

GGT			
HbA1C			1
FBS/Glucose			
Lipid Profile			
- Cholesterol	220	mg/dL	1
- Triglyceride	170	mg/dL	
- HDL-C	40	mg/dL	
- LDL-C	146	mg/dL	
Total protein		g/dL	

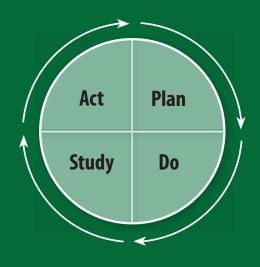


A MILLION HEARTS® ACTION GUIDE

Cholesterol Management

CHANGE PACKAGE

March 2024





The Million Hearts® Cholesterol Management Change Package was originally conceptualized and authored by Hilary K. Wall, MPH*; Lauren Owens, MPH (IHRC, Inc.)*; Angela Ryan Lee, MD, FACC; Taylor Streeter, MPH (ASRT, Inc.)*; Meg Meador, MPH, C-PHI, CPHQ†; Michael Rakotz, MD, FAHA, FAAFP†; Kate Kirley, MD, MS†; Linda Murakami, RN, BSN, MSHA†; and Brent Egan, MD.†

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Individual health care settings are shown in **bold** font.

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Cholesterol Management Change Package—Quick Reference

Focus Areas



Change Concepts and Change Ideas

Key Foundations

Make Cholesterol Management a Practice or System Priority >>

Designate a cholesterol champion in the practice

Engage care team in cholesterol management

Create a lipid clinic

Expand the care team

Implement a Policy and Process to Address Dyslipidemia for Every Patient With High Cholesterol at Every Visit >>

Develop policies and procedures to reflect prioritization of cholesterol management

Develop a flowchart/workflow for proactively tracking and managing patients for cholesterol management

Deploy cholesterol management treatment protocols and algorithms

Equipping Care Teams

Train Direct Care Staff on Cholesterol Management >>

Provide training on clinical guidelines

Provide guidance on cholesterol screening (including fasting vs. nonfasting)

Provide guidance on assessing for secondary causes of dyslipidemia

Provide guidance on statin-associated side effects

Provide guidance on atherosclerotic cardiovascular disease (ASCVD) risk estimation

Overcome diagnostic and treatment inertia

Provide guidance on appropriate use of nonstatin therapies

Provide guidance on familial hypercholesterolemia (FH)

Optimize Lipid Panel Procedures >>>

Redesign electronic health record (EHR) lab order template to include fasting and nonfasting lipid panels

Implement point-of-care lipid testing

Equip Direct Care Staff to Facilitate Patient Self-Management >>

Ensure the care team is skilled in supporting patient medication adherence

Prepare the Care Team Beforehand for Effective Cholesterol Management During Office Visits >>

Use a flowchart or dashboard with care gaps highlighted in team huddles to help care teams better support patients

Implement pre-visit planning into workflows and use clinical decision support tools to ensure that indicated orders/actions occur during the visit

Equip Care Teams to Provide Appropriate Medications >>

Facilitate patient access to statin therapies as appropriate

Facilitate patient access to nonstatin therapies as appropriate

Use protocols and follow up with patients to find a statin that works (SASE work-around, generic vs. brand, etc.)

Population Health Management

Identify Patients at High Risk for an ASCVD Event Who Could Benefit From a Statin >>

Use guideline-based clinical criteria to define high-risk patients who could benefit from statin use

Search EHR data for patients who meet the guideline-based clinical criteria

Implement a plan to ensure high-risk patients are on a statin

Identify Patients With Potentially Undiagnosed Familial Hypercholesterolemia (FH) >>

Screen patients for FH; conduct cascade screening and genetic testing as appropriate

Use EHR data and algorithms/predictive analytics to find patients with potentially undiagnosed FH

Ensure Accurate Coding and Diagnosis >>

Assess problem list diagnosis codes for use of "pure hypercholesterolemia"; recode to hyperlipidemia as appropriate

Use a Registry to Track and Manage High-Risk Patients Who Could Benefit From Statin Use \gg

Implement a cholesterol management registry

Use a defined process for outreach (e.g., via phone, mail, email, text message) to patients who could benefit from statin use and those otherwise needing follow-up

Use Clinician-Managed Protocols for Medication Adjustments and Lifestyle Recommendations >>

Use protocols to cover proactive outreach driven by registry use

Use Practice Data to Drive Improvement >>

Determine cholesterol management and related process metrics for the practice

Regularly provide a dashboard with cholesterol goals, metrics, and performance; consider stratification by demographics or comorbidities

Individual Patient Supports

Prepare Patients Before the Office Visit via Pre-Visit Patient Outreach >>

Contact patients to confirm upcoming appointments and provide instructions on how to prepare for their visit

Optimize Patient Intake to Support Cholesterol Management >>

Provide patients with educational materials to help them understand the benefits of cholesterol management, including statins

Provide patient support for cholesterol screening

Provide cholesterol management educational material specific to women

Provide patients with tools to support their visit agenda and goal setting

Reconcile medications that the patient is taking with the record's medication list

Optimize the Patient-Clinician Encounter >>

Use documentation templates to help capture key data, such as patient treatment goals and barriers to adherence

Use order sets and standing orders to support evidence-based and individualized care

Assess individual risk and therapy impact

Address patient-specific risk factors and medication adherence through motivational interviewing, shared decision making, and "teach back"

Assess patients' social drivers/determinants of health

Support Patients in Cholesterol Self-Management During Their Routine Daily Activities >>

Provide patient supports for medication adherence

Provide patient supports on what to do if they experience statin-associated side effects

Provide patient supports for tobacco cessation

Provide patient supports for increasing physical activity

Provide patient supports for dietary changes

Provide patient supports related to non-evidence-based supplements

Provide patient supports related to secondary causes of hyperlipidemia

Provide patient supports related to FH

Optimize the Encounter Closing >>

Provide patients with a written self-management plan, visit summary, and follow-up guidance at the end of each visit

Follow Up to Monitor and Reinforce Cholesterol Management Plans >>

Create a protocol to simplify the prescription refill process

Implement frequent follow-ups (e.g., email, phone calls, text messages) with patients to make sure they are continuing their medication

What Is the Cholesterol Management Change Package?

The Cholesterol Management Change Package (CMCP) presents a listing of evidence-based process improvements that outpatient clinical settings can implement as they seek optimal cholesterol management. It is composed of change concepts, change ideas, and evidence- or practice-based tools and resources.

