

# Value-Based Insurance Design (VBID) and Opportunities to Improve Medication Adherence for Cardiovascular Disease Prevention

*In partnership with the CMS Innovation Center and Million Hearts® at the Centers for Disease Control and Prevention (CDC)*

October 21, 2021

People using assistive technology may not be able to fully access information in this file. For assistance, please contact [digital@hhs.gov](mailto:digital@hhs.gov)



# Disclaimer

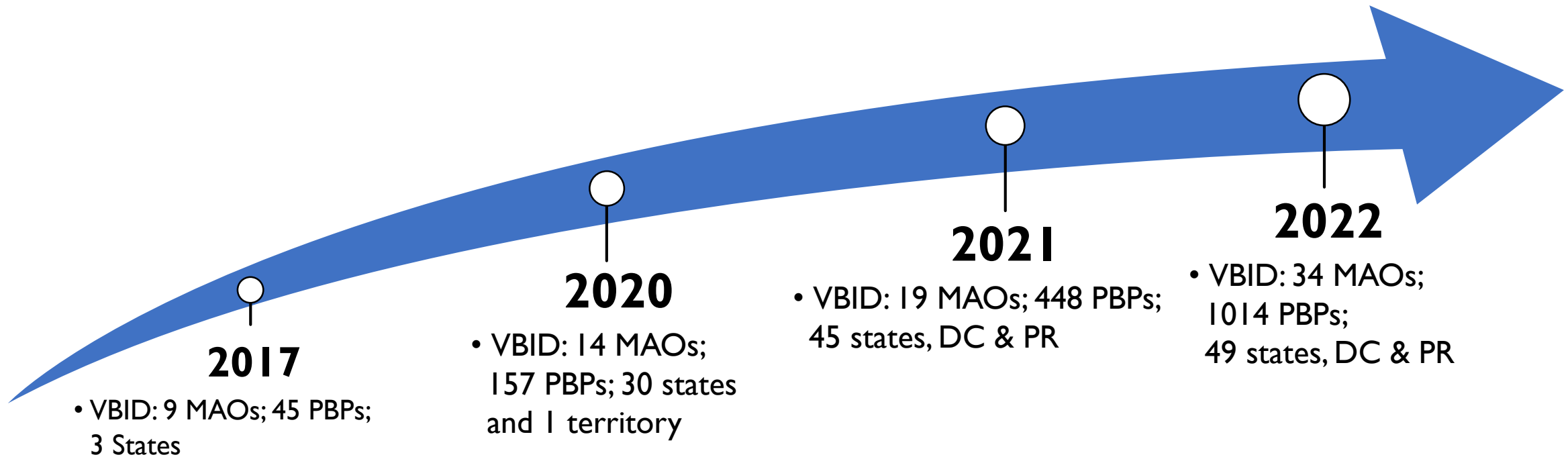
This presentation is offered only for general informational and educational purposes. As always, the agency's positions on matters may be subject to change. HHS's comments are not offered as and do not constitute legal advice or legal opinions, and no statement made during this presentation will preclude the agency and/or its law enforcement partners from enforcing any and all applicable laws, rules, and regulations.

Medicare Advantage Organizations (MAOs) and Prescription Drug Plan (PDP) Sponsors are responsible for ensuring that their actions fully comply with applicable laws, rules, and regulations, and we encourage you to consult with your own legal counsel to ensure such compliance.

# Agenda

- **Welcome**, *Sibel Ozcelik, ML, MS, Model Co-Lead, VBID Model*
- **VBID's Role in Improving Medication Adherence for Cardiovascular Disease Prevention**, *Abigale Sanft, VBID Model Part D Workstream Lead, CMMI*
- **Heart Disease and Stroke Burden and Inequities**, *Laurence Sperling, MD, FACC, FACP, FAHA, FASPC, Executive Director, Million Hearts<sup>®</sup>, Division for Heart Disease and Stroke Prevention, CDC*
- **Evidence-Based Medication Adherence Strategies for Cardiovascular Disease Prevention**, *Hilary Wall, MPH, Senior Scientist/Million Hearts<sup>®</sup> Science Lead, Division for Heart Disease and Stroke Prevention, CDC*
- **Engaging Pharmacists in Strategies to Improve Medication Adherence**, *Nicole Therrien, PharmD, MPH, ASRT, Inc., Applied Research and Evaluation Branch, Division for Heart Disease and Stroke Prevention, CDC*
- **Questions and Answers**, *Haley Stolp, MPH, Public Health Analyst III, ASRT Inc., Million Hearts<sup>®</sup>, Division for Heart Disease and Stroke Prevention, CDC*
- **Closing Remarks, Opportunities and Next Steps**, *Abigale Sanft, VBID Model Part D Workstream Lead, CMMI*

# Significant Growth in Model Adoption and Partnerships



# CY 2022 VBID Model Components

■ Began in 2021

## Tests Complementary MA Health Plan Innovations

Targeted Benefits by Condition, Socioeconomic Status (SES), or both	MA and Part D Rewards and Incentives (RI) Programs	Wellness and Health Care Planning (WHP)	Hospice Benefit Component	Cash or Monetary Rebates*	New and Existing Technologies*
<p>Tests the impact of targeted reduced or eliminated cost-sharing (including for Part D drugs) or additional supplemental benefits based on enrollees:</p> <ul style="list-style-type: none"> <li>a. Chronic Condition(s)</li> <li>b. SES</li> <li>c. Both (a) and (b)</li> </ul>	<p>Tests how R&amp;I programs that more closely reflect the expected benefit of the health related service or activity, within an annual limit, may impact enrollee decision-making about their health in more meaningful ways</p>	<p>Tests the impact of timely, coordinated approaches to wellness and health care planning, including advance care planning</p>	<p>Tests how including the Medicare hospice benefit in an enrollee's MA coverage impacts financial accountability and care coordination across the care continuum</p>	<p>Tests the impact of sharing statutory beneficiary rebates directly with enrollees, in the form of cash or cash equivalents rather than as Medicare premium payments or additional benefits</p>	<p>Tests the impact of allowing MAOs to cover new and existing FDA-approved technology not currently covered by the Medicare program</p>

\*As of CY 2021, there has been limited uptake of the Cash or Monetary Rebates Component and the New and Existing Technologies Component

# VBID Health Equity Business Case

## INCREASE MEMBER ENGAGEMENT & RETENTION

Plans that offer supplemental benefits like meals have been shown to **receive a higher net promoter score and higher member retention.**<sup>1</sup>

## IMPROVE QUALITY & MEMBER SATISFACTION

**Focusing on social needs is correlated with positive quality of life and member satisfaction**<sup>7</sup>.

According to a 2020 McKinsey study, **MA plans with an average customer experience measure rating of 4 or more Stars added 2.1 times more net members** in 2019 than their less customer-friendly competitors.<sup>2</sup>

## OFFER BENEFITS ONLY AVAILABLE TO MODEL PARTICIPANTS

VBID Model participants can **offer unique features only available to participating plans**, such as sharing beneficiary rebates more directly with members in the form of Cash or Monetary Rebates, MA and Part D RI Programs, and importantly, targeted non-primarily health-related supplemental benefits.\* **VBID tests greater customization of benefits to underserved populations.**

## LOWER MEDICAL SPENDING & UTILIZATION OF LOW-VALUE SERVICES

**Addressing health-related social needs in member populations has been shown in other contexts to:**

- Significantly lower healthcare utilization<sup>3</sup>
- Significantly lower Emergency Department (ED) visits<sup>4</sup>
- Significantly lower medical spending<sup>5</sup>
- Better chronic disease management<sup>6</sup>

## MINIMIZE COSTS BY BETTER FOCUSING INTERVENTIONS

Additional targeting flexibilities available to VBID Model participants, such as targeting by socio-economic status, tests the benefits of allowing plans to **focus interventions on populations where the largest health improvements can be realized.**

**In addition to improving member health and promoting health equity, there is a strong business case for MAOs to participate in VBID and leverage the Model's waiver authority to address health disparities.**

<sup>1</sup>XM Institute NPS and Customer Ratings Benchmarks, Qualtrics 2020, Qualtrics.com

<sup>2</sup> Refer to the [McKinsey study](#)

\*Some marketing restrictions apply

<sup>3</sup>Berkowitz, et al., 2018; Martin et al., 2018

<sup>4</sup> Ibid

<sup>5</sup>Gurvey, et al., 2013

<sup>6</sup>Refer to the [Project Angel Heart study](#)

<sup>7</sup>Refer to the [HMA MA Supplemental Benefits Report](#)

# VBID Opportunities to Address CVD

CVD is well suited to the VBID Model given heavy intersection with multiple social needs. There is a well-established evidence base for the use of cardiac rehab programs, DASH diet, use of high-intensity statins, and other interventions where VBID Model Components could encourage greater utilization.

**VBID Model participants have an opportunity to formally test the use of a suite of benefits to address disparities in CVD management and outcomes.**

Model Component	CVD Example
<b>Targeted Benefits by Condition, Socioeconomic Status (SES), or both</b>	<ul style="list-style-type: none"> <li>Plan offers <b>healthy food card or medically tailored meals</b> targeted to LIS eligible enrollees with hypertension (paired with messaging around DASH diet)</li> <li>Plan offers <b>reduced cost sharing</b> for high-value Part D drugs to address risk factors (e.g., antihypertensives, high-intensity statins)</li> <li>Plan offers eligible enrollees the opportunity to <b>participate in a care management or digital program</b> to receive the benefit</li> </ul>
<b>MA and Part D Rewards and Incentives (RI) Programs</b>	<ul style="list-style-type: none"> <li>Plan could provide a <b>reward to incentivize completion of milestones in a cardiac rehab program</b> for enrollees who have experienced a heart attack</li> <li>This could be <b>complemented with other VBID interventions</b> like \$0 cost-sharing for Cardiac Rehab visit for enrollees with CHF</li> </ul>
<b>New and Existing Technologies</b>	<ul style="list-style-type: none"> <li>Plan offers <b>targeted coverage of blood pressure monitors and cuffs</b> to enrollees with hypertension</li> </ul>

# VBID Use Case: Mark with CVD

1



- Mark is a 66 year old black male from Vicksburg, MS
- He recently had a heart attack and has unmanaged hypertension
- He receives low income subsidies (LIS) and struggles to afford his medical bills and meet his food and housing needs
- He was working full-time but has reduced his hours due to his recent heart attack

Your plan covers about \$1,579 of Mark's medical spending every month<sup>1</sup>. There are thousands of "Marks" that fall under your plan. His costs to the plan will sky rocket to \$5,229 per month<sup>2</sup> if he has a second hospitalization. If you can figure out a way to help Mark, you will help reduce some of the huge disparities in CVD (e.g., Black Americans are 30% more likely to die from CVD<sup>3</sup>).

