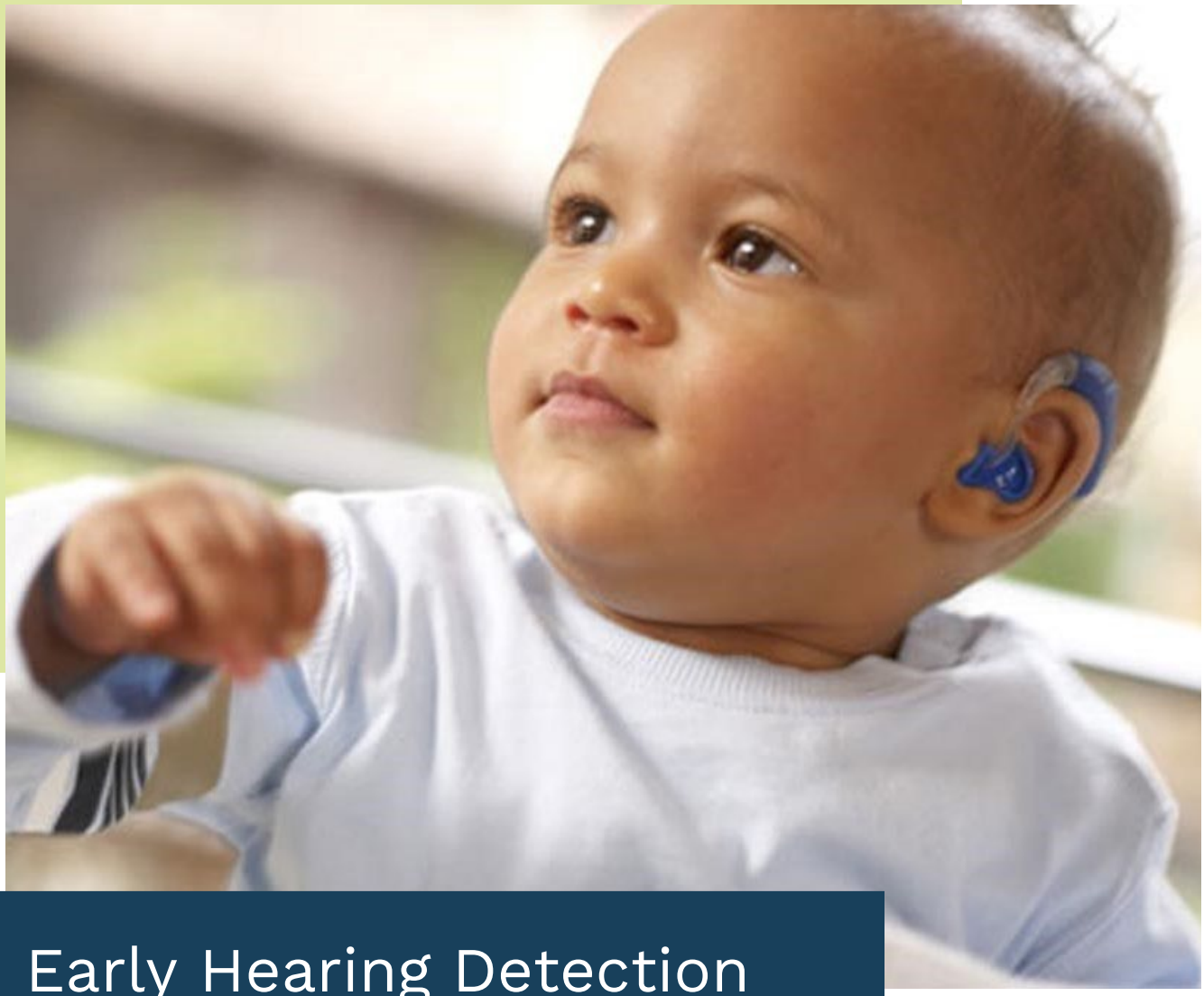

Early Hearing Detection and Intervention Best Practice Manual

Revised August 2026

IOWA Health and Human Services

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Introduction

Purpose

Each year, approximately 12,000 babies are born in the United States with permanent hearing differences (referred to as hearing loss nationally). With two to three of every 1,000 newborns having hearing differences, it is the most frequently occurring birth defect. Another two to three per 1,000 children will acquire a hearing difference after birth.

Prior to the development of Early Hearing Detection and Intervention (EHDI) programs, the average age at which children were identified with mild to moderate hearing loss in the United States was two and a half years[1]. Often, hearing loss was not detected until a child had entered elementary school. It has long been recognized that unidentified hearing loss at birth can adversely affect speech and language development, academic achievement and social-emotional development. Screening and assessment are very important, even for families who have no history of hearing differences. In fact, most babies born with hearing differences are born to parents with typical hearing. If identification does not happen until after six months of age, the child's language skills at age three will be far behind those of a child with typical hearing.[2]

Families look to physicians, audiologists and other health care providers to learn more about screening, assessment, intervention and resources available for their child and family. The purpose of the Iowa EHDI Best Practices Manual is to advance the development of a comprehensive statewide Early Hearing Detection and Intervention (EHDI) system in Iowa. This manual will assist hospitals, birthing facilities, Area Education Agencies (AEAs), health care providers and private practice and hospital-based audiologists in developing programs and written protocols for newborn hearing screening, follow-up and early intervention (EI). The manual is based upon best practices within EHDI programs as outlined in the Joint Committee on Infant Hearing and Iowa EHDI law and rules.

Acknowledgements

The EHDI program would like to take this opportunity to let you know we appreciate the work you do to ensure infants and children with hearing differences are identified as early as possible and receive ongoing support. Your efforts to assist children who are deaf or hard-

[1] Centers for Disease Control and Prevention. (2003, October 17). Infants tested for hearing loss—United States, 1999–2001. *MMWR. Morbidity and Mortality Weekly Report, 52*(41), 981–984. Erratum in *MMWR. Morbidity and Mortality Weekly Report, 52*(49), 1210. PMID: 14561955.

[2] Yoshinaga-Itano, C., Sedey, A. L., Coulter, D. K., & Mehl, A. L. (1998). Language of early- and later-identified children with hearing loss. *Pediatrics, 102*(5), 1161–1171. https://doi.org/10.1542/peds.102.5.1161 PMID: 9794949.

of-hearing (DHH) and their families will minimize delays in speech, language, cognitive and social and emotional development for years to come!

Special thanks to the parents of DHH children and hearing healthcare professionals who assisted the EHDI program personnel in the development and review of this manual in 2008 and 2025. Your knowledge and expertise were invaluable.

Acronym Guide

A

AABR – Automated Auditory Brainstem Response
AAP – American Academy of Pediatrics
ABR – Auditory Brainstem Response
AEA – Area Education Agency
ANSD – Auditory Neuropathy Spectrum Disorder
ANSI - American National Standards Institute
ASHA – American Speech-Language-Hearing Association
ASL – American Sign Language
ASSR – Auditory Steady-State Response
AUD – Audiology
AUR – Auditory Responses (contextual; appears as ABR/ASSR more formally)

B

BCEHP – British Columbia Early Hearing Program
BiCROS - Bilateral Contralateral Routing of Signals
Bluetooth – Wireless system used with hearing devices

C

CDC – Centers for Disease Control and Prevention
CE-Chirp – Click-evoked chirp stimulus
CHARGE – Coloboma, Heart Defects, Atresia choanae, Retarded growth, Genital anomalies, Ear anomalies
CM – Cochlear Microphonic
cCMV – Congenital Cytomegalovirus
CROS – Contralateral Routing of Signals

D

dB HL – Decibels Hearing Level
DHH – Deaf or Hard-of-Hearing
DPOAE – Distortion Product Otoacoustic Emissions
DSL v5 – Desired Sensation Level Version 5 (hearing aid fitting method)
DPOAE – Distortion Product Otoacoustic Emissions

E

EA – Early ACCESS
EI – Early Intervention
ENT – Ear, Nose, and Throat (Otolaryngology)
EHDI – Early Hearing Detection and Intervention

ECMO – Extracorporeal Membrane Oxygenation
EEG – Electroencephalography (contextually referenced in ABR methods)
EHDI SOC – EHDI System of Care
EHDI Family Support – Program for DHH children and families

F

FDA – Food and Drug Administration (referenced in equipment discussion)
FPT – Frequency-specific Threshold (contextual term used in ABR interpretation)

H

HHS – Iowa Department of Health and Human Services
HL – Hearing Level
HRSA – Health Resources & Services Administration

I

IA – Iowa
IAC – Iowa Administrative Code
IDEA – Individuals with Disabilities Education Act
IEC – International Electrotechnical Commission
IFSP – Individualized Family Service Plan
INSIS – Iowa Newborn Screening Information System
ISO – International Organization for Standardization

J

JCIH – Joint Committee on Infant Hearing

L

LEAD-K – Language Equality & Acquisition for Deaf Kids
LittlEARS ® - Infant Listening Questionnaire
LPN – Licensed Practical Nurse

M

MRI – Magnetic Resonance Imaging (context reference)

N

NBS – Newborn Screening (program context)
NICU – Neonatal Intensive Care Unit
NIH – National Institutes of Health

O

OAE – Otoacoustic Emissions
OCHL Study – Outcomes for Children with Hearing Loss Study
OSHA – Occupational Safety and Health Administration

P

PCP – Primary Care Provider
PEACH – Parent Evaluation of Aural/Oral Performance of Children
OCHL Study – Outcomes for Children with Hearing Loss Study

R

RECD – Real-Ear-to-Coupler Difference
RM – Remote Microphone

S

SC – Service Coordinator
SOC – System of Care

T

TEOAE – Transient Evoked Otoacoustic Emissions
TORCH – Toxoplasmosis, Other, Rubella, Cytomegalovirus, Herpes simplex

V

VRA – Visual Reinforcement Audiometry

Historical Background

EHDI Advisory Committee

In 1992, a grassroots group of professionals and consumers created the Iowa Newborn Audiology Committee. They believed that Iowa infants and toddlers with hearing loss (currently referred to as hearing differences) were not being identified as early as possible. Late identification resulted in missed opportunities for language input during the critical period for language learning. The group approached the Iowa Department of Public Health (currently referred to as the Iowa Department of Health and Human Services (Iowa HHS)) in 1994 for assistance in developing a statewide identification and intervention program for very young children with hearing differences.

The committee evolved into what is now known as the EHDI Advisory Committee. The committee is composed of a multidisciplinary group from the health care community, including the Iowa Hospital Association, private practice and hospital-based audiologists, a pediatrician and family practice physician and an otolaryngologist. Also represented are members of the deaf community, parents of children with hearing differences, advocates, Early ACCESS (IDEA, Part C, Iowa's EI program), AEAs and other stakeholders that are affected by or involved with the newborn hearing healthcare journey of children. The committee was designed to build partnerships and advise EHDI staff as the program moves to establish and implement project goals. The committee has been and continues to be an integral part of the EHDI program and is often required by grantors who provide funding to support EHDI programming.

The EHDI Advisory Committee typically meets in April, July and October from 10 a.m. until 3 p.m. at a location in Des Moines.

EHDI Law and Rules

In 2003, the Iowa legislature passed a new law to require all babies born in Iowa on or after January 1, 2004, to have a hearing screening prior to hospital discharge. The requirements also apply to children born at a location (e.g. home, birth center) other than a birth hospital.

The law further requires the results of all screenings, re-screenings, and diagnostic assessments for children under the age of three be reported to the Iowa Department of Health and Human Services (Iowa HHS), EHDI program. The law and administrative rules outline specific requirements for hospitals, birth centers, AEAs, audiologists and health care professionals who undertake primary pediatric responsibility of newborns delivered outside a hospital setting. The EHDI law and rules can be found on the EHDI website, https://hhs.iowa.gov/health-prevention/birth-maternal-care/ehdi.

Iowa EHDI Program

Overview

By code, the Iowa HHS EHDI program is responsible for providing administrative oversight, including follow-up activities in Iowa. Through funding provided by federal partners, Iowa's EHDI Program is responsible for building a sustainable system of care (SOC). Within that system, the EHDI program serves as a safety net. When handoffs between providers do not occur and a child's journey through the hearing healthcare process is stalled, EHDI program personnel step in to assist in the process. The EHDI Follow-Up Coordinators reach out to families, the infant's primary care providers (PCP) and other SOC providers to ensure the hearing healthcare journey is completed in a timely manner. The EHDI Follow-Up Coordinators also connect families to community resources, including EI and family support, based on family choice.

