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Using otoacoustic emissions to screen for hearing loss in early childhood care settings☆

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Summary

Objective: Until recently, no objective tool has been available to help health and early childhood education providers screen young children for hearing loss. The aim of this study was to screen underserved children ≤3 years of age for hearing loss using otoacoustic emissions (OAE) technology and to systematically document multi-step screening and diagnostic outcomes.
Methods: A total of 4519 children, ≤3 years of age in four states were screened by trained lay screeners using portable OAE equipment set to deliver stimuli and measurement levels sensitive to mild hearing loss as low as 25 decibels (dB) hearing level. The screening and follow-up protocol specified that children not passing the multi-step OAE screening be evaluated by local physicians and hearing specialists.
Results: Of the 4519 children screened as a part of the study, 257 (6%) ultimately required medical or audiological follow-up. One hundred and seven children were identified as having a hearing loss or disorder of the outer, middle or inner ear requiring treatment or monitoring. Of these 107 children, 5 had permanent bilateral and 2 had permanent unilateral hearing loss. The seven children with permanent hearing loss included four who had passed newborn screening, two who were not screened at birth and one who did not receive follow-up services after referring from newborn screening.
Conclusions: OAE screening, using a multi-step protocol, was found to be a feasible and accurate practice for identifying a wide range of hearing-health conditions warranting monitoring and treatment among children ≤3 years of age in early childhood care programs. Future studies are needed to: (1) further examine barriers to effective OAE screening in early childhood care settings and (2) explore the value of extending early childhood OAE hearing screening into health care clinics and settings where young children receive routine care.

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1. Background

Language deficits from undetected and untreated hearing loss can result in low level literacy, educational under-achievement, and poor socialization [1,2]. By the time children are in school, the cumulative incidence of severe permanent hearing loss has been estimated at 6 per 1000 including the 1—3 per 1000 likely to be detected and confirmed at birth [3,4]. Although newborn screening has done much to improve detection of permanent congenital hearing loss [5—7], problems remain. Data from the Centers for Disease Control and Prevention show that among the 2% of infants referred for follow-up after newborn screening, only 40% were documented as having received a diagnostic evaluation [3]. For newborns with confirmed diagnoses, there is a median time lag of 18 months between screening and intervention [1]. In addition to these newborn-screening issues, no comprehensive programs exist to detect cases of permanent hearing loss in early childhood. Public health strategies for detection, referral, and treatment of children not screened at birth, lost to follow-up from newborn screening, or presenting with post-neonatal hearing loss are still needed to prevent serious developmental problems associated with untreated hearing loss [1,8]. Further, an estimated 35% of pre-school children experience repeated episodes of ear infections and intermittent hearing loss, some untreated for extended periods, that may also interfere with language and social development [5].

Health and early education providers and professional organizations serving young children are increasingly aware of the importance of hearing screening during a child's language learning years. Concurring with recommendations by the American Academy of Pediatrics promoting periodic screening in early and middle childhood [9], authors of one multi-center study that followed screened infants to 9 months of age noted the need for subsequent screening in early childhood [10]. In that study, some programs found that up to 22% of infants passing the newborn screen were later shown to have permanent hearing loss. However, consensus on specific tests, equipment, protocols and populations (e.g., pre-school, well-baby, and high-risk infants) has yet to be reached.

At present, the use of otoacoustic emissions (OAE) technology has been increasing in early childhood education and clinical settings, but remains limited as the preponderance of attention has focused on newborn screening [11]. Pediatricians and other primary care providers have routinely utilized otoscopy, pneumatic otoscopy or tympanometry to diagnose common middle-ear disorders, but have had to rely on subjective methods such as observations of the child's behavioral response to sound (i.e., hand clapping or bell ringing) or parent perceptions of the child's behavior, to screen inner ear functioning of children $\leq$3 years of age. OAE screening, used widely in newborn hearing screening programs, holds great promise for health and early childhood care providers in screening infants and toddlers for permanent hearing loss because it is: (a) objective and independent of child's behavior; (b) painless; (c) portable, reliable and efficient; (d) simple to administer with an appropriate protocol [12].

The objective of this study was to screen underserved children $\leq$3 years of age for hearing loss using OAE technology and to systematically document multi-step screening and diagnostic outcomes.

