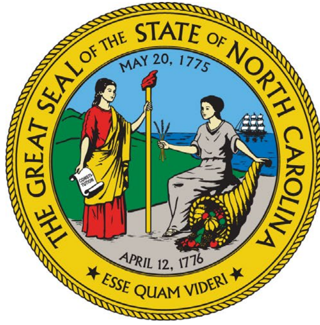

NC DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

Universal Newborn Hearing Screening (UNHS) Birthing Facility Compliance Guide Manual

North Carolina's Early Hearing Detection and Intervention (EHDI) Program

The EHDI Program cares about the hearing of newborn babies. EHDI provides assistance and education to hospitals, medical providers, and others. It supports families by connecting them to resources and helping them to receive the care their baby needs.

The NC EHDI Program is located in the North Carolina Department of Health and Human Services, Division of Child and Family Well-Being, Whole Child Health Section as part of the state Title V Maternal and Child Health Services Program. The program is administered by staff in the Genetics and Newborn Screening Unit and functions in close collaboration with several other programs for children with special health care needs.

INTRODUCTION

The EHDI Program in North Carolina developed the following guidelines to support a comprehensive and effective statewide mechanism to screen all newborns for hearing acuity, to provide prompt audiological follow-up testing for those infants who do not pass the newborn screen, and to provide timely and appropriate early intervention services for those infants who are diagnosed with hearing loss. This document should serve as a guide for birthing facilities and pediatric healthcare providers in the development and implementation of their respective Universal Newborn Hearing Screening Program. These guidelines are not intended to supersede individual hospital policy or the independent clinical assessment and judgment of physicians and medical providers in any individual case.

The goal of EHDI is to maximize linguistic competence and literacy development for children who are deaf or hard of hearing. Without appropriate opportunities to learn language, these children will fall behind their hearing peers in communication, cognition, reading, and social/ emotional development. Such delays may result in lower educational and employment levels in adulthood. To maximize the outcome for infants who are deaf or hard of hearing, the hearing of all infants should be screened at no later than **1 month** of age. Those who do not pass screening should have a comprehensive audiological evaluation at no later than **3 months** of age. Infants with confirmed hearing loss should receive appropriate intervention at no later than **6 months** of age from healthcare and education professionals with expertise in hearing loss and deafness in infants and young children. Regardless of previous

hearing screening outcomes, all infants with or without risk factors should receive ongoing surveillance of communicative development beginning at 2 months of age during well-child visits in the medical home. EHDI systems should guarantee seamless transitions for infants and their families through this process.

~Joint Committee on Infant Hearing (JCIH) 2007 Position Statement

There is a body of literature which demonstrates that children and families experience optimal outcomes when these benchmarks are met. Additionally, communication and linguistic competence (in spoken language, signed language, or both) are achievable when timelines are met, and when optimal audiologic and early intervention services are accessible.

~JCIH 2019 Position Statement

BACKGROUND

The JCIH was established in late 1969 and was composed of representatives from audiology, otolaryngology, pediatrics, and nursing. Throughout its history, the Committee has explored the complexities of hearing loss and its effect on a child's development, seeking to find newer and better methods to identify and serve the infants and their families. Today, the Joint Committee is comprised of representatives from the Alexander Graham Bell Association for the Deaf and Hard of Hearing, the American Academy of Pediatrics, the American Academy of Otolaryngology and Head and Neck Surgery, the American Speech Language Hearing Association, the American Academy of Audiology, the

Council on Education of the Deaf, and Directors of Speech and Hearing Programs in State Health and Welfare Agencies.

The Committee's primary activity has been publication of position statements summarizing the state of the science and art in infant hearing and recommending the preferred practice in early identification and appropriate intervention of newborns and infants at risk for or with hearing loss. In 1994, the JCIH endorsed universal detection of hearing loss in newborns and infants and stated that all infants with hearing loss be identified before 3 months of age and receive intervention by 6 months. With the support of the Health Resources Service Administration, Maternal and Child Health Bureau, Centers for Disease Control and Prevention, and other dedicated groups and individuals, universal screening gained momentum across the United States and all states now have newborn hearing screening programs in place. The current JCIH Position Statement was released in 2019 after years of meetings, research, revision, and hard work by many dedicated professionals and has been widely accepted as the "Gold Standard" of Universal Newborn Hearing Screening programs today.

