

Some Permanent Hearing Loss is Missed When “Switched Ear” Passes are Combined for Determining Screening Results

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Abstract: In practice, some Newborn Hearing Screening (NHS) programs designate an infant as having a bilateral “pass” by using non-simultaneous results obtained in each ear during different screening sessions (referred to in this article as switched ears or SW_EAR). This study aims to obtain evidence for determining the screening outcome of infants with SW_EAR, using data from MEDNAX-Pediatrix’s nationwide NHS program. From January 2009 to December 2012, infants with SW_EAR passes were referred for audiological evaluation. The audiological evaluations of 13,044 infants who referred (1,907 due to SW_EAR passes) out of the total infant population screened (2,212,107) were analyzed. Of the 2,816 infants identified with permanent hearing loss (PHL), 150 (5.3%) were from the group of infants with SW_EAR passes. Most of these infants (116/150, 77%) had bilateral PHL, with documented hearing aids in 89 infants and 7 infants who received cochlear implants. By not using SW_EAR passes (i.e., by not combining non-simultaneous ear passes from different screening sessions) to determine that the infant had passed the newborn screen, and instead referring those infants for audiological evaluation, a significant number of infants with PHL were identified, while maintaining program performance within benchmarks.

Key Words: Hearing screening, false-negative, infant, sensorineural hearing loss

Acronyms: AABR = automated auditory brainstem response; ANSD = auditory neuropathy spectrum disorder; ASHA = American Speech-Language-Hearing Association; CDC = Centers for Disease Control and Prevention; CHL = conductive hearing loss; FCHL = fluctuating conductive hearing loss; IP = inpatient; JCIH = Joint Committee on Infant Hearing; NHS = Newborn Hearing Screening; OAE = otoacoustic emissions; OP = outpatient; PCHL = permanent conductive hearing loss; PDX = MEDNEX-Pediatrix; PHL = permanent hearing loss; ROC = receiver operating characteristics; SNHL = sensorineural hearing loss; SW_EAR = non-simultaneous results obtained in each ear during different screening sessions

Acknowledgements: We would like to recognize Brenda Sommer, RN, and Reese H. Clark, MD, for their decisive role and continuous support in the conception, review, and completion of this work.

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Introduction

Over the last two decades Newborn Hearing Screening (NHS) programs have evolved and are being developed in many countries worldwide. As a result, the focus and challenges of NHS have shifted from implementing programs to creating more efficient and effective screening practices (Choo & Meinzen-Derr, 2010; Nelson, Bougatsos, & Nygren, 2008; White, Forsman, Eichwald, & Muñoz, 2010).

Major challenges for successful and cost-efficient screening practices include the need to maintain sufficiently low referral and false positive rates. The

use of repeat screening tests/sessions with automated auditory brainstem response (AABR) and/or otoacoustic emissions (OAE) technology has proven to be a useful approach to achieve these goals (Clemens & Davis, 2001; Gravel et al., 2005; Vohr et al., 2001; White et al., 2005). A number of well-controlled studies have demonstrated that the commonly used two-step/two-technology NHS protocols can effectively reduce the overall referral rates to $\leq 4\%$ of the total infants screened or even lower for those protocols that combine inpatient (IP) and outpatient (OP) screens (Thompson et al., 2001). However, while repeated automated screens help to enhance specificity by reducing false positive results (Clemens & Davis, 2001), they could take a toll on the protocol sensitivity and cause more

infants with hearing loss to pass the screen (an increase of false negatives) due to inherent problems of statistical artifacts associated with repeated testing (JCIH, 2007, p. 903).

It is important to systematically evaluate the various factors that could impact the overall performance of repeat testing NHS protocols. Recent studies by Turner (2013a, 2013b), using mathematical modeling and receiver operating characteristics (ROC) methodology, identified complex interactions between three basic factors that could enhance or reduce below optimum the overall performance of NHS protocols using repeat automated screens: (a) the accuracy of the screening test/technology in use, (b) the internal test correlation measuring the likelihood that repeated screens identify the same individuals as positive (refer) or negative (pass), and (c) the protocol's *stopping* criterion by which the results from repeat screens are combined to make the final pass/refer decision for the infant.

