## **Annals of Internal Medicine**

## CLINICAL GUIDELINE

# **Screening for Primary Hypertension in Children and Adolescents:** U.S. Preventive Services Task Force Recommendation Statement\*

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Description: Update of the 2003 U.S. Preventive Services Task Force (USPSTF) recommendation on screening for high blood pressure in children and adolescents.

Methods: The USPSTF reviewed the evidence on screening and diagnostic accuracy of screening tests for blood pressure in children and adolescents, the effectiveness and harms of treatment of screen-detected primary childhood hypertension, and the association of hypertension with markers of cardiovascular disease in childhood and adulthood.

Population: This recommendation applies to children and adolescents who do not have symptoms of hypertension.

Recommendation: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for primary hypertension in asymptomatic children and adolescents to prevent subsequent cardiovascular disease in childhood or adulthood.

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- † For a list of USPSTF members, see the Appendix (available at www.annals.org)

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he 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 concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for primary hypertension in asymptomatic children and adolescents to prevent subsequent cardiovascular disease in childhood or adulthood. (I statement)

See the Clinical Considerations section for suggestions for practice regarding the I statement.

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

The prevalence of hypertension in children and adolescents in the United States has been reported at 1% to 5%. Primary hypertension in children and adolescents is associated with several risk factors, the strongest of which is elevated body mass index. The prevalence of hypertension in children and adolescents has increased over the past several decades, which is probably attributable to the increase in the prevalence of childhood overweight and obesity. The prevalence of hypertension among obese children in the United States is estimated at 11%.

One rationale for screening for hypertension in children and adolescents is that early identification of primary hypertension could lead to interventions to reduce blood pressure during childhood and adolescence, resulting in a reduced risk for cardiovascular events and death in adulthood.

See also:

#### Print

Summary for Patients.....I-30



Figure. Screening for primary hypertension in children and adolescents: clinical summary of U.S. Preventive Services Task Force recommendation.

## **Annals of Internal Medicine**



## SCREENING FOR PRIMARY HYPERTENSION IN CHILDREN AND ADOLESCENTS CLINICAL SUMMARY OF U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION

Population	Children and adolescents without symptoms of hypertension	
Recommendation	No recommendation. Grade: I statement	
Risk Assessment	The strongest risk factor for primary hypertension in children is elevated BMI. Other risk factors include low birthweight, male sex, ethnicity, and a family history of hypertension.	
Screening Tests	Blood pressure screening with sphygmomanometry in the clinical setting may identify children and adolescents with hypertension with reasonable sensitivity; however, false-positive results may occur with normalization of subsequent blood pressure measurements.	
Treatment	Stage 1 hypertension in children is treated with lifestyle and pharmacologic interventions; medications are not recommended	

as first-line therapy The USPSTF found inadequate evidence on the diagnostic accuracy of screening for primary hypertension. The USPSTF also Balance of Benefits found inadequate evidence on the effectiveness of treatment and the harms of screening or treatment. Therefore, the and Harms USPSTF cannot determine the balance of benefits and harms of screening for hypertension in children and adolescents. Other Relevant USPSTF The USPSTF has made recommendations on screening for lipid disorders in children and adolescents. These Recommendations recommendations are available at www.uspreventiveservicestaskforce.org

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, please go to www.uspreventiveservicestaskforce.org

BMI = body mass index.

#### Detection

The USPSTF found inadequate evidence about the diagnostic accuracy of screening for elevated blood pressure with sphygmomanometry in the clinical setting. The 2 fair-quality studies available used different gold standards (ambulatory blood pressure monitoring and subsequent blood pressure readings) (1). Blood pressure screening with sphygmomanometry in the clinical setting may be reasonably sensitive for identifying children and adolescents with hypertension; however, false-positive results may occur with normalization of subsequent blood pressure measurements.