The North Carolina EHDI Program and the NC EHDI Advisory Board fully support early hearing detection and intervention for infants with hearing loss through integrated, interdisciplinary community, state, and federal systems of universal newborn hearing screening, evaluation, and family-centered intervention.

This document is designed to serve as a guide to assist birth facilities and other healthcare providers in the provision of services for newborns from screening, through diagnostic testing and enrollment into early intervention. It is a revised version of the original *KY Universal Hearing Screening Hospital Compliance Manual* that was distributed to Kentucky birth hospitals in 2001. The recommendations from the JCIH 2007 and 2019 Position Statements are incorporated throughout this document. The JCIH 2019 Position Statement builds on prior JCIH publications (2013 JCIH supplement on Early Intervention and 2007 JCIH Guidelines), updating best practices through literature reviews and expert consensus opinion on screening; identification; and audiological, medical, and educational management of infants and young children and their families.

North Carolina Early Hearing Detection and Intervention Program

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Standard

1

Newborn Hearing Screening Policies and Procedures

Written birthing facility policies and procedures are needed to outline how universal newborn hearing screening will be implemented within the hospital setting. Test protocols are needed to ensure consistency in screening procedures among hearing screeners and to avoid excessive screening in the birthing facility's UNHS program.

The policies and procedures clarify the responsibilities of hospital personnel involved in the UNHS program. Persons reviewing the policies and procedures will understand the following: the population to be screened, how parental consent is addressed (including documentation of declines), a defined timeframe for the initial screen and inpatient rescreen (if warranted), and an understanding that no more than 2 in-patient screens per infant are permissible. If an inpatient rescreen is warranted, both ears should be screened again regardless of initial screen results. If an inpatient rescreen is warranted, these results are documented in NC Hearing Link as the "Official Initial Screen". Policies and procedures should state who will be responsible for the following: completing the screening, documenting results, reporting, and disseminating results to parents, physicians, and the state EHDI program, monitoring the outcomes of the program on a monthly and quarterly basis, and addressing next steps for follow-up for infants that refer. Policies and Procedures should address infection control.

Standard 2

Screening Equipment

Appropriate, current documentation of calibration and/or annual maintenance is required to determine functionality/reliability of the screening equipment. Each nursery, if separated by a great distance, should have a dedicated piece of screening equipment. Each newborn should be screened on either Automated Auditory Brainstem Response (AABR) equipment or Otoacoustic Emission (OAE) equipment.

The major difference between OAE and AABR technologies lies in the portion of the auditory system being screened. Because the OAE response is generated by outer hair cells in the cochlea before it reaches the eighth nerve, it is often referred to as a "pre-neural" response. However, in AABR, the sound continues along the eighth nerve to the brain. An electrical response from that nerve is picked up by electrodes that have been placed on the infant's head.

Per the JCIH 2019 Position statement, depending on the screening technology selected, infants with auditory neuropathy may not be detected through a UNHS program. Given the low incidence of auditory neuropathy in the well-baby nursery, the JCIH recommends the use of either AABR, or OAEs or both for initial screenings and/or rescreening in the well-baby population. The recommendation to rescreen using only AABR technology for the infant who fails initial screening performed with AABR technology continues to be the Committee's preferred protocol.

In accordance with JCIH 2019, all infants who have received care in a NICU should be screened utilizing AABR. Infants who require NICU care may have had a more complicated birth associated with factors that put them at a significantly higher risk for auditory neuropathy. Therefore, JCIH recommends screening this group with the technology capable of detecting auditory neuropathy which is AABR.

Manuals for all equipment should be current and stored in a readily available location. At some time, every birthing facility will experience equipment failure. A written back-up plan for screening infants in the event of equipment malfunction is required.

Standard

3

Outpatient Rescreen Referral/Scheduling Process

Because there are many details that comprise a successful newborn hearing screening program, monitoring of specific data elements is essential. It is the birthing facility's responsibility to:

Maintain records accounting for the accuracy and integrity of their newborn hearing screening program. This should include the scheduling of a follow-up appointment for infants that refer on their inpatient hearing screen.

