Clinical Practice Guideline: **Lipid Screening**

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GUIDELINES

Practitioners, as appropriate to their education, training, experience, and scope of practice, can provide valuable screening for common risk factors and health conditions. The guidelines provided within this American Specialty Health – Specialty (ASH) Clinical Practice Guideline focus on screening procedures for lipids.

Among portal of entry practitioners, screening at risk and/or symptomatic patients for lipid imbalances is considered best practice. Providing a direct intervention (e.g., lifestyle and/or dietary changes) for patients for whom the screening results indicated a need for intervention, will depend upon the practitioner's education, training, experience, and scope of practice. In the absence of such a direct intervention, providing a referral intervention (e.g., to the patient's medical physician) is considered necessary. The screenings described in this guideline may be outside the education, training, experience, or scope of some practitioner types. In the context of best practices for these practitioners, a level of awareness that risk factors and/or signs/symptoms of the above conditions are present is required and a subsequent referral for appropriate evaluation is necessary and within the purview of all.

INTRODUCTION

Health issues identified through appropriate screening provide patients with earlier detection and increase the likelihood of successful treatment. In some cases, the detrimental effects of a disease or health condition can be mitigated or possibly reversed with appropriate early detection and care (e.g., Type 2 diabetes or cardiovascular disease). Applicable recommendations for the preventive health screenings covered in this policy are based on the United States Preventive Services Task Force (USPSTF), as well as other evidence-based guidelines from the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines for blood cholesterol.

A comprehensive review of the USPSTF evidence rating process can be found in the ASH clinical practice guideline *Preventive Care Services (CPG 140 – S)* or at the USPSTF website: http://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions

LIPID SCREENING

Lipid disorders, also called dyslipidemias, are abnormalities of lipoprotein metabolism and include elevated total cholesterol (TC), low density lipoprotein (LDL-C), or triglycerides (TG), or deficient levels of high-density lipoprotein (HDL-C). Dyslipidemias are acquired

or familial. Dyslipidemia is a modifiable risk factor for coronary artery disease. Risk factors for dyslipidemia include an atherogenic diet (diet high in saturated fatty acids, cholesterol, and sodium), diet high in added sugars, physical inactivity, obesity, abdominal obesity, metabolic syndrome, hypertension, genetic factors, age, and male sex (Chou, 2022).

ASSESSING LIPID LEVELS

The USPSTF systematically searched for evidence on the effect of screening for dyslipidemia in adults aged 21 to 39 years. It found insufficient evidence that screening for dyslipidemia in adults before age 40 years has an effect on either short- or longer-term cardiovascular outcomes. The USPSTF found no studies that evaluated the effects of screening vs no screening, treatment vs no treatment, or delayed vs earlier treatment in adults in this age group.

The USPSTF recognizes the rationale for screening for dyslipidemia in adults aged 21 to 39 years to identify those at risk for the development of early atherosclerosis, including those with familial hypercholesterolemia. Unfortunately, the evidence for prevention with statins is lacking in this age group. The USPSTF found 4 trials of statin use for primary prevention that enrolled patients younger than 40 years. However, results were not reported separately for this age group, and it comprised a small part of the overall population. One cohort study compared the effects of statins vs no statins for the treatment of familial hypercholesterolemia. However, the mean age of patients in this study was 44 years. Given the lack of data on the efficacy of screening for, or treatment of, dyslipidemia in adults aged 21 to 39 years, USPSTF recommends neither for nor against screening or treatment for dyslipidemia in this age group. The USPSTF encourages clinicians to use their clinical judgment for patients in this age group. ACA/ AHA recommendations for young adults (20 to 39 years of age), state that the priority should be given to estimating lifetime risk and promoting a healthy lifestyle. Only in select patients with moderately high LDL-C (≥160 mg/dL) or those with very high LDL-C (≥190 mg/dL) is drug therapy indicated.

A separate USPSTF (2023) recommendation statement also found insufficient evidence to assess the balance of benefits and harms of screening for lipid disorders in asymptomatic children and adolescents who are 20 years or younger.

