Screening for Hearing Loss in Early Childhood Programs

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Abstract

This study assessed the feasibility of doing hearing screening in Migrant, American Indian and Early Head Start programs using otoacoustic emissions (OAE). Staff members were trained to screen 0-3 year old children for hearing loss using hand-held OAE equipment and a multi-step screening and referral protocol. Of the 3486 children screened as a part of the study, 77% passed the initial visual and OAE screen, 18% passed after OAE re-screening and 5% were ultimately referred for medical or audiological follow-up. Eighty children were identified as having a hearing loss or disorder of the outer, middle or inner ear requiring treatment or monitoring. Of these 80, 6 had permanent bilateral or unilateral hearing loss. Although the protocol suggested that the multi-step screening procedure should be completed within a 4-week time period or less, analysis of the data showed that for children requiring more than an initial OAE screening, the length of time over which the screening was completed ranged from 7 to 12 weeks. The average length of time required to complete a single OAE screening session was 5 minutes per child. The results demonstrate that OAE screening using this protocol is practical and effective. The implications for conducting continuous hearing screening throughout early childhood are discussed.
Screening for Hearing Loss in Early Childhood Programs

In the United States, approximately 1 out of every 300 children is born with a permanent hearing loss, making it the most common birth defect in the country. Advances in technology have now made it possible to screen newborns for hearing loss and over the past 10 years the percentage of infants screened at birth has increased from 3% to 90% (White, 2004). While universal in concept, however, approximately 10% of newborns do not receive a hearing screening and in some states 50% or more of the infants who do not pass newborn hearing screening are lost to follow-up before receiving additional screening or diagnostic services (Centers for Disease Control, 2005). In addition, not all childhood hearing loss can be identified at birth because a child can lose his or her hearing at any point in early childhood. In fact, it is estimated that by school age approximately 3 out of every 300 students have a permanent sensorineural hearing loss (American Speech-Language-Hearing Association, 1993). In addition to children who have a congenital or late-onset permanent hearing loss, approximately 35% of preschoolers will have repeated episodes of ear infections that nearly always cause temporary hearing loss that can significantly disrupt language acquisition and educational progress (ASHA, 2004). Hence, continuous hearing screening throughout early childhood is critical for identifying hearing-health conditions that can impede a child’s development.

Each year Head Start provides services to more than 900,000 children with the mission to help children from low-income families start school ready to learn (Administration for Children and Families [ACF], 2005a). Head Start programs aim to address all areas of child development including early learning and literacy, health, disability services and family and community partnerships (ACF 2005b). Reflecting the relationship between hearing, language acquisition,
cognitive development, literacy, and school readiness, Head Start performance standards require that all children be screened for hearing loss within 45 calendar days of entering the program and that children not passing the screening be referred for diagnosis and intervention as needed (ACY, 2001). The emphasis being placed on helping children acquire pre-literacy and literacy skills as a part of the No Child Left Behind Act underscores the importance of identifying all children whose progress in these areas is likely to be compromised by the presence of an undetected hearing loss (The White House, 2002).

Current Head Start performance standards do not specify a particular hearing screening technique to be used. Rather, agencies are directed to consult with local content area experts and their Health Services Advisory Committees as they design and implement screening protocols (O’Brien, 2001). Unfortunately, many programs, local consultants, and/or advisory committees are not aware of available hearing screening and identification procedures and equipment or the significant technological advances which have taken place during the past decade (Eiserman, 2003). For example, Otoacoustic Emissions (OAE) technology is now used widely in hospital-based newborn hearing screening programs to screen children as young as a few hours old. This method, when used with an appropriate protocol, also lends itself to screening children birth to three years of age because it is:

- Objective and not dependent on a behavioral response from the child (can even be performed while the child is sleeping);
- Painless;
- Reliable and efficient (requiring about five minutes per child);
- Hand-held and portable (suitable for screening in either center or home-based settings);
Simple to administer when a child initially enters an early childhood program, at annual intervals, and at any other time parents or educators have concerns about the child’s hearing-health;

Straightforward to use and does not require technical skill or in-depth understanding of the auditory system.

Despite its suitability for screening the hearing of young children, OAE technology has seldom been used in early childhood screening programs like those implemented every day in Migrant, American Indian, and Early Head Start. Some Head Start programs attempt to satisfy their hearing screening requirements by referring to newborn hearing screening results, even though those results reflect the hearing status of the child only at the time of birth and the results may be many months old at the point the child is entering the program. More commonly, Head Start staff members screen infants and toddlers for hearing loss by relying on physician reports indicating that ears had been “checked” (which is not equivalent to a physiologic hearing screening), by using subjective observations of the child’s behavioral response to sound (such as hand clapping or bell ringing) or by collecting parent perceptions of the child’s behavior (Munoz, 2003). Because hearing loss is an “invisible” condition, many infants and toddlers, especially those with moderate, mild, or unilateral hearing losses, do not exhibit observable symptoms of a loss until they are older. Without reliable physiologic screening tools, such as OAE screening, infants with hearing loss have typically remained unidentified until 2½ years of age (Harrison and Roush, 2003) — far too late for optimal language development. Children with mild or moderate losses have often not been identified until 4 years of age or until entering school (Commission on Education of the Deaf, 1988; Niskar, 1998).
Each day in the life of a young child with an undetected hearing loss is a day without full access to language. When hearing loss goes undetected, the resulting language deficits can become overwhelming obstacles to literacy, educational achievement, socialization, and school readiness (Moeller, 2000). Physiologic screening has proven to be the most reliable, objective screening tool to identify young children at risk for hearing loss and subjective techniques can no longer be considered as viable, independent of objective methods (Cunningham & Cox, 2003). It is therefore important to examine the feasibility and benefits of assisting programs that serve infants and toddlers in transitioning from subjective hearing screening techniques to objective hearing screening practices that are now readily available.

In 2001 a study was initiated to answer the following research questions:

1. What are the overall hearing-health outcomes and types of conditions identified for children 0 – 3 years of age when Migrant, American Indian, and Early Head Start staff members are trained to implement an OAE-based hearing screening and follow-up program?

