INTRODUCTION

The prevalence of hearing loss has been reported to be 10 times greater among infants in the neonatal intensive care unit (NICU) than in the well-baby nursery. Therefore, the Joint Committee on Infant Hearing – 2007, advised separate hearing screening practices for infants cared for in the NICU and special care nursery (SCN) versus a well-baby nursery. This document provides recommended guidelines for newborn hearing screening programs in the special care nursery (SCN) and NICU. For hearing screening guidelines in the well-baby nursery, please refer to the *Guidelines for the Organization and Administration of Universal Newborn Hearing Screening Programs in the Well-Baby Nursery.* To help ensure that every Minnesota newborn is screened for hearing loss, state law (*Minnesota Statute 144.996)* requires that a hearing screen be performed on all newborns prior to hospital discharge.

Because of the importance of early identification of hearing loss, all screening, follow-up, and documentation procedures must, at a minimum, be consistent with national Early Hearing Detection and Intervention (EHDI) guidelines and current Minnesota Department of Health (MDH) Newborn Screening Program recommendations. Additional resources are available from the Newborn Screening Program to assist hospitals and hearing screeners with specific issues of program development and management such as training, supervision, equipment options, and quality assurance issues.

BACKGROUND

The goal of an EHDI Program is to promote communication from birth for all children through the early identification of hearing loss and the initiation of appropriate intervention services. Newborn hearing screening and follow-up play a critical role in the EHDI process by identifying newborns who are at risk for hearing loss and connecting them with diagnostic, support, and intervention services. Without EHDI, infants with hearing loss may experience delays in a variety of developmental areas, including vocabulary, articulation, intelligibility, social adjustments, and behavior.

National standards specify that hearing screening should be complete as soon as possible but at no later than one month of age; hearing loss should be clinically diagnosed as soon as possible but at no later than three months of age; and intervention should be initiated as soon as possible but at no later than six months of age or as soon as medically feasible for infants with a prolonged stay in...
Early Hearing Detection and Intervention

the special care nursery or the NICU. With prompt referral and follow-up, Minnesota children have the opportunity to receive life-changing care and services even earlier than national guidelines prescribe.

Early identification and intervention can substantially reduce, or even eliminate entirely, the developmental delays that too often stem from a late diagnosis of hearing loss. Studies have shown that if hearing loss is identified before three months of age and intervention is initiated at no later than six months of age, children perform as much as 20 to 40 percent higher on school-related measures than children with hearing loss that was not identified early. For many children with hearing loss, early identification and intervention enables them to perform on language assessments at the same level as their hearing peers.

Passing the newborn hearing screening does not guarantee that hearing will remain normal, nor does it eliminate the need to monitor the infant’s or child’s speech and language skills. Audiological re-evaluation during early childhood is recommended when parents/caregivers are concerned about hearing and/or speech/language development, as well as for those infants with risk factors for emergent hearing loss.

Best practice would also include providing the following to parents:

- The Newborn Hearing Screening Fact Sheet, which is available to order on the website at no cost, provides basic parental information. Visit our website to order them free of charge.


- Possibility of late or progressive onset of hearing loss, including otitis media.

- Developmental milestones for speech, language, and hearing. Refer to the Hearing and Speech Milestones chart for a list of milestones.

CHILD- AND FAMILY-CENTERED COMMUNICATION

Minnesota statute requires hospitals to present information to parents that covers the following topics:

- Potential risks and effects of hearing loss

- Benefits of early detection and intervention

- Nature of the screening procedure

- Applicable costs of screening procedure

- Parental options regarding screening refusal and storage and use of hearing screening results

- Parents who choose to refuse hearing screening must complete and sign the Parental Refusal of Newborn Screening form. The signed form must be entered into the child’s medical record and submitted to MDH.

- Parents who request that their infant’s newborn hearing screening results be destroyed after notification must complete and sign the Directive to Destroy form. The signed form must be submitted to MDH. If no destruction request is received, hearing screening results are kept for 18 years.

