Development & Validation

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Voss SR Herrmann BS	How does the sound pressure generated by circumaural, supra-aural, and insert earphones differ for adult and infant ears?	Ear & Hearing	2005	26: 636-650

Synopsis:
Sound pressure level (SPL) generated by any earphone depends upon the size and volume of the ear canal and the impedance at the tympanic membrane. These factors must be considered to ensure that the intensity of a signal used for screening is appropriate and matches desired specifications. Using acoustic models of the ear canal and external ear, the sound pressure delivered by each of three earphone types was evaluated. Results demonstrate that circumaural earphones (specifically, Natus Flexicoupler™) produce minimal differences between SPL delivered to adult vs. infant ears and are within 3dB at all frequencies while insert earphones produce SPL that is up to 15dB greater in infant ears compared to adult ears, especially through the high frequency portion of the acoustic range. The data presented demonstrates that using the ALGO screener with Flexicoupler earphones delivers the screening stimulus at intensities consistent with specifications and contradicts statements of authors suggesting that the Flexicoupler would generate sound pressure in an infant ear that is greater than that generated in an adult ear. Results further support a requirement for in-ear real-time calibration whenever an insert earphone is used for screening and follow-up assessment of infants.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Herrmann BS Thornton AR Joseph JM	Automated infant hearing screening using the ABR: Development and validation.	American Journal of Audiology	1995	4(2): 6-14

Synopsis:
Detailed discussion of clinical research, experimental design, and clinical reliability of ALGO® AABR® by the audiologists who originally developed the technology. The initial three investigations to determine the suitability of ABR for universal screening by studying its sensitivity and specificity as well as its ability to be optimized and automated to control costs are described. Evaluation of the resulting screener under field conditions, including data from validation studies demonstrating the accuracy of ALGO screener performance as reported by investigators published between 1987 and 1990, is summarized. Results demonstrate that ABR accurately screens infant hearing and that critical performance factors were successfully automated in the ALGO screener. Combined sensitivity data illustrates the ALGO design emphasis on not passing an infant with hearing impairment in order to control the socioeconomic costs of delayed detection. Additionally, the increased screening program costs that result from high false positive rates are addressed by the high specificity of the ALGO screener's performance that minimizes the number of infants referred for unnecessary follow-up testing.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Clark JL Dybala PD Moushegian G	Real-ear characteristics of the ALGO2™ acoustic transducer assembly.	Journal of the American Academy of Audiology	1998	9: 426-433

Synopsis:
This study evaluates how ear couplers and their placement affect the stimulus click spectrum. When the ALGO2 was used as described in the User Manual, results agreed with manufacturer specifications. Substitution of other uncalibrated couplers and probe tip couplers markedly affected measurements demonstrating that coupler type and placement can produce inaccurate screening results when instructions for use are not followed. The authors conclude that the "proper earphone couplers" as specified by the manufacturer should be used to achieve reliable results.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Jacobson JT Jacobson CA Spahr RC	Automated and conventional ABR screening techniques in high-risk infants.	Journal of the American Academy of Audiology	1990	1:187-195

Synopsis:
Study of ALGO® screener test validity by comparison of automated ABR and conventional ABR instruments demonstrating 100% sensitivity and 96% specificity for the ALGO® device. In four cases where pass results from the ALGO screener disagreed with the fail result on conventional ABR screening, all subsequently passed follow-up conventional testing yielding no false negative results for the ALGO screener in this sample. The limited number of samples (2000) collected in the conventional ABR compared to the automated data collection of as many as 15,000 sweeps to achieve the statistical match is cited as one reason for the accuracy of the ALGO screener result compared to conventional approaches. The authors conclude that the advantages of ALGO® AABR® with its dual artifact rejection system, attenuating ear couplers, and fully automated design make it a viable alternative even in hostile screening environments such as the NICU.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
van Straaten HLM Groote ME Oudesluys-Murphy AM	Evaluation of an automated auditory brainstem response infant hearing screening method in at risk neonates.	European Journal of Pediatrics	1996	155:702-705

Synopsis:
Technology validation of ALGO screener in NICU with 250 newborns. 245 infants (98%) passed and 5 (2%) referred. None of the infants who passed was discovered to have bilateral hearing loss >40dB with behavioral screening or at follow-up. Sensitivity and specificity levels are indicated.

Development & Validation (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Peters JG	An automated infant screener using advanced evoked response technology.	Hearing Journal	1986	39: 25-30

Synopsis:
The initial published description of the ALGO® AABR® screener design including results from clinical comparisons in which raw EEG data was delivered simultaneously to the ALGO screener and to a conventional signal averaging device. Comparison of automated ALGO results and the interpretation of a skilled ABR examiner yielded 98.5% agreement. In 2 cases, ALGO refer results were classified as a "pass" by the clinical interpreter upon review of the conventional waveform.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Hall JW Kileny P et. al.	Newborn auditory screening with the ALGO 1 vs. conventional auditory brainstem response.	ASHA	1987	29: 120

Synopsis:
Comparison of ALGO 1 automated results and conventional ABR outcomes for 336 ears (189 infants) yielded 100% sensitivity and 96.7% specificity for the ALGO screener. Authors conclude that "Based upon these findings and our clinical experience … ALGO 1 is a feasible alternative to operator ABR measurement for newborn auditory screening."

