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How Many Babies with Hearing Loss Will Be Missed by Repeated Newborn Hearing Screening with Transient Evoked Otoacoustic Emissions Due to Statistical Artifact?

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Abstract

Objective: It is often said that repeating OAE hearing screening more than two or three times per ear creates statistical artifacts that unacceptably increase false-negatives (i.e., passing babies who have permanent hearing loss). This study evaluated the accuracy of that recommendation for screening with transient evoked otoacoustic emissions (TEOAE).

Design: The false negative rate was estimated using a 2.0 cc coupler and three human ears with moderate or worse hearing loss. Using those results and the prevalence of hearing loss among newborns, the number of babies with hearing loss that would be missed due to repeated testing was calculated.

Results: Only 1% of ears with moderate or worse hearing loss will be missed due to statistical probability of false-negatives resulting from repeated testing.

Conclusions: Excessive repeated testing in a newborn hearing screening program wastes time; raises questions about accuracy of screening; and may disturb the infant, family, or hospital staff. Repeated TEAOE testing does not cause statistical artifacts that result in a significant number of babies with hearing loss to pass the screening test. Not repeating screening tests often enough may needlessly inflate the number of babies referred for diagnostic testing and create financial burdens and worry for families.

Acronyms: ABR = Auditory Brainstem Response, EHDI = Early Hearing Detection and Intervention, JCIH = Joint Committee on Infant Hearing, NBHS = Newborn Hearing Screening, OAE = Otoacoustic Emissions, TEOAE = Transient-Evoked Otoacoustic Emissions

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Introduction

Otoacoustic emissions (OAE) testing is used worldwide in hospitals and clinics to test cochlear function of individuals in all age groups. The most common use of OAE testing is in hospital-based newborn hearing screening programs as an objective measure to identify infants who require additional diagnostic audiologic testing to confirm the presence or absence of hearing loss. The screening test is often performed with a hand-held unit that measures the presence or absence of an OAE in response to an auditory stimulus (Kemp, 1978). Screening is done by placing a small probe in the ear canal that delivers a low-intensity signal to the structures of the cochlea in the inner ear. If the cochlea is functioning normally, the outer hair cells of the cochlea respond by producing an otoacoustic emission, sometimes described as an echo, that travels back through the middle ear and the ear canal and is detected by the screening unit (NCHAM, 2011). There is widespread agreement that doing hearing screening with OAE testing is reliable, harmless, and effective (e.g., ASHA, 2004; JCIH, 2007; Keppler, Dhooge, & Maes, 2010; White, 2014).

Currently, every state in the United States has implemented either a mandatory or voluntary newborn hearing screening (NBHS) program. Many of these programs use OAE screening equipment (White, 2014) due to the safety and ease-of-use. Every state-based Early Hearing Detection and Intervention (EHDI) program has a coordinator who collaborates with stakeholders in the state to implement and support effective newborn hearing screening programs. In 1995, the percentage of newborns screened for hearing loss was just 3%. A decade later that number had increased to 95% (White, 2006; White, Forsman, Eichwald, & Munoz, 2010), largely owing to the ease with which screening could be done and the wide acceptance of reliable and objective screening tools. The Centers for Disease Control and Prevention (CDC; 2015) report that 98% of newborns in the United States are currently screened for hearing loss.

Recomendations Regarding Repeating Newborn Hearing Screening Tests

The Joint Committee on Infant Hearing (JCIH, 2007) provides guidelines for all aspects of pediatric audiological services, such as screening and diagnostic testing protocols and hearing technology management. Many hospital-based newborn hearing screening program coordinators rely on the JCIH recommendations for guidance in developing and managing their programs. Commenting on how often the newborn hearing screening

test should be repeated for a particular baby, the most recent position statement of the JCIH (2007) makes the following statement:

> When statistical probability is used to make pass/fail decisions, as is the case for OAE and automated ABR [auditory brainstem response] screening devices, the likelihood of obtaining a pass outcome by chance alone is increased when screening is performed repeatedly. (p. 903).

