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Coalition for Global Hearing Health Hearing Care Pathways Working Group: Guidelines for Clinical Guidance for Readiness and Development of Evidence-Based Early Hearing Detection and Intervention Programs

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Editor's Note: The following article discusses the timely topic Clinical Guidance in the areas of Evidence-Based Early Hearing Detection and Intervention Programs. This article aims to discuss areas of services needed, guidance to countries/organizations attempting to initiate early hearing detection and intervention systems. Expert consensus and systematic/scoping reviews were combined to produce recommendations for evidence-based clinical practice. In Ear and Hearing, our long-term goal for the Point of View article is to stimulate the field's interest in and to enhance the appreciation of the author's area of expertise.

Abstract: Hearing is an important sense for children to develop cognitive, speech, language, and psychosocial skills. The goal of universal newborn hearing screening is to enable the detection of hearing loss in infants so that timely health and educational/therapeutic intervention can be provided as early as possible to improve outcomes. While many countries have implemented universal newborn hearing screening programs, many others are yet to start. As hearing screening is only the first step to identify children with hearing loss, many follow-up services are needed to help them thrive. However, not all of these services are universally available, even in high-income countries. The purposes of this article are (1) to discuss the areas of services needed in an integrated care system to support children with hearing loss and their families; (2) to provide guidance to countries/organizations attempting to initiate early hearing detection and intervention systems with the goal of meeting measurable benchmarks to assure quality; and (3) to help established programs expand and improve their services to support children with hearing loss to develop their full potential. Multiple databases were interrogated including PubMed, Medline (OVIDSP), Cochrane library, Google Scholar, Web of Science and One Search, ERIC, PsychInfo. Expert consensus and systematic/scoping reviews were combined to produce recommendations for evidence-based clinical practice. Eight essential areas were identified to be central to the integrated care: (1) hearing screening, (2) audiologic diagnosis and management, (3) amplification, (4) medical evaluation and management, (5) early intervention services, (6) family-to-family support, (7) D/deaf/hard of hearing leadership, and (8) data management. Checklists are provided to support the assessment of a country/organization's readiness and development in each area as well as to suggest alternative strategies for situations with limited resources. A three-tiered system (i.e., Basic, Intermediate, and Advanced) is proposed to help countries/organizations at all resource levels assess their readiness to provide the needed services and to improve their integrated care system. Future directions and policy implications are also discussed.

Key words: Childhood hearing loss, Early detection, Early identification, Early intervention, Intervention outcomes, Newborn hearing screening, Permanent childhood hearing loss, Universal hearing screening.

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BACKGROUND

The Coalition for Global Hearing Health is a nonprofit organization with the mission to promote and enhance ear and hearing health services in low- and middle-income countries and to improve the lives of people with hearing loss. Its four overarching goals are to: (1) advocate for appropriate and relevant policies, (2) define best practices and disseminate resources for providers, (3) convene stakeholders to engage in constructive dialogue and networking in conferences and meetings, and (4) educate and empower consumers, families, providers, and community members on hearing-related topics and endeavors (Coalition for Global Hearing Health 2022). In 2019, the Board of Directors elected a Best Practice Director (K.C.) to organize and to recruit experts in the field to address global hearing health needs. To facilitate better hearing care services around the world, the Coalition of Global Hearing Health recruited a group of respected experts, who met regularly for a year and a half, from each populated continent across the globe to develop this set of recommendations and readiness checklists. In addition to diverse geographical locations (Australia, Brazil, India,

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South Africa, Taiwan, United Kingdom, United States), the authors represent professionals with different experience and expertise encompassing audiology, deaf education, early intervention, hearing screening, medicine, surgery, public health, and hearing-related research. Personnel from the industry are excluded to avoid possible perceived conflict of interests. Authors from high-income countries have experience working in low-and-middle-income countries. In addition, to widen the global perspective, input on the document recommendations was obtained from reviewers from 11 different countries (Albania, Australia, Brazil, China/Hong Kong, Germany, India, New Zealand, Philippines, South Africa, United States, United Kingdom) that additionally included input from primary care physicians, parents and D/deaf/hard of hearing (DHH) professionals who provided recommendations on the guidelines. The goal was to generate guidelines that would complement the work of the World Health Organization (WHO).

The rights of a child to the "highest attainable standard of health" and to be supported to develop their "talents and mental and physical abilities to their fullest potential" are enshrined in the 1989 United Nations Convention on the Rights of the Child. The development of speech, language, communication, and psychosocial skills is central to these entitlements. Recognizing the importance of hearing, the WHO (2009) recommended the implementation of universal newborn hearing screening (UNHS) to detect hearing loss among infants so that appropriate care can be provided to reduce its negative consequences. WHO further highlighted the importance and the imperative of addressing hearing loss at all ages and presented a Call To Action in the World Report on Hearing (WHO, 2021a). In addition, based on the findings of systematic and scoping reviews (Yoshinaga-Itano et al. 2021a; Edmond et al. 2022), WHO (2022) published recommendations on maternal and newborn care for a positive postnatal experience. WHO recommendation 27 calls for the global implementation of UNHS and it emphasizes the need to both integrate ear and hearing services into health systems and to undertake service development on evidence-based principles. Note that hearing loss is used to refer to hearing levels above the normal limits. In some context, hearing level is also referred to as to avoid the word "loss."

The purpose of UNHS is to enable the detection of hearing loss in infants so that timely health and educational/therapeutic intervention can be provided as early as possible to improve outcomes (JCIH 2000, 2007, 2019). While UNHS is a necessary component, it is insufficient by itself to assure optimal outcomes. An integrated care system, such as an Early Hearing Detection and Intervention (EHDI) program that incorporates both health and early education, is needed to help children thrive. In such a system, one of the first steps of auditory habilitation is to conduct high-quality audiologic diagnostic evaluations and amplification interventions by trained pediatric audiologists or appropriate professionals whose competency is assured for all components of the EHDI system (e.g., in countries without audiologists or with too few audiologists).

Children need to be exposed to quality and frequent communication in their daily lives to optimally develop language and communication skills (Yoshinaga-Itano et al. 1998; Yoshinaga-Itano et al. 2001a, b; Kennedy et al. 2006; McCann et al. 2008; Korver et al. 2010; Sininger et al. 2010; Stevenson et al. 2010; Worsfold et al. 2010; Yoshinaga-Itano et al. 2010, 2021; Pimperton et al. 2016; Wake et al. 2016). These skills underpin socio-emotional wellbeing and improve long-term life chances of children with hearing loss. In addition, medical diagnostics, counseling, and interventions can help identify the etiology of hearing loss, other medical conditions, and intervention strategies. Another major emphasis of the integrated care system is the engagement of parents, families, DHH leaders, and diverse cultural communities. These services aim to support the families of children with hearing loss and provide the children with role models for success in life.

Evidence-based UNHS/EHDI systems consist of effective continuing collaborations between health and education. EHDI programs can alleviate the long-term negative impact of hearing loss and improve outcomes of children with hearing loss when the established UNHS/EHDI system is evidence-based (Yoshinaga-Itano et al. 2021). They also have the potential to reduce inequities and inequalities in populations of children who are DHH (Yoshinaga-Itano et al. 2021), regardless of socio-economic background or country (e.g., Nigeria [Olusanya 2012]; Philippines [Chiong et al. 2007]; South Africa [Störbeck & Pittman 2008; Störbeck & Young 2016], Thailand [Poonual et al. 2017], Turkey [Sahli 2019]).

Unfortunately, many hearing care programs established in many countries have focused predominantly or solely upon screening and diagnosis. All countries, even those with advanced and long-term programs, are missing some components. For example, few countries/systems have well-established data management systems to track quality indicators for screening, diagnosis, amplification fit, or early intervention services. While having the desire, commitment, and passion, many countries may not have the resources for a thorough pathway following UNHS, for example, the medical, diagnostic, and audiology facilities for follow-up services. These difficulties and barriers are real. One of the solutions may be to form partnerships and international connections with established programs to move forward even in a very fundamental/limited way.

