Virginia Hearing Impairment Identification and Monitoring System
Hospital Protocols for Newborn Hearing Screening

The focus of this document is to provide guidance and recommended procedures for best practice to be used by hospitals for universal newborn hearing screening programs as required by Section 32.1-64.1 of the *Code of Virginia.* Hospitals can certainly go beyond these recommendations. It is important to recognize that newborn hearing screening is only one component of a comprehensive approach to the management of childhood hearing loss. The process also requires follow-up diagnostic services, counseling, intervention programs, and parental educational programs. This comprehensive process must be administered by a multidisciplinary team consisting of individuals such as audiologists, physicians, educators, speech/language pathologists, nurses, and parents. Both otologic and genetic consultation are recommended in the management of childhood hearing loss.

Definitions

- *At risk* means considered to be in a status with a significant probability of having or developing hearing loss as a result of the presence of one or more factors identified or manifested at birth.
- *Audiologist* means a person who is licensed by the Commonwealth of Virginia to provide audiological services.
- *Auditory brainstem response* means an objective electrophysiologic measurement of the peripheral auditory system via acoustic click stimulation of the ear.
- *Automated auditory brainstem response* means objective electrophysiologic measurement of the peripheral auditory system to acoustic stimulation of the ear, obtained with equipment which automatically provides a pass/refer outcome.
- *Automated evoked otoacoustic emissions* means an objective physiologic response from the cochlea, obtained with equipment which automatically provides a pass/refer outcome.
- *Diagnostic audiologic evaluation* means physiologic and behavioral procedures required to evaluate and diagnose hearing status.
- *Discharge* means release from the hospital after birth to the care of the parent.
- *Evoked otoacoustic emissions* means an objective physiologic response generated from the cochlea, and may include click evoked otoacoustic emission and/or distortion product otoacoustic emission test procedures.
- *Follow-up* means appropriate services and procedures relating to the confirmation of hearing loss and appropriate referrals to an audiologist for infants with abnormal or inconclusive screening results.
- *Hearing loss* means a dysfunction of the auditory system of any type or degree that is sufficient to interfere with the acquisition and development of speech and language skills.
- *Hearing screening* means an objective physiological measure to be completed in order to determine the likelihood of hearing loss.
- *Incomplete result* means that the infant should be referred for a follow-up diagnostic audiological evaluation. This could include uncooperative infant, debris in ear canal and excess miogenic activity.

- *Infant* means a child under the age of one year.
- *Initial hearing screening* means the procedure(s) employed for the purpose of screening hearing prior to discharge.
- *Miss* means an infant did not have a hearing screening prior to discharge.
- *Neonatal intensive care services* means those services provided by a hospitals newborn services that are designated as both specialty level and subspecialty level as defined in subdivision D 2 of 12 VAC 5-410-440, the Rules and Regulations for the Licensure of Hospitals in Virginia.
- *Parent* means biological parent, stepparent, adoptive parent, legal guardian, or other legal custodian of a child.
- *Primary medical care provider* means the person to whom the infant will go for routine medical care following hospital discharge.
- *Referral* means to direct an infant who does not pass the initial hearing screening to an audiologist for appropriate diagnostic procedures to determine the existence and extent of a hearing loss as well as for appropriate habilitation of a hearing loss.
- *Risk factor/indicator* means a factor/indicator known to place an infant at increased risk for being born with or developing a hearing loss, including but not limited to any one of the following:

    1. Family history of hereditary, childhood sensorineural hearing loss.
    2. In utero infection (e.g., cytomegalovirus, rubella, herpes, toxoplasmosis, syphilis).
    3. Craniofacial anomalies including those with morphological abnormalities of the pinna and ear canal.
    4. Birthweight less than 1500 grams.
    5. Hyperbilirubinemia at a serum level requiring exchange transfusion.
    6. Bacterial meningitis.
    7. Apgar scores of 0 to four at one minute or 0 to six at five minutes.
    8. Ototoxic medications, including but not limited to the aminioglycosides, used in multiple courses or in combination with loop diuretics.
    9. Mechanical ventilation lasting five days or longer.
    10. Stigmata or other findings associated with a syndrome known to include a sensorineural hearing loss, a conductive hearing loss or both.
    11. Neurofibromatosis Type II.
    12. Persistent pulmonary hypertension of the newborn (PPHN).