As support for this conclusion, JCIH cites articles referring to the "false discovery rate" in other types of screening programs and how this false discovery rate is increased by repeated testing (Benjamini & Yekutieli, 2005; Hochberg & Benjamini, 1990; Zhang, Chung, & Oldenburg, 1999). The 2007 JCIH position statement does not specify what constitutes repeated screening, nor quantify the increase in the "chance pass rate." However, as shown in Table 1, many state-based EHDI programs and others have made recommendations about the need to limit repeated testing in newborn hearing screening programs.

Table 1. Examples of Statements from State EHDI Programs and Others about Repeating Newborn Hearing Screening Tests

"The initial hearing screening . . . . should consist of **no more than 2 attempts** using the same screening technique on each ear." *(Washington State EHDI Program Guidelines, 2015)*
For infants who fail the initial screen, hospitals should attempt to re-screen the infant prior to discharge. **Inpatient hearing screening will consist of no more than two attempts using the same screening technique on each ear**, assuming the infant is in an appropriate state for testing and there are neither equipment problems nor environmental interference during the test. The likelihood of obtaining a pass by chance alone is increased when screening is performed repeatedly. *(Minnesota State EHDI Program Guidelines, 2015)*
… take caution to avoid over-screening newborns! Although there may be factors that require the screen to be repeated, it is **not recommended that babies be screened more than three times.**" *(Connecticut Department of Health, 2015)*
"…excessive re-screening can increase the false negative rate (passing babies with actual hearing loss)…. Two screening sessions of no more than three screens per ear are recommended, for **a total of six screens per ear."** *(Iowa EHDI Program Guidelines, 2015)*
"Do not screen patient more than **three times per ear.** Over screening can result in a false negative result." *(Welch Allyn OAE Hearing Screener Quick Reference Guide, 2015)*
Screening too many times isn't recommended and it can lead to false results. . . . Your goal is not to pass every baby. **"With multiple screenings, babies with hearing loss may falsely pass."** *(Newborn Hearing Screening Training Curriculum, NCHAM, 2015)*

Note. Emphasis added. EHDI = Early Hearing Detection and Intervention, OAE = optoacoustic emissions.

The recommendation to limit the number of OAE screening tests performed in NBHS programs due to the potential of passing babies who have hearing loss because of the statistical probability of obtaining a false negative response appears to have become accepted as best-practice.

Materials and Method

To estimate how many babies with moderate or worse hearing loss are likely to be missed because of repeated newborn hearing screening tests, it is necessary to estimate the false negative rate of OAE screening (i.e., the probability of passing an ear with known hearing loss). Unfortunately, none of the manufacturers of the equipment used for newborn hearing screening provide such information. Consequently, this study estimated the false negative rate for a single test using the Biologic AuDx® Pro OAE Screener. Because the false negative rate could be different for other brands and types of screening equipment (e.g., Biologic versus Otodynamics, or OAE versus automated auditory brainstem response, or transient evoked versus distortion product otoacoustic emissions), the results reported here represent a starting point for addressing questions about the frequency of false-negatives attributable to statistical artifact in hearing screening programs, but these results are not the complete answer. We have demonstrated the consequences of repeated newborn hearing screening tests using TEOAEs with one of the most frequently used OAE screeners. Making similar estimates for other brands or types of screening instruments will require additional data collection. The data collection described below was approved by the Institutional Review Board at Utah State University.

Participants

To estimate the false negative rate of TEOAE testing, two participants with bilateral moderate sloping to severe-profound hearing loss provided informed consent to have repeated TEOAE tests. Audiograms for each of three ears are shown in Figure 1. One thousand transient evoked OAE (TEOAE) tests were obtained from the left ear of the first participant and in both ears of the second participant for a total of 3,000. Additionally, 1,000 TEOAEs were collected using a 2.0 cc coupler.

Equipment and Procedures

Using the Biologic AuDx® Pro OAE screener, all screening tests were completed with the TEOAE screening default test parameters (see Table 2). TEOAEs were selected for this study due to their common usage in NBHS programs and their high sensitivity and specificity in detecting outer hair cell dysfunction (Cunningham, 2011; Keppler et al., 2010; Lapsley-Miller & Marshall, 2001).