- **Change concepts** are general notions that are useful in the development of more specific ideas for changes that lead to improvement.
- Change ideas are specific, actionable ideas for changing a process. Change ideas can be rapidly tested on a small scale to determine whether they result in improvements in the local environment.
- Within each change idea, the CMCP lists evidence- or practice-based tools and **resources** that can be adapted or adopted in a health care setting to improve cholesterol management.

While the science behind cardiovascular risk reduction is continually evolving, there is strong evidence that a systematic approach to cholesterol management can significantly improve cholesterol-related care processes and outcomes. The purpose of the CMCP is to help health care practices put systems in place to care for patients with dyslipidemia more efficiently and effectively.

Cholesterol Management Guideline and Patient Management Groups

The 2018 American Heart Association (AHA)/ American College of Cardiology (ACC) multisociety Guideline on the Management of Blood Cholesterol specifies indications for screening, identifies groups that benefit from cholesterol-lowering therapies, and emphasizes the importance of shared decision making between patients and their clinicians.1 Identifying patients appropriate for screening and treatment can serve as a starting point for targeted quality improvement efforts to improve cholesterol management at a population level.

Screening for Dyslipidemia

Screening for dyslipidemia may be performed with a nonfasting lipid panel. The current guideline recommends that adults age 20 or older undergo screening and atherosclerotic cardiovascular disease (ASCVD) risk assessment every 4 to 6 years. 1 More frequent assessment is reasonable in those with risk factors or borderline cholesterol levels.

> Identifying patients appropriate for screening and treatment can serve as a starting point for targeted quality improvement efforts to improve cholesterol management at a population level.

Treatment of Dyslipidemia

In addition to lifestyle modification, statins are the cornerstone pharmacologic intervention in cholesterol management. Statins are cost-effective, with well-proven safety and cardiovascular morbidity and mortality benefit in those with or at risk of ASCVD. Four patient groups have been identified as having high risk for ASCVD events and receiving benefit from statin therapy:1

- History of clinical ASCVD
- Severe hypercholesterolemia (LDL ≥ 190 mg/dL)
- Ages 40–75 with diabetes mellitus
- Ages 40–75 without diabetes and with a 10-year risk of at least 20%

The guideline also reinforces the need for appropriate statin intensity. See <u>Table 1</u> for statin intensity and expected lipid lowering.

Additional cholesterol-lowering therapies, such as ezetimibe and PCSK9 inhibitors, are indicated in certain patients at high risk for ASCVD, as detailed in the cholesterol management guideline.¹ Other agents, such as bempedoic acid or inclisiran, may also be appropriate for specific patients. Nonstatin therapies are typically used in combination with maximally tolerated statin therapy or as an alternative therapy in the uncommon event of serious statin-associated side effects (SASE).²-³

Table 1. Statin Intensity Chart¹

Statin Intensity	LDL-C Lowering Capability	Primary Statins	Secondary Statins*
HIGH	≥50%	Atorvastatin, 40-80 mg Rosuvastatin, 20 mg	N/A
MODERATE	30-49%	Atorvastatin, 10 mg Rosuvastatin, 10 mg Simvastatin, 20-40 mg	Pravastatin, 40 mg Lovastatin, 40 mg Fluvastatin, XL 80 mg Fluvastatin, 40 mg BID Pitavastatin, 1-4 mg
LOW	<30%	Simvastatin, 10 mg	Pravastatin, 10-20 mg Lovastatin, 20 mg Fluvastatin, 20-40 mg

^{*}As delineated in the 2018 clinical guideline, LDL-C lowering capacity for primary statins was derived from the VOYAGER database. LDL-C lowering capacity of secondary statins was derived from FDA-approved product labeling.

Statin-Associated Side Effects

Concern about SASE is the most common reason for statin nonadherence. The most common SASE include statin-associated muscle symptoms (SAMS). In clinical practice, subjective myalgia is reported in up to 20% of patients on statins, a higher rate than is attributed to statins compared with placebo in randomized controlled trials. Many of these subjective muscle symptoms appear to be driven by the "nocebo effect," in which the expectation of side effects is manifested with the ingestion of a pill, regardless of whether an active drug is present. Randomized trials have demonstrated that both placebo and statin elicit similar rates of muscle symptoms.4-6 Subjective myalgia can often be successfully managed with rechallenge, dose adjustment, or trial of a different statin.

Rarer SAMS include those with objective evidence of muscle injury, such as myositis, rhabdomyolysis, and statin-associated autoimmune myopathy. Other uncommon SASE include new-onset diabetes in susceptible patients, elevated transaminases, and hepatic failure. Although some case reports suggest an effect on memory and cognition, larger randomized controlled trials have not supported this.

Areas for Quality Improvement

Focusing initial quality improvement initiatives on appropriate dyslipidemia screening and prescribing high-intensity statins in the highestrisk groups will have the greatest impact on cholesterol management. Patients who either do not have a recent documented lipid panel or fall in a patient management group known to benefit from statins but are not on statin therapy may be considered as "hiding in plain sight." These patients may be easily identified within a practice or system's EHRs and targeted for recall

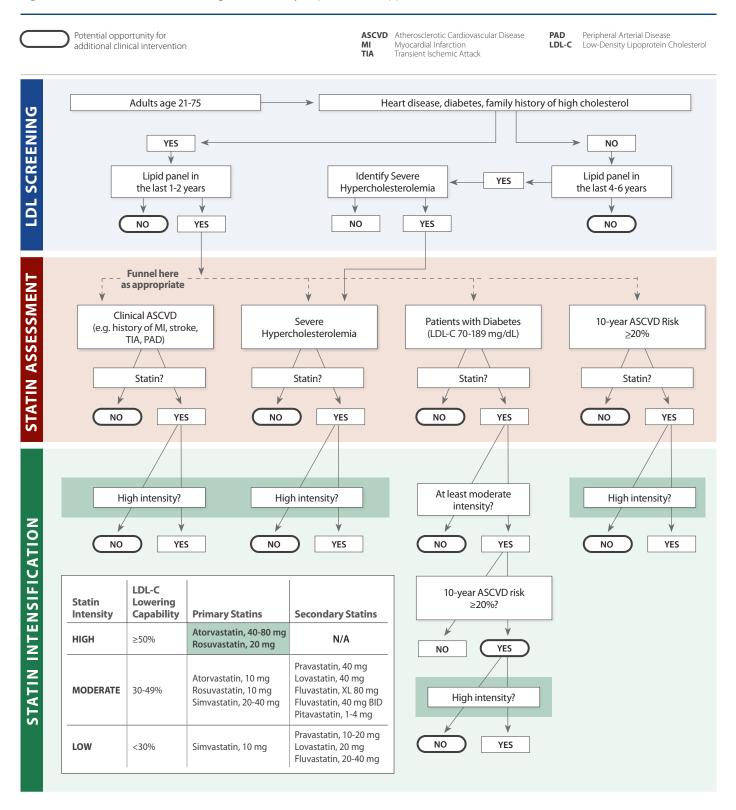
In clinical practice, subjective myalgia is reported in up to 20% of patients on statins, a higher rate than is attributed to statins compared with placebo in randomized controlled trials. Many of these subjective muscle symptoms appear to be driven by the "nocebo effect," in which the expectation of side effects is manifested with the ingestion of a pill, regardless of whether an active drug is present.

