October 5, 2020

To: The U.S. Preventive Services Task Force

From: Kate Carr, President, Hearing Industries Association

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Re: Comments On the Draft Recommendation Statement For Hearing Loss in Older Adults: Screening

The Hearing Industries Association (HIA) appreciates this opportunity to comment on the U.S. Preventive Services Task Force (USPSTF) draft recommendation statement, “Hearing Loss in Older Adults: Screening.” HIA is the national organization of the manufacturers, suppliers and distributors of hearing aids, implants, assistive listening devices, component parts and power sources. Together, these companies produced the 4 million hearing aids that were purchased in the United States last year. Given the engagement of our members with hearing health professionals and consumers, HIA’s mission is to be a trusted voice on product innovation, patient safety and education, and public policy.

HIA appreciates the extensive effort that went into the review of the data available and acknowledges the current lack of specific evidence to support a recommendation for screening adults age 50 and older who do not show signs or symptoms of hearing loss. There is a need for additional data that would add to the extensive existing literature that demonstrates the importance of good hearing in overall health, quality of life, and active aging.

Identifying individuals with hearing loss can have positive long-term effects on social and emotional well-being and may help to reduce the impact of several comorbidities that have significant healthcare costs to society. Importantly, an evidenced-based rigorous hearing screening program can identify these individuals earlier and provide awareness of the hearing loss to both the patient and to the physician, potentially leading to better outcomes.

Background: Prevalence and Comorbidities

Approximately 38 million individuals in the United States have untreated hearing loss, which is associated with cognitive and functional decline and many comorbidities. Based on current aging population trends, the number of Americans with hearing loss is projected to increase to more than 73 million by 2060. Hearing loss has been associated with negative health outcomes, including cognitive decline, dementia, falls, depression, reduced quality of life, and an increased number of emergency department visits and hospitalizations.

In just 10 years, hearing loss has moved up from the eleventh spot to become the fourth leading cause of years lived with disability – ahead of even diabetes and dementia.
According to the 2017 Lancet Commission on dementia prevention, intervention, and care, there are nine behaviorally modifiable risk factors associated with dementia, the largest of which is hearing impairment. Of the original nine risk factors and including three newly added factors (2020), there are now 12 behaviorally modifiable risk factors associated with dementia prevention, accounting for approximately 40% of dementias globally. Of note, hearing impairment accounts for approximately 9% of the modifiable risk and the Lancet Commission recommends reducing noise-related hearing loss and treating hearing loss with the use of hearing aids.

Age-related hearing loss is the third leading cause of chronic disability in older adults and has been shown to be associated with redisposing cognitive impairment and dementia (Jafari, Kolb, Mohajerani). According to research, the likelihood of significant hearing loss (average PTA >25 dB HL) for people ages 60-80 years is approximately 25%, and 65% for those ages 70 years and older. A large body of evidence demonstrates that age-related hearing loss is detrimental to physical and mental health, cognition, independence, social interaction, and quality of life in the elderly and hearing loss can precipitate early landmarks of dementia and Alzheimer’s disease. Emerging evidence indicates that hearing intervention can delay the onset or reduce the rate of cognitive decline.

Additional studies, including the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study, are expected to further address the role and efficacy of hearing treatment in reducing cognitive decline in older adults.

As hearing loss progresses, it manifests via profound consequences on verbal communication and social, functional, and psychological well-being of the person. Hearing loss, depression, and anxiety are considered as the leading causes of disability worldwide and can promote the occurrence of one another. And hearing loss is associated with a multitude of health outcomes similar to those identified for depression, anxiety, and stress, such as increased risk of cognitive impairment and dementia, reduced quality of life, low level of activity, frailty, social isolation, and poor general health. Dysfunction in social communication can be seen in an individual’s inability in coping with stressful situations and managing personal, interpersonal, or geographic environments.

It is important to note the difference between hearing and listening as it is well-known that people with similar or identical hearing thresholds often have incredibly different abilities to comprehend, understand, or untangle sound into meaningful percepts. Further, speech recognition in quiet (SIQ) does not necessarily correlate with speech recognition in noise (SIN) and there is no constant or predictable relationship between SIQ and SIN. Of note, although approximately 38 million people in the United States have hearing loss as demonstrated on an audiogram, there are an additional 26 million people who have hearing difficulty and/or speech recognition in noise problems. Difficulty understanding speech in the presence of background noise is the most common complaint among those with hearing loss and listening difficulty.

