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Letters to the Editor

To the Editor:

Further Questions about the Acceptable Noise Level Test

I appreciated the October special issue on acceptable noise level (ANL), edited by Anna Nabelek. It is a fascinating test, and I agree that the test may help us identify those at greatest need for noise-reduction technology (Nabelek et al, 2006), and perhaps it will help us in setting hearing aid algorithm levels. Adding to their conjecture, I wonder if those with good (low) ANLs would be intolerant of distortion in speech concomitant with aggressive noise reduction, whereas those with high ANLs may find that trade-off desirable.

The Nabelek et al article raises additional questions, and I wonder if the authors could provide insight. The most compelling data are provided by the logistical regression analysis, where ANLs predicted successful/unsuccessful use with 85% accuracy. Although the full-time users had 8 dB poorer pure tone averages, they reported that adding pure tone average to the logistic regression equation did not improve predictive accuracy. That is a fascinating finding, as the greater the loss, the greater the need for amplification, yet loss severity is not related to full-time use. I am wondering if the authors entered other variables into a forward, stepwise regression equation as well, to see if the predictive accuracy could be improved by adding variables of 500 Hz and/or 1000 Hz threshold, MCL, or hearing aid technology. Figure 1 shows about a 10 dB higher average threshold at 500 and 1000 Hz, so I wonder if that might be more sensitive than PTA. Lack of those thresholds improving the prediction of hearing aid "use when needed" would further strengthen the concept that tolerance of noise, rather than need, is the stronger predictor of hearing aid use.

The role of MCL in predicting hearing aid acceptance is particularly intriguing, as other cited literature indicates that for normal hearers, the higher the presentation level, the poorer the ANL. The full-time user group had an average MCL that was slightly higher, which is expected from the poorer hearing thresholds for the group. However, higher MCLs being associated with lower (better) ANLs in the full-time user group run counter to the trend seen with normal hearers. Perhaps MCL, or the sensation level of the MCL above the SRT or PTA, might be related to the ANL, or it may be a predictor of hearing aid acceptance used along with the ANL. Again, lack of finding such an association would also be informative. I wonder if the investigators have tried this "data mining," and if so, whether it improved the prediction of successful hearing aid use.

Additionally, the subjects in this study were all fit with hearing aids within the last three years, using a variety of different technologies. If it were possible to add the factor of "technology" to the logistic regression equation, that would also be fascinating. It might validate the theory that adding noise reduction technology increases user acceptance for those with moderate ANLs.

I have not yet used ANL clinically, though I plan to. I am still uncertain as to the variability I can expect with this measure, and the effect that test/retest variability may have on predictive accuracy. I would be interested in knowing the observed across sessions test-retest difference of the ANLs for the *individual* subjects. Freyaldenhoven et al (2006) provide the r values (about .94 within a session and 0.79 across sessions for normal hearers for babble noise). While an r-squared of .62 is good for a behavioral measurement across sessions, this does indicate some variability is expected. What is the size of the test-retest differences seen for the individual subjects? Is it typical to see a 2 dB, a 5 dB difference in ANL from one session to another?

Figure 2 in the Nabelek et al article provides the slope of the logistic regression equation. What was the Nagelkerke R^2 for the fit to the model? Perhaps that information is redundant if we know the predictive accuracy is 85%; if so please pardon my limited knowledge of logistic regression. There is mention that the accuracy of prediction is poorest with midrange ANL scores (7–13 dB). How accurate was the prediction for those with high and low ANLs versus those with midrange ANLs?

The test is said to require just two to three minutes to complete in one listening condition. Does that time include just one measurement of ANL, or two? I note that two was the norm in the articles in this issue. If just one measurement is made, how will that affect reliability of predictions of hearing aid success? The studies within this issue either used 1 or 2 dB step sizes. Do you have a clinical recommendation?

I shared excerpts of these articles with the NSU Class of 2008 Research Methods students. (And we thank AAA for making the journals available to student members.) They found some of the statistical reporting/interpretation a bit confusing, and we wonder if you could clarify. Harkrider and Tampas (2006, p. 672) reviewed the

differences in the amplitudes of ABR and MLR components in normal hearers with high versus low ANLs and reported it "revealed a main effect of group ($F_{4,8}$ = 2.7836, p = 0.10)." The article continues that the "amplitudes of waves V ($F_{1,11}$ = 4.381, p = 0.060) and Na-Pa ($F_{1,11}$ = 3.265, p = 0.098) contributed to the main effect of group." Since none of these statistical values fall below a probability value of 0.05, we wonder if there was a typographical error in reporting the p values.