2. How many children with permanent hearing loss or other treatable hearing problems are identified as a result of OAE screening?

3. How effective is a multi-step OAE hearing screening protocol in terms of:
   a) maximizing the identification of children having hearing-health conditions likely to interfere with normal hearing, while
   b) minimizing over-referral of children for medical or audiological follow-up who did not actually need treatment (“false-positive” referrals).

4. How feasible is it for programs serving infants and toddlers to implement a multi-step screening and follow-up protocol?
Methodology

To evaluate the feasibility of implementing OAE hearing screening in Head Start programs, all Migrant, American Indian and Early Head Start programs serving children 0 – 3 years of age in Oregon, Utah, and Washington were provided with information describing the project and invited to participate. Programs electing to participate received screening equipment, training, resource materials, and ongoing technical support and audiological supervision. In turn, programs agreed to send staff to a one-day training workshop and a subsequent one-day follow-up training meeting, to submit OAE screening and follow-up data on all children 0-3 in the program, and to communicate with the research team on a regular basis.

Prior to the initiation of this study participating programs were screening for hearing loss by relying on physician reports indicating that ears had been “checked”, by reporting newborn hearing screening results (which is indicative of hearing status only at the time the screening was conducted) and, more commonly, by using a variety of subjective hearing screening methods including parent questionnaires or a “startle test” involving ringing a bell or clapping hands behind a child. One of the programs had already purchased OAE equipment and was attempting to use it, but was not using an appropriate screening protocol and needed further training. Another program had previously attempted to initiate OAE screening, but had experienced high refer rates and had abandoned its use. Upon further investigation, it was found that the program had purchased an OAE device that was adequate for screening newborns, but was not well-designed for screening toddlers in natural settings. In interviews at the beginning of the study, staff in all of the programs expressed dissatisfaction with their current hearing screening methods, but reported that they had no means of making any improvement without appropriate guidance and assistance.
Participant Demographics

Staff from 52 sites (29 Migrant, 3 American Indian, and 20 Early Head Start sites) in Oregon, Utah, and Washington participated in the project. The 52 sites were diverse in many ways: 15 were in urban locations and 37 in rural locations; 40 served families primarily in center-based settings, 2 provided home-based services, and 10 served families in both center and home-based settings. Hence, participating programs included those where children were easily accessible in the center on a daily basis as well as home-based programs that extended across a 3000-square-mile area. While the American Indian and Early Head Start programs operated year-round, participating Migrant programs operated seasonal programs ranging from 6-9 months as well as some short-term programs ranging from 16 to 26 weeks. The mean number of children served by the participating programs was 165, ranging from 38 to 982.

Multiple staff members, ranging from 2-12 individuals, were trained in each site. Of the total screenings conducted on children, approximately 81% were performed by program staff with backgrounds in health and/or disabilities (including health coordinators, health assistants, health specialists, registered nurses, licensed practical nurses, and disability specialists) and 19% were performed by early childhood staff (including home visitors, family advocates, child development specialists, and service coordinators). Table 1 summarizes the demographic backgrounds of the children who were screened in the participating programs. All children who were screened as a part of this project were between 0 and 3 years of age.

Insert Table 1 about here
OAE Hearing Screening Methodology

Otoacoustic emissions testing is a non-invasive procedure that generates an objective response from the inner ear. During OAE screening, the screener places a small probe, fitted with a sensitive microphone, into the child’s ear canal. The probe delivers a quiet tone or clicking sound into the ear. In a healthy ear, sound is transmitted through the middle ear to the inner ear where the outer hair cells of the cochlea respond by producing an emission sometimes described as an “echo.” This emission travels back out through the middle ear and is then picked up by the microphone, analyzed by the screening unit, and a “pass” or “refer” result is displayed on the unit’s computer screen. Every normal, healthy inner ear produces an emission that can be recorded in this way (Gorga, et al, 1997).

The ear will not pass the screening if there is: a) a blockage in the ear canal; b) a structural problem in the middle ear that interferes with hearing,; c) excess fluid present in the middle ear (often due to otitis media); or d) a cochlea that is not responding normally to sound. Thus, OAE screening can help identify children who need to be evaluated for fluctuating loss associated with otitis media or middle ear infection as well as children who have permanent hearing loss. The OAE screening can be performed in a variety of natural environments, including settings where other children are playing and vocalizing at a moderate level. Figure 1 shows a child being screened by Head Start staff in the child’s classroom.

Insert Figure 1 about here

It is important to emphasize that OAE screening as performed in this study is not an audiological diagnosis of hearing status. The OAE screening protocol outlined for screeners to
follow was not designed to collect frequency-specific information on the ear’s response, nor does it screen for hearing loss associated with the neural pathway to the brain. OAE screening can, however, be performed by non-audiologists and is therefore an excellent first step in identifying children who may have a temporary or permanent hearing loss. As with any type of hearing screening, children who do not pass the OAE screening should be referred for appropriate medical and audiological diagnosis and treatment.

There are currently two methods of eliciting and measuring otoacoustic emissions: distortion product otoacoustic emissions (DPOAEs) and transient evoked otoacoustic emissions (TEOAEs). There are also a variety of handheld OAE screening units on the market utilizing one or both methods. Based on the recommendations of a panel of six pediatric audiologists with extensive experience screening young children, and for purposes of uniformity in the study, a single brand of OAE equipment, the AuDX from Bio-logic Systems Corp (http://www.blsc.com/hearing/audx1.html), was used at all sites.

The AuDX measures DPOAEs with screening parameters set to deliver stimulus and measurement levels that are sensitive to hearing loss as low as 25 decibels (dB) hearing level (HL). If an emission is not present at these low levels, a refer result is obtained. These levels are low enough to refer children with even a mild loss of hearing sensitivity. In addition, the AuDX screens DPOAEs at four key frequencies (2 – 5 kilohertz) requiring an emission to be present at three of the four frequencies screened. Absence of OAEs is associated with varying degrees of sensory hearing loss from mild/moderate to profound (Hall, 2000). While the screening is not diagnostic in nature, it is sensitive to mild to profound hearing loss and screens in the frequency (pitch or tone) range that is critical for normal speech and language development. It should be noted that rapid changes in technology and a highly competitive
market warrants review and assessment of current options to ensure the most appropriate equipment choice for screening children 0-3 years of age.