**Economic Costs: Hearing Loss and Comorbidities**

The National Institutes of Health (NIH) has found that 78.5% of participants with insufficient or poor hearing suffered from at least one additional chronic condition, leading to increased health care costs in any given year. When hearing loss does occur, early diagnosis and intervention are crucial for avoiding the negative social, emotional, and health consequences described previously. Thus, hearing screenings should be a part of every wellness check or physical exam for older adults who are at risk of age-related hearing loss.
The following are the economic realities associated with hearing loss:

- Those with diagnosed hearing loss had 33\% higher health care costs than those without hearing loss\(^5\).
- For adults over age 60, untreated hearing loss was associated with $22,434 or 46\% higher total health care costs over a 10-year period (with similar trends at two and five years) compared with costs for those without hearing loss. Additionally, more inpatient stays and greater risk for hospital readmission within 30 days were associated with persons with untreated hearing loss\(^6\).
- Up to 30\% of adults with diabetes will experience hearing loss\(^7\). Annual estimated cost: $16,752 per person.
- Underactive thyroid causes hearing loss and the hearing loss may increase based on the severity of the disease. Annual estimated cost: $343 per person\(^8\).
- Chronic kidney disease patients exhibit a higher rate of hearing loss. Annual estimated cost: $20,432 per person\(^9\).
- Almost 80\% of people with heart disease experience hearing loss. Annual estimated cost: $18,953 per person\(^10\).
- People with hearing loss have up to a five times higher risk of dementia than patients with no hearing problems and a significantly higher percentage of Alzheimer’s than normally aging peers\(^11\). Annual estimated cost: $287,000 per person in the last five years of life; $305 billion nationwide in 2020.
- Individuals with progressive hearing loss experience significantly higher rates of falls, which result in broken hips, legs, arms, and other bones. People with a mild hearing loss are three times more likely to fall, compared to individuals with normal hearing. Annual estimated cost: $92-$30,000 per person depending on age and severity of hearing loss\(^12\).
- Hearing impairment for adults aged 76 to 85 was independently associated with increased anxiety. Hearing aid use indicated 15\% lower odds of anxiety\(^13\).
- Hearing loss was independently associated with increased hospitalization and burden on the health care system for individuals over the age of 70\(^14\).

The 2017 World Health Organization (WHO) report “Global costs of unaddressed hearing loss and cost-effectiveness of interventions” assessed the financial impacts associated with increased medical costs. This report clearly states that screening programs and early intervention of hearing loss through screening of newborns, schoolchildren, and adults over 50 years of age is found to be cost-effective.

Based on the available evidence and analysis, the WHO report made the following conclusions and recommendations:

- This initial analysis shows that unaddressed hearing loss poses substantial costs to the healthcare system and to the economy as a whole.
- Current estimates show that most global healthcare and education costs linked to hearing loss are incurred in low- and middle-income countries.
- Public health interventions for prevention and early identification of hearing loss are cost-effective.
- Provision of hearing devices is a cost-effective strategy, especially when used regularly and supported with rehabilitation services.
- Hearing loss must be addressed as a public health issue.
- There is a need for policymakers to allocate resources for, and plan strategically to promote, access to ear and hearing care.
- Public health strategies should address prevention, screening, and early intervention of hearing loss.
- Country-specific data on the cost of unaddressed hearing loss and cost-effectiveness of interventions should be gathered to strengthen available evidence.

**Lack of Randomized Controlled Trial Data**

The summary findings of the USPSTF draft recommendations cite a lack of randomized control trial (RCT) findings to support the use of hearing screening for adults aged 50 years and older. Specifically, the document states:

Several screening tests can adequately detect hearing loss in adults 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.

The Randomized Controlled Trial cited was the Screening for Auditory Impairment Which Hearing Assessment Test (SAI-WHAT) study conducted on 2,305 veterans aged 50 years and older, and reported 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.” While results from additional studies were cited, it appears that the primary recommendations are anchored by the results of the Yueh et al. (2010) RCT.

Sole reliance on this study raises several concerns:

- **Lack of demographic representation.** All 2,305 participants were veterans – 94% male, mostly white, with 74% indicating “self-perceived hearing loss”. This is not reflective of the overall population with hearing loss.
- **Age of screened individuals.** Again, the veteran population is likely to experience occupational noise-induced hearing loss disproportionate to the overall population, at a younger age overall. The Yueh et al. (2010) study’s use of study participants aged 50 years does not reflect the population overall.
- **Variation in clinical outcomes reported in the VA study.** Finally, the USPSTF report states that “There was no difference in the proportion of patients who experienced a minimum clinically important difference (>6 dB points of improvement on a 0 to 100 point 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 non-screened group; p=0.39).” In the original Yueh et al. (2010) study, however, the author concluded, “No statistically significant differences in clinical outcomes measures (Inner EAR, Abbreviated Profile of Hearing Aid Benefit) were observed between arms. This was expected, because the study was powered to detect differences in hearing aid use, not patient-centered clinical outcomes measures.” The variation in clinical outcomes data for the large proportion of patients who did not receive hearing aids (>90%) outweighs the effect seen in the small percentage of hearing aid users, although patients who used hearing aids had substantial improvements in hearing-related outcomes (see supporting information, Table S1).

Although the Yueh et al. (2010) study used a RCT design, sufficient concerns exist regarding whether the subject population, patient journey, and variations of clinical outcomes are representative of the subject...
population as a whole, especially when it is the primary source of data for the USPSTF recommendations.

