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Dedication

This work is dedicated to the children and families of Balti, Moldova. I am indebted to the people of Moldova as a professional, an audiologist, and on a deeply personal level. I envision a day when every newborn is screened for hearing loss and medical and audiologic intervention for children is safe and effective, without regard to ethnicity or poverty. This goal should include every child, not only those in our country. The faces of every child I had the honor of helping are indelibly carved in my mind.

Acknowledgements

I thank my committee members, Dr. Susan Spirakis, for whom I have tremendous respect, for her help and patience in preparation and approval of this paper, Janet Stockard for giving me the opportunity to work with infants at Tampa General and for her always gracious assistance in provision of expert advise, technical information, and references, and especially to my chairperson and friend Dr. Terry Chisolm. My gratitude to you is immeasurable. This research document and the degree that it afforded would not be mine without your persistent encouragement and support. To my family, John, Jana, and Jake, I owe peace of mind and happiness in the face of challenge and change. I know you won't allow me to owe you, so I will just continue loving you. And finally, to my friends and fellow Doctors of Audiology, especially Shannon Felder, Renee Lokenberg, and Greg Spirakis, without you this experience would not have been so memorable. Thank you all.

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(ABSTRACT)

The difference in otoacoustic emission (OAE) hearing screening failure rates as a function of ethnic category was investigated in a population of newborns at Tampa General Hospital, Tampa, Florida. Clinic observation led to a concern that due to a higher incidence of outer and middle ear dysfunction in Hispanic newborns and children, screening could result in disparate failure rates, with a larger number of these infants requiring further testing. This result would warrant changes in current protocols, as well as screener training, and parent counseling practices.

Between January and July of 2000, 1407 newborns were tested utilizing distortion product otoacoustic emission screening protocols. Of those infants, only 68 failed, yielding a higher than average overall program referral rate of 5%. It is hypothesized that since later reported referral rates for this program fall below 1%, the individuals performing the screenings had not yet become experienced enough to yield low refer rates. In addition, initial screens are not repeated in this program due to staffing and funding issues, which may contribute to higher than average fail rates.

More important, however, results indicated that there is indeed a difference in failure rates as a function of ethnicity, with a greater proportion of Hispanic and African-American and “Other” newborn referrals than Caucasian or Asian newborns. This difference, however, was not significantly reliable. It is hypothesized that this difference may be the result of a generally lower socioeconomic status and access to medical care within urban minority populations in Hillsborough County, Florida. Implications are discussed.

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Childhood hearing impairment can have devastating effects on the development of speech and language abilities that may effect later cognitive ability, social interaction, emotional development, and academic performance. The earlier a child is identified as having sensorineural hearing impairment and intervention is initiated, the more successful the expected outcomes. Indeed, if intervention is initiated before six months of age, a child may incur no delay in language development (Yoshinaga-Itano, Sedey, Coulter, & Mehi, 1998).

While screening newborns at risk for hearing impairment has been recommended for many years, the average age of identification remained high at approximately 30 months of age (Harrison & Roush, 1996). Children with mild to moderate impairments were often not identified until school age years due to their inconsistent responses to sound (Elssmann, Matkin, & Sabo, 1987). Despite the obvious need for early identification and intervention, screening of all newborns was not previously thought to be cost effective or feasible due to speed of technology and manpower necessary to carry out screenings on a universal basis. What has made universal newborn screening feasible in recent years is the advancement of technology and widespread use of Otoacoustic Emissions (OAE) and Automated Auditory Brainstem Response (AABR) equipment (White, 1996).

OAE measures can be reliably used to detect sensory hearing loss in neonates at frequency ranges above 1500 Hz. The OAE is known, however, to be sensitive to outer ear canal obstructions and middle ear dysfunction, which may lead to a referral where normal sensory function is present (Chang, Vohr, Norton, & Lekas, 1993; Doyle, Burggraaff, Fujikawa, Kim, & MacArthur, 1997). Despite this limitation, both forms of OAE, Distortion Product OAE and Transient Evoked OAE, have gained acceptance for use in screening programs. This is primarily due to ease of use and portability of equipment, accuracy of measurement, and speed of testing. Though AABR programs

have slightly higher pass rates than OAE programs, both are accepted techniques for UNHS (Finitzo, Albright, & O'Neal, 1998; Johnson, Kuntz, Sia, White, & Johnson, 1997; Mason & Herman, 1998; Vorh, Carty, Moore, & Letourneau, 1998; White, 1996). Distortion Product Otoacoustic Emission (DPOAE) screening is utilized in the Tampa General Hospital program.