Procedural Protocols

Single Point of Contact

Each hospital shall designate a person to be responsible for the newborn hearing screening program in that facility. This person will act as the single point of contact between the facility and the Virginia Department of Health's Virginia Hearing Impairment Identification and Monitoring System. It is the responsibility of the facility to ensure that all screening personnel are appropriately trained to carry out the newborn hearing screening using appropriate technology. A licensed audiologist with appropriate training and experience shall advise the hospital about all aspects of the newborn hearing screening program, including screening, tracking, follow-up and referral. For hospitals that do not have access to audiological personnel, the Virginia Department of Health can provide the names of audiologists with experience in newborn hearing screening.

Screening

Beginning July 1, 1999, hospitals with neonatal intensive care services will be responsible for screening the hearing of all newborns prior to discharge after birth.

Beginning July 1, 1999 and ending June 30,2000, hospitals with newborn nurseries and no neonatal intensive care services will be responsible for identifying infants at-risk for hearing loss.

Beginning July 1, 2000, all hospitals will be responsible for screening the hearing of all newborns prior to discharge after birth.

Education and Reporting

- Beginning July 1, 1999, hospitals that are required to screen all infants (hospitals with neonatal intensive care services by July 1, 1999; all hospitals by July 1,2000) shall:

  Provide written information to the parent, prior to discharge, that includes purposes and benefits of newborn hearing screening, indicators of hearing loss, procedures used for hearing screening, results of the hearing screening, the recommendations for further testing, and where the testing can be obtained.

  Provide written information to the infant's primary medical care provider that includes procedures used for hearing screening, the limitations of screening procedures, the results of the hearing screening, and the recommendations for further testing.

  Within one week of discharge complete the Virginia Department of Health report, as required by the *Code of Virginia,* on each infant who does not pass the hearing screening and send it to the Virginia Department of Health.

  On a monthly basis, send to the Virginia Department of Health a report of the total number of births, the total number of discharges, total number of infants who passed the

newborn hearing screening, the total number who failed, and the total number not tested due to parents' objection based on their bona fide religious convictions.

- Beginning July 1, 1999 and ending June 30, 2000, hospitals that are not required to screen all infants *shall:*

    Provide written information to the parent, prior to discharge, that includes the purposes and benefits of newborn hearing screening, what to do if the parent suspects a hearing loss, the infant's risk factor(s) for hearing loss if present, the recommendations for hearing screening, and where the screening can be obtained.

    Provide written information to the infant's primary medical care provider that includes the identified risk factor(s) for hearing loss, the recommendations for hearing screening, and where the screening can be obtained.

    Within one week of discharge complete a Virginia Department of Health report on each infant identified at risk for hearing loss and send it to the Virginia Department of Health.

    On a monthly basis, send to the Virginia Department of Health a report of the total number of births, the total number of discharges, and the total number of infants who were identified at risk for hearing loss.

- Beginning July 1, 1999, hospitals that elect to screen the hearing of all infants shall:

    Provide written information to the parent, prior to discharge, that includes purposes and benefits of newborn hearing screening, indicators of hearing loss, procedures used for hearing screening, results of the hearing screening, the recommendations for further testing, and where the testing can be obtained.

    Provide written information to the infant's primary medical care provider that includes procedures used for hearing screening, the limitations of screening procedures, the results of the hearing screening, and the recommendations for further testing.

    Within one week of discharge complete the Virginia Department of Health report, as required by the *Code of Virginia,* on each infant who does not pass the hearing screening and send it to the Virginia Department of Health.

    On a monthly basis, send to the Virginia Department of Health a report of the total number of births, the total number of discharges, total number of infants who passed the newborn hearing screening, the total number who failed, and the total number not tested due to parents' objection based on their bona fide religious convictions.

- Beginning July 1, 1999, all hospitals shall report to the Virginia Department of Health, on an annual basis, the following information: the test procedures used by the facility's newborn hearing screening program; the name of the program director, name of advising audiologist; equipment utilized; equipment calibration records; screening protocols; and, referral criteria.

Follow-up

- An infant who does not pass initial hearing screening shall be referred for a diagnostic audiological evaluation at a center approved by the Virginia Department of Health. Prior to discharge the hospital shall give written information to the parent as to where this evaluation can be obtained. The Advisory Committee recommends that this evaluation occur within one month of hospital discharge.