When thinking through how to best leverage the VBID Model determine 1) your target population 2) what are the variables that could be driving disparities in this target population and 3) what VBID Component or suite of Components is best suited to address those variables driving the disparity?

2

## Estimated Cost of Enrollee with CVD<sup>4</sup>

- Mean total direct medical costs of beneficiary with CVD: **\$18,953 per year**
- Mean total direct medical costs of beneficiary with CVD after second CVD hospitalization: **\$62,755 per year** (this is 4.5 times higher compared to those who avoided inpatient stays)

## Understanding and Addressing Mark's Needs

In the past, Non-VBID plans may have tried one social needs intervention to prevent costs like those highlighted above (e.g., healthy food cards), but the intervention was expensive because it must be provided to all beneficiaries with CVD, not just the beneficiaries who couldn't afford healthy meals.

This meant non-VBID plans couldn't invest in Mark's other social needs (e.g., transportation, financial strain) and left him at heightened risk for a secondary CVD hospitalization.

3

## Tailoring a Suite of Benefits for Mark through VBID

VBID allows for a more cost effective approach to tailoring a suite of benefits to your highest cost beneficiaries. Heart disease has a number of risk factors, treating them requires a package of benefits<sup>5</sup>.

Reduced Cost Sharing for High-Intensity Statins

Reduced Cost Sharing for Antihypertensives (fixed dose combos and 1x/day dosing)

Healthy Food Card to Encourage DASH Diet

Targeted Coverage of Blood Pressure Monitors and Cuffs

RI for Completing Milestones in Cardiac Rehab (CR) & \$0 Cost Sharing for CR

1) [https://www.ajmc.com/view/ajmc\\_10marnicholswebx\\_e86to93](https://www.ajmc.com/view/ajmc_10marnicholswebx_e86to93) ; 2) Ibid; 3) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4558355/> ; 4) Ibid; 5) <https://www.cdc.gov/vitalsigns/cardiovascularisease/index.html>



# Heart Disease and Stroke Burden and Inequities

**Laurence Sperling, MD, FACC, FACP, FAHA, FASPC**

*Executive Director, Million Hearts®*

Division for Heart Disease and Stroke Prevention, CDC

Center for Clinical Standards and Quality, CMS

Katz Professor in Preventive Cardiology

Professor of Global Health

Emory University

CMS VBID Webinar

October 21, 2021



# Disclaimer/Disclosure



The opinions expressed by the speaker do not necessarily reflect the opinions of the US Department of Health and Human Services, the Public Health Service, the Centers for Disease Control and Prevention, or the Center for Medicare and Medicaid Services.

Dr. Sperling has no conflicts to disclose.

# U.S. Heart Disease and Stroke Burden

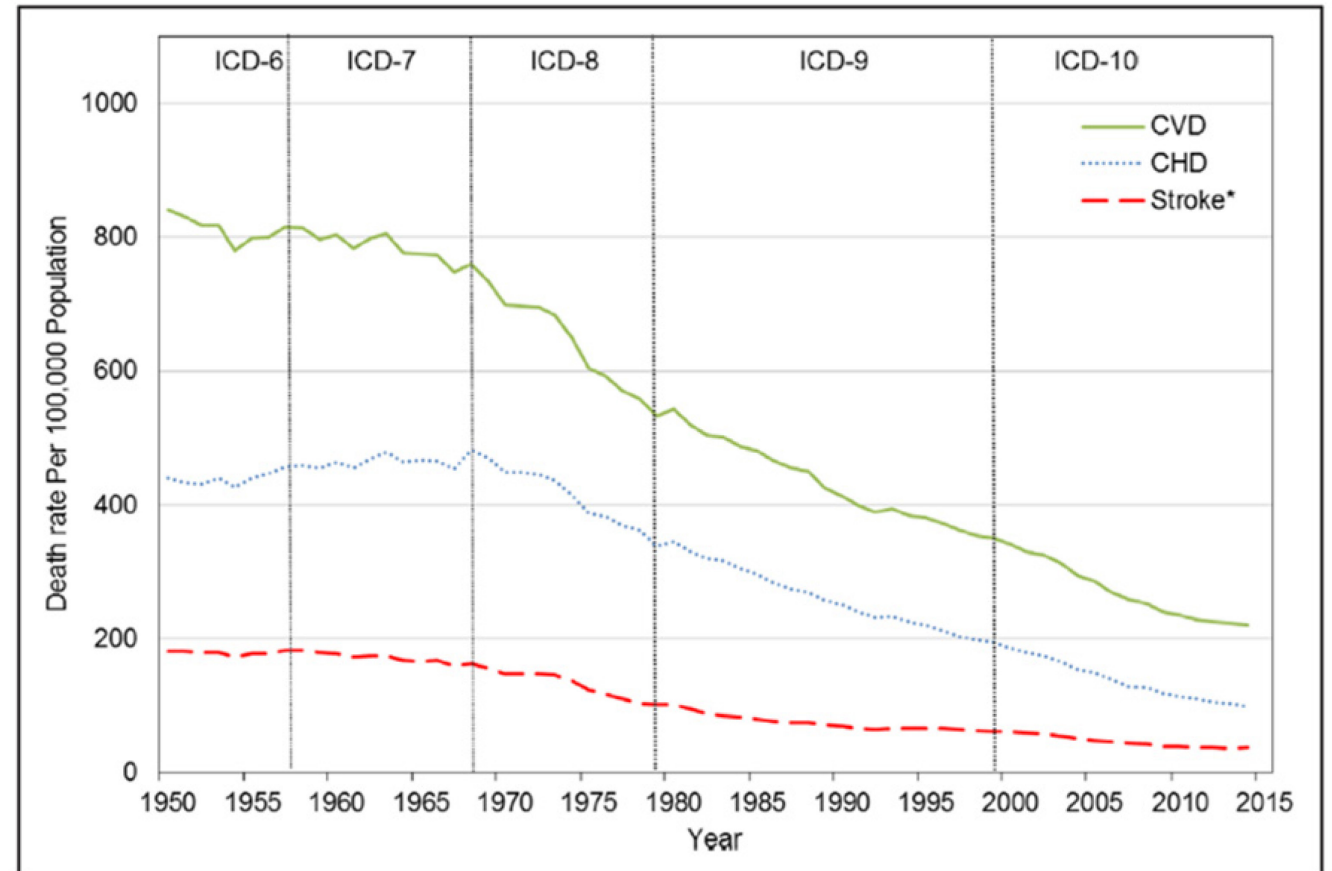
- More than **1.6 million** people in the U.S. suffer from heart attacks and strokes per year
- More than **870,000** deaths per year from cardiovascular disease (CVD)
- CVD is the greatest contributor to racial disparities in life expectancy
- Uncontrolled hypertension is the primary contributor to the morbidity and mortality rate disparities in CVD between Blacks and Whites.



Virani SS, Alonso A, Benjamin EJ, Bittencourt MS, Callaway CW, Carson AP, et al. Heart disease and stroke statistics-2020 update: a report from the American Heart Association. *Circulation*. 2020;141(9):e139-596.2.  
Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999–2017 on CDC WONDER Online Database website. <http://wonder.cdc.gov/ucd-icd10.html>. Accessed March 12 7, 2020.  
Kochanek KD, Arias E, Anderson RN. How did cause of death contribute to racial differences in life expectancy in the United States in 2010? NCHS data brief, no 125. Hyattsville, MD: National Center for Health Statistics. 2013

# Before COVID-19: Concerning Directional Change Heart Disease and Stroke Trends 1950-2015

- CVD leading cause of mortality since 1910 (with exception of flu pandemic 1918-1920)
- Racial/ ethnic disparities persistent in CVD mortality since 1968
- Current stagnation- upward trends



Mensah GA, Wei GS, Sorlie PD, et al. Decline in Cardiovascular Mortality – Possible Causes and Implications. *Circulation Research*. 2017;120:366-380.

Sidney S, et al. *JAMA Cardiol*. 2016;1:594-9

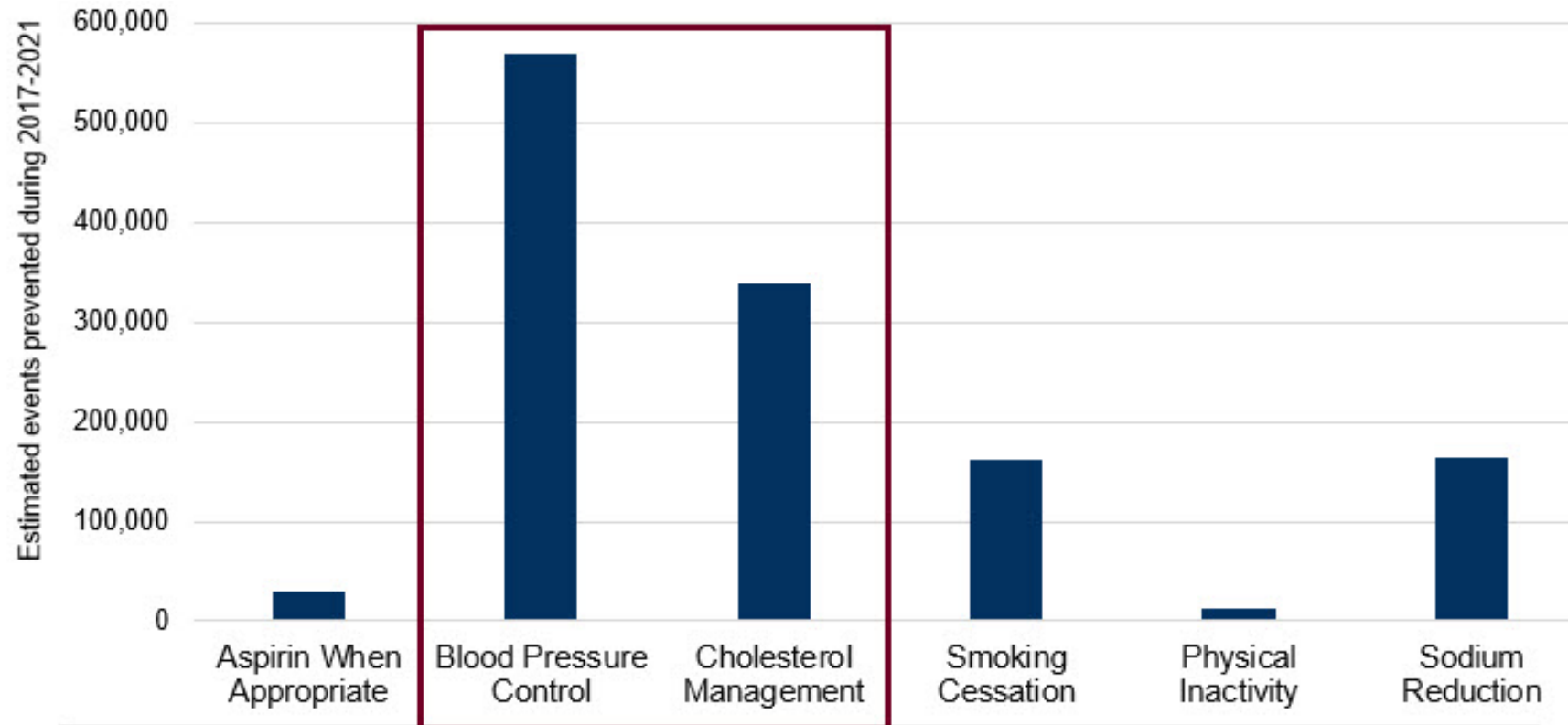
Van Dyke M, et al. *MMWR Surveill Summ*. 2018; 67:1-11