Past studies of NHS have focused on the overall efficiency/effectiveness of the most commonly implemented protocols (Gravel et al., 2005; White et al., 2005) or compared the accuracy of the screening method (OAE vs. AABR) in use (Norton et al., 2000). However, there is limited data available from NHS programs regarding the consequences of repeated automated screens or the criteria by which the results from multiple screens are used to determine the pass/refer outcome for an infant. As a result, there is a limited understanding of the impact these internal decisions may have on the overall performance of the screening protocol being used. This knowledge, when available, may provide a rational basis for further enhancements of NHS programs.

A key aspect in the implementation of NHS protocols, regardless of the technology being used, is how results from multiple automated screens are used to make a final pass/refer decision for an infant. The Expert Panel Recommendations on Newborn Hearing Screening of the American Speech-Language-Hearing Association (ASHA, 2013) state: "... the infant must pass the screening in both ears to be considered a "pass". The Recommendations also state "... If the newborn fails one ear, both ears must be screened during the re-screening"... (ASHA, 2013).

In this context, the interpretation of passing results in both ears, which were obtained at a different test session or on a different day, poses an interesting problem that needs further investigation. There are no agreed-upon criteria for deciding how to use ear passes in both ears that were not obtained within the same test time or session.

Some Newborn Hearing Screening (NHS) programs combine a pass result obtained for the left ear during one test session with a pass result obtained for the right ear during a different test session to conclude that the infant has a bilateral pass for the hearing screen even though both ears did not pass during the same test session.

Unfortunately, it is not known how many infants with PHL may be missed by considering non-simultaneous passes obtained in each ear during repeated screens (referred to in this article as switched ears or SW_EAR passes) as a bilateral "pass." By this practice, an infant who passes only one ear (left or right) during a screen session and then during a repeat screen performed at a different test time or on a different day passes the ear that previously referred, would be given a "pass-pass" or screen negative outcome. However, there is no systematic research to whether the use of such SW_EAR passes may result in infants with permanent hearing loss being missed.

Method

Study Design

A retrospective cross-sectional study compared hearing screen results and audiological outcome data collected from January 2009 to December 2012 by MEDNAX-Pediatrix's nationwide NHS program (PDX_NHS) using AABR technology. Out of the total infant population screened (2,212,107), infants who received a refer status at discharge (13,044) were categorized into two groups: (a) those with SW_EAR passes (1,907) and (b) those without SW_EAR passes (11,137).

Inclusion/Exclusion Criteria. During the four years in which data were collected for this study, PDX_NHS programs referred all infants with SW_EAR passes for a complete audiological follow-up. The hearing screen data and audiological evaluations were categorized into two groups (with and without SW_EAR passes) as described below.

Infants with SW_EAR Passes. This group included those infants who had non-simultaneous passing results which were obtained in each ear during a repeat screen performed at a different time or on a different day. The "switching" between left ear and right ears passes could have occurred during any of the screens performed prior to discharge (inpatient) or when recalled as an outpatient. These infants would have been considered a "pass" (screen negative result) prior to this study. Figure 1 illustrates an example of an SW_EAR pass result for an infant with three repeat inpatient screens.

Infants without SW_EAR Passes. The group included those infants who failed one or both ears during the final AABR screen performed, prior to discharge as an inpatient (IP) and/or when recalled as an outpatient (OP), who had no "switching" between left and right ear passes during any combination of the screens or test sessions performed.

Participants. The study included all infants who received a refer status (13,044 in total; 1,907 with SW_EAR passes) during the four-year study period (2009–2012). The total number of infants screened by PDX_NHS programs during this time was 2,212,107, which represented 99.9% of all eligible births from 320 hospitals in 29 states.