and intervention (Figure 1). Surveillance data suggest that there are 24.2 million people in the United States who are recommended to take a statin but are not currently taking one.7

After appropriate lipid screening and statin prescribing in high-risk groups are ensured, attention can then be directed toward achieving lipid-lowering goals with additional nonstatin therapies, to incrementally improve outcomes in a population at high risk for ASCVD.

Stratifying data within patient management groups by race, ethnicity, sex, age, insurance status, preferred language, transportation, and other social drivers of health is an important step to identify care gaps that may represent health disparities. Assessing and addressing disparities in dyslipidemia screening and statin prescribing for high-risk groups are key actions toward achieving health equity in preventing heart attacks and strokes.

Figure 1. Potential Cholesterol Management Quality Improvement Opportunities



How Can I Use the Cholesterol Management Change Package (CMCP)?

The CMCP is meant to serve as a menu of options from which practices can select specific interventions to improve cholesterol management. We do not recommend that any practice attempt to implement all of the interventions at once, nor is it likely that all interventions will be applicable to any single clinical setting.

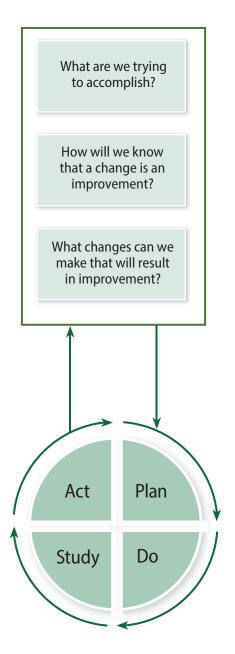
Start by assembling a team of physicians, pharmacists, nurses, medical assistants, and administrators to discuss the aspects of cholesterol management that are most in need of improvement (see **Appendix A** for additional quality improvement resources that can be useful in planning improvement activities). The team can then select corresponding interventions from the CMCP that best address those issues.

Figure 2 provides the Institute for Healthcare Improvement (IHI) Model for Improvement.8 This model suggests posing three questions:

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What changes can we make that will result in improvement?

The answers will help identify specific quality improvement objectives and related metrics, and you can choose relevant strategies from the CMCP that have been shown to result in improvement. Each strategy you choose should first be tested on a small scale (i.e., with "small tests of change") to assess feasibility and allow the team to evaluate and adjust before instituting the change on a broader, more permanent scale. This approach can be accomplished using Plan-Do-Study-Act (PDSA) cycles.

Figure 2. Institute for Healthcare Improvement (IHI) Model for Improvement⁷



Individual Patient Key Equipping **Population Health Foundations Care Teams Management Supports**

Figure 3. Cholesterol Management Change Package Focus Areas

The CMCP is broken down into four focus areas (Figure 3). For each focus area, Tables 2 through 5 contain a list of change concepts and change ideas that clinicians and practices have successfully implemented to improve cholesterol management for their patient population. Each change idea is paired with several tools and resources suggested by experts in the field who have used them successfully.

- **Key Foundations** (<u>Table 2</u>) offers ways to establish practice foundations for effective cholesterol management efforts and is likely the best place on which to focus initial quality improvement efforts. These include identifying a champion to provide leadership on focused quality improvement efforts and making cholesterol management a practice priority.
- Equipping Care Teams (Table 3) lists strategies related to training and preparing clinicians and other care team members to focus on cholesterol management. Strategies include supporting patient medication adherence and other forms of self-management.

- · Population Health Management (Table 4) presents population management tools and approaches to proactively monitor and manage cholesterol management on a practice level. Tools and approaches include clinician-driven treatment protocols and using practice data to drive improvement.
- Individual Patient Supports (<u>Table 5</u>) lists ways that practices can leverage all care steps to better manage blood cholesterol for individual patients. These supports span the patient care spectrum, from pre-visit patient outreach, check-in opportunities, interactions during the visit, check-out, to after-visit reinforcement.

Outpatient health care settings vary, so we have provided a number of different tools and resources that users can choose to tailor to their specific practice settings. We suggest selecting a single tool to begin quality improvement efforts and exploring others if you are interested in alternative approaches.

Additional quality improvement resources can be found in **Appendix A**.

Outpatient health care settings vary, so we have provided a number of different tools and resources that users can choose to tailor to their specific practice settings. We suggest selecting a single tool to begin quality improvement efforts and exploring others if you are interested in alternative approaches.

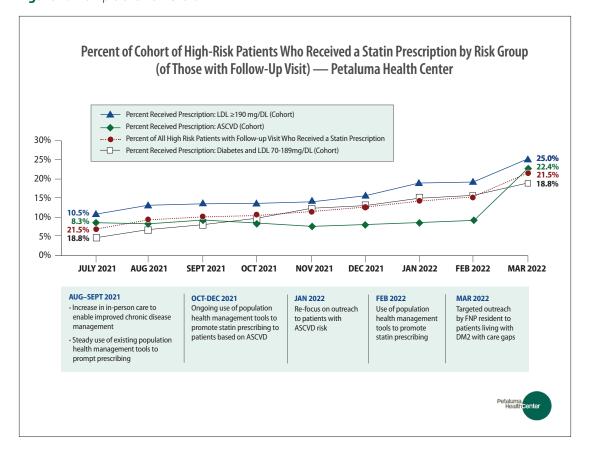
How to Measure Quality **Improvement Efforts**

Monitoring and measuring both outcomes and processes are essential for quality improvement (QI). Overall outcomes, such as improved cholesterol management, are an important measure of the effectiveness of change. Process measures, such as the percentage of newly diagnosed patients with dyslipidemia who are brought back for a follow-up visit within a designated period of time, can provide muchneeded feedback on whether interventions are being successfully implemented. Begin by identifying a process that you are interested in improving, then collect baseline data on that process. Test your change ideas on a small scale to identify potential barriers to implementation.