**Rate of Hearing Loss for Older Adults**

While there is evidence that rates of hearing loss begin to rise around the age of 50, the prevalence dramatically increases as an individual grows older as shown in Figure 1 from the MarkeTrak data. This is similar to the data shown in the USPSTF recommendations as seen in Figure 2.

![Hearing Difficulty by Age](image1.png)

**Figure 1.** Hearing difficulty by age (n=55,600) (MarkeTrak 2018)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Prevalence(^a) (% Unilateral and Bilateral)</th>
<th>Prevalence(^b) (% Bilateral)</th>
<th>Adjusted(^c) OR (95% CI) Bilateral</th>
</tr>
</thead>
<tbody>
<tr>
<td>All adults 20-65 years</td>
<td>14.1</td>
<td>7.5</td>
<td>-</td>
</tr>
<tr>
<td>Ages 20-29 years</td>
<td>2.2</td>
<td>0.8</td>
<td>reference group</td>
</tr>
<tr>
<td>Ages 30-39 years</td>
<td>3.3</td>
<td>0.9</td>
<td>1.1 (0.3 to 4.4)</td>
</tr>
<tr>
<td>Ages 40-49 years</td>
<td>7.8</td>
<td>3.4</td>
<td>3.3 (0.8 to 13.3)</td>
</tr>
<tr>
<td>Ages 50-59 years</td>
<td>23.1</td>
<td>11.2</td>
<td>13.4 (2.8 to 63.5)</td>
</tr>
<tr>
<td>Ages 60-69 years</td>
<td>39.3</td>
<td>24.7</td>
<td>39.5 (16.5 to 148.4)</td>
</tr>
</tbody>
</table>

\(^a\) Estimates are from 2011-2012 NHANES data.

\(^b\) Prevalence refers to speech-frequency hearing impairment defined by pure-tone average of thresholds across 500, 1000, 2000 and 4000 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.

![Appendix A Table 1](image2.png)

**Figure 2.** Appendix A Table 1. Estimated Prevalence of Mild or Worse Hearing Loss in the United States by Age Category (from Screening for Hearing Loss in Older Adults: An Evidence Review for the U.S. Preventive Services Task Force)

It has been demonstrated in over three decades of MarkeTrak studies that persons with hearing loss underestimate their hearing difficulty. When comparing reported hearing difficulty, individuals who have had screening or hearing testing report higher levels of hearing loss than those who have not had any testing (Figure 3). This supports the conclusion that without proper screening to advise individuals of their hearing difficulty, they will continue to deny they have a hearing loss and will not take further action to seek treatment. As the USPSTF report concludes that hearing aids significantly improve hearing specific health-related quality of life measures compared to those who were unaided, delays in proper screening could have a detrimental impact.
Figure 3. Self-Reported hearing loss – hearing aid owners and non-owners (MarkeTrak 2018)

Recommendations

HIA supports hearing screening for older adults with an evidence-based, well-developed, calibrated, efficient, and reliable test protocol. In addition we strongly support the continued use of the Initial Patient Physical Exam (IPPE) and the Annual Wellness Visit (AWV) mandated by CMS for all Medicare beneficiaries which requires a discussion by the physician regarding the hearing and balance of the patient.

To support this endeavor, it may be prudent to offer a more representative and pragmatic two-part screening protocol based on the ability to hear (i.e., perceive sound) and the ability to listen (i.e., comprehend sound). A two-part approach could use pure-tones or speech sound (i.e., phoneme)\(^{16}\) detection to represent hearing ability, and perhaps a standardized pass/fail speech-in-noise test at a fixed signal-to-noise ratio to represent listening ability. The total test time for an adult would be 3-5 minutes and would result in a more accurate representation of a functional auditory system relative to communication. Of course, these are just examples as to how screenings might be updated in the 21st century. We would anticipate a national association-based think tank of subject matter experts would need to be assembled to design, test, and recommend an actual two-part screening recommendation and protocol. (from Strom et al. HR 2020)\(^{16}\)

Additionally, HIA recognizes that more specific evidence and peer-reviewed research is needed to support a screening recommendation for older adults, including studies on protocols, procedures, and efficacy of screening and strongly supports additional focus and research in this area. Given the well-documented associated comorbidities and costs of untreated hearing loss, it is crucial to obtain evidence and data to support a screening recommendation.

Conclusion

Hearing health is essential. Untreated hearing loss is a significant problem for older adults, and the literature continues to pour in regarding the role of good hearing in overall health, quality of life, and active aging. The early identification of hearing loss through screenings can lead to further diagnosis and treatment of hearing loss and support better health outcomes. Considering the significant direct healthcare costs of untreated hearing loss as well as the inherent increased costs of associated comorbidities, hearing screening is a logical and practical method to support the health and well-being of the aging adult population.
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13. NIH (National Institutes of Health)

14. American Journal of Managed Care

15. Alzheimer's Association
16. Centers for Disease Control & Prevention & NIH (National Institutes of Health)