It is the responsibility of the birthing facility to ensure an appropriate referral pathway. Best practice is to schedule an outpatient rescreen at the birthing hospital or affiliated practice using the same screening technology as the initial screen. The outpatient rescreen should be scheduled prior to discharge and the appointment information entered in NC Hearing Link. If the birthing facility does not offer outpatient rescreens, the facility should provide the family with contact information to schedule the appointment and notify the infant's physician.

The birthing facility should have the outpatient rescreen/referral/scheduling process in written form and easily accessible to staff. The written documentation should include rescreening both ears regardless of a unilateral or bilateral fail on the inpatient screening.

This birthing facility-monitored data acts as a cross check for the data collection of the EHDI program office and allows birthing facilities to find errors in programming or equipment on a small local level, before a major disruption in hearing screening occurs.

Standard 4

Parental Education

Informed parents are vital to successful outcomes for early hearing detection and intervention. A plan for providing parents with information about newborn hearing screening is essential.

The information needs to include the results of their infant's newborn hearing screening and information on typical speech and language development. A plan for cultural differences must be a part of the parent education process. Information should be offered verbally and in writing in a language format that meets the parents' communication needs. This may include using a language line or interpreters.

If additional assistance is needed to develop parental education materials for your birthing facility, NC EHDI Program Consultants may be contacted.

Standard

5

Staff Training

The goal of this standard is to develop and maintain knowledge, purpose, and performance for the staff who directly or indirectly administer newborn hearing screenings, documentation, and data submission. Screening is the first essential step in identifying those that need additional screening and possibly diagnostic follow-up.

New staff training requirements are outlined and include a thorough review of hearing screening policies and procedures, competency on use of screening equipment, use of NC Hearing Link and accurate reporting of results as required by the birthing facility and the NC EHDI Program.

Minimal annual training for all staff directly providing newborn hearing screening services should include the following: skill competencies (including equipment operating procedures review) and a review of the birthing facility's newborn hearing screening policies and procedures. Annual training allows staff to be aware of current EHDI and newborn hearing screening trends.

Documentation of training and annual competencies for all staff should be kept current and available for review by the EHDI staff.

Standard

6

Site/Equipment Inspection

A designated area, with a controlled noise level to conduct hearing screenings, can have a major impact on the consistency and reliability of the screening results and birthing facility referral rates. Signage such as "Quiet – Hearing Screening" can be posted. A quiet room or area should be designated as the primary room for hearing screening. Be aware of noises created by ventilation systems, warmers, and other equipment that may be in the room. Stay away from areas of heavy traffic. If the hearing screening is conducted at an area other than the designated site (i.e., at bedside/mother's room), you must take into consideration the precautions listed above, related to environmental noises.

A second area, that meets the same standards as the first area, may be selected and used for hearing screening only if the primary area is not available. The ability to troubleshoot equipment problems and maintain consistency in hearing screening is compromised when areas for screening are randomly selected and vary from day to day.

EHDI Program staff will inspect newborn hearing screening equipment annually to ensure that the equipment calibration is current (within the last 12 months).

Equipment reference documents also need to be easily accessible to the newborn hearing screening staff. The test protocol should be written in such a manner that anyone who reviews it understands the step-by-step procedures for conducting the test. It may also include information regarding troubleshooting practices or who to contact when equipment breaks down

or technical assistance is needed. Test protocols should reflect procedures appropriate for the type of screening equipment used.

Standard
7

Communication and Reporting

It is important that the birthing facility staff notify the EHDI program of staffing changes. Birthing facility staff are also responsible for participating in a yearly Compliance Guide Visit and other visits as warranted to address any concerns. Birthing facility staff are expected to be responsive to requests to schedule EHDI visits (in-person and virtual) in a timely manner.

Birthing facilities are evaluated on the consistency in which discharge dates for all infants and outpatient rescreen or diagnostic appointments (as warranted) are entered in the Hearing Link appointment tab.

