REPORT

IDENTIFICATION OF HEARING LOSS AND MIDDLE EAR DYSFUNCTION IN CHILDREN

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The American Academy of Audiology believes it is important to identify children with undetected sensorineural hearing loss as well as those with hearing loss resulting from middle ear dysfunction and chronic or recurrent otitis media with effusion (OME). The selection and implementation of a screening protocol must be guided by the specific goals of an identification program. The American Academy of Audiology supports the proposition that a carefully designed and well executed identification program, under the supervision of an audiologist, can be highly effective in identifying such children. It is our view that the lack of consensus regarding existing screening protocols has been due to limitations inherent in applying a single set of guidelines to a wide variety of settings and pediatric populations. This Report highlights important considerations in the design of an identification program so audiologists responsible for these programs can implement protocols appropriate to their settings. It also provides a rationale for the Position Statement that follows. The following Report and Position Statement apply to preschool-age children (3-4 year olds), school-age children at the early elementary grade levels, and children with developmental delays or disabilities.

PREVALENCE AND SEQUELAE OF SENSORINEURAL HEARING LOSS IN CHILDREN

At least 3 out of every 1000 infants in a well-baby population is born with significant bilateral hearing impairment. When high risk infants (e.g., NICU graduates) are considered separately, the incidence increases dramatically to approximately 30-50 per 1000 (Hosford-Dunn, et al., 1987; Simmons, 1978). Consequently, numerous medical centers throughout the nation routinely screen high risk infants for hearing loss, and some have implemented programs to screen all newborn infants, as recommended by the National Institutes of Health (NIH Consensus Statement, 1993). Unfortunately, many hospitals especially those in small communities and rural areas, lack hearing screening programs even for newborns at high-risk for hearing loss. Where high-risk screening programs have been established it has been shown that only about one-half of the children with sensorineural hearing loss are accurately identified (Stein, et al., 1990). Furthermore, the possibility of an acquired or progressive hearing loss exists throughout childhood. Parental concern regarding a child's hearing status is an important reason to assess hearing, but parental suspicion alone is not sufficient for timely identification of hearing loss in young children (Watkin, Baldwin, & Laoide, 1990). Thus, there remains a strong need for systematic identification of all children with hearing loss.

The impact of congenital or early-onset sensorineural hearing loss is well documented. Hearing loss in young children affects the development of speech and language as well as academic performance and social-emotional development (Boothroyd, 1982; Levitt, et al., 1987; Ross, et al., 1991). Long-term effects on family functioning and eventually on the individual's independence and career opportunities may follow. Fortunately, early intervention, combined with the use of hearing aids and other sensory devices, can reduce the impact of sensorineural hearing loss on a young child (Yoshinaga-Itano, 1995). Early identification of hearing loss is important and necessary to ensure that families can be made aware of their child's hearing status and make well-informed decisions regarding intervention services.

PREVALENCE AND SEQUELAE OF OTITIS MEDIA IN CHILDREN

Otitis media with effusion (OME) is an inflammation of the middle ear accompanied by fluid in the middle-ear space. OME is highly prevalent in young children, particularly between the ages of six months and two years. The incidence remains high throughout the preschool years (Klein, 1978). OME may persist for weeks or even months. Teele, et al., (1989) reported that 70 percent of children still had effusion two weeks following onset of acute otitis media, 40 percent had effusion at one month, 20 percent had effusion at two months, and 10 percent had effusion at three months. In recent years, the number of OME cases has increased dramatically, particularly in children under the age of two years (Schappert, 1992).

Although the prevalence of middle ear effusion is relatively high throughout childhood, certain risk factors are associated with a higher prevalence of OME. Risk factors for toddlers and older preschool-age children include group day care, exposure to smoke, bottle vs. breast feeding, and family history, especially among siblings (Stool, et al., 1994). Other children at increased risk include those with Down syndrome or with cleft lip/palate, as well as Native Americans, including Eskimos and American Indians (Northern and Downs, 1991; Daly, 1991).