# Division for Heart Disease and Stroke Prevention (DHDSP) at CDC

- **Vision:** A heart-healthy and stroke-free world.
- **Goals**
  - Reduce the risk for high cholesterol and blood pressure (hypertension).
  - Improve management and control of high cholesterol and hypertension.
  - Reduce the burden of heart disease and stroke in the US.
- **We advance our goals and objectives by...**
  - Addressing health equity.
  - Focusing on priority populations.
  - Strategically engaging partners.
- **Aim of Million Hearts<sup>®</sup>:** prevent 1 million cardiovascular events within 5 years



# Relative Event Contributions to “the Million”

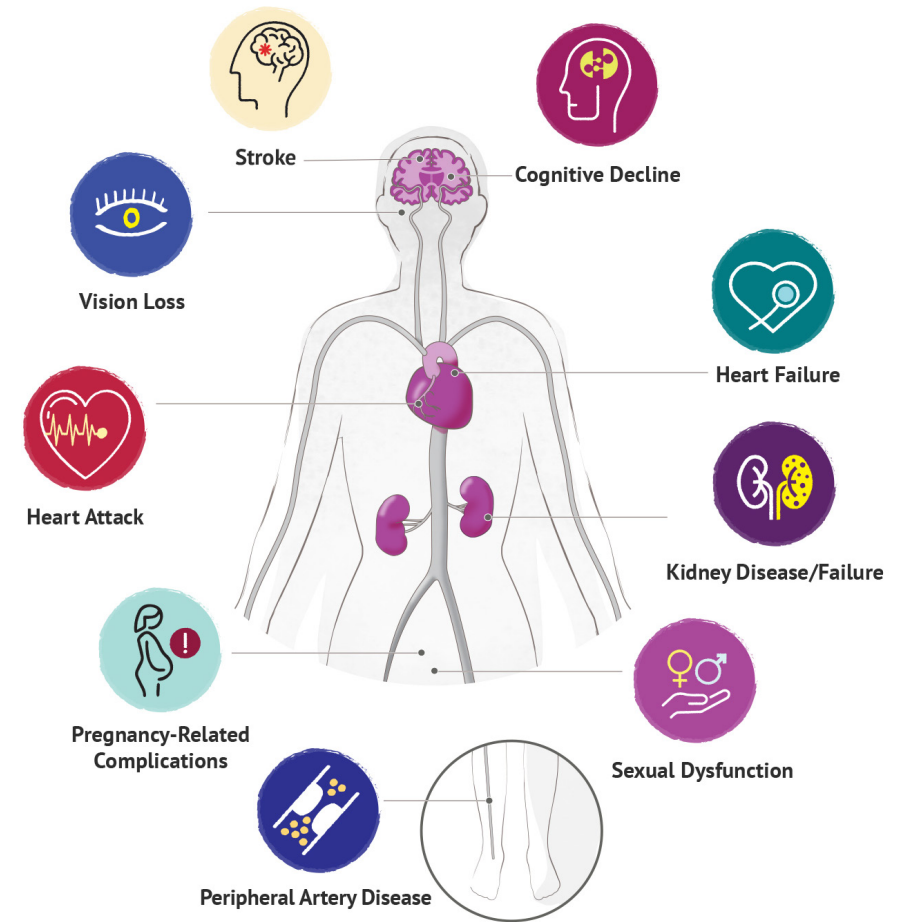


**Notes:** Aspirin when appropriate reflects aspirin use for secondary prevention only; total does not equal sum of events prevented by risk factor type as those totals are not mutually exclusive; applies ratios obtained from PRISM and ModelHealth:CVD to estimate the number of total events, to more closely align with the Million Hearts event definition

**Data sources:** Aspirin when appropriate – 2013-14 NHANES; blood pressure control and cholesterol management – 2011-14 NHANES; smoking cessation and physical inactivity – 2015 NHIS, sodium reduction – 2011-12 NHANES.

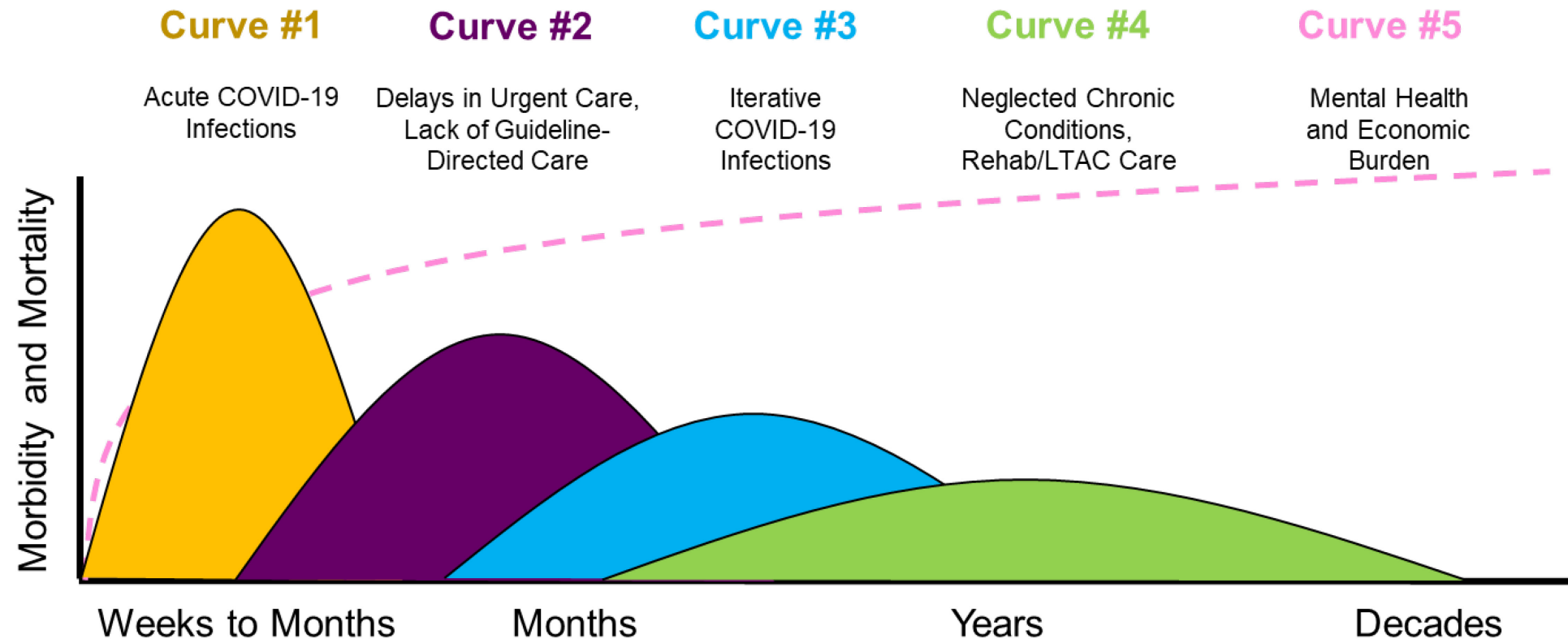
# Dangers of Uncontrolled Hypertension

- Hypertension is common, costly, and controllable.
- Nearly **1 in 2** adults have HTN
- ~80% of adults with HTN are recommended prescription medication with lifestyle modifications.
- Only **1 in 4** adults or **1 in 5** African American adults with HTN have it controlled
- Progress has stalled and socially constructed disparities persist.
- We know what works and are working to tailor, replicate, and/or scale strategies.



Centers for Disease Control and Prevention (CDC). *Hypertension Cascade: Hypertension Prevalence, Treatment and Control Estimates Among US Adults Aged 18 Years and Older Applying the Criteria From the American College of Cardiology and American Heart Association's 2017 Hypertension Guideline—NHANES 2015–2018*. Atlanta, GA: US Department of Health and Human Services; 2019. <https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html>, Accessed September 23, 2021. Image source: U.S. Department of Health and Human Services. *The Surgeon General's Call to Action to Control Hypertension*. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2020.