SCOPE AND PURPOSE

There is compelling evidence for the positive impact of early detection of hearing loss through systematic hearing screening coupled with timely intervention for earlier identification, earlier amplification, and earlier entrance into therapeutic intervention services (Yoshinaga-Itano et al. 2021a; Edmond et al. 2022). The recommendations for best practice stated in this article have been developed based on published evidence in combination with the experience of practitioners who have been involved in program implementation and ongoing quality assurance in settings around the world. The evidence includes, but is not limited to, published evidence-based policy and clinical guidelines for hearing screening, for pediatric audiologic diagnostic evaluations of infants (King 2010; Bagatto et al. 2011; Taiwan Ministry of Health 2012; AAA 2013, 2020; Australian Government Department of Health 2013; South African Speech-Language-Hearing Association [SASLHA] 2018; British Columbia Infant Diagnostic Protocols 2019; JCIH 2019), and for early intervention services, including family-to-family and DHH support (JCIH 2013; Moeller et al. 2013; 2024 a-c).

This document aims at a descriptive rather than a prescriptive approach. Recommendations within this document aiming for international consideration of adoption and implementation should be based on available resources unique to each region or country. For example, low-income regions or countries with very limited financial, human, and material resources

may prioritize elements considered feasible for adoption. Conversely, middle- and high-income regions or countries may readily implement many key elements concurrently. Thus, "Implementation Requirements" are presented in the context of "Basic," "Intermediate," and "Advanced" levels. Three levels are outlined to help screening programs that aim to provide UNHS, focus on providing follow-up diagnostic evaluations and amplification and therapeutic interventions as well as including parent-to-parent and DHH leadership and mentorship. In addition, programs can be expanded to screen more conditions that can potentially negatively affect children's hearing or speech processing, such as cytomegalovirus (CMV), genetic disorders, and auditory neuropathy spectrum disorders (ANSD). All recommendations remain sensitive to challenges and competition within health systems vying for limited available resources. The aim of this document is to provide a dynamic map to encourage continued growth while striving for the best possible program uniquely contextualized to the region or country.

Following an overview of the aims and key elements of best practice EHDI programs, this document proposes implementation requirements for programs at "Basic," "Intermediate," and "Advanced" levels. Together with the rationale, a comprehensive inventory of checklists for assessing readiness for implementation in different domains is provided. Countries may wish to draw on existing guidelines or models of implementation to support their development.

For information regarding cost-effectiveness of infant hearing and vision screening programs, refer to the cost-effectiveness model in EUSCREEN (2021a, b) which takes local circumstances into account and reports the cost of a program to be established in different countries or regions.

AIMS OF EHDI PROGRAMS

The aims of EHDI programs are to provide integrated care pathways to help children with hearing loss to develop communication, language, cognitive, and psychosocial skills to their full potential and to support their families, by:

- Aim 1: Meeting or exceeding EHDI 1-3-6 (screen by 1 month, identify by 3 months and in early intervention by 6 months) (Yoshinaga-Itano et al. 2017, 2020; Awad et al. 2019; JCIH 2019);
- Aim 2: Enabling the coordinated early provision of safe and effective audiologic assessment for, diagnosis of type, degree, and symmetry (Nikopoulos 2015; Wood et al. 2015; JCIH 2019). As programs develop and mature, detection of infants with unilateral hearing loss or lesser degree of hearing loss may be targeted (e.g., ≤35 dB HL);
- Aim 3: Enabling support for amplification technology acquisition and fitting and referral to high-quality early intervention services (Nikolopoulos 2015; Wood et al. 2015; Ching et al. 2017; JCIH 2019; Ching & Leigh 2020);
- Aim 4: Enabling the early identification of the etiology of infants with permanent congenital bilateral hearing loss ≥40 dB HL through medical evaluation (JCIH 2019; Sung et al. 2019; BAAP 2021; Li et al. 2022). The types of disorders that the hearing screening program aims to identify may be expanded to other disorders as evidence emerges for example, ANSD, genetic disorders (Kimberling et al. 2010; JCIH 2019), or hearing loss caused by CMV (Fowler 2013; BAAP 2021; Li et al. 2022) to allow families to seek intervention options for underlying medical causes of hearing loss as early as possible;
- Aim 5: Enabling the provision of family-centered early intervention systems (JCIH 2013; Moeller et al. 2013, 2024 a-c; Nicholson et al. 2016) to parents/caregivers to optimally support their child's development skills through meaningful communication with their child via spoken and/or signed language(s)/system(s);
- Aim 6: Enabling the provision of family-to-family support networks (JCIH 2013; Moeller et al. 2013, 2024 a-c; Henderson et al. 2014, 2016);
- Aim 7: Enabling DHH leadership network access (JCIH 2013; Moeller et al. 2013, 2024 a-c; Gale et al. 2021; Crace et al. 2020); and
- Aim 8: Enabling the provision of quality assurance systems, which includes data management of screening, audiologic and medical systems, and longitudinal developmental outcomes of the identified children (JCIH 2019; Davis et al. 2022).

KEY ELEMENTS

The integrated system shown in Figure 1 comprises all elements that are core to achieving the integrated EHDI program aims, paving the way for successful outcomes for children and families (Yoshinago-Itano et al. 2022). While UNHS may be only the first step in the care pathway (Allen et al. 2009; Schrijvers et al. 2012; JCIH 2019; Seys et al. 2019), it is essential that planning for implementation is undertaken in conjunction with the development of all components of the model, together with arrangements for effective data capture and management of all components of the system, which should ensure that:

1. There is representation of all stakeholders including the involvement of families, hearing professionals and DHH leaders, and educational professionals as well as policymakers at all levels of strategic planning and program delivery;
2. Hearing screening is carried out according to best practice guidelines and protocols;
3. Accurate and effective data tracking systems are in place in the integrated pathways with quality programmatic assurance and longitudinal developmental milestones of the identified children;
4. Feedback loops and fail-safe mechanisms are established to ensure that children progress along the care pathway;
5. All personnel delivering the services have and maintain appropriate skills and competencies;
6. Comprehensive information is available to families at each stage in the care pathway that promotes parental knowledge building and informed decision-making;
7. Infants who fail a screening test receive timely audiologic and medical assessment that yield diagnoses and are offered appropriate management;
8. Infants are appropriately fitted with hearing aids or cochlear implants according to their degree of hearing loss, with parental/caregiver informed consent, and whenever funding is available;
9. Following confirmation of hearing loss, skilled support and early intervention are available: (a) for families to ensure infants have early access to language and communication, (b) for the assessment and promotion of speech, (spoken/signed) language, communication, and socio-emotional development in infants, and (c) for parental informed decision-making with the help of family-to-family support and DHH leaders;

