A PROGRAMMATIC ANALYSIS OF A

NEWBORN HEARING SCREENING PROGRAM

FOR EVALUATION AND IMPROVEMENT

by

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A Programmatic Analysis of a Newborn Hearing Screening Program for

Evaluation and Improvement

Thesis directed by Professor Christine Yoshinaga-Itano

ABSTRACT

Detailed analysis of the Colorado Newborn Hearing Screening was performed to

identify factors that were related to infants not obtaining the follow-up outpatient

rescreen for the birth cohort in 2005. This analysis has shown that infants who

are born in hospitals with rescreen rates <79% are as much 7 times less likely to

receive the outpatient rescreen and infants born in hospitals with rescreen rates

between 80-90% are twice as likely not receive the outpatient rescreen as

compared to infants born in hospitals with rescreen rates >90%. Infants born in

hospitals that have an audiologist involved with the program are 27% more likely

to receive the outpatient rescreen.

Twenty-six percent of infants confirmed with a hearing loss between 2002 and

2005 were not identified until after the age of six months despite research that

identification before six months is critical to the development of normal

language. High risk factors, gender, ethnicity, mothers education, mothers age at

birth, nursery level, degree, and type of hearing loss did not yield any significant

results.

Providing audiology support may improve newborn hearing screening programs

to decrease the rescreen rates and improve the age of identification.

DEDICATION

This work is dedicated to my loving and supportive family, George, Aubree and Valerie. They made this journey possible with their love, encouragement, and patience. I am forever grateful to them.

I also would like to dedicate this to my mother, Phyllis Rahe. I was lucky to be born on her birthday. She is a wonderful mother and she inspired me to preserve through this challenge.

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me to start the first program at Boulder Community Hospital and my life has changed since that day.

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I am so blessed to have so many colleagues and friends that encouraged my work over the years that this acknowledgment could be as long as the dissertation itself.

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Introduction

The principles of screening hearing at birth have proven to be the most

effective means to ensure early identification, habilitation, and a satisfactory outcome

for normal language development in children. In 1967 Downs and Sterritt described a

universal newborn hearing screening program in seven Denver hospitals using a signal

generator and observing the behavioral responses of infants. Such subjective

techniques were replaced when electro-physiological instrumentation became

available in the 1980's. In 1998 all 54 of Colorado birthing hospitals had

implemented a universal newborn hearing screening program using objective

screening technology (either automated auditory brain stem response or otoacoustic

emissions screening). Thirty-nine states have mandated universal newborn hearing

screening, and all states and territories have an Early Hearing Detection and

Intervention (EHDI) program in place (National Center for Hearing Assessment and

Management, 2006), thus making universal newborn hearing screening the standard of

care in the United States.

Public health departments manage EHDI programs. The role of public health

for population-based screening is to ensure comprehensive systems from screening

and into appropriate and timely interventions. The purpose of this research is to

identify what factors may be associated with infants who are not receiving a follow-up

rescreen and who are not getting into diagnosis, by the recommended time of three

months of age. Identifying potential factors that are related to these questions will assist in improving the EDHI program for infants and their families.

Incidence of Hearing Loss in Children

Congenital hearing loss has recently been recognized as one of the most common birth defect present in newborns, with a prevalence of permanent hearing loss ranging from 2-3/1000 live births (Vohr, 2003). The Centers for Disease Control found an incidence of 1.09/1000 with permanent hearing loss based on data submitted from 44 state EHDI programs (Centers for Disease Control, 2006). The latter lower incidence of hearing loss utilized in this study is attributed to evolving data management systems that more accurately can follow and track infants. The definition of permanent hearing loss identified in newborn screening programs varies from a minimum level of 40dBHL in the United Kingdom (Kennedy, McCann, Campbell, Kimm, and Thornton, 2005) to 35dBHL in the United States (Morton and Nance, 2006). The Joint Committee on Infant Hearing (JCIH, 2000) defines the target population for infant screening programs as unilateral or bilateral permanent hearing loss averaging 30-40dB in the speech frequency range. Conductive hearing losses, as a result of anomalies to the outer or middle ear, are also included in the targeted screening population.

In a 2001 report by the Colorado Department of Education, "A Blueprint for Closing the Gap," 1,385 children were deaf or hard-of-hearing, age's birth to 21 in Colorado. Age of onset was less than 12 months for 75% of the children (CDE, 2001). This would indicate that 346 children were identified after the newborn period. The discrepancy between those identified from newborn hearing screening and those in the

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school population is two-fold. Some infants who pass the newborn hearing screen may have mild or atypical audiometric configurations not detected by current screening technologies. In a recent article by Johnson et al. (2005) the authors suggested that a two-stage screening with otoacoustic emissions (OAE) followed by automated auditory brainstem response (AABR) may be missing 23% of mild and unilateral congenital hearing loss. The NIH study (Norton, Gorga, Widen et al., 2000) also concluded that some hearing losses are missed with any of the available technologies. In addition there are infants who pass and will develop late onset hearing loss. The JCIH (2000) recommends the continued use of high-risk criteria to capture late onset hearing loss. Cytomegalovirus and recessive genetic factors, which are typically not screened for at birth, can also result in a significant cause of late onset hearing loss.

Historical Perspective of Universal Newborn Hearing Screening

Hearing loss is not observable and in the past was often not detected until the speech and language was significantly delayed. Severe hearing losses were not typically detected until age two and milder forms not until school age. National efforts to ameliorate the delay in the identification of hearing loss began in 1969 (Northern and Downs, 1991) when a national committee was formed that later became the Joint Committee on Infant Hearing (JCIH). Initially, the committee recommended screening newborns for hearing loss by using high-risk criteria. The JCIH expanded the high-risk criteria from five factors (JCIH, 1973) to seven factors (JCIH, 1982) and then to ten factors (JCIH, 1990). High-risk criteria included family history of childhood hearing impairment, congenital perinatal infection, anatomic malformations involving the head or neck, birth weight less than 1500 grams, hyperbilirubinemia at a

level exceeding indication for exchange transfusion, ototoxic medications, bacterial meningitis, low apgar scores at 5 minutes, prolonged mechanical ventilation, and stigmata associated with a syndrome known to include sensorineural hearing loss. Infants identified with any of these criteria were to be referred for audiologic evaluation to achieve an accurate assessment. The use of a high-risk register was later proved to have high error rates, as 50% of congenital hearing losses were missed, and the average age of identification was two years of age. This screening method did not support optimal early intervention with hearing aids and appropriate therapy due to late identification. The challenges of high-risk registries are further addressed in the literature review.

In 1989 the Maternal and Child Health Bureau and the Department of Education funded a demonstration project in Rhode Island and Hawaii using otoacoustic emissions screening (White and Behrens, 1993). The findings of this project resulted in the National Institutes of Health Consensus Development Conference and its endorsement of universal newborn hearing screening. The U.S. Department of Health and Human Services released the Healthy People 2000 initiative in 1990 and objective 17.16 was to reduce the age at which children with significant hearing impairment were identified at 12 months of age or less. The Joint Committee on Infant Hearing 1994 Position Statement also endorsed the goal of universal detection of infants with hearing loss as early as possible. The current recommended protocol by the Joint Committee Year 2000 Position Statement is defined as universal screening with objective technology by one month of age, identification by three months of age, leading to intervention by 6 months of age. Healthy People 2010

Objective 28-11 states "Increase the number of infants who are screened for hearing loss by one month, have audiologic evaluation by 3 months, and are enrolled in appropriate early intervention by six months."

The Importance of Early Identification

A number of infants identified through early universal newborn hearing screening programs provided the evidence to demonstrate that early identification and intervention of children who were deaf or hard of hearing could actually achieve nearly normal language acquisition by three years of age (Yoshinaga-Itano, Sedey, Coulter and Mehl, 1998). The researchers analyzed many demographic factors (e.g. degree of hearing loss, race/ethnicity, SES, gender, and mode of communication) and found early identification was the key to improved language outcomes. Six months of age was the critical cutoff period for early identification that would achieve normal speech and language development.

Moeller (2000) has described outcomes related to early or late intervention in a metropolitan program prior to universal newborn hearing screening. Children were identified through high-risk registries, child find programs, and parent self-referral. The cohort of 112, between the ages of two days and 54 months were enrolled in a comprehensive intervention program. Retrospective analysis of outcomes in language development related to time of diagnosis and intervention revealed that children enrolled in intervention prior to 11 months of age had superior vocabulary and verbal reasoning at 5 years of age than counterparts receiving intervention at later ages. A recent study from the United Kingdom reported higher language scores for a group of children identified at birth with bilateral permanent congenital hearing loss than a

group with similar hearing loss who had not been screened at birth. The children in this study were tested at approximately 8 years of age (Kennedy, McCann, Campbell et al, 2006).

In 1996 the Maternal and Child Health Bureau awarded a grant to the University of Colorado to establish the Marion Downs National Center. The Center provided technical assistance to state health departments to develop comprehensive systems from screening to early intervention. Currently all EHDI programs are managed by State Departments of Public Health. It is the role of these agencies to ensure that all infants are screened, and for those who fail, that they receive appropriate and timely follow-up. The success of an Early Hearing Detection and Intervention Program (EHDI) determined by the benchmarks recommended by state and federal policy to ensure early identification and intervention of hearing loss.

The Colorado Infant Hearing Program

The Colorado Infant Hearing Program began as a pilot project in 1992 to determine if newborn hearing screening was feasible prior to hospital discharge. The Colorado Department of Public Health and Environment (CDPHE), Children and Youth with Special Health Care Needs (HCP) sponsored this effort in collaboration with The Children's Hospital and the University Colorado Health Sciences Center. Research on this pilot effort was conducted by the University of Colorado and demonstrated that infants with congenital hearing loss born in pilot hospitals providing newborn hearing screens were being identified and receiving early intervention by six months of age, compared to infants identified with hearing loss at age 24 months born in non-pilot hospitals. The language outcomes for those children who were screened

and received early intervention had low normal language outcomes at age three (Yoshinaga-Itano, Coulter and Thomson, 2000).

As a result of the emerging data from the University of Colorado, the 1997 Colorado legislature mandated that all hospitals offer a newborn hearing screen. CDPHE was named as the organization responsible for the legislation requirements. If the statewide screening rate fell below 85% then rules and regulations would be promulgated to insure a higher hospital-screening rate. The legislation also required that an advisory committee be developed to provide guidance to hospitals and providers to assure a comprehensive system from screening through early intervention. The Colorado Infant Hearing Advisory Committee developed guidelines for screening, diagnosis, and early intervention. In 2005 the Colorado legislature passed an amendment to increase the mandated screening rate to 95% and maintain the advisory committee.

Initially in the Colorado pilot project, hospitals provided monthly summary reports that included the number of infants born, the number screened, the number not screened, and the number who failed the screen. Aggregate data were collected in a paper report form and voluntarily submitted by participating hospitals, and results were entered into an Access database. Because only monthly totals were reported, this manual system did not allow for tracking of individual children. One of the over-riding goals in a hearing-screening program is to ensure that infants who fail the screen receive timely and appropriate follow-up (audiologic diagnostic assessment, amplification and early intervention). In collaboration with Colorado Vital Records at CDPHE, individual hearing screening results were added to the electronic birth

certificate in 1998. A data management system was developed that provided more accurate reporting, but still did not allow tracking children through screening and into early intervention. In 2000 the Centers for Disease Control, awarded a Data Integration Grant for Early Hearing Detection and Intervention (EHDI) to the CDPHE. This grant allowed CDPHE to hire information technology personnel to develop a fully integrated data system so individual infants could be tracked from screening to diagnosis and to enrollment into early intervention.

During early implementation of universal infant screening programs, there were concerns in the medical community regarding high false positive rates at hospital discharge (Bess and Paradise, 1994). These concerns prompted Colorado to develop a protocol guiding hospitals to re-screen infants prior to hospital discharge. For infants who failed the initial inpatient screen and re-screen in one or both ears, the hospital was to request the infant to return within two weeks of discharge for an outpatient re-screen. Infants who failed an outpatient re-screen were then referred to an audiologist for confirmatory diagnostic evaluations. This protocol has become the standard of care in Colorado and has decreased the fail rate at hospital discharge to less than 4%. This strategy has further decreased the number of infants who are referred to audiologists for more costly diagnostic evaluation to less than 1%.

A fully integrated tracking system coupled with low fail rates at hospital discharge has assisted the Colorado Infant Hearing Program to eventually achieve high outpatient follow-up screening rates (86% in 2004). This improvement has enhanced communication between hospitals and CDPHE. In addition a newly adopted system contacts families when there is no record of an initial or follow-up screen.

The use of demographic data from the electronic birth certificate has allowed the identification of specific factors correlated with infants who failed to receive an initial or follow-up screen. Colorado has developed a comprehensive surveillance system that allows critical epidemiological analysis and evaluation of screening, diagnosis, and treatment activities. This research project presents analyses of such data from 2002 to 2005.

Purpose of this Study

The present research will analyze the demographic and hospital factors associated with infants not receiving the follow-up rescreen after hospital discharge. Demographic factors will be ascertained for those infants who are not diagnosed by three months of age and those who were diagnosed by three months of age. These statistical analyses will allow the Colorado Infant Hearing Program to take full advantage of its extensive hearing-screening data infrastructure. More specifically, these analyses will provide the Program with the capacity to develop evidence-based strategies to improve statewide and hospital-specific screening system performance.

CHAPTER 2

Review of the Literature

Introduction

This chapter's purpose is to review literature that provides information relevant to achieving quality indicators for Early Hearing Detection and Intervention Programs. The capacity to develop a truly comprehensive statewide system of newborn screening, diagnosis, and early intervention is the role of public health. Multiple community linkages as described by Vohr, Simon, and Letourneau (2000) must be established to ensure that community based programs are culturally sensitive and seamless for families. Thomson, Rose, O'Neal and Finitzo (1998) noted that for states to be effective in developing statewide systems, public health agencies must collaborate with other public and private agencies such as Departments of Education, Audiologists, Hospitals, Physicians, and Community Health Centers. CDC states their mission for EHDI Programs "is for every state and territory to have a complete EHDI tracking and surveillance system that ensures children with hearing loss achieve communication and social skills commensurate with their cognitive abilities. To do this, it is essential that infants with hearing loss are identified early, and appropriate intervention services are initiated. Without early identification and intervention, children with hearing loss may experience delays in the development of language, cognitive, and social skills that may prevent success in academic and occupational achievement".

The Joint Committee on Infant Hearing (2000) established four principles for EHDI programs to ensure that infants with hearing loss reach their "maximum potential". Those principles are defined as:

1. All infants should have access to hearing screening using a physiologic measure before one month of age.

2. All infants who do not pass the initial hearing screen and the subsequent rescreening should have appropriate audiologic and medical evaluation to confirm the presence of hearing loss before 3 months of age.

3. All infants with confirmed permanent hearing loss should receive intervention services before 6 months of age.

4. All infants who pass newborn hearing screening but who have risk indicators for other auditory disorders and/or speech and language delay receive ongoing audiologic and medical surveillance and monitoring for communication developments. Infants with indicators associated with late-onset, progressive, or fluctuating hearing loss as well as auditory neural conduction disorders and/or brainstem auditory pathway dysfunction should be monitored.

The purpose of the present epidemiological study is to take advantage of Colorado's well-developed EHDI data tracking and surveillance system in order to examine if the Colorado Infant Hearing Program is meeting the JCIH principles. Specifically, this research will aim to discover why *all* infants are not meeting the JCIH benchmarks of screening by one month and diagnosis by three months. This study will analyze what factors are associated with infants not receiving a timely follow-up screen and a confirmed diagnostic assessment by three months of age. The

principles of screening will be discussed in this literature review as they led to the development of Early Hearing Detection and Intervention benchmarks.

Principles of Screening and the Rationale for Newborn Hearing Screening

The rationale for instituting newborn screening is to identify a population that may have a disorder with no obvious symptoms at birth. In 1968, Wilson and Jungner (as cited in Coughlin, 2006) proposed 10 principles for public health mass screening programs. These principles included planning and evaluating population screening programs based on: the scientific evidence; the balance of risks and benefits; the availability of an effective treatment program; the acceptability of the screening test to the population; and the costs and resources required.

Vohr (2003) and the American Academy of Pediatrics (1999) state that for justification of universal newborn hearing screening for congenital hearing loss it must meet the following public health criteria: 1. Easy to use screen tests are available that possess a high degree of sensitivity and specificity to minimize unnecessary referrals for additional diagnostic assessments. 2. The condition being screened for is not otherwise detectable by clinical means. 3. Interventions are available to correct the condition once detected. 4. Early screening, detection, and intervention result in improved outcomes. 5. The screening program is documented to be an acceptable cost effective range.
The following literature review will demonstrate how these public health criteria have been achieved.

1. Easy to use screen tests are available that possess a high degree of sensitivity and specificity to minimize unnecessary referrals for additional diagnostic

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assessments. To understand the different screening tests that are currently being used, it is essential to consider the concepts of sensitivity, specificity and positive predictive value. Sensitivity is the probability of a positive test when an infant has a hearing loss. Specificity is the probability of a negative test among infants who do not have a hearing loss. A true positive is when a hearing loss is correctly identified and a true negative is when there is no hearing loss present and the screen is also negative. A false positive is when the screening results suggest further evaluation and there is no hearing loss, and a false negative is when the screening results indicate a pass even though a hearing loss is present. The positive predictive value is the proportion of infants who are correctly diagnosed through newborn hearing screening. The positive predictive value is defined at the true positives/true positives + number of false positives. An ideal screening program would have a high sensitivity, specificity, and positive predictive value. The evolution of auditory brainstem response technology and of otoacoustic emissions has been determined to meet the criteria for sensitivity and specificity to be used in newborn hearing screening programs. These technologies are discussed in detail to provide information pertinent to the understanding of sensitivity, specificity, and positive predicative value.

Auditory Brainstem Response. Auditory brainstem response (ABR) is a test of auditory function in response to auditory stimuli such as clicks, tone pips, and tone bursts. Jewett and Williston first described the ABR in 1971 (Hall, 1992). Hecox and Galambos (1974) documented the reliability and validity of the ABR to measure hearing sensitivity in infants. Surface electrodes are placed on the scalp to record the evoked potential. Typically a click stimulus is used. As the stimulus is present the

evoked potential is elicited from the cochlea to the cortex. The ABR response has a distinct, repeatable wave pattern. At high intensities there are 5 peaks beginning with Wave I, which originates in the 8th nerve to wave V in the auditory brainstem. Wave V is the most prominent peak, and as the intensity is decreased it can be traced down to the level of audiometric threshold in the 1-4000Hz ranges within 10-15dB HL. The infant ABR is very similar to that of adults with the exception of prolongation of the response. As the infant matures the ABR becomes adult like by 18 months of age. As a result there are age specific norms for infants. Conventional ABR was used for screening infants in the 1980's (Stach and Santilli, 1998; Hayes, 2003). Screenings were primarily limited to infants who were high risk due to costs of the equipment, time necessary to complete the test, and the required skills of a pediatric audiologist.

Engineers from Bell Laboratories in collaboration with the Infant Hearing Foundation and the Telephone Pioneers developed the Synap (Amochaev, 1987). The Synap was a modified ABR that allowed a volunteer organization, the Telephone Pioneers, to perform an ABR screen on high-risk infants. The screen response required an interpretation from a skilled audiologist. The Telephone Pioneers used the high-risk register recommended by the JCIH to screen 100,000 infants and perform over 10,000 ABR screens. Amochaev reported a 15% false positive rate. This equipment provided an opportunity to screen high-risk infants before hospital discharge and eliminated the need for an audiologist to be on site or the use of expensive conventional diagnostic ABR equipment. This technology did not allow for rapid growth in universal newborn hearing screening programs due to the need of an

audiologist to interpret the results. However, a 15% false positive rate was too high of a rate for a universal newborn screening program.

The development of the Automated ABR (AABR) allowed greater potential for screening all newborns. Hermann, Thornton and Joseph (1995) developed the first AABR, which led to the development of the ALGO -1 Infant Hearing Screener by Natus Medical. The ALGO-1 consisted of a signal averaging microprocessor and an artifact rejection system for myogenic, electrical, and environmental noise interference (Erenberg, 1999). The stimulus consists of a 35dBHL click stimulus with a frequency spectrum of 750-5000Hz at a rate of 37 pulses per second. The clicks are presented through disposable ear couplers. Disposable electrodes are placed on the head, nape of the neck and shoulder of the infant. The myogenic and ambient noise detectors alert the screener if there is an increase in the infant's activity or noise in the room. The screen can be paused until troubleshooting techniques resolve the issues of ambient or myogenic activity. The template is based on an averaged response from 35 infant ABR's to detect the Wave V response using a 35dB HL signal. The algorithm-matching template provides a statistical comparison for either a pass or 'refer'. There were a number of validation studies performed on the Algo (cited by Erenberg, 1999; Hayes, 2003) that demonstrated a sensitivity ranging from 93% to 100% and a specificity ranging from 78% to 98%. Van Straaten (1999) found the AABR in agreement with the conventional ABR up to 98%. Jacobson, Jacobson, Spahr (1990) compared the Algo-1 to conventional ABR and found comparable results between the two techniques.

The advantage of the automated screener is that the pass/refer criteria algorithm requires no interpretation, allowing for a variety of trained non-professional personnel to perform the screen. Although many of the validation studies determined that there was 100% sensitivity and 96% specificity it is known that the ABR technique using click stimuli will miss mild, low frequency, and high frequency hearing losses (Johnson, White, Widen, Gravel, et al., 2005). The positive predictive value has been reported to be near 19% (Mehl and Thomson, 1998) and 14% (Boshuizen, van der Lem, Kauffman-deBoer, van Zanten, Oudesluys-Murphy, and Verkerk, 2001). The advantages of using the AABR are that the response measures both cochlear and neural pathways disorders. This ability allows for disorders such as auditory neuropathy to be identified. The refer rate is relatively low, with reports of 4% to <2% (Stewart, Mehl, Hall, Thomson, Carroll, Hamlett, 2000; Mason and Herrmann, 1998). The AABR also eliminated the observer bias seen with behavioral observation. The disadvantages are that the disposables are costly and the length of time to perform the screen takes longer as the infant must be in a sleep state to eliminate myogenic artifact.

