

Guidelines for Infant Hearing Screening, Referral, Audiologic Assessment, Hearing Loss Management and Early Intervention

Florida Early Hearing Loss Detection and Intervention Advisory Council

These guidelines were developed to facilitate the confirmation of hearing loss by three (3) months of age. Health and Human Services' Healthy People 2010 includes the following goal for infants: to confirm hearing loss by three months of age with appropriate intervention no later than six months of age. With existing technology and expertise, this goal can be met routinely. The purpose of these guidelines is to identify referral protocols and the essential components of an audiologic assessment. Infants are candidates for audiologic assessment when they have not passed a two-stage hearing screening in the birthing facility using physiologic measures and an outpatient screening using physiologic measures within 2-4 weeks of discharge from the birthing facility. Procedures and protocols for the initial and outpatient hearing screenings can be found in the Florida Suggested Guidelines for Infant Hearing Screening Services.

I. An Overview of the Florida Infant Hearing System

Purpose: The purpose of the Newborn Hearing Screening Program is to support early identification and timely and appropriate intervention to prevent or minimize developmental delays due to hearing loss. The Maternal and Child Health Bureau, the Joint Committee on Infant Hearing, the American Academy of Pediatrics, and the Centers for Disease Control and Prevention have provided recommendations for Newborn Hearing Programs. These recommendations will assure that infants who are screened will receive appropriate and timely follow-up. Research conducted at the University of Colorado has demonstrated that infants who are identified and begin early intervention no later than six months of age have a higher probability of reaching language milestones that are within normal limits.

Health Surveillance Responsibility: Children's Medical Services, a division of the Florida Department of Health, administers the Newborn Screening Program, which includes hearing and metabolic screening. Newborn screening is an activity described in its capacity as a public health authority as defined by the HIPAA, Standards for Privacy of Individually Identifiable Health Information, Final Rule (Privacy Rule). Pursuant to 45 CFR 164.512(b) of the Privacy Rule, covered entities such as birthing facilities and audiologists may disclose, without individual authorization, protected health information (PHI) to public health authorities. Public health entities are authorized by law to collect or receive such information for the purpose of conducting public health surveillance, public health investigations, and public health intervention.

Data Management and Tracking: Florida Statutes 383.14 and 383.145 mandate the screening of all newborns in Florida for both hearing and metabolic disorders. In early 2005 the state metabolic laboratory will enter newborn hearing screening data into a data base. This will allow personnel at the Children's Medical Services Newborn Screening Unit to follow up on all newborns referred from birthing facilities due to a failed hearing screening or discharge without completion of the screening. Newborn Screening Unit personnel will contact parents, hospitals, physicians, and audiologists as needed to determine the result of follow up hearing testing.

Responsibility for Referring Newborns Following Hearing Screening

Identification: Physicians and hospitals are responsible for making the referral to a diagnostic audiologist. The audiologist has the professional education, skills, and equipment to perform a differential diagnosis to determine the integrity of the infant auditory system. It is important that the diagnostic evaluation be completed prior to three months of age in order to identify the hearing loss within the recommended time frame, reduce parental anxiety, and to possibly decrease the need for conscious sedation of the infant that would be required at older ages (> 3 months) to reliably perform confirmatory physiologic audiologic tests.

II. 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 State of Florida to provide audiologic services.
- *Auditory brainstem response (ABR)* is a class of auditory evoked responses intended as an objective electrophysiologic measurement of the auditory system via acoustic click (for measuring integrity of auditory nerve and brainstem pathways) or tone burst (for estimating auditory sensitivity) stimulation of the ear.
- *Auditory steady-state evoked response (ASSR)* is another type of auditory evoked potential. It is a diagnostic test that is an objective electrophysiologic measurement of the auditory system via a continuous tone that allows for evaluation of specific frequencies (i.e., pitches) and can be used to estimate the pure tone audiogram.
- *Automated auditory brainstem response* means objective electrophysiologic measurement of the auditory system to acoustic stimulation of the ear, obtained with equipment that automatically provides a pass/refer outcome.
- *Automated evoked otoacoustic emissions* means an objective physiologic response from the cochlea, obtained with equipment that 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 or guardian.
- *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 (newborn)* 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 audiologic evaluation. This could include uncooperative infant, debris in ear canal and excess myogenic (muscle movement) 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 from the birth facility. In cases of home births or those attended outside of a birth facility, the initial hearing screening can be performed in a hospital or clinical setting.
- *Miss* means an infant did not have a hearing screening prior to discharge.
- *Neonatal intensive care services* means those services provided by a hospital's newborn services that are designated as both specialty level and subspecialty level.
- *Newborn* means a child who is 28 days old or younger.
- *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 amplification fitting.
- *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 anyone of the following (Joint Committee on Infant Hearing 2000):
 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. Birth weight less than 1500 grams.
 5. Hyperbilirubinemia at a serum level requiring exchange transfusion.
 6. Bacterial meningitis.
 7. Apgar scores of 0 to 4 at one minute or 0 to 6 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).

III. ASSUMPTIONS UNDERLYING ASSESSMENT

The primary purpose of an audiologic assessment is the confirmation of hearing loss. When a hearing loss is confirmed, a description of the severity, type, and configuration may assist in the subsequent medical diagnosis and the determination of etiology. Therefore the assumptions underlying assessment of infants referred following newborn hearing screening include:

- 1) Newborns failing two or more newborn hearing screening tests or who are discharged from the hospital in refer status will be referred to an audiologist for hearing rescreen or an audiologic assessment
- 2) The audiologist should perform a battery of tests to describe and confirm hearing loss. Although audiologic assessment of infants is an ongoing process, hearing loss can be confirmed within the first months of life.

- 3) A referral from audiology to a physician, preferably to an otolaryngologist, is necessary to determine medical management needs and to obtain medical clearance for amplification.
- 4) Results of audiologic assessment are necessary to plan appropriate intervention strategies.