#### Association With Adult Hypertension and Cardiovascular Disease

The USPSTF found no direct evidence that routine blood pressure measurement accurately identifies children and adolescents who are at increased risk for cardiovascular disease in adulthood and inadequate evidence that routine blood pressure measurement accurately identifies children and adolescents who are at increased risk for adult hypertension or other intermediate measures of adult cardiovascular disease. Children and adolescents with hypertension are more likely to have hypertension as adults; however,

predictive values of childhood hypertension for adult hypertension are at best modest (65%) and vary widely (19% to 65%) (1). Most studies examining the association of hypertension and subclinical cardiovascular disease in children are cross-sectional studies and limited to children with hypertension secondary to kidney disease. Evidence about the longitudinal association between hypertension in children and adolescents and intermediate outcomes indicating cardiovascular damage in adults, such as carotid intima-media thickening or microalbuminuria, is limited and conflicting.

## Benefits of Detection and Early Intervention

The USPSTF found inadequate evidence to determine whether treatment of elevated blood pressure in children or adolescents results in sustained decreases in blood pressure in childhood because studies in this area have been of short duration; trials of the efficacy of antihypertension drugs were typically 4 weeks in duration, whereas studies of lifestyle interventions ranged from 2 months to 3 years with a median duration of 7 months (1).

The USPSTF also found inadequate evidence to determine the health outcomes associated with interventions to treat primary hypertension in childhood or adolescence.

#### Harms of Detection and Early Intervention

The USPSTF found inadequate evidence to assess the potential harms of screening for primary hypertension in children and adolescents. Only 1 good-quality study was identified, and it did not find any adverse effects, as assessed by school absenteeism, of detecting primary hypertension in childhood (2).

The USPSTF found inadequate evidence to assess the potential harms of pharmacologic or nonpharmacologic treatment of elevated blood pressure in childhood or adolescence. Short-term pharmacologic treatments generally seemed to be well-tolerated, with no serious adverse events during short-term treatment periods. However, adverse event rates were often incompletely reported, and the evidence is limited by a lack of studies with follow-up longer than several weeks. Information on adverse effects of lifestyle interventions or lifestyle interventions combined with pharmacotherapy is also limited.

#### **USPSTF** Assessment

The USPSTF concludes that the evidence to support screening for primary hypertension in children and adolescents is insufficient and that the balance of benefits and harms cannot be determined.

#### **CLINICAL CONSIDERATIONS**

#### **Patient Population Under Consideration**

This recommendation applies to children and adolescents who do not have symptoms of hypertension.

#### Assessment of Risk

The strongest risk factor for primary hypertension in children and adolescents is elevated body mass index. Other risk factors include low birthweight, male sex, ethnicity, and family history of hypertension.

#### Suggestions for Practice Regarding the I Statement

When deciding whether to screen children and adolescents for hypertension, clinicians should consider the following factors.

#### Potential Preventable Burden

The increasing prevalence of hypertension in children and adolescents, possibly driven by childhood obesity, suggests that identification and treatment of hypertension is likely to become a significant health care issue. The goal of identifying and treating children and adolescents with primary hypertension can be viewed within a larger framework of adult cardiovascular risk reduction, which includes addressing other biometric risk factors, such as elevated body mass index and lipid profiles and hyperglycemia. The variables for cardiovascular risk reduction in adults are better understood because hypertension in adults is defined by relatively consistent quantitative thresholds, the epidemiologic evidence demonstrates the association between hypertension and subsequent cardiovascular risk, and treatment trials have shown that reduction in blood pressure reduces the risk for cardiovascular events in older adults.

Extending the adult framework for cardiovascular risk reduction to children and adolescents is limited by several methodological challenges that complicate determining the potential preventable burden. Blood pressure percentiles are used to define normative values for children and adolescents, and less is known about the clinical and epidemiologic significance of these thresholds in terms of their association with adult cardiovascular disease. In addition, the performance characteristics of current methods for diagnosing hypertension during childhood are limited and of concern because of false-positive rates (blood pressure measurements that later normalize). Evidence on the association between childhood blood pressure and adult hypertension is limited, as is evidence on the longitudinal association between childhood blood pressure and other markers of adult cardiovascular disease.