# Multiple Impacts of the COVID-19 Pandemic



Adapted with permission from Victor Tseng, MD

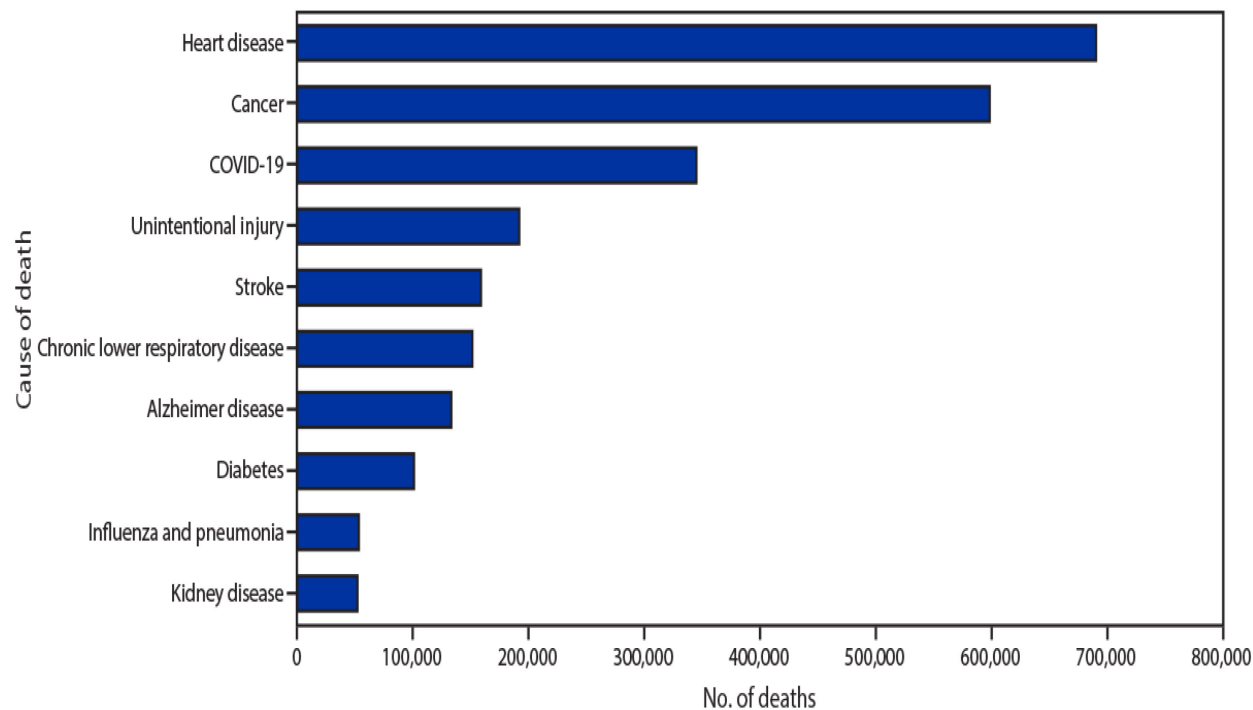


Kohli P, Virani SS. Surfing the Waves of the COVID-19 Pandemic as a Cardiovascular Clinician. *Circulation*. 2020 Jul 14;142(2):98-100..



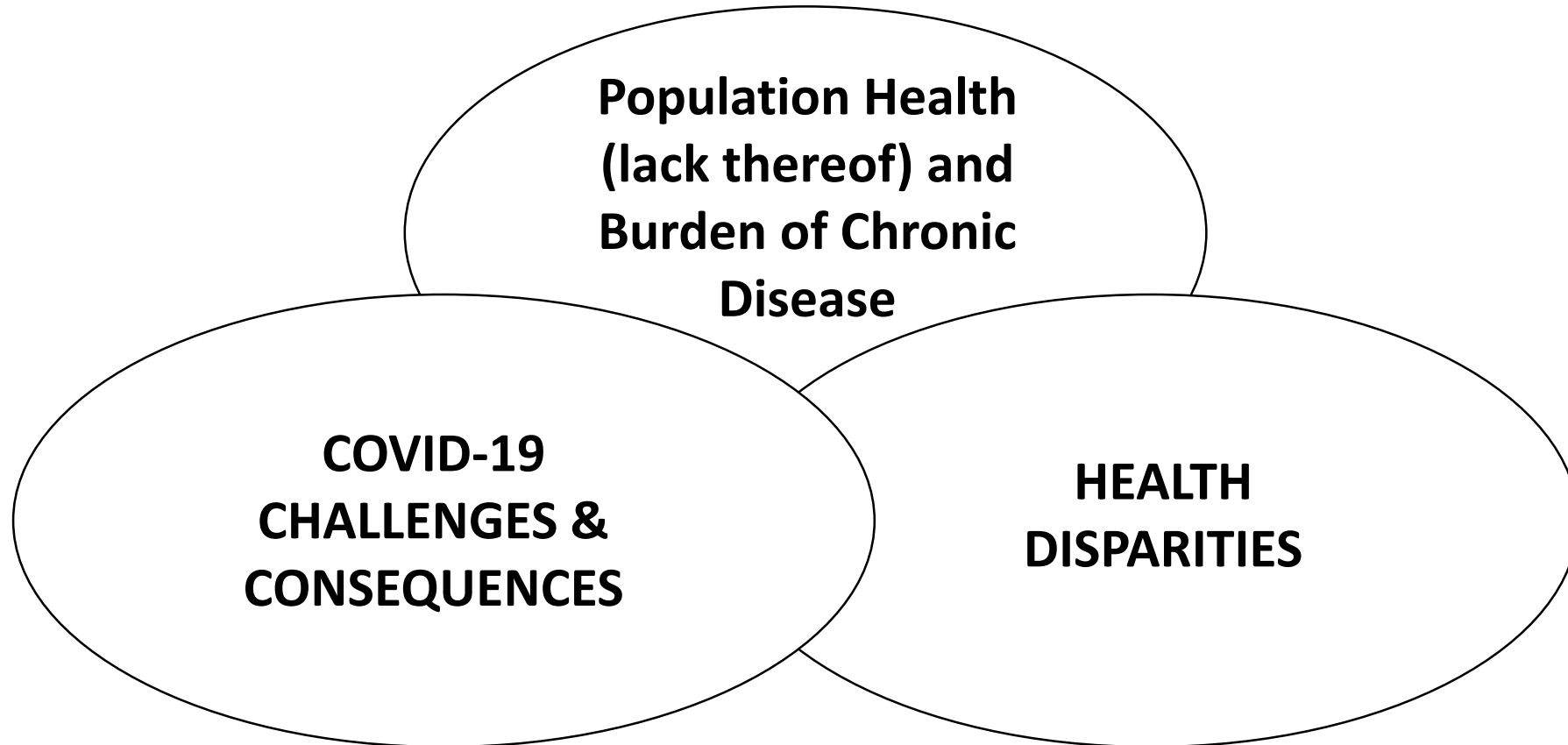
# Provisional Mortality Data, U.S., 2020

- CDC National Vital Statistics System
  - Heart Disease deaths #1
  - COVID-19 deaths #3
- Age-adjusted death rate increased by 15.9% in 2020
- Overall death rates highest in non-Hispanic Blacks and non-Hispanic American Indians and Alaska Natives
- COVID-19 death rate highest among Hispanics

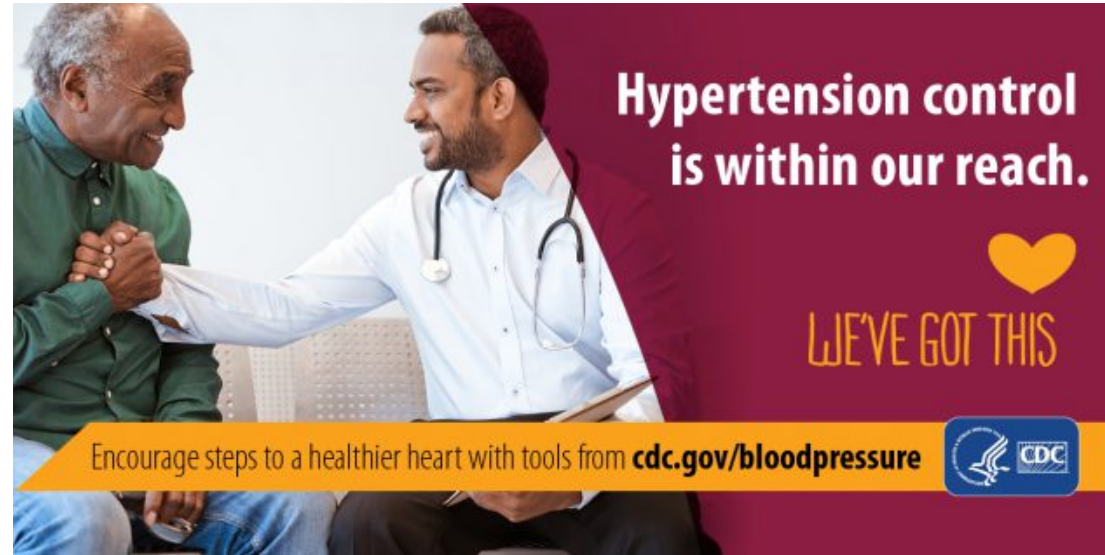


Ahmad FB, Cisewski JA, Miniño A, Anderson RN. Provisional Mortality Data — United States, 2020. *MMWR Morb Mortal Wkly Rep.* ePub: 31 March 2021.

# CONVERGING SYNDEMICS



# Join Us!



More on Million Hearts at <https://www.Millionhearts.hhs.gov>

Reach me at [LSperling@cdc.gov](mailto:LSperling@cdc.gov)

Twitter [@MillionHeartsUS](https://twitter.com/MillionHeartsUS)

<https://www.cdc.gov/bloodpressure>



# Evidence-Based Medication Adherence Strategies for Cardiovascular Disease Prevention

**Hilary Wall, MPH**

Senior Scientist/Million Hearts Science Lead  
Division for Heart Disease and Stroke Prevention  
Centers for Disease Control and Prevention

CMS VBID Webinar  
October 21, 2021



# Disclosures

No disclosures.

The opinions expressed by authors contributing to this project do not necessarily reflect the opinions of the US Department of Health and Human Services, the Public Health Service, the Centers for Disease Control and Prevention, or the authors' affiliated institutions. Use of trade names is for identification only and does not imply endorsement by any of the groups named below.



