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Screening for Hearing Loss in Older Adults: An Evidence Review for the U.S. Preventive Services Task Force

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Structured Abstract

Purpose: To systematically review the evidence on (1) benefits and harms of screening for hearing loss in adults age 50 years or older, (2) accuracy of screening tools, and (3) benefits and harms of interventions for hearing loss that was screen detected or recently diagnosed for populations and settings relevant to primary care in the United States.

Data Sources: PubMed/MEDLINE, the Cochrane Library, Embase, and trial registries through January 17, 2020; reference lists of retrieved articles; outside experts; and reviewers, with surveillance of the literature through August 5, 2020.

Study Selection: English-language controlled trials for hearing loss screening or evaluating interventions for screen-detected or newly detected hearing loss and studies of screening test accuracy.

Data Extraction: One investigator extracted data and a second checked accuracy. Two reviewers independently rated quality for all included studies using predefined criteria.

Data Synthesis: One randomized, controlled trial (RCT) enrolling veterans (2,305 participants) found that screening for hearing loss was not associated with improvements in hearing-related function at 1 year, although screening was associated with increased hearing aid use. Thirty-three studies (reported in 34 articles) evaluated the diagnostic accuracy of clinical tests, a single question, a questionnaire, a handheld audiometric device, or a mobile-based audiometric application for identifying hearing loss in older adults. For detecting mild hearing loss (>20 to 25 dB), single-question screening had a pooled sensitivity of 66 percent (95% confidence interval [CI], 58% to 73%) and a pooled specificity of 76 percent (95% CI, 68% to 83%) (10 studies, 12,637 participants); for detecting moderate hearing loss (>35 to 40 dB), the pooled sensitivity was 80 percent (95% CI, 68% to 88%) and the pooled specificity was 74 percent (95% CI, 59% to 85%) (6 studies, 8,774 participants). Too few studies reported sufficient data to pool accuracy of the Hearing Handicap Inventory for the Elderly-Screening (HHIE-S) for detecting mild hearing loss (>25); across four studies (7,194 participants), sensitivity of HHIE-S ranged from 34 to 58 percent, and specificity ranged from 76 to 95 percent. For detecting moderate hearing loss (>40 dB), the pooled sensitivity of HHIE-S was 68 percent (95% CI, 52% to 81%) and the pooled specificity was 79 percent (95% CI, 69% to 86%) (5 studies; 2,820 participants). In four studies (411 participants) assessing the AudioScope for detecting moderate hearing loss (>40 dB), sensitivities were high (range: 94% to 100%) and specificity varied widely (range: 24% to 80%). Other screening questionnaires, clinical tests (e.g., watch tick, whispered voice), and technology were assessed by few studies each, and results were often inconsistent and imprecise.

Six trials (853 participants) evaluated benefits of amplification compared with no amplification among populations with screen-detected or recently detected, untreated age-related hearing loss over 6 weeks to 4 months. Five trials reported on the HHIE (838 participants), a self-report tool designed to measure perceived effects of hearing loss in older adults; four (758 participants) found statistically significant benefit in favor of hearing aids. Three of the four trials that found statistically significant benefit enrolled veterans and reported differences in HHIE scores that were greater than the minimal important difference of 18.7. One RCT (154 participants) enrolling community volunteers found statistically significant benefit on the HHIE in favor of

two different hearing aids vs. a placebo device; however, differences between groups did not meet the level considered to be clinically meaningful. Four studies reported on general quality of life or function; few studies reported on the same measure. One RCT (194 participants) enrolling veterans with screen-detected hearing loss found significant benefit in favor of the intervention on the Short Portable Mental Status Questionnaire (difference between groups in change from baseline: -0.28 points [95% CI, 0.08 to 0.48]; p=0.008) and Geriatric Depression Scale (difference between groups in change from baseline: -0.80 points [95% CI, 0.09 to 1.51]; p=0.03) in addition to the HHIE. No studies of interventions reported on harms.

Limitations: The one trial of screening was not designed to measure hearing-related function. There has been little reproducibility in testing specific screening tests in primary care populations; most studies of screening test accuracy enroll populations from audiology or other high-prevalence settings. Trials showing clinically meaningful benefit in hearing-related function among groups receiving hearing aids vs. controls all enrolled veterans with a relatively high prevalence of hearing loss.

Conclusions: Several screening tests can adequately detect hearing loss in adults age 50 years or older. One trial of screening that enrolled veterans with a relatively high prevalence of self-perceived hearing loss did not find a benefit for hearing-related function. No controlled studies reported on the harms of screening or treatment among adults with screen-detected or newly detected hearing loss. Evidence showing benefit for hearing-related function associated with hearing aids among adults with screen-detected or newly detected hearing loss is limited to studies enrolling veterans with a high prevalence of hearing loss.

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Chapter 1. Introduction

Scope and Purpose

The U.S. Preventive Services Task Force (USPSTF) will use this report to update its recommendation on screening for hearing loss in asymptomatic older adults. In 2012, the USPSTF concluded that evidence was insufficient to assess the balance of benefits and harms of screening for hearing loss in adults age 50 years or older. The purpose of this report is to systematically review the evidence on (1) benefits and harms of screening for hearing loss in adults 50 years or older, (2) accuracy of screening tools, and (3) benefits and harms of interventions for hearing loss that was screen detected or recently diagnosed for populations and settings relevant to primary care in the United States.

Condition Definition

A person with normal hearing perceives sounds at frequencies between 20 and 20,000 Hz.[1] Frequencies between 500 and 4,000 Hz are most important for speech processing. There is often discordance between objectively measured deficits in tonal perception at specific frequencies and intensity levels (audiometrically measured as decibels [dB] hearing level) and subjective perceptions of hearing problems.[2, 3] One study found that 20 percent of persons reporting hearing difficulty had normal hearing tests, while 6.2 percent of those not reporting difficulty had significant hearing loss.[4] Hearing problems despite normal hearing tests could be caused by abnormal signal processing or sound discrimination. Because treatments for hearing loss are targeted at improving tonal perception by signal amplification, this review uses the term "hearing loss" to refer specifically to deficits found on objective testing (consistent with the prior review for the USPSTF).[5]

The standard objective test for hearing loss is the pure-tone audiogram, in which a person is tested on the ability to hear tones at a series of discrete frequencies, typically in the range of 250 to 8,000 Hz, at various decibel levels. There is no universally accepted definition for hearing loss. Reference criteria vary regarding the frequencies and intensity thresholds used to determine hearing loss and whether one or both ears are affected. Many studies and guidelines define mild hearing loss as the inability to detect frequencies associated with speech understanding under 25 dB and moderate hearing loss as the inability to detect those frequencies under 40 dB. Commonly used reference criteria to assess screening test accuracy include the Ventry and Weinstein criteria (>40 dB hearing loss at either 1,000 or 2,000 Hz in both ears or >40 dB hearing loss at 1,000 and 2,000 Hz in one ear),[3] the speech frequency pure-tone average criteria (≥25 dB average hearing loss at 500, 1,000, and 2,000 Hz in the better ear),[6] and the high-frequency pure-tone average criteria (≥25 dB average hearing loss at 1,000, 2,000, and 4,000 Hz in the better ear).[7] Epidemiologic studies of adult hearing loss prevalence commonly use World Health Organization grades of impairment, defined as the better ear average for four frequencies (500, 1,000, 2,000, and 4,000 Hz) categorized by threshold level ranging from no impairment, slight impairment (26 to 40 dB hearing loss), moderate impairment (41 to 60 dB hearing loss), severe impairment (61 to 80 dB hearing loss), to profound impairment/deafness (81 dB hearing loss or greater).[8]

Etiology and Natural History

Hearing loss may be classified into three types:[9] (1) sensorineural, involving the inner ear or the auditory nerve; (2) conductive, involving any cause that in some way limits the amount of external sound from gaining access to the inner ear (e.g., cerumen impaction or middle ear fluid); and (3) mixed loss, which is a combination of sensorineural and conductive hearing loss. Within each category, there are multiple etiologies of hearing loss. Age-related hearing loss (or presbycusis) is the most common cause of hearing loss in older adults. It refers to a type of sensorineural hearing loss involving degeneration of the cells of the organ of Corti. The hearing loss associated with presbycusis is typically gradual, progressive, and bilateral and affects the higher frequencies before progressing to the lower frequencies.[10, 11]

Hearing loss in older adults is multifactorial. In addition to age-related degeneration, other contributing factors include genetic factors, exposure to loud noises, exposure to ototoxic agents, history of middle ear infections, and presence of systemic diseases such as diabetes mellitus.[2, 12-15] In terms of progression, cohort studies measuring changes in pure-tone thresholds over time have documented an approximate 1 dB per year increase among adults age 50 years or older.[16, 17] Prospective observational studies of adults indicate that hearing impairment is associated with higher rates of incident disability and need for nursing care.[18] Additional burden associated with untreated hearing loss is summarized below.

Risk Factors

Aging is the greatest risk factor for both the incidence and progression of hearing loss, though other risk factors are also important. Besides older age, nonmodifiable risk factors include male sex,[19] white race/ethnicity,[20] and family history of hearing loss.[21] Modifiable risk factors include societal, environmental, and health-related risk factors, such as lower educational level,[19] exposure to loud noises, and inner ear infections; cardiovascular risk factors, such as smoking,[22, 23] diabetes,[24] and hypertension, are all associated with hearing loss. While hearing loss is common among the general population, U.S. Service members and veterans are particularly at risk for hearing loss because of a combination of factors.[25]

Prevalence and Burden

Prevalence

Based on 2011-2012 data from the National Health and Nutrition Examination Survey (NHANES), the prevalence of unilateral and bilateral speech-frequency hearing impairment (defined by pure-tone average of thresholds across 500, 1,000, 2,000 and 4,000 Hz >25 dB hearing level) was 14.1 percent among adults (20 to 69 years of age) (n=3,831).[26] Men had nearly twice the prevalence of hearing impairment as women (18.6% vs. 9.6%, respectively). The prevalence of speech frequency hearing loss increases significantly with age (**Appendix A Table 1**); prevalence was highest in adults age 60 to 69 years (39.3%). In addition to age, male sex (odds ratio [OR], 1.8 [95% confidence interval (CI), 1.1 to 3.0]), non-Hispanic white (OR, 2.3 [95% CI, 1.3 to 3.9]) and non-Hispanic Asian race/ethnicity (OR, 2.1 [95% CI, 1.1 to 4.2]),

lower educational level (less than high school: OR, 4.2 [95% CI, 2.1 to 8.5]), and heavy use of firearms (≥1,000 rounds fired: OR, 1.8 [95% CI, 1.1 to 3.0]) were significant risk factors.[26]

The National Health Interview Survey (NHIS) also measures prevalence of hearing loss in adults 18 years or older based on self-reported difficulty hearing without the use of an assistive device.[27] Estimates from the 2014-2016 NHIS data indicate that 15.9 percent of U.S. adults have hearing loss. The 2014 NHIS (N=35,697) also reports on prevalence by age category, and findings are consistent with estimates from NHANES data despite differences in measurement and age categorization.[28] The prevalence of self-reported hearing loss was highest among adults 70 years or older (43.2%) compared with adults ages 40 to 69 years (19.0%) and 18 to 39 years (5.5%).

Burden

A recent review in the *Lancet* reported that, in 2015, hearing loss was the fourth leading cause of years lived with disability globally.[29] Untreated hearing loss can lead to significant burden for patients, family members, and society. Moderate to severe hearing loss in older adults is associated with significantly higher impairment in instrumental activities of daily living (IADLs), such as driving and managing medications or finances, as well as impairment in basic ADLs such as ambulation, bathing, and toileting.[18, 30] Individuals in the Epidemiology of Hearing Loss Study (n=2,688) with moderate to severe hearing loss were significantly more likely than individuals without hearing loss to have impaired ADLs and IADLs after controlling for age, sex, education, arthritis, other chronic diseases, and impaired visual acuity (ADL OR, 1.54 [95% CI, 1.06 to 2.24]; IADL OR, 1.54 [95% CI, 1.18 to 2.00]).[31]

Hearing loss is also associated with other adverse health and social outcomes. A nationally representative sample of 860 females between the age of 60 and 69 found that hearing loss is associated with increased odds of social isolation (OR, 3.49 per 25-dB hearing loss [95% CI, 1.91 to 6.39]).[32] Multiple observational studies suggest an association between age-related hearing loss and cognitive decline or dementia, although the strength of association varies based on study design, cognitive measure, and other factors.[33] One systematic review (k=36 studies included in pooled estimates; 20,264 participants) found a significant association between hearing loss and cognitive impairment (pooled OR, 1.22 [95% CI, 1.24 to 4.72]) as well as dementia (pooled OR, 1.28 [95% CI, 1.02 to 1.59]), but not for Alzheimer disease specifically (OR, 1.69 [95% CI, 0.72 to 4.0]) among prospective cohort studies.[33] A cross-sectional study of 1,328 Blue Mountains Eye Study participants age 60 or older found depressive symptoms (assessed according to the mental health index) were significantly higher in participants with mild bilateral hearing loss (OR, 1.83 [95% CI, 1.18 to 2.83]) after multivariable adjustment, although participants with moderate to severe hearing loss (10.2%) did not have a higher likelihood of depressive symptoms than those with normal hearing (OR, 1.20 [95% CI, 0.66 to 2.17]).[34]

Some evidence suggests that hearing loss is also associated with increased hospitalizations and higher rates of mortality.[35-37] One prospective observational study found that hearing loss was associated with a 20 percent increased mortality risk compared with normal hearing in models adjusting for multiple demographics and cardiovascular risk factors (hazard ratio, 1.20 [95% CI, 1.03 to 1.41]).[37] However, other evidence suggests that the association is attenuated (not

statistically significant) when adjusting for factors such as subclinical atherosclerosis and inflammatory markers.[38] A 2017 systematic review (25 studies set in the United States) reported the economic costs of lost productivity associated with hearing loss varied from $1.8 to $194 billion, and direct medical costs of hearing loss ranged from $3.3 to $12.8 billion.[39, 40]

Rationale for Screening and Screening Strategies

Identifying hearing loss early, followed by appropriate interventions, may reduce the burden of functional decline associated with hearing loss. Although hearing loss is common in older adults, symptoms may be unrecognized because they can be relatively mild and slowly progressive. Older adults may also perceive hearing loss but not seek evaluation for it, or they may have difficulty recognizing or reporting hearing loss because of comorbid conditions, such as cognitive impairment. Screening could identify individuals with hearing loss who could benefit from hearing aids or other interventions to address hearing loss.

Screening tests that could be used in primary care range from direct questioning and clinician-administered tests to screening devices (**Appendix A Table 3**).[41, 42] Two common forms of direct questioning include a single-item question, "Do you have difficulty hearing?"[43] and the 10-item Hearing Handicap Inventory for the Elderly-Screening (HHIE-S) questionnaire.[44] Clinician-administered tests include the whispered voice test. Screening devices include use of a handheld audiometric device.[44]

Interventions for Hearing Loss

The primary intervention for persons with a mild or moderate sensorineural hearing loss is use of hearing aids. Hearing loss is a chronic condition that cannot be cured; the use of hearing aids is intended to improve communication and function and prevent future morbidity associated with hearing-related disability. Hearing aids do not prevent or slow progression of hearing loss. Counseling and education about alternative communication techniques and use of assistive listening devices may also be recommended. For those with severe or profound hearing loss, cochlear implants are also a potential treatment option. Hearing aids amplify the sound reaching the middle or inner ear; the degree of amplification can be adjusted to suit the person's degree of hearing loss. There is no standard of care or guideline consensus on when hearing aids are recommended. Published guidance by the Department of Veteran Affairs (VA) recommends hearing aids for thresholds of 40 dB hearing loss or greater at 500, 1,000, 2,000, 3,000, or 4,000 Hz or hearing thresholds of 26 dB at three of these frequencies, or speech recognition less than 94 percent.[45] The UK National Institute for Health and Care Excellence guidelines on hearing loss state that provision of hearing aids should be based on need (e.g., hearing loss that affects communication, awareness of warning sounds and the environment, or appreciation of music) and not only on categories of "mild," "moderate," or "severe" based on pure-tone audiogram testing.[46]

Hearing aids can vary in design and in where they are positioned: in the canal, in the ear, behind the ear, and body worn. Although amplification improves the ability to detect sounds, other disabilities associated with sensorineural hearing loss such as sound processing, discrimination,

and interpretation may be not improved. Persons with bilateral hearing loss may be offered one aid, fitted to one specific ear, or two aids fitted to both ears. Although most practitioners believe the use of two hearing aids is more effective for adults with bilateral symmetrical hearing loss, some evidence suggests that patients prefer to use only one hearing aid.[47, 48]

Assistive listening devices (ALDs) (or personal sound amplification products) and auditory (or aural) rehabilitation are potential treatment strategies that are often recommended in addition to traditional hearing aids. ALDs include a range of over-the-counter devices that help amplify sound but are not currently labeled for individuals with hearing loss. This may change due to the 2017 Over-the-Counter (OTC) Hearing Aid Act intended to enable adults with perceived mild to moderate hearing loss to access OTC hearing aids and other devices marketed for hearing loss without being seen by a hearing care professional.[49] The OTC Hearing Aid Act directed the Food and Drug Administration to establish criteria to regulate safety and labeling for OTC devices. Currently available ALDs vary in design and features, ranging from older models that include a remote transmitter connected to headphones to newer devices that include technology similar to hearing aids (Bluetooth-enabled, single-ear-worn devices that can be paired with a smartphone).[50] Auditory rehabilitation includes a range of strategies aimed at improving hearing loss–induced deficits of function, activity, participation, and quality of life (QOL) through a combination of sensory management, instruction, perceptual training, and counseling.[51] Components of auditory rehabilitation may include one or more of the following: active listening training, speech reading (e.g., education on reading facial expressions or lip contours of speakers), and communication enhancement.

Recommendations of Other Organizations

The American Academy of Family Physicians references the current (2012) Task Force I Statement for hearing loss screening in asymptomatic adults age 50 years or older.[52] The UK National Screening Committee does not recommend a national screening program for hearing loss in adults age 50 years or older.[53] Both the American Geriatrics Society and the Royal Australian College of General Practitioners recommend screening all adults age 65 years or older for hearing loss.[54, 55] The American Speech-Language-Hearing Association recommends that adults be screened by an audiologist once per decade and every 3 years after age 50 or more frequently in those with known exposures or risk factors associated with hearing loss.[56] Other guidelines recommend screening only among those with specific risk factors, exposures, or symptoms (**Appendix A Table 4**).

Clinical Practice in the United States

Screening rates for hearing loss in adult primary care are not clear; no recent estimates were found in the literature. Older surveys (from 2008) indicate that primary care clinicians generally agreed that hearing loss negatively affects their patients and reported screening rates were low.[57] A 2008 study of 710 primary care physicians found that nearly three fourths (72.4%) reported screening only if they suspect a problem or patients complain about hearing and/or balance difficulties; few screen the elderly for hearing (3.4%), balance (5.7%), or disorders in both areas (10.3%) on a routine basis.[57] Based on surveys from 2005-2008, clinicians' self-reported barriers

to screening and treatment of hearing loss include issues such as lack of knowledge, poor perception of audiology services, lack of time, and lack of reimbursement.[57-59] A more recent review article (2016) highlighted the following barriers to obtaining hearing loss healthcare among older adults: lack of awareness of hearing loss manifestations (among providers and patients); confusion about options for accessing hearing-related care (e.g., primary care assessment, audiology evaluation, over-the-counter device); and decision making related to treatment options/preferences, cost, and device effectiveness (e.g., dissatisfaction or difficulties with hearing aids). These factors may limit rates of screening and treatment for hearing loss.[60]

Chapter 2. Methods

Key Questions and Analytic Framework

The scope and key questions (KQs) were developed by the Evidence-based Practice Center (EPC) investigators, USPSTF members, and Agency for Healthcare Research and Quality (AHRQ) Medical Officers. The analytic framework and KQs that guided the review are shown in **Figure 1**. Five KQs were developed for this review:

1. a. Does screening for hearing loss in asymptomatic adults age 50 years or older lead to improved health outcomes?
   b. Does the effectiveness of screening differ for subpopulations defined by age, sex, race/ethnicity, risk of past noise exposure, or comorbidity?
2. What is the accuracy of primary care–relevant screening tests for hearing loss in adults age 50 years or older?
3. a. What are the harms of screening for hearing loss in adults age 50 years or older?
   b. Do the harms of screening for hearing loss differ for subpopulations defined by age, sex, race/ethnicity, risk of past noise exposure, or comorbid condition?
4. a. What is the efficacy of interventions for screen-detected hearing loss in improving health outcomes in adults age 50 years or older?
   b. Does the efficacy of interventions for screen-detected hearing loss differ for subpopulations defined by age, sex, race/ethnicity, risk of past noise exposure, or comorbid condition?
5. a. What are the harms of interventions for screen-detected hearing loss in adults age 50 years or older?
   b. Do the harms of interventions for screen-detected hearing loss differ for subpopulations defined by age, sex, race/ethnicity, risk of past noise exposure, or comorbid condition?

In addition to addressing the KQs, this review also looked for evidence related to three contextual questions that focused on whether adherence to hearing aid use improves health outcomes in adults with screen-detected hearing loss, the effect of interventions to improve hearing aid adherence on health outcomes, and potential barriers to obtaining hearing aids and reasons for low uptake in adults prescribed hearing aids. These contextual questions were not a part of our systematic review. They are intended to provide additional background information. Literature addressing these questions is summarized in **Appendix A**.

Data Sources and Searches

We searched PubMed/MEDLINE, the Cochrane Library, and Embase for English-language articles published through January 17, 2020. Medical Subject Headings were used as search terms when available and keywords when appropriate, focusing on terms to describe relevant populations, tests, interventions, outcomes, and study designs. Complete search terms and limits are detailed in **Appendix B1**. Targeted searches for unpublished literature were conducted by searching ClinicalTrials.gov. To supplement electronic searches, reference lists of pertinent

articles, studies suggested by reviewers, and comments received during public commenting periods were reviewed. Studies suggested by peer reviewers or public comment respondents were also be reviewed and, if appropriate, incorporated into the final review. The same inclusion and exclusion criteria were used to determine if the new citations should be incorporated into the review. Since January 17, 2020, ongoing surveillance was conducted through article alerts and targeted searches of journals to identify major studies published in the interim that might affect the conclusions or understanding of the evidence and the related USPSTF recommendation. The last surveillance was conducted on August 5, 2020, and no additional studies meeting eligibility criteria were identified. All literature search results were managed using EndNote™ version 9.2 (Thomson Reuters, New York, NY).

Study Selection

Inclusion and exclusion criteria for populations, interventions, comparators, outcomes, settings, and study designs were developed with input from the USPSTF (**Appendix B2**). For all KQs, English-language studies of adults age 50 years or older conducted in settings generalizable to primary care, including nursing homes, and in countries categorized as "very high" on the United Nations Human Development Index were included.[61] Studies focused on adults with comorbid dementia were excluded because hearing testing is often recommended for adults with cognitive dysfunction.

For KQs 1 and 3 (direct evidence of benefits and harms of screening), controlled clinical trials or cohort studies enrolling adults with asymptomatic or undetected hearing loss comparing screening with no screening were eligible. For KQ 2 (accuracy of hearing loss screening tests), cohort or cross-sectional studies of asymptomatic or unselected older adults comparing one or more screening tests with diagnostic pure-tone audiometry were included. For KQs 1 through 3, eligible screening tests included those used, available, or feasible for use in primary care settings (**Appendix A Table 3**). Studies evaluating tests not feasible for screening in primary care settings (e.g., the 25-item Hearing Handicap Inventory for the Elderly), serial screening tests, and tests primarily used to distinguish between sensorineural and conductive hearing loss (e.g., the Rinne and Weber tests) were excluded.

For KQs on benefits (KQ 4) and harms (KQ 5) of amplification, controlled clinical trials and cohort studies of adults with screen-detected or newly detected sensorineural hearing loss were included. Studies of adults with conductive hearing loss, congenital hearing loss, sudden hearing loss, hearing loss caused by recent noise, and comorbid dementia were excluded. Eligible studies compared amplification using any type of hearing aid, personal assistive listening devices, or personal sound amplification device (with or without additional education or counseling) with a no-amplification control group (no treatment, wait-list, or placebo amplification device). Studies assessing nutritional pharmaceuticals, hearing rehabilitation alone (without amplification), and cochlear implants were excluded. Eligible outcomes for KQs on the benefit of screening and treatment (KQs 1 and 4) include measures of hearing-related quality of life or function, general health–related quality of life and function, depression, cognitive impairment, falls, and social isolation.

Two investigators independently reviewed titles and abstracts; those marked for potential inclusion by either reviewer were retrieved for evaluation of the full text. The full texts were then independently reviewed by two investigators to determine final inclusion or exclusion. Disagreements were resolved by discussion and consensus. Covidence systematic review software was used to assign and track literature review decisions.[62]

Quality Assessment and Data Abstraction

Two reviewers independently assessed each study's methodological quality. Disagreements in study quality ratings were resolved through discussion or with an independent assessment from a third senior investigator. For randomized, controlled trials (RCTs), the most recent versions of the Cochrane Risk of Bias Tool (RoB 2.0) available for parallel[63] and crossover trials was used.[64] It assessed the following risk-of-bias domains: bias arising from selection or randomization, bias due to missing outcome data, bias due to departures from intended interventions, bias from measurement of outcomes, and bias from selective reporting of results. For studies of diagnostic test accuracy, the QUADAS-2 instrument was used.[65] Our risk-of-bias assessments using these instruments were translated into an overall study quality rating of good, fair, or poor using predefined criteria developed by the USPSTF and adapted for this topic (**Appendix B Table 3**). Only studies rated as having good or fair quality were included.

For each included study, one investigator extracted pertinent information about the methods, populations, interventions, comparators, outcomes, timing, settings, and study designs. A second team member reviewed all data extractions for completeness and accuracy.

Data Synthesis and Analysis

Findings for each KQ were summarized in tabular and narrative format. The overall strength of the evidence for each KQ was assessed as high, moderate, low, or insufficient based on the overall quality of the studies, consistency of results between studies, precision of findings, risk of reporting bias, and limitations of the body of evidence, using methods developed for the USPSTF (and the EPC program).[66] Additionally, the applicability of the findings to U.S. primary care populations and settings was assessed. Discrepancies were resolved through consensus discussion.

To determine whether meta-analyses were appropriate, the clinical heterogeneity and methodological heterogeneity of the studies were assessed following established guidance.[67] The populations, tests, treatments, comparators, outcomes, and study designs were assessed qualitatively, looking for similarities and differences. For KQ 2 (the only KQ with sufficient numbers of similar studies for quantitative syntheses), pooled sensitivities and specificities for screening tests were calculated using a hierarchical summary receiver operating characteristic curve analysis when at least four similar studies were available. Pooled results and synthesis of individual studies were synthesized by type of screening test, as well as severity of hearing loss (e.g., detection of mild vs. moderate hearing loss). For studies that reported on multiple definitions of hearing loss, estimates included in pooled analyses were chosen based on similarity in decibel level, frequencies included in pure-tone average (PTA), and laterality to

other included studies. Separate models were developed for each type of screening test. The metandi program in Stata version 14 was used to conduct all quantitative analyses.[68]

Expert Review and Public Comment

A draft research plan for this topic was posted on the USPSTF website for public comment from November 11, 2018, to December 13, 2018. In response to comments, the following changes were made: (1) expanded the list of eligible health outcomes (KQ 4) to include social isolation and falls, (2) expanded the list of eligible harms of screening (KQ 3) to include overdiagnosis, (3) clarified that eligible screening tests (KQ 2) include smartphone and other newer technology, and (4) clarified that eligible interventions could have multiple components (e.g., amplification and brief counseling related to hearing loss). The final version of the research plan was posted on the USPSTF website on February 14, 2019. A draft report was reviewed by content experts, representatives of Federal partners, USPSTF members, and AHRQ Medical Officers. Reviewer comments were presented to the USPSTF during its deliberations and subsequently addressed in revisions of this report when appropriate. The draft report will also be posted for public comment. Revisions will be made based on comments received, and any references suggested by public reviewers will be evaluated for inclusion/exclusion.

USPSTF Involvement

This review was funded by AHRQ. AHRQ staff and members of the USPSTF participated in developing the scope of work and reviewed draft reports, but the authors are solely responsible for the content.

Chapter 3. Results

Literature Search

This review identified 4,680 unique records and assessed 280 full-text articles for eligibility (**Figure 2**). The review excluded 218 studies for various reasons, detailed in **Appendix C**, and included 40 unique studies (described in 44 publications). Of the included studies, one RCT reported some eligible outcomes for KQ 1, 33 studies (described in 34 publications) evaluated the accuracy of one or more screening tests for hearing loss (KQ 2), and no studies met eligibility criteria for KQ 3 (harms of screening). Six RCTs (described in 8 publications) addressed the benefits (KQ 4) of amplification compared with no amplification for treatment of screen-detected hearing loss, and no studies assessed harms of amplification (KQ 5). Details of quality assessments of included studies and studies excluded because of poor quality are in **Appendix D Tables 1-16**.

Results by Key Question

KQ 1a. Does Screening for Hearing Loss in Asymptomatic Adults Age 50 Years or Older Improve Health Outcomes?

Summary

One randomized trial (included in the prior USPSTF review) found that screening with the HHIE-S, the AudioScope, or both was not associated with any statistically significant difference in hearing-related QOL compared with no screening at 1 year. Although the trial did not find a difference between groups for health outcomes, it reported that screening was associated with greater hearing aid use (its primary outcome) at 1 year compared with no screening.[69, 70] Effects of screening on hearing aid use appeared to be limited to patients with perceived hearing loss at baseline. Because 74 percent of patients enrolled in the trial reported perceived hearing loss at baseline and all patients were eligible to receive free hearing aids, results are likely to be most applicable to high-prevalence settings in which the cost of hearing aids is not a barrier.

Detailed Evidence

The review identified one randomized trial of screening for hearing loss (n=2,305), the Screening for Auditory Impairment—Which Hearing Assessment Test (SAI-WHAT) trial (**Table 1**).[69, 70] The trial compared three different screening strategies with a nonscreened control group: the AudioScope (Welch Allyn, Skaneateles Falls, New York), based on inability to hear a 40-dB tone at 2,000 Hz in either ear; the HHIE-S (based on a score >10, range 0 to 40); or the AudioScope plus the HHIE-S. Included participants were predominantly male (94%), age 50 years or older (mean 61 years), and recruited from a VA Medical Center. All participants were eligible to receive free, VA-issued hearing aids. Most participants (74%) reported perceived hearing loss at enrollment (based on a "yes" or "maybe" response to the question "Do you think you have hearing loss?"). The SAI-WHAT trial was rated as fair quality, primarily because of concerns about potential deviation from intended interventions and high overall attrition for

hearing-related function (23%). The study aims to compare screening with usual care; however, baseline assessment (prior to randomization) includes an assessment of self-perceived hearing loss. Participants who screened positive for hearing loss in any of the screening arms were told that they might have hearing loss and were given written instructions to call the audiology clinic for an evaluation (no referral was required to schedule an appointment). The nonscreened group was provided with a number for the audiology clinic if they wanted further assessment. Although there was no differential attrition, the high overall attrition for hearing-related function is a potential source of bias because it is possible that participants with worse function were less likely to respond to the survey.

Among screened groups, the proportion who screened positive was lowest in the AudioScope arm (19%) and higher in the HHIE-S arm (59%) and combined arm (64%). Hearing aid use at 1 year, the primary outcome, was significantly higher among the AudioScope arm and combined arm than the nonscreened arm (6.3% and 7.4% vs. 3.3%, respectively; $p<0.01$) but not among the HHIE-S arm compared with the nonscreened arm (4.1% vs. 3.3%; $p>0.40$). In a post hoc subgroup analysis, hearing aid use was greater among participants with perceived hearing loss at baseline (5.7% to 9.6% in screened arms vs. 4.4% in the control arm), but among those without perceived hearing loss, hearing aid use was minimal regardless of screening status (0% to 1.6%).

There was no difference in the proportion of patients who experienced a minimum clinically important difference (>6 points of improvement on a 0 to 100 scale) on the Inner Effectiveness of Aural Rehabilitation scale (a measure of hearing-related function) at 1 year (36% to 40% in the screened arms vs. 36% in the nonscreened group; $p=0.39$).

KQ 1b. Does the Effectiveness of Screening for Hearing Loss Differ for Subpopulations Defined by Age, Sex, Race/Ethnicity, Risk of Past Noise Exposure, or Comorbid Condition?

The SAI-WHAT trial of screening (described above) conducted post hoc analyses of hearing-related function for subpopulations defined by age.[69, 70] There were no differences between screened and nonscreened groups in the proportion who experienced improvement on the Inner Effectiveness of Aural Rehabilitation scale when groups were stratified by age and according to whether they had perceived hearing loss at baseline, except in a subgroup that had both perceived hearing loss at baseline and was age 65 years or older (54% in the AudioScope arm, 34% in the HHIE-S arm, 40% in the combined arm, and 34% in the control arm; $p=0.035$).

KQ 2. What Is the Accuracy of Primary Care–Relevant Screening Tests for Hearing Loss in Adults Age 50 Years or Older?