**Hearing Screening Protocol**

A screening protocol was developed for use in early childhood programs that would be practical for screeners to follow and would also reflect accepted audiological and medical practices including current recommendations and guidelines of the Head Start Performance Standards. The protocol was designed to: 1) maximize the identification of children having permanent hearing loss as well as chronic middle ear disorders or other hearing-health conditions; and 2) minimize over-referral of children for medical or audiological follow-up who did not actually need treatment (“false-positive” referrals). The resulting protocol reflected **rigor** (in ensuring that children with a range of hearing-health conditions would be identified), as well as **practicality** (in establishing a process that would be feasible for the Head Start staff and local physicians and audiologists to implement). The key components of the protocol that guided screeners are depicted in Figure 2 and are summarized.

1. The first step was for the screener to complete a visual inspection of each ear. This included examining the outer ear for abnormalities, foreign objects or blockage in the ear canal, any fluids draining from the ear, or noticeable odor. If any abnormal conditions were present, the child would be referred to a health care provider for a medical examination.
2. If the child passed the visual inspection, or upon receiving medical clearance from a health care provider after an earlier referral, the OAE screening would be conducted on each ear. If both ears passed, the child’s hearing screening would be considered complete.

3. If the child did not pass the screening on both ears, or if the screener was unable to complete the screening (generally because the child was uncooperative or the environment was too noisy) the screening would be repeated on a subsequent day. Any ear not passing the initial screening would rescreened up to two additional times over a 2- to 4-week period. If a passing result was not achieved on both ears, the child would be referred to a health care provider for medical assessment/intervention for a possible middle ear disorder.

4. After treatment and/or medical clearance was obtained, the OAE screening process would be repeated on any ear that did not pass the initial screening attempts. If the ear passed, no further testing would be needed until the next scheduled screening. However, if no OAE pass result was achieved after medical clearance, the child would referred to a pediatric audiologist for evaluation.

Although screeners were trained to follow the standard protocol, they were also instructed to exercise their own judgment when circumstances warranted more immediate referral to a health care provider. For example, if parents had concerns about the child’s hearing or if a family was likely to be relocating within a short period of time, screeners might refer a child for follow-up after an initial failed screen rather than waiting to do further OAE screening.
Data Collection and Dependent Variables

Screening and follow-up forms were designed to reflect the screening protocol, to facilitate record keeping for hearing screeners, and to collect screening outcomes for formative and summative evaluation. Head Start staff, trained to screen as part of the project, used the Hearing Screening Form to document the screening outcomes on the right and left ears of each child. This form was printed in triplicate, permitting the program to file one copy, send one to a physician or audiologist as needed, and send one to the research team for analyses. General demographic information was also collected on the Hearing Screening Form.

Diagnostic outcomes were documented on a Follow-up Form by health care providers and audiologists within the communities where the children were regularly served. These individuals did not receive additional training or supervision as a part of the study. The Follow-Up Form was used only for the smaller subset of children (approximately 5%) who were referred from screening to a physician or audiologist. It was the primary source of documentation and feedback to program staff about the medical and audiological procedures and outcomes resulting from referrals.

As part of the evaluation, notes recorded on the screening and follow-up diagnostic forms were examined and interviews were conducted with staff at each participating program on a monthly basis. Participants’ comments were also collected from emails, telephone calls, and during group evaluation meetings in which programs reported their successes, challenges, and concerns regarding implementing an OAE screening and follow-up program.

Dependent variables are summarized below.
Screening Outcome Dependent Variables

Visual Inspection Results. This variable had two potential results for each ear: 1) Pass, indicating no observable abnormalities, or; 2) Refer, indicating an observable abnormality. Potential abnormalities included a) congenital malformation of the ear which may correspond with other physical abnormalities in the auditory system, b) visible blockage of the ear canal caused by wax or other debris that could disrupt the screening process and hearing itself; c) drainage or discharge from the ear such as pus, blood or a foul odor from the ear commonly associated with middle ear infection.

OAE Screening Results. This variable had three potential results for each ear: 1) Pass, indicating normal hearing, 2) Can’t test, indicating the child was not cooperative, generally because the child was distressed or would not sit quietly during the screening; or, 3) Refer, indicating possible hearing loss of cochlear origin or the presence of outer/middle ear blockage or fluid. In addition, it is important to note that a “false positive” refer can also result from factors compromising the accuracy of the screening, including “external” noise present in the environment or excess “internal” noise produced by movement or noise generated by the child. For this reason, the protocol suggested that most children not passing the initial OAE screening should be rescreened to minimize “false positive” referrals to health care providers.

Diagnostic Outcome Dependent Variables

Diagnostic outcomes for children referred from either the visual or the OAE screening reflect the clinical judgment of various health care providers and audiologists in the communities where children were regularly served. This project did not attempt to control the diagnostic methods used for children who were referred to a health care provider or an audiologist for
evaluation. Rather, the project documented the diagnoses made by the providers conducting the evaluations.

Health Care Provider Evaluation Outcomes. When children not passing the OAE screening were referred to a health care provider, otoscopy, pneumatic otoscopy and/or tympanometry were used by the provider to check for the presence of outer or middle ear disorders. Diagnosis and treatment possibilities involving one or both ears are summarized in Table 2.

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Insert Table 2 about here

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Audiologist Evaluation. Children who were medically cleared by a health care provider and continued to refer on OAE screening were referred to an audiologist for a diagnostic evaluation. Depending on the child’s age and development level, diagnostic OAE testing, electrophysiological assessment including auditory brainstem response testing (ABR), and/or behavioral audiometry (including testing in the sound field or with headphones), visual reinforcement audiometry, or conditioned play audiometry, were used to evaluate hearing status. Diagnosis and treatment possibilities involving one or both ears included:

- The presence of a middle ear disorder necessitating referral back to the health care provider for treatment.
- Fluctuating conductive hearing loss (temporary hearing loss that improves or worsens depending upon the status of the middle ear). The presence of fluctuating conductive hearing loss often necessitates a medical referral and
justifies more aggressive medical treatment such as surgical insertion of pressure equalization tubes.

