Screening for Hearing Loss in Older Adults: U.S. Preventive Services Task Force Recommendation Statement

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Description: Update of the 1996 U.S. Preventive Services Task Force (USPSTF) recommendation statement on screening for hearing impairment in older adults.

Methods: The USPSTF reviewed evidence published between 1950 and January 2010 on screening for age-related sensorineural hearing impairment in adults aged 50 years or older without diagnosed hearing loss in the primary care setting.

Population: This recommendation applies to asymptomatic adults aged 50 years or older. It does not apply to persons seeking evaluation for perceived hearing problems or for cognitive or affective symptoms that may be related to hearing loss.

Recommendation: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for hearing loss in asymptomatic adults aged 50 years or older (I statement).


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

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The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive 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 hearing loss in asymptomatic adults aged 50 years or older (I statement).

This recommendation applies to asymptomatic adults aged 50 years or older. It does not apply to persons seeking evaluation for perceived hearing problems or for cognitive or affective symptoms that may be related to hearing loss. These persons should be assessed for objective hearing impairment and treated when indicated.

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 and Appendix Tables 1 and 2 (available at www.annals.org) for the USPSTF grades and classification of levels of certainty about net benefit.

RATIONALE

Importance

Age-related sensorineural hearing loss is a common health problem among adults aged 50 years or older. Hearing loss can affect social functioning and quality of life.

Detection

Convincing evidence shows that screening tools can reliably and accurately identify adults with objective hearing loss. Clinical tests used to screen for hearing impairment include testing whether a person can hear a whispered voice, a finger rub, or a watch tick at a specific distance. Perceived hearing loss can be assessed by asking a single question (for example, “Do you have difficulty with your hearing?”) or with a more detailed questionnaire, such as the Hearing Handicap Inventory for the Elderly—Screening Version (HHIE-S). A handheld screening instrument consisting of an otoscope with a built-in audiometer can also be used.

See also:

Print
Summary for Patients....................... I-38

Web-Only
Consumer Fact Sheet
Benefits of Detection and Early Treatment

Because of a paucity of directly applicable trials, evidence is inadequate to determine whether screening for hearing loss improves health outcomes in persons who are unaware of hearing loss or have perceived hearing loss but have not sought care. One good-quality study showed that hearing aids can improve self-reported hearing, communication, and social functioning for some adults with age-related hearing loss. This study almost exclusively evaluated white male veterans with moderate hearing loss and moderate to severe perceived hearing impairment. More than one third of whom had been referred for evaluation of hearing problems. As such, these findings were of limited applicability to a hypothetical asymptomatic, screened population. The only randomized trial that directly evaluated the effect of screening for hearing impairment—rather than the effect of treatment alone—was not primarily designed nor had sufficient statistical power to detect differences in hearing-related function. The USPSTF concludes that the evidence is inadequate to assess the benefit of screening and early treatment in an unselected screening population.

Harms of Detection and Early Treatment

Because of a lack of studies, evidence to determine the magnitude of harms of screening for hearing loss in older adults is inadequate; however, given the noninvasive nature of both screening and associated diagnostic evaluation, these harms are probably small to none. Adequate evidence shows that the harms of treatment of hearing loss in older adults are small to none.

USPSTF Assessment

The USPSTF concludes that evidence is lacking, and the balance of benefits and harms of screening for hearing loss in adults aged 50 years or older cannot be determined.

Clinical Considerations

Patient Population

This recommendation applies to asymptomatic adults aged 50 years or older. It does not apply to persons seeking evaluation for perceived hearing problems or for cognitive or affective symptoms that may be related to hearing loss. These persons should be assessed for objective hearing impairment and treated when indicated.
Risk Assessment

Aging is the most important risk factor for hearing loss. Presbycusis, a gradual, progressive decline in the ability to perceive high-frequency tones due to degeneration of hair cells in the ear, is the most common cause of hearing loss in older adults. However, hearing loss may result from several contributing factors. Other risk factors include a history of exposure to loud noises or ototoxic agents, including occupational exposures; previous recurring inner ear infections; genetic factors; and certain systemic diseases, such as diabetes.

Screening Tests

Available screening tests include physical diagnostic tests, such as the whispered voice, finger rub, and watch tick tests (bearing in mind that many modern watches no longer audibly tick); single-question screening or longer patient questionnaires; and handheld audiometers. All are relatively accurate and reliable screening tools for identifying adults with objective hearing loss. In addition, self-administered questionnaires, such as HHIE-S, can identify adults with perceived (or subjective) hearing difficulty. Not all adults with perceived hearing difficulty have objective hearing loss.