As a result of the advancement in affordable technology, universal newborn hearing screenings (UNHS) are being mandated through state legislation across the country, with the latest legislation passing in the state of Florida. Beginning October 1, 2000, all newborns in Florida must receive a hearing screening. While programs will identify hearing impairment much earlier in life, wide spread implementation may raise issues not anticipated. One such issue is a potential for disparate failure rates as a function of ethnicity.

This study investigated the difference in failure rates as a function of ethnicity in newborns not at risk for hearing impairment screened at Tampa General Hospital. The Tampa General community consists of a primarily urban population, and the birth rate is over 3,000 annually. Tampa General began a UNHS pilot program in March 1999. Through participation in this program, the investigator observed an apparent preponderance of initial hearing screening failure in Hispanic newborns, with the majority passing subsequent screenings. Though this occurrence has never been systematically investigated, other professionals in the state of Florida have made similar observations (J. Stockard, personal communication, February 2000). If indeed a higher incidence of false positive identification using OAE protocols is found among Hispanic newborns, the reason for this finding should be investigated.

For example, possible influences with respect to ethnicity include factors associated with middle ear effects on testing. It is not uncommon for newborns to exhibit middle ear dysfunction. Otitis media with effusion (OME) resulting in a conductive hearing impairment may be present at birth and clear gradually in weeks following (Balkany, Berman, Simmons, & Jafek, 1977; Cavanaugh, 1987; Jaffe, Hurtado, &

Hurtado, 1970; Stockard & Curran, 1990). Middle ear abnormalities, such as OME, can increase the noise floor of DPOAE measurements, significantly influencing pass/refer status (Popelka, Karzon, & Clary, 1998). When the noise floor of a DPOAE is increased, the level of the measured distortion product is reduced. Protocols are based on a certain level of distortion product measured at each frequency, thus increased noise floors due to OME at any or all frequencies can result in a measure not sufficient for pass status. It is reasonable to deduce that a protocol that measures fewer frequencies, such as the "Oz" system utilizing five test frequencies, would yield a higher fail rate.

Interestingly, research has shown higher rates of OME in Hispanic, versus non-Hispanic, children (Daly, 1991; Teele, Klein, & Rosner, 1980). Also, Gravel, McCarton, & Ruben (1988) noted that Hispanic high-risk infants experienced OME at younger ages than the African-American newborns in their study. This may explain the initial hearing screening failure of Hispanic newborns, if such a difference in ethnicity is found through this investigation. Implications for a positive finding may include changes in screening protocols utilized, in parental counseling practices, and in screener training practices.

Method

Participants

Initial hearing screening records of 1407 well newborns, born between January and July of 2000, and tested at Tampa General Hospital were reviewed for pass/refer status and ethnicity as indicated on demographic records. Table 1 shows the number of well newborns as a function of the ethnic categories: Hispanic, African-American, Caucasian, Asian, and "Other", as well as the number of infants who failed initial hearing screenings.

Table 1 Referrals as a function of ethnicity and birth rate.

Ethnic category	Number of Births	Number Referred
Hispanic	535	28
African-American	359	19
Caucasian	394	13
Asian	8	0
Other	111	8
Total	1407	68

Instrumentation

Each infant was screened prior to investigation with Grason-Stadler Incorporated (GSI-60) Distortion Product Otoacoustic Emission equipment. Two sets of equipment were utilized, including one computer containing "Oz" data management software.

Personnel

Either the audiologist program manager or one of three Doctor of Audiology students preformed each screening. The students underwent training and supervision for a period of at least two weeks, and had been employed by the program for at least one month.