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PERSONNEL PERFORMING HEARING SCREENING

Screening may be performed by trained personnel, including the following:

- Audiologists, audiological technicians/assistants
- Nurses
- Nursing assistants
- Other trained medical personnel

Although licensed audiologists do not need to conduct the actual hearing screening, audiologists are uniquely qualified to develop and implement all aspects of an EHDI program. Hospital screening programs benefit from direct access to audiological consultation to address screening criteria, quality assurance, follow-up assessment, and intervention services.

Training Qualified Screeners

Ensuring that all screeners are competent is critical for every screening program. Training qualified screeners is an ongoing process and should be based on current best practice procedures as reported in professional literature and recommended by the Newborn Screening Program. Training typically includes three phases: initial training and demonstration of competency and skills, ongoing quality assurance, and refresher training.

The initial training may need to be provided using multiple resources and over a number of days. Initial training and demonstration of competency and skills shall include the following, at a minimum:

- Completion of required hospital orientation, including:
  - Infection control policies and procedures
  - Hospital infant security procedures
  - Cultural sensitivity

- Completion of instructional training for newborn hearing screening:
  - Benefits of early detection of hearing loss
  - Hearing screening equipment use and care instruction
  - Knowledge of hospital or birth facility hearing screening policy and procedures
  - Documentation of screening results
  - Communicating screening results to the infant's parent/guardian and appropriate medical staff personnel

- Demonstration of competency and skills to perform hearing screening should be completed annually and documented appropriately:
  - Measure the trainee's competency based on performance in the nursery environment using the Performance Based Criterion Checklist or a similar performance evaluation tool

Ongoing quality assurance of screeners shall include the following, at a minimum:

- Performing periodic observations of each screener in the nursery environment by a skilled professional such as an audiologist and/or program manager

- Review of hearing screening data (e.g., number of screens and number of REFER results) by an audiologist and/or program manager for each screener to determine their effectiveness

Refresher training should be completed annually, with individual trainings available as needed. Refresher trainings should measure the trainee's competency based on performance in the nursery environment using the Performance Based Criterion Checklist or a similar performance evaluation tool.
Resources for training may include experienced screening program managers; local, licensed clinical and educational audiologists; MDH audiologists; hearing screening equipment manufacturers; national online training modules such as the Newborn Hearing Screening Training Curriculum10 offered by the National Center for Hearing Assessment and Management (NCHAM); or other online resources as recommended by the Newborn Screening Program. It is not a requirement that all nursery personnel be trained to perform newborn hearing screening. Each facility may select appropriate staff to carry out the hearing screening and related duties.

HEARING SCREENING EQUIPMENT

Screening programs must use objective physiological screening methods such as Automated Auditory Brainstem Response (AABR) or otoacoustic emissions (OAE). OAEs can be either distortion product (DPOAE) or transient evoked (TOAE). AABR and OAE do not require a behavioral response from the infant and have proven to be effective screening measures. All hearing screening equipment must meet technical specifications, calibration standards, and hospital safety standards. A quality screening program benefits from incorporating new and improved evidence-based technologies and procedures as they become available.

The choice of equipment used for hearing screening in the NICU must be made carefully. Hearing screening with OAE effectively identifies cochlear or conductive hearing loss but will miss hearing loss of neural origin. AABR technology reflects the status of the peripheral auditory system as well as the auditory neural pathway through the lower brainstem. Therefore, infants in the NICU for more than five days, who are presumed to be at highest risk for neural hearing loss (Joint Committee on Infant Hearing (JCIH), 2007), must have AABR included as part of their hearing screening prior to discharge in order to be effectively screened. If only one hearing screening technology is used in the NICU, JCIH guidelines (2007) recommend that it be the AABR. If nurseries complete a dual screening (AABR and OAE in tandem, not sequentially) infants who REFER on either screening should be referred to audiology for audiological assessment.

Stimulus Parameters

TOAEs should be measured in response to a click at approximately 80dB SPL (78-82dB SPL). DPOAEs should be measured in response to a series of paired tones (f1 and f2), with a ratio of 1.22 at a moderate level, where L1/L2 = 65/55dB SPL.

