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Maria Goldenberg

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**NEWBORN HEARING SCREENING: A RETROSPECTIVE
ANALYSIS OF HIT AND FALSE POSITIVE RATES IN
THE NICU AND HOW THEY ARE INFLUENCED BY RISK
FACTORS FOR HEARING LOSS IN A SUBURBAN
BIRTHING HOSPITAL**

by

Maria Goldenberg

**A Capstone Project
submitted in partial fulfillment of the
requirements for the degree of:**

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Approved by:

**William Clark Ph.D., Capstone Project Advisor
Christina Koehler M.S.S.H., Capstone Project Advisor**

Abstract: The purpose of this study was to evaluate the effectiveness of a hearing screening program, particularly focusing on hit and false positive rates in the NICU and WBN at a top-rated birthing hospital in Saint Louis, MO. Additionally, the study examined how these rates may be influenced by risk factors for hearing loss.

INTRODUCTION

Early identification and management of hearing loss has been recognized to have positive results on the development of auditory, speech and language acquisition (Flynn et al, 2004). Universal Newborn Hearing Screening (UNHS) has developed rapidly throughout the years and 37 states now implement UNHS. This growing trend of hospitals establishing UNHS programs has sparked debates among health care providers as to the benefits, costs and risks of such programs (Barsky-Firkser and Sun,1997).

An issue that has kept some providers skeptical of UNHS is the high rate of false-positive results. False-positive results have been suggested to cause emotional stress for the families of newborns until a final diagnosis is determined (Mason and Herrmann, 1998). In addition to emotional distress, a high false-positive rate can cost the hospital additional expenses of time and money for re-screening. Literature has reported false-positive rates of approximately 2.5%-8% and a poor positive predictive value of 4.0%-12% in some UNHS programs (Clements and Davis, 2001). Clemens and Davis (2001) stated that “if there are an estimated 4 million infants that receive UNHS each year, a likely 3% false-positive rate would affect 120,000 infants which would lead their families to uncertainty of their hearing health and require a follow-up”. David Luterman (2000), has been a strong advocate against UNHS, and stated: “audiologists may be providing more harm than good.” He reports that a potential adverse affect of a false-positive screening test is parental anxiety. Luterman states, “It is likely that some families are actually harmed emotionally due to the significant high false positive rates and the lengthy period of time between true identification and intervention.” Furthermore, he adds, “some people may lose faith in medical and audiological professionals as a result of

the early, often inaccurate introduction to our professions.” On the other side, supporters of the UNHS have substantial evidence to prove that UNHS is beneficial and necessary in order to catch hearing loss prior to 3 months of age. Yoshinaga-Itano (2000) found that children who were born in hospitals that implemented UNHS and were identified as having a hearing loss before 6 months of age had significantly higher speech and language development than children born in hospitals that did not implement UNHS. A study conducted at a British birthing hospital (Watkins et al, 1998) surveyed parents whose infants failed the initial screen and received a second test (3.5% total). Parents reported that they were very worried about their child’s hearing status, but were glad to have the screening performed on their infant. In another study in Wessex, parents whose babies were screened reported the same amount of anxiety and attitudes to those parents whose children were in the unscreened group. Clements, Davis and Bailey (2000) examined the false-positive results of one UNHS program so as to investigate if the false-positive rate produces a lasting maternal anxiety toward their children. Forty-nine out of 76 eligible mothers of non-NICU infants who had failed the initial screen and passed the outpatient re-screen completed the maternal anxiety survey. Of the 49 participating mothers, an estimated 80% reported that they worried about their child’s hearing before follow-up. Ninety-one percent reported that they did not treat their children differently during this time. The remaining nine percent stated that they spoke more loudly to their infant or clapped their hands to test their child’s hearing. After the second stage of screening was completed as an outpatient, 86% of mothers reported no lasting anxiety with only one mother reporting “much anxiety.” In summary, the majority of mothers,

94%, felt that hearing screenings were a good idea and were glad that their children received a hearing test prior to discharge.

BACKGROUND INFORMATION: HEARING SCREENING PROGRAMS

The American Academy of Pediatrics task force on newborn and infant hearing (1999) states that to justify universal screening, at least five criteria must be met.

1. An easy-to-use test that possesses a high degree of sensitivity and specificity to minimize referral for additional assessment is available.
2. The condition being screened for is otherwise not detectable by clinical parameters.
3. Interventions are available to correct the conditions detected by screening.
4. Early screening, detection, and intervention result in improved outcome.
5. The screening program is documented to be in an acceptable, cost-effective range.

The academy reports that a minimum of 95% of newborns must be screened successfully in order for UNHS programs to be considered effective. The methodology used in screening should have a false-positive rate of $\leq 3\%$ with a referral rate for formal audiologic testing after screening not to exceed 4% for the well baby nursery (WBN) and 10% for Neonatal Intensive Care Unit (NICU) nursery.

Evidence has suggested that the use of a well-designed hearing screening program can accurately identify those babies with hearing loss, thus reducing the devastating consequences of having a language delay. Establishing a well-organized screening program requires a thoroughly planned protocol, a well trained staff and the appropriate intervention as well as management of referrals (Iley and Addis, 2000).