Data were collected in a quiet room on each ear over a 2-week period, averaging approximately 200 tests per day. Within each data collection time period, the probe was securely placed into the canal of the ear being tested and remained in place throughout the test session. The probe was not removed and then re-fitted after each individual TEOAE test. Data were collected under the supervision of a licensed audiologist.

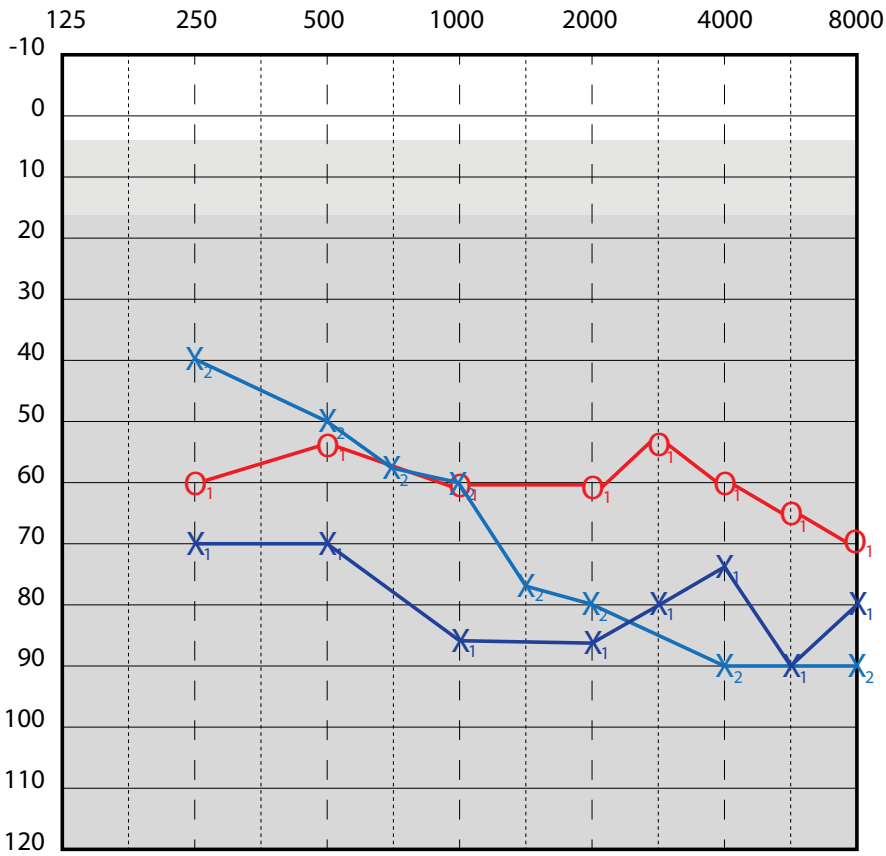

Figure 1. Audiograms for Ears Used to Estimate False-Negative Rate of Transient-Evoked Otoacoustic Emission (TEOAE) Hearing Screening Tests. Different subscripts indicate different people.

Table 2. Bio-logic AuDx® TEOAE System Default Protocol

Number of frequencies for overall pass	0	Number of samples per set	3
Checkfit trials	10	Calibration trials	10
Number of successes to pass	1	Number of calibration successes to pass	1
Number of checkfit failures until refit	7	Number of calibration failures until refit	7
Checkfit/calibration artifact rejection	250	Maximum number of samples	512
Minimum percent probe stability	95	Target amplitude (dB SPL)	80
Start time (ms)	3.50	End time (ms)	12.0
Ramp time (ms)	0.98	Artifact reject (mPa)	20

Note. TEOAE = transient-evoked otoacoustic emission.

Analysis and Results

To estimate the number of babies with moderate or worse hearing loss that would be missed due to repeated testing two pieces of information are needed: a) an estimate of the false negative rate of OAE testing due to statistical artifact; and, b) the incidence of congenital hearing loss.