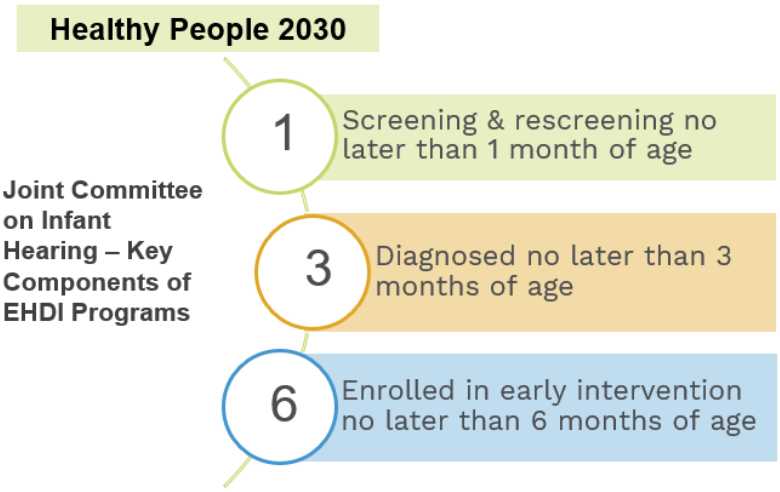
The Health Resources and Services Administration (HRSA) EHDI grant, and Centers for Disease Control and Prevention (CDC) EHDI cooperative agreement provide the framework and resources essential to advance Iowa EHDI's SOC. Iowa continues to build a strong system of coordinated leadership and partnerships to accomplish its EHDI goals and objectives. The HRSA grant goals focus on language acquisition, follow-up of children who have not completed the hearing healthcare journey, quality improvement and screening children up to age three for hearing differences. The CDC cooperative agreement goals focus on surveillance, data linkages, data analysis and program evaluation.

EHDI Mission

The EHDI program's mission is to ensure that all newborns and toddlers with hearing differences are identified as early as possible and provided with appropriate medical, audiological, educational and family support based on family choice.

EHDI Program Goals

Nationally, all EHDI programs have three primary goals, as a result of the Joint Committee on Infant JCIH) Hearing 2019 Position Statement[3]. The JCIH committee recommends best practices for EHDI programs. The EHDI national goals are referred to as the national "1-3-6 goals."



[3] Joint Committee on Infant Hearing. (2019, October 23). Year 2019 position statement: Principles and guidelines for Early Hearing Detection and Intervention Programs. *Journal of Early Hearing Detection and Intervention, 4*(2), 1–44. https://doi.org/10.15142/fptk-b748.

The goals are also included in the Healthy People 2030 initiative to improve health outcomes for children and adults.

Chapter 1: EHDI System of Care Roles and Responsibilities

Policy

Each facility and/or entity within the EHDI SOC, who provides hearing screening and diagnostic assessment services to children under the age of three, is responsible for providing good handoffs in care, making appropriate referrals and reporting results to the HHS, as required by law.

Background

It is essential for all partners to fulfill their responsibilities within the EHDI SOC, follow Iowa law and rules and best practice protocols developed by the state EHDI program reflecting guidance from the JCIH to ensure children with hearing differences are identified as DHH and enrolled in EI services in a timely manner.

State Responsibilities

Iowa HHS oversees the EHDI program including:

- management of surveillance system (known as Iowa Newborn Screening Information System, INSIS)
- oversight of reporting requirements
- follow-up through the hearing healthcare journey
- ensure referral to EI and family support
- technical assistance regarding best practices related to newborn hearing screening, diagnosis and follow-up best practices

Birthing Facilities

Each birthing hospital shall:

- Designate an employee of the hospital to be responsible for the newborn hearing screening program in that institution.
- Provide hearing screening for the newborn prior to discharge, except in the following circumstances:
    - The newborn is transferred for acute care prior to completion of the hearing screening. In this situation, the birth hospital must notify the receiving hospital of the status of the hearing screening. The receiving facility shall then be responsible for completion of the newborn hearing screening prior to discharge of the newborn from the nursery.
    - The newborn is born with a condition that is incompatible with life. If child dies, mark child as deceased in INSIS.
- Ensure newborn hearing screening is performed by an audiologist, audiology assistant, audiometrist, registered nurse, licensed physician or other person for whom newborn hearing screening is within the person's scope of practice
- Report newborn hearing screening results to the parent or guardian in written form

- Report newborn hearing screening results to the child's PCP.
- Assist family in scheduling any needed follow-up appointments for hearing re-screen or high-risk monitoring and connecting family to a PCP/medical home if they are not already connected.
    - If the baby does not pass an automated Auditory Brainstem Response (AABR) birth screen and was in the neonatal intensive care unit (NICU), the child needs a referral to a provider that uses AABR for screening or a direct referral to a pediatric audiology facility offering diagnostic ABR. It is not recommended to re-screen with Otoacoustic Emissions (OAE) in this situation as hearing losses such as Auditory Neuropathy Spectrum Disorder (ANSD) may not be detected.
- Report newborn hearing screening results to the HHS, as required by law, including refusals, deceased and transfers to other facilities in or out of state.

Birth Centers

Each birth center shall:

- Designate an employee of the birth center to be responsible for the newborn hearing screening program in that institution.
- Refer every newborn delivered in the birth center to an audiologist, physician or hospital for a newborn hearing screening, if not provided by the birth center.
- Arrange a hearing screening appointment for the newborn no later than 30 days from birth and report to the parent the appointment time, date and location prior to the infant's discharge.
- Report newborn hearing screening results to the department, as required by law, including refusals, deceased, transfers to another facility.
- Report screening results to the parent in written form.
- Report screening results to HHS in the manner prescribed by law.

Outpatient Screening Provider

Each outpatient screening provider shall:

- Perform the hearing screening within 30 days of the newborn's discharge from the birthing facility, birth center or care of a midwife, unless the parent does not attend the scheduled appointment. If the parent does not attend the appointment, the facility shall document the no show in the medical or educational record and shall report the no show to HHS.
- Report hearing screening results to the parent in written form.
- Report screening results to HHS in the manner prescribed by law.

The following should occur for babies that require a hearing re-screen:

- Both ears should be retested, even if only one ear did not pass during a previous screening.
- If a baby from the NICU does not pass an AABR for their birth screen, they should not be re-screened with OAE alone, the baby should be re-screened with AABR.

- If one or both ears did not pass on the hearing re-screen using OAE or AABR, the baby should be referred to a pediatric audiologist for diagnostic testing. **DO NOT** continue to screen or schedule an additional hearing rescreen. Refer the infant to a pediatric audiologist. To find a local pediatric audiologist who can perform diagnostic testing, go to the EHDI website, click on providers, https://hhs.iowa.gov/providers and scroll down to Diagnostic Audiology Centers.

Audiologist

Babies referred to an audiologist:

- Perform the hearing screening within 30 days of the newborn's discharge from the birthing facility, birth center or care of a midwife, unless the parent does not attend the scheduled appointment. If the parent does not attend the appointment, the facility shall document the no show in the medical or educational record and shall report the no show to HHS.
- Report hearing screening results to the parent in written form.
- Report screening results to HHS and PCP in the manner prescribed by law.

The following should occur for babies that require a hearing re-screen:

- Both ears should be retested, even if only one ear did not pass during a previous Screening.
- If a baby from the NICU does not pass an AABR for their birth screen, they should not be re-screened with OAE alone, the baby should be re-screened with AABR.
- If one or both ears did not pass on the re-screen using OAE or AABR, the baby should be referred to a pediatric audiologist for diagnostic testing. **DO NOT** continue to screen or schedule an additional hearing rescreen. Refer the infant to a pediatric audiologist. To find a local pediatric audiologist who can perform diagnostic testing, go to the EHDI website, click on providers, https://hhs.iowa.gov/providers and scroll down to Diagnostic Audiology Centers.

Primary Care Provider/Medical Home

The role of the PCP is to ensure each baby under their case has access to:

- Newborn hearing screening before hospital discharge. If a newborn is delivered in a location other than a birthing hospital or birth center, the PCP shall:
  - Refer the newborn to an audiologist, physician, or hospital for completion of the newborn hearing screening within one month of the newborn's birth.
  - Arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date, and location.
- Outpatient hearing re-screen before **1** month of age, if the baby does not pass the initial birth hearing screen.
- Diagnostic audiological evaluation before **3** months of age, if the baby does not pass the hearing re-screen.
- Medical evaluation to determine the etiology of the hearing loss and assess for associated conditions immediately following a diagnostic audiological evaluation, as needed.

- Early intervention services and hearing aids before **6** months of age, if the baby is diagnosed with sensorineural, permanent conductive, mixed hearing loss or ANSD and the family chooses to utilize these resources.
- Objective standardized screening of global development with a validated assessment tool at nine, 18, 24, and 30 months of age or any time parents and/or professionals have a concern. Infants not passing the speech-language portion of the screening or for whom there is a concern regarding hearing or language should be referred for a speech-language and audiological evaluation.

See Hearing Screening Follow-Up Flowchart which outlines the guidelines for PCP/medical home providers to follow when guiding a family through the EHDI process.

Chapter 2: Qualifications and Training of Newborn Hearing Screening Personnel

Policy

All qualified newborn hearing screening personnel shall complete the competency criteria outlined below.

Background

A wide variety of personnel, including nurses, audiologists, and technicians perform newborn hearing screens in Iowa. It is essential all screeners have an understanding of newborn hearing screening, the need for follow-up and demonstrate competency to complete their duties.

Newborn Hearing Screening Personnel

Newborn hearing screening shall be performed by one of the following personnel:

- Audiologist
- Audiology assistant
- Audiometrist
- Registered nurse
- Licensed physician
- Other person for whom newborn hearing screening is within the scope of practice (i.e. LPNs)

Qualifications

Each person who screens the hearing of newborns and infants shall meet the following criteria:

- Be 18 years of age or older
- Have a high school diploma or its equivalent
- Be current with immunizations and meet all health and safety requirements required by the facility and
- Complete required training as specified in the following section (Training Program)

Training Program

A training program for the hearing screening personnel at each facility shall be established under the direction of the staff audiologist, state consulting audiologist, or physician responsible for overseeing the medical aspects of the facility. The training program shall include:

- knowledge of the technology used for screening: AABR and/or OAE
- operation and care of the screening equipment
- anatomy and physiology of the ear
- nature of the responses being measured
- patient and non-patient factors that influence responses

- hearing screening procedures, including documentation of results
- importance of documenting high-risk factors
- follow-up for infants who are missed, did not pass, or have a high-risk factor(s)
- confidentiality requirements for sharing information
- communication skills necessary to provide accurate and appropriate information to the parent(s) and/or guardian(s)
- safety and infection control procedures, including universal precautions for blood-borne pathogens and tuberculosis, according to the medical care facility's guidelines
- medical care facility's emergency procedures
- supervised practice and individual observation outlined in the following section (Supervised Practice and Individual Observation)

Supervised Practice and Individual Observation

Supervised practice, observation and assessment should be used to determine the ability of personnel to perform duties associated with hearing screening. Hearing screening personnel shall demonstrate the following abilities:

- Work independently, accurately and consistently
- Follow the precise sequence of instructions contained in the hearing screening protocol

Ongoing assessment of proficiency should be conducted through individual observation by the birthing facility nurse manager or designated EHDI contact.

Chapter 3: Newborn Hearing Screening Protocol

Policy

All newborns and infants born in Iowa, except those born with a condition that is incompatible with life, shall be screened for hearing differences to aid in the identification of infants with permanent hearing differences.

Background

The goal of infant hearing screening is early detection of hearing differences. It has long been recognized that unidentified hearing differences at birth can adversely affect speech and language development as well as academic achievement and social-emotional development. Nationally recognized standards of care require all infants' hearing be screened/re-screened before **1** month of age, diagnosed with a hearing difference no later than **3** months of age and enrolled in early intervention no later than **6** months of age.[4]

The following screening protocols were developed by experts in Iowa and are based on nationally accepted guidelines put forth by the JCIH. The protocols are tailored to fit Iowa's system of care to help ensure that every infant receives quality screening and follow-up throughout the state.

Personnel

Every birth facility shall designate an employee to be responsible for the infant hearing screening program in that facility. If a hospital with a birthing facility employs an audiologist, that individual should be involved in program development, including equipment selection, hearing screening protocols, training, and oversight.

Infant hearing screening shall be performed by an audiologist, audiology assistant, audiometrist, registered nurse, licensed physician or other person for whom infant hearing screening is within the person's scope of practice. Refer to chapter 2 in manual called Qualifications and Training of NBHS Personnel. The provider who conducts the hearing screening shall be educated about the importance of hearing screening and timely follow-up prior to performing the screening.

Equipment Technologies

The Iowa EHDI program does not recommend or endorse a particular brand of equipment; however, the following technologies are acceptable:

a. **Automated auditory brainstem response (AABR)**

[4] Joint Committee on Infant Hearing. (2019, October 23). Year 2019 Position Statement: Principles and guidelines for early hearing detection and intervention programs. *Journal of Early Hearing Detection and Intervention, 4*(2), 1–44. https://doi.org/10.15142/fptk-b748.