Most important, the limited data on treatment of hypertension in children and adolescents do not include longer-term follow-up to show reductions in surrogate, subclinical, or clinical measures of cardiovascular disease in either later adolescence or young adulthood. This limited evidence base makes it difficult to quantify the true significance and consequences of a hypertension diagnosis in children and adolescents and the potential benefit of early intervention.

One rationale that has been suggested for screening is to identify secondary hypertension—a relatively rare condition resulting from another underlying cause, such as renal parenchymal disease or renovascular disease. Younger children are more likely than older children and adolescents to have a secondary cause of hypertension; a recent study suggests that secondary causes of hypertension are significantly more common in children younger than 6 years than in older children (3). Secondary hypertension is unlikely to be the only clinical manifestation of the underlying disorder in these cases, and management is primarily targeted at treating the underlying condition, as well as controlling hypertension. As children age into adolescence, 85% to 95% of all hypertension diagnoses are considered primary (1, 4).

#### Potential Harms

Although 1 good-quality study suggests that no adverse effects are associated with hypertension detection in childhood (2), the evidence on the diagnostic accuracy of clinic-based screening for hypertension suggests that falsepositive results may occur. Thus, unnecessary secondary evaluations or treatments may be common, particularly with frequent blood pressure screening. Pharmacologic interventions have been shown to be well-tolerated over relatively short periods. Treatment of hypertension in childhood and adolescence with pharmacologic agents is done for a much longer period, and adverse effects of such pharmacotherapy can occur.

#### Current Practice

Current screening practice for elevated blood pressure typically involves measurement of blood pressure in officebased health care settings as part of well-child or sports preparticipation examinations, often in conjunction with other vital signs and growth parameters. The National High Blood Pressure Education Program (NHBPEP) percentile charts are used to interpret systolic blood pressure (SBP) and diastolic blood pressure (DBP) measurements and categorize them as normal, prehypertension, or hypertension on the basis of the child's age, height, and sex for each year of the child's life from age 3 to 18 years.

A 2012 study analyzing data from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey assessed blood pressure screening during pediatric ambulatory office visits. It found that screening was done during 67% of preventive care visits and 35% of ambulatory visits. Screening was more common in children who were overweight or obese; 84% of these preventive care visits included screening for hypertension. It was also more likely to be done in older children (5).

#### **Screening Tests**

The consensus-based guidelines of the NHBPEP and National Heart, Lung, and Blood Institute define hypertension in children on the basis of percentiles according to age, height, and sex. Hypertension is defined as SBP or DBP at or above the 95th percentile. Hypertension is classified as stage 1 (SBP or DBP from 95th to 99th percentile, plus 5 mm Hg) or stage 2 (SBP or DBP >99th percentile, plus 5 mm Hg). The NHBPEP provides guidance on optimal blood pressure measurement techniques, such as appropriate cuff size and type of sphygmomanometer. Blood pressure should be measured in a controlled environment after 5 minutes of rest, with the patient seated and the right arm supported at heart level (6).

#### **Treatment**

Stage 1 hypertension in children is treated with lifestyle and pharmacologic interventions. Medications are not recommended as first-line therapy. Lifestyle interventions for hypertension include weight reduction in children who are overweight or obese, increased physical activity, and restricted sodium intake, as well as education and counseling. The NHBPEP recommends medication for children with stage 2 hypertension or for hypertension that is unresponsive to lifestyle modification (6).

Many medications have been approved by the U.S. Food and Drug Administration for the treatment of hypertension in children, including diuretics, angiotensinconverting enzyme inhibitors, angiotensin-receptor blockers,  $\beta$ -blockers, and vasodilators.