Treatment

Before a person receives a hearing aid, diagnosis of objective hearing loss should be confirmed with a pure-tone audiogram. Fair evidence from studies in highly selected populations shows that hearing aids can improve self-reported hearing, communication, and social functioning for some adults with age-related hearing loss.

Suggestions for Practice Regarding I Statement

Potential Preventable Burden

Finding objective hearing loss indicates eligibility for a hearing aid but does not convincingly identify persons who will find the devices helpful and wearable and will use them. One subgroup analysis of a randomized, controlled trial found that in older adults who did not have self-perceived hearing loss at study entry, screening and receipt of a free hearing aid did not increase use after 1 year compared with an unscreened control group (and overall use was low, at 0% to 1.6%) (1). However, health-related quality of life is improved for some adults with moderate to severe hearing loss who use hearing aids compared with those who do not (2).

Cost

The cost of screening varies according to the test. The cost of a questionnaire consists of the time required of both the patient and clinician. In-office clinical techniques (whispered voice, finger rub, or watch tick tests) and audiometry are quick to perform; however, handheld audiometers have up-front equipment costs. Diagnostic confirmation of a positive screen is typically done with a pure-tone audiogram, which requires a soundproof booth and trained personnel to administer the test and takes approximately 1 hour to complete. The cost of a hearing aid is a barrier to use for many older adults because it is not covered by Medicare and many private insurance companies.

Other Considerations

Research Needs and Gaps

Future studies should concentrate on patients older than 70 years and examine whether there are differential effects of treatment on outcomes at different ages (for example, older than 70 or 80 years). Adequately powered studies are needed to better evaluate the effect of screening for hearing loss on health outcomes, such as emotional and social functioning, communication ability, and cognitive function, rather than intermediate measures, such as hearing aid use or satisfaction, particularly among adults without self-perceived or established hearing loss at baseline.

The incremental benefits and costs of screening asymptomatic adults compared with only testing and treating those who seek treatment of perceived hearing impairment are unknown. Knowledge of specific factors or patient characteristics associated with increased and sustained use of hearing aids, once prescribed, could permit testing and treatment targeted to persons most likely to benefit.

Discussion

Burden of Disease

The normal human ear can process sound frequencies from 20 to 20 000 Hz, with 500 to 4000 Hz being the most important range for speech processing. There is no universally accepted definition for hearing loss because frequency and intensity thresholds vary depending on the reference criteria used. However, commonly used definitions for mild and moderate hearing loss are the inability to hear frequencies associated with speech processing at less than 25 or 40 dB of volume, respectively (3, 4).

The prevalence of hearing loss varies depending on the definition used, but population-based estimates range from 20% to 40% in adults older than 50 years to more than 80% in adults aged 80 years or older (3, 4). Onset of sensorineural hearing loss is subtle, and individuals may therefore not recognize or report symptoms to their health care providers; comorbid medical conditions, such as cognitive impairment, may also interfere with acknowledgment of hearing deficits (5). Underreporting of symptoms may also occur if the person fears social stigma as a result of diagnosis. As such, the prevalence of this condition may be underestimated.

Hearing loss can negatively affect a person’s quality of life and ability to function independently (6). Persons with hearing loss may have difficulty with speech discrimination and localization of sounds (7). Hearing impairment has been shown to be associated with increased social isolation and emotional dysfunction among older adults (8, 9).
Screening for Hearing Loss in Older Adults

Scope of Review

The USPSTF reviewed randomized, controlled trials and controlled observational studies published between 1950 and January 2010 on screening for age-related sensorineural hearing impairment in adults aged 50 years or older without diagnosed hearing loss in the primary care setting. It examined evidence on the following topics: association of screening with improved health outcomes, accuracy of screening methods, incremental benefit of early (rather than symptomatic) detection, effectiveness of treatment, and harms of screening and treatment. Congenital hearing loss, conductive hearing loss, and hearing loss due to occupational exposure or acute trauma were not included in the review.

Accuracy of Screening Tests

Several screening examinations for hearing loss can be used in primary care settings, including clinical testing methods (whispered voice, finger rub, and watch tick tests), single-question screening (asking, “Do you have difficulty with your hearing?”) or multiple-item patient questionnaires (HHIE-S), and handheld audiometers. Twenty studies, including 7 of good quality and 13 of fair quality, evaluated the diagnostic accuracy of various screening methods compared with a pure-tone audiogram for detection of hearing impairment in older adults. Six good-quality studies directly compared the accuracy of screening methods for hearing impairment in older adults (3, 4).