The 2022 USPSTF recommendation is as follows:

Population	Recommendation	Grade
Adults aged 40 to 75 years who have 1 or more cardiovascular risk factors and an estimated 10-year cardiovascular disease (CVD) risk of 10% or greater	The USPSTF recommends that clinicians prescribe a statin for the primary prevention of CVD for adults aged 40 to 75 years who have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year risk of a cardiovascular event of 10% or greater.	B
Adults aged 40 to 75 years who have 1 or more cardiovascular risk factors and an estimated 10-year CVD risk of 7.5% to less than 10%	The USPSTF recommends that clinicians selectively offer a statin for the primary prevention of CVD for adults aged 40 to 75 years who have 1 or more CVD risk factors (i.e. dyslipidemia, diabetes, hypertension, or smoking) and an estimated 10-year risk of a cardiovascular event of 7.5% to less than 10%. The likelihood of benefit is smaller in this group than in persons with a 10-year risk of 10% or greater.	C
Adults 76 years and older	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of initiating a statin for the primary prevention of CVD events and mortality in adults 76 years or older.	I

These recommendations apply to adults 40 years or older without a history of known CVD and who do not have signs and symptoms of CVD. These recommendations do not apply to adults with a low-density lipoprotein cholesterol (LDL-C) level greater than 190 mg/dL (4.92 mmol/L) or known familial hypercholesterolemia. These populations are at very high risk for CVD, and considerations on the use of statins in these populations can be found in other organizations' guidelines.

The American College of Cardiology/American Heart Association (ACC/AHA) Pooled Cohort Equations may be used to estimate 10-year risk of CVD. The estimator has separate equations based on sex and for Black persons and non-Black persons, which include the risk factors of age, cholesterol levels, systolic blood pressure level, antihypertension treatment, presence of diabetes, and smoking status, and focuses on hard clinical outcomes (myocardial infarction and death from coronary heart disease; ischemic stroke and stroke-related death) as the outcomes of interest. Age is one of the strongest risk factors for CVD, and the 10-year CVD event risk estimated by the ACC/AHA risk estimator is heavily influenced by increasing age. The risk prediction equations generally show higher risk for

Black persons than White persons. The USPSTF recognizes that race is a social construct, and it is an imperfect proxy for social determinants of health and the effects of structural racism. Concerns about calibration of the Pooled Cohort Equations exist, with many external validation studies showing overprediction in broad populations (men and women across racial and ethnic groups). Limited evidence also suggests underprediction in disadvantaged communities that could lead to underutilization of preventive therapies. Clinicians should recognize that predictions of 10-year CVD events using the Pooled Cohort Equations are estimates.

The higher a person's 10-year risk of a CVD event, the greater the chance of benefit from statin use. Thus, the expected benefit of statin therapy for persons with a 10-year CVD risk of 10% or greater exceeds the expected benefit for persons with a 10-year CVD risk of 7.5% to less than 10%. Clinicians should discuss with patients the potential risk of having a CVD event and the expected benefits and harms of statin use. For patients with an estimated 10-year CVD risk of 10% or greater and who smoke or have dyslipidemia, diabetes, or hypertension, the USPSTF recommends that clinicians prescribe a statin once the rationale has been explained and the patient agrees to take a statin. For patients with an estimated 10-year CVD risk of 7.5% to less than 10% (and who have ≥1 of the risk factors noted above), clinicians may selectively offer a statin, taking patient values and preferences into account. Patients in this estimated risk range who place a higher value on the potential benefits than on the potential harms and inconvenience of taking a daily medication may choose to initiate a statin.

Given that participants in clinical trials of statin therapy were enrolled based on the presence of 1 or more CVD risk factors, and that the magnitude of benefit of statin use is proportional to a person's estimated 10-year CVD risk, the USPSTF recommends that clinicians evaluate both the presence of CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) as well as estimated 10-year risk of CVD in determining which persons should initiate use of statins.

Periodic assessment of cardiovascular risk factors from ages 40 to 75 years, including measurement of total cholesterol, LDL-C, and HDL-C levels, is required to implement this recommendation. The optimal intervals for cardiovascular risk assessment are uncertain. Based on other guidelines and expert opinion, reasonable options include annual assessment of blood pressure and smoking status and measurement of lipid levels every 5 years. Shorter intervals may be useful for persons whose risk levels are close to those warranting therapy, and longer intervals are appropriate for persons who are not at increased risk and have repeatedly normal levels.

The 4 groups identified in the ACC/AHA guidelines for major statin benefit are:

1. Individuals with any form of clinical ASCVD
2. Individuals with primary LDL levels of ≥ 190mg per dL

3. Individuals with diabetes mellitus aged 40-75 years with LDL levels of 70-189mg per dL
4. Individuals without clinical ASCVD or diabetes who are 40 to 75 years of age with LDL-C 70- 189 mg/dL and an estimated 10-year ASCVD risk of 7.5% or higher

An easy reference guide summarizing the ACC/AHA 2019 recommendations for ASCVD risk assessment and treatment is available in the form of a flow chart online at: https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000678.

The USPSTF concludes there are limited data directly comparing the effects of different statin intensities on health outcomes. A majority of the trials reviewed by the USPSTF used moderate-intensity statin therapy. Based on available evidence, use of moderate-intensity statin therapy seems reasonable for the primary prevention of CVD in most persons.