IV. MINIMUM REQUIREMENTS FOR PROVIDERS OF INFANT AUDIOLOGIC ASSESSMENT

Equipment

Audiologists who provide pediatric services must have access to specialized equipment for this population as currently there is no certification for “pediatric audiology” in Florida. Families prefer to go to one site rather than multiple sites for their infant’s audiologic assessment and to complete the battery of tests in one visit if possible. Facilities should have access to the equipment identified below:

- Auditory evoked response equipment must be capable of various stimulus levels, stimulus types (a) clicks, b) frequency specific stimuli such as tone bursts at audiometric frequencies and c) transducers (air conduction insert earphones and bone conduction oscillator). Auditory evoked response equipment includes an option for auditory brainstem response measurement with the above capabilities and/or auditory steady state response equipment combined with auditory brainstem response capability.
- Evoked otoacoustic emissions (OAE) test equipment, either transient-evoked OAE (TEOAE) and/or distortion product OAE (DPOAE) capable of a variety of test parameters, especially adjustment of stimulus levels; and
- Middle ear acoustic immittance analyzer for tympanometry and acoustic reflex threshold measurement with multi-frequency probe tones.

Additional equipment needed for on-going assessment via behavioral audiometry:

- Sound-treated audiometric test booth;
- Audiometer; insert earphones;
- Sound-field testing capability; and
- Visual reinforcement equipment.

Practitioner Qualification

Accurate infant audiologic assessment necessitates appropriate practitioner training and experience using the differential diagnosis equipment listed above and the protocols described herein. If the audiologist does not have the expertise and equipment to follow these guidelines, the infant and family should be referred to an audiologist equipped for and experience in infant audiologic assessment and/or infant amplification fitting. Audiologists who provide the audiologic assessment must hold a current Florida license in Audiology.

V. PROTOCOL FOR INFANT AUDIOLOGIC ASSESSMENT

It is imperative that a complete audiologic assessment to identify children with significant hearing loss be completed so that intervention services can begin as soon as possible. This is not a screening protocol. It is important for infants with an indication of middle ear involvement upon initial tympanometry testing to receive a

full assessment prior to medical referral. If a child was discharged from the well-baby nursery and was referred for audiologic evaluation, and if the child has no risk factors, and responds behaviorally to environmental stimulation, clinical findings of normal OAE results should be sufficient to assure adequate auditory input for speech and language development. If a child was discharged from the neonatal intensive care unit, has a significant history of prematurity, hyperbilirubinemia, hypoxia, and/or is only inconsistently responding to environmental sounds, then the preferred diagnostic test battery should include AER as one component. Regardless if a universal newborn hearing screening failure occurred in only one ear, audiologic evaluation will occur in both ears. The test battery for audiologic assessment of infants includes the following procedures:

Child-Family History

The Joint Committee on Infant Hearing Year 2000 Position statement outlined specific risk indicators for hearing loss in infants. Child-family history is to include the documentation concerning these risk indicators. Information must be solicited from the family regarding the child's behavioral responses to environmental sound stimulation. (See Appendix A for Example Infant Hearing History Form)

Otoscopic Inspection

An otoscopic examination of the infant's outer ears should be performed to ensure that the ear canals are sufficiently clear to proceed with further testing.

Evoked Otoacoustic Emissions (OAEs) Assessment

Transient-evoked OAE (TEOAE) or distortion-product OAE (DPOAE) are the two types of OAEs. Inclusion of OAE testing is to help confirm ABR findings, and differentiate between cochlear and purely retrocochlear sites of involvement.

- OAEs reflect cochlear function at the level of the outer hair cells. Accurate OAE measurement assumes that appropriate stimuli were used, testing was conducted in a sufficiently quiet place, the protocol used met acceptable guidelines, and the infant was quiet or sleeping. Auditory neuropathy (dys-synchrony cannot be ruled out on the basis of normal OAE test results alone. Depending on the OAE protocol used, a mild sensorineural hearing loss may not be ruled out. For an example of an appropriate diagnostic protocol refer to Appendix B.

Auditory Evoked Response Assessment

Completion of the full diagnostic protocol is essential for accurate assessment and for planning the child's educational future. If any component cannot be completed with the child unsedated, then sedation is justified. Since not all facilities are equipped to handle sedation, it may be feasible for them to attempt unsedated diagnostic auditory electrophysiologic evaluations, and to refer those requiring sedation to other centers. A comprehensive sedation policy is available from JCAHO (www.JCAHO.org). SEDATION SHOULD ONLY BE ADMINISTERED ON-SITE AT THE TESTING FACILITY BY QUALIFIED MEDICAL PERSONNEL. Each facility needs to have a comprehensive conscious sedation policy, which outlines the steps required to ensure patient safety. In order for the assessment to be accurate it is

essential that the infant is in a sleep state so that there is no bodily or eye movement causing electrical activity that could obscure the auditory evoked potentials. Children under 3 months of age often will fall asleep immediately after feeding, especially if they are kept awake and not fed until arrival at the clinic, so many can be tested unседated. For older babies as well as those who do not routinely sleep well after eating, sedation is indicated. If any component cannot be completed unседated, sedation is justified. Since not all facilities are equipped to handle sedation, it may be feasible for them to attempt unседated diagnostic auditory electrophysiologic evaluations, and to refer those requiring sedation to other centers.

Auditory Brainstem Response (ABR) assessment

ABR Threshold: An ABR threshold is obtained to estimate severity, configuration, and type of hearing loss. A child who has been found to have normal responses to OAEs, click ABR and immittance does not need to have tone burst ABR procedures, however, care should be taken to identify mild hearing losses.

- ABR threshold for click stimuli will estimate the overall amount of hearing loss in the mid to high frequency range. A bracketing procedure using 10 dBnHL to 20 dBnHL descending steps and either 5 dBnHL or 10 dBnHL ascending steps is appropriate. Threshold will be considered the lowest level at which repeatable waveforms can be observed.
- Whenever possible, the lowest stimulation intensity should include 20 dBnHL and should not be greater than 30dBnHL. If a response is obtained for click stimuli in the acceptable range (i.e., 20 - 30 dBnHL) with wave V latency within age-appropriate normal limits then the test protocol may be discontinued.
- The parents should be counseled that if they notice a change in the child's responses to sound stimulation at any age, they should be promptly scheduled for a follow up a diagnostic audiologic evaluation.