Studies used different thresholds and criteria to define hearing impairment, which makes comparison of methods somewhat challenging, but evidence is consistent that common screening tests are useful in identifying persons at increased risk for hearing loss. Simple screening methods, such as the whispered voice test and single-question screening, seem to be nearly as accurate for detecting hearing loss as more detailed questionnaires or handheld audiometers (3, 4). Negative findings on handheld audiometers may be particularly helpful in ruling out hearing loss greater than 40 dB.

Median positive likelihood ratios (LRs) among the screening tests at greater than 25 or 30 dB were in the range of 3.0 to 5.1 for single-question screening, HHIE-S, and whispered voice test at 2 feet (in ascending order). Negative LRs ranged from 0.03 to 0.52 for whispered voice test, single-question screening, and HHIE-S. The median positive LR at greater than 40 dB for the AudioScope audiometer (Welch Allyn, Skaneateles Falls, New York) was 5.8 (range, 1.7 to 4.9), and the median negative LR was 0.05 (range, 0.03 to 0.08) (3, 4). Finger rub and watch tick tests had substantially stronger positive LRs (10 and 70, respectively) compared with other screening methods, but they were evaluated in only a single study (10) and the CIs were very wide (2.6 to 43 and 4.4 to 1120, respectively). Negative LRs for the finger rub and watch tick tests were 0.75 (95% CI, 0.68 to 0.84) and 0.57 (CI, 0.46 to 0.66), respectively.

Effectiveness of Early Detection and Treatment

Direct evidence of the effect of screening for hearing loss on clinical outcomes is limited. Only 1 fair-quality randomized, controlled trial examined the effect of screening on hearing aid use. The SAI-WHAT (Screening for Auditory Impairment—Which Hearing Assessment Test) trial (1) randomly assigned 2305 predominately male veterans aged 50 years or older to hearing-loss screening with a tone-emitting otoscope (AudioScope), the HHIE-S questionnaire, or combined testing versus a control group of no screening. The primary outcome was hearing aid use 1 year after screening. The mean age of participants was 61 years, and three fourths reported self-perceived hearing loss at baseline. A total of 18.6% of participants in the AudioScope group, 59.2% in the HHIE-S group, and 63.6% in the combined method group had positive screening test results. Persons in any screening group were more likely to wear hearing aids 1 year after screening than were control participants: Hearing aid use was 6.3% in the AudioScope group, 4.1% in the HHIE-S group, and 7.4% in the combined group versus 3.3% in control participants (P = 0.003 for test of equality across all 4 groups). Post hoc analysis showed that hearing aid use was more common among participants reporting self-perceived hearing loss, but regardless of screening status, hearing aid use was very low among those without perceived hearing impairment at baseline (0% to 1.6%). A secondary outcome of the trial was the effect of hearing aid use on quality of life, as measured by the Inner Effectiveness of Aural Rehabilitation scale. No statistically significant differences in scores were seen across the study groups after 1 year; however, the trial was powered to detect differences in hearing aid use rather than hearing-related function, so this finding does not definitively rule out a potential beneficial effect. The generalizability of these results is limited because the study comprised relatively younger male veterans with a high prevalence of perceived hearing loss who were eligible for free treatment services.

A good-quality trial (2) randomly assigned 194 male veterans (mean age, 72 years) with screen-detected (two thirds of participants) or previously established (one third of participants) hearing loss to immediate receipt of a free hearing aid or to a wait-list control group. Screening was done with the AudioScope when it was part of the eligibility assessment, and a positive result was defined as hearing impairment of greater than 40 dB in the better ear, with confirmation by a pure-tone audiogram. The outcome of interest was quality-of-life improvements, including social, affective, cognitive, and physical domains, at 4 months as measured by a battery of self-administered instruments, including the HHIE, Quantified Denver Scale of Communicative Function (QDS), Short Portable Mental Status Questionnaire, Geriatric Depression Scale, and Self-Evaluation of Life Function. At study entry, 63% of participants reported having severe effects on hearing-related social and emotional quality of life and functioning (as
defined by an HHIE score $\geq 42$); the mean HHIE score for all participants was 50. Moderate communication difficulty was reported by 85% of participants (as defined by a QDS score $>30$). At the 4-month follow-up, HHIE and QDS scores were unchanged in the control group, but in the group that received hearing aids, mean HHIE scores improved from 49 to 15 and mean QDS scores improved from 59 to 36. Mean between-group differences in HHIE and QDS scores at 4 months were 34 and 24, respectively. A follow-up study found that improvements in HHIE and QDS scores in the intervention group persisted at 12 months (11). Changes in Geriatric Depression Scale and Short Portable Mental Status Questionnaire scores differed significantly between the hearing aid and control groups, but the absolute effects were very small ($<1$-point difference), and baseline scores did not indicate substantial levels of depression or cognitive dysfunction in this population. The trial’s source population of white male veterans, high prevalence of moderate to severe hearing loss at study entry, and inclusion of a relatively large proportion of participants with established (rather than screen-detected) hearing impairment restricts the generalizability of these findings.