- Infants with incomplete hearing screening results shall also be referred for follow-up diagnostic audiological evaluation.

- For infants who are missed, the hospital shall inform the parent, prior to discharge, of the need for the hearing screening and provide a mechanism by which that screening can occur at no additional cost to the family.

- It is recommended that infants who are at risk for delayed onset/progressive hearing loss should be rescreened by three months of age but no later than six months of age despite passing the initial hearing screening. Hospitals should refer to Joint Committee on Infant Hearing 1994 Position Statement recommendations for indicators associated with delayed onset hearing loss.

Screening Methodologies

Introduction

A variety of technologies are currently available to identify hearing loss in the first days of life. Two of the current methodologies generally accepted as effective for universal newborn hearing screening are auditory brainstem response (ABR) and evoked otoacoustic emissions (EOAE).

NIH/NIDCD (1993), the Joint Committee on Infant Hearing (1994), and the American Academy of Pediatrics (1999) identify acceptable methodologies as ABR and EOAE either alone or in combination. These techniques are physiological measures of the status of the peripheral auditory system that are highly correlated with hearing status. The techniques permit the identification of infants with communicatively significant hearing impairment without referring large numbers of normally hearing infants for unnecessary follow-up testing.

The Advisory Committee recognizes that the majority of newborn hearing screenings will be performed by a variety of personnel including medical and non-medical personnel. Studies have documented that the actual screening can be carried out effectively by a wide variety of personnel with appropriate training. Training and quality assurance measures are vital components for the efficiency and overall effectiveness of screening programs. Recognizing the diversity in personnel, the Advisory Committee recommends the use of automated instrumentation that provides a pass / refer test outcome as the initial hearing screening device for hospitals considering the purchase of equipment.

Acceptable hearing screening protocols should have specific response attributes and measurement characteristics. Some of these desired response and methodological features are:

- the response should be robust;
- the response should be dependent upon the integrity of the peripheral auditory system;
- the response should have predictive value;
- the response should be measured non-invasively;
- the procedure should employ scientifically-based, objective criteria to define both the method for a technically correct screening test and the guidelines for a pass versus refer rule;
- the procedure should be capable of testing each ear independently;
- the procedure should be manageable in a hospital or birthing center setting in order to provide access to the greatest number of neonates, thus promoting the universality of hearing screening.

The Advisory Committee recommends that the hearing screening procedure should achieve a false-positive rate of less than or equal to three percent and a false-negative rate of 0 in order to prevent unnecessary costs and parental anxiety. In addition, newborn hearing screening can be expected to result in a referral rate of no greater than 10% for infants in neonatal intensive care services and a referral rate of less than 4% for infants in the regular nursery.

The Virginia Department of Health will regularly monitor the false-positive rates and the referral rates at individual hospitals and will assist hospitals to achieve the recommended false-positive and referral rates.

Protocols for Non-automated Hearing Screening Devices

Auditory brainstem response (ABR)

Stimulus - air conduction click (preferably delivered with an insert transducer)

Pass Criteria

- replicable waves I and/or V response @ 35dB nHL for both the right and left ears

(Click) Transient evoked otoacoustic emission (TEOAE)

Stimulus - air conduction click

- intensity - 80 ± 3 dBSPL

Pass Criteria

- frequencies - 1000 Hz through 4000 Hz
- 3 of 4 frequencies having reproducibility of minimally:
- 60% @ 1600 Hz
- 70% @ 2400 Hz, 3200 Hz, and 4000 Hz

Distortion product otoacoustic emissions (DPOAE)

Stimulus - pure tone complex

- intensity - maximum levels < 65dB SPL

Pass Criteria

- F_2= 1000 Hz, 2000 Hz, 3000 Hz, and 4000 Hz
- 3 of 4 frequencies having a distortion product ($2F_1 - F_2$) amplitude $\geq$ 5dB than measured noise floor levels

Calibration of Equipment

Hearing screening equipment should be calibrated annually and documentation maintained at the hospital. Statement of calibration shall be included in the facility's annual report to the Virginia Department of Heath.