The average hearing loss associated with OME is approximately 20-25 dB HL, but varies over a wide range from 0 to 50 dB HL (Fria, et al., 1985). The hearing of children with OME can differ substantially both in degree and symmetry (Gravel and Ellis, 1995). Timely identification is complicated by the fact that many children are asymptomatic , and parents/caretakers often have difficulty recognizing the presence of hearing loss. Indeed, it has been speculated that about half of all initial cases of children with OME would be undetected without screening (Bluestone, et al., 1986).

In addition to reduced hearing sensitivity, there are potential long-term effects of conductive hearing loss on auditory development and speech-language acquisition. There is behavioral and electrophysiological evidence to show that hearing gloss secondary to OME early in life may be associated with a reduction of auditory processing ability, particularly at the level of the brainstem, even after hearing levels have returned to normal (Hall, et al., 1990; Hall & Grose, 1993). Likewise, some children with histories of persistent or recurrent OME show reduction of speech recognition in competition even after auditory thresholds and middle ear function return to normal

(Gravel & Wallace, 1992).

Findings regarding effects of OME on speech, language, and learning have been controversial. Some studies suggest a relationship between persistent OME and reduced language skills and/or school performance (Silva, et al., 1982; Friel-Patti & Finitizo, 1990; Roberts, et al., 1989; Roberts, et al., 1995). Other studies have not supported this association. (Roberts, et al., 1986; Wright, et al., 1988). Although specific cause and effect relationships remain under investigation, it is generally accepted that persistent or recurrent OME has potentially detrimental long-term consequences for some children. These effects may be of particular concern for children already experiencing communicative disorders. Based on the predominant research conclusions, it is recurrent OME and its concomitant hearing loss place a child at increased risk for developmental delays when the condition occurs in early childhood.

Design and Selection of a Screening Protocol

Screening procedures are designed to separate from a group of apparently healthy individuals those who are at greatest risk of actually having the disease or disorder. Effective screening procedures result in high sensitivity (correct classification of diseased individuals) as well as high specificity (correct classification of non-diseased individuals). The screening test can be made more sensitive by adjusting the pass-fail cut-off; however, this generally occurs at the expense of lower specificity. The goal is to identify a cutoff that allows a reasonable balance between over-and under-referral.

Sensitivity and specificity are generally considered in the evaluation of a screening program, but prevalence and its corresponding effect on predictive value is often ignored. The predictive values of a test indicate the proportion of correct screening outcomes. (Vecchio, 1965). The predictive value is the proportion of individuals who passed the screening test who do not have the disease. Predictive value is used to estimate, based on the test outcome, the likelihood of an individual having or not having the target conditions. Sensitivity and specificity are unaffected by prevalence as long as the disease characteristics and diagnostic criteria remain constant, but predictive value is directly affected by prevalence. In OME, prevalence varies according to seasonal variation, and any conditions that place a child at increased risk. For example, statistics obtained from an unselected cohort of children will differ substantially in prevalence from those of children seen in a medical setting. Within a given cohort, children who are identified for re-screening will exhibit a higher prevalence than the larger cohort screened initially (Nozza, 1995).

A screening program must satisfy several criteria; the target condition must be a significant burden to the individual and to society; there must be an effective treatment for the disease; the screening measures employed must be properly evaluated and shown to be acceptable; there must be benefit to early identification and treatment; the screening cost must be reasonable; and there must be reasonable strategies for implementation of treatment and/or intervention (Feightner, 1992). In the context of screening with pure tones for sensorineural hearing loss, there is general consensus that these requisite conditions have been confirmed. In the context of screening for middle ear disease, it is generally agreed that most of the requisite conditions exist; however, a notable exception is the validity of the screening protocol itself (Wiley & Utech-Smith, 1995). Although acoustic immittance is recognized by audiologists as the screening method of choice, widespread acceptance of a specific protocol for acoustic immittance screening has been difficult to achieve.