Hearing Screen #1 (1/27/2011)
Right Ear: **PASS**
Left Ear: **REFER**
Decibel Level: 35

Hearing Screen #2 (1/27/2011)
Right Ear: **REFER**
Left Ear: **REFER**
Decibel Level: 35

Hearing Screen #3 (1/29/2011)
Right Ear: **REFER**
Left Ear: **PASS**
Decibel Level: 35

Figure 1. A typical example of SW_EAR hearing screen results. Three screens were performed, each at a different time or test session. Conflicting passing results in each ear (SW_EAR) were obtained during screen #1 and screen #3. These non-simultaneous passes for the Left and Right ear would be combined as a Pass-Pass or screen negative outcome for the infant if SW_EAR pass results are allowed.

Screening Protocol. The protocol combined IP and OP AABR hearing screens (when allowable per state specific guidelines) in most facilities. During the study period, the PDX_NHS screening protocol limited the number of AABR screens that could be performed for any infant to a maximum of three repeat screens during the IP stage (prior to discharge) and no more than two additional screens if recalled for OP testing session.

Equipment. All PDX_NHS programs used AABR as the method for screening with equipment manufactured, and approved for use, in the USA. However, the specific AABR testing device/model varied across hospitals from 2009–2011 and included ALGO® screeners (models ALGO 2E®, ALGO 2EC®, AIGO3®) and Bio-Logic ABAer® systems manufactured by Natus Medical Inc., as well as, Smart Screener-Plus 2® manufactured by Intelligent Hearing Systems. Specifications for each product are provided in the Hearing Review Products Technology Guides (2012) on the National Center for Hearing Assessment and Management (NCHAM) website. To facilitate program and operational standardization, a conversion to a single manufacturer of automated screening devices (Intelligent Hearing Systems, Smart Screener-Plus 2®) was initiated beginning in 2010 and completed by the end of 2011.

Data Collection. Demographic information of all infants screened by PDX_NHS program during the study, each infant's screening results, audiological evaluations, and information about use of hearing technology for all infants who were referred from the hearing screening in each group (with and without SW_EAR passes) was maintained in a web-based tracking and database management system (Soundata®). Referred infants who failed the audiological testing were followed for two years to capture as much diagnostic and hearing technology data as possible.

Data Audit. The diagnoses/outcomes data maintained in Soundata® for the infants who were referred at follow-up were audited independently by two authors to validate the audiological evaluations data used in this study. The authors specifically focused on the manual entry of the results from different Audiology/ENT reports. Different queries were posed to cross-check the data for inconsistencies in the results and/or inconclusive outcomes/diagnoses. Any detected cases were reviewed and corrected prior to final data analysis. Since a separate diagnostic category for fluctuating or temporary hearing loss due to middle ear pathology was not available for data categorization during the initial stage of the study, a full case-by-case review was conducted of all referred infants categorized as conductive hearing loss and/or middle ear disorder(s). Lastly, all cases in the SW_EAR group with a diagnosis of PHL, as well as those documented as receiving hearing technology (e.g., cochlear implants and/or hearing aids) were reviewed case-by-case and updated/corrected as needed.

Data Analysis. Upon completion of the data auditing process, the audiological outcome data of all referred infants in the study sample (with and without SW_EAR passes) were analyzed. Data analyses included descriptive and nonparametric statistics.

Audiological outcomes data. Infants who were referred during screening (with and without SW_EAR) were categorized as follows:

Permanent Hearing Loss (PHL). Included infants with unilateral or bilateral hearing loss of any of the following diagnosis/types: Sensorineural hearing losses (SNHL); Auditory Neuropathy Spectrum Disorder (ANSD); Permanent Conductive hearing loss (PCHL), and mixed hearing loss.

Fluctuating Conductive Hearing Losses (FCHL). Included infants whose only hearing loss was attributable to temporary or fluctuating unilateral or bilateral conductive hearing loss, due to middle ear pathology which was evidenced through repeat audiological testing and/or following medical intervention (e.g., pressure equalization tubes or medical treatment).