Screening Protocols

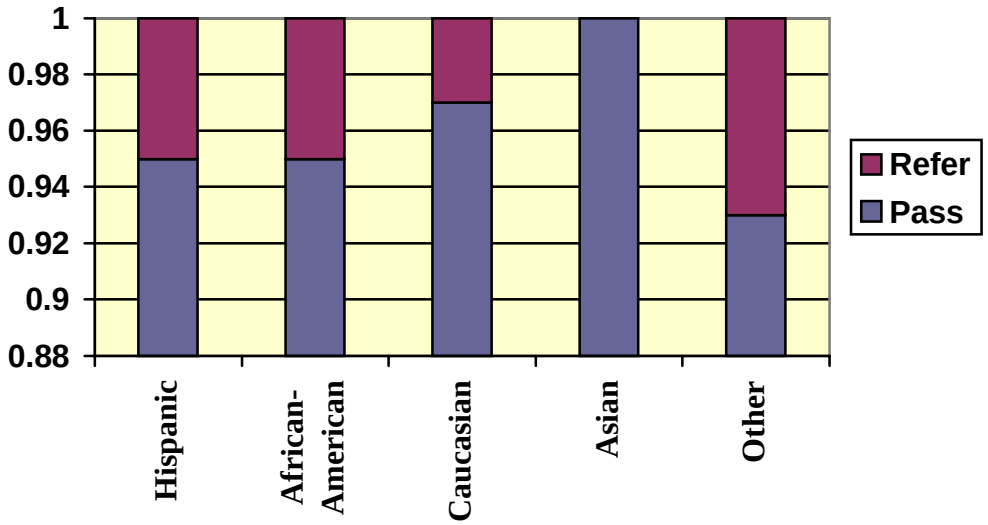
DPOAE screenings were preformed prior to discharge from the hospital, at which time infants were a minimum of 1 hour old and a maximum of 48 hours old. As stated, two pieces of equipment are utilized at Tampa General to determine pass/refer criteria. The primary equipment used is GSI-60 DPOAE with "Oz" data management software. The protocol installed to determine pass/refer status was developed to examine five frequencies for average distortion product amplitude relative to the noise floor. A minimum F1/F2 frequency ratio value of 1.21 is used at each frequency to determine pass/refer, and four of the five frequencies must achieve this value in order to pass (T. Finitzo, personal correspondence, December 6, 2000). Secondary, or back-up, equipment is GSI-60 DPOAE that utilizes Hall (1994) published normative criteria.

Results and Discussion

It will be recalled that of the 1407 newborns included in this study, 1339 passed the screening and 68 were referred for further testing (Table 1). Figure 1 illustrates the proportional pass/refer data as a function of ethnicity. It can be seen that proportionally the "Other" ethnic group had the highest fail rates. It is not clear if these newborns would have been classified in another ethnic group had the parent been available to complete the demographic information upon admission to the hospital. A newborn fell into the "Other" category in the event that a mother was unable to complete the report herself and a staff member filling out the form could not identify ethnicity. It can be reasonably assumed that this group included several newborns of varied races.

It can also be seen in Figure 1 that the next highest proportional fail rate was equally shared between the Hispanic and African-American (5%) ethnic groups. The Caucasian fail rate was only 3% and none of the Asian newborns screened were referred for further testing. Although these differences in refer rates as a function of ethnicity were observed, a chi-square test of independence failed to find a reliable difference ($\chi^2_{OBS} = 4.095 < \chi^2$ crit (.05,4) = 9.488).

Figure 1. Proportion of referrals as a function of ethnic category.



Examining factors that may influence the validity of OAE screening procedures is an important component in establishing widespread support and acceptance of results. When clinical observation raises the possibility that factors other than sensorineural hearing status might be influencing pass/refer rates it is important to systematically rule out these factors. Clinical observation at Tampa General Hospital (TGH), Tampa, Florida, led to the hypothesis that the proportion of infants failing initial OAE screening was greater in Hispanic than in other ethnic groups. Although greater fail rates were observed for Hispanic, African-American, and the "Other" ethnic groups as compared to Caucasians and Asians, statistical analysis failed to support the research hypothesis.

