VA/DoD Clinical Practice Guidelines

THE MANAGEMENT OF DYSLIPIDEMIA FOR CARDIOVASCULAR RISK REDUCTION

Provider Summary

Version 4.0 | 2020

VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF DYSLIPIDEMIA FOR CARDIOVASCULAR RISK REDUCTION

Department of Veterans Affairs

Department of Defense

Provider Summary

QUALIFYING STATEMENTS

The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This Clinical Practice Guideline is based on a systematic review of both clinical trial and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

These guidelines are not intended to represent Department of Veterans Affairs nor TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.

Version 4.0 – 2020

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Introduction

The Department of Veterans Affairs (VA) and Department of Defense (DoD) Evidence-Based Practice Work Group (EBPWG) was established and first chartered in 2004, with a mission to advise the Health Executive Committee (HEC) "…on the use of clinical and epidemiological evidence to improve the health of the population…" across the Veterans Health Administration (VHA) and Military Health System (MHS), by facilitating the development of clinical practice guidelines (CPGs) for the VA and DoD populations.[1] This CPG is intended to provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with dyslipidemia, thereby leading to improved clinical outcomes.

In 2014, the VA and DoD published a CPG for the Management of Dyslipidemia for Cardiovascular Risk Reduction (2014 VA/DoD Dyslipidemia CPG), which was based on evidence reviewed from January 2010 through February 2014. Since then, a growing body of research has expanded the general knowledge and understanding of dyslipidemia and cardiovascular (CV) risk.

A recommendation to update the 2014 VA/DoD Dyslipidemia CPG was initiated in 2019. The system-wide goal of evidence-based guidelines is to improve the patient's health and well-being. To that end, this CPG is intended to guide providers who care for patients with dyslipidemia along management pathways supported by evidence. The expected outcomes of successful implementation of this guideline include:

- Emphasizing the use of patient-centered care using risk factors and event history
- Minimizing preventable complications and morbidity
- Optimizing each individual's health outcomes and improving quality of life
- Assessing the patient's condition and collaborating with the patient, family, and caregivers to determine the optimal treatment

Scope of the CPG

This CPG is designed primarily to assist primary care providers (or other providers as applicable) in managing patients with dyslipidemia for the purpose of cardiovascular disease (CVD) risk reduction. This guideline seeks to inform providers with practical evidence-based recommendations for the most common scenarios involving patients at risk for CVD.

A. Populations Included in this Guideline

The patient population of interest for this CPG is patients ≥40 years old and eligible for care in the VA and/or DoD healthcare systems.

B. Populations Excluded from this Guideline

Patients with heart failure with reduced ejection fraction (EF) ≤35%, a limited life expectancy (<5 years), or end-stage renal disease (ESRD) were excluded from most clinical outcome trials. Although some controlled trial data exists exclusively in patients with ESRD and chronic systolic heart failure, the available evidence is comparatively sparse. Additionally, the data that is available show an absence of CV benefit in these populations. A more nuanced review of this evidence can be found in the 2014 iteration of the VA/DoD

Clinical Practice Guideline for the Management of Dyslipidemia for Cardiovascular Risk Reduction under section "Populations Excluded from this Guideline."[3] Our updated systematic review found no new evidence that would alter this position.

Genetic dyslipidemia conditions (e.g., homozygous familial hypercholesterolemia [HoFH], heterozygous familial hypercholesterolemia [HeFH], TGs >500 mg/dL, etc.) were also excluded from the guideline given their uncommon occurrence and sparse clinical trial data. Although younger patients (i.e., <40 years old) are more common in the DoD, this cohort comprises a low short-term risk population that has been excluded from dyslipidemia intervention trials.

Thus, the Work Group was unable to provide evidence-based recommendations for these populations and suggests that providers consider basing treatment decisions for these cohorts on comorbidity, quality of life, and patient's values and preferences. Such shared and informed decision-making should clearly lay out the uncertainty of benefit and known risks associated with pharmacologic treatment.