OBJECTIVES:

This is a multi-purpose, retrospective study that examines the effectiveness of a hearing screening program, particularly focusing on the hit and false positive rates in the NICU and well baby nursery (WBN) population in a large suburban birthing hospital. Additionally, the study looked at various risk factors for hearing loss in the NICU population to determine if the hit/false positive rates may be influenced by these risk factors. Furthermore, this study documents whether the hearing losses are bilateral or unilateral to determine if there is right or left ear dominance for hearing loss.

RISK FACTORS FOR HEARING LOSS

The Joint Committee on Infant Hearing-2000 Position Statement identified the following risk factors as indicators associated with sensorineural and/or conductive hearing loss. Any infant with these risk factors for progressive or delayed-onset hearing loss who has passed the birth screening should, nonetheless, receive audiologic monitoring every six months until age three years.

1. Parental concern regarding speech, language and hearing.
2. Family history of permanent childhood hearing loss.
3. In-utero infection such as toxoplasmosis, rubella, cytomegalovirus, syphilis and herpes.
4. Craniofacial anomalies, including those with morphological abnormalities of the pinna and ear canal.
5. Birth weight less than 1500 grams
6. Hyperbilirubinemia at serum level requiring exchange transfusion.
7. Ototoxic medications, including but not limited to the Aminoglycosides, used in multiple courses or in combination with loop diuretics.

8. Bacterial meningitis.
9. APGAR scores 0-4 at 1 minute or 0-6 at 5 minutes.
10. Persistent pulmonary hypertension of the newborn associated with mechanical ventilation, and conditions requiring the use of extracorporeal membrane oxygenation lasting 5 days or more.
11. Stigmata or other findings associated with a syndrome known to include a sensorineural and/or conductive hearing loss.

METHODS:

The data for this project came from archival information of a particular newborn hearing screening program between the years of 2002-2005. This information includes all infants who were born and received their initial hearing screening at this particular birthing hospital. A chart review was performed on all babies that “referred” on the initial screen and later returned for follow-up diagnostic testing as an outpatient. Specifically, the chart review included the screening device used, any risk factors that are related to hearing loss, type and degree of hearing loss if any, and the ear/ears in which hearing loss was found.

Program Overview

The program’s protocol for both the NICU and WBN states that all babies must be screened prior to discharge from the hospital. This hospital implements a two-stage screening process. For the NICU babies, stage one uses an automated Auditory Brainstem Response (ABR) and for WBN, stage one utilizes automated Otoacoustic Emissions (OAE’s). These stage one tests require no interpretation and are performed by either an audiologist, hearing technician or student. The details of these procedures will further be discussed in the screening procedure section of this paper. For the NICU protocol, if the

infant refers on the initial automated screen, a non-automated ABR (Viking ABR system) is implemented prior to discharge in order to reduce the number of infants that require outpatient testing. The results of the non-automated ABR are interpreted by an audiologist at least one day after initial refer. This is considered stage two of the screen. If a second “refer” result is obtained on the non-automated ABR, then the baby is scheduled as an outpatient for a diagnostic test within 2-3 weeks after discharge. If the baby is discharged from the hospital before it receives a second stage screen, as sometimes happens during weekend discharging, the parent(s) and pediatrician are notified, and the program schedules them as an outpatient. All information pertaining to the baby is placed in a database and the results are given to the parent(s) and pediatrician, and are also sent to the state health department. If the baby passed the initial screen but shows risk factors for hearing loss such as a syndrome or family history, it is recommended that a 6-8 month follow-up appointment be scheduled to monitor for changes in hearing status. A reminder letter is sent to the parent(s) in 6 months to ensure that a follow-up appoint is made and appropriate follow-up assessment can be conducted.

Screening Procedure

The screening procedure for babies that are admitted to the NICU is different from the babies that are admitted into the WBN. For babies that are admitted to the NICU, the screening will take place at bedside in the NICU nursery when the attending physician considers the baby ready and stable. For both NICU and WBN, screening is performed at least 24 hours after birth. A thorough chart review is performed on each baby. The baby’s information including gestational age at birth, birth-weight, risk factors for hearing loss and any other additional information such as maternal substance abuse

are recorded. An automated auditory brainstem response (AABR) is utilized in the NICU. An AABR is an electrophysiological measurement that is used to assess auditory function from the VIII cranial nerve through the auditory brainstem. The AABR measurements are obtained by placing pre-gelled snap electrodes on each mastoid and on the forehead of the baby. This is the standard one-channel ABR montage. A small probe is placed into the infant's ear and a handheld, portable AUDIOScreener (Grason Stadler) delivers a 35dB nHL click stimulus. The impedances for this system should be less than 10 KOhms, with an interelectrode impedance no greater than 5 KOhms. The device determines the presence of the response by ascertaining if the measured ABR signal-to-noise ratio exceeds a specified criterion. The ABR signal-to-noise ratio is based on the magnitude of the response when the stimulus is present (signal) divided by the magnitude of the response when the stimulus is not present (noise). The signal to noise ratio (Fsp) is evaluated with the F statistic using a value at a single point in the ABR waveform (Smith, 2001). In babies who have an ABR, the measured response is larger than the noise. For this device, an Fsp criteria is set to default at 3.2. The Fsp value for each response is based on an average of 16000 sweeps. If the Fsp value is 3.2 or greater a "pass" response is received. After the test is completed, a copy of the results is placed in the baby's chart for the attending physician. If the baby bilaterally passes the screen, a copy of the results is also placed in the infants crib for the parents.