Address any barriers and make necessary refinements before implementing the change idea on a broader scale.

One very helpful tool for displaying and monitoring improvement efforts over time is a run chart, which is a graph that longitudinally displays performance on a given process or outcome (see Figure 4 for an example). A run chart can be useful for charting performance over time to visually demonstrate to stakeholders why recommended changes are needed. You can then document when specific changes were made to show the impact that implemented changes yielded on performance. The Safety Net Medical Home Initiative has developed a **Do-It-Yourself Run Chart template** to help you get started.







Change Concepts, Change Ideas, and Tools and Resources

Bold font indicates health care settings that contributed content.

Table 2. Key Foundations		
Change Concepts	Change Ideas	Tools and Resources
	Designate a cholesterol champion in the practice	Kaiser Permanente Northern California—Cardiovascular Physician Champion Role Description
	Engage care team in cholesterol management	• Team Up for Quality Care: The Role of Primary Care Teams in Prevention of Cardiovascular Disease. Biederman C. 2021.9
		The Primary Care Team: LEAP—Share the Care Worksheet
Make Cholesterol	Create a lipid clinic	 NLA—Key Considerations for Designing and Operating Clinically Successful and Solvent Lipid Clinic and Cardiometabolic Risk Reduction Programs
Management a Practice or System Priority	Expand the care team	CDC—Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team Sample Collaborative Practice Agreement for Hypertension/ Cardiovascular Disease
		 Sinai Urban Health Institute, Sinai Health System—<u>Best Practice Guidelines</u> for Implementing and Evaluating Community Health Worker Programs in Health Care Settings
		 Minnesota Department of Health—<u>Community Health Worker (CHW)</u> <u>Toolkit: A Guide for Employers</u>
		CPSTF—Interventions Engaging Community Health Workers
	Develop policies and procedures to reflect prioritization of cholesterol management	 Kaiser Permanente <u>Atherosclerotic Cardiovascular Disease (ASCVD)</u> <u>Primary Prevention Guideline</u>
		 NACHC—Improving Use of Statin Therapy Roadmap
Implement a		 Aliados Health—<u>Template</u>: Nursing Standardized Procedure for Use of Statins in the Management of Patients at High Risk for Cardiovascular Events
Policy and Process to Address Dyslipidemia for Every Patient With High Cholesterol at Every Visit		 NYC DOHMH and HealthyHearts NYC—ABCS Toolkit for the Practice Facilitator: Use the 4 Rs to Manage Cholesterol
	Develop a flowchart/ workflow for proactively tracking and managing patients for cholesterol management	• Figure 2. Process flow map for hyperlipidaemia screening and ASCVD risk calculation. Bakhai S, et al., 2018.10
		 NYC DOHMH and HealthyHearts NYC—ABCS Toolkit for the Practice Facilitator: Suggested Workflow for Blood Pressure Control
	Deploy cholesterol management treatment	 Kaiser Permanente — Atherosclerotic Cardiovascular Disease (ASCVD) Primary Prevention Guideline: Recommended Statin Dosing
	protocols and algorithms	 Kaiser Permanente —Atherosclerotic Cardiovascular Disease (ASCVD) Secondary Prevention Guideline: Recommended Statin Dosing



Table 3. Equipping Care Teams		
Change Concepts	Change Ideas	Tools and Resources
		PCNA—The 2019 Guideline for Primary Prevention of Cardiovascular Disease (CE Course)
		NLA—Four Key Highlights from the 2018 Guideline on the Management of Blood Cholesterol
		 USPSTF—Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication: U.S. Preventive Services Task Force Recommendation Statement
	Provide training on	Kaiser Permanente—Cholesterol and Cardiovascular Risk: Clinician Guide
	clinical guidelines	 2018 Cholesterol Clinical Practice Guidelines: Synopsis of the 2018 American Heart Association/American College of Cardiology/ Multisociety Cholesterol Guideline. Grundy SM, et al., 2019.¹¹
		NACHC— <u>Statin Therapy for High-Risk Groups Summary Video</u>
		AHA & ACC— <u>Cholesterol: Adult Management Guidelines Pocketcard</u>
		NACHC— <u>Statin Guideline Snapshot</u>
		 NYC DOHMH and HealthyHearts NYC—ABCS Toolkit for the Practice Facilitator: <u>Cholesterol FAQs</u>
	Provide guidance on cholesterol screening (including fasting vs. nonfasting)	NLA— <u>Lipid Measurements in the Management of Cardiovascular Diseases:</u> <u>Scientific Statement</u>
Train Direct Care Staff on		 NLA—<u>Lipid Measurements in the Management of Cardiovascular Diseases:</u> <u>Practical Recommendations</u>
Cholesterol Management		• Fasting or Nonfasting Lipid Measurements: It Depends on the Question. Driver SL, et al., 2016. ¹²
		• Section 2.2. Measurements of LDL-C and Non-HDL-C. Grundy SM, et al., 2019.
	Provide guidance on assessing for secondary causes of dyslipidemia	• National Lipid Association Annual Summary of Clinical Lipidology 2015. Bays HE, et al., 2014. ¹³
		» <u>Table 6. Secondary causes of dyslipidemia due to disordered</u> metabolism or disease
	causes of dyshpidernia	» Table 7. Secondary causes of dyslipidemia due to drugs
		Million Hearts®—The Scoop on Statins: What Do You Need to Know?
on sta		• Statin Safety. Grundy SM, et al., 2019. 11
		 AHA & ACC—Cholesterol: Adult Management Guidelines Pocket Card: Assessment and Management of Muscle Symptoms During Statin Therapy
	Provide guidance	ACC— <u>Statin Intolerance App</u>
	Provide guidance on statin-associated	NACHC— <u>Statin-Associated Side Effects</u>
	side effects	 NLA—Scientific Statement on Statin Intolerance: A New Definition and Key Considerations for ASCVD Risk Reduction in the Statin Intolerant Patient
		• <u>Side Effect Patterns in a Crossover Trial of Statin, Placebo, and No Treatment</u> . Howard JP, et al., 2021. ⁴
		 SAMSON—SAMSON Trial (2020): N-of-1 Trial of a Statin, Placebo, or No Treatment to Assess Side Effects (Infographic)