Sounds are played to the infant's ears after adhesive bandage-like electrodes are placed on the infant's head to detect responses. This screening measures how the hearing nerve transmits sound to the brainstem and can aid in identification of infants who have a hearing difference. This equipment tends to have a lower ***did not pass*** rate since fluid or birthing debris has less of an impact during this type of testing.

b. **Evoked Otoacoustic Emissions (OAE)**
A miniature earphone, which includes a microphone, are placed in the ear. Sounds are transmitted into the ear. The cochlea (hearing organ) will "echo" back a sound, which is measured in the microphone. When an infant has a hearing difference, no response is measured on the OAE test. There are two types of OAE hearing screening equipment:
    - **Transient Evoked Otoacoustic Emissions (TEOAE)**
    Sounds are emitted in response to an acoustic stimulus of very short duration; usually clicks but can be tone-bursts.
    - **Distortion Product Otoacoustic Emissions (DPOAE)**
    Sounds are emitted in response to two simultaneous tones of different frequencies.

Stop Criteria for Well Baby Nursery

Because birthing debris in the ear canal is the primary cause of an erroneous 'did not pass' result, the preferable age of initial hearing screening is 24 hours of age in the Well Baby Nursery. Ear canal massage between screens is also recommended.

Many infants screened for hearing differences will '**pass'** their initial or inpatient hearing birth screen. Infants who receive a '**did not pass'** result on the initial hearing screen shall be rescreened prior to hospital discharge. While this is a viable means of reducing the false positive rate, excessive rescreening can increase the false negative rate (passing infants with actual hearing differences). No guidelines are currently available that address the number of times a hearing screen should be repeated on an infant before hospital discharge. Assuming that screening conditions are adequate (quiet infant, quiet room, acceptable probe fit), the following guidelines can be used until published data are available.

a. **Well Baby Nursery OAE**
    - Two screening sessions of no more than three screens per ear are recommended, for a total of six screens per ear.
    - The screening sessions should be conducted several hours apart and as close to discharge as possible.

b. **Well Baby Nursery AABR**
    - No more than two screens per ear are recommended.
    - The screens should be conducted several hours apart and as close to discharge as possible.

Both ears must be screened in a single session, or a case note must be entered as to why an ear was not screened (e.g. right ear atresia). Combining passing results in opposite ears

on successive screening **does not** make a passing result. Additionally, using a pass result from a previous session for the opposite ear **does not** make a passing result.

Stop Criteria for NICU Nursery

Assuming screening conditions are adequate (quiet infant, quiet room, acceptable electrode impedance and headphone placement), the following guidelines can be used until published data are available:

- AABR screening equipment is the only screening technology to be used when screening infants in the NICU
- If the infant is less than five days old, follow the Well Baby protocol for AABR
- If the infant is at least five days of age, stopping criteria is one screen per ear
- If the infant is expected to stay in the hospital for a prolonged period, screening needs to be performed no later than one month of age or as soon as medically feasible
- If the infant is expected to stay in the hospital for a prolonged period, and does not pass the initial hearing screen, a diagnostic assessment should be performed prior to hospital discharge
- If it is not possible to complete the diagnostic assessment prior to discharge, a hearing re-screen using AABR must be completed on an outpatient basis as soon as medically feasible
- If the infant's health status changes and includes new risk factors for hearing differences after passing an initial hearing screen, another screen must be performed prior to hospital discharge and the new risks documented under risk factors in INSIS

Tips for a Successful Hearing Screen

Below are practical tips to make OAE infant hearing screening go as smoothly as possible and to lower 'did not pass' rates

- **Find a quiet room in which to screen.** Noisy heating and cooling systems, people talking, telephones ringing, and crying babies can make testing unnecessarily challenging. Avoid waking infants during a ride down the hall, if possible. Sometimes an empty patient room is sufficient.
- **The screening room should be near the nursery.** Have cleaning supplies, extra tips, etc., readily available. It may be helpful to dim the lights.
- **Wait until the baby is at least 24 hours old, if possible.** Birthing debris clogging the ear canal can result in a higher number of did not pass results. The longer you wait, the greater your chances are for a successful screen.
- **Screen while the baby is asleep.** It is possible to screen a baby when it's awake, but this may slow down the screening time and increase your frustration level. If a baby is breathing rapidly in an alert state and is actively sucking on a pacifier, the baby's internal noise level can be louder than the emission you're trying to measure. This will result in a technical failure.
- **Swaddle the babies snugly on their sides.** You may wish to place a rolled towel along the back for support.

- **Place the probe tip deeply and firmly into the baby's ear canal.** A deep, snug probe fit often is the key to obtaining a good screen. Pull back on the ear with one hand, while inserting the probe with the other hand. Comfort the baby by putting pressure on the shoulder after placing the probe into the ear canal.
- **Massage the ear if you suspect significant birthing debris in the ear canal.** Move your index finger in a circular motion just in front of the ear canal. (Think of it as a zip-lock baggy stuck together with peanut butter and you're pulling it apart.)
- **If your first screening session is not successful, try again before the baby goes home.**

Microtia/Atresia

For infants diagnosed at birth with microtia, atresia or a combined diagnosis of microtia/atresia, they should be referred directly for diagnostic evaluation, regardless of whether they were admitted to the well-baby or NICU nursery following birth. Children with a diagnosis of atresia (with or without concomitant microtia diagnosis), may be at high risk for permanent conductive hearing loss with >85% accuracy according to studies published by the National Institutes of Health (NIH)[5] and American Speech-Language-Hearing Association (ASHA) Perspectives journal publication.[6] A list of the diagnostic centers available in Iowa can be found on the providers page of the EHDI website. In addition, the infant should be referred to EA as congenital microtia/atresia are automatically qualifying conditions for EI services.

Equipment Calibration

Screening equipment must be calibrated yearly according to the equipment vendors. Establishment of a method by which an independent entity (e.g., hospital clinical engineering, local special instrument distributors who conduct routine annual audiometric calibration of all equipment, etc.) can perform calibration or provide oversight to ensure that equipment parameters remain stable and appropriate. There is currently no American National Standard Institute specification for calibration of AABR or OAE equipment. As a result, manufacturers rely on existing international standards for factory default settings (e.g. ISO389-6 for ABR) in accordance with International Organization for Standardization (ISO) (2007); Richter & Fedtke (2005); and International Electronics Commission 60645-6 Ed. 2.0 b (2022). A log should be maintained documenting calibration and equipment repairs.

It is recommended birth facilities begin budgeting for replacement equipment after five years of use to ensure funding is available to replace the equipment before the equipment reaches 10 years of age. Depending on use and care of the equipment, it may need to be replaced sooner. Facilities maintaining calibration standards and providing annual training to

[5] Shah, K., Knight, B., & Shermetaro, C. (2022, October 3). External ear aural atresia. In StatPearls [Internet]. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK563257/.

[6] Flynn, T. (2016). Aural atresia: What audiologists need to know about bilateral versus unilateral cases. *Perspectives of the ASHA Special Interest Groups, 1*(9), 49–59. https://doi.org/10.1044/persp1.sig9.49.

personnel should not encounter high error messaging or an increase in 'did not pass' rates. If these types of situations occur, please work directly with the equipment vendor.

Parent Refusal

Although parent consent is not necessary to perform a birth hearing screen, parental objection to the screening is valid. Refusing a hearing screening at birth is a serious decision and could result in long-term developmental delays if congenital hearing differences are not identified early. Parents should discuss the risks and consequences of this choice with their infant's neonatologist/PCP to make a fully informed decision.

Parents or caregivers who refuse the birth hearing screen must complete and sign a written refusal form. The signed refusal form shall be kept in the infant's medical record according to the facility's record retention policy. A copy of the form shall be uploaded into the infant's record in the INSIS within six working days of the infant's birth.

Transferred Infants

If an infant is going to be transferred to a different hospital immediately, **do not** perform a hearing screen prior to the transfer. Communicate to the receiving hospital the need to perform the birth hearing screening. The birthing facility where the infant was born is responsible for starting a record for the infant's birth in INSIS and entering basic demographic information. The receiving hospital that discharges the infant home is responsible for performing the hearing screening and reporting the results to the family, PCP and INSIS. If the infant does not pass the birth hearing screen, the receiving hospital is responsible for following the protocol as outlined for scheduling an outpatient hearing screen.

Outpatient Hearing Screen Appointment

For infants who do not pass or do not receive (missed) the birth hearing screen, an appointment for an outpatient hearing screen is recommended 7-10 days following the initial hearing screen to allow any transient ear conditions to resolve before rescreening. Birthing facility staff should provide the appointment and stress the importance of following up to the parent or caregiver.

Infants in the Well Baby Nursery that do not pass their inpatient hearing screen may be re-screened with OAE or AABR equipment at the outpatient screen. Infants in the NICU Nursery that do not pass their inpatient hearing screen must be rescreened with AABR equipment ONLY.

Parent Notification

Information at all stages of the EHDI process is to be communicated to the parent or caregiver in a culturally sensitive and understandable format. Families who use a language other than English should be provided with an interpreter. The screener should let the parent(s) know a newborn hearing screen will be completed prior to hospital discharge. The screener should explain why the hearing screening is important and invite the parent(s) to

observe when the screen or re-screen is performed with the infant. Explain the results and next steps using plain language. To facilitate consistent and clear messaging across screeners, parents and professionals developed a one-page document to communicate hearing screening results with families.

To ensure timely follow-up for infants, it is important to familiarize yourself with what **NOT** to tell parents:

- "Fluid in the ear caused the baby to not pass their hearing screen." It may be the reason, but we don't know that for sure, and it minimizes the importance of returning for a hearing re-screen.
- "This happens all the time, don't worry." This minimizes the importance of returning for the hearing re-screen.
- "The equipment wasn't working right." This suggests you are not able to keep the equipment in working order.
- "The baby was too fussy, and I couldn't get a good test." This suggests you are not very good at doing what you need to do to get the baby tested.
- "Your baby has a hearing difference." This is only a screening, meaning we need to re-screen the baby again. The only thing we know for sure is your baby didn't pass during this screen.

The screener shall also report the results to the parent or caregiver in writing, as required by Iowa law. The Iowa Newborn Screening Program brochure can be ordered in English, Spanish and French for facilities who would like to utilize this resource to share information about newborn screening and provide hearing screen results in writing. You can also utilize the letters in INSIS (English, Spanish, Arabic, Chinese, Nuer and Bosnian), birthing facility discharge summary or some other form (e.g. postcard) so long as the information is shared in their native language. The documentation should include "next steps" if the child did not pass.

Primary Care Provider Notification

The birthing facility shall report the results of the hearing screen in writing to the infant's PCP within six working days of the screen. If the infant was not tested prior to discharge, the birthing facility will notify the infant's PCP of the hearing screen status. Birthing facilities may use their preferred method for sharing written results with the infant's PCP (e.g. fax). To facilitate reporting, PCP letters are available in the INSIS. Birthing facilities may also train physicians to locate hearing screen results using their electronic medical record.

Required Reporting

The following information shall be reported to HHS within six working days of the birth of the newborn, as required by Iowa law, using INSIS:

a. First and last name of the newborn
b. Date of birth of the newborn
c. Sex of the newborn
d. Race and ethnicity of the newborn

e. Race and ethnicity of the mother of the newborn
f. Name, address and telephone number of the mother of the newborn. If the mother is not the person designated as legally responsible for the infant's care, the name, address, telephone number and email of the caregiver (e.g. grandparents, social services, foster parent or attorney) shall be reported.
g. Family's preferred language(s) or mode of communication
h. Facility where an infant is transferred to for a higher level of care, if applicable
i. Name of the PCP that will accept responsibility for the care of the infant upon discharge from the birthing facility
j. Results of EACH infant hearing screening performed, including the date and time, recorded as either 'pass' or 'did not pass' for each ear separately. Infants, who cannot be screened, such as those with atresia, may be recorded as 'not used' for each applicable ear. Make a case note as to why the ear was marked as 'not used' (e.g. atresia).
k. Results of EACH re-screening performed, including the date and time, recorded as either 'pass' or 'did not pass', or 'not screened', for each ear separately and the equipment used for each ear separately
l. Known risk factors for hearing loss
m. Date of outpatient screening appointment
n. Any note that refers to the hearing healthcare or risk factors of the newborn

Birthing facilities must enter all the information listed above **within six working days of birth** for all infants, including those who transfer to acute care. The birthing facility shall notify the receiving facility of the status of the hearing screening. The receiving facility shall be responsible for completion of the birth hearing screening and completion of the infant's record prior to hospital discharge.

For guidance on data entry best practices, reach out to EHDI personnel.

Reports, records and other information collected by or provided to the Iowa EHDI program related to an infant's birth hearing screen or risk factors are confidential records. Iowa EHDI personnel will maintain the confidentiality of all information and records used in their review.