Inconclusive Diagnosis. Included infants who failed follow-up testing with abnormal diagnostic tests and/or rescreen results, but had insufficient data to reach a definitive audiological diagnosis (i.e., type and/or degree of hearing loss in each ear).

No Hearing Loss. Included all infants who passed the follow-up audiological testing in both ears. Passing results could be obtained with either automated screening tests alone (e.g., OAE, AABR) or were produced via a complete or incomplete diagnostic test battery (e.g., diagnostic ABR

thresholds and/or behavioral testing) as well as other audiological tests.

Program Performance Metrics. Appropriate actions for SW_EAR results within PDX_NHS program were determined by calculating the following metrics of the program during the study period and expressed as percentages:

Referral Rates: number of refers in each group divided by the number of infants screened

Permanent Hearing Loss Rate among Referrals: number of infants who had a definitive diagnosis of PHL (e.g. sensorineural, conductive, mixed and ANSD) unilateral or bilateral in each group, divided by the number of infants referred for audiological follow-up

No Hearing Loss Rate among Referrals: number of refer infants who had passing results during the audiological follow-up testing and no temporary hearing loss evidenced during the follow-up period in each group, divided by the total infants who were referred for audiological follow-up

Diagnosed PHL: number of infants who had a definitive diagnosis of PHL in each group (e.g., SNHL, PCHL, mixed, and ANSD) unilateral or bilateral, divided by the total number of infants screened

False Positives: number of infants determined to have normal hearing who failed the hearing screening, divided by the number of infants screened

Results

Figure 2 shows the results for hearing screen data and audiological diagnostic evaluation of infants who received a refer status in both groups: (a) without SW_EAR passes and (b) with SW_EAR passes. Seventy-seven percent of the infants who referred in each group during the period of the study (2009–2012) were successfully tracked and had Audiology/ENT reports in Soundata®.

Most of the infants who were successfully tracked had sufficient follow-up data (e.g., Audiology/ENT reports, test results, and/or information about use of hearing technology) for a definitive diagnosis and could be categorized as either: (a) PHL (including SNHL, PCHL, mixed or ANSD), (b) FCHL due to transient or chronic middle ear pathology, or (c) no hearing loss. However, there were a few infants who failed the initial diagnostic testing but had insufficient follow-up data for determining the nature of the hearing loss and were therefore categorized as inconclusive and omitted from further analysis (4.7% of those with SW_EAR passes).

Of the 1,907 infants in the group of infants with SW_EAR passes (Figure 2), 150 infants (7.9%) were diagnosed with PHL including SNHL, ANSD, PCHL, or mixed hearing loss. Note that the infants with SW_EAR passes constituted 14.6% (1907/13,044) of the total infants referred for audiological follow-up. The infants with SW_EAR passes who were diagnosed with PHL represented 5.3% (150/2,816) of those diagnosed with PHL in the population of 2,212,107 infants that were screened. Interestingly, in the group of infants with SW_EAR passes (1,907 infants) the proportion of PHL identified (150/1907, 7.9%) was higher than the PHL diagnosed in those infants screened who had no SW_EAR passes (2,666/2,210,200, 0.12%).

To further validate the audiological diagnosis of PHL, data were analyzed for the 183 infants in the group with SW_EAR passes who had documented use of hearing technology in Soundata® during the follow-up period. There were 89 infants diagnosed with PHL in the group with SW_EAR passes who were fit with hearing aids and 7 infants (6 SNHL, 1 ANSD) who received cochlear implants.

The type and degree of hearing loss was reviewed for each of the infants diagnosed with PHL in the group with SW_EAR passes. Three quarters of these had both ears affected (116/150, 77.3%). The severity of PHL for the total number of ears affected ($N = 266$ ears) is shown in Figure 3.

Note that about half of the infants' ears with PHL (52.6%, 140/266) had moderate-to-severe or severe-to-profound hearing loss. Also, 61% (42/70 ears) of the total ears which were classified as mild or mild-to-moderate PHL were fit with hearing aids. The frequency distribution by type of hearing loss diagnosed in both groups (with and without SW_EAR passes) is shown in Figure 4.