Summary

Thirty-three studies (reported in 34 articles) evaluated the diagnostic accuracy of clinical tests, a single question, a questionnaire, a handheld audiometric device, or a mobile-based audiometric application for identifying mild to moderate hearing loss in older adults. For detecting mild hearing loss (>20 to 25 dB), single-question screening had a pooled sensitivity of 66 percent (95% CI, 58% to 73%) and pooled specificity of 76 percent (95% CI, 68% to 83%) (10 studies, 12,637

participants);[71-80] for detecting moderate hearing loss (>35 to 40 dB averaged over 2 to 4 frequencies), pooled sensitivity was 80 percent (95% CI, 68% to 88%) and the pooled specificity was 74 percent (95% CI, 59% to 85%) (6 studies, 8,774 participants).[72-74, 80-82] Too few studies reported sufficient data to pool accuracy of the HHIE-S for detecting mild hearing loss (>25 dB at 2 to 4 frequencies); across 4 studies (7,194 participants) sensitivity of HHIE-S ranged from 34 to 58 percent, and specificity ranged from 76 to 95 percent.[73, 76, 83, 84] For detecting moderate hearing loss (>40 dB at 2 to 4 frequencies), the pooled sensitivity of HHIE-S (5 studies; 2,820 participants) was 68 percent (95% CI, 52% to 81%) and pooled specificity was 78 percent (95% CI, 67% to 86%).[3, 44, 73, 81, 83] For detecting mild hearing loss (>25 to 30 dB), pooled sensitivity of the whispered voice test was 94 percent (95% CI, 31% to 100%) and pooled specificity was 87 percent (82% to 90%) (5 studies; 669 participants).[42, 71, 85-87] Fewer studies reported on the accuracy of whispered voice to detect moderate hearing loss (>40 dB) sensitivity ranged from 30 to 60 percent and specificity ranged from 80 to 98 percent (3 studies; 296 participants).[71, 86, 88] Two studies (215 participants) assessed the accuracy of the AudioScope to detect at least mild hearing loss (>25 to >30 dB); sensitivities ranged from 64 to 93 percent, and specificities ranged from 70 to 91 percent.[83, 89] For detecting moderate hearing loss (>40 dB), four studies (411 participants) found relatively high sensitivity (94% to 100%) and variable specificity (range: 24% to 80%) for the AudioScope.[42, 44, 83, 90]

Detailed Evidence

Six good[72, 77, 80, 83, 91, 92] and 27 fair-quality studies (reported in 28 articles)[3, 42, 44, 71, 73-76, 78, 79, 81, 82, 84-90, 93-101] assessed the accuracy of 18 different screening tools for hearing loss in older adults (**Table 3**). Nineteen of the included studies were in the review conducted for the USPSTF in 2011 (as noted in **Table 3**).[5]

Nine studies evaluated a clinical test (e.g., whispered voice, finger rub).[42, 71, 85-88, 96, 99, 100] Thirteen studies evaluated a single question (e.g., "Do you have difficulty hearing?");[71-82, 84] 10 studies (reported in 11 articles) evaluated a hearing questionnaire (e.g., HHIE-S);[3, 44, 73, 76, 81, 83, 84, 92, 93, 95, 98] and 10 studies evaluated a handheld or mobile-based audiometric device.[42, 44, 83, 88-91, 94, 97, 101] Many studies assessed multiple screening tools.

All the studies used PTA as the reference standard, although the thresholds and the criteria used to diagnose hearing loss varied both across and within studies; specific criteria are shown in **Appendix E Tables 1-4** along with the test accuracy outcomes. For instance, some studies examined accuracy in relation to mild (>25 dB) or moderate (>40 dB) levels of severity, and studies varied by the particular cutpoint at which a determination of mild or moderate was made. Another variation both within and across studies was whether the better ear, worse ear, or both individual ears were used to obtain hearing thresholds. Finally, studies varied on whether thresholds were speech frequency averages (i.e., 0.5, 1, 2 kHz), four-frequency averages (i.e., 0.5, 1, 2, 4 kHz), or high frequency averages (i.e., 4, 6, 8 kHz).

In terms of screening-test delivery, studies assessing a hearing questionnaire or single question involved self-administration (**Table 2**).[3, 44, 71, 75, 76, 81-84, 91-93, 98, 100] A variety of different personnel screened participants in studies examining handheld or mobile-based audiometric devices, including audiologists, speech language pathologists, primary care clinicians, research staff, and not further described "examiners." Clinicians (i.e., neurologists, geriatricians,

otolaryngologists) and audiologists administered clinical screening tools. Five of the studies did not indicate who administered the screener.[42, 74, 79, 80, 82]

Most studies included community-dwelling older adults enrolled from various outpatient clinical or community settings; four studies included adults who were in chronic care/rehabilitation facilities.[79, 85, 90, 94] In addition, one study included cancer outpatients.[97] Most studies that reported sex of the participants included both males and females, with no more than a 75 to 25 percent ratio of one sex to the other. Exceptions include two studies that were predominantly male[90, 100] and one that was entirely female.[74] Sample sizes analyzed varied from 30 to 4,906 participants, with a median of 106. Across the 27 studies that reported on the age of enrolled participants (mean, median, or range), the median age of participants was 69 years. Two studies[3, 79] did not report age but had inclusion criteria limiting to older adults. Several studies included a minority of participants younger than 50 (the lower age boundary specified in our inclusion criteria), but in these studies the mean was at least 50, or we only included data for those who were age 50 or older. Of the 33 studies, only five[44, 76, 77, 82, 84] reported on race or ethnicity; the percentage of participants who were white ranged from 0 to 100. Few reported any socioeconomic variables, and those that did reported the data in different ways: one study reported occupational classes,[73] one study reported income,[82] and five studies reported on education,[80, 82-84, 93] using different metrics. The majority of studies (k=17) were set in the United States.[3, 44, 71, 74, 76-79, 81, 83, 89, 92, 94, 95, 98-101] The remainder were in Canada,[90, 91] the United Kingdom,[85-87] Australia,[72, 73] other European countries;[42, 75, 80, 88, 93, 96, 97] and Asia.[82, 84] We rated six studies as good quality[72, 77, 80, 83, 91, 92] and the remainder as fair quality (**Appendix D Tables 13-16**). In the studies rated as fair quality, common sources of bias included unclear description of index test administration or interpretation, unclear patient selection (e.g., no description of whether a consecutive or random sampling was used, and no or unclear description of exclusion criteria related to comorbidity or symptom status).

Screening test accuracy results are organized by test category below. Many studies reported on the accuracy of screening tests to detect hearing loss defined by multiple thresholds (e.g., >25 dB, >40 dB) averaged over different frequencies; definitions of hearing loss also varied in terms of laterality (one or both ears affected). Detailed results, including all screening test cut points and hearing loss definitions based on PTA reported by included studies, are shown in **Appendix E Tables 1-4**. **Table 3** summarizes results by test category and hearing loss severity.

Single-Question Screening

Thirteen studies assessed the accuracy of single-question screening for detecting hearing loss (**Appendix E Table 1**).[71-82, 84] The exact wording of the question varied slightly across studies (e.g., "Do you have a hearing problem now?" vs. "Do you feel you have a hearing loss?"). All studies indicated that an affirmative or "yes" response to the question was considered a positive screen; only one study noted that both affirmative and equivocal responses were considered a positive screen.[79]

For detecting mild hearing loss (>20 to 25 dB averaged over 3 to 4 frequencies), the pooled sensitivity based on 10 studies (12,637 participants) was 66 percent (95% CI, 58% to 73%) and the pooled specificity was 76 percent (95% CI, 68% to 83%) (**Table 3**; **Appendix F Figure 1**).[71-80] The pooled sensitivity to detect moderate hearing loss (>35 to 40 dB averaged over 2 to 4

frequencies) based on six studies (8,774 participants) was 80 percent (95% CI, 68% to 88%) and the pooled specificity was 74 percent (95% CI, 59% to 85%) (**Table 3**; **Appendix F Figure 2**).[72-74, 80-82] One additional study of 1,731 community-dwelling adults in Japan that did not report sufficient data to be included in pooled analyses found a sensitivity of 54 percent and a specificity of 78 percent for detecting mild hearing loss and a sensitivity 88 percent and a specificity of 67 percent for detecting moderate hearing loss.[84]

Screening Questionnaires

Eleven studies (reported in 12 articles) assessed the accuracy of screening questionnaires (**Appendix E Table 2**).[3, 44, 73, 76, 81, 83, 84, 88, 92, 93, 95, 98] Of these, eight studies assessed the accuracy of HHIE-S.[3, 44, 73, 76, 81, 83, 84, 92, 98] Too few studies reported sufficient data to pool accuracy of the HHIE-S for detecting mild hearing loss (>25 dB at 2 to 4 frequencies). Across four studies (7,194 participants), sensitivity of HHIE-S using a cut point of score >8 ranged from 34 to 58 percent, and specificity ranged from 76 to 95 percent.[73, 76, 83, 84] For detecting moderate hearing loss (>40 dB at 2 to 4 frequencies), the pooled sensitivity of HHIE-S using a cutoff score of >8 based on five studies (2820 participants) was 68 percent (95% CI, 52% to 81%) and pooled specificity was 79 percent (95% CI, 69% to 86%) (**Table 3**; **Appendix F Figure 3**).[3, 44, 73, 81, 83]

Two additional screening questionnaires were evaluated in one study each, the Hearing Self-Assessment Questionnaire (HSAQ)[93] and the Revised Five Minute Hearing Test (RFMHT).[95] For detecting mild hearing loss (>25 dB at 4 frequencies), the HSAQ had a sensitivity of 89 percent (95% CI, 78% to 96%) and specificity of 84 percent (95% CI, 72% to 92%) using a cut point of ≥15; sensitivity was slightly lower (76%) and specificity was slightly higher (96%) at a cut point of ≥19.[93] The sensitivity of the RFMHT for detecting mild hearing loss was 80 percent and specificity was 55 percent.

Clinical Tests

Nine studies[42, 71, 85-88, 96, 99, 100] evaluated the diagnostic accuracy of whispered voice, conversational voice, finger rub, watch tick, digits-in-noise (DIN), and words-in-noise (WIN) tests (**Appendix E Table 3**). Six of these studies[42, 71, 85-88] assessed the accuracy of the whispered voice test at 6 inches and/or 2 feet using letters, words, or numbers, with different passing criteria, and one assessed the accuracy of the conversational voice test at 2 feet.[85] For detecting mild hearing loss (>25 to 30 dB), pooled sensitivity of the whispered voice test was 94 percent (95% CI, 31% to 100%), and pooled specificity was 87 percent (82% to 90%) (5 studies; 669 participants) (**Appendix F Figure 4**).[42, 71, 85-87] One study included in the pooled analysis reported on sensitivity and specificity of the whispered voice test when conducted by providers with different levels of experience and found variable results.[86] A pooled analysis including data from experienced providers (vs. inexperienced/newly trained providers) was similar, but sensitivity was slightly higher (96%) and specificity was lower (79%). Sensitivity for detecting at least moderate hearing loss defined as >40 dB (3 studies; 296 participants) ranged from 30 to 60 percent and specificity ranged from 80 to 98 percent.[71, 86, 88]

Few studies assessed other clinical screening tests for hearing loss. One study (n=62) assessed the accuracy of the conversational voice test at 2 feet[85] and reported low sensitivity (47%) and high specificity (100%) for detecting mild hearing loss. Watch tick and finger rub tests for

detecting mild and moderate hearing loss were assessed in one study.[71] Sensitivities were low for the watch tick and finger rub tests for detecting both mild (44% and 27%, respectively) and moderate hearing loss (60% and 35%, respectively); specificities were high for detecting both mild (100% and 98%, respectively) and moderate hearing loss (99% and 97%, respectively). Three studies[96, 99, 100] assessed the accuracy of either DIN or WIN tests to detect mild hearing loss using different methods (**Appendix E Table 3**), including the U.S. National Hearing Test (a DIN telephone screening protocol developed for use within the VA)[100] Sensitivity of the DIN or WIN ranged from 42 to 99 percent, with a median of 90 percent; specificity ranged between 24 and 98 percent, with a median of 86 percent.

Handheld or Mobile-Based Audiometric Devices

Ten studies evaluated the accuracy of various handheld audiometric screening devices (**Appendix E Table 4**).[42, 44, 83, 88-91, 94, 97, 101]

Five evaluated the AudioScope, a device that combines an otoscope for examining middle ear function with a portable audiometer to screen for hearing loss in the 0.5 to 4 kHz range. Two studies (215 participants) assessed the accuracy of the AudioScope to detect mild hearing loss (PTA thresholds of >25 to >30 dB); sensitivities ranged from 64 to 93 percent, and specificities ranged from 70 to 91 percent.[83, 89] For detecting moderate hearing loss (≥40 dB), evidence from four studies (411 participants) found relatively high sensitivity (range: 94% to 100%) and variable specificity (range: 24% to 80%) for the AudioScope.[42, 44, 83, 90] One study[94] assessed the accuracy of both the AudioScope and a portable audiometer to detect moderate hearing loss (≥45 dB) in subpopulations defined by age decades, beginning with 50-year-olds through 90-year-olds. Across all age groups, sensitivities and specificities of both the AudioScope and portable audiometer for detecting moderate hearing loss were high (**Appendix E Table 4**). AudioScope sensitivities ranged from 85 to 90 percent, and specificities ranged from 89 to 94 percent. Similarly, sensitivities for the portable audiometer ranged from 88 to 94 percent, and specificities ranged from 90 to 94 percent.

Four studies assessed various tablet-based software audiogram apps designed for screening. Two studies by the same authors evaluated the accuracy of the uHear™ app in two separate cohorts of older adults with cancer undergoing a comprehensive geriatric assessment (78 participants) using different scoring methods to determine a positive screen.[88, 97] Using a scoring method that defined a positive screening test result based on PTA ≥40 dB at 0.5, 1.0, or 2.0 kHz, sensitivity was high in both cohorts (100%) but specificity was relatively low (38% and 36%).[88, 97] A revised scoring method to determine a positive screen was applied to both cohorts, defined as two or more nonconsecutive hearing grades below the moderate-to-severe threshold (≥56 dB) measured at five frequencies (from 0.5 to 4.0 kHz) in at least one ear.[97] Based on this method, sensitivity varied between the first and second cohorts (100% and 68%, respectively), and specificity was similar (89% and 87%).[97]

One study (33 participants)[91] assessed two iOS apps, EarTrumpet and ShoeBox, and found that both had relatively high sensitivity (88% and 100%, respectively) and specificity (96% for both) for detecting moderate hearing loss.

One RCT (107 participants)[101] assessed three different apps—EarTrumpet (n=35), Audiogram Mobile (n=37), and Hearing Test with Audiogram (n=35)—for their ability to detect mild hearing loss (≥ 20 dB hearing loss at frequencies ranging from 0.25 to 8.0 kHz) in either a clinic waiting area or a quiet exam room. Following pure-tone audiometry, patients were randomly assigned to receive only one screening app in both the waiting area and quiet exam room. The specific screening setting had a minimal effect on test accuracy. In a clinic waiting area, all three apps had relatively high sensitivity (100%, 88%, and 89%, respectively), but more variation was seen in their specificities (72%, 92%, and 68%, respectively). In a quiet exam room, sensitivity remained relatively high (96%, 85%, and 88%, respectively), and specificity remained variable (83%, 95%, and 69%, respectively).

KQ 3a. What Are the Harms of Screening for Hearing Loss in Adults Age 50 Years or Older?

KQ 3b. Do the Harms of Screening for Hearing Loss Differ for Subpopulations Defined by Age, Sex, Race/Ethnicity, Risk of Past Noise Exposure, or Comorbid Condition?

We identified no eligible studies that evaluated harms associated with screening for hearing loss in older adults.

KQ 4a. What Is the Efficacy of Interventions for Screen-Detected Hearing Loss in Improving Health Outcomes in Adults Age 50 Years or Older?

Summary

Six trials (reported in 8 articles) evaluated benefits of amplification compared with no amplification among populations with screen-detected or recently detected, untreated age-related hearing loss over 6 weeks to 4 months.[102-109] In five trials reporting on the HHIE, four found statistically significant benefit in favor of hearing aids compared with no amplification, and one crossover RCT found no difference between groups.[107] Three of the four trials that found statistically significant benefit enrolled veterans (two RCTs[102, 105] and one nonrandomized trial[104]); the difference in HHIE score changes from baseline in all three trials was greater than the 18.7-point difference considered to represent a minimal important difference.[110] One RCT enrolling community volunteers found higher HHIE score changes from baseline among groups receiving two different hearing aid interventions (-18.2 points and -12.3 points) than placebo (-5.5 points); although comparisons were statistically significant for either intervention vs. placebo ($p<0.001$), differences between groups did not meet the score change considered to represent a minimal important difference. Four studies reported on general QOL or function and other non-hearing-related health outcomes;[102, 104, 107, 108] of these, one found significant benefit in favor of the intervention on the Short Portable Mental Status Questionnaire and Geriatric Depression Scale.[102] No study examined the effect of interventions on the incidence of dementia or neurocognitive impairment. The results are most applicable to older male populations with improved access to screening and no-cost hearing aids, such as veterans' groups.

Detailed Evidence

We identified six controlled trials comparing amplification with no amplification among older adults with screen-detected or recently detected mild to moderate hearing loss (**Table 4**). Three were included in the 2011 review for the USPSTF,[102, 104, 107] and three are newly included.[105, 108, 109] All studies were set in the United States; enrolled populations included veterans (3 studies)[102, 104, 105] and community-dwelling older adults (3 studies).[107-109] Across all studies, the mean age of enrolled populations ranged from 69 to 74 years. Five studies enrolled a majority of males (56% to 100%), and one enrolled mostly females (53%).[108] In five studies, the baseline HHIE score ranged from 29 to 51 (indicating at least mild to moderate hearing-related handicap).[111] Sample sizes ranged from 15 to 380 participants. Four studies reported on race; of these, two were predominantly white (95% and 98%)[102, 109] and one was 40 percent white.[108] Interventions included ALDs (3 studies)[104, 107, 108] and traditional hearing aids (5 studies).[102, 105, 107-109] Studies varied in terms of the detail provided about hearing aid features and how they were fitted (**Table 5**). In the three studies evaluating ALDs, one did not describe the device,[104] one assessed a devise comprising a single earbud connected to a receiver via a cord,[107] and one evaluated two different ALDs: one with a remote microphone and headphones with dials for volume and tone control and a Bluetooth-enabled, single-ear-worn device that can be paired with a smartphone.[108] Three studies compared multiple interventions with a no-amplification control group, including one study that assessed provision of the same hearing-aid device via two different service delivery models (one group received fitting using best-practice services from audiologists and the other group self-selected their own pre-programmed aids in a model designed to simulate OTC purchasing)[109] and two that assessed both hearing aids and ALDs.[104, 107] Duration of followup ranged from 6 weeks to 4 months. All studies reported on at least one hearing-related QOL and/or function outcome, primarily the HHIE questionnaire; four studies also reported on non-hearing-related health outcomes.[102, 104, 107, 108] All studies were RCTs; one study also included a nonrandomized comparison of veterans who received two types of hearing aids (via randomized allocation) and a no-amplification control group that was randomized separately (to no-amplification vs. an assistive listening device).[104] All studies were rated fair quality. Common sources of bias included lack of blinding (in that only one study compared amplification with a placebo device[109]), small sample sizes, and/or select study populations with limited descriptions of their baseline characteristics, raising concern for potential selection bias.

Hearing-Related QOL and Function

All studies reported on one or more hearing-related QOL and/or function measures (**Table 5**). Most (5 studies) reported on the HHIE (25-items, score range: 0 to 100); lower HHIE scores (0 to 16) indicate no hearing handicap and higher scores indicate mild to moderate (17 to 42) or significant handicap (≥43).[111] Mean baseline HHIE scores ranged from 29 to 51 across all study arms and were slightly higher in three studies enrolling veterans eligible for free hearing aids (36 to 51) than studies enrolling community volunteers (25 to 29).[107, 109] Overall, four trials found statistically significant benefit in favor of hearing aids compared with no amplification, and one crossover RCT found no difference between groups.[107] Three of the four trials that found statistically significant benefit enrolled veterans (two RCTs[102, 105] and one nonrandomized trial[104]); the difference in HHIE score changes from baseline in all three trials was greater than the 18.7-point difference considered to represent a minimal important difference.[110] The two RCTs enrolling veterans (574 total participants) both found significantly larger changes in

baseline HHIE scores among those receiving hearing aids than controls over followup durations of 4 months (-34 points vs. 0 points; p<0.0001[102] and 10 weeks (-17.5 points vs. +1.8 points; p<0.01).[105] Results from the nonrandomized trial enrolling veterans (n=60) were consistent with the two RCTs; change in mean HHIE scores from baseline was higher among those receiving either a conventional hearing aid (-17.4 points) or a programmable hearing aid (-31.1 points) than controls (-2.2 points), p<0.001 for both comparisons.[104] However, in the same study, there was no significant difference between groups randomized to an assistive living device (-4.4 points) or control (-2.2 points) over 3 months.[104] The one RCT set in a non-VA setting that found benefit recruited participants via community advertisements at one academic institution (n=163) who were randomized to one of three arms: audiology-based best-practice fitted hearing aid, self-selection of the same hearing aid that was preprogramed and designed to simulate OTC purchasing, or a placebo device (fitted by an audiologist).[109] At 6 weeks, the HHIE score change from baseline was higher in the audiology-based hearing aid group (-18.2 points) and OTC hearing aid group (-12.3 points) than placebo (-5.5 points); although comparisons were statistically significant for either intervention vs. control (p<0.001), differences between groups did not meet the score change considered to represent a minimal important difference (-18.7 points).[109] The one study that did not find significant between-group differences in HHIE scores was a crossover RCT (n=80) enrolling community volunteers; participants were allocated to each arm for 6 weeks; there were no significant between-group differences in mean changes from baseline HHIE scores associated with hearing aids (-5.2 points), assistive listening devices (-3.2 points), hearing aids combined with assistive listening devices (-4.1 points), and no amplification (-2.2 points).[107] This study also provided HHIE score changes from baseline reported by a significant other; authors only reported mean changes from baseline that were slightly larger for hearing aids (-7.5 points), assistive listening devices (-4.4 points), and hearing aids combined with assistive listening devices (-9.5 points) than no amplification (-1.4 points).[107] No baseline scores, measures of variance, or significance of between-group differences were reported.

For other hearing-related outcomes, few studies reported on the same measure (**Table 5**). Two trials reported on the revised QDS.[104, 108] One was a nonrandomized trial enrolling veterans (n=60); changes in mean score from baseline were larger among groups receiving a standard hearing aid (-0.70 points) and programmable hearing aid (-0.86 points) than controls (-0.05 point) (p=0.01), but there was no difference between the assistive listening device (+0.03 points) and no amplification controls (-0.05).[104] The second trial (n=15) found a slightly larger change from baseline scores among the intervention group than controls (-5.9 vs. -2.1) but did not comment on whether the change was statistically significant.[108] Two trials enrolling veterans reported on the Abbreviated Profile of Hearing Aid Benefit (APHAB), a 24-item scale used to measure self-rated communication ability.[104, 105] One RCT (n=380) found larger reductions in mean scores among the hearing aid group vs. controls at 10 weeks (mean change in baseline APHAB score: -29.5 vs. +4.2; p<0.01).[105] Results from the nonrandomized comparison were similar, showing larger reductions in mean APHAB scores from baseline to 3 months among those receiving standard hearing aids (-7.7 points) and programmable hearing aids (-16.3 points) than controls (-2.7 points), (p=0.01); however, changes in scores were not significantly different among groups randomized to an assistive listening device vs. control (-2.7 vs. -6.4 points).[104] One trial reported on the WHO-DAS II (n=380) and found significantly larger changes from baseline scores among the hearing aid group than controls at 10 weeks (-2.9 vs. 3.2; p<0.01).[105] Finally, one crossover RCT (n=15) measured changes in mean HHIE-S scores (15 items, score range: 0 to 40); at 3 months, changes in baseline scores were slightly larger among those

receiving the intervention vs. controls (-8.5 vs. 0.03, respectively).[108] Authors did not provide measures of variance or comment on statistical significance; however, the magnitudes of the differences between groups (and change from baseline scores) do not meet the 10-point change considered to be a clinically meaningful difference.[112]

Other Health Outcomes

Four studies reported on at least one general (non-hearing-related) health outcome, including general measures of QOL, cognitive function, social isolation, and depression (**Table 6**).[102, 104, 107, 108] No outcome measure was assessed by more than one study. Three studies reported outcomes but did not provide numerical results[107] or did not report sufficient information to determine whether differences between groups were significant.[104, 108] One RCT enrolling veterans (n=194) found statistically significant benefit among those receiving hearing aids vs. controls on measures of cognitive function (Short Portable Mental Status Questionnaire, difference between groups in change from baseline: -0.28 points [95% CI, 0.08 to 0.48]; p=0.008) and depression (Geriatric Depression Scale, difference between groups in change from baseline: -0.80 points [95% CI, 0.09 to 1.51]; p=0.03), but no significant difference between groups on a measure of general health and function (Self Evaluation of Life Function scale, difference between groups in change from baseline: -1.9 points [95% CI, -0.1 to 4.0]; p=0.07).[102]

KQ 4b. Does the Efficacy of Interventions for Screen-Detected Hearing Loss Differ for Subpopulations Defined by Age, Sex, Race/Ethnicity, Risk of Past Noise Exposure, or Comorbid Condition?

No subpopulation analyses were reported by the included studies.

KQ 5a. What Are the Harms of Interventions for Screen-Detected Hearing Loss in Adults Age 50 Years or Older?

KQ 5b. Do the Harms of Interventions for Screen-Detected Hearing Loss Differ for Subpopulations Defined by Age, Sex, Race/Ethnicity, Risk of Past Noise Exposure, or Comorbid Condition?

No eligible studies reporting on harms were identified.

Chapter 4. Discussion

Summary of Evidence

Table 7 provides a summary of the main findings in this evidence review organized by KQ along with a description of consistency, precision, quality, limitations, strength of evidence, and applicability.

Evidence for Benefit and Harms of Screening

For benefits of screening, the SAI-WHAT trial (2,305 participants) included in the prior USPSTF review found that screening with the HHIE-S, the AudioScope, or both was not associated with any statistically significant difference in hearing-related QOL compared with no screening at 1 year. Although the trial did not find a difference between groups for health outcomes, it reported that screening with the AudioScope or combined screening with the AudioScope and HHIE-S was associated with greater hearing aid use (its primary outcome) at 1 year compared with no screening.[69, 70] Effects of screening on hearing aid use appeared to be limited to patients with perceived hearing loss at baseline. Of note, hearing aid use at 1 year was less than 10 percent in all arms, and the trial was not powered to assess improvements in hearing-related function; over one third of patients (screened or unscreened) in SAI-WHAT experienced a clinically significant improvement in hearing-related function, suggesting that factors other than hearing aid use may affect functional outcomes. Results may not be applicable to populations with a lower prevalence of perceived hearing loss. The SAI-WHAT trial enrolled only veterans eligible for free hearing aids, and 74 percent reported perceived hearing loss at baseline (based on the single question "Do you think you have a hearing-loss?"). As noted above, hearing aid use at 1 year was relatively low despite the high prevalence of perceived hearing loss at baseline. Multiple factors that may explain low uptake of hearing aids among those with perceived and/or confirmed hearing impairment, including a perception that symptoms are not severe enough, concerns about cost or stigma, and (for those who receive hearing aids) concerns about comfort and maintenance (e.g., difficulty replacing batteries, cost of repairs) may affect hearing aid use. **Appendix A Contextual Question 3** provides a detailed overview of potential barriers to obtaining hearing aids and reasons for low uptake.

We did not find direct evidence on harms of screening. Potential harms include false-positive results that lead to unnecessary testing and/or treatment, labeling, and anxiety. Based on our pooled analyses of HHIE-S for detecting moderate hearing loss (5 studies; 2,820 participants), the expected rate of false-positives tests would be 22 percent (**Table 3**). Similarly, in five studies assessing the AudioScope for detecting moderate hearing loss (reporting specificities ranging from 52 to 80), the rate of false positives was 20 to 58 percent. Other harms of screening are likely to be minimal because screening is noninvasive, and the reference standard (audiometric testing) is also noninvasive.

Diagnostic Test Accuracy

Screening tools are available for clinical practice that may reasonably identify asymptomatic older adults with hearing loss. The 33 included studies assessed the accuracy of various clinical tests, a single question, questionnaires (primarily the HHIE-S), and a handheld or mobile screening audiometric device compared with heterogeneous definitions of hearing loss based on PTA. A major limitation in interpreting studies of diagnostic accuracy is that studies used different thresholds and criteria to define hearing loss. Several studies found inconsistent screening test accuracy results when comparing the same screening test (and cut point) with different definitions for mild or moderate hearing loss (i.e., measured at different frequencies or defined by hearing thresholds in the better vs. worse ear). This limited our ability to make stronger conclusions about the accuracy of available screening tests to detect mild or moderate hearing loss.

The clinical relevance of detection of mild (25 to 40 dB) hearing loss as it pertains to effectiveness of screening is also uncertain because the only trial showing benefits of hearing aids enrolled patients with screening-detected >40 dB hearing loss.[69]

Screening tests evaluated in the included studies differ in factors such as cost, complexity/time, and convenience. Relatively simple tests, such as a single question regarding perceived hearing loss, appear to be nearly as accurate as a more detailed hearing loss questionnaire or a handheld audiometric device for detecting hearing loss. For the whisper test, an important consideration is the need for clinicians to administer the test in a standardized and consistent fashion (such as the method described in published studies of diagnostic accuracy). One study of whispered voice test accuracy found that estimates differed based on practitioner experience in administering the whispered voice; older experienced whisperers were 8 to 10 dB greater than inexperienced whisperers, which resulted in lower sensitivity (63% vs. 80%) and higher specificity (93% vs. 80%) for detecting moderate hearing loss in the same population.[86]

Some studies of screening test accuracy were limited by unclear applicability (14 of 33 studies enrolled participants from audiology clinics or other hearing-related specialty). The estimates of screening test accuracy were derived from populations with a prevalence of hearing loss (based on PTA) of approximately 14 to 63 percent for mild (>25 dB) and 11 to 69 percent for moderate (>40 dB) hearing loss.

Benefits of Interventions for Screen-Detected or Recently Diagnosed Hearing Loss

Six RCTs (reported in 8 articles) evaluated benefits of amplification compared with no amplification among populations with screen-detected or recently detected, untreated age-related hearing loss.[102-109] Of these, three were included in the 2011 review for the USPSTF, and three were newly identified. No new studies enrolling screen-detected populations from primary care settings were identified, and our overall conclusion are consistent with the prior report. We were not able to pool studies assessing benefit of interventions (KQ 4) because of limited reporting of outcome measures (HHIE) or too few studies reporting on similar outcomes (e.g., general measure of QOL or function). Three RCTs and one nonrandomized trial found significant

reductions on the HHIE among groups receiving hearing aids compared with no amplification; of these, three trials enrolled veterans[102, 104, 105] and one enrolled community volunteers.[109] Only the three trials enrolling veterans found a difference between groups in HHIE scores considered to represent a minimal important difference (18.7 points). Evidence on the efficacy of treatments for screen-detected hearing loss in primary care settings is limited. One fair-quality RCT found that hearing aids resulted in near normalization of hearing-related QOL and function (measured by the HHIE) among veterans identified by screening, based on >40 dB hearing loss using a handheld audiometric device.[102, 103] Because this trial was conducted in a VA center and almost exclusively enrolled white males eligible for free hearing aids, its generalizability to other settings may be limited.

Our conclusions regarding treatment benefit associated with hearing aids are similar to those from a 2017 Cochrane review (k=5 RCTs; 825 participants) despite differences in eligible populations and study designs. Authors concluded that hearing aids significantly improve hearing-specific health-related QoL measured by the HHIE compared with the unaided/placebo condition (mean difference -26.47 [95% CI -42.16 to -10.77]; 722 participants; 3 studies).[113]

We did not find direct evidence on harms of treatment with amplification. However, harms of treatment are likely to be minimal because treatment with hearing aids is not known to be associated with serious adverse events.

Limitations

The limitations of the included studies are discussed above in Results and Summary of Evidence. Here we focus on limitations of this review. We excluded non-English language articles. We excluded studies of persons with symptomatic hearing loss and head-to-head comparisons of different amplification interventions, aiming to identify the studies with good applicability to a screen-detected population.

Future Research Needs

Screening trials of sufficient sample size that focus on health outcomes (e.g., hearing-related function and QOL) and enroll asymptomatic older adults from a general primary care population are needed, as are studies on potential harms of screening such as labeling, harms from false-positive results, burden, inconvenience, and unnecessary testing and treatment. The existing screening trial has uncertain applicability to U.S. populations enrolled from non-VA settings where prevalence of hearing loss may be lower. Accuracy studies enrolling asymptomatic adults from primary care settings that use consistent definitions of hearing loss would improve certainty about the accuracy of primary-care relevant screening tests. In addition, trials of screening and treatment for hearing loss are needed that reflect currently available technology, including OTC options for those identified with mild hearing loss and fitting of hearing aids that reflect current treatment standards.

Conclusion

One trial of screening for hearing loss did not find a benefit for hearing-related function. No eligible study reported on potential harms of screening. Screening tools are available for clinical practice that may reasonably identify asymptomatic older adults with moderate hearing loss. Estimates of test accuracy vary based on hearing loss definition. Three trials show significant reductions in HHIE among groups receiving hearing aids compared with no amplification that meet the difference considered minimally important; all enrolled veterans. No studies of interventions reported on potential harms.