No individual or organization providing information to the Iowa EHDI program in accordance with administrative code or rules shall be held liable for divulging confidential information.

Readmitted Infants

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

Chapter 4: Outpatient Hearing Screening Protocol

Policy

All infants that do not pass the final hearing screen at birth must receive an outpatient hearing re-screen within ten days of hospital discharge. “Re-screen” means a hearing screening performed after one to two weeks of age on an infant who did not pass the initial screening.

Background

The goal of infant hearing screening is early detection of hearing differences. It has long been recognized that unidentified hearing differences at birth can adversely affect speech and language development as well as academic achievement and social-emotional development. Nationally recognized standards of care require all infants’ hearing be screened/re-screened before **1** month of age, diagnosed with a hearing loss (difference) no later than **3** months of age and enrolled in early intervention no later than **6** months of age.[7]

Many infants screened for hearing differences will pass their outpatient hearing screen. Infants should receive no more than one outpatient hearing screen, regardless of the results. Both ears must pass during a single screening session using the same equipment to be considered an overall passing result. Combining passing results in opposite ears on successive screen **does not** qualify as a passing result. Refer to Stop Criteria below for screening guidelines.

Infants in the Well Baby Nursery may be screened using OAE or AABR equipment. Infants being rescreened from the Neonatal Intensive Care Unit (NICU) shall be screened by AABR equipment **ONLY**.

The following screening protocols were 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 Iowa’s system of care to help ensure that every infant receives quality follow-up screening throughout the state. Iowa uses a two-stage hearing screening protocol to reduce referrals to specialty providers. Two-stage screening is when an infant receives their initial hearing screen at birth and does not pass in one or both ears and is seen again in an outpatient setting for a repeat hearing screen. National guidelines recommend allowing one to two weeks from the time of the initial screen to allow any transient ear conditions to be resolved before re-screening.

[7]Joint Committee on Infant Hearing. (2019, October 23). Year 2019 position statement: Principles and guidelines for early hearing detection and intervention programs. *Journal of Early Hearing Detection and Intervention, 4*(2), 1–44. https://doi.org/10.15142/fptk-b748.

Personnel

Every outpatient screening provider shall have a designated employee (when possible, an audiologist) to be responsible for the outpatient hearing screening program in that facility. Outpatient hearing screens shall be performed by an audiologist, audiology assistant, audiometrist, registered nurse, licensed physician or other person for whom newborn hearing screening is within the person's scope of practice. Refer to chapter 2 in manual titled Qualifications and Training of NBHS Screening Personnel. The screener who completes the outpatient hearing screening shall be educated about the importance of hearing screening and follow-up prior to performing the screening.

Equipment Technologies

The Iowa EHDI program does not recommend or endorse a particular brand of equipment; however, the following technologies are acceptable:

a. **Automated Auditory Brainstem Response (AABR)**
   Sounds are played to the infant's ears after adhesive bandage-like electrodes are placed on the infant's head to detect responses. This screening measures how the hearing nerve transmits to the brainstem and can aid in identification of infants who have a hearing difference. This equipment tends to have a lower ***did not pass*** rate since fluid or birthing debris has less of an impact during this type of testing.

b. **Evoked Otoacoustic Emissions (OAE)**
   A miniature earphone, which includes a microphone, are placed in the ear. Sounds are transmitted into the ear. The cochlea (hearing organ) will "echo" back a sound, which is measured in the microphone. When an infant has a hearing difference, no response is measured on the OAE test. There are two types of OAE hearing screening equipment:
   - **Transient Evoked Otoacoustic Emissions (TEOAE)**
     Sounds are emitted in response to an acoustic stimulus of very short duration; usually clicks but can be tone-bursts.
   - **Distortion Product Otoacoustic Emissions (DPOAE)**
     Sounds emitted in response to two simultaneous tones of different frequencies.

Infants in the Well Baby Nursery may be screened using OAE, AABR or a combination of this equipment. Infants in the Neonatal Intensive Care Unit (NICU) Nursery shall be screened using **AABR equipment ONLY**.

Stop Criteria for Outpatient Hearing Screens

Per JCIH, the outpatient re-screening should always include the testing of both ears, even if only one ear did not pass during the inpatient hearing screening. Assuming screening conditions are adequate (quiet infant, quiet room, acceptable probe fit), no more than one screening session is recommended. Both ears must pass during a single screening session using the same equipment to be considered an overall passing result. Combining passing results in opposite ears on successive screening does not make a passing result. Additionally, using a pass result from a previous session for the opposite ear does not qualify as a passing result.

Any infant that does not pass their outpatient hearing screen in one or both ears must immediately be referred to a pediatric audiology center for a diagnostic audiological assessment or call the EHDI program personnel at (833) 496-8040 to help find an appropriate diagnostic audiology center nearest to the family or caregiver. When the outpatient screen is performed by a pediatric audiologist, and the infant does not pass the rescreen in one or both ears, it is preferable that the diagnostic audiological assessment be initiated immediately (i.e., during the same appointment).

If an unsedated diagnostic audiological assessment cannot be performed during the same appointment, the infant must immediately be referred to a pediatric audiologist for diagnostic audiological assessment. The goal is for the infant to be diagnosed no later than three months of age. Protocols for scheduling and obtaining referrals may differ. It is the responsibility of the outpatient screening provider to ensure that a referral is completed to the diagnostic clinic or to the infant's PCP to make the referral. Ensuring this handoff occurs, increases the likelihood that the child will receive a timely diagnostic assessment.

Microtia/Atresia

For infants diagnosed at birth with microtia, atresia or a combined diagnosis of microtia/atresia, they should be referred directly for diagnostic evaluation, regardless of whether they were admitted to the well-baby or NICU nursery following birth. Children with a diagnosis of atresia (with or without concomitant microtia diagnosis), may be at high risk for permanent conductive hearing loss with >85% accuracy according to studies published by the NIH[8] and American Speech-Language-Hearing Association (ASHA) Perspectives journal publication.[9] A list of the diagnostic centers available in Iowa, can be found on the providers page of the EHDI website. In addition, the infant should be referred to EA as congenital microtia/atresia are automatically qualifying conditions for EI services.

Equipment Calibration

Screening equipment must be calibrated yearly according to equipment vendors. Establishment of a method by which an independent entity (e.g., hospital clinical engineering, local special instrument distributors who conduct routine annual audiometric calibration of all equipment, etc.) can perform calibration or provide oversight to ensure that equipment parameters remain stable and appropriate. There is currently no American National Standard Institute specification for calibration of AABR or OAE equipment. As a

[8] Shah, K., Knight, B., & Shermetaro, C. (2022, October 3). External ear aural atresia. In StatPearls [Internet]. StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK563257/

[9] Flynn, T. (2016). Aural atresia: What audiologists need to know about bilateral versus unilateral cases. *Perspectives of the ASHA Special Interest Groups, 1*(9), 49–59. https://doi.org/10.1044/persp1.sig9.49.

result, manufacturers rely on existing international standards for factory default settings (e.g. ISO389-6 for ABR) in accordance with International Organization for Standardization (ISO) (2007); Richter & Fedtke (2005); and International Electronics Commission 60645-6 Ed. 2.0 b (2022). A log should be maintained documenting calibration and equipment repairs.

It is recommended birthing or outpatient screening facilities begin budgeting for replacement equipment after five years of use to ensure funding is available to replace the equipment before the equipment reaches 10 years of age. Depending on use and care of the equipment, it may need to be replaced sooner. Facilities maintaining calibration standards and providing annual training to personnel should not encounter high error messaging or an increase in 'did not pass' rates. If these types of situations occur, please work directly with the equipment vendor.

Parent Refusal

If a family decides against a hearing re-screen being provided for their child or comes to the appointment and decides not to go through with screening or a diagnostic evaluation at any point, parent objection is valid. Parents should discuss the risks and consequences of this choice with their infant's PCP to make a fully informed decision.

Parents or caregivers who refuse the outpatient hearing screen must complete and sign a written refusal form. The signed refusal form shall be kept in the infant's medical or educational record according to the facility's record retention policy. A copy of the form shall be uploaded into the infant's record in INSIS within six working days of the hearing screen, if performed otherwise six working days of refusal.

Diagnostic Audiological Assessment Appointment

As indicated above, if the diagnostic audiological assessment cannot be performed at the outpatient screening facility, the parent or caregiver should be provided with an appointment with the pediatric audiology clinic prior to leaving the outpatient screening facility. Personnel should stress the importance of timely follow up. Diagnostic audiological assessments for young infants cannot be performed at clinics that are not included on the pediatric audiology clinic list as they do not have the proper equipment for testing or personnel. The appointment should occur no later than 30 days after the outpatient hearing screen or before the child turns three months of age.

For facilities who are unable to schedule the appointment with a pediatric audiology clinic during the outpatient appointment, the facility should provide the family with the information for the appropriate pediatric audiology clinic(s). The outpatient facility is also responsible for communicating with the infant's PCP to make the referral. The family should be informed who will contact them to schedule the appointment and timeline for scheduling. If unsure of the process or where to refer the infant, contact EHDI personnel at 1-833-496-8040. Ensuring efficient and timely handoff increases the likelihood the child will receive a timely diagnostic assessment.

Parent Notification

Information at all stages of the EHDI process is to be communicated to the parent or caregiver in a culturally sensitive and understandable format. Families who use a language other than English should be provided with an interpreter. The screener should let the parent(s) know an outpatient hearing screen will be completed. The screener should explain why the hearing screening is important and invite the parent(s) to observe when the re-screen is performed. Often, asking the parent(s) to hold the child is helpful. Explain the results and next steps using plain language. To facilitate consistent and clear messaging across screeners, parents and professionals developed a one-page document to communicate hearing screening results with families.

To ensure timely follow-up for infants, it is important to familiarize yourself with what **NOT** to tell parents:

- “Fluid in the ear caused the baby to not pass their hearing screen.” It may be the reason, but we don’t know that for sure, and it minimizes the importance of returning for a hearing re-screen.
- “This happens all the time, don’t worry.” This minimizes the importance of returning for the hearing re-screen.
- “The equipment wasn’t working right.” This suggests you are not able to keep the equipment in working order.
- “The baby was too fussy, and I couldn’t get a good test.” This suggests you are not very good at doing what you need to do to get the baby tested.
- "Your baby has a hearing difference.” This is only a screening, meaning we need to re-screen the baby again. The only thing we know for sure is your baby didn’t pass during this screen.

The screener shall also report the results to the parent or caregiver in writing, as required by Iowa law. The Iowa Newborn Screening Program brochure can be ordered in English, Spanish and French for facilities who would like to utilize this resource to share information about newborn screening and provide hearing screen results in writing. You can also utilize the letters in INSIS (English, Spanish, Arabic, Chinese, Nuer and Bosnian), facility document or some other form (e.g. postcard) so long as the information is shared in their native language. The documentation should include “next steps” if the child did not pass.

Primary Care Provider Notification

The outpatient screening facility shall report the results of the outpatient hearing screening in writing to the infant’s PCP within six working days of the outpatient hearing screen, per Iowa law. The outpatient screening facility is responsible for ensuring the PCP is aware of the need for a diagnostic audiological assessment for any infant that did not pass their outpatient hearing screen. The outpatient facility can schedule the diagnostic hearing assessment appointment or request the infant’s PCP make the appointment directly with the pediatric audiology clinic. Regardless of whether the appointment is scheduled by the outpatient screening facility or the infant’s PCP, the family should be informed who will contact them to schedule the appointment and timeline for scheduling.

The outpatient screening facility may use their preferred method for sharing written hearing screening results with the infant's PCP. To facilitate reporting, PCP letters are available in INSIS. Facilities may also train physicians to locate hearing screen results using their electronic medical record so the results can be reviewed at the next well-baby visit.

Required Reporting

The following information must be reported to HHS within six working days of the outpatient hearing screen using the INSIS:

a. First and last name of the infant
b. Date of birth of the infant
c. Sex of the infant
d. Race and ethnicity of the infant
e. Race and ethnicity of the mother of the infant
f. Birth facility location (helps to access the record in INSIS)
g. Name, address and telephone number of the mother/caregiver of the infant
h. Family's preferred language(s) or mode of communication
i. Name of the PCP that has accepted responsibility for the care of the infant upon discharge from the birthing facility or following an out of hospital birth
j. Results of outpatient hearing screen for each ear, including the date and time, recorded as a 'pass' or 'did not pass' for each ear separately
k. Known risk factors for hearing loss
l. Date of audiological assessment appointment
m. Any note that refers to the hearing healthcare or risk factors that may help someone perform appropriate follow-up

Outpatient screening facilities must enter all information listed above **within six working days of the screen.**

Reports, records and other information collected by or provided to the Iowa EHDI program related to a child's outpatient hearing screen or risk factors are confidential records. Iowa EHDI personnel will maintain confidentially all information and records used in its review.