Newborn screening AABRs typically are evoked using click stimuli at 30 to 35dBnHL at a moderate rate. Non-automated ABR testing is NOT recommended for newborn hearing screening programs in hospital nurseries due to issues of potential operator error and significant time/cost effectiveness issues.

Default stimulus parameters of either OAE or AABR equipment should be reviewed by skilled professionals such as the screening program's consulting audiologist or MDH audiologists to ensure they are appropriately set or to adjust them to be in accordance with clinically accepted national practices.

PASS/REFER Criteria

PASS/REFER criteria need to be selected and monitored carefully to maximize sensitivity and specificity. In most cases, PASS/REFER criteria is already preset into the hearing screening equipment by the manufacturer. When hearing screens are administered, a PASS or REFER result should automatically appear. There should be no interpretation of results by the hearing screener at the time of the screen. PASS/REFER criteria should be reviewed regularly by a consulting audiologist or MDH audiologist and should be in accordance with clinically accepted national practices.

OAE

Typical passing criteria for TOAEs include overall reproducibility greater than 50 percent, at least 50 low noise samples collected, stimulus stability of 75 percent or greater, and responses present at least 6dB above noise floor for at least three of the five test frequencies, with 4000Hz a mandatory passing frequency. Typical
passing criteria for DPOAEs requires absolute response amplitude of at least –6dB and responses at least 6dB above the noise floor at three or more of the test frequency bands, with the 4000Hz region a mandatory passing frequency.

**AABR**

Screening AABR pass criteria for newborns typically require repeatable Wave V evoked responses to clicks at ≤35 dB nHL for each ear, within specific latency parameters.

**HEARING SCREENING PROTOCOL**

The following screening protocols have been developed by local experts and are based on nationally accepted guidelines put forth by the JCIH. They have been tailored to fit Minnesota's system of care to help ensure that every infant receives quality screening and follow-up throughout the state. For more information please refer to the Hearing Screening Result and Follow-up Process for NICU Graduates and a sample Newborn Hearing Screening Flowchart for the NICU Nursery that outlines this process.

**Inpatient Hearing Screening**

If the newborn is expected to remain in the hospital for a prolonged period, screening needs to be performed as soon as medically feasible or prior to three months corrected age. If the infant’s health status changes and includes new risk factors for hearing loss after passing an initial hearing screen, another screen prior to discharge is warranted. Infants who receive a REFER result on the initial hearing screen should be rescreened prior to discharge.

Inpatient hearing screening should consist of **no more than two attempts** using the same screening technique for each ear – assuming the infant is calm and quiet and there are neither equipment problems nor environmental interference during either test. The likelihood of obtaining a PASS by chance alone is increased when screening is performed repeatedly, which means a child with a hearing loss may go undetected and suffer developmental consequences.

Both ears must pass a single screening to be considered an overall passing result. Combining passing results in opposite ears on successive screens does not make a passing result.

If an infant does not pass the final screening before discharge, diagnostic audiological assessment prior to discharge is optimal. If it is not possible to test prior to discharge, audiological assessment must be completed on an outpatient basis as soon as medically feasible. NICU babies screened using dual (in tandem) screening method who pass AABR but not OAE can be passed by OAE on follow-up. NICU babies who do not pass an AABR screening cannot be rescreened and passed by OAE alone.

**Follow-up/Documentation of Inpatient Hearing Screening**

Minnesota statute 144.966 requires the following:

- Screening results must be documented in the infant’s medical record.
- Screening results must be communicated to the infant’s parent(s) both verbally and in writing. The Newborn Screening Program has parent PASS/REFER notification sheets available in multiple languages and are available to order at no cost on our Education Materials and Forms webpage.

- Screening results must be communicated in writing to the infant’s primary care provider within 10 days of the final screen.
- Screening results must be reported to Newborn Screening Program staff within 10 days of the final screen.
Minnesota best practice recommends the following:

- For infants with REFER results who have an inpatient audiology assessment, audiology is responsible for reporting the results to the family, the infant’s primary care provider and the MDH Newborn Screening Program.

