Abstract

THE EFFICACY AND REPEATABILITY IN OTOACOUSTIC EMISSIONS SCREENING BY NON-AUDIOLOGY PROFESSIONALS

By John R. Warner

The purpose of this study was to investigate the repeatability and efficacy of Evoked Otoacoustic Emissions (EOAE) screenings performed by non-audiology professionals using the AuDX universal newborn hearing screening device by Bio-logic. After a brief instructional program, student clinicians and a certified audiologist performed screenings on each of five subjects. Results from student clinicians were compared to one another for repeatability. Clinician results were then compared to results obtained by the audiologist for reliability. Research from this study showed no significant difference in results obtained from non-audiology clinicians and those obtained by a certified clinical audiologist.
The Efficacy and Repeatability in Otoacoustic Emissions Screening by Non-Audiology Professionals

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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acknowledgments</td>
<td>iv</td>
</tr>
<tr>
<td>CHAPTER I</td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Purpose</td>
<td>3</td>
</tr>
<tr>
<td>Hypothesis</td>
<td>3</td>
</tr>
<tr>
<td>CHAPTER II</td>
<td></td>
</tr>
<tr>
<td>Review of Literature</td>
<td>4</td>
</tr>
<tr>
<td>Market</td>
<td>4</td>
</tr>
<tr>
<td>Infant Hearing Screening</td>
<td>6</td>
</tr>
<tr>
<td>Syndromes</td>
<td>9</td>
</tr>
<tr>
<td>Volunteer Based UNHS</td>
<td>14</td>
</tr>
<tr>
<td>Management of Hearing Loss in Infants</td>
<td>16</td>
</tr>
<tr>
<td>CHAPTER III</td>
<td>19</td>
</tr>
<tr>
<td>Methods and Procedures</td>
<td>19</td>
</tr>
<tr>
<td>Subject Selection and Criterion</td>
<td>19</td>
</tr>
<tr>
<td>Subject Clinicians</td>
<td>20</td>
</tr>
<tr>
<td>Subject Clients</td>
<td>20</td>
</tr>
<tr>
<td>Procedures</td>
<td>20</td>
</tr>
<tr>
<td>CHAPTER IV</td>
<td>23</td>
</tr>
<tr>
<td>Results</td>
<td>23</td>
</tr>
<tr>
<td>CHAPTER V</td>
<td>28</td>
</tr>
<tr>
<td>Discussion</td>
<td>28</td>
</tr>
<tr>
<td>Conclusion</td>
<td>34</td>
</tr>
<tr>
<td>Limitations</td>
<td>34</td>
</tr>
<tr>
<td>Clinical Implications and Future Research</td>
<td>37</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>39</td>
</tr>
</tbody>
</table>
APPENDICES

A. Information To Subject Clients 44
B. Information To Subject Clinicians 47
C. Subject Client Screening Questionnaire 50
D. Subject Clinician Screening Questionnaire 52
E. Directions for AuDX 53
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Before I started the program three years ago I had discovered that about eight years before that I had turned my back on the field that I was meant to be a part of. Many people had witnessed this and finally I too realized the direction in which I needed to focus my efforts.

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CHAPTER 1

Introduction

According to the National Campaign for Hearing Health (Thomas, 2000), 12,000 babies are born with deafness every year. The prevalence of newborn hearing loss is approximately one in every thousand (Jerger, Roeser, & Tobey, 2001). Only 35% of newborns receive hearing screenings and are identified for early intervention. Researchers and state authorities are now advocating universal newborn hearing screenings (UNHS) throughout the United States.

The American Speech-Language-Hearing Association (ASHA, 2002a,) reported that 39 states have implemented laws related to the screening of newborns. Some of these states require a certain percentage of newborns born within each hospital receive hearing screening. Other states require screenings of every newborn at hospitals that have over a certain number of births per year (National Center for Hearing Assessment and Management, 2000). These data do not include four states that do have voluntary hearing screening for at least 85 percent of their newborns (ASHA, 2002b).

Many hospitals now institute policies and procedures concerning the mandatory hearing screening of newborns. Screening techniques and procedures have been developed and used in the past such as “crib-o-grams.” Others are more current and include Auditory Brainstem Response testing
(ABR) and now there is an increase in the use of otoacoustic emission tests (OAE) to determine the presence or absence of normal hearing function (Minnesota Department of Health, 2001; National Campaign for Hearing Health, 2002; Vohr et al., 2001).

The U.S. Department of Labor (2002) estimated there are 33,000 practicing audiologists in the United States out of an approximate 101,000 employees in the combined field of Speech Pathology and Audiology. There is a projected rise in the number of audiologists who will become certified in the next ten years and the number is estimated to increase over 36% between the years 2000 and 2010. If the projection is accurate, there will be an increase of more than 11,880 audiologists over the next seven years.

Audiologists are required to receive extensive education and training. To become a certified and licensed audiologist, there are several requirements that are involved, including a master’s degree. To be certified as clinically competent by the American Speech-Language-Hearing Association, one must complete a master’s degree program with specific coursework requirements. The master’s degree in audiology also requires 350 clock hours of patient contact as well as completing the Praxis exam, a comprehensive national exam that concentrates on audiology specific content.
Purpose

There will be a greater increase in the number of people in need of audiology services in comparison to the proportionate increase in the number of audiology professionals. With these differential increases, healthcare professionals such as nursing staff, speech pathologists, technicians, and even trained volunteers may be called upon to perform newborn hearing screenings. The purpose of this research study was to determine the efficacy of non-audiology healthcare professionals performing OAE screenings. This study was designed to investigate the efficacy of non-audiology personnel conducting OAE screening. Efficacy was determined by measuring and comparing OAE screening repeatability results obtained by non-audiology clinicians with those obtained by a clinically certified audiologist.

Hypothesis

Null Hypothesis: Results of OAE screenings, obtained by non-audiology professionals, will show no statistically significant differences from those obtained by an ASHA certified audiologist.

Alternate Hypothesis: Results of OAE screenings, obtained by non-audiology professionals, will show statistically significant differences from those obtained by an ASHA certified audiologist.
CHAPTER II

Review of Literature

In this chapter relevant studies and articles related to universal newborn hearing screening will be discussed. When examining increases in birth rate, as well as newborn hearing screenings and audiological management, it is also necessary to consider the possible increase in syndrome and birth defect related hearing loss.