#### **Screening Intervals**

Several organizations recommend routine screening of blood pressure at well-child visits starting at age 3 years, based on consensus.

#### OTHER CONSIDERATIONS

#### Research Needs and Gaps

There are several critical evidence gaps in better understanding the potential net benefit of screening for hypertension in childhood and adolescence. Evidence about the accuracy and reliability of blood pressure screening tools and protocols in primary care among children and adolescents of varying ages and characteristics, such as those who are obese, is needed. Comparative accuracy studies that examine the different types of devices to measure blood pressure, such as newer devices that obtain several readings in 1 visit, home-based devices, and ambulatory blood pressure measurement, are needed. In addition, screening strategies that reduce the rate of false-positive diagnoses of hypertension need to be identified. Studies on the adverse effects of screening are also needed.

Prospective and retrospective cohort studies that include blood pressure measures and other cardiovascular risk factors in children and adolescents with long-term follow-up are needed to examine the adolescent and adult health outcomes of hypertension in childhood. Studies that elucidate the association among childhood hypertension, adult hypertension, and surrogate measures of cardiovascular disease in childhood and adulthood, as well as adult clinical cardiovascular disease, are also needed.

Most important, evidence to ascertain the effectiveness and comparative effectiveness of pharmacologic and lifestyle interventions to achieve sustained reductions in blood pressure and longer-term modification of adult hypertension and cardiovascular risk in children with primary hypertension is needed. Such studies should include longer follow-up intervals to determine the long-term effectiveness of these interventions in achieving sustained reductions in blood pressure during childhood and adolescence or reductions in future adult hypertension. Although trials with clinical cardiovascular end points are more challenging in children, treatment trials demonstrating changes in surrogate or subclinical cardiovascular outcomes during adolescence or young adulthood are feasible and warranted. Trials focusing on high-risk adolescent populations (such as those with obesity) that include longer-term follow-up with future hypertension and subclinical cardiovascular outcomes should be possible. Studies of treatment during childhood should include an assessment of medication harms, measures of long-term compliance, and study designs that examine individual components of multifactorial interventions.

#### **DISCUSSION**

#### Burden of Disease

The prevalence of hypertension in children and adolescents is 1% to 5%. Obese children have a higher prevalence of approximately 11%. Younger children are more likely to have secondary hypertension, whereas older children and adolescents are more likely to have primary hypertension. In school-aged children, secondary hypertension accounts for 70% to 85% of cases. As children age into adolescence, 85% to 95% of cases are primary hypertension. This recommendation focuses on primary hypertension and screening in asymptomatic children and adolescents. Secondary hypertension may not be the initial or only clinical manifestation of the underlying disorder and is therefore beyond the scope of this recommendation (1, 4, 7).

Adult hypertension is associated with an increased risk for cardiovascular events. One rationale for blood pressure screening in children and adolescents is that finding and treating hypertension early in childhood may improve cardiovascular outcomes in adulthood.

#### Scope of Review

To update its 2003 recommendation on screening for high blood pressure in children and adolescents (8), the USPSTF reviewed the evidence on screening and diagnostic accuracy of tests for blood pressure in children and adolescents, effectiveness and harms of treatment of screendetected primary childhood hypertension, and association between hypertension and markers of cardiovascular disease in childhood and adulthood. Screening for and treatment of secondary hypertension were not part of the review.

#### **Accuracy of Screening Tests**

Two studies provided evidence on the diagnostic accuracy of blood pressure measurement tools and protocols. Although different reference standards were used (ambulatory blood pressure measurement and repeated measurements using a sphygmomanometer), the studies reported similar sensitivities (0.65 and 0.72) and specificities (0.75 and 0.92). Positive predictive values in both studies were low (0.37 and 0.17). These studies suggest that there is moderate sensitivity in detecting elevated blood pressure; however, many children identified as having elevated blood pressure will not have hypertension. One study was done in a hypertension clinic in Greece, possibly limiting generalizability to a primary care population in the United States. The other study took place in a high school clinic (1).