# Million Hearts<sup>®</sup> 2022

## Keeping People Healthy

Reduce Sodium Intake

Decrease Tobacco Use

Decrease Physical Inactivity

## Optimizing Care

Improve ABCS\*

Increase Use of Cardiac Rehab

Engage Patients in  
Heart-healthy Behaviors

## Improving Outcomes for Priority Populations

Blacks/African American people with hypertension

35- to 64-year-olds

People who have had a heart attack or stroke

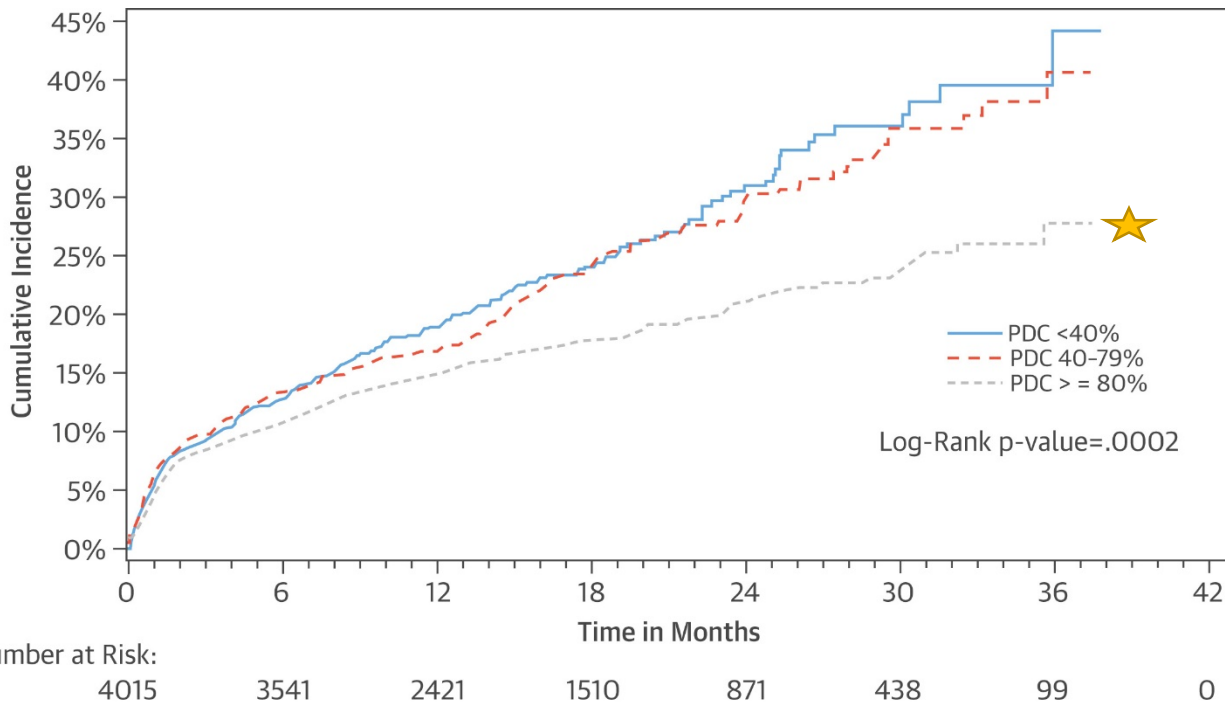
People with mental illness or substance use disorders who use tobacco



\*Aspirin when appropriate, Blood pressure control, Cholesterol management, Smoking cessation

# Medication Adherence and Cardiovascular Outcomes

## Lower Adherence Associated with Greater Risk of Major Adverse Cardiac Events

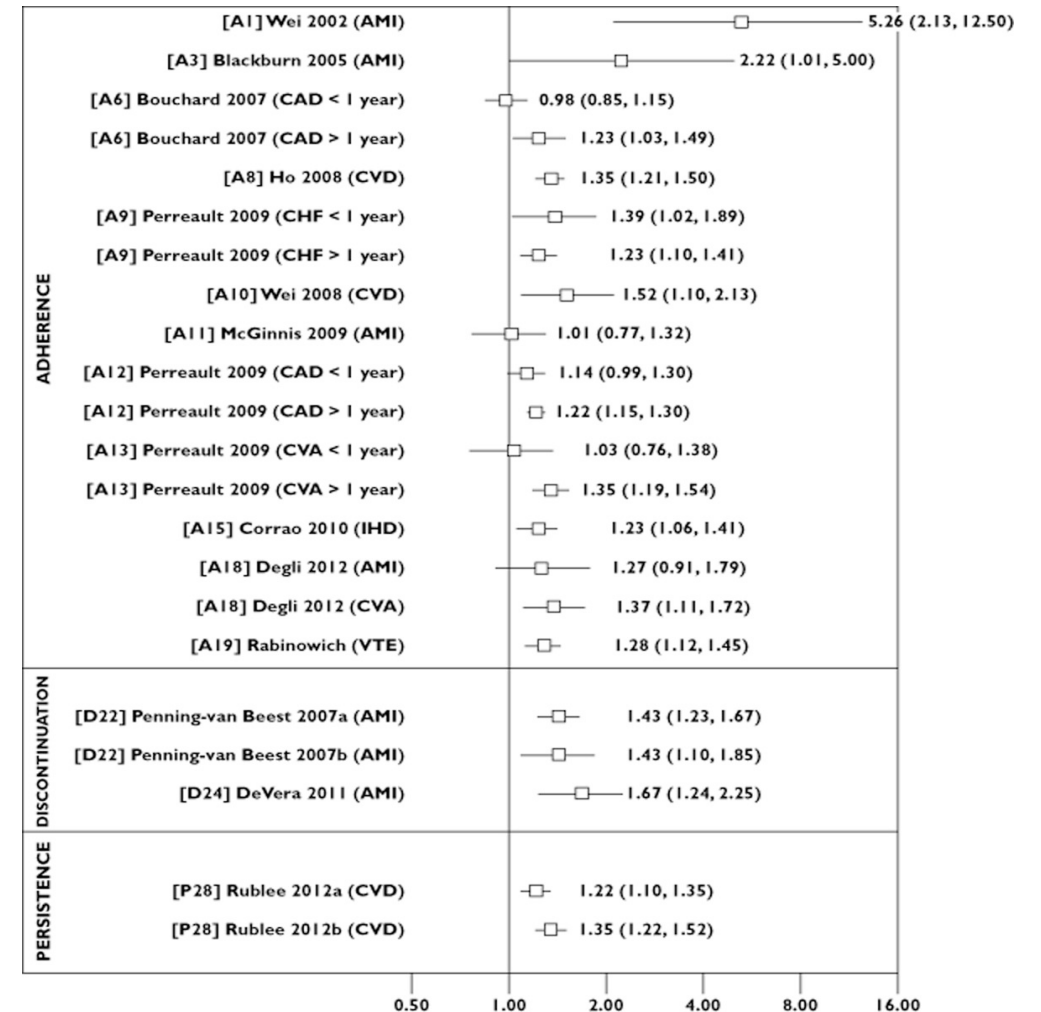


PDC = percentage of days covered. AMI, acute myocardial infarction; CAD, coronary artery disease; CHF, chronic heart failure; CVA, cerebrovascular accident; CVD, cardiovascular disease; IHD, ischemic heart disease; VTE, venous thromboembolism

Bansilal S, et al. Assessing the Impact of Medication Adherence on Long-Term Cardiovascular Outcomes. *J Am Coll Cardiol.* 2016;68(8):789-801

De Vera M, et al. Impact of statin adherence on cardiovascular disease and mortality outcomes: a systematic review. *Br J Clin Pharmacol.* 2014 Oct;78(4):684-98.

## Risk Estimates for the Association Between Statin Non-adherence and CVD Outcomes



# Huge Potential Opportunities

Issue	Burden
Hypertension Control	<p>Using <math>\geq 130/80</math> mmHg:</p> <ul style="list-style-type: none"><li>• ~45% prevalence among US adults <math>\rightarrow</math> ~108M adults</li></ul> <p>Of the 87M recommended to be on medications and lifestyle modifications:</p> <ul style="list-style-type: none"><li>• ~71% are uncontrolled <math>\rightarrow</math> ~61M adults<ul style="list-style-type: none"><li>– <b>33.6M uncontrolled and treated</b></li></ul></li></ul>
Cholesterol Management	<p>45.5% of people not using statins when indicated</p> <ul style="list-style-type: none"><li>• <math>\rightarrow</math> <b>39.1 M adults</b><ul style="list-style-type: none"><li>– Does not include people on statins who are not at goal % LDL reduction</li></ul></li></ul>



CDC. Hypertension Cascade: Hypertension Prevalence, Treatment and Control Estimates Among US Adults Aged 18 Years and Older Applying the Criteria From the American College of Cardiology and American Heart Association's 2017 Hypertension Guideline—NHANES 2015–2018. Atlanta, GA: US Department of Health and Human Services; 2019. <https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html>.  
Wall HK, et al. Vital Signs: Prevalence of Key Cardiovascular Disease Risk Factors for Million Hearts 2022 — 2011–2016. MMWR. 2018;67(35):983-991.



# Medication Adherence Challenges

Challenge	Potential Solution
• Affordability, lack of coverage	• Reduced/eliminated out-of-pocket costs
• Complexity	• Fixed-dose, single pill combinations • Once-per-day dosing
• Transportation	• Longer-duration prescriptions • Medication synchronization
• Understanding use and importance of medications • Forgetfulness	• Self-measured blood pressure monitoring • Beneficiary education • Beneficiary support – pill bottles, blister packs
• Cultural beliefs, (concerns for) side effects, cognitive limitations	• Beneficiary and family education

# Reduce/Eliminate Co-Pays

- The [Community Preventive Services Task Force](#) recommends reducing out-of-pocket-costs (ROPC)
  - 18 studies found strong evidence that ROPC improves medication adherence and blood pressure and cholesterol outcomes



The screenshot displays the 'The Community Guide' website interface. At the top, there is a navigation bar with the site logo and links for 'Topics', 'CPSTF', 'Publications & Resources', 'About', and 'GuideCompass'. A search bar is prominently featured below the navigation. The main content area is titled 'Systematic Review' and features a large, bold heading: 'Cardiovascular Disease: Reducing Out-of-Pocket Costs for Cardiovascular Disease Preventive Services for Patients with High Blood Pressure and High Cholesterol'. To the left of this heading, there is a sidebar with metadata including the topic, recommendation date, audience, setting, and strategy. Below the heading, there are four tabs: 'Snapshot', 'What the CPSTF Found', 'Supporting Materials', and 'Considerations for Implementation'. The 'Summary of CPSTF Finding' section is partially visible at the bottom of the page.