Market

According to the U.S. Census Bureau (2000), there are almost 40 million births expected between 2001 and 2010. Many birth defects and syndromes are often accompanied by hearing loss and include disorders such as Down Syndrome, Waardenburg Syndrome and Usher Syndrome.

An overall population growth is expected from increased birth rate. Also expected, is a large growth in the number of people over age 65. According to the American Speech-Language-Hearing Association (2002b), over 54 percent of the population in the United States over the age of 65 experience some degree of hearing loss. This percent amounts to almost 12.5 million people over age 65 who may eventually seek audiological services.

In the year 2010, there will be almost 32 million people affected by some type and degree of hearing loss. There are currently almost 35 million people aged 65 and over. If we include the current population between the ages of 55 and 64, this age group will increase to 58.8
million people over age 65 in the year 2010. This amounts
to an increase of almost 70 percent in this age bracket.

Of the projected 58.8 million people that will be over
65, roughly 54 percent of them (at current estimates) will
have some kind of hearing impairment. This totals to
almost 32 million older adults who have some kind of
hearing impairment. Audiological services provided to
adults generally include audiology testing, hearing aid
dispensing, alternative amplification methods, aural
rehabilitation and balance function testing. Although it
should be noted that older individuals affected with
hearing loss may seek audiology services and some may not.

The projected number of audiologists in the year 2010
is projected to be 45,000 (U.S. Department of Labor, 2002).
Given the number of older adults with hearing loss, a
potential exists for an average adult caseload of 1300
clients per audiologist. For the over 65 age bracket, this
is a significant increase from the current potential client
base of 378 clients per audiologist.

There will always be fluctuations in the number of
healthcare professionals who are available to meet the
public demand. Professionals such as nurses and nurse’s
aides, speech pathologists and hospital volunteers may all
be needed to perform many tasks outside their field of
expertise, if the projected figures prove to be accurate.
Some settings in which professionals will be required to
learn and perform tasks outside their specific practice
roles include newborn nurseries, neonatal intensive care units and doctors’ offices.

**Infant Hearing Screening**

Given the current rate of population growth and impending federal legislature for universal newborn hearing screenings, there will be continued demand for non-audiology professionals to conduct newborn hearing screenings in hospitals (Culpepper, 1998).

According to a study by Culpepper (1998), in 120 known universal newborn hearing screening programs, only 28% of screeners were actually audiologists by occupation. The largest percentage of people conducting universal newborn hearing screenings were nurses; technicians ranked as the next highest percentage of professionals.

Since the advent of infant hearing screening, many methods have been employed to get accurate, quantifiable results. Audiologists have been striving for an effective, reliable and efficient means of screening. The methodology and nature of hearing tests have been very crude, relatively inaccurate and sometimes unquantifiable. Newer methods have been developed and have become extremely accurate; however, ease and efficiency have at times been sacrificed.

In the past, audiologists were able to elicit a startle reflex known as Moro’s reflex as a newborn hearing screening method (Martin & Clark, 2003). Startle reflex is still used in controlled environments such as in test
booths and quiet offices. “Crib-o-grams” were subsequently developed and used to determine hearing function through infant motor responses to auditory stimuli (Mencher, Davis, DeVoe, Beresford, & Bamford, 2001). This device was attached to the infant’s crib and the goal of the screening was to sense changes in movement from within the crib to determine an infant response to loud sounds.

Auditory Brainstem Response testing (ABR) has been used to assess hearing function and is still used as a diagnostic site-of-lesion test for infants (Stach & Santilli, 1998). With the use of electrodes, far field nerve recordings of responses to auditory stimuli are measured, tracking the auditory conduction time to the cortex. Changes in ongoing electroencephalogram (EEG) responses are then analyzed for morphology and amplitude along with the latency of the transmission time.

A current method of hearing screening recently developed utilizes emissions reflecting from outer hair cells to diagnose auditory function. Otoacoustic Emissions (OAE) are sound energy created by the outer hair cells of the cochlea in response to a stimulus sound. The two types of evoked OAE response tests are distortion product OAEs and transient evoked OAEs. Both have proven equally repeatable and reliable for hearing screening (Dreher, Suckfull, Schneeweiss, & Schorn, 1997).

Distortion product OAE testing uses two pure-tone frequencies that are administered simultaneously into the
ear. The desired response is obtained when the higher frequency, F2, and the lower frequency, F1, are presented at a frequency ratio of 1.22. The mechanical response from the basilar membrane is dynamic and nonlinear in response to the two-tone stimulation. The frequency response of the cochlea is 2f1-f2 (Satoh, Kanzaki, O-Uchi, & Yoshihara, 1998; Oysu, 2000). The emission is monitored for presence and amplitude of the response.

In transient evoked OAEs, a frequency balanced click is placed into the ear and the whole length of the basilar membrane responds evenly. The response from the outer hair cells is measured and analyzed using a Fourier spectral analysis. The presence and amplitude of the emission corresponds with the function of the outer hair cells (Hatzopoulos, Prosser, Mazzoli, Rosignoli, & Martini, 1998).

With the advent of simplified screening devices for many diagnostic and screening procedures, it is assumed that medical staff will be able to effectively and accurately perform screening tests routinely administered to newborns in hospital settings. Health care professionals other than audiologists may be called upon to perform hearing screenings to detect normal versus abnormal hearing function. Medical staff should be able to also identify cases that need more diagnostic investigation and referrals. With initial screenings conducted by hospital personnel, audiologists will have the role of responding to
referrals for follow-up and more in-depth diagnostic testing. Follow-up diagnostic assessments often include other areas related to audiology such as fitting evaluations for amplification, vestibular evaluation, and subsequent counseling and aural rehabilitation. Medical staff will also need training to identify craniofacial anomalies of congenital syndromes commonly associated with hearing loss for proper referral.

**Syndromes**

According to Chen (2002), Down Syndrome is the best known chromosome disorder in humans, affecting over one in every 800 live births. Although many children with Down Syndrome die in utero, there are still almost 6000 children born every year affected by the disorder (Chen).

A less common but still prevalent syndrome compared to Down Syndrome, affecting three to four of every 100,000 births, is Pemphigus Erythematosus (Usher Syndrome) (Bharti, 2001). The prevalence of Usher Syndrome is about 4.4 per 100,000, and constitutes approximately 5 percent of the total deaf population (Kimberling & Möller, 1995). This syndrome has a high incidence of hearing loss, and various sub-types of Usher Syndrome have been classified according to their characteristics such as onset and symptoms.