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Figure 1. Analytic Framework

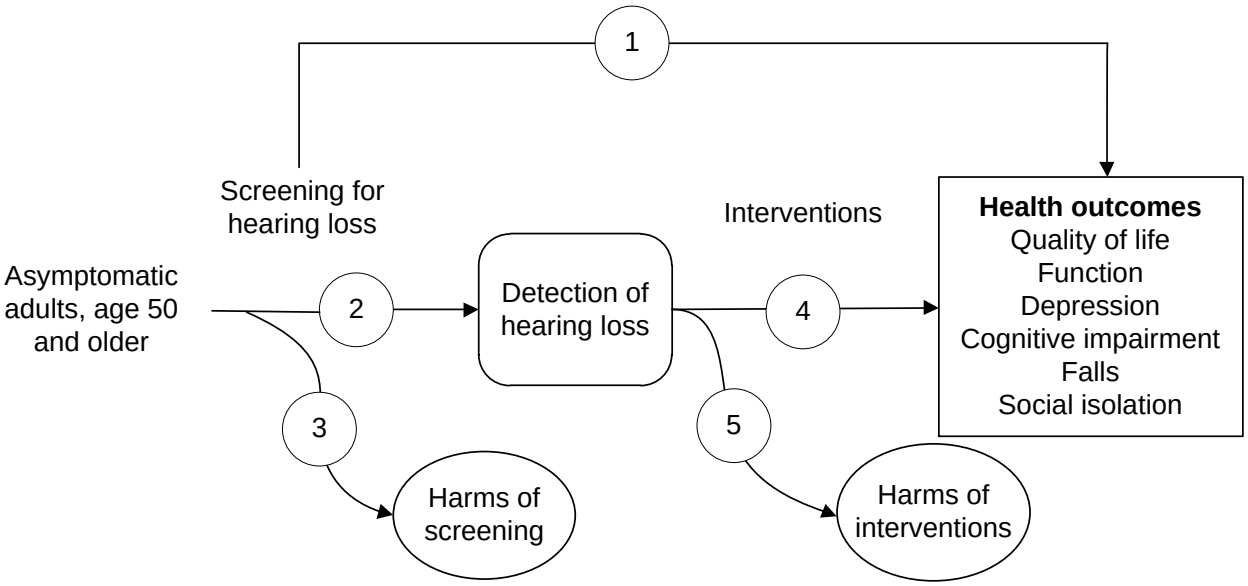

Figure 2. Summary of Evidence Search and Selection

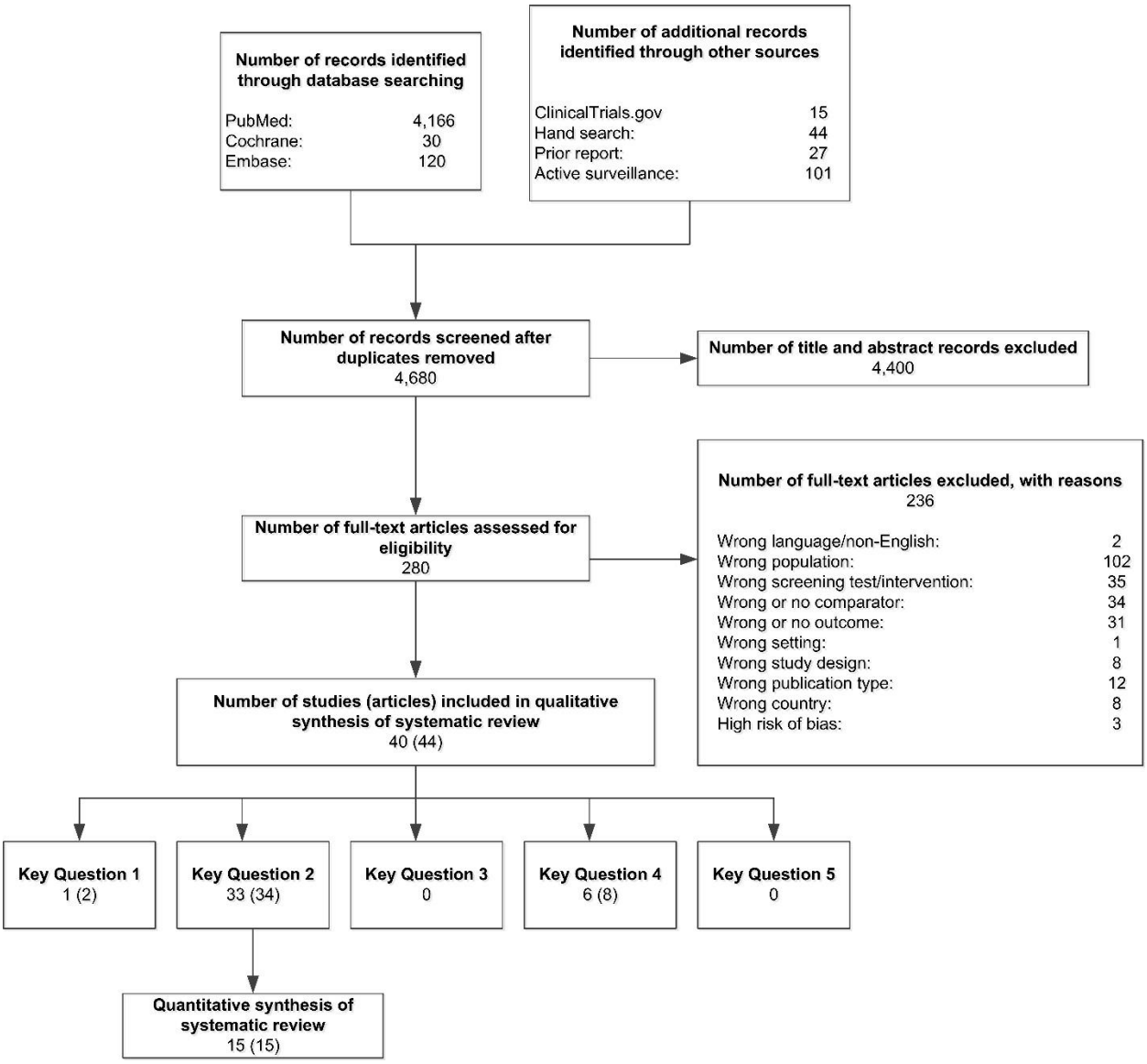

Table 1. Characteristics and Outcomes of Included Randomized, Controlled Trial for KQ 1

Author, Year Study Design (N)	Source Population (Country)	Eligibility Criteria	Baseline Characteristics	Interventions	Hearing-Related Function	Hearing Aid Use
Yueh, 2010[69]; Yueh, 2007[70] RCT (2,305)	Outpatients seeking general medical care from the VA Puget Sound Health Care system recruited via flyers and posters advertising hearing screening study (U.S.)	Age 55-79 yrs; eligible for VA-issued HAs; MMSE>25; no prior HA experience; PTA thresholds consistent with age-related, bilateral SNHL; no hearing-related pathologies specific to ear anatomy, medication use, or medical conditions	Mean age, yrs (SD): 61 (9) % male: 94 % white: 75 % with perceived hearing loss at baseline*: 74	G1: No screening (n=923) G2: Screening with tone-emitting otoscope (n=463) G3: Screening with HHIE-S (n=461) G4: Screening with both tone-emitting otoscope and HHIE-S (n=459)	% of participants who experienced an MICD (6 points) on the Inner Ear scale at 1 year (post hoc analysis): G1: 36.0 G2: 40.4 G3: 36.1 G4: 39.7 p=0.392, no difference between any arms No significant difference between groups when stratified by perceived hearing loss at baseline or age	HA use at 1 year (%): G1: 3.3 G2: 6.3 G3: 4.1 G4: 7.4 p<0.01 for G1 vs. G2 and G4 p>0.40 for G1 vs. G3

* Based on answering either "yes" or "maybe" to the question "Do you think you have a hearing loss?"

Abbreviations: G=group; HA=hearing aid; HHIE-S=Hearing Handicap Inventory for Elderly(-Screening version); KQ=key question; MICD=minimally important clinical difference; MMSE=Mini-Mental State Examination; N/n=number of participants; PTA=pure-tone average; RCT=randomized, controlled trial; SD=standard deviation; SNHL=sensorineural hearing loss; U.S.=United States; VA=Veterans Affairs.

Table 2. Characteristics of Studies Assessing Screening Test Accuracy (KQ 2)

Author, Year Quality (New vs. Previous Review)	Screening Test or Question	Person Screening	Type of Study	Population	N Screened	Setting Country	Age in Years, Mean (SD) Range	Sex (% Male)	Race/ Ethnicity (% White)
Bienvenue, 1985[89] Fair Previous review	AudioScope	Examiner	Cross-sectional	Community-dwelling adults	30	Speech and hearing clinics U.S.	NR 51-81	NR	NR
Boatman, 2007[71] Fair Previous review	Do you think you have difficulty hearing? WVT at 2 feet Watch tick at 6 inches Finger rub at 6 inches	Single question: Self-administered WVT, watch tick, finger rub: Neurologist	Cross-sectional	Community-dwelling adults	107 (214 ears)	Movement disorders clinic (patients or family) U.S.	66 (NR) 50-88	49	NR
Bonetti, 2018[93] Fair New	Hearing Self-Assessment Questionnaire	Self-administered	Cross-sectional	Community-dwelling adults	112	ENT clinic Croatia	56 (13) 24-88	57	NR
Ciurlia-Guy, 1993[90] Fair Previous review	AudioScope	Research assistant	Cross-sectional	Veteran residents of a chronic care facility	104	5 wards of chronic care facility Canada	79 (10) 60-99	88	NR
Clark, 1991[74] Fair Previous review	Would you say that you have any difficulty hearing?	NR	Cross-sectional	Community-dwelling adults	267	NR U.S.	NR 60-85	0	NR
Eekhof, 1996[42] Fair Previous review	WVT at 2 feet; AudioScope	NR	Cross-sectional	Community-dwelling adults	62 (124 ears)	Otolaryngology clinic (outpatient ENT department) Netherlands	NR ≥55	NR	NR
Frank & Petersen, 1987[94] Fair Previous review	AudioScope Pure-tone audiometer screener	Audiologist or speech-language pathologist	Cross-sectional	Community-dwelling adults and patients of a rehab center	405 (688* ears)	Speech and hearing clinic; rehab center U.S.	NR 50-96†	NR	NR
Gates, 2003[81] Fair Previous review	Do you have a hearing problem now? HHIE-S	Self-administered	Cross-sectional	Community-dwelling adults who participated in Framingham Heart Study	Single item=723 HHIE-S =546	NR U.S.	78 (4)‡ >70	36‡	NR
Hannula, 2011[75] Fair New	Do you have any difficulty with your hearing?	Self-administered	Cross-sectional	Community-dwelling adults	850	Audiology clinic Finland	NR 54-66	45	NR

Table 2. Characteristics of Studies Assessing Screening Test Accuracy (KQ 2)

Author, Year Quality (New vs. Previous Review)	Screening Test or Question	Person Screening	Type of Study	Population	N Screened	Setting Country	Age in Years, Mean (SD) Range	Sex (% Male)	Race/ Ethnicity (% White)
Kelly, 2018[101] Fair New	EarTrumpet app; Audiogram Mobile app; Hearing Test with Audiogram app	Self-administered	RCT	Community-dwelling adults	107	Audiology clinic (in either quiet exam room or clinic waiting area) U.S.	61 (NR) 19-85	58	NR
Koike, 1994[95] Fair Previous review	Revised Five Minute Hearing Test	Self-administered	Cross-sectional	Community-dwelling adults	74	Audiology clinic U.S.	72 (10) NR	47	NR
Koole, 2016[96] Fair New	DIN test	Audiologist	Prospective Cohort	Community-dwelling adults	3327	ERGO health center The Netherlands	65 (NR) >50	43	NR
Lee, 2010[82] Fair New	Self-reported HL	NR	Cross-sectional	Community-dwelling adults	912	Audiology clinic Hong Kong	72 (NR) ≥60	41	0
Lichtenstein, 1988[44] Fair Previous review	AudioScope; HHIE-S	AudioScope: internist; Self-administered HHIE-S	Cross-sectional	Community-dwelling adults	178	Six internal medicine clinics U.S.	74 (6) >65	37	78
Lycke, 2016[88] Fair New	uHear; WVT HHIE[§]	A trained and certified audiologist	Cohort	Community-dwelling adults	33 (66 ears)	Radiotherapy and oncology departments of a hospital Belgium	76 (NR) ≥70	70	NR
Lycke, 2018[97] Fair New	Modified Handzel-uHear™ screening	A trained and certified audiologist	Cohort	Cancer patients of the uHear-BIS-trial	45 (90 ears)	Radiotherapy and oncology departments of a hospital Belgium	76 (NR) ≥70	46	NR
Macphee, 1988[85] Fair Previous review	Conversational voice at 2 ft and 6 ft WVT at 2 ft and 6 ft	Geriatrician and otolaryngologist	Cross-sectional	Patients in rehabilitation wards	62 (124 ears)	Four rehabilitation wards Scotland	81 (NR) 66-96	31	NR
McBride, 1994[83] Good Previous review	HHIE-S; AudioScope	HHIE: Self-administered; AudioScope: Research associate	Cross-sectional	Community-dwelling adults	185	Community health clinic; VA Medical Center U.S.	70 (5) >60	69	NR

Table 2. Characteristics of Studies Assessing Screening Test Accuracy (KQ 2)

Author, Year Quality (New vs. Previous Review)	Screening Test or Question	Person Screening	Type of Study	Population	N Screened	Setting Country	Age in Years, Mean (SD) Range	Sex (% Male)	Race/ Ethnicity (% White)
McShefferty, 2013[86] Fair New	WVT‖	Otolaryngologists (older experienced screeners) and young inexperienced screeners	Cross-sectional	Community-dwelling adults	73 (112 ears)	Hearing research center U.K.	63 (SD) 32-73	58	NR
Nondahl, 1998;[76] Wiley, 2000[98] Fair Previous review	Do you feel you have hearing loss? HHIE-S	Self-reported	Cross-sectional	Community-dwelling adults who were in Beaver Dam Eye study	Single question =3342 HHIE-S =3471	Sound treated rooms U.S.	66 (NR) 48-92	44	99
Oosterloo, 2020[80] Good New	Do you have any difficulty with your hearing [without hearing aids]?	NR	Cohort	Community-dwelling adults	4,906	Research center (no other details reported) The Netherlands	69.6 (9.8) NR	43.7	NR
Rawool, 2008[77] Good Previous review	Do you think you have a hearing loss?	Investigator	Cross-sectional	Community-dwelling adults	30	NR U.S.	78 (NR) ≥65	27	100
Saliba, 2017[91] Good New	EarTrumpet "consumer app"; ShoeBOX "professional app"	Self-administered	Prospective	Community-dwelling adults	33 (65 ears)	Tertiary otology referral clinic at a general hospital Canada	49.7 (12) 18-65	58	NR
Sever, 1989[92] Good Previous review	HHIE-S	Self-administered	Cross-sectional	Community-dwelling adults	59	Sound-attenuated test room U.S.	69 (NR) 60-84	NR	NR
Sindhusake, 2001[73] Fair Previous review	Do you feel you have hearing loss? HHIE-S	Audiologist	Cross-sectional	Community-dwelling adults, part of Blue Mountain Hearing Study	Single question =1,931 HHIE-S =1,807	NR Australia	Median: 70¶ 55-99	43	NR
Swan, 1985[87] Fair Previous review	WVT at 2 feet	Otolaryngologists	Cross-sectional	Patients with aural symptoms	101 (202 ears)	Audiology clinic Scotland	57 (NR) 17-89	NR	NR
Swanepoel, 2013[72] Good New	Do you have a hearing impairment?	Trained research nurses	Cohort	Community-dwelling adults	1,004	NR Australia	56 (5) 45-65	46	NR

Table 2. Characteristics of Studies Assessing Screening Test Accuracy (KQ 2)

Author, Year Quality (New vs. Previous Review)	Screening Test or Question	Person Screening	Type of Study	Population	N Screened	Setting Country	Age in Years, Mean (SD) Range	Sex (% Male)	Race/ Ethnicity (% White)
Tomioka, 2013[84] Fair New	HHIE-S; Do you feel you have a hearing loss?	Self-administered	Cross-sectional	Community-dwelling adults	1,731	NR Japan	70[¶] ≥60	45	0
Torre, 2006[78] Fair Previous review	Do you feel you have a hearing loss? (Spanish)	A Spanish-/English-speaking examiner	Cross-sectional	Community-dwelling Latino adults	59	Referred from physicians or medical staff at a family clinic U.S.	62 (NR) 42-88	46	NR
Ventry & Weinstein, 1983[3] Fair Previous review	HHIE-S	Self-administered	Cross-sectional	Community-dwelling adults	104	Sound-treated test environments U.S.	NR	NR	NR
Voeks, 1993[79] Fair Previous review	Do you have trouble hearing?	NR	Cross-sectional	Nursing home-dwelling veterans	198	Skilled nursing Facility U.S.	NR	82	NR
Watson, 2012[99] Fair New	Telephone DIN test	Telephone-administered	Cohort	Community-dwelling adults	90	Small audiology office U.S.	54 (23) NR	NR	NR
Williams-Sanchez, 2014[100] Fair New	Telephone DIN test; Words-In-Noise test	Self-administered	Cohort	Community-dwelling veterans	693 (1,379 ears)	Three audiology clinics and homes in FL, TN, and CA, U.S.	65 (13) NR	97	NR

[*] Only participants >50 years included.
[†] For 546 participants.
[‡] Study included individuals as young as 20 years of age; however, they only reported accuracy by age intervals, and we therefore included only those ages 50 to 96 years.
[§] HHIE not included in outcomes.
[‖] Study examines older vs. younger examiners.
[¶] Computed by data abstractors.

Abbreviations: CA=California; DIN=Digits-in-Noise; FL=Florida; ENT=ears, nose, throat; ERGO=acronym not described; HHIE(-S)=Hearing Handicap Inventory for Elderly(-Screening version); HL=hearing loss; KQ=key question; N=number of patients; NR=not reported; SD=standard deviation; TN=Tennessee; U.S.=United States; WVT=whispered voice test.

Table 3. Summary of Accuracy for Included Screening Tests (KQ 2)

Test	HL Severity (PTA dB Range)	N Studies (Participants)	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PLR (95% CI)	NLR (95% CI)
Single question	Mild (>20 to 25)	10* (12,637)[71-76, 78-80, 114]	Pooled: 66 (58 to 73)	Pooled: 76 (68 to 83)	Pooled: 2.7 (2.2 to 3.4)	Pooled: 0.45 (0.38 to 0.53)
Single question	Moderate (>35 to 40)	6* (8,774)[72-74, 80-82]	Pooled: 80 (68 to 88)	Pooled: 74 (59 to 85)	Pooled: 3.1 (2.0 to 4.7)	Pooled: 0.27 (0.18 to 0.41)
HHIE-S score >8	Mild (>25)	4 (7,194)[73, 76, 83, 84]	58 (53 to 61)[73] 58 (45 to 70)[83] 44 (NR)[84] 34 (31 to 37)[76]	85 (83 to 87)[73] 76 (69 to 84)[83] 85 (NR)[84] 95 (94 to 96)[76]	3.9 (3.8 to 3.9)[73] 2.4 (1.7 to 3.5)[83] 2.9 (1.6 to 4.9)[84] 5.8 (6.6 to 7.0)[76]	0.49 (0.49 to 0.50)[73] 0.55 (NR)[83] 0.7 (0.6 to 0.8)[84] 0.69 (0.69 to 0.70)[76]
HHIE-S score >8	Moderate (>40)	5† (2,820)[3, 44, 73, 81, 83]	Pooled: 68 (52 to 81)	Pooled: 79 (69 to 86)	Pooled: 3.21 (2.4 to 4.2)	Pooled: 0.41 (0.28 to 0.59)
HSAQ score ≥15	Mild (>25)	1 (112)[93]	100 (89 to 100)	75 (64 to 84)	4 (2.7 to 5.9)	0
RFMHT score ≥15	Mild (>25)	1 (74)[95]	80 (NR)	55 (NR)	1.8 (NR)	0.36 (NR)
WVT	Mild (>25 to 30)	5‡ (669)[42, 71, 85-87]	Pooled: 94 (31 to 100)	Pooled: 87 (82 to 90)	Pooled: 7.1 (5.1 to 9.7)	Pooled: 0.06 (0.00 to 1.94)
WVT	Moderate (>40)	3 (296)[71, 85, 88]	46 (36 to 56)[71] 30‖ (8 to 65)[88] 100 (95 to 100)[85]	78 (68 to 86)[71] 100‖ (92 to 100)[88] 84 (70 to 81)[85]	2.08 (NR)[71] NR[88] 6.0 (4.7 to 7.7)[85]	0.69 (NR)[71] 0.69‖ [88] 0.0 (NR)[85]
Watch tick	Mild (>25)	1 (107)[71]	44 (35 to 53)	100 (NR)	NR	0.56 (NR)
Watch tick	Moderate (>40)	1 (107)[71]	60 (50 to 69)	99 (92 to 100)	60.0 (NR)	0.40 (NR)
Finger rub	Mild (>25)	1 (107)[71]	27 (20 to 36)	98 (85 to 100)	13.5 (NR)	0.74 (NR)
Finger rub	Moderate (>40)	1 (107)[71]	35 (26 to 46)	97 (90 to 99)	11.67 (NR)	0.67 (NR)
DIN	Mild (>20 to 25)	3 (4,110)[96, 99, 100]	79 (77 to 81)[96] 80 (66 to 92)[99] 81 (79 to 84)[100]	76 (74 to 78)[96] 83 (69 to 92)[99] 65 (60 to 70)[100]	3.3 (3.3 to 3.3)[96] 4.7 (3.5 to 6.3)[99] 2.3 (2.3 to 2.4)[100]	0.28 (0.27 to 0.28)[96] 0.25 (0.20 to 0.30)[99] 0.29 (0.28 to 0.29)[100]
WIN	Mild (>25)	1 (1,049)[100]	97 (96 to 98)[100]	46 (39 to 52)[100]	1.8 (1.8 to 1.8)[100]	0.06 (0.05 to 0.06)[96]
AudioScope	Mild (>25 to 30)	2 (215)[83, 89]	71 (63 to 80)[83] 93 (NR)[89]	91 (84 to 97)[83] 70 (NR)[89]	7.5 (3.7 to 15.4)[83] 3.1 (NR)[89]	0.32 (NR)[83] 0.10 (NR)[89]
AudioScope	Moderate (>40)	4§ (411)[42, 44, 83, 90]	100 (91 to 100)[42] 96 (90 to 100)[83] 97 (NR)[90] 94 (85 to 98)[44]	42 (32 to 57)[42] 80 (74 to 87)[83] 69 (NR)[90] 72 (64 to 79)[44]	1.72 (NR)[42] 4.9 (3.5 to 6.9)[83] 3.13 (NR)[90] 3.4 (3.2 to 3.6)[44]	0[42] 0.05 (NR)[83] 0.04 (NR)[98] 0.08 (0.04 to 0.15)[44]
Pure-tone audiometer screener	Moderate (>40)	1 (405)[94]	50-59 years: 94 (NR) 60-69 years: 90 (NR) 70-79 years: 90 (NR) 80-89 years: 90 (NR) 90-96 years: 88 (NR)	50-59 years: 93 (NR) 60-69 years: 94 (NR) 70-79 years: 92 (NR) 80-89 years: 90 (NR) 90-96 years: 93 (NR)	50-59 years: 13.4 (NR) 60-69 years: 15.6 (NR) 70-79 years: 10.6 (NR) 80-89 years: 9.2 (NR) 90-96 years: 11.8 (NR)	50-59 years: 0.06 (NR) 60-69 years: 0.11 (NR) 70-79 years: 0.11 (NR) 80-89 years: 0.11 (NR) 90-96 years: 0.13 (NR)
uHear™ app	Moderate (>40)	2‖ (78)[88, 97]	68 (45 to 86)[97] 100 (66 to 100)[88]	87 (76 to 94)[97] 89 (77 to 96)[88]	NR	NR
EarTrumpet app	Moderate (>40 dB)	1 (33)[91]	88 (64 to 97)[91]	96 (86 to 99)[91]	21.4 (7.9 to 58.3)[91]	0.13 (0.05 to 0.35)[91]
EarTrumpet app	Mild (>20 dB)	1 (35)[101]	Quiet exam room: 96.3 (NR) Clinic waiting area: 100 (NR)	Quiet exam room: 83.1 (NR) Clinic waiting area: 72 (NR)	NR	NR

Table 3. Summary of Accuracy for Included Screening Tests (KQ 2)

Test	HL Severity (PTA dB Range)	N Studies (Participants)	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PLR (95% CI)	NLR (95% CI)
ShoeBOX app	Moderate (>40 dB)	1 (33)[91]	100 (81 to 100)[91]	96 (86 to 99)[91]	24.5 (9.2 to 65.3)[91]	0[91]
Audiogram Mobile app	Mild (>20 dB)	1 (37)[101]	Quiet exam room: 85.3 (NR) Clinic waiting area: 87.6 (NR)	Quiet exam room: 95.1 (NR) Clinic waiting area: 92.3 (NR)	NR	NR
Hearing Test with Audiogram app	Mild (>20 dB)	1 (35)[101]	Quiet exam room: 87.8 (NR) Clinic waiting area: 89 (NR)	Quiet exam room: 69.4 (NR) Clinic waiting area: 68.2 (NR)	NR	NR

[*] One additional study of 1,731 community-dwelling adults in Japan that did not report sufficient data to be included in pooled analyses found a sensitivity of 54 percent and a specificity of 78 percent for detecting mild hearing loss, and a sensitivity 88 percent and a specificity of 67 percent for detecting moderate hearing loss.[84]

[†] One additional study of 1,731 community-dwelling adults in Japan that did not report sufficient data to be included in pooled analyses of HHIE-S using a cutoff score of >8 found similar accuracy for detecting moderate hearing loss (81% sensitivity and 78% specificity).[84]

[‡] Of these, one study (n=62) also assessed the accuracy of conversational voice at 2 feet and reported low sensitivity (47%) and high specificity (100%) for detecting mild hearing loss.[85]

[§] One additional study assessed the accuracy of both the AudioScope and a portable audiometer to detect moderate HL (≥45 dB) in subpopulations defined by age decades (50- to 90-year-olds). Across all age groups, AudioScope sensitivities ranged from 85 to 90 percent and specificities ranged from 89 to 94 percent. Similarly, sensitivities for the portable audiometer ranged from 88 to 94 percent, and specificities ranged from 90 to 94 percent.[94]

[‖] Estimates here are based on a positive screening test definition of ≥2 consecutive hearing grades starting from the moderate-severe threshold zone ranging from 0.5 to 2.0 kHz. Using a scoring method that defined a positive screening test result based on PTA ≥40 dB at 0.5, 1.0 or 2.0 kHz, sensitivity was high in both cohorts (100%), but specificity was relatively low (38% and 36%).[88, 97]

Abbreviations: app=application; CI=confidence interval; DIN=digits in noise; HHIE-S=Hearing Handicap Inventory for the Elderly-Screening version; HL=hearing loss; HSAQ=Hearing Self-Assessment Questionnaire; KQ=key question; N=number; NLR=negative likelihood ratio; NR=not reported; PLR=positive likelihood ratio; PTA=pure tone average; RFMHT=Revised Five Minute Hearing Test; WIN= words in noise; WVT=whispered voice test.

Table 4. Characteristics of Randomized, Controlled Trials of Treatment for Hearing Loss

Author, Year	Study Design	N	Setting (Country)	Source Population	Eligibility Criteria	Mean Age, Yrs (SD)	% Male	% White	Baseline HL
Humes, 2017[109]	Double-blind RCT	154	Community (U.S.)	Participants recruited via ads posted in local newspapers and around the community for a trial at Indiana University, Bloomington, IN	Age 55-79 yrs; English-speaking; MMSE>25; no prior HA experience; PTA thresholds consistent with age-related, bilateral SNHL; no hearing-related pathologies either specific to ear anatomy, medication use, or medical conditions; and willingness to be randomized.	69 (6)	56	98	Bilateral PTA (500, 1000, and 2000 Hz), mean (SD): 28.1 (8.0) dB Bilateral high-frequency PTA (1000, 2000, and 4000 Hz): mean (SD): 38.8 (7.9) dB
Jerger, 1996[107]	Crossover RCT	80	Community (U.S.)	Paid participants recruited via ads in community centers in Houston, TX	Age >60 yrs; bilateral high-frequency SNHL >15 dB in both ears; normal middle ear status; average score ≤3 on self-report physical health scale; normal MMSE score (≥24); no history of neurologic or psychiatric disorder	74 (range, 60-96)	63	NR	Bilateral PTA (500, 1000, and 2000 Hz), mean: 37.4 dB
McArdle, 2005[105, 106]	Unblinded RCT	380	VA audiology clinic (U.S.)	Community-dwelling participants from the general audiology clinics at four VA medical centers who were eligible to receive no cost HAs	Adult-onset SNHL; no asymmetry of PTA thresholds or speech-recognition scores in quiet; no prior HA use; "passing" MMSE score; at least a mild, high-frequency BEHL ≥30 dB at 2000, 3000, and 4000 Hz; no known conductive or retrocochlear pathologies, neurologic or psychiatric disorders, and no significant comorbid diseases; and access to a telephone	69.4 (9.0)	98	NR	NR
Mulrow, 1990[102]	Unblinded RCT	194	VA primary care clinic (U.S.)	Participants from one VA general medicine clinic invited for hearing screening and follow-up diagnostic testing to determine eligibility; or from other VA clinics at same institution with hearing impairment referred by providers	Age >64 yrs; formal audiologic testing confirmed HL; residence <100 miles from clinic; no current HA use; and no severe disabling comorbidities*	72 (NR)	HA group: 100 Control: 99	HA group: 98 Control: 96	Better ear PTA (1000, 2000, and 4000 Hz), mean: 52 dB

Table 4. Characteristics of Randomized, Controlled Trials of Treatment for Hearing Loss

Author, Year	Study Design	N	Setting (Country)	Source Population	Eligibility Criteria	Mean Age, Yrs (SD)	% Male	% White	Baseline HL
Nieman, 2017[108]	Unblinded RCT	15	Community (U.S.)	Community-dwelling adults recruited from three buildings that house low- to middle-income, predominantly African American older adults subsidized by a nonprofit in Baltimore, MD, recruited via flyers and invitations from service coordinators in each building	Aged ≥60 yrs; English-speaking; clinically significant mild or worse HL; no current HA use; had communication partner who would participate in study (18 yrs or older who spoke with participant daily)	Median (IQR): 70 (67-76)	47	40	Better ear PTA (1000, 2000 and 4000 Hz), median (IQR): 40 (32.5 to 53.3) dB
Yueh, 2001[104]	Unblinded RCT	30	VA audiology clinic (U.S.)	Veterans seeking diagnostic visits or hearing aid evaluations at the audiology clinic of VA Puget Sound Health Care System	Age ≥50 yrs; diagnosed with symmetric, bilateral, mild to moderately severe sensorineural HL; no asymmetric or conductive HL; or atypical causes of SNHL; no prior HA use; good cognitive function; and normal manual dexterity	69 (NR)	100	NR	Mean PTA, right ear: 32.9 dB Mean PTA, left ear: 32.4 dB

* Terminal cancer, hepatic encephalopathy, and end-stage pulmonary disease requiring home oxygen therapy; residence >100 miles from clinic).

Abbreviations: BEHL=best ear hearing level; HA=hearing aid(s); HL=hearing loss; IN=Indiana; IQR=interquartile range; MD=Maryland; MMSE=Mini-Mental State Examination; N=number of patients; NR=not reported; PTA=pure tone average; RCT=randomized, controlled trial; SD=standard deviation; SNHL=sensorineural hearing loss; TX=Texas; U.S.=United States; VA=Veterans Administration.

Table 5. Hearing-Related Outcomes in Randomized, Controlled Trials of Treatment

Author, Year	Study Design	N	Interventions (N)	Duration	HHIE	Other Hearing-Related Outcomes
Humes, 2017[109]	Double-blind RCT	154	G1: Placebo hearing aid (n=55) G2: Audiology-based HA model (digital mini-behind-the-ear open-fit devices) fitted bilaterally (n=53) G3: Consumer-driven HA model (self-selected of same HA preprogrammed to simulate OTC delivery model) (n=55)	6 wks	Baseline HHIE (SD): G1: 29.0 (16.4) G2: 27,7 (13.6) G3: 29.3 (17.3) Mean change from baseline (SD): G1: -5.5 (11.5) G2: -18.2 (14.2) G3: -12.3 (14.1) p <0.001 G2 vs. G1 and G3 vs. G1	Baseline PHAP[115] (SD): G1: 0.40 (0.13) G2: 0.36 (0.12) G3: 0.38 (0.13) Mean change from baseline (SD): G1: 0.04 (0.10) G2: 0.17 (0.12) G3: 0.12 (0.12) p <0.001 G2 vs. G1 and G3 vs. G1
Jerger, 1996[107]	Crossover RCT	80	G1: No amplification (n=80) G2: Conventionally worn behind the ear HA, described as digital/analog hybrid fitted monaural (exact device varied based on audiometry results) (n=80) G3: ALD with remote microphones (Comtek receiver) (n=80) G4: Both conventionally worn behind the ear HA (G2) and ALD with remote microphone (G3) (n=80)	6 wks	Baseline HHIE (SD): 30.2 (NR) HHIE post-treatment: G1: 28 (NR) G2: 25 (NR) G3: 27 (NR) G4: 26 (NR) No significant difference between G1 and any amplification (G2, G3, or G4)	HHIE (reported by significant other): Baseline (SD): NR Mean change from baseline (SD): G1: -1.4 (NR) G2: -7.5 (NR) G3: -4.4 (NR) G4: -9.5 (NR)
McArdle, 2005[105]	Unblinded RCT	380	G1: Delayed HA fitting (n=191) G2: HA (custom, in the ear digitally programmable, analog or fully digital), fitted in accordance with 2000 Joint Audiology Committee guidelines per authors (n=189)	10 wks	Baseline HHIE (SD): G1: 41.30 (21.46) G2: 41.42 (23.43) Mean change from baseline: G1: +1.8 (NR) G2: -17.5 (NR) p<0.01	APHAB (SD): G1: 51.21 (15.30) G2: 47.63 (16.38) Mean change from baseline: G1: 3.17 G2: -29.53 p<0.01 WHO-DAS II: G1: 15.99 (13.24) G2: 15.60 (15.59) Mean change from baseline: G1: 3.17 G2: -2.9 p<0.01

Table 5. Hearing-Related Outcomes in Randomized, Controlled Trials of Treatment

Author, Year	Study Design	N	Interventions (N)	Duration	HHIE	Other Hearing-Related Outcomes
Mulrow,1990[102]	Unblinded RCT	194	G1: Wait-list control (n=99) G2: HA (at no cost) described as mostly in-the-ear devices (98%) fitted monaurally during a single 45-min HA fitting and orientation session (n=95)	4 mos	Baseline HHIE (SD): G1: 51.2 (29.1) G2: 48.7 (27.3) Mean change from baseline (SD): G1: 0 (NR) G2: 34.0 (NR) Difference in mean change (95% CI): -34.0 (-27.3 to -40.8); p<0.0001	Baseline QDS (SD): G1: 61.0 (25.4) G2: 58.7 (24.5) Mean change from baseline (SD): G1: +1.2 (NR) G2: -23 (NR) Difference in mean change (95% CI): -24.2 (-17.2 to -31.2); p<0.001
Nieman, 2017[108]	Unblinded RCT	15	G1: Wait-list control (n=7) G2: One of two OTC devices (Bluetooth-enabled, single-ear worn device similar to HA paired to a smartphone or Pockettalker ALD device with remote microphone and headphones) with one-time individual training session (participant and communication partner), fitting and orientation to the OTC device, and communication education and counseling (n=8)	3 mos	NR	Baseline HHIE-S, median (IQR): G1: 20 (17 to 20) G2: 19 (14.5 to 27.5) HHIE-S post-treatment, median (IQR): G1: 16 (14 to 22) G2: 10 (10 to 14.5) Mean change from baseline (SD): G1: 0.3 (4.5) G2: -8.5 (15.4) Baseline Revised QDS, median (IQR): G1: 16 (12.5 to 16.6) G2: 16 (14 to 20.2) Revised QDS post-treatment, median (IQR): G1: 13 (11 to 14.5) G2: 10.5 (6 to 14.2) Mean change from baseline (SD): G1: -2.1 (4.3) G2: -5.9 (6.8)

Table 5. Hearing-Related Outcomes in Randomized, Controlled Trials of Treatment

Author, Year	Study Design	N	Interventions (N)	Duration	HHIE	Other Hearing-Related Outcomes
Yueh, 2001[104]	Unblinded RCT; non-randomized trial	60	Randomized groups (veterans with non-service-connected HL): G1: No amplification (n=15) G2: ALD (n=15) Non-randomized groups (veterans with service-connected HL) fitted with one of two half-shell in-the-ear analog HAs: G3: Standard HA (nonprogrammable nondirectional aid) (n=14) G4: Programmable HA (with switchable directional microphone and remote control) (n=16)	3 mos	Baseline HHIE (SD): G1: 35.1 (31.6) G2: 28.5 (19.5) G3: 36.4 (18.5) G4: 49.8 (26.5) Mean change from baseline (SD): G1: -2.2 (NR) G2: -4.4 (NR) G3: -17.4 (NR) G4: -31.1 (NR) p<0.001 for G3 and G4 vs. G1	Baseline APHAB (SD): G1: 38.5 (16.2) G2: 37.5 (14.5) G3: 43.1 (12.3) G4: 52.3 (18.4) Mean change from baseline (SD): G1: -2.7 (NR) G2: -6.4 (NR) G3: -7.7 (NR) G4: -16.3 (NR) p=0.01 G3 and G4 vs. G1 Revised QDS: Baseline NR Mean change from baseline (SD): G1: -0.05 G2: 0.03 G3: 0.70 G4: 0.84 p=0.01 G3 and G4 vs. G1

Abbreviations: ALD=assistive listening device(s); APHAB=Abbreviated Profile of Hearing Aid Benefit; G=group; HA=hearing aid(s); HHIE(-S)=Hearing Handicap Inventory for the Elderly(-Screening version); HL=hearing loss; IQR=interquartile ratio; N/n=number of patients in a group; NR=not reported; OTC=over the counter; QDS=Quantified Denver Scale of Communication Function; RCT=randomized, controlled trial; SD=standard deviation; vs.=versus; WHO-DAS II=World Health Organization's Disability Assessment Scale II.