Otoacoustic Emissions. Otoacoustic Emissions (OAE) are low-intensity sounds generated within the cochlea, specifically the outer hair cells, in response to acoustic stimuli (Hall, 2000). OAE's were first postulated by Thomas Gold in 1948 and then demonstrated by David Kemp in 1978 (Kemp and Ryan, 1993; Kemp, Ryan and Bray, 1990; Kemp and Ryan, 1991). OAE's have become an important tool for screening infants as well as a part of the audiological diagnostic test battery. It is still being researched on how OAE's are generated in the cochlea (Lonsbury-Martin, 2005).

OAE is an objective response that is measured via a small microphone that is placed in the infant's ear canal. Transient Evoked Otoacoustic Emissions (TEOAE) and Distortion product Otoacoustic Emissions (DPOAE) are the most common forms of OAE used in infant hearing screening. TEOAE stimulus is broadband click and thus is not frequency specific. TEOAE's used for screening, use intensity signals of 80db SPL or greater. TEOAES are absent in infants who have hearing loss greater than 30 to 40dB. DPOAEs are frequency-specific signals and there is good reliability between the DPOAE response and the pure tone audiograms (Kemp and Ryan, 1993; Lonsbury-Martin, 2005). The intensity of the two tones used in the DPOAE stimulus is set at 75/75dB SPL or 65/50dB SPL. Norton, et al.,(2000) found that higher intensity DPOAEs were present in ears with as much as a 50dB hearing loss. By using the higher 75/75dB SPL this would increase the false negative rate by passing babies who had a moderate hearing loss. Several studies (Vohr, Carty, Moore and Letourneau 1998; Aidan, Avan, and Bonfils, 1999) reported TEOAE sensitivity to be 95% and specificity to be 85%. There are disadvantages to using OAE's for newborn screening. OAE failure is higher during the first 24 hours of life due to debris in the ear canal or fluid behind the tympanic membrane (Hall, 2000; Doyle, Burggraaff, Fujikawa, and Kim, 1997). The fail rate is higher with OAEs (7% to10%) than AABR (less than 2 % to 4%) due to the sensitivity of OAEs to outer and middle ear problems. Also the fitting of the small probe must have a tight seal and requires tester experience. In addition environmental and physiologic low frequency noise will increase the fail rate. The advantages of OAE's are that newer technology eliminates using low frequencies and thus reduces the dilemma of interference with low

frequency environmental noise. OAE screeners are now automated using a pass/fail criterion, which allows trained non-professional personnel to perform the screen. The costs of the disposable probe tips are $1/baby as compared to the AABR disposables at $10/baby.

Neither technology achieves 100% sensitivity or specificity however the goal should be to achieve a high level of sensitivity (identifying those infants who have hearing loss) and specificity (passing those infants who do not have hearing loss). The JCIH 2000 Position Statement recommended a referral rate from screening to audiological assessment of 4% or less. The issue of false negative results will be discussed next to understand which populations of children with hearing loss will pass a newborn hearing screen and potentially have a significant hearing loss.

False Negative Results with AABR and OAE Screening. There are very few studies that have demonstrated the percentage of false negatives with OAE or AABR screening. Norton, Gorga, Widen, et al. (2000) through a large multisite study found that mild hearing losses were less likely to be identified with either AABR or OAE. The false negatives decreased as the hearing loss increased. Johnson, White, Widen, et al, (2005) suggested that a two-stage screening with otoacoustic emissions (OAE) followed by automated auditory brainstem response (AABR) may be missing 23% of mild congenital hearing loss cases. Both of these studies had the infants return at 8 to 12 months after the newborn hearing screen. The potential that some of the "missed" hearing loss cases were actually infants with normal hearing at the time of the screen who acquired hearing loss after birth was not considered. Potential causes of late onset hearing loss were not fully discussed. It was therefore not clear from data

presented that those infants who passed their newborn hearing screen and were later estimated as having hearing loss were truly missed by screening or if they were perhaps among a group of infants that present with late onset hearing losses from causes such as asymptomatic perinatal cytomegalovirus (CMV) infection or recessive genetic traits.

Meyer, Wittee, Hildmann, et al. (1999) studied 464 and identified 7 infants who failed their AABR screening who had passed their OAE screen. All of these infants were in the NICU and had JCIH high-risk criteria and the authors recommended that OAE screening not be used in this high-risk population. Lutman, Davis, Fortnum, and Wood (1997) found 11 of 47 children with confirmed hearing loss who had passed their TEOAE newborn hearing screen. Two of the children had documentation of acquired hearing loss with the other nine labeled as false negatives, giving the test sensitivity 80%. The authors admitted that the false negative results may be due to acquired hearing loss or progressive loss of unknown origin since the confirmation of the hearing losses were up to 9 years of age. Mason, Davis, Wood and Farnsworth (1998) found 5 infants with hearing loss out of 51 who had passed their ABR newborn hearing screen. As in Lutman, et al. study, 2 of the 5 had documented progressive hearing loss. The authors concluded that the false negatives may be due to audiometric configuration or acquired hearing loss. Cullington and Brown (1998) describe a case study of an infant who had robust OAE's with Mondini dysplasia and profound hearing loss. The disorder of auditory neuropathy/dysnchrony (AN/AD) will not be detected by otoacoustic emissions and will result in a false negative. Berg, Spitzer et al. (2005) found 115 of the 477 NICU infants who had failed ABR and

passed OAE screening in one or both ears who had an auditory neuropathy profile. The researchers did not have confirmed audiologic assessments completed on this cohort to determine if in fact all 115 infants did have AN/AD.

To reduce the incidence of false negatives the screening equipment would need to be more sensitive to milder forms of hearing loss, thus increasing the number of false positives. Infants with hearing loss caused by temporary fluid would fail the newborn hearing screen and require additional follow-up increasing the costs and burden on hospital and state EHDI systems. Children with hearing loss caused by a temporary medical condition, i.e. fluid, are considered false positives despite the fact that the children at the time of the screen did have a hearing loss. Currently the sensitivity and specificity of OAE and AABR technology have reached acceptable levels. This research will address the issue of false negatives versus late onset in those infants identified through the Colorado Infant Hearing Program.

2. The condition being screened for is not otherwise detectable by clinical means. As described in the historical perspectives of newborn hearing screening (Appendix A) behavioral observation, the crib-o-gram, the auditory response cradle and high-risk registries failed to identify the majority of hearing losses at birth. In addition primary care physicians do non use objective technology to routinely screen for hearing loss at well baby visits.

3. Interventions are available to correct the condition once detected and (4) early screening, detection, and intervention result in improved outcomes. Several researchers have published the evidence for early intervention of hearing loss (Yoshinaga-Itano, Sedey, Coulter and Mehl, 1998; Sininger, Doyle, and Moore, 1999;

Moeller, 2000). Yoshinaga-Itano, Sedey, Coulter and Mehl (1998) demonstrated that children with all degrees of hearing loss who had intervention by six months of age had language scores comparable to their normal hearing peers. This research also provided evidence that language scores for children identified after six months of age through 25 months of age were not significantly different. This meant that infants identified at nine months of age had similar language scores as children identified at 25 months of age and were not comparable to normal language levels. These data would suggest that early identification and intervention by six months of age is the critical time period for learning language.

Yoshinaga-Itano, Coulter and Thomson (2001) showed infants that are screened in birthing hospitals were identified earlier and had better outcomes than children born in non-screening hospitals. Recent research from the UK (Kennedy, McCann, Campbell, et al., 2006) also demonstrated an association between early identification and higher language scores. The researchers studied 120 children, of which 61 were born during the period that universal newborn hearing screening was available and the remaining 59 were born without screening. Children who were confirmed by nine months of age had significantly higher receptive language scores than children who were identified later.

5. The screening program is documented to be an acceptable cost effective range. Costs studies began to emerge as well as the debate over which technology should be used. Downs (1994) justified early identification at birth based on the costs to lost income for the deaf and the cost of education alone. Proponents of the AABR were concerned about the high refer rates and costs associated with the

follow-up. TEOAE advocates argued that the much lower costs of the disposables (probe tips vs. electrodes and ear cuffs) made OAE a better choice. The costs of universal newborn screening using TEOAE were determined to be about $26 per infant and $4,376 to identify a child with sensorineural hearing loss (Maxon,White, Behrens,Vohr,1995). Mehl and Thomson (1998) compared the costs of newborn hearing screening to the costs of routine newborn screens (metabolic blood spot screen) and found the costs to be on average, $25 per infant screened and diagnosis around $9,600 per infant diagnosed, using AABR as the screening technology. This included costs predictions for early intervention with hearing aids. This outlay was still favorable in comparison to the other common genetic/metabolic (e.g.,hypothyroidism, phenylketonuria, cystic fibrosis, hemoglobinopathy) disorders commonly screened for in the newborn period. Mason and Herrmann (1998) gave figures of $17 per infant to screen and $17,750 to identify a true bilateral hearing loss using AABR. Kemper and Downs (2000) found the screening cost to be $15 per infant with an identified case costing $18,990 using TEOAE as the first screen followed by AABR. Vohr, Oh, Stewart, Bentkoven, Gabbard, Lemons, Papile, and Pye (2001) compared the cost between OAE only, AABR only, and a two step with TEOAE followed by AABR. Their results found that AABR alone had the lowest refer rate at discharge and the highest cost per screen. The AABR costs were $32.81 per infant. The two-step protocol costs $33.05 per infant and the TEOAE only costs $28.69. The costs to identify an infant were $16,405, $16, 527 and $14,347 for the AABR, TEOAE/AABR, TEOAE respectively.

The American Academy of Pediatrics, Task Force on Newborn and Infant Hearing (1999) endorsed universal newborn hearing screening due to the published and unpublished data indicating that all of the screening criteria (as outlined above in Principles of Screening) were met. The movement from hospital based newborn hearing screening programs to the development of statewide comprehensive systems was critical to ensure that all infants are screened by one month, diagnosed by three months and enrolled into early intervention by six months, to achieve the outcome of normal speech and language.

The Development of Early Hearing Detection and Intervention Programs

Although the previous discussion demonstrated that the screening technologies were safe, effective and cost efficient, the most compelling research was the evidence for early intervention. The process of screening and ultimately enrollment into early intervention by six months of age required the development of comprehensive statewide systems that would ensure an infant who failed his/her newborn hearing screening received timely and appropriate follow-up. Many individual hospital and state programs were successful at completing the screening but infants were not being identified until after six months of age. To provide this vital technical assistance, The Marion Downs National Center (MDNC) for Infant Hearing was established in 1996 through a Maternal and Child Health (MCH) Grant awarded to the University of Colorado. The goals of the grant were to implement statewide systems of newborn hearing screening, audiologic assessment, and early intervention in 19 states. The goals set forth were: (1) States will achieve universal newborn hearing screening. (2) States will achieve diagnosis of hearing loss by 4 months of age and begin

intervention by 6 months of age. (3) States will document the developmental profiles of infants and toddlers with hearing loss through their early intervention programs. (4) State Maternal and Child Health Programs will have coordinated systems for newborn hearing screening, diagnosis and early intervention.

The effort of the MDNC promoted the idea that Directors of Speech and Hearing Programs in State Health and Welfare Agencies (DSHPSHWA) take the lead in developing comprehensive, statewide systems of care, from screening through early intervention. The Centers for Disease Control, the Maternal Child and Health Bureau, and the Joint Committee on Infant Hearing (2000) have adopted the MDNC goals of screening by one month of age, diagnosis by three months of age, and enrollment into early intervention by six months of age. The term EHDI, Early Hearing Detection and Intervention was becoming the acronym to describe a system that went beyond universal newborn hearing screening and included the assessments and early intervention processes.

The MDNC promoted a data-driven approach to provide families with objective information about their child's development and to achieve goal three for the early intervention programs (Thomson, et al., 1999). The MDNC also promoted the role of parent input into the development of EHDI system. Parent participation at the national, state and local levels are encouraged to ensure that the materials, protocols, and systems being developed were meeting parents' needs. Surveys of the 17 states showed that less than 15% of early intervention programs had parents serving in any capacity (DesGeorges, 2003). The Centers for Disease Control (CDC) has issued National Goals and Program Objectives (2006) that includes the development of state

advisory boards with the inclusion of parents who have children who are deaf or hard of hearing. The Joint Committee on Infant Hearing in their 2000 Position Statement acknowledged the importance of parental input into developing the EHDI system.

There has been little research to determine the effects of newborn hearing screening, diagnosis and early identification on parents. Bess and Paradise (1994) stated that the recommendation of universal newborn hearing screening would potentially cause "parental anxiety, distraction, and potential misunderstanding, of disturbance of family function, and of unnecessary or harmful procedures or treatments carried out on children…" Thompson, et al., (2001) also expressed concern in their paper about parent anxiety due to false positive screens. In 1997, results of two surveys of parents' perceptions regarding hospital-based screening were published by Utah (Barringer, et al.) and Colorado (Abdala and Yoshinaga-Itano). Both papers came to the conclusion that the benefits of early detection far outweigh any anxiety that a parent may experience from their baby not passing a hearing screening. Clemens, et al (2000) surveyed families after a positive screen and then following a negative rescreen and found that there was not any lasting anxiety with false-positive hearing screening. Luterman and Kurtzer-White (1999) found that 83% of parents who had a child who was deaf wanted to know at the time of birth that they should begin the early intervention process. A study in Sweden (Magnuson and Hergils, 1999; Hergils and Hergils, 2000) found that 91% of parents had a positive attitude toward screening and found the screening reassuring. In contrast Hergils (1999) reported that parents of children who were late identified (after age two) all wished

they were given the opportunity to participate in a newborn hearing screening program to prevent the grief and anxiety they experienced due to late identification.

An investigation by Stewart, Moretz, and Yang (2000) looked at the level of stress mothers' experienced following a positive screen outcome and found no difference between those mothers whose infants failed a screen and those whose infants had passed. Vohr (2001) found that by decreasing the false positive rate, and the interval of time between an inpatient screen and an outpatient screen, significantly reduced the mother's anxiety levels. The most recent study by Danhauer and Johnson (2006) had 36 parents responding to questionnaires about the hearing screening and referral process. The parents were generally positive and a failed screen did not have a negative impact on bonding with their baby. A recent survey project completed by Thomson and DesGeorges (2006) found that generally parents were satisfied with the services they received from screening through early intervention. Parents did comment they wish they had someone explain the screening results verbally so they better understood the recommendations for follow-up and this potentially would have decreased the process into diagnosis and ultimately intervention.

Despite efforts to build comprehensive EHDI systems that meet the needs of families there are remaining issues regarding follow-up from newborn hearing screening. This present research will be addressing factors that are correlated to infants who fail the newborn hearing screen in the Colorado Infant Hearing Program and who are late identified.

Newborn Hearing Screening Follow-up. One of the major concerns for EHDI programs is ensuring that infants who fail the screen receive timely and appropriate

follow-up. The benchmark for follow-up from newborn screening is diagnosis by 3 months of age. Downs and Sterritt (1967) had the foresight 40 years ago to suggest a data tracking system that utilized the PKU blood spot cards for infants who failed the screen. During the evolution of newborn hearing screening in the early 1990's there was more of a focus on the number of infants being screened rather than those that actually received follow-up. In 2003 CDC (Nemes, 2006) reported that only 55.2% of newborns who failed their hearing screen had documentation of an audiological evaluation. Mehl and Thomson (1998, 2002) analyzed the Colorado Infant Hearing Program that showed a decrease over a seven-year period (1992-1999) in the fail rate at hospital discharge and an increase in rescreen rate. Only 50% of infants who failed had documentation of either an outpatient rescreen at the hospital or evaluation by an audiologist. In 1999 the percentage of infants who failed initial screening and who received a follow-up screen increased to 70%. In a multisite investigation (Stewart, et al., 2000) the authors found that using AABR technology for screening reduced the refer rates and thus decreased the lost to follow-up rate. Colorado has developed a data tracking system linked to the electronic birth certificate that has increased the documented follow-up rate to 82%. In a recent analysis by Christensen,Thomson, and Letson (2007) 82% of infants, between 2002-2004, received a follow-up rescreen after a failed inpatient screen. This analysis also found one Denver hospital that has a high fail rate (9%) at hospital discharge coupled with a very high (98%) return rate due to their follow-up protocol of having infants return for the rescreen at the time of the first well baby visit. Interestingly the primary care physicians are located on the same floor as the outpatient audiology department where a screener is available during well baby

visits. Finitzo, Albright, and O'Neal (1998) report a 31.55% lost to follow-up in 1996, with a decrease to 20% in 1997. The authors attribute increase in follow-up to improvements in screening technology, providing education to physicians on the importance of follow-up, improving service coordination to families, and automating the data management system to track infants from screening into diagnosis.

Parkland Memorial Hospital in Dallas, Texas, with 17,000 births, had an initial 40-50% lost to follow-up rate (Shoup, Owen, Jackson, and Laptook, 2005). The hospital used AABR technology and adopted a protocol, which required infants to be rescreened with AABR by a technician. If the infant still failed then an audiologist performed a third screen prior to discharge and also performed the outpatient rescreens. This decreased the lost to follow-up rate to 10%. The authors concluded that this protocol significantly reduced the false positives and allowed greater resources for following those infants who failed at discharge.

As programs improve the false positive screens and subsequently improve the rescreen there are still concerns whether those infants who fail the rescreen obtain a diagnosis by three months of age. Mehl and Thomson (1998) reported that 75 of 94 (80%) infants had completed diagnosis and were enrolled into early intervention between 3-6 months of age. In a later study by Mehl and Thomson (2002) 148,240 infants were screened and 291 infants were identified with hearing loss. The median age of diagnosis was 2.1 months, with 92% of the infants diagnosed by 5 months of age. Dalzell, Orlando, MacDonald et al. (2000) report the median age of identification at 3 months of age for 85 infants identified with permanent hearing loss, out of 43,331 screened. Kennedy, McCann, et al. (2005) performed an 8 year follow-up study. They

found that children who were in the universal newborn hearing screening program were more likely to be referred to an audiologist by six months of age than those not in the UNHS cohort (74% vs. 34%). Uus and Bamford (2006) report out of 169,487 screens, 169 infants were identified with permanent bilateral moderate or greater hearing loss. The median age of identification for well baby vs. NICU infants was 10 weeks and 13 weeks of age, respectively.

In contrast, White (2003) surveyed the EHDI coordinators who estimated that only 56% of infants who failed a screen received a diagnostic evaluation by 3 months of age. The EHDI coordinators attributed this to the lack of pediatric audiologists. Only 57% of the states have written guidelines for pediatric assessments. EHDI coordinators also attributed poor follow-up to inadequate reimbursement for follow-up services, physician attitudes about the importance of follow-up, families not understanding the consequences of late identification, and the need for state integrated data management systems to track infants who fail the screen. Moeller, White and Shisler (2006) disseminated 12,211 surveys to primary care physicians in 21 states and 1 territory regarding their knowledge, practices, and attitudes about newborn hearing screening. They found that overall physicians were knowledgeable about newborn hearing screening and recognize the benefits of early identification and intervention. The researchers did find gaps in physicians' knowledge about what to do when an infant fails a screen or is diagnosed with permanent hearing loss. In the survey conducted by Thomson and DesGeorges (2006) several parents commented that their physician did not feel a newborn hearing rescreen was important. These issues along with the previous studies cited would also indicate that hospital screening programs

play a significant role in achieving low fail rates and a follow-up protocol, which ensures the families receive a follow-up rescreen. Follow-up from newborn screening and into diagnosis and early interventions are critical for the success of an EHDI program.

The Colorado Infant Hearing Program

In 1991, the Colorado Newborn Hearing Screening Project was founded as a collaborative effort between the Health Care Program for Children with Special Needs (HCP), the Colorado Responds to Children with Special Needs (birth defects registry) at the Colorado Department of Public Health, The Children's Hospital, and the University of Colorado Health Sciences Center (Thomson, 1997). The Colorado Project started with a plan to implement universal screening in 10 large birthing hospitals, expanding over the next 5 years to include all hospitals. Although the project did not promote either AABR or TEOAE technology, admittedly most of the audiologists involved in the Project felt more comfortable with the AABR due to the well-understood ABR technology and its validity of detecting hearing loss in infants. The initial results of the Rhode Island Hearing Assessment Program (RIHAP) using OAE's had a fail rate of 26.9% at hospital discharge (White, Vohr, Behrens, 1993). The low specificity with OAE vs. AABR also provided impetus to primarily use AABR in the Colorado pilot hospitals.

Colorado passed legislation in 1997 requiring all birthing hospitals to implement a newborn hearing-screening program. House Bill 97-1095 requires the Colorado Infant Hearing Advisory Committee to develop guidelines for reporting and

for assuring that identified children receive referral for appropriate follow-up. In 2005 the Colorado legislature passed an amendment to increase the mandated screening rate to 95% and maintain the advisory committee. Colorado has successfully reached the benchmark of screening 95% or greater for since 2002, due in part to the data management and tracking system.

There are many challenges in developing a comprehensive statewide Early Hearing Detection and Intervention (EHDI) program. Effective tracking of infants from screening through diagnosis and then to early intervention was and remains the most difficult task. In 1998 the Health Care Program for Children with Special Needs (HCP) developed a data management system that was populated by data from Colorado's electronic birth certificate (EBC) data. Fields were added to the Genesis™ EBC application that included specific ear results of pass or fail, and the reasons if there was not a screen completed (e.g. missed, transferred, deceased, parent refusal). Colorado was awarded a Center for Disease Control and Prevention (CDC) Early Hearing Detection and Intervention (EHDI) data integration cooperative agreement in 2000. This cooperative agreement allowed HCP to develop and implement a more comprehensive application to manage the EHDI follow-up program. This agreement has greatly improved the data integrity for the program. The EHDI data management program also has the capability to build capacity and to enhance the processes of reporting by other providers. The next step was to design, develop, and implement the NEST (Newborn Evaluation, Screening and Tracking), which is a centralized database and application. NEST integrates newborn hearing screening, Colorado Responds to Children with Special Needs (CRCSN, Colorado's birth defects surveillance registry),

and the newborn metabolic screening program (blood spot). This data integration allows HCP to integrate referral services and makes those referrals more efficient and timely. NEST has the capability to report individual identifiable data on screening results including child's date of birth, infant gender, maternal race, maternal ethnicity, and maternal education level, date of screen, and results of the screen or reason not screened. The NEST provides comprehensive data for surveillance of newborn screens, which allows the EHDI program to use a data driven approach for strategic planning. The data in the EHDI CHIRP can be analyzed to monitor hospital-screening activities, racial disparities in screening and follow-up, and clusters of hearing loss that may indicate genetic disorders.

