

Chapter 1

The Evolution of EHDI: From Concept to Standard of Care

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Introduction

This chapter summarizes the principles of effective screening programs, provides an historical overview of efforts to identify permanent hearing loss among infants and young children, describes the status of newborn hearing screening, and describes the degree to which each of the National Goals for Early Hearing Detection and Intervention (EHDI) programs established by the federal government are being achieved. Although almost all newborns are now being screened for hearing loss prior to hospital discharge, significant improvement is needed with respect to the availability of pediatric audiologists, implementation of effective tracking and data management

systems, program evaluation and quality assurance, availability of appropriate early intervention programs, and linkages with health care providers who are well-informed about permanent hearing loss among infants and young children.

More than 70 years ago, Ewing and Ewing (1944) called for earlier identification of permanent hearing loss when they noted:

... an urgent need to study further and more critically methods of testing hearing in young children ... during this first year the existence of deafness needs to be ascertained ... training needs to be begun at the earliest age that the diagnosis of deafness can be established (pp. 309-310).

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Since then, much time and effort has been devoted to finding the most efficient and accurate procedures, protocols, and equipment for screening, diagnosing, and treating children who are deaf or hard of hearing (DHH; see sidenote).

In 1960, with support from the Children’s Bureau in the U.S. Department of Health, Education, and Welfare, the American Speech and Hearing Association convened an expert working group to develop guidelines for “Identification Audiometry.” With respect to infants, the report of this group concluded that:

In the testing of a child from birth until approximately 2 months of age, use can be made of the startle response. . . . In a baby with good hearing and an intact central nervous system, any sudden moderately loud sound will bring about a widespread response: The ongoing muscular activity is inhibited, the hands are pronated, the eyelids blink, etc. These startle responses are so uncomplicated, relatively speaking, that they may be easily observed (Darley, 1961, p. 21).

Efforts of many people over the next 30 years would prove that hearing screening for infants and young children was not as easy as it appeared to the participants of that conference in 1960. In fact, 5 years later at the Toronto Conference on “The Young Deaf Child: Identification and Management (Ireland & Davis, 1965), Hardy reported the results of one of the first prospective screening studies of a relatively large number of newborns (n=1,388) done at Johns Hopkins Medical Hospital in Baltimore from 1959-1962. Hardy’s conclusions were hardly optimistic:

“In my opinion, testing of the newborns, as we have been doing, it is useless, and we plan to discontinue it.”

Many others were having similar experiences. Indeed, progress in finding accurate and feasible methods for identifying infants and young children who were DHH was painfully slow during the next 25 years. In response to a conclusion by the National Institutes of Health (NIH) Consensus Development Panel (1993) that recommended “screening of all newborns . . . for hearing impairment prior to discharge,” Bess and Paradise (1994), in a widely cited Pediatrics article, argued that “. . . universal newborn hearing screening in our present state of knowledge is not necessarily the only, or the best, or the most cost-effective way to achieve [early identification of hearing loss] and more importantly . . . the benefits of universal newborn hearing screening may be outweighed by its risks.” By 1996, the U.S. Preventive Services Task Force, while acknowledging that “congenital hearing loss is a serious health problem associated with developmental delay and speech and language function,” concluded that “there is little evidence to support the use of routine universal screening for all neonates.”

By the late 1990s, however, there was a combination of advances in screening and diagnostic equipment, action by various professional organizations, legislative initiatives, and government-funded demonstration programs in various countries. This resulted in a dramatic improvement in our ability to identify and provide services to infants and young children who were DHH and their families.

This chapter summarizes the principles that should guide any health-related screening program, briefly reviews the global situation related to infant hearing screening, and describes the current status of EHDI (see sidenote) programs in the United States with particular attention to the evidence-based practices for establishing and operating efficient and effective hearing screening programs for infants.

NOTE: Many different terms are used to refer to children with permanent hearing loss (e.g., deafness, hearing impairment, hearing loss, auditory disorders). Recognizing that there are limitations to any single term, this chapter will use the term “children who are deaf or hard of hearing (DHH),” except in those cases where a source is quoted.

NOTE: Recognizing the importance of linking hearing screening programs to diagnostic and treatment programs, most people have replaced the term “universal newborn hearing screening” (UNHS) program by the more inclusive term “early hearing detection and intervention” (EHDI) program. This change recognizes that screening is just the first step in the process needed to help children who are DHH reach their full potential.

Principles of Effective Public Health Screening Programs

Almost 50 years ago, Wilson and Jungner (1968) proposed principles that have become the accepted criteria for deciding if and how to implement public health screening programs. The report, commissioned by the World Health Organization (WHO) came at a time that technological advances in medicine had made screening a topic of growing importance and controversy.

Their suggestions are worth considering whenever the design and operation of screening programs are being considered. According to Wilson and Jungner:

In theory, therefore, screening is an admirable method of combating disease . . . In practice, there are snags . . . The central idea of early disease detection and treatment is essentially simple. However, the path to its successful achievement (on the one hand, bringing to treatment those with previously undetected disease, and, on the other, avoiding harm to those persons not in need of treatment) is far from simple, though sometimes it may appear deceptively easy (pp. 7 & 26).