#### Association With Adult Hypertension and Cardiovascular Disease

Ten longitudinal studies provided evidence on the association between elevated blood pressure in childhood and adulthood (7 studies), carotid intima-media thickness (2 studies), and microalbuminuria (1 study). Eight of the studies were based on U.S. longitudinal data. These studies used different thresholds for defining elevated blood pressure and hypertension in children and different definitions of hypertension in adults (1).

Four studies reported that elevated blood pressure in childhood and adolescence was significantly associated with hypertension in adulthood, with odds ratios ranging from 1.1 to 4.5 and relative risks ranging from 1.5 to 9; however, the 2 studies that reported the sensitivity and specificity of detecting hypertension in childhood and adolescence for adult hypertension gave widely differing estimates (sensitivity, 0.0 to 0.66; specificity, 0.77 to 1.0). Positive predictive values ranged from 0.19 to 0.65 (1).

Three studies examined the association between childhood and adolescent hypertension and other intermediate outcomes related to hypertension in adulthood. The association between childhood hypertension and carotid intima-media thickness is inconclusive because of conflicting results from 2 studies (1).

One study found that childhood hypertension was significantly associated with microalbuminuria in black adults but not white adults. No evidence showed an association between hypertension in childhood and other intermediate or final hypertension-related outcomes in adulthood (1).

#### Effectiveness of Early Detection and Treatment

No direct evidence demonstrated that screening children and adolescents for hypertension is effective in delaying the onset of or reducing the risk for adverse cardiovascular health outcomes related to hypertension, either in childhood or adulthood.

No studies reported on the effectiveness of treatments for primary childhood hypertension and subsequent reduction of blood pressure or other intermediate cardiovascular outcomes in adults.

#### Pharmacologic Interventions

Fourteen studies examined the effectiveness of interventions to reduce blood pressure in children and adolescents. Seven randomized, controlled trials of monotherapy with pharmacologic interventions were small, of fair quality, and mostly limited to children or adolescents with primary hypertension. All 7 trials reported either reductions in the absolute level of blood pressure or increased proportions of children achieving normotensive blood pressure. However, the antihypertension effects were of variable magnitude, not consistently present for any given agent across both SBP and DBP measurements, and not always significantly different from placebo or baseline (or this difference was not reported). In addition, none of the medications were evaluated in more than 1 study. The studies were also of short duration, with the longest trials lasting 4 weeks, and most were done in older children (mean age, 12 vears) (1).

#### Lifestyle Modification

The only trial of medication combined with various lifestyle components showed evidence of sustained reduction of blood pressure after 6 months; this trial was an intensive, school-based intervention. Of 6 trials that assessed lifestyle interventions, only 1 (a small, Danish, school-based trial of increased number of exercise classes) reported a significant decrease in blood pressure after 8 months (1).

#### Potential Harms of Screening and Treatment

One small (85 patients), good-quality, prospective study examined children labeled with hypertension compared with a control group matched by age and sex. School absenteeism rates did not differ significantly in the year after identification of elevated blood pressure. Data on other potential harms of screening were not reported (2).

Commonly reported adverse events associated with hypertension medications included headache, cardiac events, gastrointestinal events, and cough. Medications for treating primary hypertension in children seemed to be welltolerated, with 1 of 13 studies showing significant differences in rates of adverse events and serious adverse events between active intervention and placebo groups. However, studies of harms associated with pharmacologic interventions were limited by quality and generalizability and provided no information about the long-term risk for adverse effects. For example, most studies enrolled mixed populations of children with primary and secondary hypertension, used open-label periods to examine adverse effects, and had limited power to identify rare adverse events (1).

No studies reported on harms associated with lifestyle interventions. Evidence on adverse events associated with interventions that combine medication and lifestyle modifications is lacking.