The 2018 and 2019 ACC/AHA guidelines define cardiovascular risk categories as high (10-year risk of cardiovascular events ≥20%), intermediate (10-year risk of cardiovascular events ≥7.5% to <20%), and borderline (10-year risk of cardiovascular events 5% to <7.5%). The guidelines recommend initiation of statin therapy in persons at intermediate or high risk and a risk discussion for persons at borderline risk and recommend consideration of risk enhancers to refine risk assessments based on the Pooled Cohort Equations and inform decision-making for persons at intermediate and borderline risk. These risk enhancers include family history of early coronary heart disease, presence of chronic kidney disease, metabolic syndrome, preeclampsia, premature menopause, inflammatory diseases, HIV, and South Asian ancestry.

For primary prevention, the 2020 US Department of Veterans Affairs/US Department of Defense Clinical Practice Guideline recommends initiation of a moderate-dose statin in persons with an estimated 10-year cardiovascular risk of 12% or greater and shared decision-making for persons with an estimated 10-year cardiovascular risk of 6% to 12%. The USPSTF determined that the current evidence for screening for children and adolescents 20 years or younger is insufficient to assess the balance of benefits and harms of screening for lipid disorders in children and adolescents 20 years or younger.

TESTING FOR LIPID LEVELS

According to the USPSTF, for the purposes of this recommendation, dyslipidemia is defined as an LDL-C level greater than 130 mg/dL or a high-density lipoprotein cholesterol (HDL-C) level less than 40 mg/dL (to convert HDL-C values to mmol/L, multiply by 0.0259). Most participants enrolled in trials of statin use for the prevention of CVD had an LDL-C level of 130 to 190 mg/dL or a diabetes diagnosis; hypertension and smoking were also common among trial participants. Persons with an LDL-C level greater than 190 mg/dL were usually excluded from trial participation, as it was not considered appropriate to randomly assign them to placebo. Thus, these recommendations do not pertain to

persons with very high cholesterol levels (i.e., LDL-C >190 mg/dL) or familial hypercholesterolemia, as they were excluded from most prevention trials.

INTERVENTIONS

Therapeutic Lifestyle Change (TLC). The National Heart, Lung and Blood Institute of the National Institutes of Health recommends a program of TLC to regulate dyslipidemia. The main components of TLC* are:

- Reduced dietary saturated fat (to compose < 7% of total caloric intake);
- Increased plant sterols (add 2 g/day) and soluble fiber (add 5-10 g/day) to lower LDL;
- Reduce dietary cholesterol to less than 200 mg/day
- 25–35 percent of daily calories from total fat (includes saturated fat calories)
- Weight reduction for patients with obesity or overweight;
- Increased physical activity (at least 30 minutes of a moderate intensity physical activity, such as brisk walking, on most, and preferably all, days of the week.

*Lifestyle modifications (diet and physical activity) are appropriate initial therapies for most patients with some achieving significant lipid level reductions from dietary changes alone.

According to the ACC/AHA guidelines, "lifestyle modification (i.e., adhering to a heart healthy diet, regular exercise habits, avoidance of tobacco products, and maintenance of a healthy weight) remains a critical component of health promotion and ASCVD risk reduction, both prior to and in concert with the use of cholesterol-lowering drug therapies."

Drug Therapy is considered to be effective for most people with a history of heart disease in improving lipid profiles. Medications may be needed to achieve therapeutic goals. However, treatment must consider the risks involved, costs, and patient preferences.

Medications can also have adverse effects. Acute renal failure, moderate or severe myopathy, moderate to severe liver dysfunction, cataract formation, and diabetes have been reported side effects by patients using statin therapy. Ray et al. (2010) noted, "in some subgroups statins cause serious unrecognized harm, which negates the beneficial effects if the benefit is small – i.e., most primary prevention settings."

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the patient to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a patient's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is essential for the practitioner to refer the patient for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

Practitioner & Member Resources

Publicly available resources can be found at:

- USPSTF Screening Recommendations https://www.uspreventiveservicestaskforce.org/BrowseRec/Index/browse-recommendations
- 10 Year Risk Calculator for Atherosclerotic Cardiovascular Disease http://tools.acc.org/ASCVD-Risk-Estimator/
- National Institutes of Health Medline Plus. Cholesterol: http://www.nlm.nih.gov/medlineplus/cholesterol.html#cat57
- American Heart Association. Cholesterol home page: https://www.heart.org/en/health-topics/cholesterol
- HealthFinder.gov. Get Your Cholesterol Checked: http://www.healthfinder.gov/HealthTopics/Category/doctor-visits/screening-tests/get-your-cholesterol-checked

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