For babies that are admitted into the WBN baby nursery, screening takes place in a quiet room specifically designated for hearing tests. Similar to the NICU, a chart review is performed for each baby, and unless an infant has been identified with risk factors for hearing loss, testing is conducted utilizing distortion product otoacoustic emissions

(DPOAE's). Otoacoustic emissions are used to assess cochlear integrity and are physiologic measurements of the response of the outer hair cells to acoustic stimuli. The WBN uses the Clarity screening system (SonaMed Corp) that can dispense both DPOAE's and ABR's within the same system. For DPOAE's the intensity levels are 65 and 55 dB SPL. DPOAE's are conducted for 2000, 2500, 3200, 4000 and 5000 Hz. Passing criteria is four out of five frequencies. If the baby fails DPOAE's, an ABR measure is performed. The ABR measurements are obtained by applying pre-gelled electrodes at the forehead and the nape of neck, and a ground electrode on the shoulder to serve as ground. The Clarity system compares the infant's waveforms with a template from the appropriate normative data and on the basis of this comparison a pass or fail response is determined. If the baby passes, results are given to the parent(s) and pediatrician. If the baby refers, an attempt to re-screen is made the following day if the baby is still in the hospital. If the baby refers the second time or is discharged before the re-screen is performed a follow-up appointment 2-3 weeks following discharge is scheduled prior to discharge.

RESULTS:

Table 1 presents aggregate data for the NICU nursery between the years of 2002-2005. The outcome measures include the number and percent of infants screened for each year of the program, the number of infants that required a referral as an outpatient, the referral rate of the program for each year and the percentage of infants that returned for follow-up. The table also shows the number of babies that were identified with a hearing loss. The false positive rate in percent is calculated as well as the positive predictive

value for each year. Sensitivity of this screening program could not be assessed because the number of false-negatives (those infants passing the initial screen and later identified with hearing impairment) was not collected. The true negative results were “assumed” to be truly- true negative in order to calculate specificity.

A total of 3,480 babies or 99.6% were screened between the years of 2002-2005 for the NICU. The 99.6% screen results met the Joint Committee on Infant Hearing (JCIH) and American Academy of Pediatrics (ACP) guidelines of screening at least 95% of all babies admitted to the NICU. Over the four-year period, 140 infants failed the screening. This is a referral rate of 3.9%, which is well within the recommended JCIH, and ACP guidelines of less than 10% referral rate in the NICU. Of the 140 infants, 135 or 98% returned for follow-up evaluation. The babies that did not return for follow-up (2%) are considered “lost to follow-up”. The parents of these babies may have opted to receive their follow-up evaluation at another facility, moved out of state, or just chose not to return for follow-up and did not contact the program with their results. Over the 4-year period, 35 babies were identified with hearing loss requiring intervention.

Year 2002 was the best year in terms of referral rate, return for follow-up rate, the percent of false-positive calculated and the predictive value. The program screened 99% of all infants and had 14 babies that required follow-up as outpatients. All 14 infants returned for follow-up. The referral rate for 2002 was 1.8%, which fell well below the recommended guidelines of less than 10%. The positive predictive value was 57%, which substantially exceeds the reported 4-12% predictive value found in the literature. The false positive rate of 1.75% is also well within the JCIH guidelines of less than 3%.

Year 2002 was the first year this hospital implemented a UNHS program and it had met all the requirements of an early hearing detection and intervention program according to JCIH.

Year 2004 was the least successful of the four years. A total of 919 infants were screened (99.7%) and 51 of those infants required follow-up as an outpatient. This is a referral rate of 5.5%, which is still within the guidelines; however, out of the 49 babies that returned for follow-up (98%), only eight were confirmed to have a hearing loss. This is a false positive rate of 6.1%, which is above the recommended 3% rate. Additionally, the positive predictive value was 16%, a 41% difference compared to 2002. Overall the program showed to be effective with an average referral rate of 3.9% for the combined four years. The false positive rate of 3.8% slightly exceeds the recommended 3%, but is towards the low end of the 2.5-8% rate that is reported in the literature.

| | NICU DATA | 2002 | 2003 | 2004 | 2005 | TOTAL |
|----|----------------------------|-------------|-------------|-------------|-------------|--------------|
| A. | Total screened | 773 | 840 | 919 | 948 | 3480 |
| B. | % of infants screened | 99% | 99.9% | 99.7% | 99.9% | 99.6% |
| C. | N refers for follow-up | 14 | 31 | 51 | 44 | 140 |
| D. | Referral rate | 1.8% | 3.7% | 5.5% | 4.6% | 3.9% |
| E. | % Return for follow-up | 100% | 100% | 98% | 93% | 98% |
| F. | N of babies return for f/u | 14 | 31 | 49 | 41 | 135 |
| G. | N babies identified w/HL | 8 | 9 | 8 | 10 | 35 |
| H. | N babies w/o HL | 6 | 22 | 41 | 31 | 100 |
| I. | False positive rate in % | 1.75% | 3.4% | 6.1% | 4.1% | 3.8% |
| J. | Positive predictive value | 57% | 29% | 16% | 24% | 31.5% |
| K. | Specificity | 99.2% | 97.3% | 95.4% | 96.6% | 97% |

Note: The TOTAL column for D, E, I-K is based on the average of the 4 years.