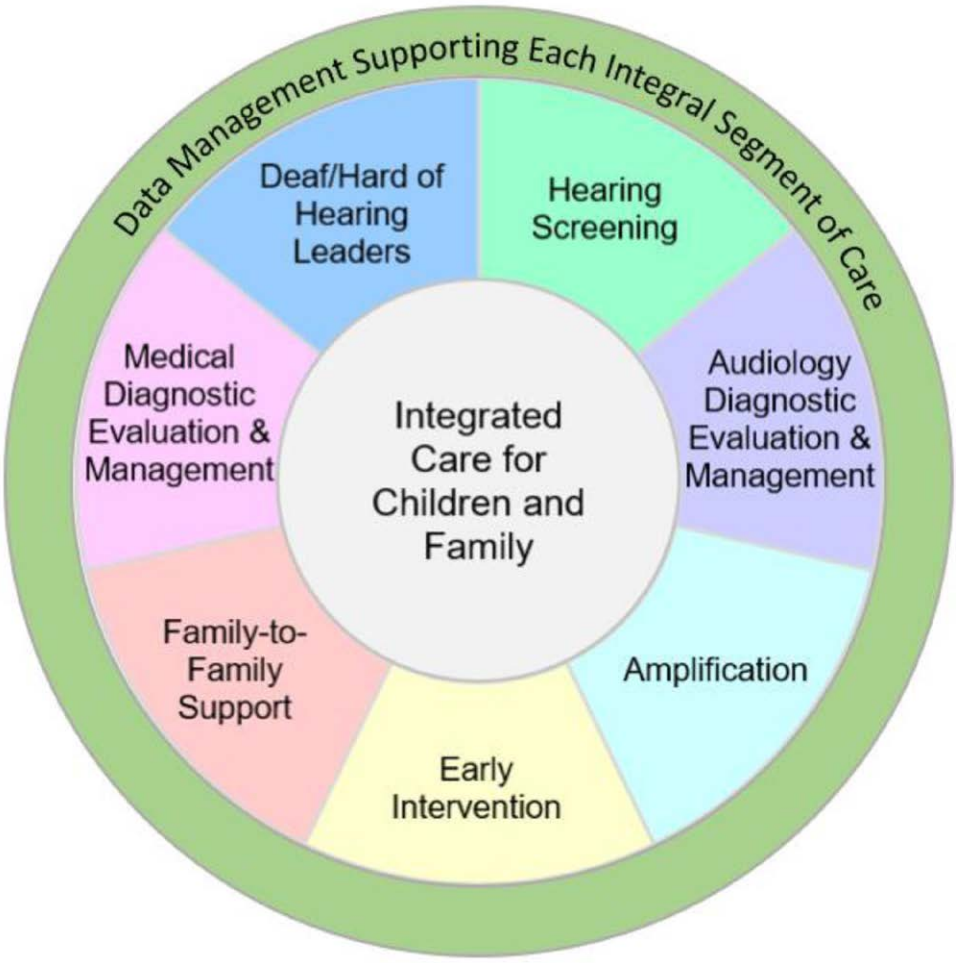

Fig. 1. Model of an EHDI program's integrated care for children and family (Yoshinaga-Itano et al. 2022). EHDI indicates Early Hearing Detection and Intervention.

10. Good flow of communication is provided along and within the care pathways with effective professional management which ensures a coordinated experience for families; and
11. Local policy and practice guidelines are published and disseminated.

IMPLEMENTATION REQUIREMENTS AND LEVELS

This document suggests requirements for different stages of implementation in order to assess the needs of countries or programs:

Basic may apply to those settings where programs are in the early stages of implementation and the service coverage is low.

Intermediate may apply to settings where some screening activity is underway with elements of follow-up taking place, but there is an identified need to formally systematize a sustainable program and the service coverage is <95% of the population.

Advanced may apply to programs that have ≥95% of service coverage and seek to enhance or expand service provision.

Note that the Intermediate and Advanced levels build on the preparations and services at lower level(s). Programs may comprise elements at different levels, with some existing practice or expertise at a more Advanced level than others. For example, programs in the United Kingdom and the United States initially started as early as the 1970s for family-centered intervention, with some parent education programs beginning in the 1950s. UNHS programs began as early as 1950s, with little or no funding and relied upon creative systems that included volunteers (e.g., retirees, students, hospital personnel who could expand duties), donations or fund raising for equipment and/or barter for exchange of early intervention services. The overarching goal of the programs is to build on strengths and opportunities and to develop elements that are lacking to achieve integrated care (Table 1).

Central to all levels are considerations relating to:

1. increasing the quality of existing components within the system;
2. initiating pilot programs with expansion plans; engagement of strategic and community leaders and local professionals;
3. engaging parent leaders and families with children who are DHH, as well as adult representatives from the DHH communities;
4. preparing a communications strategy (e.g., printed, oral, video, and in the family's required language) for both professionals and families;

TABLE 1. Implementation requirements for Basic, Intermediate, and Advanced levels

Basic	Intermediate	Advanced
1. Form an advisory board and develop a strategic plan. 2. Decide whether to implement "Well-Baby" screening for all newborns or only newborns admitted to the NICU, or both to ensure all newborns are screened. 3. Run a small pilot in one or two selected locations/hospitals. 4. Audit equipment/personnel needs, and financial support. 5. Identify medical and audiologic diagnostic evaluation sites before initiating screening and establish collaboration. 6. Develop culturally appropriate balanced and accessible information for families that promotes understanding and assists informed decision-making. 7. Start with education of community and prospective families, training of personnel/professionals for screening, diagnosis, amplification, and family-centered intervention. 8. Identify DHH professionals. 9. Begin with a small cohort and work toward full implementation in that cohort before expansion. 10. Start a data management system. Initially even a paper-based system can provide important data especially at the pilot stage. 11. Develop protocols to monitor child development at least every 6 mos.	1. Determine if there are components under Basic that have not yet been addressed or established. Set goals and begin to establish. 2. Expand high-quality pilots to other locations/ hospitals. 3. Identify challenging areas and develop improvement plans for: screening, diagnostic evaluations, middle ear evaluation, provision of amplification or implant, medical evaluation and care, early intervention services, data management, family-to-family support, and/or DHH leadership 4. Examine quality indicators and progress toward meeting quality standards. 5. Develop and implement a multidisciplinary team approach to provide coordination of care and support for families. 6. Refine data management system. 7. Audit personnel training needs, consider a train-the-trainer model, and provide continuing education for staff involved in the EHDI pathway.	1. Implement regional or national programs. 2. Identify challenging areas and develop improvement plans: system-wide parent-to-parent support networks, system-wide DHH leadership/ mentors/role models, data management, diagnostic and rehabilitative services, medical investigations, evaluation of children with middle ear involvement, ANSD, or other medically complex conditions, quality and availability of early intervention services, and measurement of developmental outcomes. 3. Chart progress toward meeting quality standards for screening, identification, amplification, and early intervention. 4. Ensure that multidisciplinary coordination functions well by establishing mechanisms for family feedback on their experiences to inform continuous improvement. 5. Expand and improve data management system, for example, integrating other areas of child health. 6. Involve research and evaluation in all components of the program.

ANSD, auditory neuropathy spectrum disorders; DHH, D/deaf/hard of hearing; EHDI, Early Hearing Detection and Intervention; NICU, neonatal intensive care unit.

5. developing and implementing strategies that will ensure the program has longer-term sustainability and can demonstrate its value; and
6. undertaking ongoing quality assurance across the entire pathway.

PRE-IMPLEMENTATION PREPARATION

Develop an Advisory Board/Council/Committee at a Regional and/or National level

The advisory board should have diverse representation (e.g., physicians, teachers of the deaf, parent leaders, families, DHH professionals/representatives, speech/language therapists, audiologists, social workers, psychologists, and community leaders who have good reputations in the community and become the entry point to the community) to steer the development strategically and to develop operational guidance and governance (JCIH 2000, 2007, 2013, 2019). This will involve designing the program structure, establishing guidelines, timelines, data management procedures, protocols, training, and quality indicators, ensuring that all perspectives/voices are equitably represented and respected. Note that training must be developed (or adopted/adapted from already designed examples) and implemented before commencing screening and be continuously provided to improve skills as the program matures.