Kimberling and Möller (1995) described Usher Syndrome in relation to origin and progression of vision and hearing loss. Different genes are responsible for Usher Syndrome type I and type II. People diagnosed with type I Usher
Syndrome experience a fast profound progression of hearing loss either present or beginning at birth, where people diagnosed with type II experience a slower progression and milder severity of hearing loss. Progression of the syndrome necessitates early diagnosis for the purposes of safety, education and social development of the child as well as genetic counseling for the parents. Usher Syndrome carries a multi-sensory deficit and may have a psychological effect on the child as well.

Early diagnosis may also play a factor in how the family and audiologist decide to proceed with intervention. Visual cues may become a problem in communication ability and may not be relied on for communication purposes. Visual ability will influence the mode of communication used with the child. Early diagnosis and intervention will alert parents and educators to the child’s sensory potential for making important educational decisions (Kimberling & Möller, 1995).

Kimberling and Möller (1995) point to an increased need of audiologists to properly diagnose and treat individuals with Usher Syndrome. Manifestations to hearing often are not immediately identified after birth. All family members need regular screening if there is a family history of Usher Syndrome. The pediatric patient with Usher Syndrome should have regular hearing screenings due to the possible deterioration of hearing. As their hearing
loss progresses a further increase in audiological services is needed.

Hearing aids have been successfully used by individuals affected by type II Usher Syndrome. Rarely have hearing aids been successful for patients with type I. With the decision to use hearing aids comes the time needed to properly fit them. Hearing aid fitting procedures include time needed for a case history, a fitting evaluation, orientation and parent education, counseling, and follow-up evaluations, as well as hearing aid checks and routine maintenance conducted while patients are in the office.

Although type I affected individuals usually experience more success in schools for the deaf and are not good hearing aid candidates, the audiologists’ time and expertise is needed here as well for obtaining a case history, parent education, and habilitative counseling for parents. The audiologist may need time to discuss information about appropriate educational facilities and services available for their child.

Waardenburg Syndrome affects approximately one in every 12,000 births (Bason & Krantz, 2002). An increase in Waardenburg Syndrome affected births will also affect the number of people seeking audiological services. Hearing loss that accompanies Waardenburg Syndrome can start from birth, or begin later in life. Earlier manifestations can impact speech and language development and type of
educational placement. A child with Waardenburg Syndrome warrants regular screenings to avoid developmental delays during early formative years.

Waardenburg Syndrome involves sensorineural hearing loss in many cases and a discoloration of skin, eyes and hair. Waardenburg Syndrome is classified into type I and type II varieties. The main difference between types I and II is the presence (type I) or absence (type II) of a characteristic called dystopia canthorum, which is a displacement of the inner canthi of the eyes (Oysu, 2000).

The penetrance of congenital hearing loss is reported in 35 to 70 percent for type I and between 55 and 85 percent in type II. Hearing loss can be unilateral or bilateral, ranging from mild to profound in severity for both types. Variations in loss configuration are very wide ranged. It can present as a low frequency or a high frequency loss, or even be a reverse “cookie bite” configuration.

People who have Waardenburg syndrome can become successful hearing aid users, and because of the variety of hearing loss configurations, it is necessary to obtain as much frequency specific information as possible during the evaluation process to properly be able to fit hearing aids.

Auditory Brainstem Response testing (ABR) is one assessment tool used to identify hearing loss severity in infants. An assessment using ABR takes over an hour to perform. The assessment involves a thorough case history,
electrode preparation, and time needed to perform and interpret the test.

The lack of frequency specific information obtained from ABR is a drawback for certain types of losses. It can detect responses to auditory stimuli, however the click stimulus of ABR is non-frequency specific. ABR will show responses at appropriate degree levels when in fact losses involving specific frequency ranges can be overlooked.

Oysu (2000) suggests increased frequency specificity determination through distortion product otoacoustic emissions testing (DPOAE). DPOAE is a frequency specific analysis of cochlear function and will detect normal cochlear responses to stimuli at various frequency ranges within the speech spectrum.

Oysu (2000) utilized otoscopy, tympanometry, pure-tone audiometry, and DPOAE to evaluate Waardenburg subjects. Otoscopy was normal in all cases along with type A tympanograms. Results of hearing evaluations determined 83 percent with a hearing loss; 75 percent of patients diagnosed with type I Waardenburg Syndrome and 91 percent of those diagnosed with type II. No progression of hearing loss was noted in follow up evaluations that were done. Follow up evaluations were conducted and ranged anywhere from 8 months to 7 years after the initial evaluation.

Oysu (2000) advocated the use of DPOAE to detect high frequency losses in situations where click ABR had been used to determine hearing thresholds. The test battery
approach was necessary for early fitting of amplification devices. Use of DPOAE helped to properly assess hearing acuity and avoid over-amplification in lower frequencies where high frequency hearing loss was the primary cause for elevated thresholds found in ABR results.

Volunteer Based Universal Newborn Hearing Screening

Messner, Price, Kwast, Gallagher, and Forte (2001) trained volunteers to perform universal newborn hearing screenings. The goal of their study was partially to analyze the efficacy of using volunteers. However, they were also interested in the viability of having a volunteer-based newborn hearing screening system for initial screenings. Screening methods in their study included automated ABR, TEOAE, or DPOAE.

Volunteers participated in a two-hour training conducted by a pediatric audiologist. A three-hour practical training followed with an experienced volunteer. The training was also followed by a brief examination verifying their knowledge in automated acoustic brainstem response testing (AABR). Each volunteer then performed an AABR under supervision of the pediatric audiologist.

All initial screenings were performed by volunteers in the well-baby nursery. In the level-three and intermediate-intensive care units, volunteers performed most of the initial screenings. Nurses provided backup when babies were ready for discharge and had not had their
hearing screened. Pediatric audiologists performed all follow-up diagnostic TPOAE testing.

Equipment used for the AABR initial screening was the ALGO-II™. Broadband click stimulus was used at 35 dBHL with both ears typically tested at the same time. The automated screener either reported a pass or a fail. No diagnostic decisions were made by volunteers.

Well-baby screenings usually took place within 24 hours to 72 hours after birth. Of 6340 babies that were born during the year of the study, 95 percent were screened as a result of the volunteer program. Of the 6340 babies screened, 21 infants were identified, nine of which were not “at risk” for hearing loss. The overall cost for screening these babies averaged $27.41 per infant.

