Validity of Pure-Tone Hearing Screening at Well-Child Visits

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Objective: To estimate the sensitivity and specificity of pure-tone audiometry hearing screening in the primary care setting.

Design: Prospective cohort study.

Setting: Eight academic and private pediatric practices.

Participants: A subset of children from a convenience sample of 1061 children between 3 and 19 years of age were screened for hearing loss using pure-tone audiometry.

Intervention: Formal audiologic evaluations (gold standard) for those children referred by their primary care physician (28 children) and for a random sample of children not referred (102 children).

Main Exposure: Pure-tone audiometry screening.

Main Outcome Measures: Audiologic evaluations.

Results: A total of 28 children were referred to an audiologist for formal hearing testing after pure-tone audiometry screening during a well-child visit, at which 25 children did not pass the initial screening and 3 could not complete the screening. Of the 25 children, only 7 were evaluated by an audiologist, for a follow-up rate of 25%. One child was diagnosed as having hearing loss. Formal audiologic assessment was also performed on a random sample of 102 children who were not referred to the audiologist. For the random sample, hearing loss was identified in 2 of 76 (3%) children who passed and 1 of 16 (6%) children who did not pass pure tone audiometry screening. The sensitivity and specificity of pure-tone audiometry were 50% and 78%, respectively.

Conclusion: In light of the increasing burden on physicians to provide preventive care, this study calls into question the value of hearing screening using pure-tone audiometry during well-child visits given the lack of follow-up after referral and the poor sensitivity.


Ten percent of children do not pass the hearing screening performed at school and at well-child visits. Such hearing screening is designed to identify hearing loss early in order to minimize the detrimental effect on communication and educational performance. This high failure rate compares with a rate of hearing impairment detected at newborn screening of only 1 to 3 per 1000 newborns. Although late-onset and acquired hearing loss occur throughout childhood, this is a high rate of failure for a screening test that requires referral to either an audiologist for formal hearing testing or an otolaryngologist for intervention. Despite this, nationally, approximately 50% of young children with significant hearing problems are unidentified, with a recent study estimating that 1.4 million children and adolescents have hearing loss.

To identify children with legitimate hearing deficits, the National Institutes of Health recommends hearing screening at school entry, while the American Academy of Pediatrics currently advocates hearing screening at 4, 5, 6, 8, and 10 years of age and risk assessment at all other well-child visits. This policy represents a large reduction in the frequency of hearing screening recommended in childhood from previous statements, which also recommended screening at 3 years of age, as well as at 12, 15, and 18 years of age.

To adhere to these guidelines, most practices use pure-tone audiometry to determine the type and degree of hearing loss. Pure-tone audiometry relies on calibrated, pure tone stimuli to determine the hearing sensitivity, or threshold of hearing, in each ear. Pure-tone audiometry is capable of identifying unilateral or bilateral sensorineural and/or conductive hearing loss. Potential problems have been raised regarding the use of pure-tone audiometry as a method of hearing screening. Such concerns include high ambient noise level, environmental distractions, equipment calibration, testing proce-
dures, tester competence, time requirements, patient behavior, and screening levels that compromise the validity of the screening tool. In addition, pure-tone audiometry screenings require active participation of the child being tested, which is affected by the child’s age, developmental status, and language skills. Children who cannot fully participate in the screening test may be improperly passed or not passed.

Ensuring the validity of methods used to screen hearing in the primary care setting is critical to avoid the medical, psychological, economic, and legal implications of inaccurate screening results. The purpose of our study was to determine the validity of pure-tone hearing screening during well-child visits in children aged 3 to 19 years.

METHODS

From February 17, 1998, through March 13, 2000, a convenience sample of children aged 3 to 19 years was recruited during well-child visits. The population and study design of the first phase of this study have been previously described. Briefly, the original population included 1061 children, primarily Medicaid insured (77%), male (53%), and African American (73%).

During well-child visits in children aged 3 to 19 years. The population and study design of the first phase of this study have been previously described. Briefly, the original population included 1061 children, primarily Medicaid insured (77%), male (53%), and African American (73%).

During the second phase of study, audiologic evaluations were obtained for those children referred by the pediatrician after the pure tone hearing screening. In addition, a stratified random sample of children not referred by their pediatrician underwent a full evaluation by an audiologist. When children from the random sample did not undergo audiologic evaluations after 3 attempts at scheduling, another child was randomly selected. Consent was obtained at the time of initial enrollment allowing permission to access medical records for any follow-up. Medical records were obtained from the audiologist and/or otolaryngologist to whom the child was initially referred, as well as those audiologic practices associated with Children’s Hospital of Alabama and the University of Alabama at Tuscaloosa, for up to 18 months following study enrollment.