2. Methods

2.1. Subjects

A total of 4519 children, $\leq$3 years of age enrolled in Early, Migrant and American Indian Head Start programs in Kansas, Oregon, Utah and Washington participated in the study. As part of Head Start requirements, all enrolled children must receive some type of hearing screening annually in conjunction with other health screenings. This allowed researchers to implement a standardized screening and follow-up protocol across 65 sites. Table 1 summarizes the demographic backgrounds of the children. Hearing screenings were conducted by lay screeners who attended a 6-h training session and had subsequent access to audiological technical support. Subjects were screened in a range of natural environments including classroom play settings and homes. Screening and follow-up outcome data were collected on each subject. Approval for human

Table 1 Demographic characteristics of 4519 OAE screened children

Gender	
Female	2107 (47%)
Male	2347 (52%)
Unknown	65 (1%)
Age (months) (mean = 22, S.D. = 13)	
0—12	1120 (25%)
13—24	1084 (24%)
25—36	1453 (32%)
36—48	862 (19%)
Type of program	
Migrant Head Start	2049 (46%
Early Head Start	2226 (49%)
American Indian Head Start	244 (5%)
Ethnicity	
Hispanic	2437 (54%)
Caucasian	1331 (29%)
American Indian	271 (6%)
African American	158 (4%)
Bi-racial	98 (2%)
Asian	21 (1%)
Unknown	203 (4%)

subjects enrollment in this study was provided through the on-going Head Start screening program administration.

2.2. OAE hearing screening methodology

This study utilized Bio-logic AuDX distortion product otoacoustic emissions instruments in all screening sites set to deliver stimuli and measurement levels sensitive to mild hearing loss as low as 25 decibels (dB) hearing level. The collection parameters included F2 frequencies of 5000, 4000, 3000, and 2000 Hz each with an intensity level of 65 dB SPL for F1 and 55 dB SPL for F2. A typical F2/F1 ratio of 1.22 was used. Frequency specific pass/refer criteria included a minimum distortion product (DP) amplitude of −6 at 5000, −5 at 4000, −8 at 3000 and −7 at 2000 with a DP-NF (noise floor) of 6. The number of frequencies for an overall screening pass was 3.

During OAE screening, the screener places a small probe in the ear canal that is designed to deliver the sound stimuli and also to collect a response via a sensitive receiving microphone. In a healthy ear, sound stimuli from the probe are transmitted through the middle ear to the inner ear where outer hair cells of the cochlea respond by producing an emission. This emission is picked up by the microphone, analyzed by the screening unit, and a "pass" or "refer" result is displayed on the unit's screen [13]. The ear will refer on the screening if there is: (a) a blockage in the ear canal; (b) a structural problem or excess fluid in the middle ear that interferes with hearing; or (c) an impaired cochlea that is not responding normally to sound. For purposes of this study, additional error messages generated by the equipment related to excessive external noise in the environment or internal noise generated by the child's movement which prevented a valid test from being completed were categorized as "can't test."

In two large-scale OAE screening studies reported previously, sensitivity was found to be 85% [14] and 100% [15] with specificity of 95% in both studies. Additionally, in a small-scale study of 110 children age 6 months to 15 years recovering from meningitis, OAE screening was found to be highly sensitive (100%) and reasonably specific (91%) [16].

2.3. Hearing screening protocol and variables

Standardized procedures and manuals were used to train all screeners in performing OAE screening and adhering to a follow-up protocol [17]. Children with no follow-up data after 6 months were categorized as exiting the study. Key components of the protocol included a visual inspection of the ear and up to three OAE screenings over a 2—4-week period [18]. This protocol was designed to significantly limit false positive findings by specifying that children not passing the initial OAE screening be screened up to two more times before receiving an evaluation. From a practical standpoint, it also minimized potential over-referral to health care providers for transient conditions such as temporary congestion due to head colds, etc.

The screening and follow-up protocol further specified that children not passing the multi-step OAE screening be evaluated by a health care provider associated with the center or family, and, as needed, by a pediatric audiologist or other hearing specialist. All health care providers and audiologists followed their own standard diagnostic procedures including tympanometry when available. No changes in medical care were introduced by this study. Key data included:

- *Visual inspections*: (1) pass, no observable abnormalities, or (2) refer, an observable abnormality.
- *OAE screening outcomes*: (1) pass, (2) can't test, generally due to child's excessive movement or distress, or (3) refer, possible hearing loss.
- *Diagnostic outcomes*: diagnoses of hearing-health conditions were made by health care providers and audiologists in the communities where children were located.

