Uses aspirin (%)	50	49	1.8	0.04	0.76
Uses antihypertensives based on Part D[d] (%)	91	90	0.3	0.01	0.71
Uses statins based on Part D[d] (%)	71	69	1.3	0.03	0.46
Intensity of statin use based on Part D[d] (%)					
Low intensity	7	7	-0.4	-0.01	0.22
Medium intensity	43	41	2.1	0.04	
High intensity	20	21	-0.4	-0.01	
Beneficiary's demographic and Medicare enrollment characteristics					
Age [standard deviation]	74 [4]	74 [4]	-0.2	-0.04	0.42
Black race (%)	7	7	0.7	0.03	0.78
Male (%)	65	67	-1.8	-0.04	0.22
Dually enrolled in Medicare and Medicaid (%)	8	8	-0.2	-0.01	0.93
Originally entitled to Medicare because of disability (%)	11	11	0.1	0.00	0.93
Beneficiary's health and comorbid conditions					
HCC score [standard deviation]	1.31 [0.98]	1.30 [0.98]	0.0	0.01	0.76
Number of chronic conditions	2.6	2.5	0.1	0.03	0.53
Has chronic kidney disease (%)	36	35	0.9	0.02	0.74
Has ischemic heart disease (%)	36	38	-1.5	-0.03	0.70
Has congestive heart failure (%)	12	13	-0.6	-0.02	0.69
Has atrial fibrillation (%)	11	11	-0.3	-0.01	0.85
Has morbid obesity (%)	9	9	0.0	0.00	1.00
Beneficiary's medical service use and spending in year before model enrollment					
Total Medicare Parts A and B annualized expenditures ($) [standard deviation]	7,378 [14,676]	7,196 [14,519]	182.0	0.01	0.65
Hospital admissions (per 1,000 beneficiaries)	178	173	5.4	0.01	0.65
CVD-related hospital admissions (per 1,000 beneficiaries)[e]	40	38	2.0	0.01	0.76
Outpatient ED visits or observation	346	325	20.5	0.02	0.24

Characteristic	Intervention group mean (N 15,078)	Control group mean (N 8,060)	Difference	Standardized difference[a]	*p* value[b]
stays (per 1,000 beneficiaries)					
CVD-related outpatient ED visits or observation stays (per 1,000 beneficiaries)[e]	25	25	0.4	0.00	0.89
Office visits (per 1,000 beneficiaries)	9,642	9,029	612.3	0.09	0.26
Office visits with model-aligned providers (per 1,000 beneficiaries)	3,457	3,252	205.0	0.06	0.64
Cardiologist visits (per 1,000 beneficiaries)	1,952	2,008	-56.2	-0.01	0.85
Beneficiary's CVD related procedures in year before model enrollment					
Received echocardiogram (%)	41	40	0.9	0.02	0.78
Received electrocardiogram (%)	72	73	-0.9	-0.02	0.81
Received cardiac stress test (%)	28	29	-0.5	-0.01	0.85
Characteristics of organization enrolling the beneficiary					
Total number of practitioners	127	128	-0.9	0.00	0.99
[standard deviation]	[170]	[349]			
Total number of service sites	29	18	10.8	0.36	0.25
[standard deviation]	[28]	[32]			
Organization type (%)					
Primary care	54	58	-3.9	-0.08	0.09
Specialty or multispecialty	40	31	9.1	0.19	
FQHC, RHC, or other health center	3	4	-1.3	-0.07	
CAH or rural hospital	0	2	-1.4	-0.15	
Acute care hospital	3	5	-2.5	-0.13	
Organization was participating in, or had application pending for, another model at application (%)	71	60	11.1	0.23	0.35
Organization-level mean Medicare spending and use[f]					
Parts A and B spending	7,392	7,481	-89.3	-0.06	0.78
Hospital admissions (per 1,000 beneficiaries)	184	190	-6.1	-0.16	0.52
Outpatient ED visits (per 1,000 beneficiaries)	379	356	23.2	0.25	0.22
Characteristics of clinician enrolling the beneficiary					
Provider specialty (%)					
Primary care physician	66	65	0.3	0.01	0.97
Cardiologist	21	24	-3.1	-0.07	0.74
Physician with other specialty	2	0	1.5	0.14	0.12
Not a physician (for example, NP or PA)	11	9	2.1	0.07	0.33
Characteristics of beneficiary's region					
Rural (%)	28	24	4.1	0.09	0.53
Census region (%)					
Northeast	17	21	-3.6	-0.09	0.05
Midwest	23	34	-10.3	-0.23	
South	54	29	25.4	0.53	
West	5	16	-11.4	-0.38	
County-level health measures					
AMI hospitalizations per 1,000	11	11	-0.3	-0.09	0.65

Characteristic	Intervention group mean (N 15,078)	Control group mean (N 8,060)	Difference	Standardized difference[a]	*p* value[b]
Medicare beneficiaries ages 65 and older in 2014–2016					
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	24	22	1.4	0.32	0.11
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,508	4,376	131.4	0.22	0.27
Per capita total Medicare Part A and B spending in 2016	9,769	9,732	36.8	0.03	0.89
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	284	274	10.4	0.25	0.21
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	714	673	41.5	0.33	0.13
Characteristics of beneficiary's Million Hearts Model enrollment					
Days between model launch (1/3/2017) and enrollment date [standard deviation]	96 [74]	111 [82]	-15.0	-0.19	0.07
Enrollment date is in (%)					
First quarter of the year	54	46	8.1	0.16	0.08
Second quarter of the year	32	33	-0.9	-0.02	0.77
Third quarter of the year	11	16	-5.2	-0.15	0.04
Fourth quarter of the year	3	5	-1.9	-0.10	0.03
Data submitted to the registry using bulk upload (%)[g]	38	47	-8.5	-0.17	0.47

Sources: Million Hearts Data Registry for clinical indicators on cardiovascular risk; Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending, and CVD-related procedures; the organizations' applications to the Million Hearts Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the U.S. Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics; and Million Hearts Data Registry for characteristics of model enrollment.

Notes: This population in this table is limited to high-risk beneficiaries who were eligible for and received a reassessment visit by December 31, 2018. We defined the population eligible for a reassessment visit as high-risk beneficiaries whose enrollment date was on or before October 31, 2017. This is so their window for a reassessment visit 10 to 14 months after enrollment occurred by December 31, 2018. We excluded from the definition of eligible beneficiaries any beneficiary who died, had an AMI or stroke, enrolled in Medicare Advantage, or lost Medicare as the primary payer within 14 months of the enrollment date. We determined eligibility based on the enrollment date used for CMS payments, rather than the adjusted date used for the evaluation. However, baseline characteristics in this table reflect characteristics as of the adjusted date—that is, the first date after model launch that a beneficiary visited the enrolling organization and for which we have complete data needed to calculate a baseline risk score. See Conwell et al. 2019 for details of this baseline date adjustment.

For all measures, means are calculated over nonmissing values. The following chronic conditions are defined by using the Chronic Condition Warehouse algorithms: atrial fibrillation, chronic kidney disease, 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 second annual report (Peterson et al. 2019) for details on variable construction.

[a] The standardized difference is the difference between the intervention and control group means, divided by the standard deviation across the intervention and control groups.

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

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

[d] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 10,529 for the intervention group and N = 5,690 for the control group). This accounted for 70 percent of all beneficiaries enrolled in the intervention group and 71 percent in the control group.

[e] We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the second annual report, 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.

[f] See Appendix D for details on measure construction. To estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organization-level means included in this table are the variance-shrunken means for each organization.

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

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

4. Baseline characteristics of the attributed population used for robustness checks

As described in Appendix C, the attribution population includes all attributed beneficiaries who met the study inclusion criteria. However, for the analyses using this population, because we could not observe CVD risk scores, we weighted each beneficiary according to his or her *predicted* probability of being high or medium risk (combined) or just high risk. For the tables showing baseline balance between the intervention and control groups for this population, we also weighted each beneficiary by their predicted probability of being in the relevant risk group.

Among attributed beneficiaries weighted to reflect the high- and medium-risk population combined, the intervention and control groups were well balanced at baseline (the date of attribution) on demographics and claims-based beneficiary characteristics such as age, sex, predicted CVD risk, medication use, recent service use, and Medicare spending (Table E.6). The two groups differed somewhat on certain organizational characteristics. The intervention group beneficiaries tended to be attributed to larger organizations—that is, organizations with more providers (123 versus 98 mean practitioners) and more sites (24 versus 13). The intervention group beneficiaries were more likely to be attributed to organizations participating in or having applied to participate in another model when they applied to the Million Hearts Model (66 versus 49 percent). Intervention beneficiaries were also more likely than control beneficiaries to be living in the Northeast (29 versus 20 percent) or South (44 versus 39 percent).

Table E.6. Baseline characteristics of high- and medium-risk (predicted) Medicare beneficiaries attributed to participating organizations: Intervention versus control

Characteristic	Intervention group mean (N 247,789)	Control group mean (N 164,785)	Difference	Standardized difference[a]
Clinical indicators of beneficiary's cardiovascular risk				
Predicted CVD risk score	26	26	-0.1	-0.01
[standard deviation]	[9]	[9]		
Has diabetes (%)	38	38	-0.1	-0.00
Has hypertension (%)[b]	77	77	0.4	0.01
Has hyperlipidemia (%)[b]	51	51	0.1	0.00
Is current smoker (%)[b]	8	9	-0.5	-0.02
Uses aspirin (%)[b]	13	13	0.1	0.00
Beneficiary's medication use in year before attribution				
Uses antihypertensive medications (%)[c]				
No	12	12	0.0	0.00
Yes	55	54	0.6	0.01
Uses statins (%)[c]				
No	26	26	-0.1	-0.00
Low intensity	4	4	-0.0	-0.00
Moderate intensity	25	24	0.8	0.02
High intensity	12	12	-0.1	-0.00
Beneficiary's demographic and Medicare enrollment characteristics				
Age	72	72	-0.1	-0.01
[standard deviation]	[5]	[5]		
Black race (%)	9	8	0.4	0.01
Male (%)	59	59	-0.4	-0.01
Dually enrolled in Medicare and Medicaid (%)	11	12	-1.0	-0.03
Originally entitled to Medicare because of disability (%)	15	15	-0.8	-0.02
Beneficiary's health and comorbid conditions				
HCC score	1.21	1.21	0.00	0.00
[standard deviation]	[1.08]	[1.09]		
Number of chronic conditions	2.16	2.14	0.02	0.01
Has chronic kidney disease (%)	25	24	0.2	0.01
Has ischemic heart disease (%)	34	34	0.1	0.00
Has congestive heart failure (%)	12	13	-0.5	-0.02
Has atrial fibrillation (%)[b]	10	10	-0.1	-0.00
Has morbid obesity (%)	7	7	-0.0	-0.00
Has diabetes with complications (%)	24	23	0.4	0.01
Beneficiary's medical service use and spending in year before attribution				
Total Medicare Parts A and B annualized expenditures ($)	8,918	8,605	313	0.01
[standard deviation]	[28,446]	[30,838]		
Hospital admissions (per 1,000 beneficiaries)	226	229	-3.3	-0.00
CVD-related hospital admissions (per 1,000 beneficiaries)[d]	53	54	-1.0	-0.00
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	432	437	-5.0	-0.00
CVD-related ED visits or observation stays (per 1,000 beneficiaries)[d]	35	36	-0.4	-0.00
Office visits (per 1,000 beneficiaries)	9,222	8,846	376.2	0.04
Office visits with model-aligned providers (per 1,000 beneficiaries)	1,918	1,988	-70.0	-0.02
Cardiologist visits (per 1,000 beneficiaries)	1,901	1,789	112.6	0.02