The cost of the hearing screening per patient compares with other programs cited that were not volunteer-based. White and Mason (1995) reported an average cost of $26.05 per neonate. Mehl and Thompson (1998) reported an average cost of $25.00 per neonate (as cited in Messner, Price, Kwast, Gallagher, & Forte, 2001).

Messner et al. (2001) listed advantages and disadvantages of the volunteer based hearing screening program. Along with high turnover rate, a recruiting task force must replenish the volunteer workforce and continue training. Time and energy for coordination is at a maximum. They stated that profits obtained from the low cost of the screening were diminished due to administrative
demands. They stated that if a strong core group of volunteers can get established the cost should decrease over time.

Messner et al. (2001) reported a 91 percent screening rate for all newborns. Hospital staff and volunteers screened another four percent as outpatients. The overall screening rate was 95 percent. Messner et al. cited this to be the minimum effective rate according to the American Academy of Pediatrics Task Force on Newborn and Infant Hearing (1999).

Costs involved in the screening program include costs of equipment maintenance and the full-time audiologist for administrative functions. However, a significant cost to the individual infant screening relative to the total cost per child was the Algo-pak. This was the disposable portion of the equipment that was used for each patient and then discarded.

Messner et al. (2001) concluded that a volunteer based hearing screening program was a viable alternative to trained audiologists providing services. A volunteer based newborn hearing screening program was cost effective and comparable in price to other non-volunteer programs.

Management of Hearing Loss in Infants

Jerger, Roeser, and Tobey (2001) advocated five principles for the management of hearing loss in infants: accurate identification; family and parental counseling; selection and fitting of amplification; management and
counseling to help achieve optimal development; and outcomes assessment and documentation. They estimated there are as many as 33 children born per day with significant hearing loss. They noted that the age of identification for hearing loss can ranges up to three years of age. However the upper age range of identification has decreased since the development of UNHS.

Jerger et al. (2001) stated the importance of identifying a child with a loss and creating a comprehensive picture, including other physical and mental disabilities that may accompany the hearing impairment. It is necessary to also define the type and degree of loss with frequency specific information. Regular follow-up evaluations must be done to monitor the degree of loss and possible deterioration.

The five habilitation/rehabilitation principles described by Jerger et al. (2001) serve to support the necessary time requirements needed from audiology professionals for every child who exhibits signs of hearing loss. Without the proper attention and follow up care, the child is not only at risk developmentally, but its future education is at risk due to possible cognitive, social, and language delays.

Given the expected population growth and individuals needing audiology services, as well as the disproportionate growth in the number of audiologists, non-audiology professionals and volunteers can be called on to perform
universal newborn hearing screenings. Literature supports that with the increase in birth rate there is a resulting increase in hearing related issues, and therefore an increase in the number of children who will need services. Audiologists will be needed to conduct follow-up testing and evaluation as well as other services that go along with direct audiological services such as appropriate hearing aid counseling, and educational intervention as well as monitoring of the child’s hearing.

The research presented here clearly indicates universal newborn hearing screening can be and currently is being done by non-audiology professionals. However with the advent of new screening devices such as OAE, it is necessary to begin research on adult populations as a logical first step to integrating its use into the neonatal population.
CHAPTER III

Methods and Procedures

Subject Selection and Criterion

Subjects consisted of 16 volunteers: 14 female graduate students, one male graduate student, and one clinically certified female audiologist. Subjects were divided into one group that consisted of 10 volunteer subject clinician subjects and a group of five client subjects. Groups were divided randomly, and subject clinicians tested subject clients in a randomized order.

Subject Clinicians

Subject clinicians were students majoring in Speech Pathology. All were first year graduate students with the exception of one who was a senior undergraduate student also in the field of speech pathology. The mean age of clinician subjects was 22.4 years and all were either 22 or 23 years old.

Surveys were administered to each subject clinician to determine the knowledge base of each clinician and the experience level each clinician had with otoacoustic emissions and screening (Appendix D). All subject clinicians signed consent forms approved by the Miami University Institutional Review Board (Appendix A).
**Subject Clients**

Subject clients consisted of one male and 4 female graduate school students from within the field of Speech Pathology and Audiology. The mean age of subject clients was 27.2 years of age ranging between the ages of 22 and 37.

Surveys were administered to subject clients to assess their current state of upper respiratory health as well as any history that might pertain to, or create less than favorable conditions for successful otoacoustic emission screening (Appendix C). Each subject then was required to pass an audiological screening battery. All subject clients signed consent forms approved by the Miami University Institutional Review Board (Appendix B).

**Procedures**

Subject clients were subjected to a pre-screening test battery that included otoscopy, pure tone audiometry and 226 Hz tympanometry conducted by the researcher and audiologist. The battery involved otoscopy using a Welch-Allyn otoscope, model 93150. Pure tone audiological screenings were performed using headphones (Model TDH-39), and a Grason-Stadler 61 clinical audiometer in a sound-treated booth. Screenings were performed at 20dBHL for the frequencies 250 Hz – 8,000 Hertz (Hz). Screenings included the standard inter-octave frequencies of 750, 1500, 3000, and 6000 Hz.
Tympanometry was then conducted on a Grason-Stadler 33 impedance bridge. All subjects were screened for normal volume (0.2 cm$^3$ to 2.0 cm$^3$), normal compliance (0.2 cm$^3$ to 1.4 cm$^3$), and normal middle ear pressure (-150 to +100 daPa) (American Speech-Language-Hearing Association, 1990).

The audiologist then performed transient OAE screening on subject clients using the AuDX otoacoustic emission screener. Transient evoked otoacoustic emissions (TEOAE) were measured and recorded. Click stimuli were presented at 70dBL. A Fourier analysis was used for analysis of the targeted frequencies of 1500 Hz, 2000 Hz, 3000Hz, and 4000 Hz. An overall passing rate consisted of 70 percent repeatability at any three of the four target frequencies analyzed. Repeatability scores for each frequency were calculated by the AuDX and are the percentage of cochlear responses at each frequency accepted by the screening device. Acceptable responses were defined as amplitudes $> 6$ dB above the noise floor.

Each of the five subject clients was examined using otoscopy and then screened for otoacoustic emissions by each of ten subject clinicians using the AuDX otoacoustic emission screener. Each subject client was selected in random order for screening by each subject clinician. Results from each screening were printed on labels and affixed to the back of each subject clinician’s prescreening survey with the client and clinician assigned numbers written on each. This procedure was used to keep
the personal case history and identity of each subject client confidential.

