

**ENVIRONMENTAL SCAN of the
EARLY HEARING DETECTION AND INTERVENTION PROGRAM EXPANSION TO INCLUDE
SCREENING THE HEARING OF CHILDREN UP TO 3 YEARS OF AGE**

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INTRODUCTION

The Reauthorization of the Early Hearing Detection and Intervention (EHDI) Act of 2017 includes an expanded focus on identifying children who are deaf or hard of hearing up to three years of age. Expanding access to hearing screening requires that program leaders carefully consider many factors. These factors include identifying, partnering, and training staff in community-based programs serving young children; assisting these programs in determining appropriate equipment, protocols, and reporting; and ensuring that data systems are capable of handling additional children beyond the newborn period. This environmental scan explores evidence-based and evidence-informed hearing screening methods appropriate for this age group, the contextual considerations, collaboration and referral mechanisms, and possible roles for Early Hearing Detection and Intervention (EHDI) programs.

Considering the many different conditions and illnesses that can have a potential impact upon a child's health and development, how do we determine which conditions warrant inclusion in standard health screenings and for which populations? The World Health Organization outlines a set of guiding principles for health screening, reflecting what is commonly known as the *Wilson Criteria for Screening*,¹ helping us know when it is important to invest time and resources necessary to engage in specific health screenings:

- the condition should be an important health problem
- the natural history of the condition should be understood
- there should be a recognizable latent or early symptomatic stage
- there should be a test that is easy to perform and interpret, acceptable, accurate, reliable, sensitive and specific
- there should be an accepted treatment recognized for the disease
- treatment should be more effective if started early
- there should be a policy on who should be treated
- diagnosis and treatment should be cost-effective
- case-finding should be a continuous process

When it comes to permanent hearing loss, science, technology and service systems have developed to the point where these key criteria have been met. Hearing loss is widely understood as an important health problem that has broad implications for the educational, social-emotional, and overall development of the developing child. The incidence of permanent congenital hearing loss has been widely described as approximately 1-3 per thousand.² Evidence-based, easy-to-use, and reasonably priced screening tools that lay individuals can utilize are available. Diagnostic tools are increasingly accessible as are a range of treatments/ interventions that, as the criteria suggest, are found to be the most effective when provided soon after diagnosis. The satisfaction of these criteria has served as the justification for the

EHDI newborn hearing screening system. Increased recognition that the incidence of permanent hearing loss in children at least doubles between birth and school age² is reflected in the Reauthorization of the EHDI Act of 2017 which suggests that the WHO criteria has been met for this larger age group to be screened.

For nearly 30 years, EHDI programs have focused on newborn hearing screening and immediate follow-up as the primary means of identifying permanent hearing loss in young children. The Joint Committee on Infant Hearing (JCIH)³ has established the 1-3-6 guidelines for newborn hearing screening to be completed before one month of age, audiological diagnostic evaluations to be completed before three months of age, and Early Intervention/Part C offered before six months of age. The most recent JCIH recommendations acknowledge the need for identification efforts beyond the newborn period, but currently do not call for universal implementation of screening during early childhood and suggest that “further research and technologic advances may allow for an expanded recommendation in the future.”³

Expanding hearing screening for children up to 3 years of age will require a range of broad programmatic changes:

- A new population of children to be screened and followed.
- Screening methodologies and protocols to be implemented that are appropriate for the target population and feasible to use in the settings where screening can potentially be conducted.
- Screener training specifically tailored for, and provided to, staff in programs/settings where young children are currently being served.
- New screening and reporting partnerships to be established.
- Potential modifications to data systems.

Starting three decades ago, newborn hearing screening programs developed slowly over time into what are now full-fledged programs whereby over 98% of babies receive a screening, diagnostic audiological evaluations for those who don't pass and early intervention and family-to-family support services available for those infants identified as deaf or hard of hearing (DHH). Screening program growth has relied heavily on the utilization of trained lay screeners (non-audiologists), which has permitted the system to expand dramatically. EHDI programs have developed step-by-step with strategies, partnerships, and systems based on new research, adopting effective practices from other state-based EHDI programs, and newly developed resources. The expansion of EHDI beyond the newborn period will build upon the foundation that has been laid in implementing newborn hearing screening.

An environmental scan of community-based early childhood screening up to the age of 3 is useful to guide EHDI programs through the planning process of developing strategies for providing periodic hearing screening to children for whom there are no identified risk indicators for hearing loss. Children with known risk indicators³ are recommended to be surveilled according to condition-specific periodicity schedules (Appendix 1).

This environmental scan, focusing on early childhood hearing screening research, effective program strategies, and guidelines from the field, includes:

- Evidence-based and evidence-informed approaches to hearing screening, including periodicity schedules, protocols, guidelines, and regulations.
- Recommended locations to do screening, including policies and practices of potential partners.
- Collaboration and referral mechanisms, including data sharing agreements, data systems, reporting by audiologists, and privacy issues.
- Potential roles for EHDI programs, including strategies, stakeholders, educational methods, and progress.

Evidence-based and evidence-informed material for the environmental scan was obtained from a variety of sources and information-gathering experiences:

- Research investigations of hearing screening methods and implementation;
- Guidelines for effective practices by professional associations;
- Pediatric audiology text books;
- Expertise of a cadre of pediatric audiologists, National Center for Hearing Assessment and Management (NCHAM) staff, and national consultants engaged in developing, implementing, and refining the Early Childhood Hearing Outreach (ECHO) Initiative's Otoacoustic Emissions (OAE) hearing screening training/technical assistance program.
- The ECHO Initiative's twenty years of experience providing technical assistance to staff from hundreds of community-based early care and education programs across nearly every state and territory in planning, developing and implementing OAE hearing screening and follow-up practices for children birth to three years of age, often in collaboration with local pediatric audiologists, state EHDI program staff and early childhood specialists. Additionally over 250 in-person and live web-based trainings on developing OAE hearing screening and follow-up practices for Early Head Start, Migrant Head Start and American Indian/Alaska Native Head Start programs have been provided.
- Nine focus groups with pediatric audiologists, EHDI stakeholders, and early childhood partners (Head Start, Part C/Early Intervention) from 2013-2018.
- Grant applications by EHDI programs for HRSA funding.
- Potential partner websites.

DEFINITIONS

Evidence-Based, Evidence-Informed

Evidence-Based⁴ - Pertains to practices that have been studied and evaluated under highly controlled conditions and then are implemented similarly (Appendix 2).

Evidence-Informed⁵ - Relies on research outcomes but also factor in adaptations due to contextual factors that likely were not controlled in the research studies (Appendix 2).

These terms are especially relevant when recommendations or guidelines do not specify a method but do specify the use of a method that is “evidence-based” or “evidence-informed.”

The American Speech-Language-Hearing Association (ASHA)⁶ and the American Academy of Audiology (AAA)^{2,7} have developed hearing screening guidelines (Appendix 3). Both professional organizations have conducted comprehensive literature reviews (external scientific evidence) to examine evidence-based research and have engaged audiologists with extensive clinical expertise in identifying evidence-informed practices for hearing screening with this age group. The clinical practice guidelines that ASHA has listed is the New York State Department of Health’s Clinical Practice Guideline which was given a Level B (moderate) Evidence rating. The British Health Technology Assessment concluded that there was level III evidence (cohort or case-controlled study) for the effectiveness of preschool hearing screening.⁸

“In developing evidence-based clinical practice guidelines, the process of reviewing the scientific literature to find evidence-based answers to specific clinical questions is challenging. Many of the specific clinical issues of interest have not been studied in well-designed studies to determine if the method is effective. Even when well-designed studies have been conducted on a particular clinical topic, the study findings themselves seldom present totally straightforward and unambiguous answers to the clinical questions of interest.

Careful analysis of the studies and considerable judgment are always needed when using the findings of research studies to help in making informed clinical decisions and developing clinical practice guidelines.

In developing practice guidelines for most clinical topics, it is unusual to find studies that evaluate exactly the clinical situations and types of subjects that are of interest.”⁷

Sensitivity, Specificity

Sensitivity - “The percentage of all persons with the condition who have a positive test correctly identifying the condition (the true positive rate). A method with a high sensitivity does a good job identifying persons who have the condition. The higher the sensitivity of a method, the lower the false negative rate.”⁹

Specificity - “The percentage of all persons who do not have the condition who have negative test results (the true negative rate). A method with a high specificity does a good job identifying persons who do not have the condition. The higher the specificity of a method, the lower the false positive rate.”⁹

Permanent Hearing Loss, Transient Hearing Loss

Permanent Hearing Loss - A permanent hearing loss typically results from problems with the cochlea (inner ear) or auditory nerve. Cochlear losses are called sensory or sensorineural while a loss such as auditory neuropathy spectrum disorder (ANSD) originates from the auditory nerve and beyond. Some permanent hearing loss is the result of sound not being able to get from the outer or middle ear to the inner ear. This type of hearing loss is categorized as a conductive hearing loss and can be permanent if untreated. Permanent conductive hearing loss is less common than permanent sensorineural hearing loss. Examples include malformation of the three bones in the middle ear (referred to as ossicular chain malformation), separation of the bones at the joints (referred to as disarticulation), or a malformation of the outer ear and canal (called atresia).

Transient Hearing Loss - A transient hearing loss is a temporary hearing loss, often the result of inflammation or infection of the middle ear (known as otitis media) or a collection of fluid in the middle ear (known as otitis media with effusion or OME).

Subjective and Objective Hearing Screening

Subjective Hearing Screening - A subjective screening requires a behavioral response to a stimulus that the screener can observe. Common subjective audiologic screenings for young children include Visual Reinforcement Audiometry (VRA) and Conditioned Play Audiometry (CPA). Less reliable subjective hearing screening approaches include observation of a child’s behavioral response to hand clapping or ringing a bell and also parent/caregiver/teacher questionnaires about a child’s perceived response to speech and other sounds.

Objective Hearing Screening - An objective hearing screening is a measurement of a physiologic response to a specific stimulus. Objective hearing screening approaches include Automated Auditory Brainstem Response (AABR) and otoacoustic emissions (OAE). Immittance (tympanometry) is not a measure of hearing but is an objective measure of middle ear function.

Hearing Screening, Audiologic Evaluation

Hearing screening - “The purpose of screening is to identify children most likely to have a targeted disease or disorder in need of treatment. It is important to differentiate screening from diagnostic procedures. Screening is applied to populations with no apparent signs or symptoms of the target disorder.”¹⁰ Health screenings for specific conditions are done because it is not feasible to provide diagnostic evaluations to the larger population. Hearing screening is therefore a process to identify the smaller group of children who are at risk of having a hearing

loss from the larger population who are far less likely to have the condition. Children not passing a hearing screening then receive medical and audiological follow-up diagnostic assessment to definitively identify which individuals have a permanent hearing loss.

Audiologic evaluation - An audiologic evaluation determines an individual's hearing ability relative to age-appropriate hearing levels within normal limits to determine if a hearing loss is present, where it occurs, and its degree, type, and configuration.¹¹

Pass, Refer, Other Result

Pass - Automated equipment will report results as Pass or Refer/Fail.⁶ A Pass result occurs when pre-determined criteria are met. The criteria for early childhood hearing screening with automatic equipment involves detection of specified physiological or electrophysiological signals in response to auditory stimuli. These signals must be of a certain magnitude within a pre-determined time frame. The criteria is set to include specified signals that occur if hearing is within the normal to mild hearing loss range. "A Pass result from a particular screening...indicates that a child is not at an increased likelihood for hearing loss. If a child has a Pass result, no additional steps should be taken beyond typical observation, although children may develop hearing loss later in life."¹²

Refer - Automated equipment will report results as Pass or Refer/Fail.⁶ A Refer result occurs when pre-determined criteria are not met. The criteria for early childhood hearing screening with automatic equipment involves detection of specified physiological or electrophysiological signals in response to auditory stimuli. "When evaluating the efficacy of any physiologic screening measure, it is important to recognize that the sensitivity and specificity of the measure are dependent on the criteria used for defining hearing loss, the criteria used for pass/refer, and the technical procedures involved in the test."⁹ Although the criteria is set to return a "Refer" if OAEs are not present, which should reliably identify children with moderate to severe hearing loss, different equipment may yield somewhat different results contingent upon the specific test parameters which are often set by the manufacturer. Technical procedure variability, such as probe fit, or the presence of internal/external noise, can also introduce error and interfere with the equipment's ability to accurately determine whether OAEs are present at the specified level. Despite limitations in specificity, in general, a Refer result from a particular screening...indicates that a child is at an increased likelihood for hearing loss. A Refer result means that the child requires further evaluation or the next step in the screening protocol.¹²

"...(T)he term *refer* for a hearing screening result that is a not-pass outcome is avoided, due to lack of clarity and confusion about the meaning and implications of the word refer. The term *fail*, which in years past had been discouraged in the belief that it would stigmatize infants, is recognized as a commonly-used term in the medical world to describe the outcome of a binary screening and has been adopted for use in this document."³ Although the terminology for talking with parents about a child's non-passing result has changed over time, the term "Refer"

is still in common use, particularly as it relates to how results are recorded or displayed on the screening equipment units.

Other Result - For children who could not complete screening due to lack of cooperation, internal or external noise that did not allow the test to proceed and yield a result, or other reasons, the findings can be recorded as "Could Not Screen."⁶

EVIDENCE-BASED AND EVIDENCE-INFORMED HEARING SCREENING APPROACHES FOR CHILDREN UP TO THREE YEARS OF AGE

Hearing screening for this age group requires reliable approaches which are consistent with the literature and with the developmental capabilities of the young children. Key factors to consider in selecting the screening approach include:

- The type of hearing loss to be identified
- The sensitivity and specificity of the approach
- The capacity of lay screeners to conduct quality screenings
- The cost of basic screening equipment and supplies
- The population to be screened
- The environments in which screening will occur

Otoacoustic emissions (OAEs) and, with limitations, tympanometry are recommended by the American Speech Language Hearing Association⁶ and the American Academy of Audiology^{2,7} as the hearing screening approaches to use to identify children up to three years of age who are at risk for permanent hearing loss.

