Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk Factors: U.S. Preventive Services Task Force Recommendation Statement

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Description: Update and refinement of the 2003 U.S. Preventive Services Task Force (USPSTF) recommendation on dietary counseling for adults with risk factors for cardiovascular disease (CVD).

Methods: The USPSTF reviewed the evidence on whether primary care–relevant counseling interventions for a healthful diet and physical activity modify self-reported behaviors, intermediate physiologic outcomes, diabetes incidence, and cardiovascular morbidity or mortality in adults with CVD risk factors, as well as the adverse effects of counseling interventions.

Population: This recommendation applies to adults aged 18 years or older in primary care settings who are overweight or obese and have known CVD risk factors (hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome).

Recommendation: The USPSTF recommends offering or referring adults who are overweight or obese and have additional CVD risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention. (B recommendation)


For author affiliation, see end of text.

The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

SUMMARY OF RECOMMENDATION AND EVIDENCE

The USPSTF recommends offering or referring adults who are overweight or obese and have additional cardiovascular disease (CVD) risk factors to intensive behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention. (B recommendation)

See the Clinical Considerations section for more information about CVD risk factors.

See the Figure for a summary of the recommendation and suggestions for clinical practice.

Appendix Table 1 describes the USPSTF grades, and Appendix Table 2 describes the USPSTF classification of levels of certainty about net benefit (both tables are available at www.annals.org).

RATIONALE

Importance

Cardiovascular disease, primarily in the forms of heart disease and stroke, is a leading cause of death in the United States (1). Obesity is associated with increased CVD mortality (2). Adults who adhere to national guidelines for a healthful diet (3) and physical activity (4) have lower cardiovascular morbidity and mortality than those who do not. All persons, regardless of CVD risk status, can accrue the health benefits of improved nutrition, healthy eating behaviors, and increased physical activity (5).

Benefits of Behavioral Counseling Interventions

The USPSTF found adequate evidence that intensive behavioral counseling interventions have moderate benefits
for CVD risk in overweight or obese adults who are at increased risk for CVD, including decreases in blood pressure, lipid and fasting glucose levels, and body mass index (BMI) and increases in levels of physical activity. The reduction in glucose levels was large enough to decrease the incidence of a diabetes diagnosis. The USPSTF found inadequate direct evidence that intensive behavioral counseling interventions lead to decreases in mortality or CVD rates.

**Harms of Behavioral Counseling Interventions**

The USPSTF found adequate evidence that the harms of behavioral counseling interventions are small to none. None of the dietary intervention studies explicitly reported adverse events. Studies of physical activity interventions reported mostly minor adverse events, and intense physical activity was rarely associated with cardiovascular events.

**USPSTF Assessment**

The USPSTF concludes with moderate certainty that intensive behavioral counseling interventions to promote a healthful diet and physical activity have a moderate net benefit in overweight or obese adults who are at increased risk for CVD.

**Clinical Considerations**

**Patient Population Under Consideration**

This recommendation applies to adults aged 18 years or older in primary care settings who are overweight or obese and have known CVD risk factors (hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome). In the studies reviewed by the USPSTF, a substantial majority of participants had a BMI greater than 25 kg/m².

**Behavioral Counseling Interventions**

Most studies evaluated interventions that combined counseling on a healthful diet and physical activity and were intensive, with multiple contacts (which may have included individual or group counseling sessions) over extended periods. Interventions involved an average of 5 to 16 contacts over 9 to 12 months depending on their intensity (6). Most of the sessions were in-person, and many included additional telephone contacts. Interventions generally focused on behavior change, and all included didactic education plus additional support. Most included audit and feedback, problem-solving skills, and individualized care plans. Some trials also focused on medication adher-
Interventions were delivered by specially trained professionals, including dietitians or nutritionists, physiotherapists or exercise professionals, health educators, and psychologists.

Many types of intensive counseling interventions were effective. However, it was not clear how the magnitude of the effect was related to the format of the intervention (for example, face-to-face, individual, group, or telephone), the person providing the counseling, the duration of the intervention, or the number of sessions because different combinations of components were effective (see the Implementation section for more information on effective interventions). Because of the intensity and expertise required, most interventions were referred from primary care and delivered outside that setting.