Table 6. General Health-Related Quality of Life and Function and Other Health Outcomes in Randomized, Controlled Trials of Treatment

Study, Year	Study Design	N	Intervention (N)	Duration	General Health-Related QOL and Function Outcomes	Other Health Outcome*
Jerger,1996[107]	Crossover RCT	80	G1: No amplification (n=80) G2: Conventionally worn behind-the-ear HA (n=80) G3: ALD with remote microphones (n=80) G4: Conventionally worn behind-the-ear HA (G2) and ALD with remote microphone (G3) (n=80)	6 wks	Affect Balance Scale: no differences between interventions and control per authors (data NR; shown in figures only)	Social Activity Scale and Brief Symptom Inventory: no differences between interventions and control per authors (data NR, shown in figures only)
Mulrow, 1990[102]	Unblinded RCT	194	G1: Wait-list control (n=99) G2: HA (at no cost), single 45 min HA fitting and orientation session (n=95)	4 mos	Mean baseline SELF (SD): G1: 95.6 (18.0) G2: 92.7 (16.5) Post-treatment mean: G1: 96.8 (18.8) G2: 92.0 (18.2). Difference in mean change from baseline: (95% CI): 1.9 (-1.6 to 5.4); p=0.27)	Mean baseline SPMSQ (SD): G1: 0.18 (0.46) G2: 0.47 (0.75) Post-treatment mean (SD): G1: 0.28 (0.66) G2: 0.29 (0.66) Difference in mean change from baseline (95% CI): -0.28 (0.08 to 0.49); p=0.008 Mean baseline GDS (SD): G1: 3.5 (3.56) G2: 3.1 (2.81) Post-treatment mean (SD): G1: 3.8 (3.57) G2: 2.6 (2.79) Difference in mean change from baseline (95% CI): 0.80 (0.09 to 1.51); p=0.03

Table 6. General Health-Related Quality of Life and Function and Other Health Outcomes in Randomized, Controlled Trials of Treatment

Study, Year	Study Design	N	Intervention (N)	Duration	General Health-Related QOL and Function Outcomes	Other Health Outcome*
Nieman, 2017[108]	Unblinded RCT	15	G1: Wait-list control (n=7) G2: One of two OTC devices (HA or ALD) with one-time individual training session (participant and communication partner), fitting and orientation to the OTC device, and communication education and counseling (n=8)	3 mos	Baseline SF-36 Mental component: G1: 56.6 (49.7 to 59.3) G2: 50.9 (38.0 to 57.2) Mean change from baseline (SD): G1: 1.7 (14) G2: 2.1 (14.7) Baseline SF-36 Physical component: G1: 50.6 (49.7 to 59.3) G2: 41.5 (40.3 to 47.0) Mean change from baseline: G1: -1.3 (5.4) G2: 3.6 (5.8)	Baseline Revised UCLA Loneliness Scale, median (IQR): G1: 46 (37.5 to 55.5) G2: 46 (34.8 to 54) Mean change from baseline (SD): G1: -4 (5.2) G2: -2.1 (10.8) Baseline PHQ-9: G1: 8 (3 to 8.3) G2: 9.5 (4.8 to13.8) Mean change from baseline (SD): G1: -1.0 (1.7) G2: -4.4 (6.4)
Yueh, 2001[104]	Unblinded RCT	30	Randomized groups (veterans with non-service-connected HL): G1: No amplification (n=15) G2: ALD (n=15) Non-randomized groups (veterans with service-connected HL): G3: Standard HA (n=14) G4: Programmable HA (n=16)	3 mos	NR	Proportion reporting less social isolation, n (%):† G1: 0 (0) G2: 0 (0) G3: 2 (14) G4: 10 (52)

* Includes measures of cognitive function, depression, social isolation, and social function.

† Participants were asked to maintain a hearing diary for the duration of the study, which included the number of hours each day that they encountered hearing-related difficulties. Authors performed a qualitative analysis of open-ended comments from the diaries, organizing open-ended comments into categories of issues raised by individual participants, which included social impairment.

Abbreviations: ALD=assistive listening device(s); CI=confidence interval; G=group; GDS=Geriatric Depression Scale; HA=hearing aid; HL=hearing loss; IQR=interquartile range; N/n=number of patients in a group; NR=not reported; OTC=over-the-counter; PHQ-9=Patient Health Questionnaire-9; QOL=quality of life; RCT=randomized, controlled trial; SD=standard deviation; SELF=Self-Evaluation of Life Function; SF-36=36-Item Short Form Survey; SPMSQ=Short Portable Mental Status Questionnaire; UCLA=University of California-Los Angeles.

Table 7. Summary of Evidence for Screening for Hearing Loss in Older Adults

Key Question and Topic	No. of Studies; No. of Participants (n)	Summary of Findings	Consistency and Precision	Study Quality	Limitations (Including Reporting Bias)	Overall Strength of Evidence	Applicability
KQ 1. Benefits of screening	1 RCT (2,305)	One RCT found that screening with HHIE-S, AudioScope, or both was not associated with any differences in hearing-related QOL compared with no screening.	Unknown; imprecise	Fair	High overall attrition (23% for hearing-related function); not designed to assess differences in hearing-related QOL.	Insufficient	Participants recruited from a VA setting with high prevalence of HL (74% reported perceived HL at baseline) and all patients were eligible to receive free hearing aids; results may not be applicable to lower-prevalence settings in which the cost or access of hearing aids is a barrier
KQ 2. Accuracy of screening tests for detecting mild (>20 to 25 dB) HL (by test)	Single question: 10 (12,637)	Pooled: Sn: 66 (58 to 73) Sp: 76 (68 to 83)	Mostly consistent; imprecise (more imprecise for Sn than Sp)	2 Good; 8 Fair	Only one study specified how equivocal screening test responses were handled; HL definitions varied in frequencies measured and ears affected	Moderate for adequate accuracy	Most studies were conducted in specialty or other high-prevalence settings
	HHIE-S score >8 4 (7,194)	Sn: range 34 to 58 across studies Sp: range 76 to 95 across studies	Mostly consistent (more consistent for Sp than Sn); imprecise	1 Good; 3 Fair	HL definitions varied in frequencies measured and ears affected	Low for adequate accuracy	Most studies were conducted in specialty or other high-prevalence settings
	WVT: 5 (669)	Pooled: Sn: 94 (31 to 100) Sp: 87 (82 to 90)	Inconsistent; imprecise (more imprecise for Sn than Sp)†	5 Fair	HL definitions varied in thresholds (>25, >29 and >30 dB) and number of frequencies measured; one study found inconsistent results based on experience level of whisperer[86]	Low for adequate accuracy	Most studies were conducted in specialty or other high-prevalence settings where screening was delivered by hearing specialists

Table 7. Summary of Evidence for Screening for Hearing Loss in Older Adults

Key Question and Topic	No. of Studies; No. of Participants (n)	Summary of Findings	Consistency and Precision	Study Quality	Limitations (Including Reporting Bias)	Overall Strength of Evidence	Applicability
	AudioScope: 2 (215)	Sn: range 71 to 93 across studies Sp: range 70 to 91 across studies	Inconsistent; imprecise	1 Good; 1 Fair	Studies used different criteria to determine positive screening test based on AudioScope (number of frequencies, and specific frequencies included)	Insufficient	Both studies were conducted in specialty settings
	DIN: 2 (3,417)	Sn: range 79 to 80 across studies Sp: range 76 to 83 across studies	Consistent; imprecise (more imprecise for Sp than Sn)	2 Fair	Methods of administering screening test varied across studies	Low for adequate accuracy	Screening tests were administered by audiologists
KQ 2. Accuracy of screening tests for detecting moderate (>35 to 40 dB) HL	Single question: 6 (8,774)	Pooled Sn: 80 (68 to 88) Sp: 74 (59 to 85)	Inconsistent‡; precise (more precise for Sn than Sp)	2 Good; 4 Fair	Only one study specified how equivocal screening test responses were handled; HL definitions varied in frequencies measured and ears affected	Moderate for adequate accuracy	Most studies were conducted in specialty or other high-prevalence settings
	HHIE-S score>8: 5 (2,820)	Pooled: Sn: 68 (52 to 81) Sp: 66 (55 to 79)	Mostly consistent; imprecise§	1 Good; 4 Fair	HL definitions varied in frequencies measured and ears affected	Moderate for adequate accuracy	Most studies were conducted in specialty or other high-prevalence settings
	WVT: 3 (296)	Sn: range 30 to 100 across studies Sp: range: 79 to 100 across studies	Inconsistent; imprecise (more imprecise for Sn)	3 Fair	HL definitions varied in terms of frequencies measured and ears affected; one study found inconsistent results based on experience level of whisperer[86]	Low for inadequate accuracy	Studies were conducted in specialty or other high-prevalence settings where screening was delivered by hearing specialists
	AudioScope: 4 (411)	Sn: range 94 to 100 across studies Sp: range 41 to 80 across studies	Mostly consistent (more consistent for Sn than Sp); precise (more precise for Sn than Sp)	1 Good; 3 Fair	Studies used different criteria to define a positive screening test based on AudioScope; HL definitions varied in frequencies measured	Moderate for adequate accuracy	Studies were conducted in specialty settings or other high-prevalence settings

Table 7. Summary of Evidence for Screening for Hearing Loss in Older Adults

Key Question and Topic	No. of Studies; No. of Participants (n)	Summary of Findings	Consistency and Precision	Study Quality	Limitations (Including Reporting Bias)	Overall Strength of Evidence	Applicability
	uHear™ app 2 (78)	Sn: range 68 to 100 across studies Sp: range 87 to 89 across studies	Inconsistent (more for Sn than Sp); imprecise (more imprecise for Sn than Sp)	2 Fair	Sensitivity varied within studies based on positive screening test definition, and between studies using the same screening test definition	Insufficient	Both studies enrolled older adults with cancer undergoing a comprehensive geriatric assessment
KQ 3. Harms of screening	k=0; 0	No eligible studies	NA	NA	NA	Insufficient	NA
KQ 4. Benefits of interventions for screen-detected HL	k=6 RCTs (8 publications), 3,188 participants	In 5 trials (3,173 participants) reporting on the HHIE, 4 found significant benefit in favor of hearing aids vs. no amplification over 6 weeks to 4 months and one crossover trial found no significant difference between groups over 6 weeks. Few studies reported on other hearing-related outcomes.	Consistent, imprecise	Fair	Most studies were unblinded; follow-up duration was relatively short (6 weeks to 4 months); only one study enrolled participants identified by screening in primary care	Low	Three of four studies showing benefit enrolled populations from VA settings with baseline HHIE scores indicating moderate HL handicap (46 to 51) and who were eligible to receive free hearing aids
KQ 5. Harms of interventions for screen-detected HL	k=0; 0	No eligible studies	NA	NA	NA	Insufficient	NA

* Based on Appendix F Figure 1, the 95 percent prediction region indicates the results are reasonable consistent; based on the confidence interval, estimates are imprecise.
† Based on Appendix F Figure 4, the 95 percent prediction region indicates the results are moderately inconsistent; based on the 95 percent confidence region, estimates are imprecise (more imprecise for sensitivity than specificity).
‡ Based on Appendix F Figure 2, the 95 percent prediction region indicates the results are moderately inconsistent; based on the 95 percent confidence region, estimates are imprecise.
§ Based on Appendix F Figure 3, the 95 percent prediction region is relatively large, covering approximately a third of the ROC space; the 95 percent confidence region is relatively precise (more precise for sensitivity than specificity).

Abbreviations: DIN=Digits-in-Noise; HHIE(-S)=Hearing Handicap Inventory for the Elderly(-Screening version); HL=hearing loss; k=number of studies; KQ=key question; n=number of participants; NA=not applicable; QOL=quality of life; RCT(s)=randomized, controlled trial(s); ROC=receiver operating characteristics; Sn=sensitivity; Sp=specificity; VA=Veterans Affairs; WVT=whispered voice test.

Appendix A Table 1. Estimated Prevalence of Mild or Worse Hearing Loss in the United States by Age Category[a]

Detailed Summary of Hearing Loss Prevalence

The National Health and Nutrition Examination Survey (NHANES) measures the prevalence of hearing loss among adults (ages 20 to 69 years) using audiometric measurements; based on 2011-2012 data (n=3,831), the prevalence of unilateral and bilateral speech-frequency hearing impairment (defined by pure-tone average of thresholds across 500, 1,000, 2,000, and 4,000 Hz >25 dB hearing level) was 14.1 percent.[1] Men had nearly twice the prevalence of hearing impairment as women (18.6% vs. 9.6%, respectively). The prevalence of speech-frequency hearing loss increases significantly with age (**Appendix A Table 1**); prevalence was highest in adults ages 60 to 69 years (39.3%).

Age Group	Prevalence[b] (%) Unilateral and Bilateral	Prevalence[b] (%) Bilateral	Adjusted[c] OR (95% CI) Bilateral
All adults 20-65 years	14.1	7.5	-
Ages 20-29 years	2.2	0.8	reference group
Ages 30-39 years	3.3	0.9	1.1 (0.3 to 4.4)
Ages 40-49 years	7.8	3.4	3.3 (0.8 to 13.3)
Ages 50-59 years	23.1	11.2	13.4 (2.8 to 63.5)
Ages 60-69 years	39.3	24.7	39.5 (10.5 to 149.4)

[a] Estimates are from 2011-2012 NHANES data.[1]

[b] Prevalence refers to speech-frequency hearing impairment defined by pure-tone average of thresholds across 500, 1,000, 2,000 and 4,000 Hz >25 dB hearing level in either one ear (unilateral) or both ears (bilateral).

[c] Adjusted for sex, race/ethnicity, education, smoking, history of hypertension, history of diabetes, past noise exposure.

Abbreviations: CI=confidence interval; OR=odds ratio.

In adjusted multivariable analyses for bilateral speech-frequency hearing impairment, age was the major risk factor (**Appendix A Table 1**); compared with the reference age group (ages 20 to 29 years), the odds ratio (OR) for adults ages 60 to 69 years is 39.5 (95% confidence interval [CI], 10.5 to 149.4). Male sex (OR, 1.8 [95% CI, 1.1 to 3.0]), non-Hispanic white (OR, 2.3 [95% CI, 1.3 to 3.9]), non-Hispanic Asian race/ethnicity (OR, 2.1 [95% CI, 1.1 to 4.2]), lower educational level (less than high school: OR, 4.2 [95% CI, 2.1 to 8.5]), and heavy use of firearms (≥1,000 rounds fired: OR, 1.8 [95% CI, 1.1 to 3.0]) were also significant risk factors.[1]

Appendix A Table 2. Estimated Prevalence of Unilateral and Bilateral Hearing Loss in the United States by Age Category and Severity[a]

Likewise, based on NHANES data from 2001-2010 (n=9,648), the prevalence of unilateral and bilateral speech-frequency hearing impairment (as defined above) increased with age regardless of severity level: mild (>25 to 40 dB), moderate (>40 to 60 dB), and severe (>60 to 80 dB) (**Appendix A Table 2**).[2] Prevalence was highest in adults age ≥80 years (mild: 31.4%, moderate: 40.8%, and severe: 13.8%).

Age Group	Prevalence[b] (%) Mild (>25 to 40 dB)	Prevalence[b] (%) Moderate (>40 to 60 dB)	Prevalence[b] (%) Severe (>60 to 80 dB)
Ages 20-29 years	2.3	0.6	<0.1
Ages 30-39 years	3.5	1.4	0.3
Ages 40-49 years	10.0	2.0	0.9
Ages 50-59 years	21.3	5.5	0.8
Ages 60-69 years	29.4	12.1	2.1
Ages 70-79 years	37.5	21.1	7.5
Age ≥80 years	31.4	40.8	13.8

[a] Estimates are from 2001-2010 NHANES data.[2]

[b] Prevalence refers to speech-frequency hearing impairment defined by pure-tone average of thresholds across 500, 1,000, 2,000, and 4,000 Hz >25 dB hearing level in either one ear (unilateral) or both ears (bilateral).

Abbreviations: dB=decibels; Hz=Hertz.

The National Health Interview Survey (NHIS) also measures prevalence of hearing loss in adults age 18 years or older based on self-reported difficulty hearing without the use of an assistive device.[3] Estimates from the 2014-2016 NHIS data indicate that 15.9 percent of U.S. adults have hearing loss. The 2014 NHIS (N=35,697) also reports on prevalence by age category, and findings are consistent with estimates from NHANES data despite differences in measurement and age categorization.[4] The prevalence of self-reported hearing loss was highest among adults age 70 years or older (43.2%) compared with adults age 40 to 69 years (19.0%) and 18 to 39 years (5.5%).

Appendix A Table 3. Screening Tests Used in Primary Care to Detect Hearing Loss in Adults

Screening Test	Description/Example
Clinical tests • Whispered voice • Finger rub • Watch tick • Digits-in-noise • Words-in-noise	• Assesses patients' ability to repeat a combination of words (or series of numbers) correctly that were whispered by a provider standing at different distances from the patients, such as 6 inches or 2 feet away • Assesses patients' ability to hear a series of finger rubs 6 inches away • Assesses patients' ability to hear a series of watch ticks 6 inches away • Assesses patients' ability to repeat digits in different amounts of signal to noise • Assesses patients' ability to repeat multisyllabic words in background noise
Single-question screening	Asks patients: "Do you have difficulty hearing?" or "Would you say that you have any difficulty hearing?"[5]
Screening questionnaires • HHIE-S • HSAQ • Revised Five Minute Hearing Test	• A 10-item self-administered questionnaire that assesses social and emotional factors associated with hearing loss and requires about 2 minutes to complete • A 10-item self-administered scale that assesses functional and socioemotional consequences of hearing loss • A 15-item self-administered questionnaire that assesses functional and social effects of hearing loss
Portable audiometric devices • AudioScope • Audiometer Screener • EarTrumpet consumer app • ShoeBox professional app • uHear	• A handheld screening instrument consisting of an otoscope with a built-in audiometer that presents tones at 0.5, 1, 2, and 4 kHz at fixed hearing level • A portable audiometer used to obtain pure-tone thresholds • An iOS app for self-administration that obtains thresholds at 10 frequencies (0.25 to 8 kHz) • An automated iPad audiometer for self- or clinician administration that obtains thresholds at four frequencies • A self-administered or clinician-administered iOS app to obtain automated pure-tone hearing thresholds at six frequencies (0.25 to 6 kHz)

Abbreviations: HHIE-S=Hearing Handicap Inventory for the Elderly-Screening version; HSAQ=Hearing Self-Assessment Questionnaire.

Appendix A Table 4. Recommendations Made by Organizations Regarding Screening for Hearing Loss

Organization, Year	Population	Recommendation
Academy of Doctors of Audiology, publication year NR[6]	All adults	Screen annually for hearing loss in adults (regardless of age) presenting with a history of smoking or diabetes or who are at risk of developing diabetes, as well as adults >60 years old who present with dementia-like symptoms.
American Academy of Family Physicians, 2012[7]	Adults ≥50 years	Supports the USPSTF's 2012 recommendation: Insufficient evidence to either recommend for or against screening adults age 50 years or older for hearing loss.
American Geriatric Society, 2016[8]	Adults ≥65 years	Older adults ≥65 years should be screened annually for hearing loss.
American Speech-Language-Hearing Association, 2006[9]	All adults	Screen adults at least every decade through age 50 and at 3-year intervals thereafter or more frequently on exposure to noise, toxic medications, or other risk factors associated with hearing loss.
Hearing Loss Association of America, 2015[10]	All adults	A standardized approach to screening for hearing loss should be implemented in primary health care settings and include both a subjective and objective component in all adults during routine physicals, the "Welcome to Medicare" assessment, and annual Medicare risk assessments.
National Institute for Health and Care Excellence, 2018[11]	All adults	Schedule an audiological assessment of adults who initially present with hearing difficulties or in whom hearing difficulties are suspected. Consider proactively screening the following specific groups for hearing loss every 2 years: (1) adults with diagnosed or suspected dementia or mild cognitive impairment and (2) adults with a diagnosed learning disability.
Royal Australian College of General Practitioners, 2016[12]	Older adults ≥65 years	Older adults should be screened annually for hearing loss. Recommended tests include the whispered voice test, finger rub test, and a single question about hearing difficulty.
UK National Screening Committee, 2016[13]	Older adults ≥50 years	A national screening program for hearing loss in older adults is not recommended in the UK until further research is done in the UK.

Abbreviations: NR=not reported; UK=United Kingdom; USPSTF=United States Preventive Services Task Force.

CQ 1. Does Adherence to Hearing Aid Use Improve Health Outcomes in Adults With Screen-Detected Hearing Loss Who Are Prescribed Hearing Aids?

Older adults with hearing loss may not adhere to hearing aid use because of cosmetic or psychosocial reasons, difficulty using the hearing aids, discomfort, cost, or perceived lack of benefit. In large population-based cohort studies, among the approximately one third of older adults with hearing loss who had ever used hearing aids, 20 to 30 percent were no longer using them.[14, 15] Despite the high rate of nonuse or nonadherence to hearing aids, we found limited evidence on whether increased adherence to hearing aid use improves health outcomes among adults who are prescribed hearing aids. In one RCT (n=194) enrolling veterans (also included for KQ 4), adherence to hearing aid use was measured at 6 weeks and 4 months by self-reported hours of hearing aid use per day.[16] At 6 weeks, 15 percent of the intervention group reported wearing their aids fewer than 4 hours daily, and 30 percent reported more than 8 hours of daily use. Participants who reported greater hours of use had greater improvements on HHIE scores (but not Quantified Denver Scale of Communication Function [QDS] scores).[16]

CQ 2. Do Interventions to Improve Hearing Aid Adherence Improve Health Outcomes?

We identified one Cochrane review assessing RCTs of interventions designed to improve or promote hearing aid use in adults with acquired hearing loss.[17] Primary outcomes were hearing aid use (measured as adherence or daily hours of use) and adverse effects (inappropriate advice or clinical practice, or patient complaints); secondary outcomes included quality of life, hearing handicap, hearing aid benefit, and communication. Thirty-seven RCTs (4,129 participants) were included; interventions were heterogeneous, and few (k=6) followed participants for longer than 1 year. Included studies primarily focused on self-management skills and service-delivery interventions and not specifically on increasing adherence. Two included self-management interventions reported on adherence, and neither reported on health outcomes. One included trial enrolling veterans (n=644) randomized participants to receive hearing aid visits in an individual versus group format; over 6 months, there were no significant differences in Inner EAR scores or in the number of hours per day hearing aids were worn.[18]

CQ 3. In Adults Who Are Prescribed Hearing Aids, What Are the Potential Barriers to Obtaining Hearing Aids and Reasons for Low Uptake?

This question was motivated by the low uptake of hearing aids in the elderly[19]: of those who are age 60 or older, only 20 percent with a self-reported hearing loss use hearing aids, and 75 percent of Medicaid beneficiaries who need a hearing aid do not have one. Moreover, the one study in our review that examined the benefits of hearing screening in the elderly, the Screening for Auditory Impairment—Which Hearing Assessment Test (SAI-WHAT) trial,[20, 21] found that fewer than half of the VA participants in any arm contacted audiology services, and fewer than

10 percent of participants across the arms were fit with hearing aids and used them at the 1-year followup.

To address this question, we first examined the applicability of studies that were included in our review. One study[22] included help-seeking, uptake, use, or satisfaction with hearing aids as part of the trial examining benefits of hearing aids. In addition, as part of our abstract and full-text review, we identified six studies[23-28] that were relevant to address this question. In addition, we did a hand search of references in the articles and a Google Scholar search of very recent articles using the terms "hearing aid uptake," "hearing aid use," and "hearing aid satisfaction." Altogether, we included 12 studies to address this question.[19, 23-33]

Two studies were systematic reviews,[30, 31] one was a scoping study,[32] three used prospective designs,[23, 27, 33] and the remainder were cohort or cross sectional.[24-26, 28, 29, 34] Studies comprised all older adults (>60 years), or the mean age was greater than 60 years. Studies were generally located in countries ranked as very high on the Human Development Index, including the United States, United Kingdom, Australia, Norway, and Israel. In five studies, all participants had received hearing aids; the remainder included samples without hearing aids or had subgroups that varied in their hearing aid status (i.e., not sought help hearing, received a recommendation for a hearing aid but had not received one, had a hearing aid but varied in the amount of time that they used it).

Failure to Seek Help. Yueh and colleagues[20] found that fewer than half of any of the participants in any arm of their RCT contacted audiology services following screening. Several studies have addressed the issue of why those who fail a hearing screen do not seek audiology services. In one study,[23] 36 percent of the 193 participants who failed the telephone-based hearing screening sought professional help. Results of a followup interview identified two factors that were more common in the help-seekers: correctly recalling failing the hearing screening and considering hearing aids prior to the screening. In contrast, of the 83 non-help-seeking participants, 64 percent indicated that their hearing difficulties were not severe enough to justify further evaluation. A retrospective study[35] of individuals presenting with hearing loss included a group who had not sought help regarding hearing impairment and a group who had sought professional help but had not availed themselves of hearing aids. As others found,[23] the primary reason that the nonconsulters (40%) indicated for not seeking help was that they did not perceive that their hearing difficulties were bad enough. Other reasons included the experiences of others, lack of time, expense, and not a priority. In contrast, the group who had consulted hearing professionals recognized more potential benefit of hearing aids and had more activity limitations due to hearing loss. However, activity limitations did not have much influence on hearing aid uptake. Finally, a systematic review of factors influencing help-seeking and other aspects of hearing aid behaviors[31] reported that help seeking is related to social pressure by others, personality factors of individuals seeking help (e.g., less neurotic, more pragmatic, higher internal locus of control), greater hearing loss, and perception of an impact of the loss. Although neither gender nor age was related to help-seeking, those who experienced hearing loss before retirement were more likely to seek help.

Barriers to Hearing Aid Uptake. As the RCT of screening benefit reported,[20] fewer than 10 percent of participants in all arms were fit for a hearing aid. Studies have offered a variety of reasons for failing to get hearing aids that are financial, attitudinal and belief based, and audiologist related. Cost is one barrier indicated in several studies and reviews,[30, 34] and it may be individuals' perception of the cost-benefit of hearing aids as much as the actual cost.

Importantly, not all the studies were from the United States, where hearing aids are not currently covered by Medicare. Studies and reviews also cited pre-fitting attitudes, especially stigma, as an often-cited reason for not getting hearing aids.[23, 30, 31, 33, 35] Wallhagen's qualitative study[33] concluded that stigma was a function of three interrelated factors—altered self-perception, ageism, and vanity—that not only affect the uptake of hearing aids but also affect resistance to seeking help and wearing hearing aids. Further, the presence of supportive family can mitigate the stigma. One study[36] reported that pre-fitting expectations regarding the benefit of hearing aids and stigma along with self-rated hearing discriminated between those who declined and accepted hearing aids. Finally, one study[26] examined experiences of the participants during their hearing evaluation, finding that audiologists' use of complex language was significantly associated with reduced odds for obtaining hearing aids.

Failure to Use Hearing Aids. Although the SAI-WHAT trial[20] found that most individuals across all arms who were fit with a hearing aid used them at the 1-year followup, use was low in all groups, ranging from 3.3 to 7.4 percent. Similarly, Meyer and colleagues[23] reported that 3 percent of their sample used hearing aids for more than 1 hour per day. Because of the considerable investment in hearing aids, it is important to know why individuals do not use their hearing aids.

Studies and systematic reviews that have examined reasons for not wearing hearing aids cite fit and comfort,[24, 25, 32] which includes excessive amplification and noise. Other common reasons include care and maintenance, such as difficulty replacing batteries and the cost of repairs and batteries,[25, 32] and stigma.[32, 33] In contrast, research has found that those characterized as successful hearing aid users received positive support from family and significant others,[24, 34] were confident about their ability to use the device,[24, 34] and had greater hearing loss relative to nonusers.[24, 30, 31, 34] Moreover, among dually eligible for Medicaid and Medicare beneficiaries with hearing aids, 27 percent had a lot of trouble hearing with their aids, and only 29 percent of them received hearing aid services,[29] indicating that cost (of additional services such as adjustments) continues to be an issue and may lead to nonuse. Not surprisingly, individuals who are satisfied with their hearing aids are more likely to use them more frequently.[25, 28]

Appendix B1. Original Search Strategies

PubMed, 2/8/2019

Total Unduplicated Yield = 3,680

Screening Benefits (KQ 1) and Harms (KQ 3) Searches

Search	Query	Items Found
#1	Search ((((“Hearing Loss”[Mesh]) OR “Hearing Disorders”[Mesh])) AND “Mass Screening”[Mesh]) Sort by: Best Match	2580
#2	Search (((((((“Randomized Controlled Trial” [Publication Type] OR “Randomized Controlled Trials as Topic”[Mesh] OR “Controlled Clinical Trial” [Publication Type]) OR “Single-Blind Method”[Mesh]) OR “Double-Blind Method”[Mesh]) OR “Random Allocation”[Mesh])) OR “Cohort Studies”[Mesh]) OR “Comparative Study” [Publication Type] OR “Diagnostic Screening Programs”[Mesh]) Sort by: Best Match	3808601
#3	Search (#1 AND #2) Sort by: Best Match	780
#4	Search (#1 AND #2) Sort by: Best Match Filters: Publication date from 2010/01/01; Humans; English; Adult: 19+ years	49

Screening Test Accuracy (KQ 2)

Search	Query	Items Found
#1	Search (((((((“Hearing Tests/methods”[Mesh] OR “Hearing Tests/standards”[Mesh])) OR “Presbycusis/diagnosis”[Mesh]) OR “Audiometry/methods”[Mesh]) OR “Hearing Loss/diagnosis”[Mesh]))) Sort by: Best Match	18735
#2	Search ((“Hearing Loss”[Mesh]) OR “Auditory Perception”[Mesh]) AND ((“Mass Screening/methods”[Mesh]) OR “Sensitivity and Specificity”[Mesh]) Sort by: Best Match	2911
#3	Search ((“Hearing Loss/diagnosis”[Mesh])) AND ((((“smartphone”[MeSH Terms]) OR “computers, handheld”[MeSH Terms]) OR “mobile applications”[MeSH Terms]) OR “telemedicine”[MeSH Terms)) Sort by: Best Match	44
#4	Search (#1 OR #2 OR #3) Sort by: Best Match	20222
#5	Search ((((“Cross-Sectional Studies”[Mesh]) OR “Cohort Studies”[Mesh]))) OR ((“Comparative Study” [Publication Type]) OR “Validation Studies” [Publication Type]) Sort by: Best Match	3599498
#6	Search (#4 AND #5) Sort by: Best Match	6210
#7	Search (#4 AND #5) Sort by: Best Match Filters: Publication date from 2010/01/01; Humans; English; Adult: 19+ years	1463

Amplification Benefits (KQ 4) and Harms (KQ 5)

Search	Query	Items Found
#1	Search (((((“Hearing Aids”[Mesh]) OR “Correction of Hearing Impairment”[Mesh])))) OR (((((“Hearing Loss”[Mesh]) OR “Hearing Disorders”[Mesh]))))) OR “Auditory Perception”[Mesh])) Sort by: Best Match	144450
#2	Search ((((“Treatment Outcome”[Mesh]) OR “Outcome Assessment (Health Care)”[Mesh]) OR “Treatment Failure”[Mesh])) OR ((((((“Health Status”[Mesh] OR “Health Status Indicators”[Mesh]) OR “Quality of Life”[Mesh])) OR “Mood Disorders”[Mesh]) OR “Social Isolation”[Mesh]) OR “Communication”[Mesh]) OR “Cognition”[Mesh] Sort by: Best Match	1948313
#3	Search (#14 AND #15) Sort by: Best Match	30186
#4	Search (((((((“Randomized Controlled Trial” [Publication Type] OR “Randomized Controlled Trials as Topic”[Mesh] OR “Controlled Clinical Trial” [Publication Type]) OR “Single-Blind Method”[Mesh]) OR “Double-Blind Method”[Mesh]) OR “Random Allocation”[Mesh])) OR ((“Comparative Study” [Publication Type]) OR ((((“Controlled Clinical Trial” [Publication Type]) OR “Cohort Studies”[Mesh]) OR “Case-Control Studies”[Mesh]))))) Sort by: Best Match	3984497
#5	Search (#16 AND #17) Sort by: Best Match	8942
#6	Search (#16 AND #17) Sort by: Best Match Filters: Publication date from 2010/01/01; Humans; English; Adult: 19+ years	2719

Cochrane Review, 2/8/2019

Yield: 9 results, 0 imported

Cochrane Central Trials, 2/8/2019

Yield: 109 results, 18 imported

Embase, 2/8/2019

Yield: 293 results, 109 imported

Gray Literature Searches, 2/8/2019

ClinicalTrials.gov Searches

Yield: 46 results, 12 imported

Update Searches

PubMed, 1/17/2020

Total Unduplicated Yield = 486

Screening Benefits (KQ 1) and Harms (KQ 3) Searches

Search	Query	Items Found
#1	Search ((((“Hearing Loss”[Mesh]) OR “Hearing Disorders”[Mesh])) AND “Mass Screening”[Mesh]) Sort by: Best Match	2671
#2	Search (((((((“Randomized Controlled Trial” [Publication Type] OR “Randomized Controlled Trials as Topic”[Mesh] OR “Controlled Clinical Trial” [Publication Type]) OR “Single-Blind Method”[Mesh]) OR “Double-Blind Method”[Mesh]) OR “Random Allocation”[Mesh])) OR “Cohort Studies”[Mesh]) OR “Comparative Study” [Publication Type] OR “Diagnostic Screening Programs”[Mesh]) Sort by: Best Match	3972502
#3	Search (#1 AND #2) Sort by: Best Match	809
#4	Search (#1 AND #2) Sort by: Best Match Filters: Publication date from 2017/10/01; Humans; English; Adult: 19+ years	13 **(7 new)**