RECOMMENDED SCREENING APPROACHES

Otoacoustic Emissions (Appendix 4)

When the outer hair cells of the cochlea/inner ear are stimulated by sound, an otoacoustic emission is created which travels outward through the middle and outer ear and can then be measured. Two types of otoacoustic emissions can be measured: Distortion Product OAEs (DPOAEs) and Transient Evoked OAEs (TEOAEs). DPOAEs and TEOAEs assess cochlear/outer hair cell functioning. Although not a direct measure of hearing, OAEs are sensitive to abnormalities of the outer hair cells in the cochlea where most permanent hearing loss in children occurs and yield an indirect estimate of peripheral hearing sensitivity.⁷

OAEs are measured by placing a small probe in the ear canal after checking to make sure there are no malformations or blockages. The stimuli for DPOAEs consist of two tones having a frequency ratio (f_1/f_2) of 1.22 (typically at 2000, 3000, and 4000 Hz) at intensities of 65 and 55 dB SPL respectively. TEOAE stimuli are transient clicks or frequency bands in the ranges of 2000 - 3000 Hz and 3000 - 4000 Hz presented at 85 dB SPL. OAEs are recordable from most ears with normal peripheral (outer hair cell) function. Ears manifesting otitis media with effusion (OME) typically will result in absent OAEs due to fluid in the middle ear.⁶ DPOAEs may be seen in some ears with hearing sensitivity in the mild to moderate range (20-50 dB HL).¹³ TEOAEs may be recorded in some ears with hearing sensitivity in the mild range (20-30 dB in the 2000 to 4000 Hz region).² Refer rates for TEOAEs range from 9% to 21% for children aged 2 - 9 years.² A multi-step DPOAE screening protocol with children less than 3 years of age yielded a Refer rate of 6%.¹⁴

OAEs are not influenced by “listener variables (which) include chronological or developmental age, cognitive level, language skills, or motor abilities.”¹⁵ Screening with OAEs is appropriate for use with all ages, including children with developmental levels less than 3 years, since it does not require a behavioral response and can be used with patent pressure equalization (PE) tubes.² OAEs are used effectively for newborn hearing screening and, for more than 20 years, in Early Head Start programs for children up to 3 years of age. The ECHO Initiative has demonstrated the feasibility of training lay screeners to conduct DPOAE hearing screenings.¹⁶ Quick, objective screening results, typically in less than 5 minutes, can be obtained in environments with a modest amount of ambient noise.

Advantages

- DPOAEs and TEOAEs are quick, with results often obtained in less than 5 minutes ¹⁶
- DPOAEs and TEOAEs can be conducted by trained lay or para-professional screeners and by speech-language pathologists¹⁶
- On-line training is available for DPOAEs
- DPOAEs and TEOAEs can be performed successfully in primary care, preschool, and educational settings ^{16,17}
- DPOAEs and TEOAEs are not influenced by listener variables ¹⁵
- DPOAE and TEOAE screening is ear specific with ears being screened independently
- DPOAE and TEOAE equipment is portable and hand-held with Pass/Refer outcomes displayed
- DPOAEs and TEOAEs do not require a behavioral response
- DPOAEs and TEOAEs may be used with patent pressure-equalization tubes²
- DPOAE equipment is less sensitive to environmental noise than TEOAEs
- DPOAE equipment has more availability in the U.S. than TEOAEs

Limitations

- DPOAEs and TEOAEs may have varying sensitivity and specificity due to criteria used for Pass/Refer.⁹
- DPOAEs and TEOAEs have test parameters set by the manufacturers so different equipment may have different results.⁹
- DPOAEs and TEOAEs may not identify every type of hearing disorder. For example, Auditory Neuropathy Spectrum Disorder (ANSO) cannot be identified by OAE in the absence of AABR⁹ which is not feasible for this age group in community-based hearing screening programs.

Immittance (Tympanometry)

Immittance (Tympanometry) is a measure of middle ear function but not a measure of hearing sensitivity. Tympanometry measures the volume of the ear canal as pressure is varied and can indicate middle ear dysfunction such as a tympanic membrane perforation, negative middle pressure, or fluid in the middle ear space which accompanies otitis media with effusion (OME). Some middle ear disorders, such as OME, may result in a transient (temporary) conductive hearing loss.

Tympanometry can be used with all ages. With very young children (newborn to 9 months) a probe tone of 1000 Hz should be used instead of the 226 Hz probe tone that is used with older individuals.⁷ Similar to OAEs, tympanometry can be performed in quiet settings such as clinics, classrooms, or homes. A variety of professionals and para-professionals, such as audiologists and providers in healthcare, early care and education, Part C/Early Intervention, special education, and home visitation programs can conduct tympanometry testing.

The use of tympanometry introduces more complexity in training, implementation, and recording, as well as expense of equipment, disposables, and calibration. For example, the probe tone frequency needs to be changed if the child is younger than 9 months. A probe pressure seal is more difficult to obtain than the acoustic seal needed for OAE screening and additional screening time is needed to conduct tympanometry.

SCREENING APPROACHES NOT RECOMMENDED

The remaining approaches of hearing screening for this age group are not recommended for community-based screening programs.

Automated Auditory Brainstem Response (AABR)

Automated Auditory Brainstem Response (AABR) is used extensively in newborn hearing screening. Testing with AABR requires that the child be very still which is attainable with sleep for the first few months of life.³ However, beyond six months of age, sedation is often needed to achieve the state of quiet needed for an AABR test. If sedation is required, a diagnostic evaluation would be conducted rather than a screening. "When evaluating the efficacy of any physiologic screening measure, it is important to recognize that the sensitivity and specificity of the measure are dependent on the criteria used for defining hearing loss, the criteria used for pass/refer, and the technical procedures involved in the test."⁹ Different equipment may yield different screening results because automated screening equipment often has test parameters set by the manufacturer. In addition, AABR equipment is expensive and may not be affordable for many programs. Therefore, AABR screening is not recommended beyond the newborn period in a community-based setting.

Behavioral Observation

Observing a child's reaction to sounds such as a bell ringing, finger snapping, or a whisper is not recommended as a screening approach. Sounds like these are of unknown pitch (frequency) and loudness (intensity) so this process has low sensitivity, specificity, and reliability. Additionally, behavioral observation of a child's response to sound in the sound field (without listening through earphones) is actually only indicative of hearing in the better ear so unilateral losses would be missed.

Visual Reinforcement Audiometry (VRA)

Visual Reinforcement Audiometry (VRA) is a subjective hearing assessment approach for children from 6 months to 24 months. Typically, VRA will be conducted by an audiologist with an assistant in a sound booth set up with appropriate reinforcers to establish thresholds rather than screening. Although, it is most commonly carried out in a sound treated environment, it can be conducted in quiet environments (50, 58, and 76 dB SPL respectively for 1000, 2000, and 4000 Hz) with insert earphones. VRA requires novel visual reinforcers to reward and maintain a specific response to auditory stimuli and typically requires an assistant to re-direct the child's attention following a response. Some children cannot be conditioned to the task. If a child resists earphones, the auditory stimuli may be presented in the sound field in which case only the better ear is tested.⁷ VRA is not practical in most, if not all, community-based hearing screening programs conducted in natural environments by lay individuals because of the need for specialized reinforcers and training.

Conditioned Play Audiometry (CPA)

Conditioned Play Audiometry (CPA) is appropriate for screening young children with a developmental age of 3 years or more. Typically, CPA is conducted with headphones and can occur in a quiet sound field (50, 58, and 76 dB SPL respectively for 1000, 2000, and 4000 Hz)^{2,7} which is conducive to community-based screenings in many settings. Not all children can be conditioned to perform a task in response to repeated sound stimuli, however. As reported in one recent study¹⁸, nearly half of 3 year old children could not be tested with CPA. If a child resists earphones, the auditory stimuli may be presented in the sound field in which case only the better ear is tested.⁷ Although CPA is a viable option for screening the population of children who are developmentally able to be conditioned, it is not recommended as a reliable screening procedure for children under 3 years of age.

Periodicity Schedules

Periodicity schedules specify the age or frequency of screenings and assessment. The 1-3-6 periodicity schedule (screening before one month, diagnostic evaluation before three months, and enrollment in early intervention before six months of age) is the most common one for EHDI programs. A recognized periodicity schedule that includes hearing screening is the American Academy of Pediatrics' Bright Futures which specifies an objective hearing screening at birth and 4 years of age with risk assessments at all other interactions¹⁹ (Appendix 5). Thirty two states and territories have adopted the Bright Futures hearing screening periodicity schedule as their periodicity schedule while others have made minor modifications.²⁰ This schedule is the minimum level of services provided by healthcare providers and does not inform a stepped-up screening system in community-based settings targeting children under three years of age.

Conducting actual screenings rather than risk assessments can facilitate earlier identification and intervention.

Typically, annual hearing screenings are conducted with the under three year old population in Early Head Start programs. Some programs will screen all children at a particular point in the year while others will screen children on a more individualized schedule such as the child's birthday. The EHDI 1-3-6 follow-up could potentially be adopted by early childhood screening programs by specifying that a second screening be conducted within two weeks, audiological evaluations within three months, and engagement with early intervention within six months of the initial screening.

Protocols and Guidelines

A protocol is a flowchart or roadmap of a set of procedures or steps leading to a final result. Multi-step protocols are often used in newborn hearing screening settings and are also frequently employed when screening children 0 – 3 years of age. A multi-step protocol can reduce factors that negatively affect the accuracy of the screening process, such as screening instrument malfunction, lay-screener error, environmental interference due to noise, and temporary conditions affecting the child's auditory pathway or willingness to allow the screening to proceed. In establishing a protocol in an early childhood setting, it is advisable to carefully consider factors such as access to the children being screened, screener skill level, child/family access to follow-up healthcare and audiological assessment, as well as the prevalence of temporary conditions (common cold or upper respiratory infections) that can interfere with accurate screening. Selecting and following a protocol that will work best for the population being served within a specific setting will help to reduce error and minimize false-positive referrals to healthcare providers and audiologists, while simultaneously maximizing accurate and timely referral and follow-up. It is also important for individuals involved in implementing specific screening protocols to collect and publish data on outcomes to help guide future implementation efforts.

Evidence-Based Protocol

The Early Childhood Hearing Outreach (ECHO) Initiative developed an evidence-based protocol to conduct OAE hearing screenings for young children less than three years old in Early Head Start settings with the outcome of identifying permanent hearing loss. If a parent or provider indicates concern about a child's hearing or speech development, the ECHO protocol suggests the child should be referred for further evaluation regardless of the OAE screening result. For the majority of children for whom there are no concerns, the protocol (Figure 1) specifies that if an ear passes an OAE screen, that ear is "complete." If an ear does not pass, a second screening of the non-passing ear should be done within two weeks. If the previously non-passing ear does not pass the second screening, a referral is made to a health care provider for a middle ear evaluation and any necessary treatment. Once any middle ear problems are resolved, a re-screen should be conducted on the non-passing ear(s). If the ear still does not pass, an audiological evaluation should be conducted and the results reported to the program.

Lay screeners are taught a simple rule for determining when a child's hearing screening process is complete: the screening and follow-up process is complete when each ear has passed or the child has received an audiological evaluation and the program has received the results report.

In the ECHO protocol, the status of the middle ear system for any ear that doesn't pass the second OAE screening is obtained through a referral to child's healthcare provider for a middle ear consultation which should include tympanometry and/or pneumatic otoscopy.²¹

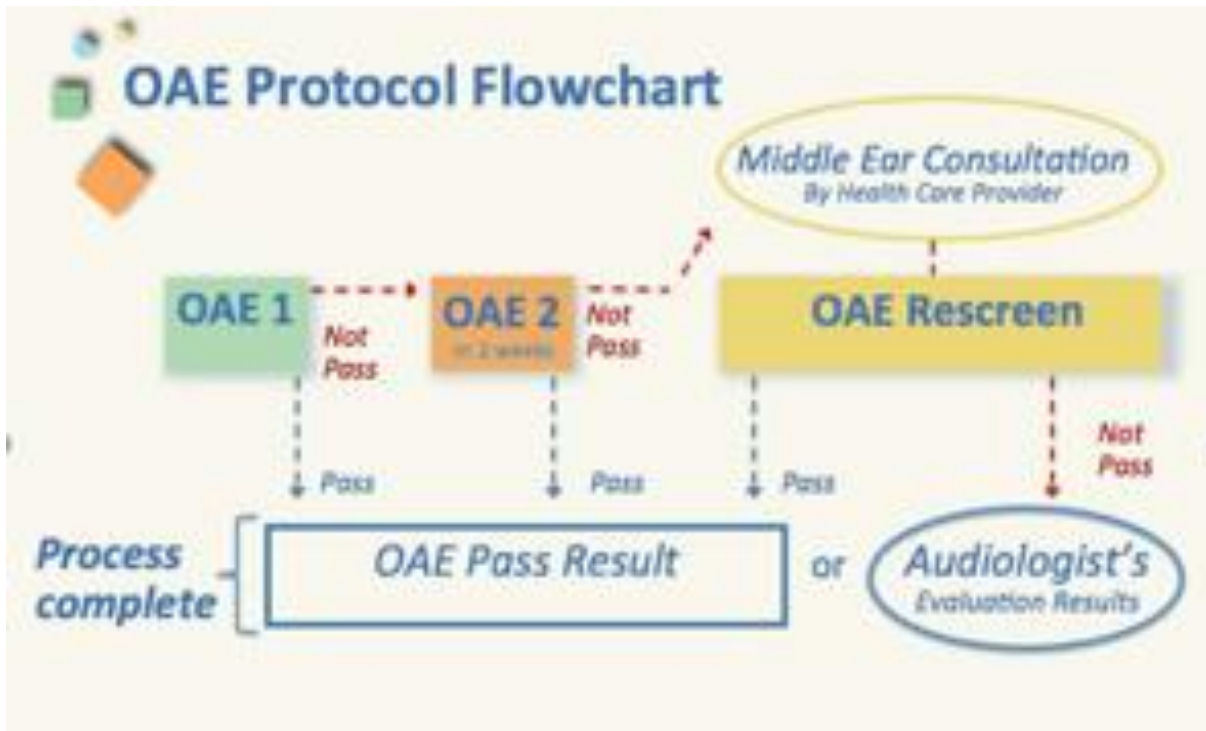


Figure 1. ECHO OAE Protocol Flowchart

This protocol has been extensively tested in Early Head Start settings with child-specific data on 4,519 children being collected to document outcomes at each stage of the protocol.¹⁶ One finding that is important to note is that if only a single-stage OAE screening had been used, 24% of children would have been referred for further assessment. The addition of a second-stage OAE screening for children who did not pass, conducted approximately two weeks later, reduced that number to approximately 13% of the total number of children in the study needing further follow-up. The multi-stage screening protocol was particularly important because the healthcare providers serving the Early Head Start programs involved in the study had expressed concern that lay screeners would over-refer based on children having common colds and temporary effusion. After middle-ear evaluation, treatment and a subsequent OAE screening, under 6% of the total population of children were referred to a pediatric audiologist for a complete audiological evaluation. The advantage of this multi-step protocol is that false-positive referrals to providers were minimized; the disadvantage is that children had to be tracked for a greater length of time with an increased chance of loss to follow-up. This

protocol is especially suitable for programs that have easy access to the children being screened such as in center- or home-based programs with a regular service delivery schedule.