Other Approaches to Prevention

Tobacco use continues to be one of the most important risk factors for CVD. Helping patients with tobacco cessation is a critical component of CVD prevention. The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions to those who use such products (7). The U.S. Public Health Service has published guidelines to further help clinicians (8).

Multifaceted approaches with linkages between primary care practices and community resources could increase the effectiveness of interventions (9). Effective interactions between health care and community interventions, specifically public health and health policy interventions (such as healthy community design and built environment), can support and enhance the effectiveness of clinical interventions (more information is available at www.cdc.gov/healthyplaces). The Community Preventive Services Task Force recommends several community-based interventions to promote physical activity, including community-wide campaigns, social support interventions, school-based physical education, and environmental and policy approaches. It also recommends programs promoting diet and physical activity for persons who are at increased risk for type 2 diabetes on the basis of strong evidence of the effectiveness of these programs in reducing the incidence of new-onset diabetes. These recommendations are available at www.thecommunityguide.org.

The Million Hearts initiative (http://millionhearts.hhs.gov) aims to decrease the number of heart attacks and strokes by 1 million by 2017. It emphasizes the use of effective clinical preventive services combined with multifaceted community prevention strategies.

In 2010, the U.S. Department of Agriculture and the U.S. Department of Health and Human Services jointly issued the “Dietary Guidelines for Americans” (3). The latter also issued complementary physical activity guidelines (4).

Useful Resources

The USPSTF has a wide range of recommendations focusing on CVD prevention. The current recommendation focuses on behavioral counseling that encourages healthy eating and physical activity behaviors to improve cardiovascular health. It does not address weight-loss programs. The USPSTF recommends that clinicians selectively initiate behavioral counseling to promote a healthful diet and physical activity in patients who are not obese and not at increased cardiovascular risk. The USPSTF does not address behavioral counseling in patients with a BMI less than 25 kg/m² who are at increased risk for CVD. However, for patients with a BMI of 30 kg/m² or greater, the USPSTF recommends screening these patients for obesity and offering or referring them to intensive, multicomponent behavioral counseling for weight loss.

In another recommendation, the USPSTF recommends screening for lipid disorders in adults according to age and risk factors. It also recommends screening for blood pressure in adults, screening for diabetes in patients with elevated blood pressure, and aspirin use when appropriate. These recommendations are available at www.uspreventiveservicestaskforce.org.

Other Considerations

Implementation

The USPSTF defines behavioral counseling interventions as preventive services that are designed to help persons engage in healthy behaviors and limit unhealthy ones (10). The USPSTF previously described the challenges of developing behavioral counseling recommendations that are feasible for primary care delivery or available for referral from primary care and delivered in other settings (10). Two well-researched interventions, the DPP (Diabetes Prevention Program) and PREMIER, could feasibly be adapted and delivered in the primary care setting or by local community providers. These interventions are described in further detail because they can be provided by an appropriately trained counselor (typically a dietitian, nutritionist, health educator, or psychologist) and their materials are publicly available. Descriptions of all of the reviewed interventions are included in the evidence review (6).

The DPP focused on whether weight reduction through a healthful diet and physical activity could prevent or delay the onset of type 2 diabetes (11). Participants in the lifestyle intervention group received intensive training in diet, physical activity, and behavior modification from a case manager or lifestyle coach. Lifestyle coaches were dietitians or persons with a master’s degree and training in exercise physiology, behavioral psychology, or health education. Participants received basic information about nutrition, physical activity, and behavioral self-management. The program addressed problem solving and strategies to deal with eating at restaurants, stress, and lapses. Participants and coaches engaged in face-to-face sessions at least
oncet every 2 months and talked by telephone at least once between visits. The DPP study documents, including coach and participant materials, are available online in English and Spanish (https://dppos.bsc.gwu.edu/web/dppos/lifestyle). At least 1 trial included in the review (12) used an adapted DPP lifestyle intervention in patients recruited from a primary care setting. The trial was conducted in a large multispecialty group practice. Investigators tested a coach-led intervention and a home-based, DVD-facilitated intervention, as well as a Web-based portal for goal setting and self-monitoring. The materials used for the intervention are available online from the University of Pittsburgh Diabetes Prevention Support Center (www.diabetesprevention.pitt.edu).

