

#### — EARLY HEARING DETECTION AND INTERVENTION —

# Guidelines for the Organization and Administration of Universal Newborn Hearing Screening Programs for Out-of-Hospital Births

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#### INTRODUCTION

This document is intended to provide recommended guidelines for newborn hearing screening programs for midwives delivering newborns in out-of-hospital birth settings, including home births and non-hospital birth centers. Until recently, most Minnesota midwives did not have access to screening equipment and therefore referred their clients elsewhere for screening. Thanks to a successful collaboration between the Minnesota Department of Health (MDH) and the Minnesota Council of Certified Professional Midwives (MCCPM), many Minnesota midwives are now trained as screeners and have access to equipment to screen infants for hearing loss outside of the hospital.

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



For midwives who do not have access to hearing screening equipment, Minnesota Statute 144.966¹ requires that all health professionals attending a birth outside of a hospital provide both oral and written information to parents about the importance of hearing screening and where they can have their infant screened. MCCPM members trained as hearing screeners also offer newborn hearing screening to families who are not clients in their practice.

#### **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 plays 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 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. 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.



# CHILD- AND FAMILY-CENTERED COMMUNICATION

Minnesota statute requires midwives to present information to parents prior to performing the hearing screen 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 and storage of hearing test results
  - » Parents who choose to refuse hearing screening must complete and sign the <u>Parental Refusal of</u> <u>Newborn Screening</u><sup>2</sup> 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 <u>Directive to Destroy</u><sup>3</sup> form. The signed form must be submitted to MDH. If no destruction request is received, hearing screening results are kept for 18 years.

Best practice includes providing the following information to parents along with the results of their infant's screen:

- Prevalence of and risk factors for permanent childhood hearing loss (see <u>Appendix A</u><sup>4</sup>)
- Possibility of late or progressive onset of hearing loss, including otitis media
- Developmental milestones for speech, language, and hearing (see <u>Appendix B</u><sup>5</sup>)

# PERSONNEL PERFORMING HEARING SCREENING

Screening may be performed by anyone who has been properly trained. Hearing screeners benefit from direct access to audiological consultation in order to address screening criteria, quality assurance, follow-up assessment, and intervention services.

#### **Training Qualified Screeners**

Ensuring the skills and competencies of all screeners is critical for screening programs. Training 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 annual refresher training.

Initial training often involves the use of multiple resources over several days. Initial training and demonstration of competency and skills shall include the following, at a minimum:

☑ Completion of orientation, including:

- Infection control policies and procedures
- · Infant security procedures
- Cultural sensitivity

Completion of instructional training for newborn hearing screening:

- Benefits of early detection of hearing loss
- Knowledge of hearing screening policy and procedure
- Documentation of screening results
- Communicating screening results to the infant's parent/guardian, infant's primary care provider, and the Newborn Screening Program

☑ Demonstration of competency and skills to perform hearing screening should be completed and documented appropriately:

• Measure the trainee's competency using the Performance-Based Criterion Checklist<sup>6</sup> (see Appendix C) or a similar performance evaluation tool.

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

Periodic observations of each screener

Review of hearing screening data (e.g., number of screens and number of REFER results) 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 using the Performance-Based Criterion Checklist<sup>6</sup> (see Appendix C) or a similar performance evaluation tool.

Resources for training may include experienced screeners; local, licensed clinical and educational audiologists; MDH audiologists; hearing screening equipment manufacturers; and online resources as recommended by the Newborn Screening Program. Each midwife 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). OAE technologies include distortion product otoacoustic emissions (DPOAE) and transient evoked otoacoustic emissions (TEOAE). AABR and OAE do not require a behavioral response from the infant and have proven to be effective screening measures for newborns. All hearing screening equipment must meet technical specifications, calibration standards, and safety standards. A quality screening program benefits from incorporating Hearing screening equipment use and care instruction new and improved evidence-based technologies and procedures as they become available.

#### Stimulus Parameters

TOAEs should be measured in response to a click at approximately 80 dB SPL (78-82 dB 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 = 65/55 dB SPL.

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

Default stimulus parameters of both OAE and AABR equipment should be reviewed by skilled professionals, such as a consulting audiologist or MDH audiologist, 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 6 dB above noise floor for at least three of the five test frequencies, with 4000 Hz a mandatory passing frequency.

