INTRODUCTION:

The Audiology Working Group of the Advisory Council for Newborn Hearing Screening developed these guidelines. This group of volunteers convened on August 10, 2005. The protocols contained in this document represent best practices in newborn hearing screening. Individual hospitals are encouraged to develop their own unique UNHS manual. There is no substitute for a thorough, site-specific, step-by-step Standard Operating Procedure. This guideline is designed to provide a model for greater statewide consistency and quality in newborn hearing assessment and management.

National recommendations specify that all infants with hearing impairment should be identified by 3 months of age and receive intervention by 6 months of age. To achieve this goal, a hearing screen must be performed on all newborns within the first month of life. This test is commonly referred to as universal newborn hearing screening (UNHS). Important aspects of any UNHS program include personnel selection, training and supervision, equipment selection and maintenance, screening protocols, including pass/refer and retest criteria, parent communication, educational follow-up and case management.

BACKGROUND:

On October 1, 1999, Maryland became the 13th State to mandate hearing testing of all babies born in the State (HB 884/SB 624). The new directive, an extension of the Program to Identify Hearing Impaired Infants housed at the Department of Health and Mental Hygiene (DHMH) since 1984, required that:

- Each hospital that provides obstetrical services institute a Universal Newborn Hearing Screening program to ensure that all newborns born in the hospital are screened for hearing loss before discharge.
- Screening results on each infant with a risk factor are reported to DHMH on the form specified by the State.
- DHMH develop and maintain a system to gather and maintain data.
- DHMH communicate results of the hearing screenings to parents, guardians and primary care providers, making referrals to appropriate resources as necessary, including the establishment of a telephone hotline.
- An Advisory Council gives support to the State program.
In addition, the law requires:

- Early identification and follow-up of babies who are referred by the hearing screen and/or have risk factors, and,
- Mandatory insurance coverage of the hearing screening.

PURPOSE OF UNHS:

The goal of a UNHS program is the identification of newborns and young infants at risk for hearing impairments that may affect health, speech and language development, communication and general learning. Early identification allows timely audiological, medical and educational intervention. A secondary benefit of a UNHS program is the confirmation of normal peripheral auditory function in newborns at the time of screening.

PERSONNEL:

Licensed audiologists are uniquely qualified professionals with expertise in the development, implementation, and on-going operation of a UNHS Program. Licensed audiologists shall be responsible for advising the hospital about all aspects of the newborn hearing screening program. Comprehensive audiological supervision for screening protocols, technology, personnel, training, data tracking, follow-up and referral is provided by the audiologist/manager for each program.

Although audiologists do not need to conduct actual screening tests, they act as consultants, make pass/refer decisions, provide follow-up assessment and enable intervention services.

It is highly recommended that an audiologist be involved in “making rounds” to inform parents of hearing screening results. In the case of a no-pass screening result, it is strongly advised that the audiologist make direct contact with the parent. In the case of a no-pass hearing screening, involvement of the audiologist from the start establishes an initial point-of-contact for the parents/caregivers. This relationship helps to avoid a breakdown in continuing evaluation and follow-up.
Hands-on screening by any of the following personnel is acceptable:

- Audiological staff (audiologists and audiological technicians)
- Trained paraprofessional staff
- Trained nursing staff
- Trained volunteers.

Each hospital will appoint a person as a designated point of contact (POC) for newborn screening activities. A licensed audiologist is the preferred POC. This individual will act as the liaison between the hospital and DHMH.

**TRAINING AND SUPERVISION:**

Assuring screener competency is critical to UNHS. Training qualified screeners has been demonstrated to be an on-going process.

Resources for training may include experienced UNHS program managers, local licensed audiologists, web-based programs, other multimedia resources.

Training modules should be based on best practices as reported in current professional literature.

The three phases of a training program are:

1. Initial instruction and competency-based demonstration of trainees' skills in the nursery environment. A shadowing/observation period is advised.
2. Periodic direct observation by an audiologist in the nursery environment: A competency based checklist demonstrating a trainee’s performance should be signed off by the supervising audiologist at regular intervals.
3. Periodic refresher training and continual training support.