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Kileny PH	New insights on infant ABR screening.	Scandinavian Audiology (Supplement)	1998	30: 81-88

Synopsis:
Data presented from multi-center clinical trials for 507 ears (286 infants) from the high-risk population. EEG data from ALGO screening was analyzed offline by playback through conventional commercial systems in order to standardize test parameters. The incidence of hearing loss was 4.3% in this population. There were no false negatives and 3.85% false positives.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Stewart DL Bibb K Pearlman A	Automated newborn hearing testing with the ALGO-1 screener.	Clinical Pediatrics	1993	32(5): 308-311

Synopsis:
Study of 841 NICU infants screened with ALGO vs. risk criteria. The prediction rate for positive results in infants screened was 95% and the frequency of confirmed hearing loss was 3% in this population. The study demonstrates that electrophysiological screening is an advantage over targeted screening using risk criteria.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Murray G Ormson MC et. al.	Evaluation of the Natus ALGO 3 Newborn Hearing Screener.	Journal of Obstetrics, Gynecologic, & Neonatal Nursing	2004	33 (2): 183-190

Synopsis:
Comparison of the average screening time and refer rates of the ALGO 3 screener to the ALGO 2e in 3 hospitals with 194 infants. The ALGO 3 was 23% faster and yielded 48% fewer refer results demonstrating that technology enhancements in the ALGO 3 increase efficiency and accuracy.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
van Straaten HLM Brand M Kok J H	ALGO 1e versus ALGO 1 Plus hearing screener: reliable and much quicker.	Pediatric Research	1998	44, 431–431; doi:10.1203/00006450-199809000-00109

Synopsis:
Performance of the ALGO 1e versus ALGO 1 Plus was evaluated in very preterm newborns in a neonatal intensive care setting. 25 newborns completed both ALGO 1e and ALGO 1 Plus screening performed by an inexperienced resident. 18/25 patients had ≥ 3 Joint Committee on Infant Hearing risk factors. Test results (pass and refer) as well as Preparation Time (PT), Test Time (TT) and Total Test Time (TTT) with both devices were noted. Results were statistically analyzed with the unpaired, 2-tailed student t-test. Total Test Time for ALGO 1e is significantly reduced compared to ALGO 1 Plus, with equivalent reliability of results.

Results from Screening Programs

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Barker MJ Hughes EK Wake M	NICU-only versus universal screening for newborn hearing loss: Population audit.	Journal of Paediatrics and Child Health	2012	doi:10.1111/j.1440-1754.2012.02472.x

Synopsis:
Two consecutive screening programs in the four NICUs in Victoria, Australia are compared. During the first 23 month NICU-only screening period, 4704 infants were admitted with a 71% capture rate for screening using AccuScreen and with an 85.8% follow-up rate. During the 15 month UNHS period, 3160 infants were admitted to the NICU with a 95.4% capture rate using ALGO 3i exclusively and achieving a 3.3% refer rate with a 96% follow-up rate. The ALGO UNHS program out-performed the stand-alone NICU screening on all measured parameters.

Results from Screening Programs (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Stewart DL Mehl A et. al.	Universal newborn hearing screening with automated auditory brainstem response: a multisite investigation.	Journal of Perinatology	2000	20: S128-S131

Synopsis:
Refer rate for universal ALGO screening was <2% independent both of test personnel and time after birth for 11,711 infants at 5 clinically different sites. Incidence of confirmed hearing loss in this population was 2.7 per thousand newborns with a cumulative false-positive rate of 0.9% and 0% false-negatives.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Lim G Fortaleza K	Overcoming challenges in newborn hearing screening.	Journal of Perinatology	2000	S138-S142

Synopsis:
Retrospective data analysis on 66,292 newborns screened at 46 sites within 5 regions of the US using ALGO® AABR®. A collective final refer rate of 1.01% was achieved. The incidence of hearing loss among the 46 sites ranged from 1.4-2.3 per 1000 live births. Of 114 infants confirmed with hearing loss, 60% exhibited no risk factors.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Mason JA Herrmann KR	Universal infant hearing screening by automated auditory brainstem response measurement.	Pediatrics	1998	101 (2): 221-228

Synopsis:
Report of 10,372 infants screened in universal ALGO® AABR® screening program initiated in Hawaii from 1992-97 demonstrating that benchmarks later adopted by the JCIH were already being met in programs using ALGO® screening technology. Infants with mild, moderate, and severe loss were reliably detected and received intervention prior to age 6 months with well infants achieving age-appropriate speech and language development outcomes.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Messner AH Price M et. al.	Volunteer-based universal newborn hearing screening.	International Journal of Pediatric Otorhinolaryngology	2001	60: 123-130

Synopsis:
Evaluation of the efficacy and cost of volunteer-based universal screening was conducted with data from 5771 infants from the well-baby nursery. Coverage of 91% was achieved with 5% of the infants requiring follow-up. The study concludes that volunteer personnel offer a viable option for staffing UNHS, but did not result in significant cost savings during the first 2 years of operation.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Oudesluys-Murphy AM Harlaar J	Neonatal hearing screening with an automated auditory brainstem response screener in the infant's home.	Acta Paediatrica	1997	8: 651-655

Synopsis:
Increasingly short hospital stays and local policies for health care services mean that hearing screening cannot always occur in the newborn nursery. In the Netherlands, Well Baby Clinics offer home screening by nurses using ALGO® AABR® that is a feasible alternative as demonstrated by this study and added only 18 minutes to the usual length of a home visit without screening. Parental acceptance was excellent (98%) in this.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Tan PL, Daniel LM, Lim SB, Yeoh A, Hee K, Balakrishnan A	The Universal Newborn Hearing Screen (UNHS): Results of a programme for 44,000 Infants in KK Women's and Children's Hospital (KKWCH), Singapore	NHS Research Poster	2006	N/A

Objective: To describe the method, administration and the results of the UNHS program in KK Women's and Children's Hospital, Singapore.

Method: The UNHS was started in KKWCH in April 2002 using the Automated Auditory Brainstem response. Newborns who did not pass the inpatient screen had an outpatient screen at 4-6 weeks of life. Those who did not pass the second screen were referred to the Otolaryngology department and underwent further audiological assessment. Infants with confirmed hearing loss (HL) were referred for intervention (auditory, verbal or natural auditory oral therapy, hearing amplification and cochlear implantation) when appropriate. Data on babies born between 01/04/2002 and 30/06/05 were collected prospectively using a data collecting system.