Table 1.

For the WBN the collective data is summarized in Table 2. For the year 2005, the parents of three babies refused to have their newborns screened. A total of 24,383 babies, or 99.9% of all babies, were screened between the years of 2002-2005. These results met the Joint Committee on Infant Hearing (JCIH) and American Academy of Pediatrics

(ACP) guidelines of screening at least 95% of all babies admitted to the WBN. Over the four-year period, 229 infants failed the screening. This is a referral rate of 1.34%, which is well within the recommended JCIH and ACP guidelines of less than 4% referral rate in the WBN. Of the 229 infants, 224 or 99% returned for follow-up evaluation. As in the case of NICU, babies that did not return for follow-up (1%) are considered “lost to follow-up”. Over the 4-year period, 24 babies were identified with hearing loss requiring intervention.

Unlike the NICU, the year 2004 was the best in terms of referral rate, return for follow-up rate, the percent of false-positive calculated and the predictive value. The program screened 100% of all infants and had 28 babies that required follow-up as outpatients. All 28 infants returned for follow-up. The referral rate for 2004 was 1.38%, which fell well below the recommended guidelines of less than 4%. The positive predictive value was 35% and proved that this was a successful year for the WBN. The false positive rate of 2.6% is also well within the JCIH guidelines of less than 3%.

Last year, 2005, was the least successful of the four years. A total of 6,563 infants were screened (99.9%) and 129 of those infants required follow-up as an outpatient. This was a referral rate of 1.96%, which is still within the guidelines, however out of the 126 babies that returned (98%) only four were confirmed to have a hearing loss. This is a false positive rate of 31.5%, which is significantly above the recommended 3% rate. Additionally, the positive predictive value is .03%, demonstrating a very poor prediction of outcome. There are some factors that may have contributed to the high false positive rate for 2005. First, the pass criteria was lowered from 35 dB nHL to 30 dB nHL which increased the referral rate from the previous years. Additionally, the Clarity (ABR/OAE)

system manufacturer introduced a new upgraded template, which was later found to have “glitches” in the software. This could have caused a higher number of babies to refer. Although it is difficult to pinpoint the exact cause of the high false-positive and refer rates, the factors listed above should be taken into consideration when reviewing data for 2005. Over the four-year period, the WBN program maintained a referral rate of 1.34% and screened 99.9% of all newborns. The false-positive rate of 12.3% was higher than recommended and should be evaluated so as to reduce this rate in the future. Compared to the WBN, the NICU had better outcomes in both false positive rates and in positive predictive values.

| | WBN DATA | 2002 | 2003 | 2004 | 2005 | TOTAL |
|----|----------------------------|-------------|-------------|-------------|-------------|--------------|
| A. | Total screened | 5,543 | 5,819 | 6,458 | 6,563 | 24,383 |
| B. | % of infants screened | 99.9% | 99.9% | 100% | 99.9% | 99.9% |
| C. | N refers for follow-up | 34 | 38 | 28 | 129* | 229 |
| D. | Referral rate | 1% | 1% | 1.38% | 1.96% | 1.34% |
| E. | % Return for follow-up | 100% | 100% | 96% | 98% | 99% |
| F. | N of babies return for f/u | 34 | 38 | 26 | 126 | 224 |
| G. | N babies identified w/HL | 6 | 4 | 10 | 4 | 24 |
| H. | N babies w/o HL | 28 | 34 | 16 | 122 | 200 |
| I. | False positive rate in % | 5.6% | 9.5% | 2.6% | 31.5% | 12.3% |
| J. | Positive predictive value | 18% | 11% | 35% | .03% | 16% |
| K. | Specificity | 99.4% | 99.4% | 99.7% | 98.1% | 99.2% |

* 3 refused screening

Note: The TOTAL column for D, E, I-K is based on the average of the 4 years.

Table 2.

False-positives

In order to estimate the true incidence of hearing loss in the NICU populations between the years of 2002-2005, the number of infants identified as having a hearing loss is divided by the total number of infants screened. The estimated incidence of hearing

loss in a population is 10 per 1000 infants in the NICU nursery for the years of 2002-2005. For the WBN that incidence is 1 per 1000 infants between the years 2002-2005. As previously mentioned, data on false-negative tests was not collected, therefore sensitivity of this screening program could not be evaluated. A good screening program is one that has both high sensitivity and specificity. The specificity of the program was very high for both NICU and WBN. For the NICU, specificity for the four years was 97%, for the WBN specificity was 99%.

Risk factors in NICU

Babies confirmed to have a hearing loss were examined and recorded as either having or not having risk factors for hearing loss. These results are presented in Figure 1. For all years, excluding 2002, more babies were found to have a risk factor associated with hearing loss and a confirmed hearing loss than those babies with no risk factors. The percent of NICU infants identified as having a hearing loss who had no reported risk factors was 34% between the years of 2002 and 2005 compared to 66% of infants who had risk factors.