- Permanent conductive hearing loss that cannot be resolved without surgical intervention on the structures that comprise the middle ear.

- Permanent sensorineural hearing loss that is cochlear (inner ear) or neural in nature. This type of loss cannot be resolved by routine medical treatment or procedures.

- Mixed hearing loss that has both a conductive and sensorineural component. This often happens when a child who has a permanent sensorineural hearing loss also gets a middle ear infection further affecting the conduction of sound.

- Other anatomical abnormalities may also include the peripheral and central auditory system.

The treatment and intervention strategies for the above diagnoses are highly individualized depending upon type and severity of the hearing loss and availability of services. Options may include medical or surgical intervention, amplification, cochlear implantation, and/or early intervention.

In addition to the quantitative data collected from each participating program’s hearing screening results, qualitative data were collected through:

- Notes and other written documentation accompanying screening and follow-up diagnostic forms.

- Monthly interviews with staff at each participating program.
• Reports by participants via email, telephone calls, or during group evaluation meetings about their successes, challenges and concerns about the OAE screening and follow-up program.

Training

Training workshops for people doing the screening were hosted in Head Start programs where children were available to be screened. Multiple programs were often involved in a training session, with each program being encouraged to have at least two members per site trained in order to minimize problems related to staff turnover and to ensure that each screener had at least one potential “screening partner” upon return to their programs. The total number of participants trained totaled 112 with an average of 14 participants per training workshop.

Training required approximately six hours to complete and included the following elements:

- Large-group instruction in which a training team of 3 – 4 people provided general information to the entire group of 12 – 16 trainees.

- Small-group instruction in which each trainer assisted 3 – 4 screener trainees in learning to use the equipment by screening one another. Trainers then supervised these small groups of trainees as each participant screened at least five children. Screening forms were completed on children exactly as they would be during a normal screening.

- Audio-visual and written materials were used during the training and were given to participants to ensure standardized training approach and to give trainees materials that could be reviewed later.
At the end of each training workshop, 89% of participants reported that “just the right amount” of time was spent on the various sections of the training. Similarly, 95% of participants reported that the information provided was either “very clear” or “clear.”

**Results and Discussion**

As described earlier, four research questions were investigated as a part of this study. Results related to each of those questions are summarized below.

**Research Question #1:** What are the overall hearing-health outcomes and types of conditions identified for children 0 – 3 years of age when Migrant, American Indian, and Early Head Start staff members are trained to implement an OAE-based hearing screening and follow-up program?

Based on the multi-step screening protocol, of the original 3486 children who were screened, a total of 183 (5%) were referred for medical or audiological follow-up. As shown in Table 3, of the 183 children referred for follow-up from screening, 80 were identified with a hearing loss or disorder requiring treatment or monitoring. Table 3 shows a breakdown of these 80 cases with 6 children identified as having a permanent hearing loss and 63 children diagnosed with otitis media, 11 of whom were further diagnosed to have fluctuating conductive hearing loss associated with chronic middle ear infection. Two children were treated for occluded pressure equalization tubes while nine were treated for excessive earwax or congestion.

Insert Table 3 about here
Of the 183 referred children, 17 were diagnosed as “normal” requiring no treatment, while 22 who were initially referred for medical or audiological follow-up had their appointments cancelled after passing a fourth OAE screening attempt that cleared them from the referral roster. It is not possible to determine whether these 39 cases, representing 1% of the total number of children screened, were initially “false positive” referrals or whether the children did indeed have an identifiable condition at the time of screening, such as a wax blockage in the outer ear or fluid in the middle ear, that was resolved prior to further screening or examination by a health care provider. Because most of the screeners in the study were trained only to perform the OAE screening, further examination of the ear canal and the tympanic membrane at time of the screening, through otoscopy or tympanometry, was not part of the suggested protocol. This finding suggests that when OAE screening is done in a setting where professionals and equipment are available to perform pneumatic otoscopy, tympanometry or reflectometry, it could be beneficial to add these steps to the screening protocol to determine whether the child has an outer or middle ear condition warranting immediate referral or treatment.

A total of 64 children who were referred from the OAE screening exited the Head Start program before medical or audiological referrals could be completed. Unfortunately, it is impossible to determine the hearing status for these children. Of the 119 children who did receive a diagnosis, 80 (67%) had a hearing loss or disorder requiring treatment. Using the same percentages to extrapolate to the 64 children who exited the program, it is probable that approximately 42 of the 64 had a hearing loss or disorder requiring treatment and that approximately 3 of those 64 may have had a permanent hearing loss that remained unidentified. This extrapolation suggests that if programs are able to ensure that follow-up screenings and
referrals occur in a more timely way, the incidence of children identified with hearing health conditions in Head Start may be even greater than the findings presented in this study.

**Research Question #2: How many children with permanent hearing loss or other treatable hearing problems were identified as a result of OAE-based screening?**

As a result of the OAE screening and follow-up assessment, 6 out of the 3486 children in the Head Start programs were found to have a permanent hearing loss. Table 4 summarizes additional information about these 6 children, including type of hearing loss, the age at diagnosis, newborn screening results, along with background and current treatment information. Three of these children had a permanent sensorineural hearing loss (originating in the cochlea) while 3 had a permanent conductive loss (originating in the middle ear).