For Elevated ABR Thresholds

For children who have elevated ABR thresholds or who have abnormal latencies, perform a threshold estimation for high (e.g., 4000 Hz) and low (e.g., 500 Hz) tone burst signals, or OAEs to determine the status of cochlear function throughout the speech frequency region. When elevated ABR thresholds are obtained for click signals, additional information is necessary to adequately describe auditory status.

- ABR recordings for high intensity level signals with rarefaction polarity and condensation polarity should be compared to rule out the presence of a cochlear microphonic, and to rule out auditory dys-synchrony. The presence of a cochlear microphonic for rarefaction and condensation click stimulus polarities is consistent with auditory neuropathy (dys-synchrony) These results should be interpreted in conjunction with the performance of otoacoustic emission measurement.
- Routinely, low frequency (500 Hz) and higher frequency (2000 and 4000 Hz) tone bursts need to be part of the diagnostic ABR in order to provide frequency specific information necessary for amplification fitting. For tone burst measurement start with 20 msec. Increase to 30 msec only as necessary to track a low frequency stimulus to threshold. It is preferable to use a 20 msec window and a curvilinear (Blackman) stimulus envelope to effectively limit spectral

splatter. Again, Wave V needs to be replicable at threshold. Since toneburst responses are often less replicable than clicks, three or four repetitions may be necessary to obtain clear replication.

- Minimally, an initial hearing aid fitting could occur using 500Hz tone burst and ABR thresholds for click stimulus. Preferably, hearing aid fitting would rely on frequency specific information for 500, 1000, 2000, 4000 Hz regardless of diagnostic equipment used. It is assumed that tympanometry results will be obtained and that hearing aid fitting will consider any middle ear status concerns.
- In infants less than 3 months of age poor response to 500 Hz tonebursts is a common finding due to neurological immaturity, and is not necessarily indicative of hearing loss. If tone burst testing at 500 Hz is not possible due to testing complications, it is possible to fit amplification conservatively on the basis of high frequency ABR responses with behavioral testing as part of a continuing test battery.
- As a general rule, bone conduction should be included in the ABR test battery when the findings for air conduction click stimulus suggest conductive hearing loss (e.g., delayed wave I and elevated ABR threshold) or other audiologic or medical findings suggest conductive hearing loss or middle ear disease. The audiologist may decide to not obtain a bone conduction response initially if other portions of the test battery have higher priority.

Auditory Steady State Response (ASSR)

- An additional technology to obtain frequency specific information is ASSR. The ASSR has the capability of focusing on discrete frequencies between 250 and 8000 Hz. The ASSR equipment determines statistically when there is an existence of coherent responses at a high level of probability (e.g., 98%). The ASSR can be used to estimate degree of residual hearing sensitivity at each frequency. The procedure currently is most valid delineating hearing losses in the moderate-severe to profound hearing loss range. The maximum intensity limitation for ASSR can be up to 130 dB HL to determine if any residual hearing is evident, even for patients without evidence of an ABR at maximum stimulus intensity levels. The patient noise floor needs to be as low as possible, therefore sedation may be necessary for some children.

Integrity of Auditory Pathway

To assess the integrity of the auditory neural pathway:

- High level (70 to 80dB nHL) click ABR stimuli are useful to evaluate absolute and interpeak latencies and compare these values with age appropriate norms. If a child has no wave 1 latency it may be appropriate to present high level clicks at 70-95 dB nHL.
- If no ABR is identified, then one must compare recordings obtained for rarefaction and condensation clicks presented at 80 to 90 dB nHL using a fast click rate (>30/second). If a response (e.g., cochlear microphonic) is observed, an auditory neuropathy may be present.

Middle Ear Measures

Middle ear acoustic immittance measures are part of a comprehensive audiologic assessment and may help to further define type of hearing loss. Tympanometry assesses middle ear function. Acoustic reflex thresholds may help predict severity of loss. Multi-component/multi-frequency testing is highly recommended for children under six (6) months of age. If a single low frequency probe tone is utilized, results for infants under 6 months of age should be interpreted cautiously. It is recommended that for infants 4 months and younger that at least a 660-Hz probe tone, and preferably a 1000-Hz probe tone be used for tympanometry and middle ear muscle response assessment.

Behavioral Response

When electrophysiological test results are found to be abnormal, then a cross check using behavioral observation audiometry (BOA) techniques is recommended. The infant's behavioral response to sound, or the lack of it, should be obtained via direct observation during Behavioral Observation Audiometry and/or parent report (the Early Listening Function test can assist parents in systematically observing child responses to sound; to download the ELF contact: www.phonak.com professional resources section. Perform BOA to a speech stimulus and/or a 500 and 2000 Hz tone or noise, by air conduction and bone conduction. Identify any minimal responses and attempt to obtain startle responses. Perform Visual Reinforcement Audiometry (VRA) with infants that are developmentally six months of age and older. The Early Intervention Program can assist in working with the parents to complete the Early Listening Function (ELF) test and communicating the results with the audiologist.

VI. INTERPRETATION OF AUDIOLOGIC ASSESSMENT RESULTS

What normal OAE means: Normal outer hair cell function may be inferred for all frequencies when OAEs are present and amplitude values for all frequencies are within an appropriate normative region. Note that at high stimulus levels used for evoking the response, children with minimal and mild sensory hearing loss may exhibit OAEs.

What the absence of OAEs mean: The absence of OAEs may indicate a sensory hearing loss greater than 30 dB HL and/or middle ear dysfunction.

What partly normal OAEs mean: The presence of OAEs at some frequencies but not at others may be consistent with a sensory hearing loss, and may provide some frequency-specific information on the hearing loss. OAEs cannot, however, be confidently used to estimate the degree of hearing loss. Distortion product otoacoustic emissions, in particular, are of value in detecting the frequency of the knee point of precipitously sloping high frequency hearing losses or reverse slope hearing losses.

Normal OAEs throughout the frequency range from 2000 to 6000 Hz suggest that middle ear and cochlear status is adequate for speech and language development.