Recommendations

The following recommendations were made using a systematic approach considering four domains as per the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach as detailed in the section on Methods and Appendix A in the full text Dyslipidemia CPG. These domains include: confidence in the quality of the evidence, balance of desirable and undesirable outcomes (i.e., benefits and harms), patient or provider values and preferences, and other implications, as appropriate (e.g., resource use, equity, acceptability).

Topic	Sub-topic	#	Recommendation	Strength[a]
Primary Prevention: Screening and Assessment of Cardiovascular Risk		1.	For primary prevention in patients over age 40 and not on statin therapy who have not developed new cardiovascular risk factors (e.g., diabetes, hypertension, tobacco use), we suggest against offering a cardiovascular disease risk assessment more frequently than every five years.	Weak against
		2.	For primary prevention in patients not on statin therapy, we suggest against routinely ordering a lipid panel more frequently than every 10 years.	Weak against
		3.	For cardiovascular risk assessment in primary prevention, we suggest using a 10-year risk calculator.	Weak for
		4.	We suggest against the routine use of coronary artery calcium testing.	Weak against
		5.	We suggest against the routine use of additional risk markers (e.g., high-sensitivity C-reactive protein, ankle-brachial index, coronary artery calcium) when assessing cardiovascular risk.	Weak against

Topic	Sub-topic	#	Recommendation	Strength[a]
Pharmacotherapy, Supplements, and Nutraceuticals	*a. Primary Prevention*	6.	For primary prevention, we recommend offering a moderate-dose statin in patients with a ≥12% 10-year cardiovascular risk or low-density lipoprotein cholesterol ≥190 mg/dL or diabetes.	Strong for
		7.	For primary prevention, we suggest offering a moderate-dose statin for patients with a 10-year cardiovascular risk between 6% and 12% following a discussion of risks, limited benefit, and an exploration of the patient's values and preferences.	Weak for
		8.	For primary prevention in patients on moderate-dose statins, we suggest against maximizing the statin dose due to the lack of evidence proving added cardiovascular benefits and the risks of higher dose statins.	Weak against
		9.	For primary prevention, there is insufficient evidence to recommend for or against using ezetimibe with or without statins.	Neither for nor against
		10.	For primary prevention, we recommend against offering PCSK9 inhibitors due to unknown long-term safety, inconclusive evidence for benefit, and high cost.	Strong against
	b. Secondary Prevention	11.	For secondary prevention, we recommend using at least a moderate-dose statin.*	Strong for
		12.	For secondary prevention in higher risk patients** who are willing to intensify treatment, we suggest offering high-dose statins for reducing non-fatal cardiovascular events after discussion of the risk of high-dose statins and an exploration of the patient's values and preferences.	Weak for
		13.	For secondary prevention in higher risk patients** who are willing to intensify treatment, we suggest adding ezetimibe to either moderate- or high-dose statins for reducing non-fatal cardiovascular events following a discussion of the risks, additional benefits, and an exploration of the patient's values and preferences.	Weak for
		14.	For secondary prevention in higher risk patients** who are willing to intensify treatment, we suggest offering a PCSK9 inhibitor in addition to a maximally tolerated statin dose with ezetimibe for reducing non-fatal cardiovascular events following a discussion of their uncertain long-term safety, additional benefits, and an exploration of the patient's values and preferences.	Weak for
	c. Other Medications, Supplements, and Nutraceuticals	15.	For primary or secondary prevention, we recommend against using niacin (i.e., supplements or prescriptions).	Strong against
		16.	For primary or secondary prevention, we suggest against adding fibrates to statins.	Weak against
		17.	There is insufficient evidence to recommend for or against using bempedoic acid with or without statins for either primary or secondary prevention.	Neither for nor against