Screening Test Accuracy (KQ 2)

Search	Query	Items Found
#1	Search ((((((((“Hearing Tests/methods”[Mesh] OR “Hearing Tests/standards”[Mesh])) OR “Presbycusis/diagnosis”[Mesh]) OR “Audiometry/methods”[Mesh]) OR “Hearing Loss/diagnosis”[Mesh]))))) Sort by: Best Match	19556
#2	Search ((“Hearing Loss”[Mesh]) OR “Auditory Perception”[Mesh]) AND ((“Mass Screening/methods”[Mesh]) OR “Sensitivity and Specificity”[Mesh]) Sort by: Best Match	3123
#3	Search ((“Hearing Loss/diagnosis”[Mesh])) AND ((((“smartphone”[MeSH Terms]) OR “computers, handheld”[MeSH Terms]) OR “mobile applications”[MeSH Terms]) OR “telemedicine”[MeSH Terms)) Sort by: Best Match	53
#4	Search (#1 OR #2 OR #3) Sort by: Best Match	21154
#5	Search ((((“Cross-Sectional Studies”[Mesh]) OR “Cohort Studies”[Mesh]))) OR ((“Comparative Study” [Publication Type]) OR “Validation Studies” [Publication Type]) Sort by: Best Match	3695778
#10	Search (#4 AND #5) Sort by: Best Match Filters: Publication date from 2017/10/01; Humans; English; Adult: 19+ years	382 **(211 new)**

Amplification Benefits (KQ 4) and Harms (KQ 5)

Search	Query	Items Found
#1	Search (((((“Hearing Aids”[Mesh]) OR “Correction of Hearing Impairment”[Mesh])))) OR (((((“Hearing Loss”[Mesh]) OR “Hearing Disorders”[Mesh]))))) OR “Auditory Perception”[Mesh])) Sort by: Best Match	149817
#2	Search ((((“Treatment Outcome”[Mesh]) OR “Outcome Assessment (Health Care)”[Mesh]) OR “Treatment Failure”[Mesh])) OR ((((((“Health Status”[Mesh] OR “Health Status Indicators”[Mesh]) OR “Quality of Life”[Mesh])) OR “Mood Disorders”[Mesh]) OR “Social Isolation”[Mesh]) OR “Communication”[Mesh]) OR “Cognition”[Mesh] Sort by: Best Match	2014572
#3	Search (#1 AND #2) Sort by: Best Match	31713
#4	Search (((((((“Randomized Controlled Trial” [Publication Type] OR “Randomized Controlled Trials as Topic”[Mesh] OR “Controlled Clinical Trial” [Publication Type]) OR “Single-Blind Method”[Mesh]) OR “Double-Blind Method”[Mesh]) OR “Random Allocation”[Mesh])) OR ((“Comparative Study” [Publication Type]) OR ((((“Controlled Clinical Trial” [Publication Type]) OR “Cohort Studies”[Mesh]) OR “Case-Control Studies”[Mesh]))))) Sort by: Best Match	4156939
#5	Search (#3 AND #4) Sort by: Best Match	9370
#9	Search (#3 AND #4) Sort by: Best Match Filters: Publication date from 2017/10/01; Humans; English; Adult: 19+ years	540 **(268 new)**

Cochrane Review, 1/17/2020

Yield: 14 results, 0 imported

Cochrane Central Trials, 1/17/2020

Yield: 36 results, 12 imported

Embase, 1/17/2020

Yield: 14 results, 11 imported

Gray Literature Searches, 1/17/2020

ClinicalTrials.gov Searches

Yield: 4 results, 2 imported

Appendix B2. Eligibility Criteria

	Include	Exclude
Populations	**KQs 1-3:** Adults age ≥50 years* without diagnosed hearing loss, including those with comorbid depression, mild cognitive dysfunction, or diabetes **KQs 4, 5:** Adults age ≥50 years* diagnosed with screen-detected (or recently detected) sensorineural hearing loss or presbycusis	**KQs 1-3:** Adults age <50 years; adults with previously diagnosed hearing loss, adults who currently use a hearing aid (within the past 6 months), or adults with comorbid dementia **KQs 4, 5:** Adults with conductive hearing loss, congenital hearing loss, sudden hearing loss, or hearing loss caused by recent noise, or adults with comorbid dementia
Screening test or intervention	**KQs 1-3:** Screening tests that are used, available, or feasible for use in primary care settings, including the whispered voice test, finger rub test, watch tick test, single-question screening regarding perceived hearing loss, hearing loss questionnaire, and screening audiometry (e.g., via handheld device or smartphone) **KQs 4, 5:** Amplification with hearing aids (any type), personal assistive listening devices, and personal sound amplification devices, with or without additional education or counseling	**KQs 1-3:** Screening tests that are not used or available in primary care settings; Rinne and Weber tests (i.e., tests used to distinguish between sensorineural and conductive hearing loss); evaluations of serial screening tests **KQs 4, 5:** Nutritional pharmaceuticals, hearing rehabilitation alone (without amplification), and cochlear implants
Comparisons	**KQs 1, 3:** Screened vs. nonscreened groups **KQ 2:** Eligible screening tests vs. diagnostic pure-tone audiometry testing **KQs 4, 5:** Amplification vs. no intervention, wait-list control, or placebo amplification device	**All KQs**: No comparison **KQs 4, 5:** Studies comparing two different amplification devices
Outcomes	**KQs 1, 4:** Hearing-related quality of life and/or function (e.g., Hearing Handicap Inventory for the Elderly), general health-related quality of life and/or function (e.g., 36-Item Short-Form Health Survey), cognitive impairment, depression, social isolation, and falls (including injuries attributed to falls) **KQ 2:** Sensitivity, specificity, positive and negative predictive value, positive and negative likelihood ratio, and diagnostic odds ratio **KQs 3, 5:** False-positive results, overdiagnosis, labeling, anxiety, and any other significant harms	**KQs 1, 4:** Outcomes related to hearing aid performance and efficacy (e.g., speech intelligibility and quality of the listening experience)
Study designs	**KQs 1, 4:** Randomized, controlled trials and controlled cohort studies **KQ 2:** Cross-sectional or cohort studies **KQs 3, 5:** Randomized, controlled trials; controlled cohort studies; and case-control studies	All other study designs†
Setting	**All KQs:** Studies performed in settings generalizable to primary care, including nursing home settings **KQs 2, 4, 5:** Studies performed in specialty clinics	Studies performed in occupational health settings
Country	Studies conducted in countries categorized as "Very High" on the 2018 Human Development Index (as defined by the United Nations Development Program) **"Very High" on Human Development Index**: Andorra, Argentina, Australia, Austria, Bahamas, Bahrain, Barbados, Belarus, Belgium, Brunei Darussalam, Bulgaria, Canada, Chile, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Kazakhstan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Montenegro, Netherlands, New Zealand, Norway, Oman, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom, United States, Uruguay	Studies conducted in countries not categorized as "Very High" on the 2018 Human Development Index

Appendix B2. Eligibility Criteria

	Include	Exclude
Language	Full text published in English	Non-English
Study quality	Good or fair	Poor (according to design-specific USPSTF criteria)

* For studies including older adults and those <50 years, we included studies that enrolled a sample with a mean age ≥50 years (or include a majority of participants ≥50 years, depending on how age is reported).
† Systematic reviews were excluded from the evidence review. However, separate searches were conducted to identify relevant systematic reviews, and the citations of all studies included in those systematic reviews were reviewed to ensure that database searches capture all relevant primary studies.

Abbreviations: KQ=key question; USPSTF=U.S. Preventive Services Task Force.

Randomized, Controlled Trials and Cohort Studies

Criteria

- Initial assembly of comparable groups
- Randomized, controlled trials (RCTs)—adequate randomization, including concealment and whether potential confounders were distributed equally among groups; cohort studies—consideration of potential confounders with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts
- Maintenance of comparable groups (includes attrition, crossovers, adherence, and contamination)
- Important differential loss to followup or overall high loss to followup
- Measurements that are equal, reliable, and valid (includes masking of outcome assessment)
- Clear definition of interventions
- Important outcomes considered
- Analysis: Adjustment for potential confounders for cohort studies or intention-to-treat analysis for RCTs; for cluster RCTs, correction for correlation coefficient

Definition of Ratings Based on Above Criteria

Good: Meets all criteria: Comparable groups are assembled initially and maintained throughout the study (followup ≥80%); reliable and valid measurement instruments are used and applied equally to the groups; interventions are spelled out clearly; important outcomes are considered; and appropriate attention is given to confounders in analysis. In addition, intention-to-treat analysis is used for RCTs.

Fair: Studies will be graded "fair" if any or all of the following problems occur, without the important limitations noted in the "poor" category below: Generally comparable groups are assembled initially, but some question remains on whether some (although not major) differences occurred in followup; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention-to-treat analysis is lacking for RCTs.

Poor: Studies will be graded "poor" if any of the following major limitations exist: Groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. Intention-to-treat analysis is lacking for RCTs.

Source: U.S. Preventive Services Task Force. U.S. Preventive Services Task Force, Procedure Manual, Appendix VI. Rockville, MD: U.S. Preventive Services Task Force; 2015[37]

Diagnostic Accuracy Studies

Criteria:

- Screening test relevant, available for primary care, and adequately described
- Credible reference standard, performed regardless of test results
- Reference standard interpreted independently of screening test
- Indeterminate results handled in a reasonable manner
- Spectrum of patients included in study
- Sample size
- Reliable screening test

Definition of Ratings Based on Above Criteria:

Good: Evaluates relevant available screening test; uses a credible reference standard; interprets reference standard independently of screening test; assesses reliability of test; has few or handles indeterminate results in a reasonable manner; includes large number (greater than 100) of broad-spectrum patients with and without disease.

Fair: Evaluates relevant available screening test; uses reasonable although not best standard; interprets reference standard independent of screening test; has moderate sample size (50 to 100 subjects) and a "medium" spectrum of patients.

Poor: Has a fatal flaw, such as: uses inappropriate reference standard; improperly administers screening test; biased ascertainment of reference standard; has very small sample size or very narrow selected spectrum of patients.

Source: U.S. Preventive Services Task Force. U.S. Preventive Services Task Force, Procedure Manual, Appendix VI. Rockville, MD: U.S. Preventive Services Task Force; 2015[37]

Appendix C. Excluded Studies

X1: Ineligible population
X2: Ineligible or no screening or treatment
X3: Ineligible or no eligible outcome reported
X4: Ineligible or no comparator
X5: Ineligible setting
X6: Ineligible study design
X7: Ineligible publication type
X8: Non-English
X9: Ineligible country
X10: Poor quality rating

1. Hearing Aids for Tinnitus with Hearing Loss (HUSH). International Standard Randomised Controlled Trial Number. 2018PMID: CN-01905914. Exclusion Code: X3.
2. Hearing Impairment, Strategies, and Outcomes in Emergency Departments. ClinicalTrials.gov. 2018PMID: CN-01661303. Exclusion Code: X3.
3. Academy of Doctors of Audiology. Preventive medicine and the need for routine hearing screening in adults; Unitron. 2474 MANL 09-12. n.d. https://www.audiologist.org/item/diabetes-hearing-loss-resources Exclusion Code: X7.
4. Adrait A, Perrot X, Nguyen MF, et al. Do hearing aids influence behavioral and psychological symptoms of dementia and quality of life in hearing impaired Alzheimer's disease patients and their caregivers? J Alzheimers Dis. 2017;58(1):109-21. doi: 10.3233/jad-160792. PMID: 25811932. Exclusion Code: X1.
5. Ahmed OH, Gallant SC, Ruiz R, et al. Validity of the hum test, a simple and reliable alternative to the Weber test. Ann Otol Rhinol Laryngol. 2018 Jun;127(6):402-5. doi: 10.1177/0003489418772860. PMID: 29490364. Exclusion Code: X1.
6. Aiello CP, Lima, II, Ferrari DV. Validity and reliability of the hearing handicap inventory for adults. Braz J Otorhinolaryngol. 2011 Jul-Aug;77(4):432-8. PMID: 21521901. Exclusion Code: X3.
7. Albu S, Chirtes F. Intratympanic dexamethasone plus melatonin versus melatonin only in the treatment of unilateral acute idiopathic tinnitus. Am J Otolaryngol. 2014 Sep-Oct;35(5):617-22. doi: 10.1016/j.amjoto.2014.06.009. PMID: 24770406. Exclusion Code: X2.
8. Alcas O, Salazar MA. Complications of cochlear implant surgery: a ten-year experience in a referral hospital in Peru, 2006-2015. Cochlear Implants Int. 2016 Sep;17(5):238-42. doi: 10.1080/14670100.2016.1219480. PMID: 26632254. Exclusion Code: X2.
9. Alexander TH, Harris JP, Nguyen QT, et al. Dose effect of intratympanic dexamethasone for idiopathic sudden sensorineural hearing loss: 24 mg/mL Is superior to 10 mg/mL. Otol Neurotol. 2015 Sep;36(8):1321-7. doi: 10.1097/mao.0000000000000834. PMID: 25583631. Exclusion Code: X2.
10. Ali H, Hazrati O, Tobey EA, et al. Evaluation of adaptive dynamic

range optimization in adverse listening conditions for cochlear implants. J Acoust Soc Am. 2014 Sep;136(3):El242. doi: 10.1121/1.4893334. PMID: 24907838. Exclusion Code: X1.

11. Ambrosch P, Muller-Deile J, Aschendorff A, et al. European adult multi-centre HiRes(R) 120 study--an update on 65 subjects. Cochlear Implants Int. 2010 Jun;11 Suppl 1:406-11. doi: 10.1179/146701010x12671177204183. PMID: 21174276. Exclusion Code: X1.
12. American Academy of Family Physicians. Clinical preventive service recommendation: hearing. 2012. https://www.aafp.org/patient-care/clinical-recommendations/all/hearing.html. Accessed August 16, 2018. Exclusion Code: X7.
13. Amieva H, Ouvrard C, Giulioli C, et al. Self-reported hearing loss, hearing aids, and cognitive decline in elderly adults: a 25-year study. J Am Geriatr Soc. 2015;63(10):2099-104. Exclusion Code: X1.
14. Amieva H, Ouvrard C, Meillon C, et al. Death, Depression, Disability, and Dementia Associated With Self-reported Hearing Problems: A 25-Year Study. J Gerontol A Biol Sci Med Sci. 2018 Sep 11;73(10):1383-9. doi: 10.1093/gerona/glx250. PMID: 30248131. Exclusion Code: X3.
15. Arndt S, Laszig R, Aschendorff A, et al. [Unilateral deafness and cochlear implantation: audiological diagnostic evaluation and outcomes]. HNO. 2011;59(5):437-46. Exclusion Code: X8.
16. Barbara M, Biagini M, Lazzarino AI, et al. Hearing and quality of life in a south European BAHA population. Acta Otolaryngol. 2010 Sep;130(9):1040-7. doi: 10.3109/00016481003591756. PMID: 21756638. Exclusion Code: X1.
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Appendix D Table 1. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4), Part 1

First Author, Year Trial Name Outcome of Interest	1.1. Random allocation conceal-ment?	1.2. Allocation sequence concealed until participants enrolled and assigned to intervention?	1.3. Baseline differences suggesting a problem with randomi-zation process?	ROB due to Randomi-zation Process	Comments on Randomization Process	2.1. Participants aware of assigned intervention during trial?	2.2. Carers and people delivering interventions aware of participant assignments?	2.3. If Y/PY/NI to 2.2, deviations from intended intervention because of experimental context?	2.4. If Y/PY to 2.3, deviations from intended intervention balanced between group?	2.5. If N/PN/NI to 2.4, deviations likely to have affected outcome?
Mulrow, 1990;[16] Mulrow, 1992[38] QOL and function	Y	Y	PN	Low		Y	PY	NI	NA	NA
Yueh, 2001[22] Hearing-related QOL	Y	Y	PN	Some concerns	Participants were randomized separately based on whether they had hearing loss that was considered service-connected (randomized to a standard aid vs. programmable aid) or nonservice connected (randomized to no-amplification or assistive listening device); samples in all 4 groups were small (n=14-16). Compared with the control group, the assistive listening device group had a higher HHIE score. Participants in the hearing aid groups were older and had slightly higher HHIE scores than the control group.	Y	Y	PN	NA	NA

Appendix D Table 1. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4), Part 1

First Author, Year Trial Name Outcome of Interest	1.1. Random allocation conceal-ment?	1.2. Allocation sequence concealed until participants enrolled and assigned to intervention?	1.3. Baseline differences suggesting a problem with randomi-zation process?	ROB due to Randomi-zation Process	Comments on Randomization Process	2.1. Participants aware of assigned intervention during trial?	2.2. Carers and people delivering interventions aware of participant assignments?	2.3. If Y/PY/NI to 2.2, deviations from intended intervention because of experimental context?	2.4. If Y/PY to 2.3, deviations from intended intervention balanced between group?	2.5. If N/PN/NI to 2.4, deviations likely to have affected outcome?
Nieman, 2016[39] Hearing-related function, QOL	Y	NI	PN	Some concerns	Small sample (n=15); minor differences between groups at baseline unlikely related to randomization process. Delayed treatment group was slightly older than intervention group (72 vs. 70 years).	Y	Y	NI	NA	NA
Humes, 2017[40] Hearing-related function, QOL	Y	Y	N	Low		PN	PN	NA	NA	NA
McArdle, 2005;[41] Chisolm, 2005[42] Disability, hearing-related function	NI	NI	PN	Some concerns	Randomization and allocation sequences not described; few baseline characteristics reported. Participants were similar in terms of baseline scores on hearing outcome assessments.	Y	Y	NI	NA	NA
Yueh, 2010;[20] Yueh, 2007[21] SAI-WHAT Hearing-related QOL	PY	Y	N	Low		Y	Y	PY	PN	PY

Abbreviations: HHIE=Hearing Handicap Inventory for the Elderly; KQ=key question; n=number of participants; N=no; NA=not applicable; NI=no information; PN=probably no; PY=probably yes; QOL=quality of life; ROB=risk of bias; SAI-WHAT=Screening for Auditory Impairment – Which Hearing Assessment Test; vs.=versus; Y=yes.

Appendix D Table 2. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4), Part 2

First Author, Year Trial Name Outcome of Interest	2.6. Appropriate analysis used to estimate effect of intervention assignment?	2.7. If N/PN/NI to 2.6, potential for substantial impact (on result) of failure to analyze participant in group to which randomized?	ROB due to deviation from intended intervention?	Comments on Deviation from Intended Intervention	3.1. Outcome data available for all (or nearly all) participants?	3.2. If N/PN/NI to 3.1, evidence of bias by missing outcome data?	3.3. If N/PN to 3.2, could missingness in outcome depend on true value?	3.4. If Y/PY/NI to 3.3, likely that missingness in outcome depended on true value?	ROB due to Missing Outcome Data	Comments on Missing Outcome Data Bias
Mulrow, 1990;[16] Mulrow, 1992[38] QOL and function	Y	NA	Some concerns	Participants were not blinded to intervention assignment; carers and people delivering the interventions were likely aware of participants' assigned intervention during the trial.	Y	NA	NA	NA	Low	
Yueh, 2001[22] Hearing-related QOL	Y	NA	Some concerns	Lack of blinding may have introduced bias; knowledge of hearing loss status in control group may have led participants to expect difficulties in hearing-related function.	Y (5% were not included)	NA	NA	NA	Low	

Appendix D Table 2. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4), Part 2

First Author, Year Trial Name Outcome of Interest	2.6. Appropriate analysis used to estimate effect of intervention assignment?	2.7. If N/PN/NI to 2.6, potential for substantial impact (on result) of failure to analyze participant in group to which randomized?	ROB due to deviation from intended intervention?	Comments on Deviation from Intended Intervention	3.1. Outcome data available for all (or nearly all) participants?	3.2. If N/PN/NI to 3.1, evidence of bias by missing outcome data?	3.3. If N/PN to 3.2, could missingness in outcome depend on true value?	3.4. If Y/PY/NI to 3.3, likely that missingness in outcome depended on true value?	ROB due to Missing Outcome Data	Comments on Missing Outcome Data Bias
Nieman, 2016[39] Hearing-related function, QOL	Y	NA	Some concerns	Lack of blinding and repeat assessment of hearing-related function and QOL may have led to expectation of worsening function among control group.	Y	NA	NA	NA	Low	
Humes, 2017[40] Hearing-related function, QOL	Y	NA	Low		PY (5% excluded because of problems with intervention) (ear/health problems, could not use HA)	NA	NA	NA	Low	
McArdle, 2005;[41] Chisolm, 2005[42] Disability, hearing-related function	PY	NA	Some concerns	No blinding. Unclear whether assignment to intervention or delayed treatment may have affected participant response on disability and hearing handicap assessments.	Y (approximately 5% attrition; however, ITT analyses imputed missing data)	NA	NA	NA	Low	

Appendix D Table 2. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4), Part 2

First Author, Year Trial Name Outcome of Interest	2.6. Appropriate analysis used to estimate effect of intervention assignment?	2.7. If N/PN/NI to 2.6, potential for substantial impact (on result) of failure to analyze participant in group to which randomized?	ROB due to deviation from intended intervention?	Comments on Deviation from Intended Intervention	3.1. Outcome data available for all (or nearly all) participants?	3.2. If N/PN/NI to 3.1, evidence of bias by missing outcome data?	3.3. If N/PN to 3.2, could missingness in outcome depend on true value?	3.4. If Y/PY/NI to 3.3, likely that missingness in outcome depended on true value?	ROB due to Missing Outcome Data	Comments on Missing Outcome Data Bias
Yueh, 2010;[20] Yueh, 2007[21] SAI-WHAT Hearing-related QOL	Y	NA	Some concerns	Bias towards null hypothesis	N	PN	PY	PN	Some concerns	High attrition (approxi-mately 23% for hearing-related function); no differential attrition.

Abbreviations: HA=hearing aid; ITT=intent-to-treat; KQ=key question; n=number of participants; N=no; NA=not applicable; NI=no information; PN=probably no; PY=probably yes; QOL=quality of life; ROB=risk of bias; SAI-WHAT=Screening for Auditory Impairment – Which Hearing Assessment Test; vs.=versus; Y=yes.

Appendix D Table 3. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4), Part 3

First Author, Year Trial Name Outcome of Interest	4.1. Inappropriate method of measuring outcome?	4.2. Outcome ascertainment /measurement different between groups?	4.3. If N/PN/NI to 4.1 and 4.2, outcome assessors aware of intervention received by participants?	4.4. If Y/PY/NI to 4.3, outcome assessment influenced by knowledge of intervention received?	4.5. If Y/PY/NI to 4.4, likely that outcome assessment influenced by knowledge of intervention received?	ROB due to Outcome Measurement	Comments on Outcome Measurement
Mulrow, 1990;[16] Mulrow, 1992[38] QOL and function	N	PN	PY	PN	NA	Low	
Yueh, 2001[22] Hearing-related QOL	N	PN	Y	PY	PN	Some concerns	Lack of blinding may have influenced outcome assessment.
Nieman, 2016[39] Hearing-related function, QOL	N	PN	Y	PY	PN	Some concerns	Lack of blinding may have influenced assessment of outcomes.
Humes, 2017[40] Hearing-related function, QOL	PN	PN	PN	NA	NA	Some concerns	For some followup and outcome assessments, procedures differed between intervention and placebo devices.
McArdle, 2005;[41] Chisolm, 2005[42] Disability, hearing-related function	PN	PN	Y	PN	NA	Some concerns	Knowledge of intervention status may have influenced ascertainment of outcomes.
Yueh, 2010;[20] Yueh, 2007[21] SAI-WHAT Hearing-related QOL	N (unclear if outcome assessors were masked)	N	NI	PY	PN	Some concerns	Study not powered to detect a difference in function and also failed to meet recruitment target to detect a significant difference in the primary outcome (hearing aid adherence).

Abbreviations: KQ=key question; N=no; NA=not applicable; NI=no information; PN=probably no; PY=probably yes; QOL=quality of life; ROB=risk of bias; SAI-WHAT=Screening for Auditory Impairment – Which Hearing Assessment Test; Y=yes.

Appendix D Table 4. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4), Part 4

First Author, Year Trial Name Outcome of Interest	5.1. Were data producing results of interest analyzed according to prespecified plan finalized before unblinded outcome data available for analysis?	5.2. Numerical result being assessed likely to have been selected, on basis of results, from multiple outcome measurements?	5.3. Numerical result being assessed likely to have been selected, on basis of results, from multiple analyses of data?	ROB due to Selection of Reported Result	Comments on Selection of Reported Result
Mulrow, 1990;[16] Mulrow, 1992[38] QOL and function	Y	PN	PN	Low	
Yueh, 2001[22] Hearing-related QOL	PY	PN	PN	Low	
Nieman, 2016[39] Hearing-related function, QOL	PY	PN	PN	Low	
Humes, 2017[40] Hearing-related function, QOL	PY	NI	NI	Some concerns	Unclear whether numerical results assessed may have been selected on the basis of results from multiple outcome measurements or multiple analyses of the data.
McArdle, 2005;[41] Chisolm, 2005[42] Disability, hearing-related function	NI	NI	NI	Some concerns	No information on whether outcomes assessed were prespecified, including specific outcome measurements or whether multiple analyses of data were conducted.
Yueh, 2010;[20] Yueh, 2007[21] SAI-WHAT Hearing-related QOL	Y	PN	PN	Low	

Abbreviations: KQ=key question; NI=no information; PN=probably no; PY=probably yes; QOL=quality of life; ROB=risk of bias; SAI-WHAT=Screening for Auditory Impairment – Which Hearing Assessment Test; Y=yes.

Appendix D Table 5. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4): Domain Rating Summary and Overall Rating

First Author, Year Trial Name Outcome of Interest	Randomization Process Domain	Deviations from Intended Interventions Domain	Missing Outcome Data Domain	Outcome Measurement Domain	Selection of Reported Result Domain	Overall ROB	Comments
Mulrow, 1990;[16] Mulrow, 1992[38] QOL and function	Low	Some concerns	Low	Low	Low	Some concerns	Participants were not blinded. Carers and outcome assessors were likely aware of intervention assignment during the trial.
Yueh, 2001[22] Hearing-related QOL	Some concerns	Some concerns	Low	Some concerns	Low	Some concerns	Potential for selection bias because of minor differences between groups at baseline. Lack of blinding may have influenced outcome assessment.
Nieman, 2016[39] Hearing-related function, QOL	Some concerns	Some concerns	Low	Some concerns	Low	Some concerns	Allocation concealment not described; however minor baseline difference between groups likely because of small sample size (n=15). Lack of blinding may have influenced measurement of outcomes.
Humes, 2017[40] Hearing-related function, QOL	Low	Low	Low	Some concerns	Some concerns	Some concerns	For certain followup and outcome assessments, procedures differed between intervention and placebo devices. Unclear whether numerical results assessed may have been selected on the basis of results from multiple outcome measurements or multiple analyses of the data.
McArdle, 2005;[41] Chisolm, 2005[42] Disability, hearing-related function	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns	Randomization and allocation sequences not described; few baseline characteristics reported. Participants similar in terms of baseline scores on hearing outcome assessments. Lack of blinding may have affected participant response on disability and hearing handicap assessments. Knowledge of intervention status may have influenced ascertainment of outcomes.

Appendix D Table 5. Quality Assessment of Parallel Randomized, Controlled Trials (KQs 1 and 4): Domain Rating Summary and Overall Rating

First Author, Year Trial Name Outcome of Interest	Randomization Process Domain	Deviations from Intended Interventions Domain	Missing Outcome Data Domain	Outcome Measurement Domain	Selection of Reported Result Domain	Overall ROB	Comments
Yueh, 2010;[20] Yueh, 2007[21] SAI-WHAT Hearing-related QOL	Low	Some concerns	Some concerns	Some concerns	Low	Some concerns	Study aims to compare screening with usual care; however, baseline assessment (prior to randomization) included an assessment of self-perceived HL. Control group and those who screened negative for HL were provided with a number for the audiology clinic if they wanted further assessment. High overall attrition for hearing related function is a potential source of bias; although there was no differential attrition, it is possible that participants with worse function were less likely to respond to the survey. In addition to high attrition, study was not powered to detect a difference in function and also failed to meet recruitment target to detect a significant difference in the primary outcome (hearing aid adherence).

Abbreviations: HL=hearing loss; KQ=key question; n=number of participants; QOL=quality of life; ROB=risk of bias; SAI-WHAT=Screening for Auditory Impairment – Which Hearing Assessment Test; Y=yes.

Appendix D Table 6. Quality Assessment of Crossover Randomized, Controlled Trials (KQs 1 and 4), Part 1

First Author, Year Trial Name Outcome of Interest	1.1. Random allocation concealment?	1.2. Allocation sequence concealed until participants enrolled and assigned to interventions?	1.3. Baseline differences suggesting a problem with randomization process?	1.4. Roughly equal proportion of participant allocated to each group?	1.5. If N/PN/NI to 1.4, are period effects included in analysis?	ROB due to Randomi-zation Process	Comments on Randomization Process	2.1. Participants aware of assigned intervention during each period of trial?	2.2. Carers and people delivering interventions aware of participant assignments during each period of trial?	2.3. If Y/PY/NI to 2.1 or 2.2, deviations from intended interventions beyond what would be expected in usual practice?
Jerger, 1996[43] NA QOL and function	NI	NI	NI	NI	NA	Some concerns	Randomization procedures not described.	Y	PY	NI

Abbreviations: KQ=key question; N=no; NA=not applicable; NI=no information; NR=not reported; PN=probably no; PY=probably yes; QOL=quality of life; ROB=risk of bias; Y=yes.

Appendix D Table 7. Quality Assessment of Crossover Randomized, Controlled Trials (KQs 1 and 4), Part 2

First Author, Year Trial Name Outcome of Interest	2.4. If Y/PY to 2.3, deviations from intended interventions unbalanced between groups *and* likely to have affected outcome?	2.5. Sufficient time for any carryover effects to disappear before outcome assessment in second period?	ROB due to deviation from intended interven-tion?	Comments on Deviation from Intended Intervention	3.1. Outcome data available for all (or nearly all) participants?	3.2. If N/PN/NI to 3.1, proportions of (and reasons for) missing outcome data similar across interventions?	3.3. If N/PN to 3.1, evidence that results were robust to presence of missing outcome data?	ROB due to Missing Outcome Data	Comments on Missing Outcome Data Bias
Jerger, 1996[43] NA QOL and function	NA	PN	Some concerns	Unclear whether there was imbalance in participant variables at the start of the first crossover period; no wash-out period between each 6-week outcome assessment and intervention assignment.	PY	NA	NA	Low	

Abbreviations: KQ=key question; N=no; NA=not applicable; NI=no information; NR=not reported; PN=probably no; PY=probably yes; QOL=quality of life; ROB=risk of bias; vs.=versus; Y=yes.

Appendix D Table 8. Quality Assessment of Crossover Randomized, Controlled Trials (KQs 1 and 4), Part 3

First Author, Year Trial Name Outcome of Interest	4.1. Outcome assessors aware of intervention received by participants?	4.2. If Y/PY/NI to 4.1, likely that outcome assessment influenced by knowledge of intervention received?	ROB due to Outcome Measurement	Comments on Outcome Measurement
Jerger, 1996[43] NA QOL and function	Y	PN	Some concerns	No statistical adjustments were made for potential imbalances in baseline characteristics, nor was it clear if the investigators had any reason to suspect a need for adjusted analyses of study outcomes.

Abbreviations: KQ=key question; NA=not applicable; NI=no information; NR=not reported; PN=probably no; PY=probably yes; QOL=quality of life; ROB=risk of bias; vs.=versus; Y=yes.

Appendix D Table 9. Quality Assessment of Crossover Randomized, Controlled Trials (KQs 1 and 4), Part 4

First Author, Year Trial Name Outcome of Interest	5.1. Reported outcome data likely to have been selected, on basis of results, from multiple outcome measurements within outcome domain?	5.2. Reported outcome data likely to have been selected, on basis of results, from multiple analyses of data?	5.3. Reported outcome data likely to have been selected, on basis of results, from outcome of statistical test for carryover?	ROB due to Selection of Reported Result	Comments on Selection of Reported Result
Jerger, 1996[43] NA QOL and function	NI	NI	PY	Some concerns	Reporting on statistical analysis, including how the investigators chose their statistical approach, is unclear. Authors note that they used a "within-subjects" (subject-by-condition) analysis of variance for each outcome.

Abbreviations: KQ=key question; NA=not applicable; NI=no information; PY=probably yes; QOL=quality of life; ROB=risk of bias.

Appendix D Table 10. Quality Assessment of Crossover Randomized, Controlled Trials (KQs 1 and 4): Domain Rating Summary and Overall Rating

First Author, Year Trial Name Outcome of Interest	Randomization Process Domain	Deviations from Intended Interventions Domain	Missing Outcome Data Domain	Outcome Measurement Domain	Selection of Reported Result Domain	Overall ROB	Comments
Jerger, 1996[43] NA QOL and function	Some concerns	Some concerns	Low	Some concerns	Some concerns	Some concerns	Authors note that subjects were randomly allocated to the intervention and control arms but do not comment on baseline differences at the start of the crossover. No wash-out period between crossover to new amplification device or control. Reporting on statistical analysis, including how the investigators chose their statistical approach, is unclear.

Abbreviations: KQ=key question; NA=not applicable; QOL=quality of life; ROB=risk of bias.

Appendix D Table 11. Quality Assessment of Controlled Cohort Studies (KQs 1 and 4), Part 1

First Author, Year Trial Name Outcome of Interest	Bias due to confounding?	Comments	Bias in selection of participants into the study?	Comments	Bias in classification of intervention?	Comments
Mahmoudi, 2019[44] NA Health outcomes	High	Participants selected from claims data based on diagnosis of HL and use vs. non-use of HAs. Those using HAs had lower rates of various comorbidities that are also associated with adverse health outcomes. Groups may have also differed by other (unmeasured) factors associated with higher rates of HL and poor health outcomes (e.g., socioeconomic status, education, past noise exposure).	High	Study used claims and diagnostic codes to define HL and use of HAs. Participants who have true HL, but no official diagnoses would not have been included; participants may also have had a HL diagnosis entered before undergoing diagnostic evaluation with audiometry.	High	Intervention classification was defined based only on HA procedure codes. Participants may have obtained HAs but not used them; some may have obtained OTC hearing amplification in the non-user group. Severity of HL was also not defined; some "non-users" may not have met criteria for prescription HAs.

Abbreviations: HA=hearing aid; HL=hearing loss; NA=not applicable; OTC=over-the-counter.