In what has deservedly become a classic in the public health literature, Wilson and Jungner outlined 10 criteria for deciding whether screening should be done for a particular condition (see *Table 1*). They noted that these criteria were “especially important when case-finding is carried out by a public health agency, where the pitfalls may be more numerous than when screening is performed by a personal physician” (p. 26). Even though there is still room for improvement, newborn hearing screening meets all of the criteria proposed by Wilson and Jungner.

Table 1 Ten Newborn Hearing Screening Criteria

- 1 The condition to be detected by screening should be an important health problem.
- 2 There should be an accepted treatment for cases identified.
- 3 Facilities for diagnosis and treatment should be available.
- 4 There should be a recognizable latent or early symptomatic stage.
- 5 There should be a suitable screening test.
- 6 The test should be acceptable to the population.
- 7 The natural history of the condition should be understood.
- 8 There should be an agreed policy on whom to treat as patients.
- 9 The cost of case-finding (including diagnosis and treatment of those diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
- 10 Case-finding should be a continuing process and not a “once and for all” project.

The criteria suggested by Wilson and Jungner in 1968 are still relevant today. They provide a useful framework by which hearing screening programs can continue to be refined and outcomes can be improved.

Global Status of Newborn Hearing Screening

At least seven countries (Austria, Netherlands, Oman, Poland, Slovakia, the United Kingdom, and the United States) provide hearing screenings for more than 90% of their births, and nine other countries screen 30-89% of their births (Australia, Belgium, Canada, Germany, Ireland, Philippines, Russia, Singapore,

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and Taiwan). At least 60 other studies have published reports of smaller-scale universal newborn hearing screening (UNHS) programs in their countries and are working towards establishing national systems (NCHAM, 2013a; White, 2011).

In 1995, WHO urged member states “to prepare national plans for early detection in babies, toddlers, and children” (Resolution 48.9) and recommended “that a policy of universal neonatal screening be adopted in all countries and communities with available rehabilitation services, and that the policy be extended to other countries and communities as rehabilitation services are established” (WHO, 2010).

In 2009, WHO published guiding principles for action related to infant hearing screening. The report noted that in spite of the global progress that has been made toward UNHS, there are still many countries where the implementation of such a program is considered too costly and/or its value is questioned. Even in countries where a significant number of newborns are screened for hearing, there is often no consistent approach or quality control procedures, oversight is frequently not implemented, and resources for follow-up are often limited. However, WHO noted that the operation of effective hearing screening programs for infants and young children is not always related to resources—some wealthy countries have fragmented and ineffective programs, while other less-wealthy countries have very successful EHDI programs. The report noted that, “Quality assurance issues in particular are vital to successful newborn and infant hearing screening and related interventions—in some settings, it is estimated that the poor training and performance of screeners renders up to 80% of screening useless” (WHO, 2010).

Although the WHO report concluded that all newborns should be screened for hearing loss using a physiological measure, such as otoacoustic emissions (OAE) or automated auditory brainstem response (A-ABR), it acknowledged that some countries cannot implement such programs because of limited financial resources or appropriate equipment

and personnel are not available. In such situations, WHO recommended that some combination of targeting particular subgroups of the population or the use of questionnaires completed by family members or behavioral testing be considered (see *Figure 1*).

Questionnaires can be used to ask parents or other caregivers about the response of the infant to sounds and the infant’s use of language, including early indicators of language, such as babbling and other vocalizations. Infants and young children who perform poorly on such measures can then be referred for more comprehensive audiologic assessment. While some researchers have reported encouraging results for such questionnaires in screening children for hearing loss (e.g., Newton et al., 2001), others have recommended against using questionnaires because of relatively high false-positive and false-negative rates (e.g., Li et al., 2009; Watkin et al., 1990). The usefulness of questionnaires may depend, in part, on the age of children being screened, the degree of hearing loss targeted for detection, and the knowledge of parents or caregivers about normal language development. Even though questionnaires are relatively inexpensive, more evidence about their specificity and sensitivity is needed before wide-scale use can be recommended. In those situations where physiological screening is impossible, questionnaires will likely result in some children who are DHH being identified, but the negative effects associated with potential false-negatives and false-positives are of great concern.

Behavioral measures, such as noisemakers or other more sophisticated audiologic procedures and equipment, can also be used to identify infants and young children who are DHH. However, such methods also have relatively large numbers of false negatives and false positives when used with babies less than 12 months of age. For example, Watkin et al. (1990) did a retrospective analysis of over 55,000 2- to 15-year-old children in England who had completed a behavioral evaluation for hearing when they were 7-12 months of

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Figure 1
Hearing Screening Options Recommended by WHO (2010)

		Screening methods		
		Questionnaire completed by family	Behavioral	Physiological
Infants to be screened	Targeted by:			
	Geographical subset			
	NICU babies			
	Babies with risk factors			
	Population-based			

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age. Of the 39 children later identified with severe to profound bilateral hearing losses, only 44% were identified when they were 7-12 months old based on the behavioral evaluation. The remaining children were identified later based on school-age screening programs, parental concern, or by health care providers. For children with mild to moderate bilateral hearing losses and children with unilateral hearing losses, the behavioral evaluation at 7-12 months of age identified only 25% and less than 10%, respectively. Even when home visitors are specifically trained to do behavioral evaluations of hearing in a home setting, most young children who are DHH will be missed using such procedures.