# High Value Generics Recommended to be Covered with No Cost Sharing

- [CMS's HHS Notice of Benefit and Payment Parameters for 2021 Final Rule](#)
- Suggests value-based plans cover 15 high-value generic drug classes with zero cost-sharing
- **6 of the 15 high value generic drug classes relate to CVD prevention**

---

## High-Value Generic Drug Classes with Zero-Cost Sharing

---

### **ACE inhibitors and ARBs**

Antidepressants

Antipsychotics

Antiresorptive therapy

Antiretrovirals

**Antithrombotics/anticoagulants**

**Beta blockers**

Buprenorphine-naloxone

**Glucose-lowering agents**

Inhaled corticosteroids

Naloxone

Rheumatoid arthritis medications

**Statins**

Thyroid-related

**Tobacco cessation treatments**



# Not All Statins Are Created Equally

	High-intensity	Moderate-intensity	Low-intensity
<b>LDL-C lowering</b>	≥50%	30%-49%	<30%
<b>Statins</b>	Atorvastatin (40mg‡) 80 mg Rosuvastatin 20 mg (40 mg)	Atorvastatin 10 mg (20mg) Rosuvastatin (5 mg) 10 mg Simvastatin 20-40 mg§	Simvastatin 10 mg
	...	Pravastatin 40 mg (80 mg) Lovastatin 40 mg (80 mg) Fluvastatin XL 80 mg Fluvastatin 40mg BID Pitavastatin 1-4 mg	Pravastatin 10-20 mg Lovastatin 20 mg Fluvastatin 20-40 mg

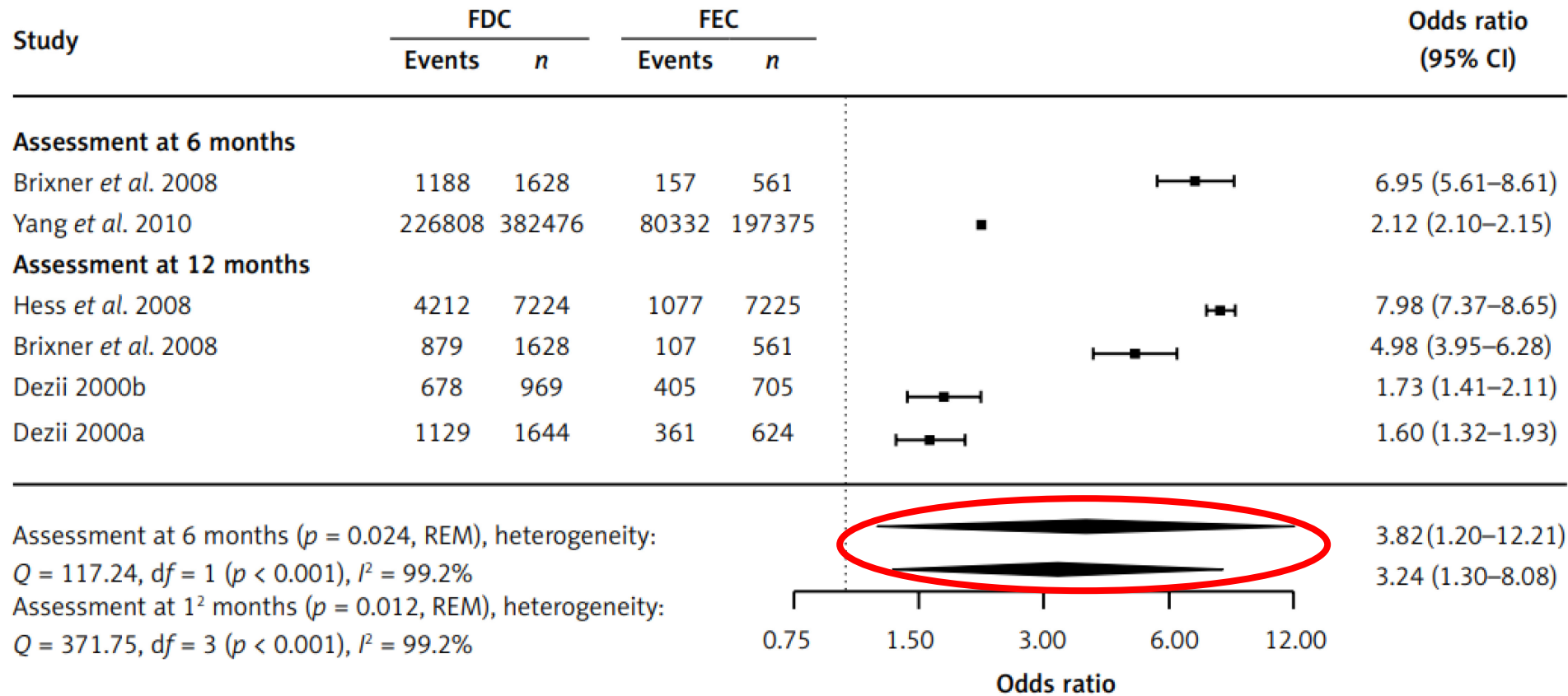


# Fixed-Dose/Single Pill Combination Medications

- 2017 AHA/ACC blood pressure guidelines recommend initial combination therapy for most
  - Yet ~40% of people with hypertension are on monotherapy
- Fixed-dose combinations (FDCs) – the combination of  $\geq 2$  medications in one pill
- FDCs were associated with a 14.9% absolute increase in mean adherence; 13.1% increase in the average medicine possession ratio

Tung YC, et al. J Clin Hypertens. 2017;19:983-989  
Derington CG, et al. Hypertension. 2020;75:973–81.  
An J, et al. Curr Hypertens Rep. 2020 Oct 14;22(11):95.  
Benjamin IJ, et al. Lancet. 2019;394(10199):637-638.  
Kawalec P, et al. Arch Med Sci. 2018 Aug;14(5):1125-1136.  
Parati G, et al.. Hypertension. 2021 Feb;77(2):692-705.

# FDCs vs. Free-Equivalent Combinations (FECs)



- FDCs more likely to support medication persistence at 6- and 12-months of follow up

**Figure 4.** Meta-analysis of persistence. Events represent the number of patients meeting the definition of persistence. Odds ratio (OR) presented for FDC in comparison with FEC, with 95% confidence intervals (CI)

# FDCs of the Future?

- Quadruple combination single pill for hypertension control
- RCT vs. standard monotherapy:
  - Lower BP and better HTN control in the intervention group at 12- and 52-weeks
- SPRINT suggests 32% and 24% of patients will need at least three and four antihypertensives, respectively for <120/80 mmHg

Articles

## Initial treatment with a single pill containing quadruple combination of quarter doses of blood pressure medicines versus standard dose monotherapy in patients with hypertension (QUARTET): a phase 3, randomised, double-blind, active-controlled trial



Clara K Chow, Emily R Atkins, Graham S Hillis, Mark R Nelson, Christopher M Reid, Markus P Schlaich, Peter Hay, Kris Rogers, Laurent Billot, Michael Burke, John Chalmers, Bruce Neal, Anushka Patel, Tim Usherwood, Ruth Webster, Anthony Rodgers, on behalf of the QUARTET Investigators

### Summary

**Background** Treatment inertia is a recognised barrier to blood pressure control, and simpler, more effective treatment strategies are needed. We hypothesised that a hypertension management strategy starting with a single pill containing ultra-low-dose quadruple combination therapy would be more effective than a strategy of starting with monotherapy.

**Methods** QUARTET was a multicentre, double-blind, parallel-group, randomised, phase 3 trial among Australian adults (≥18 years) with hypertension, who were untreated or receiving monotherapy. Participants were randomly assigned to either treatment, that started with the quadpill (containing irbesartan at 37.5 mg, amlodipine at 1.25 mg, indapamide at 0.625 mg, and bisoprolol at 2.5 mg) or an indistinguishable monotherapy control (irbesartan 150 mg). If blood pressure was not at target, additional medications could be added in both groups, starting with amlodipine at 5 mg. Participants were randomly assigned using an online central randomisation service. There was a 1:1 allocation, stratified by site. Allocation was masked to all participants and study team members (including investigators and those assessing outcomes) except the manufacturer of the investigational product and one unmasked statistician. The primary outcome was difference in unattended office systolic blood pressure at 12 weeks. Secondary outcomes included blood pressure control (standard office blood pressure <140/90 mm Hg), safety, and tolerability. A subgroup continued randomly assigned allocation to 12 months to assess long-term effects. Analyses were per intention to treat. This trial was prospectively registered with the Australian New Zealand Clinical Trials Registry, ACTRN12616001144404, and is now complete.

Published Online  
August 25, 2021  
[https://doi.org/10.1016/S0140-6736\(21\)01922-X](https://doi.org/10.1016/S0140-6736(21)01922-X)  
Westmead Applied Research Centre, Faculty of Medicine and Health, University of Sydney, Sydney, NSW, Australia (Prof C K Chow PhD, E R Atkins PhD, Prof T Usherwood MD); The George Institute for Global Health, UNSW, Sydney, NSW, Australia (E R Atkins, K Rogers PhD, L Billot MSc, Prof J Chalmers MD); Prof B Neal PhD, Prof A Patel PhD, Prof T Usherwood, R Webster PhD, Prof A Rodgers PhD; Royal Perth Hospital and Medical School (Prof G S Hillis PhD), and Doonay Hypertension Centre, Royal Perth Hospital Research

# Once-per-day Dosing

- Once-daily vs. twice-daily
- One systematic review of nine studies of antihypertensives showed relative improvement in adherence from 8% to 19.6%
- Also pertinent to broader classes of cardiovascular disease meds

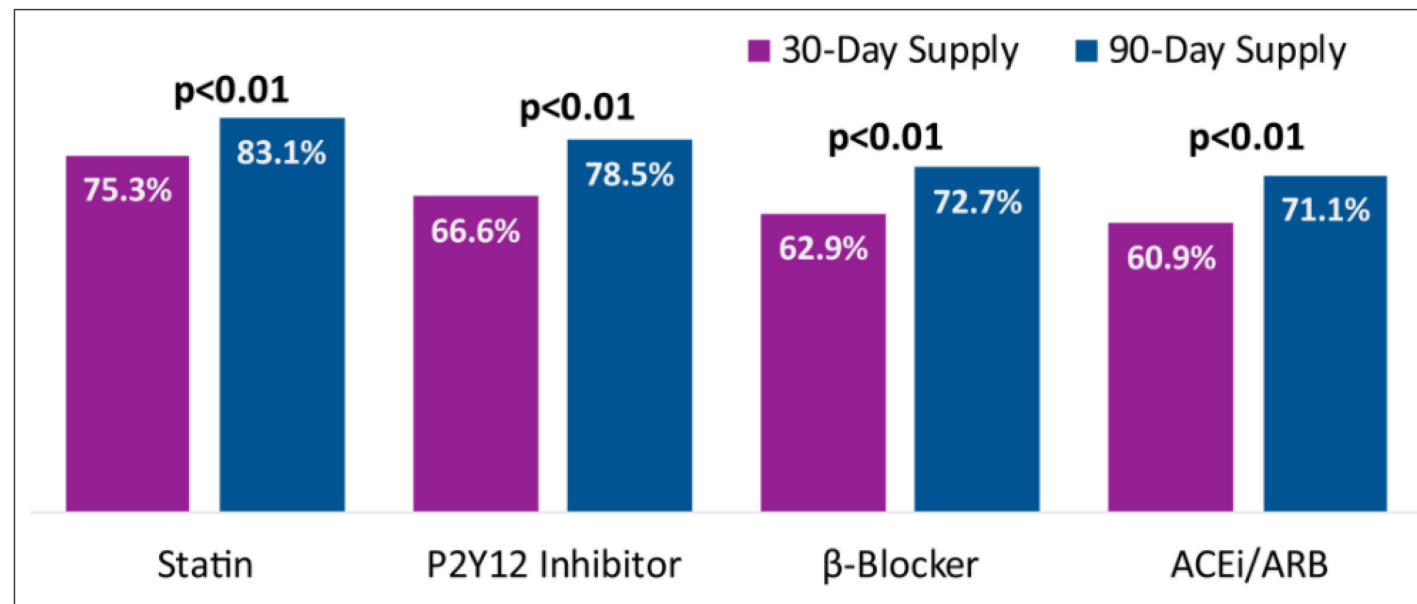


Weeda ER, et al. Impact of once- or twice-daily dosing frequency on adherence to chronic cardiovascular disease medications: A meta-regression analysis. *Int J Cardiol.* 2016 Aug 1;216:104-9.  
Schroeder K, et al. *Cochrane Database of Systematic Reviews* 2004, Issue 3. Art. No.: CD004804.