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Insert Table 4 about here

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In understanding the implications of these findings, it is helpful to remember that the number of children with hearing loss that newborn hearing screening programs expect to identify at birth is approximately 3 per 1000 (National Center for Hearing Assessment and Management, 2005). Although the number of children screened in this study is not a large enough sample to draw firm conclusions about prevalence rates, these data suggest that 2 additional children per 1000 with permanent hearing loss could be identified by screening in Head Start programs. These include children who referred from newborn hearing screening programs and were lost to follow-up before an assessment was completed, children who passed the newborn screening and experience a loss during early childhood, and those who were not screened at all as newborns. Screening in other early childhood programs would likely increase this number even more.
Case #1 serves as an example of how continuous screening throughout early childhood can help to identify children who refer from the newborn hearing screening and are lost to follow-up before assessment and intervention could be provided. Although this child did not pass the newborn hearing screening, and also had a family history of hearing loss, he was not identified until 9 months of age when screened with OAE equipment at a Head Start program. At this point, the Head Start staff was able to assist the family in obtaining the needed diagnostic and intervention services. It is important to note that the number of children lost to follow-up from newborn hearing screening is significant—some states report that as many as 50% of infants who need follow-up after newborn hearing screening may not be receiving it in a timely way or at all. (CDC, 2005)

Cases #2, #5, and #6 demonstrate that continuous screening beyond the newborn period is also vital for identifying children whose hearing loss is probably not congenital, but likely originated during early childhood (often described as a “late onset” loss). Despite passing the hearing screening at birth, by 15 to 30 months of age, these children referred on the OAE screening. Although their hearing loss at the point of diagnosis was considered to be mild/moderate, and in two cases unilateral, it is important to remember that hearing loss among young children is often a progressive condition, worsening over time. The implication of early identification in these cases is that the children can be provided with additional services during the critical language-learning years and also be monitored closely to modify the treatment as necessary.

Finally, Cases #3 and #4 illustrate that continuous screening is important because some children were never screened at birth because they were born at home, were not born at hospitals performing newborn hearing screening, were discharged from the hospital without being screened,
or were born in a country not doing universal newborn hearing screening. In the cases noted above, one of the children was adopted from another country while one was a child of a migrant family. It is not known whether the hearing loss was congenital or presented during early childhood. However, had the loss remained unidentified, these children would have likely experienced language delays and academic under-achievement (Moeller, 2000).

The value of using the OAE equipment to screen children for permanent hearing loss after fluctuating middle ear conditions have been resolved is also highlighted by these cases, because 2 of the 6 children were diagnosed as having a “mixed” hearing loss that included both otitis media and a permanent hearing loss. Early education program providers often assume, incorrectly, that if the child is referred to a health care provider that all “ear” or “hearing” disorders will be identified and treated. The reality is that while most health care providers are familiar with treating middle ear infection, very few have the capacity to objectively screen children for a permanent hearing loss.

Finally, of the 6 children identified with permanent hearing loss, 4 were diagnosed as having a bilateral loss (both ears) while 2 had a unilateral loss (one ear). Although the advantage of identifying a bilateral hearing loss is widely understood, the significance of identifying unilateral hearing loss tends to be under-appreciated. An assumption is often made that a hearing loss in one ear can be easily compensated for by the other ear. Because children with unilateral hearing loss often respond to sound in a way that would indicate they are hearing, particularly in one-on-one interactions, a unilateral loss is especially difficult to identify using subjective methods. Furthermore, although children with unilateral hearing loss, or even mild bilateral loss, may be able to compensate for that loss within some contexts, their ability to discriminate speech sounds in an environment where competing background noise is present is often compromised.
This is why unilateral or mild hearing loss often goes unidentified until children are in school and language and academic delays become apparent (ASHA, 2004b; Bess, Dodd-Murphy, & Parker, 1998). Unilateral hearing loss can also be associated with progressive loss that may eventually affect the other ear. Therefore, identifying both bilateral or unilateral losses is important because both can have a significant negative effect on language acquisition, socialization, and academic development.

**Research Question #3:** How effective was a multi-step OAE hearing screening protocol in terms of:

a) maximizing the identification of children having hearing-health conditions likely to interfere with normal hearing, while

b) minimizing over-referral of children for medical or audiological follow-up who did not actually need treatment (“false-positive” referrals).

Data on 3486 children screened during the 36-month project period were coded and analyzed to assess the outcomes of the multi-step screening and follow-up process to determine if the goals of the protocol were met. 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 found, these anomalies were noted and children were referred directly for medical follow-up. As is shown in Figure 3, a total of 6 children (< 1%) were referred for medical follow-up from the visual inspection. The 3480 (>99%) children passing the visual inspection were then screened using OAE equipment.

**OAE Screen 1 Outcomes.** Of the 3480 children receiving an initial OAE screening, 2665 (77%) passed and required no further follow-up. A total of 608 (17%) “failed” or “referred” on this first screening, while 207 (6%) were documented as “can’t test” (generally because children
were uncooperative on that day). Thus, a total of 815 (23%) children did not pass the initial OAE screening. Although the screening protocol suggested that children not passing the initial screening should typically be referred for a subsequent OAE screening before being referred for medical or audiological follow-up, screeners were instructed to exercise their own judgment in making a direct referral to a health care provider if circumstances warranted (e.g., if a child had a known history of ear infection, parents voiced concern about the child’s hearing, the Head Start program would be closing in the near future before subsequent screening could be performed, etc.) Thus, of the 815 children who did not pass this initial OAE screening, 32 (4%) were referred directly to a health care provider on the basis of these types of additional concerns. Note that if a one-step OAE screening process had been used, all 815 children not passing the initial screening would have been referred at this point which would likely represent unnecessary referrals to health care providers. Using a multi-step protocol, however, 783 children were expected to receive an OAE Screen 2 rather than being referred directly to a health-care provider.

OAE Screen 2 Outcomes. Of the 783 children needing a second screening, 392 (50%) passed and required no further follow-up. A total of 199 (25%) “failed” or “referred” on the screening and 78 (10%) could not be tested. The remaining 114 (15%), however, did not receive this second screening due to the program closing for the year/season or the child exiting the Head Start program. Of the 277 children who did not pass this second OAE screening, 26 (9%) were referred directly to a health care provider due to additional concerns. Thus, in accordance with the three-step screening protocol, a total of 251 children were expected to receive an OAE Screen 3.
At this point in the screening process, a total of 3057 (87%) of the original 3486 children had passed the OAE screening which represents an 11% increase from OAE Screen 1 outcomes. It would therefore appear that adding a second screening step is very helpful in minimizing “false-positive” referrals because children who were uncooperative and could not be tested, or who referred on OAE 1, possibly due to screener error or temporary congestion associated with head colds, passed the OAE screen 2. A less positive aspect of the multi-step screening process, however, was that over that same time period, 114 children, representing approximately 3% of the total, did not receive the second screening because they had exited the program or the program had closed.