The WHO report also recommended that when it is not feasible to implement universal hearing screening programs for all newborns, countries should consider starting with a hearing screening program that focuses on a subset of infants and young children. For example, when newborn hearing screening programs are being established, it is not unusual to focus on babies in a particular geographical region, because they are more accessible or equipment and personnel are more available. Because the incidence of

permanent hearing loss is much higher among neonates who require intensive medical care during the first few days of life, hearing screening programs should focus on those admitted to a neonatal intensive care unit if they are unable to screen all babies.

There is a great deal of evidence that babies with certain “risk indicators” have much higher rates of permanent hearing loss than those who do not. The Joint Committee on Infant Hearing (JCIH, 2007) has identified 11 risk indicators (e.g., family history of permanent childhood hearing loss, being in a neonatal intensive care unit for more than 5 days, presence of craniofacial anomalies) that are associated with permanent congenital or delayed-onset hearing loss. Even though only about 10% of all newborns exhibit one or more of these risk indicators, about 50% of the infants who are DHH will be in this group. Unfortunately, hearing screening programs that target only infants with risk indicators have not been successful in identifying many of the babies with hearing loss in this high-risk group. For example, Mahoney and Eichwald (1987) reported the results of a newborn hearing screening program that targeted all babies with a high-risk indicator born in their state over an 8-year period.

Information about the presence of risk indicators was incorporated into the state's legally-required birth certificate, so information about risk indicators was collected on virtually all babies. A computerized mailing system and follow-up phone calls were used to offer all parents of children with risk indicators a free diagnostic audiologic assessment at local health department offices. Also a mobile van traveled around the state to provide free diagnostic testing for families in the rural parts of the state. Mahoney and Eichwald (1987) reported that only about 50% of the families who had a baby with a risk indicator made appointments for an audiologic assessment, and only about 50% of those actually came to the appointment. The program was discontinued after 8 years because of the small number of babies identified (the prevalence of babies identified as being DHH was less than 0.30 per 1,000 or about 10% of the babies who were likely DHH in that cohort).

Before implementing a hearing screening program that targets only those babies with one of the JCIH-recommended risk indicators, it is important to remember that 95% of the babies who have one of the risk factors do not have hearing loss, and that approximately half the babies who do have congenital hearing loss will not exhibit any risk factors (Mauk, White, Mortensen, & Behrens, 1991). Thus, even if a risk-based newborn hearing screening program worked perfectly, it would only identify half of the babies with permanent hearing loss. However, the yield from operational high-risk hearing screening programs has been much lower. Furthermore, the risk factors that are most predictive of hearing loss in babies will vary from country to country, so it is important to have local data about the sensitivity and specificity of risk factors before using this as a method of identifying children who are DHH.

Alternatives to UNHS based on physiological measures, such as OAEs or A-ABRs, do need to be considered in some situations. However, unless and until better data are available to demonstrate acceptable sensitivity and specificity

of alternative approaches (e.g., parent questionnaires, behavioral measures, and programs targeting high-risk babies), program planners should recognize that most previous programs using these methods have had significant limitations. Such alternatives should be viewed as an interim step towards establishing a UNHS program. Recognizing that different approaches will need to be taken in different circumstances, the WHO report (2010) emphasized that all newborn hearing screening programs should have:

- Clearly stated goals with well-specified roles and responsibilities for the people involved.
- A clearly designated person who is responsible for the program.
- Hands-on training for people who will be doing the screening.
- Regular monitoring to ensure that the protocol is being correctly implemented.
- Specific procedures about how to inform parents about the screening results.
- Recording and reporting of information about the screening for each child in a health record.
- A documented protocol based on local circumstances.

It is also important to remember that successful newborn hearing screening programs have been implemented in many countries in many different ways. Despite the variety of circumstances in which they operated, WHO (2010, p. 34) noted that:

[T]he aims of [newborn hearing screening] programmes are widely accepted as both highly worthwhile and attainable and . . . should be expanded to include all neonates and infants. Although UNHS using OAE or A-ABR should be the goal for all countries, interim approaches using targeted screening based on questionnaires, behavioural methods, and/or physiological methods guided by evidence from well-conducted pilot studies will also be beneficial. Whatever approach is used, it is important that the EHDI programme

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is linked to existing health care, social and educational systems, and that the procedures and outcomes of the programme be documented so that ongoing quality assurance activities can be implemented and experiences shared.

belief that this goal could be achieved was relatively new.