My professor for nonparametric statistics argued convincingly that if data are not parametric by nature, the researcher should not attempt to utilize parametric statistics; nonparametric alternatives are more accurate and more powerful. Freyaldenhoven et al (2006) list correlation coefficients (r) values for test/retest reliability of five-point semantic differential scale questions (table 4). Wouldn't a Spearman's rho be more appropriate in this case? Nabelek et al (pp. 633–634) reported that "Correlational analysis indicated that both unaided and aided ANLs were not related to gender," and table 2 provides an r value. We are confused on how a parametric test can be applied to a dichotomous variable.

Our quibbling with some statistics notwithstanding, we very much appreciate the fascinating research and look forward to seeing for ourselves how this works in clinical situations. Additional information to help us understand the test/retest reliability and predictive validity would be greatly appreciated.

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Further Questions about the Acceptable Noise Level Test: A Response to Dr. Hamill

We appreciate Dr. Hamill's interest in the acceptable noise level (ANL) test and the opportunity to address her questions regarding the procedures. As mentioned in our paper (Nabelek et al, 2006), the addition of pure-tone average as a variable in the logistic regression equation did not improve the accuracy of predicting success with hearing aids. Listeners in our studies had mild to moderate hearing loss; perhaps listeners with more severe hearing losses will behave differently and should be evaluated in future studies. Furthermore, the addition of most comfortable listening level (MCL) and 500 and 1000 Hz thresholds to the equation did not improve the predictive ability of ANL.

Data have been collected examining the growth of the ANL with an increase in speech presentation level above MCL in listeners with normal hearing (Franklin et al, 2006; Tampas and Harkrider, 2006) and listeners with impaired hearing (Freyaldenhoven et al, forthcoming). The growth of the ANL is linear, but not uniform among listeners. The growth is steeper for listeners with high conventional ANLs (collected at MCL) than for listeners with low conventional ANLs.

In the Nabelek et al (2006) manuscript, the raw data were inspected for hearing aid type (analog versus digital) effects, and no differences were found; therefore, the calculations were performed regardless of hearing aid technology. However, the absence of control over the listeners' hearing aid type may account for this finding since listeners wore numerous types of instruments ranging from basic analog to high performance digital instruments. New data are being collected by our group with the goal of determining how hearing aid technology can affect ANL. Furthermore, two studies have shown that hearing aid technology can change an ANL in the laboratory. Mueller et al (2006) published data examining the effects of digital noise reduction on ANL and reported reduced ANLs when DNR was activated. Furthermore, Freyaldenhoven et al (2005) published data demonstrating ANLs can be improved with the use of directional hearing aid technology.

Reliability of the ANL has been previously reported in 50 listeners with impaired hearing (Nabelek et al, 2004), and the test-retest difference for individual listeners was approximately 2 dB. With regard to the Freyaldenhoven, Smiley, et al

(2006) data comparing individual ANLs within and across test session, the following results were obtained for the two types of noises: For speech spectrum noise, individual data demonstrated an ANL within session range of 0–6 dB with median values of 2, 1, and 1 dB for sessions 1, 2, and 3, respectively. For speech babble noise, individual data demonstrated an ANL within session range of 0–8 dB with median values of 1, 2, and 1 dB for sessions 1, 2, and 3, respectively. Individual data further showed a range in ANLs from 0–12.3 dB for speech spectrum noise and 0–14.3 dB for speech babble noise across sessions. Furthermore, when each listener's within session ANLs were averaged and compared to the average of the next sessions' ANLs, the median ANL difference between sessions was 1.7 dB for speech spectrum noise and 2.0 dB for speech babble noise.

The Nagelkerke R Square value for the Nabelek et al (2006) data was 0.656. It is important not to confuse ANL's accuracy of predicting hearing aid outcome with a listener's probability of successful hearing aid use. The accuracy in predicting hearing aid success using ANL was 82% while the precision for predicting lack of success was 83.6% (Table 4), meaning about 25% of listeners will be misclassified with the ANL procedure. The probability of hearing aid success/unsuccess with a given ANL score is expressed in Figure 2. The probability of success is very high for listeners with low ANLs (no greater than 7 dB), and the probability is very poor for listeners with high ANLs (greater than 13 dB). The probability of success in listeners with mid-range ANLs between 7 and 13 dB is more ambiguous (i.e., a listener with an ANL of 10 dB has a 50% chance of success with hearing aids). Therefore, for listeners with mid-range ANLs, the prediction of success with hearing aids using ANL is not very useful, and we are looking for ways to remove this ambiguity. We have recently submitted data (Freyaldenhoven, Nabelek, et al, 2006) comparing ANLs with the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire (Cox and Alexander, 1995), and the results suggest that the combination of these measures provides valuable information regarding hearing aid success for listeners with mid-range ANLs.