Table 2 Summary of diagnostic outcomes among 257 referred from screening

Diagnostic outcomes	Number of children
Hearing loss or disorder requiring treatment or monitoring	107 (42%)
Permanent hearing loss	7
Otitis media (ear infection)	83
Occluded pressure equalization (PE) tubes	2
Excessive earwax or congestion	15
No treatment recommended	52 (20%)
Exited before diagnosis completed/ referral appointment completed	98 (38%)
Total	$n = 257$

3. Results

Based on the multi-step screening protocol, of the 4519 children screened, 257 (6%) required medical or audiological follow-up. As shown in Table 2, of the 159 (62%) children who actually received diagnostic follow-up services, 107 (67%) were identified with a hearing loss or disorder requiring treatment or monitoring. Further analysis of these 107 cases revealed that 7 children had permanent hearing loss, 83 had otitis media, 2 had occluded pressure equalization tubes, and 15 had excessive earwax or congestion. The remaining 52 of the 159 receiving follow-up were diagnosed as normal and no further treatment was recommended. Finally, of the 257 children needing diagnostic follow-up after the OAE screening, 98 (38%) exited the Head Start program before this was completed. Their diagnostic status remains unknown.

As a result of the OAE screening and follow-up assessment, 7 of 4519 (1.5 per 1000) children who were screened were found to have a permanent hearing loss. Table 3 summarizes additional information about these seven children with detected permanent hearing loss, including type of hearing loss, age at diagnosis and newborn-screening results. Four of the children had a permanent sensorineural hearing loss while three had a permanent conductive loss.

3.1. Protocol evaluation

Data from this 36-month screening project were coded and analyzed to evaluate the multi-step screening and follow-up protocol (see Fig. 1). The median time for a single screening was 4.0 min (mean of 4.8 min) ranging from 1 to 30 min.

3.1.1. Visual inspection outcomes

The first step in the screening process was the visual inspection of the outer ear for abnormalities or obvious indicators of active ear infection. If anomalies were noted, the next step was a medical evaluation. Eight children (<1%) did not pass the visual inspection and required direct follow-up from a health care provider.

3.1.2. OAE screen 1 outcomes

The 4511 (>99%) children passing the visual inspection were then screened using OAE equipment. Of the 4511 children receiving an initial OAE screening, 3412 (76%) passed and required no further follow-up. A total of 809 (18%) "failed" or "referred" on this first screening, while 290 (6%) were documented as "can't test" (generally because children were uncooperative on that day). Thus, a total of 1099 (24%) children did not pass the initial OAE screening. Although the screening protocol specified that children not passing the initial screening should typically receive a subsequent OAE screening before receiving medical or audiological evaluation, screeners were instructed to exercise their own judgment in directly initiating a medical evaluation if circumstances warranted (e.g., if a child had a known history of ear infection, parents voiced concern about the child's hearing, etc.). Thus, of the

Table 3 Information on children identified with permanent hearing loss

Case	Diagnosis and age at diagnosis	Newborn hearing screening results
1	Bilateral, severe sensorineural loss and otitis media (9 months)	Referred; subsequently lost to follow-up
2	Bilateral, severe conductive loss (2.5 years)	Passed
3	Bilateral, mild/moderate conductive loss and otitis media (3 years)	Not screened at birth
4	Bilateral, mild/moderate conductive loss (2 years)	Not born in U.S., not screened at birth
5	Unilateral, mild/moderate sensorineural loss in left ear (15 months)	Passed
6	Unilateral, mild/moderate high frequency sensorineural loss in left ear (2 years)	Passed
7	Bilateral, severe, sensorineural loss and otitis media (2.5 years)	Passed