Characteristic	Intervention group mean (N 247,789)	Control group mean (N 164,785)	Difference	Standardized difference[a]
Beneficiary's CVD related procedures in year before attribution				
Received echocardiogram (%)	40	39	1.3	0.03
Received electrocardiogram (%)	70	69	1.3	0.03
Received cardiac stress test (%)	25	25	0.1	0.00
Characteristics of organization the beneficiary was attributed to				
Total number of practitioners [standard deviation]	122.9 [186.3]	97.7 [271.3]	25.2	0.11
Total number of service sites	23.7	13.4	10.3	0.41
Organization type (%)				
Primary care	49	51	-1.1	-0.02
Specialty or multispecialty	38	36	2.8	0.06
FQHC, RHC, or other health center	4	6	-1.1	-0.05
CAH, rural hospital, acute care hospital, other, or unknown	8	8	-0.5	-0.02
Organization was participating in, or had application pending for, another model at application (%)	66	49	17.3	0.36
Organization-level mean Medicare spending and use[e]				
Parts A and B Medicare spending	7,934	7,774	160	0.10
Hospital admissions (per 1,000 beneficiaries)	187	196	-9.7	-0.23
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	378	380	-1.6	-0.01
Characteristics of clinician the beneficiary was attributed to				
Provider specialty (%)				
Primary care physician	52	57	-5.1	-0.10
Cardiologist	35	32	3.2	0.07
Physician with other specialty	4	2	1.8	0.11
Not a physician (for example, NP or PA)	9	9	-0.0	-0.00
Characteristics of beneficiary's region				
Rural (%)	23	27	-4.0	-0.09
Census region (%)				
Northeast	29	20	9.3	0.22
Midwest	17	26	-9.3	-0.23
South	44	39	4.9	0.10
West	10	15	-4.9	-0.15
County-level health measures				
AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	11.0	11.7	-0.7	-0.22
Stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016	23.2	23.1	0.0	0.01
Age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016	4,335	4,424	-89	-0.15
Per capita total Medicare Part A and B spending in 2016	10,009	9,841	168	0.11
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	274	277	-2.7	-0.06
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	685	696	-11.8	-0.09

Characteristic	Intervention group mean (N 247,789)	Control group mean (N 164,785)	Difference	Standardized difference[a]
Characteristics of beneficiary's attribution to participating practices				
Days between model launch (1/3/2017) and the office visit used for attribution	183	187	-4.3	-0.02
[standard deviation]	[174]	[171]		
Beneficiary attributed in (%)				
2017 (as opposed to 2018)	84	83	0.3	0.01
First quarter of the year	45	44	1.2	0.02
Second quarter of the year	29	28	0.5	0.01
Third quarter of the year	15	16	-0.9	-0.02
Fourth quarter of the year	11	11	-0.8	-0.03

Sources: Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending, CVD-related procedures, and attribution; the organizations' applications to the Million Hearts Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics.

Notes: We attributed beneficiaries and predicted their risk scores using the approach described in Appendix C. The table reports weighted means, with weights defined as the predicted probability of being high or medium risk. The following chronic conditions and risk factors are defined using the Chronic Condition Warehouse algorithms: hyperlipidemia, tobacco use, chronic kidney disease, ischemic heart disease, congestive heart failure, and atrial fibrillation. The following chronic conditions are defined using HCC algorithms: diabetes (with and without complications), congestive heart failure, morbid obesity, and the count of chronic conditions. All procedures are defined using Clinical Classifications Software indicators. Hypertension was identified using procedure and diagnosis claims following the algorithms developed by the Million Hearts implementation contractor; results were similar with the CCW and HCC algorithms. (See the second annual report, Appendix A [Peterson et al. 2019].)

[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] This variable was defined based on diagnoses present in the Medicare claims data. In the enrolled population used for most analyses in this report, this variable was defined instead based on information reported in the Million Hearts Data Registry.

[c] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 166,697 for the intervention group and N = 109,813 for the control group). This accounted for 67 percent of all beneficiaries enrolled in the intervention group and 67 percent in the control group.

[d] We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the second annual report, Appendix C), including those related to heart failure, hypertension, and angina. This measure excludes heart attacks and strokes because any beneficiaries who had these events before their first visit after model launch with a Million Hearts Model provider were excluded from the analytic population.

[e] See Appendix D for details on measure construction. To estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organization-level means included in this table are the variance-shrunken means for each organization.

CAH = critical access hospital; CCW = Chronic Conditions Warehouse; 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; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

Consistent with the predicted high- and medium-risk combined population, the intervention and control groups with predicted high risk were well balanced at baseline on demographic and claims-based beneficiary characteristics such as age, sex, predicted CVD risk, medication use,

recent service use, and Medicare spending (Table E.7). Also consistent, the two groups differed on some organizational characteristics. Compared to control group beneficiaries, the intervention group beneficiaries tended to be attributed to organizations with more providers (144 versus 109) and more sites (25.5 versus 14.7). Intervention group beneficiaries were more likely to be attributed to organizations participating in or having applied to participate in another model when they applied to the Million Hearts model (66 versus 49 percent). In addition, the intervention group beneficiaries were more likely to be attributed to specialty or multispecialty organizations (42 versus 35 percent). Also consistent with the full high- and medium-risk attributed population, high-risk beneficiaries in the intervention group were more likely than those in the control group to reside in the Northeast (26 versus 19 percent) or South (48 versus 41 percent).

Table E.7. Baseline characteristics of high-risk (predicted) Medicare beneficiaries attributed to participating organizations: Intervention versus control

Characteristic	Intervention group mean (N 83,915)	Control group mean (N 53,488)	Difference	Standardized difference[a]
Clinical indicators of beneficiary's cardiovascular risk				
Predicted CVD risk score	34	34	-0.2	-0.03
[standard deviation]	[9]	[9]		
Has diabetes (%)	61	62	-1.0	-0.02
Has hypertension (%)[b]	86	86	-0.0	-0.00
Has hyperlipidemia (%)[b]	58	58	-0.2	-0.00
Is current smoker (%)[b]	9	9	-0.5	-0.02
Uses aspirin (%)[b]	15	15	0.1	0.00
Beneficiary's CVD related medication use in year before attribution				
Uses antihypertensive medications (%)[c]				
No	8	8	0.1	0.00
Yes	62	61	0.5	0.01
Uses statins (%)[c]				
No	23	23	-0.0	-0.00
Low intensity	5	5	-0.0	-0.00
Moderate intensity	28	27	0.6	0.01
High intensity	14	14	-0.0	-0.00
Beneficiary's demographic and Medicare enrollment characteristics				
Age	74	74	-0.2	-0.04
[standard deviation]	[5]	[5]		
Black race (%)	9	8	0.4	0.01
Male (%)	65	66	-0.2	-0.00
Dually enrolled in Medicare and Medicaid (%)	11	11	-0.8	-0.03
Originally entitled to Medicare because of disability (%)	13	14	-0.6	-0.02
Beneficiary's health and comorbid conditions				
HCC score	1.41	1.41	-0.01	-0.01
[standard deviation]	[1.13]	[1.13]		
Number of chronic conditions	2.67	2.67	0.00	0.00
Has chronic kidney disease (%)	35	35	-0.1	-0.00
Has ischemic heart disease (%)	40	40	0.1	0.00

Characteristic	Intervention group mean (N 83,915)	Control group mean (N 53,488)	Difference	Standardized difference[a]
Has congestive heart failure (%)	14	15	-0.7	-0.02
Has atrial fibrillation (%)[b]	12	12	-0.0	-0.00
Has morbid obesity (%)	8	8	-0.3	-0.01
Has diabetes with complications (%)	39	39	0.3	0.01
Beneficiary's medical service use and spending in year before attribution				
Total Medicare Parts A and B annualized expenditures ($)	9,230	8,914	316	0.01
[standard deviation]	[25,714]	[23,974]		
Hospital admissions (per 1,000 beneficiaries)	240	241	-0.8	-0.00
CVD-related hospital admissions (per 1,000 beneficiaries)[d]	59	62	-2.3	-0.00
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	436	434	2.4	0.00
CVD-related ED visits or observation stays (per 1,000 beneficiaries)[d]	40	36	3.6	0.01
Office visits (per 1,000 beneficiaries)	9,835	9,401	434.4	0.05
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,318	2,295	23.5	0.01
Cardiologist visits (per 1,000 beneficiaries)	2,090	1,983	107.2	0.01
Beneficiary's CVD related procedures in year before attribution				
Received echocardiogram (%)	44	43	0.9	0.02
Received electrocardiogram (%)	74	73	0.5	0.01
Received cardiac stress test (%)	28	28	0.1	0.00
Characteristics of organization the beneficiary was attributed to				
Total number of practitioners	143.9	109.2	34.8	0.13
[standard deviation]	[217.7]	[302.6]		
Total number of service sites	25.5	14.7	10.8	0.40
Organization type (%)				
Primary care	46	49	-3.2	-0.07
Specialty or multispecialty	42	35	6.7	0.14
FQHC, RHC, or other health center	4	5	-1.3	-0.06
CAH, rural hospital, acute care hospital, other, or unknown	7	10	-2.2	-0.08
Organization was participating in, or had application pending for, another model at application (%)	66	49	17.3	0.35
Organization-level mean Medicare spending and use[e]				
Parts A and B Medicare spending	7,910	7,800	110	0.07
Hospital admissions (per 1,000 beneficiaries)	188	198	-10.6	-0.25
Number of outpatient ED visits or observation stays (per 1,000 beneficiaries)	380	383	-2.5	-0.02
Characteristics of clinician the beneficiary was attributed to				
Provider specialty (%)				
Primary care physician	52	55	-3.5	-0.07
Cardiologist	35	34	1.7	0.04
Physician with other specialty	4	2	1.8	0.10
Not a physician (for example, NP or PA)	9	9	0.0	0.00

Characteristic	Intervention group mean (N 83,915)	Control group mean (N 53,488)	Difference	Standardized difference[a]
Characteristics of beneficiary's region				
Rural (%)	27	28	-1.7	-0.04
Census region (%)				
Northeast	26	19	6.9	0.17
Midwest	15	26	-10.1	-0.25
South	48	41	6.8	0.14
West	10	14	-3.7	-0.11
County-level baseline outcomes, spending, and use				
AMI hospitalizations per 1,000 Medicare beneficiaries aged 65+ in 2014-2016	10.9	11.9	-1.0	-0.28
Stroke hospitalizations per 1,000 Medicare beneficiaries aged 65+ in 2014-2016	23.4	23.3	0.1	0.02
Age-adjusted mortality per 100,000 for residents aged 65+ in 2014-2016	4,378	4,449	-71	-0.12
Per capita total Medicare Part A and B spending in 2016	9,989	9,855	134	0.09
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	276	278	-2.1	-0.05
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	695	700	-4.8	-0.04
Characteristics of beneficiary's attribution to participating practices				
Days between model launch (1/3/2017) and the office visit used for attribution	169	174	-5.2	-0.03
[standard deviation]	[170]	[167]		
Enrollment date is in (%)				
2017 (as opposed to 2018)	85	85	0.4	0.01
First quarter of the year	49	47	1.6	0.03
Second quarter of the year	28	28	-0.1	-0.00
Third quarter of the year	14	15	-0.9	-0.03
Fourth quarter of the year	10	10	-0.7	-0.02

See Table E.6 for table notes and acronyms, other than table note c.

[c] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment (N = 58,320 for the intervention group and N = 36,883 for the control group). This accounted for 69 percent of all beneficiaries enrolled in the intervention group and 69 percent in the control group.