The relationship between ethnicity and incidence of OME has been reported extensively in the literature. Though evidence supports that Hispanic children have the highest prevalence of any ethnic group, there remains inconsistency regarding prevalence rates of Caucasian and African-American children (Lee, Gomez-Martin, & Lee, 1996; Paradise, et al., 1997). In an investigation of incidence of OME over a one-year period, Gravel, et al. (1988) reported comparable percentages of incidence in Hispanic and African-American infant populations. It will be recalled that this investigation yielded similar proportions of fail rates in these two ethnic categories. Many authors have speculated about the reasons for this difference in ethnicity, however, there has been no preponderance of evidence to support any one reason. Through an extensive, long-term investigation by Paradise, et.al. (1997), one of the most important risk factors for OME was determined to be socioeconomic status.

It is of interest to note that in Hillsborough County, Florida, the median income among Caucasians is higher than among African-American and Hispanic ethnic groups (U.S. Census, 1990), equaling $30,350, $17,409, and $23,748, respectively.[1] It is not unreasonable to hypothesize that the quality of prenatal health care may be positively related to income level (e.g. McDonald & Coburn, 1988; Shapiro, Weiner, & Densen, 1958), and that poor prenatal care may negatively affect various aspects of health status, including auditory function and middle ear status, at birth. As stated, socioeconomic

[1] Census 2000 data were not yet available upon completion of this investigation.

status has been correlated with the incidence of OME (e.g. Bush & Rabin, 1980; Paradise, 1980; Stahlberg, Ruuskanen, & Virolainen, 1986). In a comparison of prenatal care by Caucasian and African-American women in their third trimester, Kogan, Kotelchuck, & Johnson (1993), found that African-American women were less likely to attend scheduled appointments despite payment status and barriers to care. Thus, the observation of a possible ethnic influence on failure of newborn OAE screenings might have been the result of the relation of ethnicity to income level, access to medical care, and cultural differences, rather than due to any other reported differences in ethnic groups. This hypothesis can be examined in future investigation.

Another important consideration is the finding of an overall referral rate of 5% for the population of infants under investigation in a period of seven months. This rate is higher than that recommended by Joint Committee on Infant Hearing: 2000 Position Statement. The statement recommends an annual referral rate of less than 4% within one year of program initiation. The national average referral rate of programs in operation for one year or longer is reportedly under 2% annually (Yoshinago-Itano, 2000). Fail rates at TGH have improved considerably and are currently estimated to be less that 1% (J. Stockard, personal communication, November 20, 2000). It will be recalled that the individuals performing screenings at TGH are students in a Doctor of Audiology program. As such, they are likely to have more knowledge of audiometric and early intervention issues and a high level of motivation to administer a successful newborn hearing screening program.

One possible explanation for the higher than average referral rate reported in this investigation is that due in part to limited staff and funding, screeners at TGH rarely have more than one opportunity to test infants prior to hospital discharge. Many programs have the opportunity to test infants who fail initial screenings over a period of several days. McNellis & Klein (1997) and Vorh, Kemp, Maxon, & White (1991) found that OAE pass rates improve significantly upon repeat testing between the first and second day of life. It is hypothesized that the initial presence and gradual clearing of debris (vernix caseosa) in the ear canal or fluid in the middle ear is the cause of increased pass

rates over time. Cavanaugh (1987), Chang, et al. (1993), and Doyle, Rogers, Fujikawa, & Newman (2000), also support this finding.

While fail rates will become less as screener skills improve and time of testing increases, it is important to consider all factors that may influence initial screening failure. When it is recommended that an infant be retested, unnecessary parental concerns may arise. As was reported by Sorenson, Levy, Mangione, and Sepe (1984), retesting infants can result in anxiety if the process and need for further testing is not adequately explained. The information provided by this investigation regarding factors other that sensorineural hearing loss that may potentially influence pass/refer rates may be useful as a counseling tool to aid minimizing parental anxiety. In conclusion, this investigation supports the continuation and implementation of protocols as outlined here, including the use of OAE screening by experienced professionals and trained, knowledgeable non-professionals, regardless of newborn ethnicity.