False Negative Rate of OAE Testing

The false negative rate for OAE screening is the number of times a pass result is obtained for an ear that has hearing loss. Of the three ears with hearing loss that were tested 1,000 times, one ear had 999 fails, a second had 1,000 fails, and the third had 998 fails. Testing with the 2.0 cc coupler had similar results with 1,000 fails. Based on these results, the false negative rate for this piece of TEOAE screening equipment was estimated to be 1 per 1,000. The fact that the false negative rate was based on adult ears instead of infant ears is a limitation. However, the authors of the study decided that it was not practical or appropriate to repeat a screening test 1,000 times on a newborn. If the false negative rate for newborns is substantially higher for newborns than for adults, the results would be different. However, as discussed below, even in the unlikely event that the false negative rate for newborns is ten times as high as the rate estimated for adults, it does not change the basic conclusions of this study.

Prevalence of Congenital Hearing Loss

In the latest data available, staff at state-based EHDI programs reported an average of 1.5 babies per 1,000 with permanent hearing loss (CDC, 2015). However, as noted by White (2014) this number is likely a low estimate of the number of babies with congenital hearing loss due to high rates of loss to follow-up in many states and inefficient newborn hearing screening programs and/or poor documentation in some states. White (2014) suggested that a better estimate is 3.0 per 1,000 births. For this study, the higher number for the incidence of congenital hearing loss was used to estimate a worst case scenario of how many babies with hearing loss were likely to be missed due to repeated TEOAE testing.

Analyses

In calculating the number of ears with permanent hearing loss that are likely to be missed due to repeated screening, we must first focus on only those ears that have hearing loss, because it is impossible to "miss" ears that have normal hearing. If 10,000 ears with hearing loss were tested with the probability of an accurate test being 0.9990 as estimated above, ten ears with permanent hearing loss would be missed as shown in the first row of Table 3.

Table 3. Number of Ears with Permanent Hearing Loss in a General Population Sample of 100,000 that are Missed Due to Repeated Screening Tests if False Negative Rate is 1 per 1,000.

Based on a True False Negative Rate of 1 per 1,000					
Probability of an ear with hearing loss failing the test	**# of screening tests**	False negatives per 10,000 ears with hearing loss	False negatives per 10,000,000 newborns ears in the general population	**False negatives per 100,000 newborn ears in the general population**	**% of "missed" newborn ears with hearing loss**
0.9990	**1**	10.0	30.0	**0.30**	0.10%
0.9980	**2**	20.0	60.0	**0.60**	0.20%
0.9970	**3**	30.0	89.9	**0.90**	0.30%
0.9960	**4**	39.9	119.8	**1.20**	0.40%
0.9950	**5**	49.9	149.7	**1.50**	0.50%
0.9900	**10**	99.6	298.7	**2.99**	1.00%
0.9851	**15**	149.0	446.9	**4.47**	1.49%
0.9802	**20**	198.1	594.3	**5.94**	1.98%
0.9753	**25**	247.0	741.1	**7.41**	2.47%

The incidence of a missed hearing loss if every ear is tested once is obtained by multiplying the incidence of a false negative in the population of ears with hearing loss (10 per 10,000) by the incidence of hearing loss in the general population (3 per 1,000). Thus, the incidence of missed ears if only one screening test were done is 30 per 10,000,000. Converting this to a number that is more realistic for state-based EHDI programs, 0.30 ears with hearing loss would be missed for every 100,000 ears in the general population as shown in the first row of the right-most column in Table 3.

But what happens if the screening test is repeated multiple times? As noted in the JCIH (2007, p. 903) position statement, when a test is less than 100% accurate, "the likelihood of obtaining a pass outcome by chance alone is increased when screening is performed repeatedly." In this case, it was estimated that the test is only 99.9% accurate, so there is no question that the likelihood of a false negative will be increased—but by how much and is it enough to be concerned?