Evidence-Informed Protocols

The American Speech-Language-Hearing Association (ASHA) and the American Academy of Audiology (AAA) have also developed hearing screening protocols and guidelines. Both professional organizations have conducted comprehensive literature reviews (external scientific evidence) to examine research and have engaged audiologists with extensive clinical expertise in identifying evidence-informed practices for hearing screening with this age group.

ASHA's recommended protocols²² include use of OAE Only (Appendix 6) or OAE and Tympanometry (Appendix 7). Following a Refer result on the first OAE screening, the OAE Only protocol recommends waiting four weeks to re-screen. If the child does not pass the rescreen, the child is referred to a healthcare provider for consultation/treatment with an additional OAE rescreen four weeks after treatment is complete. If the child still does not pass at this point, the child is again referred to a healthcare provider with a referral for an audiologic evaluation. ASHA recommends that a re-screening be conducted four weeks after a screening or medical consultation.

The American Speech-Language-Hearing Association⁶ provides the option of including tympanometry to rule out possible middle ear dysfunction. These protocols insert optional tympanometry into the first OAE screening if one or both ears Refer.

The American Academy of Audiology (AAA) recommends OAE screening for children with a developmental level less than 3 years. Primary levels for DPOAE are 65 dB SPL and for TEOAE is 80 dB SPL \pm 3 dB. AAA recommends that tympanometry be performed if a child does not pass the initial OAE screening with a re-screen in 8 - 10 weeks.^{2,7}

Protocol Considerations

A multi-step protocol is generally recommended to increase the accuracy of outcomes obtained by lay screeners who are conducting the OAE screening procedure. Although OAE equipment is reliable in determining a "Pass" result, it is not precise in determining when a true "Refer" result has been obtained. Technical procedure variability, such as poor probe fit or the presence of internal/external noise, may cause the equipment to return a "Refer" result. This could potentially result in over-referrals to both healthcare providers and audiologists. When feasible, adding a second OAE screening in approximately two weeks will allow temporary conditions (environmental noise, congestion caused by a common cold, or a child's unwillingness to sit quietly for the screening to be conducted) to be resolved. The rescreen also serves as a reminder to screeners to optimize probe fit and screening conditions.

For newborn hearing screening, JCIH specifies that both ears should be re-screened even if only one ear did not pass the initial OAE screening.³ The ECHO Initiative staff found that lay

screeners in Early Head Start programs needed a very clear understanding of when screening an ear is complete. If the purpose of the screening program is to identify those ears that are at risk of permanent hearing loss, there should be no need to re-screen a passing ear. Re-screening both ears, even when one has already passed, leads to screener confusion about the reliability of a passing screening result. From a pragmatic perspective, re-screening an ear that has already passed the initial screening increases the time needed to screen.

A subsequent middle ear evaluation, which may include otoscopy (visual examination of the outer and middle ear), tympanometry and/or pneumatic otoscopy, is an important component of an early childhood hearing screening and follow-up protocol. Understanding the purpose of middle ear evaluation is important when developing early childhood hearing screening practices. While middle ear evaluations conducted as a part of a hearing screening programs will sometimes identify children with middle ear dysfunction, which may be accompanied by temporary hearing loss, middle ear dysfunction is not a logical target condition of a hearing screening program of the general population. Ear infections affect approximately 23% of the 0-3 population at any given time and, increasingly, the recommended treatment is to “watch and wait”. Mass screening for middle ear disorders would result in unmanageable over-referrals to healthcare providers. Healthcare providers routinely provide middle ear assessment as part of well-child checks. In acute cases, ear infections are accompanied by observable fevers, pain or other identifiable symptoms which are commonly identified by parents and caregivers and for which medical care is justifiably sought. Screening for transient middle ear conditions would be akin to screening for the common cold. Hence, when tympanometry and other middle ear evaluation methods are used as a part of the diagnostic “ruling out” process when screening for permanent hearing loss, it should not be understood to suggest that middle ear disorder is the target condition of a mass screening program.

The purpose of the middle ear evaluation in an OAE screening protocol is to help determine the nature of an OAE “Refer” result and to guide follow-up. When a given ear does not pass the OAE screening (according to some protocols, after two attempts separated by approximately 2 weeks), a middle ear evaluation is needed to determine if an infection or fluid is present that may have prevented the inner ear from having been successfully screened during the OAE procedure. If middle ear dysfunction is found during this evaluation, the healthcare provider will determine the treatment or observation period. Once the ear is deemed healthy and clear, the OAE screening procedure is repeated and usually a result is obtained. For purposes of efficiency and expediency, the middle ear evaluation is best done by healthcare providers who will determine a treatment or observation plan, or if no condition is found and if the ear still does not pass the OAE screening, can play a role in making a referral to an audiologist.

Some professionals have suggested potential advantages to including tympanometry as a procedure provided by lay screeners at the time of the OAE screening. The rationale is that if a given ear does not pass the OAE screening, but does pass tympanometry, and if it is possible to make a direct referral to an audiologist without first seeing and obtaining a referral from a healthcare provider, this can potentially speed up the diagnostic evaluation process. This scenario is relatively unusual and although it represents a modest potential benefit to pairing

OAE and tympanometry, it would typically not warrant designing a screening program around this assumption. It is far more common that an ear not passing an OAE would also not pass tympanometry, thus necessitating referral to a healthcare provider who would routinely conduct a middle ear evaluation, often including tympanometry, to determine a treatment plan. In most cases, the addition of tympanometry by the lay screener would therefore not deliver an additional benefit. Any potential advantages of pairing tympanometry with the OAE screening must be carefully weighed against the fact that it adds: 1) Complexity in terms of lay-screener training; 2) Screening time in implementing the procedure and accurately documenting results; and 3) Expense of equipment, disposables and equipment calibration.

SCREENING SETTINGS

Settings and Variables

Hearing screening methods which do not require specific environmental settings, such as a sound booth, sound field speakers, or other supplementary equipment, can be utilized in a variety of settings. Being able to take OAE equipment to where the child is located offers many advantages to complete the screening process without undue burden on the child's family. A common location for screening is the child's early care and education setting, such as daycares, preschools, and Early Head Start classrooms, as well as the child's home for home visiting programs. Medical clinics are another setting where screenings may be conducted. These include primary care provider offices, county health departments, Federally Qualified Health Centers, Indian Health Service facilities, migrant health centers, and hospitals. Less common, but equally valid, sites include mobile vans, community centers, schools, libraries, and public housing sites.

Conditions which contribute to a viable screening program (Appendix 8) include:

- Ongoing access to and relationships with children and families, especially if the access is frequent to facilitate any follow-up that may be needed.
- Access to medical and audiological services when referrals are indicated.
- Tracking system which documents ear-specific results and any follow-up referrals and results.
- Adequate staffing with substitute screeners available.
- Adequate budget for disposable supplies, calibration, repairs, etc.
- Focus on child language development and hearing to maintain screening as a priority especially if hearing screening is not a requirement.
- Sufficient collaborative capacity to support ongoing communication, training, and technical assistance.²³

Regardless of the location in which hearing screening is provided, there are variables to consider which may either facilitate or hinder successful completion. A child's natural environment is often somewhat noisy, a factor which can interfere with obtaining accurate screening results. Ambient noise levels between 34 dBA and 51 dBA have been found to be acceptable for OAE screenings.² Screening during naptime is an option because both the child

and environment are quiet. Other environmental factors to consider include having adequate space, especially a quiet area of the room, to conduct the screening. An assistant is helpful to keep the child comfortable and distracted with interesting manipulatives. A setting in which adults with whom the child is familiar is also helpful by providing a calming and reassuring presence.

The screening setting and protocol are influenced by the general screening program model that a program selects. A screening model that many Early Head Start and medical clinics adopt is “centralized” in which the screenings and follow-up occur in the program’s classroom or office and are coordinated by program/agency staff. Programs contracting with an outside agency to conduct hearing screenings may find that the screener is not available within a reasonable time frame to screen any children who were absent or who referred on the initial screening. Another model is the “health fair” approach which often leads to challenges because managing follow-up referrals may not be possible.

Potential Partner Organizations

Since 2001, EHDI programs in many states have partnered with community-based early childhood and health programs to establish hearing screening for young children. Most have accessed the vast array of training and support resources developed and implemented by the ECHO Initiative at NCHAM. The resources, which follow a sequence of Outreach->Planning Technical Assistance->Training->Follow-up Technical Assistance, are available for use in establishing new hearing screening programs. The resources include [discussion guides](#), planning checklists, equipment profiles, training videos and webinars, guides, forms, and a data log among many others (Appendix 9).

Many EHDI programs have initiated partnerships with two federally-funded programs that have regulations regarding hearing screenings for enrolled children up to the age of 3 years. Early Head Start and Part C/Early Intervention are programs that have both the commitment to screening and the capacity to support follow-up.²¹ Other government funded programs for young children may partner with EHDI programs to support early childhood hearing screening by linking with families or providing space for screening while others may actually conduct hearing screenings. These programs include Newborn Bloodspot Screening Program; Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV); Special Supplemental Nutrition Program for Women, Infants and Children (WIC); Title V Children and Youth with Special Health Care Needs (CYSHCN) Program; and Family to Family Health Information Centers (Appendices 11 - 15) for program profiles). A review of the HRSA grant applications on <https://www.infanthearing.org> reveals over 40 actual and potential expansion partners (Appendix 10).

Early Head Start

Head Start is a federal program that promotes school readiness for children in low-income families by offering educational, nutritional, health, social, and other services. One of the

largest programs serving low-income infants and young children, Head Start includes preschool programs for children 3 - 5 years of age and Early Head Start programs for children 0 - 3 years of age. Additionally, Migrant Head Start and American Indian/Alaska Native (AIAN) Head Start programs serve children 0 - 5 years of age in their respective populations. Currently Early Head Start and Head Start programs are found in every state. Each is required by Head Start Performance Standards to ensure that every child receives an annual hearing screening using an evidence-based method. A precise screening methodology is not specified, permitting for changes in best practice to evolve over time without the need for updating the Standards. Although many Early, AIAN, and Migrant Head Start programs have adopted OAE hearing screening over the last 20 years through the ECHO Initiative, some are using newborn hearing screening results, parent report, or observation.^{24,25,26}

Each local Early Head Start grantee (program) is a direct recipient of federal Office of Head Start funding. Before making contact with individual programs within a state, it can be helpful to contact the Head Start State Collaboration Office (HSSCO).²⁷ This Office coordinates with other state systems and may assist in disseminating information and establishing connections with individual community-based programs. While HSSCOs do not have oversight authority pertaining to individual Early Head Start or Head Start programs at the local program level, they can provide information about the Head Start infrastructure, programmatic components, how to locate various programs, and how to facilitate connections. They may also help establish a formal collaboration agreement between EHDI programs and individual programs.²⁸

The Head Start Center Locator²⁹ provides the locations of all of the local community-based programs within a state or community. Every program has its own local Health Services Advisory Committee (HSAC) that, among other things, provides guidance on screening methods to be used in the program. It is important to note that relatively few HSACs include a pediatric audiologist to help determine hearing screening practices. As a result, programs within a state may not all use the same screening method and some may not use methods considered current or evidence-based.

The Head Start Program Performance Standards specify the time frame for screening to occur and require an evidence-based screening. The standards require certain follow-up actions, tracking/monitoring of referrals and plans, and assisting parents. (Figure 2)

1302.42 Child health status and care.³⁰

b) Ensuring up-to-date child health status.

(2) Within 45 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, a program must either obtain or perform evidence-based vision and hearing screenings.

d) Extended follow-up care. (1) A program must facilitate further diagnostic testing, evaluation, treatment, and follow-up plan, as appropriate, by a licensed or certified professional for each

child with a health problem or developmental delay, such as elevated lead levels or abnormal hearing or vision results that may affect child’s development, learning, or behavior.

(2) A program must develop a system to track referrals and services provided and monitor the implementation of a follow-up plan to meet any treatment needs associated with a health, oral health, social and emotional, or developmental problem.

(3) A program must assist parents, as needed, in obtaining any prescribed medications, aids or equipment for medical and oral health conditions.

Figure 2. Excerpt from Head Start Program Performance Standards

Part C/Early Intervention of the Individuals with Disabilities Education (IDEA) Act

Part C/Early Intervention programs not only serve children 0 – 3 years of age already identified as DHH, often from the EHDI system, but also actively engage in “Child Find” efforts of their own. Hence, Part C represents not only an opportunity to link previously identified children with early intervention services, but also exists as a system that can actively help to identify additional children with late onset or progressive hearing loss or children who were lost to follow-up after newborn screening.

Children who are manifesting a range of developmental delays or behavioral issues may be referred to the Part C system for evaluation to determine their eligibility for enrollment. It is important to remember, and to remind programs, however, that children who have an unidentified hearing loss will not necessarily present with indicators that would cause parents or professionals to suspect hearing as a primary source of concern. There is evidence that not all children entering Part C/Early Intervention programs receive a hearing screening or evaluation.³¹ This may be true even when children present with concerns about speech and language development, one of the most common reasons for referral to Part C.