Results: 99.8% of 44,579 eligible babies were screened before discharge of which 97.8% passed. 1,040 (2.3%) were referred for outpatient screening (including 91 who missed the inpatient screen). 940 (90.4%) were screened, of which 768 (81.7%) passed. 87 (8.3%) declined or were uncontactable. 13 (1.3%) were awaiting assessment. 254 infants were referred to the Otolaryngology department (0.6% of the eligible population), of which 172 (67.7%) did not pass the UNHS, 32 (12.6%) had aural/cranofacial malformations and 50 (19.7%) passed the outpatient UNHS with a sweep count of >3,500. 194 (76.4%) have completed their assessment. Of these, 145 (74.7%) had confirmed HL. 41 (16.1%)were waiting for assessment and 19 (7.5%) declined or were uncontactable. The features of the HL were as follows: Profound 40 (27.6%), Severe 28 (19.3%), Moderate 52 (35.9%), Mild 25 (17.2%), bilateral 83 (57.2%), unilateral 62 (42.8%), Sensorineural 86 (59.3%), conductive 45 (31%), mixed 12 (8.3%), Auditory Neuropathy 2 (1.4%). The incidences of any HL and severe/profound HL were 3.3 and 1.5 per 1000 babies, respectively.

Conclusion: The UNHS has facilitated early diagnosis of infants with HL, thus increasing their chances of early intervention and age-appropriate speech and language development.

Results from Screening Programs (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Mehl A Thomson V	The Colorado newborn hearing screening project, 1992-1999: On the threshold of effective population-based universal newborn hearing screening.	Pediatrics	2002	109 (1): 1-8

Synopsis:
Beginning with voluntary universal newborn hearing screening at 4 hospitals in 1992 and ending with combined data from 57 hospitals screening all newborns by 1999, this study reports data from148,240 infants. 52 of those hospitals chose ALGO® AABR® as the screening method for a total of 49, 325 infants with a combined refer rate of 1.5%. Three hospitals used OAE to screen 1957 infants with an 11% refer rate, and 2 used a two-step protocol to screen 4042 infants with an 8.4% refer rate. Detailed data on type and degree of loss for infants identified in 1999 reveal that losses ranged from mild to profound with only 32 of the 86 affected infants exhibiting a risk indicator. For 1999, the median age of diagnosis of congenital hearing loss was 2.1 months and 92% of affected infants were identified by 5 months of age. Results support the feasibility of statewide programs and highlight program and procedural factors associated with achieving current benchmarks for screening coverage, refer rates, and follow-up.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Mehl AL Thomson V	Newborn hearing screening: The great omission.	Pediatrics	1998	101 (1): 1-6

Synopsis:
The rationale for universal newborn hearing screening is discussed along with the results of a feasibility, accuracy, and cost-effectiveness study conducted in Colorado hospitals from 1992 to 1996. A total of 41,796 infants screened with the ALGO® AABR® demonstrated sensitivity "at or near 100%" with false-positive rates moving from 6% down to 2% with evolving technology. Cost comparisons with other screened congenital conditions result in comparable cost per case diagnosed given the much higher incidence of hearing impairment compared to other congenital diseases. Costs of screening and intervention are compared with monetary savings achieved by avoiding delayed detection and a model for this comparison suggests that recovery of costs associated with implementing universal newborn hearing screening are recovered within 10 years.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Dauman R Roussey M et. al.	Screening to detect permanent childhood hearing impairment in neonates transferred from the newborn nursery.	International Journal of Pediatric Otorhinolaryngology	2009	73 (3): 457-65

Synopsis:
This report describes hearing screening of newborns transferred from the regular nursery to a specialized area to determine whether screening coverage was achieved; whether the linkage between neonatal screening and diagnostic follow-up was carried out correctly; and to establish the incidence of permanent childhood hearing impairment (PCHI) in this at-risk population. Six population centers averaging 12,000 births annually participated (Bordeaux, Lille, Paris, Marseille, Toulouse and Lyon). ALGO 3i screening results for 4972 "transferred" neonates compared with those of non-transferred neonates (N=112,131) revealed that screening coverage was significantly lower (75.4%) in "transferred" babies compared to 97.5% coverage in the non-transferred group. Refer results from the first AABR were higher in "transferred" infants (11.1%) than in the non-transferred population (6.5%). Of the 415 "transferred" newborns with initial refer results, 91.3% were rechecked as stipulated in the project protocol. Of the 183 "transferred" infants with refer results after rescreening, only 70.5% returned to the audiology center for diagnostic follow-up. The incidence of bilateral PCHI was markedly higher (4/1000) in "transferred" infants than in the non-transferred population (1.08/1000). The difficulty of obtaining universal screening coverage in "transferred" infants was found to be similar to reports from the U.S.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Verhaert N Willems M et. al.	Impact of early hearing screening and treatment on language development and education level: Evaluation of 6 years of universal newborn hearing screening (ALGO®) in Flanders, Belgium.	International Journal of Pediatric Otorhinolaryngology	2008	72: 599-608

Synopsis:
Retrospective analysis of 229 children detected by the Flemish universal newborn hearing screening program reveals that 85.4% of the children with moderate, severe, or profound hearing loss and no additional disability older than 5.5 years achieve mainstream education. Distribution of degree of hearing loss in this cohort includes mild (21-40dB) 22.7%, moderate (41-70dB) 30.6%, severe (71-90dB) 20.1%, and Profound (91-120dB) 26.6%.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Stehel EK Shoup AG et. al.	Newborn hearing screening and detection of congenital cytomegalovirus infection.	Pediatrics	2008	121 (5): 970-975

Synopsis:
The objective of this study was to determine the frequency of congenital cytomegalovirus infection among newborns who did not pass hearing screening and to determine how often refer results were the only manifestation of congenital cytomegalovirus infection. Retrospective chart review was performed for newborns with refer results and positive urine cytomegalovirus culture results at Parkland Memorial Hospital between September 1, 1999, and August 31, 2004. During the 5-year study period, 572 of 79047 newborns (7 of 1000 live births) did not pass hearing screening. Cytomegalovirus infection was identified in 24 (5%) of 483 tested infants and 16 (6%) of the 256 infants with subsequently confirmed hearing impairment. Of those 16 infants, 12 (75%) were identified as having congenital cytomegalovirus infection only because of failure to pass newborn hearing screening.