In 1989, Dr. C. Everett Koop, Surgeon General of the United States, called for increased efforts to identify congenital hearing loss during the first few months of life (Northern & Downs, 1991) when he stated:

Current Status of EHDI Programs in the United States

EHDI programs have expanded dramatically in the United States during the last 20 years. In 1999, the U.S. Department of Health and Human Services (HHS) established the following goal related to EHDI programs as a part of its objectives for *Healthy People 2010*:

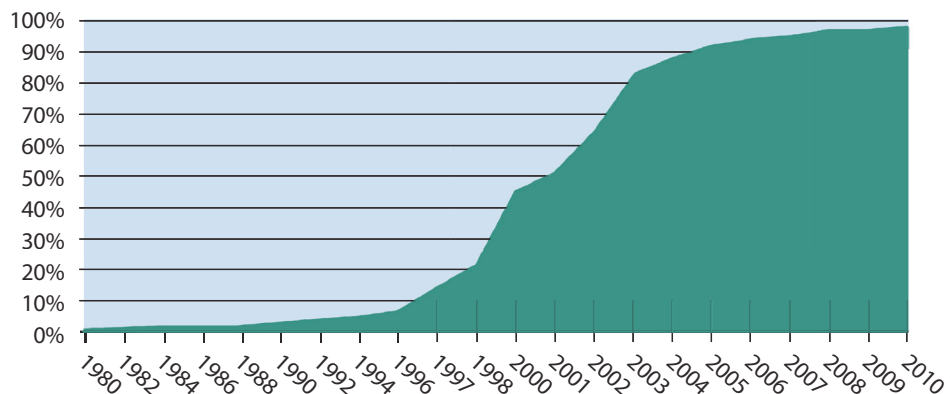
Increase the proportion of newborns who are screened for hearing loss by age 1 month, have audiologic evaluation by age 3 months, and are enrolled in appropriate intervention services by age 6 months.

This goal represented a major shift in the belief that children who are DHH could be identified earlier and provided with services that would enable them to be as successful as their normally hearing peers. The value of identifying congenital hearing loss during the first few months of life had been recognized for decades, but the

. . . hearing-impaired children who receive early help require less costly special education services later. . . I am optimistic. I foresee a time in this country . . . when no child reaches his or her first birthday with an undetected hearing impairment.

Many people were surprised by Dr. Koop's enthusiasm and his optimism that UNHS programs could be successfully established given the fact that fewer than 3% of all newborns in the United States were being screened for hearing loss at that time. Over the next 25 years, Dr. Koop's enthusiasm proved to be well founded, as shown by the fact that more than 98% of all newborns in the United States are now screened for hearing loss (Centers for Disease Control and Prevention [CDC], 2013; see *Figure 2*). Understanding the factors that led to such a significant change can be useful as work continues to make hearing screening programs more effective and efficient.

Figure 2
Percentage of Newborns Screened for Hearing Loss in the United States during the Last 30 Years



Factors Contributing to the Expansion of Newborn Hearing Screening Programs

The establishment, expansion, and improvement of newborn hearing screening programs in the United States has been facilitated by:

- Policy initiatives by government, professional associations, and advocacy groups.
- Financial assistance from the federal government.
- Improvements in technology.
- Legislative initiatives.
- The demonstrated success of early implementations.

Policy initiatives. The value of identifying children who are DHH as early as possible is not a new concept for health care providers and administrators in the United States. For example, the Babbidge Report issued by the U.S. Department of Health, Education, and Welfare in 1965 recommended the development and nationwide implementation of “. . . universally applied procedures for early identification and evaluation of hearing impairment.” Four years later in 1969, based on the pioneering work of Marion Downs (Downs & Hemenway, 1971), the JCIH (2007) was established by a group of professional associations (e.g., American Speech-Language-Hearing Association, American Academy of Pediatrics, American Academy of Otolaryngology–Head and Neck Surgery, among others). Even though the JCIH had no formal authority and few resources, they became—and have remained—a powerful force in advocating for earlier identification and better treatment of children who are DHH.

When it was first established, the JCIH focused on screening high-risk babies, because inexpensive and effective hearing screening technology was not yet available. As new hearing screening technologies became available in the late 1980s, more resources were devoted to early identification of children who were DHH. These efforts were stimulated in part by a

recommendation from the congressionally mandated Commission on Education of the Deaf (Toward Equality, 1988) that “the Department of Education, in collaboration with the HHS, should . . . assist states in implementing improved screening procedures for each live birth.”

A few years later, *Healthy People 2000* established a goal to “reduce the average age at which children with significant hearing impairment are identified to no more than 12 months.”

...it is difficult, if not impossible, for many [children with congenital hearing loss] to acquire the fundamental language, social, and cognitive skills that provide the foundation for later schooling and success in society. When early identification and intervention occur, hearing-impaired children make dramatic progress, are more successful in school, and become more productive members of society. The earlier intervention and habilitation begin, the more dramatic the benefits (HHS, 1990, p. 460).

Although similar goals had been discussed for 30 years, this one was different, because it was linked to a federal mandate that progress toward each objective had to be tracked and reported at regular intervals.

Another major step forward happened in 1993 when a Consensus Development Panel convened by NIH recommended that “all infants [who are DHH] should be identified and treatment initiated by 6 months of age” and concluded that UNHS was the best way to accomplish this goal. To the surprise of many, progress was slow. It would be another 12 years before more than 90% of the newborns in the United States were screened prior to discharge (see *Figure 2*).