5. Selection of attributed beneficiaries into the intervention and control groups

To determine whether the Million Hearts Model was more likely to serve some beneficiaries than others, we compared the characteristics of beneficiaries who were enrolled in the Million Hearts Model to those who appeared eligible for the model but were not enrolled. We conducted these comparisons using the population of 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 that we could replicate in claims (with any level of CVD risk at baseline). We present results from this analysis in Table E.8. An abridged version of this table also appears in Chapter IV. As noted in the chapter, the enrolled beneficiaries differed in some important

respects from beneficiaries who appeared eligible but were not enrolled. This was true for both the intervention group (first three columns) and the control group (last three columns). Indeed, the differences between the enrolled versus the not enrolled populations were similar for the intervention and control groups, indicating selection into the enrolled population was similar in the two groups. For example, enrolled beneficiaries in the intervention group had a mean HCC score at baseline of 1.05 versus 1.19 for those who appeared eligible but were not enrolled. Similarly, enrolled beneficiaries in the control group had a mean HCC score at baseline of 1.05 versus 1.20 for those who appeared eligible but were not enrolled.

Table E.8. Characteristics of enrolled beneficiaries versus beneficiaries eligible but not enrolled, 2017 to 2018, by intervention arm

Characteristic	Intervention group			Control group		
	Enrolled in the model (N = 228,112)	Not enrolled in the model (N 206,559)	Difference	Enrolled in the model (N 154,172)	Not enrolled in the model (N 138,874)	Difference
Clinical indicators of beneficiary's cardiovascular risk						
Predicted CVD risk score	20	19	0.3	20	19	0.3
[standard deviation]	[11]	[11]		[11]	[11]	
Has diabetes (%)	28	27	0.5	28	28	0.7
Has hypertension (%)[a]	67	65	2.0	67	65	2.1
Has hyperlipidemia (%)[a]	45	42	3.6	46	41	5.4
Is current smoker (%)[a]	8	9	-1.1	8	10	-1.6
Uses aspirin (%)[a]	10	12	-1.6	10	12	-2.0
Beneficiary CVD related medication use in year before attribution						
Uses antihypertensive medications (%)[b]						
No	18	18	-0.2	18	18	0.1
Yes	48	45	2.8	47	44	2.9
Not enrolled in Part D	34	37	-2.6	35	38	-3.0
Uses statins (%)[b]						
No	28	29	-0.9	28	30	-2.2
Low	4	3	0.6	4	3	0.7
Moderate	23	20	2.8	23	19	3.8
High	10	10	-0.0	11	10	0.6
Not enrolled in Part D	34	37	-2.6	35	38	-3.0
Beneficiary demographic and Medicare enrollment characteristics						
Age	69	68	0.4	69	68	0.6
[standard deviation]	[7]	[8]		[7]	[8]	
Black race (%)	8	10	-1.2	7	11	-3.2
Male (%)	44	46	-1.9	45	46	-0.8
Dually enrolled in Medicare and Medicaid (%)	14	16	-2.3	15	18	-3.5
Originally entitled to Medicare because of disability (%)	23	26	-3.0	23	27	-4.2
Beneficiary health and comorbid conditions						
HCC score	1.05	1.19	-0.15	1.05	1.20	-0.15
[standard deviation]	[0.95]	[1.15]		[0.95]	[1.16]	
Number of chronic conditions	1.78	2.06	-0.28	1.77	2.05	-0.28
Has chronic kidney disease (%)	18	20	-1.5	18	20	-1.5
Has ischemic heart disease (%)	25	30	-5.3	26	28	-2.1
Has congestive heart failure (%)	9	12	-2.6	9	12	-2.6

Characteristic	Intervention group: Enrolled in the model (N = 228,112)	Intervention group: Not enrolled in the model (N 206,559)	Intervention group: Difference	Control group: Enrolled in the model (N 154,172)	Control group: Not enrolled in the model (N 138,874)	Control group: Difference
Has atrial fibrillation (%)[a]	7	8	-1.0	7	8	-1.3
Has morbid obesity (%)	7	7	-0.0	7	8	-0.6
Has diabetes with complications (%)	17	17	-0.3	17	17	-0.3
Beneficiary medical service use and spending in year before attribution						
Total Medicare Parts A and B annualized expenditures ($)	7,446	10,318	-2,872	7,356	9,765	-2,409
[standard deviation]	[23,015]	[34,446]		[30,308]	[32,145]	
Hospital admissions (per 1,000 beneficiaries)	182	274	-92.2	183	271	-88.2
CVD-related hospital admissions (per 1,000 beneficiaries)[c]	35	58	-23.0	38	58	-20.4
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	435	582	-147.2	424	614	-190.0
CVD-related ED visits or observation stays (per 1,000 beneficiaries)[c]	25	39	-14.0	25	42	-17.5
Office visits (per 1,000 beneficiaries)	8,688	9,465	-777.4	8,421	9,090	-669.1
Cardiologist visits (per 1,000 beneficiaries)	1,491	1,831	-339.5	1,450	1,680	-230.7
Office visits with model-aligned providers (per 1,000 beneficiaries)	2,202	1,277	925.0	2,235	1,467	767.9
Beneficiary CVD related procedures in year before attribution						
Received echocardiogram (%)	33	36	-3.7	32	35	-2.6
Received electrocardiogram (%)	63	65	-2.0	62	63	-1.0
Received cardiac stress test (%)	21	21	-0.6	21	21	0.2
Characteristics of organization the beneficiary was attributed to						
Total number of practitioners	124.1	121.1	2.9	121.8	86.4	35.4
[standard deviation]	[160.2]	[191.1]		[317.8]	[231.6]	
Total number of service sites	25.1	23.0	2.1	15.1	11.9	3.1
Organization type (%)						
Primary care	56	47	8.5	53	49	4.0
Specialty or multispecialty	33	38	-4.4	33	35	-2.1
FQHC, RHC, or other health center	6	6	0.6	6	7	-0.6
CAH, rural hospital, acute care hospital, other, or unknown	5	10	-4.7	8	9	-1.3
Organization was participating in, or had application pending for, another model at randomization (%)	70	63	7.1	55	44	11.2
Organization level mean Medicare spending and utilization[d]						
Parts A and B Medicare spending	7,571	8,111	-540	7,596	7,852	-256
Hospital admissions (per 1,000 beneficiaries)	182	187	-5.2	190	198	-8.3

Characteristic	Intervention group: Enrolled in the model (N = 228,112)	Intervention group: Not enrolled in the model (N 206,559)	Intervention group: Difference	Control group: Enrolled in the model (N 154,172)	Control group: Not enrolled in the model (N 138,874)	Control group: Difference
Outpatient ED visits or observation stays (per 1,000 beneficiaries)	381	378	2.7	368	396	-28.0
Characteristics of clinician the beneficiary was attributed to						
Provider specialty (%)						
Primary care physician	63	44	18.5	65	54	10.7
Cardiologist	23	40	-16.2	23	33	-10.2
Physician with other specialty	3	6	-2.6	1	3	-2.2
Not a physician (for example, NP or PA)	11	10	0.4	11	9	1.8
Characteristics of beneficiary's region						
Rural (%)	23	21	2.5	25	28	-2.7
Census region (%)						
Northeast	27	33	-6.3	23	18	5.2
Midwest	20	15	5.8	29	23	6.5
South	45	39	5.3	32	43	-11.1
West	8	12	-4.9	15	16	-0.6
County-level baseline outcomes, spending, and utilization						
AMI hospitalizations per 1,000 Medicare beneficiaries aged 65+ in 2014-2016	11.0	10.9	0.1	11.5	11.8	-0.3
Stroke hospitalizations per 1,000 Medicare beneficiaries aged 65+ in 2014-2016	23.4	22.9	0.5	22.7	23.4	-0.7
Age-adjusted mortality per 100,000 for residents age 65+ in 2014-2016	4,377	4,282	96	4,395	4,437	-42
Per capital total Medicare Part A and B spending in 2016	9,950	10,092	-142	9,839	9,821	18
Hospital admissions per 1,000 Medicare FFS beneficiaries in 2016	278	270	8.2	276	277	-1.1
Outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016	696	673	23.1	684	709	-25.7
Characteristics of beneficiary's attribution to participating practices						
Days between office visit used for attribution and January 3, 2017	143	248	-104.7	150	247	-98.0
[standard deviation]	145	196		146	190	
Beneficiary attributed in (%)						
2017 (as opposed to 2018)	91	72	18.7	90	73	17.3
First quarter of the year	51	36	14.6	50	35	14.5
Second quarter of the year	29	28	0.5	28	28	0.4
Third quarter of the year	13	20	-7.3	13	21	-8.0

Characteristic	Intervention group: Enrolled in the model (N = 228,112)	Intervention group: Not enrolled in the model (N 206,559)	Intervention group: Difference	Control group: Enrolled in the model (N 154,172)	Control group: Not enrolled in the model (N 138,874)	Control group: Difference
Fourth quarter of the year	8	15	-7.8	9	16	-6.9

Sources: Medicare enrollment database for beneficiary demographic and Medicare enrollment characteristics; Medicare claims for health and comorbid conditions, medical service use and spending, CVD-related procedures, and attribution; the organizations' applications to the Million Hearts Model, linked to NPPES, for organizational characteristics; registry data linked to NPPES for clinician-level characteristics; beneficiaries' zip codes from the Medicare enrollment database, linked to data from the Census Bureau, as well as beneficiaries' county codes from the Medicare enrollment database linked separately to data from the Centers for Disease Control and Prevention and CMS's Medicare Geographic Variation Public Use File for regional characteristics.

Notes: We attributed beneficiaries and predicted their risk scores using the approach described inAppendix C. The table reports weighted means, with weights defined as the predicted probability of being high or medium risk. The following chronic conditions and risk factors are defined using the Chronic Condition Warehouse algorithms: hyperlipidemia, tobacco use, chronic kidney disease, ischemic heart disease, congestive heart failure, and atrial fibrillation. The following chronic conditions are defined using HCC algorithms: diabetes (with and without complications), congestive heart failure, morbid obesity, and the count of chronic conditions. All procedures are defined using Clinical Classifications Software indicators. Hypertension was identified using procedure and diagnosis claims following the algorithms developed by the Million Hearts implementation contractor; results were similar with the CCW and HCC algorithms. (See the second annual report, Appendix A [Peterson et al. 2019].)

[a] This variable was defined based on diagnoses present in the Medicare claims data. In the enrolled population used for most analyses in this report, this variable was defined instead based on information reported in the Million Hearts Data Registry.

[b] Measured among beneficiaries who also had 12 months of Part D coverage before enrollment.

[c] We defined CVD-related admissions and ED visits using more than 300 CVD-related diagnosis codes (listed in the second annual report, Appendix C), including those related to heart failure, hypertension, and angina. This measure excludes heart attacks and strokes because any beneficiaries who had these events before their first visit after model launch with a Million Hearts Model provider were excluded from the analytic population.

[d] See Appendix D for details on measure construction. To estimate organizational-level mean Medicare spending and use per beneficiary, we used pre-enrollment data only from beneficiaries enrolled in 2017. Because many of the 2017 intervention group beneficiaries enrolled within the first few months of the year, their baseline period is more likely to span the period before the intervention start and, importantly, before the model might have affected organizations' use and spending for their Medicare populations. The organization-level means included in this table are the variance-shrunken means for each organization.

CAH = critical access hospital; CCW = Chronic Conditions Warehouse; 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; NP = nurse practitioner; NPPES = National Plan and Provider Enumeration System; PA = physician assistant; RHC = rural health center.