The ANL test requires 2–3 minutes to complete one measurement. Based on previous studies and the test/retest reliability of ANL, one measurement would be sufficient if the listener understands the task. However, we recommend replicating the test as a way to re-check your data because of the small amount of time the ANL test takes to administer. Additionally, we would recommend a 2 dB step size in clinical measurement.

The question regarding statistics reported by Harkrider and Tampas (2006, p. 672) is addressed within the paper on page 671. It is stated in the text and in Figure 1 that the findings are significant at $p < 0.1$. It is important to note that we emphasize the exploratory nature of the study and the limited subject pool and refer to the findings as "trends in the data." These trends were investigated further by Tampas and Harkrider (2006), who concluded "group differences in the auditory brainstem response, auditory middle latency response, and cortical, auditory late latency response indicate that differences in more central regions of the nervous system account for, at least in part, the variability in listeners' willingness to accept background noise when listening to speech."

As mentioned in the Nabelek et al (2006) manuscript, the parametric statistics were applied to determine which measurements could differentiate the *three* groups of hearing aid users, and were not applied to dichotomous variables. Because the mean unaided ANL for the part-time users was not significantly different from the non-users, the groups were redefined for further statistical analyses. Full-time users were considered successful users, and part-time and non-users were collapsed into one group termed unsuccessful users. Using unaided ANL as the predictor variable, logistic regression analysis was employed to predict the probability an individual would be a successful hearing aid user. The correlational analyses in Table 2 on page 631 were performed prior to the dichotomization of data.

Freyaldenhoven, Smiley, et al (2006) listed intraclass correlation coefficients for the questionnaire reliability analysis due to their comparison of three values (i.e., the questionnaire responses were obtained a total of three times). Since the intraclass correlation coefficient is a measure of consistency between cases, it was utilized to compare all three questionnaire responses simultaneously. Using bivariate Spearman's rho, the correlation coefficients between like questions in sessions 1, 2, and 3 were comparable to the reported correlations.

We are thankful for Dr. Hamill's interest in our work and for her constructive comments and insightful questions. We appreciate the opportunity to respond and hope that our research will help us, as hearing health care providers, in understanding and solving the perplexing problem of hearing aid rejection.

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Usefulness of Acoustic Reflexes Still Unproven in Newborns and Young Infants

Re: Berlin C, Hood LJ, Morlet T, Wilensky D, St. John P, Montgomery E, Thibodaux M. (2005) Absent or elevated middle ear muscle reflexes in the presence of normal otoacoustic emissions: a universal finding in 136 cases of auditory neuropathy/ dys-synchrony. *J Am Acad Audiol* 16:546–553.

This valuable paper highlights the absence of middle ear muscle (acoustic) reflexes in auditory neuropathy /dys-synchrony (AN/AD), at least in the older children and adults that formed the vast majority of the subjects. However, the authors implicitly assume these conclusions are also valid in newborns and young infants. This has not yet been shown, given that only four of their cases under four months of age were clearly tested with a high-frequency probe tone, which is essential to record valid reflexes in this age group (see below). Perhaps more importantly, we have very little knowledge and experience about the practicability of reflex testing in very young babies, and what we know suggests it would not fulfil the criteria for a good screening test. Current (very limited) evidence suggests that using reflexes as part of a newborn screening protocol would lead to an unacceptably high false alarm rate and would cause immense harm, in terms of parent anxiety and overload of follow-up assessment services. Hence, the authors' call for a radical change in newborn screening protocols (adding reflexes following an OAE-only screen pass) cannot yet be justified. If there is concern about missing AN/AD in well babies (itself a debatable point), ABR is still the only proven technique and is useable (in automated form) as a screening test.