**EQUIPMENT AND MAINTENANCE:**

The existing physiologic screening procedures for newborn hearing screening are otoacoustic emissions (OAE) and auditory brainstem responses (ABR).

There are two OAE technologies that are currently used for hearing screening; transient otoacoustic emissions (TOAE) and distortion product otoacoustic emissions (DPOAE). OAEs can be screened on automated or diagnostic equipment.
ABR can be screened on automated or diagnostic equipment. Screening equipment is often referred to as AABR (automated auditory brainstem response) or SABR (screening auditory brainstem response).

Commercial screening equipment utilizing either/both of these methods and meeting ANSI specifications and calibration standards are acceptable. A quality UNHS program must continue to assimilate new and improved technology.

SCREENING PROTOCOLS:

LEVEL I: INITIAL NEWBORN HEARING SCREENING PRIOR TO HOSPITAL/BIRTHING FACILITY DISCHARGE

Level I screenings shall be performed on all babies prior to discharge. Following the NIH protocol, repeat screenings, should be done as often as possible while the baby remains in the hospital. Results of screenings/re-screenings must be put into a data tracking system established for each hospital’s UNHS program.

Results of hearing screening shall be recorded on the metabolic screening form (PKU form) that is sent to the state Laboratory. The Lab enters the data into the DHMH infant hearing database.

If parents refuse hearing screening it must be noted on the metabolic screen form sent to the state and in the hospital data tracking system.

Parents should be provided with the results of the hearing screening and any recommendations for follow-up. The pediatrician should be provided with similar information. This communication with parent and physician may be in the form of a letter or any other written format.

It is strongly recommended that a licensed audiologist provide the parents with results of the screening, particularly when there is a referral for follow-up screening.

For babies who are referred for outpatient screening, a State of Maryland Level II form must be filled out. Results of the outpatient screening are recorded on the Level II form. The original is to be sent to the Maryland DHMH and the blue copy to the newborn’s pediatrician. If the baby does not return for outpatient screening, “no show” status is indicated and the form is forwarded to the state.

In order to identify auditory neuropathy/dysynchrony, OAE plus ABR screening is recommended for all newborns when possible. OAE and ABR screening is strongly advised when there is a family history of childhood hearing loss and for all NICU babies.
Hospitals are mandated to screen the hearing of all newborns. An efficient program should screen 95% plus of the newborn population. An acceptable protocol should aim for a referral rate of no more than 4% for well babies who have no known risk factors for hearing impairment and no more than 10% for infants with known risk factors for hearing impairment.

**LEVEL II: FOLLOW-UP OF NEWBORNS REFERRED BY INITIAL SCREENING**

As stated in the Level I outline above - For babies who are referred for outpatient screening, a State of Maryland Level II form must be filled out. Results of the outpatient screening are recorded on the Level II form and sent to the Maryland DHMH and the baby’s pediatrician. If the baby does not return for outpatient screening, "no show" status is indicated and the form is forwarded to the state. (Note: a Level III form is used for diagnostic testing results only.)

LEVEL II (outpatient screening) may be performed with the same equipment and protocols as the inpatient (LEVEL I) screen. The screen should be done by one month of age.

**PASS/REFER CRITERIA:**

**Non-automated screening equipment:**

The screening program should establish evidence-based pass/refer criteria. For example, for TEOAE technology, parameters should be established for number of frequencies (3 out of 5 or 4 out of 5) and acceptable stimulus range (78-84dBpe.).

Both right and left ears must be tested. If a response is absent from either ear a retest must follow. Both ears should be tested each time.

The hospital discharging the infant to home is responsible for the screening, even if the infant was screened and passed at a previous hospital. In the event that follow up screening is indicated, the discharging hospital is responsible for follow up. Changes in the newborn’s health status and impact on hearing are accommodated by this procedure.

**Comment [13]:** I would be reluctant to put any threshold screening criteria since the legislation does not stipulate any. Hospitals should strive for 100%.