Results from Screening Programs (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Declau F Boudewyns A et. al.	Etiologic and audiologic evaluations after universal neonatal hearing screening: Analysis of 170 referred neonates.	Pediatrics	2008	121 (6): 1119-1126

Synopsis:
A prospective analysis of 170 consecutive records of neonates referred to a tertiary center after universal hearing screening failure, between 1998 and 2006 was performed. The data represented the equivalent of 87000 screened newborns. Screening results were validated by clinical ear, nose, and throat examination and electrophysiological testing, including diagnostic auditory brainstem response, automated steady state response, and/or behavioral testing. A diagnostic evaluation protocol for identification of etiology in collaboration with genetics and pediatrics departments was included.

Permanent hearing loss was confirmed in 116 children (68.2%). Bilateral hearing loss was diagnosed in 68 infants (58.6%) and unilateral hearing loss in 48 infants (41.4%). Median thresholds for those with confirmed hearing loss in unilateral and bilateral cases were 70 dB nHL and 80 dB nHL, respectively. No risk factors for hearing loss were found in 55.8% of the infants. In 60.4%, the initial automated auditory brainstem response diagnosis was totally in agreement with the audiologic evaluation results. In 8.3% of those confirmed, a unilateral refer result was later classified as bilateral hearing loss. An etiologic factor could be identified in 55.2% of the cases. Of the causes identified, genetic mechanism was present in 60.4%, peripartal problems in 20.8%, and congenital cytomegalovirus infection in 18.8%.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Marlowe J	Screening all newborns for hearing impairment in a community hospital.	American Journal of Audiology	1993	22-25

Synopsis:
Description of the development and implementation of universal newborn hearing screening as a private initiative in a community hospital prior to national recommendations and legislation. Initial experiences with conventional ABR screening led to the adoption of ALGO® AABR® shortly after it became commercially available in this volunteer staffed program.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Yee-Arellano H Leal-Garza F Pauli-Müller K	Universal newborn hearing screening in Mexico: Results of the first 2 years.	International Journal of Pediatric Otorhinolaryngology	2006	70 (11): 1863-1870

Synopsis:
This study summarizes results of the first 2 years of universal AABR newborn hearing screening and the prevalence of congenital hearing loss in Monterey, Mexico. A total of 3066 newborns were screened (99.9% of births). The prevalence of sensorineural and bilateral hearing loss was 0.65/1000 newborns. Seventy-three neonates (2.37%) had a risk factor for hearing impairment. A total of 0.22% (n=7) of those studied were referred for ABR testing. Of the patients referred to the audiologist, 100% were seen. The positive predictive value for sensorineural hearing loss was 71.4% (95% CI 30.2–94.8) and the false positive rate was 0.065%.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Hille ETM Verkerk PH van Straaten H LM	Bilateral haring impairment in Dutch neonatal intensive care unit infants with unilateral failure on hearing screening.	Pediatrics	2004	113 (5): 1467-1468

Synopsis:
Since 1998, AABR hearing screening has been used in Dutch NICUs. After unilateral or bilateral failure at the second screening, infants were referred for diagnostic conventional auditory brainstem response. Data for all children were registered centrally to facilitate screening and follow-up. A cohort of 9450 surviving newborns, with a mean gestational age of 33 weeks (SD: 4.6 weeks) and mean birth weight of 1928 g (SD: 992 g), were included in this program between January 10, 1998, and January 1, 2003. Parents of 132 (1.4%) refused screening. An additional 34 (0.4%) could not be screened. Of the remaining 9284 NICU infants, 322 (3.5%) were referred for diagnostic evaluation. 137 of these had a unilateral AABR failure. Diagnostic evaluation established bilateral hearing impairment in 40 (29%) of them. Our program detected a total of 184 NICU infants with bilateral hearing impairment. If only bilateral failures were referred for diagnostic evaluation, 22% (40 of 184) would not have been detected. This result supports diagnostic evaluation of unilateral as well as bilateral screening failures.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
van Straaten H LM Tibosch CH et. al.	Efficacy of automated auditory brainstem response hearing screening in very preterm newborns.	Journal of Pediatrics	2001	138 (5): 674-678

Synopsis:
In this prospective cohort study, 90 consecutive preterm newborns (<32 weeks' gestational age) had AABR hearing screening weekly from birth until a bilateral pass result was obtained. If the newborn had a unilateral pass result, AABR screening was repeated in the same week. Median gestational age was 29.5 weeks (range, 25.3-31.9 weeks), and median birth weight was 1115 g (range, 600-1960 g). Mean age was 6.2 days (SD 4.3) at first test, 15.7 (SD 8.1) at second test, and 21.4 (SD 8.6) at third test. Eighty percent (CI: 70.2%-89.8%) of the newborns passed at 30.3 weeks' postmenstrual age, 90% (CI: 83.6%-96.4%) passed at 31.2 weeks, and 100% passed at 34 weeks' postmenstrual age. The attainment of these pass rates correlated to postmenstrual age was not significantly influenced by sex, growth restriction, or gestational age at birth. Postnatal pass rates (in days) were strongly influenced by gestational age.

