

A Multisite Study to Examine the Efficacy of the Otoacoustic Emission/Automated Auditory Brainstem Response Newborn Hearing Screening Protocol: Introduction and Overview of the Study

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Purpose: This article is the 1st in a series of 4 articles on a recently completed multistate study of newborn hearing screening.

Method: The study examined the efficacy of the 2-stage otoacoustic emission/automated auditory brainstem response (OAE/A-ABR) protocol for identifying hearing loss in newborns.

Results: The study found that the 2-stage OAE/A-ABR protocol did miss a significant number of babies who exhibited a permanent hearing

loss by 1 year of age. Three subsequent articles will describe the research design and results in detail, discuss the behavioral assessment of infants, and summarize the implications of the study for policy, practice, and research.

Key Words: universal newborn hearing screening, otoacoustic emissions, automated auditory brainstem response, visual reinforcement audiometry

Since the early 1990s, universal newborn hearing screening (UNHS) has expanded exponentially from pilot projects in a few hospitals to become the standard of care in newborn nurseries and birthing centers (White, 2003). The percentage of infants screened for hearing loss in the United States has increased from less than 3% in 1993 to 93% at the beginning of 2005 (National Center for Hearing Assessment and Management, 2005). This article provides the background and an introduction to the three subsequent articles on a recently completed study to examine the efficacy of the two-stage otoacoustic emission/automated auditory brainstem response (OAE/A-ABR) protocol widely employed for identifying permanent hearing loss in newborns.

Key Studies of UNHS in the United States

A number of previous large-scale studies of the efficacy of newborn hearing screening have contributed substantially to the rapid expansion of UNHS. These studies and their findings are described in the following paragraphs.

Rhode Island Hearing Assessment Project. The Rhode Island Hearing Assessment Project (RIHAP) was the first large-scale project to demonstrate the feasibility of screening all newborns for hearing loss prior to hospital discharge. The project, begun in 1989, tested newborns in both neonatal intensive care units (NICUs) and well baby nurseries (White, Vohr, & Behrens, 1993). A total of 1,850 newborns were screened in the hospital using transient evoked otoacoustic emissions (TEOAEs). Of those 1,850 babies, 497 (27%) were referred for rescreening based on the in-hospital screening. Rescreening was accomplished for 403 (81%) of those referred from the in-hospital screening. A total of 115 infants (23% of the referred group, or 6.2% of the total group) referred from outpatient rescreening had diagnostic audiologic evaluations. Of those infants, 11 were identified with sensorineural hearing loss, 6 with bilateral severe-to-profound loss, and 1 with unilateral moderate loss.

The Rhode Island study demonstrated conclusively that universal screening prior to discharge could significantly reduce the age of identification for babies with a severe-to-profound hearing loss. By expanding that study to include selected hospitals in Hawaii, it was further demonstrated that once babies were identified, audiologic evaluation, early intervention, and family-support services

could be effectively incorporated into a statewide system of services for infants and toddlers (Johnson et al., 1993).

Multicenter Consortium on Identification of Neonatal Hearing Impairment. Following RIHAP's successful demonstration of the efficacy of UNHS, the National Institute on Deafness and Other Communication Disorders (NIDCD) issued a request for proposals in 1993 to fund a study to determine the sensitivity and specificity of the technologies used for screening hearing in newborns. The NIDCD provided funding for a national multisite study that examined the three physiologic measures used most frequently for newborn hearing screening: TEOAEs, distortion product otoacoustic emissions (DPOAEs), and ABR. That landmark study in newborn hearing screening (Prieve, 2000) is summarized below.

A total of 7,179 infants were recruited for the study, including 4,478 babies from NICUs, 353 well babies with one or more risk factors for hearing loss, and 2,348 well babies with no risk factors (Norton et al., 2000). A total of 4,911 babies who were "at risk" were followed and evaluated using a method of behavioral testing of hearing, specifically visual reinforcement audiometry (VRA) at 8 to 12 months corrected age. The NIDCD study validated the feasibility of using any of those three physiological measures for newborn hearing screening and the reliability of the VRA for the assessment of infant hearing (Widen et al., 2000).