**OAE Screen 3 Outcomes.** Of the 251 children needing a third screening, 84 (34%) passed and required no further follow-up. A total of 95 (38%) “failed” or “referred” on the screening and 24 (10%) could not be tested. The remaining 48 (19%) however, did not receive this third screening due to the program closing for the year/season or the child exiting the Head Start program. Thus, in accordance with the three-step screening protocol, 119 children were referred for medical follow-up from the third screening. At this point in the screening process, a total of 3141 (90%) of the original children had passed the OAE screening which represents only a 2% increase in the overall pass rate from OAE Screen 2. Because the improvement in “pass rate” from the second to the third screen is not nearly as large as the improvement from the first to the second screen, the value of the third screen may be questioned.

**Medical or Audiological Follow-up Outcomes.** Including the children who had been referred from the Visual Inspection (6), directly after OAE Screen 1 (32) or directly after OAE Screen 2 (26), as well as those not passing after completing all three steps of the screening process (119), a total of 183 children were referred for medical or audiological follow-up. This represents
a referral rate of only 5% of the total 3486 children in the study. As described previously in Table 3, 80 (44%) of the 183 children were found to have a hearing loss or disorder while 39 (21%) did not complete an evaluation because they passed a subsequent OAE screening or were diagnosed as “normal” by the health-care provider or audiologist. The remaining 64 (35%) exited the Head Start program, or the program closed, before the follow-up could be conducted.

The outcomes of the medical and audiological follow-up indicate that the multi-step OAE screening was successful in identifying children with a wide range of hearing-health conditions that are likely to interfere with normal hearing. The overall referral rate of 5% also compares favorably with the referral rates reported by effective hospital-based newborn hearing screening programs (White, 2003). Conversely, the fact that only 39 children of the original 3486 children (1%), failed the screening protocol and were found to have normal hearing, suggests that a multi-step screening protocol is effective in minimizing the “false-positive” referral rate. Thus, the implementation of OAE hearing screening in Head Start programs did not overburden local health care providers. Instead, it allowed health care providers and audiologists the opportunity to diagnose and treat children in need of their services.

Research Question #4: How feasible is it for programs to implement a multi-step screening and follow-up protocol?

To further evaluate the practicality of implementing an OAE-based hearing screening program in early childhood programs, screeners were asked to note the approximate amount of time required to conduct each screening session which included preparing the individual child, conducting the screening, and documenting the screening results for that child. The average time was 5 minutes, ranging from 1 to 30 minutes. None of the programs reported that they needed to hire additional staff or increase work hours for existing staff to complete the OAE screenings.
An analysis of the dates at which first, second, and third OAE screenings were done revealed that screeners were not always successful in completing the screening during the time frame suggested by the protocol. The protocol stated that if subsequent screening was needed for a child, it should be performed within 2 weeks of the previous attempt. Thus the entire 3-step screening protocol should have been completed within a 30-day time frame. Instead, the average length of time elapsing between OAE Screen 1 and OAE Screen 2 for the 669 affected children was 49 days. The average length of time between OAE Screen 2 and OAE Screen 3 for the 203 affected children was 35 days. Interviews with Head Start staff suggested that a number of factors contributed to the time lag between screenings, including competing demands on staff time at the beginning of the program year and the significant distance staff sometimes had to travel to screen/rescreen children in home-based programs. Finally, staff may not have understood the importance of conducting the rescreens in a timely way to maximize the effectiveness of the screening process.

Conclusions

The dramatic improvements in hearing screening technology and the steady growth of hospital-based newborn hearing screening programs over the past decade hold important implications for improving hearing screening practices in early childhood programs. Advances in OAE technology mean that programs no longer need to use less reliable, informal behavioral observations or parent questionnaires when screening children 0 - 3 years of age. Similar to previous findings in hospital-based newborn hearing screening programs, this study showed that Head Start staff members from a variety of backgrounds were able to use OAE equipment to efficiently complete physiological hearing screening of infants and toddlers. They were also able to successfully identify children who were ultimately diagnosed with a wide range of
hearing-health conditions warranting monitoring and treatment. As a result of the OAE screening conducted in this study, 6 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 a hearing loss at some point during their early childhood years. Thus, not only can early childhood programs benefit from the recent development of Early Hearing Detection and Intervention (EHDI) programs in each of the states, they can also play an important role within a state’s EHDI system by providing ongoing hearing screening throughout early childhood and by linking identified children to available services. The six children identified with permanent losses in this study were connected with audiological services, local early intervention services, and family support programs. Furthermore, an additional 74 children in the study were diagnosed with a hearing-health condition requiring treatment. Audiological evaluation revealed that at least 11 of the 63 children with otitis media were also experiencing a temporary hearing loss and that 2 children currently being treated for otitis media had occluded pressure equalization tubes that were not functioning as intended. Thus, the OAE screening was valuable in providing much-needed information to health care providers on the status of the children’s hearing health.

The outcomes of the screening activities implemented by Head Start programs in this study were largely attributed to the OAE technology being used; however it was also critical that people doing the screening were provided with:

- comprehensive training, including “hands-on” screening experience
- a structured, appropriate protocol to follow,
- forms for recording results and tracking children who needed further follow-up, and
- ongoing support and monitoring from a pediatric audiologist.
Feedback from program participants throughout the study reinforced the value and importance of these activities. Although the equipment itself is designed for use by non-audiologists and does not require interpretation of results, some skills are required relative to setting up an appropriate screening environment, inserting the probe correctly in the ear canal, and maintaining a child’s cooperation during the screening process. Equipment distributors are often well versed in demonstrating and explaining the various functions of the equipment, but they seldom have extensive experience screening young children nor are they prepared to provide the information and training necessary for establishing a complete hearing screening program. This underscores the importance of having a skilled pediatric audiologist involved in establishing an OAE screening and follow-up program.