Results from Screening Programs (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Fukushima K Minaki N et. al.	Pilot study of universal newborn hearing screening in Japan: District-based screening program in Okayama.	Annals of Otology, Thinology & Laryngology	2008	117 (3): 166-171

Synopsis:
This report describes newborn hearing screening implemented in Okayama Prefecture in 2001 as part of a nationwide pilot study. Data from 47,346 infants (95% of the infants born in the 44 gynecologic institutions in this district) screened using automated ABR and followed for at least 2 years are included.

After undergoing the screening process twice, 248 infants (0.52%) received referrals; 108 bilateral and 140 unilateral. Among the bilateral refers, hearing impairment was confirmed in 40 infants, for a total prevalence of 0.08%. In 3 additional infants who received a bilateral pass result and 1 infant who received a unilateral pass result, hearing impairment that was progressive or late onset was subsequently diagnosed. Positive predictive value of 40% and negative predictive value of 99.993% were calculated.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Mitsiakos G Giougi E Karagianni P Chatziioannidis E Tsakalidis C Nikolaidis N.	Investigation of hearing impairment in post-neonatal intensive care unit infants by using automated auditory brainstem response.	Pediatrics	2008	121;S138

Synopsis:
To investigate the prevalence of hearing impairment in the NICU and its association with risk indicators 422 post-NICU infant >34 weeks GA were examined for history of perinatal asphyxia, craniofacial deformities, furosemide and aminoglycoside therapy (duration of administration), meningitis, duration of mechanical ventilation, and nursing duration in an incubator. ALGO 3 screening was performed with 2.84% (12 of 422 newborns) referred. Follow-up conventional ABR found 6 with normal responses, and 6 with confirmed hearing loss. Multivariate analysis revealed a statistically significant association between hearing loss and craniofacial deformities, meningitis, and duration of mechanical ventilation (P .001, P.001, and P.038, respectively).

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Kayano K Suzuki H Nakano H Hayashido K Kimura T Tatemoto K Nishiyama A Fukushima T	Automated infant auditory screening using the Natus-ALGO 2e in the NICU.	Nihon Jibiinkoka Gakkai Kaiho	2000	Aug;103(8):885-93.

Synopsis:
[Article in Japanese] ALGO 2e results in NICU infants were compared with results of conventional ABR in this study. Mean conceptional age at the time of screening was 40.4 +/- 3.0 weeks. 60 ears of 30 high-risk infants, including "refer" infants, were tested both by ALGO 2e and conventional ABR to compare results. ALGO 2e screening time averaged 2 minutes 58 seconds. With conventional ABR, 14 of 53 ears passed by ALGO 2e initially failed the conventional ABR screening. Of these 14 ears, 11 were subsequently found to be normal, and conventional ABR in the remaining 3 was later interpreted as normal. Among those ears that passed ALGO 2e screening but failed the conventional ABR, the number of ALGO sweeps was significantly greater than with typical ABR protocols. Of the 7 ears of 4 patients that were referred on the basis of ALGO 2e screening and failed by the conventional ABR, 3 ears screened by ABR were normal when retested, and one ear passed later ALGO 2e screening.

Technology Evaluation

Author(s):	Title:	Journal:	Year:	Vol: Pages:
I. J. McGurgan N. Patil	Hearing screening of high-risk infants using automated auditory brainstem response: a retrospective analysis of referral rates.	Irish Journal of Medical Science	2013	doi: 10.1007/s11845-013-1028-5

Synopsis:
UNHS in the process of nationwide implementation in the Republic of Ireland used TEOAE for initial screening. This study analyses the effects of ALGO AABR as the initial screening on refer rates to audiology services. Retrospective analysis of all screening data which was confined to infants with one or more known risk factors for permanent childhood hearing impairment in Letterkenny General Hospital from January 2008 to December 2012 was completed. Of the 1,163 infants screened with ALGO AABR, 50 (4.3 %) referred on the initial AABR. 16 of these 50 referred on the repeat AABR, resulting in an overall 1.38% referral rate to audiology. The authors conclude that results demonstrate strikingly low overall refer rates, well below international benchmarks and initial Irish UNHS program results that support ALGO AABR as an alternative to TEOAE nationwide.

Technology Evaluation (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Korver AMH van Zanten GA Meuwese-Jongejeugd van Straaten HLM Oudesluys-Murphy AM	Auditory neuropathy in a low-risk population: A review of the literature.	International Journal of Pediatric Otorhinolaryngology	2012	76 (12) 1708-1711

Synopsis:
PubMed and EMBASE were searched for relevant articles published between 1996 and 2010 for Medical Subject Headings terms including original well baby studies reporting the prevalence of auditory neuropathy. Of 519 citations, 4 articles met inclusion criteria. The population based prevalence of auditory neuropathy in children was found to vary between 0.006% (SD 0.006) and 0.03% (SD 0.02). The false negative rate, caused by missed children with auditory neuropathy is estimated between 4 and 17% if otoacoustic emission screening is used in the first stage of a neonatal hearing screening program.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Harumi A Shibata Y et. al.	Newborn Auditory Screening with Automated ABR, Transient Evoked Otoacoustic Emissions TEOAEs and Conventional ABR.	Audiology Japan	2000	43 (3): 201-209

Synopsis:
This study was intended to validate ALGO2e results vs. conventional signal-averaged ABR, and to compare AABR with transient evoked otoacoustic emissions(TEOAE) for universal hearing screening to identify neonates with a bilateral, permanent hearing loss. 49 full-term neonates were studied with AABR, TEOAE and conventional ABR. 100% were successfully screened by AABR and 97.9% by TEOAE. The specificity of AABR was 97.9% compared to 93.6% for TEOAE. No sensitivity was calculated as no neonates with bilateral hearing loss were identified in this study. The mean test duration of AABR was 6min. 27sec. and that of TEOAE was 12min. 36sec. Because of its high specificity and shorter test duration, AABR was more suitable for newborn hearing screening than TEOAE or conventional ABR.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Gabbard SA Northern JL Yoshinaga-Itano C	Hearing screening in newborns under 24 hours of age.	Seminars in Hearing	1999	20 (4): 291-305