APPENDIX F

ESTIMATING IMPACTS ON BENEFICIARIES' OUTCOMES: DETAILED METHODS AND SUPPLEMENTAL RESULTS

In Chapters V, VI, and VII, we reported estimates of the impacts of the Million Hearts Model on the initiation or intensification of cardiovascular disease (CVD) medications, CVD risk and individual risk factors, first-time heart attacks and strokes, Medicare spending, and other outcomes. This appendix details our methods for estimating impacts and presents additional results. Appendices A and C–E describe the beneficiaries included in the impact analyses, data sources for constructing outcomes, and characteristics of beneficiaries in the intervention and control groups before they enrolled in the model.

1. Methods for estimating impacts using claims data

The core design for estimating impacts used the cluster randomized trial, in which the Centers for Medicare & Medicaid Services (CMS) randomly assigned 516 organizations (the clusters) to intervention and control groups. CMS assigned organizations to the two groups in a way that ensured that, on average, the 260 intervention organizations and the 256 control organizations were similar in their locations (as defined by 10 U.S. Department of Health and Human Services regions), number of service sites, number of practitioners, and self-reported number of Medicare beneficiaries (NORC 2016a, b). Although the unit of random assignment was the organization, the unit of analysis for most study outcomes was the beneficiary. That is, we estimated impacts as the regression-adjusted differences in outcomes between intervention and control *beneficiaries*. We estimated impacts for (1) the medium- and high-risk beneficiaries combined and (2) the high-risk beneficiaries alone. Beneficiaries were considered high risk if, at the time of enrollment, their estimated 10-year risk of first-time heart attack and stroke was 30 percent or higher, medium risk if it was 15 percent or higher and less than 30 percent, and low risk if it was less than 15 percent.

Because beneficiaries enrolled at different times, our follow-up data on their outcomes cover different calendar periods for each beneficiary. For each beneficiary, we measured claims-based outcomes from the beneficiary's date of enrollment (in 2017 or 2018) through October 2019 (or the date a person died or became unobservable in Medicare claims).[29] The median follow-up period across all beneficiaries included in these analysis was 26.6 months, with a range from one day to just under 34 months. We measured spending and acute care use at the beneficiary-quarter level. Given the date we pulled the claims data and the rolling enrollment, we observed each beneficiary from 1 to 11 quarters for a beneficiary, depending on how early in 2017 or 2018 the beneficiary enrolled in the model (and whether he or she was still alive and observable in claims at the start of the quarter). We used an intent-to-treat design, following beneficiaries for all months after they entered the Million Hearts Model, whether or not 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—

[29] The antihypertensive medication and statin intensification and initiation outcome measures cover the first year after beneficiaries were enrolled and include only beneficiaries enrolled in the model in 2017. These analyses relied on Part D claims data through March 2019. This time period enabled us to identify medication initiation or intensification within the first year of enrollment for every beneficiary in the study population, along with an additional three months needed to confirm intensification. That is, we considered a beneficiary to intensify antihypertensive therapy if he or she took a new antihypertensive medication within a year of enrollment, and still took his or her old medications at least once within the three months after starting a new medication.

that is, lead to differences in mean outcomes between the intervention and control groups that were not due to model impacts. Nonetheless, this approach does not *guarantee* unbiased estimates, especially because some of the randomized organizations have dropped out of the study, more providers participated in the model at intervention organizations than at control organizations, and some eligible beneficiaries in the included organizations might not be risk stratified or reported to the registry.

We estimated model impacts as the regression-adjusted differences in claims-based outcomes for beneficiaries enrolled by the intervention and control organizations in 2017 and 2018—the first two years of the Million Hearts Model. We tailored the regression models to the type of outcome:

1. We used Cox proportional hazard models to measure impacts on first-time incidence of heart attack, stroke, or transient ischemic attack (TIA) 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, October 2019). The models generated hazard ratios, which equal 1.00 if the risk of having an event over time is the same in the intervention and control groups. If the hypothesis that the model reduced first-time incidence of heart-attack or stroke is correct, we would expect a hazard ratio less than 1.00.
2. We used linear regression models to measure impacts on Medicare spending and service use, with one observation per beneficiary per quarter. The models generated differences in mean 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 to analyze impacts on medication initiation and intensification (Part D-based outcomes), with one observation per beneficiary. 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.

We described the regression models for these three types of outcomes in more detail in Appendix D of our second annual report (Peterson et al. 2019). All models accounted for clustering of beneficiaries within organizations, which is needed to correctly estimate standard errors, *p*-values, and confidence intervals.

The regression models adjusted for beneficiaries' characteristics at baseline to increase the precision and to adjust for observed differences between the groups. Regression adjustment is appropriate because CMS used a relatively sophisticated method for assigning organizations to the intervention and control groups rather than simple random assignment (Ciolino et al. 2019). Further, even though the intervention and control groups were similar at baseline on many demographics, there were some observed differences between the two groups (see Appendix E),

which made it important to control for these factors in regression models (Schochet 2010). Table F.1 provides a full list of covariates, with several of the specific covariates we used varying based on whether we defined the study population as beneficiaries enrolled through the registry (described in Appendix A) versus those we attributed to organizations using Medicare claims data (described in Appendix C). 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.

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

Baseline covariate	Included in regression models with the population of:	
	Enrolled beneficiaries	Attributed beneficiaries
CVD risk score[a, b]	■	
Predicted CVD risk score[b]		■
Predicted probabilities of belonging to the high- or medium-, high-, medium-, and low-CVD risk groups (four variables)		■
Modifiable risk[a, b, c]	■	
Claims-based CVD risk score (assuming optimal values for clinical values)		■
Has diabetes (yes/no)[a]	■	
Evidence of diabetes in claims (yes/no)		■
Systolic blood pressure (mm Hg)[a]	■	
Evidence of hypertension in claims over previous 24 months (yes/no)		■
Evidence of hypertension in claims since 1999 (yes/no)		■
Total cholesterol (mg/dL)[a]	■	
HDL cholesterol (mg/dL)[a]	■	
LDL cholesterol (mg/dL)[a, c]	■	
Evidence of hyperlipidemia in claims over previous 12 months (yes/no)		■
Is treated for or diagnosed with hypertension (yes/no)[a]	■	
Is current smoker (yes/no)[a]	■	
Evidence of tobacco use in claims over previous 24 months (yes/no)		■
Uses aspirin (yes/no)[a]	■	
Evidence of aspirin use in claims over previous 24 months (yes/no)		■

Baseline covariate	Included in regression models with the population of:	
	Enrolled beneficiaries	Attributed beneficiaries
Antihypertensive medications in baseline year (yes/no/without Part D enrollment)	■	■
Statins in baseline year (no/low/moderate/high/without Part D enrollment)	■	■
Age (separately by age group)[b]	■	■
Black race (yes/no)	■	■
Male (yes/no)	■	■
Dually enrolled in Medicare and Medicaid (yes/no)	■	■
Originally entitled to Medicare due to disability (yes/no)	■	■
Received Part D low-income subsidy for at least one month over previous year	■	■
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)	■	■
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)	■	■
Total Medicare Parts A and B annualized expenditures[b, d]	■	■
Total inpatient annualized expenditures[d]	■	■
Number of hospital admissions[d]	■	■
Number of CVD-related hospital admissions [d]	■	■

Baseline covariate	Included in regression models with the population of:	
	Enrolled beneficiaries	Attributed beneficiaries
Number of outpatient ED visits or observation stays[d]	■	■
Number of CVD-related ED visits or observation stays[d]	■	■
Number of office visits[d]	■	■
Number of office visits with model-aligned providers[d]	■	■
Number of cardiologist office visits[d]	■	■
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)	■	■
Total number of practitioners (1 to 5 or 6 to 19 or 20 or more)	■	■
Total number of service sites (1 or 2 to 5 or 6 or more)	■	■
Organization type: (primary care, specialty or multispecialty, FQHC, RHC, or other health center, CAH, rural hospital, acute care hospital, or other)	■	■
Organization was participating in, or had application pending for, another model at random assignment (yes/no)	■	■
Organization-level mean Parts A and B Medicare spending[d, g]	■	■
Organization-level mean hospital admissions (per 1,000 beneficiaries)[d, g]	■	■
Organization-level mean outpatient ED visits or observation stays (per 1,000 beneficiaries)[d, g]	■	■
Provider specialty (cardiovascular-related physician/primary care physician [noncardiovascular]/other physician/other provider type [nonphysician])	■	■
Rural (yes/no)	■	■
Census region (Midwest, South, West, or other)	■	■
County-level AMI hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016[d]	■	■

Baseline covariate	Included in regression models with the population of: Enrolled beneficiaries	Attributed beneficiaries
County-level stroke hospitalizations per 1,000 Medicare beneficiaries ages 65 and older in 2014–2016[d]	■	■
County-level age-adjusted mortality per 100,000 for residents ages 65 and older in 2014–2016[d]	■	■
County-level per capital total Medicare Part A and B spending in 2016[d]	■	■
County-level hospital admissions per 1,000 Medicare FFS beneficiaries in 2016[d]	■	■
County-level outpatient ED visits per 1,000 Medicare FFS beneficiaries in 2016[d]	■	■
Days between enrollment and January 3, 2017[d]	■	■
Calendar quarter the enrollment date is in (one of eight quarters in 2017 and 2018)	■	■
Fewer than 12 months observable in Medicare claims in the year before enrollment (yes/no)	■	■
Data submitted to the registry using bulk upload (yes/no)[a, c]	■	

Note: 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 they were 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] This variable was constructed using data from the Million Hearts registry.

[b] We included an interaction term between this variable and the high-risk group indicator in models that included both medium- and high-risk enrolled beneficiaries. We interreacted this variable with the probability of belonging to the high-risk CVD group for analyses of attributed beneficiaries.

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

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

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

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

[g] See Appendix D 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.

[h] 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.

CAH = critical access hospital; CVD = cardiovascular disease; ED = emergency department; FQHC = federally qualified health center; HCC = hierarchical condition category; HDL= high-density lipoprotein; LDL = low-density lipoprotein; RHC = rural health center.

2. Methods for estimating impacts on CVD risk scores using registry data

To estimate impacts of the Million Hearts Model on change in CVD risk scores one year after enrollment for high-risk beneficiaries, we used linear regression models to measure differences in regression-adjusted outcomes between beneficiaries in the intervention and control groups. The regression models included one observation per period. The specific regression model was:

(F.1) $$y_{i1} = \alpha + \delta MH_i + \beta x_i + \gamma y_{i0} + \varepsilon_i ¤$$

where y_{i1} is the outcome measured for beneficiary i at reassessment, MH_i equals one for beneficiaries in intervention organizations and zero for beneficiaries in control organizations, x_i is a set of baseline covariates, and y_{i0} is the outcome measured for beneficiary i at model enrollment. The Greek letters $(\alpha, \delta, \beta, and\ \gamma)$ in Equation (F.1) are parameters to be estimated, and the model was estimated by least squares, with each beneficiary receiving equal weight. To account for the clustering of beneficiaries within organizations, we report *p*-values and confidence intervals based on robust standard errors, clustered at the organization level.

The coefficient δ is our parameter of interest—it captures the impact of exposure to the model on CVD risk scores. Because we controlled for CVD risk scores at enrollment (y_{i0}), this coefficient can be interpreted as the average impact of the model on the change in CVD risk scores during the year between enrollment and reassessment. The vector of coefficients, β, accounts for observed differences between the intervention and control groups in baseline covariates (x_i) and improves the precision of the impact estimates. The covariates are the same variables we listed in Table F.1, plus 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.