- For infants with REFER results, and if inpatient audiological diagnosis cannot be completed, an outpatient follow-up appointment for a pediatric audiological evaluation should be scheduled before the infant is discharged from the hospital. The infant’s primary care provider and Newborn Screening Program staff should be promptly notified of the date/location of the diagnostic appointment to help encourage the family to complete follow-up.

- Families of infants who receive REFER results on newborn hearing screening should be provided information about the importance of timely follow-up.

- Screening results should be available to the primary care provider at the first clinic visit.

When outpatient follow-up is needed for NICU graduates, Minnesota best practice recommends the following:

- Follow-up must occur within 1 month of final hospital screen.

- Both ears must be assessed.

- If AABR technology was utilized and the infant received a REFER result for inpatient screening/rescreening, the infant should not be assessed using OAE alone.

Follow-up/Documentation of Outpatient Results

Minnesota statue 144.9664 requires the following:

- Outpatient audiological results must be documented in the infant’s medical record.

- Outpatient audiological results must be communicated to the infant’s parent(s) both verbally and in writing. The Newborn Screening Program has parent PASS/REFER notification sheets available in multiple languages and are available to order at no cost on our Education Materials and Forms webpage.

- Outpatient audiological results must be communicated to the infant’s primary care provider in writing within 7 days.

- Outpatient audiological results must be reported to the Newborn Screening Program staff within 7 days.

Minnesota best practice recommends the following:

- For infants who do not receive a definitive diagnosis at the outpatient audiological visit, a diagnostic audiology appointment should be scheduled for the family before they leave. The primary care provider and Newborn Screening Program staff should be promptly notified of the date/time of the diagnostic audiology appointment to help facilitate timely services.

- Families of infants who do not have a definitive audiological diagnosis at the outpatient audiological visit should be provided information about the importance of follow-up. Review of data from newborns screened in Minnesota has demonstrated that between 30 and 50 percent of infants who receive a REFER result on the initial outpatient rescreen are later diagnosed with confirmed hearing loss.

Outpatient Follow-up

General outpatient rescreening for NICU infants (i.e., through primary care clinic or as an outpatient in the hospital nursery) is not recommended. JCIH guidelines recommend direct referral to an audiologist for an outpatient audiological follow-up assessment and for comprehensive audiological evaluation when indicated. Ideally, any audiological follow-up and diagnosis should happen prior to the infant’s discharge from the hospital.
Missed Hearing Screen

Rarely, hearing screening may not be completed prior to hospital discharge. If this occurs, the hospital or unit discharging the infant home should:

- Report that the hearing screen was “missed” on the newborn screening card or hearing tear off sheet
- Indicate that hearing screening was not performed in the infant’s discharge summary and ensure that the infant’s parent(s) and primary care provider receives this notice
- Schedule the infant for screening as soon as medically feasible following discharge, and communicate this appointment information to the parent(s), primary care provider, and the Newborn Screening Program

If the infant returns to the nursery for screening, follow the process above for follow-up/documentation of inpatient hearing screening.

Refusal/Opt Out

Refusing newborn hearing screening is a serious decision and could result in long-term developmental delays if congenital hearing loss is not identified early. Parents should discuss the risks and consequences of this choice with their infant’s neonatologist/primary care provider to make a fully-informed decision. Parents who choose to refuse newborn hearing screening must complete and sign the Parental Refusal of Newborn Screening form prior to hospital discharge. The hospital/unit discharging the infant to home is responsible for faxing this form to the Newborn Screening Program and providing copies to the parent(s) and primary care provider.

Parents also have the option to destroy newborn screening blood spots and test results and/or hearing screening test results after screening is complete. A copy of the necessary form can be found on the Newborn Screening Program Education Materials and Forms webpage.

Transferred Infants

If an infant is transferred to a different hospital or unit within the same hospital, conduct the newborn hearing screening before transfer, if possible, and communicate the results with the receiving facility or unit. It is important for the transferring hospital/unit to inform the receiving hospital/unit about all screening that has been done. If newborn hearing screening cannot occur before the transfer, alert the Newborn Screening Program of the infant’s transfer using the Newborn Hearing Screening Transfer form and provide this form to the receiving hospital/unit. Transfers between various units within the same hospital (e.g., NICU to PCVICU or PICU) frequently result in missed hearing screening. Clear communication about the hearing screening status can avoid a missed screen. The hospital or unit that discharges the infant home is responsible for screening the infants hearing and reporting the results to the family, primary care provider, and the Newborn Screening Program.