Topic	Sub-topic	#	Recommendation	Strength[a]
Pharmacotherapy, Supplements, and Nutraceuticals (cont.)	*c. Other Medications, Supplements, and Nutraceuticals (cont.)*	18.	For primary prevention, there is insufficient evidence to recommend for or against icosapent ethyl in patients on statin therapy with persistently elevated fasting triglycerides.	Neither for nor against
		19.	For secondary prevention, we suggest offering icosapent ethyl in patients on statin therapy with persistently elevated fasting triglycerides >150 mg/dL to reduce cardiovascular morbidity and mortality.	Weak for
		20.	For primary or secondary prevention, we suggest against the use of omega-3 fatty acids as a dietary supplement to reduce cardiovascular disease risk.	Weak against
		21.	There is insufficient evidence to recommend for or against the use of fiber, garlic, ginger, green tea, and red yeast rice supplements to reduce cardiovascular risks.	Neither for nor against
	d. Monitoring and Adherence	22.	We suggest against the routine monitoring of lipid levels in patients taking statins.	Weak against
		23.	For patients who cannot tolerate a statin, we suggest a washout period followed by a re-challenge with the same or a different statin or lower dose, and if that fails, a trial of intermittent (nondaily) dosing.	Weak for
		24.	We suggest offering intensified patient care (e.g., phone calls, emails, patient education, drug regimen simplification) to improve adherence to lipid-lowering medications.	Weak for
Lifestyle Interventions		25.	For primary and secondary prevention of cardiovascular disease, we suggest a dietitian-led Mediterranean diet.	Weak for
		26.	For primary and secondary prevention of cardiovascular disease, we suggest regular aerobic physical activity of any intensity and duration.	Weak for
		27.	We recommend a structured, exercise-based cardiac rehabilitation program for patients with recent occurrence of coronary heart disease (i.e., myocardial infarction, diagnosis of coronary artery disease, coronary artery bypass grafting, or percutaneous coronary intervention) to reduce cardiovascular morbidity and mortality.	Strong for

[a] For additional information, please refer to the section on Grading Recommendations in the full text Dyslipidemia CPG

* Statin doses listed as "moderate" are equivalent to moderate intensity; statin doses listed as "high" are equivalent to high intensity

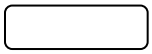
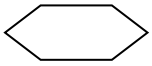
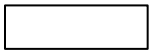
** Higher risk patients include those with (1) MI or ACS in past 12 months; (2) recurrent ACS, MI, or CVA; or (3) established CVD and with additional risk factors (e.g., currently smoking, DM, PAD, or CABG/PCI)