We used this same linear regression model to estimate impacts of Million Hearts Model on change in continuous CVD risk factors, including systolic blood pressure, total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol, one year after enrollment. In these models, y_{i1} and y_{i0} are the risk factor values at reassessment and enrollment, respectively. To estimate the impacts for the binary risk factors, smoking status and aspirin use, we estimated the model using logistic regression (estimated by maximum likelihood).

We then used the output from these models to express impacts as percentage point differences in the probability of the outcome (smoking or aspirin use) at reassessment.[30]

[30] 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,

3. Unadjusted cumulative probabilities of CVD events and death

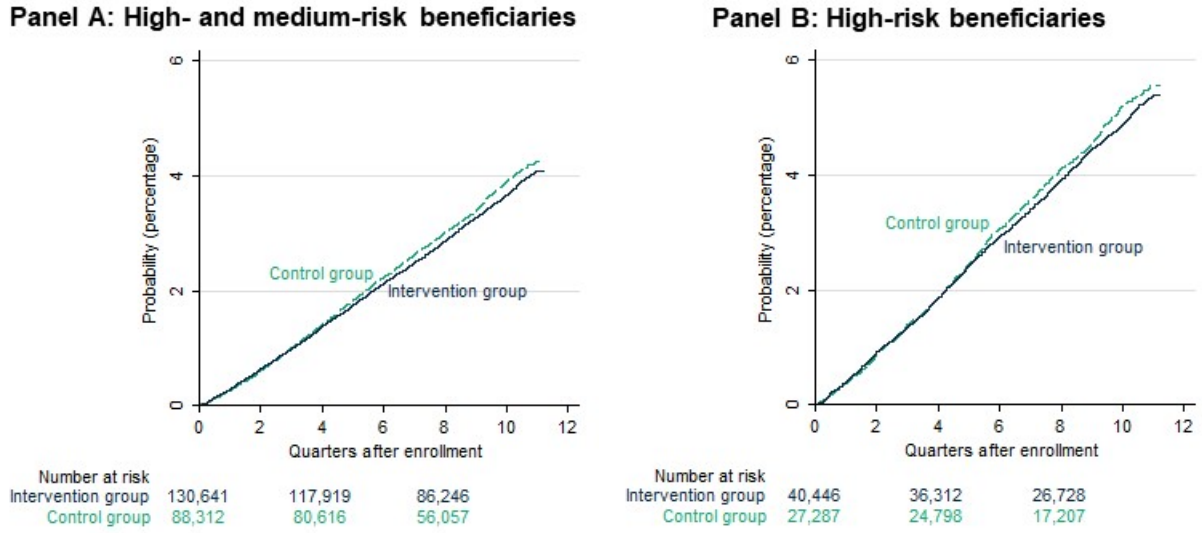
Figures F.1 and F.2 present unadjusted (Kaplan-Meier) estimates of the cumulative probability of having a first-time heart attack, stroke or TIA (composite measure), or of dying for each day following enrollment for the intervention and control groups, respectively. The cumulative probability is defined as 1 minus the Kaplan-Meier estimate of the survival function. The survival function gives the probability that a beneficiary does not have the event (for example, dying) within a specified time.

The curves showing the cumulative probabilities of CVD events for the intervention and control groups were initially similar but began to diverge after about a year (Figure F.1). These unadjusted estimates suggest the incidence of first-time CVD events was lower in the intervention group than the control group. However, regression-adjusted analyses, presented in Chapter VII, indicate CVD events rates were similar for the intervention and control groups after we controlled for differences in baseline characteristics between the intervention and control groups. (Section F.4 of this appendix discusses this topic further.) In both panels of the figure, the cumulative probabilities of first-time CVD events increase at a fairly constant rate.

Figure F.2 depicts lower cumulative probability of dying (for any reason) among high- and medium-risk beneficiaries in the intervention group compared to the control group (Panel A). Further, this difference grew steadily over time. There was little difference in the cumulative probability of dying among high-risk beneficiaries (Panel B).

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, but 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 that removing this variable from the model had minimal impact on the impact estimates.

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

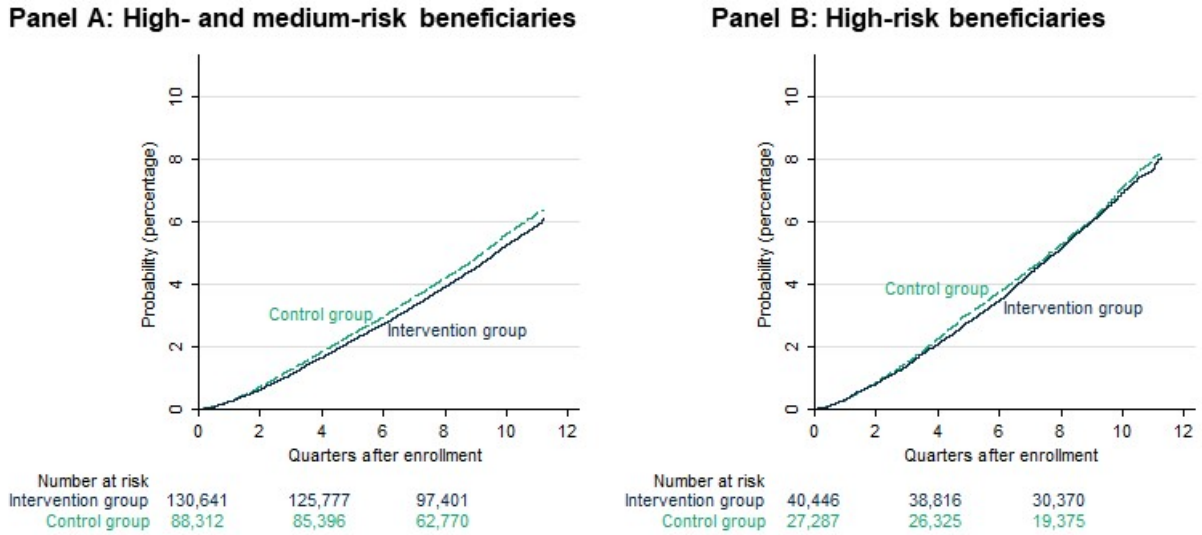


Source: Unadjusted results from Medicare claims.

Note: The cumulative probability is defined as 1 minus the Kaplan-Meier estimate of the survival function. The survival function gives the probability that a beneficiary does not have a heart attack, stroke, or TIA within a specified time.

TIA = transient ischemic attack.

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



Source: Unadjusted results from Medicare enrollment data.

Note:The cumulative probability is defined as 1 minus the Kaplan-Meier estimate of the survival function. The survival function gives the probability that a beneficiary does not die within a specified time.

4. Supplemental regression results

Table F.2 describes where this report presents various impact analyses and Table F.3 presents the corresponding sample sizes. Appendices A and C describe the definition of the population for the analyses, and Appendix E compares the intervention and control groups on baseline characteristics. In the claims-based analyses (the first row), the intervention group in this population is about 48 percent larger than the control group. A major reason for this difference is that CMS allowed up to 20 providers in control organizations to enroll beneficiaries but did not apply a similar cap for intervention organizations. The analyses for medication initiation and intensification included about half the beneficiaries included from the first row, because the analyses were limited to beneficiaries enrolled in the model in 2017, enrolled in Part D, and meeting the inclusion criteria for the outcome measures. The analysis of follow-up CVD risk scores was limited to high-risk beneficiaries for whom organizations submitted reassessment data via the Million Hearts Data Registry.

Tables F.4 through F.13 present results from several robustness checks we conducted to assess the sensitivity of the impact analysis results to alternative methodologies and exploratory analyses. The results are largely organized around the type of outcome measure (see Table F.2). For comparative purposes, the tables also include the results from our impact analyses of the primary study population of enrolled high- and medium-risk beneficiaries (labeled "main analysis").

Table F.2. Locations of different impact estimates in this report

Main or alternative analysis	CVD events	Mortality	Inpatient admissions	ED visits	Medicare spending	Office visits	CVD medications	CVD risk scores
Main analysis	Tables VII.A.1 and F.4	Tables VII.B.1 and F.5	Tables VII.C.1 and F.6	Tables VII.C.1 and F.7	Tables VII.D.1 and F.8	Tables V.C.1 and F.9	Tables V.B.1 and F.12	Tables VI.A.1 and F.13
Trimmed study population	Table F.4	Table F.5	Table F.6	Table F.7	Table F.8	n.a.	Table F.12	Table F.13
Population of attributed beneficiaries	Table F.4	Table F.5	Table F.6	Table F.7	Table F.8	Table F.9	n.a.	n.a.
Narrower definitions of CVD events	Table F.4	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Unadjusted impact estimates	Table F.4 and Figure F.1	Table F.5 and Figure F.2	Table F.6	Table F.7	Table F.8	Table F.9	Figure V.B.1	Table F.13
Binary outcome measures	Table F.10	Table F.10	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Medium risk beneficiaries	n.a.	Table F.11	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Main or alternative analysis	CVD events	Mortality	Inpatient admissions	ED visits	Medicare spending	Office visits	CVD medications	CVD risk scores
Drop potential candidates for antihypertensive medication if they have systolic blood pressure <140 mmHg	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	Table F.12	n.a.
Restrict reassessment data collected 10 to 14 months after enrollment	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	Table F.13
Control for changes in medication use	n.a.	Table F.5	n.a.	n.a.	n.a.	n.a.	n.a.	Table F.14

CVD = cardiovascular disease; n.a. = not applicable.

Trimmed study population. We reestimated impacts for the beneficiaries enrolled in the model but trimming the intervention group in a way that attempted to mimic the 20-provider cap applied to the control group. The enrollment patterns in the control group suggest the control organizations—faced with the 20-provider cap—largely selected their 20 model-participating providers using a rule that 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 that enrolled a beneficiary when working at a large organization (with large organizations defined as having more than 20 providers enrolling beneficiaries), (2) ranking those providers by the number of beneficiaries they enrolled in 2017, (3) selecting the top 20 providers, and (4) removing from the study population any beneficiaries enrolled in 2017 by providers at large organizations not ranked in the top 20. In our first annual report (Conwell et al. 2019), we showed this trimming makes the intervention and control groups more similar in both overall size and in the proportion of beneficiaries enrolled by large organizations. Therefore, it helps address the limitation that large organizations were more likely to enroll intervention group beneficiaries—which could potentially confound the impact estimates if the size of the enrolling organization correlated with the outcome. As noted in the chapter, the impact estimates for the trimmed population mostly aligned with the impact results for the main analyses.

Analyses with attributed beneficiaries. We reestimated impacts on claims-based outcomes in a population we defined by attributing Medicare fee-for-service (FFS) beneficiaries to the participating organizations using Medicare claims data.[31] This approach limited potential biases in impact estimates that could stem from differences in the types of beneficiaries that organizations chose to enroll, because the population included all eligible beneficiaries (to the

[31] We cannot analyze Part D 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.

extent eligibility could be replicated in claims)—whether or not they actually enrolled. Appendix C discusses the methods and rationale for defining this population and predicting risk scores for the beneficiaries, and it explains how we used weights to make the population resemble high- and medium-risk beneficiaries. For the purpose of comparing the impact estimates with the attributed beneficiaries to the main analysis, in the tables, we adjusted the regression model output to account for the fact that not all beneficiaries in the attribution-based intervention group were enrolled in the model. For example, in Table F.8, we estimated the model increased Medicare spending by $7 for attributed beneficiaries with high- and medium-predicted risk, but only 57 percent of the beneficiaries in this regression model were actually enrolled, suggesting an impact of $13 ($7.27 / 0.57), assuming the model had no spillover effects to beneficiaries attributed to the organization but not enrolled into the model. As noted in Chapter VII, these results mostly align with the impact results for the main analyses.[32] Although we used the attribution-based results primarily as a check for the main registry-based results, some might be interested in the attribution-based results in their own right. These estimates reflected our best estimate of the impact of the model among all Medicare beneficiaries eligible for the model who had office or clinic visits with participating providers, regardless of whether the providers' organization enrolled them.