That so much time elapsed between the recommendation by NIH and the achievement of UNHS was in part due to the lack of research evidence about the value of and experience for such broad-scale implementation of newborn hearing screening. In the words of one skeptic in a

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commentary entitled, *Universal Newborn Hearing Screening: Should We Leap Before We Look?* (Paradise, 1999, pp. 670-671):

Across the nation, pediatricians are being importuned, and indeed propelled, to implement universal newborn hearing screening, despite a total lack of information concerning ultimate costs and particularly risks. . . . I feel compelled to try here once again to be heard, quixotic though it may seem in the face of such apparently formidable odds. My main objections to a universal screening program for presumably normal, low-risk newborns remain essentially unchanged . . . recent reports from screening programs offer no basis for greater optimism about reducing the numbers of false-positive identifications.

Federal support for EHDI initiatives. Partly because there was so little research about and experience with newborn hearing screening programs, significantly more federal funding was devoted to research, demonstration, and technical assistance projects related to newborn hearing screening during the late 1980s and early 1990s. Some of the best known were the Rhode Island Hearing Assessment Project (White & Behrens, 1993), the Marion Downs Hearing Center (MDHCF, 2013), and the National Center for Hearing Assessment and Management at Utah State University (NCHAM, 2013b), but there were many others.

Successful implementation of screening programs. Although the concerns about newborn hearing screening expressed by Bess and Paradise (1994) and Paradise (1999) were widely criticized (e.g., White & Maxon, 1995), Bess and Paradise were correct in pointing out that there was very little research in 1993 from large, systematically-implemented UNHS programs to support the recommendations of the NIH Consensus Panel. Besides the Rhode Island Hearing Assessment Project (White & Behrens, 1993), the available evidence about newborn hearing screening was based on small samples of infants [primarily from NICUs (neonatal intensive care units)] over short periods

of time. The controversy about the NIH recommendations generated by Bess and Paradise stimulated a great deal of activity between 1994 and 1999 as the percentage of babies being screened for hearing loss prior to hospital discharge increased steadily (see Figure 2). By 1998, there was a growing body of research supporting the feasibility, cost-efficiency, and benefits of newborn hearing screening (e.g., Finitzo, Albright, & O’Neal, 1998; Mehl & Thomson, 1998; White, 1997), and dozens of large-scale UNHS programs had become operational in various states. Since that time, more and more research has been published showing the benefits of newborn hearing screening (e.g., McCann et al., 2009), and the **U. S. Preventive Services Task Force** now “recommends screening of hearing loss in all newborn infants” (USPSTF, 2008, p. 143).

Endorsements by professional and advocacy groups. Published research studies combined with statewide UNHS programs that were identifying hundreds of babies at ever-younger ages led to more endorsements and policy statements by government, professional, and advocacy organizations—including the American Academy of Pediatrics, American Speech-Language-Hearing Association, American Academy of Audiology, National Association of the Deaf, March of Dimes, and American College of Medical Genetics (see NCHAM, 2013c for a summary of endorsements by various organizations).

By the end of 2001, EHDI programs were clearly established as a part of the public health system in the United States, with all 50 states having established an EHDI program (White, 2003). Also in 1998, the federal Maternal and Child Health Bureau (MCHB) began requiring states to report the percent of newborns they had screened for hearing impairment before hospital discharge as 1 of 18 core performance measures states must report annually to receive federal MCHB block grant funding (MCHB, 2002).

Legislation related to newborn hearing screening. The preceding activities were important in creating an atmosphere where many newborn hearing screening programs

could be implemented, but legislative and administrative actions in the late 1990s and early 2000s contributed to expanding the reach and sustainability of these programs. There are now 43 states with statutes or rules related to newborn hearing screening. A recent analysis by Green et al. (2007) concluded that states with legislation were much more likely to be screening 95% or more of their babies than those without legislation. Copies of each statute and/or rule, as well as an analysis of the provisions of each statute, is available at NCHAM (2013d).

Several points about existing legislation are worth noting (see *Table 2*). It is important to note that legislation specifies the minimum expectations of state policy but often does not describe what is actually happening in the state's EHDI program. For example, the Rhode Island EHDI program has one of the nation's best tracking and reporting systems, reports data to the Department of Health, and has an advisory committee, even though none of these are required by the Rhode Island hearing screening legislation (NCHAM, 2013d).

National Goals for EHDI Programs

As a result of work done by the MCHB, CDC, and JCIH, most people have stopped using the phrase “universal newborn hearing screening” (UNHS) in favor of “Early Hearing Detection and Intervention” (EHDI). The change is important, because it underscores that successfully identifying and serving infants and young children who are DHH requires more than an effective newborn hearing screening program. To be effective, the screening program must be connected to a system that includes audiologic diagnosis and appropriate medical, audiologic, and educational intervention. Newborn hearing screening programs should also be coordinated with the child's primary health care provider (often referred to as the child's Medical Home), a tracking and surveillance system, and a process for monitoring/evaluating how the system is functioning.