The importance of continued audiological supervision beyond the initial training must also be underscored. In this study it was found that from 1 – 2 hours per program per month of audiological consultation were necessary throughout the course of the screening and follow-up process because screeners did not always understand how to use the equipment to its full potential to detect hearing loss. A small number of programs that experienced higher-than-average refer rates sometimes needed assistance in assessing whether their equipment was functioning properly or whether they needed to improve their screening techniques. Programs frequently had to be reminded to engage in follow-up screening after children were seen or treated by primary care providers. Good audiological practice dictates that a child’s hearing must again be screened after treatment for otitis media to assess whether additional, undetected, permanent loss might also be present in addition to the middle-ear condition. Screeners who do not have enough knowledge about how OAE screening works, a viable screening/referral protocol to follow, and/or are not operating under appropriate audiological guidance are likely to
erroneously assume that any problems related to the initial referral are resolved as part of the primary care services. They may therefore unwittingly fail to complete a critical part of the screening and referral process necessary to detect additional permanent hearing losses. A number of participants tended to erroneously assume that the primary care providers were able to objectively assess hearing as a part of the follow-up services rendered, which is not commonly the case. Continued oversight and consultation from an audiologist is therefore important in maintaining appropriate referral rates, in troubleshooting and maintaining equipment, and in assisting programs to arrange follow-up assessment when needed.

Several questions remain related to refining the hearing screening protocol in order to maximize the number of children appropriately referred for follow-up while minimizing false positive referrals. These include closer examination of the optimal OAE screening protocol and the potential for using additional screening tools to expedite referrals to a health care provider. Although it is clear that a multi-step OAE screening protocol is helpful in minimizing “false positive” referrals, this study raises questions on the relative advantages and disadvantages of implementing a 2-step, rather than a 3-step, OAE screening protocol.

Advantages of a 2-step screening process potentially include: 1) decreasing the number who exit the program before diagnosis can be made and treatment initiated, and 2) decreasing the length of time it takes for programs to complete the screening and make a referral. In this study, 48 children exited the program before receiving a third screening and an additional 64 exited after the third screening, but before an evaluation was completed. It is highly likely that some percentage of these children had a permanent or fluctuating hearing loss that remained unidentified. In addition, the fact that many programs conducted the screening steps over a protracted period of time may have resulted in the under-identification of children experiencing
an episode of otitis media at the time of the screening which resolved naturally before examination by a health care provider. The objective of the multi-step screening protocol was to allow 7-14 days to elapse between screenings so that minor head-cold congestion could be resolved while more serious middle ear conditions, which would be unlikely to resolve spontaneously within the total 4-week period, would be identified. In many instances the time elapsing between screenings was much longer than desired. Children who were referred to a health care provider from the multi-step OAE screening, but were diagnosed by the provider as “normal” and subsequently passed a fourth OAE screening, may not represent “false positive” screening results. These referrals may instead represent cases where fluctuating middle ear conditions existed at the time of screening, but were never documented in the child’s medical records. This would be an unfortunate outcome since each occurrence of otitis media needs to be documented, even if not treated initially. At this time, health care providers monitor the condition and counsel the parents on adaptations that can be made to accommodate any temporary hearing loss that may be occurring (Rosenfeld, et al., 2004). The unintended effects of an extended screening protocol were probably exacerbated by the fact that not all children were seen promptly by a provider even after a referral was made. No child-specific data was collected to assess the amount of time elapsing after a referral was made before the child was seen by a provider, but anecdotal data from staff suggested that it could be challenging to get children assessed by providers in a timely way.

Conversely, the disadvantages of a 2-step screening protocol, rather than a 3-step protocol, may include an increased number of “false positive” referrals to health care providers. Most hospital-based newborn hearing screening programs utilizing OAE equipment use a 2-step protocol. One significant difference, however, is that toddlers are more difficult to screen than
infants because of their increased physical activity levels, therefore screeners are likely to generate more “false positive” results. In the present study, if the OAE screening 3 step were eliminated, 319 children, rather than 183, would have been referred for follow-up, representing a 9%, rather than a 5%, referral rate. This would be acceptable if the majority of children were found to have conditions requiring monitoring or treatment, but would represent an overly high referral rate if no treatable conditions were identified. Further study will be necessary to determine whether a 2- or 3-step protocol creates the best balance in minimizing the “false positive” refer rate while maximizing the number of children who are seen by a provider in a timely way.

The potential for expediting referrals to a health care provider when the individual performing the OAE screening is also qualified to perform screening specific to middle ear disorders also merits further exploration. Because most of the screeners in the study were not nurses and were trained only to perform the OAE screening, further examination of the ear canal and the tympanic membrane through otoscopy at time of the screening was not part of the suggested protocol. Likewise, neither tympanometry nor reflectometry were available and screeners were therefore not trained to attempt any further screening of the middle ear. When individuals conducting the OAE screening are also qualified to perform a more in-depth visual screen of the ear canal and the tympanic membrane, or to conduct tympanometry or reflectometry, this could potentially increase the efficiency of how children who are referred to a health care provider in a timely way.

If Head Start and other early childhood programs are to help children start school ready to learn, it is critical that any barriers to learning be identified as early as possible. National programs like the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) service and Part C of the Individuals with Disabilities Education Act also have existing commitments to the
provision of hearing screenings for young children; however, subjective methods are still typically used in these programs as well. The close connection between hearing, language acquisition, literacy and school readiness demands that as technology improves, so also should the quality of hearing screening during the early childhood period. The results of this study demonstrate that OAE technology, when used with an appropriate screening and follow-up protocol, can make a valuable contribution in helping to identify a wide range of hearing-health conditions that can potentially disrupt language acquisition, literacy, socialization and overall school readiness.
References