Narrower definitions of CVD events. We calculated impact estimates with our composite measure of CVD events redefined using two narrower definitions, excluding TIAs and stroke symptoms and certain acute myocardial infarctions (AMIs)—specifically AMIs that are not Type 1 AMIs—from being considered CVD events. See Appendix C of the second annual report (Peterson et al. 2019) for detailed definitions of the outcome measures. The impact estimates (hazard ratios) for this narrower definition of the CVD events were qualitatively similar to the estimates with the primary definition. Specifically, the estimates do not indicate the model reduced the first-time incidence of heart attack or stroke.

Unadjusted impact estimates. The unadjusted impact estimates relied on the regression models used for the main analyses, except that 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 Appendix A show the intervention and control groups were fairly similar (for example, absolute standardized differences in means below 0.10) on many covariates. However, covariate adjustment could affect our impact estimates for several reasons:

- In a clustered randomized trial such as this, it is possible that some covariates differed between intervention and control practices (clusters). This was more likely to happen when (1) some covariates were measured at the practice level; (2) beneficiary-level covariates were associated with the practice characteristics (for example, U.S. Census region correlated with

[32] Our second annual report (Peterson et al. 2019) used a different algorithm for attributing beneficiaries to participating organizations. Impact analyses with this alternative definition of the attribution population did not support the main findings for inpatient admissions and outpatient emergency department visits.

beneficiaries' race or ethnicity); or (3) many beneficiaries in the analysis population were concentrated in a relatively small proportion of the practices.

- Even small differences in the means between the intervention and control groups could have undue effects on the impact estimate if the covariates were strongly associated with outcomes.
- Small differences in means between the intervention and control groups could add up to have a large *cumulative* effect on the impact estimates if they tended to work in the same direction.

Take for example our estimate of the impact of the Million Hearts model on CVD events in Table F.4. The hazard ratio was substantially smaller before regression adjustment than after (0.95 versus 1.00), indicating regression adjustment materially affected our estimate of the model impacts. Specifically, the difference in these estimates suggests that the treatment group would have experienced lower rates of CVD events than the control group if the model had no effects, given differences in baseline covariates. After we adjusted for those differences, we found very similar rates of CVD events for the intervention and control groups. In exploratory analyses (not shown), we found that several variables drove this difference between the adjusted and unadjusted impact estimates, including the rate of CVD events in the beneficiary that the beneficiaries lived (which tended to be lower for intervention group beneficiaries than control group beneficiaries, and also strongly predicted CVD events). Regression adjustment similarly affected the impact estimates for a few other outcomes (for example, all-cause emergency department [ED] visits and observation stays), but did not affect impact estimates for other outcomes to the same degree (for example, mortality).

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.

Binary measures of CVD events and mortality. We used a beneficiary-level logit regression model to estimate the effects of the Million Hearts Model on the proportion of beneficiaries with a first-time heart attack, stroke, or TIA during a specified period, using the subset of beneficiaries who enrolled early enough to observe for the full period. For example, we estimated effects on the proportion of beneficiaries who had a first-time heart attack, stroke, or TIA within two years of enrollment, limiting the analysis to the subset of beneficiaries who enrolled early enough to follow for two full years in available claims data. As with the Cox proportional hazard models, the impact estimates were small and not statistically significant. When we repeated the process for death (for any reason), the results for medium- and high-risk beneficiaries indicated a statistically significant decrease in the probability of death, again supporting the results from the main modeling approach.

Medium-risk beneficiaries. We estimated impacts of the Million Hearts Model on mortality among only beneficiaries with medium CVD risk. We did this to understand how much the impacts among medium-risk beneficiaries drove impacts for the full sample of high- and medium-risk beneficiaries. The death rate was about 10 percent lower in the intervention group

than in the control group among medium-risk beneficiaries (Table F.11, row 1), a difference that is statistically significant ($p = 0.001$). This is a larger impact on the ratio of the hazard of dying than we found for either high- and medium-risk beneficiaries combined or for high-risk beneficiaries alone (Table F.5, row 1). However, it is important to remember that the death rate is lower overall for medium-risk beneficiaries than it is for high-risk beneficiaries—meaning the same reduction in death *rates* for each population would lead to a bigger impact for medium-risk beneficiaries on the hazard *ratio* (which conveys the death rate in the intervention group divided by the death rate for the control group). In this case, the estimated impact on two-year probability of death was almost identical for both the high-risk and medium-risk beneficiaries. Specifically, about 3.4 percent of medium-risk beneficiaries in the intervention group died within two years of enrollment, compared to 3.7 percent for the control group (Table F.11, row 3). This implies a 0.3 percentage point impact on the probability of dying, which is similar in magnitude to what we found for the high- and medium-risk beneficiaries combined and for the high-risk beneficiaries alone (both also 0.3; Table F.10, row 4).

Impacts on antihypertensive medication intensification or initiation of dropping some potential candidates. We conducted a sensitivity analysis by redefining *potential candidates* for antihypertensive medication initiation or intensification as those with systolic blood pressures at baseline of 140 mmHg or higher (as opposed to 130 mmHg or higher). The models with this smaller sample were consistent with the findings from the main analysis.

Impacts on CVD risk scores restricting to reassessment data collected 10 to 14 months after enrollment. CMS expected that 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. More than 80 percent of reassessment visits occurred within this recommended window, but others occurred as much as 23 months after enrollment. Our main analysis used all reassessment data, even if organizations submitted it beyond the 14-month window. We included these visits outside the 10- to 14-month window to maximize the size of the study population and the share of eligible high-risk beneficiaries with reassessment data. However, as a robustness check, we also reestimated impacts on CVD risk scores one year after enrollment, restricting the sample to only beneficiaries who had reassessment data recorded 10 to 14 months after enrollment. Although we controlled for time between enrollment and reassessment visits, this robustness check addressed the limitation that impacts for reassessment visits could differ within the recommended time frame. Estimates from this robustness check aligned with the impact results for the main analyses.

Impacts on CVD risk scores and mortality before and after controlling for changes in medication use. As an exploratory analysis, we estimated impact estimates for reductions in CVD risk scores before and after controlling for changes in medication use after enrolling in the model. In addition to restricting to beneficiaries who had reassessment data, as described previously, in this analysis we restricted to beneficiaries enrolled in Medicare Part D in the year before Million Hearts Model enrollment through the date of their first annual reassessment. After restricting to beneficiaries enrolled in Part D, the impact of the Million Hearts Model on CVD risk scores was similar to the main result shown in Chapter VI (1.5 percentage points, compared

to 1.2 percentage points among all beneficiaries with reassessment data). After controlling for initiation or intensification of statins or antihypertensives in the time between enrollment and reassessment, the impact estimate remained similar. We discuss the implications of these findings in Chapter VI.

We also conducted an analogous analysis for the outcome of all-cause mortality (Table F.5). After restricting to beneficiaries enrolled in Part D who were candidates for CVD medication initiation or intensification, the impact of the Million Hearts Model on CVD risk scores was similar to the main result shown in Chapter VII (a hazard ratio of 0.95, compared to 0.94 among all beneficiaries). After controlling for initiation or intensification of statins or antihypertensives in the time between enrollment and reassessment, the impact estimate moved to 0.96, which is closer to 1 (which would indicate no effect, after accounting for increases in medication use). Because the estimated impact on mortality moved only slightly, as with impacts on risk scores, it seems model impacts on CVD medications explain only part of the overall impacts on mortality.

Table F.3. Sizes of the studies population used for different impact estimates

Alternative outcome measure, population, or model specification	Analysis of high and medium risk beneficiaries				Analysis of high risk beneficiaries			
	Number of organizations		Number of beneficiaries (sum of weights [a])		Number of organizations		Number of beneficiaries (sum of weights [a])	
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Analysis of claims based outcomes with the population of 2017 and 2018 enrolled beneficiaries [b]								
Main analysis	**172**	**170**	**130,641**	**88,312**	**170**	**165**	**40,446**	**27,287**
Followed at least one year	172	169	127,976	87,035	170	165	39,661	26,937
Followed at least two years	170	161	101,787	65,967	168	155	32,116	20,621
Trim sample to 20 or fewer providers per organization	172	170	90,063	88,125	170	165	28,774	27,227
Beneficiaries enrolled in Part D who were candidates for CVD medication initiation or intensification	169	161	67,269	45,076	165	155	21,791	14,649
Analysis of claims based outcomes with the population of attributed beneficiaries [b]								
Attribution	172	171	434,671 (247,789)	293,046 (164,785)	172	171	434,671 (83,915)	293,046 (53,488)
Followed at least one year	172	170	428,238 (244,487)	289,458 (162,929)	172	170	428,238 (82,908)	28,9458 (52,941)
Followed at least two years	169	161	333,311 (195,092)	222,647 (128,084)	169	161	333,311 (67,964)	222,647 (42,755)
Analysis of Part D outcomes with the population of enrolled beneficiaries								
Composite measure: Statin or antihypertensive medication intensification or initiation	169	161	67,269	45,076	165	155	21,791	14,649
Antihypertensive medication intensification or initiation	168	159	44,464	30,247	164	153	17,624	11,882
Initiation	157	152	9,071	6,319	141	139	2,499	1,736
Intensification	167	158	35,393	23,928	162	152	15,125	10,146

Alternative outcome measure, population, or model specification	Analysis of high and medium risk beneficiaries				Analysis of high risk beneficiaries			
	Number of organizations		Number of beneficiaries (sum of weights [a])		Number of organizations		Number of beneficiaries (sum of weights [a])	
	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group	Intervention group	Control group
Statin intensification or initiation	168	161	58,013	38,403	164	154	17,328	11,594
Initiation	166	155	29,130	19,214	158	152	7,961	5,434
Intensification	165	159	28,883	19,189	158	148	9,367	6,160
Trim sample to 20 or fewer providers per organization (composite measure)	169	161	45,537	45,043	165	155	15,286	14,633
Using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification	166	155	23,538	16,156	162	150	10,973	7,445
Analysis of follow up risk scores and risk factors with the population of enrolled beneficiaries								
Main analysis	n.a.	n.a.	n.a.	n.a.	124	99	15,078	8,060
Trim sample to 20 or fewer providers per organization	n.a.	n.a.	n.a.	n.a.	124	99	10,624	8,054
Beneficiaries who had reassessment data recorded 10 to 14 months after enrollment	n.a.	n.a.	n.a.	n.a.	121	96	12,702	6,707
Beneficiaries also in Part D	n.a.	n.a.	n.a.	n.a.	120	98	10,478	5,656

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

[a] The population of attributed beneficiaries includes beneficiaries of any risk level. For the robustness check impact analyses, we weighted the population to reflect high- and medium-risk beneficiaries or high-risk beneficiaries, as we described in Appendix C. The sum of the weights is the effective sample size for the analyses.

[b] Claims-based outcomes include CVD events, death, Medicare spending, CVD-related and all-cause hospitalizations, CVD-related and all-cause outpatient ED visits and observation stays, and office visits.