Newborn hearing screening programs in the United States are almost always

hospital-based, because that is where the vast majority of babies are born. The basic process is similar, even though the specifics vary to a considerable degree. For example, screening may be done by nurses, technicians, audiologists, or someone else. Some programs use OAEs, some use A-ABRs, and some use both. Screening is almost always done before the baby is discharged from the birth admission, but it can be completed at different times of the day depending on the hospital's routine and in different locations (e.g., nursery, mother's room, a room designated specifically for screening). Some hospitals do diagnostic evaluations for babies who do not pass the screening test, and others refer those babies elsewhere. Because newborn hearing screening has become a part of routine medical care for newborns, the screening procedures must conform with the hospital's practices related to such matters as safety, privacy, and infection control. A short video that was produced to show expectant parents how newborn hearing screening is typically done can be viewed at <http://www.infanthearing.org/videos/newborn-screening>

As newborn hearing screening programs expanded during the mid-1990s, it became clear that screening was only the first step in an intertwined process of identifying infants with hearing loss and providing them and their families with timely and appropriate services. Understanding how to best implement and maintain this first step (screening) requires a brief discussion of the other steps (many of which are discussed in more detail in other chapters of this book).

In collaboration with state EHDI program coordinators and representatives from other federal, professional, and advocacy agencies, CDC has developed National EHDI Goals, Program Objectives, and Performance Indicators that are based on EHDI guidelines from various states and the position statements of the JCIH (2007) and the Academy of Pediatrics (1999). These National Goals (CDC, 2004) are summarized in *Table 3* and is discussed in the remainder of this section.

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Table 2

Important Points to Note about Existing Legislation

It is important to note that legislation specifies the minimum expectations of state policy but often does not describe what is actually happening in the state's EHDI program.

1

Most legislation (34 of 43 states) was approved after 1998. The increase in legislative activity was probably influenced by the publication of the position statement by the American Academy of Pediatrics (1999) and the increased amount of research evidence about the efficacy, accuracy, and feasibility of newborn hearing screening programs.

2

The existence of legislation is neither necessary nor sufficient to guarantee an effective EHDI program, as demonstrated by the fact that some states that have not passed legislation have EHDI programs that are functioning as well or better than some states with statutes.

3

Only 28 of 43 states (65%) require all babies to be screened. Some states set the standard as low as 85% of all newborns, which raises questions about equal access to hearing screening—at least in those states.

4

The fact that only 7 states (16%) require parents to provide written informed consent suggests that most states view hearing screening as a routine part of newborn health care.

5

Twenty-nine of 43 states (67%) require hospitals to report data from newborn hearing screening to the State Department of Health—suggesting that these states are treating EHDI as a public health program.

6

Twenty-one statutes (49%) indicate that newborn hearing screening must be a covered benefit of health insurance policies issued in the state. However, because of how insurance reimbursement is done, many hospitals do not receive money for screening, because payments are made as a lump sum for all services associated with the birth. The federal Affordable Care Act stipulates that newborn hearing screening is a covered preventive service. More information about the implications of the Affordable Care Act for how EHDI programs actually function and what services are available to children and families is available at NCHAM (2013e).



Photo courtesy of Phonak

Table 3

National Goals for EHDI Programs (CDC, 2004)

Goal 1. All newborns will be screened for hearing loss before 1 month of age, preferably before hospital discharge.

Hospitals will have a written protocol to ensure all births are screened, results are reported to the infant's parents and PCHP, and referred infants ($\leq 4\%$) are referred for diagnostic evaluation. Demographic data will be collected for each infant and appropriate educational material provided to parents. States will reduce/eliminate financial barriers to screening and ensure screening of out-of-hospital births.

Goal 2. All infants who screen positive will have a diagnostic audiologic evaluation before 3 months of age.

States will develop audiologic diagnostic guidelines and maintain a list of qualified providers to ensure infants referred from screening receive a comprehensive audiologic evaluation before 3 months of age and are referred to appropriate services. States will provide appropriate education and/or training about diagnostic audiologic evaluation to parents, PCHPs, and audiologists.

Goal 3. All infants identified with hearing loss will receive appropriate early intervention services before 6 months of age (medical, audiologic, and early intervention).

States will develop policies and resource guides to ensure all parents of children with hearing loss receive appropriate medical (including vision screening and genetic services), audiologic, and early intervention services (based on the communication mode chosen by the family). States will ensure that early intervention service providers are educated about issues related to infants and young children with hearing loss.

Goal 4. All infants and children with late onset or progressive hearing loss will be identified at the earliest possible time.

Hospitals and others will report information about risk factors for hearing loss to the state, who will monitor the status of children with risk factors and provide appropriate follow-up services.

Goal 5. All infants with hearing loss will have a medical home as defined by the American Academy of Pediatrics.

A primary care provider who assists the family in obtaining appropriate services will be identified for all infants with confirmed hearing loss before 3 months of age. The state will provide unbiased education about issues related to hearing loss for parents and medical home providers.

Goal 6. Every state will have an EHDI tracking and surveillance system that minimizes loss to follow-up.

A computerized statewide tracking and reporting system will record information about screening results, risk factors, and follow-up for all births. The system will have appropriate safeguards, be linked to other relevant state data systems, and be accessible to authorized health care providers.

Goal 7. Every state will have a system that monitors and evaluates the progress towards the EHDI goals and objectives.

A systematic plan for monitoring and evaluation will be developed and implemented by an advisory committee to regularly collect data and provide feedback to families and ensure that infants and children with hearing loss receive appropriate services.

Goal 1 All newborns will be screened for hearing loss.

A small but important subgroup that is not being well served by current EHDI programs are babies who are born at home. Midwives are well positioned to screen and follow-up with babies born outside of the hospital, but most are not well informed about the importance of newborn hearing screening.