The EHDI system has a two-pronged connection with the Part C system:

- a. Children identified as DHH as a result of newborn hearing screening and follow-up are referred to Part C to access early intervention services. These are predominantly children with congenital hearing loss.
- b. Children referred to Part C from other systems who are evaluated and identified as being deaf or hard of hearing as a result of the Part C intake and evaluation process and then referred to the EHDI system to obtain additional support and information for families; predominantly children with late-onset or progressive hearing loss, or children who did not receive a newborn hearing screening or were lost to follow-up.³²

Each state has a Part C Coordinator³³ with whom EHDI program staff may want to meet to discuss relevant regulations and practices, keeping in mind the two-pronged connection between EHDI and Part C. Prior to meeting, it is helpful to learn more about Part C regulations^{34,35} (especially as they relate to multidisciplinary evaluation and assessment³⁶).

The ECHO Initiative sought guidance from the Office of Special Education Programs specifically with regard to the second prong regarding hearing screening requirements within Part C. According to the guidance provided, states have the option to include hearing screening and, for children receiving treatment for middle ear infections, the 45 day time line may be extended due to exceptional family circumstances.³⁷

The Regulations for Part C of the Individuals with Disabilities Education Act (IDEA) indicate that screening is an optional procedure to determine if a child has a suspected disability (Figure 3). If there is a suspected disability, the child will be evaluated and assessed. Screening involves the administration of appropriate instruments by personnel trained to administer those instruments.³⁸

34 CFR § 303.320 - Screening procedures (optional)³⁸

(b) Definition of screening procedures. Screening procedures -

(1) Means activities under paragraphs (a)(1) and (a)(2) of this section that are carried out by, or under the supervision of, the lead agency or EIS provider to identify, at the earliest possible age, infants and toddlers suspected of having a disability and in need of early intervention services; and

(2) Includes the administration of appropriate instruments by personnel trained to administer those instruments.

Figure 3. Excerpt from IDEA Part C Regulations

POLICIES AND PRACTICES OF SPECIFIC HEALTH AND/OR SERVICE PROGRAMS

Early Periodic Screening, Diagnosis, and Treatment (EPSDT)

The EPSDT benefit provides comprehensive health coverage for all children under age 21 enrolled in Medicaid. Required in every state, EPSDT finances appropriate and necessary pediatric health services. This benefit requirement includes children enrolled in a state's Children's Health Insurance Program (CHIP), but not those in separate, private CHIP health plans.

The Title V Maternal and Child Health Services (MCH) Block Grant³⁹ program and the Medicaid program are required under federal law to coordinate activities, using coordination agreements and partnerships between state Medicaid agencies and Title V MCH program grantees to improve access to services for children and pregnant women (Section 505 [42 U.S.C. 705] (a)(5)(F)). The agencies maintain websites that describe the law and the opportunities that states are using to coordinate Title V and Medicaid.^{40,41} In particular, coordination with the EPSDT benefit is required.

Since Medicaid covers approximately one-third of 1-6 year old children in the US, it offers a way to ensure that young children receive appropriate physical, dental, developmental, and mental health services from prevention to treatment.³⁹

Hearing Screening Services for Children

Medicaid coverage for children provides low-income children with services that can detect and address hearing problems. Children enrolled in Medicaid should receive a risk assessment at each well-child check-up in addition to newborn hearing screening per JCIH³ and a hearing screening at 4 years of age. If a primary care provider suspects that a child has a hearing problem due to the risk assessment, the child should receive further screening, evaluation, and necessary treatment.

In addition to Head Start and Part C/Early Intervention programs, states may have other programs that include early childhood hearing screening. These may reside in local health departments, school districts, home visiting programs or healthcare settings. It may also be helpful to identify services systems that may partner with EHDI programs in outreach activities to promote periodic early childhood hearing screening and the importance of follow-up when screenings have been completed. Potential partners may include:

- Newborn Bloodspot Screening Program.^{42,43,44} (Appendix 11)
- Special Supplemental Nutrition Program for Women, Infants and Children (WIC)⁴⁵ (Appendix 12)
- Title V Children and Youth with Special Health Care Needs Program⁴⁶ (Appendix 13)
- Family-to-Family Health Information Centers^{47,48} (Appendix 14)
- Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program^{49,50,51} (Appendix 15)

COLLABORATION AND REFERRAL MECHANISMS

Data Sharing Agreements

To prevent data misuse, abuse, or unregulated dissemination, EHDI programs often establish data sharing agreements with partners to outline which data will be shared and how the data will be shared and used. A memorandum of understanding or agreement outlines the agreement that an EHDI has reached with another entity. Both types of documents are used by EHDI programs to collaborate, exchange demographic information, and track 1-3-6 services.

A review of the EHDI data sharing agreements and MOUs/MOAs described in the HRSA grant narratives on <http://www.infanthearing.org> revealed the types of current and planned agreements, the types of partners with whom agreements are reached, and the types of information to be shared.

Nearly half of the EHDI programs have data sharing agreements or MOUs/MOAs in place and about one-third have them planned for the current funding cycle. Agreements with Part C/Early Intervention programs are the most common, with 19 EHDI programs having them in existence and agreements planned by 12 other EHDI programs. The most common types of data to be shared include referrals, dates of referral and enrollment, IFSP and services coordination information, developmental outcomes, and primary disability. While the vast majority of agreements specify that the shared data will be individually-identifiable, several include only aggregate data which does not support one-to-one matching of services or results to a specific child.

Other programs with which EHDI programs should consider establishing agreements include Early Head Start, Vital Records (birth certificates), Birth Defects Registry, Dried Blood Spot, and MIECHV, Children and Youth with Special Health Care Needs (CYSHCN), Women-Infant-Children (WIC), and Hands & Voices. The purpose of these agreements vary. For example, Vital Records (birth certificates) linkages can provide accurate identification and birth event information, as well as maternal demographics such as race/ethnicity, education, age, marital status, etc. Data from WIC can provide current contact information.

Another example of data sharing is with Early Head Start programs which can provide comprehensive early childhood screening results which can sometimes be matched to an EHDI program's lost to follow-up/documentation (LTF/D) as well as an indication of the program's level of effort and adherence to a recommended protocol. Six EHDI programs in New England developed an Interstate Exchange Agreement in 2008 to be able to share hearing screening and follow-up results of "border babies" (babies born in one state but residing in a neighboring state).

As with any governmental agreements, the programs' legal departments should be involved in the development of any MOU/MOA and data sharing agreement.

Database Systems

EHDI data systems have continued to evolve as EHDI programs have become established and expanded beyond screening to include diagnostics, early intervention, and family-to-family support services. Expansion of hearing screening for young children up to the age of 3 years will serve as a catalyst for an even greater expansion as new data records will be need to be created for children not born in the state. Additionally, data matching will become increasingly difficult as the names of children may not be a one-to-one match with records already in the EHDI data system. Several programs are using probabilistic linkage algorithms or deterministic matching to improve the matching of records from two different data systems.

A variety of EHDI data systems are in use with some being commercially-available and some being custom-made for a specific EHDI program. Data systems such as Oz, Hi*Track, and Neometrics emerged as common commercially available data systems from review of 40 grant applications while about an equal number of EHDI programs have custom data systems.

The Centers for Disease Control and Prevention (CDC) EHDI has funded many states to acquire or develop data systems (Appendix 16). Of the 31 data system descriptions reviewed, about half were created prior to 2010 while the other half have been created more recently. CDC EHDI receives annual EHDI Hearing Screening and Follow-Up Survey aggregate reports from EHDI programs which contain specific data points regarding maternal demographics, hearing screening, audiologic diagnoses, and early Intervention services. To date, these annual reports are focused on newborn hearing screening and do not include children beyond that age.

EHDI data systems differ in the source of the records and data and the type of data. For example, some newborn hearing screening records are automatically generated from birth certificates in the Vital Records system while others are created from dried blood spot records or even manually. Records generated from birth certificates are advantageous because all occurrent births are recorded and maternal demographics are transferred or accessible. Many of the birth facility hearing screening records are entered manually either at the birthing facility, the dried blood spot laboratory, or by the EHDI program. Some EHDI data systems are becoming increasingly sophisticated by retrieving screening results in HL7 format directly from birthing facility electronic health records or from the hearing screening equipment which creates real-time information. Experience has shown that the fewer times data is manually recorded, the less errors are made.

Data systems acquire audiologic diagnostic results in several different ways. Some systems permit audiologists to directly access a child's record and directly input the audiological results while others depend upon written or faxed results which are input by EHDI staff. Similarly, Part C/Early Intervention data such as referral and enrollment dates, Individualized Family Service Plan (IFSP) information, or primary disability category may be accessed directly from the Part C/Early Intervention data system or by written reports. Most EHDI programs acquire individually-identifiable Part C/Early Intervention results but a few only receive aggregate reports. Aggregate reports are problematic because even though the number of children

identified with a hearing loss may equal the number receiving early intervention services, those may actually be different children.

EHDI data systems are often linked to other data systems to facilitate more accurate and rapid access and transfer of data. Of the EHDI records reviewed, about two-thirds are linked to vital records/birth certificate systems and about one-third are linked to the dried blood spot data system. Other linkages include birth defects, immunization, Medicaid, critical congenital heart disease (CCHD), Children and Youth with Special Health Care Needs (CYSHCN), Part C, Cleft Lip/Palate, Supplemental Nutritional Assistance Program (SNAP), Women-Infant-Children (WIC), and Pregnancy Risk Assessment Monitoring System (PRAMS).

EHDI programs use data in multiple ways. Of course, the primary purpose is to be able to track those babies who need some type of follow-up and to notify providers and parents of the follow-up needs. The capacity to generate a variety of reports is extremely important for EHDI quality improvement efforts. Generating “report cards” for birthing facilities and analyzing the reasons for Loss to Follow-up/Documentation are two important QI efforts. The capacity to easily complete CDC’s EHDI Hearing Screening and Follow-Up Survey is also important because of the details about hundreds or thousands of children in the 1-3-6 data system.

Many EHDI programs have created or use powerful data systems to manage their public health programs. Many have been able to establish their system as a module of a more expansive system such as vital records/birth certificate systems or statewide comprehensive health information exchanges. Expanding the age range to 3 years and adding new hearing screening programs may be challenging for some EHDI programs with data systems that don’t support adding new modules or don’t have the capacity to add records for children that were born in another state. Deciding how hearing screening results for 0-3 year old children will be formatted for submission will need to be carefully considered so as not to burden either EHDI or partner program staff with undue recording or inputting of results. And, finally, adding a new cohort of children in potentially many early childhood programs will require additional training about data recording and reporting.

Careful consideration should be given to the purpose and the amount and type of data that an EHDI program plans to collect from community-based hearing screening programs, keeping in mind that many programs will likely be collaborating on a voluntary basis. Does the data collected need to be as comprehensive as is currently being managed by EHDI programs? Does individually-identifiable hearing screening results need to be collected or will de-identified or aggregate data be sufficient? Do all screening results need to be reported or only information about those children identified with a permanent hearing loss? The two primary early childhood programs (Early Head Start, Part C/Early Intervention) have their own recording and tracking systems so do EHDI programs need to replicate those efforts? How much data needs to be collected to provide quality improvement technical assistance? How much new data are the EHDI program staff and data systems capable of recording and tracking? There are no definitive answers to these questions that will fit all EHDI programs and their screening partners.

However, EHDI programs will need to determine their capacity to manage new data sets and the purposes for which that data will be used.

Role of Audiologists

Audiologists fulfill various roles in the process of identification and habilitation of hearing loss in young children. A primary role is to conduct diagnostic evaluations to determine if a child is DHH and, if so, the type, degree, laterality, and configuration of the hearing loss. Other important roles include screening for hearing loss, and provision of hearing technology such as hearing aids, FM systems and cochlear implants.

Roles within the EHDI system which become increasingly important as the focus of EHDI programs expands to include children up to age 3 years are provision of planning, training, technical assistance, and quality improvement for community screening programs. Audiologists also can serve as public health administrators, staff, advisors, or consultants to EHDI programs.

A challenging aspect of EHDI programs is to ensure that hearing screening and diagnostic evaluation reports are received in a timely manner to support follow-up services, reporting, and quality improvement efforts. Expansion of the age range to include children up to 3 years of age increases the importance of efficient reporting practices. In fact, at least four EHDI programs are now governed by statutes that expand the mandatory reporting of screening and diagnostic results to age three years and beyond.

To determine how EHDI programs are currently fulfilling this need, 40 EHDI grant applications for the current funding cycle on <https://www.infanthearing.org> were reviewed. Of those applications, 31 included information about audiologists' reporting to EHDI programs.

As EHDI data systems have evolved over the last two decades, programs have moved from paper forms and faxing to online reporting. Of the grant applications reviewed, six continue to receive reports via fax, although that may not be the only method of reporting. Several EHDI programs have developed fillable forms so that information is reported in a consistent manner which is helpful for staff who input the screening and diagnostic results into the EHDI system. However, completion of an EHDI form may increase the administrative workload of the audiologist. At least 18 EHDI data systems have the capacity for audiologists to directly input screening and audiological results online. Several programs report having or developing the capacity to transfer results directly from screening/diagnostic equipment or from electronic medical records using HL7 interoperability standards that incorporate file-based transactions and methods to exchange electronic health information. Health Level Seven International (HL7) is an organization that leads the world in creating standards to exchange and share information in healthcare. This cutting-edge approach makes results available in real-time rather than the 1 to 10 day reporting requirement that several EHDI programs have adopted. Reporting is a requirement specified by law, regulation, or rule in 25% of the EHDI programs included in the application review. Reporting remains voluntary in 10% of the EHDI programs whose application were reviewed.

In a 2021 study of barriers to reporting audiological results to ELDI programs,⁵² 64% of the audiologists reported results online while nearly half had the option of faxing results.⁵² While many audiologists reported no reporting barriers, the 42% that did, reported four different barriers:

- ELDI data system is not user-friendly
- Lack of administrative time to report results
- Not understanding the reporting requirements
- Challenges with the reporting method, e.g., no internet connection in rural areas

Privacy Regulations

As ELDI programs expand hearing screening beyond newborn hearing screening to encompass young children up to the age of 3 years, there may be a need for individually-identifiable information to be exchanged between the screening provider and ELDI. Exchange of information requires that certain legal confidentiality requirements be met. Depending on the type of collaborative organization, the Health Insurance Portability and Accountability Act (HIPAA), the Federal Educational Rights and Privacy Act (FERPA), and/or the Part C Privacy Regulations must be followed.