Table 3. Equipping Care Teams (continued)		
Change Concepts	Change Ideas	Tools and Resources
	Provide guidance on ASCVD risk estimation	 ACC—ASCVD Risk Estimator Plus 2018 Cholesterol Clinical Practice Guidelines: Synopsis of the 2018 American Heart Association/American College of Cardiology/Multisociety Cholesterol Guideline. Grundy SM, et al., 2019.¹¹ ACC—LDL-C Manager App NLA—Lp(a) Screening for Individuals at High ASCVD Risk
	Overcome diagnostic and treatment inertia	 NACHC—<u>Statin Clinical Inertia Assessment Tool</u> Azara Healthcare—<u>ASCVD Alerts Available on Patient Visit Planning Tool</u> NACHC—<u>Treating Patients with Statins: Tips from a Clinician to Clinicians</u>
Train Direct Care Staff on Cholesterol	Provide guidance on appropriate use of nonstatin therapies	 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. Writing Committee, et al., 2022.³ » New Expert Consensus Decision Pathway Addresses Use of Newer Nonstatin Therapies for Managing LDL-C in ASCVD Patients • NLA—Enhancing the Value of PCSK9 Monoclonal Antibodies by Identifying Patients Most Likely to Benefit
Management (continued)	Provide guidance on familial hypercholesterolemia (FH)	 FH Foundation—Familial Hypercholesterolemia Fact Sheet FH Foundation—Homozygous Familial Hypercholesterolemia (HoFH) Fact Sheet FH Foundation—FH Diagnosis, Management, and Family Screening My Approach to the Patient with Familial Hypercholesterolemia. Safarova MS, Kullo IJ, 2016.¹⁴ Table 2. Criteria for Diagnosing Homozygous FH Table 3. Dutch Lipid Clinic Network Clinical Criteria for Diagnosing Heterozygous FH Figure 1. Evaluation and treatment of patients with familial hypercholesterolemia (FH) Figure 8. LDL cholesterol burden in individuals with or without familial hypercholesterolaemia as a function of the age of initiation of statin therapy. Nordestgaard MG, et al., 2013.¹⁵ FH Foundation—2018 Guideline: What does it mean for FH? The Agenda for Familial Hypercholesterolemia: A Scientific Statement from the American Heart Association. Gidding SS, et al., 2015.¹⁶





Table 3. Equipping Care Teams (continued)		
Change Concepts	Change Ideas	Tools and Resources
Optimize Lipid Panel Procedures	Redesign EHR lab order template to include fasting and nonfasting lipid panels	• Winding Waters Health Center—POC Lipid Screening
	Implement point-of-care lipid testing	 Million Hearts®—Million Hearts Learning Lab: Managing Cholesterol Using Technology
		 Million Hearts®—Improving Medication Adherence Among Patients with Hypertension: A Tip Sheet for Health Care Professionals
		ACC— <u>Statin Intolerance Tool</u>
	Ensure the care team is skilled in supporting patient medication adherence	 Kaiser Permanente — Cardiovascular Risk and Dyslipidemia Management Clinician Guide: Statin Drug Interactions
		PCNA—Pearls for Medication Adherence
Equip Direct Care Staff to		NACHC— <u>Statin Adherence</u>
Facilitate Patient		AMA—Medication Adherence: Improve Patient Outcomes and Reduce Costs
Self-Management		» Deescalation and Deprescribing Worksheets
		» Questions to Help Uncover Nonadherence
		 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. Writing Committee, et al., 2022.³ Figure 7. Adults with Possible Statin-Associated Side Effects
	Use a flowchart or	
	dashboard with care gaps highlighted in team huddles to help care teams better support patients	 Azara Healthcare—Provider Dashboard
Dropayo the Care		 Azara Healthcare—Population Dashboard
Team Beforehand for Effective Cholesterol Management During Office Iteams better patients Implement planning in and use clin		 Azara Healthcare—<u>PVP Visualizations: LDL Alert Definitions</u>
	Implement pre-visit	 Azara Healthcare—PVP Alert: ASCVD Risk Calculator Data Missing
	planning into workflows and use clinical decision	Azara Healthcare—PVP Alert: Elevated ASCVD Risk & Statin Rx
	support tools to ensure	Azara Healthcare—PVP Alert: Statin Therapy
	that indicated orders/	• Family Health Centers of San Diego—Health Maintenance Reminders
	actions occur during the visit	• Family Health Centers of San Diego—EHR Decision Aid



Table 3. Equipping Care Teams (continued)		
Change Concepts	Change Ideas	Tools and Resources
Equip Care Teams to Provide Appropriate Medications	Facilitate patient access to statin therapies as appropriate	FH Foundation— <u>Affording Treatment for Familial Hypercholesterolemia</u> (also applicable for non-FH)
	Facilitate patient access to nonstatin therapies as appropriate	 ABC—ABC Access to Care Prior Authorization Resource Kit for Providers: Lipid Disorders (PCSK9i focused) » Facilitating Patient Access to PCSK9 Inhibitors: 10 Actions That Optimize the Approval Process PCSK9 inhibitor access barriers—issues and recommendations: Improving the access process for patients, clinicians and payers. Baum SJ, et al., 2017.¹⁷ PCSK9 Inhibitor Prior Authorization Form PCSK9 Inhibitor Appeal Letter Template FH Foundation—Affording Treatment for Familial Hypercholesterolemia (also applicable for non-FH) NLA—Checklist for Seeking Approval for a PCSK9 Inhibitor AMA—Medication Management: Save Time by Simplifying Your Prescribing and Refill Process Tips and Resources to Alleviate Prior Authorization Burdens
		Kaiser Permanente—Cardiovascular Risk and Dyslipidemia Management:
Use protocols and follow up with patients to find a statin that works (SASE work-around, generic vs. brand, etc.)	 Clinician Guide Kaiser Permanente—Cholesterol and Cardiovascular Risk: Clinician Guide AHA & ACC—Cholesterol: Adult Management Guidelines Pocket Card: Statin Therapy: Monitoring Therapeutic Response and Adherence ACC—Statin Intolerance App Figure 2: Algorithm for Management of Statin Intolerance. Abdullah K, Rohatgi A., 2014.¹⁸ Table 1. HMG-CoA Reductase Inhibitors. Kheloussi S, 2018.¹⁹ 	