Unadjusted odds ratios and χ² tests were used to assess predictors of compliance with referrals. Audiologic evaluations were used as the gold standard to allow calculation of the sensitivity and specificity of pure-tone hearing screening at the well-child visit. Sensitivity was calculated as the percentage of children with hearing loss based on audiologic evaluation who did not pass the pure-tone hearing screening. Specificity was calculated as the percentage of children with no hearing loss based on audiologic evaluation who passed the pure-tone hearing screening. The positive predictive value, or posttest probability of disease, was the proportion of patients with a positive screening (who did not pass the screening) who are correctly diagnosed as having hearing loss. Positive predictive value was calculated as follows:

\[ \text{Positive Predictive Value} = \frac{\text{Sensitivity} \times \text{Prevalence}}{(\text{Sensitivity} \times \text{Prevalence}) + (1 - \text{Sensitivity}) \times (1 - \text{Prevalence})} \]

Negative predictive value is the proportion of patients with a negative screening (who passed the screening) who are correctly diagnosed as having normal hearing. Negative predictive value was calculated as follows:

\[ \text{Negative Predictive Value} = \frac{\text{Specificity} \times (1 - \text{Prevalence})}{(1 - \text{Specificity}) \times \text{Prevalence} + \text{Specificity} \times (1 - \text{Prevalence})} \]

A total of 1061 children were enrolled in the first phase of the study. During the second phase, children were referred to an audiologist by the primary care physician or randomly selected for audiologic evaluation according to the study protocol. Referred children were classified as compliant or noncompliant based on whether they were seen by an audiologist (Table 1). Bivariate statistics were calculated for each of the characteristics listed in Table 1. There were no statistically significant differences for children seen vs those not seen by an audiologist after referral by the primary care provider.

A total of 130 children underwent formal hearing testing: 28 children (22%) were referred to an audiologist/otolaryngologist by the primary care physician for formal hearing testing, while 102 children (78%) were seen as part of the random sample (Figure). Four of the 130 children had hearing loss confirmed by an audiologist: 2 after not passing and 2 after passing the screening test. Eighteen of the 25 children who were referred by their primary care physician after not passing the screening test and all 3 children who were referred by their primary care physician after being unable to complete the screen were never seen by an audiologist. Therefore, 21 of 28 children (75%) referred to an audiologist were noncompliant. Referred patients who were compliant were seen by an audiologist a mean (SD) of 84 (128) days after the initial screening (range, 2-370 days). All of the children who could not be tested and then were seen by an audiologist had normal findings from the audiologic evaluations. Despite not passing the screening test, several subjects in the original study population were not
A pure-tone hearing screening test that was not passed in our primary care setting had poor sensitivity (50%) and only fair specificity (78%), with a positive predictive value of only 7.6%. In addition, 75% of children did not present for audiologic evaluation despite referral by their primary care physician. No single characteristic was predictive of noncompliance with referral.

Previous researchers have noted that pure-tone audiometry is time consuming, requiring good rapport between the child and the screener, and depends on a child's developmental level and on the environmental conditions where the test is performed. Potential problems include inadequately trained screeners and improperly maintained equipment. Others have questioned the cost-benefit ratio of pure-tone audiometry and questioned its reliability as a tool to identify middle ear disorders.

Using audiometry as a gold standard, we have confirmed the low sensitivity and specificity of pure-tone audiometry in the primary care setting found by previous researchers in other settings. Hind et al found pure tone audiometry to have a low sensitivity and specificity during a school screening program and argued that a questionnaire to assess hearing may be a better screening tool.

This contradicts findings by other authors, including FitzZaland and Zink, who found a sensitivity and specificity of 93% and 99%, respectively, although the authors point out that their success was due, in large part, to a high level of training of screeners and the effective monitoring of environmental noise factors, which was unlikely to occur in the average primary care settings of the present study. In addition, formal evaluation was completed within 2 days of screening in the study by FitzZaland and Zink. This may be an unrealistic goal for screening follow-up in the primary care setting and may provide an explanation for the change in screening validity as patients may have had otitis media with effusions that resolved before formal testing or vice versa. Similarly, in a mass school screening program, pure-tone audiometry sensitivity was 78% to 100% and specificity was 70% to 89%, with 25% of children not passing pure-tone audiometry screening. However, this study used a same-day audiogram by an audiologist who was on site as the gold standard, which does not reflect standard practice.