No individual or organization providing information to the Iowa EHDI program in accordance with administrative code or rules shall be held liable for divulging confidential information.

Chapter 5: Pediatric Diagnostic Audiological Assessment Protocol

Policy

All infants that do not pass the hearing re-screen must receive a diagnostic audiological assessment within two to three weeks of the re-screen or no later than three months of age. Infants should be referred to a pediatric audiologist who can perform a diagnostic audiological assessment. Using a hearing protocol which includes a screening tool (e.g., DPOAE or automated ABR) and impedance measures is **NOT** equivalent to a diagnostic assessment, even if completed by an audiologist.

The assessment is a comprehensive evaluation, which includes a case history and battery of physiologic tests that may determine whether the infant has typical hearing, or will define type, degree and configuration of hearing differences for each ear. Use of evidence-based practice guidelines is critical to provide high-quality consistent care to Iowa's children. The Joint Committee on Infant Hearing recommends only one outpatient hearing screening prior to referral for diagnostic audiologic assessment, which includes diagnostic Auditory Brainstem Response (ABR) testing.

Background

Hearing loss (hearing differences) is one of the most common congenital conditions with an estimated incidence of one to three per 1000 births. Over 90% of congenitally DHH children are born to typical hearing parents. Without early diagnosis of hearing differences and appropriate EI, DHH children are at risk for delays in speech, language, behavioral and social/emotional developmental skills. The target age for the initial diagnostic assessment is four to eight weeks of age, with a goal of the assessment being completed no later than three months of age. Diagnostic Auditory Brainstem Response (ABR) testing **should not** be delayed solely due to middle ear dysfunction.

Following best practice improves the likelihood that type and degree of hearing differences can be determined before three months of age (or when medically feasible for NICU graduates), even when multiple diagnostic visits are necessary. This earlier age avoids the need for sedation, as infants are more likely to sleep for prolonged periods of time. In cases of concurrent middle ear dysfunction, results from an ABR can help guide the clinical decision-making process for the otolaryngology and audiology team and inform further care.

For infants with lengthy NICU admissions, the managing team should consider a full diagnostic ABR prior to hospital discharge. This may be especially feasible in conjunction with other sedated studies completed during the NICU stay. This may not be possible in NICU facilities that do not also have pediatric audiology services onsite; therefore, in these cases the child should be referred to and scheduled for diagnostic ABR testing at a pediatric audiology clinic prior to hospital discharge. For children with special health care needs, delay in diagnosis of hearing differences may be unavoidable due to attention paid to other

health/ time-urgent diagnostic and treatment procedures, however, every effort should be made to minimize the delays.

This document provides recommended guidelines for early diagnosis of hearing differences in infants who do not pass their newborn and outpatient hearing screening. It is intended to promote a more standardized and consistent approach to follow-up hearing healthcare. The following diagnostic protocols have been developed by local subject matter experts and are based on national guidelines put forth by the JCIH and national audiology guidelines.

Personnel

Audiologic diagnosis of the infant is the sole purview of the audiologist with specific skills, knowledge and access to all necessary equipment for infant and early childhood audiologic diagnostic evaluations. It is incumbent upon the audiologist who lacks experience or equipment to refer infants to pediatric audiology clinics where timely and comprehensive evaluation can be accomplished. Only through consultation with a pediatric audiologist can accurate diagnosis occur, and timely EI for the infant and family be assured.[10] Pediatric audiology clinics can be found on the **EHDI website** (diagnostic audiology centers).

Diagnostic Audiological Evaluation Components

When evaluating infants, it is important to use a combination of objective electro-physiologic assessments, a reliable form of parent interview in the parent's native language and a complete review of previous hearing screening and assessments. A complete evaluation should include a battery of physiologic tests that define type, degree and configuration of hearing difference for each ear. The following components are needed to form a complete diagnostic infant hearing evaluation.

Case History

Providers should document a full medical and developmental history of the child including:

- Prenatal history, including significant pregnancy complications
- Perinatal history – TORCH infections (Toxoplasmosis, Other Infections, Rubella, Cytomegalovirus, or Herpes Simplex)
- Family history of childhood hearing differences, syndromes or other disorders associated with hearing differences
- Review of any prior hearing screen or audiological testing results
- Review of risk factors for hearing difference or delayed onset hearing difference (e.g. Aminoglycoside exposure for greater than five days, length of NICU stay and parent concern)

[10] Joint Committee on Infant Hearing. (2019, October 23). Year 2019 position statement: Principles and guidelines for early hearing detection and intervention programs. *Journal of Early Hearing Detection and Intervention, 4*(2), 1–44. https://doi.org/10.15142/fptk-b748.

- Parent impressions about their infant's auditory responses (or lack thereof)

Otoscopic Exam

The primary purpose of an otoscopic exam is to rule out any obstruction or debris that could impact the diagnostic audiological evaluation and might warrant a referral to a physician prior to the evaluation. Shape of pinnae, presence of skin tags or pits or other craniofacial abnormalities may also be noted during this exam.

Auditory Brainstem Response

Auditory brainstem response (ABR) is the gold standard test for threshold estimation for infants and children who cannot a complete behavioral audiologic assessment. ABR provides ear- and frequency-specific threshold estimates that are necessary for the diagnosis of the type, degree and configuration of hearing differences and provision of amplification (Gorga et al., 2006). Additionally, ABR testing provides the opportunity for the audiologist to examine the function of the auditory pathways and observe possible abnormalities indicative of ANSD (Norrix and Velenovsky, 2014; Berlin et al., 2010; Guidelines Development Conference 2008).

In the diagnostic ABR, recording of electrophysiologic response requires the newborn or infant to sleep soundly for a prolonged period of time so quiet responses, unmarred by artifact and noise, can be obtained. In some cases, sedation or anesthesia may be needed to ensure quiet time for all diagnostic measures. However, with proper preparation, natural sleep recordings are feasible in infants. Unsedated ABR responses are recommended for children through 4-5 months of age (adjusted for gestational age in premature infants). At approximately 6 months of age, it may be difficult to obtain the necessary amount of information needed for diagnosis with natural sleep (Munoz et al, 2011). Frequency-specific tone-burst and/or chirp stimuli are used to elicit neural responses that enable prediction of thresholds and form the foundation for determining hearing aid amplification characteristics. Thresholds for both air-conducted and bone-conducted stimuli are measured to determine the type of hearing differences type (i.e., conductive, sensorineural or mixed). Bone conduction thresholds are necessary to estimate additional hearing aid gain and output if there is a conductive component. When the ABR shows no response, a specialized protocol is used to assess for the presence of a cochlear microphonic (CM). This protocol entails a high intensity click stimulus presented in rarefaction, condensation and alternating polarities. In many cases of ANSD, a CM will be observed in the first few milliseconds of the response and reverses with stimulus polarity changes. To differentiate a CM from stimulus artifact, audiologists should also complete a single polarity tracing at the same high intensity with the transducer clamped. A true CM will disappear with the interruption of the sound, whereas stimulus artifact will persist in this no sound tracing. Waveforms, subsequent to the CM, are typically absent or significantly abnormal (e.g., poorly- defined, delayed and/or low-amplitude subsequent waveforms). This ABR protocol is the current gold standard and substantiated method for determining ANSD (Starr, Picton, Sininger, Hood, & Berlin, 1996). ANSD may also be determined in the absence of CM if DPOAEs are present during the diagnostic session.

Research has indicated a good correlation between ABR tone-burst thresholds and behavioral thresholds in the middle to high frequencies in infants and young children (Gorga et al., 2006; McCreery, Kaminski, et al., 2015). For infants and young children displaying sensorineural hearing differences, tone-burst ABR hearing threshold estimates range from 5 decibels (dB) better to 5 dB poorer than the nominal intensity, depending on the stimulus presentation intensity and frequency. A single correction factor for predicting hearing threshold from ABR threshold estimates is less accurate than use of a level-dependent correction factor (McCreery, Kaminski, et al., 2015). For example, ABR results at lower intensities tend to overestimate hearing thresholds (suggesting hearing differences when there is none), while ABR threshold estimates at higher intensities tend to underestimate the hearing thresholds (i.e. suggesting hearing is better than it actually is). In keeping with the cross-check principle, while tone-burst and/or chirp stimuli serve as the basis for the initial hearing aid fitting; it should be accompanied by ear-specific and frequency-specific behavioral response hearing testing using a VRA protocol (conditioned response) beginning at approximately four to five months of age, depending on the infant's developmental status (American Academy of Audiology Assessment of Hearing in Infants and Young Children, 2020; Widen et al., 2005). When VRA is conducted according to careful stimulus, response and conditioning paradigms, valid and reliable thresholds can be obtained from the typically developing infant. Despite the correlation in average ABR threshold responses to behavioral hearing thresholds across all infants, individual differences vary, and for this reason, validation of ABR thresholds by behavioral testing should occur at the earliest opportunity. Further, since it is not uncommon that children exhibit progressive hearing differences in the first months and years of life, on-going audiological evaluation is essential for any child who is at risk for hearing differences, or any child who wears hearing aids.

Although use of tone-bursts in conducting ABR testing is the gold standard for estimating hearing thresholds in the infant, other evoked-response protocols, stimuli, and technologies are emerging that demonstrate frequency specificity, as well as equivalent, if not superior, test efficiency (e.g., ABR or Automated Steady-State Response [ASSR] using pure-tone or broadband [chirp or click-evoked-chirp stimuli], Cebulla & Elberling, 2015; Cebulla, Lurz, & Shehata-Dieler, 2014). Any technology, protocol or stimulus used for objective determination of frequency-specific hearing thresholds should be rigorously and independently validated for the ability to accurately predict behavioral hearing thresholds in infants and young children of all ages and all types and degrees of hearing differences.

Use of novel stimuli (brief-tone chirp or click evoked [CE]-chirp) has recently received attention as a potential alternative to click and tone burst stimuli, with reported improvements in frequency-specificity and shortened test duration. ASSR recordings can be made of multiple frequencies simultaneously, and stimuli can be presented binaurally. Binaural presentation, however, decreases the amplitude of the response; and may not be indicated for use in a child with bilateral hearing loss (Cebulla et al., 2014; Ferm, Lightfoot, & Stevens, 2013). In a study comparing ABR response amplitudes for tone-pip stimuli at four frequencies (500, 1000, 2000, 4000 Hz) to narrowband CE-Chirps at corresponding

frequencies, authors reported increased amplitude with fewer stimulus presentations in infants with normal hearing (Cebulla et al., 2014; Ferm et al., 2013; Stuart & Cobb, 2014). Use of a correction factor was proposed to increase the accuracy of estimating hearing thresholds.

Van Maanen and Stapells (2010) observed that there are few studies of deaf and hard-of-hearing infants and young children comparing ASSR thresholds to ABR thresholds. Results of their study demonstrated that hearing thresholds in children could be reliably classified as typical or elevated based on ASSR thresholds. It was noted, however, there is insufficient data comparing deaf and hard-of-hearing infants or infants with typical hearing and young children using both air- and bone-conduction stimuli. Higher thresholds are seen in preterm infants as compared with full-term infants. This gap resolved by age 18 months, suggesting auditory maturation of preterm infants (Sousa, Didoné, & Sleifer, 2016). The ability of ASSR to distinguish between typical hearing and mild hearing thresholds is limited (Sousa et al., 2016). There is greater variability in ASSR threshold estimates in infants with typical hearing, such that a standard correction factor cannot be generated (Alaerts, Luts, Van Dun, Desloovere, & Wouters, 2010). Additionally, the mean air-bone gap for low-frequency ASSR thresholds is significantly greater than that for behavioral (visual reinforcement audiometry), with wide variations across infants (Casey & Small, 2014). Accurate estimates of bone-conduction thresholds as elicited by ASSR have not been reported (Casey & Small, 2014). As studies are published examining these relationships across different ages, hearing thresholds, and etiologies future endorsement may become possible.

Emerging data suggests that new approaches to ABR recording, such as using specialized filtering, advanced signal processing techniques and placing the pre-amplifier at the position of the electrode, may improve the signal-to-noise ratio in children who are not soundly sleeping. Limited data exist demonstrating the validity of frequency-specific hearing levels obtained using these techniques in non-sedated/awake recordings (Cone & Norrix, 2015). Independent evidence is insufficient currently for the JCIH to endorse this methodology for acquisition of reliable and valid ABR or ASSR threshold estimates in a child of any age who is moving, vocalizing or otherwise not relatively quiet and still.

Tympanometry

In the audiological diagnostic audiological assessment, measures of eardrum mobility assist in the differentiation of conductive and sensory or neural sites. At the time of newborn hearing screening, infants may have retained amniotic fluid in the middle ear space or may have residual vernix in the ear canal from the birthing process, causing a ‘did not pass’ response. The standard measure for detecting middle ear dysfunction in infants is tympanometry with a high frequency probe tone (1000 Hz), due to greater sensitivity and specificity compared with standard 226 Hz tympanometry. Use of the 1000 probe tone is recommended up to age 9 months (Hoffmann et al., 2013).