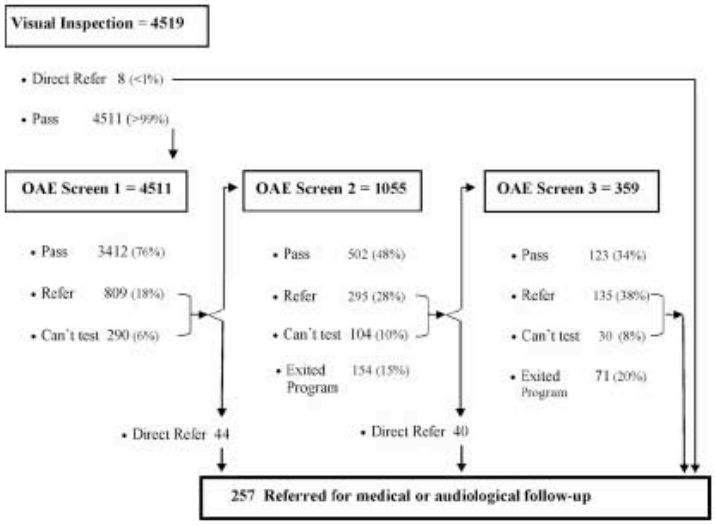

Fig. 1 Flow chart of screening results at each step in the hearing screening protocol.

1099 children who did not pass this initial OAE screening, 44 (4%) were determined to need direct evaluation by a health care provider on the basis of these additional concerns.

3.1.3. OAE screen 2 outcomes

Of the 1055 children needing a second screening, 502 (48%) passed and required no further follow-up. A total of 295 (28%) "failed" or "referred" on the screening and 104 (10%) could not be tested. The remaining 154 (15%), however, did not receive this second screening due to the Head Start program closing for the year/season or the child exiting the program. Of the 399 children who did not pass this second OAE screening, 40 (10%) were determined to need direct evaluation by a health care provider due to additional concerns.

3.1.4. OAE screen 3 outcomes

Of the 359 children needing and available for a third screening, 123 (34%) passed and required no further follow-up. A total of 135 (38%) "failed" or "referred" on the screening and 30 (8%) could not be tested. The remaining 71 (20%) however, did not receive this third screening due to the Head Start program closing for the year/season or the child exiting program. Thus, 165 children were identified as needing medical evaluation after the third screening.

3.1.5. Medical or audiological follow-up outcomes

A total of 257 (6%) of the 4519 children in the study required medical or audiological follow-up as a result of screening. As described above, of the 247 children, 107 (42%) were found to have hearing problems, 52 (20%) were determined to have "normal" hearing and the remaining 98 (38%) exited the Head Start program, or the program closed, before the diagnostic follow-up could be completed. Of the 4511 children who were screened, 4420 either passed the screen ($n = 4261$) or had evaluation data available at the completion of the process ($n = 159$). Of the 159 children with evaluation data, 52 had normal hearing and 107 had a hearing problem. Because follow-up assessment was not completed on children passing the screening, "gold standard" criteria [19] for assessing sensitivity cannot be applied. However, available data can be used to determine that the positive predictive value (true positives/[true positives + false positives] was 67.3%. Since the false negative fraction necessary to calculate the negative predictive value (true negatives/(true negatives + false negatives)) of this screening procedure is unknown, the estimated negative yield (negatives/[negatives + false positives]) was calculated at 98.8%. Given an estimated number of false negatives of 19 based on the lowest published sensitivity of 85% for OAE tests [14], the estimated negative predictive value would be similarly high at 99.6%. A breakdown of the types of hearing problems detected is given in Table 2.

4. Discussion

This study showed that a multi-step OAE screening protocol led to the identification of children who were ultimately diagnosed with a wide range of

hearing-health conditions warranting monitoring and treatment. The 5.7% fail/refer rate compares favorably with rates reported by effective hospital-based newborn hearing screening programs [20] given that the fail/refer rate for infants and toddlers is expected to be higher than newborns due to transient middle-ear conditions that are more prevalent in this population. The data-derived positive predictive value of negative 67.3% indicates that over-referral was not occurring. It may also be an under-estimate of the underlying positive predictive value given the high probability of outer and middle-ear conditions that can resolve prior to a clinical diagnostic visit. Furthermore, the estimated negative yield and estimated negative predictive value may be over-estimates as they are based on results without follow-up of those testing negative. However, the literature indicates sensitivity to be high and thus the false negative fraction among those with hearing loss to be low (from 0 to 15%) [14–16].

As a result of the OAE screening conducted in this study, seven children with permanent hearing loss were identified who were either not screened at birth, were screened and subsequently lost to follow-up after hospital discharge, or who passed the newborn hearing screen but presented with post-neonatal hearing loss. As a result of the identification through screening and follow-up, these children were connected with audiological services, local early intervention services, and family support programs.