Identification of Hearing Loss: Pure Tone Screening

Pure tone screening procedures consist of pure tones presented at specific test frequencies at a single intensity level. Screening is conducted by an examiner who instructs the child to respond behaviorally using an age-appropriate response task. A child who fails to respond in either ear at any frequency is generally referred for complete audiologic assessment, although in many settings rescreening is often provided on site, prior to referral. It is imperative that ambient noise levels be carefully monitored to insure compliance with existing standards (ANSI S3.1, 1991).

There are significant limitations to the use of speech stimuli in hearing screening. Although speech may be inherently more interesting to children, the spectral characteristics of the speech signal are such that children with high frequency hearing loss may demonstrate normal speech recognition through the use of low frequency cues. Indeed, false-negative rates as high as 58 percent have been reported for screening tests using speech stimuli (Mencher and McCulloch, 1970). Consequently, for the age groups pertinent to this Report, pure tone audiometric screening remains the preferred behavioral method of identifying undetected sensorineural hearing loss.

Identification of Middle Ear Dysfunction: Acoustic Immittance Measurements

Difficulties achieving consensus on an immittance screening protocol are due, in part, to limitations inherent in attempting to apply a single set of guidelines to a wide variety of settings and pediatric populations. Moreover, comparison of research on acoustic immittance measures is complicated by numerous instrumentation and recording variables including differences in probe frequency, pump speed, direction of pressure sweep, ear canal volume compensation, and inclusion of the acoustic reflex. Analysis of middle ear screening data may be skewed by subject grouping and the manner in which pass-fail criteria are applied and analyzed with respect to medical referral. Nozza, (1995) points out that the statistical measures of validity will be influenced by whether the analysis is conducted "by ear" or "by child." Specificity will be lower when the analysis is done by child because two normal ears are required to pas the screening. But sensitivity will increase because a fail on either ear would constitute a referral. These issues must be fully considered when attempting to compare test performance data.

The issue of re-screening must also be considered. Re-screening is advocated in most protocols because a single point test will not differentiate those individuals with transient or self-limiting episodes from those with chronic middle ear effusion. But the ideal re-screening interval has not been determined. Subjects identified for re-screening will have a higher prevalence of middle ear disease than those seen initially, but the implications of a screening "fail" are different depending on whether the fail occurs at the first or second screening. An initial fail resulting in re-screening at a later date may be less costly than a failure at re-

screening that leads to medical referral (Nozza, 1995).

Numerous studies have been conducted to evaluate the efficacy of acoustic immittance screening protocols (Beery, et al., 1975; Cantekin, et al.; 1980), and several have been directed at specific screening protocols (Lous, 1983; Roush and Tait, 1985; Lucker, 1980; Karson, 1991; Roush, et al., 1992; 1995), but only a few studies have used surgical confirmation (myringotomy) as the "gold standard." Although myringotomy is general considered to be the best validation criteria, it allows examination of immittance measures only in populations with chronic or recurrent OME, e.g., those scheduled for placement of tympanostomy tubes. Moreover, the inevitable delay between screening, referral, and medical examination results in errors of sensitivity and specificity.

Despite these limitations, examination of studies that used myringotomy as a validation criterion permit useful comparison of immittance measures. Wiley and Utech-Smith (1995), in a review of middle ear screening studies that employed direct verification of middle ear status from myringotomy, not that reduced static admittance appears to be a good predictor of middle ear effusion (Finitzo, et al., 1992), although some overlap is likely to occur between ears with and without effusion (Paradise, et al., 1976; Nozza, et al., 1992a; 1992b; 1994). Likewise, flat tympanograms accompanied by abnormally large ear canal volume estimates are generally seen when there is a perforation of the tympanic membrane or patent ventilation tube in the presence of normal middle ear mucosa (Shanks, et al., 1992). Measures of tympanometric shape, including gradient and width, appear to provide reasonable sensitivity (Fiellau-Nickolajsen, 1983; Paradise, et al., 1976; Nozza, et al., 1992a; 1992b; 1994), but because they are highly correlated with peak admittance measures, "wide" tympanograms may provide information that confirms rather than supplements other measures (Wiley & Utech-Smith, 1995). Nozza, et al. (1994), reported that among a battery of admittance measures, tympanometric width had the single best performance in the identification of middle ear effusion, although the optimal cut-off values differed for children with OME histories (high-risk) compared to those more typical of the general population. This finding underscores the importance of applying normative data obtained from subjects having the same population characteristics as the group targeted for screening. In addition to OME history, age-related developmental changes in static admittance, ear canal volume, and tympanometric width have been reported (Koebsel & Margolis, 1986; Roush, et al., 1995). Finally, several studies have shown that tympanometric peak pressure is of minimal value in detecting the presence of middle ear effusion (Fiellau-Nikolajsen, 1983; Haughton, 1977; Nozza, et al., 1992a, 1992b).