New York State UNHS Demonstration Project. Based on the RIHAP results obtained in two small states (Rhode Island and Hawaii), officials in New York became interested in exploring the feasibility of UNHS in their state, which has approximately 250,000 births per year. Specifically, they wanted to determine whether timely intervention for infants with hearing loss following identification could be accommodated by New York's intervention and tracking system. A major focus of the project was linkage of the screening programs with the state's Part C Early Intervention Program. The project was initiated in January 1995, and seven perinatal centers using either OAEs or ABR as screening tools (each hospital could choose the specific screening techniques) were chosen as demonstration sites (Prieve & Stevens, 2000).

Results from the New York State UNHS project indicated that UNHS is feasible for hospitals across varied regions of a large, diverse state. The value of the UNHS was demonstrated by lower ages of hearing loss diagnosis, hearing aid

Table 1. Key large-scale newborn hearing screening studies in the United States.

Study location/name, dates, authors	Cohort size/type	Nurseries	Screening technique (referral rates)	Follow-up rate (%)	Prevalence per 1,000 cases of hearing loss
Rhode Island; 8/90–2/91; White et al., 1993	1,850/research	NICU and WBN	OAE/ABR (26.9%)	73	5.95
Colorado; 1/92–12/99; Mehl & Thomson, 2002	148,240/population	NICU and WBN	OAE & ABR	48–95 ^a	2.56
Rhode Island; 1/93–2/95; Vohr et al., 1998	53,121/population	NICU and WBN	OAE/ABR (14.7%)	74–88 ^a	2.00
Texas; 1/93–12/95; Finitzo et al., 1998	15,749/population	NICU and WBN	ABR (3%)	N/A	3.3 overall, 2.0 WBN, 13.0 NICU
Hawaii; 1/94–12/95; Johnson, 1997	9,605/population	WBN	OAE	89	4.15
New Jersey; 1/94–6/97; Barsky-Firkser & Sun, 1997	54,228/population	NICU and WBN	OAE & ABR (3.5%)	82.3	3.14
NIDCD; 1/94–10/96; Norton et al., 2000	4,478;2,701/research	NICU and WBN	N/A	64.4	56.0
New York; 1/96–12/96; Spivak et al., 2000	69,761/population	NICU and WBN	OAE & A-ABR	72	8.00 NICU, 0.9 WBN
Washington, DC; 2/97–12/02; Herer, 2003	39,437/population	NICU and WBN	TEOAE (1.6%)	82.7	2.3 overall, 1.9 WBN, 6.8 NICU
ATPM/CDC; 5/01–1/03; Johnson et al., 2004	86,634/research	NICU and WBN	OAE (4.8%), A-ABR (1.0%)	63.8/85.8 ^b	2.37

Note. NICU = neonatal intensive care unit; WBN = well baby nursery; OAE = otoacoustic emission; ABR = auditory brainstem response; NIDCD = National Institute on Deafness and Other Communication Disorders; A-ABR = automated auditory brainstem response; TEOAE = transient evoked otoacoustic emission; ATPM = Association of Teachers of Preventive Medicine; CDC = Centers for Disease Control and Prevention.

^aImprovements in follow-up rate over reported period. ^b63.8% for the study group; 85.8% for the comparison group.

fitting, and initiation of intervention services than when no UNHS programs were in place (Spivak et al., 2000).

Other studies. Since 1995, a number of published and unpublished studies have contributed to the growing body of knowledge about the efficacy and effectiveness of UNHS. The results of some of the key studies completed in the United States are shown in Table 1. Included in the table are both multistate research studies and population reports from other large-scale UNHS efforts. Although the method of reporting results was not consistent across studies, the results suggest that the percentage of newborns who were referred from in-hospital screening generally declined over time while the percentage of newborns who were successfully followed into diagnosis and intervention services increased.