Fluctuating conductive hearing loss due to temporary and/or chronic middle ear disorders was more frequently diagnosed in the group with SW_EAR passes than in the group without SW_EAR passes (Chi square = 71.65; $p < 0.000$). Also, the proportion of PCHL was lower in the group with SW_EAR passes compared to the group without SW_EAR passes (Chi square = 16.59; $p < 0.000$). Given that PDX_NHS policies stipulated that infants with ear atresia should not be screened, but should be referred directly for audiological follow-up, PCHL secondary to ear atresia/microtia was not represented in the group with SW_EAR passes. The remaining types of PHL showed similar frequency distributions for refer infants with and without SW_EAR passes (SNHL: Chi Square = 3.19; $p < 0.07$; ANSD: Chi Square = 1.56; $p < 0.21$; Mixed: Chi Square = 1.10; $p < 0.29$).

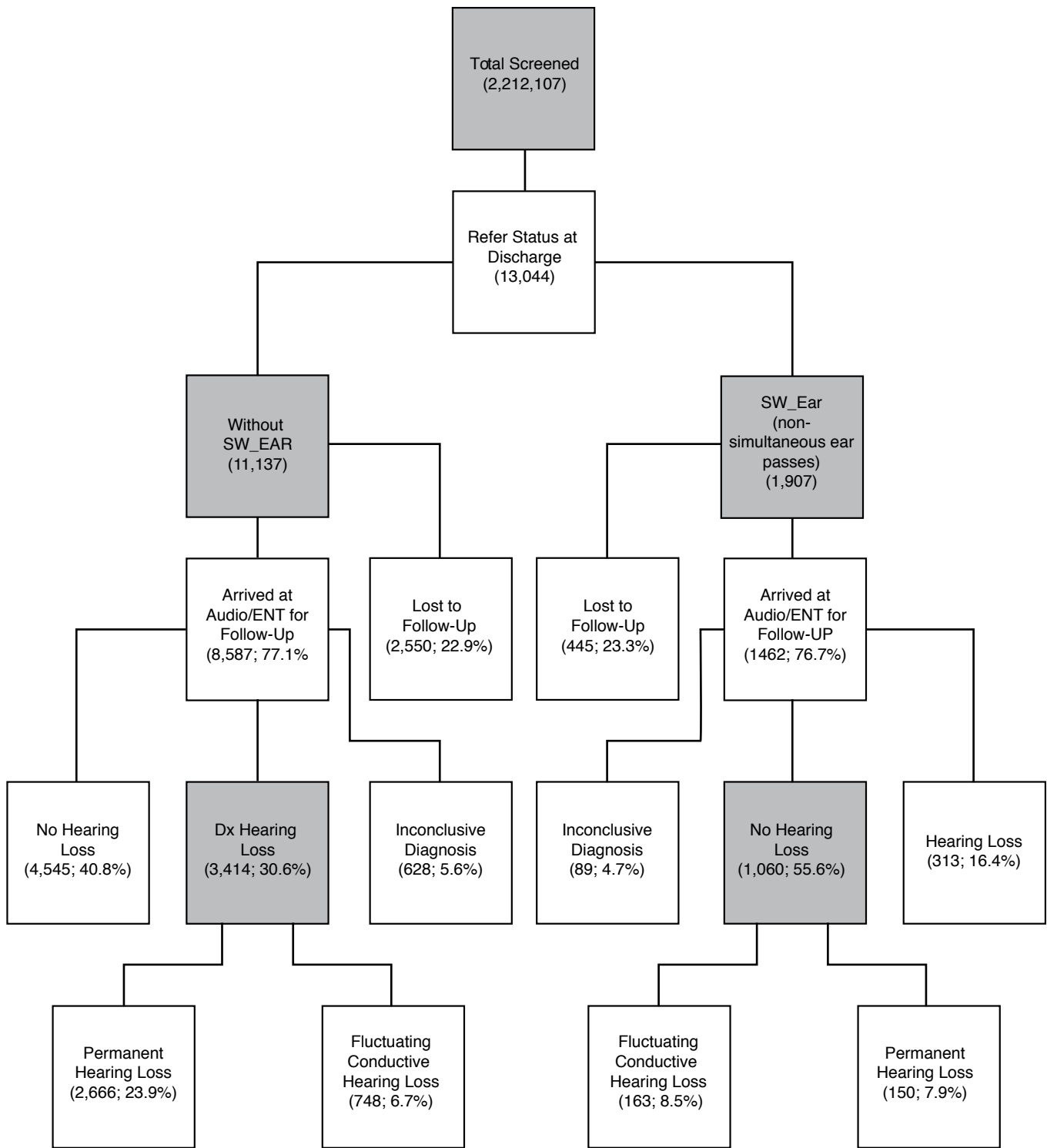


Figure 2. Flowchart summarizing the hearing screen data and audiological diagnostic outcomes of the infants who received a refer status in both groups: (a) without SW_EAR and (b) with SW_EAR passes. Lost to Follow-up category includes all refer infants that were lost (no audiological follow-up) including those unsuccessfully tracked as well as the parents/physician refusals, ineligible due to medical constraints, etc.

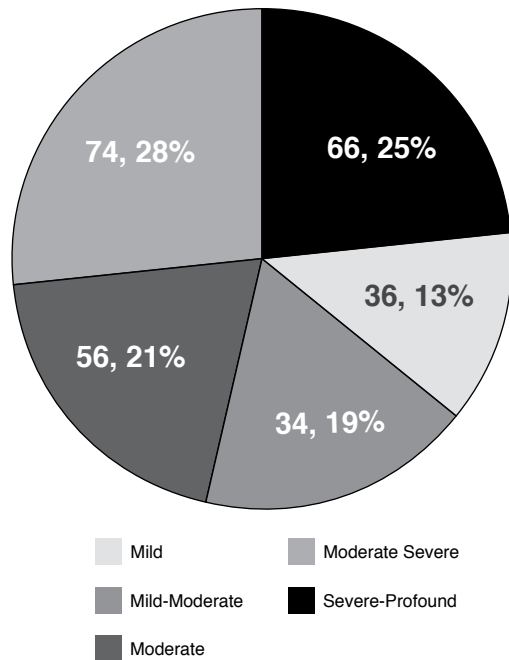


Figure 3. Severity of permanent hearing loss (PHL) diagnosed in infants with SW_EAR passes. (Total number of ears affected (N = 266)).

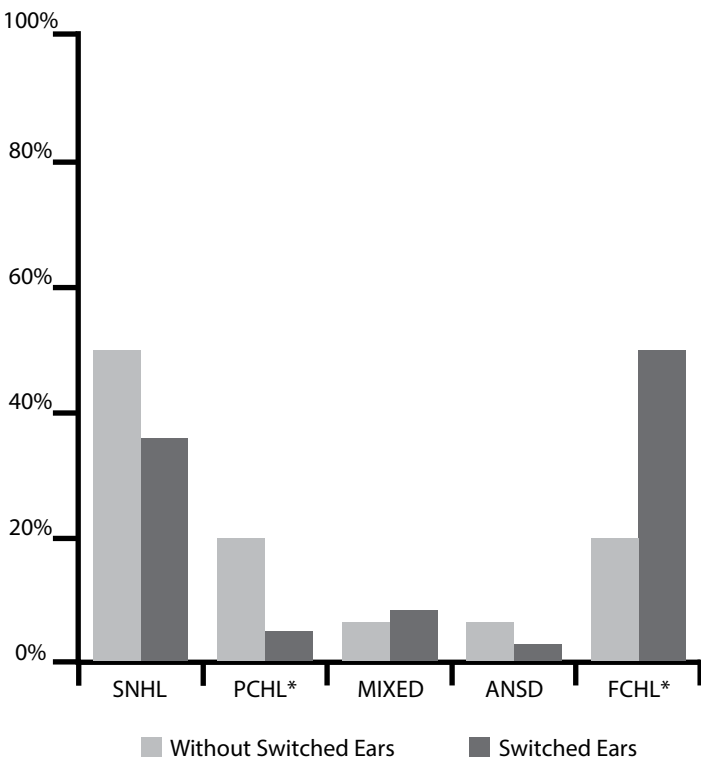


Figure 4. Type of permanent hearing loss (PHL) identified in infants with and without non-simultaneous passes obtained in each ear during different screening sessions (SW_EAR).