Synopsis:
The impact of early discharge is investigated by comparing ALGO® AABR® and TEOAE on 110 infants with a mean age of 15 hours. AABR screen yielded 97% pass rates compared to 63% for TEOAE. A significant age-related effect was associated with TEOAE, Average AABR test time was 11 minutes 46 seconds compared to TEOAE at 12 minutes 47 seconds. The authors conclude that young infants are best screened by AABR as it is more effective and time efficient.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Doyle KJ Fujikawa S et. al.	Comparison of newborn hearing screening by transient otoacoustic emissions and auditory brainstem response using ALGO-2®.	International Journal of Pediatric Otorhinolaryngology	1998	20 (4): 291-305

Synopsis:
Comparison of ABR and OAE pass rates using a later generation of technology with 232 ears in 116 newborns aged 5-48 hours. 92% of ears passed AABR compared to an earlier study in which 88.5% passed while 57% passed OAE, a decreased pass rate from the previous study results. Test time for AABR was 5.7 minutes compared to 5.2 minutes for OAE.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Doyle KJ Burggraaff B et. al.	Newborn hearing screening by otoacoustic emissions and automated brainstem response.	International Journal of Pediatric Otorhinolaryngology	1997	41: 111-119

Synopsis:
Comparison of OAE and ABR pass rates in 200 well infants as a function of age (5 hours to 120 hours, with an average age of 24 hours) is the focus of this study. ALGO® AABR® pass rates were 88.5% compared to 79% for OAE. While pass rates for infants <24 hours did not differ significantly from those >24 hours, there was a significant improvement for OAE pass rates >24 hours compared to the younger group.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Salamy A Eldredge L Sweetow R	Transient evoked otoacoustic emissions: Feasibility in the nursery.	Ear & Hearing	1996	17 (1): 42-48

Synopsis:
TEOAEs and ABRs recorded from 149 ears at bedside in at-risk infants yielding 63.5% pass rate for both procedures, 5% who failed both, and 31.5% who passed ABR but failed TEOAE. No statistical difference for nursery type, ear, or gender were found. The study concludes that TEOAEs are associated with high false positive rates and that TEOAE failures increase test time and negate any saving compared to using ABR alone.

Technology Evaluation (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Jacobson J Jacobson CA	Current technology in newborn universal hearing detection.	Seminars in Hearing	1996	17 (2) 125-138

Synopsis:
Previously published performance data for automated ABR and OAE technologies is analyzed in light of recommendations, issues, and concerns surrounding technology choices for early detection. A rationale for the continued use of ABR and comprehensive charts summarizing data from multiple studies provide useful tools for decision making.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Oudesluys-Murphy AM van Straaten HLM et. al.	Neonatal hearing screening.	European Journal of Pediatrics	1996	155: 429-435

Synopsis:
A review of the rationale for early detection and available hearing screening methods concludes that automated auditory brainstem response is "the most valuable" method for neonatal hearing screening due to its high sensitivity and specificity.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Zheng-min X Wen-xia C Xiao-lin Y	Performance of two hearing screening protocols in NICU in Shanghai.	International Journal of Pediatric Otorhinolaryngology	2011	75: 1225-1229

Synopsis:
The sensitivity and specificity of DPOAE only vs. a combined DPOAE/AABR protocol using ALGO 3i were evaluated. 3000 NICU infants were screened using both protocols. The DPOAE only refer rate was 8% with a false-positive rate of 4.96% and false-negative rate of 0.8% compared to the combined DPOAE/AABR protocol with a 5.03% refer rate, false-positive rate of 2% and false negative rate of 0.06%. 22 infants who passed DPOAE but referred on ALGO 3i screening were confirmed with severe to profound hearing loss further diagnosed as auditory neuropathy.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Clarke P Iqbal M Mitchell S	A comparison of transient-evoked otoacoustic emissions and automated auditory brainstem responses for pre-discharge neonatal hearing screening.	International Journal of Audiology	2003	Dec; 42 (8):443-7

Synopsis:
Eighty-one newborns completed one-step hearing screening using the ALGO 3 screener. These were compared with 81 newborns completing a two-step screening protocol using TEOAE followed by ALGO AABR. The pass rate for the ALGO one-step screen was 78/81 (96.3%), for the two-step screen 74/81(91.4%), and for TEOAE alone 54/81 (66.7%). There was no significant difference in time required to complete the screening protocols. The authors conclude that use of TEOAE alone for pre-discharge screening is associated with an excessively high false-positive rate. One-step ALGO screening resulted in a lower referral rate compared with a two-step approach.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Iley KL Addis RJ	Impact of Technology Choice on Service Provision for Universal Newborn Hearing Screening Within a Busy District Hospital.	Journal of Perinatology	2000	20 (8):S122-S127

Synopsis:
To investigate the implications of technology choice between AABR and TEOAE, well babies were screened. Age at testing, test duration, pass/refer results, problems experienced, parent or user perceived differences between ALGO 2ec and the current TEOAE screen were recorded. A single user carried out all screening. Forty-four mothers consented to AABR and results were achieved in all 44 babies. 42 babies passed the initial screen bilaterally and 2 referred in a single ear only. Test duration was less than 5 minutes for 36 of 44 babies. Applying results to a UNHS model generated a per screen cost of £15.98 for two-stage OAE/AABR and £14.25 for AABR-only. Parents found AABR acceptable and being able to discuss the screen and hearing during screening was time-efficient and reassuring to parents. Models using two-stage OAE/AABR would have generated 509 infants for second-stage AABR screening before audiological follow up while AABR-only would have generated 72 infants for second stage. ALGO hearing screening was practical, time, and cost-efficient. The low initial referral rate would not only save money, but keep parental anxiety at a minimum. The high tolerance of ambient noise allowed flexibility in screening location and timing, improving ability to screen before discharge. The authors conclude that AABR as primary screen is more practical and less expensive than TEOAE.