In addition, HCP hired a full time EHDI Follow-up Coordinator. The Follow-up Coordinator has been instrumental in monitoring hospital and provider data that allows tracking and surveillance activities for newborn hearing. Every hospital has a designated EHDI Hospital Coordinator. Each month the EHDI Follow-up Coordinator disseminates a report to the hospitals with a list of infants born in their hospital that either failed the screen in one or both ears or were not screened. The hospital coordinator then updates the information on any new screens or rescreens. This data entry process is not automated.

Audiologists submit an Audiological Assessment report on every child from birth to seven years of age who has a confirmed hearing loss. These reports include demographic information, screening results and high risk factors. Audiologists also submit this report on infants who are referred to them from screening and subsequently pass an evaluation. These reports are submitted on paper and entered

manually into the data system. At 3 months after birth, if the EHDI CHIRP database indicates that a baby has failed the hospital screen and failed an outpatient screen but has not been seen by an audiologist, a report is generated and the local HCP Regional office contacts the family via letter or telephone call. At 3 months after birth, the EHDI Follow-up Coordinator sends a letter to all infants who failed the hospital screen in one or both ears, or were missed, or were home-birthed, and with no indication of subsequent follow-up, and encourages them to obtain a screen or rescreen. This notification also gives the family the opportunity to report results or gives the family information on how to obtain a screen. This process has increased the percentage of infants born at home who receive a hearing screen from 10% in 2003 to 30% in 2005. The data management system has been essential in providing the demographic information to increase the rescreen rate and home births screens.

Colorado has developed a system of referral from diagnosis to early intervention. When an audiologist identifies an infant with a hearing loss they notify the EHDI program with the Audiological Assessment report and refers the family to a local Colorado Hearing Resource (CO-Hear) Coordinator. Each CO-Hear Coordinator is an expert in deafness and holds a master's degree in speech pathology, audiology, or deaf education. They work collaboratively with Part C of the Individuals with Disabilities Education Act (IDEA) to assure that families receive unbiased information and referrals to resources on early intervention programs for their infant. The CO-Hear Coordinators input information directly into the EHDI CHIRP. This is currently being accomplished with virtual private network software CITRIX. The Follow-up Report form and the Intake form completed by the

audiologists and the CO-Hears provide individual data on the degree of hearing loss, type of hearing loss, age of amplification, type of amplification, high risk factors associated with hearing loss, name of medical home/primary care provider, age of enrollment into early intervention and types of services families are choosing. This information also serves as a safety net when there is not an Audiological Follow-up form. The Follow-up Coordinator contacts the audiologist to obtain their report. Data, however continue to either not be reported by these two groups or are delayed in reporting.

Implications for Research

The Colorado EHDI program has been in development and refinement for 15 years. The advantage of an active (data collected directly from the electronic birth certificate) and passive (data collected from providers) management system allows the opportunity to analyze factors that prevent an infant from receiving a newborn hearing screen by one month, diagnosis by three months and enrollment into early intervention by six months. In a study of the Colorado Infant Hearing Program, Christensen, Thomson, and Letson (2007) looked at which factors may be associated with receiving/not receiving the initial or outpatient follow-up screen. Variables in the database included maternal demographics and birth-related characteristics as well as hospital of birth. Demographic factors include mother's age at delivery, infant gender, marital status, mother's who smoke, maternal education, birth hospital, race/ethnicity, birth weight, and APGAR score at 5 minutes. Descriptive, bivariate and logistic regression analyses were performed using SAS statistical software version 9.1. Variables were selected for the logistic regression model if Pearson correlation

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coefficients with the outcome variable reached statistical significance of <.05.

Multicolinearity diagnostics were performed and results showed all variables shared

small correlations below Pearson's r < .33. Missing values on some demographic

characteristics reduced the population totals about 2% for the statistical analysis

procedures. For example, infants who had high risk factors of low birth weight (less

than 2500 grams) and APGAR scores of less than 7 at 5 minutes were most likely not

to receive the initial screen. The average follow-up screening rate from 2002-2004

across 57 hospitals was 82%. Some hospitals have follow-up rates above 95%, and

other hospitals have follow-up rates around 60%. Findings showed that hospital

screening rates were influenced by maternal education, and that Latina mothers were

much more likely than non-Latina mothers to report low education levels. The

variables (e.g. gender, mother's age, race/ethnicity) in this research did not yield other

potential hospital factors (e.g. what is the hospital follow-up protocols, who provides

the outpatient screen, is there a charge for the screen?) that could explain the

differences in the follow-up rate after screening or the delay in obtaining a

confirmatory diagnosis by three months of age.

Purpose for Current Research

These current research hypotheses will investigate further the factors

associated with not receiving a follow-up screen and failure to achieve diagnosis by

three months of age. The first hypothesis will determine if the hospital protocol for the

outpatient rescreen yields a higher return rate. In other words, do hospitals that have a

follow-up protocol for failed screens, which require the family to return to the hospital

nursery (vs. an outpatient audiology facility or private audiologist), have a higher

return rate for follow-up. As noted in the literature review above hospitals play an important role in the refer rates and the outpatient rescreen rates. If the null hypothesis is that the hospital follow-up protocol does not impact the return rate for follow-up, then the Colorado Infant Hearing Program can begin to identify what other factors explain why a hospital has a higher return rate. Models of best practices can then be developed and their use encouraged throughout the statewide screening program.

The second hypothesis will look at why infants who fail their newborn hearing screen are not identified by the three-month benchmark. Are infants who have comorbidities less likely to receive their diagnostic evaluations by three months of age? Are there factors such as race/ethnicity, mother's age, and mother's education that influences the follow-up into diagnosis? As identified in the literature review other factors such as physician referral, parents not understanding the urgency for follow-up, and costs may be associated with delayed identification.

This research will also enhance the role of public health in evaluation to identify how EHDI programs can ensure a comprehensive system that will identify hearing loss in infants by three months of age to allow enrollment into early intervention by six months of age to achieve the outcome of normal speech and language.

CHAPTER 3

Methods and Analysis

Introduction

The Colorado Infant Hearing Program has improved its follow-up rates from

screening significantly from 76% in 2001 to 83% in 2005. Important improvements

were made to the Colorado system that improved the follow-through rates. These

improvements included: 1) the development of the data management system that

tracks individual infants from birth through the screening and rescreening processes,

2) better reporting from diagnostic facilities, 3) the ability of the CO-Hear

Coordinators to directly access of the data management system for documenting

intervention programming. In 2005 there were 69,474 births and 67,446 (97%) were

screened. Of those infants there were 3,154 (4.6%) who failed the screen and there

was documentation that 2,615 (82.9%) received an outpatient rescreen. Reducing the

failure to follow-through rate requires a further in-depth analysis of other potential

causes. This proposal will discuss the methods used to analyze variables that are

associated with two critical questions: 1) factors associated with higher outpatient

rescreen rates following a failed screen at hospital discharge and, 2) factors associated

with failed screens that are identified with permanent hearing loss by 3 months of age

versus later.

Question 1

What factors are associated with higher rescreen rates? The hypothesis for this

question is that hospitals that have a follow-up protocol for a failed screen, which

requires the family to return to the hospital nursery (vs. an outpatient audiology facility or private audiologist), have a higher return rate for follow-up of 83% or greater.

Subjects

In 2005 there were 56 birthing hospitals ranging from 9 to 4,954 births. The data analyzed for this hypothesis will be birthing hospital outpatient rescreen rates during January 1, 2005 through December 31, 2005. There were 69,479 live births and 68,450 were born in birthing hospitals. The remaining 1,029 infants were born at home, in route to the hospital, non-birthing hospitals, or Colorado residents born out-of-state. Only birthing hospitals will be included in this analysis.

The Colorado Infant Hearing Program for 2005 data documented that 97% (n=67,446) of infants were screened. Fifty-three of the 56 birthing hospitals achieved a screening rate of 95% or greater meeting the JCIH recommendations and Colorado Guidelines. The statewide total fail/refer rate at hospital discharge was 4.6% (n=3,154). The individual hospital fail rates varied from .5% to 18%. The percent of those infants who failed the initial screen and returned for follow-up was 83%. The individual hospital return for follow-up rates varied from 100% to 48%.

Procedure

Demographic data for Colorado's newborn hearing screening program are populated by the state's electronic birth certificate (EBC). Hospital birth clerks enter the final hearing screen results prior to hospital discharge in a file that is downloaded to Vital Records at the Colorado Department of Public Health and Environment (CDPHE). Designated Hospital Coordinators receive a Monthly Report from the

Colorado Infant Hearing Follow-up Coordinator. This report lists all the names of infants who were missed, were screened after the EBC was downloaded, or failed the screen in one or both ears. The Hospital Coordinator completes any updated screening results on the Monthly Report Form and submits this back to the Follow-up Coordinator, within the following month. The Follow-up Coordinator inputs any new screening results into the Infant Hearing Database (EHDI CHIRP).

Infants who were missed at the birth hospital and those receiving follow-up failed screens receive hearing screenings on an outpatient basis. The Hospital Coordinators and audiologists submit outpatient-screening results to the Colorado Infant Hearing Program via Monthly Report forms, Audiology Follow-up forms, or directly to the Follow-up Coordinator by phone or email.

Data will be analyzed for the birth cohort in 2005 to identify factors that may be associated with receiving/not receiving the outpatient rescreen. Variables in the database obtained from the EBC include maternal demographics and birth-related characteristics as well as hospital of birth. The Infant Hearing database collects the screening results on individual infants, and the results on infants who obtained follow-up screening.

Hospitals that have families return for follow-up to the same birthing unit or facility do have the advantage of familiarity. In addition there may be factors between hospitals such as making the appointment before discharge or not charging for the rescreen. If families have to return to a different facility there may be additional charges, lack of transportation, and issues with medical referral. Hospital surveys were obtained in 2005 from 45 hospitals. The remaining hospitals will be surveyed via

phone to collect the remaining data. In addition a more specific question will be asked

to ascertain whether the rescreen is performed at the birthing hospital, in the nursery,

or at a different location such as the audiology department affiliated with the hospital.

Data Collection.

There are three sources that will be used for data collection:

1. Birth Certificate Data: Maternal factors and demographic information will be

    obtained from the birth certificate data on those infants who did not receive the

    follow-up screen. Demographic factors include mother's age at delivery, infant

    gender, maternal education, race/ethnicity, birth weight, and Apgar score at 5

    minutes. Coding for these variables is in Table 1.

Table 1. Coding for EBC demographic data.

Mother's age at birth	Race/ Ethnicity	Mothers Education	Gender	Birth weight	Apgar@5	Rescreen
0 = 11-18 yrs	0=Hispanic	0=1-12	0 = girl	0 = <1500gms	0 = 1-6	0 = no
1 = 19-25 yrs	1=Non-Hispanic	1=13+	1 = boy	1 = >1500 to <2500	1 = 7-10	1 = yes
2 = 25+				2 = > 2500 gms		

2. Infant Hearing Database: Hospital birthing populations, refer rates, and rescreen

    rates will be analyzed. Hospitals will be coded into groups based on their number

    of birth cohorts, refer rates and rescreen rates.Coding for these variables is in

    Table 2.

Table 2. Hospital variables obtained from the Colorado Infant Hearing database

Hospital Births	Refer rates	Rescreen rates
0 = 1-100 (n=11)	0 = 0 – 2.0% (n=9)	0 = 90-100% (n=23)
1 = 101-500 (n = 11)	1 = 2.1 – 4.0% (n=16)	1 = 89-80% (n=14)
2 = 501-1000 (n = 10)	2 = 4.1 – 10.0% (n=20)	3 = 79-70% (n=6)
3 = 1001- 2000 (n = 10)	3 = 10.1 + (n=10)	4 = 69% or less (12)
4 = 2001 – 3000 (n = 8) 5 = 3001 + (n = 5)		

3. Hospital variables obtained by survey data: The following characteristics will be

    analyzed to determine if there is a significant ($p =< .05$) correlation to high follow-

    up rescreen rates (Table 3):

Table 3. Characteristics of hospital programs for analysis

1. What is the highest level of care is offered in your hospital?
   - Level I – well baby
   - Level II – Neonatal Intensive Care Unit (NICU)
   - Level III

2. Is an audiologist involved with your hospitals screening program?
   - Yes
   - No

 3. Level of audiology involvement will be ascertained from the question "Is an audiologist involved with your hospital's newborn hearing screening program?" If hospitals respond yes then the level of involvement will be analyzed by the following parameters. Hospitals could check all that applied.
   - Screens a significant percentage of the babies prior to discharge
   - Supervises day to day operation of the program
   - Consults as needed
   - Manages patient information and data for tracking and follow-up
   - Does significant percentage of outpatient hearing screening
   - Does diagnostic evaluations for infants referred from the screening program

4. Who provides the screening? In a typical week, who performs the newborn hearing screenings? Please indicate the percentage of screenings completed by each of the following groups in a typical week, so that the total percent for question 5 equals 100%.
   - Nurses
   - Medical Assistants/Technicians
   - Volunteers
   - Audiologists
   - Contract with Pediatrix, Inc

5. Type of Screening equipment used:
   - OAE only
   - AABR only
   - OAE and AABR

6. Does your hospital provide the outpatient rescreen?
- Yes, the rescreen is performed at the birthing hospital, in the nursery.
- Yes, the rescreen is performed at the birthing hospital in the audiology department.
- Yes, the rescreen is performed through the audiology department located on a different campus.
- No, the rescreen is performed outside the hospital system.

7. For infants that do not pass the initial hearing screen, does your program set up an appointment for a follow-up rescreen prior to discharge?
- Yes, prior to discharge
- No, after discharge
- Parents' make the appointment

8. Is there a charge assessed for outpatient rescreening?
- Yes
- No

Coding for the above variables are in Tables 4, 5 and 6.

Data Analysis.

Using SAS 9.1 software, there are three types of analysis that will be performed with the outcome (dependent) variable of hospital rescreen rates. A linear regression will be used on rescreen rates from 100% (highest) to 52% (lowest). A logistic regression model will separate those who screen above and below 83%. A generalized logistic model will allow for a multiple group analysis as suggested in Table 3 for separating the hospitals into 4 groups based on rescreen rates. This will be a descriptive analysis with a p-value of $<.05$ for each independent variable to be used in the final multiple regression models.

Table 4. Coding for level of nursery, audiologist affiliated, level of audiology involvement.

Level	Audiologist?	Level of Involvement
0 = well baby	0 = no	0 = Screens a significant percentage of the babies prior to discharge
1 = NICU 2 = Level 2 NICU	1 = yes	1 = Supervises 2 = Consults as needed 3 = Manages data 4 = Performs significant % outpatient screen 5 = Does diagnostic evaluations for infants referred from screen 6 = Other

Table 5. Coding for who provides the screen, type of equipment used, determination of location of outpatient rescreen.

Who Screens?	Type of equipment?	Hospital Outpatient Rescreen
0 = Nurses	0 = OAE only	0 = yes at birth hospital
1 = MA/Technicians	1 = AABR only	1 = yes at birth hospital/audiology dept.
2 = Volunteers	2 = AABR and OAE	2 = yes at audiology dept different campus
3 = Audiologists		3 = no
4 = Contract employees		

Table 6. Coding for setting up the appt for the rescreen and the charge for the rescreen.

Does the hospital set up the resceen appt.?	Is there a charge for the rescreen?
0 = yes, prior to discharge	0 = no
1 = no, after discharge	1 = yes
2 = Parents make the appt.	

These analyses will determine what factors affect the return rate from newborn hearing screening and potential programmatic changes that could improve the follow-up system from 83% closer to 100%. The next analysis is critical for ensuring that infants who fail the screen receive timely and appropriate follow-up to meet the benchmark of identification by 3 months of age.

Question 2

What factors are associated with an infant who fails newborn hearing screening not confirmed with hearing loss by three months of age? The hypothesis for this question is infants who fail their newborn hearing screening and were not identified by three months of age have comorbidities or other conditions that impacted their ability to complete the diagnostic process by three months of age. Further investigation would identify if this population has other factors such as infant gender, race/ethnicity, mother's age at birth, marital status, and mother's education. The null hypothesis

would be there is no difference between this cohort of infants and those who were identified by three months of age.

Subjects

There are 386 infants who have a confirmed permanent hearing loss between 2002 and 2005. The degrees of hearing losses range from mild to profound.

Procedure

Variables in the database obtained from the EBC include maternal demographics and birth-related characteristics as well as hospital of birth. The Infant Hearing database collects the number of births, the individual infants screened, infants who failed the screen, and the infants who obtained follow-up screening. The Colorado Responds to Children with Special Needs (CRCSN), Colorado's birth defects registry contains reportable hospital discharge data. Hospitals use the International Classification for Diseases, 9th Version (ICD-9) codes to report conditions that are associated with hearing loss such as stigmata and other findings associated with a syndrome known to include sensorineural hearing loss, craniofacial anomalies, in utero infection such as cytomegalovirus, herpes, toxoplasmosis, or rubella. In addition the length of hospital stay is included. Individual case records for the Infant Hearing database will be compared to the CRCSN database for ICD 9 codes. Audiologists report additional risk factors that are not included in the ICD 9 codes such as family history and progression from unilateral to bilateral. This information is obtained from the Audiological Follow-up Form and entered into the Infant Hearing database. These to categories (ICD 9 Codes and Risk Factors) will be combined for independent variable of "comorbidity."

Data Analysis

Using SAS 9.1 software, there are three types of analysis that will be performed with the outcome (dependent) variable of high risk factors (ICD 9 Codes and risks reported on Audiological Follow-up Form). A linear regression will be used on the outcome variable month of identification from 1 month (lowest) to 50 (highest) months of age. A logistic regression model will allow for a multiple group analysis as suggested in Table 7 for separating age of identification into smaller groups.

A descriptive analysis of ICD 9 codes associated with hearing loss and demographic data will be conducted to determine if there is an association between these variables and late identification for a failed screen. This analysis may also predict if specific factors are correlated to a later identification date. For example does hospital length of stay significantly correlate to a later identification date as compared to craniofacial anomalies? Coding for the variable 'hospital length of stay' will be determined after the data is collected from CRCSN. Coding for the hospital rescreen rates will be determined after the analysis is complete for the first hypothesis. All data analyses will be performed using SAS 9.1 to identify strong/significant correlations, associations and confounding variables using a logistic regression model. This will be a descriptive analysis with a p-value of $<.05$ for each variable in the final multiple regression model.

Table 7. Coding for the analysis of age of ID, presence of a high risk factor, mother's age, mother's education and level of hospital care.

Age of ID	Race /Ethnicity	Mother's age at birth	Mothers Education	Birth Hospital
0=0-3 mths	0=non latino	0 = 11-18 yrs	0=1-12	1=Level I
1=4-6 mths	1=latino	1 = 19-25 yrs	1=13+	2=Level II
2=7-9 mths		2 = 25+		3=Level III
3=10-12 mths				
4=13-24 mths				
5=25-50 mths				

Gender	Apgar Score at 5 mins	Comorbidity		
0= Boy	0=1-6	0=no		
1 = Girl	1=7-10	1=yes		

Table 8. Coding for ICD 9 Codes

Description	ICD 9 code
Early congenital syphilis	0900=1
Other congenital infections	7712=2
Chondrodystropy	7564=3
Mucopolysaccharidosis	277.5=4
Bacterial meningitis	320=5
Congenital hydrocephalus	742.3=6
Congenital anomalies of ear, face, and neck	744=7
Anomalies of inner ear	744.05=8
Absence of auditory canal, atresia	744.01=9
Absence of ear lobe	744.21=10
Branchial cleft cyst	744.42=11
Cleft lip	749.1=12
Cleft palate with cleft lip	749.2=13
Renal agenesis	753.0=14
Other deformities	754.89=15
Aperts syndrome	755.55=16
Anomalies of skull and face	756.0=17
Klippel-Feil syndrome	756.16=18
Down's syndrome	758.0=19
Cri-du-chat syndrome	758.31=20
Velo-cardio-facial syndrome	758.32=21
Turner's syndrome	758.32=22
Klinefelter's syndrome	758.7=23
Prader-Willi syndrome	759.81=24
Fragile X syndrome	759.83=25
Other syndromes	759.89=26
Fetal alcohol syndrome	760.71=27
Low birth weight ≤1500	765.1=28
Congenital rubella	771.0=29
Congenital CMV	771.1=30
Other congenital infections	771.2=31
Child abuse	955.5=32

These analyses will determine if late confirmation of hearing loss is associated with comorbidities or other factors. These analyses will provide guidance to the Colorado Infant Hearing Program to plan and implement new protocols at the state and local levels to ensure that infants receive timely diagnostic confirmation of hearing loss.

CHAPTER 4

Results

Question Number 1

Demographic Variables

In 2005 Colorado had 69,533 births and 68,478 of those births occurred in 56

birthing hospitals. Resident births that occurred at home, out of state, in transit, and

in unknown facilities were excluded from the analysis for the first hypothesis. There

were 67,261 (98.22%) infants who were screened and 1,217(1.78%) who did not

receive a screen. Additionally, 3,144 (4.7%) infants failed the initial inpatient screen

and 622 (20%) of those infants did not receive a follow-up outpatient screen. Of the

2,531 infants who did receive the outpatient follow-up screen there were 143 infants

who failed the outpatient follow-up screen and should have been referred to a

pediatric audiologist. Fifty-one infants (35.7%) were confirmed with a permanent

hearing loss, 10 infants (7%) passed an audiologic evaluation, and 82 (57%) did not

have any documentation of follow-up. There were 115 infants identified with

permanent hearing loss from this birth cohort and 59 (52.7%) of the infants who

'missed' the follow-up rescreen were confirmed with a hearing loss.

Table 9 displays federal ethnicity and race. Figure 1 shows the

variability between the Hispanic and Non-Hispanic populations for births, screened,

failed, and did/did not receive a follow-up screen. The Hispanic population accounts

for 32.3% screened, 41.4% who failed the initial screen, and 45.8% who did not

receive the follow-up screen.