In order to be effective, it is important for a program to achieve good coverage, and high uptake from the population. It is also necessary to ensure that the screening tests have high sensitivity (i.e., refer >90% of infants who do have the target condition) and high specificity (i.e., do not refer >90% of infants who do not have the target condition). Specificity and sensitivity are affected not only by choice of equipment, pass and fail criteria, and the age of the baby at the time of screening, but also the competence of the screeners, equipment calibration and functional status, and the environment in which the screening is undertaken. To achieve high sensitivity and specificity, decisions on program structure should be informed by the results of the readiness survey on all elements of the care pathway, taking into account the agreed benchmarks and guided by the goals of Care Pathways (Allen et al. 2009; Schrijvers et al. 2012; Seys et al. 2019).

Develop Agreed Benchmarks

Currently, benchmarks are not available for most of the components of the integrated EHDI programs, with the exception of the screening component. The Joint Committee for Infant Hearing (JCIH 2019) recommends the following EHDI benchmarks for well-babies and infants in the NICU:

- Complete the screen before 4 weeks of age for infants born after 37 weeks of gestation. For premature infants, this benchmark should reference the corrected age;
- Undertake audiologic assessment before 3 months of age (apply the same assumptions for full term/premature infants as in No. 1); and
- Fit amplification and begin early intervention before 6 months of age (apply the same assumptions for full-term/premature infants as in Table 2).

JCIH further recommends UNHS programs that meet EDHI 1-3-6 (i.e., screened by 1 month, diagnosed by 3 months, and enrolled in early intervention by 6 months) move to the 1-2-3 model (i.e., screened by 1 month, diagnosed by 2 months, and enrolled in early intervention by 3 months). These goals may be challenging to meet for programs at the early stages of implementation, but should be aspired to.

Countries with advanced programs need to strive for continuous improvement. They may aspire for earlier intervention initiation dates (e.g., 2 to 3 months) and aim to further increase service coverage to under-represented and under-served populations. In order to decrease inequities/inequalities, a number of successful programs (e.g., the United Kingdom, and Colorado in the United States) refer entry to early intervention as soon as hearing loss is identified, which may precede the completion of the audiologic evaluation and amplification fit. Inequalities often exist because of social and economic barriers. In many places, these inequities can also be culturally based, where health and education systems are not attuned to diverse communities, particularly in indigenous and refugee/immigrant communities. The implementations of UNHS/EHDI programs, therefore, must take these issues into account and seek improvements.

In addition, most advanced programs do not have all the EHDI service components or universal service coverage of every components. Efforts must be made to:

- Ensure family-to-family support;
- Ensure DHH leadership support;
- Monitor and increase percentage of children with hearing loss who maintain age-level or cognitively appropriate language and social-emotional milestones, throughout childhood and at least every 6 months in early childhood;
- Utilize data management systems to track metrics of quality assurance and to inform appropriate remedial action when quality falls below effective levels; and
- Expand the target testing condition or service coverage for hearing screening, for example,
  - Basic: May focus on a small UNHS pilot program or on NICU screen or only on bilateral moderate to profound hearing loss;
  - Intermediate: May focus on unilateral and/or mild-moderate bilateral hearing loss, especially amplification intervention and early intervention services; and
  - Advanced: May consider expanding to the identification of all hearing losses including ANSD, unilateral, mild-moderate bilateral hearing losses, CMV, or genetic hearing loss, children with autism, and other developmental disorders.

TABLE 2. Goals of the internationally recommended care pathway

Service Level	Hearing Screened	Hearing Loss Identified	Early Intervention Started	Initial Amplification Provided
Basic EHDI 1-3-6	By 1 mo	By 3 mos	By 6 mos	By 6 mos
Intermediate EHDI 1-3-6	By 1 mo	By 3 mos	By 3 mos	By 6 mos
Advanced EHDI 1-2-3	By 1 mo	By 2 mos	By 3 mos	By 3 mos

EHDI, Early Hearing Detection and Intervention.

Conduct a Readiness or Level of Development Survey for All Components of EHDI Programs

Many aspects of infrastructure and resources need to be ready or set in motion in order to establish a successful integrated EHDI program. Before setting up a program, many factors will need to be considered to determine the types of resources needed.

Hearing Screening Readiness • The prevalence of congenital hearing loss among infants varies with the hearing loss criteria, types of hearing and medical tests used, whether temporary hearing loss is included, health of the infants, and the countries of survey (Neumann et al. 2020, 2022). For example, meta-analyses indicate the prevalence of bilateral hearing loss is 1.2 to 1.3 per 1000 screened babies whereas the prevalence of unilateral hearing loss is 0.8 per 1000 babies (Butcher et al. 2019; Bussé et al. 2020). The overall prevalence for both unilateral and bilateral hearing loss is ~2.2 per 1000 screened infants (Butcher et al. 2019; Bussé et al. 2020). However, when these estimates are calculated separately for well-babies and infants in NICUs, infants admitted to NICUs have at least 5 to 8 times higher likelihood than well-babies to have hearing loss (5.9 to 15.7 per 1000) (Butcher et al. 2019; Bussé et al. 2020).

Available data on congenital hearing loss point to several important causes:

- Genetic causes (~50–60%) among which
  - ~70% are not associated with a syndrome (i.e., non-syndromic) and
  - ~30% are associated with a known syndrome(s) (i.e., syndromic, Smith et al. 2005; Lammens et al. 2013).
- Environmental causes (~25%), such as infections, drugs, or trauma. Among the infections,
  - CMV is the main cause of non-genetic congenital hearing loss;
  - rubella continues to be prevalent in unvaccinated countries; and
  - Zika virus can also cause congenital or late-onset hearing loss.
- Other unknown causes (~25%, CDC 2020a, b, c; Renauld & Basch 2021, Fig. 2)

To make decisions about whether there is capacity to begin a newborn hearing screening program, it is important to determine what resources and infrastructure are available, to understand the prevailing legal setting, to give consideration to the choice of screening protocols equipment, screening personnel, and their training, and to support the education of families (BAAP/BAPA 2008). Decisions relating to the test protocols, the number of personnel needed, and the units of equipment required will be influenced by the number of infants born, the settings in which the children are born (hospital versus home birth), the duration of hospital stay for the mother and baby, the age of the infant at the time of screen, and noise levels within the testing environment. Each decision has specific ramifications related to reasonable costs, low false positive and false negative rates adequate personnel required for a low loss to follow-up rate, in order to ensure optimal developmental outcomes for the infants identified with hearing loss.

The hearing screening protocol and the types of equipment will be determined by many factors, for example:

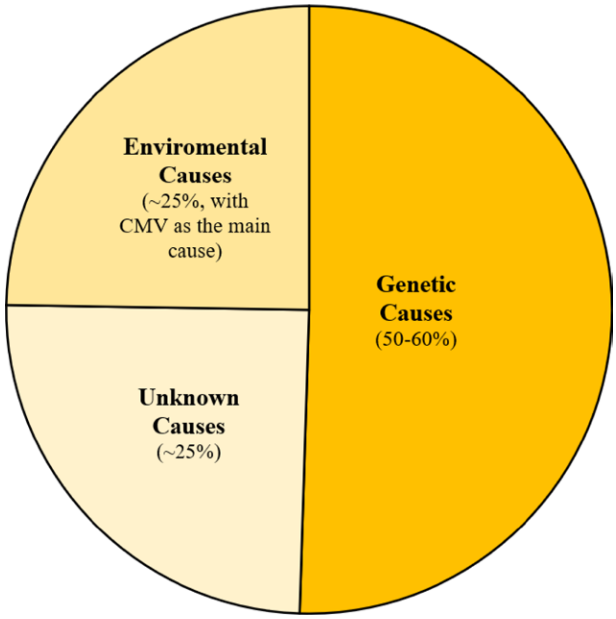

Fig. 2. The causes of congenital hearing loss according to Centers for Disease Control, United States. CMV indicates cytomegalovirus.