In the present study, 75% of children who were referred to an audiologist did not undergo an evaluation. Allen et al found a similarly high rate of noncompliance in a preschool hearing screening program through Head Start, with 68% of children referred for medical examinations not being evaluated. In contrast, a parental survey found 25% did not have a follow-up examination; however, the survey response rate was 53%, which was likely to have resulted in a biased sample and included follow-up with a primary care physician as being "compliant." The survey also found that parental belief in the accuracy of the screen was the primary barrier to obtaining follow-up care. The lack of follow-up may be related to several factors, including limited availability of audiologists, delays in follow-up appointments with audiologists, and lack of parental belief in the existence of hearing deficits. In the present study, the high noncompliance rate also may be due to lack of transportation, lack of a social support to coordinate follow-up appointments, and other access issues associated with a Medicaid-insured population.

### Table 1. Characteristics of Children Referred to an Audiologist for Formal Hearing Testing

<table>
<thead>
<tr>
<th>Sex</th>
<th>Compliant Referrals (n=7)</th>
<th>Noncompliant Referrals (n=21)</th>
<th>Random Sample (n=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>4 (57)</td>
<td>10 (48)</td>
<td>57 (56)</td>
</tr>
<tr>
<td>Female</td>
<td>3 (43)</td>
<td>11 (52)</td>
<td>45 (44)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>4 (57)</td>
<td>13 (62)</td>
<td>33 (32)</td>
</tr>
<tr>
<td>White</td>
<td>3 (43)</td>
<td>8 (38)</td>
<td>64 (63)</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>3 (14)</td>
<td>21 (21)</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>3 (14)</td>
<td>21 (21)</td>
</tr>
<tr>
<td>5</td>
<td>2 (29)</td>
<td>3 (14)</td>
<td>25 (24)</td>
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<tr>
<td>≥6</td>
<td>5 (71)</td>
<td>12 (57)</td>
<td>35 (34)</td>
</tr>
<tr>
<td>Insuranc e</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>6 (86)</td>
<td>12 (57)</td>
<td>38 (37)</td>
</tr>
<tr>
<td>Private</td>
<td>1 (14)</td>
<td>8 (38)</td>
<td>64 (63)</td>
</tr>
<tr>
<td>Practice</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Academic</td>
<td>6 (86)</td>
<td>18 (86)</td>
<td>49 (48)</td>
</tr>
<tr>
<td>Private</td>
<td>1 (14)</td>
<td>3 (14)</td>
<td>53 (52)</td>
</tr>
<tr>
<td>Risk factors</td>
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<tr>
<td>Present</td>
<td>1 (14)</td>
<td>2 (10)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Absent</td>
<td>6 (86)</td>
<td>19 (90)</td>
<td>100 (98)</td>
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<tr>
<td>Development</td>
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<td></td>
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<tr>
<td>Delayed</td>
<td>2 (29)</td>
<td>5 (24)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Normal</td>
<td>5 (71)</td>
<td>16 (76)</td>
<td>101 (99)</td>
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<tr>
<td>Parental concern</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Present</td>
<td>0</td>
<td>3 (14)</td>
<td>0</td>
</tr>
<tr>
<td>Absent</td>
<td>7 (100)</td>
<td>18 (86)</td>
<td>102 (100)</td>
</tr>
</tbody>
</table>

*There were no statistically significant differences in characteristics across compliant, noncompliant, and random sample subjects.
*One child with no insurance (neither private nor Medicaid) was referred and did not present for follow-up.
*Represents a child with 1 or more risk factors for hearing loss.

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**COMMENT**

A pure-tone hearing screening test that was not passed in our primary care setting had poor sensitivity (50%) and only fair specificity (78%), with a positive predictive value of only 7.6%. In addition, 75% of children did not present for audiologic evaluation despite referral by their primary care physician. No single characteristic was predictive of noncompliance with referral.