Standard 8

Data Submission (via Hearing Link)

The NC EHDI Program is a direct child find program that provides resources for infants and families. Early brain research and developmental science conclude that infants with hearing loss must be screened before 1 month of age, tested diagnostically before 3 months of age, and given access to appropriate amplification options and enrolled in early intervention before 6 months of age. The only way to achieve these goals is through timely screening, accurate data submission following the newborn hearing screening, documentation of warranted referrals following the rescreen and/or diagnostic services, and linkage to early intervention services for those identified with permanent hearing loss.

Birthing facility staff should have a monitoring system in place to ensure that hearing screening results for infants who do not pass prior to discharge are submitted within 5 days of completion, and for infants that do not pass their rescreen are submitted within 5 days of completion in accordance with State Law 15A NCAC 21F.1204.

North Carolina's GS 130-125, effective Aug.1, 2000 mandated universal newborn hearing screening prior to birthing facility discharge and identified the Children's Special Health Services of the Children and Youth Branch of the Division of Public Health as the responsible agency for tracking and surveillance of UNHS. Since implementation in October 2000, the

NC Hearing Link has been the defined method of submitting hearing screening data to the NC EHDI Program. This data submission is necessary to meet mandated requirements.

The NC EHDI Regional Consultants provide technical assistance to birthing facility programs. They may be contacted to arrange training for any facility having difficulty meeting data submission requirements. Training may include developing internal tracking and organizing data submission procedures.

Standard

9

Benchmarks and Quality Indicators

The JCIH Position Statement 2019 supports the concept of regular measurements of performance and recommends routine monitoring of these measures for inter-program comparison and continuous quality improvement. Performance benchmarks represent a consensus of expert opinion in the field of newborn hearing screening and intervention. Monitoring of these benchmarks ensures that the policies, procedures, and protocols are implemented so that all babies are screened prior to discharge, and that the numbers of false positives are low.

North Carolina provides quarterly and annual data to each birthing facility through a Quality Assurance Report. Quality indicators for screening are as follows:

- Percentage of all newborn infants who complete their initial screening before discharge; the recommended benchmark is more than 95%.
- Percentage of all newborn infants who fail (refer) inpatient screening; the recommended benchmark is less than 4%.
- Percentage of all newborn infants who complete their rescreen; the recommend benchmark is 80% or greater.

- Percentage of all newborn infants who complete their rescreen by 30 days: the recommended benchmark is 75% or greater.
- Percentage of all newborn infants who complete screening by 30 days, including initial screen pass; the recommended benchmark is 95% or greater.

It is the responsibility of the birthing facility to ensure that every baby has been screened before discharge. Documentation should be provided in each infant's medical chart including the date and time of screening, results, and follow-up as warranted. Documentation should be included in the infant's medical chart and in Hearing Link if parents decline the hearing screening.

Birthing facilities are accountable for their pass and refer rates. Any birthing facility failing to meet expectations is advised to begin a remediation plan with the NC EHDI Regional Consultants.

WEBSITES

NC Early Hearing Detection and Intervention, C& Y Branch, NC DPH

http://www.ncnewbornhearing.org

The Joint Committee on Infant Hearing 2019 Position Statement:

http://jcih.org/posstatemts.htm

The National Center for Hearing Assessment and Management:

http://www.infanthearing.org/

Centers for Disease Control and Prevention

http://www.cdc.gov/ncbddd/hearingloss/index.html

American Speech-Language-Hearing Association

http://www.asha.org/

American Academy of Audiology

http://www.audiology.org

My Baby's Hearing

http://www.babyhearing.org/

Hands and Voices (parent support group)

http://www.handsandvoices.org/

UNHS Competency Checklist

NAME: ______________________________ TITLE: ______________________________

SKILL Newborn Hearing-screening	CRITERIA MET	CRITERIA NOT MET *	REVIEWER INITIALS AND DATE	REPEAT SKILL DATE	CRITERIA MET	CRITERIA NOT MET *	REPEAT REVIEWER INITIALS AND DATE
1. Demonstrates understanding of protocols involving time factors for screening and number and/or type of screenings.							
2. Prepares newborn for screening. (Proper selection and insertion of probe tip for OAE screen or proper prep and/or application of electrode sensors and ear cups for AABR)							
3. Enters appropriate data							
4. Runs screening bilaterally.							
5. Prints results and places in chart.							
6. Records results in logbook.							
7. Completes Hearing-screening Report and appropriately disseminates copies.							
8. Demonstrates knowledge of Hearing Risk Factors.							
9. Notifies parents of screening results, obtains signature, and gives parents the yellow copy of results.							
10. Chart documentation adequate							