Purpose of the Current Study

In 1993, the NIDCD, within the National Institutes of Health (NIH), held a Consensus Development Conference on early identification of hearing loss. Acknowledging the positive results of RIHAP, the NIH recommended that all infants be screened for hearing loss during the first 6 months of life. Further, the NIH recommendation called for a two-stage protocol (NIH, 1993): “The preferred model for screening should begin with an evoked oto-

acoustic emissions test and should be followed by an auditory brainstem response test [italics added] for all infants who fail the evoked otoacoustic emissions test” (p. 1).

Interestingly, this protocol had never been validated in a large-scale study. Rather, the recommendation reflected a policy intended to minimize the initial cost of screening and reduce the percentage of infants referred for follow-up to make the implementation of UNHS more acceptable to hospital administrators and physicians (Mehl & Thomson, 1998). As OAE and ABR screening equipment continued to evolve, more hospitals began implementing screening programs using automated devices, particularly for ABR. Currently, most ABR equipment used in newborn hearing screening programs is A-ABR that uses a statistical algorithm to determine whether a baby passes or fails the hearing test.

Use of the two-stage protocol was an attractive option for managers of UNHS because it helped reduce the cost of the initial screening while also reducing high false-positive rates, so that ultimately fewer infants were lost to follow-up (Stein, 1999). As more UNHS programs implemented the recommended protocol, substituting A-ABR for ABR, concerns emerged that some babies who failed the OAE but then passed the A-ABR actually had permanent hearing loss.

Responding to these concerns, the Centers for Disease Control and Prevention (CDC) issued a request for applications (RFA) in January 2000 for a study that would test the efficacy of the two-stage OAE/A-ABR newborn hearing screening protocol. The RFA was based on the fact that “concerns have been raised about infants who fail OAE but pass ABR and are then dismissed from follow-up. These infants may have a mild hearing loss that was missed by ABR” (Association of Teachers of Preventive Medicine [ATPM], 2000, p. 2). In response to that RFA, the study reported in this series of articles was developed and subsequently funded by the CDC with a grant from the ATPM. It was designed to determine how many infants who fail the OAE but pass the A-ABR in a two-stage newborn hearing screening protocol do have a permanent hearing loss when they are approximately 1 year old.

Although the potential negative impact of mild-to-moderate or unilateral sensorineural hearing loss was recognized more than a decade ago (Mauk & Behrens, 1993), the primary impetus for UNHS in the early 1990s was to identify bilateral severely-to-profoundly hearing impaired children for whom academic and vocational outcomes traditionally were much poorer than for their normally hearing peers (Commission on Education of the Deaf, 1988). Thus, most of the early UNHS programs focused on the identification of these more severe levels of *binaural* hearing loss, with limited concerns over mild-to-moderate or unilateral sensorineural hearing loss.

However, as technology advances increased the ability to identify milder degrees of hearing loss (Kemp & Ryan, 1991) and as research documented the deleterious effects of mild and unilateral hearing loss (Bess, Dodd-Murphy, & Parker, 1998), concerns grew about the group of infants targeted in UNHS. Specifically, could UNHS optimize its usefulness through the identification of children with mild and unilateral hearing losses? Bess and colleagues (1998) and Tharp (2005) have suggested that professionals may have minimized the impact of lesser degrees of hearing loss through the use of terms such as “mild” and “minimal” and thereby trivialized the potential negative effects of the disability in discussions with policy makers and other professionals. Yoshinaga-Itano, Sedey, Coulter, and Mehl (1998) established that, although children with a mild-to-moderate loss have better language skills than children with more severe degrees of hearing loss, they do not have language quotients comparable to their hearing peers. In this study, “mild” loss was defined as 26–40 dB HL and “moderate” loss as 41–55 dB HL. The language skills of the children were assessed in 6-month intervals with the last assessment occurring at 36 months of age. In this group of children with mild-to-moderate loss, identification and intervention prior to 6 months of age made as significant a difference in language skills as it did for those with a moderate-to-profound loss.