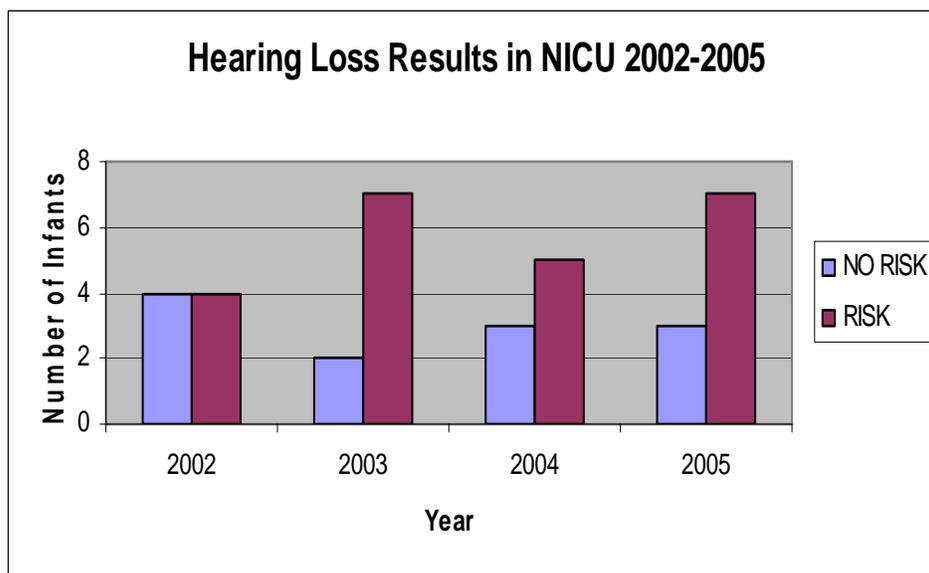
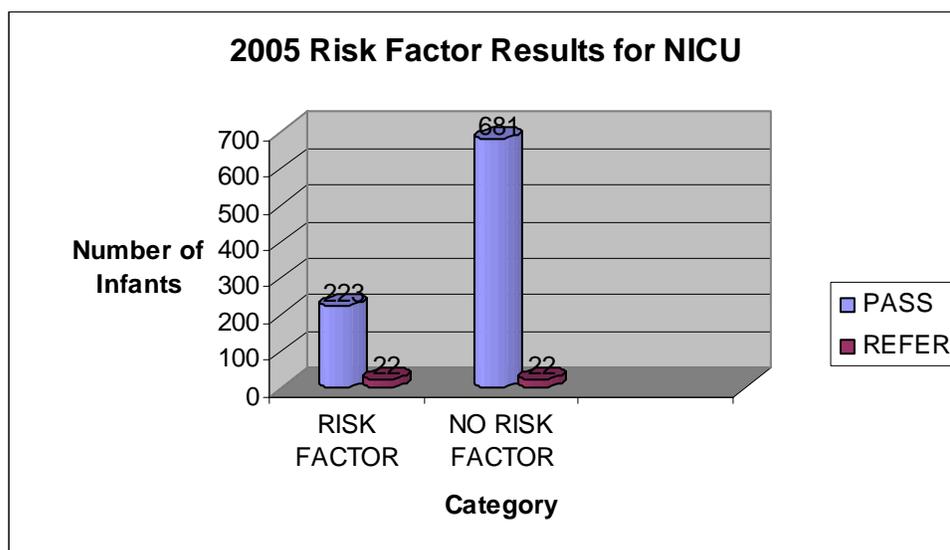


Figure 1.**Figure 2**

In the year 2005, all NICU infants (those that passed and referred) were examined for risk factors associated with hearing loss. The purpose of this was to determine how many infants who have risk factor(s) for hearing loss passed the screening. Those infants that did not have risk factors were also examined to determine how many babies without risk factors failed the screening. This data is illustrated in figure 2 above. There were a total of 245 infants who presented with risk factors for hearing loss. Out of those, 22 babies referred on the screening. A total of 703 babies were identified as not having risk factors, and out of those babies, 22 referred on the screening. If screening was performed only on those babies who presented with a risk factor on the high risk registry, 22 infants would have been missed that could potentially have a hearing loss.

Risk factors in WBN

The results for WBN are displayed in figure 3. Risk factors for hearing loss did not have as much effect on hearing loss as they did for the NICU population. Years 2003

and 2004 had more babies that presented with risk factors associated with hearing loss and confirmed hearing loss than the year previously and subsequently. When looking at the average between the four years, 33% of infants had no risk factors for hearing loss, compared to 67% of infants that were recorded to have at least one risk factor for hearing loss.

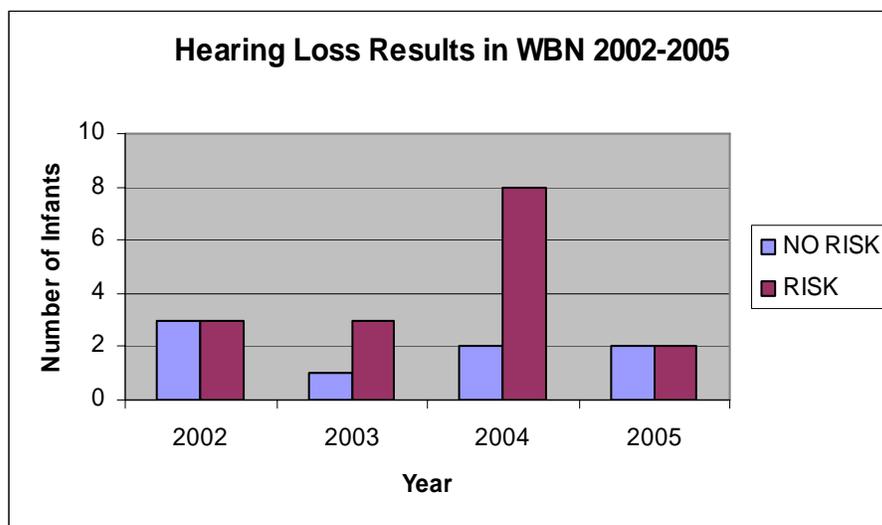


Figure 3.