- If click ABR thresholds and OAEs are normal, diagnostic pediatric assessment may be terminated. Given a normal click ABR threshold, normal sensitivity may be inferred for all frequencies at which OAEs are present.
- Infants who have passed ABR screening but who do not pass OAEs shall undergo tympanometry in an effort to determine the presence of middle ear involvement. If OAE and tympanogram results are abnormal, a medical referral to the child's primary care physician is warranted to rule out external and/or middle ear pathology. A repeat audiologic assessment shall be recommended.
- The presence of auditory neuropathy (Auditory Dys-synchrony) is indicated when there are normal OAE responses and any or all of the following combination of test results: (1) absent or severely abnormal ABR, (2) absent middle ear muscle reflexes, and (3) present cochlear microphonic (inversion with reversal of polarities).

If the diagnostic audiologic test battery results are normal, infants who are at risk for delayed-onset hearing loss (Joint Committee on Infant Hearing Risk Indicators, see definitions) should receive communication monitoring within their medical home. If a concern about hearing and/or communication development arises by the physician or parent, an immediate referral for audiologic evaluation should occur.

VII. FOLLOW-UP RECOMMENDATIONS

Normal Hearing

- If the assessment performed above resulted in a finding of normal hearing, follow up is recommended if a parent notices a decrease in hearing or at the physician's request. If risk factors for late onset hearing loss are present the audiologist should counsel the parent on the importance of vigilance of being aware of the child's hearing behavior and the need to return for reevaluation if any concern about the child's hearing arises. Parents should be given information about typical language, speech and auditory development, and progressive and delayed-onset hearing loss.
- Review results of the audiologic assessment, implications of the audiologic findings, and recommendations with the parents including information about typical speech, language and listening developmental milestones. This information is available on the Universal Newborn Hearing Screening: An Important Beginning brochure or the Newborn Hearing Screening and Your Baby brochure, free from Children's Medical Services Infant Hearing Program (850-245-4200).
- For every child referred from universal newborn hearing screening the audiologist is required to complete the "Follow-up Diagnostic Evaluation Results Form for Community Audiologists" and fax it to the Children's Medical Services Newborn Screening Unit as noted (see "Follow-up Diagnostic Evaluation Results Form for

Community Audiologists" Form,
http://www.cmskids.com/InfantHearing/current_audfollowup.doc).

Abnormal Hearing

Specific follow up procedures are necessary if the assessment performed above results in a finding of estimated average hearing loss of 25 dB HL or greater bilaterally or an estimated unilateral hearing threshold of greater than 50 dB HL. Refer to C for the Part C Eligibility Criteria for Significant Hearing Loss. In some instances a conductive component should not prevent fitting of amplification if the conductive element is not amenable to surgical or medical intervention and if medical clearance has been obtained that is specific to that conductive component. Based on the Healthy People 2010 goal, the following should be completed by audiologists for infants who have confirmed hearing loss, prior to the infants turning three (3) months of age. In all instances parents should be given information about typical language, speech and auditory development, and progressive and delayed-onset hearing loss.

The following should be completed immediately after assessment for infants with hearing loss:

- Complete the "Follow-up Diagnostic Evaluation Results Form for Community Audiologists" with copies to be faxed to the Children's Medical Services Newborn Screening Unit as noted (see "Follow-up Diagnostic Evaluation Results Form for Community Audiologists" Form, http://www.cms-kids.com/InfantHearing/current_audfollowup.doc)
- The "Follow-up Diagnostic Evaluation Results Form for Community Audiologists" form should also be faxed to the local Early Intervention Program within 2 working days of confirmation of hearing loss. Audiologists should refer the child to early intervention at the point of confirmation of hearing loss and not delay the referral until complete threshold information is obtained. This fax will constitute a referral and will satisfy the requirements of the Federal Law (CFR 303.321d).
- Review results of the audiologic assessment, implications of the audiologic findings, and recommendations for intervention with the parents including:
 - Information regarding the need for medical evaluation and medical clearance for amplification;
 - Share the brochure that describes the Serving Hearing Impaired Newborns Effectively (SHINE) component of Early Intervention. This will provide the parents with information regarding the importance of early intervention, the specialized component of early intervention to meet the needs of families of children with hearing loss, and the requirement of audiologists to refer children with confirmed hearing loss to early intervention. A Florida Resource Guide for Families with Infants and Toddlers who are Deaf/Hard of Hearing has been developed for families that have an infant who has a confirmed hearing loss. This Resource Guide is distributed to families as a part of the SHINE initial services or can be accessed at www.cms-kids.com.

- The availability and importance of parent-to-parent support (also to be addressed through the early intervention system)
- In consultation with the infant's primary care physician, refer the infant/family to an otolaryngologist for medical evaluation.
- Describe amplification options to the parents. It is advised to not provide this information immediately after confirmation of hearing loss to reduce the degree to which the family feels overwhelmed. Upon receipt of medical clearance, the audiologist should initiate the amplification fitting process.
- As appropriate, discuss additional specialty evaluations (e.g., genetics, ophthalmology, audiologic evaluation of siblings) with the parents and the infant's primary care physician.
- If the audiologic assessment results are abnormal, and it appears that conductive involvement is likely, the infant should be referred to his or her primary care physician for exam. Even in cases where conductive hearing loss is suspected, sensorineural hearing loss should be ruled out by the performance of auditory brainstem response testing by 3 months of age. If results are found to be sensorineural in nature proceed with amplification fitting and referral to the local Early Intervention Program.
- If the audiologic assessment results are abnormal and the hearing loss appears to be sensorineural, otology referral, initial steps toward amplification fitting, and referral to EIP should be occurring concurrently.
- When auditory dyssynchrony (auditory neuropathy) is identified discuss the results and implications with the parents, give them information regarding typical auditory, speech, and language developmental milestones, and retest the infant behaviorally through visual reinforcement audiometry at six (6) months developmental age. As the effect of auditory neuropathy on auditory, language, and speech skills can vary tremendously from one individual to another, behavioral audiologic follow-up is a critical piece in determining the child's needs for intervention. A referral should be made to the local Early Intervention program as these children qualify for early intervention services that are specific to the needs of children with hearing impairment. Refer to <http://www.cms-kids.com/ContactUs/EIPdir.pdf> for a list of local Early Intervention Program (EIP) contact information. These services can assist in monitoring communication and auditory skill development. Share audiologic results and recommendations with the child's primary physician and advise that neurological consultation be considered.