ALGO® 5 Newborn Hearing Screener - Competency Evaluation Form

Name: _________________________ **ID#:** ___________________________

Title: _________________________ **Date:** ___________________________

Procedure:	√

Select a baby appropriate for screening
• Term, healthy newborns
• NICU graduates, 34 weeks gestational age or older (and not older than six months of age)
• Newborns with normal outer ear anatomy and no obvious deformities of the head or neck
• Ready for discharge, or scheduled to go home within a few days
• Receiving no central nervous system (CNS) stimulants
• Sleeping or in a relaxed state (usually after a recent feeding)
• In an open crib
 	
Set-up screener
• Turn on the screener.
  ✓ First, push the main power switch to the on (I) position.
  ✓ Press and hold the computer power switch until the computer power light comes on. The screener begins its startup routine.
  ✓ Press the printer power switch. The printer power light turns on. The printer will also automatically turn on when printing the first label.
  ✓ After a series of startup messages, the Login window appears.
• Select the **SCREEN BABY (F1)** command button.
• Enter patient information (babies with mo previous screening history).
  ✓ Type the patient's medical record number and press the tab key. Repeat for Last Name, First Name, Gender, and DOB fields.
  ✓ Enter information into any other fields that are set as mandatory by the system administrator, or any additional information you desire to capture.
• Enter patient information (babies with previous screening history).
  ✓ Type the patient's medical record number and press the tab key.
  ✓ Confirm that you are using the correct patient and medical record number.
  ✓ Review all information that automatically appears in the data fields; correct or update entries as necessary.
• Enter the risk factors information by highlighting the **+** button for yes, the **–** button for no, or the? button for unknown.
• Select a screening method. The device is defaulted to screen both ears simultaneously.
• Once the screener set-up is complete, select **Continue (F1)** to proceed to the Baby Preparation Window.
 	
Prepare the Baby for Screening
• Collect supplies.
  ✓ Flexicoupler disposable earphones (a pair)
  ✓ Jelly Tab sensors (a triplet)
  ✓ Prepping materials (for example, soap, gauze sponge or washcloth, NuPrep gel)
• Attach the sensor cable clips to the sensors.
• Identify three sites for sensor placement and clean or prepare skin.
• Place sensor/clips over sites.	

- ✓ Sensor with **WHITE** clip to **NAPE** site (center and back of the neck)
- ✓ Sensor with **GREEN** clip to **COMMON** site (shoulder)
- ✓ Sensor with **BLACK** clip to **VERTEX** site (center forehead, as high as possible without placing above the natural hair line)

- Check to make sure both impedance readings are less than 12 kOhms. If not, further prep site.
- Attach acoustic transducers to earphones and apply earphones to baby.
  - ✓ **Red** transducer: **Right** ear
  - ✓ **Blue** transducer: **Left** ear

Running the Screening Procedure

- Once the baby is in a quiet or sleep state, select **Continue (F1)** to be directed to the screening window.
- Select **Begin Screening (F1).**
- Monitor interference and impedance and adjust sensors if impedance becomes too high.
- If needed, pause the screen by selecting **Pause Screening (F1)**.
- Resume screening after intervention by selecting **Resume Screening (F1)**.
- Observe and record results.
- Provide parents with results and Developmental Milestones.
- If a baby **REFERS**, rescreen once when the baby is in an appropriate state or according to hospital protocol.
- Set follow-up consultation for babies that **REFER**.

Cleanup and Shutdown

- Remove the clips from the sensor cable.
- Remove sensors from the skin. Dispose of single patient use sensors.
- Clean sensor cable according to hospital guideline for cleaning equipment that has come into contact with patients.
- Store sensor cable in the cart storage drawer or on the cable hanger assembly at the back of the cart.
- Remove earphones and acoustic transducers together from the baby.
- Remove the acoustic transducers from earphones and dispose of Flexicoupler single patient use earphone.
- Clean earphone cables according to hospital guideline for cleaning equipment that has come into contact with patients.
- Store earphone cable in the cart drawer.