The risk factors for hearing loss are divided into categories as seen in figure 4. This graph displays the nine most common risk factors for hearing loss plus an ‘other’ category which may include hydrocephalus, maternal substance abuse in utero, and other syndromes not directly associated with hearing loss but that are serious to the overall development of the child. The most common risk factors for hearing loss found in the NICU were syndromes and craniofacial anomalies. For WBN the most common risk factor was family history and craniofacial anomalies. The three most common risk factors found in both populations were craniofacial anomalies, followed by family history and syndromes. For each risk factor besides family history, the NICU infants were found to have more of each risk factors than the WBN.

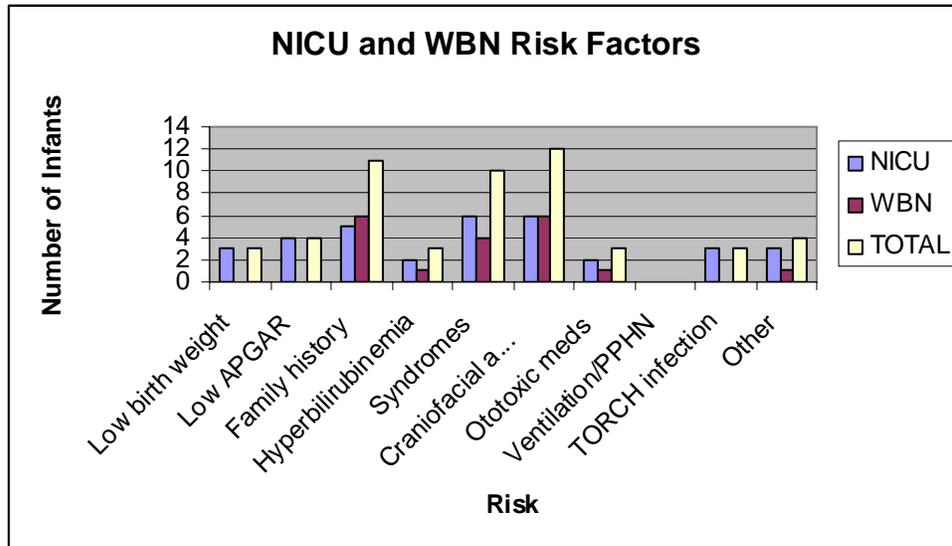


Figure 4.

Bilateral vs. Unilateral HL

Figure 5 demonstrates the breakdown of unilateral vs. bilateral hearing loss. Of the 35 NICU babies identified with hearing loss for the years 2002-2005, sixteen infants (46%) had a unilateral hearing loss in left ear. Bilateral hearing loss was found in 12 infants (34%), followed by unilateral hearing loss in the right ear only which was found in 7 (20%) of infants.

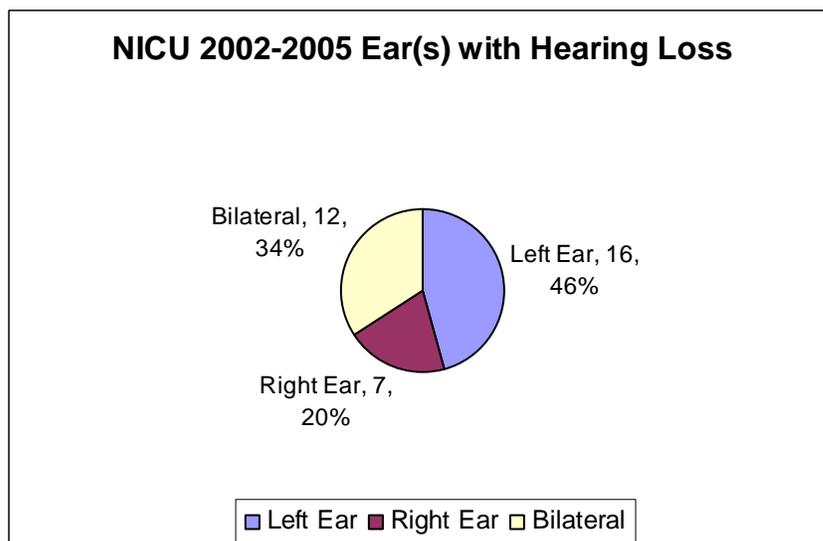
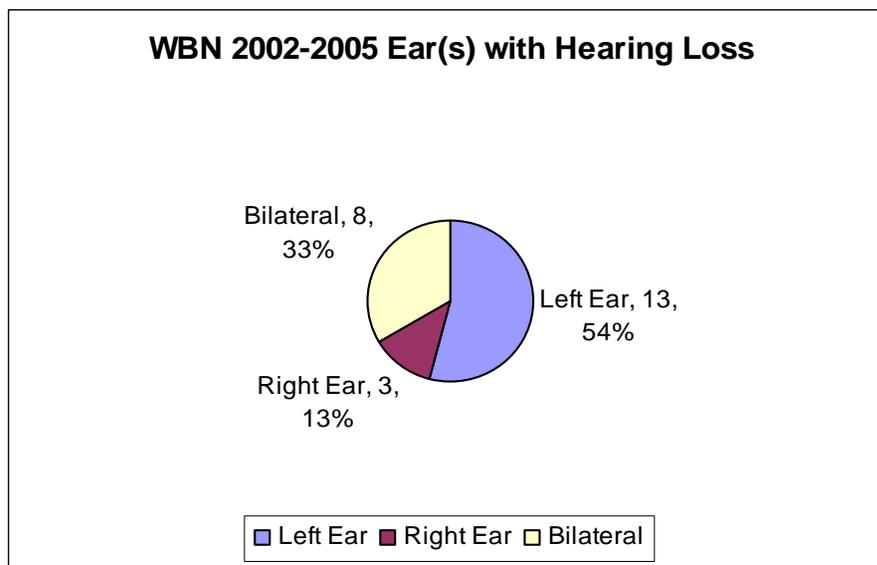