VIII. Guidelines for fitting of hearing aids:

A child needs hearing aids when there is a chronic conductive or sensorineural, bilateral peripheral hearing loss. Some children with variable and/or unilateral hearing losses will also benefit from hearing aids. There are no empirical studies that delineate the specific degree of hearing loss at which the need for amplification begins. However, if one considers the acoustic spectrum of speech at normal

conversational levels in the 1000-4000 Hz range, hearing thresholds of 25dB HL or greater can be assumed to impede a child's ability to perceive the acoustic features of speech necessary for optimum aural/oral language development. Hence, thresholds equal to or poorer than 25 dB HL would indicate candidacy for hearing loss intervention in some form. Amplification should be considered for children with unilateral hearing loss, rising or high-frequency hearing loss above 2000Hz and/or milder degrees of hearing loss (<25dB HL). The need for amplification should be based on the audiogram plus additional information including cognitive function, the existence of other disabilities, and the child's performance within the home environment.

The following information should be obtained:

- Threshold estimates for a minimum of one low frequency and one high frequency in each ear
- Medical clearance for amplification from physician, preferably an otolaryngologist
- Real Ear to Coupler Difference (RECD) measures

The following factors must be taken into consideration when fitting amplification devices:

Preselection Physical Characteristics

While consideration needs to be given to physical factors, the ultimate goal is the consistency and integrity of the amplified signal that the child receives. Providing the best possible amplified speech signal should not be compromised for cosmetic purposes, particularly in the early years of life when speech-language learning is occurring at a rapid pace.

Even at a very young age, consideration should be given to the availability of appropriate coupling options on hearing aids so that the child will have maximum flexibility for accessing the various forms of current assistive device technology. Consequently, hearing aids for most children should include the following features: Direct Audio Input (DAI), telecoil (T), and microphone-telecoil (M-T) switching options, if available. Hearing aids used with young children also require more flexibility in electro-acoustic parameters (e.g. tone, gain, output limiting, automatic feedback control) than for adults, as well as more safety-related features such as tamper resistant battery and volume controls.

The physical fit of the hearing aids and ear molds is important for both comfort and retention. Color of the hearing aids and earmolds needs to be considered across ages. Ear molds should be constructed of a soft material. Appropriate coupling to the hearing aid can be accomplished using either a custom made earmold or use of temporary or disposable earmold products (e.g. wrapped strips around tubing, miniature compressible plugs).

Binaural amplification should always be provided to young children unless there is a clear contraindication. Even if there is audiometric asymmetry between ears as evidenced by pure tones or speech perception, hearing aids should be fitted binaurally until it is apparent from behavioral evidence that a hearing aid fitted to the poorer ear is detrimental or not beneficial to performance.

Behind-the-ear (BTE) hearing aids are the style of choice for most children. However, for children with profound hearing loss, body aids, FM systems, or amplification with feedback limiting circuitry may be more appropriate because of acoustic feedback problems limiting sufficient gain to provide full audibility of the speech signal. Other circumstances that may indicate the need for body-worn amplification include children with restricted motor capacities and those confined by a head restraint. In-the-ear (ITE) hearing aids should not be considered for young children. Some children with hearing loss of severe to profound degree are candidates for transpositional hearing aids or cochlear implantation. Hearing aid considerations should be made in conjunction with a child's cochlear implant team as appropriate.

Other considerations:

Paying for Amplification Devices:

Part C of the Individuals with Disabilities Act allows for the provision of appropriate assistive technology to infants and toddlers with disabilities. As such, the local Early Steps Early Intervention Program (EIP) is the payer of last resort for children who are not Medicaid eligible, do not have insurance coverage for hearing aids, or for whom there are no other resources available to pay for appropriate amplification. There are guidelines available that allow Early Steps Programs to reimburse for services and devices related to providing amplification to young children with hearing loss.

An audiologist is required to refer a child with hearing loss to the local Early Steps Program upon confirmation of a hearing loss that meets the Part C eligibility requirements (Appendix C). The SHINE Service Coordinator makes contact with the family and an interim Individual Family Support Plan (IFSP) is developed in conjunction with the family and the SHINE Initial Service Provider. If amplification recommendations have been made, the IFSP will contain the recommendation for hearing aid fitting specifying the wholesale price for the hearing instruments from the referring audiologist (to a maximum of \$500 or an average of \$1000 for binaural analog, programmable, or digital amplification). The audiologist would also work in conjunction with the child's EIP Service Coordinator if a loaner hearing aid(s) will be fit to the child. Hearing aids are available to infants and toddlers with hearing loss who are enrolled in Part C early intervention services. For more information contact the Children's Hearing Help Fund Hearing Aid Loan Bank for Infants and Toddlers at www.childrenshearinghelpfund.org. Hearing aid follow up visits can also be reimbursed through the local Early Intervention program. Contact the local Early Intervention program SHINE service coordinator for more information on reimbursement for amplification, hearing aid follow up visits, hearing aid insurance, or the hearing aid loan bank for infants and toddlers. Contact information for local EIPs at <http://www.cms-kids.com/ContactUs/EIPdir.pdf>

Cochlear implants and related mapping services are not reimbursed under Part C. SHINE services or ongoing early intervention services or habilitation are available to families of children with hearing loss, including those who are candidates for cochlear implants or children who have been implanted. Loaner hearing aids from the Children's Hearing Help Fund are available to families whose children are undergoing trial amplification use as a part of the cochlear implant evaluation process.

The following equipment is needed to fit amplification on this population:

Test equipment that meets current ANSI standards to verify that the electroacoustical characteristics meet the manufacturer's specifications. In situ measurements to verify the frequency gain characteristics and maximum power output.

Communicating with Families when fitting an amplification device:

Families need information about the hearing aid or other amplification device. Communication should be in written as well as 1:1 to allow questions to be answered.