Entities covered by the Health Insurance Portability and Accountability Act (HIPAA)⁵³ are health plans, clearinghouses, and healthcare providers who bill for services. These entities do not need written consent to share hearing screening results with ELDI programs because screening is a public health activity and is needed to facilitate ongoing health care. Sharing Protected Health Information (PHI), which is individually identifiable health information that is transmitted or maintained by any of the covered entities, requires a signed consent if the information is to be used for marketing or research. Signed consent is not needed for healthcare providers to exchange information for public health purposes or for treatment, payment or healthcare operations. However, obtaining signed consent can be considered best practice even if it is not required. A record of shared information must be kept.

The Federal Educational Rights and Privacy Act (FERPA)⁵⁴ requires signed consent for programs funded by the Department of Education to share educational records that contain personally identifiable information. This includes any health information included in educational records such as an IEP. A signed consent is not needed in cases of health or safety emergencies or to disclose contact information, enrollment status, honors, or attendance as long as there is an annual "intent to share" notification. FERPA does not apply until a child is enrolled in a program that receives federal education funding.

Part C Privacy Regulations⁵⁵ are more restrictive than HIPAA and FERPA and apply when a child is referred to Part C. Written consent is needed for any information held by Part C to be shared with non-participating providers which are entities outside of the Part C system. Signed consent is not needed to refer a child to Part C or for Part C to share information with a "participating provider."

POTENTIAL ROLES FOR EHDI PROGRAMS

A review of State EHDI grant proposals indicates that roughly two-thirds of the States are in the initial stages of planning screening program development activities that include the identification of children who are DHH up to three years of age. Approximately one-third of the States have already been actively engaged in this effort and described strategies that would be targeted toward sustaining and/or expanding their current activities.

The range of stakeholders that could potentially be engaged in moving this work forward were previously outlined in the section Hearing Screening Services for Children. About a quarter of the States also specifically referenced an intention to work with the Early Childhood Hearing Outreach (ECHO) Initiative in pursuing their screening program development goals. As a National Technical Assistance Resource Center (NTRC), the ECHO Initiative was central in assisting Head Start/Early Head Start programs in developing evidence-based hearing screening and follow-up practices for children under five years of age. In addition to providing direct technical assistance and training to early childhood programs across the country, it also offered assistance, training, and practical resources to a wide range of state and local leaders. All previously developed ECHO resources are available on kidshearing.org. However, the NTRC does not have a directive or funding to provide significant amount of training or technical assistance for this expansion.

Successful strategies and partnering activities described in EHDI State grant proposals, and in previous ECHO Initiative work, can be conceptualized and undertaken at both the State and local-community program levels. A systematic and comprehensive approach for EHDI programs engaging in hearing screening program development in early care and education settings is described below.

Engaging in Program Development

Statewide Outreach

State EHDI program staff may engage in statewide outreach to educate professionals and parents about the need for periodic hearing screening and the evidence-based practices to identify children at risk for permanent hearing loss. This can include general information about the incidence of hearing loss in young children and the importance of early identification, as well as information about how the State EHDI program is helping to address this need. Most people are unaware of how many young children are affected by permanent hearing loss. Many parents and professionals erroneously assume that when healthcare providers examine a child's ears during well-child visits, possibly using tympanometry or pneumatic otoscopy, they are screening a child's hearing. In reality, providers are typically looking at the general health of the outer and middle ear and do not have the equipment needed to conduct evidence-based hearing screening with children under 3 years of age.

Consequently, healthcare providers and early care and education professionals, as well as parents, will benefit from learning about the importance of ongoing early childhood hearing screening, and currently recommended evidence-based hearing screening practices for children 0 - 3 years of age. A broad outreach effort can raise awareness of the issues while at the same time making the public aware of the State EHDI Program as the “go to” source for more information. An awareness and education campaign can target specific provider groups or it may be very broad. Potential activities can include:

- Electronic dissemination of resources (email).
- Live presentations at professional conferences or community coordination meetings.
- Individual correspondence via email, phone or social media to share ideas and resources.
- Targeted inquiries to specific providers or provider groups to learn about current interest.
- Practices pertaining to early childhood hearing screening.

Leadership and Planning resources on infanthearing.org include ready-to-use handouts, short video clips, and links to resources that can be used to build awareness.

Identify Stakeholders

EHDI programs may find it beneficial to identify potential partners (programs, agencies, or individuals regularly serving children 0 – 3 years of age) that are already providing, or could be trained to provide, hearing screening services. Although there are a number of early care and education settings where partnerships can be explored and outreach efforts undertaken, not every context will support successful hearing screening program implementation. State EHDI Coordinators may want to initiate partnerships with programs that have both the commitment to screening and the capacity to support follow-up. As with newborn hearing screening, periodic screening must be integrated into a comprehensive protocol that includes medical and audiological assessment of children not passing the screening. Some early care and education programs lack the structure essential for supporting effective follow-up. As EHDI programs engage with a range of programs, it can be helpful to use this list of considerations in evaluating program capacity.⁵⁶ Focusing intensive training efforts and energies on programs that already have a service infrastructure that has the potential to support and sustain screening and follow-up is likely to be the most productive use of resources.

Two particular partnerships merit exploration because of existing program commitment to determining the hearing status of children being served and the capacity to support follow-up:

Early Head Start. One of the largest programs serving low-income infants and young children, Head Start includes preschool programs for children 3 - 5 years of age and **Early Head Start** programs for children 0 - 3 years of age. Additionally, **Migrant Head Start** and **American Indian/Alaska Native Head Start** programs serve children 0 - 5 years of age in their respective populations. Early Head Start and Head Start programs are found in every state, each of which is required by Head Start Performance Standards to ensure that every

child receives an annual hearing screening using an evidence-based method.³⁰ A precise screening methodology is not specified, permitting for changes in best practice to evolve over time without the need for updating the Standards. Given this, the involvement of state and local experts in operationalizing the Performance Standards is critical, especially in technical areas like hearing screening.

Early Intervention programs operated under Part C of the Individuals with Disabilities Education (IDEA) Act. These programs not only serve children 0 – 3 years of age already identified as deaf or hard of hearing, often from the EHDI system, but also actively engage in “Child Find” efforts of their own. Hence, Part C represents not only an opportunity to link previously identified children with early intervention services, but also exists as a system that can actively help to identify additional children with late onset hearing loss or children who were lost to follow-up after newborn screening.

It may be important for EHDI Coordinators to remind Part C programs that children who have an unidentified hearing loss will not necessarily present with indicators that would cause parents or professionals to suspect hearing as a primary source of concern. Not all children entering Part C early intervention programs receive a hearing screening or evaluation even when children are referred for common concerns about speech and language development. Children who are manifesting a range of developmental delays or behavioral issues may be referred to the Part C system for evaluation to determine their eligibility for enrollment⁵⁷ and hearing screening is often an essential aspect of drawing an accurate profile of the child’s abilities and needs.

Learning About Programs

If a stakeholder partner program has State-level leadership or representation, meet with the representative to:

- Learn about program organization and infrastructure and any existing guidelines that inform hearing screening practices.
- Share information about evidence-based hearing screening practices, EHDI goals, and State EHDI/ECHO resources.
- Explore what is/is not known about the hearing screening capacity of each local program, needs for Training and Technical Assistance (TA) and how to effectively make contact with local Coordinators to further collaborate on initiating, sustaining or expanding quality screening practices. You may also want to explore reporting and data sharing agreements.

It is essential that EHDI programs take time to learn about the system infrastructure and culture of each potential partner. Collaboration is essential and clarifying the goals of each organization and exploring the different types of linkages that might be established will lead to productive outcomes. In some cases, a partner-stakeholder may simply disseminate information about early childhood hearing loss and the EHDI program to the families that are

served. In others, screening program implementation may be a realistic goal. And, as screening and follow-up practices are established, data sharing agreements may be appropriate.

The following information and links will help EHDl programs to get better acquainted with Early Head Start and Part C representation at the State level and also serves as an example of how EHDl programs can approach collaboration with other stakeholders:

Early Head Start. Each local Early Head Start grantee (program) is a direct recipient of federal Office of Head Start funding. Before making contact with individual programs within a State, it may be useful to contact the Head Start State Collaboration Office (HSSCO)²⁷. This Office coordinates with other state systems and assists in disseminating information and establishing connections with individual community-based programs. While HSSCO's do not have oversight authority for individual Early Head Start or Head Start programs operating at the local program level, they can provide information about the Head Start infrastructure, programmatic components, how to locate local programs, and facilitate connections. They may also help establish any formal collaboration agreements EHDl programs may wish to enter into with individual community programs.

The Head Start Center Locator²⁹ can help EHDl programs locate all of the local community-based Head Start programs within a State or community. Every program has its own local Health Services Advisory Committee (HSAC) that, among other things, provides guidance on screening methods to be used in the program. It is important to note that relatively few HSACs include a pediatric audiologist to help determine hearing screening practices. As a result, programs within a state may not all use the same screening method and some may not use methods considered current or evidence-based.

While many local programs have adopted evidence-based hearing screening practices as a consequence of earlier training and technical assistance offered by the ECHO Initiative, not all have, and sustaining quality practices is an ongoing challenge. State EHDl programs have a potential role in updating screening practices across all Early Head Start programs and, if desired, in establishing data and information sharing agreements that will enhance the overall quality of follow-up services provided to children identified from these screening efforts. Experiential hands-on training of staff, typically teachers, assistants, or health/disability specialists, can be provided either in-person or via distance learning.

Sustaining quality practices can be an ongoing challenge when staff turnover occurs, especially when screening and other program activities are "gearing up" for the year. Staff turnover is a factor for program planning:

- Multiple trained screeners ensure continuity of hearing screening.
- Easy-to-operate equipment facilitates competency for new staff.
- An OAE-only, easy-to-follow protocol supports better implementation.

Quality practices include not only the actual screening techniques but also the adherence to an evidence-based follow-up protocol (Figure 1).

State EHDI programs have a potential role in updating screening practices across all Early Head Start programs and, if desired, in establishing data and information sharing agreements that will enhance the overall quality of follow-up services provided to children identified from these screening efforts.²¹

Based on an analysis of the EHDI project narratives for the 2020-24 HRSA funding cycle, about one-third of the states are maintaining or expanding their current collaboration with EHS programs while about two thirds of the states are in the process of developing plans to collaborate in order to provide hearing screening for young children.

Of the EHDI programs with current collaborations about half have established data-sharing agreements with EHS programs and are receiving EHS hearing screening results. Several of the EHS data sharing agreements also include other early childhood programs.

Part C Early Intervention Programs. Part C of the Individuals with Disabilities Education (IDEA) act provides for a range of services for children birth to three years of age with disabilities (or at risk for disabilities). The EHDI system has a two-pronged connection with the Part C system:

Children identified as being DHH as a result of newborn hearing screening and follow-up are referred to Part C to access early intervention services. These are predominantly children with congenital hearing loss.

Children referred to Part C from other systems are evaluated and identified as being deaf or hard of hearing as a result of the Part C intake and evaluation process and then referred to the EHDI system to obtain additional support and information for families. These are predominantly children with late-onset hearing loss or children who did not receive a newborn hearing screening or were lost to follow-up.

Each state has a Part C Coordinator³³ with whom EHDI program staff may want to meet to discuss relevant regulations and practices, keeping in mind the two-pronged connection between EHDI and Part C. Prior to meeting, it is helpful to learn more about Part C regulations^{34,35} (especially as they relate to multidisciplinary evaluation and assessment).³⁶

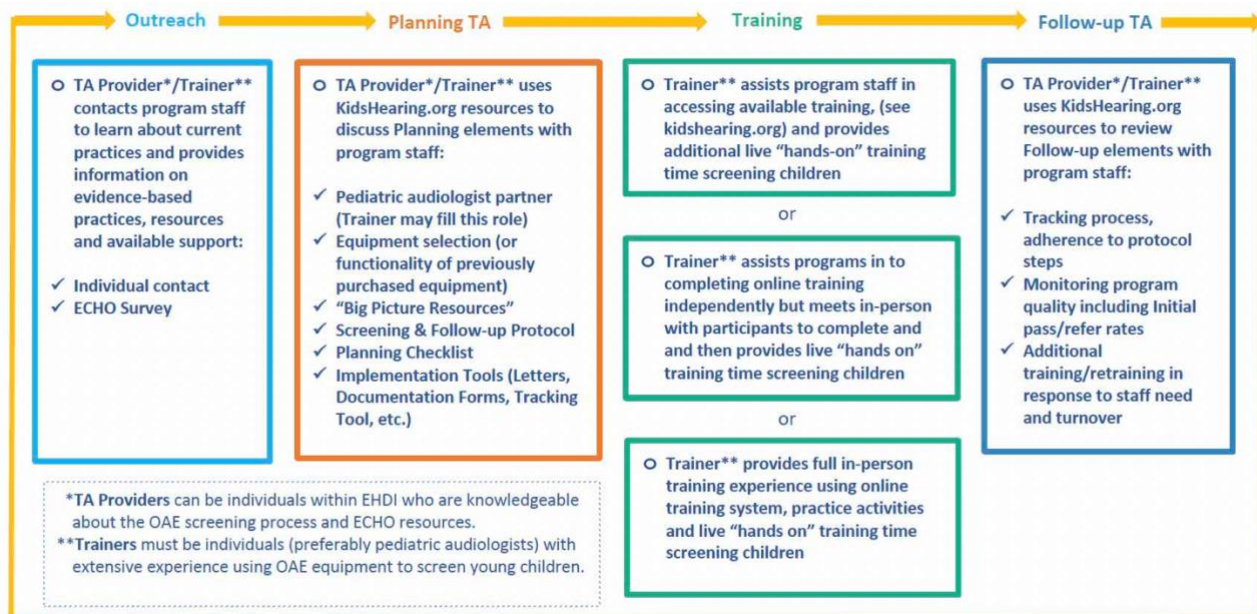
It may be helpful for EHDI leaders to address the following questions with State Part C Coordinators:

- Where in the eligibility determination/intake process does or can a hearing evaluation/screening occur? How might this vary from program to program?