Results were compiled and analyzed using the programs Microsoft Excel and the Statistical Package for the Social Sciences (SPSS). Microsoft Excel was used to calculate simple percentages and cumulative scoring of repeatability percentages along with standard deviations and variances. To calculate statistical significances, SPSS statistical software was used.
CHAPTER IV

Results

Fifteen subjects and an audiologist participated in collecting data. Ten were subject clinicians, five were subject clients, and the audiologist was involved for prescreening and collecting “gold standard” data. Data were collected from each of ten clinicians. Data consisted of results from five screening tests per clinician, one test from each subject client. A total of 50 test trials were completed. The repeatability percentage was collected from each trial test for each of the four frequencies tested. The range and overall percentage along with the standard deviation were also computed.

Using Microsoft Excel, data were analyzed giving four separate repeatability scores, one per frequency for each clinician, and an overall repeatability. The clinician averages were calculated and then compared with the results obtained from the audiologist (Figure 1). Data were also analyzed to see the comparisons of each clinician to one another and to the audiologist (Figure 2). Overall repeatability for clinicians was 74.8% as compared to the audiologist who obtained a repeatability score of 79.9%.

Data were then entered into SPSS. Multivariate analysis showed no statistically significant differences between any of the variables. No variable interaction was present between clinician or client with testing order or frequency ($p < .05$).
A general linear model for repeated measures was calculated for overall clinician results. There was a statistical significance in repeatability among repeatability results. Statistical significance of .005 was noted for within clinician results.

High statistical significance existed between subject clients for tested frequencies. This analyzed the results obtained for each frequency by client. Statistical significance in repeatability scores was noted among client results of .009 (p < 0.05).
Figure Caption

Figure 1. Repeatability Averages by Frequency

Figure 2. Overall Repeatability by Clinician
Figure 1: Mean of test repeatability across four frequencies for clinicians (n=10) and the audiologist (n=1) including overall repeatability.
Figure 2: Mean overall repeatability across clinicians with overall clinician (O.C.) to audiologist (AUD) comparison for clinicians (n=10) and the audiologist (n=1).
Screening devices are being used more frequently to meet high demand and an increased number of patients seeking healthcare services. The screening devices, such as medical lab tests, health surveys, and even hearing screening tests have been designed to be relatively simple, effective and reliable. Many factors contribute to an increased need for audiology professionals. These variables include an increase in the population of adults over age 65 and an increase in birth rates over the next ten years, and an increase in the number of states requiring universal newborn hearing screening. However, there is a slower - proportionate - projected rate of increase in the number of audiology professionals entering the field. The purpose of this study was to see if non-audiology professionals could obtain comparable hearing screening results to those obtained by a certified clinical audiologist.

One clinically certified audiologist, an untrained set of 10 subject clinicians, and a set of five subject clients participated in this screening study. Results from OAE tests were obtained with the audiologist and ten subject clinicians performing screenings on each of five subject clients. Results of subject clinicians were compared within the group to determine overall consistency and repeatability of results among clinicians. Results were
also analyzed for consistency and repeatability with results obtained by the audiologist. The working hypothesis was that non-audiology professionals would be able to effectively perform OAE screenings with the Biologic AuDX to detect hearing loss. Overall clinician repeatability across clinicians was excellent with the exception of one subject.

Anecdotal observations suggested the subject had difficulty in placement of the probe correctly in the ear canal. It was noted that in one particular test the probe tip was held in place and the sound tube pressed against the canal wall. In this study clinicians were provided with only a one page written set of instructions. It is possible repeatability scores for this individual would increase if the individual had orientation to the device by an experienced clinician. In the previous study by Messner, Price, Kwast, Gallagher, and Forte (2001) there was a high level of training involved with volunteers while the overall repeatability for this study suggests that extensive training is not necessary, however limited hands-on orientation would be advantageous in incorporating the AuDX into formal hearing screening protocols.

These results do not take into account the exception of one clinician who had lesser repeatability than the other clinicians. No sound was able to reach the cochlea.

Currently, newborn hearing screenings are being conducted by licensed, certified clinical audiologists.
State laws have been created as well as programs instituted in some states dictating the performance of newborn screenings. However, regulations do not require screenings to be performed by any particular type of professional. They only recommend the administrative supervision of a physician (Marlatt, 2003). Audiology professionals may be skeptical about the possible accuracy of results and interpretation of test results performed by untrained medical personnel.

The OAE repeatability results from the clinicians were compared to those from the certified audiologist. There was no significant difference in results between the audiologist and the non-audiology clinicians. It is important to note there was no significant difference when the clinicians’ results were compared with one another as well. Each clinician was able to obtain repeatable results using the AuDX.

OAEs have become a reliable screening device for neonatal screenings. According to Stach and Santilli (1998), both transient evoked and distortion product OAEs are an effective way to evaluate the presence of normal hearing. When a child passes an OAE screening, there is a high confidence level that normal outer and middle ear and cochlear functioning are present. Over the last several years, OAE screening has developed and become both a time and cost efficient method to screen for the presence of infant hearing (Stach & Santilli, 1998).
Given research done by Culpepper (1998) and Messner et al. (2001), there is evidence that newborn hearing screening is currently being done by non-audiology personnel and, with appropriate training programs, can continue to be done effectively by these personnel.

Results of this study indicate the possible effective use of the AuDX OAE screeners by personnel with no formal training. Reliable and repeatable results were obtained when non-audiology personnel performed OAE screenings on subject clinicians. This finding lends more possibilities to the use of the AuDX with universal newborn hearing screening.

A common situation that occurred in the present study that did not seem to have a notable effect on results was the choosing of probe tip size. The certified audiologist commonly used the full size adult probe tip and was able to roll the EAR plug down to fit it into the ear canals of subject clients. Subject clinicians had a tendency to use smaller probe tips designed for pediatric canals. Through researcher observation, passing screening results were still obtained even with the use of the smaller probe tips.

Unrelated to screening results, but interesting to note, was the subject clinicians’ overall success with otoscopy. When asked, most subject clinicians stated they had never used an otoscope. Every subject clinician was able to obtain a view of tympanic membranes in every client. Several viewings by one clinician in particular
were described as painful. With the help of follow up otoscopy, no physical injury to subject clients was sustained, only temporary mild irritation was noted.

