Quality Improvement Initiative in Newborn Hearing Screening

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It began in Austin, Texas. Two company presidents met to discuss quality improvements in newborn hearing screening (NHS). Between them they sketched a proposal to bring service provider and equipment manufacturer together to collect clinical data in the well-baby nursery and neonatal intensive care unit (NICU) at several birthing hospitals in Texas.

Pain Points of a Service Provider

Ears & Hearing, PA is an independent service provider of newborn hearing screening programs for 18 hospitals in Texas. Following best practices, a team of hearing specialists apply their clinical expertise to lead and coordinate programs with a focus on quality outcomes.

In the delivery of newborn hearing screening services, Ears & Hearing noted these key pain points:

- Significant difficulty obtaining results when muscular artifact is present
- Equipment too sensitive to acoustic noise which prevents the completion of a test
- Typically difficult to obtain results in the NICU
- Testing sometimes runs more than 30 minutes before a result is generated
- Results can be inconsistent from one screen to the next
- Outpatient rescreening is costly, and leads to follow-up issues
- Equipment "cuts out" during testing which requires testing to be restarted

Vivosonic Inc, as a manufacturer of hearing screening and diagnostic equipment, believed it had designed an automated ABR hearing screening system that would overcome these issues. The company was eager to validate the system in the field, and collect data to further optimize its statistical automated ABR algorithm.

Methodology in a Nutshell

A formal plan was established to evaluate Aurix, the new hearing screening system at four hospital sites. The aim was to collect data from 100 well-babies and 100 NICU babies to assess Aurix's performance and usability,[1] and to compare its performance to the hospital's automated ABR screening product.

The procedures for the ABR screening followed each hospital's hearing screening program guidelines. Babies scheduled for newborn hearing screening with automated ABR were tested. These included those who failed automated OAE testing, and babies more than 5 days in the NICU. Each baby was screened twice, first with the hospital's equipment, followed by Vivosonic's Aurix.

Performance measures included screening time, variability of screening time, and refer/fail rates on initial screening only. Product usability was assessed through questionnaires, interviews, and the observations of the experienced hearing screening specialists.

Findings and Implications

Hearing screening data was collected from 179 babies at three birthing hospitals in Texas.

The experienced hearing screening technicians found Aurix easy to learn, and were immediately productive after a brief period of hands-on training. At the same time, not surprisingly, the data show that screening outcomes improved with more hands-on experience. Overall, when compared to the hospital's equipment, Aurix demonstrated better performance on the initial screen (Table 1).

The data also suggest that several other factors affect automated ABR outcomes (Table 2): impedance, state of baby, birth age, gestational age, screening equipment, and magnetic noise.[2] As a consequence, the detection algorithm has been optimized to minimize the effects of the factors shown to increase referral rates and/or screening time.

Table 1. Data from Initial Screen Comparing Performance of Hospital's Screening Equipment to Aurix[2]

Performance of Initial Screen	Hospital (141 ears)	Aurix (355 ears)
% of ears passed	83%	95%
Average test time (mm:ss)	5:00	1:56
Maximum test time (mm:ss)	35:00	11:38
Variability of test time (mm:ss)	12:15	3:06

Table 2. Conditions that Significantly Affected Initial Screen Performance[2]

Test Condition	Hospital (141 ears)		Aurix (355 ears)	
	Time (mm:ss)	% Pass	Time (mm:ss)	% Pass
Infant wakes during testing	7:32	72%	2:33	96%
High magnetic interference >=20 mG noise	-	-	1:42	95%
Premature infants	5:16	83%	1:54	95%
Infants < 24 hours old	7:15	75%	2:02	93%
Impedance difference > 5 kΩ	5:50	90%	1:50	95%

Emily Bonilla is Program Director, Ears & Hearing, Texas. This article was provided by Vivosonic. Aurix is a registered trademark of Vivosonic.

Feedback from technicians indicated that for the most part they preferred Aurix over their current equipment as it addresses key pain points. Working with the manufacturer, technicians evaluated iterative improvements to the system and clinical techniques used to prepare the babies for screening.