The paper contains a crucial misconception about probe tones and recording of reflexes under four months of age, which is still commonly found in the literature. While Berlin et al are aware of research pointing to the need for a higher probe tone in young infants, they imply that only tympanometry requires this, not reflex measurement. This is not so. They state as the reason reflexes might not be seen at 220 Hz: "The implication is that an 'artifactually normal tympanogram' arising from collapsing canal walls does not 'see' obstructive middle ear residue blocking the recording of the reflex. However, if the emissions can pass through unobstructed, it is not reasonable to think that the reflexes would

be obstructed while the emissions would not" (p. 551). In other words, the authors are assuming that it is middle ear effusion (undetected by a 220 Hz tympanogram) that blocks the reflex recording. This is misleading—all evidence suggests it is the *mechanics of the neonatal eardrum* that prevents the recording of the reflex at 220 Hz, and this is independent of whether middle ear residue is present or not. Therefore it *is* entirely reasonable to expect a present OAE and an absent reflex, because the reflex is not "obstructed" but just not recordable using a 220 Hz probe. (In this context the actual tympanogram is thus a red herring, and I will leave to one side what role, if any, canal wall movement has in determining the shape.)

The key point is that *acoustic reflex recording (not just tympanometry) in newborns and very young infants requires a high-frequency probe tone.* Weatherby and Bennett's landmark 1980 paper on the neonatal middle ear reflex pinpointed both the problem and the explanation using measurements and modelling, and deserves to be more widely studied. To quote: "The low impedance of the tympanum at frequencies below about 500 Hz is the reason why the acoustic reflex cannot be detected with a 220 Hz probe tone. The low impedance effectively shunts the higher impedance of the middle ear system and small changes in impedance such as caused by the reflex cannot be seen." This shunting effect is removed by using a probe tone above 800 Hz. They showed that reflexes were not seen in any of their neonates at 220 Hz probe tone but were present in all of them using 1000 Hz.

Other data confirm that at 220 Hz, reflexes are seen either infrequently or not at all (Bennett 1973; Keith 1973; Keith and Bench 1978; Stream et al, 1978; McMillan et al, 1985), but they are at higher probe tones (Weatherby and Bennett, 1980, Bennett and Weatherby, 1982; Sprague et al, 1985; McMillan et al, 1985; Geddes, 1987). More recent work has confirmed Weatherby and Bennett's model and that the very young infant drum has a lower resonance frequency and its middle ear is mass- rather than stiffness-dominated, developing into a more adult system with a transition around four months (Holte et al, 1991; Keefe and Levi, 1996; McKinley et al, 1997; Meyer et al, 1997).

Thus, although the middle ear reflex is present and working from birth, at 220 Hz reflexes almost invariably appear to be absent in newborns and only become reliably recordable above about four months. *Hence, neonatally the absence of reflexes at 220 Hz tells us nothing at all about AN/AD, and although absent reflexes at 1000 Hz might, we do not yet have the evidence.* In their study, Berlin et al have helpfully separated the data on their 14 cases under six months: in only four cases was a high probe tone definitely used in reflex measurement (with two more at 220 Hz and unspecified in the remaining eight). Although all four showed absent reflexes, it cannot be sensible to base a fundamental change of screening policy on such a small number, and without considering how many normal ears would also test negative.

Thus, their data support the usefulness of reflexes in investigating possible AN/AD in children over the age of six months but not below. When drawing up the UK guidelines for assessment of AN/AD following the newborn screen (Sutton et al 2004), we concluded that the lack of evidence and experience meant we should not yet include reflexes as part of the essential battery for assessment following screen referral in this very young age group. Clearly, it would be valuable to extend the evidence on the issue.

In terms of newborn screening, the authors argue that if an OAE screen is passed, then reflexes should be tested and absence of reflexes in presence of OAEs used as a marker for further ABR testing for AN/AD. However, based on what we know, such testing would be a waste of time at 220 Hz, and even at 1000 Hz might turn out not to be as useful as hoped. The practical difficulties of recording reflexes, particularly in newborns, should not be underestimated. Most workers suggest it is far from straightforward (e.g., Weatherby and Bennett, 1980; Marchant et al, 1986). Leonardy-Doller and Sesterhann (1987) failed to record reflexes in 11 out of 40 neonates, either because of stirring (7) or absence of response (4) despite apparently normal hearing. Sutton et al (1996) found that only 40–50% of normal newborn ears showed recordable clear reflexes using commercial equipment. Hence, major questions remain. Does reflex presence at 1000 Hz rule out AN/AD? Are there any artefact problems? My own belief is that reflexes will most likely have a role as part of the battery of assessment tests on referral from screening but not as part of the screen itself.

However, the authors are clearly correct in stating that screening using OAEs alone does run the risk of missing AN/AD, although this risk may be very low for well babies. Until we know more, anyone concerned about screening for AN/AD in newborns should use an ABR screen as part of the routine screen protocol and discharge the baby only if this is clear. In the UK, this is done for all babies on NICU or SCBU for 48 hours or more.