Readmitted Infants

Infants readmitted to the hospital during the first month of life who have conditions associated with potential hearing loss (e.g., hyperbilirubinemia, meningitis, sepsis) need to have the hearing screen repeated prior to discharge. Because of the high incidence of neural hearing loss associated with significantly elevated bilirubin, these infants should be referred for audiological assessment to include ABR measures.

- It is possible that infants with total serum bilirubin concentrations lower than the total serum bilirubin concentration at which exchange transfusion is indicated may develop auditory neuropathy spectrum disorder. Until further evidence exists of a safe total serum bilirubin level for bilirubin-induced auditory toxicity, an exchange transfusion should be used as the criterion for triggering comprehensive auditory evaluation.
- A rescreen for cases of bacterial and viral meningitis is recommended. Bacterial meningitis is more highly associated with hearing loss. Therefore, infants passing rescreen following bacterial meningitis should be rescreened once again in another 6 months.
- If a hearing screen prior to discharge cannot be completed for infants that are readmitted during the first month of life then an appointment with an audiologist experienced in testing children should be scheduled.
TIMELY CASE MANAGEMENT

The purpose of hearing screening is to identify infants who need further testing. It is important to remember that a hearing screen is not a diagnostic tool.

EHDI is part of a continuum of care that progresses from parental education, to screening, to assessment, to amplification (if elected), to educational intervention. Many professionals – working in different facilities and at different phases of the EHDI process – need to work together and clearly communicate follow-up steps in order to provide quality care and ensure early diagnosis of hearing loss. Hospital screening staff plays a critical role in this process. For infants who do not pass newborn screening and subsequent rescreening, assessment referrals must be made to audiologists with expertise in pediatric physiological and behavioral assessment and management. Refer to the Minnesota EHDI Provider Search webpage\(^{14}\) and/or the national EHDI Pediatric Audiology Links to Services (EHDI PALS) directory\(^{15}\) to locate providers that offer pediatric diagnostic assessments and habilitation services in Minnesota.

The nationally recommended timeline for hearing screening and follow-up is commonly referred to as the 1-3-6 plan. The timeline includes the following benchmarks:

- Screening is complete no later than one month corrected age or as soon as medically feasible
- Diagnostic audiological assessment is complete no later than three months corrected age or as soon as medically feasible
- Intervention services, including amplification (if elected), are initiated no later than six months corrected age or as soon as medically feasible

Without an adequate follow-up plan, even the best EHDI program is ineffective. Please refer to the current Guidelines for Infant Audiologic Assessment\(^{16}\) and Guidelines for Pediatric Amplification\(^{17}\) for additional information on recommended best practices.

Follow-up for Middle Ear Effusion

Although persistent middle ear effusion necessitates medical referral, which might delay the evaluation timeline several weeks, diagnostic audiological evaluation must not be repeatedly postponed solely due to middle ear dysfunction and should be completed before 3 months corrected age. The information from the diagnostic audiological evaluation is valuable both in determining the extent of the effect of the middle ear condition on the infant’s hearing, and identifying whether an underlying sensorineural hearing loss exists, thereby impacting the course of both medical and educational intervention.

Follow-up for Infants with Positive Risk Factors (JCIH 2007 clarification document)

The timing and number of hearing re-evaluations for children with risk factors should be customized and individualized depending on the relative likelihood of a subsequent delayed-onset hearing loss. For a list of risk factors please refer to Risk Factors Associated with Permanent Congenital, Delayed-onset, or Progressive Hearing Loss in Childhood\(^{7}\). Infants who pass the neonatal screening – but have a risk factor – should have at least one diagnostic audiological assessment by 24 to 30 months of age. Early and more frequent assessment may be indicated for children with the following risk factors:
• Cytomegalovirus (CMV) infection
• Syndromes associated with progressive hearing loss
• Neurodegenerative disorders
• Head trauma
• Culture-positive postnatal infections associated with sensorineural hearing loss
• Receipt of extracorporeal membrane oxygenation (ECMO) or chemotherapy
• Caregiver concern or a family history of hearing loss