- What hearing screening/evaluation method(s) are used and what follow-up protocol is implemented?
- Do all children entering Part C service receive a hearing screening/evaluation and, if not, what criteria is used to determine who does?
- What are the current needs for technical assistance or training to ensure evidence-based practices are being used for hearing screening/evaluations of children in Part C?²¹

Engage in Local Program-level Partner Outreach, TA and Training

With a general understanding of the overarching organizational structure and guidelines shaping local approaches to service provision and screening, EHDI Coordinators are prepared to reach out to local programs serving children 0 - 3 years of age within the State to learn about their current screening capacity and methods. Some of the potential roles that State EHDI staff could play in providing Technical Assistance and/or training are summarized in the figure below:



Outreach

In addition to providing general awareness information such as described above, outreach activities may specifically target early care and education providers with information aimed at helping them move forward in developing evidence-based screening and facilitating their access to technical assistance and training. This level of outreach would inform programs about available support in terms of identifying a local pediatric audiologist to assist with program development, assistance with planning hearing screening programs, guidance for accessing training, and information about ongoing available technical assistance.

Initial contact might be made through email, phone calls and/or through disseminating any of the resources found under Early Childhood Hearing Screening - Leadership and Planning tools at www.infanthearing.org. You may also consider gathering information from programs about current screening practices and needs for training and technical assistance.

Planning

When a program or provider indicates a serious commitment to developing evidence-based hearing screening practices, the first step is to complete a set of planning activities. Rather than starting with training, planning activities ensure that appropriate groundwork has been prepared prior to training so that the actual training is immediately followed by implementation. Planning activities supported by an EHDI coordinator, pediatric audiologist, or experienced screener is recommended. One of the ways EHDI leadership can assist local, community-based programs is in locating local pediatric audiologists with whom local programs can consult when developing screening activities, selecting equipment, and obtaining training. During the planning phase EHDI leaders can also explore what data sharing agreements, if any, they would like to have with the program and establish systems for facilitating this. Keep in mind, you are exploring partnerships with existing programs that may already have requirements related to data sharing. The Planning Checklist for Implementing an OAE Screening Program⁵⁸ can be useful in helping programs think through the most critical planning components.

Training

Once planning has been completed, training in evidence-based hearing screening is an important next step. While equipment distributors often offer “training,” it is important to note that rarely will this constitute the type of training needed. Distributors are typically prepared to acquaint users with the functions of the equipment but usually they are not able to prepare lay screeners to develop screening skills with a variety of children being screened in a range of environments nor to develop the other features of a screening program that pertains to documentation of outcomes, implementing a follow-up protocol, or sharing screening outcomes.

Based on more than 20 years of experience providing training on evidence-based hearing screening with young children, NCHAM’s ECHO Initiative identified key content areas as well as hands-on practice experiences that are recommended as a part of a training process focusing on either the OAE or Pure Tone Audiometry screening methods. Information on how program staff can access screener training that incorporates these elements is provided on www.kidshearing.org.

Technical Assistance (TA)

Once training has been completed and implementation of evidence-based hearing screening practices is underway, a TA provider or trainer can assist participants with various elements of the screening program including:

- Screening techniques
- Tracking process and adherence to follow-up protocol steps
- Monitoring program quality including initial pass/refer rates

State Leaders can facilitate any of the above TA options and/or serve as the TA providers or trainer if s/he has the skills to do so.

Rarely are all programs within a State at the same place in developing and implementing evidence-based hearing screening. Therefore, the outreach-planning-training-technical assistance process is completed either for one program at a time, or in small cohorts of programs and then the process is replicated with another program or group of programs, allowing the leadership to refine its process over time. This process also allows leadership to explore how experience with one provider group, such as Early Head Start, may inform replication activities in another provider group such as Part C Early Intervention evaluation teams. Note that all of the primary training, technical assistance resources and Implementation Tools were designed for easy adaptation across program settings and contexts. Also be aware that staff turn-over is a reality in nearly every early childhood system. This means that it is usually essential to repeat these processes, in part or in entirety, with programs on an as-needed basis, often annually.

APPENDICES

Appendix 1. JCIH Recommended Risk Factors for Early Childhood Hearing Loss³

Risk Factors for Early Childhood Hearing Loss: Guidelines for Infants who Pass the Newborn Hearing Screen

	Risk Factor Classification	Recommended Diagnostic Follow-up	Monitoring Frequency
	Perinatal		
1	Family history* of early, progressive, or delayed onset permanent childhood hearing loss	by 9 months	Based on etiology of family hearing loss and caregiver concern
2	Neonatal intensive care of more than 5 days	by 9 months	As per concerns of on-going surveillance of hearing skills and speech milestones
3	Hyperbilirubinemia with exchange transfusion regardless of length of stay	by 9 months	
4	Aminoglycoside administration for more than 5 days**	by 9 months	
5	Asphyxia or Hypoxic Ischemic Encephalopathy	by 9 months	
6	Extracorporeal membrane oxygenation (ECMO)*	No later than 3 months after occurrence	Every 12 months to school age or at shorter intervals based on concerns of parent or provider
7	In utero infections, such as herpes, rubella, syphilis, and toxoplasmosis	by 9 months	As per concerns of on-going surveillance
	In utero infection with cytomegalovirus (CMV)*	No later than 3 months after occurrence	Every 12 months to age 3 or at shorter intervals based on parent/provider concerns
	Mother + Zika and infant with <u>no</u> laboratory evidence & no clinical findings	standard	As per AAP (2017) Periodicity schedule
	Mother + Zika and infant with laboratory evidence of Zika + clinical findings Mother + Zika and infant with laboratory evidence of Zika - clinical findings	AABR by 1 month AABR by 1 month	ABR by 4-6 months or VRA by 9 months ABR by 4-6 months Monitor as per AAP (2017) Periodicity schedule (Adebanjo et al., 2017)
8	Certain birth conditions or findings: • Craniofacial malformations including microtia/atresia, ear dysplasia, oral facial clefting, white forelock, and microphthalmia • Congenital microcephaly, congenital or acquired hydrocephalus • Temporal bone abnormalities	by 9 months	As per concerns of on-going surveillance of hearing skills and speech milestones
9	Over 400 syndromes have been identified with atypical hearing thresholds***. For more information, visit the Hereditary Hearing Loss website (Van Camp & Smith, 2016)	by 9 months	According to natural history of syndrome or concerns
	Perinatal or Postnatal		
10	Culture-positive infections associated with sensorineural hearing loss***, including confirmed bacterial and viral (especially herpes viruses and varicella) meningitis or encephalitis	No later than 3 months after occurrence	Every 12 months to school age or at shorter intervals based on concerns of parent or provider
11	Events associated with hearing loss: • Significant head trauma especially basal skull/temporal bone fractures • Chemotherapy	No later than 3 months after occurrence	According to findings and or continued concerns
12	Caregiver concern**** regarding hearing, speech, language, developmental delay and or developmental regression	Immediate referral	According to findings and or continued concerns

Note. AAP = American Academy of Pediatrics; ABR = auditory brainstem response; AABR = automated auditory brainstem response.

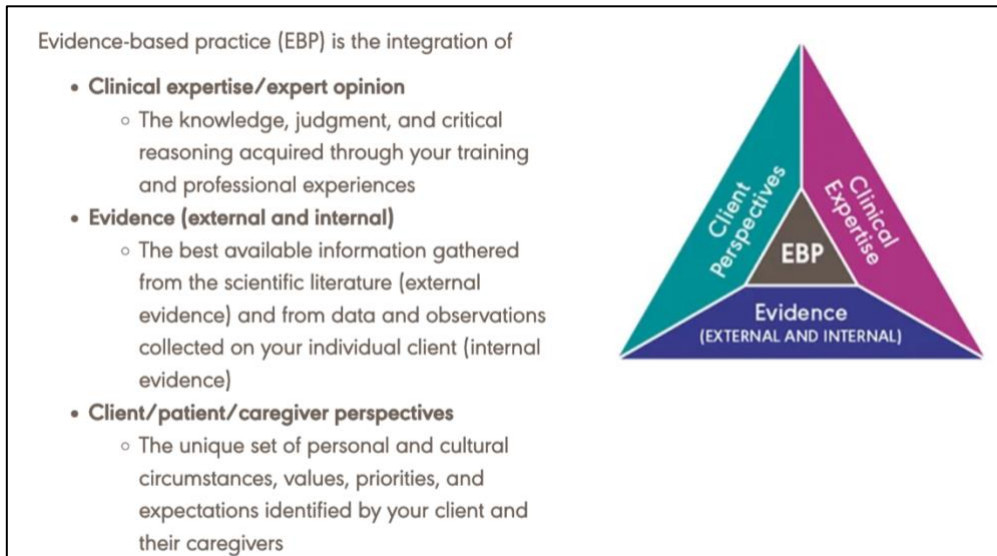
* Infants at increased risk of delayed onset or progressive hearing loss

**Infants with toxic levels or with a known genetic susceptibility remain at risk

***Syndromes (Van Camp & Smith, 2016)

****Parental/caregiver concern should always prompt further evaluation.

Appendix 2. Models of Evidence-Based and Evidence-informed Practice.



Evidence-Based Practice⁴



Evidence-Informed Practice⁵

Appendix 3. Guidelines

American Academy of Audiology (AAA)^{2,7}

AAA used the US Preventive Task Force's levels of evidence:

Level I: randomized controlled trial

Level II: non-randomized control trial

Level III: cohort or case-control study

Level IV: ecological or descriptive studies

Level V: opinions of respected authorities based on clinical experience, descriptive studies or reports of expert committees

American Academy of Audiology Clinical Practice Guidelines Childhood Screening. September 2011.²

American Academy of Audiology Clinical Guidance Document Assessment of Hearing in Infants and Young Children. January 23, 2020.⁷

American Speech Language Hearing Association (ASHA)⁶

ASHA categorizes its evidence ratings as follows:

Level A Evidence: strong evidence

Level B Evidence: moderate evidence

Level C Evidence: limited evidence

Level D1 Evidence: consensus panel opinion based on topics where a systematic review has been conducted

Level D2 Evidence: consensus panel opinion not based on findings from a systematic review

Appendix 4. Otoacoustic Emissions - Advantages and Limitations

Screening Type	Advantages	Limitations
<p>DPOAE & TEOAE</p>	<p>Quick (less than 5 minutes)¹⁶ Conducted by trained para-professionals and speech-language pathologists^{6,15,17} On-line training available Not influenced by listener variables: age (chronological, developmental), cognitive level, language skills, motor abilities)¹⁵ Portable, hand held equipment⁹ Outcome displayed⁹</p> <p>Does not require a behavioral response and may be an appropriate hearing screening option for children who cannot be conditioned to respond to a pure-tone stimulus⁶</p>	<p>Stimulus and response mediated by middle ear⁶ May miss mild hearing loss²</p> <p>When evaluating the efficacy of any physiologic screening measure, it is important to recognize that the sensitivity and specificity of the measure are dependent on the criteria used for defining hearing loss, the criteria used for pass/refer, and the technical procedures involved in the test⁶</p> <p>Automated screening equipment often has test parameters set by the manufacturer. Therefore, different equipment may yield different screening results⁶</p> <p>May fail to identify certain conditions (e.g. auditory neuropathy).⁶</p>

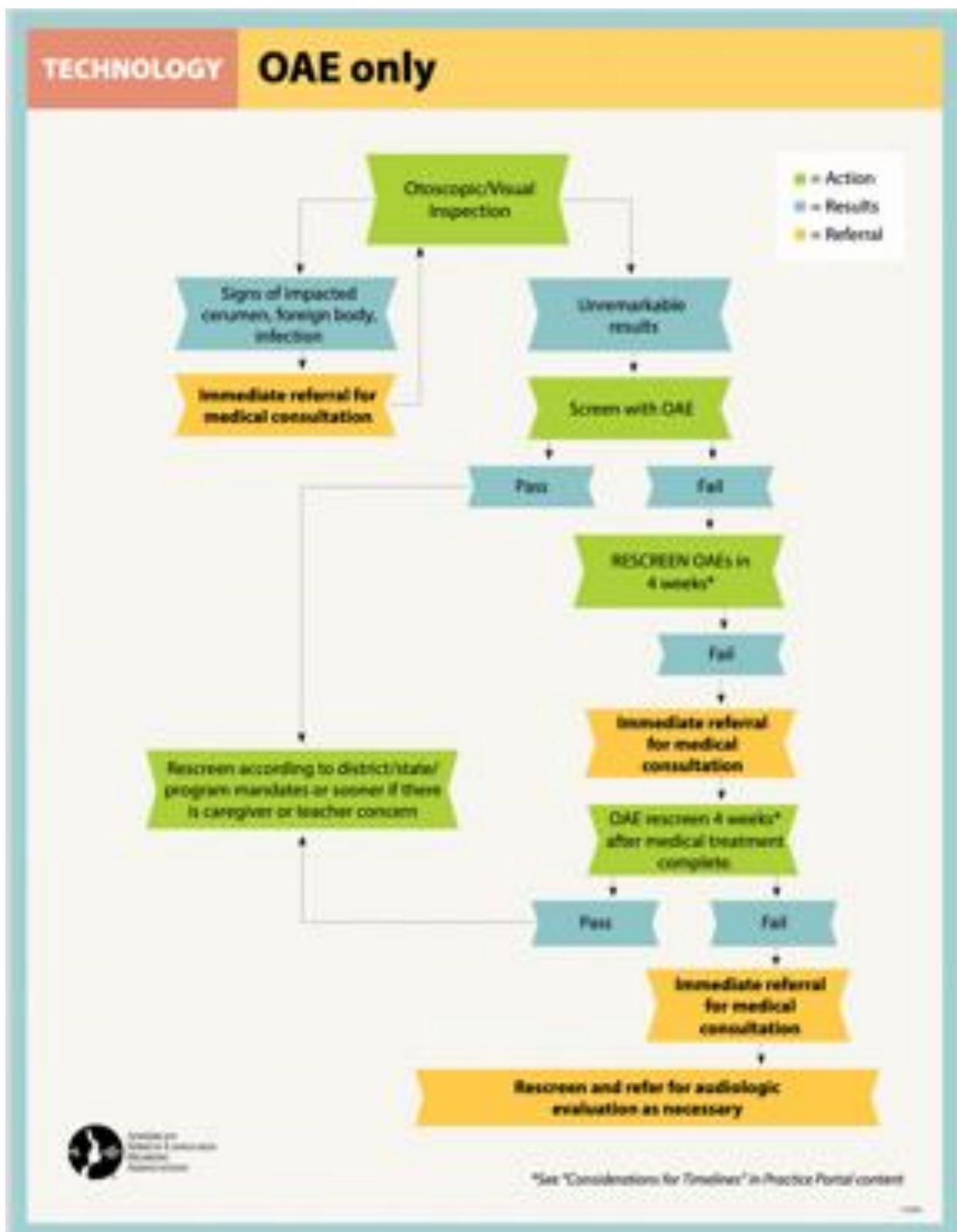
APPENDIX 5 - AAP Periodicity Schedule^{19,20}

AAP periodicity schedule shows the ages when a child should receive screening services. States must adopt periodicity schedules for vision and hearing screening that meet reasonable standards of medical practice. States also should update the schedules as necessary to stay current with published guidelines. When adopting or updating a periodicity schedule, states must consult with recognized medical organizations involved in child healthcare, such as the [American Academy of Pediatrics](#) (AAP). In addition to periodic screenings, children are entitled to receive “interperiodic” screenings whenever a provider, a parent, or a health, developmental, or educational professional suspects a possible problem.