Hearing Aid Listening Kits are available at no cost from the Infant Hearing Program by indicating this request on the audiology referral form (http://www.cms-kids.com/InfantHearing/current_audfollowup.doc). The kits can be requested by audiologists for use with a specific family. The child's birth date and the primary language of the family need to be specified so that the written instruction materials can be read by family members if possible. Communication when training a family on the use of amplification should include:

- Information from the manufacturer about the device
 - Use/care/function
 - Disposal of batteries
 - Hazards of battery ingestion
- Information about hearing aid follow-up visits that will be required to replace earmolds and adjust amplification
- Information on repeat audiologic testing. The standard of care is for infants and toddlers with hearing loss to receive repeat audiologic evaluation at 3 month intervals during the child's first 3 years of wearing amplification.
- Information on how children develop auditory skills (child's "hearing aid age") and the usefulness of observing children's responses to speech and sounds in the home and other daily environments. The Early Listening Function (ELF) checklist can be completed by the parent with the support of the SHINE service provider and can assist parent awareness of the degree to which the child is benefiting from amplification (www.cms-kids.com, Infant Hearing Program).
- Instruction on how to do listening checks (detailed instructions are provided in the Hearing Aid Listening Kit)
- Instruction on taking care of the hearing aids
- The need to provide insurance coverage for the hearing aids throughout childhood. Hearing aid insurance can be reimbursed by the local EI program when the manufacturer's warranty/loss and damage insurance expires.

IX. ONGOING ASSESSMENT & MONITORING

Monitoring for children who are hard of hearing or Deaf should occur every three months during the first three years of using amplification, up to age three.

Monitoring exams may include:

- An audiometric evaluation
- Hearing aid follow up visits . The local EI program will reimburse for up to 12 hearing aid follow up visits in the first 12 months of life, 6 visits from 13 months to 2 years and another 6 visits from 2 years through 35 months. The hearing aid follow up visits will be conducted by a pediatric audiologist and will contain at least two of the following activities that are not otherwise reimbursable by health insurance:
 - a) ear canal probe microphone measurements
 - b) adjustment/programming of hearing instruments
 - c) behavioral audiometric measurements
 - d) electroacoustic hearing aid analysis
 - e) validation measures
 - f) in-office repairs of hearing instruments (not to include delivery after manufacturer repair)
 - g) family training
 - h) earmold impressions
- The parent/caregiver should be provided a log/checklist for documenting certain behaviors in order to monitor auditory function in their natural environment. The Early Listening Function (ELF) is available on www.cms-kids.com website under Infant Hearing Program and can be useful in documenting auditory responses in the natural environment.

Assessment at developmental age of 6 months to 36 months of age:

Children with hearing concerns or communication delays require audiologic assessment to rule out the presence of hearing loss. Children who have gone through the Early Intervention Program multidisciplinary assessment will have a hearing history and observation screening form completed that may accompany a child's referral for audiologic assessment. The goal of the audiologic assessment is to obtain separate ear, discreet frequency, and hearing threshold information. Preferably, the audiologist will perform VRA, tympanograms, and middle ear muscle reflex assessment. If VRA is not successful or the results are not normal, then an OAE and/or AER should comprise the audiologic test battery. Specifically, the following assessment(s) should be completed:

1. History on auditory behavior, health and family, birth, developmental status
2. Determine threshold hearing levels- frequency specific and ear specific. The assessment may include:
 - VRA audiogram using insert earphones for both ears at 500,1000, 2000 and 4000 Hz.
 - Acoustic reflex measures
 - OAE-same on each side. If OAEs are not available, ear specific behavioral information is adequate, preferably with symmetrical acoustic reflexes present
 - Frequency specific Auditory Evoked Potentials

- Hearing levels must be 25 dB HL or better hearing in both ears for hearing to be considered normal.
3. Tympanometry. If abnormal results are obtained a medical referral should be made.
 4. Middle ear muscle reflex (MEMR), i.e. acoustic reflexes. The MEMR results should be used as a cross check of other diagnostic tests
 5. With normal sound field responses, follow up in 3 months with another attempt at ear specific assessment, if a sedated ABR/OAE cannot be completed within that 3 months. Normal sound field responses are considered to be responses that are obtained with a speaker arrangement at 90 and 270 degrees that are within 20-25 dB HL
 6. Equipment must be calibrated to current ANSI standards annually.

IX. TRANSITION TO EARLY INTERVENTION

The outcomes of a successful early hearing detection and intervention (EHDI) program are that a) all infants with hearing loss are identified as soon as possible, preferably within three months of age; and b) infants with confirmed hearing loss begin receiving early intervention services, as appropriate for the child and family, as soon as possible and preferably by six months of age. The audiologist's follow-up audiologic care for an infant or toddler with a confirmed hearing loss should include confirming that other early intervention services are meeting the needs of the child and family. The audiologist is encouraged to participate in planning these services, such as being an active team member in the development and ongoing review of the child's Individualized Family Support Plan.

SELECTED REFERENCES

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Cone-Wesson, B., & Ramirez, G.M. (1997). Hearing sensitivity in newborns estimated from ABRs to bone-conducted sounds. *Journal of the American Academy of Audiology*, 8, 299-307.

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Hood, L.J. (1998). *Clinical Applications of the Auditory Brainstem Response*. San Diego: Singular Publishing Group, Inc.

Joint Committee on Infant Hearing (2000). Year 2000 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs. *American Journal of Audiology*, 9, 9-29.

Roizen, N.J & Diefendorf, A.O. (Eds) (1999). Hearing Loss in Children. *Pediatric Clinics of North America*. 46(1).

