

# Minimizing False-Positives in Universal Newborn Hearing Screening: A Simple Solution

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**ABSTRACT.** *Background and Objectives.* The false-positive rates of previously reported universal newborn hearing screening (UNHS) programs range between 2.5% and 8%. Critics of UNHS programs have claimed that this rate is too high and might lead to a number of the negative effects produced by false-positive screening tests, namely emotional trauma, disease labeling, iatrogenesis from unnecessary testing, and increased expense in terms of time and money.

We previously reported, based on some preliminary data, that as many as 80% of newborns who failed the initial hearing screen subsequently passed when they were retested the following day, before being discharged from the hospital. We now present the results of this intervention for our entire UNHS program during a 7-month period.

*Methods.* We analyzed data from 3142 non-neonatal intensive care unit infants screened with an automated auditory brainstem response at the Women's Hospital of Greensboro from November 1, 1999 to May 31, 2000. A protocol was developed wherein all infants who failed the initial UNHS were rescreened with another automated auditory brainstem response before hospital discharge. Data collected included pass/fail rates during the inpatient stay as well as follow-up data and risk factors for congenital hearing loss.

*Results.* Confirmed hearing loss occurred in 8 non-neonatal intensive care unit infants, a rate of 2.5/1000. Eighty percent of newborns who failed the initial hearing screen passed on rescreening before hospital discharge. This produced a false-positive rate of 0.8% and a corresponding positive predictive value of 24%. If in-hospital rescreening had not occurred, our false-positive rate and positive predictive value would have been 3.9% and 6.1%, respectively.

*Conclusions.* Our simple intervention of rescreening all infants who failed their initial UNHS before hospital discharge reduced the false-positive rate of UNHS to 0.8%. We suggest that this simple, inexpensive intervention should be instituted for all similar UNHS programs. *Pediatrics* 2001;107(3). URL: <http://www.pediatrics.org/cgi/content/full/107/3/e29>; *universal newborn hearing screening, screening, false-positive, hearing, audiology, automated auditory brainstem response.*

ABBREVIATIONS. UNHS, universal newborn hearing screening; AABR, automated auditory brainstem response test; WHOG, Women's Hospital of Greensboro; NICU, neonatal intensive care unit.

Universal newborn hearing screening (UNHS), which is aimed at the early detection of and intervention for children with congenital hearing loss,<sup>1</sup> has been mandated by a number of states, including North Carolina, during the past few years.<sup>2,3</sup> However, critics have reasonably argued that current UNHS practices produce an unacceptably high rate of false-positive tests.<sup>4-6</sup> In fact, rates reported in the literature vary from ~2.5% to 8% and produce correspondingly poor positive predictive values of 4.0% to 12%.<sup>7-12</sup> Assuming that all 4 million infants born each year in the United States received UNHS, a 3% false-positive rate would cause 120 000 families of newborns to leave the hospital questioning the hearing ability of their infant and needing to return for follow-up. Similarly, assuming a positive predictive value of 5%, 95 of every 100 infants failing UNHS would subsequently be found to have normal hearing.

The harmful consequences of false-positive results of any screening test may not be minimal. Disease labeling and emotional distress have been reported<sup>6,13-17</sup>; there is a risk of iatrogenesis from additional, unnecessary diagnostic testing<sup>5</sup>; and false-positive results squander time and dollars.<sup>5,18</sup> In the vast majority of UNHS programs, follow-up testing does not occur until a number of weeks after the initial screen. Therefore, minimizing false-positive results is critical in making UNHS a more acceptable screening tool.

In a previously published study, we reported preliminary data from a convenience sample of newborns where we found that 80% of the infants who had initially failed an initial automated auditory brainstem response test (AABR), passed when they were retested with another AABR the following day, while still in the hospital.<sup>19</sup> Because of the potential biases of a convenience sample, we sought to implement a systematic rescreening program of every newborn who failed the initial screening test. We hypothesized that this systematic rescreening program would result in <1% of newborns leaving the hospital in need of any type of follow-up for their hearing—a much more acceptable false-positive rate for a screening test.

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## METHODS

The Women's Hospital of Greensboro (WHOG) is part of the Moses Cone Health System and is the only maternity hospital that serves Guilford County as well as a number of surrounding counties. On July 6, 1998, UNHS began at WHOG. Hearing screening occurred 7 days a week by a trained technician who uses an Algo 2 or an Algo 2e AABR screener (Natus Medical Inc, San Carlos, CA). This automated hearing screener uses a 35-dB nHL alternating polarity click to assess the neural response of the auditory nerve. The equipment has a built-in artifact rejection for myogenic, electrical, and environmental noise interference that stops the screen when testing conditions would preclude adequate testing. The AABR provides a pass/refer result that requires no interpretation. An immediate retest was performed on obtaining a refer result and was considered part of the initial screen. This initial screen was designated stage 1a. Informed consent was received from the mother before the hearing screen.