Study Design

To determine whether there would be a significant number of children with permanent loss at 1 year of age among those who had passed a newborn hearing screening

A-ABR, a multicenter, prospective cohort study was developed with a geographically diverse group of seven birthing centers. To be included in the study, hospitals had to have at least 2,000 births per year and have a successful program of UNHS using a two-stage OAE/A-ABR protocol. “Successful” was defined as having operated a UNHS for at least a 6-month period with referral rates of less than 10% for OAE and 4% for A-ABR, and existence of a tracking and follow-up system with $\geq 85\%$ of infants referred from screening returning for diagnostic assessment. Also required was access to a diagnostic center where infants in the sample could be evaluated by experienced pediatric audiologists with demonstrated competence using VRA and other procedures in the diagnosis of hearing loss in infants less than 1 year old. Each diagnostic center had to be willing to collaboratively develop and use a standardized VRA protocol.

Infants were recruited over a 21-month period (May 2001 through January 2003). Informed consent was obtained from the mother of each newborn enrolled in the study. Only infants from families whose primary language was English or Spanish were recruited and enrolled in the study. The percentage of births with a primary language other than English or Spanish was very low at each of the sites in the study. Families with a primary language other than English or Spanish were not included because, within the available resources, it would not have been possible to provide translated materials and fluent speakers to ensure informed consent and facilitate follow-up contact with the families.

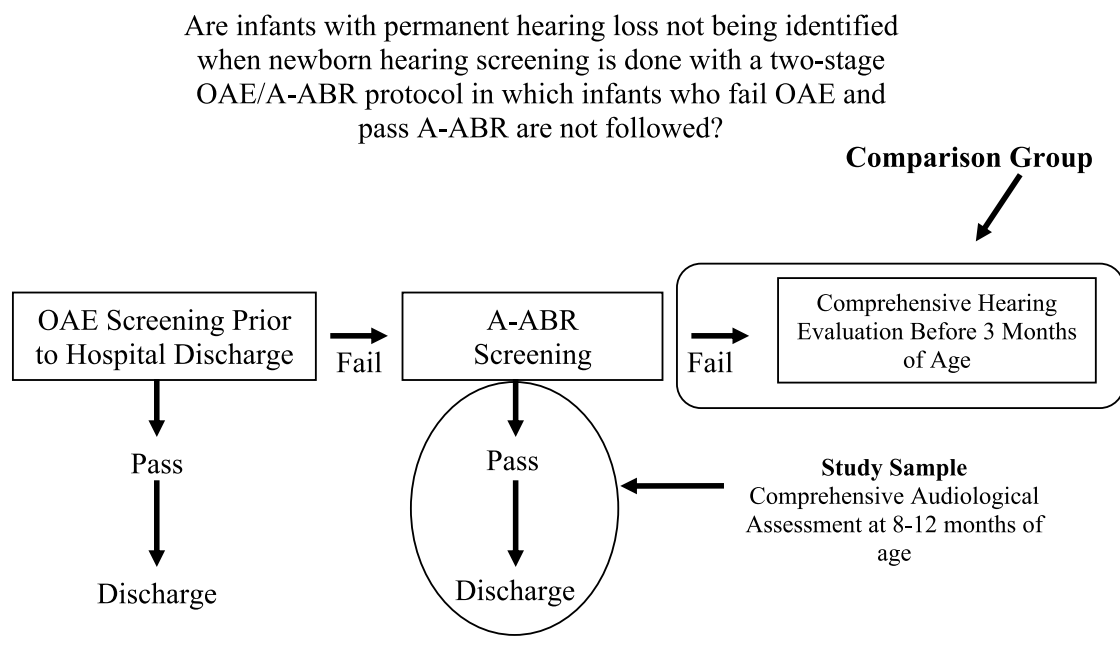
Additionally, in five of the seven centers, infants from the well baby nursery and the NICU participated in the study. In the remaining two centers, only infants from the well baby nursery were included because these two hospitals used only a single screening technology (A-ABR) in their NICU.