The probability of a false negative result due to statistical artifacts of repeated testing is estimated by multiplying the accuracy of each test in the series and subtracting the result from 1.0. Thus, the probability of a false negative for two tests is:

$$1 - (0.999 \times 0.999) = 0.998.$$

The probability when three tests are given is:

$$1 - (0.999 \times 0.999 \times 0.999) = 0.997.$$

Similar calculations can be done for however many tests are given and selected results are shown in Table 3. The number of ears that would be missed due to statistical artifact if every ear were tested from 2–25 times is very small because the false negative rate of each individual test is only 1 per 1,000 and the incidence of hearing loss among babies is only 3 per 1,000. For example, in a population of 50,000 babies (or 100,000 ears), we would expect 150 babies with permanent hearing loss (3 babies per 1,000 × 50,000 babies). But, if every one of these 50,000 babies were tested ten times in each ear, only 2.99 ears (or about 1.0% of the 300 ears with permanent hearing loss) would be missed due to statistical artifact.

Table 4 shows the number of babies' ears that would be missed due to statistical artifact if there were 10 times as many false negatives (i.e., 1 per 100 instead of 1 per 1,000). Table 4 is provided to emphasize how unlikely it is that a mistake in estimating the false negative rate per 1,000 would change the basic conclusions of this analysis.

Calculating the number of babies that would be missed due to statistical artifact in the birth cohort of 50,000 requires differentiating between babies with unilateral hearing loss and babies with bilateral hearing loss. According to the CDC (2015), 40% of babies reported in 2013 as having congenital hearing loss were unilateral. Thus, if there were 300 ears with permanent hearing loss missed in the population of 100,000 ears tested, there would be 113 babies with bilateral losses (226 ears) and 74 babies with unilateral losses (74 ears) for a total of 187 babies and 300 ears. If 1% of these ears were missed, it would be one baby with bilateral loss and one with unilateral loss. However, the probability of missing both ears in a baby with bilateral loss due to statistical artifact when one ear is tested right after the other is 1 in 1,000,000 instead of 1 in 1,000 because the probability of two independent events happening in sequence is the product of the probabilities of each of those events happening independently. Thus, the chance of a baby with bilateral hearing loss being missed due to statistical artifact approaches zero because one or the other of the ears would fail the testing and both ears would be identified during follow-up diagnostic testing. Therefore, the only baby missed would be the one with unilateral loss. To summarize, in a birth cohort of 50,000 babies, there would be 150 babies with congenital hearing loss, and 1 baby with unilateral loss (0.67%) would be missed due to the statistical artifact of repeated testing.

Table 4. Number of Ears with Permanent Hearing Loss in a General Population Sample of 100,000 that are Missed Due to Repeated Screening Tests if False Negative Rate is 1 per 100.

Based on a True False Negative Rate of 1 per 100					
Probability of an ear with hearing loss failing a test	**# of screening tests**	False negatives per 10,000 ears with hearing loss	False negatives per 10,000,000 newborns ears in the general population	**False negatives per 100,000 newborn ears in the general population**	**% of "missed" newborn ears with hearing loss**
0.9900	**1**	100.0	300.0	**3.00**	1.00%
0.9801	**2**	199.0	597.0	**5.97**	1.99%
0.9791	**3**	208.8	626.4	**6.26**	2.09%
0.9781	**4**	218.6	655.8	**6.56**	2.19%
0.9772	**5**	228.4	685.1	**6.85**	2.28%
0.9723	**10**	277.1	831.4	**8.31**	2.77%
0.9674	**15**	325.7	977.0	**9.77**	3.26%
0.9626	**20**	373.9	1121.8	**11.22**	3.74%
0.9578	**25**	422.0	1265.9	**12.66**	4.22%

Discussion

The positive impact of effective NBHS programs on the linguistic and academic development of children who are deaf or hard of hearing has been well documented (Kennedy et al., 2006; Marge & Marge, 2005; Moeller, 2000; Yoshinaga-Itano, Sedey, Coutler, & Mehl, 1998). Although programs should seek to improve screening methods and minimize false OAE test results, the goal of a screening program should not be to pass every baby tested. Instead, programs should identify and implement effective screening protocols and procedures with well-trained personnel so that the results of screening tests are reliable and accurate.