Table 9: Ethnicity and race by cohort by percent and N.

Variable	Births N=68478	Screened N=67261	Failed Screens N=3144	F/U Result Yes N=2531	F/U result No N=622	CHL N=115
Race						
Afro-American	4.4 (3019)	4.4 (2944)	5.2 (165)	5.3 (134)	5.0 (31)	6.3 (8)
Am. Indian	0.8 (546)	0.8 (435)	1.0 (30)	1.0 (24)	1.0 (6)	1.0 (2)
Asian	2.1 (1433)	2.1 (1414)	2.2 (68)	2.5 (62)	1.0 (6)	1.8 (2)
Caucasian	85.8 (58771)	85.6 (57746)	84.0 (2647)	84.0 (2126)	83.8 (521)	83.0 (94)
Other	6.5 (4457)	6.5 (4372)	7.4 (233)	7.0 (9176)	9.2 (57)	8.0 (9)
Pacific Islander	0.4 (252)	0.4 (250)	0.3 (10)	0.4 (9)	0.2 (1)	0.0
Ethnicity						
Hispanic	32.3 (22112)	32.3 (21515)	41.4 (1304)	40.3 (1019)	45.8 (285)	37.5 (44)
Non Hispanic	67.7 (46366)	67.7 (45546)	58.6 (1839)	59.7 (1512)	55.2 (337)	62.5 (71)

Fig.1 Ethnicity by Cohort
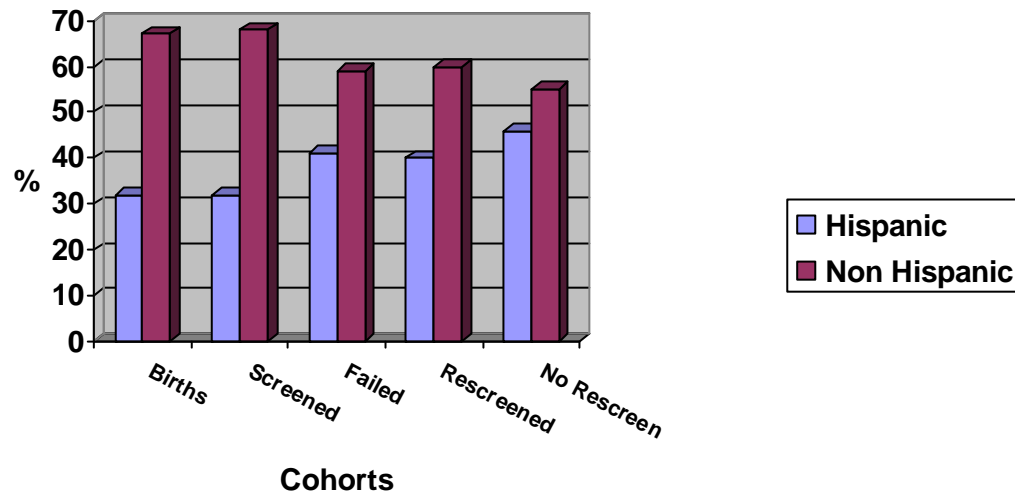
Table 10 displays infant gender, gestational age, birth weight, and Apgar score at 5 minutes. Males account for 51.4% of the population and 60.6% of those who do not receive a follow-up screen. Thirty-nine infants (1.2%) with low Apgar scores failed the initial screen and 14 infants (2.3%) did not receive a follow-up rescreen. Infants with lower birth weight, gestational age, and low Apgar scores have higher percentages in the confirmed hearing loss category. These are high risk factors for hearing loss and this outcome is therefore not surprising.

Table 10. Infant variables by cohort by percentage and N.

Variable	Births N=68,478	Screened N=67261	Failed Screens N=3144	F/U Result Yes N=2531	F/U result No N=622	CHL N=115
Gender						
Female	48.5 (3322)	48.6 (32690)	43.9 (1385)	45.0 (1140)	39.4 (245)	39.3 (46)
Male	51.5 (3525)	51.4 (34571)	56.1 (1768)	55.0 (1391)	60.6 (377)	61.7 (69)
Gest. Age						
<30 weeks	0.8 (576)	0.7 (460)	1.7 (52)	1.7 (43)	1.5 (9)	5.5 (7)
>30 <36	9.2 (6303)	9.0 (6103)	9.0 (287)	8.6 (217)	11.3 (70)	16.5 (19)
36+	89.0 (6259)	90.2 (60698)	89.3 (2814)	89.7 (2271)	87.3 (583)	78.0 (89)
Birth wgt						
<1500 gms	1.4 (953)	1.0 (638)	1.9 (61)	1.8 (45)	2.6 (16)	8.0 (10)
>1500gms-<2500gms	8.0 (5511)	7.9 (5325)	8.3 (261)	8.1 (205)	9.0 (56)	15.2 (18)
>2500gms	90.0 (6201)	91.1 (61298)	89.9 (2831)	90.1 (2281)	88.4 (550)	76.8 (87)
Apgar 5						
1-5	1.2 (820)	0.8 (526)	1.2 (39)	1.0 (25)	2.3 (14)	4.0 (5)
6-10	98.8 (6765)	99.2 (66735)	98.8 (3111)	99.0 (2504)	97.8 (607)	96.0 (110)

Table 11 describes the mother's age, marital status, and education at birth. Infants born to teenage mothers (11-19 years) are 8.3% of the entire cohort, 11.6% of their babies failed the screen, and 14% of their infants did not receive a follow-up rescreen. Twenty-seven percent of the infants of the entire cohort are born to mothers who are not married and 30.9(??is that right)% of infants born to single mothers did not receive the follow-up screen. Mothers who have less than 12 years of education (48.9%) are at higher risk for not receiving the follow-up outpatient screen (64.3%).

Table 11. Mother variables by cohort in percentages and N.

Variable	Births N=68,478	Screened N=67261	Failed Screens N=3144	F/U Result Yes N=2531	F/U result No N=622	CHL N=115
Age						
11-19 yrs	8.3 (5647)	8.2 (5509)	11.6 (366)	11.0 (279)	14.0 (87)	12.5 (15)
20-25 yrs	23.1 (15842)	23.1 (15542)	28.4 (894)	27.7 (702)	30.9 (192)	19.6 (23)
25+	68.6 (46987)	67.5 (46208)	60.0 (1893)	61.2 (1550)	55.1 (353)	67.9 (77)
Marital Status						
No	27.1 (18582)	27.0 (18582)	31.1 (980)	29.2 (739)	39.2 (231)	28.6 (35)
Yes	72.9 (49896)	73.0 (49896)	68.3 (2153)	70.1 (1775)	60.8 (378)	72.4 (80)
Educ						
1-12 yrs	48.9 (33494)	48.8 (32792)	57.7 (1819)	56.1 (141)	64.3 (400)	47.3 (54)
13+ yrs	48.9 (33511)	49.2 (33058)	40.3 (1269)	42.0 (1062)	33.3 (207)	47.3 (54)
Unknown	2.2 (1473)	2.1 (1411)	2.1 (65)	2.0 (50)	2.4 (15)	5.4 (7)

Hospital Variables

Table 12 shows the data by number of annual hospital births (categorized into 6 groups) and nursery level. Hospitals that have lower birth rates (between 100-1000) have a higher percentage of infants who do not receive the follow-up screen in comparison to their birth cohort This is noted with caution, as small birthing hospitals may appear to have a higher percentage of loss to follow-up due to their small numbers. Hospitals with more than 3000 births deliver 42% of the infants confirmed with hearing loss. These 6 hospitals account for 33.5% of the entire birth cohort and have either a Level II or Level III neonatal intensive care unit (NICU).

Table 12. Hospital by births and nursery level.

Variables	Hospital N=56	Births N=68479	Screened N=67246	Failed N=3144	Yes Rescreen N=2534	No Rescreen N=622	CHL N=115
N Births							
0-100	17.8 (10)	0.6 (433)	0.6 (420)	0.9 (27)	0.8 (5)	0.9 (22)	3.0 (5)
1001-500	23.2 (13)	5.4 (3658)	5.3 (3557)	8.3 (260)	8.2 (206)	8.7 (54)	1.8 (2)
501-1000	16.1 (9)	9.7 (6633)	9.7 (6490)	10.3 (325)	9.4 (238)	14.1 (87)	9.1 (10)
1001-2000	17.9 (10)	22.0 (15044)	22.0 (14796)	27.9 (878)	29.2 (738)	22.6 (140)	25.5 (28)
2001-3000	14.3 (8)	28.8 (19694)	29.0 (19505)	17.2 (542)	16.6 (420)	19.7 (122)	20.9 (23)
3001+	10.7 (6)	33.5 (22908)	33.4 (22478)	35.1 (1112)	35.7 (901)	34.1 (211)	42.7 (47)
Nursery							
Level 1	50.0 (28)	14.6 (9984)	14.4 (9707)	24.0 (755)	24.2 (612)	23.1(143)	14.5 (20)
Level 2	32.1 (18)	51.6 (35285)	52.0 (34959)	47.2 (1483)	48.0 (1213)	43.6(270)	51.0 (58)
Level 3	17.9 (10)	33.7 (23045)	33.6 (22580)	28.8 (906)	27.7 (700)	33.2(206)	34.5 (37)

Table 13 displays information regarding the extent of hospital audiologist involvement. Level of involvement was dichotomized into the 2 categories of supervision or consultation only. Fifty-seven percent of the hospital coordinators surveyed indicated that they did not have an audiologist involved with their program. Twenty percent (N=12) of hospitals have audiologists who supervise the screening program, which accounts for 36.9% of the births and 46.6% of infants who failed the screen. These 12 hospitals have audiologists on staff and audiology diagnostic programs on site.

Table 13. Cohort by audiologist and level of audiology involvement

Variables	Hospital N=56	Births N=68479	Screened N=67246	Failed N=3144	Yes Rescreen N=2534	No Rescreen N=622	CHL N=115
Audiologist							
yes	42.9 (24)	56.5 (38636)	56.5 (37977)	71.2 (2237)	73.2 (1855)	62.8 (389)	61.8 (71)
no	57.1 (32)	43.5 (29747)	43.5 (29269)	28.9 (907)	26.8 (679)	37.2 (230)	38.2 (44)
Audio Involve							
Consult	23 (13)	13.5 (9231)	13.8 (9294)	19.0 (601)	19.1 (484)	18.7 (116)	6.3 (8)
Supervise	20 (12)	36.9 (25301)	36.4 (24495)	46.6 (1469)	48.6 (1229)	38.6 (240)	43.8 (50)
None	57 (32)	51.6 (35285)	49.8 (33531)	34.4 (1086)	32.3 (818)	42.8 (266)	50.0 (57)

Table 14 describes the technology used for screening, the refer rates, and
information on who screens the infants. The hospital coordinator survey did not
differentiate between the technology used and who provided the inpatient or
outpatient screen. Automated auditory brainstem response (AABR) alone is used in
the majority of the birthing hospitals (60.7%). The statewide refer rate was 4.68% at
hospital discharge, and 1% after outpatient rescreen. Nineteen of the hospitals had
refer rates between 4.1 and 10% that accounted for 49.7% of the births and 64% of
the births who did not receive a follow-up screen.

Hospital coordinators designated a percentage of who provided the screen.
The highest percentage given on the survey was used to determine into which
category (nurses, technicians, volunteers, audiologists, and contract) hospitals were
grouped. Fifty-nine percent of the hospitals use nurses for screening. The percentage
of births screened by nurses, medical assistants/technicians, and volunteers is 25.9%,
25.2%, and 31.2%, respectively. The highest percent (38.6) of infants who do not
receive a follow-up rescreen are born in hospitals that use volunteers for screening
and 41.8% of infants who are confirmed with a hearing loss are born in these same
hospitals. Eighty-three percent of the infants born in hospitals that use volunteers

have an audiologist involved in the program. One rural hospital has an audiologist who performs all the screens. Five hospitals contract out for the screening service.

Table 14. Technology, refer rates, and who performed the screens by cohort.

Variables	Hospital N=56	Births N=68479	Screened N=67246	Failed N=3144	Yes Rescreen N=2534	No Rescreen N=622	CHL N=115
Technology							
OAE only	25.0 (14)	6.4 (4377)	6.9 (4232)	12.4 (391)	12.8 (315))	12.3 (76)	8.2 (9)
AABR only	60.7 (34)	73.5 (50603)	81.0 (49401)	60.0 (1887)	58.6 (1479)	65.9 (408)	69.1(79)
AABR/OAE	14.3 (8)	20.1 (13403)	20.2 (13613)	28.0 (866)	29.0 (731)	21.8 (135)	22.7 (27)
Refer Rates							
0-2.0%	17.0 (9)	18.5 (12992)	18.6 (12523)	3.5 (110)	2.9 (74)	5.8 (36)	16.4 (18)
2.1-4.0%	28.3 (15)	24.0 (16412)	24.1 (16227)	13.3 (418)	12.7 (319)	16.0 (99)	21.8 (25)
4.1-10%	35.9 (19)	49.7 (33507)	49.6 (33347)	62.2 (1952)	61.7 (1555)	64.1 (397)	56.4 (64)
10% >	18.9 (10)	7.7 (5472)	7.7 (5149)	21.0 (661)	22.8 (574)	14.1 (87)	5.5 (8)
Screening Personnel							
Nurses	58.9 (33)	25.9 (17759)	26.0 (17472)	30.4 (956)	30.2 (762)	31.3 (194)	19.1 (22)
MA, Techs	14.3 (8)	25.2 (17085)	25.2 (16939)	33.3 (1047)	35.1 (885)	26.2 (162)	27.3 (32)
Volunteers	16.1 (9)	31.2 (21191)	31.1 (20895)	31.3 (984)	29.5 (745)	38.6 (239)	41.8 (48)
Audiologists	1.8 (1)	0.1 (65)	0.1 (65)	0.4 (12)	0.4 (11)	0.2 (1)	0.0
Contract	8.9 (5)	17.6 (12308)	17.7 (11875)	4.6 (145)	4.8 (122)	3.7 (23)	11.8 (13)

Table 15 shows how the follow-up appointment is scheduled, if there is a charge for the follow-up appointment, and where the follow-up appointment occurs. Hospitals that schedule the follow-up rescreen appointment before discharge have a higher follow-up rate (45.7%) than those that rely on the parents to call for an appointment after discharge (41.3%). Fifty five percent of infants who do not receive a follow-up rescreen were born in hospitals that charge for the outpatient rescreen. Forty-one hospitals (78.6%) bring the infants back to the nursery for the follow-up appointment and 10 hospitals (17.9%) have the families return to the audiology department on the same campus as the nursery. These two protocols account for 94.5% of the births. Interestingly, the protocol for returning to the audiology department accounts for 34.8% of the birth cohort and 44.1% of the infants who failed the screen. Further investigation reveals that six out of the nine hospitals that use volunteers have audiologists on staff.

Table 15. Follow-up appointment by cohort.

Variables	Hospital N=56	Births N=68479	Screened N=67246	Failed N=3144	Yes Rescreen N=2534	No Rescreen N=622	CHL N=115
F/U Appt							
At discharge	46.4 (26)	38.1 (25985)	38.2 (25655)	42.9 (1348)	45.7 (1155)	31.1 (193)	40.0 (46)
After discharge	16.1 (9)	16.8 (11625)	16.7 (11238)	13.8 (434)	12.9 (325)	17.6 (109)	20.9(24)
Parent Responsible	37.5 (21)	45.1 (26773)	45.1 (30353)	43.3 (1362)	41.3 (1045)	51.2 (317)	39.1(45)
Charge							
Yes	33.9 (19)	46.2 (31456)	46.1 (30975)	52.5 (1652)	51.9 (1310)	55.3 (342)	56.4 (64)
No	66.1 (36)	53.8 (36927)	53.9 (36271)	47.4 (1491)	48.1 (1214)	44.6 (277)	43.6 (51)
Outpt. Screen							
Nursery	78.6 (41)	59.7 (41029)	59.9 (40282)	52.8 (1659)	53.0 (1339)	51.7 (320)	48.2 (55)
Audiology Dept.	17.9 (10)	34.8 (23797)	34.5 (23201)	44.1 (1386)	44.2 (1116)	43.6 (270)	44.6 (52)
Audiology Off Campus	1.8 (1)	2.2 (1368)	2.2 (1493)	1.2 (39)	1.3 (6)	1.0 (6)	6.4 (7)
Referred to local audio.	1.8 (1)	3.4 (2325)	3.4 (2270)	1.9 (60)	1.5 (37)	3.7(23)	0.9 (1)
Rescreen Rates							
0-70%	23.1 (12)	14.9 (10257)	14.8 (9915)	9.1 (286)	6.2 (155)	21.3 (131)	11.8 (16)
71-80%	9.6 (5)	16.8 (11625)	16.6 (11161)	20.1 (655)	18.6 (469)	30.2 (186)	15.5 (17)
81-90%	26.9 (14)	35.4 (23934)	35.5 (23849)	38.4 (1204)	39.5 (995)	33.9 (209)	32.7 (36)
91% >	40.4 (21)	32.9 (22566)	33.2 (22280)	31.6 (993)	35.8 (903)	14.6 (90)	40.0 (46)

Table16 displays the Analysis of Variance (ANOVA) showing the degrees of freedom, the F value, and the P value for the entire and failed screened cohorts. Race and birth weight variable are not significant for both cohorts. The race variable is coded into 7 categories and may preclude a particular race from being significant. Birth weight and gestational age may not be as good of a predictor of the infants health as Apgar scores. The charge variable is not significant for the failed screened cohort indicating that a charging for the outpatient rescreen is not a deterrent from obtaining the rescreen.

Table 16. Analysis of Variance for Entire Birth Cohort and Failed Screen Cohort by Demographic Variable.

	Births N=68490			Failed Screens		
	F	Df	P	F	Df	P
Ethnicity	76.15	1,68488	<.0001	6.37	1,3151	<.011
Race	4.27	6,6848	<.0987	1.82	6,3147	<.106
Gender	20.22	1,68488	<.0001	6.49	1,3151	<.0109
Gest. Age	13.94	2,68487	<.0001	2.23	2,3150	<.107
Birthweight	1.97	2,68487	<.1396	1.14	2,3150	<.318
Apgar 5	1.05	1,68488	<.3058	6.54	1,3148	<.010
Mother age	14.14	2,68473	<.0001	4.31	2,3150	<.0136
Marital status	7.14	1,68476	<.0075	10.73	2,3150	<.0001
Mother educ.	26.04	2,68487	<.0001	7.88	2,3150	<.0004
Audiologist	571.08	1,68411	<.0001	26.37	1,3139	<.0001
Audio. Involve	312.65	2,68487	<.0001	13.38	2,3150	<.0001
Technology	319.95	2,68410	<.0001	6.88	2,3138	<.0010
Refer Rates	11.56	3,3137	<.0001	11.56	3,3137	<.0001
Screening Personnel	187.61	4,68408	<.0001	6.94	4,3136	<.0001
Charge	74.17	1,68411	<.0001	2.23	1,3139	<.1352
F/U appt.	58.37	1,68411	<.0001	22.08	2,3138	<.0001
Outpt. Screen	90.81	3,68409	<.0001	4.62	3,3137	<.0031
Rescreen	82.75	3,3134	<.0001	82.75	3,3134	<.0001

Analysis

Logistic Regression Model

A logistic regression analysis was performed to determine which variables are important for obtaining the follow-up outpatient rescreen. The confirmed hearing losses cases were removed for the regression analysis. There are 3,027 infants in the cohort with 2,469 (81%) receiving the follow-up outpatient screen and 558 (18%) not receiving the follow-up outpatient screen. The logistic regression was performed based on whether the infant did or did not receive the follow-up screen. Table 17 shows the variables and their respective coding for the regression model. To perform the logistic regression, categorical variables need to be 'dummy' coded. For example, mother's age at birth is categorized into three variables. Infants born to mothers over age 25 are the reference variable labeled '0'. If there are only two

categories then the regression is based on the larger number (1). Ethnicity is

categorized into Hispanic and Non-Hispanic so the regression is based on the Non-

Hispanic population.

Table 17. Variables and Coding for the Logistic Regression Model.

Variable	Coding
Ethnicity	1=Hispanic, 2=Non-Hispanic
Gender	1=Female, 2 =Male
Gestational age	0=>36 weeks, 1=<36 weeks
Birth weight	0=>2500 gms, 1=<2500gms
APGAR 5	0=>7, 1=<7
Mother's age	0=25+, 1=20 – 24, 1=11 – 19
Marital Status	0=yes, 1=no
Mothers Education	0=>12, 1=<12
Birthrate	0=>3001, 1=2001-3000, 1=1001-2000, 1=<1000
Nursery Level	0=Well baby, 1=Level 2, 1=Level 3
Audiologist	1=yes, 2=no
Technology	0=AABR only, 1=OAE only, 1=Both
Refer Rates	0=0-5%, 1=5.1-10%, 1=>10%
Screening Personnel	0=Nurses, 1=Techs, 1=Volunteers, v
Follow-up Appt. scheduling	0=prior to discharge, 1=after discharge, 1=parent responsible
Charge	1=yes, 2= no
Outpatient Screen	0=nursery, 1=audiology dept, 1=Refer out
Rescreen Rates	0=90-100%, 1=80-90%, 1=>79%

Variables were recoded into smaller groups to make the groups more evenly

distributed. Gestational age was recoded from 3 groups into two groups above or

below 36 week of age. Birth weight was recoded into two groups above or below

2500 grams at birth. Apgar score at 5 minutes was recoded into above or below an

Apgar score of 7 (versus 6). Hospitals with less than 500 births were added to those

with 500-1000 births decreasing the number of groups from 5 to 4. The variable

determining the level of audiology involvement was removed due to the variety of

options hospital coordinators could choose from (e.g. consultation only, supervise,

manage the data) which resulted in 18 different categories. The variable of whether

there was or was not an audiologist involved with the program was kept in the

regression. Refer rates were recoded into 3 groups. The reference group includes

hospitals with rates between 4 and 5%, which includes the statewide average refer rate of 4.68%. In the screening personnel variable, the cohort screened by the audiologist was combined with the cohort screened by technicians since this accounted for only 12 infants and one hospital. Contract employees were also combined with technicians since the number was small (N=145) in comparison to the other groups. The variable for how the follow-up appointment is scheduled was combined into two groups based on when the appointment is scheduled (prior to or after discharge) and whether the parents are responsible for scheduling the rescreen appointment after discharge. The variable describing where the outpatient screen occurred combined the audiology department on a campus different from the nursery with the audiology department on the same campus as the nursery. Lastly, the rescreen rate was reorganized into 3 groups with 90-100% as the reference group. Table 18 displays the variables and their respective odds ratios, 95% confidence intervals, and p values. Table 19 provides an explanation of the odds ratios for each of the variables.