- The results of otoacoustic emissions (OAE) screening can be affected by fluid in infants' middle ear. With OAE equipment alone, this may result in multiple screens in order to obtain targeted refer rates. Multiple screens beyond two screens per session, both in the hospital or at out-patient follow-up, are not evidence-based practice and could negatively affect program accuracy. OAE screening will result in a higher refer rate and a higher diagnosis of children with mild hearing loss than automated auditory brainstem response (ABR) screening (the hearing thresholds that would pass OAEs are 30 to 35 dB HL, and those that would pass automated ABR are approximately 40 to 45 dB HL) (JCIH 2019). If the infant must be tested within the first 12 hr after birth, then automated ABR equipment is recommended in order to avoid the 40% or higher refer rates that may result from OAE screening alone (Gabbard et al. 1999; van Dyk et al. 2015);
- Automated ABR screening with specific manufacturers could result in refer rates <4%. Double technology screen, for example, OAE followed by automated ABR, is optimal to identify infants with hearing loss and will also drop refer rates below 4%. An efficient EHDI program should strive for a refer rate to diagnostic evaluation in the range of 0.5 to 4% in the well-baby population.

Detailed procedures about performing hearing screening can be found in the publications of more established systems (BAAP/BAPA 2008; NCHAM Newborn Hearing Screening Training Curriculum 2008; Winston-Gerson & Ditty 2021). Appendix A in Supplemental Digital Content, http://links.lww.com/EANDH/B365, provides a checklist for assessing the readiness for providing hearing screening. Note that the appendices are designed to be worksheets that programs can use to check the necessary steps for establishing different components of the EHDI system. Space is provided in the middle column for response/evaluation and the third column provides some rationale and guidance.

Alternative Strategies for Initiating UNHS.

a. In places where newborns are not born in hospitals:

   - Identify pathway of care for newborns born at home for other opportunities for universal capture, for example, well-baby checks, immunization clinics, genetic/metabolic screening. What is the age of the child at each of these contact points?

b. If government funding is unlikely or may take a long time to obtain:

   - Investigate private healthcare systems and birthing hospitals or public-private partnerships;
   - Provide information to private hospital systems to implement EHDI programs;
   - Investigate the possibility of alternate sources of funding for a pilot project in a specific geographic area to develop an EHDI program, for example, purchase equipment for screening and diagnostic audiology services, locate/offer calibration services, provide training for personnel, develop and provide information to families;
   - Develop an EHDI program including early intervention follow-up, family-to-family support, and DHH leadership support. These service components are critically important, especially when amplification technology is not readily available; and
   - Replicate success in other regions.

Audiologic Evaluation and Management Readiness • Diagnostic evaluations of newborns require specialized knowledge and skills (King 2010; Bagatto et al. 2011; AAA Clinic Practice Guideline 2013; JCIH 2019). In high-income countries, most systems have specialized centers with trained personnel who have the expertise to perform infant audiologic diagnostic evaluations and who evaluate a large number of infants each year for hearing status. Accuracy of diagnostic test results on newborns is related to the experience of the professionals and the number of tests that they perform each year using evidence-based practice.

Beginning programs need to consider establishing "centers of excellence" that have relatively high volumes of diagnostic evaluations of infants that will support quality of the services.

Not every audiologic diagnostic facility is capable of assessing newborns due to the equipment and the professional expertise required to provide such services. Assessment during sleep is more likely to be successful if conducted within the first few months of life because most newborns spend the vast proportion of each day sleeping. Older infants may require sedation for diagnostic ABR or auditory steady-state response (ASSR) testing. The ABR diagnostic evaluation can provide information to diagnose the type of hearing loss, that is, conductive, sensory, neural (including ANSD), or mixed hearing loss. This evaluation can determine the laterality (unilateral or bilateral) and symmetry (symmetrical or asymmetrical) of the hearing loss. Audiologists should confirm the hearing thresholds with behavioral testing as soon as possible because the variability between the hearing thresholds determined by electrophysiologic measures and behavioral tests can be significant for individual child at individual frequencies (Stapells et al. 1995; Rance et al. 2005). Infants typically can be tested using behavioral visual reinforcement audiometry when they are between 6 and 9 months.

The hearing threshold levels at specific frequencies for each ear are vital for fitting hearing aids. The audiologic diagnosis of hearing loss should aim at being completed in one session for most infants (Awad et al. 2019). For infants with complex needs, more than one test session may be required. The diagnostic protocol must follow best practice guidelines to assure that the thresholds are close to predicted behavioral thresholds (Stapells et al. 1995; Rance et al. 2005). Otherwise, the amplification may over-amplify or may not meet the listening needs of the child. Appendix B in Supplemental Digital Content, http://links.lww.com/EANDH/B366, provides a checklist for assessing the readiness of audiologic evaluation and management.

There are no alternative scientific strategies for diagnosing hearing loss or obtaining thresholds of infants apart from using ABR or ASSR.

Amplification Provision Readiness • With parental or caregiver informed consent, services must be ready to provide as soon as possible, preferably within 1 month after the diagnosis of the hearing loss (King 2010; Bagatto et al. 2011; AAA Clinical Practice Guidelines 2013; JCIH 2019). The sooner a child is enabled to hear spoken language, the more likely the child will develop spoken language at a rate similar to their hearing peers (Ching et al. 2017).

Initial amplification needs are informed by the hearing thresholds obtained from the diagnostic evaluation. Appropriate fitting prescriptions for newborns include Desired Sensation Level version 5 (DSL v5, Scollie et al. 2005) and National Acoustics Laboratory Nonlinear version 2 (NAL-NL2, Keidser et al. 2012). Frequent monitoring of amplification fit includes transitions from thresholds obtained using electrophysiological tests (e.g., ABR or ASSR) to behavioral thresholds (e.g., visual reinforcement or play audiometry), as well as monitoring the stability of behavioral thresholds because of the high incidence of progressive hearing loss.

Children with bilateral hearing loss need to be provided with hearing aids or cochlear implants in both ears. Auditory deprivation leads to a decline in speech understanding in the unaided ear and can cause binaural interference, where speech understanding is poorer when listening with both ears than with one ear (Silman et al. 1984; Silverman & Silman 1990; Jerger et al. 1993; Schoepflin 2007). Bilateral amplification would also allow them to have better localization and speech understanding abilities, especially in noise (Sebkova & Bamford 1981; Markides 1982; Litovsky et al. 2006) and to take advantage of binaural hearing (Litovsky et al. 2021). Clinicians, therefore, need to be aware of the negative consequences of monaural fitting and provide binaural amplification.

The benefits of amplification will be maximized 1) when hearing aids are worn correctly and consistently during most of the child's waking hours, and 2) when the hearing aids are in good working conditions (e.g., functional batteries, ear molds free of impacted wax). Audiologic and early intervention service providers, therefore, will need to teach parents/caregivers how to correctly put the hearing aids in the infant's ears, how to check, maintain, and troubleshoot the hearing aids, and how to assess the effectiveness of amplification for their Infants. Audiologic service providers, parents/caregivers, and early intervention professionals supporting families need to monitor the child's progress and the benefits of hearing aids. Early referral to cochlear implantation is essential if the child obtains

limited benefits from hearing aids, and if spoken language development is the desired outcome.

Where parents choose to pursue spoken language development for their child, it is essential that the child is exposed to high-quality spoken communication. Appropriate early intervention providers need to teach parents/caregivers communication skills and strategies for ensuring that their infants experience a spoken-language-rich environment when wearing hearing aids.

Visual communication approaches should also be explored, including for those with access to amplification technology. The providers may encourage parents, caregivers, and family members to acquire sign language skills as an adjunct or as a primary language (see Appendix C for assessing Amplification Readiness in Supplemental Digital Content, http://links.lww.com/EANDH/B367). Early access to language, spoken and/or visual, is essential.