Findings related to the use of Aurix and the pain points described by Ears & Hearing are summarized in the following table. Implications of these findings for improved service provision are also noted.

Table 3. Findings and Implications

Findings Related to Pain Points	Implications for Service Provision
Able to test babies who woke up or moved during the test.	• Better handling of myogenic artifact reduces the need to reschedule or rescreen.
Less sensitive to intermittent noise. No need to stop testing when intermittent noise is present.	• Better handling of intermittent noise reduces or eliminates the need to restart a test.
Able to obtain screening results in the NICU environment, including babies in isolettes.	• No need to remove babies from the NICU (or isolettes) or delay screening until out of the NICU.
On average, a result is generated within 2 minutes for each ear, with a maximum time of 15 minutes for both ears.	• Fast test times reduce inconvenience to medical staff and families who require access to the baby.
Screening time is less variable.	• Less variability simplifies scheduling.
More consistent test results from one screen to the next.	• More confidence in the accuracy of the test results.
Fewer outpatient rescreens required.	• Cost savings. Avoids "lost to follow-up" issues.
Stable and reliable performance of equipment.	• Eliminates technician frustration due to unreliable equipment.

Discussion

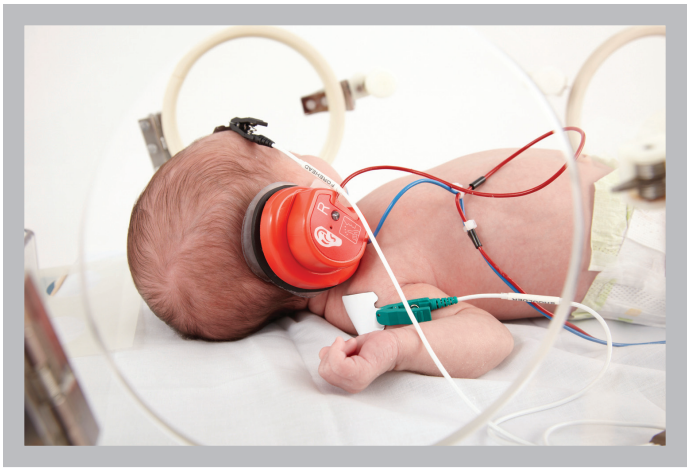
The pain points encountered by Ears & Hearing are typical of many newborn hearing screening programs in the United States. Oftentimes, attempts to mitigate these issues are managed by establishing rigorous procedures and training based on best practices. With advancements in technology, it is now possible to further impact and improve the quality of newborn hearing screening programs and outcomes by introducing new and innovative technologies.

Advances in digital signal processing that do not rely on artifact rejection techniques are better able to handle myogenic artifact common to babies who wake during testing. The Aurix system uses a sophisticated statistical detection algorithm based on Kalman Weighted Averaging and a proprietary method of adaptively estimating noise.

Better immunity to high magnetic field noise often present in NICU environments is made possible by reducing the distance between the electrodes and the amplifier, an enhanced design of the amplifier (filter), and enabling wireless communication between the recording component and the computer.

Statistical techniques used to identify signal from noise based on waveform amplitudes provide more accurate testing of premature infants compared to template or pattern matching approaches derived from term infants. This should be considered when screening infants in the NICU.

The initiative that began in Austin, Texas, has led to significant quality improvements in the development of an advanced newborn hearing screening product, with findings that have important implications for newborn hearing screening programs worldwide. What started as an exchange of ideas has become a rewarding partnership.



References

1 International Standard, IEC 62366 ed1.0 (2007-10). Medical devices–Application of usability engineering to medical devices. Geneva, Switzerland.

2 Kurtz I, Steinman AH and Stepanov S (2010). Factors Affecting Screening Time and Rates of Referral in Automatic ABR and Solutions to Improve Performance. Poster presentation at nhs 2010 Conference, Cernobbio, Italy, June 8-10, 2010.