PREMIER tested whether counseling on comprehensive lifestyle changes could prevent or control high blood pressure (13). Participants in the intensive intervention group were counseled over 6 months to track their diet (including calorie and sodium consumption) and physical activity and received printed materials about blood pressure and lifestyle changes. In addition, they were taught to follow the Dietary Approaches to Stop Hypertension (DASH) diet, which is rich in fruits, vegetables, and low-fat dairy products and emphasizes reduced intake of saturated and total fat. The intervention was delivered by dietitians or health educators with a master’s degree. The materials from this intervention, including participant manuals, food and fitness guides, and food diaries, are available online at www.kpchr.org/research/public/premier/premier.htm. Information about the DASH diet is available from the National Heart, Lung, and Blood Institute (14).

Research Needs and Gaps

Trials examining the effectiveness of less intensive counseling that can be delivered in the primary care setting, including the minimum intensity, number of interactions, and duration necessary for effectiveness, are needed, as are studies examining the duration of effect beyond 2 to 3 years of follow-up or beyond the intensive counseling intervention period. The effectiveness of interventions for physical activity alone has not been well-studied. Trials examining the interaction or potentiation of clinical counseling and community-based lifestyle interventions are needed. Finally, the lack of direct evidence of effect on CVD events is an important research gap. Advances in management of CVD risk factors and relatively low rates of CVD events in study populations present a challenge to researchers trying to assess differences in CVD outcomes.

DISCUSSION

Burden of Disease

Cardiovascular disease is a leading cause of death in the United States, and well-established CVD risk factors, such as obesity, hypertension, hyperlipidemia, and diabetes, are common in adults. The Centers for Disease Control and Prevention estimates that nearly half of all U.S. adults aged 20 years or older have at least 1 of the following CVD risk factors: uncontrolled hypertension, uncontrolled elevated low-density lipoprotein (LDL) cholesterol level, or current smoking (15). It also estimates that nearly 70% of U.S. adults are overweight or obese (16).

Scope of Review

The evidence review (6) for this recommendation addressed whether primary care–relevant counseling interventions for a healthful diet and/or physical activity modify self-reported behaviors, intermediate physiologic outcomes (such as lipid levels, blood pressure, glucose tolerance, weight, and BMI), diabetes incidence, and cardiovascular morbidity or mortality in adults with known cardiovascular risk factors (hypertension, dyslipidemia, impaired fasting glucose or glucose intolerance, or the metabolic syndrome). The adverse effects of counseling interventions were also reviewed.

This recommendation is intended to complement the USPSTF’s 2012 recommendation on behavioral counseling interventions to promote a healthful diet and physical activity for CVD prevention in persons without cardiovascular risk factors (C recommendation). The evidence review did not include interventions specifically focused on weight loss, which are addressed in the USPSTF’s recommendation on screening and counseling for obesity (B recommendation). Trials conducted exclusively in persons with diabetes were excluded.

Effectiveness of Behavioral Counseling Interventions

The USPSTF considered 74 trials (with 77 intervention groups) in its review (6). Interventions that combined a healthful diet and physical activity were evaluated in 49 trial groups, diet-only interventions were evaluated in 18, and interventions involving only physical activity were evaluated in 10. Of the interventions reviewed, 2 were low-intensity, 48 were medium-intensity, and 37 were high-intensity. Interventions were defined as low-, medium-, or high-intensity on the basis of the amount of interaction with a provider (≤30, 31 to 360, and >360 minutes, respectively). Interventions targeted various risk factors, including dyslipidemia (17 trials), hypertension (18 trials), impaired fasting glucose or glucose tolerance (16 trials), and a combination of risk factors (26 trials). A substantial majority of trial participants had a BMI greater than 25 kg/m². The median BMI was 29.8 kg/m² (interquartile range, 28.4 to 31.2 kg/m²).