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

Table F.4. Estimated ratio of the hazard of a first-time heart attack, stroke, or TIA between intervention and control beneficiaries: Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	Hazard ratio (*p* value) [90 percent confidence interval]	
	High and medium risk beneficiaries	High risk beneficiaries
Analyses with enrolled beneficiaries		
First-time heart attack, stroke, or TIA (main analysis)[a]	**1.00 (*p* = 0.90) [0.95, 1.04]**	**1.01 (*p* = 0.84) [0.94, 1.08]**
First-time heart attack or stroke using narrower definition[b]	1.00 (*p* = 0.92) [0.95, 1.05]	1.02 (*p* = 0.59) [0.95, 1.10]
First-time heart attack or stroke using narrowest definition[c]	1.00 (*p* = 0.94) [0.95, 1.06]	1.01 (*p* = 0.86) [0.94, 1.09]
Trim sample to 20 or fewer providers per organization	0.99 (*p* = 0.74) [0.94, 1.04]	1.01 (*p* = 0.87) [0.93, 1.09]
Unadjusted impact estimates	0.95 (*p* = 0.25) [0.89, 1.02]	0.96 (*p* = 0.38) [0.89, 1.04]
Analyses with attributed beneficiaries		
First-time heart attack, stroke, or TIA[a]	1.01 (*p* = 0.77) [0.97, 1.04]	1.00 (*p* = 0.88) [0.96, 1.04]
Implied effect for enrolled beneficiaries[d]	*1.01 [0.95, 1.07]*	*1.01 [0.93, 1.08]*
Unadjusted impact estimates	0.97 (*p* = 0.44) [0.91, 1.03]	0.96 (*p* = 0.24) [0.91, 1.02]
Implied effect for enrolled beneficiaries[d]	*0.95 [0.85, 1.06]*	*0.93 [0.83, 1.03]*

Source: Regression-based impact estimates using Medicare claims.

Note: Sample sizes are in Table F.2.

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

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

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

dividing the regression model coefficient corresponding to the impact estimate by the percentage of beneficiaries who were enrolled, then expressing this scaled regression coefficient as a hazard ratio.

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

Table F.5. Estimated ratio of the hazard of dying (for any reason) between intervention and control beneficiaries: Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	Hazard ratio (p value) [90 percent confidence interval]	
	High and medium risk beneficiaries	High risk beneficiaries
Analyses with enrolled beneficiaries		
Main analysis	**0.94 (*p* = 0.007) [0.90, 0.97]**	**0.98 (*p* = 0.65) [0.93, 1.04]**
Trim sample to 20 or fewer providers per organization	0.94 (*p* = 0.02) [0.90, 0.98]	0.99 (*p* = 0.79) [0.93, 1.05]
Unadjusted impact estimates	0.93 (*p* = 0.12) [0.87, 1.00]	0.97 (*p* = 0.55) [0.90, 1.05]
Main regression model specification, trimming sample to beneficiaries enrolled in Part D who were candidates for CVD medication initiation or intensification	0.95 (*p* = 0.10) [0.90, 1.00]	0.97 (*p* = 0.50) [0.90, 1.05]
Analysis after controlling for medication initiation or intensification, trimming sample to beneficiaries enrolled in Part D who were candidates for CVD medication initiation or intensification	0.96 (*p* = 0.16) [0.91, 1.01]	0.98 (*p* = 0.60) [0.90, 1.05]
Analyses with attributed beneficiaries		
Main regression model specification	0.98 (*p* = 0.32) [0.95, 1.01]	0.97 (*p* = 0.17) [0.93, 1.01]
Implied effect for enrolled beneficiaries[a]	*0.97* [*0.91, 1.02*]	*0.94* [*0.88, 1.01*]
Unadjusted impact estimates	0.97 (*p* = 0.50) [0.91, 1.04]	0.96 (*p* = 0.30) [0.91, 1.02]
Implied effect for enrolled beneficiaries[a]	*0.95* [*0.84, 1.07*]	*0.93* [*0.84, 1.04*]

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

Note: Sample sizes are in Table F.2.

[a] This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the regression model coefficient corresponding to the impact estimate by the percentage of beneficiaries who were enrolled, then expressing this scaled regression coefficient as a hazard ratio.

Table F.6. Estimated impacts on the number of inpatient admissions (number per 1,000 beneficiaries per quarter): Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	High and medium risk beneficiaries				High risk beneficiaries			
	Intervention group mean	Control group mean	Difference [90 percent CI]		Intervention group mean	Control group mean	Difference [90 percent CI]	
Number of CVD related inpatient admissions								
Main analysis	**14.0**	**13.7**	**0.35**	**[-0.2, 0.9]**	**19.0**	**17.9**	**1.05**	**[0.1, 2.0]**
Trim sample to 20 or fewer providers per organization	14.4	14.1	0.30	[-0.3, 0.9]	19.1	18.2	0.94	[-0.1, 1.9]
Unadjusted impact estimates	14.0	14.2	-0.14	[-1.8, 1.6]	19.0	18.5	0.49	[-1.4, 2.4]
Main regression model specification, using the population of attributed beneficiaries	16.8	16.3	0.46	[-0.0, 1.0]	21.1	20.3	0.79	[0.1, 1.4]
Implied effect for enrolled beneficiaries[a]			*0.80*	*[-0.1, 1.7]*			*1.38*	*[0.3, 2.5]*
Unadjusted impact estimates, using the population of attributed beneficiaries	16.8	16.7	0.03	[-1.8, 1.9]	21.1	21.0	0.04	[-2.0, 2.1]
Implied effect for enrolled beneficiaries[a]			*0.06*	*[-3.2, 3.3]*			*0.07*	*[-3.5, 3.6]*
Number of all cause inpatient admissions								
Main analysis	**64.5**	**62.2**	**2.35**	**[0.9, 3.8]**	**77.2**	**73.6**	**3.63**	**[1.0, 6.2]**
Trim sample to 20 or fewer providers per organization	65.1	62.6	2.50	[1.0, 4.0]	77.5	73.8	3.77	[1.1, 6.5]
Unadjusted impact estimates (registry population)	64.5	63.4	1.12	[-3.2, 5.4]	77.2	75.0	2.23	[-2.5, 7.0]
Main regression model specification, using the population of attributed beneficiaries	74.3	72.4	1.86	[0.5, 3.2]	85.5	83.8	1.73	[-0.2, 3.7]
Implied effect for enrolled beneficiaries[a]			*3.27*	*[0.9, 5.6]*			*3.03*	*[-0.4, 6.5]*
Unadjusted impact estimates, using the population of attributed beneficiaries	74.3	73.4	0.94	[-3.6, 5.5]	85.5	85.2	0.26	[-4.6, 5.2]
Implied effect for enrolled beneficiaries[a]			*1.65*	*[-6.2, 9.6]*			*0.46*	*[-8.1, 9.1]*

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 Table F.2.
[a] This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.
CI = confidence interval; CVD = cardiovascular disease.

Table F.7. Estimated impacts on the number of outpatient ED visits and observation stays (number per 1,000 beneficiaries per quarter): Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	High and medium risk beneficiaries				High risk beneficiaries			
	Intervention group mean	Control group mean	Difference	[90 percent CI]	Intervention group mean	Control group mean	Difference	[90 percent CI]
Number of CVD related outpatient ED visits and observation stays								
Main analysis	**8.2**	**8.1**	**0.13**	**[-0.4, 0.7]**	**9.9**	**9.5**	**0.36**	**[-0.4, 1.1]**
Trim sample to 20 or fewer providers per organization	8.8	8.6	0.17	[-0.4, 0.7]	10.5	10.1	0.39	[-0.4, 1.2]
Unadjusted impact estimates	8.2	8.5	-0.23	[-1.3, 0.9]	9.9	10.0	-0.13	[-1.4, 1.2]
Main regression model specification, using the population of attributed beneficiaries	9.7	9.2	0.55	[-0.1, 1.2]	10.9	10.3	0.62	[-0.1, 1.3]
Implied effect for enrolled beneficiaries[a]			*0.96*	[*-0.1, 2.0*]			*1.09*	[*-0.2, 2.3*]
Unadjusted impact estimates, using the population of attributed beneficiaries	9.7	9.7	-0.04	[-1.3, 1.2]	10.9	11.1	-0.15	[-1.6, 1.3]
Implied effect for enrolled beneficiaries[a]			*-0.06*	[*-2.3, 2.2*]			*-0.26*	[*-2.7, 2.2*]
Number of all cause outpatient ED visits and observation stays								
Main analysis	**102.3**	**98.7**	**3.56**	**[0.7, 6.4]**	**111.2**	**105.4**	**5.77**	**[2.5, 9.0]**
Trim sample to 20 or fewer providers per organization	103.7	100.8	2.84	[-0.1, 5.7]	113.0	107.1	5.95	[2.4, 9.5]
Unadjusted impact estimates	102.3	99.4	2.86	[-4.7, 10.4]	111.2	106.6	4.60	[-3.6, 12.8]
Main regression model specification, using the population of attributed beneficiaries	113.7	110.6	3.15	[0.4, 5.9]	120.6	117.6	3.03	[-0.1, 6.1]
Implied effect for enrolled beneficiaries[a]			*5.52*	[*0.6, 10.4*]			*5.32*	[*-0.1, 10.7*]
Unadjusted impact estimates, using the population of attributed beneficiaries	113.7	114.3	-0.61	[-8.5, 7.3]	120.6	121.7	-1.12	[-9.4, 7.1]
Implied effect for enrolled beneficiaries[a]			*-1.06*	[*-14.9, 12.8*]			*-1.96*	[*-16.4, 12.5*]

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 Table F.2.

[a] This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.

CI = confidence interval; CVD = cardiovascular disease; ED = emergency department.

Table F.8. Estimated impacts on Medicare spending (dollars per beneficiary per quarter): Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	High and medium risk beneficiaries				High risk beneficiaries			
	Intervention group mean	Control group mean	Difference [90 percent CI]		Intervention group mean	Control group mean	Difference [90 percent CI]	
Analyses with enrolled beneficiaries								
Main analysis: Parts A and B spending	**$ 903**	**$ 898**	**$ 4**	**[-14, 23]**	**$ 1,031**	**$ 1,006**	**$ 25**	**[-3, 52]**
Parts A and B spending plus average model payments[a]	$ 905	$ 898	$ 7	[-12, 25]	n.a.	n.a.	n.a.	n.a.
Trim sample to 20 or fewer providers per organization	$ 917	$ 910	$ 8	[-10, 26]	$ 1,041	$ 1,014	$ 27	[-1, 55]
Unadjusted impact estimates	$ 903	$ 894	$ 9	[-43, 60]	$ 1,031	$ 1,004	$ 27	[-30, 83]
Analyses with attributed beneficiaries								
Parts A and B spending	$ 1,025	$ 1,018	$ 7	[-12, 27]	$ 1,130	$ 1,125	$ 5	[-20, 30]
Implied effect for enrolled beneficiaries[b]			*$ 13*	*[-21, 47]*			*$ 8*	*[-36, 53]*
Parts A and B spending plus average model payments[a]	$ 1,026	$ 1,018	$ 8	[-11, 28]	n.a.	n.a.	n.a.	n.a.
Implied effect for enrolled beneficiaries[b]								
Unadjusted impact estimates	$ 1,025	$ 992	$ 33	[-22, 87]	$ 1,130	$ 1,104	$ 26	[-35, 86]
Implied effect for enrolled beneficiaries[b]			*$ 58*	*[-38, 153]*			*$ 45*	*[-60, 151]*

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. Inpatient and other spending might not sum to total spending because the impact estimates and regression-adjusted means were calculated from separate regression models. Sample sizes are in Table F.2.

[a] Total Million Hearts Model payments paid to intervention group organizations included in the impact evaluation for the first five performance periods were $6,733,435. This amount was divided by the number of beneficiary-quarters in the respective analysis to calculate the average cost per quarter per intervention group beneficiary, and then added to the intervention group beneficiaries' spending in each quarter. The number of beneficiary-quarters was calculated for each analysis, so the average model cost per beneficiary per quarter varies across analyses. (For analyses with the population of attributed beneficiaries, we accounted for the weights assigned to each beneficiary-quarter in these calculations.)