Figure 5.

For the WBN, a total of 24 babies were found to have a hearing loss between the years of 2002-2005. Of those babies, 13 (54%) had hearing loss in the left ear only. Bilateral hearing loss was found in eight babies (33%) and the right ear was the least likely to have hearing loss, with three infants (13%) exhibiting a hearing loss in that ear. Both the NICU and WBN babies exhibited left ear dominance for hearing loss. Bilateral hearing loss was the next common type of hearing loss, followed by hearing loss in the right ear for both baby populations.

**Figure 6****DISCUSSION:**

The goal of a successful hearing screening program is to correctly identify those infants with a hearing loss and at the same time keep referral of normal hearing infants and false-positive rates to a minimum.

False Positives

Overall, the false-positive rates in this study were in agreement with those reported in the literature. For NICU babies the average false positive rate between the years of 2002-2005 was 3.8% with a predictive value of 31.5%. The false positive rates varied from 1.75% to 6.1% in the four-year period. The majority of literature on false-positive rates of NBHS programs tends to group the NICU and WBN data together, making it difficult to distinguish the true incidence of each. Additionally, false-positive rates are often reported for either stage 1 or stage 2 screening, many times not distinguishing between the two. Two studies, the Connolly et al (2005) and the controlled trial of universal neonatal screening for early identification of permanent childhood hearing loss, conducted in Wessex (1998) also examined false positive rates for UNHS programs. False positive rates of the 2-stage program for the Wessex (1998) study were 1.5%, signifying excellent results. For the Connolly et al (2005) study, false-positive rates were 3.6%, similar to the 3.8% found in this study.

Regarding the incidence of hearing loss for both populations, this study's data coincides well with those previously published. In the Rhode Island study (1998), the NICU hearing loss rate was 9.17/1000 and the WBN rate was 1.27/1000. These results are in accord with this study's results of 10/1000 infants in NICU and 1/1000 infants in WBN. Other studies by Finitzo (1998) and Connolly (2005) showed hearing impairment of 1.2 to 3 per 1,000 in WBN and 13 per 1,000 in NICU.

How can false positive rates be decreased in both WBN and NICU? False positive rates vary among facilities and are influenced by the strategy and timing of the test as well as the training and dedication of the staff. Clements and Davis (2001) noted "often a change of the infant's position or activity or a change in the location of the test

will frequently change the result of the screen from fail to pass.” The Colorado Newborn Hearing Screening Project (Mehl et al, 1998), reported a 6% cumulative false positive rate in the beginning of their study and with improved technology and expertise, the rate went down to 2%. Mehl et al (1998) stated “it is important to interpret this rate carefully in the context of a disease that is many times more common than other conditions screened.” The NICU false positive rates in this study did increase since the program first started in 2002. It is important to address factors that could have contributed to this increase. First, the year 2002 had the least amount of babies out of all four years. Additionally, in 2002 all testing was performed and interpreted by audiologists. In the following years more babies were born per year, which required hiring and training of additional staff. This change of staff from audiologists to students or technicians and the time necessary to appropriately train them may have played a role in the amount of false positive rates.

Risk Factors in the NICU and WBN

Before 1994, the Joint Committee on Infant Hearing (JCIH) recommended testing only “high-risk” babies. Through the years, multiple studies including Maulk et al (1991), Yoshinaga Itano et al (2001) and Mehl et al (1998) demonstrated that high-risk registry has a poor positive predictive value and that nearly 50% of infants with hearing loss do not have a risk factor for hearing loss and therefore would not be screened.

The following study found that there is a relationship between having risk factor(s) for hearing loss, not passing a hearing screen, and then later having a confirmed hearing loss. The study established that for the NICU, 34% of babies that had confirmed hearing loss had no risk factors and 66% had risk factors for hearing loss. Similarly, for

the WBN, 33% of babies that were confirmed to have a hearing loss had no risk factors and 67% of babies had at least one risk factor. A comparable study by Vohr (1998) et al examined a UNHS program in Rhode Island, one of the first implemented hearing screening programs in the United States, between the years of 1993 and 1996. Unlike the present study, the screening technique of choice for the NICU nursery in Rhode Island was the transient evoked otoacoustic emissions (TEOAE) followed by an ABR if a refer result was acquired. For the WBN, TEOAS were used. A total of 111 infants were identified with permanent hearing loss (NICU and WBN combined) 44 infants had no risk factors for hearing loss (40%), 49 had one risk factor (44%), 8 had two risk factors (7%) and 10 of the infants had three or more risk factors or more (9%). The Rhode Island study lumped NICU and WBN together and like the present study, found that there are more babies (60%) who have risk factors, fail the screen and have confirmed hearing loss, than those (40%) that have no risk factors and a confirmed hearing loss.