Beginning on November 1, 1999, the UNHS policy at WHOG changed so that all newborns who failed stage 1a screening received another AABR before discharge (ie, within the subsequent 12–24 hours). This rescreen while still in the hospital was designated as stage 1b. Newborns failing stage 1b were referred for outpatient screening, designated stage 2. Stage 2 screening was performed by an audiologist and consisted of an AABR and, if necessary, a diagnostic ABR. Failure of stage 2 initiated a referral for additional evaluation (ie, otolaryngologist, additional diagnostic testing, hearing aid evaluation).

Data were collected on all non-neonatal intensive care unit (NICU) infants screened at WHOG between November 1, 1999 and May 31, 2000 as well as on those infants who required any follow-up screening or evaluation. Data were analyzed using the statistical software *SPSS, Version 9.0* (SPSS, Chicago, IL). The study was approved by the Moses Cone Hospital Internal Review Board.

## RESULTS

Between November 1, 1999 and May 31, 2000, 3144 healthy term non-NICU newborns were born at WHOG for which 3142 hearing screens (99.9%) were performed. Eight of these infants (2/1000) were found to have some degree of hearing loss. Two had mild bilateral loss, 2 had mild unilateral hearing loss, and 4 had severe unilateral hearing loss. Three of the 8 (38%) had some type of risk factor for hearing loss. Seven of the 8 infants had confirmed sensorineural hearing loss by an otolaryngologist or by diagnostic audiologic testing. One infant (with mild unilateral hearing loss) had conductive loss that subsequently resolved after a few months.

As shown in Table 1, of the newborns screened, 131 (4.17%) failed stage 1a and, of these, 125 (95.4%) received stage 1b testing. Of the 6 infants who did not receive stage 1b after referral, 5 were discharged

**TABLE 1.** Results of UNHS at WHOG From November 1, 1999 to May 31, 2000 for Non-NICU Newborns

Category	<i>n</i>	% of Previous	% of Total Screened
Normal newborns (non-NICU)	3144	—	—
Total screened	3142	99.9	—
Failed stage 1a screen*	131	4.17	4.17
Received stage 1b screen†	125	95.4	4.00
Failed stage 1b screen	33	26.4	1.05
Received stage 2 screen‡	33	100	1.05
Failed stage 2	8	24	0.25

\* Stage 1a screen—initial hearing screen.

† Stage 1b screen—repeat hearing screen before hospital discharge of newborn.

‡ Stage 2 screen—outpatient screen by trained audiologist (this does not include the 6 infants who missed stage 1b screening).

early and 1 resulted from a documentation error. All 6 of these infants passed on rescreening as an outpatient. Only 33 of the 125 newborns (26.4%) who failed stage 1a also failed stage 1b screening, producing an overall stage 1 failure rate of 1.05%. Subtracting the 8 infants with confirmed hearing loss, the false-positive rate of our UNHS program was 0.8%. By using stage 1b testing, the false-positive rate was decreased from 3.9% to .8%, a drop of 80%. Similarly, the utilization of stage 1b testing increased the positive predictive value of our screening program from 6.1% to 24%.

## DISCUSSION

By implementing AABR rescreening before hospital discharge of all newborns who fail an initial AABR screen, we report a false-positive rate of 0.8% and a positive predictive value of 24%. To our knowledge, this false-positive rate is significantly lower than any other reported in the literature. Failure to perform stage 1b rescreening would have increased our false-positive rate by 80% to 3.9% and decreased our positive predictive value by fourfold to 5.6%, both similar to those reported in the literature.<sup>7,8</sup> These results confirm our preliminary observations of an earlier study.<sup>19</sup> Using the example of an annual US birth cohort of 4 million and a conservative estimate of a 3% false-positive rate, instituting our method of UNHS could prevent 88 000 false-positive results per year and greatly reduce the subsequent negative impact that false-positive results create.

A recently published study using the transient evoked otoacoustic emission test and followed immediately by AABR on those infants who failed the transient evoked otoacoustic emission test, reported a fairly low false-positive rate of 1.6%.<sup>20</sup> This study coupled with our results suggests that retesting within a short interval (ie, hours rather than days or weeks) is effective in reducing false-positives regardless which testing equipment or screening method is used. This is logical given that ear canal debris, ambient sound, and myogenic interference are among the most commonly implicated factors in failed screenings.<sup>21,22</sup> 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 optimal time of rescreening still needs to be determined.

The implementation of a UNHS program such as ours is certainly feasible for other similar hospitals. WHOG is a nonacademically affiliated, community hospital with over 5000 deliveries per year and is beginning its third year of its UNHS program. We estimated that the addition of stage 1b screening required very little additional expense to the overall UNHS program in terms of time and money. In fact, in this study, stage 1b screening was provided to 125 infants during the 7-month study, not much more than 1 extra screen every 2 days. In no case was a newborn's hospitalization prolonged to retest his or her hearing.

Therefore, based on the significance of our results

and the ease in which this intervention can be implemented, we recommend that all UNHS programs consider changing their protocol so that all newborns who fail the initial hearing screening will be retested before hospital discharge.

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