Table 18. Logistic regression odds ratios and confidence intervals for each variable predicting whether an infant does not receive the outpatient follow-up screen.

Variable	Coding	Frequency % and N	OR	95% CI	Pr > ChiSq
Ethnicity	1=Hispanic,	41.6 (1260)			
	2=Non-Hispanic	58.4 (1767)	0.773	0.643-0.930	0.0064
Gender	1=Female	44.1 (1334)			
	2=Male	55.9 (1693)	1.252	1.038-1.509	0.0188
Gestational age	0=>36 weeks	89.5 (2709)	1.0		
	1=<36 weeks	10.5 (318)	1.232	0.926-1.639	0.1521
Birth weight	0=>2500 gms	90.3 (2731)	1.0		
	1=<2500gms	9.7 (294)	1.123	0.83-1.518	0.4507
Apgar 5	0=>7	88.8 (2687)	1.0		
	1=<7	11.2 (340)	1.449	1.108-1.896	0.0067
Mother's age	0=25+	59.7 (1807)	1.0		
	1=20 – 24	28.7 (870)	1.292	1.127-1.967	0.0148
	1=11 – 19	11.5 (350)	1.489	1.093-1.868	0.0051
Marital Status	0=yes	68.6 (20681)	1.0		
	1=no	31.4 (945)	1.568	1.296-1.897	<.0001
Mothers Education	0=>12	40.7 (1209)	1.0		
	1=<12	593 (1759)	1.522	1.251-1.852	<.0001
Birthrate	0=>3001	35.2 (1065)	1.0		
	1=2001-3000	17.2 (519)	1.375	1.058-1.787	0.0173
	1=1001-2000	28.1 (850)	0.866	0.677-1.108	0.2530
	1=<1000	19.6 (593)	1.440	1.122-1.848	0.0042
Nursery Level	0=Well baby	24.2 (732)	1.0		
	1=Level 2	47.1 (1427)	0.964	0.762-1.219	0.7604
	1=Level 3	28.7 (868)	1.266	0.986-1.626	0.0644
Audiologist	1=yes	71.6 (2168)	1.0		
	2=no	28.4 (859)	1.628	1.341-1.976	<.0001
Technology	0=AABR only	59.8 (1810)	1.0		
	1=OAE only	12.4 (376)	0.865	0.650-1.152	0.3215
	1=Both	27.8 (841)	0.665	0.532-0.832	0.0003
Refer Rates	0=0-5%	29.7 (898)	1.0		
	1=5.1-10%	48.7 (1474)	0.950	0.773-1.169	0.6299
	1=>10%	21.6 (655)	0.571	0.431-0.756	<.0001
Screening Personnel	0=Nurses	30.7 (928)	1.0		
	1=Techs	38.4 (1161)	0.633	0.501-0.798	0.0001
	1=Volunteers	31.0 (938)	1.194	0.957-1.491	0.1163
Follow-up Appt. Scheduling	0=hospital schedules	1.00			
	1=parent schedules	43.4 (1315)	1.608	1.337-1.933	<.0001
Charge	1=yes	52.4 (1586)	1.0		
	2=no	47.6 (1441)	0.902	0.750-1.085	0.2749
Outpatient Screen	0=nursery	52.8 (1599)	1.0		
	1=audiology dept	45.2 (1369)	0.975	0.808-1.176	0.7907
	1=Refer out	2.9 (59)	2.872	1.676-4.920	0.0001
Rescreen Rates	0=90-100%	30.0 (877)	1.0		
	1=80-90%	39.5 (1197)	2.418	1.788-3.271	<.0001
	1=>79%	31.5 (953)	6.337	4.734-8.483	<.0001

Table 19. Explanation of the Odds Ratio for Variables in the Regression Model.

Variable	Explanation
Ethnicity	Non-Hispanic infants are 39% (OR=. 773) more likely to receive the follow-up outpatient rescreen at p <.006.
Gender	Males infants are 25% less likely to receive the follow-up outpatient screen at p<.02.
Gestational age	Infants who are 36 weeks gestational age or less are 23% less likely to receive the follow-up outpatient rescreen at p<.15.
Birth weight	Infants who weight less than 2500 gms are 12% less likely to receive the follow-up outpatient rescreen at p<.45.
Apgar 5	Infants who have Apgar scores of 7 or below at 5 minutes are 45% less likely to receive the follow-up outpatient screen at p<.006.
Mother's age	Infants born to mothers who are between 20-25 years of age are 29% less likely to receive the follow-up outpatient screen at p<.01 as compared to infants who are born to mothers 25 years of age or older.
	Infants born to mothers who are between 13-19 years of age are 49% less likely to receive the follow-up outpatient screen at p<.0005.
Marital Status	Infants born to mothers who are not married are 57% less likely to receive the follow-up outpatient screen at p<.0001.
Mothers Education	Infants born to mothers who have 12 years of education or less are 52% less likely to receive the outpatient follow-up screen at p< 0001.
Birthrate	Infants born in hospital with 2-3000 births are 38% less likely to receive the outpatient follow-up screen at p<.02.
	Infants born in hospitals with 1000 births or fewer are 45% less likely to receive the outpatient follow-up screen at p<.004 as compared to infants born in hospitals with greater than 3000 births.
Nursery Level	Infants born in hospitals with a level 3 neonatal intensive care unit are 27% less likely to receive the outpatient follow-up screen at p<.06 as compared to those born in hospitals with only a well baby nursery.
Audiologist	Infants born in hospitals who do not have an audiologist involved with the screening program are 63% less likely to receive the outpatient follow-up screen at p<.001.
Technology	Infants born in hospitals that use both OAE and AABR are 67% more likely to receive the outpatient follow-up screen at p<.0003.
Refer Rates	Infants born in hospitals with refer rates greater than 10% are 60% more likely to receive the outpatient follow-up screen at p<. 0001.
Screening Personnel	Infants born in hospitals that are screened by technicians (vs. nurses) are 59% more likely to receive the outpatient follow-up screen at p<.0002.
	Infants born in hospitals that are screened by contract staff are 70% more likely to receive the outpatient follow-up screen at p<.06.
Follow-up Appt. Scheduling	Infants born in hospitals who schedule the follow-up outpatient rescreen after discharge are 96% less likely not to receive the outpatient screen at p<.0001 as compared to hospitals who schedule the appointment prior to hospital discharge.
	Infants who are born in hospitals who rely on parents to schedule follow-up appointment are 95% less likely to receive the follow-up outpatient screen at p<.0001.
Charge	Infants born in hospitals that do not charge for the outpatient screen are 11% more likely to receive the outpatient follow-up screen at p<. 27.
Outpatient Screen	Infants born in hospitals who refer outside their hospital system are almost 3 times less likely to receive the outpatient follow rescreen at p<.0004 as compared to hospitals that bring infants back to the hospital nursery.
Rescreen Rates	Infants born in hospitals that have rescreen rates between 80-90% are 2.5 times less likely not to receive the outpatient rescreen at p<.0001 as compared to hospitals that have rescreen rates ≥90%.
	Infants born in hospitals that have rescreen rates less than 79% are 6.3 times less likely not to receive the outpatient rescreen at p<.0001.

Hospital Variables

Table 21 provides the variables used in the regression model beginning with Model 1 through the final Model 4. Rescreen rates are the most significant variable for obtaining or not obtaining a rescreen in Model 1. In Model 2, the birth rate variable is added to the regression model and there are no main effects. There is an interaction between those hospitals with a birth census between 1000 and 2000 and those that have rescreen rates <79% at p<.0005. Further analysis shows there are only 23 infants in this cohort and one hospital is in this category (Figure 1). When the audiologist variable is added to the regression, the interaction remains the same for the one hospital with 23 infants. Birth rate was removed from the model due to this confounding variable.

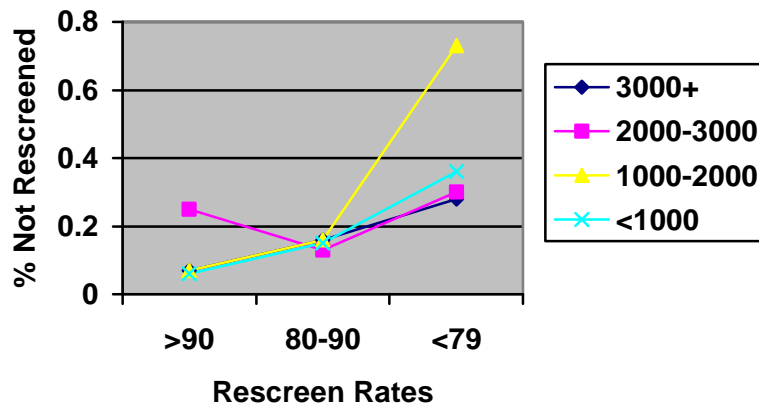**Fig.2 Birth Rates by Rescreen Rates**

Table 20 displays the frequency and number for each of the birth rate categories and variables for the cohort of infants (n=558) who did not receive the outpatient rescreen.

Variable	3000+ 32.4% N=181	2-3000 20.4% N=114	1-2000 22.9% N=128	<1000 24.2% N=135	Total %
Nursery Level					
Well Baby	0.0	0.0	38.0 (49)	62.0 (89)	23.0 (129)
Level II	34.0 (83)	25.8 (63)	21.3 (52)	18.8 (46)	43.7 (244)
Level III	53.0 (98)	27.6 (51)	14.6 (27)	4.9 (9)	33.2 (185)
Audiologist					
Yes	50.6 (179)	17.6 (62)	23.9 (84)	7.7 (27)	63.1 (352)
No	0.9 (2)	25.2 (52)	21.4 (44)	52.4 (108)	36.9 (206)
Technology					
OAE	0.0	0.0	26.5 (18)	73.5 (50)	12.2 (68)
AABR	43.8 (161)	15.5 (57)	21.2 (78)	19.2 (72)	66.0 (368)
AABR/OAE	16.4 (20)	46.7 (57)	26.2 (32)	10.6 (13)	21.9 (122)
Who Screens					
Nurses	0.0	15.1 (28)	29.7 (5)	55.1 (102)	33.2 (185)
Technicians	32.4 (52)	13.3 (21)	44.3 (70)	8.2 (13)	28.3 (158)
Volunteers	59.1 (27)	30.2 (65)	1.4 (3)	9.3 (20)	38.5 (215)
Follow-up Appt Scheduling					
Hospital responsible	25.2 (66)	6.1 (16)	43.2 (73)	36.6 (96)	47.0 (262)
Parent responsible	38.9 (115)	33.1 (98)	14.9 (44)	13.2 (39)	53.0 (296)
Charge					
Yes	42.8 (130)	26.3 (80)	15.5 (47)	15.5 (47)	54.5 (304)
No	20.1 (51)	13.4 (34)	31.9 (81)	34.7 (88)	45.5 (254)
Outpt Screen					
Nursery	0.7 (2)	16.8 (49)	37.9 (110)	44.7 (130)	52.2 (291)
Audiology Dept.	73.4 (179)	17.2 (42)	7.4 (18)	2.1 (5)	43.7 (244)
Referred Out	0.0	100.0(23)	0.0	0.0	4.1 (23)
Refer Rate					
0-5%	18.5 (34)	39.1 (72)	23.9 (44)	18.5 (34)	33.0 (184)
5.1-10%	50.7 (147)	14.5 (42)	15.2 (44)	19.6 (57)	52.0 (290)
>10%	0.0	0.0	47.6 (40)	52.4 (44)	15.0 (84)
Rescreen Rate					
>90%	54.8 (34)	1.6 (1)	29.0 (18)	14.5 (9)	11.1 (62)
80-90%	17.2 (32)	17.7 (33)	50.0 (93)	15.1 (28)	33.3 (186)
<79%	37.1 (115)	25.8 (80)	5.5 (17)	31.6 (98)	55.6 (310)

When nursery level (Well baby, NICU Level 2, NICU Level 3) is added to the regression model, Level 3 NICU is significant at p>.01 with an odds ratio of .72, meaning infants born in Level 3 NICU's are 38% more likely to obtain the follow-up rescreen as compared to hospitals with only a well baby nursery. Six of the nine hospitals that have a Level 3 NICU have pediatric audiologists on staff. Thirty three percent (185) of infants who did not receive a follow-up screen were born in hospitals with a Level 3 nursery. In addition, 62% of these infants are born in a Level 3

hospital with a rescreen rate of less than 79%. There is not a significant interaction between nursery level and rescreen rates. Adding the audiologist variable to this model results in $p < .04$ and the nursery level lose significance for the main effect. After the nursery level variable is removed, the audiologist variable increases to a $p < .003$ and 37% of the infants who are born in hospitals without an audiologist involved fail to receive the outpatient rescreen. There is not a significant interaction between the rescreen rates and audiologist variable but the audiologist variable is still significant for the main effect.

Hospital refer rates added to the rescreen model show a level of significance ($< .009$) for refer rates between 6 and 10%. Infants born in these hospitals are 32% more likely to receive the follow-up rescreen. Since this is counter-intuitive to what would be expected, further analysis shows that refer rates are related to whether an audiologist is involved in the program. When the audiologist variable is added, the p value decreases to $< .06$. Figures 3 and 4 display the variations between refer rates and rescreen rates with the audiology variable. Refer rates were not significant for the main effect in the rescreen rate model.

Fig. 3 Audiologist and Refer Rates
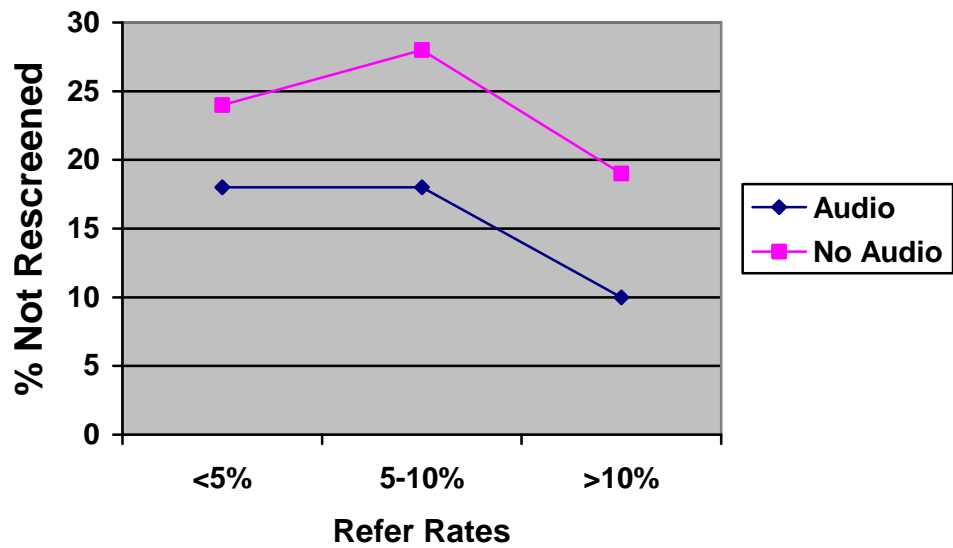
Fig.4 Audiologist and Rescreen Rates
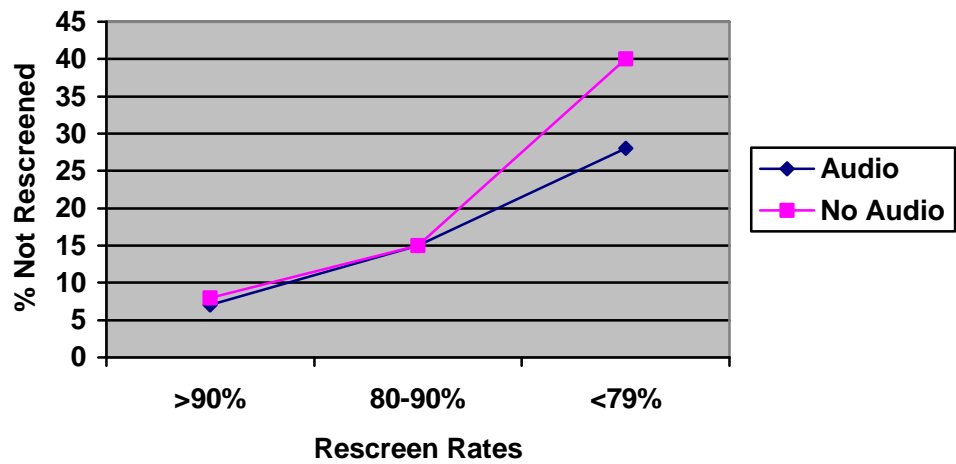
The technology variable is not significant when added to the rescreen rate

model. Technology and the audiology variables alone are significant and there is a

significant interaction between hospitals that use both technologies (AABR, OAE).

Figure 5 demonstrates this interaction. Infants born in hospitals that use both

technologies and do not have an audiologist involved, are 40% less likely to receive

the follow-up rescreen. Only hospitals that have <2000 birth use OAE technology only and their percentage of infant who do not receive the outpatient rescreen increases when an audiologist is not involved with the program. When the screening personnel variable is added to the model, volunteers are significant at p<.008 and an odds ratio of .70 meaning infants are 43% more likely to obtain the follow-up rescreen. When audiologist is added to the model this effect disappears for screening personnel.

Fig.5 Audiologist and Technology
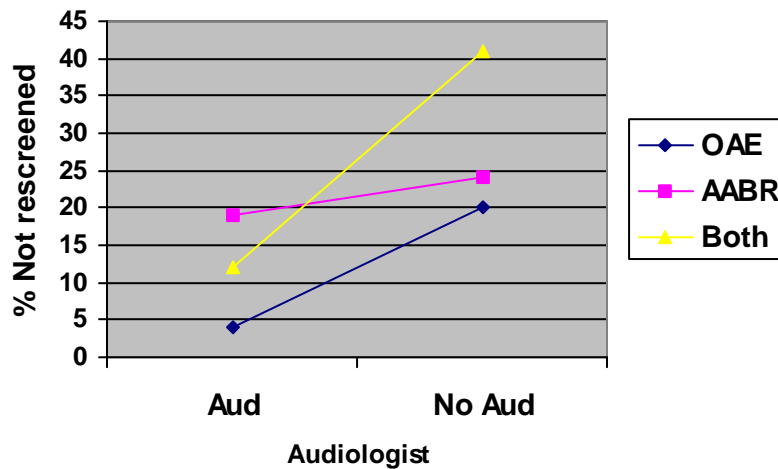
The variable for screening personnel was significant at p<.002 for volunteers with an odds ratio of .66, when added to the rescreen model. This means that 51% of the infants born in hospitals that use volunteers are more likely to receive an outpatient screen when compared to hospitals in which nurses do the screening. There was not a significant interaction between the rescreen rates and the screening personnel variables. In the initial logistic regression analysis (Table 18, 19) infants born in hospitals that use volunteers to screen were 21% less likely to receive the

follow-up screen. Figure 6 further explains why the screening personnel variable

changes when added to the rescreen model. This shows that infants are 50%

(technicians), 39% (nurses), and 28% (volunteers) less likely to receive the screen in

hospitals with refer rates less than 79%.

Fig.6 Rescreen Rates and Screening Personnel
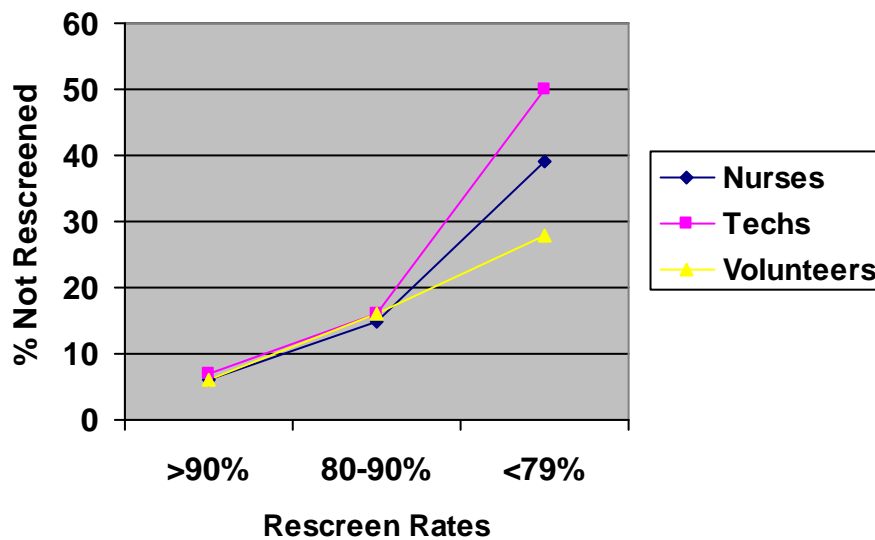
When the audiologist variable is added to the model the main effect for

screening personnel variable is not significant. When the rescreen variable is removed

the volunteer variable remains significant at $p<.001$ and the audiologist is significant

at $p<.0001$. There is an interaction and the volunteer variable is no longer significant

and the technician variable is at $p<.01$ for the main effect and $p<.03$ for the

interaction. Figure 7 shows the higher percentage of infants do not receive the follow-

up rescreen when they are born in hospitals that use technicians and do not have an

audiologist involved in the program. There is also a linear increase for volunteers and

nurses when there is not an audiologist involved.