Algorithm

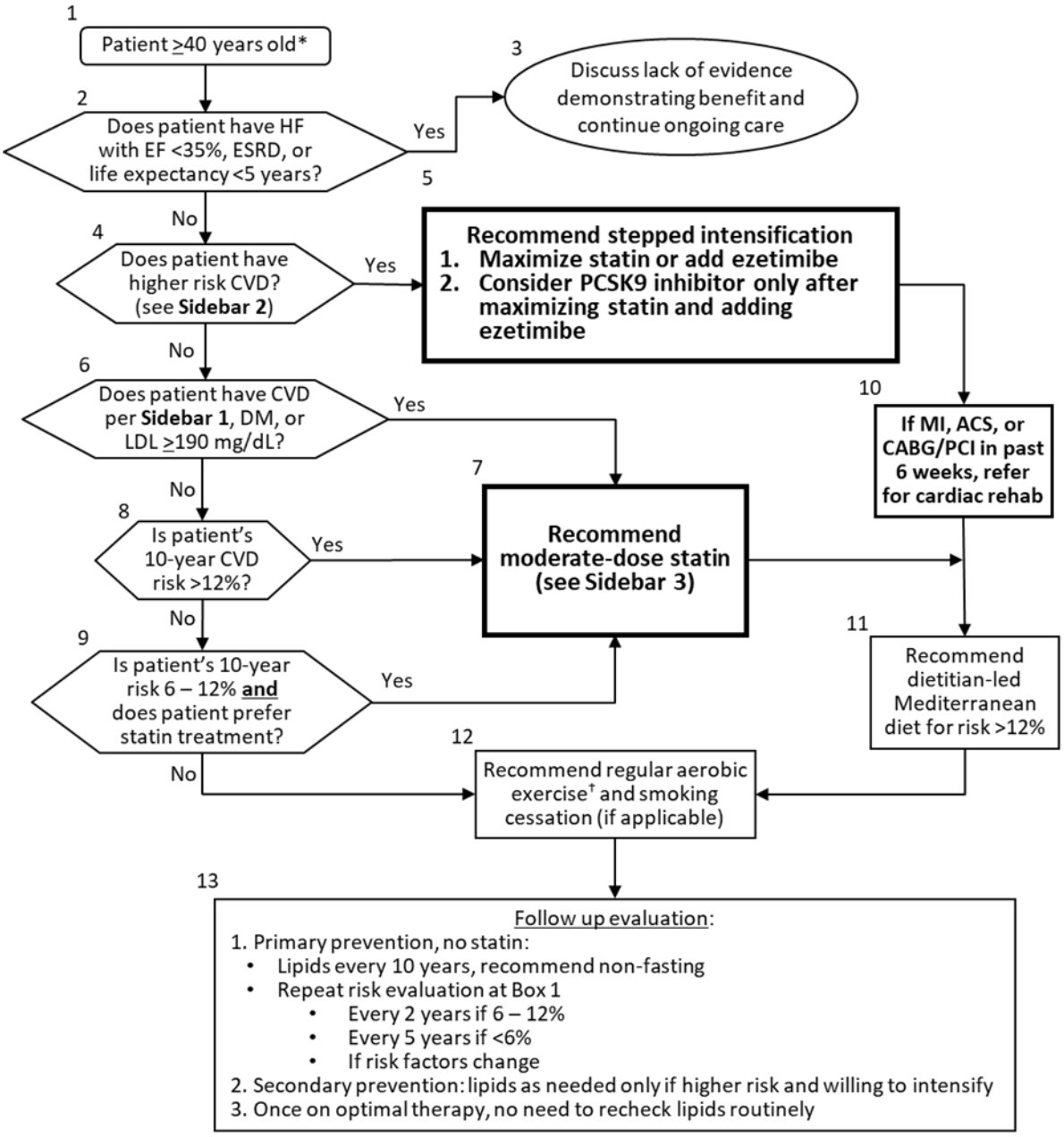
This CPG's algorithm is designed to facilitate understanding of the clinical pathway and decision-making process used in identifying patients at risk for CVD who are then eligible for management of their dyslipidemia. This algorithm format represents a simplified flow of the management of patients with dyslipidemia and helps foster efficient decision making by providers. It includes:

- An ordered sequence of steps of care
- Recommended decision criteria
- Decisions to be considered
- Actions to be taken

The algorithm is a step-by-step decision tree. Standardized symbols are used to display each step, and arrows connect the numbered boxes indicating the order in which the steps should be followed.[2] Sidebars provide more detailed information to assist in defining and interpreting elements in the boxes.

Shape	Description
	Rounded rectangles represent a clinical state or condition
	Hexagons represent a decision point in the guideline, formulated as a question that can be answered "Yes" or "No"
	Rectangles represent an action in the process of care
	Ovals represent a link to another section within the guideline

Algorithm: Management of Dyslipidemia for Cardiovascular Risk Reduction



* There are no evidence-based recommendations for patients under age 40 because there is no evidence for the benefit of lipid screening and treatment within this age group. In patients younger than 40 years old interested in pursuing lipid testing and management, shared decision making is recommended to discuss the risks and unknown benefit of pharmacotherapy, with therapeutic lifestyle changes being the primary focus of CVD primary prevention.

† Suggest regular aerobic activity of any intensity or duration. Although incremental benefit is associated with increased doses of physical activity, lower doses including leisure time activity (i.e., walking, landscaping, washing dishes) are associated with benefit when compared to mostly sedentary behavior. A provider's considerations when recommending physical activity might include a patient's motivation, functional capacity, and physical activity preferences.