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Given the poor validity of pure tone audiometry, other methods of hearing screening should be considered for the primary care setting. One such option that practices and schools are increasingly using is otoacoustic emissions. Otoacoustic emissions provide an objective measure of hearing without requiring a behavioral response from the child. It is quick and painless and assesses the integrity of the cochlea; however, it does not assess the integrity of the neural transmission of sound from the eighth nerve to the brainstem and, therefore, is not truly a test of hearing. Another option is a questionnaire such as the Childhood Middle Ear Disease and Hearing Questionnaire (CMEDHQ), which has had promising preliminary results in the United Kingdom.26 A final option is impedance testing such as tympanometry. Although not a hearing test, tympanometry, when used in conjunction with pure-tone audiometry, is likely to better identify middle ear effusions as the cause of not passing a screening test, allowing for fewer false-positive referrals.24,25

Concerns for poor sensitivity and specificity, as well as low follow-up rates, are not unique to hearing screening. Another option is a questionnaire such as the Childhood Middle Ear Disease and Hearing Questionnaire (CMEDHQ), which has had promising preliminary results in the United Kingdom.26 A final option is impedance testing such as tympanometry. Although not a hearing test, tympanometry, when used in conjunction with pure-tone audiometry, is likely to better identify middle ear effusions as the cause of not passing a screening test, allowing for fewer false-positive referrals.24,25

In a study completed in the Pediatric Research in Office Settings (PROS) network, of those children who did not pass the vision screening, 57% were scheduled for re-screening (typically in 12 months), 15% were told to follow-up as needed, 21% were newly referred to an eye specialist, and 5% were referred back to their eye care provider.31 Parents demonstrated poor understanding of the screening process and results. Parents whose children had not passed the vision screening often were unaware of the abnormal screen result (50%); another 9% were aware of the result and planned to make a follow-up appointment, and 33% had already made or kept a follow-up appointment. (Because of rounding, percentages may not total 100.) However, of the children who had been referred to an eye specialist, most (85%) had either made or kept an appointment.

Although an appropriate screening environment may be critical part of the successful completion of pure-tone audiometry, we purposely allowed practices to continue their routine to allow the study to reflect the validity of the screen in a real world environment.3 Similarly, audioligic evaluation was not immediately performed, al-
Following the study to reflect a real world experience in which evaluation may take weeks to complete after a screening test. The lower sample size in some calculations is of concern but reflects follow-up of more than 1000 children in the first phase of the study. The small numbers are due, in large part, to the poor compliance rate, which is, in itself, a notable finding. The study population was primarily Medicaid-insured, African American children, which, in addition to the smaller sample size, may limit the generalizability of the findings to clinics with similar screening procedures and patient populations. In the present study, the high noncompliance rate may be due to lack of transportation, lack of social support to coordinate follow-up appointments, and other access issues associated with a Medicaid-insured population. The effect of time to follow-up is unclear as the time between screening and follow-up was not recorded for those who were noncompliant with follow-up.

CONCLUSIONS

Well-child visits account for 23% of pediatric visits, and the number of preventive services to be provided during these visits continues to expand at a rapid pace. Although hearing loss is an important health problem and there is increasing evidence that early treatment is beneficial, pure-tone audiometry has not been shown to be accurate, with poor sensitivity. Therefore, this method does not meet traditional criteria for screening programs. This conclusion is compounded by a lack of treatment due, in large part, to lack of follow-up. Better training of screeners, improved adherence to recommendations for screening (including screening in quiet areas and arrangement of follow-up), and beginning screening at years of age may improve the validity of the pure-tone audiometry screenings. Other practices may choose to use otoacoustic emissions screening during childhood; however, there are several problems with this method. First and most important, it is not a test of hearing but rather a screen of middle ear function; the external and middle ear must show no abnormalities and be free of cerumen for the child to pass the screen. In addition, this tool is sensitive to child movement and external noise, which is likely to be problematic in the primary care setting. This study provides further evidence supporting the call by the Joint Committee on Infant Hearing for additional studies to investigate more reliable forms of hearing screening to be implemented in the primary care setting.

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Author Contributions: Drs Halloran and Wall had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Hardin and Wall. Acquisition of data: Wall. Analysis and interpretation of data: Halloran, Hardin, and Wall. Drafting of the manuscript: Halloran.

Critical revision of the manuscript for important intellectual content: Halloran, Hardin, and Wall. Statistical analysis: Halloran and Hardin. Obtained funding: Wall. Administrative, technical, and material support: Wall. Study supervision: Wall.

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REFERENCES


**Announcement**

**Submissions.** The Editors welcome contributions to Picture of the Month. Submissions should describe common problems presenting uncommonly, rather than total zebras. Cases should be of interest to practicing pediatricians, highlighting problems that they are likely to at least occasionally encounter in the office or hospital setting. High-quality clinical images (in either 35-mm slide or electronic format) along with parent or patient permission to use these images must accompany the submission. The entire discussion should comprise no more than 750 words. Articles and photographs accepted for publication will bear the contributor’s name. There is no charge for reproduction and printing of color illustrations. For details regarding electronic submission, please see: http://archpedi.ama-assn.org.