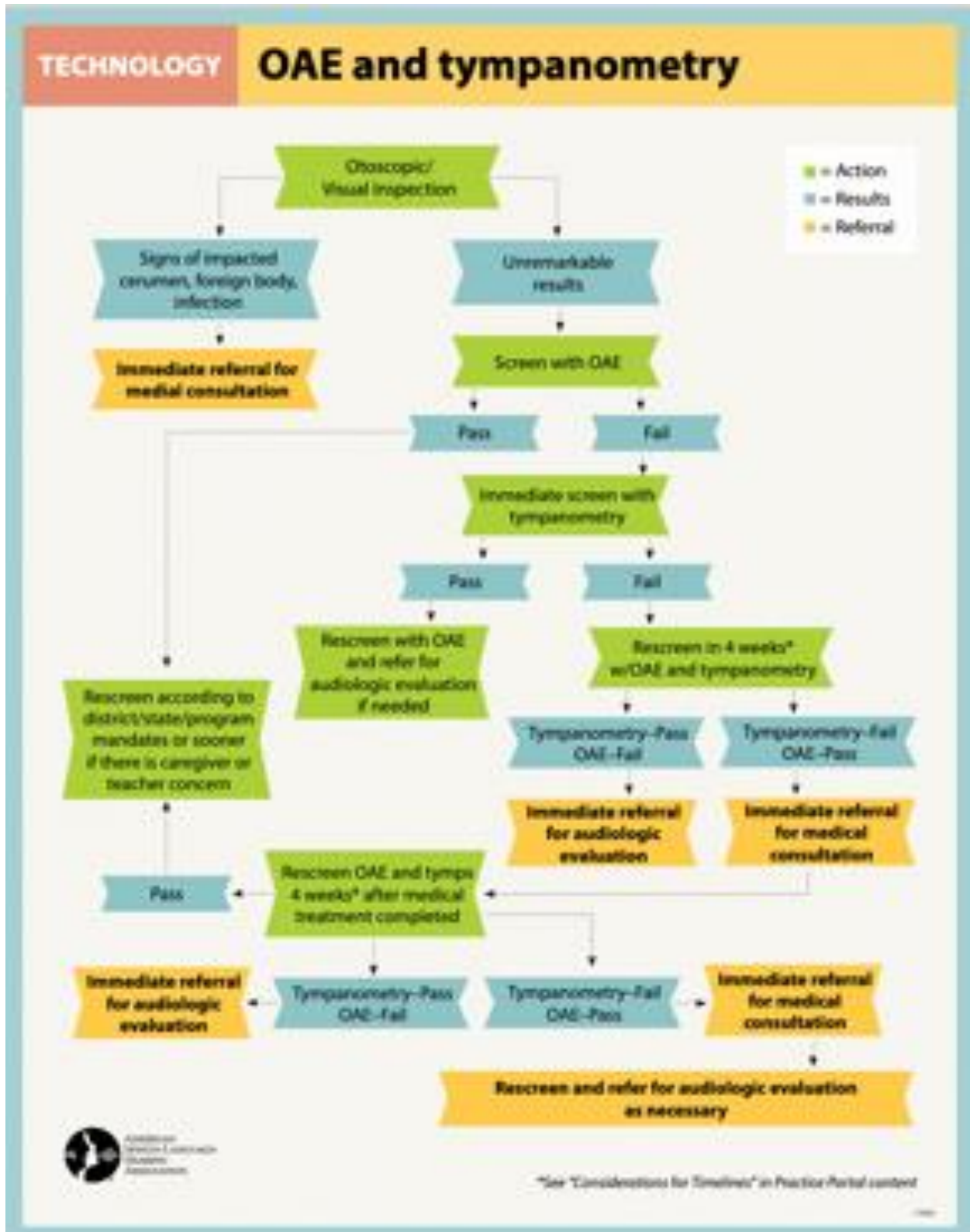
States must [set standards](#) for conducting and documenting age-appropriate vision and hearing assessments. CMS has directed states to consult with ophthalmologists, optometrists, and audiologists to determine screening procedures to use and the criteria for determining when a child is referred for diagnostic examination.

When a screening shows possible vision or hearing problems the child should be referred for further evaluation. EPSDT requires Medicaid coverage of necessary diagnostic and treatment services, including further testing, eyeglasses, hearing aids, replacement batteries, and cochlear implants, even if the services are not covered for adults. States must arrange for treatment, and the treatment must be provided with reasonable promptness.²⁰

6. ASHA OAE Only Hearing Screening Protocol²²



Appendix 7. ASHA OAE and Tympanometry Hearing Screening Protocol²²



Appendix 8 - Contextual Considerations²³



Is My Setting an Appropriate Context for Successful Otoacoustic Emissions (OAE) Screening of Children Birth to Three Years of Age?

Otoacoustic emissions (OAE) screening, as an evidence-based practice, requires more than access to equipment or a policy mandating that screening be conducted. The likelihood that an early childhood education or health care provider will meet with success in implementing an OAE hearing screening program is dependent in large part on the context into which the hearing screening activities will be integrated. These broader contextual conditions need to be carefully considered before proceeding.

Hearing screening activities are more likely to be successful when administrators can answer “yes” to the primary contextual variables listed below:

- ◆ Access to/Relationships with Children and Families. Does your service system support staff in spending 3 - 5 minutes with individual children to complete a screening activity? Does your system have ongoing, face-to-face supportive contact with children and families that will allow you to initiate and complete a multi-step follow-up process which may last 6 weeks or more for a small subset of the children initially screened?

Related considerations: Do you serve a large number of children and/or is the geographic dispersal of families high? If so, hearing screening can be more challenging to implement and it may be wise to consider whether implementation can be rolled out over time, first focusing on a target sub-population, then extending the screening to larger numbers as experience is gained. A related consideration is whether children will be screened in a central location or in their homes. The latter often requires more staff to be trained and equipment to be purchased.

- ◆ Access to Medical and Audiological Services. Is your service system able to assist children/families in accessing medical and audiological services either through direct provision or through a referral process?
- ◆ Tracking System. Does your service system have a tracking system that allows you to document screening information about individual children and track a subset who will need to receive follow-up services?

- ◆ Staffing. Does your system have relatively stable staffing so that time invested in training staff members to conduct screening is likely to result in a sustainable program?

Related considerations: In selecting who will be trained to conduct screening, consider how likely it is that the prospective trainees will remain in your organization. If staff turnover is unavoidable, what measures can be taken to minimize it and/or to facilitate new screener training so that screening program sustainability is not compromised?

- ◆ Budget. Does your service system have a budget to support the purchase and maintenance of equipment and supplies?
- ◆ Focus on Child Language Development and Hearing. Does your service system have as one of its objectives to foster young children's language development and, more specifically, to monitor and promote their hearing health? Do you have access to audiological support on a contracted or volunteer basis to assist with training and implementation efforts?

Related considerations: Do administrators and staff perceive hearing screening to be a valuable investment, worth the costs associated with equipment, the time required for screener training and the screening and follow-up activities? Is hearing screening perceived as complementary, rather than disruptive of or in competition with, other services being provided? Are there organizational policies that require the provision of hearing screenings and, if so, what do they suggest about specific methodology, the time frame within which screenings are to be completed, screening periodicity, who can screen, etc.? Do you have clarity about the ages of children you intend to screen and what types of hearing loss (permanent or fluctuating) you are intending to screen for?

- ◆ Collaborative Capacity. Are you aware of state policies or regulations that inform if and how you can implement hearing screening practices? Do you have a mutually agreed upon understanding of how screening outcomes will be shared with other agencies charged with promoting children's hearing health, especially your state's Early Hearing Detection and Intervention (EHDI) program?

When these contextual conditions are present in an early childhood educational or healthcare system, periodic OAE screening can often be integrated seamlessly and with great success.

APPENDIX 9 - ECHO Initiative Resources at www.kidshearing.org.



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- [Home](#)
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EHD System

- [Newborn Hearing Screening](#)
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- [Program Evaluation](#)

Early Childhood Hearing Screening

- [Leadership and Planning Tools](#)
- [Recorded Webinars:](#)
 - Mar 3, 2022, "Introduction to Evidence-based Hearing Screening and Evaluation Practices for Children 0-5 Years of Age."



Early Childhood Hearing Screening

The number of children with hearing loss doubles during early childhood--from approximately 3 in 1000 at birth to 6 in 1000 by school age. Providing hearing screening during the early language-learning years is critical for helping more children receive the benefits of early identification and intervention. Since 2000, NCHAM has provided resources and learning opportunities aimed at improving the availability of evidence-based early childhood hearing screening.

How EHD Staff Can Expand 0-3 Screening

[Expanding EHD for Children Up to Three Years of Age - Training Module](#)



Leadership and Planning Tools

Early Care & Education Providers Training and Implementation Resources



Planning Resources

- ▣ [Big Picture Resources](#)
- ▣ [Find an Audiologist](#)
- ▣ [Screening Equipment](#)

Access Training

- ▣ [OAE Training](#)
- ▣ [Pure Tone Audiometry Training](#)

Screening Resources

- ▣ [Prepare for Screening](#)
- ▣ [Protocol Guides & Forms](#)
- ▣ [Share Results: Letters & Scripts](#)

Follow-up Resources

- ▣ [Track Child Progress](#)
- ▣ [Monitor Program Quality](#)

Archives

- [Previously Recorded Webinars](#)
- [Previous Materials and Tools](#)

Early Care & Education Providers Training and Implementation Resources

Planning Resources

Big Picture Resources

- [Introductory Webinar](#)
- **OAE Screening**
 - [Overview of OAE Screening \[PDF\]](#)
 - [Frequently Asked OAE Questions \[PDF\]](#)
 - [Published articles](#)
- **General Information**
 - [Hearing screening fact sheet \(English\)](#)
 - [Hearing screening fact sheet \(Spanish\)](#)
 - [Pure Tone/OAE Screening Considerations \[PDF\]](#)
 - [Newborn Screening Followup Handout for Parents \[PDF\]](#) in English and [Spanish \[PDF\]](#)

Find an Audiologist

- [Contact your state Early Hearing Detection and Intervention \(EHDI\) Program Coordinator](#)
- [Access American Speech-Language-Hearing Association directory](#)

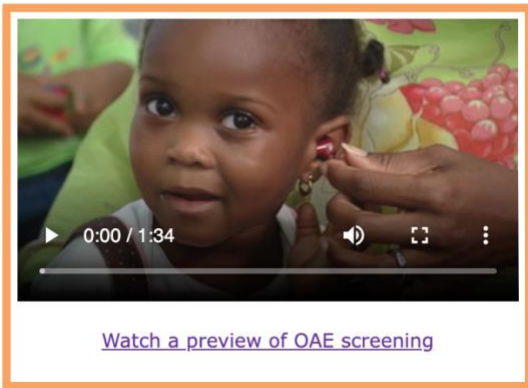
Screening Equipment

- **OAE Screening**
 - [Elements to Consider When Selecting OAE Equipment \[PDF\]](#)
 - [OAE Equipment Options](#)
 - [Mini-Grant Proposal Template \[DOC\]](#)
- **Pure Tone Screening**
 - [Recommendations for Pure Tone Screening](#)

Access Training

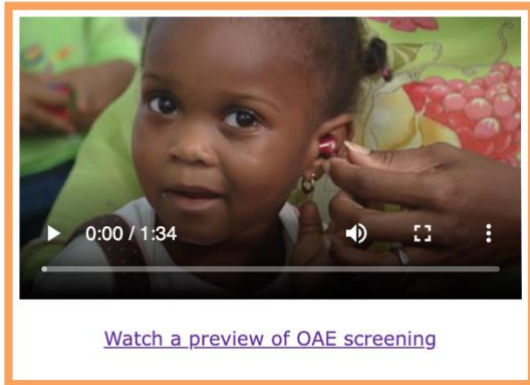
OAE Training

Pure Tone Audiometry Training



[Watch a preview of OAE screening](#)

Early Care & Education Providers Training and Implementation Resources



Screening Resources

▾ Prepare for Screening

• Preparing Screeners

- ["To Do" List: Get Ready for Screening \[PDF\]](#)

• Preparing Parents

- [Hearing Screening Handout for Parents \[PDF\]](#) in English and [Spanish \[PDF\]](#)
- [Information for Parents \[DOCX\]](#)

• Preparing Teachers/Adult Assistants

- [Information for Teachers \[PDF\]](#)

• Preparing Health Care Providers

- [Information for Health Care Providers \[DOC\]](#)

• Preparing Children

- [Listen Up Sing-Along Video: View | Download \[ZIP\]](#)

▾ Protocol Guides & Forms

• OAE Screening

- [Recommended OAE Screening Protocol \[PDF\]](#)
- [OAE Screening Form \[PDF\]](#) in English and [Spanish \[PDF\]](#)
- [OAE Hearing Screening Form \[Fillable PDF\]](#)
- [Diagnostic Follow-up Form \[PDF\]](#) in English and [Spanish \[PDF\]](#)
- [OAE Hearing Screening Form for Health Care Providers \[PDF\]](#)

• Pure Tone Screening

- [Recommended Pure Tone Screening Protocol \[PDF\]](#)
- [Pure Tone Screening Form \[PDF\]](#)
- [Diagnostic Follow-up Form \(Pure Tone Version\) \[PDF\]](#)

Early Care & Education Providers Training and Implementation Resources



[Watch a preview of OAE screening](#)