Typical passing criteria for DPOAEs requires absolute response amplitude of at least –6 dB and responses at least 6 dB above the noise floor at three or more of the test frequency bands, with the 4000Hz region a mandatory passing frequency.

#### **AABR**

Typical passing criteria requires 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 Joint Committee on Infant Hearing (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. See Appendix D for details about the <u>Hearing Screening Result and Follow-up Process</u><sup>7</sup> and Appendix E for a sample <u>Newborn Hearing Screening Flowchart for Out-of-Hospital Births</u><sup>8</sup>, which outlines the follow-up process.

#### **Initial Hearing Screening**

The initial hearing screen is the first screen performed on a newborn. It is best performed after 12 hours of age but at no later than three days postpartum. The screen may be performed before 12 hours of age if needed; however, early screens have a higher REFER (not pass) rate due



OAE screening equipment measures the sound the cochlea produces in response to external stimuli.



AABR screening equipment measures the electrical currents that are generated by the brain when the auditory system is excited by stimulus.

to residual birthing debris in the ear canal. Infants who do not pass the initial hearing screen should ideally be rescreened at the two-week postpartum check or at no later than one month of age.

The initial hearing screening should consist of *no more* than two attempts using the same screening technique on each ear—assuming that the infant is calm and quiet and there are neither equipment problems nor environmental interference during either test. The likelihood of obtaining a passing result 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 as an overall passing result. Combining passing results in opposite ears on successive screens does not make a passing result.

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#### Follow-up/Documentation of Initial Hearing Screening

Initial hearing screening results should be:

- · Documented in the infant's health record
- Communicated to the infant's parent(s) both verbally and in writing
- Communicated to the infant's primary care provider in writing when routine well-child care commences
- Reported to Newborn Screening Program staff within 10 days of the screen.

Minnesota best practice recommends the following:

- For infants with REFER results on the initial screen, a follow-up appointment for a hearing rescreening or pediatric audiological evaluation should be scheduled for the family as soon as possible. The infant's primary care provider (if applicable) and Newborn Screening Program staff should be promptly notified of the date and location of the follow-up rescreen or diagnostic appointment to help facilitate timely services.
- Families of infants who receive REFER results on the initial newborn hearing screening should be provided with information about the importance of follow-up.

#### Rescreening

For infants with REFER results on the initial screen, at least one rescreening at a later time or date is necessary to achieve appropriate referral of infants most at risk to specialty providers. If the infant does not pass the *initial* hearing screening in one or both ears, he or she should have a rescreen completed ideally at the two week postpartum check, or at no later than one month of age. National guidelines recommend allowing one to two weeks from the time of the initial screen to allow any transient ear conditions to resolve before rescreening. 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.

Best practice includes the following recommendations for rescreening:

 Use either AABR or OAE, regardless of which technology was used for the initial hearing screening. Note, however, that there is a slight risk of missing neural hearing loss if an infant is rescreened using OAE after receiving a refer result using AABR.

- Rescreen both ears even if only one ear did not pass the initial hearing screening.
- The rescreen should consist of a maximum of two attempts on each ear, assuming that the infant is calm and quiet and there are neither equipment problems nor environmental interference during either attempt.

#### Follow-up/Documentation of Rescreening

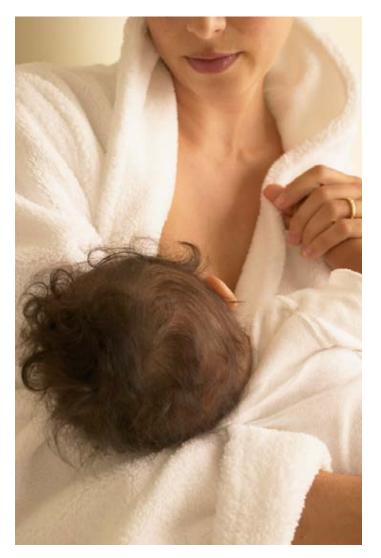
Rescreen hearing results should be:

- · Documented in the infant's health record
- Communicated to the infant's parent(s) both verbally and in writing
- Communicated to the infant's primary care provider in writing within 10 days
- Reported to Newborn Screening Program staff within 10 days.



Minnesota best practice recommends the following:

- For infants with REFER results on the rescreening, 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 and location of the diagnostic audiology appointment to help facilitate timely services.
- Families of infants who receive REFER results on the rescreening should be provided information about the importance of follow-up. Data from newborns screened in Minnesota in recent years shows that infants who do not pass the outpatient rescreen have a 30 to 50 percent chance of confirmed hearing loss.