**Comment [14]:** I would be cautious about calling it an acceptable protocol. Current survey data varies depending on equipment used for screening, plus these numbers have changed over time. Last EDHI survey data I believe quoted 2% in the well baby population and 7-8% in the NICU population which is significantly different from the data in the early 90’s of 22-25%. If the council recommends 4 and 10% as acceptable criteria, hospitals will be able to cite this as the standard and not institute tighter controls on screening.

**Comment [15]:** Most of the screening programs that are clamoring for these protocols are not capable of doing evidence based research to establish a pass/fail criteria and are using a hodge podge of criteria be it manufacturer’s recommendations to "I don’t know that’s just what’s on the computer". I would strongly urge the group to put forward a specific pass criteria, e.g. 4dB at 4 frequencies for TOAE, et. A lit review with published norms even with the cavaer, just like with ABR, that each site establish their own norms.
COMMUNICATION TO STAKEHOLDERS:

Reports of newborn hearing screening results should be provided:

1. To Parents:
   - Reasons for doing newborn hearing screening
   - Explanation of the test method/procedure.
   - A written review of the test results and any follow-up instructions.
   - Information on developmental milestones for speech, language, and hearing
   - Risk factors for late or progressive onset of hearing loss, including otitis media
   - Parental option to refuse the screening
2. To the State of Maryland via state approved forms.
3. To Primary Care Physicians - via method established by the screening program/hospital. The blue copies of the level 2 form should be sent to the pediatrician
4. To Early Intervention Programs - via communication of the audiologist POC.

FOLLOW UP PROTOCOLS:

UNHS is part of a continuum of care that progresses from screening to assessment to amplification to educational intervention. Referrals for diagnostic assessment should be made to audiologists with expertise in pediatric management.

The recommended time line includes:

- Complete screening by one month of age
- Diagnostic assessment by three months of age
- Initiation of amplification and intervention by six months of age.

Without an adequate follow-up plan, even the best UNHS program is ineffective.

QUALITY ASSURANCE:
Components of a quality assurance program include data management, screener performance, site performance, outcome measures, and follow-up compliance.

**RECOMMENDED PROTOCOLS**

**LEVEL 3 DIAGNOSTICS**

The following protocol was developed to facilitate the diagnosis of hearing loss by three months of age. Audiologists providing services to the infant and toddler population should have the necessary equipment (ABR with bone conduction and tone bursts, OAE, high frequency tympanometry, etc.) and be experienced in the assessment of infants. If the audiologist does not have the equipment or expertise they should refer the infant to a center with those skills.

Within the first two months of life, the procedures outlined below should be completed on all infants referred from the screening process. Use the *Newborn Audiological Assessment Checklist* found in Appendix 1 to assure that all recommended follow-up activities have been completed. Send a copy of this Checklist to the Pediatrician, Early Childhood Interventionist or to the audiologist if the child’s audiologic care is transferred. This will allow others to see quickly the services already provided and those that might need further attention.

The following audiologic services should be available and provided as needed to infants referred for Level III Diagnostic testing.

- Otoscopic examination
- Threshold click ABR - 25dBHL or lower each ear
- Bone conduction ABR if click stimuli thresholds elevated (above 25dBHL)
- Ear specific bone conduction ABR if thresholds elevated bilaterally or asymmetric loss suspected
- Threshold tone burst ABR 500Hz and 3,000 or 4,000Hz
- Repeat OAE
- Acoustic immittance using high frequency tone
- Acoustic reflex thresholds 500Hz, 1,000Hz and 4,000Hz
- Family counseling on findings and recommendations
- Appropriate referrals- i.e. ENT, Parent- Infant-Toddler, etc. with parent’s consent.
- Complete Level 3 Form and return to DHMH
- Schedule follow-up appointments for additional testing and any intervention indicated.

*Comment [18]*: Should there not be some recommended testing parameters in here and recommended pass criteria for tone burst?

*Comment [19]*: Diagnostic OAE as opposed to screening OAE????

*Comment [10]*: Are these services? Seems like these should be somewhere else or the listing should be a time line or list of follow-up procedures