Appendix D Table 12. Quality Assessment of Controlled Cohort Studies (KQs 1 and 4), Part 2

First Author, Year Trial Name Outcome of Interest	Bias due to deviation from intended intervention (assignment to the intervention)?	Bias due to missing data?	Bias in measurement of outcomes?	Comments	Bias in selection of reported result?	Overall Rating	Comments
Mahmoudi, 2019[44] NA Health outcomes	No Information	Low	Medium	Authors measured incident dementia, anxiety, depression, and injurious fall rates by limiting data to participants with no diagnosis claims for these conditions one year prior to a HL diagnosis. Diagnostic codes may not have fully captured people who were free of these conditions before receiving a HL diagnosis.	Low	Poor	High risk of confounding (measured and unmeasured), selection bias, intervention classification bias, and measurement bias.

Abbreviations: HL=hearing loss; NA=not applicable.

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Bienvenue, 1985[45] AudioScope	Unclear	Yes	Unclear	Unclear	Little is known about how patients were selected.	Yes	Yes	Low
Boatman, 2007[46] Finger rub test	Yes	Yes	Yes	Low		Yes	Yes	Low
Boatman, 2007[46] Single question ("Do you think you have difficulty hearing?")	Yes	Yes	Yes	Low		Yes	NA	Low
Boatman, 2007[46] Watch tick test	Yes	Yes	Yes	Low		Yes	Yes	Low
Boatman, 2007[46] WVT	Yes	Yes	Yes	Low		Yes	Yes	Low
Bonetti, 2018[47] HSAQ	Yes	Yes	No	Low		Yes	No	Unclear
Ciurlia-Guy, 1993[48] AudioScope	Yes	Yes	Yes	Low		Yes	Yes	Low
Clark, 1991[5] Single question ("Would you say that you have any difficulty hearing?")	Unclear	Yes	Yes	Unclear	Women were enrolled from two communities in rural Iowa; no details about patient selection provided. Of women participating in larger observational study of bone density, 94% of sample completed the hearing assessment.	Unclear	Yes	Unclear
Eekhof, 1996[49] AudioScope	Yes	Yes	Yes	Low		Unclear	Yes	Unclear

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Eekhof, 1996[49] WVT at 2 feet	Yes	Yes	Yes	Low		Unclear	Yes	Unclear
Frank, 1987[50] AudioScope	Yes	Yes	Yes	Unclear	Unclear if the sample included patients with dementia because there was no screening for it (30 participants could not follow instructions).	Yes	Yes	Unclear
Frank, 1987[50] PTA screening with portable audiometer	Yes	Yes	Yes	Unclear	Unclear if the sample included patients with dementia because there was no screening for it (30 participants could not follow instructions).	Yes	Yes	Unclear
Gates, 2003[51] HHIE-S	Yes	Yes	Yes	Low		Unclear	Yes	Low
Gates, 2003[51] Single question ("Do you have a hearing problem now?")	Yes	Yes	Yes	Low		Unclear	Yes	Low
Hannula, 2011[52] Single question ("Q1. Do you have any difficulty with your hearing?")	Yes	Yes	Yes	Low		Unclear	NA	Unclear
Kelly, 2018[53] EarTrumpet app	Unclear	Yes	Yes	Unclear	Patients included those coming to clinic for symptoms such as HL. Not clear how many reported HL symptoms or even had SNHL (vs. other types of HL).	Yes	Yes	Low

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Kelly, 2018[53] Audiogram Mobile app	Unclear	Yes	Yes	Unclear	Patients included those coming to clinic for symptoms such as HL. Not clear how many reported HL symptoms or even had SNHL (vs. other types of HL).	Yes	Yes	Low
Kelly, 2018[53] Hearing Test with Audiogram app	Unclear	Yes	Yes	Unclear	Patients included those coming to clinic for symptoms such as HL. Not clear how many reported HL symptoms or even had SNHL (vs. other types of HL).	Yes	Yes	Low
Koike, 1994[54] Five Minute Hearing Test	Unclear	Yes	Unclear	Unclear	No information about exclusion of patients during enrollment or whether sample was consecutively or randomly chosen	Yes	Yes	Low
Koole, 2016[55] DIN test	Unclear	Yes	Yes	Unclear	Participants are from larger Rotterdam Study (population cohort from the Netherlands focused on risk factors for common diseases in the elderly); unclear how participants were selected or what proportion underwent hearing evaluation.	Unclear	Yes	Unclear

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Lee, 2010[56] Self-reported hearing loss	Unclear	Yes	Unclear	Unclear	Community-dwelling adults presenting for care in community centers Hong Kong were enrolled; those with MMSE score ≥18 (n=99) were excluded. Unclear what proportion of included sample may have had mild cognitive impairment.	Unclear	NA	Unclear
Lichtenstein, 1988[57] AudioScope	Yes	Yes	Yes	Low		Unclear	Yes	Unclear
Lichtenstein, 1988[57] HHIE-S	Yes	Yes	Yes	Low		Unclear	NA	Unclear
Lycke, 2016[58] uHear	Yes	Yes	Yes	Low		Unclear	NA	Unclear
Lycke, 2016[58] WVT	Yes	Yes	Yes	Low		Unclear	Yes	Unclear
Lycke, 2018[59] uHear™ (iOS-based app)	Unclear	Yes	Yes	Unclear	Unclear patient selection process	Yes	Yes	Low
Macphee, 1988[60] Conversational voice test at 2 feet	Yes	Yes	Yes	Unclear	11/62 patients (22/124 ears, or 17.7%) were previous HA users.	Yes	Yes	Unclear
Macphee, 1988[60] WVT at 2 feet	Yes	Yes	Yes	Unclear	11/62 patients (22/124 ears, or 17.7%) were previous HA users.	Yes	Yes	Unclear
Macphee, 1988[60] WVT at 6 inches	Yes	Yes	Yes	Unclear	11/62 patients (22/124 ears, or 17.7%) were previous HA users.	Yes	Yes	Unclear

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
McBride, 1994[61] AudioScope	Yes	Yes	Unclear	Unclear	Of those eligible, 7% declined to participate and 6% were excluded because of cerumen impaction or severe comorbid illness. Unclear what comorbid illnesses led to exclusions.	Yes	Yes	Low
McBride, 1994[61] HHIE-S	Yes	Yes	Unclear	Unclear	Of those eligible, 7% declined to participate and 6% were excluded because of cerumen impaction or severe comorbid illness. Unclear what comorbid illnesses led to exclusions.	Yes	Yes	Low
McShefferty, 2013[62] WVT	Unclear	Yes	Yes	Unclear	Whether the sample was consecutive or random is unknown	Yes	Unclear	Unclear
Nondahl, 1998,[63] Wiley, 2000[64] Single question ("Do you feel you have hearing loss?")	Yes	Yes	Yes	Low		Unclear	Yes	Unclear
Nondahl, 1998,[63] Wiley, 2000[64] HHIE-S	Yes	Yes	Yes	Low		Unclear	Yes	Unclear
Nondahl, 1998,[63] Wiley, 2000[64] Single question ("In general, would you say your hearing is fair or poor?")	Yes	Yes	Yes	Low		Unclear	Yes	Unclear

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Oosterloo, 2020[65] Single question ("Do you have any difficulty with your hearing [without hearing aids]?")	Yes	Yes	Yes	Low		Yes	Yes	Low
Rawool, 2008[66] Single question ("Do you think you have a hearing loss?")	Yes	Yes	Yes	Low		Unclear	Yes	Unclear
Saliba, 2017[67] Mobile-based hearing test (iOS-based app)	Yes	Yes	Yes	Low		Yes	Yes	Low
Salonen, 2011[68] HHIE-S (Finnish)	No	Yes	Yes	Unclear	Participants selected based on initial of last name from a larger Finnish cohort study.	Yes	NA	Low
Salonen, 2011[68] Single question ("Do you feel you have hearing loss?")	No	Yes	Yes	Unclear	Participants selected based on initial of last name from a larger Finnish cohort study.	Yes	NA	Low
Sever, 1989[69] HHIE-S	Yes	Yes	Yes	Low		Yes	Yes	Low
Sindhusake, 2001[70] Single question ("Do you feel you have hearing loss?)	Unclear	Yes	Yes	Unclear	74.7% of eligible patients from the original Blue Mountains Eye Study cohort participated, and unclear how much their risk of HL differed from that of the 25.3% who declined to participate.	Unclear	Yes	Unclear

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Sindhusake, 2001[70] HHIE-S	Unclear	Yes	Yes	Unclear	74.7% of eligible patients from the original Blue Mountains Eye Study cohort participated, and unclear how much their risk of HL differed from that of the 25.3% who declined to participate.	Unclear	Yes	Unclear
Swan, 1985[71] WVT at 2 feet	Yes	Yes	Unclear	Unclear	No exclusion criteria listed.	Yes	Yes	Unclear
Swanepoel de, 2013[72] Single question ("Do you have a hearing impairment? Yes or No")	Yes	Yes	Yes	Low		Unclear	Yes	Low
Tomioka, 2013[73] HHIE-S	No	Yes	Unclear	Unclear	Insufficient information given about recruitment—whether consecutive or by some other method, those who could not walk independently were excluded.	Unclear	Yes	Unclear
Tomioka, 2013[73] Single question ("Do you feel you have hearing loss?")	Unclear	Yes	Unclear	Unclear	No description provided about patient sampling (whether consecutive or by some other method); those who could not walk independently were excluded.	Unclear	NA	Unclear
Torre, 2006[74] Single question ("Do you feel you have a hearing loss?")	Unclear	Yes	Yes	Unclear	Unclear what criteria were used by physicians and staff when referring patients for study.	Unclear	Yes	Unclear

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Ventry, 1983[75] HHIE-S	Unclear	Yes	Yes	Unclear	No description of whether the community sample (N=104) was selected consecutively.	Unclear	Yes	Unclear
Voeks, 1993[76] Single question ("Do you have trouble hearing?")	Yes	Yes	Yes	Unclear	Consecutive sample of participants being admitted to a VA skilled nursing facility were eligible. Those who refused or who were too ill to participate were excluded (no criteria for illness exclusions described). Authors included participants who may have been previously identified with HL but did not describe proportion with known or suspected HL.	Unclear	NA	Unclear
Watson, 2012[77] Telephone DIN test	Unclear	Yes	Unclear	Unclear	No description of whether selection was consecutive or random. Participants were enrolled from one hearing clinic and from a newspaper advertisement. No description of inclusion/exclusion criteria.	Yes	No	High
Weinstein, 1986[78] HHIE-S	Unclear	Yes	Unclear	Unclear	Some may have had prior audiological evaluation and had hearing aids; unclear recruitment information.	Yes	Yes	Low

Appendix D Table 13. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 1

First Author, Year Index Test	Consecutive or random sample of patients used?	Case control design avoided?	Did the study avoid inappropriate exclusions?	Bias due to patient selection?	Comments about Patient Selection	Test and reference standard results interpreted independently (blinded)?	If a threshold was used, was it pre-specified?	Bias due to index test?
Weinstein, 1986[78] PTA screening: 40 dB HL at 1 kHz and 2 kHz in each ear	Unclear	Yes	Unclear	Unclear	Some may have had prior audiological evaluation and had hearing aids; unclear recruitment information.	Yes	Yes	Low
Williams-Sanchez, 2014[79] U.S. NHT	No	Yes	Unclear	Unclear	Participant selection described as "convenience sampling," but not clearly described; inclusion/exclusion criteria not described.	Unclear	Yes	Unclear
Williams-Sanchez, 2014[79] WIN test	No	Yes	Unclear	Unclear	Participant selection described as "convenience sampling," but not clearly described; inclusion/exclusion criteria not described.	Unclear	Yes	Unclear

Abbreviations: DIN=Digits-in-Noise; HA=hearing aid; HHIE-S=Hearing Handicap Inventory for the Elderly – Screening Version; HL=hearing loss; HSAQ=Haring Self-Assessment Questionnaire; KQ=key question; MMSE=Mini-Mental State Examination; n=number of patients in a group; N=number of patients in overall sample; NA=not applicable; NHT=National Hearing Test; PTA=pure-tone audiometry; SNHL=sensorineural hearing loss; U.S.=United States; vs.=versus; VA=Veterans Administration; WIN=Words-in-Noise; WVT=whispered voice test.

Appendix D Table 14. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 2

First Author, Year Index Test	Comments about Index Test	Is the reference standard likely to correctly classify the target condition?	If the reference standard includes additional diagnostic criteria (other than pure-tone thresholds), were the reference standard results interpreted without knowledge of the results of the index test?	Bias due to the reference standard?	Comments about Reference Standard
Bienvenue, 1985[45] AudioScope		Yes	NA	Low	
Boatman, 2007[46] Finger rub test		Yes	NA	Low	
Boatman, 2007[46] Single question ("Do you think you have difficulty hearing?")		Yes	NA	Low	
Boatman, 2007[46] Watch tick test		Yes	NA	Low	
Boatman, 2007[46] WVT		Yes	NA	Low	
Bonetti, 2018[47] HSAQ	Used ROC to determine cut point	Yes	NA	Low	
Ciurlia-Guy, 1993[48] AudioScope		Yes	NA	Low	
Clark, 1991[5] Single question ("Would you say that you have any difficulty hearing?")	Unclear whether index test and reference standard were interpreted independently	Yes	NA	Low	
Eekhof, 1996[49] AudioScope	Unclear if results were interpreted independently	Yes	NA	Low	
Eekhof, 1996[49] WVT at 2 feet	Index and reference testing were performed in an audiology clinic; unclear if results were interpreted independently.	Yes	NA	Low	

Appendix D Table 14. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 2

First Author, Year Index Test	Comments about Index Test	Is the reference standard likely to correctly classify the target condition?	If the reference standard includes additional diagnostic criteria (other than pure-tone thresholds), were the reference standard results interpreted without knowledge of the results of the index test?	Bias due to the reference standard?	Comments about Reference Standard
Frank, 1987[50] AudioScope	40-dB HL version; they tested both ears, and if subjects did not hear one or more tones in one or each ear, they were immediately reinstructed and rescreened in the same manner as the original screening. This was done for both screening tests to minimize the incidence of false negatives. The results of the second screening were used for data analysis.	Yes	NA	Low	
Frank, 1987[50] PTA screening with portable audiometer	40-dB HL version; they tested both ears, and if subjects did not hear one or more tones in one or each ear, they were immediately reinstructed and rescreened in the same manner as the original screening. This was done for both screening tests to minimize the incidence of false negatives. The results of the second screening were used for data analysis.	Yes	NA	Low	
Gates, 2003[51] HHIE-S		Yes	NA	Low	
Gates, 2003[51] Single question (“Do you have a hearing problem now?”)		Yes	NA	Low	
Hannula, 2011[52] Single question (“Q1. Do you have any difficulty with your hearing?”)	Sequence of testing was not specified.	Yes	NA	Low	
Kelly, 2018[53] EarTrumpet app		Yes	NA	Low	

Appendix D Table 14. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 2

First Author, Year Index Test	Comments about Index Test	Is the reference standard likely to correctly classify the target condition?	If the reference standard includes additional diagnostic criteria (other than pure-tone thresholds), were the reference standard results interpreted without knowledge of the results of the index test?	Bias due to the reference standard?	Comments about Reference Standard
Kelly, 2018[53] Audiogram Mobile app		Yes	NA	Low	
Kelly, 2018[53] Hearing Test with Audiogram app		Yes	NA	Low	
Koike, 1994[54] Five Minute Hearing Test		Yes	NA	Low	
Koole, 2016[55] DIN test	PTA was performed before DIN screening, but unclear if results from the two tests were interpreted independently.	Yes	NA	Low	
Lee, 2010[56] Self-reported hearing loss	No description of how self-perceived hearing loss was measured or whether it was asked independent of reference test results.	Yes	NA	Low	
Lichtenstein, 1988[57] AudioScope	Unclear if index and reference test were interpreted independently; index test also repeated by audiologist at time of referral (in addition to reference test).	Yes	NA	Low	
Lichtenstein, 1988[57] HHIE-S	Unclear if index and reference test were interpreted independently; index test also repeated by audiologist at time of referral (in addition to reference test).	Yes	NA	Low	
Lycke, 2016[58] uHear	Unclear whether index test and reference standard were interpreted independently. The uHear™ app measures hearing at different frequencies (not threshold for positive/negative screening test used).	Yes	NA	Low	

Appendix D Table 14. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 2

First Author, Year Index Test	Comments about Index Test	Is the reference standard likely to correctly classify the target condition?	If the reference standard includes additional diagnostic criteria (other than pure-tone thresholds), were the reference standard results interpreted without knowledge of the results of the index test?	Bias due to the reference standard?	Comments about Reference Standard
Lycke, 2016[58] WVT	Unclear whether index test and reference standard were interpreted independently. A pass was given if patient could repeat all 3 numbers correctly at each level of loudness, or ≥50% success over 3 consecutive triplet sets.	Yes	NA	Low	
Lycke, 2018[59] uHear™ (iOS-based app)		Yes	NA	Low	
Macphee, 1988[60] Conversational voice test at 2 feet	While criteria for passing are clear, it is not obvious that administration was uniform.	Yes	NA	Low	
Macphee, 1988[60] WVT at 2 feet	While criteria for passing are clear, it is not obvious that administration was uniform.	Yes	NA	Low	
Macphee, 1988[60] WVT at 6 inches	While criteria for passing are clear, it is not obvious that administration was uniform.	Yes	NA	Low	
McBride, 1994[61] AudioScope		Yes	NA	Low	
McBride, 1994[61] HHIE-S		Yes	NA	Low	
McShefferty, 2013[62] WVT	Unclear what the criteria are for fail.	Yes	NA	Low	
Nondahl, 1998,[63] Wiley, 2000[64] Single question ("Do you feel you have hearing loss?")	Unclear whether the screening question was conducted and interpreted independent of PTA.	Yes	NA	Low	
Nondahl, 1998,[63] Wiley, 2000[64] HHIE-S	Unclear whether the HHIE-S was conducted and interpreted independent of PTA.	Yes	NA	Low	

Appendix D Table 14. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 2

First Author, Year Index Test	Comments about Index Test	Is the reference standard likely to correctly classify the target condition?	If the reference standard includes additional diagnostic criteria (other than pure-tone thresholds), were the reference standard results interpreted without knowledge of the results of the index test?	Bias due to the reference standard?	Comments about Reference Standard
Nondahl, 1998,[63] Wiley, 2000[64] Single question ("In general, would you say your hearing is fair or poor?")	Unclear whether the screening question was conducted and interpreted independent of PTA.	Yes	NA	Low	
Oosterloo, 2020[65] Single question ("Do you have any difficulty with your hearing [without hearing aids]?")		Yes	NA	Low	
Rawool, 2008[66] Single question ("Do you think you have a hearing loss?")	Not clear whether the screening question was asked prior to PTA.	Yes	NA	Low	
Saliba, 2017[67] Mobile-based hearing test (iOS-based app)		Yes	NA	Low	
Salonen, 2011[68] HHIE-S (Finnish)		Yes	NA	Low	
Salonen, 2011[68] Single question ("Do you feel you have hearing loss?")		Yes	NA	Low	
Sever, 1989[69] HHIE-S		Yes	NA	Low	
Sindhusake, 2001[70] Single question ("Do you feel you have hearing loss?)	Unclear whether index test and reference standard were interpreted independently.	Yes	NA	Low	
Sindhusake, 2001[70] HHIE-S	Unclear whether index test and reference standard were interpreted independently.	Yes	NA	Low	
Swan, 1985[71] WVT at 2 feet	Unclear how consistently the whisper test was applied in terms of who performed the test and the actual volume used.	Yes	NA	Low	

Appendix D Table 14. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 2

First Author, Year Index Test	Comments about Index Test	Is the reference standard likely to correctly classify the target condition?	If the reference standard includes additional diagnostic criteria (other than pure-tone thresholds), were the reference standard results interpreted without knowledge of the results of the index test?	Bias due to the reference standard?	Comments about Reference Standard
Swanepoel de, 2013[72] Single question ("Do you have a hearing impairment? Yes or No")		Yes	NA	Low	
Tomioka, 2013[73] HHIE-S	Unclear whether index test and reference test were interpreted independently.	Yes	NA	Low	
Tomioka, 2013[73] Single question ("Do you feel you have hearing loss?")	Unclear whether index test and reference test were interpreted independently.	Yes	NA	Low	
Torre, 2006[74] Single question ("Do you feel you have a hearing loss?")	Unclear whether the single screening question was administered before PTA testing.	Yes	NA	Low	
Ventry, 1983[75] HHIE-S	Unclear if index and reference test were interpreted independently.	Yes	NA	Low	
Voeks, 1993[76] Single question ("Do you have trouble hearing?")	Unclear whether index test and reference test were interpreted independently. Screening question implies yes/no answer; however, authors report number of participants who replied with an equivocal response and count those as "yes" to the single-question screener in analyses.	Yes	NA	Low	
Watson, 2012[77] Telephone DIN test	Threshold for positive screening test was not prespecified; authors presented accuracy for two thresholds but did not provide a rationale for why these were chosen. Accuracy statistics for two thresholds reported vary substantially.	Yes	NA	Low	

Appendix D Table 14. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 2

First Author, Year Index Test	Comments about Index Test	Is the reference standard likely to correctly classify the target condition?	If the reference standard includes additional diagnostic criteria (other than pure-tone thresholds), were the reference standard results interpreted without knowledge of the results of the index test?	Bias due to the reference standard?	Comments about Reference Standard
Weinstein, 1986[78] HHIE-S		Unclear	Yes	High	Reference standard was the audiologist's recommendation for followup, and audiologists did not follow a protocol in terms of weighting the results of their PTA when making a recommendation.
Weinstein, 1986[78] PTA screening: 40 dB HL at 1 kHz and 2 kHz in each ear		Unclear	Yes	High	Reference standard was the audiologist's recommendation for followup, and audiologists did not follow a protocol in terms of weighting the results of their PTA when making a recommendation.
Williams-Sanchez, 2014[79] U.S. NHT	Unclear if results from the NHT and PTA were interpreted independently.	Yes	NA	Low	
Williams-Sanchez, 2014[79] WIN test	Unclear if results from the WIN test and PTA were interpreted independently.	Yes	NA	Low	

Abbreviations: DIN=Digits-in-Noise; HHIE-S=Hearing Handicap Inventory for the Elderly – Screening Version; HL=hearing loss; HSAQ=Haring Self-Assessment Questionnaire; KQ=key question; NA=not applicable; NHT=National Hearing Test; PTA=pure-tone audiometry; ROC=receiver operating characteristic; U.S.=United States; WIN=Words-in-Noise; WVT=whispered voice test.

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Bienvenue, 1985[45] AudioScope	Yes	Yes	Yes		Yes	Low	
Boatman, 2007[46] Finger rub test	Yes	Yes	Yes	NA	Unclear	Unclear	Authors used modeling to account for within-subject correlation between ear measurements (screening tests were conducted in both ears); reference standard definition of HL was >25 dB at one or more frequencies in either ear. For PPV calculations, authors used prevalence of HL by age group from the literature (not prevalence in included sample).
Boatman, 2007[46] Single question ("Do you think you have difficulty hearing?")	Yes	Yes	Yes	NA	Unclear	Unclear	Authors used modeling to account for within-subject correlation between ear measurements (screening tests were conducted in both ears); reference standard definition of HL was >25 dB at one or more frequencies in either ear. For PPV calculations, authors used prevalence of HL by age group from the literature (not prevalence in included sample).
Boatman, 2007[46] Watch tick test	Yes	Yes	Yes	NA	Unclear	Unclear	Authors used modeling to account for within-subject correlation between ear measurements (screening tests were conducted in both ears); reference standard definition of HL was >25 dB at one or more frequencies in either ear. For PPV calculations, authors used prevalence of HL by age group from the literature (not prevalence in included sample).

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Boatman, 2007[46] WVT	Yes	Yes	Yes	NA	Unclear	Unclear	Authors used modeling to account for within-subject correlation between ear measurements (screening tests were conducted in both ears); reference standard definition of HL was >25 dB at one or more frequencies in either ear. For PPV calculations, authors used prevalence of HL by age group from the literature (not prevalence in included sample).
Bonetti, 2018[47] HSAQ	Yes	Yes	Yes		Yes	Low	
Ciurlia-Guy, 1993[48] AudioScope	Yes	Yes	No	4.8%	Unclear	Unclear	Numbers do not match when attempting to replicate authors' calculated sensitivity and specificity outcomes, so it is necessary to accept their calculations of sensitivity and specificity as correct.
Clark, 1991[5] Single question ("Would you say that you have any difficulty hearing?")	Yes	Yes	Yes	NA	Yes	Low	
Eekhof, 1996[49] AudioScope	Yes	Yes	Yes	NA	Yes	Low	
Eekhof, 1996[49] WVT at 2 feet	Yes	Yes	Yes	NA	Yes	Low	
Frank, 1987[50] AudioScope	Yes	Yes	No	10.8% ears (146/1,356)	Yes	Low	
Frank, 1987[50] PTA screening with portable audiometer	Yes	Yes	No	10.8% ears (146/1,356)	Yes	Low	

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Gates, 2003[51] HHIE-S	Yes	Yes	No	25% (546/723); 8% (546/597) when accounting for those excluded because of known hearing aid use	No	High	Unclear how participants with a HHIE-S score of 9 were categorized in analyses; cutoff is defined as 0-8 vs. ≥10; risk of selection bias because of high attrition; however, the largest proportion excluded were those wearing hearing aids.
Gates, 2003[51] Single question ("Do you have a hearing problem now?")	Yes	Yes	No	25% (546/723); 8% (546/597) when accounting for those excluded because of known hearing aid use	Yes	High	Risk of selection bias because of high attrition may introduce bias; however, the largest proportion excluded were those wearing hearing aids.
Hannula, 2011[52] Single question ("Q1. Do you have any difficulty with your hearing?")	Yes	Yes	Yes		Yes	Low	
Kelly, 2018[53] EarTrumpet app	Yes	Yes	No	7/114 (6.1%) of those enrolled overall	No	Unclear	Only Se and Sp were reported, but not the data needed to calculate those outcomes or other measures of test accuracy. Table 1 data do not agree with information in text. Study's definition of HL not clearly defined in terms of ears or frequencies used.

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Kelly, 2018[53] Audiogram Mobile app	Yes	Yes	No	7/114 (6.1%) of those enrolled overall	No	Unclear	Only Se and Sp were reported, but not the data needed to calculate those outcomes or other measures of test accuracy. Table 1 data do not agree with information in text. Study's definition of HL not clearly defined in terms of ears or frequencies used.
Kelly, 2018[53] Hearing Test with Audiogram app	Yes	Yes	No	7/114 (6.1%) of those enrolled overall	No	Unclear	Only Se and Sp were reported, but not the data needed to calculate those outcomes or other measures of test accuracy. Table 1 data do not agree with information in text. Study's definition of HL not clearly defined in terms of ears or frequencies used.
Koike, 1994[54] Five Minute Hearing Test	Yes	Yes	Unclear	NR	Yes	Unclear	No information on how many failed the reference test and whether all were included in the analysis.
Koole, 2016[55] DIN test	Yes	Yes	No	7.8% patients (283/3,610) were excluded because of having an air and bone gap of ≥15 dB at the best ear, failing to complete the DIN test, and having an average SNR deviation of >3.7 dB (+2 SDs above the mean)	Yes	Unclear	Possible that participants may have experienced fatigue when completing the DIN screening test, according to the authors, but it "probably" did not play a major role in the test's accuracy.
Lee, 2010[56] Self-reported hearing loss	Yes	Yes	No	6/1.019= 0.6%	Yes	Low	

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Lichtenstein, 1988[57] AudioScope	Yes	Yes	No	41% (126/304) of those screened and referred to the study did not keep their appointments for PTA retesting. Additionally, for patients who did complete PTA testing and were included in the final sample, data were missing for a range of 1.7% (3/178 for right ear at 500-2.000 Hz) to 3.9% (7/178 for left ear at 4.000 Hz) of patients.	Yes	High	Of those initially screened, only 41% followed up for reference standard testing; nonresponders had a slightly lower rate of HL identified via AudioScope screening (42% vs. 48%) and lower mean HHIE-S scores (7.6 vs. 10.0).
Lichtenstein, 1988[57] HHIE-S	Yes	Yes	No	41% (126/304) of those screened and referred to the study did not keep their appointments for PTA retesting. Additionally, for patients who did complete PTA testing and were included in the final sample, data were missing for a range of 1.7% (3/178 for right ear at 500-2.000 Hz) to 3.9% (7/178 for left ear at 4.000 Hz) of patients.	Yes	High	Of those initially screened, only 41% followed up for reference standard testing; nonresponders had a slightly lower rate of HL identified via AudioScope screening (42% vs. 48%) and lower mean HHIE-S scores (7.6 vs. 10.0).
Lycke, 2016[58] uHear	Yes	Yes	No	1 person (3%) withdrew; one additional person's ear was excluded because of a known hearing condition.	Yes	Low	

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Lycke, 2016[58] WVT	Yes	Yes	No	1 person (3%) withdrew; one additional person's ear was excluded because of a known hearing condition.	Yes	Low	
Lycke, 2018[59] uHear™ (iOS-based app)	Yes	Yes	Yes		Yes	Low	
Macphee, 1988[60] Conversational voice test at 2 feet	Yes	Yes	Yes	NA	Yes	Low	
Macphee, 1988[60] WVT at 2 feet	Yes	Yes	Yes	NA	Yes	Low	
Macphee, 1988[60] WVT at 6 inches	Yes	Yes	Yes	NA	Yes	Low	
McBride, 1994[61] AudioScope	Yes	Yes	Yes	NA	Yes	Low	
McBride, 1994[61] HHIE-S	Yes	Yes	Yes	NA	Yes	Low	
McShefferty, 2013[62] WVT	Yes	Yes	Yes		Yes	Low	
Nondahl, 1998,[63] Wiley, 2000[64] Single question ("Do you feel you have hearing loss?")	Unclear	Yes	No	11% patients (411/3,753)	Yes	Unclear	Unclear if there was an appropriate interval between tests.

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Nondahl, 1998,[63] Wiley, 2000[64] HHIE-S	Unclear	Yes	No	7.5% patients (282/3,753)	Yes	Unclear	Unclear if there was an appropriate interval between tests.
Nondahl, 1998,[63] Wiley, 2000[64] Single question ("In general, would you say your hearing is fair or poor?")	Unclear	Yes	No	6.2% patients (231/3,753)	Yes	Unclear	Unclear if there was an appropriate interval between tests.
Oosterloo, 2020[65] Single question ("Do you have any difficulty with your hearing [without hearing aids]?")	Yes	Yes	Yes		Yes	Low	
Rawool, 2008[66] Single question ("Do you think you have a hearing loss?")	Yes	Yes	Yes	NA	Yes	Low	
Saliba, 2017[67] Mobile-based hearing test (iOS-based app)	Yes	Yes	Yes		Yes	Low	Note that a single ear (1.5% of all 66 ears originally recruited) was excluded.

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Salonen, 2011[68] HHIE-S (Finnish)	Yes	Yes	No	Of those who responded to the questionnaire, 164/262 = 37% did not attend the hearing examination	Yes	High	High attrition (37% did not attend audiometry), a higher proportion of those who attended audiometry had an HHIE-S score >8 than nonattenders.
Salonen, 2011[68] Single question ("Do you feel you have hearing loss?")	Yes	Yes	No	Of those who responded to the questionnaire, 164/262 = 37% did not attend the hearing examination	Yes	High	Subjects with self-perceived hearing difficulty were more likely to respond to questionnaires and attend hearing exam than those without hearing problems.
Sever, 1989[69] HHIE-S	Yes	Yes	Yes	NA	Yes	Low	
Sindhusake, 2001[70] Single question ("Do you feel you have hearing loss?)	Yes	Yes	No	3.6% (72/1,879) with missing values	Yes	Low	
Sindhusake, 2001[70] HHIE-S	Yes	Yes	No	9.8% (198/2,005) with missing responses	Yes	Low	
Swan, 1985[71] WVT at 2 feet	Yes	Yes	Yes		Yes	Low	
Swanepoel de, 2013[72] Single question ("Do you have a hearing impairment? Yes or No")	Yes	Yes	No	6% (947/1,004)	Yes	Low	

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Tomioka, 2013[73] HHIE-S	Yes	Yes	No	1.7% (30/1,761) were excluded for incomplete information on demographic and hearing-related comorbidity	Unclear	Unclear	Number of individuals who failed reference test are missing, so independent checking of accuracy is not possible.
Tomioka, 2013[73] Single question ("Do you feel you have hearing loss?")	Yes	Yes	No	1.7% (30/1,761) were excluded for incomplete information on demographic and hearing-related comorbidity	Unclear	Unclear	Number of participants who failed reference test is not described, so independent checking of accuracy is not possible.
Torre, 2006[74] Single question ("Do you feel you have a hearing loss?")	Yes	Yes	Yes	NA	Yes	Low	
Ventry, 1983[75] HHIE-S	Unclear	Yes	Unclear	NA	Yes	Unclear	Unclear how long the interval was between the questionnaire and PTA tests or if all patients were included in the analysis.
Voeks, 1993[76] Single question ("Do you have trouble hearing?")	Yes	Yes	No	17.1% (41/239) excluded because of poor audiometric response reliability (defined as >5 dB difference in repeat measurement at 1,000 Hz after all other frequencies were tested)	Yes	Unclear	Relatively high proportion of participants excluded because of poor reliability on PTA (17%); no description of whether excluded participants with poor audiometric response were more likely to report trouble hearing. Reference standard was offered via sound-proof booth or room environment (via earphones) to accommodate those in a wheelchair; unclear if difference in setting may have affected test performance.

Appendix D Table 15. Quality Assessment of Screening Test Accuracy Studies (KQ 2), Part 3

First Author, Year Index Test	Appropriate interval between index test and reference standard?	Did all patients (or a random sample) receive the same reference standard?	All patients included in the analysis?	If "No" to the previous question, proportion of patients not included in the analysis?	Methods for calculating accuracy clearly reported and valid or sufficient data provided to allow calculation of accuracy measures (both sens and spec)?	Bias due to flow and timing?	Comments about Flow and Timing
Watson, 2012[77] Telephone DIN test	Yes	Yes	Yes	NA	Yes	Low	
Weinstein, 1986[78] HHIE-S	Unclear	Yes	Unclear	NR	Yes	Unclear	Unclear if there was an appropriate interval between tests.
Weinstein, 1986[78] PTA screening: 40 dB HL at 1 kHz and 2 kHz in each ear	Unclear	Yes	Unclear	NR	Yes	Unclear	Unclear if there was an appropriate interval between tests.
Williams-Sanchez, 2014[79] U.S. NHT	Yes	Yes	Unclear	NR	Yes	Unclear	No description of enrolled participants who declined to participate or who were excluded from analyses because of missing data.
Williams-Sanchez, 2014[79] WIN test	Yes	Yes	Unclear	NR	Yes	Unclear	No description of enrolled participants who declined to participate or who were excluded from analyses because of missing data.