VIRGINIA DEPARTMENT OF HEALTH

PROTOCOLS FOR DIAGNOSTIC AUDIOLOGICAL ASSESSMENT: FOLLOW-UP FOR NEWBORN HEARING SCREENING

It is recommended that infants who are referred for assessment after birth be evaluated using these protocols. The protocols were developed by a Task Force comprised of six audiologists, licensed in Virginia, with extensive knowledge and experience in the screening and diagnosis of newborns. The judgement regarding a facility's ability to provide diagnostic audiological services to infants is equipment-driven, as there is currently no certification for pediatric audiology.

Definitions

- *At risk* means considered to be in a status with a significant probability of having or developing hearing loss as a result of the presence of one or more factors identified or manifested at birth.
- *Audiologist* means a person who is licensed by the Commonwealth of Virginia to provide audiological services.
- *Auditory brainstem response* means an objective electrophysiologic measurement of the peripheral auditory system via acoustic click stimulation of the ear.
- *Automated auditory brainstem response* means objective electrophysiologic measurement of the peripheral auditory system to acoustic stimulation of the ear, obtained with equipment which automatically provides a pass/refer outcome.
- *Automated evoked otoacoustic emissions* means an objective physiologic response from the cochlea, obtained with equipment which automatically provides a pass/refer outcome.
- *Diagnostic audiologic evaluation* means physiologic and behavioral procedures required to evaluate and diagnose hearing status.
- *Discharge* means release from the hospital after birth to the care of the parent.
- *Evoked otoacoustic emissions* means an objective physiologic response generated from the cochlea, and may include click evoked otoacoustic emission and/or distortion product otoacoustic emission test procedures.
- *Follow-up* means appropriate services and procedures relating to the confirmation of hearing loss and appropriate referrals to an audiologist for infants with abnormal or inconclusive screening results.
- *Hearing loss* means a dysfunction of the auditory system of any type or degree that is sufficient to interfere with the acquisition and development of speech and language skills.
- *Hearing screening* means an objective physiological measure to be completed in order to determine the likelihood of hearing loss.
- *Incomplete result* means that the infant should be referred for a follow-up diagnostic audiological evaluation. This could include uncooperative infant, debris in ear canal and excess miogenic activity.
- *Infant* means a child under the age of one year.
- *Initial hearing screening* means the procedure(s) employed for the purpose of screening hearing prior to discharge.
- *Miss* means an infant did not have a hearing screening prior to discharge.

- *Neonatal intensive care services* means those services provided by a hospitals newborn services that are designated as both specialty level and subspecialty level as defined in subdivision D 2 of 12 VAC 5-410-440, the Rules and Regulations for the Licensure of Hospitals in Virginia.
- *Parent* means biological parent, stepparent, adoptive parent, legal guardian, or other legal custodian of a child.
- *Primary medical care provider* means the person to whom the infant will go for routine medical care following hospital discharge.
- *Referral* means to direct an infant who does not pass the initial hearing screening to an audiologist for appropriate diagnostic procedures to determine the existence and extent of a hearing loss as well as for appropriate habilitation of a hearing loss.
- *Risk factor/indicator* means a factor/indicator known to place an infant at increased risk for being born with or developing a hearing loss, including but not limited to any one of the following:

    1. Family history of hereditary, childhood sensorineural hearing loss.
    2. In utero infection (e.g., cytomegalovirus, rubella, herpes, toxoplasmosis, syphilis).
    3. Craniofacial anomalies including those with morphological abnormalities of the pinna and ear canal.
    4. Birthweight less than 1500 grams.
    5. Hyperbilirubinemia at a serum level requiring exchange transfusion.
    6. Bacterial meningitis.
    7. Apgar scores of 0 to four at one minute or 0 to six at five minutes.
    8. Ototoxic medications, including but not limited to the aminoglycosides, used in multiple courses or in combination with loop diuretics.
    9. Mechanical ventilation lasting five days or longer.
    10. Stigmata or other findings associated with a syndrome known to include a sensorineural hearing loss, a conductive hearing loss or both.
    11. Neurofibromatosis Type II.
    12. Persistent pulmonary hypertension of the newborn (PPHN).

General Information

The parent will receive information on a child's hearing screening status prior to hospital discharge. Both the parent and primary medical care provider will be advised that any child who refers from a hospital newborn hearing screening program should receive follow-up within a Month. The goal of Virginia's Newborn Hearing Screening Program is diagnosis of congenital hearing loss by three months of age and appropriate amplification and/or intervention by six months of age.