Turn off screener

- Press the main power switch at the back of the screener to the off (O) position. Note: Wait 15 seconds after the completion of the final screen and printing of the results label to ensure proper computer storage of the last screening result.
- Disconnect and store power cord by draping power cord loosely around the top of the mast behind the monitor.

Date Completed: ______________________________

Observed By: ______________________________

Competency Evaluation for Screening with the ALGO® 3i Newborn Hearing Screener

NAME: ____

POSITION: ____________________________________

ID#: ____

PROCEDURE	√	COMMENTS
1. Power on and start-up		
Turn on the screener by sliding the on/Off switch upward and releasing it.		
2. Select screening mode and enter patient information		
Select optional SpeedScreen™ mode to immediately begin screening and enter patient information during the screening process (*This mode is disabled at the default setting.)*		
Select default Enter Data/ScreenBaby mode to enter patient information prior to screening.		
3. Prepare Baby and attach supplies		
Collect Supplies		
Evaluate sensor sites and prep if necessary		
Connect the colored sensor clips to the sensors		
Place sensor with attached clip on the baby in the proper locations **Black clip** to **Vertex (**center forehead, as high as possible) **White** clip to **Nape** (center and back of neck) **Green** clip to **Common** (shoulder)		
Check impedance and adjust sensor connections if necessary		
Attach transducers to earphones		
Place earphones on baby **Blue** transducer: **Left** ear **Red** transducer: **Right** ear		
Allow baby to quiet down or fall asleep		

ALGO 3i Competency Evaluation (cont'd)

4. Select screening parameters 35 dB nHL – Simultaneous, Sequential, or Single-ear screening Optional 40 dB nHL (*disabled at default setting*) – Sequential or Single-ear screening (Simultaneous screening not available at this intensity)		
5. Begin and observe screening in progress		
Select OK		
Observe screening as necessary (monitor impedances)		
View Results		
6. Remove discard supplies Remove supplies from baby and discard		
7 Return to Main Menu/Disposition screening record		
Return to the Main Menu or go to the Data Management option for printing, exporting, or deleting the screening record		
8. Record results according to screening protocol		
9. Power off Turn off the device by sliding and holding the on/Off switch for 3 seconds		
10. Clean up and shut down screener		
11. Charge battery pack		

_____________________ has been observed in the completion of the above skills.

OBSERVED BY: _____________________ DATE: ___________________

Additional Training Resources for Nursery Staff

Hospital Training Module for reporting newborn hearing screening, CCHD, and metabolic screen results to NC DHHS (should be used to establish an account in WCSweb/hearing link for all new users)

http://www.surveygizmo.com/s3/2734152/Hearing-Link-Hospital-User-Training-Module-Registration

Newborn Hearing Screening

- **Hearing Screener Sensitivity Training**
  https://www.surveygizmo.com/s3/4361910/HEARING-SCREENER-SENSITIVITY-TRAINING-REGISTRATION
- **NCHAM- National Center for Hearing Assessment and Management Newborn Hearing Screening Training Curriculum- NHSTC**
  https://www.infanthearing.org/nhstc/index.html

Critical Congenital Heart Disease (CCHD)

- **Critical Congenital Heart Disease Screening in NC, CCHD part 1**
  https://vimeo.com/163933536
- **Safe and Effective CCHD Screening in NC, CCHD series part 2**
  https://vimeo.com/163933601

- **Hearing Link Training Update for reporting CCHD results to NC**
  https://ncdhhschildrenandyouth.adobeconnect.com/p44qcd1k9l8k/?proto=true

Metabolic Screening

- **Pre-collection Process Training from NC DHHS (1 Clinical Education Credit annually)**
  https://slph.adobeconnect.com/_a1110789422/nbspt1/
- **Collection and Transportation Process Training from NC DHHS (1 Clinical Education Credit annually)**
  https://slph.adobeconnect.com/_a1110789422/nbspt2/

Other information for families and providers about **CCHD, Metabolic Screening, and Severe Combined Immunodeficiency (SCID)** can be found at
https://publichealth.nc.gov/wch/families/newbornmetabolic.htm
Other information for families and providers about **Newborn Hearing Screening** can be found at http://www.ncnewbornhearing.org