Patient Health Outcomes

The USPSTF considered 16 trials reporting effects on patient health outcomes (such as CVD events, mortality, quality of life, or depression symptoms) (6). Five of these trials reported cardiovascular events, including mortality; of these, 4 found no reduction in CVD events or mortality at 6 to 79 months. However, CVD event rates were low. One trial, the Risk Factor Intervention Study, showed a
Behavioral Counseling in Adults With Cardiovascular Risk Factors

The evidence reviewed by the USPSTF shows the effectiveness of intensive behavioral counseling interventions in making small but important changes in health behavior outcomes and selected intermediate clinical outcomes after 12 to 24 months. Total cholesterol levels decreased by approximately 0.08 to 0.16 mmol/L (3 to 6 mg/dL), and LDL cholesterol levels decreased by approximately 0.04 to 0.17 mmol/L (1.40 to 5.98 mg/dL), triglyceride levels by 0.09 mmol/L (8.33 mg/dL) (CI, 0.03 to 0.16 mmol/L [2.86 to 13.80 mg/dL]), systolic blood pressure by 2.06 mm Hg (CI, 1.08 to 3.03 mm Hg), diastolic blood pressure by 1.30 mm Hg (CI, 0.68 to 1.93 mm Hg), fasting glucose levels by 0.10 mmol/L (1.86 mg/dL) (CI, 0.03 to 0.18 mmol/L [0.49 to 3.24 mg/dL]), weight by a standardized mean difference of 0.24 (CI, 0.14 to 0.35), and diabetes incidence by a relative risk of 0.54 (CI, 0.34 to 0.88). These effects were assessed across all trials that reported each outcome at 12 to 24 months.

Intensive diet-only interventions reduced total cholesterol levels by 0.10 mmol/L (3.75 mg/dL) (CI, 0.03 to 0.17 mmol/L [1.01 to 6.50 mg/dL]), LDL cholesterol levels by 0.11 mmol/L (4.27 mg/dL) (CI, 0.02 to 0.20 mmol/L [0.70 to 7.84 mg/dL]), and triglyceride levels by 0.20 mmol/L (17.86 mg/dL) (CI, 0.03 to 0.37 mmol/L [2.62 to 33.10 mg/dL]). Few trials that evaluated only physical activity reported intermediate outcomes, making it difficult to estimate average effects. Most of these interventions were medium-intensity, and there were important differences among populations, interventions, and outcomes. Overall, there is no consistent evidence of benefit on intermediate health outcomes for interventions involving physical activity only.

**Health Behavior Outcomes**

The USPSTF considered 61 trials (n = 31,751) reporting outcomes related to health behaviors (6). Three of these trials reported only health behavior outcomes and not intermediate health outcomes. Overall, objectively measured and self-reported changes in dietary intake (such as decreased total and saturated fat, increased fruits and vegetables, and total calories) and physical activity were consistent with intermediate outcome findings. Several trials in persons already receiving medication to decrease blood pressure or cholesterol level reported statistically significant improvements in dietary intake and physical activity but found no benefit on intermediate outcomes.

The DPP was a good-quality, high-intensity trial of a combined behavioral counseling intervention aimed at preventing diabetes in overweight persons with impaired fasting glucose (11) (see the Implementation section for more detail). It was one of the few trials included in the review that assessed health, intermediate, and behavioral outcomes. The trial enrolled 2161 participants in the intervention and placebo groups (mean age, 51 years). More than one quarter (26.9%) and one third (34.6%) of participants had hypertension or dyslipidemia, respectively, and the mean BMI was 34 kg/m². Overall, at 3 years, persons in the intervention group had a 0.22 mmol/L (4 mg/dL) decrease in fasting blood glucose level, a 58% reduction in diabetes incidence, and decreases in blood pressure and lipid measures.

PREMIER was a good-quality trial aimed at decreasing blood pressure in persons who were not yet receiving medication (13) (see the Implementation section for more detail). The trial enrolled 304 participants in the hypertension subgroup (mean age, 52 years; mean systolic blood pressure, 144 mm Hg) (6). Approximately two thirds of participants had a BMI greater than 30 kg/m². After 18 months, only 21% of persons in the intensive counseling intervention group versus 41% in the usual care group were receiving hypertension medication. Participants in the intervention group also had decreases in blood pressure and lipid measures after 6 months; however, the improvements generally decreased after 18 months.