Table 4. Population Health Management		
Change Concepts	Change Ideas	Tools and Resources
	Use guideline-based clinical criteria to define high-risk patients who could benefit from statin use	 Kaiser Permanente—Cardiovascular Risk and Dyslipidemia Management Clinician Guide: <u>Figure 1: ASCVD Statin Benefit Groups</u> See also <u>Figure 1</u> above
Identify Patients at High Risk for an ASCVD Event Who Could Benefit From a Statin	Search EHR data for patients who meet the guideline-based clinical criteria	 Aliados Health—Statin Care Gap for LDL >/=190 mg/dL Azara Healthcare—Registry Azara Healthcare—Patients "Hiding in Plain Sight" Azara Healthcare—Ptients "Hiding in Plain Sight" Azara Healthcare—PVP Alert: Lipid Lower Rx Figure. Algorithm for determining whether EHR data query accurately detected statin prescription failures in patients with CAD. Shin EY, et al., 2018.²⁰ Rate of Statin Prescription in Younger Patients with Severe Dyslipidemia. Al-Kindi SG, et al., 2017.²¹ Keystone Rural Health Consortia, Inc.—Huddle Data Mining and Presentation Program (i2i) Family Health Centers of San Diego—EHR Decision Aid Family Health Centers of San Diego—EHR Query
	Implement a plan to ensure high-risk patients are on a statin	 Azara Healthcare—<u>ASCVD Alerts Available on Patient Visit Planning Tool</u> Aliados Health—<u>Statin Care Gap for LDL >/=190 mg/dL</u>
Identify Patients with Potentially Undiagnosed Familial Hyper- cholesterolemia (FH)	Screen patients for FH; conduct cascade screening and genetic testing as appropriate	 FH Foundation—FH Diagnosis, Management, and Family Screening My Approach to the Patient with Familial Hypercholesterolemia. Safarova MS, Kullo IJ, 2016.¹⁴ Table 2. Criteria for Diagnosing Homozygous FH Table 3. Dutch Lipid Clinic Network Clinical Criteria for Diagnosing Heterozygous FH Figure 1. Evaluation and treatment of patients with familial hypercholesterolemia (FH) The Agenda for Familial Hypercholesterolemia: A Scientific Statement from the American Heart Association. Gidding SS, et al., 2015.¹⁶ Aliados Health—Statin Care Gap for LDL >/=190 mg/dL
	Use EHR data and algorithms/predictive analytics to find patients with potentially undiagnosed FH	 Table 2. Top 20 features in the classifier that flag patients with FH. Banda, JM, et al., 2019.²² Precision screening for familial hypercholesterolemia: A machine learning study applied to electronic health encounter data. Myers KD, et al., 2019.²³



Table 4. Population Health Management (continued)		
Change Concepts	Change Ideas	Tools and Resources
Ensure Accurate Coding and Diagnosis	Assess problem list diagnosis codes for use of "pure hypercholesterolemia"; recode to hyperlipidemia as appropriate	• NLA—Commonly Used Lipidcentric ICD-10 (ICD-9) Codes
Use a Registry to Track and Manage High-Risk Patients Who Could Benefit From Statin Use	Implement a cholesterol management registry	 Azara Healthcare—<u>Registry</u> Azara Healthcare—<u>ASCVD Ten Year Risk Registry</u> Effect of an Automated Patient Dashboard Using Active Choice and Peer Comparison Performance Feedback to Physicians on Statin Prescribing: The PRESCRIBE Cluster Randomized Clinical Trial. Patel MS, et al., 2018.²⁴ » eFigure 1. Active Choice Intervention Dashboard (example 1)
	Use a defined process for outreach (e.g., via phone, mail, email, text message) to patients who could benefit from statin use and those otherwise needing follow-up	• JAMA—Automated Outreach to Increase Primary Adherence to Cholesterol- Lowering Medications. Derose SF, et al., 2013. ²⁵ » eAppendix. Call Script CC. » Figure 2. Flowchart of Study Intervention.
Use Clinician- Managed Protocols for Medication Adjustments and Lifestyle Recommendations	Use protocols to cover proactive outreach driven by registry use	 JAMA—Automated Outreach to Increase Primary Adherence to Cholesterol-Lowering Medications. Derose SF, et al., 2013.²⁵ Aliados Health—Template: Nursing Standardized Procedure for Use of Statins in the Management of Patients at High Risk for Cardiovascular Events
	Determine cholesterol management and related process metrics for the practice	 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease— <u>CMS 347 specification</u> Azara Healthcare—<u>Statin Measures</u>
Use Practice Data to Drive Improvement	Regularly provide a dashboard with cholesterol goals, metrics, and performance; consider stratification by demographics and comorbidities	 Miami Beach Community Health Center—Dashboard with Provider Scorecard Azara Healthcare—Provider Dashboard Azara Healthcare—Population Dashboard Azara Healthcare—Statin Measures



Table 5. Individual Patient Supports		
Change Concepts	Change Ideas	Tools and Resources
Prepare Patients Before the Office Visit via Pre-Visit Patient Outreach	Contact patients to confirm upcoming appointments and provide instructions on how to prepare for their visit	 AMA—<u>Pre-Visit Laboratory Testing (CME module)</u> and <u>resources</u>: » Visit planner checklist: Order sheet for patient visits » <u>Pre-visit laboratory testing implementation checklist</u>
Optimize Patient Intake to Support Cholesterol Management	Provide patients with educational materials to help them understand the benefits of cholesterol management, including statins	 Intermountain Healthcare—Understanding Cholesterol English Spanish Health Information Translations—Cholesterol (multiple languages) PCNA—Diabetes and Your Heart: Close Connections English Spanish NACHC—How Do Statins Prevent Heart Attacks and Strokes? [video] English Spanish NACHC—How Do Statins Prevent Heart Attacks and Strokes: Patient Education Infographic English Spanish NACHC—Statins and Lifestyle: Patient Education Infographic English Spanish NACHC—Million Hearts®: Common Patient Questions About Statins CardioSmart—What is Cholesterol? CardioSmart—What is Cholesterol Levels Affect My Risk of Heart Attack and Stroke? English Spanish FDA—Cholesterol and Statins PCNA—Cholesterol: What You Need to Know English Spanish
	Provide patient supports for cholesterol screening	 CDC—<u>Get a Cholesterol Test</u> Mayo Clinic—<u>Cholesterol Test</u> Intermountain Healthcare—<u>Coronary Calcium CT Scan</u>
	Provide cholesterol management educational material specific to women	 NLA—<u>Lipid Treatment in Conception, Pregnancy, and Lactation</u> NLA—<u>Polycystic Ovarian Syndrome and Heart Disease Risk</u> CardioSmart—<u>Be Your Own Heart Hero</u>