Advantages to using the AuDX OAE screener in place of an ABR or AABR for initial newborn hearing screenings might include low cost, faster accurate results, and ease of equipment use, along with a quicker learning curve. With the AABR via the ALGO-II™, in the newborn nursery, a minimum of 50 minutes is necessary for set-up. This time includes placement of three electrodes and the use of various materials such as electrode gel and skin prep for use with the electrodes. The disposable earphones are another costly component of the ALGO-II™. Each set of disposable earphones costs about $9.00 (Messner et al., 2001). Much training must be provided for the relatively complex procedure involved with the ALGO-II™. After the procedure is complete, it is necessary to clean-up the infant, removing the electrodes, gel and skin prep products. The ALGO-II™ gives a pass/fail result with no frequency specific information.

The AuDX involves only the use of two EAR receiver tips. Simple insertion into the ear canal is the only preparation necessary to perform the screening using the AuDX. Simple buttons are used by the individual screening the child. The hand-held equipment provides ongoing instruction to begin the test, and then to print the results when the test is completed. Removal of the tips is
simple and there is no clean up. Printed results give a
definite pass/fail result along with frequency specific
information as to which frequencies resulted in the
strongest amplitudes and which were not within acceptable
range.

Results from the AuDX can be used by an audiologist to
help in determining the type and degree of hearing loss,
along with frequency specific information. If a child
presents a loss, the audiologist can use the AuDX results
to follow-up appropriately with further diagnostic testing.

Incorporation of the AuDX OAE screening device to a
universal newborn hearing screening program would be
advantageous. It would enable non-audiology personnel to
quickly and effectively perform initial screening for both
well-baby nurseries and infants from neonatal intensive
care units or infants who fall into “at risk” categories
for hearing loss. A good screening protocol for infants
would include OAE screening via the AuDX, along with
otoscopy and tympanometry. If infants are requiring more
in-depth diagnostic testing beyond the initial screening,
referral to a trained audiologist can be done. Audiologists
can then perform more specialized diagnostic tests
necessary for further assessments.
Conclusion

Results from this study support the utilization of non-audiology clinicians conducting otoacoustic emissions screening using the AuDX Otoacoustic Emission Screener by Bio-logic. Non-audiology clinicians performing screening appears to be effective, accurate, and statistically comparable to results obtained by a certified audiologist.

Limitations

Some of the limitations of this study include sample size and the subject type limited to professionals coming from one field of study. A limitation that should also be considered is the fact that anyone performing any kind of clinically significant test such as a hearing screening would have some sort of training or in-service related to the device. The sample populations were not trained, nor were they given any information about the test, except for the simple written directions they were to follow to complete the screening test (Appendix E).

A situation that occurred, that potentially influenced the results obtained by some clinicians, was the tendency to hold the probe tip in place during testing instead of using the lapel clip. When clinicians held the probe tip, inaccurate results were obtained in at least one instance. The result was the tip resting against the ear canal wall blocking the sound tube portion so no sound reached the cochlea. Screening results in this particular case were
returned as false referrals. The false referral only occurred in one case.

Subject clinicians were from only one field of study and currently enrolled in classes at Miami University in the Department of Speech Pathology. A larger study containing more subject clinicians from two or three disciplines of study may enable more generalizing of conclusions and may also reveal some trends in results based on profession. Use of other disciplines may give more conclusive evidence as to the field of the alternate clinician best suited to perform hearing screenings.

In this study, the number of subject clinicians could have been increased. An increase in number of clinicians would aid in the strength of the study by improving the variety of individuals in the experiment. Adding groups from different fields of study would be helpful as well. Professionals such as nurses and possibly nurse’s aides may also be good candidates for further study and analysis. The field of speech pathology is an adjunct area of study to the field of audiology and potentially a good substitute for screening hearing when an audiologist is not available.

The purpose of only five subject clients was to avoid threats to internal validity such as maturation. Clinicians were not supposed to get used to the device so measurements of untrained, inexperienced clinicians could be made. Children and infants should also be included.
The sample size was relatively small and could have been increased. The samples across all subject types could have been increased to include more subject clinicians as well as a larger number of audiologists and clients. One audiologist was used as a “gold standard” upon which to base the significance or insignificance of clinician results. An ASHA certified clinical audiologist with experience in otoacoustic emissions as well as experience with the AuDX was used so that results would be reliable.

This study had a degree of bias in subject selection. Students used as subject clinicians were Speech Pathology majors and currently enrolled in classes within the department. Speech Pathology is an adjunct to the field of Audiology and the Speech Pathology and Audiology program requires all majors to take classes from their major field as well as from the adjunct field. Students studying speech pathology have had more education in the area of audiology than individuals in other fields of study.

Subject selection for clients was of another bias. Subjects were all adult individuals with normal cognitive functioning. This allowed for cooperation that may be absent in the infant population. Subjects were instructed to sit quietly and say nothing, allowing subject clinicians to make their own decisions and function without intervention of any kind.
Clinical Implications and Future Research

This study was designed to collect preliminary data. Only ten subject clinicians were used for the sake of timeliness. It could be expanded to include multiple groups of clinicians and more clients. Formalized training should also be incorporated as an in-service to appropriately acquaint subject clinicians with the equipment they will be using in the study.

The AuDX by Bio-logic was chosen as a screening instrument due to its simplicity of operation as well as the frequency specific result information that is reported. The machine is versatile in that either distortion product OAEs or transient evoked OAEs can be performed.

This study shows a high correlation between screening repeatability results obtained by subject clinicians and the results obtained by a certified clinical audiologist. Follow-up study could be done with an increased number of subjects and children along with groups of subject clinicians from selected professions. Further study should not only be conducted to verify research from this study, but also to validate the efficacy and reliability of having non-audiology professionals conduct universal newborn hearing screenings.

The research presented here clearly indicates that volunteers without a background in audiology are capable of conducting reliable OAE screening tests on adults. Previous research has supported that volunteers can also perform ABR
and tympanometric screenings in well baby and intensive care units. The next step in the research process is to ensure that OAE screening can be performed on neonates by non-audiology personnel. It can be argued, however, that the devices now available to perform OAE on neonates use similar skills as those needed for ABR and tympanometry. Consequently, an individual who is able to perform OAE screening on adults with no training should be able to perform the same test with a minimum of training on neonates.
References


Appendix A

Information To the Subject Clinicians

BACKGROUND:
With rising healthcare costs, the resulting decrease in numbers of professional personnel in healthcare institutions, and the use of personnel for performing duties outside their field of expertise, a question remains as to how effective and appropriate is it to have such personnel perform screenings and tests pertaining to health issues outside their field of expertise. As non-audiology professionals, you are invited to participate in evaluating a new screening device used in screening for normal hearing function.