Fig.7 Audiologist and Screening Personnel
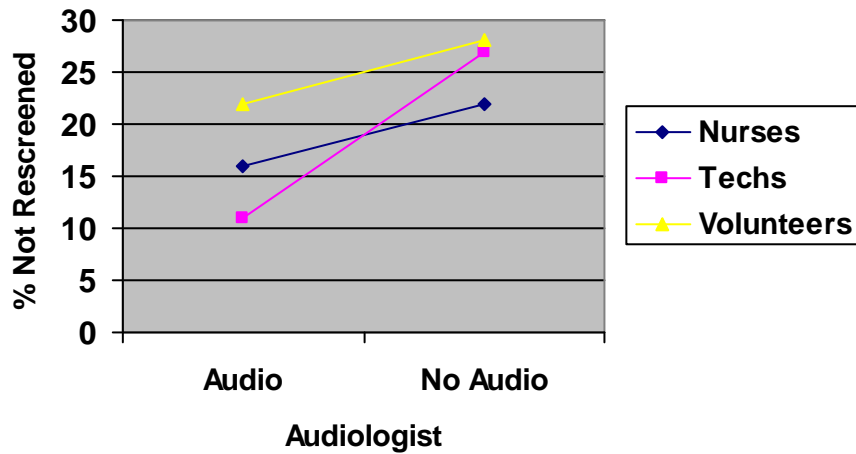
The next variable in the logistic regression rescreen rate model is the scheduling follow-up protocol variable. When infants are born in hospitals that require the parents to schedule the follow-up appointment, there is an odds ratio of .71 at a p<.003 meaning 41% more likely to obtain the follow-up rescreen. This is opposite of the initial regression (Table 18. 19) which shows that 60% of infants are less likely to obtain the follow-up rescreen when parents are responsible for scheduling the outpatient rescreen appointment. Figure 8 shows that as the rescreen rate becomes poorer infants born in hospitals that require parents to schedule the appointment are more likely to obtain the follow-up rescreen. Although there is not a significant interaction between the two variables there a significant difference between rescreen rates.

Fig.8 Scheduling
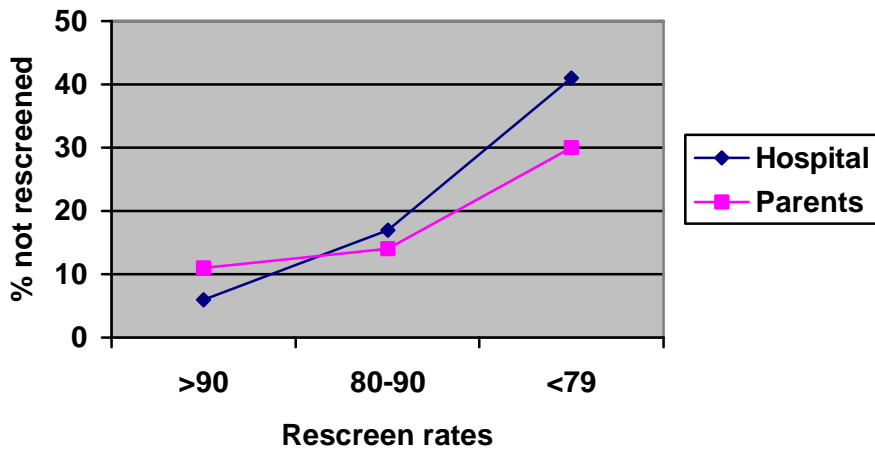
When the audiologist and the scheduling follow-up appointment variables are in the regression model without the rescreen rate variable, there is a significant interaction of p<.001 and an odds ratio of 1.60 and 1.63, for the parent scheduling and the audiologist variable, respectively. Figure 9 displays this interaction.

Fig 9 Audiologist and Follow-up Scheduling
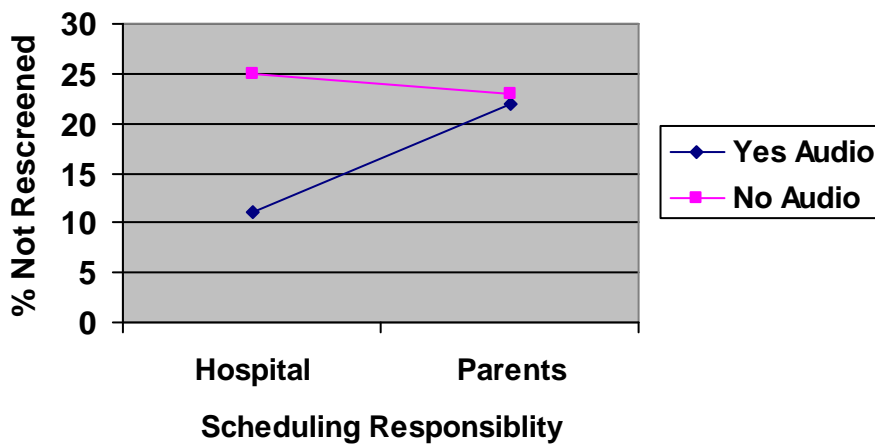
When screening personnel and the follow-up appointment variables are placed into a regression model alone, technicians are significant at p<.003 with an odds ratio of .65, and parents scheduling are significant at p<.0007 with an odds ratio of 1.42. Although there is not a significant interaction Figure 10 shows the relationship between the two variables. The follow-up rate is poorer when hospitals rely on parents to schedule the appointment. When the audiologist variable is added to the regression model there is a significant interaction between audiologist and parents scheduling, and technicians and parents scheduling. Figure11 displays this complex interaction. When hospitals without an audiologist involved take responsibility for scheduling the appointment (versus parents) they have very poor rescreen rates, notably for volunteers. When hospitals with an audiologist involved take responsibility, volunteer programs have a better follow-up rate. Follow-up scheduling was not included in the final model due to the interaction and it loses significance for the main effect.

Fig.10 Screening Personnel and Follow-up Scheduling
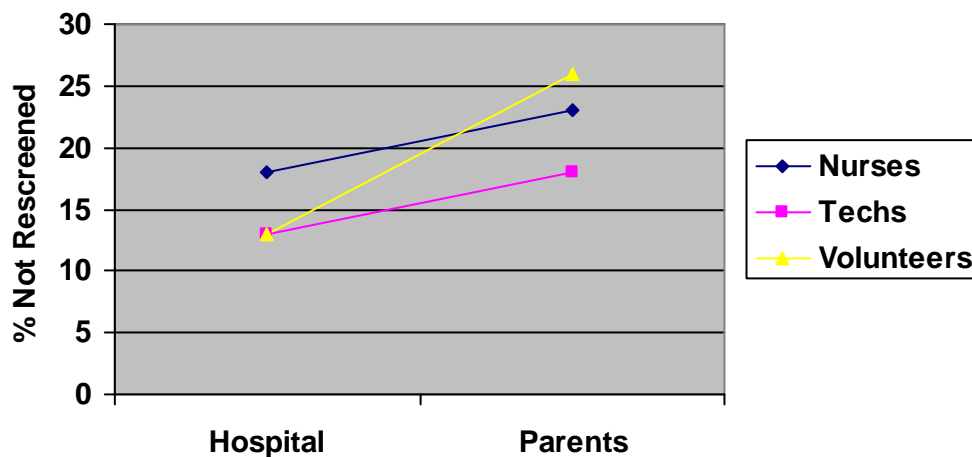
Fig.11 Screening Personnel, Audiologist and Follow-up Scheduling
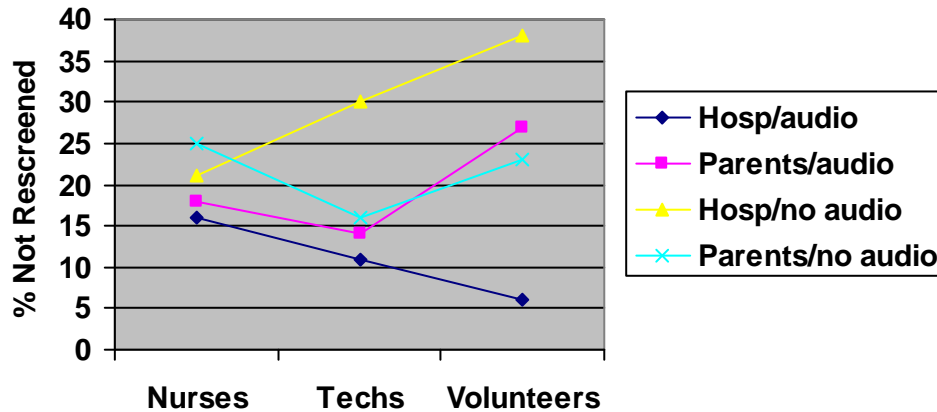
The location the family returns to obtain the outpatient rescreen is added to the regression model. The audiology clinic variable is significant at p<.03 and an odds ratio of .79 or infants who are born in hospitals that have families return to the audiology department are 27% more likely to obtain the follow-up screen as compared to those infants screened when returning to the nursery. There is a significant interaction between hospitals that have <79% rescreen rates and returning to the community audiologist. Figure 10 displays this interaction. Further analysis shows only one hospital (N=59) which refers families to audiologists in the community. Infants born in this hospital were 40% more likely not to obtain an outpatient rescreen.

Fig.12 Rescreen Rates and Outpatient Rescreen
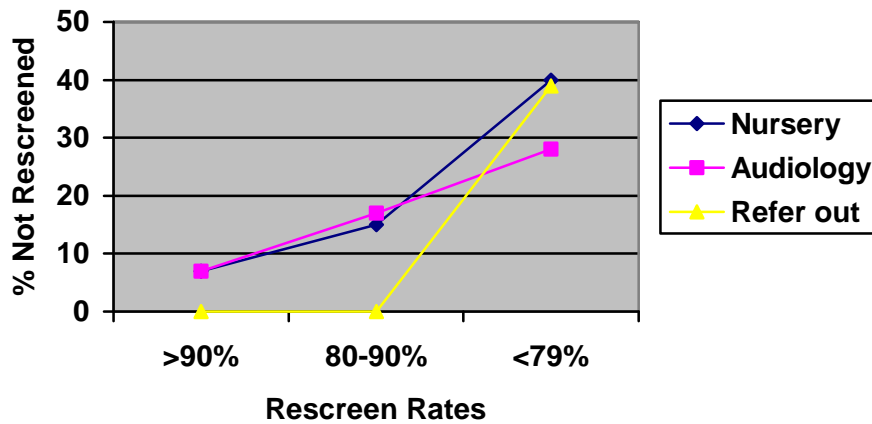
When the audiologist variable is added to the regression model the outpatient rescreen loses significance for the main effect. When the rescreen rate is removed, both the audiologist and the outpatient rescreen variables are significant at $p < .05$. This again shows how important the audiologist is to the follow-up variables.

Demographic Variables

Ethnicity, gender, Apgar at 5 minutes, and mother's education are all significant variables for the rescreen rate model. Mother's marital status and mother's age at birth of baby are significant for the main effect until mother's education is added to the model. The infant's gestational age and birth weight were not significant variables in the model. Table 20 displays the odds ratio, 95% confidence intervals, and p values for Model 3.

Final Regression Model

The final regression model contained the rescreen rate, audiologist, ethnicity, gender, Apgar <7 at 5 minutes, and mother's education variables. Ethnicity does have an interaction with hospitals that have a rescreen rate between 80-90%.

When the audiologist variable is added to the regression model there is not an interaction between the ethnicity and audiologist variables but the initial interaction remains. Figure 13 shows this interaction. Overall the Non-Hispanic population has lower percentages (a better chance) in receiving the follow-up rescreen. The interaction shows that the rescreen rates for the Hispanic population is slightly lower in the hospitals with rescreen rates between 80-90% that do not have an audiologist. There is also a strong correlation between ethnicity and mother's education at $p<.000$ with an odds ratio of .69. This means that Non-Hispanic mothers with low education are 45% more likely to obtain the follow-up rescreen. Figure 14 shows this interaction with rescreen rates

Fig.13 Ethnicity and Rescreen Rates

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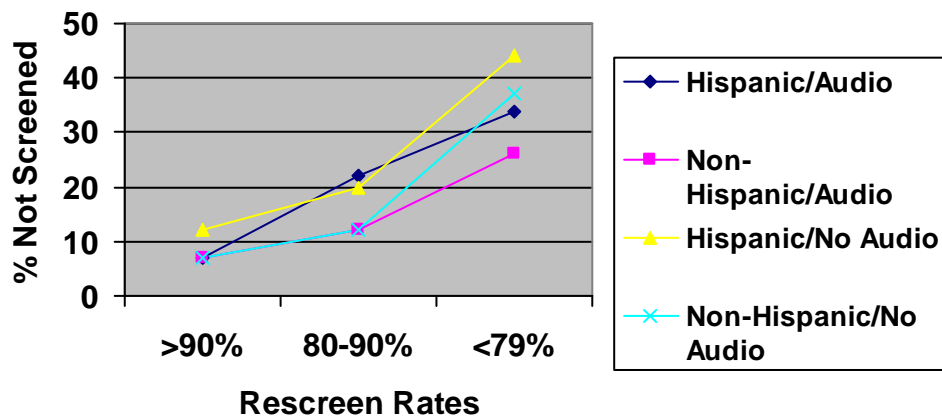
Fig.14 Ethnicity, Education and Rescreen Rates
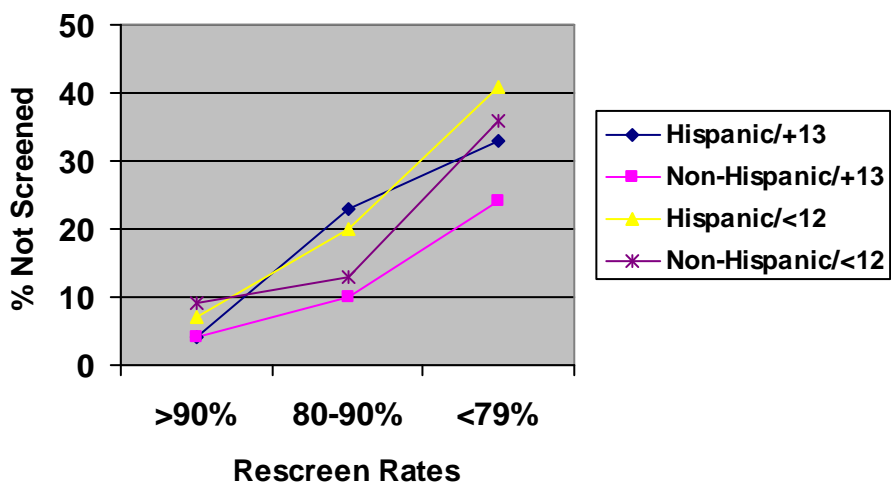
Males are 23% (odds ratio=1.23, p<.04) less likely to receive the outpatient rescreen. There is not an interaction between gender and ethnicity or gender and Apgar score but a significant interaction between gender and mother's education.

Fig. 15 Gender and Mother's Education
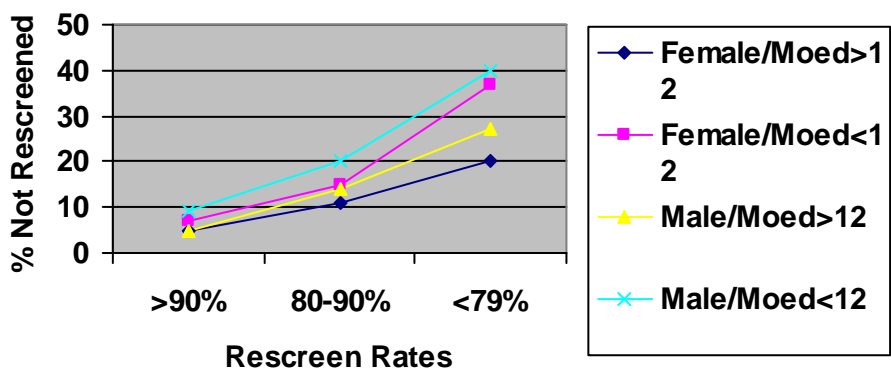
There were no other interactions between the variables with or without the recreen rate variable. Table 21 displays the odds ratios, 95% confidence intervals,

and p values for the final regression model. Table 21 shows the means for whether

the infant received or missed the follow-up rescreen.

Table 21. Regression Models with Odds Ratios, 95% CI, and P Values

Variable	Model	OR	95% CI	Pr > ChiSq
	Model 1			
>90%		1.0		
80-90%		2.418	1.788 – 3.271	<.0001
<79%		6.337	4.734 – 8.483	<.0001
	Model 2			
>90%		1.0		
80-90%		2.307	1.703 - 3.126	<.0001
<79%		6.004	4.476 - 8.055	<.0001
Audiologist		1.0		
No Audiologist		1.357	1.109 - 1.661	0.0030
	Model 3			
>90%		1.0		
80-90%		2.635	1.936 – 3.587	<.0001
<79%		7.155	5.298 – 9.664	<.0001
Hispanic		1.0		
Non-Hispanic		0.690	0.558 – 0.852	0.0006
Females		1.0		
Males		1.229	1.009 – 1.498	0.0405
Apgar >7		1.0		
Apgar <7 at 5 minutes		1.544	1.161 – 2.055	0.0029
Mother's Education>13				
Mother's Education≤12		1.506	1.210 – 1.875	0.0002
	Final Model			
>90%		1.0		
80-90%		2.515	1.844 - 3.431	<.0001
<79%		6.782	5.008 - 9.186	<.0001
Hispanic		1.0		
Non-Hispanic		0.704	0.569 - 0.871	0.0012
Females		1.0		
Males		1.232	1.011 - 1.501	0.0389
Apgar >7		1.0		
Apgar <7 at 5 minutes		1.536	1.154 - 2.045	0.0033
Mother's Education>13		1.0		
Mother's Education≤12		1.491	1.191 - 1.856	0.0004
Audiologist		1.0		
No Audiologist		1.277	1.037 - 1.572	0.0212
Somer D=.426				

Table 22 shows the means for screened and missed for each of the

variables in the final regression model. The Agpar scores <7 and rescreen rates

variables demonstrate the highest percentages of infants who fail to receive the

outpatient rescreen.

Table 22. Means for the variables in the regression model.

Variable	Coding	N Screened/Missed	Mean Screened/Missed
Ethnicity	1= Hispanic, 2=Non-Hispanic	2469/558	.59/.53
Gender	1=Female, 2=Male	2469/558	.55/.61
Apgar 5	0=>7, 1=<7	2469/558	9.09/6.66
Mother's ed	0=1-13+, 1=0-12 years,	2421/547	.75/.66
Audiologist	1=yes, 2=no	2469/558	.26/.37
Rescreen Rates	0= 90-100%, 1=80-90% 1=>79%	2469/558	.93/2.44

Question Number 2

Demographic Variables

During 2002-2005, 426 infants were confirmed with permanent hearing loss

born in Colorado. 386 infants in this cohort had a confirmed screen date and date of

confirmation for this analysis. Table 23 lists the basic descriptive statistics for this

cohort. There were 148 infants with unilateral hearing loss and 238 infants with

bilateral hearing loss.

Table 23. Percentage and N for degree and type of hearing loss.

	Unilateral N=148	Bilateral N=238	Total N=386
Degree			
Mild	25.7 (38)	36.1 (86)	32.1 (124)
Moderate	42.6 (63)	34.9 (83)	37.8 (146)
Severe	15.5 (23)	19.3 (46)	17.9 (69)
Profound	13.5 (20)	13.5 (22)	10.9 (42)
Unknown	2.7 (4)	0.4 (1)	1.3 (5)
Type			
Conductive	15.8 (61)	14.5 (56)	30.3 (117)
Sensorineural	15.8 (61)	38.6 (149)	54.4 (210)
Mixed	1.3 (5)	2.1 (8)	3.4 (13)
AN/AD	1.0 (4)	4.4 (17)	5.4 (21)
Unknown	4.2 (16)	2.3 (9)	6.5 (25)

To determine infants with comorbidities, data was collected from the Audiology Follow-up Reports and the Colorado Responds to Children with Special Needs database (CRCSN). The CRCSN database collects high risk data by the ICD 9 diagnostic codes. To simplify the determination of comorbidity, infants were categorized into one of the nine high risk factors. Infants that had multiple high risk factors were assigned to one risk factor (Table 24). The Audiology Follow-up Reports documented 117 infants with a high risk factor and CRCSN reported 134 cases. Table 25 displays the combined cohort for the comorbidity variable with 51% (N=197) with a high risk factor and 49% (N=187) without a high risk factor.

Table 24. Percentage and N by High Risk Factors

	F/U Report N=386	CRCSN N=386
No High Risk Factor	69.7 (269)	65.3 (252)
High Risk Factor		
NICU >48 hours	9.3 (36)	0.0
Stigmata	4.9 (19)	7.3 (28)
Family History	5.2 (20)	0.0
Craniofacial Anomalies	9.8 (38)	18.4 (71)
TORCH	0.5 (2)	0.8 (3)
Hypertension	0.5 (2)	0.0
BWGMS<1500	0.0	8.0 (31)
Meningitis	0.0	0.3 (1)

Table 25. Percentage and N by risk factors and laterality.

	Unilateral N=147	Bilateral N=239	Total N=386
No High Risk Factor N=189	36.0 (68)	64.0 (121)	49.0 (189)
High Risk Factor N=197			
NICU >48 hours	35.3 (6)	67.4 (11)	4.4 (17)
Stigmata	37.1 (13)	62.9 (22)	9.1 (35)
Family History	42.9 (6)	57.1 (8)	3.6 (14)
Craniofacial Anomalies	41.4 (41)	58.6 (58)	25.7 (99)
TORCH	0.0	100.0 (4)	1.0 (4)
Hypertension	0.0	100.0 (1)	.3 (1)
BWGMS<1500	53.9 (14)	46.2 (12)	6.7 (26)
Meningitis	0.0	100.0 (1)	.3 (1)

Age of identification was categorized into 5 groups. Age of identification ranged from 1 to 50 months of age. Table 26 displays the coding for this analysis and the frequency for this variable. Table 27 displays the frequencies of high risk factors by age of identification. Table 28 describes the frequencies of laterality, degree, and type by age of identification.

Table 26. Coding for age of identification.

Age of Identification	Coding	Frequency % and N
0-3 months	0	54.2 (209)
4-6 months	1	19.4 (75)
7-9 months	2	7.8 11)
10-12 months	3	5.2 (20)
13-24 months	4	4.7 (18)
>24 months	5	8.8 (34)

Table 27. Risk factor by age of identification.