#### Estimate of Magnitude of Net Benefit

The USPSTF found inadequate evidence on the diagnostic accuracy of screening for primary hypertension. The USPSTF also found inadequate evidence on the effectiveness of treatment and harms of screening or treatment. Therefore, the USPSTF concludes that the evidence on the benefits and harms of screening for hypertension in children and adolescents is lacking and that the balance of benefits and harms cannot be determined.

#### How Does Evidence Fit With Biological Understanding?

The proportion of children with primary hypertension who revert to normal blood pressure over time, without any intervention, and those who will continue to have hypertension in adulthood is unknown.

Persistent elevation of blood pressure in adults is an established risk factor for cardiovascular and cerebrovascular disorders and renal impairment. However, these conditions are often distant future events for children and adolescents. As a result, intermediate measures of target end-organ injury, including physical alterations to the structure of vascular walls (early atherosclerosis, thickening of arteries) and the heart (increased left ventricle mass) and altered renal function (microalbuminuria), are examined. At present, the evidence about the relationship between elevated blood pressure or intermediate outcomes in children and the presence of hypertension and intermediate outcomes in adults is inconsistent.

#### Response to Public Comments

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 26 February to 25 March 2013. Several comments noted the importance of detecting secondary hypertension through screening. In response to these comments, the USPSTF added additional information about secondary hypertension to the Clinical Considerations. Additional text was also added to clarify the scope of the review and address evidence gaps in the Benefits of Detection and Early Intervention, Suggestions for Practice Regarding the I Statement, and Research Needs and Gaps sections.

#### UPDATE OF PREVIOUS USPSTF RECOMMENDATION

This recommendation updates the child portion of the 2003 recommendation on screening for high blood pressure. The updated recommendation on screening for high blood pressure in adults was published separately. This recommendation is similar to the 2003 recommendation in that the evidence to assess the balance of benefits and harms is still insufficient.

#### **RECOMMENDATIONS OF OTHERS**

The American Academy of Pediatrics officially endorsed the NHBPEP 2004 recommendation that children aged 3 years and older have blood pressure measurement at least once at every "health care episode" (6). The National Heart, Lung, and Blood Institute's Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents recommends annual blood pressure screening in children from ages 3 to 17 years (9). Bright Futures (10) and other organizations, such as the American Heart Association (11), recommend routine screening for increased blood pressure in children during annual well-child visits beginning at age 3 years. The American Academy of Family Physicians states that there is insufficient evidence for or against routine screening for high blood pressure in children and adolescents (12).

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

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Potential Conflicts of Interest: Disclosure forms from USPSTF members can be viewed at www.acponline.org/authors/icmje/ConflictOf InterestForms.do?msNum=M13-1914.

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

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# APPENDIX: U.S. PREVENTIVE SERVICES TASK FORCE MEMBERS

Members of the U.S. Preventive Services Task Force at the time this recommendation was finalized‡ are Virginia A. Moyer, MD, MPH, Chair (American Board of Pediatrics, Chapel Hill, North Carolina); Michael L. LeFevre, MD, MSPH, Co-Vice 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); Linda Ciofu Baumann, PhD, RN (University of Wisconsin, Madison, Wisconsin); Kirsten Bibbins-Domingo, PhD, MD (University of California, San Francisco, San Francisco, California); Susan J. Curry, PhD (University of Iowa College of Public Health, Iowa City, Iowa); Mark Ebell, MD, MS (University of Georgia, Athens, Georgia); Glenn Flores, MD (University of Texas South-

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

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

Grade	Definition	Suggestions for Practice
А	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
В	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.	Offer/provide this service.
С	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.	Offer/provide this service for selected patients depending on individual circumstances.
D	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.	Discourage the use of this service.
I statement	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.	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.

#### Appendix Table 2. USPSTF Levels of Certainty Regarding Net Benefit

Level of Certainty*	Description	
High	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.	
Moderate	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.	
Low	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.	

<sup>\*</sup> 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.

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