Table 5. Individual Patient Supports (continued)		
Change Concepts	Change Ideas	Tools and Resources
Optimize Patient Intake to Support Cholesterol Management (continued)	Provide patients with tools to support their visit agenda and goal setting	 AHA—Check. Change. Control. Cholesterol: Take Action. Live Healthy! My Cholesterol Guide Your Treatment Plan & Lifestyle Changes PCNA—Heart Healthy Toolbox: Helping Your Patients Overcome Barriers to a Healthier Lifestyle: Navigating the Hurdles AMA—Step 2: Create an Accurate List by Reconciling Medications Table 1. MedRec gap analysis questionnaire. Elbeddini A, et al., 2021.²⁶ CardioSmart—My Plan for Starting a PCSK9 Inhibitor
	Reconcile medications that a patient is taking with the record's medication list	• NYC DOHMH—My Medication Log — Keep it Handy
	Use documentation templates to help capture key data, such as patient treatment goals and barriers to adherence	 Family Health Centers of San Diego—SMART Goal Setting Template St. Charles Health System—EHR Care Plan Template
	Use order sets and standing orders to support evidence-based and individualized care	AMA—Medication Management: Save Time by Simplifying Your Prescribing and Refill Process Refill Standing Order Sample Medication List
Optimize the	Assess individual risk and therapy impact	 Mayo Clinic—Statin Choice Decision Aid » Demo Statin/Aspirin Choice Decision Aid [video] ACC—ASCVD Risk Estimator Plus
Patient-Clinician Encounter	Address patient- specific risk factors and medication adherence through motivational interviewing, shared decision making, and "teach back"	 NLA—Motivational Interviewing to Promote Behavior Change NLA—Setting SMART Goals with Your Patients NLA—The 5-Minute Nutrition Counseling Guide Million Hearts®—Protocol for Identifying and Treating Patients Who Use Tobacco Physical Activity Counseling. Meriwether RA, et al., 2008.²⁷ Intermountain Healthcare—A Primary Care Guide to Lifestyle and Weight Management: Helping patients find their way to LiVe Well » LiVe Well Readiness Worksheet » Rx to LiVe Well » LiVe Well Action Plan



Table 5. Individual Patient Supports (continued)				
Change Concepts	Change Ideas	Tools and Resources		
Optimize the Patient-Clinician Encounter (continued)	Assess patients' social drivers/determinants of health	 Intermountain Healthcare—Care Process Model: Social Determinants of Health NACHC—PRAPARE Screening Tool UCSF—Guide to Implementing Social Risk Screening and Referral-making OPCA—Empathic Inquiry Patient Support Questionnaire (English and Spanish) Patient-Centered Social Needs Screening Conversation Guide Findhelp.org (formerly known as Aunt Bertha) Azara Healthcare—Statin Therapy Treatment by Race Azara Healthcare—Inequities in ASCVD, Hyperlipidemia, and Diabetes Diagnoses KFF—Beyond Health Care: The Role of Social Determinants in Promoting 		
	Provide patient supports for medication adherence	 Health and Health Equity AHA—Check. Change. Control. Cholesterol: Take Action. Live Healthy! My Cholesterol Guide NYC DOHMH—Protect Your Heart—Control Your Cholesterol: Take Your Medicine—Statins CardioSmart—My Plan for Starting a PCSK9 Inhibitor 		
Support Patients	Provide patient supports on what to do if they experience statin- associated side effects	 NACHC—Million Hearts®: Common Patient Questions About Statins Million Hearts®—The Scoop on Statins: What Do You Need to Know? English Spanish CardioSmart—Statins: What You Need to Know 		
in Cholesterol Self-Management During Their Routine Daily Activities	Provide patient supports for tobacco cessation	 AAFP—Quit Smoking Guide VA—Patient Guide: Tobacco Cessation Therapy English Spanish NYC DOHMH and NY State Smokers' Quitline—NYC Quits Kit 		
	Provide patient supports for increasing physical activity	 CardioSmart—My Plan for Heart Healthier Living: Commit to Regular Exercise AHA—Check. Change. Control. Cholesterol: Take Action. Live Healthy! My Cholesterol Guide Your Treatment Plan & Lifestyle Changes PCNA—Daily Exercise Log PCNA—Exercise Program for Individuals with Heart Disease CardioSmart—Active and Mindful Living infographic 		



Table 5. Individual Patient Supports (continued)					
Change Concepts	Change Ideas	Tools and Resources			
Support Patients in Cholesterol Self-Management During Their	Provide patient supports for dietary changes	 London Health Sciences Centre—In Depth: The Portfolio Diet FDA—Cholesterol in Nutrition ABC—Cooking for Your Heart and Soul CardioSmart—My Plan for Heart Healthier Living: Nutrition and Eating Heart Healthy AHA—Check. Change. Control. Cholesterol: Take Action. Live Healthy! My Cholesterol Guide Your Treatment Plan & Lifestyle Changes NLA—Clinician's Lifestyle Modification Toolbox (see Cardioprotective Dietary Patterns) [also available in Spanish and Hindi] Heart-Healthy Eating on a Budget Heart-Healthy Eating Mediterranean Style Heart-Healthy Eating Latino Style Heart-Healthy Eating: Plant-Based Style NLA—The Newest Nutrition Recommendations to Prevent Heart Disease ADA—Nutrition Therapy for High Cholesterol VA/DoD—Mediterranean Diet NYC DOHMH—Protect Your Heart—Lower Your Cholesterol: Learn to Read Food Labels AHA—How Can I Improve My Cholesterol? 			
Routine Daily Activities (continued)	Provide patient supports related to non–evidence-based supplements (e.g., red yeast rice, coenzyme Q10)	NACHC—Million Hearts®: Common Patient Questions About Statins NIH—Cholesterol Management at a Glance			
	Provide patient supports related to secondary causes of hyperlipidemia (e.g., steroid use)	NLA—Effects of Low-Carbohydrate and Very-Low-Carbohydrate Diets (Including Ketogenic) - Cardiometabolic Impact NLA—Polycystic Ovarian Syndrome and Heart Disease Risk			
	Provide patient supports related to FH	 PCNA—What is Familial Hypercholesterolemia? English Spanish NLA—What You Need to Know: Familial Hypercholesterolemia FH Foundation—Affording Treatment for Familial Hypercholesterolemia: Where to Look for Help FH Foundation—Do You #KnowFH Infographic FH Foundation—Dear Family Member Letter Template FH Foundation—CASCADE FH® Registry Digital Brochure FH Foundation—Homozygous Familial Hypercholesterolemia (HoFH) Infographic FH Foundation—Navigating Insurance Guide 			