Note. ANSD = auditory neuropathy spectrum disorder; FCHL = fluctuating conductive hearing loss; MIXED = mixed hearing loss; PCHL = permanent conductive hearing loss; SNHL = sensorineural hearing loss.

* Indicates statistical significance ($p < 0.05$) between infants referred with SW_EAR and without SW_EAR.

Finally, selected metrics of program performance were analyzed for the group of infants without SW_EAR passes and for all infants in the sample (see Table 1). Note that the addition of the group with SW_EAR passes allowed the identification of an average of one more infant with PHL in every hundred with positive screening results (PHL rates increased from 21.7% for infants without SW_EAR to 22.9% when infants with SW_EAR passes were referred for audiological follow-up). Also, there was a slight increase in the referral rates (from 0.50% to 0.58%, as well as in the proportion of infants with no HL (from 34.8% to 42.9%).

Discussion

The need for systematic evaluation and monitoring of NHS program performance has been recognized as an important area for clinical research (White, Forsman, Eichwald, & Muñoz, 2010, ASHA, 2013). This population-based study, conducted within the context of PDX_NHS nationwide program provides convincing evidence that a significant number of infants with permanent hearing loss will be missed if infants with SW_EAR passes are not referred for audiological evaluation. Furthermore, results constitute strong empirical support for the current NHS recommendations (ASHA, 2013) that both ears must pass the screening for an infant to be screened negative. In addition, it supports clarification of the recommendation that both ear passes must be obtained during the same test time or during the same session.

Evidence from the retrospective analysis of diagnostic audiological evaluations collected during a four-year period (2009–2012) for 13,044 referred infants (of which 1,907 infants had SW_EAR passes) out of the

Table 1
Impact of referring infants with SW_EAR passes on the performance of PDX_NHS program

Screening Metrics	Infants without SW_EAR passes (n = 2,210,200)	All infants in sample (N = 2,212,107)
Referral Rates	0.50 [0.44-0.55]	0.58 [0.50-0.65]
No HL Rate	33.8 [31.8-35.9]	41.2 [37.8-44.6]
PHL Rate	21.7 [19.5-23.7]	22.9 [20.7-25.1]
False Positive	0.20 [0.16-0.23]	0.24 [0.2-0.3]
Permanent HL	0.12 [0.11-0.12]	0.13 [0.12-0.14]

Note. Data based on quarterly estimates for each metric calculated across sites (320 hospitals in 29 states) during the four years study (2009–2012). HL = hearing loss; PHL = permanent hearing loss; PDX_NHS = MEDNEX-Pediatrix newborn hearing screening; SW_EAR passes = non-simultaneous passes obtained in each ear during different screening sessions.

total population screened (2,212,107) showed that by completing the audiological follow-up on infants with SW_EAR passes, PDX_NHS program identified one more infant with PHL in every hundred infants who were referred from the newborn hearing screening program. The infants in group of SW_EAR passes who were diagnosed at follow-up with permanent hearing loss (150/1,907, 7.3%) represent 5.3% of all infants identified with PHL in this sample of 2,212,107 infants who were screened. It is also important to note that the program maintained very low referral rates (0.58%) even though additional infants were being referred.