Wideband reflectance has been studied for use with infants, due to reported superior sensitivity and specificity than standard tympanometry. Prieve, Vander Werff, Preston, &

Georgantas (2013) noted that conductive hearing loss can be detected in infants using either 1000 Hz tympanometry or wideband reflectance. Reflectance measures are sensitive to transient middle-ear conditions in infants who did not pass birth screening and subsequently passed screening at age 1 month (Voss, Herrmann, Horton, Amadei, & Kujawa, 2016). Wideband reflectance measures show promise for differential diagnosis because they can assess not only the presence of middle ear effusion but also the relative impact on hearing status (Hunter et al. 2008). However, its use in the clinical setting has been limited.

Acoustic Reflex

Acoustic reflex testing, especially when reflexes are present, may play a role in cross-checking reliability of other diagnostic findings, or to assess the possibility of ANSD if ABR testing is unavailable. Since methods for testing middle ear function are constantly evolving, audiologists are encouraged to regularly review current literature. For infants less than nine months of age, the recommended procedure is high frequency probe tone (0.66 to 1 kHz) with ipsilateral stimulation using broadband noise or tones (1 or 2 kHz) at levels not to exceed 105 dB SPL (Hunter & Blankenship, 2017). Reflex presence can be shown with repeatable deflections that are negative or positive from baseline (Kei, 2012). National/international guidelines generally say acoustic reflex testing is discretional, in part because absence of reflexes in newborns is not always clinically significant (British Columbia Early Hearing Program, BCEHP; 2012).

Otoacoustic Emissions

OAE (distortion product or transient evoked) testing is essential in the pediatric diagnostic evaluation (Holte et al., 2012; Norton et al., 2000a; Prieve, Schooling, Venediktov, & Franceschini, 2015). OAEs are evoked, measurable sound responses that occur when the cochlea is stimulated with a low-intensity click or pure-tone stimuli. The OAEs are recorded via a probe assembly with a microphone, placed in the external ear canal. Diagnostic OAEs provide information about the presence/absence of outer hair cell function, from which hearing level (typical vs. elevated) can be inferred, in patients without evidence of concurrent middle ear dysfunction. Although it is possible to display OAEs in the presence of mild sensory hearing differences, the magnitude of the emission diminishes with increasingly elevated thresholds, and the emissions are not observed in hearing thresholds greater than 30–35 dB HL. Mild degrees of hearing loss are difficult to define using OAE technology; however, DPOAEs accurately separate typical hearing ears from those with moderate and greater degrees of hearing loss (Gorga et al., 2000). The amplitude of an infant OAE is greater than an adult response, and as such, the detection of the emission is facilitated. Generally, infants with present DPOAEs are predicted to have hearing thresholds better than 30 dB HL. Infants with absent DPOAEs (in the presence of typical tympanometry or wide band reflectance) are predicted to have hearing thresholds poorer than 30 dB HL (American Academy of Audiology [AAA], 2011, 2012).

DPOAE screenings are not sufficient for determining hearing thresholds and cannot be used in isolation to determine hearing aid specifications. It is important to remember

the otoacoustic emission only reflects activity in the cochlea. Infants with ANSD or more central auditory pathologies are expected to have a typical OAE yet clearly do not have typical auditory function.[11]

Equipment Calibration

Diagnostic testing equipment must be calibrated yearly according to equipment vendors and is recommended by the U.S Occupational Health and Safety Administration (OSHA), NIH and Iowa's EHDI program to ensure accurate and valid test results. There is currently no American National Standards Institute (ANSI) specification for calibrating AABR or OAE equipment. As a result, manufacturers rely on existing international standards for default factory settings (e.g., ISO 389-6 for ABR) in accordance with ISO (2007), Richter & Fedtke (2005), and IEC 60645-6 Ed. 2.0 (2022). A log should be maintained documenting all calibrations and equipment repairs.

Parent Refusal

Refusing diagnostic audiological assessment is a serious decision and may lead in long-term developmental delays if a congenital hearing difference is not identified early. Parents should discuss the risks and implications of this choice with their infant's PCP and audiologist to make a fully informed decision.

Parents or caregivers who refuse further diagnostic audiological assessment must complete and sign a written refusal form. The signed refusal form shall be kept in the infant's medical record according to the facility's record retention policy. A copy of the form shall be uploaded to the infant's record in INSIS within six working days of the testing.

Parent Notification

Information at all stages of the EHDI audiological assessment process is to be communicated to the parent or caregiver in a culturally sensitive and understandable format. Similarly, the option of observing when the diagnostic assessment is performed with the infant should be provided, unless sedation is required. Families who use a language other than English should be provided with an interpreter.

Following diagnosis of a child with a hearing difference, audiologists should allow ample time to:

- Use clear, simple (lay) language
- Listen to families and answer their questions
- Support family decision-making
- Provide guidance on communication modes, methodologies and technologies in a comprehensive and unbiased manner

[11] Joint Committee on Infant Hearing. (2019, October 23). Year 2019 position statement: Principles and guidelines for early hearing detection and intervention programs. *Journal of Early Hearing Detection and Intervention, 4*(2), 1–44. https://doi.org/10.15142/fptk-b748.

- Discuss visual strategies and resources
- Provide additional resource information
- Provide information and referral to EI
- Provide information and referral to family support
- Encourage families to advocate for the needs of their child and family
- Explain what will happen next (e.g. next appointment or recommended referrals)

While this list provides guidance of topics that should be covered following diagnosis, it is important to meet parents where they are emotionally following the news. Some parents may be ready and eager to receive additional information, while others may need a short time to process the information.

When counseling families, information regarding communication modes, methodologies and technologies should be provided in a comprehensive and non-biased fashion. Information about listening and spoken language, signed language and combined approaches should be provided. Additionally, information about amplification options (hearing aids, cochlear implants, visual and auditory assistive technologies) should be provided as appropriate for the infant's audiologic diagnosis, recognizing the possibility of progression of hearing thresholds to a more severe degree (ASHA, 2008a).

Primary Care Provider Notification

The pediatric audiologist shall report the results of the diagnostic audiological assessment in writing to the infant's PCP within 6 days of the assessment, as required by Iowa Administrative Rules. Assessment results should include a statement of severity (slight, mild, moderate, moderately severe, severe, profound or undetermined) and type of hearing difference (sensorineural, conductive, mixed, ANSD or undetermined).
The audiologist should include any recommendations for additional testing, referrals to specialists, EI or information about communication opportunities. Known risk factors for hearing differences should also be noted within the report to physicians. (AAP Committee, 2023; AAP, 2017).

Required Reporting

The following information shall be reported to the Iowa EHDI program within six working days of the audiological diagnostic assessment, as required by law, using INSIS:

a. First and last name of the infant
b. Date of birth of the infant
c. Sex of the infant
d. Race and ethnicity of the infant
e. Race and ethnicity of the mother of the infant
f. Birth facility location (helps provider locate record in INSIS)
g. Name, address, telephone number and email of the mother/caregiver of the infant
h. Family preferred language(s) or mode of communication

i. Name of the PCP that has accepted responsibility for the care of the infant upon discharge from the birthing facility or following an out-of-hospital birth
j. Results of the physiologic tests for each ear individually, including the date, severity (e.g. slight, mild, moderate, moderately severe, severe, profound or undetermined) and type (e.g. sensorineural, conductive, mixed, ANSD or undetermined)
k. Recommendations for further testing, referrals to specialists, EI or information about communication opportunities
l. Known risk factors for hearing differences
m. Any note about hearing healthcare or risk factors that may help someone perform follow-up

Reports, records and other information collected by or provided to the Iowa EHDI program related to an infant's newborn hearing screen, rescreen and diagnostic audiologic assessment are confidential records. Iowa EHDI personnel will maintain confidentially of all information and records used in their review.

Iowa law also mandates reporting the results to an infant's primary medical care provider within 6 days of screening, rescreening or assessment. Results of the physiologic tests for each ear individually should be reported, including the date. Assessment results should include a statement of severity (mild, moderate, moderately severe, severe, profound or undetermined) and type (sensorineural, conductive, mixed or undetermined) of hearing difference, as well as any recommendations for additional testing, referrals to specialists, EI or information about communication opportunities. Known risk factors for hearing differences should also be noted within the report to physicians.

No individual or organization providing information to the Iowa EHDI program in accordance with its rules shall be deemed to be or held liable for divulging confidential information.

Referrals

Early Intervention

The purpose of EI is to achieve optimal child and family outcomes. The audiologist is the primary professional who conveys initial information about EI opportunities and the importance for the child's development. Early, mindful and comprehensive education of families and caregivers regarding the nature of language acquisition is invaluable in encouraging families to seek appropriate EI services for their child. Hence, the audiologist must make the referral for Part C EI (IDEA, 2004) services as quickly as possible following confirmation that a child is DHH. In Iowa, EI is known as Early ACCESS (EA). Federal regulations require that this referral be made within seven working days of diagnosis (IDEA, 2004). JCIH recommends it is best practice if the referral is made within 48 hours of diagnosis (JCIH, 2019). Based on the national 1-3-6 guidelines, referral to EI should always be completed as soon as a child is diagnosed as DHH, and always prior to six months of age.

In cases of congenital aural atresia or known Congenital Cytomegalovirus (cCMV), the referral to EI can, and should be, made by the birth hospital. If the referral was not made, the audiologist should make the referral as both conditions are automatic qualifying conditions. Referral to EI should not be deferred until an audiologic diagnostic evaluation and hearing aid fitting are completed. For all infants confirmed with a hearing difference, whether unilateral or permanent bilateral, the diagnostic facility must discuss a referral to EI at the time of diagnosis. Referral should not be delayed unless requested by the child's parent/guardian.

Research shows infants who are identified early and provided with timely early interventions demonstrate better linguistic outcomes than late-identified children (Holte, et. Al, 2012). All EI referrals can be made directly through Iowa Family Support Network. A case note should be added to the child's record in INSIS.

Refusing an EI referral is a serious decision and could result in lack of EI support. Parents and caregivers should discuss the risks and implications of this choice with their infant's PCP and audiologist to make a fully informed decision. If the family makes that decision, the refusal of EI must be recorded in the child's record in INSIS. Should a family refuse EI initially, the audiologist should revisit EI at a future appointment as the family's journey continues and needs change.

Family-to-Family or Family-to-Deaf Partner Support

Families often benefit from contact with other parents/caregivers who are trained to provide family-to-family support, and benefit from contact with a trained professional who is deaf or hard-of-hearing (Moeller et al., 2013). Families may have concerns, frustrations, and needs only another parent will understand. Connecting with parents who have similar experiences can play an important in a family's hearing healthcare journey with their child. All referrals can be made directly through the EHDI program for family support, ccid@hhs.iowa.gov.

Research included within the *Outcomes for Children with Hearing Loss (OCHL)* study indicates the importance of support to families for improving amplification wear time, which can have a positive impact on language development outcomes in children with hearing differences (Walker et al, 2015). This is often something learned from another family who has already been through the process.

Refusing a family support referral is a serious decision and could result in lack of family support resources and services. Parents and caregivers should discuss the risks and implications of this choice with their infant's PCP and audiologist to make a fully informed decision. The refusal of the family support referral must be recorded in the child's record in INSIS. Should a family refuse family support initially, the audiologist should revisit family support at a future appointment as the family's journey continues and needs change.

Additional Referrals

The pediatric audiologist may offer additional referrals, such as an Ophthalmologist or Geneticist) to families or recommend referrals in their report to the child's primary medical care provider when the nature of the child's hearing difference or other developmental concerns makes it appropriate. A checklist of recommended potential post-diagnosis referrals can be found on the Iowa EHDI website on the providers page.

Chapter 6: Pediatric Amplification Protocol

Policy

All Iowa children who are DHH and who can benefit from amplification will receive hearing aid services in a timely manner with the best contemporary hearing aid fitting strategies.

Background

Because a child's development of speech and language depends on the optimal audibility of the speech signal, audiologists need to have the equipment and skills to provide state-of-the art hearing aid and remote microphone (RM) services.

This pediatric amplification protocol was developed using guidelines published by the American Academy of Audiology, American Speech-Language-Hearing Association and the Pediatric Working Group Conference on Amplification for Children with Auditory Deficits, along with the following textbook: McCreery, R. W., & Walker, E. A. (2017). *Pediatric amplification: enhancing auditory access*. Plural Publishing.