	0-3 mths N=209	3-6mths N=75	6-9mths N=30	9-12mths N=20	12-24 N=18	>24mths N=34	Total N=386
No High Risk Factor	56.5 (118)	32.0 (24)	5.8 (11)	3.2 (6)	5.8 (11)	10.1 (19)	49.2 (189)
High Risk Factor							
NICU >48 hours	64.7 (11)	5.9 (1)	17.7 (3)	5.9 (1)	5.9 (1)	0.0	4.4 (17)
Stigmata	48.6 (17)	22.9 (8)	5.7 (2)	8.6 (3)	2.9 (1)	11.4 (4)	9.1 (35)
Family History	57.1 (8)	28.6 (4)	14.3 (2)	0.0	0.0	0.0	3.6 (14)
Craniofacial Anomalies	48.5 (48)	22.2 (22)	9.1 (9)	7.1 (7)	3.0 (3)	10.0 (10)	25.7 (99)
TORCH	0.0	75.0 (3)	0.0	0.0	0.0	25.0 (1)	1.0 (4)
Hyperbilirubin	100.0 (1)	0.0	0.0	0.0	0.0	0.0	0.3 (1)
BWGMS<1500	19.2 (5)	50.0 (13)	11.5 (3)	11.5 (3)	7.7 (2)	0.0	6.7 (26)
Meningitis	100.0 (1)	0.0	0.0	0.0	0.0	0.0	0.3 (1)
Total	54.2(209)	19.4 (75)	7.8 (11)	5.2 (20)	4.7(18)	8.8 (34)	386

Table 28. Degree, type and laterality by age of identification.

Degree	0-3 mths N=209	3-6mths N=75	6-9mths N=30	9-12mths N=20	12-24 N=18	>24mths N=34	Total N=386
Mild	54.8 (68)	21.8 (27)	6.5 (8)	4.8 (6)	1.6 (2)	10.5 (13)	32.1 (124)
Moderate	50.7 (74)	20.6 (30	8.2 (12)	4.8 (7)	4.8 (7)	11.0 (16)	37.8 (146)
Severe	65.2 (45)	14.5 (10)	7.3 (5)	5.8 (4)	4.4 (3)	2.9 (2)	17.9 (69)
Profound	45.2 (19)	16.7 (7)	11.9 (5)	7.1 (3)	11.9 (5)	7.1 (3)	10.9 (42)
Unknown	60.0 (3)	20.0 (1)	0	0	20.0 (1)	0	1.3 (5)
Type							
Cond Bil	46.4 (26)	28.6 (16)	7.1 (4)	0	3.6 (2)	14.3 (8)	14.5 (56)
Sensori. Bil	57.7 (86)	16.1 (24)	6.7 (10)	6.7 (11)	7.4 (11)	5.4 (8)	38.6 (149)
Mixed Bil	25.0 (2)	12.5 (1)	0	25.0 (2)	0	37.5 (3)	2.1 (8)
AN/AD Bil	41.2 (7)	35.3 (6)	11.8 (2)	11.8 (2)	0	0	4.4 (17)
UNK Bil	44.4 (4)	44.4 (4)	0	0	0	11.1 (1)	2.3 (9)
Cond Uni	57.4 (35)	14.8 (9)	8.2 (5)	4.9 (3)	1.6 (1)	13.1 (8)	15.8 (61)
Sensori Uni	57.4 (35)	18.0 (11)	8.2 (6)	4.9 (3)	4.9 (3)	6.6 (4)	15.8 (61)
Mixed Uni	40.0 (2)	20.0 (1)	20.0 (1)	0	20.0 (1)	0	1.3 (5)
AN/AD Uni	75.0 (3)	0	25.0 (1)	0	0	0	1.0 (4)
UNK Uni	56.1 (9)	18.8 (3)	12.5 (2)	0	0	12.5 (2)	4.2 (16)
Laterality							
Bilateral	59.8 (125)	68.0 (51	53.3 (16)	70.0 (14)	72.2(13)	58.8 (20)	61.9 (239)
Unilateral	40.2 (84)	32.0 (24)	46.7 (14)	30.0 (6)	27.8 (5)	41.2 (14)	38.1 (147)

Analysis

To develop the regression model age of identification (dependent variable) was categorized into before six months and after six months of age. Research by Yoshinaga-Itano, et al. (1998) has demonstrated that age of identification before six months is critical to improved outcomes for language. There are 284 (74%) infants who were identified before 6 months of age and 102(26%) identified after six months of age. High risk factors were categorized into either having or not having a high risk factor. Table 29 displays the coding and frequency for the variables used in the regression model.

Table 29. Logistic regression odds ratios and confidence intervals for each variable predicting age of identification before and after six months of age.

Variable	Coding	Frequency % and N	OR	95% CI	Pr > ChiSq
Comorbidity	0= no	49.0 (189)			
	1= yes	51.0 (197)	1.170	0.744-1.842	0.4969
Laterality	0=Bilateral	61.9 (239)			
	1=Unilateral	38.1 (147)	1.009	0.633-1.607	0.9705
Type	0=Sensorineural	54.4 (210)	1.0		
	1=Conductive	30.3 (117)	0.534	0.623-1.741	0.8773
	2=Mixed	3.4 (13)	3.370	1.085-10.470	0.0356
	3= AN/AD	5.4 (21)	0.903	0.316-2.582	0.8487
	4=Unknown	6.5 (25)	0.722	0.258-2.018	0.5348
Degree	0=Mild	32.1 (134)	1.0		
	1=Moderate	37.8 (136)	1.323	0.764-2.290	0.3177
	2=Severe	17.9 (69)	0.834	0.406-1.712	0.6205
	3=Profound	10.9 (42)	2.016	0.953-4.263	0.0665
	4=Unknown	1.3 (5)	0.819	0.088-7.619	0.8607
Ethnicity	0=Hispanic	40.0 (134)	1.0		
	1=Non-Hispanic	60.0 (162)	0.747	0.473-1.181	0.2117
Gender	0=Female	43.5 (168)	1.0		
	1=Male	56.5 (218)	1.139	0.720-1.802	0.5774
Nursery Level	0=Well baby	13.2 (51)	1.0		
	1= NICU Level 2	50.8 (196)	0.800	0.404-1.585	0.5223
	2= NICU Level 3	36.0 (139)	0.903	0.445-1.834	0.7777
Mother's Age	0=25+	67.9 (262)	1.0		
	1=20 – 24	19.7 (76)	1.068	0.602-1.894	0.8220
	1=11 – 19	12.4 (48)	0.932	0.459-1.894	0.8465

The only variable significant for age of identification is those infants with a mixed hearing loss. They are 3 times less likely to be identified with hearing loss before six months of age. Table 29 contains the means for each of the variables. When the high risk factors are analyzed separately, it is interesting to note that there is one infant diagnosed as having a TORCH infection (toxoplasmosis, other infection, rubella, cytomegalovirus, and herpes simplex) and the age of identification was 12 months.

Table 30. Means for age of identification by month and variable.

Variable	Frequency	Mean	Standard Deviation	Minimum	Maximum
No High Risk Factor	49.0 (189)	3.9	5.9	0.0	50.0
High Risk Factor					
NICU >48 hours	4.4 (17)	4.8	5.8	1.0	23.0
Stigmata	9.1 (35)	4.4	5.0	0.0	25.0
Family History	3.6 (14)	3.4	2.7	1.0	9.0
Craniofacial Anomalies	25.7 (99)	4.3	4.6	0.0	31.0
TORCH	1.0 (4)	14.3	18.5	4.0	42.0
Hypertension	.3 (1)	3.0	0.0	3.0	3.0
BWGMS<1500	6.7 (26)	6.4	4.5	2.0	22.0
Meningitis	.3 (1)	3.0	0.0	3.0	3.0
Laterality					
Bilateral	61.9 (239)	4.5	5.2	0.0	42.0
Unilateral	38.1 (147)	4.1	6.2	0.0	50.0
Degree					
Mild	32.1 (124)	4.0	5.1	0.0	42.0
Moderate	37.8 (146)	4.4	5.5	0.0	39.0
Severe	17.9 (69)	3.5	3.8	0.0	17.0
Profound	10.9 (42)	6.5	8.8	0.0	50.0
Unknown	1.3 (5)	4.8	6.4	1.0	16.0
Type					
Conductive	30.3 (117)	3.6	4.7	0.0	39.0
Sensorineural	54.4 (210)	4.6	5.7	0.0	50.0
Mixed	3.4 (13)	10.8	12.2	0.0	42.0
AN/AD	5.4 (21)	4.5	3.1	1.0	12.0
Unknown	6.5 (25)	2.7	2.6	0.0	9.0
Ethnicity					
Hispanic	40.0 (134)	4.9	6.4	0.0	60.0
Non-Hispanic	60.0 (162)	4.0	5.1	0.0	39.0
Gender					
Female	43.5 (168)	4.3	6.3	0.0	50.0
Male	56.5 (218)	4.4	5.1	0.0	39.0
Nursery Level					
Well baby	13.2 (51)	4.4	7.6	0.0	50.0
NICU Level 2	50.8 (196)	4.5	6.7	0.0	42.0
NICU Level 3	36.0 (139)	4.1	4.7	0.0	31.0
Mother's age					
25+	67.9 (262)	4.0	4.8	0.0	39.0
20 – 24	19.7 (76)	4.5	6.3	0.0	50.0
11 – 19	12.4 (48)	4.0	4.8	0.0	39.0

DISCUSSION

The purpose of this study was to identify hospital and demographic factors that are associated with an infant not receiving a follow-up outpatient rescreen. A second purpose was to identify factors that are associated with infants who fail the newborn hearing screen but are not identified until after six months of age. This study was designed to evaluate the Colorado Infant Hearing Program and identify areas that need improvement in developing systems to ensure timely and appropriate follow-up.

Question 1

In 2005 Colorado had 69,533 births and 68,478 of those births occurred in 56 birthing hospitals. Resident births that occurred at home, out of state, in transit, and in unknown facilities were excluded from the analysis for the first hypothesis. Infants who were confirmed with a permanent hearing loss were also removed. For the regression analysis there were 3,027 infants who failed the initial screen and 558 infants who did not have documentation of receiving follow-up for either an outpatient rescreen or an audiological evaluation. The Colorado Infant Hearing Advisory Committee has implemented guidelines recommending that hospitals offer an outpatient rescreen rather than refer directly to an audiologist for infants who fail the inpatient rescreen. This protocol was established to decrease the number of infants who are referred for more costly evaluations. Colorado has rural and frontier areas that do not have a pediatric audiologist located near the birthing facilities. Pediatric assessments require special diagnostic equipment (ABR, OAE) and expertise. Pediatric audiologists are located primarily in large urban facilities.

The dependent variable was whether the infant received the outpatient rescreen. The independent hospital variables included birth rate, nursery level, if an audiologist was involved in the hospital program, technology used for screening, screening personnel, how the outpatient screen was scheduled, and location of the outpatient rescreen, if there is a charge for the rescreen, refer rates at discharge, and rescreen rates. The independent demographic variables included ethnicity, gender, gestational age, birth weight, Apgar score at 5 minutes, marital status, and mother's level of education.

This analysis failed to reject the first hypothesis that infants who return to the nursery for the follow-up outpatient rescreen are more likely to receive the rescreen. In fact the analysis shows that infants who return to audiology departments are 27% more likely to receive the follow-up outpatient screen then returning to the nursery. The most significant variables were the rescreen rates, audiology involvement, ethnicity, gender, Apgar score at 5 minutes and mother's education. Discussion of the individual variables will assist the reader in understanding the complexity of this issue.

Hospital Variables

Audiologist

An audiologist involved with the program was one of the most significant variables in the regression model at $p < .003$ with an odds ratio of 1.357, meaning infants born in hospitals without audiology support were 36% less likely to receive the rescreen. Infants who were born in hospitals with an audiologist involved accounted for 71% (N=2,168) of the 3,027 infants who failed the initial screen. There were 84%

(N=1816) of this cohort who received a resceen and 16% (N=352) who did not receive

the rescreen. Hospitals without an audiologist accounted for 28% (N=859) who failed

the initial screen. There were 76% (N=653) who received the rescreen and 24%

(N=209) that did not receive the rescreen. The audiology variable was significant in

the regression model with the other hospital variables.

It is challenging to develop community-based systems of care for newborn

hearing screening when a community is too small to support a pediatric audiologist.

The Colorado Infant Hearing Program has enlisted local audiologists, called

Audiology Regional Coordinators, to provide technical support to smaller hospitals.

Audiology Regional Coordinators are assigned to each hospital to provide technical

assistance. Only 24 (43%) of the birthing hospital coordinators marked on their survey

they had an audiologist involved in their program. This data indicates that over 50% of

the birthing hospitals do not view the Audiology Regional Coordinator as 'involved'

in their program. Their scope of work is to monitor hospital screening outcomes and

provide technical assistance. One solution will be to increase their funding and time to

support hospitals in providing technical assistance in every aspect of the program. The

Audiology Regional Coordinators can assist hospitals and physicians with identifying

the closest pediatric audiologist to ensure infants receive timely and appropriate

follow-up.

Rescreen Rates

Rescreen rates were the most significant variable in the regression analysis

for obtaining a follow-up rescreen. Although this is intuitive, the significance was

powerful. Infants who are born in hospitals with rescreen rates between 80-90% are

2.5 times less likely to receive the outpatient rescreen as compared to hospitals that have rescreen rates >90%. Infants who are born in hospitals with rates <79% are almost 7 times more likely not to receive the outpatient rescreen. When the audiologist variable is added to the regression the effect is noticed for hospitals that have <79% rescreen rates. For the cohort of infants who failed the initial screen born in hospitals with an audiologist involved, 28% (N= 619) were born in hospitals with rescreen rates of <79%. Infants who failed the initial screen born in hospitals without an audiologist accounted for 40% (N=334) of the infants who did not receive the follow-up screen for this cohort.

Hospital Birth Rate

Hospital birth rates were grouped into 4 categories. The initial regression analysis on hospital birth rates shows infants born in hospitals that have 2-3000 births are 38% less likely to receive the rescreen at p<.01. Of the 558 infants who did not receive the rescreen this population accounts for 20.4% (N=114). Although the logistic regression analysis did not have interactions with the other variables the hospitals in this cohort do have a higher percentage of volunteers for screening and they require the parents to take responsibility for scheduling the outpatient appointment. Hospitals with <1000 births are 44% less likely to receive the rescreen at p<004. Of the 558 infants who did not receive the rescreen this population accounts for 24.2% (N=135) that were born in hospitals with fewer than 1000 births. These hospitals have refer rates >10% and rescreen rates <79%. These hospitals are located in the rural and frontier areas of Colorado and typically do not have an audiologist involved in the program to provide technical assistance with technology and follow-up

protocols. Increasing the role of the Audiology Regional Coordinator should assist in

decreasing refer rates and increasing rescreen rates.

Level of NICU

The regression analysis shows that infants born in hospitals with a Level 3

NICU are 38% more likely, than infants born in well baby hospitals, to receive the

rescreen. Looking at the rescreen rates alone show that some of the hospitals that have

Level 3 NICU's have rescreen rates <79%. Thirty three percent (185) of infants who

did not receive a follow-up screen were born in hospitals with a Level 3 nursery and

62% of these infants are born in a Level 3 hospital with a rescreen rate of less than

79%. These hospitals have the most vulnerable infants that are high risk for hearing

loss. In addition, infants with low Apgar scores are 54% less likely not to receive the

follow-up rescreen. Christensen, et al. (2007) found that infants who had low Apgar

scores at 5 minutes were also less likely to receive the initial screen. The researchers

suspected that Level 3 NICU's have a significant proportion of out of state residents

and after further investigation this was not the issue. The poor follow-up rate for

NICU infants has been a concern expressed at national meetings. Most hospitals defer

the screening until just before discharge when the infant's health is most improved.

Physicians may discharge the infant sooner than expected. It is often more difficult for

families to return for an outpatient screen when infants have other complex problems.

Current efforts are underway by the Program to meet with audiologist, hospitals, and

physician groups to strengthen the protocol for NICU infants to ensure the hearing

screen is obtained prior to discharge. There is the potential to provide diagnostic

evaluations in the NICU prior to discharge for 3 of the 10 hospitals that have a Level 3

NICU. Although this may be a goal of many professionals it is important that the infants and the family needs are considered first.

Technology

Colorado's newborn hearing legislation does not mandate the type of screening technology hospitals should use in their programs. When Colorado started the newborn screening program most hospitals were encouraged to use AABR due to the lower refer rate and at the time OAE's were not automated. In 2005 60% of Colorado birthing hospitals used AABR only. Hospitals began to replace old technology with new technology that contained both AABR and OAE. This newer technology has the advantages of decreasing the cost of disposables associated with the AABR and using OAE in the well baby nursery. It also provides the hospitals with meeting the recommendations set forth by the Colorado Infant Hearing Advisory Committee and the JCIH for AABR screening in the NICU where there is a higher incidence of auditory neuropathy that can only be detected by AABR.

As evidence in the analysis the recreen rates are poorer when an audiologist is not involved with the programs that use both OAE and AABR. The new technologies were initially wrought with problems. Manufacturers had problems with OAE probes, AABR algorithms, and there was not the technical support present as had been with the original Natus Algo AABR or the Otodynamics OAE equipment. Audiologists who are involved in screening programs have the expertise to work directly with the manufacturers to solve these issues and provide technical assistance to the screening staff. The obvious solution to this problem is increasing the

audiology support to every hospital for technical assistance and training on screening equipment.

Refer Rates

The analysis shows that infants born in hospitals with higher refer rates at discharge are more likely to receive the outpatient rescreen as compared to hospitals that have refer rates <5%. This is not what would be expected. Further investigation found that this was directly correlated to the audiology variable. Hospitals that have an audiologist involved in the program have higher percentages of infants who obtain the rescreen.

The debate over the importance of refer rates have been ongoing since the inception of newborn hearing screening. Colorado prefers to report refer rates based on hospital discharge rather than refer rates based on the outpatient rescreen. In 2005 the average statewide refer rate at hospital discharge was 4.7%. If we calculated those infants who failed the outpatient rescreen that need to be referred to an audiologist for a diagnostic evaluation the 'refer' rate would appear to be only .2% (143 infants who failed the outpatient rescreen/by the entire screened cohort of 67,261). It is this author's opinion that deflating the refer rates only causes harm to newborn hearing screening programs. In this analysis poor rescreen rates were highly related to the whether the infant received the rescreen. To achieve screening programs that meet quality benchmarks requires resources at the hospital, local, and state levels. In Colorado there are no general state funds to support the newborn hearing program. Many states have increased the newborn screening fee to provide funding to the newborn hearing programs. Additional funding would provide audiology support for

hospitals and improve the data management system to track infants more quickly through refer, rescreen, and diagnostic processes. If state or national legislatures perceive that follow-up is not an issue then they will not be interested in funding programs for improvement through grants or state general monies.

Screening Personnel

The screening personnel variable was also directly correlated with whether an audiologist is involved in the program. Since hospitals are not funded to provide the newborn hearing screen it is the hospitals discretion who they choose to use for screening. Of the infants who did not receive the follow-up rescreen 33% (N=185), 28% (N=158), and 39% (215) were born in hospitals that use nurses, technicians, and volunteers, respectively. The initial regression analysis on the follow-up result show that infants born in hospitals that use technicians are 52% (odd ratio=.66) more likely than nurses to receive the rescreen. This would make sense if the responsibility for screening were the technician's job responsibility, as a lab technician's job responsibility is to draw the blood for the newborn metabolic screen. Volunteers were recommended as the choice of screener in the beginning stages of newborn hearing screening. The advent of automated technology did not require an audiologist to perform the screen. There are several hospitals that have been successful with using volunteers if they have an audiologist on site who provides direct supervision and training. The regression analysis shows that there is not a difference in rescreen rates for the screening personnel when rescreen rates are at 80% or greater but when rescreen rates are <79%, hospitals that use volunteers do better in comparison because they typically have an audiologist on staff who has responsibility for the program.

Nurses are the primary screeners in hospitals with lower births and technicians and volunteers are used in the higher birthing hospitals. Again, increasing the support with local audiologists for the smaller or more rural hospitals will be implemented to improve the follow-up outpatient rescreen.

The author is working closely with the National Center for Hearing Assessment and Management to develop training materials for screening personnel. The materials include the importance of early identification and intervention of hearing loss in infants, trouble shooting techniques for screening equipment, how to give parents the results, and the importance of follow-up recommendations.

Scheduling the Outpatient Rescreen

Forty-seven percent (N=262) of the infants who did not receive a rescreen were born in hospitals that schedule the appointment prior to or after discharge. The remaining 53% (N=296) are born in hospitals that ask the parents to call for an outpatient rescreen appointment. The initial regression analysis shows that infants born in hospitals who ask parents to take responsibility for scheduling the outpatient rescreen are 60% less likely to receive the rescreen than if the hospitals takes responsibility. This variable was directly related to the audiologist variable. When infants are born in hospitals without an audiologist involved they are 62% more likely not to receive the outpatient screen.

This is an area for dramatic improvement. Screening programs need to make the recommendation for the follow-up appointment in a manner that families understand the importance of the outpatient rescreens. The Colorado Infant Hearing Program is working with Hands and Voices to develop materials that can be given to

families at discharge that will explain the importance of follow-up from the parents'
perspective. Utilizing the Audiology Regional Coordinators to work with hospital staff
on protocols and materials for the outpatient screen will also be implemented.

Location of the Outpatient Rescreen

Of the 558 infants who did not receive the outpatient rescreen 52%
(N=291) should have returned to the nursery, 44% (N=244) to the audiology
department, and 4% (N=23) to local audiologists. This variable was the crux of the
hypothesis. Although this analysis failed to reject the null hypothesis it did prove that
hospitals which bring families back to the nursery or to the audiology department are
far more likely to have higher rescreen rates and this is further strengthened when an
audiologist is involved in the program. When hospitals have an audiology department,
infants are 27% more likely to receive the outpatient rescreen than returning to the
nursery. In these situations the audiologist is on staff and also supervises and
coordinates the screening program. When hospitals refer families outside the hospital
system for the follow-up rescreen there is a 40% chance the family will not return.