**Summary**

The evidence reviewed by the USPSTF shows the effectiveness of intensive behavioral counseling interventions in making small but important changes in health behavior outcomes and selected intermediate clinical outcomes after 12 to 24 months. Total cholesterol levels decreased by approximately 0.08 to 0.16 mmol/L (3 to 6 mg/dL), and LDL cholesterol levels decreased by approximately 0.04 to 0.17 mmol/L (1.01 to 6.50 mg/dL), and triglyceride levels decreased by 0.11 mmol/L (4.27 mg/dL) (CI, 0.02 to 0.20 mmol/L [0.70 to 7.84 mg/dL]), and systolic blood pressure decreased by 2.06 mm Hg (CI, 1.08 to 3.03 mm Hg), and diastolic blood pressure decreased by 1.30 mm Hg (CI, 0.68 to 1.93 mm Hg), and fasting glucose level decreased by 0.10 mmol/L (1.86 mg/dL) (CI, 0.03 to 0.18 mmol/L [0.49 to 3.24 mg/dL]), and weight decreased by a standardized mean difference of 0.24 (CI, 0.14 to 0.35), and diabetes incidence decreased by a relative risk of 0.54 (CI, 0.34 to 0.88).
Behavioral Counseling in Adults With Cardiovascular Risk Factors

0.13 mmol/L (1.5 to 5 mg/dL). Systolic and diastolic blood pressures decreased by 1 to 3 mm Hg and 1 to 2 mm Hg, respectively. Fasting glucose levels decreased by approximately 0.06 to 0.17 mmol/L (1 to 3 mg/dL). Diabetes incidence decreased by as much as 42% in trials reporting outcomes after 3 years. Weight decreased by a standardized mean difference of 0.26, which is roughly equivalent to a BMI reduction of 0.5 to 1.5 kg/m², or approximately 3 kg. Based on self-reported physical activity, the proportion of persons who participated in moderate-intensity exercise for 150 minutes per week increased from 10% to 25%. Epidemiologic data suggest that even small improvements in lipid levels, blood pressure, glycemic control, and weight can decrease the risk for heart disease and stroke in persons at increased risk for CVD.

Potential Harms of Behavioral Counseling Interventions

Of the 74 trials reviewed by the USPSTF, only 6 specifically reported adverse events during the trial and 6 specifically reported no adverse events (6). Few trials reported details about the adverse events, but most were minor, including musculoskeletal and gastrointestinal symptoms. In trials evaluating physical activity interventions, a few participants reported fatigue, muscle soreness, or other minor musculoskeletal injuries. Serious adverse events were rare. There was no consistent evidence that behavioral counseling interventions led to paradoxical changes in intermediate or behavioral outcomes.

Estimate of Magnitude of Net Benefit

The USPSTF assessed the overall effectiveness of intensive behavioral counseling interventions on intermediate and behavioral health outcomes to be moderate. The changes in lipid and blood pressure measures were generally small, but these effects were combined with reductions in weight and sustained improvements in healthy lifestyle behaviors. The effects are consistent across a substantive body of evidence for various CVD risk factors and interventions. The USPSTF concludes that, because a substantial majority of trial participants were overweight or obese, these persons will accrue benefits from these interventions. The potential harms are small at most; therefore, the USPSTF concludes that these interventions have a moderate net benefit.

Response to Public Comments

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 13 May to 9 June 2014. Thirty-three comments were received. In response to these comments, the USPSTF clarified how this recommendation fits with related ones on healthy lifestyles and screening for obesity. It clarified the population under consideration throughout the recommendation statement and more explicitly defined the connections between the populations studied and the target population of the recommendation. The USPSTF also provided more detail on the evidence gap for CVD outcomes and added to the Research Needs and Gaps section. In addition, it added or updated several references and made other minor editorial changes.

Update of Previous USPSTF Recommendation

This recommendation is an update and refinement of the USPSTF’s 2003 recommendation on dietary counseling for adults with CVD risk factors (B recommendation). At that time, the USPSTF recommended intensive behavioral dietary counseling for adult patients with known CVD risk factors, including hyperlipidemia and other diet-related chronic diseases. In contrast, this new recommendation targets overweight or obese adults who have additional CVD risk factors (such as hypertension, dyslipidemia, impaired fasting glucose, or the metabolic syndrome). Interventions assessed for this recommendation focused on improving healthy eating, increasing physical activity, or combined approaches to developing a healthier lifestyle.