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Education

Doctor of Audiology (Au.D.) Degree, University of South Florida, Tampa, Florida, December 2000
Master of Science, Audiology, University of South Florida (USF), Fall 1999
Bachelor of Arts, *cum laude*, Communication Sciences and Disorders, USF, Summer 1997
Associate of Arts, Edison Community College, Punta Gorda, Florida, Spring 1995

Related Employment History

Audiology Clinical Fellow, Central Florida Speech and Hearing Center (CFSHC), Lakeland, Florida. CFSHC is a busy, non-profit service center providing hearing care to individuals of all ages. Provided diagnostic, electrophysiological (including supervised sedated ABR), and rehabilitative Audiology services to infants and children with multiple and varied disabilities, adults with special needs, and elderly patients. Gained valuable experience filling patients' amplification needs, including advanced technology. Conducted occasional on site industrial hearing conservation screenings. Performed screenings and participated in team meetings of Polk County Children's Medical Services (CMS) Craniofacial Clinic. Provided consultation to the Lakeland Regional Medical Center to comply with state Universal Newborn Hearing Screening requirements. February-December 2000.

Audiometric Consultation, CMS Craniofacial Clinic, Hillsborough County, May 2000. Responsibilities included hearing screenings and craniofacial team meeting.

Audiology Clerkship (part time), CFSHC, Lakeland, Florida, for the completion of the Au.D. Degree. Encouraged to remain at CFSHC following a Summer Externship experience, with increased responsibility and independence. Fall, 1999.

Audiology Clerkship (part time), Tampa General Hospital Pediatric Department, Tampa, Florida, toward completion of Au.D. Degree. Responsible for diagnostic evaluation, via otoacoustic emission, visual reinforcement audiometry, play audiometry, and standard response techniques, of patients ranging in age from birth to 18 years. Fall, 1999.

Universal Newborn Hearing Screening Program Employee, Children's Medical Services at Tampa General Hospital, Tampa, Florida. During nine-month employment, assisted in the coordination of the program by assuring daily shift coverage and communication with the program director. Duties included hearing screening of approximately 10 infants per workday, in both the well infant nursery and the Neonatal Intensive Care Unit. 1999.

Audiology Externship, CFSHC, toward completion of the Master of Science Degree. Performed audiologic services under supervision (see above). Summer, 1999.

Audiology Externship, Sun Coast Hospital, Largo, Florida, toward completion of Master of Science Degree. Sun Coast Hospital Audiology Clinic primarily serves adult and elderly individuals. Gained valuable experience in diagnosis of adult hearing impairment and advanced technology hearing instrument evaluation and fitting. 1998.

Extended Day Coordinator, Independent Day School, Tampa, Florida. Organized the activities of up to 30 children, ages 4 to 14, in a safe educational environment. Gained experience as a half time substitute teacher. Duties included creative lesson planning and teaching physical education classes to students grades Pre-K through 5. 1997.

Office Administrator/Special Equipment Trainer and **Interim President, Hearing Impaired Persons of Charlotte County**, Port Charlotte, Florida. HIP is a community service center that assists deaf and hard of hearing individuals with a variety of needs. Coordinated, supervised work and project responsibilities of volunteer staff; gained and used knowledge of issues, services, and equipment of deaf and hard of hearing persons, including Americans with Disabilities Act; assisted in preparation of funding applications and contracts; coordinated efforts to provide sign language interpreters. 1992-93.

Honors

- Guest Panelist, AuD Featured Session, American Academy of Audiology 2000 Convention, Chicago, IL, March 17, 2000.
- Chapter Leadership Scholarship, National Association of Future Doctors of Audiology, August 2000.
- Phi Theta Kappa International Honors Society Public Relations Officer, 1994-1995
- Member of Brain Bowl Competitive Academic Team, 1995

Humanitarian/Volunteer Activities

- Moldovan Children's Audiology Program
  Founding Member/ Current Program Co-Administrator
  Traveled to Balti, Moldova, May 19-26, 2000, to evaluate 105 children, fit 81 hearing aids, deliver antibiotics, and train physicians to continue administration of the program. Continued fundraising and securing of equipment donations from manufacturers, made presentations to local civic organizations, gave interviews to newspaper and television media. Continued training two Moldovan doctors in the Tampa Bay area, August 2000. Long-range goals include provision of needed equipment and implementation of the first Audiology Clinic in Balti, as well as return trips to monitor progress.