[b] This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.

CI = confidence interval; n.a.= not applicable.

Table F.9. Estimated impacts on office visits: Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	High and medium risk beneficiaries				High risk beneficiaries			
	Intervention group mean	Control group mean	Difference	[90 percent CI]	Intervention group mean	Control group mean	Difference	[90 percent CI]
Number of office visits (per 1,000 beneficiaries per quarter)[a]								
Main analysis	**2,722**	**2,684**	**37.6**	**[4.4, 70.8]**	**2,922**	**2,871**	**50.4**	**[9.5, 91.2]**
Unadjusted impact estimates	2,722	2,612	109.5	[-45.7, 264.7]	2,922	2,787	134.8	[-28.6, 298.3]
Main regression model specification, using the population of attributed beneficiaries	2,838	2,825	13.4	[-22.6, 49.4]	3,022	3,005	16.6	[-27.5, 60.6]
Implied effect for enrolled beneficiaries[b]			*23.5*	*[-39.5, 86.4]*			*29.1*	*[-48.0, 106.2]*
Number of office visits with a cardiologist (per 1,000 beneficiaries per quarter)[a]								
Main analysis	**571**	**575**	**-4.2**	**[-32.4, 23.9]**	**655**	**656**	**-1.0**	**[-38.5, 36.5]**
Unadjusted impact estimates	571	577	-6.4	[-115.6, 102.9]	655	658	-2.4	[-115.6, 110.8]
Main regression model specification, using the population of attributed beneficiaries	661	656	4.6	[-26.0, 35.2]	726	723	2.4	[-33.8, 38.5]
Implied effect for enrolled beneficiaries[b]			*8.1*	*[-45.4, 61.5]*			*4.1*	*[-59.0, 67.3]*
Number of office visits with a Million Hearts provider (per 1,000 beneficiaries per quarter)[a]								
Main analysis	**826**	**795**	**30.4**	**[-13.8, 74.7]**	**921**	**883**	**38.4**	**[-12.3, 89.1]**
Unadjusted impact estimates	826	783	42.6	[-66.4, 151.6]	921	857	64.5	[-69.5, 198.6]
Main regression model specification, using the population of attributed beneficiaries	747	745	2.2	[-36.2, 40.6]	841	838	2.8	[-38.9, 44.4]
Implied effect for enrolled beneficiaries[b]			*3.8*	*[-63.3, 71.0]*			*4.8*	*[-68.0, 77.7]*
Percentage with an office visit with a Million Hearts provider 10 to 15 months after enrollment[c]								
Main analysis	**73.4**	**70.3**	**3.1**	**[-0.5, 6.7]**	**75.9**	**72.3**	**3.6**	**[-0.3, 7.5]**
Unadjusted impact estimates	73.4	70.7	2.6	[-1.7, 7.0]	75.9	72.4	3.5	[-1.5, 8.5]
Main regression model specification, using the population of attributed beneficiaries	65.9	65.2	0.7	[-2.0, 3.5]	68.8	68.3	0.4	[-2.3, 3.2]
Implied effect for enrolled beneficiaries[b]			*1.3*	*[-3.6, 6.2]*			*0.8*	*[-4.1, 5.7]*

Source: Regression-adjusted results from Medicare claims data.
Note: Sample sizes are in Table F.2.
[a] 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.
[b] This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.
[c] Analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled in October 2019.
CI = confidence interval.

Table F.10. Estimated impacts on binary measures of CVD events and mortality

Outcome[a]	High and medium risk beneficiaries				High risk beneficiaries			
	Intervention group mean	Control group mean	Difference [90 percent CI]		Intervention group mean	Control group mean	Difference [90 percent CI]	
Analyses with enrolled beneficiaries								
Percentage with a first-time heart attack, stroke, or TIA								
Within 12 months of enrollment	1.3	1.3	0.0	[-0.1, 0.1]	1.8	1.7	0.1	[-0.1, 0.2]
Within 24 months of enrollment	2.7	2.7	-0.0	[-0.1, 0.1]	3.6	3.6	-0.0	[-0.3, 0.2]
Percentage who died								
Within 12 months of enrollment	1.6	1.8	-0.2	[-0.3, -0.1]	2.1	2.2	-0.1	[-0.3, 0.1]
Within 24 months of enrollment	3.9	4.2	-0.3	[-0.5, -0.1]	5.1	5.3	-0.3	[-0.6, 0.1]
Analyses with enrolled beneficiaries and sample trimmed to 20 or fewer providers per organization								
Percentage with a first-time heart attack, stroke, or TIA								
Within 12 months of enrollment	1.4	1.3	0.0	[-0.1, 0.1]	1.8	1.8	0.0	[-0.1, 0.2]
Within 24 months of enrollment	2.7	2.8	-0.0	[-0.2, 0.1]	3.6	3.7	-0.1	[-0.4, 0.3]
Percentage who died								
Within 12 months of enrollment	1.7	1.9	-0.2	[-0.4, -0.1]	2.1	2.3	-0.2	[-0.4, 0.0]
Within 24 months of enrollment	4.0	4.3	-0.3	[-0.5, -0.1]	5.2	5.5	-0.3	[-0.7, 0.1]
Analyses with attributed beneficiaries								
Percentage with a first-time heart attack, stroke, or TIA								
Within 12 months of enrollment	1.6	1.7	-0.0	[-0.1, 0.0]	2.0	2.1	-0.1	[-0.2, 0.0]
Implied effect for enrolled beneficiaries[b]			*-0.1*	*[-0.2, 0.1]*			*-0.1*	*[-0.3, 0.1]*
Within 24 months of enrollment	3.1	3.1	-0.0	[-0.1, 0.1]	3.8	3.8	-0.0	[-0.2, 0.2]
Implied effect for enrolled beneficiaries[b]			*-0.0*	*[-0.2, 0.1]*			*-0.0*	*[-0.3, 0.3]*
Percentage who died								
Within 12 months of enrollment	2.3	2.4	-0.1	[-0.1, 0.0]	2.9	3.0	-0.1	[-0.2, 0.0]
Implied effect for enrolled beneficiaries[b]			*-0.1*	*[-0.3, 0.1]*			*-0.2*	*[-0.5, 0.1]*
Within 24 months of enrollment	5.0	5.2	-0.2	[-0.3, 0.0]	6.3	6.6	-0.4	[-0.6, -0.1]
Implied effect for enrolled beneficiaries[b]			*-0.3*	*[-0.5, 0.0]*			*-0.6*	*[-1.0, -0.2]*

Source: Regression-based impact estimates using Medicare claims.
Note: Sample sizes are in Table F.2.
[a] Analysis was limited to beneficiaries enrolled early enough to be observed at least the designated number of months, because claims were pulled in October 2019.
[b] This row presents the implied impact for enrolled beneficiaries assuming overall impacts among attributed beneficiaries come solely through the subset of beneficiaries enrolled in the model. This estimate is obtained by dividing the overall impact estimate by the percentage of beneficiaries who were enrolled.
CI = confidence interval; CVD = cardiovascular disease; TIA = transient ischemic attack.

Table F.11. Estimated impacts on all-cause mortality for medium-risk beneficiaries

Alternative analysis	Intervention group mean	Control group mean (adjusted)	Regression adjusted impact estimate			Number of beneficiaries (organizations) included in the analysis	
			Estimate	*p* value	90% confidence interval	Intervention group	Control group
Regression-adjusted ratio of hazard of dying (for any reason) between intervention and control beneficiaries	n.a.	n.a.	0.90	0.001	[0.86, 0.95]	90,195 (167)	61,025 (169)
Regression-adjusted difference in the percentage of beneficiaries who died within one year of enrollment	1.5	1.7	-0.2	0.013	[-0.3, -0.1]	88,315 [a] (166)	60,098 [a] (169)
Regression-adjusted difference in the percentage of beneficiaries who died within two years of enrollment	3.4	3.7	-0.3	0.005	[-0.5, -0.1]	69,671 [b] (158)	45,346 [b] (168)

Source: Regression-adjusted results from Medicare enrollment data.

Note: These analyses include beneficiaries with baseline cardiovascular disease risk scores of at least 15 percent but less than 30 percent.

[a] Percentages calculated among beneficiaries who enrolled by October 31, 2018, so we could follow them for at least one year (or until death) before the end of the claims and enrollment data period on October 31, 2019.

[b] Percentages calculated among beneficiaries who enrolled by October 31, 2017, so we could follow them for at least two years (or until death) before the end of the claims and enrollment data period on October 31, 2019.

Table F.12. Estimated impacts on the initiation or intensification of CVD medications: Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	High and medium risk beneficiaries				High risk beneficiaries			
	Intervention group mean	Control group mean	Difference	[90 percent CI]	Intervention group mean	Control group mean	Difference	[90 percent CI]
Statin or antihypertensive medication intensification or initiation								
Main analysis	**30.9**	**27.3**	**3.6**	**[2.5, 4.7]**	**37.3**	**32.4**	**4.8**	**[3.3, 6.4]**
Trim sample to 20 or fewer providers per organization	30.6	27.4	3.2	[2.1, 4.4]	36.7	32.4	4.3	[2.5, 6.0]
Antihypertensive medication intensification or initiation								
Main analysis	**28.9**	**26.5**	**2.5**	**[1.5, 3.4]**	**32.4**	**29.8**	**2.6**	**[1.3, 3.9]**
Using a higher blood pressure threshold to define potential candidates for antihypertensive medication initiation or intensification[a]	35.2	32.1	3.1	[1.7, 4.5]	37.5	34.1	3.4	[1.7, 5.1]

Source: Regression-based impact estimates using Medicare claims.

Note: Sample sizes are in Table F.2.

[a] This analysis limits the sample to beneficiaries with SBP of at least 140 mmHg at enrollment. The main analysis was limited to beneficiaries with SBP of 130 mmHg or higher.

CI = confidence interval; CVD = cardiovascular disease; SBP = systolic blood pressure.

Table F.13. Estimated impacts on CVD risk scores among high-risk beneficiaries with reassessment data: Sensitivity tests and exploratory analyses

Alternative outcome measure, population, or model specification	Regression adjusted difference in CVD risk score between intervention and control groups at reassessment [90% confidence interval]
Main analysis	**-1.2 [-1.9, -0.4]**
Trim sample to 20 or fewer providers per organization	-1.0 [-1.8, -0.3]
Restrict to beneficiaries with reassessment data 10 to 14 months after enrollment	-1.2 [-1.9, -0.5]
Unadjusted impact estimates	-0.8 [-1.4, -0.2]

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

Note: Sample sizes are in Table F.2.

CVD = cardiovascular disease.

Table F.14. Estimated impacts on CVD risk scores before and after controlling for medication initiation or intensification, among high-risk beneficiaries with reassessment data and enrolled in Part D

Analysis before and after controlling for medication initiation or intensification	Regression adjusted difference in CVD risk score between intervention and control groups at reassessment [90% confidence interval]	Percentage change in estimate after controlling for medication initiation or intensification
Main regression model specification	-1.5 (p = 0.001) [-2.2, -0.7]	n.a.
Analysis after controlling for medication initiation or intensification	-1.4 (p = 0.002) [-2.2, -0.7]	-2%

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

Note: Medications include statins and antihypertension medications. Percentage impacts are relative to the regression-adjusted control group mean. Sample sizes are in Table F.2.

CVD = cardiovascular disease; n.a. = not applicable.

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