Personnel Qualifications

- Qualified audiologists are the most appropriate professionals to select and fit all forms of amplification for children (including personal hearing aids, RM systems, cochlear implants and other assistive technologies).
- Qualified audiologists should have experience and expertise with this population as well as the listening devices.
- Qualified audiologists have a master's and/or clinical doctoral degree in audiology from an accredited university and meet all state licensure and/or regulatory requirements.
- Qualified audiologists fitting hearing instruments on infants and young children must have access to the equipment necessary to complete all tests described in this protocol.

Candidacy

- Amplification should be considered if a child has any degree of hearing loss, including sensorineural, permanent conductive or mixed type hearing losses.
- Expected outcomes may be influenced by factors such as laterality, degree and configuration of hearing loss and the child's cognitive, medical or socio-economic status.

Pre-selection

The following should be considered in device selection:

- Electroacoustic appropriateness, including frequency response
- Listening needs

- Ability to couple to assistive hearing technology (telecoil, RM compatibility, streamer compatibility and/or Bluetooth)
- Tamper resistant features (battery compartment, volume control, program switches)
- Advanced features (directional microphones, noise reduction, multiple memories)
- Pediatric sized tone hooks
- Ear mold considerations (style, venting, material, color, canal length, ear canal size)
- Cost
- Durability
- Warranty
- Battery life
- Color options

Bilateral amplification for those with bilateral hearing loss is considered a standard recommendation. Decisions regarding amplification for unilateral hearing losses should be made on a case-by-case basis.

Air conduction hearing aids are the most common hearing aid type and are used for most pediatric hearing aid fittings. Bone conduction hearing aids may be considered for children who are unable to wear air conduction devices due to a malformation of the outer ear or recurrent middle ear drainage.

It is generally accepted that the compression threshold should be as low as possible to ensure that softer speech or softer speech components have the maximum likelihood of being audible.

Multiple channels allow for greater flexibility in adjusting the frequency response, although some adjustments can be achieved by using filtered tone hooks.

Using multiple programs or memories may have some usefulness with children, such as using RM plus environmental microphone program with older children. However, multiple programs with very young children should be approached with caution, as the programs may be inadvertently changed during everyday use.

The importance of a young child learning the meaning of environmental sounds and the impact of incidental listening on language learning should be considered when directional microphones and noise reduction strategies are considered. These devices should be used cautiously in young children. For children with severe to profound unilateral hearing loss, amplification using Contralateral Routing of Signals (CROS) may be considered, but only when the child can give feedback about the benefit they get from this type of amplification. Bilateral Contralateral Routing of Signals (BiCROS) might be an option for a child with a severe/profound hearing difference.

Fitting Method

The fitting method to determine hearing instrument electroacoustic characteristics should be audibility-based to provide audibility of speech regardless of the input level or vocal effort.

- The hearing aid will initially be fit according to ***DSLv5*** prescriptive targets based on the child's ABR or behavioral thresholds.
- If thresholds were obtained via ABR, **do not** select ABR (nHL) as the Verifit HL transducer, as this will "double correct" the ABR thresholds.

Verification of Targets

The goal of amplification is to provide consistent and comfortable access to the speech spectrum for soft, average and loud inputs. Evidence-based verification strategies should be used to determine if the goal of amplification is accomplished. Ear acoustics should be accounted for in the hearing aid fitting process. Measured Real-Ear-to-Coupler Difference (RECD) or On-Ear Speech Mapping is preferred, but age-specific averages can be used if the audiologist determines it is appropriate.

Behavioral Verification

Behavioral methods include amplified speech perception testing and amplified sound field thresholds (ASFTs). ASFTs are **not** recommended for verification with hearing aids and should only be used during verification with cochlear implants or bone conduction hearing aids.

Electroacoustic Verification

Gain targets will be verified using simulated or in-situ speech mapping. Input levels should be 50-55 dB (soft), 60-65 dB (average), 70-75 dB (loud) and maximum power output (simulated mode recommended).

RECDs are the procedure that allows audiologists to use probe tube measurements for children who are very young, incapable of maintaining necessary head control or cooperation for extensive probe tube measurements.

- RECDs measure the acoustics of both the coupler and the ear canal, and the difference between the two is added to the coupler response to estimate the real-ear response.
- RECDs vary considerably during early childhood, changing most rapidly in the first two years and nearing adult values by seven years of age.
- If an audiologist can only measure the RECD for one ear, it is more appropriate to use that RECD for the opposite ear, rather than using an average RECD for the opposite ear.
- For more information on probe microphone and RECD measures, including video tutorials, please visit: http://www.babyhearing.org/Audiologists/verification/index.asp.

Parent Orientation

The audiologist should provide information to parents/caregivers and allow time for practice and skill development in use and care of the hearing instruments. Orientation should not be viewed as a one-time event, but rather an ongoing process throughout the child's life.

Orientation and training with the hearing instruments should include:

- Demonstrate/review function of main components (ear mold, microphone, battery compartment, volume control, receiver, switches/remote controls)
- Daily use and care
- Listening checks
- Cleaning
- Moisture prevention and solutions
- Data logging capacities
- Suggested wearing schedule (how long hearing aids should be worn at first; ideal amount of time hearing aids should be worn)
- Retention options (clips, bonnets, etc.)
- Insertion, removal, retention and storage of devices and ear molds
- Insertion, removal and storage of batteries
- Battery life, disposal, and toxicity
- Maintenance of devices
- Troubleshooting
- Warranty
- Use with telephone and assistive devices
- Tools for maintenance and care (battery tester, listening stethoscope, ear mold air blower, dehumidifying system)
- Recommended follow-up appointments to monitor use and effectiveness

Hearing Instrument Tool Kits

Some hearing instrument manufacturers make care kits that have most of the tools that are important for hearing aid use and care. The tools are:

- Extra batteries and battery tester
- Listening tube or hearing instrument stethoscope
- Hearing instrument dehumidifier
- Brush and wax pick
- Retention devices
- Ear mold blower

Validation

Validation of amplified auditory function is an ongoing process that should demonstrate the benefits and limitations of the child's aided listening abilities. This process begins immediately after amplification use is initiated. Validation measures are either subjective or objective.

Subjective Validation

Subjective validation involves use of functional assessment tools, often questionnaires. Parents, teachers and occasionally children are asked to judge attention and listening performance in a variety of real-world environments. Examples include the *LittlEARS Questionnaire* or the *PEACH (Parent Evaluation of Aural/Oral Performance of Children)*.

Objective Validation

Objective validation measures often are completed in a controlled clinical environment, such as an audiological test booth. These tools typically evaluate how well the child can identify or understand environmental signals and/or speech. They compare performance before and after hearing instrument fitting or modification, or performance in aided and unaided conditions. Language and vocabulary development of the child will determine which objective measures can be used, many are not applicable for children under 36 months of age. For children too young to complete speech perception testing, audiologists may consider presenting Ling sounds at a fixed intensity (35 dB HL) to ensure they can be identified either by picture-pointing or having the child repeat back the Ling sounds.

Follow-up and Monitoring

A planned, regular schedule for follow-up testing and monitoring is important for the long-term success of a child with a hearing difference.

At a minimum, follow-up is recommended every three months during the first two years of life, and every six months until five to six years of age. More frequent follow-up may be necessary if signs of fluctuating hearing or progression in hearing thresholds are present.

Follow-up appointments should include:

- Behavioral audiometric evaluation and tympanometry
- Checking the fit and condition of the child's ear molds and replacing ear molds, as needed
- Real ear verification with simulated or on-ear speech mapping, depending on the age and attention level of the child (on-ear mapping must be done for hearing aids with slim tubes or receivers in the canal
- Repeating RECD measures with new ear molds or at least annually if ear molds are not replaced
- Testing hearing instrument performance, including both electroacoustic analysis and listening checks
- Adjusting hearing instruments as needed
- Checking and recording data logging
- Completing measures of amplified auditory performance, as appropriate for the child's age and developmental level.

Functional Gain Testing

Warble tonal threshold testing is **not** an appropriate tool to verify hearing aids. This testing does not need to be completed unless a child uses cochlear implants or bone conduction hearing aids.

Chapter 7: Early Intervention Referral

Policy

All Iowa children who are identified as DHH should have access to timely and coordinated entry into an EI program to support child outcomes in language acquisition, social-emotional development and academic achievement.

Background

Research shows infants who are identified early and provided with timely early interventions demonstrate better linguistic outcomes than late-identified children (Holte, et. Al, 2012). The purpose of EI is to achieve optimal child and family outcomes. The audiologist is the primary professional who conveys initial information about EI opportunities and the importance for the child's development. Early, mindful and comprehensive education of families and caregivers regarding the nature of language acquisition is invaluable in encouraging families to seek appropriate EI services for their child.

Referral Process for EI

The diagnosing audiologist must make this referral within 48 hours of diagnosis and no later than seven days from the date of diagnosis per IDEA best practice guidelines. If a referral is not made within the required timeframe, a case note must be entered in INSIS explaining why a referral was not completed at the time of diagnosis and outlining the plan for a discussion about the EI referral later.

There is an online statewide system for submitting a referral to Early ACCESS, which includes an easy-to-use online referral form through Iowa Family Support Network. You can click on the link directly or go through INSIS to access the direct link. Once you click on the link, fill in the following referral information:

- Child demographics
- Residential address
- Parent/guardian demographics and contact information
- Referral source
- Reason for referral
- Upload documentation, if applicable

A case note should also be made within the child's record in the INSIS.

Parent Refusal

Refusing an EI referral is a serious decision and could result in lack of EI support. Parents and caregivers should discuss the risks and implications of this choice with their infant's PCP and audiologist to make a fully informed decision. If the family makes that decision, the refusal of the EI must be recorded in the child's record in INSIS. Should a family refuse EI initially, the audiologist should revisit EI at a future appointment as the family's journey continues and needs change.

EA Service Coordinator Activities

Every child referred to EA is assigned an EA service coordinator. The service coordinator (SC) attempts to contact families within two business days of receiving the referral. The SC will:

- Make a minimum of three attempts to contact (e.g. phone call, text, email) family within 14 calendar days from the referral.
- Use a variety of attempts to contact the family at different times of day and different days of the week.
- Document all attempts to contact the family.

If the family and the service coordinator connect, the SC will:

- Provide an overview of EA services, including purpose, a family's right to a service coordinator, eligibility criteria, information on the evaluation/assessment process, the different types of services available and explanation of no cost to families for service coordination, evaluation/assessment and early intervention services.
- Listen and engage with the family to identify strengths, interests, concerns and needs, while beginning to anticipate evaluation needs based upon the child and family priorities.
- Seek consent for evaluation and assessment. If the parent requests only one or two developmental areas to be evaluated, the SC must explain to the family that all areas are required to be evaluated.

If the SC is unable to reach the family, the SC will:

- Mail a letter to the parents indicating attempts to make contact and request that the parents contact the SC within 14 days, or the referral will be closed.
- If the SC has no contact with the family after 28 calendar days after the referral date, the SC will end the referral.

EA Enrollment – Service Coordinator Responsibilities

If the family chooses to enroll in EA, the SC is the family's primary contact for the program. Responsibilities include:

- Explaining the system of services and resources within EA.
- Coordinating evaluations and assessments.
- Assisting parents and/or caregivers in obtaining access to needed EI services and other services identified in the Iowa Family Service Plan (IFSP), including referrals to providers outside the EA system for needed services and assisting parents in scheduling appointments.
- Coordinating the provision of EI services and other services (such as educational, social and medical services that are not provided for diagnostic or evaluative purposes) the child needs or is being provided.
- Facilitating and participating in the development, review and evaluation of IFSPs.

- Coordinating, facilitating and monitoring the delivery of required services to ensure services are provided in a timely manner.
- Conducting follow-up activities to determine that appropriate EI services are being provided.
- As child nears age three, facilitating the development of a transition plan to preschool, school or, if appropriate, other services.

EA Resources

To learn more about EA, visit:

- Iowa Family Support Network: www.iafamilysupportnetwork.org
- i3 Iowa IDEA Information: https://iowaideainformation.org/early-intervention/

Chapter 8: EHDI Family Support Referral

Policy

All Iowa children from birth to three years of age, identified as DHH, should be referred to Family Support. The goal is to provide resources and opportunities for families to learn and engage with others while empowering them in raising a child with hearing differences.

Background

Providing comprehensive resources and support opportunities for families to make appropriate, educated decisions for their child with a hearing difference and knowing they are not alone is an important goal of the EHDI Family Support Program.

This protocol provides recommended guidelines for referral to Family Support to promote a standardized approach in family support offerings to ensure consistency in outcomes of language and communication development and exposure. The following Family Support protocols are based on national guidelines put forth by the JCIH and the Language Equality & Acquisition for Deaf Kids (LEAD-K) bill in Iowa.

Family choice is always respected throughout EHDI programming. While it is important all families be offered the same opportunities and resources to ensure equitable decision-making for their child, it is ultimately a family's decision on whether they would like to move forward with connecting with a Family and or Deaf Mentor and the level of involvement in family support activities.