Share Results: Letters & Scripts

• General

- [Generic Referral Letter to Parents \[DOC\]](#) English/ Spanish
- [Generic Pass Letter to Parents \[DOCX\]](#) English/ Spanish
- [Explaining Screening Results to Parents \[PDF\]](#) in English and [Spanish \[PDF\]](#)

• OAE Screening

- [OAE Referral Letter to Partner Health Care Providers \[DOC\]](#)
- [OAE Pass Letter to Partner Health Care Providers \[DOC\]](#)

• Pure Tone Screening

- [Pure Tone Results Letter to Partner Health Care Providers \[DOC\]](#)

• Share Results: Letters and Scripts

- General
 - [Generic Referral Letter to Parents \[DOC\]](#) English/ Spanish

Follow-up Resources

Track Child Progress

- [ECHO Hearing Screening & Diagnostic Log \(2016\) \[XLSX\]](#)
- [Instructions for using the Hearing Screening & Diagnostic Log \[PDF\]](#)
- [Video Tutorial for using the Hearing Screening & Diagnostic Log \(22 mins.\)](#)

Monitor Program Quality

- [Helpful Hints to OAE Screening \[PDF\]](#)
- [Monitoring for OAE Program Quality \[PDF\]](#)
- [OAE Screening Skills Checklist \[PDF\]](#)
- [Pure Tone Screening Skills Checklist \[PDF\]](#)

APPENDIX 10 - Potential Expansion Partners from HRSA-EHDI Funding Applications

HEALTH/MEDICAL

Health professionals
Obstetricians
Family Medicine Doctors
Pediatricians
Otologists
County health departments
Women-Infant-Children (WIC)
Federally Qualified Health Centers
Midwives
Birthing facilities
County health departments

AUDIOLOGY

Local university audiology students
Local speech and hearing agency
Preschool/School audiologist
Audiology programs

EDUCATION/CHILD DEVELOPMENT

Early Head Start programs
Parents As Teachers programs
Head Start programs
American Indian - Alaska Native programs
Migrant Head Start programs
Migrant programs
Child development centers

ASSOCIATIONS

Head Start Associations
AAP EHDI Chapter Champion
Regional Genetics Collaborative

HOME VISITING

Home visiting programs
Maternal, Infant, and Early Childhood Home
Visiting Program (MIECHV)

PARENT PROGRAMS

Hands & Voices
Family-to-Family Health Information
Centers
FL3 Centers
Family Voices

PUBLIC HEALTH / EDUCATION / DISABILITY PROGRAMS

Office of Minority Health & Health
Disparities
Children's Medical Services
Title V programs
Language and Literacy Initiatives
Department of Education
Part C/Early Intervention
Children and Youth with Special Health Care
Needs
Newborn Dried Blood Spot Screening
program
Maternal and Child Health programs
Head Start State Collaboration Office
Department of Early Childhood Education
& Care
Licensing bodies

APPENDIX 11 - Newborn Bloodspot Screening Program^{42,43,44}

“Newborn screening (NBS) is a state-based public health program in the United States. This means that each state or territory has its own NBS program. Also, state or territory level policies govern which conditions are included in their NBS program.

“Most states and territories screen for some or all of the conditions on the Recommended Uniform Screening Panel (RUSP). Many states also choose to screen for additional conditions.

“The RUSP is a list of disorders that the Secretary of the Department of Health and Human Services (HHS) recommends for states to screen as part of their state universal newborn screening (NBS) programs.^{42,43}

Disorders on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments. It is recommended that every newborn be screened for all disorders on the RUSP. Most states screen for the majority of disorders on the RUSP; newer conditions are still in process of adoption. Some states also screen for additional disorders.

Although states ultimately determine what disorders their NBS program will screen for, the RUSP establishes a standardized list of disorders that have been supported by the Advisory Committee on Heritable Disorders in Newborns and Children and recommended by the Secretary of HHS.

Conditions listed on the RUSP are part of the comprehensive preventive health guidelines supported by HRSA for infants and children under section 2713 of the Public Health Service Act. Non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years beginning on or after the date that is one year from the Secretary’s adoption of the condition for screening. “⁴³

“The RUSP divides these conditions into two main groups: core and secondary conditions.

- **Core conditions:** The HHS Secretary recommends including these in every NBS program. Newborn screening is specifically designed to assess whether your baby might have these conditions.
- **Secondary conditions:** These may be found while screening for a core condition. Although NBS is not specifically designed to assess whether your baby might have these conditions, it sometimes finds babies likely to have them.”⁴⁴

APPENDIX 12 - Special Supplemental Nutrition Program for Women, Infants and Children (WIC)⁴⁵

“WIC is a federal grant program for which Congress authorizes a specific amount of funds each year for the program. WIC is

- administered at the federal level by FNS
- administered by 90 WIC state agencies, through approximately 47,000 authorized retailers.
- WIC operates through 1,900 local agencies in 10,000 clinic sites, in 50 state health departments, 34 Indian Tribal Organizations, the District of Columbia, and five territories (Northern Mariana, American Samoa, Guam, Puerto Rico, and the Virgin Islands).

WIC is not an entitlement program as Congress does not set aside funds to allow every eligible individual to participate in the program.

The WIC target population are low-income, nutritionally at risk:

- Pregnant women (through pregnancy and up to 6 weeks after birth or after pregnancy ends).
- Breastfeeding women (up to infant’s 1st birthday)
- Non-breastfeeding postpartum women (up to 6 months after the birth of an infant or after pregnancy ends)
- Infants (up to 1st birthday). WIC serves 53 percent of all infants born in the United States.
- Children up to their 5th birthday.

The following benefits are provided to WIC participants:

- Supplemental nutritious foods
- Nutrition education and counseling at WIC clinics
- Screening and referrals to other health, welfare and social services

Where WIC services are provided

- county health departments
- hospitals
- mobile clinics (vans)
- community centers
- schools
- public housing sites
- migrant health centers and camps
- Indian Health Service facilities”

APPENDIX 13 - Title V Children and Youth with Special Health Care Needs (CYSHCN) Program⁴⁶

The Children and Youth with Special Health Care Needs (CYSHCN) Program supports CYSHCN and their families during each stage of life, from infancy through adulthood. With our committed partners, our programs promote coordinated, comprehensive, family-centered systems of services where:

- Children and youth are screened early and continuously
- CYSHCN receive a medical home model of care that is patient-centered, coordinated, comprehensive, and ongoing
- Community-based services are organized so families can use them easily
- CYSHCN receive services necessary to make transitions to adult life, including healthcare
- Families have adequate insurance and funding to pay for services they need
- Families of CYSHCN are partners in decision-making at all levels of care, from direct care to the organizations that serve them.

Within each state, the Maternal and Child Health (MCH) and CYSHCN program (known as the Title V program) is charged with providing family-centered, community-based coordinated care. Authorized by Title V of the Social Security Act, the MCH Services Block Grant supports the infrastructure for MCH in every state and territory. Consisting of the state MCH and CYSHCN programs, Title V supports efforts within the public and private sectors to shape and monitor health-related services for women, children and youth. Although several state programs provide services for CYSHCN, ideally, the Title V CYSHCN programs are valued for their expertise in reaching CYSHCN populations, maintaining their strong connection to networks of pediatric specialists, and having the high-quality data on the service needs of CYSHCN and their families.

MCHB also identified six quality indicators of a system of services that have influenced state activities and state priorities:

- Family Professional Partnerships: Families of CYSHCN will partner in decision making at all levels and will be satisfied with the services they receive.
- Medical Home: CYSHCN will receive family-centered, coordinated, ongoing comprehensive care within a medical home.
- Adequate Insurance and Financing: Families of CYSHCN have adequate private and/or public insurance and financing to pay for the services they need.
- Early and Continuous Screening and Referral: Children are screened early and continuously for special healthcare needs.
- Easy to Use Services and Supports: Services for CYSHCN and their families will be organized in ways that families can use them easily and include access to patient and family-centered care coordination.
- Transition to Adulthood: Youth with special healthcare needs receive the services necessary to make transitions to all aspects of adult life, including adult healthcare, work and independence.

APPENDIX 14 - Family to Family Health Information Centers^{47,48}

“Family-to-Family Health Information Centers (F2Fs) are family-led centers funded by the Health Resources and Services Administration (HRSA). There is one F2F in each state, in the District of Columbia, in five U.S. territories, and there are three F2Fs serving tribal communities. Each F2F is staffed by highly-skilled, knowledgeable family members who have first-hand experience and understanding of the challenges faced by families of CYSHCN. These uniquely qualified staff provide critical support to families caring for CYSHCN, particularly families of children with complex needs and those from diverse communities.

F2Fs also assist providers, state and federal agencies, legislators, and other stakeholders to better understand and serve CYSHCN and their families.”⁴⁷

“The purpose of Family-to-Family Health Information Centers (F2F HICs) Program is to provide information, education, technical assistance, and peer support to families of children and youth with special healthcare needs (CYSHCN) and the professionals who serve them.”⁴⁸

APPENDIX 15 - Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV)^{49,50,51}

“Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program – Formula grant. The purpose of this program is to support the delivery of coordinated and comprehensive high-quality, and voluntary early childhood home visiting services to eligible families. HRSA administers this program in partnership with the Administration for Children and Families (ACF).”⁴⁹

Home visitors and families develop strong relationships and trust through meeting regularly and addressing families’ needs.

Home visitors:

- Support healthy pregnancy practices
- Provide information on topics such as breastfeeding, safe sleep, preventing unintended child injuries, and nutrition
- Encourage early language development and early learning at home
- Teach positive parenting skills like reading, playing, and praising good behaviors
- Work with caregivers to set goals for the future, continue their education, and find employment and child care solutions
- Connect families to other services and resources in their community”⁵⁰

MIECHV models:⁵¹

[Attachment and Biobehavioral Catch-Up \(ABC\) -Infant Child First](#)

[Early Head Start Home-Based Option](#)

[Early Intervention Program for Adolescent Mothers](#)

[Early Start \(New Zealand\)](#)

[Family Check-Up® For Children](#)

[Family Connects](#)

[Family Spirit®](#)

[Health Access Nurturing Development Services \(HANDS\) Program](#)

[Healthy Beginnings](#)

[Healthy Families America \(HFA\)®](#)

[Home Instruction for Parents of Preschool Youngsters \(HIPPI\)®](#)

[Maternal Early Childhood Sustained Home-Visiting Program \(MECSH\)](#)

[Maternal Infant Health Program \(MIHP\)](#)

[Minding the Baby® Home Visiting \(MTB-HV\)](#)

[Nurse-Family Partnership \(NFP\)®](#)

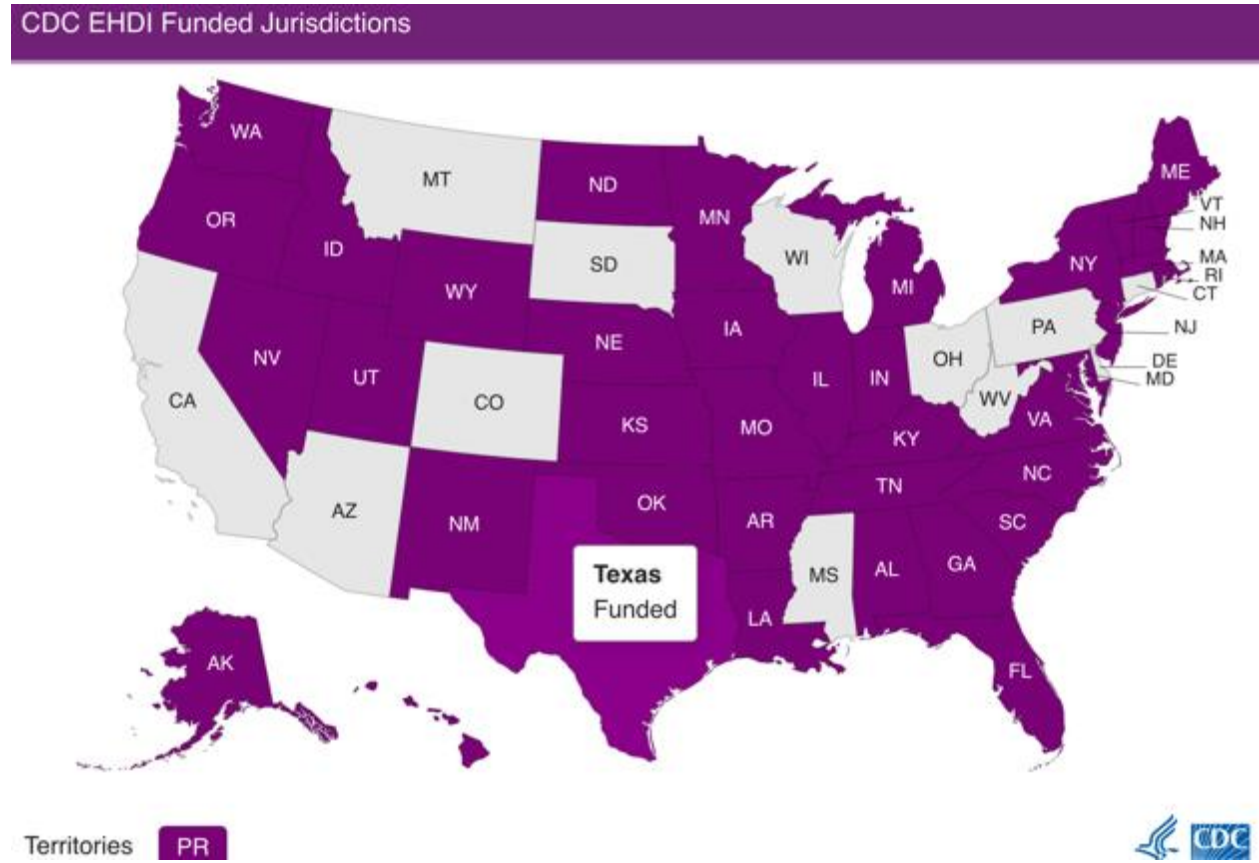
[Parents as Teachers \(PAT\)®](#)

[Play and Learning Strategies \(PALS\) Infant](#)

[Promoting First Relationships®—Home Visiting Intervention Model](#)

[SafeCare Augmented](#)

Appendix 16. Jurisdictions funded by Centers for Disease Control and Prevention (CDC) EHD1



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