QUALITY ASSURANCE/QUALITY IMPROVEMENT

MDH and hospitals work together to ensure and improve the quality of screening programs across the state so that every Minnesota infant receives comprehensive screening and follow-up. To help hospitals evaluate and improve their performance, MDH sends semi-annual quality assurance reports to each hospital’s nursery manager and laboratory director. Currently, MDH does not have separate reports for the SCN and NICU. Each hospital can contribute to quality assurance by monitoring and improving the quality of its own screening program.

Hospitals should establish a quality assurance protocol and be able to report critical performance data annually including, but not limited to, the following:

• Total number of live births
• Number of newborns screened
• Number of newborns who passed the hearing screening
• Number of newborns who did not pass the hearing screening (results by right ear, left ear, and both ears)
• Number of newborns whose parent/guardian refused newborn hearing screening
• Number of newborns whose parent/guardian did not refuse screening but who were “missed” (not screened)
• Number of follow-up appointments scheduled for newborns who did not pass the hearing screen or were missed
• Total number of newborns transferred in/out of the facility
• Number of newborns screened who were transferred in/out of the facility
• Number of deceased newborns

At a minimum, methods should be in place for monitoring referral rates—in order to ensure effective screening—and for monitoring parent satisfaction with the hearing screening process. A hospital NICU nursery with an effective hearing screening program is expected to have a referral rate between 7-10 percent.

All nurseries need written protocols for newborn hearing screening that include quality assurance approaches. Components of a quality assurance program include data management, screener performance, site performance, outcome measures, and follow-up compliance. The goal of quality assurance is information management and accountability to the following stakeholders:

• Infants and their families
• Advocates
• Clinical and educational audiologists
• EHDI managers
• Hospitals
• Infants and their families
• Medical and educational specialists
• Otolaryngologists
• Primary care providers
• Screeners
• State of Minnesota
REFERENCES


CDC EHDI National Goals and Objectives, Final Version by the EHDI Data Committee, July 13, 2006.


National Consortium for Newborn Hearing Screening. (Nov 16-18, 1995). *TEOAE-based universal newborn hearing screening*. Georgetown University School of Medicine, Washington DC.


Ontario Health and Long-Term Care Ministry—Infant Hearing Program (2002). *Universal infant hearing screening assessment and communication development: Local implementation support document*.

SELECTED LINKS

1 Guidelines for the Organization and Administration of Universal Newborn Hearing Screening Programs in the Well-Baby Nursery

2 Minnesota Statute 144.966
https://www.revisor.mn.gov/statutes/?id=144.966

3 Parental Refusal of Newborn Screening form

4 Directive to Destroy Newborn Screening Blood Spots and Test Results and/or Hearing Screening Test Results

5 Newborn Hearing Screening Fact Sheet

6 Newborn Screening Orderable Education Materials
http://www.health.state.mn.us/divs/phl/newborn/materials/education.html

7 Risk Factors Associated with Permanent Congenital, Delayed-onset, or Progressive Hearing Loss in Childhood

8 Hearing and Speech Milestones

9 Performance Based Criterion Checklist

10 NCHAM Newborn Hearing Screening Training Curriculum
http://www.infanthearing.org/nhstc/index.html

11 Hearing Screening Result and Follow-up Process for NICU Graduates

12 Newborn Hearing Screening Flowchart for the Neonatal Intensive Care Unit

13 Newborn Hearing Screening Transfer Form: Reporting Results for Transferred Infants
http://www.health.state.mn.us/divs/phl/newborn/materials/nicutransf.pdf

14 EHDI Website Provider Search
http://www.improveehdi.org/mn/providers.cfm

15 National EHDI Pediatric Audiology Links to Services (EHDI PALS) Directory
http://www.ehdipals.org/

16 Guidelines for Infant Audiologic Assessment

17 Guidelines for Pediatric Amplification