If a family initially declines EHDI Family Support services, they will still have the opportunity up until the age of three, to participate in any EHDI Family Support services offered.

Referral Process for EHDI Family Support

Family Support referrals should be made to the EHDI Family Support Coordinator, who will communicate directly with the family and triage their needs to provide appropriate resources and connections based on the needs of the child.

All children under three who are diagnosed with a hearing difference, regardless of any other developmental concerns or medical conditions, are contacted by the EHDI Family Support Coordinator. Making a referral upon diagnosis speeds up the process to connect families to other families or a deaf adult with lived experience and additional support.

EHDI Family Support Services

The EHDI Family Support Coordinator offers a variety of services and supports to the family after diagnosis. Each family can decide to participate in one or more of the family support resources. Below is a list of support offerings to share with families of children under the age of three.

Family Partners

Family partners are parents or caregivers of children who are DHH, trained by the EHDI Family Support Coordinator, to provide unbiased support and resources for families interested in connecting with another family. Family Partners are matched with families to share knowledge, experience and emotional support.

If a family is interested in being connected with a Family Partner, the Family Support Coordinator coordinates the first meeting and interpretation, as needed. If a family initially declines being connected to a Family Partner but later decides they would like to meet with a Family Partner (and their child is under the age of three), the Family Support Coordinator can be contacted to arrange for this connection.

Any provider, family member or medical provider working with the family can make the referral, if they have received consent from the family to do so. To make a referral, go to the EHDI website and use the Family Partner Request Form. The EHDI Family Support Coordinator will reach out to the family directly.

EHDI Family Support Newsletter and Social Media

The EHDI Family Support Coordinator sends a monthly e-newsletter to families enrolled in EHDI Family Support. The newsletter offers several resources for families as well as information on upcoming events or opportunities to connect with other families.

The Family Support Coordinator also reaches families through the Iowa EHDI Facebook page and creates posts relevant for families of children with hearing differences. Posts include resources and activities in Iowa communities.

EHDI Family Support Events

EHDI Book Club for Tots

Monthly virtual book club for families of children, ages birth to three with hearing differences. Each month a different children's book is chosen to be used during this virtual story time. The Family Support Coordinator schedules Deaf Mentors and ASL Interpreters to read and sign the story to families. The Deaf Mentor teaches the family the story signs to practice at home while reading to their children.

EHDI Hands & Tales

Bi-monthly event that takes place in different communities across Iowa. This story-time event is like the virtual Book Club for Tots but is held in person. A Deaf Mentor and an ASL interpreter read and sign a story, teach the signs and then a craft and social time takes place for the children and parents.

EHDI New to the Journey

This event is a quarterly webinar for families of DHH to provide education on different topics related to hearing differences. The Family Support Coordinator manages

schedule, registration, topics and presenters (parents and professionals with expertise).

In-person family events

EHDI hosts in-person or virtual events throughout the year for families of children ages birth to three years of age with hearing differences. The program also collaborates with other providers to open events to families of children of all ages with hearing differences. The EHDI program has partnered with several providers for events, including the Iowa School for the Deaf, Iowa Hands & Voices and the Iowa Deafblind Project. The Family Support Coordinator is responsible for planning, organizing and hosting events for the families as well as gathering feedback after for program evaluation.

Referrals for Other Support

During the initial communication between the EHDI Family Support Coordinator and parent/guardian, a variety of services and supports are offered. The Family Support Coordinator ensures the audiologist has made a referral to EA and if not, the family is offered EI support, and a referral is made during that call. If a parent has vision concerns for their child, the Family Support Coordinator will send a referral to the Iowa Deafblind Project with family consent. If a family is interested in being connected with a Deaf Mentor, a referral is made to ISD's Family Support Mentoring Program.

Deaf Mentors are DHH adults trained to serve as positive role models, teach American Sign Language (ASL) and work alongside families to increase a family's ability to successfully communicate with their DHH child. A Deaf Mentor is there to provide unbiased support and increase parents' appreciation for and understanding of ASL, Deaf Culture, and exposure to the Deaf Community. Deaf Mentors assist in supporting the child's language development, communication, and self-identity through interaction with a DHH adult. Through the LEAD-K legislation, Iowa School for the Deaf's (ISD) Family Support Mentoring Program hires and coordinates all the Deaf Mentors.

If a family initially declines being connected with a Deaf Mentor but later decides they would like to meet with one, and their child is still under age three, they can contact the Family Support Coordinator or complete the Deaf Mentor request form. The Family Support Coordinator will reach out to make the connection. A team member or medical provider working with the family can also fill out the form for the family if they have received verbal consent to do so at any time.

Families of Older DHH Children

The Family Support Coordinator will connect families of children older than three years of age to other family support organizations. This includes the Iowa School for the Deaf, Iowa Hands & Voices, Iowa DeafBlind Project and ASK Resource Center.

Chapter 9: Monitoring Children with Risk Factors

Policy

All Iowa children identified with a risk factor related to late onset or progressive hearing loss will be monitored so that if a hearing difference develops, it will be detected as early as possible.

Background

The EHDI Monitoring Protocol is based upon the JCIH 2019 position statement. Regardless of previous hearing screening outcomes, all infants with or without risk factors should receive ongoing surveillance of communicative development beginning at two months of age during well-child visits in the medical home (AAP Committee, 2017). This recommendation provides an alternative, more inclusive strategy of surveillance of all children within the medical home based on the pediatric periodicity schedule through ***Bright Futures***.

Should a parent have concern regarding speech, language, developmental delay or developmental regression, an immediate referral should be made to an audiologist and speech-language pathologist for further evaluation. The Iowa EHDI program developed a high-risk monitoring protocol and guidelines based on the JCIH 2019 position statement. The Iowa protocol describes the follow-up process for children with risk factors.

Provider Responsibilities

According to Iowa law and EHDI best practices, risk factors for late-onset hearing differences must be reported in INSIS. Follow-up with families of children at risk for hearing differences can only be successful if risk factors for late onset hearing differences are reported accurately to the EHDI program and families are encouraged to complete the recommended follow-up screening.

Risk Factors Associated with Hearing Differences & Timeline for Re-screen

Children with the following risk factors should see an audiologist for a hearing evaluation at the times listed below based upon JCIH recommendations.

Three Month

- Bacterial and viral meningitis or encephalitis (especially herpes viruses and varicella)
- Congenital Cytomegalovirus, confirmed in infant
- Extra-corporeal membrane oxygenation
- Head injury (especially basal skull/temporal bone fracture)
- Chemotherapy

Nine Month

- Family history of early, progressive or delayed hearing difference(s) during childhood
- Cranio-facial anomalies (includes cleft lip or palate)
- In utero infections (herpes, rubella, syphllis and toxoplasmosis)
- Atresia/Microtia, ear dysplasia, Microphthalmia, White Forelock
- Congenital microcephaly, congenital or acquired hydrocephalus
- Temporal bone abnormalities
- Hyperbilirubinemia with exchange transfusion regardless of length of stay
- NICU stays longer than five days
- Aminoglycoside (includes Gentamycin, Vacomycin, Kanamycin, Streptomycin, Tobramycin) administered for more than five days (toxic levels or known genetic susceptibility)
- In utero infections such as herpes, rubella, syphilis and toxoplasmosis
- Asphyxia or Hypoxic Ischemic Encephalopathy
- Syndromes (includes Trisomy 21-Down syndrome, Goldenhar, Pierre Robin, CHARGE association, Rubinstein-Taybi, Stickler, Usher, Osteopetrosis, Neurofibromatosis type II, Treacher Collins, Hunter syndrome, Friedreich's ataxia, Charcot-Marie-Tooth syndrome or visit the Hereditary Hearing Loss website)
- Mother + Zika with infant lab evidence

EHDI Program Responsibilities

- Search INSIS for infants born within the previous two months who have identified risk factors.
- Prepare 3 and 9-month risk factor letters and send to the infant's primary contact and PCP providing guidance on recommended hearing healthcare follow-up.
- Infants with more than one risk factor will receive the letter based upon the most current follow-up need (e.g. if infant has a risk factor where the recommendation is 3-month re-screen and a risk factor where the recommendation is a 9-month re-screen, the letter will reflect the 3-month re-screen).
- EHDI staff will correct the infant's medical record if the infant's PCP contacts the EHDI program to report a risk factor was reported incorrectly based upon hospital or clinic records. The EHDI staff will also notify the provider who reported the risk factor(s) incorrectly and offer education, as needed.

Chapter 10: Quality Assurance for Hearing Screening Programs and Diagnostic Clinics

Policy

Each provider (e.g. birthing facility, midwife, outpatient screening clinic or diagnostic clinic) will have a system of checks and balances in place to ensure a quality newborn hearing screening and diagnostic assessment clinic for children.

Background

High quality programs are essential to successfully meet national EHDI 1-3-6 goals. Because there are many details that compromise a successful newborn hearing screening program or diagnostic assessment clinic, monitoring of specific data elements and care of the child is essential to ensure appropriate and timely follow-up for children who may be diagnosed as DHH.

Birthing Facilities and Midwife Policy and Procedures

Written policy and procedures outline and describe various steps of the newborn hearing screening program. Elements of the policy should outline the following:

- Screening personnel roles
- Initial and annual screening personnel training requirements
- Screening procedures
- Parent education and information
- Timelines and procedure for reporting to parent(s), PCP/Medical Home and the EHDI program
- Procedures for children who missed their hearing screen, did not pass and/or have risk factors for hearing differences
- Documentation of demographics, screening results and risk factors in INSIS within six working days of birth
- Process for communicating results of quarterly quality assurance reports from the EHDI program and plan to address deficiencies

Diagnostic Assessment Clinics Policy and Procedures

Written policy and procedures outline and describe various steps of the diagnostic assessment and follow-up care process. Elements of the policy should outline the following:

- Audiology and Ear, Nose and Throat doctor responsibilities
- Initial and annual diagnostic assessment training requirements
- Diagnostic assessment procedures
- Parent education and information
- Timelines and procedure for reporting to parent(s), PCP/Medical Home and the EHDI program

- Procedures for children who missed their diagnostic assessment, were determined to have a hearing difference and/or infants with a possible medical condition requiring attention
- Documentation of demographics, diagnostic assessment results and risk factors in INSIS within six working days of appointment
- Process for communicating results of quarterly quality assurance reports from the EHDI program and plan to address deficiencies

Quality Assurance of Data Reporting

All newborns in Iowa are required to be screened for hearing differences and results must be reported to the department in accordance with 641 IAC 3.1 (135.131). Instructions for data entry are included in the INSIS User Manual for the following instances:

- **Deceased**
  Occasionally an infant may die during care. In these instances, it is very important to mark the patient as deceased within the record so no further follow-up is done with the family. Providers can also reach EHDI personnel to mark the records by calling 1-833-496-8040.
- **Transfer**
  There may be times when an infant must be transferred to another facility for specialized care, or when an infant requires additional follow-up care. All transfers and follow-up needs must be documented in the child's record in INSIS.
- **Refusal**
  - Although parental consent is not required to perform newborn hearing screening, parents should be informed and parental objection to the screening must be honored.
  - If a parent declines hearing screening or a diagnostic assessment for their child as a part of the hearing healthcare journey, it is very important to obtain a written refusal from the parent or guardian on the HHS refusal form, record the refusal and upload the form in INSIS.
  - The original refusal form should be maintained in the infant's medical record following the policy set forth at your facility. This will stop all communication regarding follow-up care.
- **Missed**
  - Hospitals should have procedures in place to ensure children are screened prior to hospital discharge or later if born outside of the hospital. In the event screening is not possible, a record for the child must still be created in INSIS. A case note confirming the missed screen and date for follow-up screen should be included.
  - If the infant misses a diagnostic assessment, a case note should be made within INSIS. If rescheduled, note the date the infant is to return.

- **Medically Fragile**
    - Occasionally an infant may become medically fragile during care and screenings, treatments, or other procedures postponed or placed on hold.
    - Birthing facilities, midwives or audiology providers should make a case note in INSIS and contact EHDI personnel by calling 1-833-496-8040.
    - All communications will cease, the record will be marked accordingly, and EHDI personnel will monitor at a distance in case hearing healthcare may resume later.

Quarterly Quality Assurance Reports

Providers are required by law to report specific data to the EHDI program for hearing screens, re-screens and diagnostic assessments. That data is used for surveillance to ensure infants are identified with hearing differences as soon as possible and provided with appropriate services and support throughout the hearing healthcare journey. The data is also used to track Iowa's progress in meeting the national 1-3-6 goals, child outcomes, reporting required of federal funders and for program evaluation and quality improvement activities.

Each quarter birthing facilities and diagnostic centers receive a quality assurance report based on various metrics tied to EHDI recommended best practice guidelines. The quality assurance reports encourage consistent and equitable practice and correction, when needed, among Iowa providers.