When Resources for Amplification Technology Are Unavailable or Limited. Bilateral amplification is the ultimate goal and every effort should be made to fit bilaterally at the earliest age possible.

a. If amplification technology is limited or when only one hearing aid is available for children with bilateral hearing loss:

- Ensure early intervention services immediately after audiologic diagnostic identification of hearing loss;
- Ensure evidence-based protocols are used to identify which ear to fit. In general, aid the better ear. If both ears are equal, make molds for both ears and train early intervention professionals to work with families to determine whether the infant responds better when the hearing aid is in the right or the left ear;
- Alternate the hearing aid between ears if the hearing loss is symmetric, as this can potentially ameliorate the negative effects of monaural fitting (Hattori 1993);
- Plan to fit the other ear with hearing loss as soon as possible; and
- Provide additional communication approaches such as those that incorporate visual approaches (e.g., sign language, Cued Speech).

b. If amplification technology is rarely available for families:

- Provide immediate early intervention services. Other communication approaches that provide visual approaches (e.g., sign language, Cued Speech), when accessed early can result in age-appropriate language development.
- Identify children with mild degrees of hearing loss. Many of them can hear conversational speech and louder sounds even without amplification technology. Trained early intervention professionals can facilitate auditory skill development with or without amplification technology and support development of sign language and visual approaches to communication so that infants have immediate access to language. When children have a language base, spoken language growth will be enhanced when amplification technology becomes accessible;
- Investigate accessing amplification technology through donated hearing aids or low-priced amplification options; and
- Investigate grant funding for the provision of hearing aids to infants through nonprofit organizations, hearing aid companies, or foundations.

c. If an earmold lab is not readily accessible:

- Explore low-cost procedures for making permanent earmolds;
- Obtain material and train local individuals to make instant earmolds or more permanent earmolds;
- Repurpose existing earmolds using shaping and smoothing with drill bits, and
- Monitor and ensure the earmolds are suitable as the infant's ears grow.

d. If hearing aid batteries are not readily available or too expensive:

- Identify a means to provide batteries to families at minimal or no cost.
- Investigate the feasibility of hearing aids with rechargeable solar batteries.

Medical Evaluation and Management Readiness • Early medical evaluation contributes to better overall care for the child, together with better information for the family and caregivers. Medical evaluations for infants/children who are DHH may include:

- Full clinical history (including antenatal history, birth and postnatal history, family history, and monitoring of developmental milestones),
- Full clinical examination,
- Family audiograms and examination,
- Electrocardiography,
- Ophthalmic assessment,
- Urine examination,
- CMV testing,
- Genomic/genetic testing and counseling,
- MRI of the internal auditory meatus, and,
- Other investigations (e.g., serology, rubella, renal ultrasound, chromosome analysis) may be undertaken when indicated by the history and medical findings.

Medical evaluation of a child identified with hearing loss is a key component of integrated care for children and should be undertaken as soon as possible (Sung et al. 2019; BAAP 2021; Li et al. 2022). Establishing etiology as well as early identification of any other systemic health condition associated with hearing loss leads to better management, not only in addressing health conditions that may be potentially reversible, but also in enabling investigation of any medical disorders. For example, there is only a short window of opportunity to offer anti-viral treatment for infants with confirmed congenital CMV.

Every integrated care service for children should have appropriate medical practitioners in the team supporting the child and family. It is essential that referral relationships are established among practitioners and effective coordination is in place. The types of medical practitioners involved in an EHDI program may differ, depending on the situation and circumstances in different settings or countries. They may include pediatricians, otolaryngologists/ear, nose and throat specialists, audio-vestibular physicians, geneticists, and primary care practitioners. Specialists such as ophthalmologists and other allied health professionals may also be needed (e.g., speech/language pathologists, occupational therapists, physical therapists, psychologists), depending on the child- or family-specific clinical presentations. There should be a lead medical practitioner,

preferably at a consultant level, to coordinate healthcare input across the team and throughout the care pathway. Clinical decisions should always be based on accepted best practice protocols and be discussed with the family. Appendix D in Supplemental Digital Content, http://links.lww.com/EANDH/B368, has a checklist for assessing Readiness to Conduct Medical Evaluations on Newborns and Children who are DHH.

Early Intervention Readiness • Early intervention services should be conducted through best practice protocols for family-centered early intervention (JCIH 2013; Moeller et al. 2013, 2024 a-c; Narr & Kemmery 2015; Nicholson et al. 2016; Giallini et al. 2021; Wright et al. 2021; Szarkowski et al. 2024 a-d; Moodie et al. 2024). Early intervention refers to the support given by professionals and peers (i.e., both family-to-family and DHH professionals and mentors) following the early identification of hearing loss.

Early intervention providers can assist families to understand the nature of their child's hearing loss, the importance of early language input and communication, as well as amplification choices. Recommended protocols for the delivery of early intervention services for families who have infants and very young children identified as DHH can be found at www.fcei.at.

Unlike other special education services, early intervention services for children below 3 years of age are directed to the families so that they can learn communication strategies that are essential to supporting their child's development of age-appropriate language, cognitive, social-emotional, auditory/speech milestones. These early intervention providers, especially in countries where teachers of the deaf are key professionals in early intervention (e.g., in the United Kingdom or New Zealand), also support families in promoting their children's early development in play, pre-literacy, and other early educational skills. Appendix E in Supplemental Digital Content, http://links.lww.com/EANDH/B369, provides a checklist on the readiness for early intervention programs.

Strategies to Initiate System-Wide Family-Centered Early Intervention.

- Identify professionals to develop and conduct training—systems may have to look outside the country;
- Identify individuals within communities with the following characteristics: (1) willing and motivated to learn, and (2) respected in the community to be trained, or other suitably experienced individuals, such as experience and training with parenting a child who is DHH, or professionals experienced working with families and children with other communication disorders;
- Begin training and provide supervision and mentoring through teletherapy if technology is available and can be accessed via computer or cellphone through the internet; and
- Identify teachers who are willing to be trained to provide early intervention services.

Family-to-Family Support Readiness • Family-to-family support can improve follow-up from newborn screening, facilitate family audiologic, medical, and intervention appointment scheduling and attendance, facilitate family follow-up on amplification decisions and intervention enrollment, and provide timely support that can reduce grieving, facilitate the acceptance of the diagnosis, and improve the ability to follow-up (JCIH 2013; Moeller et al. 2013, 2024 a-c; Henderson et al. 2014, 2016; Narr & Kemmery 2015; Szarkowski et al. 2024 a-d; Moodie et al. 2024). It is essential to recognize that effective early intervention requires not only professional services provision but also support systems for families, which can enable the sharing of lived experience of hearing loss and provide family peer support.

The JCIH Early Intervention Supplement (2013) recommends that families be active participants in the development and implementation of EHDI systems at the state/regional/territory and local levels. They also recommend that all families have access to other families who have children who are DHH and who are appropriately trained to provide culturally and linguistically sensitive support, mentorship, and guidance. A best practice protocol for the provision of early intervention services that ensures family-to-family support can be found at the Global Coalition of Parents of Children who are Deaf or Hard of Hearing, National Organization for Parents, ad Hands & Voices (https://handsandvoices.org/fl3/topics/fam-fam-support/give-support.html and https://handsandvoices.org/fl3/fl3-docs/Fam-Fam-support-guidelines-8-30-2018.pdf).

Families gain significant support from others who share similar life experiences (Schor & American Academy of Pediatrics Task Force 2003; Reichmuth et al. 2013; Bray et al. 2017; King et al. 2017). Parent/family leaders who have been trained to provide unbiased support to other parents/families offer a non-threatening support system that is independent of direct professional services. Parents/families report that they can share their feelings and experiences with greater ease when they have parent/family support systems (DesGeorges 2003). See Appendix F in Supplemental Digital Content, http://links.lww.com/EANDH/B370, for a checklist on readiness for family-to-family support.