SELECTED WEB SITES

www.audiology.org

American Academy of Audiology

www.asha.org

American Speech-Language-Hearing Association

www.audiospeech.ubc.ca/haplab/haplab.htm

Human Auditory Physiology Laboratory

www.colorado.edu/slhs/mdnc

Marion Downs National Center for Infant Hearing

www.kdhe.state.ks.us/bcyf/cds/newborn_hearing.html

KDHE Newborn Hearing Screening Program

www.infanthearing.org

National Center for Hearing Assessment and Management

www.nih.gov/nidcd

National Institute on Deafness and Other Communication Disorders

PEOPLE PARTICIPATING ON TASK FORCE CONFERENCE CALL(S):

Bob Fifer*	Paula Golson	Gail Lim	Janet Sullivan
Kathy Slifer	Christina Thors	Fred Rahe*	Jay Hall
Holle Whitaker*	Emily McClain	Patricia Carr	Karen Anderson*
Tonya Steed	Kathy Slifer	Stan Gustetic*	

* Members of the EHDI Advisory Council

Appendix A: Infant Hearing History Form

Appendix B: Example Diagnostic Protocol

Appendix C: Follow-up Diagnostic Evaluation Results Form for Audiologists

For additional information on the development of the guidelines or the Early Hearing Loss Detection and Intervention Program, contact Karen Anderson, Audiology Consultant, Department of Health, Children's Medical Services, Bureau of Early Interventions at (850)245-4444 x 2269 or Karen_Anderson@doh.state.fl.us.

INFANT HEARING HISTORY

Child's Name: _____ **Birth date:** _____

Parent's Name: _____ **Today's Date:** _____

- 1. Were there any complications during your pregnancy or delivery? NO YES
- 2. Did your baby receive oxygen or ventilation after delivery? NO YES
- 3. Was your baby cared for in a special care nursery? (NICU) NO YES
- 4. Birth weight: _____ lbs _____ oz Premature birth (less than 37 weeks)? NO YES

Risk factors that may develop as a result of certain conditions apparent at birth or essential medical interventions in the treatment of an ill child. Check all that pertain to your child:

- Family history of hearing loss: One or more blood relatives of the child had permanent hearing loss in early childhood: parent, grandparent, aunt, uncle, child's first cousin, brother, sister.
Specify who : _____
- Mother had rubella (measles), cytomegalovirus (CMV), herpes, toxoplasmosis, or syphilis during pregnancy
- Child required a blood transfusion shortly after birth due to hyperbilirubinemia
- Child required mechanical ventilation (breathing machine) for 5 or more days after birth
- Child was in the NICU after birth and required ECMO (forced oxygen into tissues)
- Child had an infection after birth such as meningitis, mumps, or measles
- Child was hospitalized after birth and required IV antibiotics or chemotherapy
- Child experienced head trauma (i.e., a serious fall causing a concussion or skull fracture)
- Child has been diagnosed with a particular syndrome or disorder (i.e., Down's Syndrome, cleft palate)
Specify _____
- Child has had many ear problems (ear infections or fluid behind the eardrum), such as:
 - more than 4 ear problems in the last 12 months (i.e. 5 different ear infections, not 5 appointments to check on if the ear medicine has worked)
 - had more than 4 prescriptions filled for antibiotics to treat ear problems in the last 12 months
 - draining ear(s) for more than 3 days (odor, pain, blood, pus – not earwax)
 - ear problems that lasted longer than 3 months (i.e., child took antibiotics daily for 3 or more months and the fluid or infection was still present)
 - tubes have been inserted in the child's eardrums (or any ear surgery). If a hearing test was performed after this surgery obtain a copy of results.

BEHAVIORAL OBSERVATIONS

Every child has times when they do not seem to be listening. If this occurs only occasionally, then hearing ability is not usually questioned. If this occurs often, then it is natural to wonder if the child is able to hear normally. Have you observed a number of behaviors over time, which has caused concerns about hearing? Yes No

If Yes continue with the examples below:

BEHAVIORS	APPROXIMATE AGE
<input type="checkbox"/> Child does not seem to respond to sounds in the environment that are easy to hear, unusual, or otherwise alerting (i.e., dog bark, door bell, item dropped from behind)	Older than 3 months
<input type="checkbox"/> Child does not seem to respond to name or noise when the parent would have expected him or her to respond (i.e. the room is quiet and the child is not otherwise playing or distracted)	Older than 3 months
<input type="checkbox"/> Child seemed to be responding to sound but now the child seems to respond less to sound then when s/he was younger	Older than 6 months
<input type="checkbox"/> Child seems to mainly turn to one side when sounds occur	Older than 7-9 months
<input type="checkbox"/> Child mishears sounds, such as mistaking what was said for a word that rhymes or sounds similar (i.e. gets the doll when asked to get the dog)	Older than 14 months

Other than the behaviors on the list, please share any observations you have made of the child's hearing behavior that have caused concerns (i.e. sounds not responded to under what conditions)

Auditory Development (complete only if your child is under age 3 years)

Look at the age level that is closest to your child's age (or corrected age if the child was born prematurely). Check the skills that you have observed your child doing. If fewer than ½ are checked in the age appropriate range, consider the skills in the prior age range (i.e. if only two items checked in 12 months then consider the skills in the 7 month range to determine if ½ have been observed).

By 1 month:	
startle response to loud sounds (throws arms out)	attends to music and voice
soothed by parent or caregiver voice	enjoys time face-to-face with caregiver
hears caregiver before being picked up	moves arms or legs to speech patterns
By 3 months:	
looks around for what is making sound	enjoys parent or caregivers voice
attends to toys or objects that make sound	imitates vowel sounds (i.e. ay, ee, oo, ah)
By 7 months:	
uses toys or objects to make sounds	likes to plays with things that make sound
pays attention to music or unusual sounds	enjoys rhythm games (i.e. patty cake)
responds to change in tone of caregiver's voice	notices toys or things that make sounds
moves eyes in direction of sounds heard	quiets when talked to with a soothing voice
By 12 months:	
watches TV for short periods (short commercial)	turns head to direction of new sounds heard
enjoys rhymes and songs	enjoys hiding game (Where's Johnny?)
responds to vocal games (So big! Peek a boo)	turns or looks to own name
babbles using a variety of sounds (baba, geegoo)	babbles using speech-like patterns (intonation)
By 18 months:	
dances to music	attends to simple stories, rhymes, songs
follows simple commands ("Come here")	indicates wants and needs with vocalizations
understands or uses 3-20 words	
By 24 months:	
points to some body parts	enjoys listening to stories
understands many words (300+)	
By 36 months:	
notices different sounds (phone, doorbell)	listens to story in a group
goes with parent to answer door knock or doorbell	understands most things said to him/her

____ **Fewer than ½ of the items listed in under the child's age category were checked**

IF your child does not show auditory behaviors that are typical of other child his or her age, do think that this may be due to another condition causing delay rather than to a possible hearing problem?