The USPSTF also reviewed 2 fair-quality trials and 1 poor-quality trial of treatment of hearing loss with hearing aids. One trial found no clear difference between an assistive listening device and no treatment on changes in mean baseline scores on the HHIE-S, Abbreviated Profile of Hearing Aid Benefit, or Revised QDS in veterans who were ineligible for free hearing aids (12). Another trial found no difference between a hearing aid, assistive listening device, or both and no amplification in mean scores on the HHIE-S, Brief Symptom Inventory, Activity Scale, Life Satisfaction in the Elderly Scale, or Affect Balance Scale in a subset of patients who had mild baseline hearing loss and were not using hearing aids at enrollment (13). The third trial did not report outcomes with sufficient detail for reliable interpretation (14).

**Potential Harms of Early Detection and Treatment**

No randomized trials or controlled observational studies evaluated potential adverse effects associated with screening or treating hearing impairment using hearing aids. In community-based and primary care settings, rates of false-positive test results (using $>25$ dB as a threshold for a positive screen) ranged from 5% to 41% (3, 4), depending on the test and the population. Screening could also potentially be associated with anxiety, labeling and stigma, or other psychosocial effects, but no studies were available to estimate these outcomes. According to case reports, treatment with hearing aids may be associated with cerumen impaction, dermatitis, accidental retention of molds, otitis externa, and associated middle ear problems (3, 4). Because screening and confirmatory testing for hearing impairment are noninvasive and serious harms of treatment are rare, there are probably little to no adverse effects of screening for hearing loss.

**Estimate of Magnitude of Net Benefit**

A fair-quality randomized trial that directly evaluated the effect of screening for hearing impairment showed a statistically significant increase in the use of hearing aids among screened groups after 1 year; however, no conclusions could be drawn about the effect of screening on health outcomes, such as improved quality of life and ability to function. One good-quality randomized trial of treatment showed that hearing aids can improve communication ability and social function for some older adults with known hearing impairment. In both trials, however, the study population was essentially limited to white male veterans with self-perceived or established moderate to severe hearing loss; as such, the applicability of the findings to a broader asymptomatic population is unclear. Furthermore, adherence to hearing aid use among participants diagnosed with hearing impairment in the SAI-WHAT trial was low, particularly among those who did not report self-perceived hearing loss at baseline. Although studies have consistently demonstrated that various screening tests (including clinical examinations, single- or multiple-item questionnaires, and handheld audiometers) can successfully identify persons with objective hearing loss, it is less clear how to recognize persons who will adhere to—and thus benefit from—treatment. The incremental value of screening and diagnosing asymptomatic older adults with hearing impairment in advance of presentation with symptoms is therefore unclear.

Given unknown efficacy in a general, asymptomatic population, the USPSTF concludes that the evidence is insufficient to determine the net benefit of screening for hearing loss in older adults.

**How Does the Evidence Fit With Biological Understanding?**

Although sensorineural hearing loss is a relatively common consequence of aging, onset of presbycusis is gradual, so many older adults may not recognize that they have an impairment or may not perceive their sensory deficits to be a problem. Some persons may simply alter their daily activities to adapt to the loss. In addition, some older adults may resist seeking treatment of hearing impairment or adhering to use of a hearing aid because of fear of social stigma or loss of independence. Limited evidence suggests that, when used, hearing aids can improve quality of life and ability to function in selected populations with moderate to severe hearing loss; sustained hearing aid use seems to be most closely associated with self-perceived hearing impairment or a greater magnitude of hearing loss. Without additional study, the relative value and likelihood of success of detecting and treating hearing loss in persons who are not aware of a problem before screening or have not sought care for perceived hearing loss are unclear.
Response to Public Comments

A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 4 October to 11 November 2011 and again from 30 November to 13 December 2011. In response to the comments, the USPSTF has clarified its interest in health and functional outcomes related to screening and treatment of hearing loss and added language to emphasize that some persons with moderate to severe hearing loss have shown improvements in quality of life with hearing aid use. It also clarified the patient population to which the recommendation applies.