#### Missed Screen / Equipment Malfunction

If an equipment malfunction or family circumstance prevents the completion of the initial screen as planned, the MDH newborn screening program and the provider working with the infant for routine well-child care during the first month of life should be notified in writing that the hearing screening was missed. The primary provider should then assist the family in arranging a time and location for completing the hearing screen. The screen should take place as soon as possible but at no later than one month post-partum. Alternate screening options include other midwife practices with training and screening equipment, audiology clinics, and certain primary care clinics.

#### **Transferred Infants**

If an infant is going to be transferred to a hospital, conduct the newborn hearing screening before transfer, if possible, and communicate the results to the receiving facility. If the hearing screen cannot occur before transfer, alert the Newborn Screening Program of the infant's transfer and provide the *Hearing Screening Form for Transferred Infants*<sup>9</sup> (see Appendix F) to the receiving facility. This form alerts the receiving facility that the infant's hearing needs to be screened and requests that they fax the form with the hearing screening results to the Newborn Screening Program. Ultimately, the hospital or midwife that sends the infant home is responsible for screening the infant's hearing and reporting the results to the family, the primary care provider, and the Newborn Screening Program.

#### **Hospital Births**

See the MDH <u>Guidelines for the Organization and</u>
<u>Administration of Universal Newborn Hearing Screening</u>
<u>Programs in the Well-Baby Nursery</u><sup>10</sup> and <u>Guidelines for the</u>
<u>Organization and Administration of Universal Newborn</u>
<u>Hearing Screening Programs in the Special Care Nursery and</u>
<u>NICU<sup>11</sup> for additional information.</u>

#### **Infants Needing Additional Care**

Infants identified as needing additional care during the first month of life with conditions associated with potential hearing loss (e.g., hyperbilirubinemia, meningitis, sepsis) need to have a hearing screen repeated after recommended care. Because of the high incidence of neural hearing loss associated with significantly elevated bilirubin, these infants should be referred for audiological assessment to include diagnostic ABR measures.

#### **TIMELY CASE MANAGEMENT**

The purpose of a hearing screen 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 parent education, to screening, to assessment, to amplification (if elected), to educational intervention. Many professionals—working in different entities and at different phases of the EHDI process—must work together and clearly communicate follow-up steps in order to provide quality care and ensure early diagnosis of hearing loss. Midwives play a critical role in this process. For infants who do not pass the newborn hearing screening and subsequent outpatient rescreening, assessment referrals must be made to audiologists with expertise in pediatric physiological and behavioral assessment and management. See the Minnesota EHDI website<sup>12</sup> to locate providers that offer pediatric diagnostic assessments and habilitation services in Minnesota.

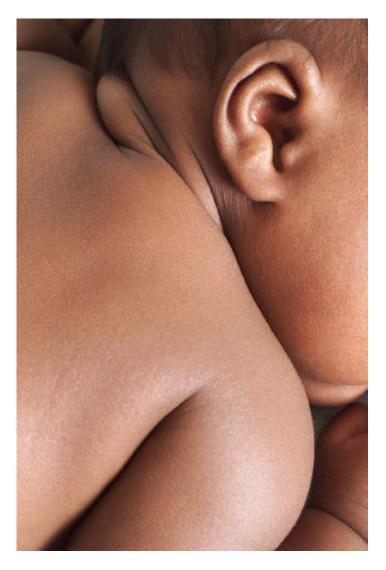
The nationally recommended timeline for hearing screening and follow-up is commonly referred to as the 1-3-6 plan. The timeline includes the following benchmarks:

- Screening is complete at no later than one month of age
- Diagnostic audiological assessment is complete at no later than <u>three months</u> of age
- Amplification (if elected) and/or intervention services are initiated at no later than six months of age

With prompt referral and follow-up, Minnesota children can receive appropriate care and services even earlier than the nationally recommended timeline. Yet without an adequate follow-up plan, even the best EHDI program is ineffective. Please refer to the current <u>Guidelines</u> for Infant Audiologic Assessment<sup>13</sup> and <u>Guidelines for Pediatric Amplification</u><sup>14</sup> for additional information on recommended best practices.