In summary, it is suggested that the lessons for practice are these:

1. Always use a 1000 Hz probe tone for any reflex and tympanometric testing in babies under four months.
2. Gather more evidence on reflexes on babies referred from newborn screening to clarify practical recording issues, and obtain more data on reflexes in babies with AN/AD, babies with developmental delay, and babies with normal hearing.
3. Screen all high-risk babies using AABR as well as OAE.

This is undoubtedly a fruitful area for more research, and we look forward to more data both on reflexes in young babies and especially in AN/AD cases.

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Dr. Berlin Replies to Dr. Sutton

Dr. Sutton's suggests that, to avoid missing AN/AD, we should use ABR as a hearing screening tool instead of OAEs. This is exactly the subtext of our paper. We do not propose to diagnose AN/AD by adding reflexes, only to sharpen the screening process so that we can tell when an ABR *is* needed even if normal OAEs are recorded. From his point of view as a leader in the UK's NHS, we can easily see how this could be taken as a premature national policy recommendation that might not be cost-effective in the UK without more reflex data on neonates. But we stand firmly by the concept of coupling reflexes with OAEs to avoid missing AN/AD.

Sutton challenged the logic that says the tympanometric tone is irrelevant to reflex measurement if the emissions can be seen. If this is in fact an error, it is entirely mine (CB). It was done by deduction from my own experience in the early 80s successfully acquiring reflexes with a 220 Hz probe in some infants and even small mammals. From our subsequent experience with AN/AD patients, I saw no reason to believe

that reflexes would be present at birth in AN/AD patients but suddenly disappear just a few months later when lower-frequency probe tones could be more efficiently used. However, I am responsible for overlooking Dr. Sutton's shunting analysis derived from Bennett and Weatherby. He correctly states that we were aware of the importance of high-frequency probe-tone use, and we did state specifically, "Whether a higher tympanogram frequency is called for in screening is not clear . . . . [,and] the need for a higher probe frequency to detect the reflex [here we perhaps should have said "more efficiently"] should be reexamined" (p. 551).

Is AN/AD a "Rare Occurrence" as Sutton Suggests?

The paper was compiled at the request of the Chair of the Joint Commission on Hearing and addressed to recommend a change to the decision makers who had already recommended OAEs as a complete screening test for hearing. In the United States, EHDI was championed by colleagues (e.g., White et al) who believed at the time that OAEs were an ideal hearing test, and they convinced the NIDCD review panel to make that recommendation. At the time, the extent and prevalence of AN/AD was unclear. We now know that 10-15% of the Deaf (Cheng et al, 2005) and 40% of NICU graduates (Rea and Gibson, 2003) show residual otoacoustic emissions and poor neural synchrony. Thus, the notion that AN/AD is rare cannot be supported by data. AN/AD is only rare if one does not look for it, and as Dr. Sutton said, ABR is the preferred tool.

In the United States, once a hospital has made the decision to screen with OAEs, it is permitted to keep that posture and still be in compliance with EHDI guidelines. This posture would miss what may prove to be an epidemic of AN/AD diagnoses. Therefore, we recommended to installations who were already committed to OAEs that they add MEMRs (here perhaps we should have specifically added "using high-frequency probe tones") and, if the reflexes were not normal, to move to ABR, which was the Sutton suggestion to begin with.

What is most important is that we are not suggesting that any neonatal screening programs in this or any other country use OAEs and reflexes as a *diagnostic* tool. These are, after all, screening tests. But we suggest that, if OAEs have been chosen as the *only* screening tool, accuracy can be improved by adding reflexes as an index of when and whether to add an ABR. If the reflexes are normal, no ABR would be called for. If the reflexes were absent, however, an ABR would be called for, as a matter of course, without worrying the parents, thus avoiding the anxiety that Sutton et al feel would follow an incorrect diagnosis.

Recommending that screeners with infants use high-frequency probe tones for MEMRs is an important and welcome addition to the conclusion of our paper, but we stand by our conclusion that using normal OAEs to declare a child as "normal in hearing" should be tempered with a MEMR test as soon as feasible. If we do that, we will see that AN/AD is not rare and that many of our "hearing aid failures" to date who have already been implanted have had unrecognized AN/AD all along.

Take-Home Message

If your screening program uses *only* ABR, add emissions during the diagnostic phase of workup. If your screening program uses only emissions, use MEMR (with appropriately chosen probe frequency) to guide you whether and when to do a two-polarity ABR.

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