Programs, Personnel & Protocol Considerations

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Marlowe J	Newborn hearing screening: Testing, follow-up and communication with families.	Practice Monograph	2003	N/A

Synopsis:
This practice monograph is intended for nurses participating in universal newborn hearing screening programs to acquaint them with the rationale for early detection, hearing impairment and methods of detection, screening results and their implications, as well as practical information to support interactions with families and other professionals.

Programs, Personnel & Protocol Considerations (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Herrmann BS, Thornton AR	Audiologic follow-up after failure of an infant hearing screening.	Current Opinion in Otolaryngology & Head and Neck Surgery	1996	4: 367-370

Synopsis:
The effectiveness of universal newborn hearing screening depends upon timely diagnostic evaluation and intervention. Screening protocols must be simple and clearly outlined to ensure that infants who require further evaluation and treatment do not experience delay since the improved outcome associated with early detection are linked to intervention within the first 2 months of life. Multi-stage screening programs aimed at reducing high refer rates delay identification and intervention as well as increasing opportunities for infants being lost to follow-up.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Marlowe J	Communications in early detection and intervention programs. Legal and risk management perspectives.	Seminars in Hearing	1999	20 (4): 279-290

Synopsis:
A review of the issues associated with informed consent, notification of results, documentation, and management of confidential communication in operating universal newborn hearing screening programs is presented to assist policy and procedural decisions.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Marlowe J	Legal and risk management issues in newborn hearing screening.	Seminars in Hearing	1996	17 (2): 153-164

Synopsis:
The development of a standard of care in health practices and the identification and management of risk when implementing and managing universal newborn hearing screening programs is discussed with an emphasis on practical strategies to incorporate in policies and protocols.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Herrmann BS	Perspectives and implications of early identification of hearing loss.	Current Opinion in Otolaryngology & Head and Neck Surgery	1994	2: 449-54

Synopsis:
The rationale for early identification through universal newborn hearing screening as well as advances in technology that make this approach feasible are outlined. A discussion of cost justification makes the point that implementation of programs screening only high risk infants is not without expense and may total more than $30 per baby, yet not identify all infants with hearing impairment. The need for monitoring hearing status during infancy and early childhood for delayed onset and progressive hearing loss is also noted.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Chang KW JO-Lee T Price M	Evaluation of unilateral referrals on neonatal hearing screening.	Journal of Medical Screening	2009	16:17–21 DOI: 10.1258/ms.2009.007113

Synopsis:
Examination of neonatal hearing screening practices around the world suggests greater attention to bilateral hearing screening refers than to infants who refer in one ear. This study investigates how screening limitations demand continued audiologic evaluations in unilateral refers. 16,007 infants screened with ALGO AABR at a single academic pediatric hospital from February 1998 to February 2002 were reviewed.

Eighteen infants who failed the screen in one ear but passed in the other ear were analyzed. The final outcome after four years in both the pass and fail ear were examined. Results for one group of unilateral refers had obvious anatomic reasons for the ear failing (canal atresia/stenosis). For five patients the ear that passed the screen was later found on audiologic evaluation to have significant hearing loss. Literature review was also completed to examine the methods by which unilateral screening referrals are commonly reported and whether or not this affected follow-up diagnostic evaluation. The conclusion supported that infants who pass one ear and refer one ear on neonatal hearing screening need to have thorough and prompt evaluations since the ear that passed can be found to have significant hearing loss.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Rouev P Mumdzhiev H Spiridonova J Dimov P	Universal newborn hearing screening program in Bulgaria.	International Journal of Pediatric Otorhinolaryngology	2004	68(6):805-10. DOI:10.1016/j.ijporl.2004.01.013

Synopsis:
This protocol to screen healthy babies after 6 hours of age used ALGO 2 simultaneous 35-dBnHL screening with confirmation using conventional non-automated ABR. NICU babies were screened just prior to discharge. ALGO 2 refer results were immediately retested. Infants in need of an outpatient screen were recalled at age 3-4 weeks. The cost for UNHSP in Bulgaria was calculated as EUR 1407 per case identified.

False Positive Results

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Clemens CJ Davis SA Bailey AR	The false-positive in universal newborn hearing screening.	Pediatrics	2000	106 (1): 1-5

Synopsis:
False positive results and their potential impact upon parental emotions and bonding prompted this study that describes the data from 5010 infants screened in a UNHS program along with methods to reduce false-positives as well as maternal anxiety and attitudes towards universal screening. A false-positive rate of 1.9% pre-discharge was achieved by rescreening. Further, maternal surveys reveal no long lasting detrimental emotional impact from false-positive results and suggest that improved parental education regarding UNHS may reduce concern further.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Shoup AG Owens KE et. al.	The Parkland Memorial Hospital experience in ensuring compliance with universal newborn hearing screening follow-up.	The Journal of Pediatrics	2005	146: 66-72

Synopsis:
Report of the pilot program and data from first four years of universal newborn hearing screening at the largest single-site birthing hospital in the U.S. (~17,000 annually) are analyzed. In addition to its large birth rate, Parkland's early hospital discharge and mobile, culturally diverse population required minimizing false positive results and coordinating follow-up services at the birthing hospital to improve continuity of care. By establishing a schedule for initial and follow-up screening, Parkland reports a PPV for bilateral sensori-neural hearing loss of 77% and 55% for years 1 and 2 of the program, surpassing PPVs reported in the literature and increasing compliance.