#### Follow-up for Middle Ear Effusion

Although persistent middle ear effusion requires medical referral, which may delay the evaluation timeline several weeks, diagnostic audiological evaluation must not be postponed solely due to middle ear dysfunction and should be complete before three months of age. The information gained from a diagnostic audiological evaluation is valuable both in determining the extent of the effect of the middle ear condition on the infant's



# month: screening complete months: diagnosis complete months: intervention services initiated

hearing and in 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 individualized depending on the relative likelihood of a subsequent delayed-onset hearing loss. Infants who pass the neonatal screening—but have a risk factor—should have at least one diagnostic audiology assessment by 24 to 30 months of age. Early and more frequent assessments may be necessary for children with the following risk factors (see Appendix A for a detailed list):

- 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 its external partners 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. Midwives can contribute to quality assurance by monitoring and improving the quality of their own screening performance.

The Newborn Screening Program recommends that midwives establish a quality assurance protocol and be able to report, on an annual basis, critical performance data including, but not limited to, the following:



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- 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 to a hospital
- Number of newborns screened who were transferred to a hospital
- · Number of deceased newborns

At a minimum, methods should be in place for monitoring REFER rates in order to ensure effective screening and for monitoring parent satisfaction with the hearing screening process. An effective hearing screening program should have a REFER rate of 4 percent or less.

The overall 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
- Medical and educational specialists
- Otolaryngologists
- Primary care providers
- Screeners
- · State of Minnesota



#### **REFERENCES**

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#### **SELECTED LINKS**

- <sup>1</sup> Minnesota Statute 144.966 https://www.revisor.mn.gov/statutes/?id=144.966
- <sup>2</sup> Parental Refusal of Newborn Screening form http://www.health.state.mn.us/newbornscreening/docs/ parental\_refusal.pdf
- <sup>3</sup> Directive to Destroy Newborn Hearing Screening Test Results form <a href="http://www.health.state.mn.us/newbornscreening/docs/hearingdestruction.pdf">http://www.health.state.mn.us/newbornscreening/docs/hearingdestruction.pdf</a>
- <sup>4</sup> Appendix A: Risk Factors Associated with Permanent Congenital, Delayed-onset, or Progressive Hearing Loss in Childhood

http://www.improveehdi.org/wi/library/files/Risk%20 Indicators%20from%20JCIH%202007%20Position%20 Statement.pdf

- <sup>5</sup> Appendix B: Hearing and Speech Milestones http://www.improveehdi.org/wi/library/files/Hearing%20 and%20Speech%20Milestones%20from%20AAP%20 and%20AAA.pdf
- <sup>6</sup> Appendix C: Performance Based Criterion Checklist http://www.improveehdi.org/wi/library/files/ Competency%20Checklist.pdf

- <sup>7</sup> Appendix D: Hearing Screening Result and Follow-up Process
- http://www.improveehdi.org/wi/library/files/Hearing%20 Screening%20Result%20and%20Follow-up%20Process.pdf
- <sup>8</sup> Appendix E: Newborn Hearing Screening Flowchart for the Out-of-Hospital Births <u>http://www.improveehdi.org/mn/library/files/Out-of-</u> Hospital%20Birth%20Flowchart%20with%20Myths.pdf
- <sup>9</sup> Appendix F: Hearing Screening Form for Transferred Infants <a href="http://www.health.state.mn.us/newbornscreening/docs/nicutransf.pdf">http://www.health.state.mn.us/newbornscreening/docs/nicutransf.pdf</a>
- <sup>10</sup> Guidelines for the Organization and Administration of Universal Newborn Hearing Screening Programs in the Well-Baby Nursery <a href="http://www.improveehdi.org/mn/library/files/">http://www.improveehdi.org/mn/library/files/</a> wbnguidelines.pdf
- <sup>11</sup> Guidelines for the Organization and Administration of Universal Newborn Hearing Screening Programs in the Special Care Nursery and NICU <a href="http://www.health.state.mn.us/newbornscreening/docs/nicu-hear-quidelines.pdf">http://www.health.state.mn.us/newbornscreening/docs/nicu-hear-quidelines.pdf</a>
- <sup>12</sup> EHDI Website Provider Search http://www.improveehdi.org/mn/providers.cfm
- <sup>13</sup> Guidelines for Infant Audiologic Assessment http://www.improveehdi.org/wi/library/files/MDH%20 Audiologic%20Assessment%20Guidelines%281%29.pdf