Strategies for Establishing Family-to-Family Support Systems.

- Identify parents who have children who are DHH and who are willing to be trained as leaders.
- Include diversity—families with children who communicate with spoken and sign languages or visually supported communication, as well as parents of children with additional disabilities, representing diverse cultures.
- Reach out to Global Coalition of Parents of Children who are Deaf or Hard of Hearing and the organizations listed in National Organization for Parents and
- Develop and implement training program.

DHH Leader Readiness • Family interaction with DHH leaders/professionals early in their journey can facilitate movement through the adjustment/grief process by providing families with successful and knowledgeable adult role models and mentors (Yoshinaga-Itano 2015; Olson & Putz 2019; Deafness Leadership International Alliance [DLIA 2021]; Crace et al. 2021). They can be professionals who themselves are DHH. Families have been reported to share information or ask questions of professionals/leaders who are DHH that they may not have shared with hearing professionals. Because professionals/leaders who are DHH have personal experience with communication difficulties, they can provide families with strategies and insights that those who are hearing cannot.

Family access to leaders/professionals who are DHH, is particularly beneficial (JCIH 2013). JCIH Early Intervention Supplement (2007) includes quality indicators for US EHDI programs that encourage

- Sign language instruction of the indigenous sign language of the country be provided by DHH instructors with fluent/native skills;
- Individuals who are DHH be active participants in the development and implementation of EHDI Systems at the national, state/territory, and local levels;
- All children who are DHH and their families have access to support, mentorship, and guidance from individuals who are DHH.

Access to DHH leaders can have a positive effect on a family's adjustment, grief, or mourning as they experience the diversity of successful outcomes. DHH leaders have experience and knowledge growing up as DHH in society and can support families as they raise their children. Most families with infants identified through EHDI programs have never known an individual who is DHH, either child or adult. The ability to meet and interact with leaders and professionals who are DHH can provide families with a diverse representation of leaders who are DHH and who communicate through sign and/or spoken language. Information on DHH professionals/leaders can be found at www.dliaconnect.org.

These DHH leaders may be teachers, audiologists, early intervention therapists, psychologists, social workers, physicians, or any other occupations, such as musicians, artists, actors, writers. In addition, families that choose to learn sign language can interact and learn from DHH leaders who are native/fluent in the indigenous sign language of the country. These individuals can provide families with strategies for assuring that their child has full access to language and communication and can assist in strategies that can support age-appropriate social-emotional and cognitive development. The following resources can be adapted to cultural contexts.

1. https://handsandvoices.org/fl3/fl3-docs/FL3_DHH_Adult_Support_Training_Resources.pdf, in some contexts Parent and Deaf Leadership have joined together in EHDI systems,
2. DHH parent and adults: tips for meaningful participation in EHDI systems (2018). https://www.handsandvoices.org/fl3/fl3-docs/Final-DHHadults-in-EHDI_8-30-2018.pdf,
3. Creating Cohesive Deaf and Hard of Hearing Leadership in EHDI system and Beyond: How our Community Drafts a Blueprint for DHH Leaders (https://ehdimeeting.org/System/Uploads/pdfs/18878_10176KarenPutz.pdf?v=1.47), and
4. Deaf Leadership International Alliance www.dliaconnect.org

Appendix G in Supplemental Digital Content, http://links.lww.com/EANDH/B371 is a checklist on establishing Deaf/Hard of Hearing Leadership support.

Strategies for Developing DHH Leadership Support.

- Identify communities and organizations with DHH leaders;
- Include diversity, for example, native sign language users, cochlear implant users, hearing aid users, DHH parents with DHH children;
- Provide training for DHH leaders in supporting families in early intervention;
- Connect hearing parents with DHH parents;
- Reach out to Deaf Leadership International Alliance in Family-Centered Early Intervention (DLIA);
- Develop (with international support) training programs and implement training; and
- DHH leaders can provide:
    - Sign language instruction,
    - Information about growing up as a child who is DHH, and
    - Strategies to assure that infants and children are accessing language and communicating utilizing both visual and auditory information. The leaders can serve as role models who are successful in their lives, leading independent lives and participating fully in society.

Data Management System Readiness • For effective program management and quality assurance of EHDI programs, it is essential to have accurate and timely data (Public Health England 2014; Holzinger et al. 2021; Davis et al. 2022). There needs to be agreement on what data are needed, the definitions for each data point and coding. Data analysis processes are expected to evolve with scientific progress. The data should allow for two purposes: (1) tracking, managing, and monitoring the system, quality of service provided, and effectiveness and identification of any failing in the system as well as (2) tracking and monitoring infant development, including those with risk factors and other special populations. Data need to be able to document whether major milestones are met (e.g., the EHDI 1-3-6 or EHDI 1-2-3 goal in Table 2).

Monitoring of developmental outcomes of family and child should be undertaken at least every 6 months during early childhood. Monitoring of access to family-to-family support and DHH Leaders should also take place. Appendix H in Supplemental Digital Content, http://links.lww.com/EANDH/B372, is a checklist to assess the readiness of the data management system.

Steps for Developing Data Management System.

- Identify already existing health data management system;
- Attempt to collaborate with other data management systems, for example, birth registry, immunization, genetic/metabolic screen, well-baby checks;
- Examine data/analyze data after 3, 6, 9, and 12 months;

  Take action if data revealed that expectations were not met;
- Evaluate the effectiveness of the action taken; and
- Start on a small initial can be documented using a pen and paper approach.

FUTURE DIRECTIONS AND POLICY IMPLICATIONS

Many challenges experienced in early childhood hearing screenings will be ameliorated with current emerging advancing technological ease of communication. To avoid poor outcomes from unrealistic forecasting, there are many promising future technologies that would make childhood hearing screening not only attainable but also affordable and accessible.

Universally, the largest obstacle to remediation after failed hearing screening has been the "loss to follow-up" (Ravi et al. 2016). Such failures are due to a variety of reasons: mobile populations, poor information systems, inadequate training of screeners, inadequate training of screening managers, incomplete or inadequate data monitoring systems, inaccessibility to the small number of professionals who provide appropriate rehabilitation, limited or unavailable counseling, and family support measures. Technological advances that would certainly

improve outcomes of early identification of hearing loss in childhood include: (1) affordable advanced information systems; (2) greater use of artificial intelligence in a variety of smaller electronic devices; (3) improved communication systems that are sensitive to radio frequency identification, and (4) ethical biometric identification to identify locations of people according to their electronic devices which would likewise match a trained and qualified ear and hearing care specialist.

Access to UNHS/EHDI systems could become a reality even for the most remote parts of the world with advances in artificial intelligence, hearing screening, and remote diagnostic assessments (e.g., through tele-practice, McCarthy et al. 2010; Swanepoel & Hall 2010; Houston et al. 2021). Tele-training and tele-practice can also provide access for training and updating personnel to maintain a specific level of competence. Every screening conducted would be monitored through advanced information systems to assure the set benchmark is consistently met, and would identify whether further training or equipment inconsistencies can be completed. Advanced information systems can collect the much-needed population data about prevalence/incidence as well as treatment for any identified hearing loss according to etiology. As technologies advance, those challenges that once seemed insurmountable, will continue to dwindle away with good strategic planning.