# Days Supplied Per Fill

- Longer duration prescriptions (90-days vs 30-days) can reduce burden of monthly refill
- Analysis of MI patients from National Cardiovascular Data Registry found medication adherence was significantly higher for 90-day vs 30-day refills

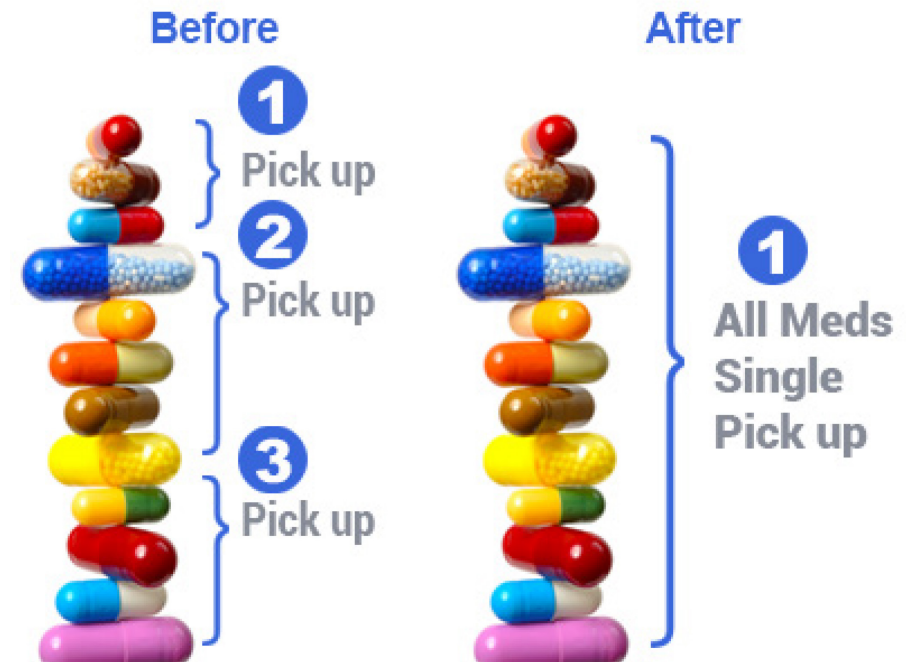


**Figure 1.** Adherence by evidence-based medication class and prescription days' supply at 12 months. ACEi indicates angiotensin-converting enzyme inhibitors; and ARBs, angiotensin receptor blockers.

# Medication Synchronization

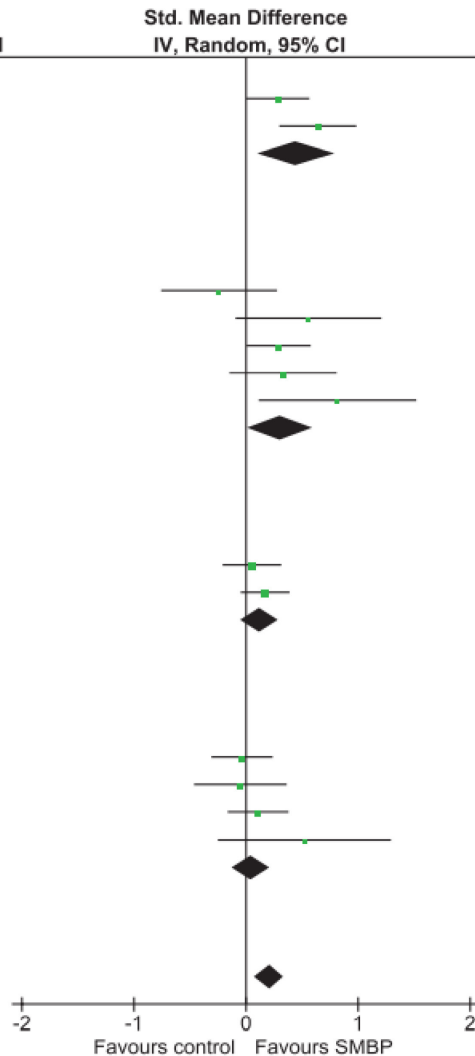
- Having all of a beneficiary's medications refilled at the same time (e.g., monthly or quarterly fill date)
- Among Medicare Advantage recipients, larger proportion of synchronized refill group were adherent for antihypertensives (6% higher) and statins (15% higher) compared to control

## Medication Synchronization



# Self-Measured Blood Pressure (SMBP) and Medication Adherence

Study or Subgroup	SMBP		Control		Std. Mean Difference		Weight	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total		
<b>1.1.1 Electronic monitoring</b>								
Marquez-Contreras 2006	89.4	15.2	100	83.7	23.6	100	10.5%	0.29 [0.01, 0.56]
Rudd 2004	80.5	23	69	62.9	31.1	68	8.4%	0.64 [0.30, 0.98]
<b>Subtotal (95% CI)</b>			<b>169</b>			<b>168</b>	<b>18.8%</b>	<b>0.45 [0.10, 0.79]</b>
Heterogeneity: Tau <sup>2</sup> = 0.04; Chi <sup>2</sup> = 2.47, df = 1 (P = 0.12); I <sup>2</sup> = 59% Test for overall effect: Z = 2.54 (P = 0.01)								
<b>1.1.2 Pill count</b>								
Bailey 1999	88	27.4	30	94	21.2	28	4.8%	-0.24 [-0.76, 0.28]
Haynes 1976	65.8	36.7	20	43.2	42.9	18	3.4%	0.56 [-0.09, 1.21]
Hosseininasab 2014	99	5	94	97.8	3	96	10.2%	0.29 [0.00, 0.58]
Johnson 1978	78	31.5	34	65.5	42.6	34	5.4%	0.33 [-0.15, 0.81]
McKenney 1992	100.2	7	17	93.6	8.7	17	2.9%	0.82 [0.11, 1.52]
<b>Subtotal (95% CI)</b>			<b>195</b>			<b>193</b>	<b>26.8%</b>	<b>0.30 [0.01, 0.59]</b>
Heterogeneity: Tau <sup>2</sup> = 0.04; Chi <sup>2</sup> = 6.87, df = 4 (P = 0.14); I <sup>2</sup> = 42% Test for overall effect: Z = 2.04 (P = 0.04)								
<b>1.1.3 Pharmacy fill</b>								
Magid 2011	0.85	0.19	112	0.84	0.19	112	11.1%	0.05 [-0.21, 0.31]
Stewart 2014	0.94	0.35	174	0.89	0.21	151	12.8%	0.17 [-0.05, 0.39]
<b>Subtotal (95% CI)</b>			<b>286</b>			<b>263</b>	<b>23.9%</b>	<b>0.12 [-0.05, 0.29]</b>
Heterogeneity: Tau <sup>2</sup> = 0.00; Chi <sup>2</sup> = 0.46, df = 1 (P = 0.50); I <sup>2</sup> = 0% Test for overall effect: Z = 1.42 (P = 0.15)								
<b>1.1.4 Self report</b>								
Bove 2013	3.56	0.81	99	3.59	0.85	107	10.6%	-0.04 [-0.31, 0.24]
Green 2014	0.1	2	44	0.2	1.9	46	6.7%	-0.05 [-0.46, 0.36]
Wakefield 2012	99.8	1.4	102	99.6	2.2	107	10.7%	0.11 [-0.16, 0.38]
Zarnke 1997	6.95	0.2	20	6.8	0.4	10	2.5%	0.52 [-0.25, 1.29]
<b>Subtotal (95% CI)</b>			<b>265</b>			<b>270</b>	<b>30.5%</b>	<b>0.05 [-0.13, 0.22]</b>
Heterogeneity: Tau <sup>2</sup> = 0.00; Chi <sup>2</sup> = 2.21, df = 3 (P = 0.53); I <sup>2</sup> = 0% Test for overall effect: Z = 0.52 (P = 0.60)								
<b>Total (95% CI)</b>			<b>915</b>			<b>894</b>	<b>100.0%</b>	<b>0.21 [0.08, 0.34]</b>
Heterogeneity: Tau <sup>2</sup> = 0.02; Chi <sup>2</sup> = 20.88, df = 12 (P = 0.05); I <sup>2</sup> = 43% Test for overall effect: Z = 3.11 (P = 0.002) Test for subgroup differences: Chi <sup>2</sup> = 5.47, df = 3 (P = 0.14), I <sup>2</sup> = 45.1%								



- Systematic review and meta-analysis showed that SMBP interventions had a small but significant impact on medication adherence
- More information about the value of SMBP and ways to optimize SMBP use: [Million Hearts: Value-Based Insurance Design Opportunities for Cardiovascular Disease Prevention and Management](#) webinar recording (Access Passcode: iG2M7\$^N).

# Beneficiary Education

- Opportunities for beneficiary and/or family/caregiver education and support?
  - Newsletters
  - Emails
  - Pill boxes
  - Access to pre-packaged medication solutions (e.g., Amazon PillPack)
  - Incentives



# Resources



# Hot Off the Presses

Choudhry NK, et al. **Medication Adherence and Blood Pressure Control: A Scientific Statement From the American Heart Association.** Hypertension. 2021 Oct 7:Epub ahead of print. PMID: 34615363.

**Table 4. Strategies for Improving Antihypertensive Medication Adherence Categorized by Key Stakeholder**

Intervention strategy	Stakeholder			
	Patient	Clinician network	Pharmacy	Health insurer
Patient education		X	X	X
Pharmacist consultation		X	X	X
Motivational interviewing		X	X	X
Dose consolidation		X		
Refill reminders			X	X
Text message reminders	X	X	X	X
Electronic monitoring and feedback	X	X	X	
Medication refill synchronization			X	X
SMBP	X	X		X
Patient financial incentives		X		X

SMBP indicates self-monitoring of blood pressure.