The cases detected in this screening program demonstrate common problems in child hearing health that merit further discussion. Case #1 is a child who did not pass the newborn hearing screening and who did not receive follow-up from health-care providers or audiologists. Loss to follow-up from newborn hearing screening is significant in some states—as high as 50–60% of infants who need follow-up [3].

Cases #2, #5, #6, and #7 are children with probable post-neonatal hearing loss. Despite passing the hearing screening at birth, these children referred on OAE screening by 15–30 months of age. Although hearing loss was then diagnosed as mild/moderate, and in two cases unilateral, hearing loss among young children often increases over time [21]. There has been no single definitive study of the rate of post-natal hearing loss, but the literature indicates that from 11 to 50% of all cases of permanent hearing loss are likely post-natal [22]. Additionally, Cases #3 and #4 illustrate that periodic screening is important since some children were not screened at birth. It is possible but unknown at this time if these cases were congenital.

The value of using OAE equipment to screen children for permanent hearing loss after fluctuating middle-ear conditions have been resolved is also highlighted by this study. Three of the seven children were diagnosed with permanent sensorineural hearing loss in addition to otitis media. Parents and community-based hearing screening programs often assume, incorrectly, that health care providers have the capacity to objectively screen for permanent hearing loss. The reality is that while many health care providers regularly diagnose and treat fluctuating middle-ear conditions, very few are equipped to screen cochlear functioning or to detect permanent hearing loss in children $\leq$3 years of age.

Finally, of the seven children identified with permanent hearing loss, five were diagnosed as having a bilateral loss while two had unilateral loss. The repercussions of unilateral hearing loss have historically been minimized. However, unilateral loss is associated with progressive declines that can affect the other ear [23]. Children with unilateral hearing loss often respond to sound in a way that would indicate they are hearing, particularly in one-on-one interactions, which makes unilateral loss especially difficult to identify using subjective methods. Both unilateral and mild hearing losses often go unidentified until children are in school when language and academic delays are apparent [24,25].

In addition to the 7 children identified with permanent hearing loss, 100 other children in the study were diagnosed with hearing problems—primarily otitis media (n = 85) including two with occluded PE tubes. Although there is professional debate on the effect that otitis media may have on language development and on what constitutes optimal intervention [26,27], the OAE hearing screening process was valuable in helping to identify children with compromised hearing health who needed further monitoring or treatment.

Unfortunately, 98 children who did not pass the multi-step OAE screening process exited the Head Start program before a diagnostic evaluation could be completed. Of the 159 children who were referred for and received a diagnostic evaluation, 107 (67%) were diagnosed with a hearing disorder. Using this percentage to extrapolate to the 98 children who exited, it can be estimated that 66 of the 98 had a hearing loss or disorder and that approximately 4 of those 98 may have had a permanent hearing loss. Given the 7 cases detected and a potential 4 additional cases from those who exited the program, the data suggest that the use of OAE screening during early childhood would result in 2.4 per 1000 newly detected cases of permanent hearing loss in addition to the 1–3 per 1000 expected from newborn screening.

These data provide an estimate of the percentage of children whose hearing loss could potentially be

identified through early childhood hearing screening practices. Future investigation of hearing screening in early educational settings is warranted and would include: Strategies for minimizing loss to follow-up, protocol refinement in determining the optimal number of screening steps prior to referral, optimizing testing conditions (e.g., reducing internal and external noise), quality and consistency of screener training, monitoring protocol adherence, and outcomes resulting when a protocol-trained panel of health care providers/audiologists provide follow-up for children not passing screening. Likewise, studies examining the feasibility of extending OAE screening into health care settings would be timely [28]. At a minimum, providers involved in follow-up care for young children being treated for otitis media should ensure that children's cochlear functioning is assessed after fluctuating middle-ear disorders have been resolved.

The results of this study demonstrate that OAE technology, when used with a multi-step screening and follow-up protocol, can make a valuable contribution by identifying hearing loss that can potentially disrupt language acquisition, literacy, socialization and overall school readiness. An objective screening tool, OAE technology holds great promise for health and early education care providers in reliably screening infants and toddlers for hearing loss during the critical language-learning years. As educational program directors and individual practitioners make decisions about how to meet children's hearing-health needs, and as professional organizations make broader recommendations on how and when periodic hearing screening should be conducted, the implementation of objective hearing screening techniques during early childhood should be considered.

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