Inclusion of the acoustic reflex, typically elicited using an ipsilateral stimulus at a level of approximately 105 dB SPL, has produced mixed results (Cantekin, et al., 1980; Wachtendorf, et al., 1984; Silman, et al., 1992; Nozza, et al., 1992; Roush, et al, 1992; Utech-Smith, et al., 1993). The few investigations employing surgical verification as a gold standard reveal good sensitivity for acoustic reflex measures; however, specificity has varied substantially (Wiley & Utech-Smith, 1995). Comparison of studies that have included the acoustic reflex is complicated by differences in stimulus and recording parameters. Silman, et al., (1992), demonstrated improved performance when the activator stimulus is delivered at a higher intensity level than that employed by immittance screening instruments. Sells, et al., (1997), demonstrated that different reflex elicitation systems (pulsed vs. simultaneous presentation of the stimulus and probe tone) may result in markedly different screening outcomes. Further research is needed to determine the relative contribution of the acoustic reflex in a screening protocol, its specificity as well as sensitivity, and the optimal presentation level and mode of presentation for elicitation of the acoustic reflex (Silman and Emmer, 19950. The acoustic reflex is potentially valuable in separating "wide" tympanograms with and without middle ear effusion.

Otoacoustic Emissions

Otoacoustic emissions (OAEs) are present in most normally functioning ear and absent or reduced in ears with sensorineural losses of 30-40 dB HL. Because of the ease and speed with which the OAE test can be conducted, it is potentially an excellent method of screening for hearing loss. OAE is achieving considerable success in the area of newborn hearing screening, although one of the confounding factors in measurement of OAEs is the inability to record a response in the presence of middle ear dysfunction. Viewing the effect of middle ear status on measurement of OAEs as a problem assumes that the measurement is used exclusively to identify sensorineural hearing loss (Van Cauwenberge, 1995). Since the goal of school-age screening is to identify both sensorineural hearing loss and middle ear pathology, OAEs could potentially replace two separate screening tests (pure tone and immittance screening) with a single measure.

Considering the sensitivity of OAEs to both hearing gloss and middle ear dysfunction, OAEs have been suggested as an effective first stage screening procedure for both conditions (Decreten, et al., 1991; Nozza & Sabor, 1992). Although data are limited at this time, there is preliminary evidence of useful OAE applications in this context. Decreten, et al., (1991), is a group of children four to eight years of age, demonstrated that OAEs separated children with sensorineural hearing gloss from children with normal hearing. They also separated children with middle ear pathology from those with normal middle ear function and normal hearing. Nozza & Sabo, (1992), reported data on screening children five to 10 years of age in a school setting using evoked OAEs. Nozza and Sabo did not replicate the high specificity reported by Decreten, et al., (1991), but did find that specificity was sufficiently high to warrant further investigation of OAEs as a combined screening tool. Even with a false positive rate of 15-20%, Nozza and Sabo note that more than 75% of the children with normal peripheral auditory function would be expected to pass an OAE screening procedure and thus would require no further evaluation. Children who "failed" the screening could have sensorineural hearing loss, middle ear pathology, or both. In summary, the data from Decreten, et al., (1991) and Nozza and Sabo, (1992), suggest that there may be an important role for otoacoustic emissions in hearing and middle ear screening of young children. As with other measures, normative data are needed or the age groups of interest and controlled clinical trials must be carried out to determine the sensitivity, specificity, and predictive value of OAEs for detection of hearing loss and middle ear dysfunction.