Recommendations of Others

The American College of Sports Medicine has published recommendations for health professionals who counsel healthy adults on individualized exercise programs. It recommends 150 minutes of moderate-intensity exercise per week and 2 to 3 days of resistance, flexibility, and neuromotor exercises per week (20). Previous statements by the American Academy of Family Physicians about counseling for diet and physical activity have been consistent with those of the USPSTF; it is currently updating its recommendations (21).

From the U.S. Preventive Services Task Force, Rockville, Maryland.

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Requests for Single Reprints: Reprints are available from the USPSTF Web site (www.uspreventiveservicestaskforce.org).

References
APPENDIX: U.S. PREVENTIVE SERVICES TASK FORCE

Members of the U.S. Preventive Services Task Force at the time this recommendation was finalized† are Michael L. LeFevre, MD, MSPH, Chair (University of Missouri School of Medicine, Columbia, Missouri); Albert L. Siu, MD, MSPH, Co-Vice Chair (Mount Sinai School of Medicine, New York, and James J. Peters Veterans Affairs Medical Center, Bronx, New York); Kirsten Bibbins-Domingo, PhD, MD, Co-Vice Chair (University of California, San Francisco, San Francisco, California); Linda Ciofu Baumann, PhD, RN (University of Wisconsin, Madison, Wisconsin); Susan J. Curry, PhD (University of Iowa College of Public Health, Iowa City, Iowa); Karina W. Davidson, PhD, MASc (Columbia University, New York, New York); Mark Ebell, MD, MS (University of Georgia, Athens, Georgia); Francisco A.R. García, MD, MPH (Pima County Department of Health, Tucson, Arizona); Matthew Gillman, MD, SM (Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, Massachusetts); Jessica Herzerstein, MD, MPH (Air Products, Allentown, Pennsylvania); Alex R. Kemper, MD, MPH, MS (Duke University, Durham, North Carolina); Ann E. Kurth, PhD, RN, MSN, MPH (New York University, New York, New York); Douglas K. Owens, MD, MS (Veterans Affairs Palo Alto Health Care System, Palo Alto, and Stanford University, Stanford, California); William R. Phillips, MD, MPH (University of Washington, Seattle, Washington); Maureen G. Phipps, MD, MPH (Brown University, Providence, Rhode Island); and Michael P. Pignone, MD, MPH (University of North Carolina, Chapel Hill, North Carolina).

† For a list of current Task Force members, go to www.uspreventiveservicestaskforce.org/members.htm.

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**Appendix Table 1. What the USPSTF Grades Mean and Suggestions for Practice**

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<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
<th>Suggestions for Practice</th>
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<tbody>
<tr>
<td>A</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is substantial.</td>
<td>Offer/provide this service.</td>
</tr>
<tr>
<td>B</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.</td>
<td>Offer/provide this service.</td>
</tr>
<tr>
<td>C</td>
<td>The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.</td>
<td>Offer/provide this service for selected patients depending on individual circumstances.</td>
</tr>
<tr>
<td>D</td>
<td>The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.</td>
<td>Discourage the use of this service.</td>
</tr>
<tr>
<td>I statement</td>
<td>The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.</td>
<td>Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.</td>
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**Appendix Table 2. USPSTF Levels of Certainty Regarding Net Benefit**

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<th>Level of Certainty*</th>
<th>Description</th>
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<tr>
<td>High</td>
<td>The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.</td>
</tr>
<tr>
<td>Moderate</td>
<td>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: the number, size, or quality of individual studies; inconsistency of findings across individual studies; limited generalizability of findings to routine primary care practice; and lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</td>
</tr>
<tr>
<td>Low</td>
<td>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies; important flaws in study design or methods; inconsistency of findings across individual studies; gaps in the chain of evidence; findings that are not generalizable to routine primary care practice; and a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.</td>
</tr>
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</table>

* The USPSTF defines certainty as “likelihood that the USPSTF assessment of the net benefit of a preventive service is correct.” The net benefit is defined as benefit minus harm of the preventive service as implemented in a general primary care population. The USPSTF assigns a certainty level on the basis of the nature of the overall evidence available to assess the net benefit of a preventive service.