Table 1

Summary of Child Demographics

<table>
<thead>
<tr>
<th>Demographic Variable</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1623</td>
<td>(52%)</td>
</tr>
<tr>
<td>Male</td>
<td>1806</td>
<td>(47%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>57</td>
<td>(1%)</td>
</tr>
<tr>
<td><strong>Age (months)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean= 22  SD=(13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-12</td>
<td>941</td>
<td>(27%)</td>
</tr>
<tr>
<td>13-24</td>
<td>895</td>
<td>(26%)</td>
</tr>
<tr>
<td>25-36</td>
<td>1086</td>
<td>(31%)</td>
</tr>
<tr>
<td>36-48</td>
<td>564</td>
<td>(16%)</td>
</tr>
<tr>
<td><strong>Type of Program</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migrant Head Start</td>
<td>2049</td>
<td>(59%)</td>
</tr>
<tr>
<td>Early Head Start</td>
<td>1272</td>
<td>(36%)</td>
</tr>
<tr>
<td>American Indian Head Start</td>
<td>165</td>
<td>(5%)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>2269</td>
<td>(65%)</td>
</tr>
<tr>
<td>Caucasian</td>
<td>727</td>
<td>(21%)</td>
</tr>
<tr>
<td>American Indian</td>
<td>212</td>
<td>(6%)</td>
</tr>
<tr>
<td>African American</td>
<td>87</td>
<td>(3%)</td>
</tr>
<tr>
<td>Bi-racial</td>
<td>53</td>
<td>(2%)</td>
</tr>
<tr>
<td>Asian</td>
<td>12</td>
<td>(1%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>126</td>
<td>(4%)</td>
</tr>
</tbody>
</table>
### Table 2
Summary of Potential Diagnoses and Treatments

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment Possibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>External ear canal obstruction</td>
<td>Removal of wax or other debris</td>
</tr>
<tr>
<td>Acute otitis media</td>
<td>Antibiotics, ear drops, pain medication and/or monitoring</td>
</tr>
<tr>
<td>Chronic otitis media with effusion (fluid)</td>
<td>Monitoring, prophylactic antibiotics, and/or insertion of pressure equalization (PE) tubes</td>
</tr>
<tr>
<td>Non patent PE Tubes</td>
<td>Blocked or plugged tubes may need to be cleared, removed and/or replaced</td>
</tr>
<tr>
<td>Other abnormalities of the outer or middle ear</td>
<td>Further referral and evaluation by an otolaryngologist (ENT)</td>
</tr>
</tbody>
</table>
Table 3
Summary of Diagnostic Outcomes

<table>
<thead>
<tr>
<th>Diagnostic Outcomes</th>
<th>Number of Children</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hearing loss or disorder requiring treatment or monitoring</strong></td>
<td>80 (44%)</td>
</tr>
<tr>
<td>Permanent hearing loss</td>
<td>6</td>
</tr>
<tr>
<td>Otitis media (ear infection)</td>
<td>52</td>
</tr>
<tr>
<td>Otitis media and documented fluctuating conductive loss</td>
<td>11</td>
</tr>
<tr>
<td>Occluded pressure equalization (PE) tubes</td>
<td>2</td>
</tr>
<tr>
<td>Excessive ear wax requiring removal</td>
<td>7</td>
</tr>
<tr>
<td>Congestion – decongestant recommended</td>
<td>2</td>
</tr>
<tr>
<td><strong>No treatment required</strong></td>
<td>17 (9%)</td>
</tr>
<tr>
<td>*14 pass subsequent OAE screening and determined to have “normal hearing”, 3 not rescreened/hearing status unknown</td>
<td></td>
</tr>
<tr>
<td><strong>No referral completed-passed subsequent OAE screening</strong></td>
<td>22 (12%)</td>
</tr>
<tr>
<td><strong>Existed before diagnosis completed/referral appointment completed</strong></td>
<td>64 (35%)</td>
</tr>
</tbody>
</table>

n=183
<table>
<thead>
<tr>
<th>Case</th>
<th>Diagnosis and Age at Diagnosis</th>
<th>Newborn Hearing Screening Results</th>
<th>Additional Background and Current Treatment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bilateral, severe sensorineural loss and Otitis Media (9 months)</td>
<td>Referred; subsequently lost to follow-up</td>
<td>Family history of hearing loss (older sibling); treated for chronic otitis media (including pressure equalization tube insertion); fitted with hearing aids; enrolled in early intervention services.</td>
</tr>
<tr>
<td>2</td>
<td>Bilateral, severe conductive loss (2-1/2 years)</td>
<td>Passed</td>
<td>Family history of hearing loss and Fragile X syndrome, received early intervention services.</td>
</tr>
<tr>
<td>3</td>
<td>Bilateral, mild/moderate conductive loss and Otitis Media (3 years)</td>
<td>Not screened at birth</td>
<td>Treated for chronic otitis media (including PE tube insertion); receiving speech and language therapy; received further services from local education agency.</td>
</tr>
<tr>
<td>4</td>
<td>Bilateral, mild/moderate conductive loss (2 years)</td>
<td>Not born in U.S., not screened at birth</td>
<td>Audiologist did not recommend immediate amplification; received limited speech and language therapy.</td>
</tr>
<tr>
<td>5</td>
<td>Unilateral, mild/moderate sensorineural loss in left ear (15 months)</td>
<td>Passed</td>
<td>Underwent surgery at 3 months of age for cranial stenosis; has speech delay; received speech &amp; language therapy; possible progressive loss in right ear.</td>
</tr>
<tr>
<td>6</td>
<td>Unilateral, mild/moderate high frequency sensorineural loss in left ear (2 years)</td>
<td>Passed</td>
<td>Permanent high frequency loss in left ear; received speech/language therapy; possible progressive loss in right ear.</td>
</tr>
</tbody>
</table>
Figure 1. Photo of child being screened using OAE technology.
Figure 2. OAE hearing screening protocol.
Visual Inspection = 3486

- Direct Refer 6 (<1%)
- Pass 3480 (>99%)

OAE Screen 1 = 3480

- Pass 2665 (77%)
- Refer 608 (17%)
- Can’t test 207 (6%)

- Direct Refer 32

OAE Screen 2 = 783

- Pass 392 (50%)
- Refer 199 (25%)
- Can’t test 78 (10%)
- Exited Program 114 (15%)

- Direct Refer 26

OAE Screen 3 = 251

- Pass 84 (33%)
- Refer 95 (38%)
- Can’t test 24 (10%)
- Exited Program 48 (19%)

183 Referred for medical or audiological follow-up

Figure 3. Flow chart documenting screening results at each step in the hearing screening protocol.