Several commenters asked the USPSTF to consider data about the effect of hearing loss on social functioning of affected persons, their partners and families, and employment issues. Commenters were concerned about hearing loss being potentially misinterpreted by clinicians or caregivers as cognitive impairment. The USPSTF was also asked to consider potential benefits of incidental detection of other health conditions (for example, acoustic neuromas or multiple sclerosis) or prevention of ongoing hearing deterioration. Although the USPSTF agrees that these are important issues surrounding hearing loss, available evidence does not permit conclusions to be drawn about the actual effect of screening on any of these factors. Beneficial effects of hearing conservation measures should be detectable through the broader evaluation of hearing outcomes over time.

Several commenters asked the USPSTF to consider whether an alternative recommendation should be offered for higher-risk groups. The USPSTF has specified populations that are at higher risk for hearing loss in the recommendation statement; however, the net benefit of screening in these groups and whether it differs from the general population are unknown.

Finally, commenters asked for direction from the USPSTF on standardizing screening approaches in clinical practice. Given the underlying uncertainty about the net benefit of screening, it is presently difficult to provide evidence-based guidance on optimum screening approaches. Currently, no single standard of care seems to exist. Therefore, additional research is needed to clarify the ultimate effect of screening and treatment of hearing loss and to better define best practices to maximize potential for benefit.

Update of Previous USPSTF Recommendation

This recommendation replaces the 1996 recommendation, in which the USPSTF recommended periodically questioning older adults about their hearing, counseling them about the availability of hearing aids, and making referrals when appropriate (15). This conclusion was based on the best available evidence at that time, which was indirect in nature and largely limited to studies of diagnostic accuracy and treatment of persons with established or perceived hearing loss. The previous USPSTF noted that no controlled trials could prove the effectiveness of screening asymptomatic older adults for hearing impairment. Screening and diagnostic evaluation are 2 distinct activities, and treatments may vary in effectiveness depending on how the condition is identified. There may be important differences between a person who has subjective hearing symptoms and is diagnosed with objective impairment as a result of symptoms and a person without self-perceived hearing difficulties who has a routine and automatic screening examination that detects a personally inapparent but objectively identifiable decline in hearing function.

Since the 1996 recommendation was published, direct evidence from a randomized, controlled trial evaluating the effect of screening itself, rather than treatment alone, has become available (1). Although this trial found that screening was associated with an increase in hearing aid use, the benefit seemed to be limited to persons who had self-perceived loss of hearing at baseline—no difference in use was seen for asymptomatic persons with objective hearing loss detected with screening. Of note, screening was not found to have a discernible effect on hearing-related quality of life; however, the trial was not primarily designed nor did it have sufficient statistical power to detect health or functional outcomes, so additional research would be helpful to draw more definitive conclusions. Therefore, the USPSTF now concludes that the evidence is insufficient to assess the balance of benefits and harms of screening for hearing loss in asymptomatic adults aged 50 years or older (I statement).

Recommendations of Others

The American Speech-Language-Hearing Association recommends that adults be screened once per decade and every 3 years after age 50 years (16). The American Congress of Obstetricians and Gynecologists recommends that female patients aged 13 years or older be evaluated and counseled on hearing as part of the periodic health assessment (17). The American Academy of Family Physicians is in the process of updating its recommendation.

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

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Financial Support: The USPSTF is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF.

Potential Conflicts of Interest: Disclosure forms from USPSTF members can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M12-1766.

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


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**FAST TRACK REVIEW**

*Annals* will consider manuscripts of high quality for expedited review and early publication (Fast Track) if they have findings that are likely to affect practice or policy immediately and if they are judged valid. We give priority to fast-tracking large clinical trials with clinical outcomes and manuscripts reporting results that are likely to have an immediate impact on patient safety. Authors wishing to fast-track their articles should contact Senior Deputy Editor Dr. Cynthia Mulrow (e-mail, cynthiam@acponline.org) and provide an electronic version of their manuscript along with a request and justification for expedited review and, for trials, the protocol and registry identification number.
Appendix Table 1. What the USPSTF Grades Mean and Suggestions for Practice

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<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>Note: The following statement is undergoing revision. Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms, there is likely to be only a small benefit from this service.</td>
<td>Offer/provide this service only if other considerations support offering or providing the service in an individual patient.</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

<table>
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<th>Level of Certainty</th>
<th>Description</th>
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<tr>
<td><strong>High</strong></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><strong>Moderate</strong></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><strong>Low</strong></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>
</tbody>
</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.