___ **no, probably not** ___ **yes, possibly due to other problems**

___ **my child is receiving early intervention or therapy services for special developmental needs**

Parent Comments:

**Florida Infant Hearing Guidelines
Auditory Brainstem Response (ABR) Protocols**

Parameters	Protocol		
	Air-Conduction		Bone-Conduction
	Click	Tone-Burst	Click
Stimulus			
Transducer	insert earphones		B-70 or B-71 oscillator
Type	click	tone-burst	click
Duration	0.1 msec	2 cycles rise/fall 0 cycle plateau	0.1 msec
window (ramp)	N.A.*	Blackman	N.A.
polarity	rarefaction **	rarefaction, condensation, or alternating	alternating
rate	19.1 to 39.9/sec ***	19 to 39/sec	11.1 to 19.9/sec
intensity	variable (dB nHL) ****	same	same
repetitions	< 2000 *****	< 2000	< 2000
Acquisition			
sensitivity/gain	20 or 50 μ V/100,000	same	same
electrode array			
non-inverting	Fz (high forehead)	same	same
inverting	Ai (ipsilateral earlobe)		
common	forehead or nape of neck		
analysis time window	20 msec	20 or 30 msec	20 msec
filter settings			
high pass	30 Hz	same	same
low pass	1500 or 3000 Hz	same	same
notch	none (disabled)	same	same
sweeps	< 2000 *****	same	same

-
- * N.A. = not applicable
 - ** use each polarity to detect cochlear microphonic (CM) if auditory neuropathy is suspected
 - *** a stimulus rate between these limits is appropriate; select an odd number (e.g., 23.7 or 39.1) to minimize interaction of signal averaging with 60 Hz electrical artifact; a slower rate is appropriate to improve waveform morphology or for identification of ABR wave I
 - **** dB nHL is referenced to normal behavioral hearing threshold (0 dB nHL) for each signal (air-conduction click, bone-conduction click, each air-conduction tone burst frequency)
 - ***** Averaging may be terminated with lower number of repetitions (sweeps) if ABR waves are clear and reliable; averaging may be continued beyond 2000 repetitions (sweeps) if ABR waves are not clear and reliable.

Appendix C

**Qualification & Management of Infants & Toddlers with Hearing Loss
FLORIDA**

**Infants & Toddlers Early Intervention Program
Part C Criteria Specifying Hearing Loss Considered
to be a “Significant Sensory Impairment”**

The degrees of hearing loss specified below are to be considered significant sensory impairments that place an infant or toddler at risk for developmental delays. As such, infants and toddlers with hearing loss of the specified degrees or greater should be considered eligible for audiological management (including provision of hearing instruments when appropriate) and family-centered early intervention services.

Criteria for significant hearing loss is for referral to Children's Medical Services' Infants and Toddlers Early Intervention Program (Part C). Hearing loss, as defined by Florida below, is an established condition under Part C and does not require additional delays to be evident prior to initiation of services. It is acknowledged that the criterion specified below differ from Part B eligibility criterion for school age populations. Infants and toddlers evidencing hearing loss conditions that meet the Part C criterion are eligible for evaluation and services as appropriate under Part C. Differing service providers, including public school programs for 0-3 children with hearing loss, may choose to employ different eligibility criterion. It is the responsibility of the local CMS Infants and Toddlers Early Intervention Program to identify service providers that will serve children's needs appropriately.

This hearing loss criteria is more inclusive than that defined by Medicaid, which specifies: (a) an average hearing loss of 40 dB HL at 500 Hz, 1000 Hz, and 2000 Hz by pure tone air conduction, or (b) a difference between thresholds at 1000 Hz and 2000 Hz of 20 dB or greater, while the average of the air conduction level at 500 Hz and 1000 Hz is 30 dB or greater.

CRITERIA

1. Evidence of a documented permanent hearing threshold level (re: ANSI 1996) of:
 - a) 25 dB or greater based on pure tone average of 500, 1000, and 2000 Hz unaided in the better ear (Air –bone gap not to exceed 10 dB HL)
 - b) Air conduction thresholds, unaided in the better ear, greater than 25 dB HL at two or more frequencies in the high frequency range (2000, 3000, 4000, 6000 Hz) in both ears with air-bone gaps no greater than 10 dB HL
 - c) Evidence of an anatomical malformation of the outer and/or middle ear in conjunction with a hearing loss \geq 30 dB HL pure tone average of 500, 1000, and 2000 Hz in the better ear (atresia, stenosis, etc; ABR AC – BC \geq 25 dB HL).

2. Evidence of a documented unresolved or chronically recurrent conductive hearing loss in combination with at least 4 of the following:
 - a) 4 or more episodes of otitis media in 12 months; primarily occurring in both ears
 - b) single episode of otitis media lasting longer than 3 months; primarily occurring in both ears
 - c) indication of fluctuating hearing loss (audiological hearing evaluation(s) revealing pure tone average of 20 dB or worse in the better-hearing ear; OR caregiver or physician report)
 - d) caregiver or physician concern over speech and/or language development (i.e., as compared to “Sequence of Development for Infants and Toddlers: Auditory, Language, and Speech”)
 - e) caregiver concern over behavioral response when child is given a direction or placed in new situations

f) chronological age of 18 months or greater

3. Evidence of auditory dys-synchrony¹ (auditory neuropathy) in both ears characterized by a unique constellation of behavioral and physiologic auditory test results².

¹ Persons with auditory dys-synchrony do not generally benefit from hearing aids and may not learn language by the auditory channel alone. There is considerable variability in individuals based on the level of dys-synchrony.

² In behavioral evaluations children with auditory dys-synchrony may exhibit a mild to profound hearing loss and poor speech function. In physiologic evaluations these children will demonstrate normal otoacoustic emissions and atypical or absent auditory brainstem responses (Joint Committee on Infant Hearing Position Statement, 2000).