	Table 5. Individual Patient Supports (continued)					
Change Concepts Change Ideas		Tools and Resources				
Optimize the Encounter Closing	Provide patients with a written self-management plan, visit summary, and follow-up guidance at the end of each visit	 ONC—Providing Patients in Ambulatory Care Settings with a Clinical Summary of the Office Visit AHA—Check. Change. Control. Cholesterol: Take Action. Live Healthy! My Cholesterol Guide AHA—What Does My LDL Cholesterol Number Mean? English Spanish CardioSmart—My Plan for Starting a PCSK9 Inhibitor Foundation of the National Lipid Association—How to Read a Lipid Panel Mended Hearts—Expert Answers to Your Frequently Asked Questions about Managing Lipids [video] 				
Follow Up to	Create a protocol to simplify the prescription refill process	AMA— <u>Figure 1. Techniques to Improve and Simplify Prescription Renewals</u>				
Monitor and Reinforce Cholesterol Management Plans	Implement frequent follow-ups (e.g., email, phone calls, text messages) with patients to make sure they are continuing their medication	JAMA—Automated Outreach to Increase Primary Adherence to Cholesterol- Lowering Medications. Derose SF, et al., 2013. ²⁵ ** eAppendix. Call Script CC *** Figure 2. Flowchart of Study Intervention				

Appendix A: Additional Quality Improvement Resources

If you are new to continuous quality improvement (QI), there are many useful QI tools to assist you in your efforts. For example, the Institute for Healthcare Improvement (IHI) provides a number of QI tools that support its Model for Improvement (Figure 2). Their Quality **Improvement Essentials Toolkit** provides an excellent introduction for starting QI initiatives. It includes a **Project Planning Form** to help teams think systematically about their improvement project; the **Cause and Effect Diagram (or "fishbone")** to identify specific areas for improvement; and the Plan-Do-Study-Act Worksheet, which walks the user through documenting a test of change. These resources may be helpful for planning, assigning responsibilities, and carrying out small tests of change for improving cholesterol management.

Another useful QI reference and toolkit is the **Guide to Improving Care Processes and** Outcomes in Health Centers, available from the Health Resources and Services Administration (HRSA) Health Information Technology, Evaluation, and Quality Center (HITEQ), which supports the U.S. health care safety net. This resource includes worksheets, such as the **Clinical Decision Support-enabled Quality Improvement Worksheet**, for analyzing current work processes and information flows and considering improvements for targets such as improving cholesterol management.

The ACC's **QI Toolkit** provides useful resources on QI using the stepwise FOCUS-PDSA method. The QI Toolkit includes downloadable resources for brainstorming, creating prioritization matrices and flow charts, and performing root cause analysis.

Alternatively, you may also find the **ABCS Toolkit for the Practice Facilitator—Workflow** Mapping Worksheet, from the New York City (NYC) Department of Health and Mental Hygiene and HealthyHearts NYC, useful for laying out current care processes, identifying gaps, and brainstorming solutions. The CMCP can help identify promising, evidence-based approaches to enhancing care processes to improve cholesterol management.

Finally, the Healthcare Information and Management Systems Society (HIMSS) publishes a guidebook series on improving care delivery and outcomes with clinical decision support (CDS).²⁸⁻²⁹ These guidebooks can help you apply the **CDS 5 Rights framework** to ensure that all the right people, including patients, get the right information in the right formats via the right channels at the right times to optimize healthrelated decisions and actions. The guidebooks help health care practices and their partners set up programs that deliver CDS interventions to reliably improve outcomes. They also provide detailed guidance on how to successfully develop, launch, and monitor such interventions so that all stakeholders benefit.

Acronyms

	AAFP	American Academy of Family	LDL	Low-density lipoprotein
	ABC	Physicians Association of Black Cardiologists,	LEAP	Learning from Effective Ambulatory Practices
		Inc.	Lp(a)	Lipoprotein (a)
	ABCS	Aspirin as appropriate, blood pressure control, cholesterol management, smoking cessation	NACHC	National Association of Community Health Centers
	ACC	American College of Cardiology	NIH	National Institutes of Health
	ADA	American Dietetic Association	NLA	National Lipid Association
	AHA	American Heart Association	NYC DOHMH	New York City Department of Health and Mental Hygiene
	AMA	American Medical Association	ONC	Office of the National Coordinator for
	ASCVD	Atherosclerotic cardiovascular	OTTE	Health Information Technology
	CD C	disease	OPCA	Oregon Primary Care Association
	CDC	Centers for Disease Control and Prevention	PCSK9i	Proprotein convertase subtilisin/kevin type 9 inhibitor
	CDS	Clinical decision support	PDSA	Plan-Do-Study-Act
	CE	Continuing education		Protocol for Responding to and Assessing Patients' Assets, Risks,
	CHW	Community health worker		
	CPSTF	Community Preventive Services Task Force	PCNA	and Experiences Preventive Cardiovascular Nurses
	EHR	Electronic health record		Association
	FDA	U.S. Food and Drug Administration	PVP	Patient visit planning
	FH	Familial hypercholesterolemia	QI	Quality improvement
	FH	Family Heart (Foundation)	SASE	Statin-associated side effects
	HIMSS	Healthcare Information and Management Systems Society	SAMS	Statin-associated muscle symptoms
			UCSF	University of California, San Francisco
	HITEQ	Health Information Technology, Evaluation, and Quality Center	USPSTF	United States Preventive Services Task Force
	HRSA	Health Resources and Services	VA	Department of Veterans Affairs
		Administration	VA/DoD	Department of Veterans Affairs/ Department of Defense
	IHI	Institute for Healthcare Improvement		
	KFF	Kaiser Family Foundation		

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