It is important that you read and understand several general principles that apply to all individuals who take part in this research study. First, taking part in this study is completely voluntary. Second, personal benefit may not result from taking part in this study, but knowledge may be gained that may benefit others. Third, you may withdraw from this study at any time without penalty. You are urged to discuss any questions you may have about this study with the individual who explains it to you. The nature of this study, the risks, inconveniences and other pertinent information about this study are discussed below.

STUDY PROCEDURES:
By agreeing to participate, you will be evaluated for candidacy as a subject clinician. You will be required to fill out a brief survey. You will then be expected to use a written set of instructions to perform several screenings without assistance.

At the beginning of the study, as a subject clinician, you will complete a brief questionnaire assessing your knowledge of otoacoustic emissions. As a subject clinician, it is imperative to the study that you have little or no knowledge of otoacoustic emissions or the methods, modes, or principles related to screening and testing for them. The survey itself should take no longer than about 15 minutes. It will be necessary for you to perform five screenings: one per subject client. It should take less than an hour to complete all five screenings.

After all screenings have been completed, you will receive a packet of information related to otoacoustic emissions, and may ask questions at that time related to the study and the screening device.
DESCRIPTIONS OF RISKS AND DISCOMFORTS:
  As a subject clinician, risks and discomforts should be non-existent. Risks will not exceed the risks of a normal clinicians working within the Audiology Clinic.

BENEFITS:
  The purpose of this study is to gain information regarding the repeatability and reliability of having non-audiology professionals perform screenings of an audiological nature on patients. For graduate students from the Department of Speech Pathology and Audiology performing the function of subject clinicians, since the study will be supervised by a certified audiologist, client contact hours will be awarded for Audiology in the area of Adult Screening hours for each participant. For all students involved in the study, an educational introduction to otoacoustic emissions will be provided for those interested.

CONFIDENTIALITY:
  The results in raw data form for this study will be kept in a separate locked filing cabinet. Only the investigators will have access to the subject specific identifying information and all steps will be taken to assure confidentiality. You will be assigned a code number and your name will not appear on any written or computer documents beyond the case history forms and the questionnaires. All identifying information will be stored separately, preventing any link between you, and the screening results and tests. The results of this study may be published for scientific or advertisement purposes. By Federal Law, the information gathered in this study may be reviewed by the United States Food and Drug Administration.

CONTACTS:
  Should you have any questions about this study, they will be answered by John Warner, Dr. Kathleen Hutchinson or Dr. Laura Kelly at Miami University Department of Speech Pathology and Audiology. (513) 529-2500.

INSTITUTIONAL REVIEW BOARD:
  If you have any questions as to your rights as a subject, or if problems arise which you feel you can not discuss with the investigators, please contact the Miami University Office for the Advancement of Scholarship and Teaching (513) 529-3734.

VOLUNTARY PARTICIPATION:
  Participation in this study is completely voluntary and you may choose not to participate in this study at any time. If you choose not to participate, you can withdraw without affecting your scholastics or any other university matters.
RIGHT TO WITHDRAW SUBJECTS:
During the course of this study, there may arise a situation in which the investigators, John Warner, Dr. Hutchinson or Dr. Kelly, may encounter a circumstance under which the subject’s participation may be terminated without regard to the subject’s consent. Such circumstances may occur if health problems arise or occur from the study. If the subject encounters a condition where he/she is not able to participate in the study, then the subject would be withdrawn from the study.

COSTS TO SUBJECTS:
None.

NEW INFORMATION:
If significant new findings develop, or are encountered during the course of this research, which may be related to the subject of otoacoustic emissions and/or related to screening or testing, depending on the detail of the information, the information may be provided as part of the educational introduction to otoacoustic emissions.

CONSENT:
Upon consideration of the possible benefits and risks of this study, I voluntarily agree to participate. My signature indicates that I have read and understood the information provided above, my questions regarding participation in this study have been answered, and I understand the explanation. My signature also indicates that I have received a copy of this consent form.

Participant:

__________________________________________(Print)

__________________________________________(Signature)  ___________Date

Witness:

__________________________________________(Signature)  ___________Date
Appendix B

Information To the Subject Clients

BACKGROUND:

With rising healthcare costs, the resulting decrease in numbers of professional personnel in healthcare institutions, and the use of personnel for performing duties outside their field of expertise, a question remains as to how effective and appropriate is it to have such personnel perform screenings and tests pertaining to health issues outside their field of expertise. As non-audiology professionals, you are invited to participate in evaluating a new screening device used in screening for normal hearing function.

It is important that you read and understand several general principles that apply to all individuals who take part in this research study. First, taking part in this study is completely voluntary. Second, personal benefit may not result from taking part in this study, but knowledge may be gained that may benefit others. Third, you may withdraw from this study at any time without penalty. You are urged to discuss any questions you may have about this study with the individual who explains it to you. The nature of this study, the risks, inconveniences and other pertinent information about this study are discussed below.

STUDY PROCEDURES:

By agreeing to participate, you will be evaluated for candidacy as a subject client. As a subject client, you will be expected to be evaluated for subject candidacy by going through several audiology screening tests including otoscopic inspection, tympanometric screening, and a brief audiology pure-tone screening test. As a subject client, you will also be expected to have no less than 11 otoacoustic emissions screening tests performed on you.

As a subject client you will be expected to fill out a brief case history form related to your hearing and any problems medical or perceptual that may relate to it. As a subject client, it will be necessary that you have no otoscopic anomalies, or medical conditions that affect the outer ear, and that normal middle ear functioning exists. You must also have hearing acuity within normal limits for the frequencies screened. Each screening should take no longer than 5 to 10 minutes. You will be screened by one individual, and then there will be waiting periods while other subject clients are being tested, which may have you waiting up to 30-45 minutes between your screenings. Be sure and bring something to do during down times.
After all screenings have been completed, you will receive a packet of information related to otoacoustic emissions, and may ask questions at that time related to the study, the screening device and any of your screening results.

DESCRIPTIONS OF RISKS AND DISCOMFORTS:
As a subject client, there may be mild risks possibly associated with being a subject client. Risks will not exceed the risks of a normal patient seen in the Audiology Clinic. The only exception to this is that there is a possibility of mild skin irritation to the pinna and external ear canal due to repetitive procedures within the study as well as the inexperience of subject clinicians. The risk of minor skin irritation is possible yet very minimal.