Research is being conducted about the efficacy of mass implementation of national targeted early CMV screening coupled with hearing screenings as standard of care for newborns (Cannon et al. 2014; Diener et al. 2017; Fowler et al. 2017; Beswick et al. 2019; Kadambari & Andersson 2021). As one of the most common congenital viruses impacting infants, congenital CMV can result in not only hearing loss but also other significant permanent health problems and even stillborn (Walter et al. 2008; Meyer et al. 2017; Barbi et al., 2006; Pesch & Schleiss, 2022). The discussion on the implementation of the screening procedures are often centered around 1) should the screening be targeted or universal? 2) Should the CMV screening occur simultaneously with infant hearing screening or should it be sequentially provided only in the presence of a failed early hearing screening? Counseling mothers early in the pregnancy to avoid contact with blood and body fluids of infected children and adults may prevent contraction of CMV during pregnancy (CDC, 2018; Schleiss & Shoup, 2024). Currently, there is no effective treatment for mothers with CMV infection and the timing of the infection before and during pregnancy also affects outcome. The current gold standards for confirming cCMV is to conduct saliva or urine-PCR (polymerase chain reaction) tests within 3 weeks of birth because a) the CMV viral load is usually the highest in saliva and urine (Cannon et al. 2011), b) the CMV viral load is significantly higher in children with moderate or severe symptomatic disease than in asymptomatic children (Ross et al. 2011), and 3) testing after 3 weeks makes the distinction of cCMV or postnatally contracted CMV difficult (Pellegrinelli et al. 2020). The accuracy of the saliva test, however, can be compromised if the infant is breast-fed from an infected mother for just one time, leaving the urine test as the practical definitive test with 99% sensitivity and 100% specificity (Schleiss & Shoup, 2024). Recent development in dried blood spot test with viral DNA extraction and PCR enhancement (DBS-PCR) improved its sensitivity to 73.2-85.7% and 100% specificity (Dollard et al. 2021). As collecting blood samples is already a routine procedure for babies born in hospitals, it is much easier and more feasible than collecting urine samples. DBS-PCR, therefore, are usually used in newborn cCMV screenings. Infants with positive DBS-PCR results are then followed up by the urine tests to provide definitive diagnosis (Schleiss & Shoup, 2024). Once diagnosed, antiviral drugs can be administered to reduce the symptoms associated with CMV and the child is monitored for potential progressive hearing loss and other symptoms. Whichever approach is used will require a great deal of unique data processing and significant infrastructure. Countries may strive toward making CMV screening a standard for infants. Different systems may be faced with implementation challenges.

Further advances in whole genome sequencing (WGS) (Linden et al. 2013; Phillips et al. 2013; Guo et al. 2019; McDermott et al. 2019; Shearer et al. 2019; Roman et al. 2020; Hopkins 2021) that was once considered an impossibility and incredibly expensive test a few years ago, are now on the verge of being affordable and globally accessible. WGS will have implications for the development of appropriately skilled workforce to provide genetic diagnostics and genetic counseling as part of medical services and overall support. Linden and colleagues (2013) wrote about the future role of genetic screening to detect newborns at risk of childhood-onset hearing loss but it has been almost 10 years since the authors discussed such issues. NHS England and the UK National Screening Committee have since commissioned work to consult on and discuss WGS of all births for the purpose of screening for many conditions including newborn hearing loss. The dialogue/focus group participants are broadly supportive of the use of WGS in newborn screening. They expect proper consideration to be given to designing and planning any future use of this technology. The recommendation includes "involving the public and ensuring appropriate resources, investment, and safeguards are in place" (Hopkins 2021).

Despite increasing pressure to adopt WGS technologies in the United Kingdom and elsewhere, a major barrier for genetic/genomic screening in hearing loss is the uncertain clinical significance of the identified mutations and their interactions. Only when a reliable estimate of the future risk of hearing loss can be made at a reasonable cost will WGS screening become viable. Given the speed of technological advancement, this may be achieved within the next 10 years.

Decision-makers will be called to consider if or how hearing screening could augment other associated screening programs as well as remaining mindful of the associated data processing and storage requirements as the screening programs become more complex. From the policy perspective, it will be imperative to include developing workforce, providing education and training, building infrastructure, and acquiring equipment as well as building relationships with the commercial sector. In the interim, informed decision makers will need to consider the benefits of (1) a national newborn hearing screening program; and (2) genetically testing for single or clusters of genes or genomically testing all the genes in all newborns and children with hearing loss to determine etiology and to increase knowledge of the genetic causes of hearing loss. In addition, screening pregnant women for genetic traits may be considered to contribute to the identification of hearing loss in their children (e.g., the m.1555A > G mutation to reduce the risk of aminoglycoside antibiotic-associated hearing loss).

The World Report on Hearing recommends taking urgent and evidence-based approaches to prevent, identify, and rehabilitate hearing loss (WHO 2021b). The implementation of EHDI programs will improve the ability to identify and address congenital hearing loss shortly after birth. However, some infants with hearing loss may be missed by infant hearing screening programs or may be lost to follow-up. There are also infants who have normal hearing at birth but develop hearing loss later (progressive or late onset) in childhood. Undetected and untreated hearing loss in a child's formative years can have substantial consequences on the child's life and development (Yoshinaga-Itano et al. 1998; Kennedy et al. 2006). Therefore, special measures are essential to screen for hearing loss and provide early treatment at different stages across the life course.

LIMITATIONS

Although a number of countries (e.g., Republic of Congo, Zambia, Kenya, Uganda, Panama, India, Albania, Ukraine, Indonesia, Haiti, Panama, Puerto Rico, Thailand), particularly low-resourced countries, are currently piloting parts of the Guidelines, there is not yet outcome data on the use of these guidelines or field-testing. South Africa's EHDI program, not yet universal, but progressing significantly has successfully implemented most of the guidelines including family-to-family support, family-centered early intervention, DHH and parent leadership, and recommended guidelines for screening, diagnosis and amplification fit, though they may not yet have a data management system that includes all aspects of the system including developmental outcomes. Each country may have different starting points. Each country may focus on different aspects of the guidelines initially. Currently, there is no complete EHDI model in low-resourced countries, although a number of countries have successfully accomplished some aspects of EHDI. High-resourced countries began development of their EHDI systems as early as the 1990s, i.e., more than 30 years ago if screening in the newborn intensive care units is considered.

The purpose of EHDI systems is to raise the developmental outcomes of children who are deaf or hard of hearing. Beginning systems do not yet have this outcome data. Though higher-income countries have significantly more financial resources, they have all struggled with the implementation of different aspects of EHDI systems, and are still developing components. High-resourced countries have a significant proportion of the families that are immigrants/refugees from low-resourced countries. Strategies developed to optimize participation and follow-through with the services for these populations provide helpful insights but may or may not be applicable to their countries of origin. Further developments in high-resourced countries need to focus on (1) CMV and genetic screening, (2) data management systems, (3) collecting developmental outcome data on children identified through EHDI as compared with children before EHDI, (4) family-centered early intervention systems, (5) family-to-family support systems, and (6) DHH and parent leadership infusion.

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Erratum

Hearing Loss and Dementia: Where to From Here?: Erratum

In the article that published in the in the May-Jun 2024, volume 45 issue of *Ear and Hearing,* "**Hearing Loss and Dementia: Where to From Here?**" by P. Dawes and K.J. Munro, an error was discovered on page 532 by the authors.

The published paper text reads:

Invariably, almost any research study on hearing loss published today will provide a background for the research by saying something like "hearing loss is a marker of risk for dementia" (including papers that we have coauthored, e.g., Allum, Meredith, Uus, Kirkham & Dawes 2023; Dawes et al. 2015; Taylor, Dawes, Kapadia, Shryane & Norman 2023).

The correct text is noted below:

Invariably, almost any research study on hearing loss published today will provide a background for the research by saying something like 'hearing loss is important because hearing loss is risk for dementia' (including papers that we have co-authored, e.g. (Allum, Meredith, Uus, Kirkham, & Dawes, 2023; Dawes et al., 2015; Taylor, Dawes, Kapadia, Shryane, & Norman, 2023)).

Reference

Dawes, P., & Munro, K. J. (2024). Hearing loss and dementia: where to from here?. *Ear Hear*, *45*(3), 529–536.