The Virginia Department of Health's Virginia Hearing Impairment Identification and Monitoring System database will track infants who are identified as at-risk for hearing loss, infants who refer on the hearing screening prior to discharge from the hospital after birth and infants who pass but are at-risk for progressive or emergent hearing loss. The Virginia Department of Health (VDH) will send a letter to the parent of these infants to insure that they have received the appropriate recommendations at discharge. VDH will also send letters to the parent of any child who is diagnosed with hearing loss, again to assure that they have access to the information they need to make informed decisions for their child.

For persons who provide audiological services to infants following discharge from the hospital after birth, the following responsibilities are outlined in the proposed amended Regulations for Administration of the Virginia Hearing impairment Identification and Monitoring System:

- provide the screening or evaluation results to the parent and to the child's primary medical care provider;
- send a Virginia Department of Health report including test results, diagnosis and recommendations to the Virginia Department of Health within two weeks of the visit;
- advise the parent about and offer referral to local early intervention or education programs; and,
- give resource information to the parent of any child found to have a hearing loss, including but not limited to the degrees and effects of hearing loss, communication options, the importance of medical follow-up, and agencies and organizations that provide services to children with hearing loss and their families.

VDH is currently working on a Parent Resource and Information Guide designed for parents of children who are diagnosed with hearing loss. It is anticipated that this will be available by the end of the year. This guide will be made available to any audiologist or facility that provides diagnostic audiological services to children.

Diagnostic Protocols

Infants will be referred from hospitals for three reasons:

- they did not pass the hearing screen in the hospital prior to discharge;
- they passed but were at risk for progressive/late onset hearing loss; or
- they were identified as at-risk for hearing loss.

Obtain hospital screening results and a medical history. Otoacoustic Emissions (OAE) * (see pass criteria at the end of this document) is required as the initial re-test procedure. If the infant passes, then the evaluation is complete unless the audiologist feels that there is a need for further comprehensive testing based on the medical history. For infants who are at-risk for progressive or emergent hearing loss, the parent should be counseled regarding the need for continued monitoring.

If the infant fails or refers from the OAE in one or both ears, an air conduction threshold Auditory Brainstem Response (ABR) * (sec pass criteria at the end of this document) should be completed at the same visit.

- If the infant passes, then the evaluation is complete. For infants who are at-risk for progressive or emergent hearing loss, the parent should be counseled regarding the need for continued monitoring.
- If results are 25-40 dB nHL, bone conduction threshold ABR should be obtained.
  - If bone conduction results arc equal to or less than 20 dB nHL, perform acoustic immittance/otoscopy.
  - Refer for medical evaluation of ears and follow-up in three months.
  - On the return visit following medical referral for possible conductive bearing loss, repeat OAE and ABR if fail, as well as acoustic immittance, same as previous protocol.

- If results are indicative of hearing loss (25 dB nHL or greater without middle ear pathology), child should be seen/referred for:
  - a medical evaluation,
  - genetic counseling,
  - local early intervention services,
  - amplification,
  - behavioral testing and
  - routine follow-up.

At the time of each visit, the parent should be given the test results, as well as appropriate explanations and information. Results should be sent to the primary medical care provider and to VDH within two weeks of the visit.

All diagnostic audiological equipment should have annual calibration meeting current ANSI standards.

*Criteria

(Click) Transient evoked otoacoustic emission (TEOAE)

Stimulus - air conduction click
- intensity - 80 ± 3 dBSPL

Pass Criteria
- frequencies - 1000 Hz through 4000 Hz
- 3 of 4 frequencies having reproducibility of minimally:
  - 60% @ 1600 Hz
  - 70% @ 2400 Hz, 3200 Hz, and 4000 Hz

Distortion product otoacoustic emissions (DPOAE)

Stimulus - pure tone complex
- intensity - maximum levels $\leq$ 65dB SPL

Pass Criteria
- F_2 = 1000 Hz, 2000 Hz, 3000 Hz, and 4000 Hz
- 3 of 4 frequencies having a distortion product ($2F_1 - F_2$) amplitude $\geq$ 5dB than measured noise floor levels

Auditory brainstem response (ABR)

Pass Criteria
- replicable wave V response thresholds less than or equal to 20 dB nHL click stimulus for both ears