CDC (2013) reported that 98.4% of newborns were screened in 2011 (excluding infant deaths and parent refusals). Interestingly, no particular protocol or type of screening equipment is the clear preference of hospital-based screening programs. As shown in *Table 4*, a survey conducted by NCHAM (2013f) showed that 50.3% of all screening programs were using OAE testing, and 62.4% were using A-ABRs (percentages sum to more than 100%, because some programs use both OAE and A-ABR). Approximately 40% of programs did all of their screening prior to hospital discharge, while about 60% of programs used a two-stage protocol in which screening was not completed until an outpatient screening was done following discharge. The variety of screening protocols being used suggests that no single protocol is “best” for all situations. Because the JCIH (2007, p. 904) now recommends “ABR technology as the only appropriate screening technique for use in the NICU,” the percentage of programs using A-ABR is expected to increase.

Deciding what type of equipment and which protocol to use in a newborn hearing screening program depends on the circumstances and preferences of the program administrators. In situations where an outpatient screening is a part of the protocol, and it is difficult to get babies to come back, A-ABR has an advantage, because refer rates at time of discharge are typically lower (but the cost of equipment and consumables is somewhat higher). It is also important to consider what degree of hearing loss is targeted by the screening program. Most of the currently available A-ABR screening equipment uses a 35 dBnHL click for the stimulus, which means that many babies with mild hearing loss will likely pass the screening test (Johnson et al., 2005). In most states, the decision about what type of hearing screening equipment and protocol to use

is left to the discretion of the hospital screening program administrator. In fact, NCHAM (2013f) found that only 67% of state EHDI coordinators even keep track of what equipment and/or protocol was used by hospital-based screening programs.

A small but important subgroup that is not being well served by current EHDI programs are babies who are born at home. With 1-2% of all births in the United States occurring outside the hospital, this represents 40,000 to 80,000 babies per year. Only 21 states reported that they had a systematic program in place to screen these births, and those states were only screened an estimated 41% of out-of-hospital births (NCHAM, 2013f). Midwives are well positioned to screen and follow-up with babies born outside of the hospital, but Goedert, Moeller, and White (2011) reported that most respondents to a national survey of the American College of Nurses-Midwives members were not well informed about the importance of newborn hearing screening and had significant gaps in their knowledge about screening procedures, steps for referral, and the availability of resources when newborns did not pass the test.



Photo courtesy of NCHAM

Table 4
Protocols Used in EHDI Programs

Before Hospital Discharge	After Hospital Discharge	% of Newborns Screened
OAE	—	11.6%
ABR	—	23.3%
OAE/ABR	—	6.7%
OAE	OAE	21.4%
OAE	ABR	4.2%
ABR	OAE	2.8%
ABR	ABR	23.2%
OAE/ABR	OAE/ABR	6.4%
Other protocol	—	0.3%

For babies who do not pass the newborn screening test, audiological diagnosis should be completed as soon as possible, but no later than 3 months of age.

Goal 2 Referred infants will be diagnosed before 3 months of age.

For babies who do not pass the newborn screening test, audiological diagnosis should be completed as soon as possible, but no later than 3 months of age. *Figure 3* shows that in states with well-developed EHDI programs, the average age of diagnosis for children who are identified as DHH has dropped dramatically over the last 25 years.

Unfortunately, CDC (2013a) reported that in 2011 for the country as a whole, state EHDI programs were not able to document whether diagnostic evaluations were actually completed for 35.3% of the infants who needed them. Most states (90%) have developed written guidelines for conducting diagnostic audiological evaluations, and most (78%) had compiled a list of centers or individuals who were qualified and had appropriate equipment and experience to do diagnostic audiological evaluations for infants under 3 months of age (NCHAM, 2013f).

Unfortunately, there is not general agreement on what constitutes a qualified pediatric audiologist, and these lists are mostly comprised of self-defined pediatric audiologists. Most state EHDI coordinators (79%) said it would be “beneficial if there were a license or certification for audiologists who specialize in diagnostic assessments and/or hearing aid fitting for infants and toddlers.” In 2011, the American Board of Audiology launched the Pediatric Audiology Specialty Certification (PASC) that is supposed to address this need. The PASC was “developed to elevate professional standards in pediatric audiology, enhance individual performance, and recognize those professionals who have acquired specialized knowledge in the field of pediatric audiology” (American Board of Audiology, 2013). The program is still new (only 43 audiologists were certified as of November 15, 2013), so time will

Recently, CDC made a web-based service available to help parents and others find qualified pediatric audiologists throughout the nation. EHDI-PALS (EHDI-Pediatric Audiology Links to Services) provides up-to-date information about facilities that offer pediatric audiology services.

tell whether the availability of the PASC improves pediatric audiology services.