BENEFITS:
The purpose of this study is to gain information regarding the repeatability and reliability of having non-audiology professionals perform screenings of an audiological nature on patients. For all students involved in the study, an educational introduction to otoacoustic emissions will be provided for those interested.

CONFIDENTIALITY:
The results in raw data form for this study will be kept in a separate locked filing cabinet. Only the investigators will have access to the subject specific identifying information and all steps will be taken to assure confidentiality. You will be assigned a code number and your name will not appear on any written or computer documents beyond the case history forms and the questionnaires. All identifying information will be stored separately, preventing any link between you, and the screening results and tests. The results of this study may be published for scientific or advertisement purposes. By Federal Law, the information gathered in this study may be reviewed by the United States Food and Drug Administration.

CONTACTS:
Should you have any questions about this study, they will be answered by John Warner, Dr. Kathleen Hutchinson, or Dr. Laura Kelly, at Miami University Department of Speech Pathology and Audiology. (513) 529-2500.

INSTITUTIONAL REVIEW BOARD:
If you have any questions as to your rights as a subject, or if problems arise which you feel you can not discuss with the investigators, please contact the Miami University Office for the Advancement of Scholarship and Teaching (513) 529-3734.
VOLUNTARY PARTICIPATION:
Participation in this study is completely voluntary and you may choose not to participate in this study at any time. If you choose not to participate, you can withdraw without affecting your scholastics or any other university matters.

RIGHT TO WITHDRAW SUBJECTS:
During the course of this study, there may arise a situation in which the investigators, John Warner, Dr. Hutchinson or Dr. Kelly, may encounter a circumstance under which the subject’s participation may be terminated without regard to the subject’s consent. Such circumstances may occur if health problems arise or occur from the study. If the subject encounters a condition where he/she is not able to participate in the study, then the subject would be withdrawn from the study.

COSTS TO SUBJECTS:
None.

NEW INFORMATION:
If significant new findings develop, or are encountered during the course of this research, which may be related to the subject of otoacoustic emissions and/or related to screening or testing, depending on the detail of the information, the information may be provided as part of the educational introduction to otoacoustic emissions.

CONSENT:
Upon consideration of the possible benefits and risks of this study, I voluntarily agree to participate. My signature indicates that I have read and understood the information provided above, my questions regarding participation in this study have been answered, and I understand the explanation. My signature also indicates that I have received a copy of this consent form.

Participant:

__________________________________________(Print)

_________________________________________(Signature)  _________________Date

Witness:

__________________________________________(Signature)  _________________Date
Appendix C

SUBJECT CLIENT SCREENING QUESTIONNAIRE

NAME: ____________________________________________________
DATE OF BIRTH: _____________________________________________
LATEST EDUCATION COMPLETED: ______________________________
HIGHEST DEGREE COMPLETED: ________________________________
FIELD OF STUDY IF MORE THAN HIGH SCHOOL: _______________________

CASE HISTORY:

1. Do you have any history of ear infections: (if so when was last episode)
   Outer/External Ear: ________________________________________
   Middle/otitis media: ______________________________
   Inner/cochlear: _________________________________________

2. Do you have any ear drainage at this time? __________

3. Have you had any history of general infections that might affect your hearing such as spinal meningitis, or viral labyrinthitis?

4. Have you had any history of medications that might affect your hearing?
   (These meds include any chemotherapy drugs, quinine or other ototoxic drugs or antibiotics such as gentamycin, tobramycin, etc..., (Yes/No)

   If Yes, which one(s) were they, when were they last taken, and for how long did you take them?
   ____________________________________________________________________________
   ____________________________________________________________________________
   ____________________________________________________________________________
5. Do you have a history of noise exposure, i.e. loud music, gun fire, etc.? (Please include all work and recreational situations.) Yes/No

If so, What kind of exposure did you have?

______________________________________________________________________________

For how many years did you experience the exposure?

______________________________________________________________________________

Did you use hearing protection? Yes/No

6. Does anyone in your family have a history of hearing loss? Yes/No

If so, What is the relationship to family member?

______________________________________________________________________________

7. Do you feel you have any signs of hearing loss? Yes/No

If so, Do you have problems understanding speech in quiet? Yes/No

Do you have problems understanding speech in noise? Yes/No

8. Do you have any, or have a history of experiencing, tinnitus? ("ringing" in the ears) Yes/No

If so, Please describe sound (low pitch roaring, or a squealing higher pitch . . .)

______________________________________________________________________________

Is it episodic or constant? (circle)

If episodic, Does it have a regular time of onset like right before falling asleep, or after a particular activity you involve yourself in? Yes/No

If yes, when does it occur?

______________________________________________________________________________

9. Do you have any problems with balance or with becoming unbalanced or dizzy? Yes/No

If yes, Please describe:

______________________________________________________________________________

Appendix D

SUBJECT CLINICIAN SCREENING QUESTIONNAIRE

NAME: __________________________________________________________

DATE OF BIRTH: ________________________________________________

LATEST EDUCATION COMPLETED: _________________________________

HIGHEST DEGREE COMPLETED: _________________________________

FIELD OF STUDY IF MORE THAN HIGH SCHOOL:
________________________________________________________________

1. What are otoacoustic emissions?
________________________________________________________________

2. Why are otoacoustic emissions important?
________________________________________________________________

3. Have you had any experience with the AuDX otoacoustic emission screening device, or any other screening device of this type? Yes/No
________________________________________________________________

4. What is the presence or absence of otoacoustic emissions indicative of?
________________________________________________________________
Appendix E

Directions for AuDX

1. Perform Otoscopy and determine clear canals by looking for the ear drum
2. Assess the size of the ear canal to determine probe tip size
3. Apply E.A.R. plug tip to end of receiver making sure clear plastic flange is firm against the black plastic housing
4. Roll tip between thumb and forefinger to compress the plug
5. Insert receiver quickly into ear canal, being careful not to push receiver into the ear canal beyond where the outer edge of the probe tip is visible.
6. Press the “On” button
7. Press select button until “Perform TEOAE” appears on the screen.
8. Press select button again to display “Test R Ear”
9. Use the up and down arrows to select Left or Right ear.
10. Press Select to begin the test.
11. If “Probe in Ear? – Refit and Retry” appears on the screen, remove tip and repeat steps 4 and 5 again. – Press “Select” again to retry the test.
12. Test is finished when either “Pass” or “Fail” along with “1500” appears in the display.
13. When Test is completed, remove receiver from ear and remove tip and place E.A.R. tip in the sterilizing solution.