Currently the standard of care and recommendations by the Colorado
Infant Hearing Advisory is to bring families back to the hospital. Several large
hospitals have recently closed their audiology departments and are considering
referring families out to local audiologists. This is of grave concern to the Program as
evidenced by the one hospital that chose this option and had very poor rescreen rates.
There are many issues with this protocol. Families may not obtain a referral from their
PCP for an audiologist who has the capability to appropriately assess infants. Families
will not be familiar with another system and may be less likely for follow through.

Audiologists do not always report their findings even though reporting of hearing loss is required in state statute.

The outpatient rescreens need to be accessible to families without barriers such as language, transportation, or ability to pay. The variable for whether a charge is incurred was not significant but the Colorado Infant Hearing Program does receive phone calls from parents requesting alternatives to the outpatient rescreen when the ability to pay is an issue. Fortunately all of the educational audiologists have OAE equipment and are willing to see these families. Without this option many families would not have been able to receive a rescreen for their infant.

Involving the primary care physicians is a top priority for the Program. As with the newborn metabolic screen, the PCP should be notified when their patient fails the screen or misses the screen. Engaging the PCP to take responsibility for follow-up may improve the rescreen outcomes.

Demographic Variables

Ethnicity

The Hispanic population is most likely not to receive the outpatient rescreen. Hispanic infants accounted for 47.7% (N=261) of the infants who did not receive the outpatient rescreen and Non-Hispanics were 53.2% (N=297) of this cohort. Non-Hispanics are 45% more likely to receive the outpatient rescreen than the Hispanic population. The Program will need to identify ways to improve this process. One Colorado Health Department program improved the weight gain for Hispanic mothers through public service announcements on Spanish-speaking radio stations and

television. The Colorado Infant Hearing brochure is in Spanish but this alone is not enough. Families need to be given the results verbally and in a variety of ways.

Christensen, et al. (2007) found that one Denver hospital had a very high Hispanic population and a very high rescreen rate. Interviews with the audiology staff found that the majority of the families returned to the Denver Health campus for primary care. The primary care physician would send the family directly over to the audiology department for the outpatient rescreen at the two-week well child visit. Although this is a unique situation, providing easier access for rescreens for this population could be made available. A pilot program with one federally qualified health center in Boulder has a trained staff person to perform otoacoustic emissions on infants when they come in for their well baby check. Data has not been obtained to date to determine if this is a successful model for capturing the rescreen on infants who are born to Hispanic or low income families.

Gender

Infant boys are 25% less likely to receive the follow-up rescreen. This analysis demonstrated that gender was correlated to mother's education. At the rescreen rate decreases, males in both mother's education level are more likely to miss the screen. It is important to note that 60% of males did not receive the outpatient screen as compared to 40% of females. This could not be explained by nursery level or ethnicity.

Mother's Education

Thirty-two percent (N=179) and 67.3% (N=368) of infants were born to mothers with > 12 years of education and <12 years of education, respectively. Infants

born to mothers who have 12 years of education or less were 49% less likely to obtain the rescreen. This variable is used to estimate socioeconomic status. As noted in the initial regression 11% of this population was born to teenage mothers. Mother's education and ethnicity shows the Hispanic populations have poorer rescreen rates than Non-Hispanic populations for both levels of education.

The Program must identify resources to ensure that all families have access to the services they need and families understand the follow-up recommendations and the importance. The Boulder County Health Department is targeting teen mothers to ensure their infants receive all the newborn screens and immunizations. The Colorado Infant Hearing Program is going to collaborate with the nurse home visiting program, EPSDT, and local public health nurses to develop strategies for improving the follow-up in these vulnerable populations.

Hypothesis Number 2

Identification of hearing loss by six months of age has proven to be the benchmark for successful language outcomes. This analysis failed to reject the null hypothesis that infants with comorbidities are less likely to be identified early. The regression analysis shows only infants diagnosed with a mixed hearing loss are significant at $p<.03$. They are 3 times more likely to be diagnosed after 6 months of age. This is probably due to challenge of being able to confirm the diagnosis if there is a conductive loss that may be fluctuating and confounding the issue. The average age of diagnosis, for an infant weighing less than 1500gms, is 6.4 months. This is not surprising since these infants are very premature and in the neonatal intensive care unit

for many months. With the exception of the one infant with cytomegalovirus, the remaining variables have a means of less than six months.

Although the analysis failed to reject the null hypothesis there were 102 infants (26%) who were not identified by six months of age. Further research must be completed to identify the reasons for late identification. As noted in the previous hypothesis rescreen rates and the role of the audiologist play a significant part in successful screening programs. The Colorado Infant Hearing Program will need to ensure that infants who fail the newborn hearing screen receive appropriate and timely follow-up with a pediatric audiologist. Enhancing the role of the Audiology Regional Coordinators may provide the additional support to achieve community-based systems for families. The Regional Coordinators and State EHDI staff must work with local hospitals, health departments, audiologists, the CO-Hear Coordinators, and primary care physicians to develop protocols that refer infants only to pediatric audiologists that have the equipment and expertise to diagnose infants effectively and efficiently. Resources must be made available to ensure that every family regardless of ethnic background or income can receive optimal services.

Age of identification for unilateral hearing loss did not show a significant difference when compared to bilateral hearing loss. Yet we know that unilateral hearing loss is often under reported or not referred for a rescreen. The importance of early identification and intervention of unilateral hearing loss is known and further education to audiologists and physicians will be needed to ensure these infants also receive timely and appropriate follow-up.

Conclusion

This research failed to reject the null hypothesis for both questions. The first question postulated there would be higher rescreen rates for hospitals that had a follow-up protocol where families returned to the nursery for the outpatient rescreen appointment. The analysis has shown that rescreens rates and whether an audiologist is involved with the screening program is the most significant factors for families returning for the follow-up appointment. Hospitals have higher rescreen rates when they implement a protocol requesting the families return to either the nursery or audiology facility on site. Hospitals that have an audiologist involved in the program have better rescreen rates for technology, screening personnel, nursery level, refer rates and rescreen rates.

The second question was to determine if infants with comorbidities were more likely not to be identified by three months of age. The analysis failed to reject the null hypothesis and found there was not a significant difference between age of identification for infants with comorbidities, degree of hearing loss, type of hearing loss, ethnicity, gender, nursery level, and mother's age at birth. The analysis did show that 26% of the infants in the cohort of 386 were identified after six months of age. Further research needs to investigate the factors associated with late identification.

The Colorado Infant Hearing Program has been a model nationally and internationally. This has been achieved by the dedication and collaboration of strong leaders in audiology, pediatrics, early intervention, parents and state agencies. Hospitals have achieved a high screening rate considering there are no state funds to

support their programs. The issue is screening alone will not provide the positive outcome of early identification.

Developing a comprehensive system from screening through diagnosis requires a data management system that can monitor hospital, audiology, and early intervention outcomes to identify gaps in every aspect of the process. The current analysis was only possible by the data integration efforts with the electronic birth certificate though funding from the CDC. There needs to be continued efforts and resources to enhance data integration efforts. Automating the reports between hospitals and the Program will increase efficiencies and decrease paper and FTE for both the hospital and the State. Obtaining the screening results electronically will expedite the results to the State and then directly to primary care physicians who can help with ensuring their patients receive follow-up, as they do for the newborn metabolic screens. Automation between audiologists and the State will make the reporting processes more efficient and provide better data. As noted on the first page of the results there were 59 (52%) of the infants confirmed with a hearing loss designated as missing the rescreen. There is a high probability that these infants skipped the rescreen and were evaluated by an audiologist after discharge, but the data is unclear.

This research has shown the importance in achieving high rescreens rates by establishing a protocol that brings the family back to the hospital for a rescreen. This analysis has demonstrated that rescreen rates are critical for ensuring that infants receive a follow-up screen. We can not be content with an 80% rescreen rate that will

make it twice as likely an infant will not receive follow-up. Our goal should be to achieve 95% or greater.

This research also confirms that having an audiologist involved with the program is significant to hospital outcomes. Providing technical assistance from a trained audiologist will give the hospital staff the expertise in improving follow-up outpatient rescreen rates and eventually led to earlier diagnosis. Audiologists can provide consistent training to new screening staff on how to troubleshoot equipment. They can work with the staff and primary care physicians to establish follow-up protocols for families when the infant fails the outpatient rescreen to ensure they are referred to a pediatric audiologist.

Several hospitals have the audiology capability to provide diagnostic evaluations and early interventions for these infants prior to discharge. Nance and Dodson (2007) suggest that all infants should be diagnosed at birth and begin early interventions (including genetic testing and counseling) immediately before discharge. Although this may be the future goal of some professionals it is important that we always consider the needs of the family and the infant first. This is also not a realistic goal for the majority of Colorado hospitals that do not have an audiology department or a pediatric audiologist in their community. The future of technology in diagnostic equipment and telemedicine may provide real solutions for the concept of diagnosis before discharge.

This research focused on hospital births but home births also need to be addressed. Currently in-services are provided to midwives about the importance of newborn screening and where their families can obtain a newborn hearing screen. The

State has purchased OAE equipment for every health department so families have an option for obtaining a free rescreen. The screening of home births has improved over the years from 0 to 17.6% in 2005. Additional OAE equipment was recently purchased to train midwives with the assistance of the Audiology Regional Coordinators. Future data will demonstrate if this is a feasible model.

Engaging the medical home or primary care physician is the next important step to ensure families receive the follow-up recommendations from screening to diagnosis. The Colorado legislature recently passed an immunization registry bill that has the potential to notify the primary care physician of the newborn metabolic and newborn hearing screening results. Until the logistics of this can be figured out the Program is going to send letters to primary care physicians notifying them when an infant fails or misses a newborn hearing screen. The Follow-up Coordinator is going to call families for all infants who fail the outpatient screen and assist them in obtaining a diagnostic evaluation.

Future considerations at the national and state level are looking into the feasibility of using the newborn blood spot screen to diagnosis infants with CMV. Fowler et al. (1999) have demonstrated CMV is the most common cause of non-genetic deafness. CMV may account for a high proportion of infants who pass the newborn hearing screen and are later identified with hearing loss. The technology is currently available on the blood spot screen but there needs to be more research to discern how positive CMV results will be followed since many infants will not develop hearing loss.

The advancement in genetic research also provides families the opportunities to further identify the cause of their infants hearing loss. Currently Colorado has a genetic counselor who provides families with counseling and information. Additional funding resources are needed to implement the capacity for all families to receive this valuable information and genetic testing if they choose.

The social and economic disparities for newborn hearing screening must be addressed. Hispanic families are at much higher risk for not obtaining a rescreen. There are many opportunities to improve the follow-up rescreen rates by targeting Hispanic families and low socioeconomic families with materials and resources. Local Healthcare Programs for Children with Special Needs (HCP) are available to provide care coordination to families. They can assist the family with enrolling the infant into Medicaid and referring families to services that accept Medicaid reimbursement. Cultural competency is an issue in every aspect of public and private health. Resources are needed at every level from screening through early intervention to have professionals who can speak the language of the family and understand their culture. The CDPHE is developing classes on ethnic disparities and cultural competency. These and other trainings can be offered to professionals that work with these populations to improve the outcomes in screening, diagnosis and early intervention.

Newborn hearing screening has improved the lives of families and children who are deaf and hard of hearing. It has been the greatest achievement in public health over the past ten years. This research has shown we still have a long way to go to develop truly comprehensive systems of care that are community based and culturally competent for all the families we serve. The importance of an audiologist intimately

involved with screening programs will undoubtedly help to improve the rescreen rates

and ensure infants are identified three months of age.

APPENDIX A

Historical Perspectives of Newborn Hearing Screening

This appendix provides the reader with a detailed history of previous screening technologies and recommendations that paved the path for the current Early Hearing Detection and Intervention Programs.

Behavioral Observation. Ewing and Ewing (1944) described the quality of a deaf infants voice using gramophone recordings is indistinguishable from a hearing infants voice during the first year of life. They stressed the importance of identifying deafness in early infancy to begin early intervention such as lip-reading while the infant is in close proximity to care-givers, before the infant begins walking and expanding their world. The authors categorized infant responses to speech and noise maker stimuli using behavioral observation such as eye widening and blinking graduating to head turns as the infant became six months or older. Froeschels and Beebe (as cited by Downs, 2000 and Hayes, 2003) first describe the auropalprebral reflex to sound.

Downs and Sterritt (1967) promoted the early identification of infants optimally before six months of age to provide the opportunity for medical and educational intervention. They trained volunteers in seven Denver hospitals to observe newborns responses to auditory stimuli. They used sound generators, also know as Warblets, that produced an acoustic signal around 3000Hz at high intensity levels of 70-100dB. The sound was presented 4-10 inches from the infant's ears. The goal was to identify hearing loss in infants who had moderate to severe hearing losses. The trained observers worked in pairs with one holding the Warblet while the other

observer looked for an eye blink response or auropalpebral reflex, cessation of activity or arousal response. The responses were recorded on a five-point scale from no response to more response. If the response was questionable, slight or not present the screen was repeated. The results were placed in the infants chart. If there were no responses to the second screen the infant was referred to the audiologist for an auditory electroencephalographic evaluation (the precursor to the auditory brainstem response). If there was not an audiologist on site the physician was notified and the volunteer contacted the physician at six weeks to determine the outcome of any follow-up testing. The authors suggested that for tracking purposes the hearing screens should be placed on the same card as the PKU screens. The similarities between the universal hearing screening programs then and today are astounding. Many hospitals today are using either the PKU (newborn blood spot screen) or electronic birth certificate to track hearing screening results. Downs and Hemenway (1969) published screening results of 17,000 infants and found 17 with hearing loss. Bergstrom, Hemenway and Downs (1971) discuss the disadvantages of behavioral observation screening associated with false negatives due to high frequency configurations or permanent conductive hearing losses. Their findings of 1/1000 infants with hearing loss are similar to the incidence figures cited in the literature today from statewide screening programs (Centers for Disease Control, 2006). It is no wonder that Marion Downs is considered the 'godmother' of infant hearing screening.

Crib-O-Gram. The Crib-O-Gram was developed by Simmons and Russ (1974) to decrease the observer error associated with behavioral testing using the warblet. The equipment was designed to present a 3000Hz sound at 92dB SPL to the

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infant. A motion sensitive transducer was placed under the mattress to detect a startle response. A strip chart recorder printed out the infant's activity prior to and following the stimulus presentation and was manually. Cox (1988) describes the false positive rate as being 8% in the well baby and 20% in the Neonatal Intensive Care Unit (NICU). Although the Crib-O-Gram became more automated, eliminating the manual scoring, there were later concerns about the validity of the equipment when compared to auditory brain stem response (ABR) testing (Durieux-Smith, Picton, Edwards, Goodman, and MacMurray, 1985). The researchers found that one-third of the infants with normal ABR responses failed the Crib-O-Gram and that only severe to profound losses were identified. The Crib-O-Gram also failed to detect unilateral hearing losses.

Auditory Response Cradle. Tucker and Bhattacharya (1992) describe the use of Auditory Response Cradle (ARC) on 6000 infants. The ARC is a fully automatic microprocessor that was designed in Great Britain. The ARC has a pressure sensitive mattress and headrest that monitors head turn, head startle and body activity. The baby's respiration activity is monitored using a polyethylene band over the abdomen. A high pass band noise is presented bilaterally via earphones at 85dB SPL. The high pass band noise was used to detect the more common congenital hearing losses in the high frequency regions. The infants motor and respiration responses are detected automatically and stored in the microprocessor. The ARC also has the capability to present an equal number of silent trials to determine if the baby's responses are to the stimuli rather than spontaneous movement. The baby is considered a 'pass' when 97% of the responses, within 10 trials, are not by chance. The baby 'refers' when this

criteria is not met. The screening procedure ranged from 2-10 minutes. Infants who

failed 2 screens were referred for an audiometric evaluation consisting of ABR, OAE,

and acoustic reflex testing. The results of this research showed an initial 8.1% fail rate

that was reduced 1.7% (N=102) after the second screen. Seventy-nine (1.3%) were

determined to have normal hearing following the audiolologic evaluations indicating

the false positive rate of the ARC screening procedure. Twenty infants were found to

have hearing loss, which included 5 with conductive hearing loss. The cohort was

followed for three years and an additional 7 children were found to have permanent

hearing loss. This technique showed great promise but the objective measures of

otoacoustic emissions and auditory brainstem response techniques that were emerging

simultaneously based on physiologic responses are considered more reliable.

High Risk Registries. A national committee on neonatal hearing screening,

chaired by Marion Downs was formed in 1968 (Northern and Downs, 1991, and

Downs, 2000), and lead to the development of the Joint Committee on Infant Hearing

(JCIH). The JCIH has had an international influence on the screening of newborns.

Originally the committee was comprised of members from the American Speech and

Hearing Association, the American Academy of Ophthalmology and Otolaryngology,

and the American Academy of Pediatrics. Later, the American Academy of

Audiology, the Council on Education of the Deaf, and the Directors of Speech and

Hearing Programs in State Health and Welfare Agencies joined this prestigious group.

In 1973 (JCIH, 1982) the Joint Committee on Infant Hearing Screening recommended

using five criteria for identifying infants at risk for hearing loss. The Committee did

not recommend universal screening of all infants using 'acoustic testing' due to the

high false positive and false-negatives.   In 1975, Mencher (as cited in Mahoney, 1984) recommended that all infants should be universally screened using the JCIH five criteria. He also recommended that the World Health Organizations, national and local governments legalize a program of infant screening. In 1982 the JCIH expanded the criteria to six criteria (family history of childhood hearing loss, congenital perinatal infections, anatomical malformations involving the head or neck, birth weight less than 1500 grams, hyperbilirubinemia at level exceeding indications for exchange transfusion and bacterial meningitis). In addition the Committee recommended the use of auditory evoked potentials, as part of the audiometric evaluation, for those infants who were identified as high risk. This began the evolution of screening infants with electrophysiological measures rather than behavioral testing.

In 1982 the Directors of Speech and Hearing in State Health and Welfare Agencies (DSHPSHWA) convened in Toronto, Ontario (Mahoney, 1984). Various states and territories presented their high-risk programs. The Colorado Department of Public Health was cited as having a statewide program implemented by the Colorado Department of Health, Hearing and Speech Services. Twenty participating hospitals reported infants that were high risk to the Health Department. When the infant turned six months of age the parents were sent a letter that described speech and language milestones and appropriate behaviors. If an infant was not demonstrating these behaviors a free hearing screening was offered. Due to the lack of statewide pediatric audiologists, Hal Weber developed a portable visual reinforcement unit that was used in the Health Department Otology Clinics across the state. Infants who were

identified with "serious" hearing losses were enrolled in the Home Intervention

Program. The health department program though did not document tracking and

follow. DSHPSHWA members met again in 1984 and recommended the universal

implementation of the 1982 JCIH position statement. They also stressed the need for

more training in pediatric audiology.

Mahoney and Eichwald (1987) estimated that 15% of infants were subjected to

the high risk register but less than half actually were tested for hearing. High risk

registries were also plagued with high false-positive information on family history.

Research demonstrated that the high risk register criteria recommended by the JCIH

identifies only 50% of infants with significant hearing loss (Mahoney and Eichwald,

1987; Mauk and Behrens, 1993; Mehl and Thomson, 2002). Mauk, White, Mortensen

and Behrens (1991) studied a cohort of 70 children ages 6-9 years of age enrolled in

the Utah School for the Deaf. Utah had implemented high risk criteria into the birth

certificate this allowed the researchers to retrieve data regarding the neonatal high risk

status. Data was collected from parents/guardians using a telephone survey on the

auditory related behaviors during the early months of life; actions of the professionals

who parents first contacted because of concern for their child's hearing; age of

suspicion of hearing loss; age of confirmation of hearing loss; age of amplification;

and age of habilitation. Results supported other findings, that 50% would not have

been identified through the high risk register. Only 33% of parents whose children

were contacted as having risk factors at birth requested an appointment for an

audiological evaluation and only one third of those parents followed through with an

appointment. Most of the parents did not respond or responded that they had no

concerns. The age of suspicion of hearing problems and age of confirmation was as high as eight months. This corroborates with findings from Harrison and Roush (1996) when they revealed that there is a substantial delay between parent suspicions of hearing loss and the identification and early intervention of hearing loss.

The JCIH 1990 Position Statement once again expanded the high-risk criteria to include stigmata or findings associated with a syndrome known to include sensorienural hearing loss and prolonged mechanical ventilation for duration equal to or greater than 10 days.

Federal initiatives to support newborn hearing screening began as early as 1965 with the Babbige Report, which recommended "universally applied procedures for early identification and evaluation of hearing impairment" (CDC, 2006). The Babbige Report was in response to the poor educational outcomes of children who were deaf. The National Conference on Education of the Deaf was held in 1967 and recommended a high risk register be implemented and the cost-effectiveness of screening all children ages 5-12 months should be investigated. Twenty years later, the Commission on Education for the Deaf reported that the average age of identification was still 2.5 years and "the Department of Education and the Department of Health and Human Services should issue federal guidelines to assist states in implementing improved screening procedures for live births" (Mauk and Behrens, 1993). As a result an advisory group on early identification of children with hearing impairment convened and recommended that demonstration projects on the feasibility of universal newborn hearing screening be implemented. In the same year, 1988, General

Surgeon, C. Everett Koop issued the Healthy People 2000 Initiatives that stated all children with significant hearing loss should be identified by 12 months of age.

Johnson, Mauk, Takekawa, Simon, et al. (1993) detailed the status of state sponsored early identification programs in the late 1980's. They acknowledge that programs must go beyond screening to include a system of early intervention, family support, audiological and medical services. The authors used the findings from Blake and Hall (1990) on the status of statewide hearing screening programs and updated the information with telephone interviews. Sixteen states had a legislative mandate for newborn hearing screening but only 9 of those states were actually operating some form of a program. An addition 14 states had programs without a mandate but only six had any aspect of an operational program. The majority of the programs focused only on NICU infants or if an infant had one of the JCIH (1982) risk criteria. In the 1980's, 20 Colorado hospitals reported high risk factors to the Colorado Department of Pubic Health and Environment (CDPHE), Health Care Program for Children with Special Needs (HCP). There was not a system to track these infants to assure they received any form of follow-up or an audiological evaluation. It was estimated that nationally, only 3% of the total population was being screened using the high risk register and receiving subsequent follow-up. This indicated the United States had a long way to go to reach the challenge put forth by Dr. C. Everett Koop.

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