The current study found that the most common risk factor for the NICU population was syndromes followed by craniofacial anomalies. This study did not consider prematurity as a risk factor for hearing loss because almost all NICU babies are premature. If prematurity was considered a risk factor for hearing loss in this study, it would most likely be the number one risk factor for the NICU population. For the WBN, family history of hearing loss, followed by craniofacial anomalies were the most common risk factors. For both groups, craniofacial anomalies, family history and then syndromes were the most common. Data by Korres et al (2005) looked at risk factors for hearing loss in the NICU and WBN. Korres' study of 25, 288 NICU and WBN babies revealed that for the NICU the most common risk factor was ototoxicity, mechanical ventilation,

prematurity and low birth weight. This was different from this study, which did not look at prematurity as a risk factor. However, when examining the risk factors in WBN, both Korres and this study found that family history for hearing loss and craniofacial anomalies were the most common. Likewise, both studies found that for both the NICU and WBN the most important risk factors for failing screenings were craniofacial anomalies and syndromes. A weakness of this study was that the presence of more than one risk factor for hearing loss was not examined. It would also be useful to examine whether the presence of more than one risk factor would contribute to a greater risk for failing screenings and/ or incidence of hearing loss.

Bilateral vs. Unilateral Hearing Loss

A retrospective study by Lim and Fortaleza (2000) analyzed factors that contribute to overall hearing screening programs' success, with a focus on risk factors for hearing loss. A total of 46 sites were examined in 1999 and a total of 114 babies were identified with hearing loss. This study did not specify whether hearing loss was sensorineural, conductive, or both. Fifty percent were identified as having a bilateral hearing loss. For unilateral hearing loss, a higher incidence of left ear unilateral hearing loss (29%) versus right ear unilateral loss (21%) was found. Additionally, of the 114 infants identified with hearing loss, only 40% were identified with risk factors for hearing loss, leaving 60% of babies with hearing loss and no risk factors. The Colorado Newborn Hearing Screening Project (1998) and the Connolly study (2005) similarly found more bilateral hearing loss vs. unilateral hearing loss when examining congenital sensorineural and conductive hearing losses. Unlike the previously published literature, in the present

study there were more unilateral losses than bilateral losses in both the NICU and WBN. The left ear, however, was found to be most prominent for hearing loss in all the studies.

This study does present some limitations. Sensitivity of this screening program could not be assessed because the number of false-negatives (those infants passing the initial screen and later identified with hearing impairment) was not collected. Yoshinaga-Itano et al (2000) stated that there are a small percentage of infants who pass the initial newborn screen, but develop hearing loss in later months or even years.

The Joint Committee on Infant Hearing has stated that such conditions as cytomegalovirus, recessive genetic factors, exposure to ototoxic medications and persistent pulmonary hypertension can all result in acquired hearing loss.

Additionally, babies that referred on automated ABR and then passed after receiving a non-automated ABR before discharge were not recorded separately. These babies were recorded as “pass” before discharge. This makes it difficult to calculate the false-positive rate before outpatient screen. The false-positive rate was therefore calculated by taking the number of babies that referred and returned for follow-up as outpatients, divided by the number of babies identified as having a hearing loss.

CONCLUSION:

After evaluating the efficiency and efficacy of this particular UNHS program, the evidence demonstrates that this hearing screening program is effective in identifying, tracking and following up on infants identified as having a hearing loss. The false-positive rate for this program does slightly exceed those that are recommended by the Academy, however, it is successful in keeping a low-referral rate, thereby reducing the

number of infants returning as outpatients. There are clear benefits to implementing a UNHS program. This program demonstrates a high specificity rate, good positive predictive values and low referral rates for both NICU and WBN. This program is in its fourth year of implementation. Several more years of data collection and evaluation will help to further improve and strengthen this NHS program.

As previously stated, the study found that there is a relationship between having risk factor(s) for hearing loss, not passing a hearing screen, and then later having a confirmed hearing loss. The study established that for the NICU, 34% of babies that had confirmed hearing loss had no risk factors and 66% had risk factors for hearing loss. For the WBN, 33% of babies that were confirmed to have a hearing loss had no risk factors and 67% of babies had at least one risk factor. For both populations, hearing loss is more common in those babies with risk factors.

Additional areas of research are needed to further assess the effectiveness of this and other hearing screening programs. One area of interest may be to evaluate protocols from other area hospitals so as to compare and contrast the most effective screening procedure. Assessing cost-effectiveness is another area of research that is crucial for a well-designed hearing screening program. Additional area of study could include assessing the time it takes to screen a baby in both the WBN and/or NICU babies. Furthermore, a follow-up study on those babies that passed their initial screen, but have one or more risk factors for hearing loss would be useful in determining how many cases of progressive hearing loss occur with that particular population. Furthermore, a longitudinal study of children that have been identified with a permanent hearing loss

may be an area of interest so as to track and monitor their development of speech and language.

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