Even though it is estimated that less than 1% of the babies with moderate or worse permanent hearing would be missed due to statistical artifacts, there are a number of other potentially adverse effects if OAE screening tests are repeated too often in a newborn hearing screening program. For example, frequent repetition of OAE screening may:
1. Be an inefficient use of resources because staff are often repeating tests that are unlikely to have different results.
2. Decrease the confidence that health care providers (e.g., nurses, physicians, etc.) and parents have about the efficacy of the NBHS program or the testing process because tests are being repeated so frequently.

Conversely, not repeating the OAE test enough times to get an accurate result can result in an excessive number of false positive results where infants with normal hearing are discharged from the hospital with a failed OAE test result. For example, it is well known that cerumen or other debris in the ear canal of newborns can cause a fail screening result for babies with normal hearing (White, 2014). Such debris often clears after a few hours and a baby with normal hearing who has failed the initial screening will often pass a subsequent screening. Similarly, a baby with normal hearing who is very agitated during a screening test may fail because the probe is not positioned correctly or there is too much noise in the screening environment. Retesting at a later time will often result in an accurate pass result.

If too many babies with normal hearing have failed the screening test when they leave the hospital, overall screening costs increase due to a large number of babies who must be followed and brought back for additional testing. Doing follow-up testing with an unnecessarily high number of infants not only increases costs, but it may cause parents undue alarm and anxiety, undermining confidence in the screening program among all stakeholders (Clemens, Davis, & Bailey, 2000).

The ramifications of over-testing or under-testing illustrate the importance of effective and appropriate screening protocols (Wada, Kubo, Aiba, & Yamane, 2004). In addressing potential program improvements to increase the accuracy of hearing screening procedures, program administrators may benefit from re-evaluating their procedures, including clarifications for when to test, how to test, and providing a clear protocol for what constitutes a testing attempt. For example, attempting to test when the baby is agitated or when the test environment is excessively noisy will often result in a failed screening result even if the baby has normal hearing. Debris in the test probe, excessive cerumen in the infant's ear canal, or the probe tip blocked against the canal wall also should be identified so that effective adjustments can be made prior to attempting the OAE test. Well-trained screeners can readily identify adverse test conditions, ensure proper probe fit, and proceed with testing only when conditions are conducive to obtaining an accurate test result.

There are a number of resources that can guide NBHS program administrators to evaluate their current program procedures and identify potential areas of improvement. For example, NCHAM offers free online training modules for newborn hearing screening programs (http://www.infanthearing.org/nhstc/). Even those who believe their screening programs are highly effective may benefit from regularly evaluating program processes to ensure the screening follows best-practice recommendations.

Conclusions

It is appropriate for administrators of newborn hearing screening programs to be concerned about how often OAE screening should be repeated—but not because repeated screening prior to discharge will result in a high number of false negative results due to statistical artifacts. As shown in this article, very few babies with permanent hearing loss are likely to pass a newborn hearing screen test because the test was repeated multiple times. Even if a TEOAE screening test were repeated ten times for every baby, fewer than 1% of those with permanent hearing loss would pass because of repeated testing.

It should be noted that once a baby has failed the newborn hearing screening test, diagnostic assessment to determine the baby's hearing status should be done as soon as possible. The results of this study should not be used to justify repeated OAE screening after the baby is discharged from the hospital as a prerequisite for doing the diagnostic evaluation. Such a practice has nothing to do with false negatives as a result of statistical artifacts of repeated testing and will only delay diagnosis and commencement of appropriate early intervention.

It is important for administrators of NBHS programs to be thoughtful about how often newborn hearing screening tests are repeated and to train their screeners accordingly. Not repeating the test often enough will lead to inappropriately high numbers of babies with normal hearing who fail a screen. This will lead to higher costs for follow-up screening and diagnostic testing. Repeating screening tests too often is also an inefficient use of staff time and may undermine the credibility of the program.

Newborn hearing screening programs should have well-trained screeners who recognize when to attempt testing and when to repeat OAE testing to obtain an accurate test result rather than focusing on the number of tests performed. To do otherwise can undermine the success of the screening program by wasting time, disturbing the baby, and upsetting parents and health care providers.

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