Abbreviations: ACS: acute coronary syndrome; CABG: coronary artery bypass grafting; CVD: cardiovascular disease; DM: diabetes mellitus; EF: ejection fraction; ESRD: end-stage renal disease; HF: heart failure; LDL: low-density lipoprotein cholesterol; mg/dL: milligrams per deciliter; MI: myocardial infarction; PCI: percutaneous coronary intervention

Sidebar 1: CVD and Equivalents
• MI or ACS • CABG/PCI • Stable CAD (angina or equivalent) • Atherosclerotic CVA/TIA • PAD (claudication or AAA) • Does **not** include asymptomatic incidental finding of potential atherosclerosis (e.g., CAC)

Abbreviations: AAA: abdominal aortic aneurysm; ACS: acute coronary syndrome; CABG: coronary artery bypass grafting; CAC: coronary artery calcium; CAD: coronary artery disease; CVA: cerebrovascular accident; CVD: cardiovascular disease; MI: myocardial infarction; PAD: peripheral arterial disease; PCI: percutaneous coronary intervention; TIA: transient ischemic attack

Sidebar 2: Higher Risk CVD Patients
• MI or ACS in past 12 months; or • Recurrent ACS, MI, or CVA; or • Known CVD (see **Sidebar 1**) and any of the following: currently smoking, DM, PAD, or CABG/PCI

Abbreviations: ACS: acute coronary syndrome; CABG: coronary artery bypass grafting; CVA: cerebrovascular accident; CVD: cardiovascular disease; DM: diabetes mellitus; MI: myocardial infarction; PAD: peripheral arterial disease; PCI: percutaneous coronary intervention

Sidebar 3: Drug Doses

Generic name	Moderate-dose‡	High-dose
Atorvastatin	10 – 20 mg	40 – 80 mg
Rosuvastatin	5 – 10 mg	20 – 40 mg
Simvastatin	20 – 40 mg	N/A
Pravastatin	40 – 80 mg	N/A
Lovastatin	40 – 80 mg	N/A
Fluvastatin	80 mg (XL) or 40 mg BID	N/A
Pitavastatin	1 – 4 mg	N/A

- In patients who are intolerant of statins: after washout (e.g., 1 month), re-challenge with same or a different statin or lower dose, and if that fails, a trial of intermittent (nondaily) dosing
- Intensified patient care (e.g., phone calls, emails, patient education, drug regimen simplification) may improve adherence to lipid-lowering medications

‡ Statin doses listed as "moderate" are equivalent to moderate intensity; statin doses listed as "high" are equivalent to high intensity

Abbreviations: BID: twice per day; mg: milligrams; XL: sustained release

Statin and Non-statin Pharmacologic Agents

Table 1. Summary of Statin and Non-statin Pharmacologic Agents*

	Drug Category	Dose	Major Drug Interactions	Adverse Drug Reactions	Notes
Statins	Atorvastatin	10 – 80 mg once daily	Since statins vary in their metabolic pathway, refer to product labeling for drug-drug interactions and statin dose limits	Risk for myalgia, myopathy and, very rarely, rhabdomyolysis. Other risks include diabetes, LFT elevations, and asymptomatic CK elevations.	First line therapy for primary or secondary prevention of CVD
	Rosuvastatin	5 – 40 mg once daily			
	Simvastatin	5 – 40 mg once daily			
	Lovastatin	20 – 80 mg once daily			
	Pravastatin	10 – 80 mg once daily			
	Fluvastatin	20 – 80 mg per day			
	Pitavastatin	1 – 4 mg once daily			
Cholesterol absorption inhibitors	Ezetimibe	10 mg once daily	Increased incidence of transaminase elevation >3x ULN when combined with statins versus statins alone (1.3% versus 0.4%, respectively)	Generally well tolerated	Benefit for reducing non-fatal CV events in secondary prevention patients in addition to statin
PCSK9 inhibitors	Alirocumab	75 mg once every 2 weeks *OR* 300 mg once every 4 weeks Max: 150 mg every 2 weeks	No known significant interactions	• Injection site reactions (3 – 7%). Adverse reactions with PCSK9 inhibitors reported in RCTs appear to be similar to placebo. • Alirocumab had higher incidence of influenza, bronchitis, myalgia, muscle spasm, sinusitis, cough, and musculoskeletal pain compared to placebo • Evolocumab had a higher incidence of cough, arthralgia, and fatigue	• Benefit for reducing non-fatal CV events in secondary prevention in addition to maximally tolerated statin +/- ezetimibe • It is recommended that patients receive maximally tolerated statins plus ezetimibe prior to adding alirocumab or evolocumab • Limited data on long-term safety
	Evolocumab	140 mg once every 2 weeks *OR* 420 mg once monthly			