The hearing loss diagnosed in the group of children with SW_EAR passes should be further analyzed. Most of these infants diagnosed with PHL (116/150, 77%) had bilateral hearing losses and about half of these infants' ears (52%, 140/266) had moderate-to-severe or severe-to-profound hearing losses. In addition, a high proportion of infants with SW_EAR passes (136/1,907, 8.5%) were diagnosed with fluctuating conductive hearing losses (FCHL) due to middle ear effusion. This type of dysfunction could "switch" from one ear to the other, and be reflected in non-simultaneous ear passing results at different test times. An elevated incidence of temporary middle ear dysfunction in the neonatal period associated with the development of middle ear pathology has been well documented by many authors (Doyle, Kong, Strobel, Dallaire, & Ray, 2004; Doyle, Rodgers, Fujikawa, & Newman, 2000). The fact that the relative proportion of FCHL was significantly higher in the infants with SW_EAR passes compared to those without SW_EAR passes is consistent with the hypothesis that middle ear pathology may be a plausible explanation for part of the hearing loss diagnosed in the SW_EAR group.

Another possible explanation for the hearing losses identified in infants with SW_EAR passes that should be analyzed is the problems associated with the use of automated screening technology. There are many operational factors that may affect screening results (e.g., accuracy of earphone placement, artifacts due to baby movement, environmental noise, etc.) as well as technical issues (e.g., problems of repeat screening attempts and lack of standardization of automated screening technology). Although these issues have been mentioned in the literature (JCIH, 2007; ASHA, 2013), they have not been adequately explored.

One limitation of this study is that different types of AABR equipment were used during the study. Given that each type of equipment/manufacturer uses different algorithms for determining the pass/refer decision in any single screen performed, the likelihood of an infant having SW_EAR passes might vary for the different devices. This possibility needs to be explored with all types of AABR manufactured equipment. Also, the possibility that similar results would be obtained with OAE equipment needs to be investigated.

Another limitation of the study is the number of repeat automated screens that were performed for determining the final outcome for an infant. During this period of the study, up to five screens (3 IP + 2 OP) were allowed. As more screens are performed, the statistical problems of sequential testing (Stürzebecher, Cebulla, & Elberling, 2005; Stürzebecher & Cebulla, 2013) may increase the probability of falsely passing PHL, but this needs to be investigated.

The implications of this study for clinical practice are important. Current best practice guidelines state that both ears should pass for an infant to pass the screen (ASHA, 2013). Also, the recommendations state that both ears must be tested during re-screening. The empirical data provided in this study supports the above recommendations and indicates that both ears should pass within the same screening session for an infant to be considered a pass (screen negative outcome). The fact that PHL, mostly bilateral and of significant magnitude, was diagnosed in this group, suggests that infants with non-simultaneous ear passes should be referred and tracked for audiological follow-up with the same urgency as repeat "non-switching" unilateral or bilateral refers.

The results of this study also demand refocused attention on how parents are counseled regarding SW_EAR results by screeners, pediatricians, and audiologists. Providers should not suggest that because a pass result was obtained for both ears, albeit at different times, that the diagnostic evaluation is likely to result in a conclusion that the infant has normal hearing. Indeed only 55.6% of the 1,907 infants who had SW_EAR passes were determined to have normal hearing, with the remainder being diagnosed with PHL (7.9%) or conductive hearing loss (CHL; 8.5%), having inconclusive results (4.7%), or not returning for the audiological evaluation (23.3%). These data suggest that if providers minimize the importance of parents completing diagnostic follow-up testing, there is a real possibility of missing infants with permanent and conductive hearing loss with a consequential detrimental effect for infant development (Yoshinaga-Itano, Coulter, & Thomson, 2001).

Conclusion

This retrospective study of 2,212,107 screened infants, 1,907 of whom had SW_EAR passes, provides evidence for eliminating the practice of passing infants by combining "switched ear" passes from repeat screens and therefore missing potential permanent hearing loss. Results support the current ASHA best practice recommendation which requires both ears to pass the screening for an infant to be screened negative with the added specification that both ear passes should be obtained within the same screening session. Furthermore, all hearing health care providers

involved in clinical follow-up care of refer infants should be cautious about concluding that an infant has normal hearing based on non-simultaneous passes on each ear from repeat screens.

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