Abbreviations: DIN=Digits-in-Noise; HHIE-S=Hearing Handicap Inventory for the Elderly – Screening Version; HL=hearing loss; HSAQ=Haring Self-Assessment Questionnaire; KQ=key question; NA=not applicable; NR=not reported; PPV=positive predictive value; PTA=pure-tone audiometry; NHT=National Hearing Test; SD=standard deviation; SNR=sound-to-noise ratio; Se or sens=sensitivity; Sp or spec=specificity; U.S.=United States; vs.=versus; WIN=Words-in-Noise; WVT=whispered voice test.

Appendix D Table 16. Quality Assessment of Screening Test Accuracy Studies (KQ 2): Domain Rating Summary and Overall Rating

First Author, Year Index Test	Bias due to patient selection?	Bias due to index test?	Bias due to the reference standard?	Bias due to flow and timing?	Quality Rating	Rationale
Bienvenue, 1985[45] AudioScope	Unclear	Low	Low	Low	Fair	Patient selection unclear
Boatman, 2007[46] Finger rub test	Low	Low	Low	Unclear	Fair	Methods for calculating PPV and sens/spec unclear in terms of how logistic regression/modeling was used to adjust values.
Boatman, 2007[46] Single question ("Do you think you have difficulty hearing?")	Low	Low	Low	Unclear	Fair	Methods for calculating PPV and sens/spec unclear in terms of how logistic regression/modeling was used to adjust values.
Boatman, 2007[46] Watch tick test	Low	Low	Low	Unclear	Fair	Methods for calculating PPV and sens/spec unclear in terms of how logistic regression/modeling was used to adjust values.
Boatman, 2007[46] WVT	Low	Low	Low	Unclear	Fair	Methods for calculating PPV and sens/spec unclear in terms of how logistic regression/modeling was used to adjust values.
Bonetti, 2018[47] HSAQ	Low	Unclear	Low	Low	Fair	Index test used ROC to determine cut point.
Ciurlia-Guy, 1993[48] AudioScope	Low	Low	Low	Unclear	Fair	Flow and timing: unclear methods for accuracy.
Clark, 1991[5] Single question ("Would you say that you have any difficulty hearing?")	Unclear	Unclear	Low	Low	Fair	Unclear sampling strategy; no description of whether index and reference test were interpreted independently.
Eekhof, 1996[49] AudioScope	Low	Unclear	Low	Low	Fair	Unclear whether index and reference test were interpreted independently.
Eekhof, 1996[49] WVT at 2 feet	Low	Unclear	Low	Low	Fair	Unclear whether index and reference test were interpreted independently.
Frank, 1987[50] AudioScope	Unclear	Unclear	Low	Low	Fair	Unclear ROB because of patient selection (no screening for dementia, even though 30 patients were excluded because they could not repeat back the screening instructions) and index test (investigators screened patients in a way that would reduce false-negative rates)
Frank, 1987[50] PTA screening with portable audiometer	Unclear	Unclear	Low	Low	Fair	Unclear ROB because of patient selection (no screening for dementia, even though 30 patients were excluded because they could not repeat back the screening instructions) and index test (investigators screened patients in a way that would reduce false-negative rates)
Gates, 2003[51] HHIE-S	Low	Low	Low	High	Fair	Unclear how participants with an HHIE-S score of 9 were categorized in analyses; cut-off defined as 0=8 vs. ≥10; risk of selection bias because of high attrition; however, the largest proportion excluded were those wearing hearing aids.

Appendix D Table 16. Quality Assessment of Screening Test Accuracy Studies (KQ 2): Domain Rating Summary and Overall Rating

First Author, Year Index Test	Bias due to patient selection?	Bias due to index test?	Bias due to the reference standard?	Bias due to flow and timing?	Quality Rating	Rationale
Gates, 2003[51] Single question ("Do you have a hearing problem now?")	Low	Low	Low	High	Fair	Risk of selection bias because of high attrition may introduce bias; however, the largest proportion excluded were those wearing hearing aids.
Hannula, 2011[52] Single question ("Q1. Do you have any difficulty with your hearing?")	Low	Unclear	Low	Low	Fair	Index test
Kelly, 2018[53] EarTrumpet app	Unclear	Low	Low	Unclear	Fair	Unclear risk of bias due to patient selection (inclusion of some unknown number of patients with suspected HL and possibly HL that was not sensorineural) and flow and timing (no data provided to calculate any accuracy measures).
Kelly, 2018[53] Audiogram Mobile app	Unclear	Low	Low	Unclear	Fair	Unclear risk of bias due to patient selection (inclusion of some unknown number of patients with suspected HL and possibly HL that was not sensorineural) and flow and timing (no data provided to calculate any accuracy measures).
Kelly, 2018[53] Hearing Test with Audiogram app	Unclear	Low	Low	Unclear	Fair	Unclear risk of bias due to patient selection (inclusion of some unknown number of patients with suspected HL and possibly HL that was not sensorineural) and flow and timing (no data provided to calculate any accuracy measures).
Koike, 1994[54] Five Minute Hearing Test	Unclear	Low	Low	Unclear	Fair	Unclear to what extent the study avoided inappropriate exclusions when enrolling patients or prior to analysis. This could be a lack of reporting issue, rather than a potential flaw in the study's design.
Koole, 2016[55] DIN test	Unclear	Unclear	Low	Unclear	Fair	Unclear whether their results were interpreted independently. Also, possible that participant fatigue reduced the accuracy of the DIN test because HL testing was part of a full day of testing for the Rotterdam Study.
Lee, 2010[56] Self-reported hearing loss	Unclear	Unclear	Low	Low	Fair	Methods do not state how self-perceived HL was measured and assessed or whether it was asked independently of reference test results.
Lichtenstein, 1988[57] AudioScope	Low	Unclear	Low	High	Fair	Potential for bias because of high attrition (41% screened followed up for reference standard testing); mean HHIE-S scores and proportion with HL identified via AudioScope were slightly higher among nonresponders than responders.
Lichtenstein, 1988[57] HHIE-S	Low	Unclear	Low	High	Fair	Potential for bias because of high attrition (41% screened followed up for reference standard testing); mean HHIE-S scores and proportion with HL identified via AudioScope were slightly higher among nonresponders than responders.

Appendix D Table 16. Quality Assessment of Screening Test Accuracy Studies (KQ 2): Domain Rating Summary and Overall Rating

First Author, Year Index Test	Bias due to patient selection?	Bias due to index test?	Bias due to the reference standard?	Bias due to flow and timing?	Quality Rating	Rationale
Lycke, 2016[58] uHear	Low	Unclear	Low	Low	Fair	Unclear if uHear and PTA tests were interpreted independent of one another.
Lycke, 2016[58] WVT	Low	Unclear	Low	Low	Fair	Unclear if WVT and PTA tests were interpreted independent of one another.
Lycke, 2018[59] uHear™ (iOS-based app)	Unclear	Low	Low	Low	Fair	Unclear patient selection process. No description of the N of participants approached who declined to participate.
Macphee, 1988[60] Conversational voice test at 2 feet	Unclear	Unclear	Low	Low	Fair	Unclear risk of patient selection bias (17.7% of patients were previous HA users) and also bias related to the index test because it was unclear if administration was uniform.
Macphee, 1988[60] WVT at 2 feet	Unclear	Unclear	Low	Low	Fair	Unclear risk of patient selection bias (17.7% of patients were previous HA users) and also bias related to the index test because it was unclear if administration was uniform.
Macphee, 1988[60] WVT at 6 inches	Unclear	Unclear	Low	Low	Fair	Unclear risk of patient selection bias (17.7% of patients were previous HA users) and also bias related to the index test because it was unclear if administration was uniform.
McBride, 1994[61] AudioScope	Unclear	Low	Low	Low	Good	
McBride, 1994[61] HHIE-S	Unclear	Low	Low	Low	Good	
McShefferty, 2013[62] WVT	Unclear	Unclear	Low	Low	Fair	Patient selection and index test were unclear.
Nondahl, 1998,[63] Wiley, 2000[64] Single question (“Do you feel you have hearing loss?”)	Low	Unclear	Low	Unclear	Fair	Unclear whether the screening question was conducted and interpreted independent of PTA or if there was an appropriate interval between tests.
Nondahl, 1998,[63] Wiley, 2000[64] HHIE-S	Low	Unclear	Low	Unclear	Fair	Unclear whether the HHIE-S was conducted and interpreted independent of PTA or if there was an appropriate interval between tests.
Nondahl, 1998,[63] Wiley, 2000[64] Single question (“In general, would you say your hearing is fair or poor?”)	Low	Unclear	Low	Unclear	Fair	Unclear whether the screening question was conducted and interpreted independent of PTA or if there was an appropriate interval between tests.

Appendix D Table 16. Quality Assessment of Screening Test Accuracy Studies (KQ 2): Domain Rating Summary and Overall Rating

First Author, Year Index Test	Bias due to patient selection?	Bias due to index test?	Bias due to the reference standard?	Bias due to flow and timing?	Quality Rating	Rationale
Oosterloo, 2020[65] Single question ("Do you have any difficulty with your hearing [without hearing aids]?")	Low	Low	Low	Low	Good	
Rawool, 2008[66] Single question ("Do you think you have a hearing loss?")	Low	Unclear	Low	Low	Good	
Saliba, 2017[67] Mobile-based hearing test (iOS-based app)	Low	Low	Low	Low	Good	
Salonen, 2011[68] HHIE-S (Finnish)	Unclear	Low	Low	High	Poor	Of those who responded to the initial questionnaire, 164/262=37% did not attend the hearing examination. Subjects with self-perceived hearing difficulty were more likely to respond to questionnaires and attend hearing exam than those without hearing problems.
Salonen, 2011[68] Single question ("Do you feel you have hearing loss?")	Unclear	Low	Low	High	Poor	Of those who responded to the initial questionnaire, 164/262=37% did not attend the hearing examination. Subjects with self-perceived hearing difficulty were more likely to respond to questionnaires and attend hearing exam than those without hearing problems.
Sever, 1989[69] HHIE-S	Low	Low	Low	Low	Good	
Sindhusake, 2001[70] Single question ("Do you feel you have hearing loss?)	Unclear	Unclear	Low	Low	Fair	Unclear risk of selection bias because 26% of eligible patients did not participate, and unclear if index test and reference standard were interpreted independently.
Sindhusake, 2001[70] HHIE-S	Unclear	Unclear	Low	Low	Fair	Unclear risk of selection bias because 26% of eligible patients did not participate, and unclear if index test and reference standard were interpreted independently.
Swan, 1985[71] WVT at 2 feet	Unclear	Unclear	Low	Low	Fair	Unclear ROB because of index test; unclear how consistently the whisper test was applied in terms of who performed the test and the actual volume used.
Swanepoel de, 2013[72] Single question ("Do you have a hearing impairment? Yes or No")	Low	Low	Low	Low	Good	
Tomioka, 2013[73] HHIE-S	Unclear	Unclear	Low	Unclear	Fair	Patient selection, index test, flow, and timing are all unclear.

Appendix D Table 16. Quality Assessment of Screening Test Accuracy Studies (KQ 2): Domain Rating Summary and Overall Rating

First Author, Year Index Test	Bias due to patient selection?	Bias due to index test?	Bias due to the reference standard?	Bias due to flow and timing?	Quality Rating	Rationale
Tomioka, 2013[73] Single question ("Do you feel you have hearing loss?")	Unclear	Unclear	Low	Unclear	Fair	No description provided about patient sampling (whether consecutive or by some other method); those who could not walk independently were excluded. Unclear whether index and screening tests were interpreted independently.
Torre, 2006[74] Single question ("Do you feel you have a hearing loss?")	Unclear	Unclear	Low	Low	Fair	Unclear risk of patient selection bias because of lack of detail about criteria physicians and staff used when referring patients for study, and unclear if index test was administered before PTA testing.
Ventry, 1983[75] HHIE-S	Unclear	Unclear	Low	Unclear	Fair	Selection of participants unclear; no description of whether index and reference tests were interpreted independently; unclear how long the interval was between the questionnaire and PTA tests; and unclear if all patients were included in the analysis.
Voeks, 1993[76] Single question ("Do you have trouble hearing?")	Unclear	Unclear	Low	Unclear	Fair	Relatively high proportion of participants excluded because of poor reliability on PTA (17%); no description of whether excluded participants with poor audiometric response were more likely to report trouble hearing. Risk of selection bias because of exclusion of participants with illness/comorbidity (not described in detail) and inclusion of some residents who likely had known hearing loss (proportion not described).
Watson, 2012[77] Telephone DIN test	Unclear	High	Low	Low	Fair	No description of whether selection was consecutive or random. Threshold for positive screening test was not prespecified; authors presented accuracy for two thresholds but did not provide a rationale for why these were chosen. Accuracy statistics for two thresholds reported vary substantially.
Weinstein, 1986[78] HHIE-S	Unclear	Low	High	Unclear	Poor	Potential ROB because of possible enrollment of patients with prior audiological evaluation and HA use, the reference standard's subjective nature (audiologist's recommendation for followup, which was informed by audiometry and information from patient interviews), and lack of clarity about how much time elapsed between screening visits and audiology exams.
Weinstein, 1986[78] PTA screening: 40 dB HL at 1 kHz and 2 kHz in each ear	Unclear	Low	High	Unclear	Poor	Potential ROB because of possible enrollment of patients with prior audiological evaluation and HA use, the reference standard's subjective nature (audiologist's recommendation for followup, which was informed by audiometry and information from patient interviews), and lack of clarity about how much time elapsed between screening visits and audiology exams.

Appendix D Table 16. Quality Assessment of Screening Test Accuracy Studies (KQ 2): Domain Rating Summary and Overall Rating

First Author, Year Index Test	Bias due to patient selection?	Bias due to index test?	Bias due to the reference standard?	Bias due to flow and timing?	Quality Rating	Rationale
Williams-Sanchez, 2014[79] U.S. NHT	Unclear	Unclear	Low	Unclear	Fair	Participant selection described as "convenience sampling" but not clearly described. No description of proportion of participants approached who declined to participate or whether some participants were excluded from analyses because of missing data. Unclear whether index and reference test were interpreted independently. No adjustments for the effect of screening location (VA clinic vs. home), given that NHT accuracy outcomes varied by location.
Williams-Sanchez, 2014[79] WIN test	Unclear	Unclear	Low	Unclear	Fair	Participant selection "convenience sampling" but not clearly described; inclusion/exclusion criteria not described. No description of enrolled participants who declined to participate or who were excluded from analyses because of missing data. Unclear whether index and reference test were interpreted independently.

Abbreviations: DIN=Digits-in-Noise; HA=hearing aid; HHIE-S=Hearing Handicap Inventory for the Elderly – Screening Version; HL=hearing loss; HSAQ=Haring Self-Assessment Questionnaire; KQ=key question; N=number; NHT= National Hearing Test; PPV=positive predictive value; PTA=pure-tone audiometry; ROB=risk of bias; ROC=receiver operating characteristic; sens=sensitivity; spec=specificity; U.S.=United States; VA=Veterans Administration; vs.=versus; WIN=Words-in-Noise; WVT=whispered voice test.

Appendix E Table 1. Detailed Evidence Table of Single-Question Test Accuracy

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Boatman, 2007[46]	Do you think you have difficulty hearing? An affirmative response to the question	PTA >25 dB at 0.5, 1, 2, and 4 kHz in either ear: 63%	107 (214 ears)	27 (19 to 37)	89 (66 to 97)	2.45 (NR)	0.82 (NR)
Clark, 1991[5]	Would you say that you have any difficulty hearing? An affirmative response to the question	PTA better ear >25 dB at 1 and 2 kHz: 34%	267	66 (55 to 75)	80 (74 to 85)	3.31 (3.08 to 3.57)	0.43 (0.41 to 0.46)
Clark, 1991[5]	Would you say that you have any difficulty hearing? An affirmative response to the question	PTA >25 dB at 1, 2, 3, and 4 kHz in better ear: 45%	267	56 (47 to 65)	82 (75 to 87)	3.09 (2.81 to 3.40)	0.53 (0.51 to 0.56)
Clark, 1991[5]	Would you say that you have any difficulty hearing? An affirmative response to the question	PTA >40 dB at 1 and 2 kHz in better ear: 11%	267	90 (74 to 98)	71 (66 to 77)	3.10 (2.98 to 3.21)	0.15 (0.08 to 0.28)
Clark, 1991[5]	Would you say that you have any difficulty hearing? An affirmative response to the question	PTA >40 dB at 1, 2, 3, and 4 kHz in better ear: 18%	267	83 (73 to 94)	75 (70 to 81)	3.32 (3.17 to 3.47)	0.22 (0.17 to 0.29)
Gates, 2003[51]	Do you have a hearing problem now? Affirmative response	PTA ≥40 dB at 1 and 2 kHz in one ear or at 1 or 2 kHz in both ears: 27%	723	71 (NR)	72 (NR)	2.5 (NR)	0.40 (NR)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at 0.5, 1, and 2 kHz in better ear: NR	850	77 (68 to 83)	69 (66 to 73)	2.48 (NR)	0.33 (NR)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at 0.5, 1, 2, and 4 kHz in better ear: NR	850	69 (62 to 74)	74 (71 to 78)	2.65 (NR)	0.42 (NR)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at 4 kHz in better ear: NR	850	51 (47 to 56)	84 (80 to 88)	3.19 (NR)	0.58 (NR)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at 4, 6, and 8 kHz in better ear: NR	850	45 (41 to 49)	85 (79 to 89)	3.0 (NR)	0.65 (NR)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at Hz 0.5, 1, and 2 kHz in worse ear: NR	850	69 (63 to 75)	75 (71 to 78)	2.76 (NR)	0.41 (NR)

Appendix E Table 1. Detailed Evidence Table of Single-Question Test Accuracy

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at 0.5, 1, 2, and 4 kHz in worse ear: NR	850	62 (57 to 67)	81 (78 to 84)	3.36 (NR)	0.47 (NR)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at 4 kHz in worse ear: NR	850	43 (40 to 47)	87 (81 to 91)	3.31 (NR)	0.66 (NR)
Hannula, 2011[52]	Do you have any difficulty with your hearing? "Yes" response	PTA ≥20 dB at 4, 6, and 8 kHz in worse ear: NR	850	40 (36 to 43)	85 (77 to 91)	2.67 (NR)	0.71 (NR)
Lee, 2010[56]	Self-reported HL Endorsement of HL in questionnaire	PTA >40 dB at 0.5, 1, 2, and 4 kHz: 34.2%	912	84.3 (80 to 88)	48 (44 to 52)	1.62 (1.60 to 1.63)	0.33 (0.31 to 0.34)
Nondahl, 1998[63]	Do you feel you have hearing loss? Yes response	PTA >25 dB at 0.5, 1, 2, and 4 kHz in worse ear: NR	3342	71 (69 to 73)	71 (68 to 74)	2.45 (2.43 to 2.47)	0.41 (0.40 to 0.41)
Oosterloo, 2020[65]	Mild: All positive responses ("sometimes," "regularly," "often")	PTA ≥20 dB at 500, 1,000, 2,000, and 4,000 Hz in better ear: 52.6%	4,906	69.9 (68.1 to 71.6)	69.2 (67.3 to 71.1)	2.3 (2.27 to 2.28)	0.43 (0.43 to 0.44)
Oosterloo, 2020[65]	Moderate: "Regularly" and "often" responses	PTA ≥35 dB at 500, 1,000, 2,000, and 4,000 Hz in better ear: 19.8%	4,906	54.8 (51.6 to 57.9)	91.4 (90.4 to 92.2)	6.34 (6.28 to 6.39)	0.50 (0.49 to 0.50)
Rawool, 2008[66]	Do you think you have a hearing loss? An affirmative response to the question	PTA >25 dB at 0.5, 1, 2, 3, and 4 kHz in better ear: 63%	30	68 (46 to 85)	82 (52 to 95)	3.8 (1.3 to 10.8)	0.39 (0.27 to 0.56)
Sindhusake, 2001[70]	Do you feel you have hearing loss? An affirmative response to the question	PTA >25 dB at 0.5, 1, 2, and 4 kHz in better ear: 39.1%	1931	78 (75 to 81)	67 (64 to 70)	2.36 (2.34 to 2.38)	0.33 (0.32 to 0.33)
Sindhusake, 2001[70]	Do you feel you have hearing loss? An affirmative response to the question	PTA >40 dB at 0.5, 1, 2, and 4 kHz in better ear: 13.4%	1931	93 (89 to 96)	56 (53 to 58)	2.11 (2.10 to 2.12)	0.13 (0.11 to 0.14)
Swanepoel, 2013[72]	Do you have a hearing impairment? An affirmative response to the question	PTA >25 dB at 0.5, 1, 2, and 4 kHz in worse ear: 14.3%	947	59 (51 to 67)	90 (88 to 92)	5.9 (5.7 to 6.2)	0.45 (0.44 to 0.47)

Appendix E Table 1. Detailed Evidence Table of Single-Question Test Accuracy

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Swanepoel, 2013[72]	Do you have a hearing impairment? An affirmative response to the question	PTA >35 dB at 4 and 8 kHz in worse ear: 32.0%	947	40 (35 to 45)	94 (92 to 96)	6.6 (6.1 to 7.1)	0.64 (0.63 to 0.65)
Swanepoel, 2013[72]	Do you have a hearing impairment? An affirmative response to the question	PTA >40 dB at 0.5, 1, 2, and 4 kHz binaurally: 2.1%	947	90 (70 to 97)	85 (83 to 87)	6.0 (5.8 to 6.2)	0.12 (0.04 to 0.31)
Swanepoel, 2013[72]	Do you have a hearing impairment? An affirmative response to the question	4F PTA >25 dB at 0.5, 1, 2, and 4 kHz in better ear: 5.9%	947	68 (55 to 79)	87 (85 to 89)	5.2 (5.0 to 5.4)	0.37 (0.33 to 0.41)
Tomioka, 2013[73]	Do you feel you have a hearing loss? "Yes" response	PTA >25 dB at 0.5, 1, 2, and 4 kHz in better ear: NR	1,731	54 (NR)	78 (NR)	2.5 (1.6 to 3.8)	0.6 (0.5 to 0.7)
Tomioka, 2013[73]	Do you feel you have a hearing loss? "Yes" response	PTA >40 at 0.5, 1, 2, and 4 kHz in better ear: NR	1,731	88 (NR)	69 (NR)	2.8 (2.2 to 3.6)	0.2 (0.1 to 0.4)
Torre, 2006[74]	Do you feel you have a hearing loss? (Spanish) An affirmative response to the question	PTA >25 dB at 0.5, 1, 2, and 4 kHz in worse ear: 62.7%	59	76 (60 to 87)	73 (52 to 87)	2.78 (1.96 to 3.93)	0.33 (0.26 to 0.44)
Voeks, 1993[76]	Do you have trouble hearing? An affirmative or equivocal response to the question	PTA >25 dB at 0.5, 1, and 2 kHz in better ear: 54%	198	69 (60 to 77)	51 (40 to 61)	1.4 (1.32 to 1.48)	0.61 (0.55 to 0.68)

Abbreviations: 4F=four-frequency; CI=confidence interval; HL=hearing loss; KQ=key question; N=number of patients; NLR=negative likelihood ratio; NR=not reported; PLR=positive likelihood ratio; PTA=pure tone average.

Appendix E Table 2. Detailed Evidence Table of Questionnaire Screening Test Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Gates, 2003[51]	HHIE-S Score >8	PTA ≥40 dB at 1 and 2 kHz in one ear or 1 or 2 kHz in both ears: 27%	546	36 (29 to 44)	92 (89 to 94)	4.5 (4.0 to 5.1)	0.69 (0.68 to 0.71)
Lichtenstein, 1988[57]	HHIE-S Score >8	PTA ≥40 dB at 1 and 2 kHz in one ear or 1 or 2 kHz in both ears: 30%	178	76 (62 to 85)	71 (63 to 78)	2.6 (2.4 to 2.8)	0.34 (0.29 to 0.40)
McBride, 1994[61]	HHIE-S Score >8	PTA: >25 dB at 0.5, 1, 2 kHz in better ear: NR	185	58 (45 to 70)	76 (69 to 84)	2.42 (1.65 to 3.54)	0.55 (NR)
McBride, 1994[61]	HHIE-S Score >8	PTA: >25 at 1, 2, 4 kHz in better ear: NR	185	48 (39 to 58)	86 (79 to 94)	3.60 (1.96 to 6.61)	0.60 (NR)
McBride, 1994[61]	HHIE-S Score >8	PTA ≥40 dB in both ears at 1 or 2 kHz or 1 and 2 kHz Hz in one ear: NR	185	63 (49 to 76)	75 (68 to 82)	2.52 (1.75 to 3.63)	0.49 (NR)
Nondahl, 1998[63]; Wiley, 2000[64]	HHIE-S Score >8	PTA >25 dB at 0.5, 1, 2, 4 kHz in worse ear: 31.6%	3471	34 (31 to 37)	95 (94 to 96)	6.8 (6.6 to 7.0)	0.69 (0.69 to 0.70)
Sever, 1989[69]	HHIE-S Score ≥10	PTA ≥25 dB at 0.5, 1, 2 in better ear kHz: 36%	59	71 (50 to 86)	61 (45 to 74)	1.81 (1.51 to 2.17)	0.47 (0.32 to 0.69)
Sever, 1989[69]	HHIE-S Score ≥10	PTA ≥40 dB in one ear at 1 and 2 kHz or 1 or 2 kHz in both ears: 27%	59	81 (57 to 93)	56 (41 to 70)	1.84 (1.6 to 2.11)	0.34 (0.16 to 0.69)
Sindhusake, 2001[70]	HHIE-S Score >8	PTA >25 dB at 0.5, 1, 2, 4 kHz in better ear: 39.1%;	1807	58 (53 to 61)	85 (83 to 87)	3.87 (3.82 to 3.93)	0.49 (0.49 to 0.50)
Sindhusake, 2001[70]	HHIE-S Score >8	PTA >40 dB at 0.5, 1, 2, 4 kHz in better ear: 13.4%	1807	80 (74 to 85)	76 (73 to 78)	3.34 (3.31 to 3.34)	0.26 (0.25 to 0.27)
Tomioka, 2013[73]	HHIE-S Score >8	PTA >25 dB at 0.5, 1, 2, 4 kHz in better ear: NR	1,731	44 (NR)	85 (NR)	2.9 (1.6 to 4.9)	0.7 (0.6 to 0.8)
Tomioka, 2013[73]	HHIE-S Score >8	PTA >40 dB at 0.5, 1, 2, 4 kHz in better ear: NR	1,731	82 (NR)	78 (NR)	3.6 (2.6 to 5.0)	0.2 (0.1 to 0.5)
Ventry & Weinstein, 1983[75]	HHIE-S Score >8	PTA ≥40 dB at 1 or 2 kHz in each ear: 41%	104	72 (57 to 83)	66 (53 to 76)	2.1 (1.9 to 2.4)	0.43 (0.35 to 0.51)
Bonetti, 2018[47]	HSAQ Score ≥15	PTA >25 dB at 0.5, 1, 2 kHz in better ear: 28.6%	112	100 (89 to 100)	75 (64 to 84)	4 (2.7 to 5.9)	0.00
Bonetti, 2018[47]	HSAQ Score ≥19	PTA >25 dB at 0.5, 1, 2 kHz in better ear: 28.6%	112	100 (89 to 100)	88 (78 to 94)	8 (4.5 to 14.3)	0.00
Bonetti, 2018[47]	HSAQ Score ≥15	PTA >25 dB at 0.5, 1, 2, 4 kHz in better ear: 49.1%	112	89 (78 to 96)	84 (72 to 92)	5.6 (3.1 to 10.4)	0.13 (0.06 to 0.28)

Appendix E Table 2. Detailed Evidence Table of Questionnaire Screening Test Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Bonetti, 2018[47]	HSAQ Score ≥19	PTA >25 dB at 0.5, 1, 2, 4 kHz in better ear: 49.1%	112	76 (63 to 87)	96 (88 to 100)	21.8 (5.5 to 85.6)	0.24 (0.15 to 0.39)
Bonetti, 2018[47]	HSAQ Score ≥15	PTA >25 at, 1, 2, 4 kHz in better ear: 49.1%	112	93 (82 to 98)	88 (76 to 95)	7.6 (3.8 to 15.2)	0.08 (0.03 to 0.21)
Bonetti, 2018[47]	HSAQ Score ≥19	PTA >25 at 1, 2, 4 kHz in better ear: 49.1%	112	75 (62 to 85)	95 (85 to 99)	14.2 (4.7 to 43.1)	0.27 (0.17 to 0.42)
Koike, 1994[54]	Revised Five Minute Hearing Test Score >15	PTA >25 dB at 0.5, 1, 2 kHz: NR	74	80 (NR)	55 (NR)	1.8 (NR)	0.36 (NR)

Abbreviations: CI=confidence interval; HHIE-S=Hearing Handicap Inventory for the Elderly-Screening version; HSAQ=Hearing Self-Assessment Questionnaire; KQ=key question; N=number of patients; NLR=negative likelihood ratio; NR=not reported; PLR=positive likelihood ratio; PTA=pure tone average.

Appendix E Table 3. Detailed Evidence Table of Clinical Test Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Boatman, 2007[46]	WVT at 2 feet Inability to repeat 2 or more words from two 3-word combinations	PTA >25 dB at 0.5, 1, 2, and 4 kHz in either ear: NR	107 (214 ears)	27 (19 to 37)	89 (66 to 97)	2.45 (NR)	0.82 (NR)
Boatman, 2007[46]	WVT at 2 feet Inability to repeat 2 or more words from two 3-word combinations	PTA >40 dB at 0.5, 1, 2, and 4 kHz in either ear: NR	107 (214 ears)	46 (36 to 56)	78 (68 to 86)	2.09 (NR)	0.69 (NR)
Eekhof, 1996[49]	WVT at 2 feet Inability to repeat 2 or more combinations correctly	PTA >30 dB in either ear: 59%)	62 (124 ears)	90 (82 to 95)	80 (67 to 89)	4.6 (3.8 to 5.6)	0.12 (0.09 to 0.16)
Lycke, 2016[58]	WVT at 6 in. and 2 ft .and Conversational voice at 6 in. and 6 ft. Could not repeat all 3 numbers correctly at each level of loudness or <50% success over 3 successive triplets per ear	PTA ≥40 dB at 0.5, 1, and 2 kHz in either ear: 15.4%	65 ears	30 (8 to 65)	100 (92 to 100)	Undefined	0.70 (0.53 to 0.93)
Macphee, 1988[60]	WVT at 2 ft. Inability to repeat all 3 numbers or ≤50% of 3 triplet sets of numbers	PTA >30 dB at 0.5, 1, and 2 kHz: 61%	62 (124 ears)	100 (95 to 100)	84 (70 to 91)	6.0 (4.7 to 7.7)	0.00
Macphee, 1988[60]	WVT at 6 in. Inability to repeat all 3 numbers or ≤50% of 3 triplet sets of numbers	PTA >30 dB at 0.5, 1, and 2 kHz: 61%	62 (124 ears)	73 (62 to 82)	100 (93 to 100)	Undefined	0.27 (0.24 to 0.29)
Macphee, 1988[60]	Conversational voice at 2 ft Inability to repeat all 3 numbers or ≤50% of 3 triplet sets of numbers	PTA >30 dB at 0.5, 1, and 2 kHz: 61%	62 (124 ears)	47 (36 to 58)	100 (93 to 100)	Undefined	0.53 (0.50 to 0.55)
McShefferty, 2013[62]	WVT delivered by older experienced whisperers >50% correct identification of digit sequences provided	PTA >29 dB at 0.5, 1, and 2 kHz in either ear: 53%*	73 subjects (112 ears analyzed)	23 (21 to 25)	98 (97 to 99)	11.5 (NR)	0.79 (NR)
McShefferty, 2013[62]	WVT delivered by younger inexperienced whisperers >50% correct identification of digit sequences provided	PTA >29 dB at 0.5, 1, and 2 kHz in either ear: 53%[a]	73 subjects (112 ears analyzed)	80 (78 to 82)	52 (50 to 55)	1.7 (NR)	0.38 (NR)

Appendix E Table 3. Detailed Evidence Table of Clinical Test Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
McShefferty, 2013[62]	WVT delivered by older experienced whisperers >50% correct identification of digit sequences provided	PTA >40 dB at 0.5, 1, and 2 kHz in either ear: NR	73 subjects (112 ears analyzed)	63 (58 to 68)	93 (92 to 94)	9 (NR)	0.4 (NR)
McShefferty, 2013[62]	WVT delivered by younger inexperienced whisperers >50% correct identification of digit sequences provided	PTA >40 dB at 0.5, 1, and 2 kHz in either ear: NR	73 subjects (112 ears analyzed)	87 (83 to 90)	38 (37 to 40)	1.4 (NR)	0.34 (NR)
McShefferty, 2013[62]	WVT delivered by older experienced whisperers >50% correct identification of digit sequences provided	PTA >30 dB at 0.5, 1, 2, and 4 kHz in either ear: NR	73 subjects (112 ears analyzed)	19 (18 to 21)	100 (99 to 100)	Undefined	0.81 (NR)
McShefferty, 2013[62]	WVT delivered by younger inexperienced whisperers >50% correct identification of digit sequences provided	PTA >30 dB at 0.5, 1, 2, and 4 kHz in either ear: NR	73 subjects (112 ears analyzed)	80 (78 to 81)	65 (62 to 68)	2.29 (NR)	0.31 (NR)
McShefferty, 2013[62]	WVT delivered by older experienced whisperers >50% correct identification of digit sequences provided	PTA >43 dB at 0.5, 1, 2, and 4 kHz in either ear: NR	73 subjects (112 ears analyzed)	56 (52 to 60)	98 (97 to 99)	28 (NR)	0.45 (NR)
McShefferty, 2013[62]	WVT delivered by younger inexperienced whisperers >50% correct identification of digit sequences provided	PTA >43 dB at 0.5, 1, 2, and 4 kHz in either ear: NR	73 subjects (112 ears analyzed)	97 (95 to 98)	44 (42 to 46)	1.73 (NR)	0.07 (NR)
Swan, 1985[71]	WVT at 2 ft. Unable to correctly repeat at least 3 out of 6 letters or numerals that were whispered by the examiner	PTA >30 dB at 0.5, 1, and 2 kHz in either ear: 43% (87/202)	101 (202 ears)	100 (96 to 100)	87 (80 to 92)	7.7 (6.7 to 8.7)	0
Boatman, 2007[46]	Watch tick at 6 in. No response to 2 or more of 6 presentations of watch tick	PTA >25 dB at 0.5, 1, 2, and 4 kHz in either ear: 63%	107 (214 ears)	44 (35–53)	100 (NR)	Undefined	0.56 (NR)
Boatman, 2007[46]	Watch tick at 6 in. No response to 2 or more of 6 presentations of watch tick	PTA >40 dB at 0.5, 1, 2, and 4 kHz in either ear: 63%	107 (214 ears)	60 (50 to 69)	99 (92 to 100)	60 (NR)	0.40 (NR)
Boatman, 2007[46]	Finger rub at 6 in. No response to 2 or more of 6 finger rubs	PTA >25 dB at 0.5, 1, 2, and 4 kHz in either ear: 63%	107 (214 ears)	27 (20–36)	98 (85 to 100)	13.5 (NR)	0.74 (NR)