	Drug Category	Dose	Major Drug Interactions	Adverse Drug Reactions	Notes
Omega-3 fatty acids	Icosapent ethyl	2 gm twice daily with meals	May enhance antiplatelet and anticoagulation effects. Caution with concomitant agents that increase risk of bleeding.	Arthralgia (2.3%), oropharyngeal pain, peripheral edema, constipation, gout, and atrial fibrillation. Potential for allergic reactions in patients with fish allergy.	• Benefit for reduction of CV mortality and morbidity in patients treated for secondary prevention on statins with persistently elevated TG (>150 mg/dL); evidence is limited to one RCT • Hospitalization for atrial fibrillation or flutter was statistically higher with icosapent and a non-significant trend towards a higher incidence of hospitalization for serious bleeding events was also observed

* Refer to product prescribing insert for more information regarding use restrictions, dose modification, dosing in special populations (e.g., renal or liver impairment, advanced age, pregnancy, etc.), drug-drug interactions, and adverse events

Abbreviations: CK: creatine kinase; CV: cardiovascular; CVD: cardiovascular disease; dL: deciliter; gm: grams; LFT: liver function test; mg: milligrams; PCSK9: proprotein convertase subtilisin/kexin type 9; RCT: randomized controlled trial; TG: triglyceride; ULN: upper limit of the normal range

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Methods

The 2020 Dyslipidemia CPG is an update to the 2014 VA/DoD Dyslipidemia CPG. The methodology used in developing the 2020 CPG follows the *Guideline for Guidelines*, a VA and DoD EBPWG document that was updated in January 2019.[4] The *Guideline for Guidelines* can be downloaded from http://www.healthquality.va.gov/policy/index.asp and a full description of this guideline's methodology is available at https://www.healthquality.va.gov/guidelines/cd/lipids/.

Patient-centered Care

VA/DoD CPGs encourage a patient-centered care approach (i.e., individualized treatment based on patient needs, characteristics, and preferences) that is culturally appropriate and available to people with limited literacy skills, and physical, sensory, or learning disabilities. Regardless of the setting, all patients should be able to access evidence-based care that is appropriate to them. Patient-centered care may decrease patient anxiety, increase trust in providers, and improve treatment adherence.[8-10] Good communication is essential and should be supported by evidence-based information tailored to the patient's needs. An empathetic and non-judgmental approach facilitates discussions sensitive to sex, culture, ethnicity, and other differences. The focus is using an individual's risk factors and event history to guide the various treatment and management strategies among patients at risk for CVD morbidity and mortality.

Shared Decision Making

The authors of this CPG encourage providers to practice shared decision making. Shared decision making was emphasized in *Crossing the Quality Chasm,* an Institute of Medicine (IOM) (now the NAM) report, in 2001.[11] Providers must be adept at presenting information to their patients regarding individual treatments, expected risks, expected outcomes, and levels and/or locations of care, especially as differences between risks and benefits become less clear. Shared decision making strategies should be used to individualize treatment goals and plans based on patient capabilities, needs, and preferences.

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Access to the full guideline and additional resources are available at the following link: https://www.healthquality.va.gov/guidelines/CD/lipids