Costs of Universal Newborn Hearing Screening

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Lemons J Fanaroff A et. al.	Newborn hearing screening: Costs of establishing a program.	Journal of Perinatology	2002	22 (2): 120-24

Synopsis:
Costs and performance characteristics in the earliest implementation phase of universal screening are discussed for AABR and OAE. Data from 1500 newborn screenings or until a <5% discharge refer rate was collected for analysis of refer rates, utilization of personnel, equipment, and supplies. Neonatal nurses administered the AABR screening when infants averaged 9.5 hours old while master's level audiologists performed OAE screening when infants averaged 29 hours of age. Within the first 24 hours after delivery, 84% of infants were screened by AABR compared to 35% in the OAE based program. Refer rates at discharge remained at 15% for OAE throughout the study, but decreased from 8% to less than 4% in the AABR program. Total pre-discharge program costs calculated were $49,316 for OAE and $47,553 for AABR with AABR demonstrating the lowest refer rates and shorter time to achieve them.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Vohr BR Oh W et. al.	Comparison of costs and referral rates of 3 universal newborn hearing screening protocols.	The Journal of Pediatrics	2001	139: 238-44

Synopsis:
This study compares referral rates from 12,081 newborns at 5 sites screening with TEOAE, AABR, or a two-step protocol using both technologies. Significant differences were identified in referral rates (AABR, 3.21%;two-step, 4.67%, and TEOAE, 6.49%). Total costs per infant screened were similar in a prospective activity-based costing analysis applied to 1056 infants.

Professional Guidelines & Recommendations

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Joint Committee on Infant Hearing	Year 2019 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs. Year 2007 Position Statement	Pediatrics Pediatrics	2019 2007	4 (2): 1-44 120 (4): 898-921

Synopsis:
The current 2019 position statement builds on prior Joint Committee on Infant Hearing (JCIH) publications (2013 JCIH supplement on Early Intervention and 2007 JCIH Guidelines), updating best practices through literature reviews and expert consensus opinion on screening; identification; and audiological, medical, and educational management of infants and young children and their families. Emphasis is placed upon the importance of following best-practices for early diagnosis of hearing loss, recognizing the value of the State EHDI programs, and on the importance of continued surveillance of both auditory and speech language development as the frequency and impact of progressive and delayed onset hearing loss is significant. Furthermore, the updated position statement suggests that states meeting the current 1-3-6 benchmarks are now encouraged to meet a 1-2-3 month timeline. Additional updates are highlighted in the categories of screening policies, diagnostic assessment, early intervention/family support and medical considerations.

The Year 2007 Position Statement updates the definition of targeted hearing loss to include neural (Auditory Neuropathy) for NICU infants and recommends ABR screening in the NICU since OAE does not detect neural hearing loss. Risk indicators for delayed onset/progressive hearing loss are modified.

Professional Guidelines & Recommendations (continued)

Author(s):	Title:	Journal:	Year:	Vol: Pages:
American Academy of Pediatrics Task Force on Newborn and Infant Hearing	Newborn and infant hearing loss: detection and intervention.	Pediatrics	1999	103 (2): 527-530

Synopsis:
This statement reviews the criteria for universal screening confirming that congenital hearing impairment is frequent, has serious consequences, and that early detection through universal screening should be implemented. The components of screening, tracking, follow-up, diagnosis, and intervention are reviewed with specific guidelines for evaluating the performance of universal early detection programs. Physiologic measures able to detect hearing impairment > 35dB in the better ear with referral rates not exceeding 4% are advocated. The role of the primary care physician in monitoring hearing throughout childhood is advanced.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
American Academy of Audiology	Infection control in audiological practice.	Audiology Today	2003	15 (5):

Synopsis:
Procedures for hearing screening, assessment, and intervention require close patient contact and opportunities for exposure to contamination. This official guideline outlines appropriate procedures for cleaning, disinfecting, and sterilizing equipment such as probe tips and insert earphones. The guideline cites the advantage of using disposable supplies to reduce the likelihood of cross-contamination. Infectious diseases that are important to those delivering Audiology services are identified in a table listing incubation periods and potential outcomes.

Rationale for Universal Early Detection

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Olusanya BO	Can the world's infants with hearing loss wait?	International Journal of Pediatric Otorhinolaryngology	2005	69, 735-38

Synopsis:
The arguments for extending universal newborn hearing screening to developing countries as a means of achieving literacy and improved social outcomes is summarized with recommendations for well-designed pilot projects and local leadership in order to address the unique requirements of diverse populations.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Yoshinaga-Itano C Sedey AL et. al.	Language of early- and later-identified children with hearing loss.	Pediatrics	1998	102 (5): 1161-71

Synopsis:
Receptive and expressive language of 72 children whose hearing impairments were identified by age 6 months were compared with 78 children whose hearing losses were identified after age 6 months. Both groups of children received intervention services within 2 months of identification. Results from the Minnesota Child Development Inventory demonstrated that the early-identified children had significantly better language scores independent of degree of hearing loss, socioeconomic status, gender, and the presence or absence of secondary disability. Age of identification emerged as the significant variable explaining the improved outcome for the early-identified group and was limited to those identified by 6 months of age compared to groups identified at 7-10 months and later.

Author(s):	Title:	Journal:	Year:	Vol: Pages:
Downs MP	The case for detection and intervention at birth.	Seminars in Hearing	1994	15 (2): 76-83

Synopsis:
Economic data associated with the costs of hearing impairment in lost income, as well as in education and training, are associated with language and learning deficits resulting from late detection. The high cost of undetected hearing loss in light of emerging information regarding critical periods of neural development and the availability of technology to reliably screen newborns for hearing is presented as a compelling argument for implementing universal screening programs without further delay.

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