Appendix E Table 3. Detailed Evidence Table of Clinical Test Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Boatman, 2007[46]	Finger rub at 6 in. No response to 2 or more of 6 finger rubs	PTA >40 dB at 0.5, 1, 2, and 4 kHz in either ear: 63%	107 (214 ears)	35 (26 to 46)	97 (90 to 99)	11.67 (NR)	0.67 (NR)
Koole, 2016[55]	DIN test SRT of -5 dB SNR (average of the last 20 of 24-digit triplets)	PTA ≥20 dB at 0.5, 1, 2, and 4 kHz in better ear: 46.1%	3327	79 (77 to 81)	76 (74 to 78)	3.29 (3.28 to 3.31)	0.28 (0.27 to 0.28)
Koole, 2016[55]	DIN test SRT of -4 dB SNR (average of the last 20 of 24-digit triplets)	PTA ≥20 dB at 0.5, 1, 2, and 4 kHz in better ear: 46.1%	3327	65 (63 to 67)	92 (91 to 93)	8.1 (8.0 to 8.3)	0.38 (0.38 to 0.38)
Koole, 2016[55]	DIN test SRT of -3 dB SNR (average of the last 20 of 24-digit triplets)	PTA ≥20 dB at 0.5, 1, 2, and 4 kHz in better ear: 46.1%	3327	53 (50 to 56)	97 (96 to 98)	17.6 (16.9 to 18.3)	0.48 (0.48 to 0.49)
Koole, 2016[55]	DIN test SRT of -2 dB SNR (average of the last 20 of 24-digit triplets)	PTA ≥20 dB at 0.5, 1, 2, and 4 kHz in better ear: 46.1%	3327	42 (40 to 44)	98 (97 to 99)	20.9 (19.7 to 22.2)	0.59 (0.59 to 0.59)
Koole, 2016[55]	DIN test SRT of -5 dB, -4 dB, -3 dB, or -2 dB SNR (average of the last 20 of 24-digit triplets)	PTA ≥35 dB at 0.5, 1, 2, and 4 kHz in better ear: 10.4%	3327	99 (98 to 100)	61 (59 to 63)	2.54 (2.54 to 2.55)	0.01 (0.01 to 0.03)
Koole, 2016[55]	DIN test SRT of -5 dB, -4 dB, -3 dB, or -2 dB SNR (average of the last 20 of 24-digit triplets)	PTA ≥35 dB at 0.5, 1, 2, and 4 kHz in better ear: 10.4%	3327	99 (98 to 100)	75 (73 to 77)	3.97 (3.96 to 3.98)	0.01 (0.01 to 0.02)
Koole, 2016[55]	DIN test SRT of -5 dB, -4 dB, -3 dB, or -2 dB SNR (average of the last 20 of 24-digit triplets)	PTA ≥35 dB at 0.5, 1, 2, and 4 kHz in better ear: 10.4%	3327	99 (98 to 100)	84 (83 to 85)	6.2 (6.17 to 6.22)	0.01 (0.01 to 0.02)
Koole, 2016[55]	DIN test SRT of -5 dB, -4 dB, -3 dB, or -2 dB SNR (average of the last 20 of 24-digit triplets)	PTA ear ≥35 dB at 0.5, 1, 2, and 4 kHz in better ear: 10.4%	3327	95 (92 to 97)	90 (89 to 91)	9.51 (9.45 to 9.58)	0.05 (0.05 to 0.06)

Appendix E Table 3. Detailed Evidence Table of Clinical Test Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Watson, 2012[77]	Telephone DIN test SNR >-5.7 dB (need evaluation)	PTA >20 dB at 0.5, 1, 2, and 4 kHz: 54.4%	90	80 (66 to 88)	83 (69 to 92)	4.66 (3.48 to 6.25)	0.25 (0.20 to 0.30)
Watson, 2012[77]	Telephone DIN test SNR <-7.4 dB (within normal range)	PTA >20 dB at 0.5, 1, 2, and 4 kHz: 54.4%	90	94 (84 to 98)	37 (24 to 52)	1.48 (1.37 to 1.60)	0.17 (0.07 to 0.40)
Williams-Sanchez, 2014[79]	U.S. NHT (3-digit telephone test) SNR of -5.9 dB or worse (higher)	PTA >25 dB at 0.5, 1, and 2 kHz: 58.4% ears	693 subjects (1379 ears)	87 (85 to 90)	54 (50 to 58)	1.89 (1.88 to 1.91)	0.23 (0.23 to 0.24)
Williams-Sanchez, 2014[79]	U.S. NHT (3-digit telephone test) SNR of -5.9 dB or worse (higher)	PTA >25 dB at 0.5, 1, 2, and 4 kHz: 76.2% ears	693 subjects (1379 ears)	81 (79 to 84)	65 (60 to 70)	2.32 (2.28 to 2.36)	0.29 (0.28 to 0.29)
Williams-Sanchez, 2014[79]	WIN test SNR of -5.9 dB or worse (higher)	PTA >25 dB at 0.5, 1, and 2 kHz: 58.4% ears	1049 ears	98 (97 to 99)	24 (20 to 28)	1.3 (1.29 to 1.3)	0.08 (0.06 to 0.10)
Williams-Sanchez, 2014[79]	WIN test SNR of -5.9 dB or worse (higher)	4-Freq PTA >25 dB at 0.5, 1, 2, and 4 kHz: 76.2% ears	1049 ears	97 (96 to 98)	46 (39 to 52)	1.79 (1.77 to 1.83)	0.06 (0.05 to 0.06)

Abbreviations: CI=confidence interval; DIN=Digits-in-Noise; N=number of patients; U.S. NHT=United States National Hearing Test; NLR=negative likelihood ratio; NR=not reported; PLR=positive likelihood ratio; PTA=pure tone average; SNR=signal-to-noise ratio; SRT=speech reception threshold; WIN=Words-In-Noise; WVT=whispered voice test.

* Note that prevalence is given for 3F PTA >30 dB and authors examined whispered voice against 3F PTA >29 dB.

Appendix E Table 4. Detailed Evidence Table of Handheld or Mobile-Based Device Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Bienvenue, 1985[45]	AudioScope Failure to hear 25 dB at 0.5, 1, 2, and 4 kHz	PTA ≥30 dB at 0.5, 1, 2, 4 kHz: NR	30	93 (NR)	70 (NR)	3.1 (NR)	0.10 (NR)
Ciurlia-Guy, 1993[48]	AudioScope Failure to hear 40 dB at 1 or 2 kHz in either ear	PTA >40 dB at 1 kHz in either ear: 69%	99	98 (NR)	24 (NR)	1.29 (NR)	0.08 (NR)
Eekhof, 1996[49]	AudioScope Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz using AudioScope	PTA >40 dB in either ear: 33%	62 (124 ears)	100 (91 to 100)	42 (32 to 53)	1.74 (1.7 to 1.8)	0.00
Frank & Petersen, 1987[50]	AudioScope Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	50-59 years: 82 (146 ears)	90 (NR)	94 (NR)	15.5 (NR)	0.11 (NR)
Frank & Petersen, 1987[50]	AudioScope Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	60-69 years: 84 (146 ears)	89 (NR)	90 (NR)	9.2 (NR)	0.12 (NR)
Frank & Petersen, 1987[50]	AudioScope Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	70-79: 94 (158 ears)	85 (NR)	90 (NR)	8.7 (NR)	0.17 (NR)
Frank & Petersen, 1987[50]	AudioScope Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	80-89: 73 (125 ears)	86 (NR)	89 (NR)	8.1 (NR)	0.16 (NR)
Frank & Petersen, 1987[50]	AudioScope Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	90-96 years: 72 (102 ears)	86 (NR)	91 (NR)	9.1 (NR)	0.15 (NR)
Lichtenstein, 1988[57]	AudioScope Failure to hear 40 dB at 1 or 2 kHz in both ears or 40 dB loss at 1 and 2 kHz in one ear	PTA ≥40 dB in one ear at 1 and 2 kHz or 1 or 2 kHz in both ears: 30%	178	94 (85 to 98)	72 (64 to 79)	3.4 (3.2 to 3.6)	0.08 (0.04 to 0.15)
McBride, 1994[61]	AudioScope Failure to hear 40 dB at 2 kHz in better ear	PTA >25 dB at 0.5, 1, 2 kHz in better ear: NR	185	64 (52 to 77)	89 (83 to 94)	5.79 (3.42 to 9.84)	0.40 (NR)

Appendix E Table 4. Detailed Evidence Table of Handheld or Mobile-Based Device Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
McBride, 1994[61]	AudioScope Failure to hear 40 dB at 2 kHz in better ear	PTA >25 dB at 1, 2, 4 kHz in better ear: NR	185	71 (63 to 80)	91 (84 to 97)	7.52 (3.68 to 15.38)	0.32 (NR)
McBride, 1994[61]	AudioScope Failure to hear 40 dB at 2 kHz in better ear	PTA >40 dB at 1 or 2 kHz in both ears or 1 and 2 kHz in one ear: NR	185	96 (90 to 100)	80 (74 to 87)	4.86 (3.45 to 6.85)	0.05 (NR)
Frank & Petersen, 1987[50]	Pure-tone audiometer screener Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	50-59 years: 82 (146 ears)	94 (NR)	93 (NR)	13.4 (NR)	0.06 (NR)
Frank & Petersen, 1987[50]	Pure-tone audiometer screener Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	60-69 years: 84 (146 ears)	90 (NR)	94 (NR)	15.6 (NR)	0.11 (NR)
Frank & Petersen, 1987[50]	Pure-tone audiometer screener Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	70-79 years: 94 (158 ears)	90 (NR)	92 (NR)	10.6 (NR)	0.11 (NR)
Frank & Petersen, 1987[50]	Pure-tone audiometer screener Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	80-89 years: 73 (125 ears)	90 (NR)	90 (NR)	9.2 (NR)	0.11 (NR)
Frank & Petersen, 1987[50]	Pure-tone audiometer screener Failure to hear 40 dB at 0.5, 1, 2, and 4 kHz	PTA ≥45 dB at 0.5, 1, 2, 4 kHz: NR	90-96 years: 72 (102 ears)	88 (NR)	93 (NR)	11.8 (NR)	0.13 (NR)
Kelly, 2018[53]	EarTrumpet app Failure to hear >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear **in clinic waiting area**	PTA >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear: 53%	35	100 (NR)	72 (NR)	NR	NR
Kelly, 2018[53]	EarTrumpet app Failure to hear >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear **in quiet exam room**	PTA >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear: 53%	35	96.3 (NR)	83.1 (NR)	NR	NR

Appendix E Table 4. Detailed Evidence Table of Handheld or Mobile-Based Device Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Kelly, 2018[53]	Audiogram Mobile app Failure to hear >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear **in clinic waiting area**	PTA >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear: 53%	37	87.6 (NR)	92.3 (NR)	NR	NR
Kelly, 2018[53]	Audiogram Mobile app Failure to hear >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear **in quiet exam room**	PTA >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear: 53%	37	85.3 (NR)	95.1 (NR)	NR	NR
Kelly, 2018[53]	Hearing Test with Audiogram app Failure to hear >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear **in clinic waiting area**	PTA >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear: 53%	35	89 (NR)	68.2 (NR)	NR	NR
Kelly, 2018[53]	Hearing Test with Audiogram app Failure to hear >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear **in quiet exam room**	PTA >20 dB at 0.25, 0.5, 1, 2, 4, 6, or 8 kHz in either ear: 53%	35	87.8 (NR)	69.4 (NR)	NR	NR
Lycke, 2016[58]	uHear Lowest threshold with two responses out of three excursions recorded as hearing sensitivity; used PTA >40 dB	PTA ≥40 dB at 0.5, 1, 2, kHz in either ear: 15.4%	33 (65 ears)	100 (66 to 100)	36 (24 to 51)	1.57 (1.49 to 1.66)	0.00
Lycke, 2018[59]	Modified Handzel-uHear™ screening ≥2 consecutive hearing grades starting from the moderate-severe threshold zone ranging from 0.5 to 2.0 kHz	PTA >40 dB at 0.5, 1, 2, kHz in either ear: 24.4%	45 (90 ears)	68 (45 to 86)	87 (76 to 94)	5.15 (3.9 to 6.8)	0.37 (0.28 to 0.49)

Appendix E Table 4. Detailed Evidence Table of Handheld or Mobile-Based Device Screening Accuracy (KQ 2)

Author, Year	Screening Test or Question Definition of a Positive Screening Test	Definition of a Case, and Proportion with Hearing Loss	Total N Analyzed	Sensitivity % (95% CI)	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Saliba, 2017[67]	EarTrumpet "consumer app" PTA >40 dB at 0.5, 1, 2, and 4 kHz	PTA >40 dB at 0.5, 1, 2, 4 kHz in each ear: 24% (16 ears)	33 (65 ears)	88 (64 to 97)	96 (86 to 99)	21.44 (7.89 to 58.27)	0.13 (0.05 to 0.35)
Saliba, 2017[67]	ShoeBox "professional app" PTA >40 dB at 0.5, 1, 2, and 4 kHz	PTA >40 dB at 0.5, 1, 2, 4 kHz in each ear: 24% (16 ears)	33 (65 ears)	100 (81 to 100)	96 (86 to 99)	24.5 (9.20 to 65.28)	0.00

Abbreviations: CI=confidence interval; KQ=key question; N=number of patients; NLR=negative likelihood ratio; NR=not reported; PLR=positive likelihood ratio; PTA=pure tone average.

Appendix F Figure 1. Summary Receiver Operating Characteristics Curve for Screening Test Accuracy of the Single Question for Detecting Mild Hearing Loss (20 to 25 dB)

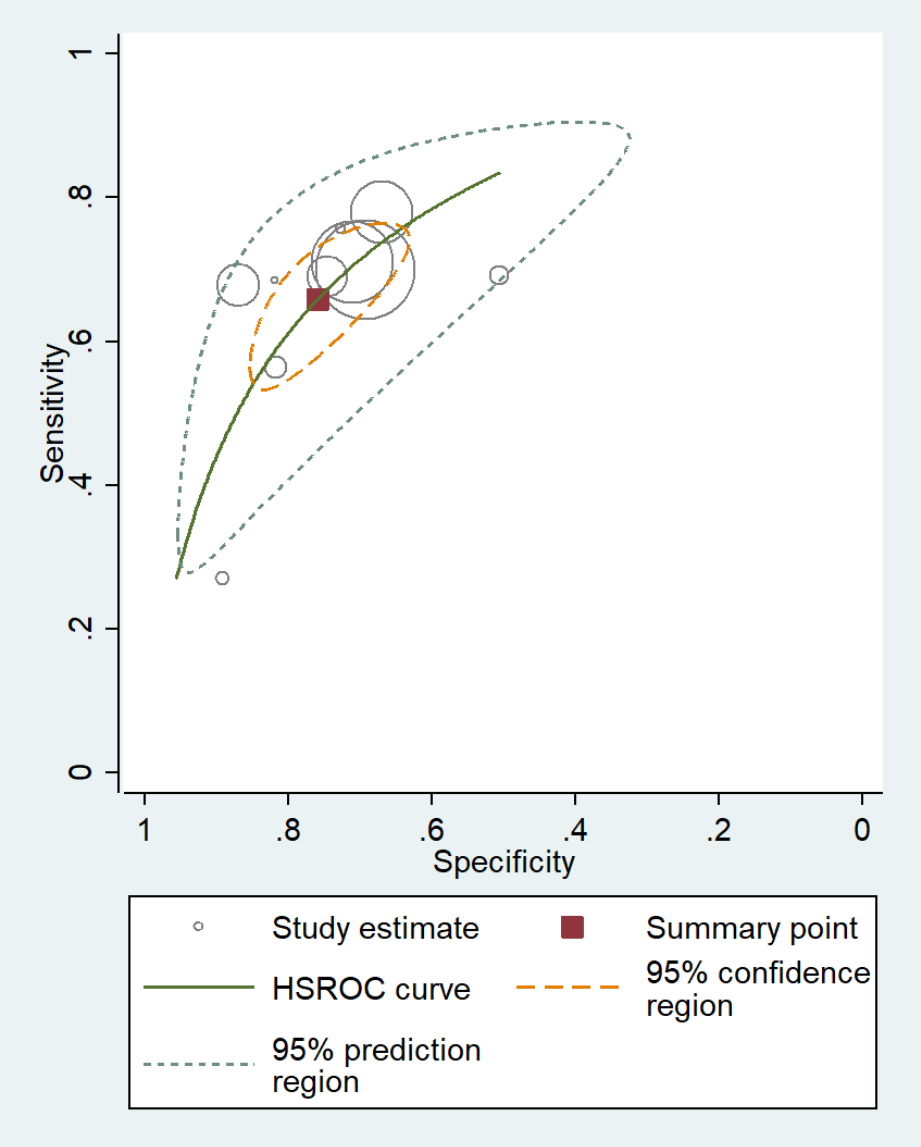

Figure Notes: The 95 percent confidence region provides a visual estimate of the amount of variation around the pooled estimate that is due to sampling variation (i.e., chance). It is the region within which we expect the true pooled summary point to lie. It can be used to assess precision of the pooled estimate. The smaller the region, the more precise the estimate. In this figure, precision of the estimates for specificity is higher compared with the precision of the estimates for sensitivity. The 95 percent prediction region provides a visual estimate of the between-study variability that cannot be attributed to chance. It is the region within which we expect any future individual study estimate to lie. It can be used to assess the consistency of study findings. The larger the prediction region is within the SROC space and relative to the size of the confidence region, the more inconsistency (i.e., heterogeneity) is present.

Abbreviations: HSROC=hierarchical summary receiver operating characteristic; SROC=summary receiver operating characteristic.

Appendix F Figure 2. Summary Receiver Operating Characteristics Curve for Screening Test Accuracy of the Single Question for Detecting Moderate Hearing Loss (at 35 to 40 dB)

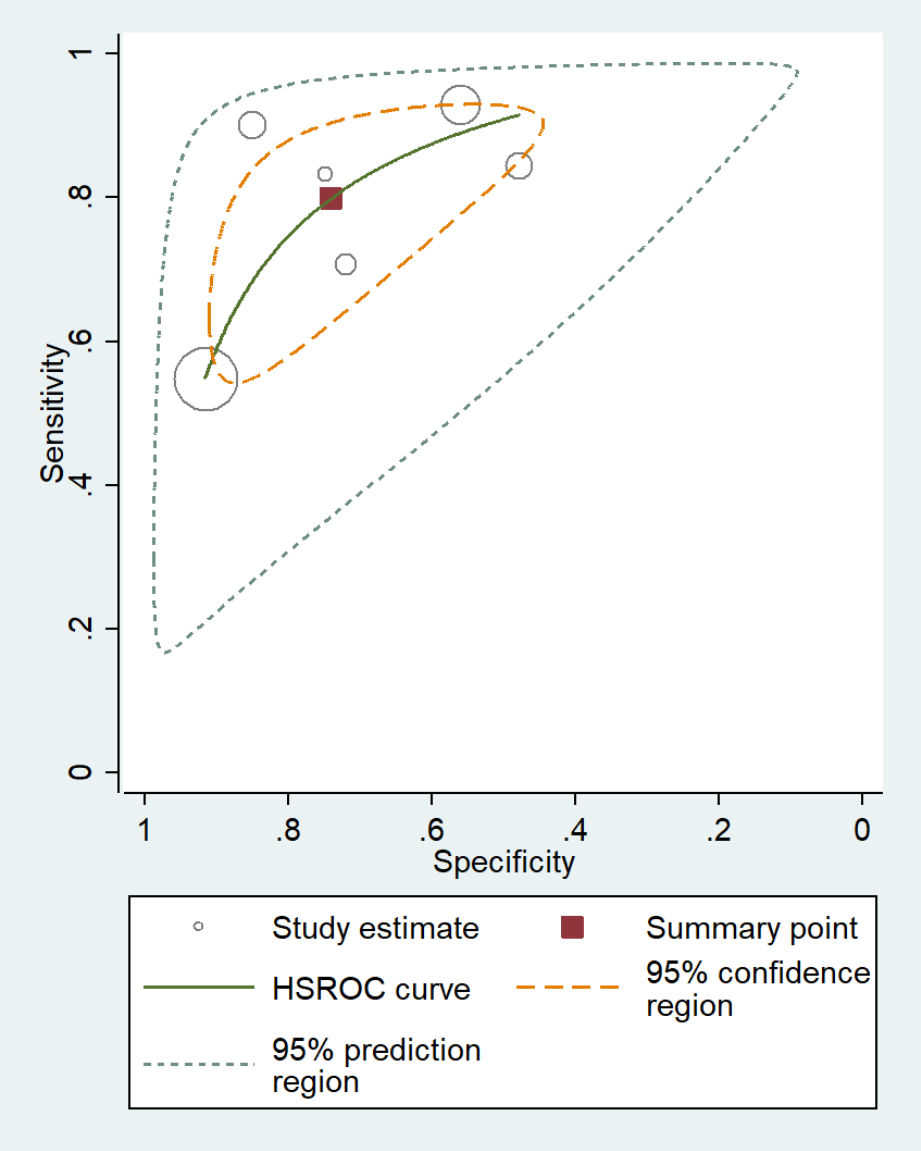

Figure Notes: The 95 percent confidence region provides a visual estimate of the amount of variation around the pooled estimate that is due to sampling variation (i.e., chance). It is the region within which we expect the true pooled summary point to lie. It can be used to assess precision of the pooled estimate. The smaller the region, the more precise the estimate. In this figure, precision of the estimates for specificity is higher compared with the precision of the estimates for sensitivity. The 95 percent prediction region provides a visual estimate of the between-study variability that cannot be attributed to chance. It is the region within which we expect any future individual study estimate to lie. It can be used to assess the consistency of study findings. The larger the prediction region is within the SROC space and relative to the size of the confidence region, the more inconsistency (i.e., heterogeneity) is present.

Abbreviations: HSROC=hierarchical summary receiver operating characteristic; SROC=summary receiver operating characteristic.

Appendix F Figure 3. Summary Receiver Operating Characteristics Curve for Screening Test Accuracy of HHIE-S for Detecting Moderate Hearing Loss (at 40 dB)

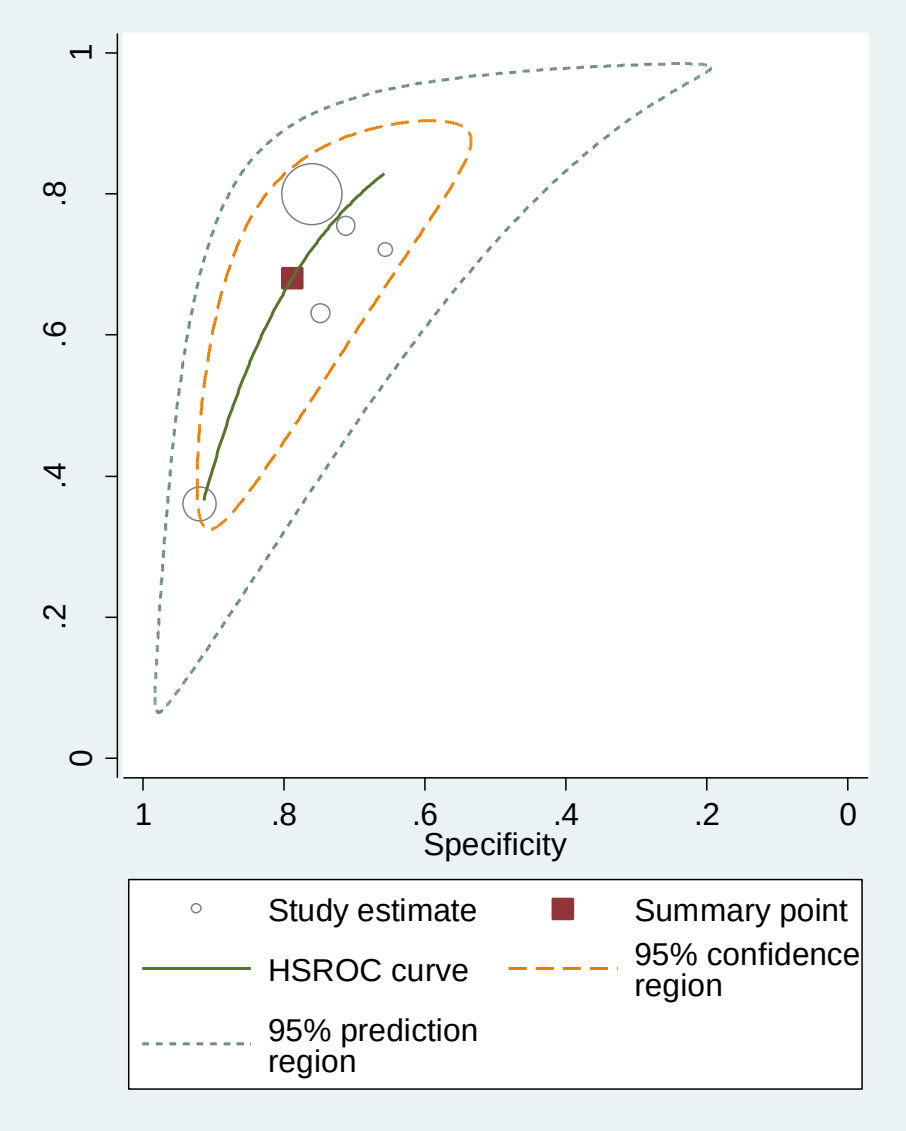

Figure Notes: The 95 percent confidence region provides a visual estimate of the amount of variation around the pooled estimate that is due to sampling variation (i.e., chance). It is the region within which we expect the true pooled summary point to lie. It can be used to assess precision of the pooled estimate. The smaller the region, the more precise the estimate. In this figure, precision of the estimates for specificity is higher compared with the precision of the estimates for sensitivity. The 95 percent prediction region provides a visual estimate of the between-study variability that cannot be attributed to chance. It is the region within which we expect any future individual study estimate to lie. It can be used to assess the consistency of study findings. The larger the prediction region is within the SROC space and relative to the size of the confidence region, the more inconsistency (i.e., heterogeneity) is present.

Abbreviations: HHIE-S=Hearing Handicap Inventory-Screening Version; HSROC=hierarchical summary receiver operating characteristic; SROC=summary receiver operating characteristic.

Appendix F Figure 4. Summary Receiver Operating Characteristics Curve for Screening Test Accuracy of the Whispered Voice Test for Detecting Mild Hearing Loss (at 25 to 30 dB)

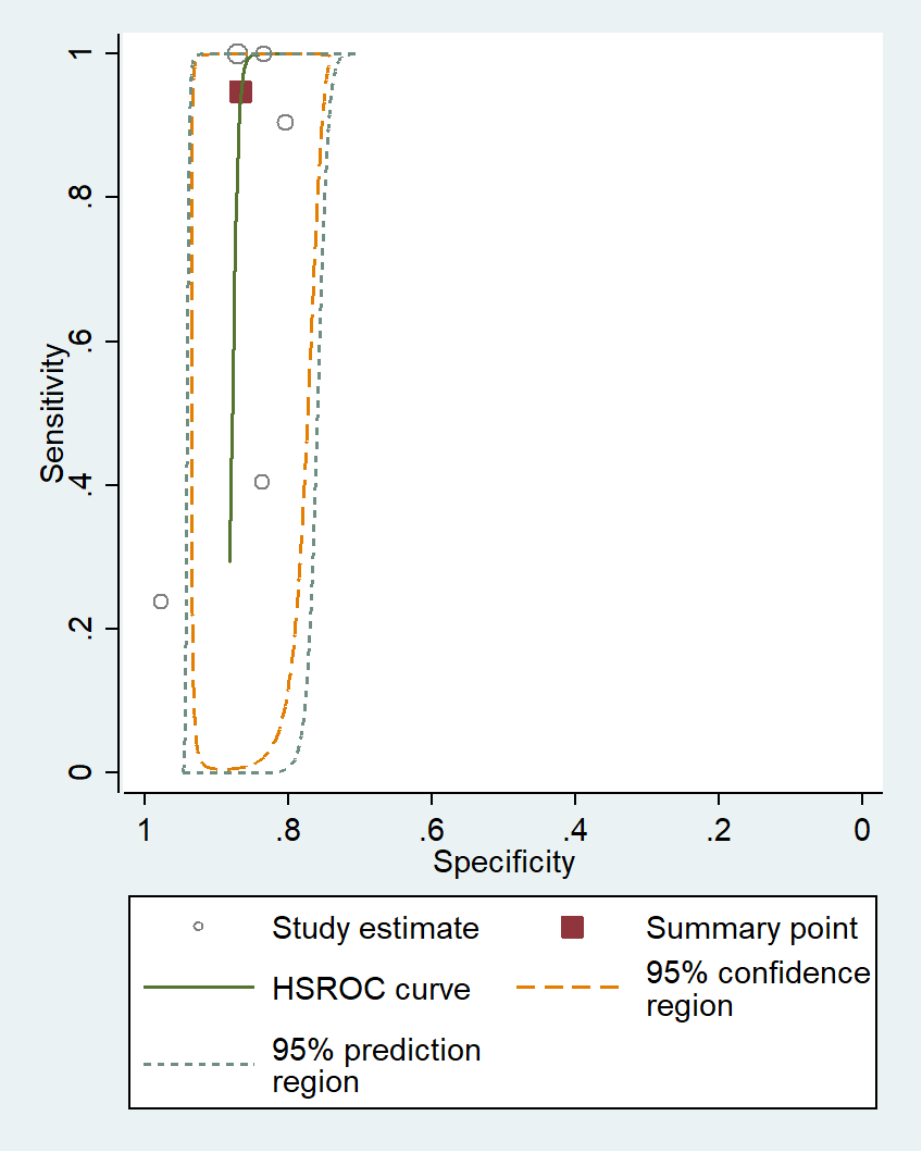

Figure Notes:
* The 95 percent confidence region provides a visual estimate of the amount of variation around the pooled estimate that is due to sampling variation (i.e., chance). It is the region within which we expect the true pooled summary point to lie. It can be used to assess precision of the pooled estimate. The smaller the region, the more precise the estimate. In this figure, precision of the estimates for specificity is higher compared with the precision of the estimates for sensitivity. The 95 percent prediction region provides a visual estimate of the between-study variability that cannot be attributed to chance. It is the region within which we expect any future individual study estimate to lie. It can be used to assess the consistency of study findings. The larger the prediction region is within the SROC space and relative to the size of the confidence region, the more inconsistency (i.e., heterogeneity) is present.
† One study[62] included in this analysis measured the accuracy of the whispered voice test when applied by older experienced or younger inexperienced providers. For this analysis, only the inexperienced provider data were used. A sensitivity analysis was also done using experienced provider data instead, and the pooled sensitivity was slightly higher (96% [95% CI, 55% to 100%]) and specificity was slightly lower (79% [95% CI, 68% to 87%]).

Abbreviations: CI=confidence interval; HSROC=hierarchical summary receiver operating characteristic; SROC=summary receiver operating characteristic.

Appendix G. Description of Quality of Life or Function Measures

Outcome Measure	Description	Score Ranges and Interpretations	MCIDs
Affect Balance Scale[80]	A 10-item scale that measures global feelings toward one's present life by asking participants whether they have experienced 10 specific feelings (i.e., five positive and five negative feelings) in the past 2 weeks	Overall scores range from 0 to 5, with higher scores indicating more affect balance and, therefore, more desirable outcomes	Unclear
APHAB[81]	A 24-item questionnaire in which individuals report the amount of trouble they have with communication or noises in various everyday situations	Scored from 0 to 100, with higher scores indicating greater dysfunction	Improvement on all 3 subscales by ≥5 points
Brief Symptom Inventory[82]	A 58-item self-report inventory that measures emotional status by asking participants to determine the extent to which each item has been a "bother" in the past 2 weeks. Subscales of the scale address paranoia, irritability, anxiety, and interpersonal sensitivity.	Scored from 0 to 5, with higher scores indicating greater dysfunction	Unclear
Geriatric Depression Scale[83]	A 15-item self-report scale that assesses depression in older adults	Scored from 0 to 15, with higher scores indicating greater dysfunction	None established yet
HHIE[84]	A 25-item questionnaire that consists of 13 emotional and 12 social questions	Total scale scores range from 0 to 100, with higher scores indicating greater perceived difficulties	Change of ≥18.7 points
HHIE-S[85]	A 10-item self-administered questionnaire and screening version of the full HHIE that assesses the degree of social and emotional handicap associated with hearing loss and requires about 2 minutes to complete	Subscale scores range from 0 to 40, with higher scores indicating greater perceived difficulties	Change of ≥9 points
QDS[86]	A 25-item questionnaire that assesses perceived communication difficulties due to hearing loss	Scored from 0 to 100, with higher scores indicating greater dysfunction	Unclear
SELF[87]	A 54-item global scale that assesses six areas of functioning: physical disability (13 items), social satisfaction (6 items), symptoms of aging (13 items), depression (11 items), self-esteem (7 items), and personal control (4 items).	Scored from 54 to 216, with higher scores indicating greater dysfunction	Unclear
Short Portable Mental Status Questionnaire[88]	A 10-item clinician-administered scale that assesses cognitive function	Scored from 0 to 10, with higher scores indicating greater intellectual impairment	Unclear
WHO-DAS II[42]	A 36-item instrument that provides 6 domain scores—communication, mobility, self-care, interpersonal; life activities at home and work, and participation—and a total score. In the WHO-DAS II, if respondents do not work, only 32 items are administered, and the life activities score is based only on participation in home-related activities.	Raw scores are transformed into standardized scores ranging from 0 to 100, with 0 indicating the best health state and 100 indicating the poorest health state	None established yet

Abbreviations: APHAB=Abbreviated Profile of Hearing Aid Benefit; HHIE(-S)=Hearing Handicap Inventory for the Elderly(-Screening version); MCID=minimal clinically important difference; QDS=Quantified Denver Scale of Communication Function; SELF=Self-Evaluation of Life Function; WHO-DAS II=World Health Organization's Disability Assessment Scale II.

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