# Hypertension Control Change Package

## 2<sup>nd</sup> Edition, 2020

**Million Hearts®**

**A MILLION HEARTS® ACTION GUIDE**

**Hypertension Control**

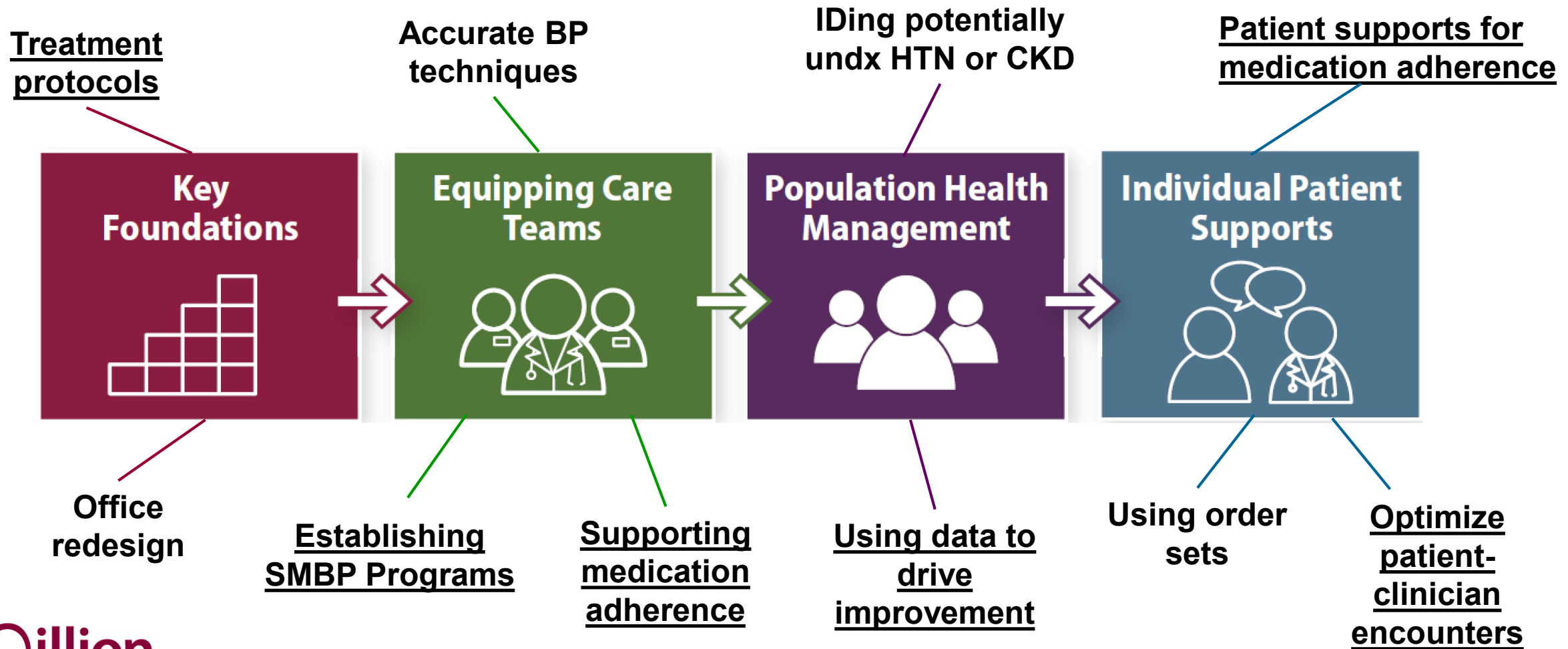
**CHANGE PACKAGE**

Second Edition

Table 1. Key Foundations (continued)		
Change Concept	Change Idea	Tools and Resources
Implement a Policy or Process to Address BP for Every Patient with HTN at Every Visit	Manage resi	<ul style="list-style-type: none"> <li>• NYC Health &amp; Hospitals — Adult Hypertension Clinical Practice Guidelines: <a href="#">Treatment of Resistant Hypertension</a></li> <li>• Zuffall Health — Guidelines for Screening, Diagnosis and Management of Hypertension (pp. 12–13)</li> <li>• Resistant Hypertension: Detection, Evaluation, and Management: A</li> </ul>
	Evaluate all   with HTN for diagnose an if appropriat	
Table 2. Equipping Care Teams		
Change Concept	Change Idea	Tools and Resources
Train and Evaluate Direct Care Staff on Accurate BP Measurement and Documenting	Adopt a clinician/staff training policy to train and retrain staff	<ul style="list-style-type: none"> <li>• AMGF — Measure Up Pressure Down Provider Toolkit to Improve Hypertension Control: <a href="#">Plank 1, Tool 9: Blood Pressure Champion and CDS Education and Auditing Process for New Staff</a>, <b>HealthPartners</b></li> </ul>
	Provide guidance on measuring BP accurately	<ul style="list-style-type: none"> <li>• <b>Cheshire Medical Center/Dartmouth-Hitchcock</b> — Obtaining Accurate Blood Pressure Measurements in the Ambulatory Setting: How Do You Size a Blood Pressure Cuff? (pp. 14–19)</li> <li>• Target: BP — <a href="#">Blood Pressure Measurement: Measure Accurately</a></li> <li>• Target: BP — <a href="#">7 Simple Tips to Get an Accurate Blood Pressure Reading</a></li> <li>• AHA — <a href="#">The Importance of Measuring Blood Pressure Accurately Webinar</a> [video] (CE credits)</li> <li>• AMGF — Measure Up Pressure Down Provider Toolkit to Improve Hypertension Control: <a href="#">Plank 1, Tool 11: Blood Pressure Accuracy and Variability Quick Reference</a>, <b>HealthPartners</b></li> <li>• AMGF — Measure Up Pressure Down Provider Toolkit to Improve Hypertension Control: Plank 1: Tool 7: <a href="#">How to Take Blood Pressure Properly</a> [video] <ul style="list-style-type: none"> <li>– <a href="#">How to Take Blood Pressure Properly: The Wrong Way</a>, <b>Cornerstone Health Care</b> (now Wake Forest Baptist Health) [video]</li> <li>– <a href="#">How to Take Blood Pressure Properly: The Right Way</a>, <b>Cornerstone Health Care</b> (now Wake Forest Baptist Health) [video]</li> </ul> </li> <li>• AMGF — Measure Up Pressure Down Provider Toolkit to Improve Hypertension Control: Plank 1: Tool 14: <a href="#">Accurate Blood Pressure Measurement</a>, <b>Premier Medical Associates</b> [video]</li> <li>• <a href="#">Table 8. Checklist for Accurate Measurement of BP</a>. 2017 ACC/AHA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Whelton PK, et al. 2017.</li> </ul>

Access the Change Package at:  
<https://millionhearts.hhs.gov/tools-protocols/action-guides/htn-change-package/index.html>

# Focus Areas





# Questions?

Hilary Wall – [hwall@cdc.gov](mailto:hwall@cdc.gov)



# Engaging Pharmacists in Strategies to Improve Medication Adherence

Nicole Therrien, PharmD, MPH

ASRT, Inc.

Applied Research and Evaluation Branch

Division for Heart Disease and Stroke Prevention

# Tailored Pharmacy-Based Interventions to Improve Medication Adherence

The Community Guide

Topics CPSTF Publications & Resources About GuideCompass

Search The Community Guide search the guide Search

Home » Topic » Cardiovascular Disease

Heart Disease and Stroke Prevention

Research » Research & Reports » The Community Guide Resources

## Cardiovascular Disease

Cardiovascular disease (CVD) refers to several types of conditions that affect the heart and blood vessels. Many CVD risk factors such as high blood pressure, high cholesterol, excess weight, poor diet, smoking, and diabetes can be prevented or treated through health behavior change and appropriate medication (CDC).

### Task Force Findings

Displaying 1 - 5 of 12

[Cardiovascular Disease: Tailored Pharmacy-based Interventions to Improve Medication Adherence](#)

Recommended (strong evidence) | Completed April 2019

Cardiovascular Disease

## Tailored Pharmacy-Based Interventions to Improve Medication Adherence

In [The Community Guide](#), the Community Preventive Services Task Force (CPSTF) recommends [tailored pharmacy-based interventions](#) to support adherence to medications prescribed to prevent cardiovascular disease (CVD).<sup>1</sup> The CPSTF found these interventions to be cost-effective for preventing CVD.<sup>1</sup>

The Surgeon General's 2020 [Call to Action to Control Hypertension](#) also encourages the use of supportive strategies for medication adherence, including pharmacists as integral members of hypertension care teams.<sup>2</sup>

Public health practitioners and state and local health departments can support use of the CPSTF recommendation by promoting and helping pharmacies implement tailored pharmacy-based interventions.

On This Page

- Strategies
- Considering the Costs and Benefits of Implementation
- CDC and Partner Tools and Resources
- Stories From the Field
- References

For more information, visit the [The Community Guide](#) and the [Community Preventative Services Task Force Review](#)

# Medication Therapy Management (MTM)

- A **broad range** of professional activities performed by pharmacists to ensure that patients are achieving **optimal therapeutic outcomes**.
- MTM can reduce total healthcare costs.
- MTM can improve clinical outcomes.



# Medicare Part D Medication Therapy Management Program (MTMP)

- Eligible Beneficiaries
- Scope of MTM Services
  - Comprehensive Medication Review (CMR)
  - Targeted Medication Review (TMR)
  - Documentation and Follow-up

# Summary

Pharmacists are trained to identify and resolve issues related to medications, including patient-specific barriers to medication adherence



# Additional Resources

- Medication Adherence Resources
  - [Medication Adherence | Million Hearts® \(hhs.gov\)](#)
  - [Cardiovascular Health Medication Adherence: Action Steps for Health Benefit Managers \(hhs.gov\)](#)
  - [Tailored Pharmacy-Based Interventions to Improve Medication Adherence | cdc.gov](#)
  - [Pharmacy Resources | cdc.gov](#)
- Cholesterol Management
  - Million Hearts® Learning Lab - [NACHC Million Hearts Learning Lab: Cholesterol Management/Optimal Use of Statin Therapy \(09.15.2021\) – YouTube](#) (Register for the series [here](#))
  - [Cholesterol Management | Million Hearts® \(hhs.gov\)](#)
- CDC Public Health Grand Rounds - [Overcoming Barriers to Medication Adherence for Chronic Diseases | Public Health Grand Rounds | CDC](#)
  - [CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities | MMWR](#)



# Questions?

**Please enter your questions in the Q&A.**

***(Please do not enter questions in the chat.)***



**Thank you for joining us today!**

Please email us with questions or to discuss your interests at  
[VBID@cms.hhs.gov](mailto:VBID@cms.hhs.gov)