To assist in interpreting the results, the study included a comparison group of those newborns in the same birth cohort at the same birthing centers who failed both the OAE and A-ABR screening and subsequently were referred for a diagnostic audiologic evaluation. The study design is diagrammed in Figure 1.

Summary of Current Study

As shown in Table 1, the sample cohort for this study (identified as ATPM/CDC) was the largest reported for any published UNHS research study in the United States. Over the 21 months of enrollment, 86,634 babies were screened at the study sites. Of those babies, 3,462 (4.0%) were eligible for enrollment in the study because they were referred based on failing the OAE screening but subsequently passing the A-ABR screening. OAE screening at all but one site used TEOAE using an automated algorithm; the other site used DPOAE also using an automated algorithm. The A-ABR screening, using clicks, was completed at 35 dB nHL. A baby was eligible for the study population whether one or both ears failed the OAE screening and subsequently passed the A-ABR screening. Of those babies who were eligible, 1,524 mothers whose

Figure 1. Diagram of study design.



primary language was English or Spanish were invited and consented to participate, and their babies were enrolled in the study. Of those enrolled, 973 (63.8%) of those babies returned for a diagnostic assessment after the babies were 7 months of adjusted age. The enrollment summaries, by site, for the current study are shown in Table 2.

Carefully crafted exclusionary definitions were developed for the analysis of the diagnostic assessment to determine how many babies who were referred based on the OAE screening but then who passed the A-ABR screening did indeed have a permanent hearing loss by approximately 12 months of age. A detailed explanation of those defini-

tions and their operational implementation, along with the results, will be discussed in subsequent articles.

Other Information From Current Study

In addition to answering the specific research questions for which it was designed, the study further contributed to the growing body of knowledge on UNHS. For example, the OAE (first stage) screening resulted in average referral rates of 4.8% (range = 3.1%–9.6%), averaged on multiple screens; the A-ABR referral rates averaged 1.0% (range = 0.8%–2.8%) based on a single screen. Both these average

Table 2. Enrollment dates, births, and referral rate by site.

Site	Enrollment period	Births during enrollment	Recruitment from	Enrollment by nursery	Referral rate for OAE (%), technique ^a	Referral rate for A-ABR ^b (%)
1	May 1, 2001–December 31, 2002	16,608	WBN/NICU	185/6	6.3, TEOAE	0.8
2	June 1, 2001–January 31, 2003	9,393	WBN/NICU	259/111	4.5, DPOAE	0.9
3	September 20, 2001–January 31, 2003	4,509	WB	84	8.0, TEOAE	1.0
4	May 15, 2001–January 31, 2003	9,252	WB	147	3.1, TEOAE	0.8
5	May 1, 2001–January 31, 2003	24,032	WBN/NICU	146/24	2.4, TEOAE	0.8
6	May 1, 2001–January 31, 2003	6,217	WBN/NICU	286/10	9.6, TEOAE	2.8
7	May 1, 2001–January 31, 2003	16,623	WBN/NICU	257/9	5.3, TEOAE	1.2
Total		86,634	WBN/NICU	1,364/160	4.8, TEOAE	1.0

Note. DPOAE = distortion product otoacoustic emission.

^aOtodynamics EchoCheck used by Sites 1, 3, 5, and 6; Otodynamics Echoport also used by Site 5; Biologic AuDX used by Site 2; and Otodynamics IL088 used by Sites 4 and 7.

^bNatus Algo 2 used by Sites 2, 3, and 6; Natus Algo 2E used by Site 7; Natus Algo 2E Color used by Sites 3 and 7; Natus Algo 3 used by Site 1; and Natus Algo 3 Color used by Site 5.

rates, and the rates at each of the facilities, were well below the referral rates recommended by the Joint Committee on Infant Hearing (2000) for an effective screening program. Similarly, the follow-up rate for those infants in the comparison group who were referred based on failing both screening measures was 85%, demonstrating that sites were successful in completing diagnostic evaluations for almost all of the referred babies. These findings, while not a question to be addressed by the study, provided evidence of the continuing improvements in lowered referral rates and improved follow-up rates.

An additional finding of the study was the large differences between sites in a number of indicators, including recruitment differences, range in referral rates, and differential success in achieving follow-up. These differences will be discussed in detail in the following articles.

Description of Subsequent Articles

To date, only three large, multistate UNHS research studies have been reported in the literature. The articles to follow were written, in part, to assist future researchers as they design studies to answer the many remaining unanswered questions related to identifying, following, and intervening with infants with permanent hearing loss. These three articles will detail the findings of the study, outline evidence-based recommendations for future policy and practice, and identify questions that need to be answered as the nation strives toward early identification and intervention for all infants with permanent hearing loss.

A Multisite Study to Examine the Efficacy of the Otoacoustic Emission/Automated Auditory Brainstem Response Newborn Hearing Screening Protocol: Research Design and Results of the Study. In this article, Karl R. White, lead author, describes the research design and data management procedures for the study. As additional studies of UNHS are undertaken to contribute to the growing body of literature on evidence-based practices, information on the specifics of managing a study of this size and scope can be helpful to future researchers. The article also discusses the resource implications in lowering the threshold of identification while maintaining optimal follow-up rates.

White also describes in detail the results of the study and the prevalence of permanent hearing loss in both the study group and comparison group. The stringent criteria and process developed to classify permanent hearing loss will be illustrated. He discusses the challenges of appropriately interpreting the results given the differences in the percentages of children in the study and comparison groups who returned for diagnostic evaluation. Significant differences occurred among sites in screening referral rates, rates of recruitment into the study, rates for success in completing the diagnostic process, and rates of permanent hearing loss. The implications of this finding are thoroughly discussed.

A Multisite Study to Examine the Efficacy of the Otoacoustic Emission/Automated Auditory Brainstem Response Newborn Hearing Screening Protocol: Results

of Visual Reinforcement Audiometry. Judith E. Widen, lead author, details the results of the audiologic assessments performed on the 973 babies who returned for evaluation. Widen describes instrumentation requirements for participation, the training provided for participating audiologists, and the challenges that arose in completing comprehensive assessments on this large number of babies. The VRA protocol required the use of insert earphones calibrated to American National Standards Institute standards using a 2-cc coupler. An analysis of the diagnostic variability across sites is also discussed.

The results of the audiologic diagnostic process at multiple sites represent an important contribution to the body of literature on infant assessment. Case reviews are presented on some of the unique findings among babies enrolled in the study with reference to the recommendations for diagnostic testing contained in the new guidelines from the American Speech-Language-Hearing Association (2004). Included in this article is a discussion of the importance of reconciling apparently contradictory results among VRA, OAE, and tympanometry. Detailed case studies are presented on all the infants identified with more than a mild hearing loss.

A Multisite Study to Examine the Efficacy of the Otoacoustic Emission/Automated Auditory Brainstem Response Newborn Hearing Screening Protocol: Recommendations for Policy, Practice, and Research. In the final article of this series, Judith S. Gravel, lead author, summarizes the recommendations for policy, practice, and research that evolved from the study. This study identifies the critical need for continued surveillance of hearing status in early childhood. Gravel discusses the need for increasing the availability of well-trained, experienced, pediatric audiologists, and how preservice and in-service training can provide the skills necessary for the diagnosis of hearing loss in infants. The obvious calibration issues raised by the study will be clarified. The relative advantages and disadvantages of using the two-stage OAE/A-ABR protocol, especially in communities where the probability for follow-up is low, are addressed. The cost-benefits as they relate to policy and practice are also discussed.

The needs for future research that this study identifies are outlined. Data remain elusive on the prevalence and predictive characteristics of late onset and progressive hearing loss. The article concludes with a discussion of whether UNHS has evolved to a point where increased consideration should be given to the identification of mild and unilateral hearing loss and the implications of those decisions for modifying state eligibility criteria under Part C of the Individuals with Disabilities Education Improvement Act to ensure that services are provided to infants who are identified and referred for services.

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