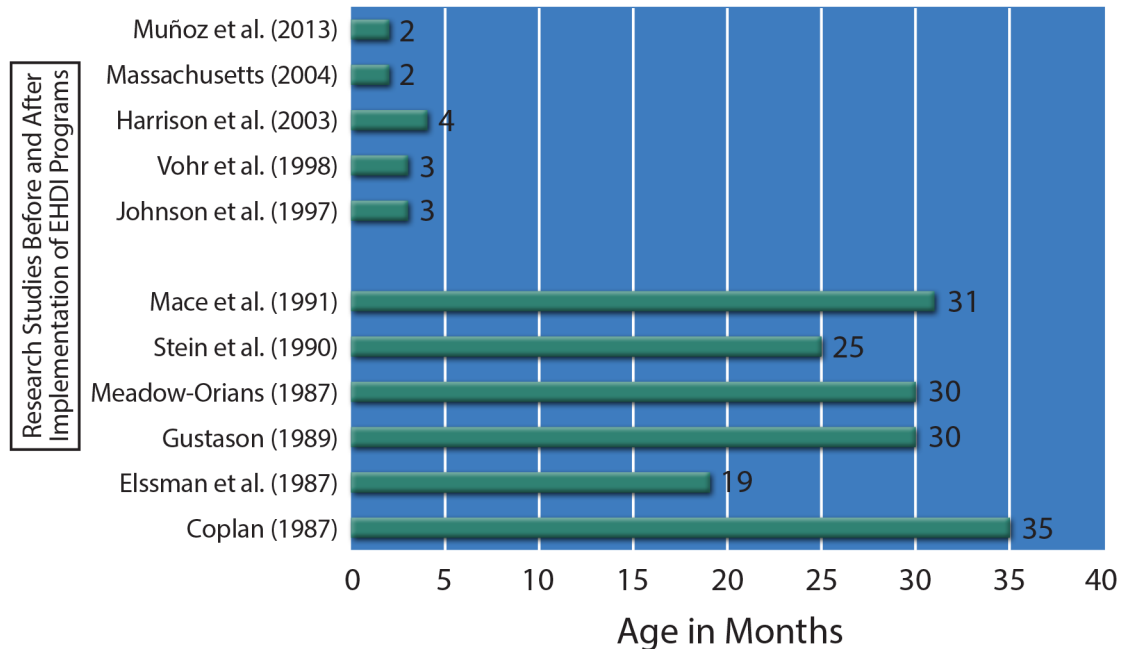
Recently, CDC made a web-based service available to help parents and others find qualified pediatric audiologists throughout the nation. Developed in conjunction with collaborators from ASHA, AAA, JCIH, Hands & Voices, NCHAM, and others, EHDI-PALS (EHDI-Pediatric Audiology Links to Services) provides up-to-date information about facilities that offer pediatric audiology services. All of the facilities listed must report that they have appropriate equipment and expertise to serve children and have licensed audiologists. Similar to other web-based search tools, EHDI-PALS users are asked to answer a few simple questions that help pinpoint their location and need. Then the program generates a list of the nearest audiology facilities that match the request. Each listing comes with information about that facility, including types of services offered, availability of language

interpretation services, payment options, and appointment availability. The service is free and is not linked to any commercial products or services. The system can be accessed at <http://www.ehdipals.org/>

In a national evaluation of newborn hearing screening and intervention programs reported by Shulman et al. (2010), the following factors were identified as contributing to poor follow-up rates for audiologic diagnosis:

- Lack of qualified audiologists to do diagnostic evaluations.
- Lack of appropriate equipment.
- Lack of knowledge among health providers about the importance and urgency of follow-up testing.
- Difficulties with transportation, ability to pay, and motivation on the part of families.
- Poor communication among primary health care providers, audiologists, and the state EHDI program.

Figure 3
Age in Months at Which Permanent Hearing Loss Was Diagnosed



Goal 3 Provision of appropriate medical, audiologic, and educational intervention before 6 months of age.

Providing appropriate medical, audiologic, and educational services to infants and young children who are DHH is a complex, multifaceted undertaking.

Providing appropriate medical, audiologic, and educational services to infants and young children who are DHH is a complex, multifaceted undertaking. The shortage of experienced and qualified pediatric audiologists often interferes with fitting appropriate hearing technology as early as desired. Another problem is that many primary health care providers (PHCPs) are not up-to-date regarding early identification of hearing loss. For example, JCIH (2007) recommends that all infants with confirmed hearing loss be referred to a geneticist and an ophthalmologist who has “knowledge of pediatric hearing loss.” However, when almost 2,000 PHCPs who care for children in 22 different states and territories responded to a question on a 2005 survey about to whom they would refer a newborn patient who had been “diagnosed with a moderate to profound bilateral hearing loss . . . [when] no other indications are present,” only 0.6% said they would refer to an ophthalmologist and 8.9% to a geneticist. When asked at what age an infant could be fit with hearing

aids, only 47.3% knew that hearing aids could be fit on children under 4 months of age (Moeller, White, & Shisler, 2006). In a similar survey completed in 2013 (NCHAM, 2013g), a national sample of over 2,000 PHCPs from 26 states responded similarly—only 2.2% and 9.3% would refer to an ophthalmologist or geneticist, respectively, and only 39.1% knew that children under 4 months of age could be fit with a hearing aid. Clearly, more work needs to be done educating PHCPs, so that they can be better partners in providing and supporting families who have children who are DHH.

According to state EHDI coordinators, appropriate educational intervention programs for infants and toddlers with hearing loss are not as widely available as needed. Part C of the federal Individuals with Disabilities Education Act (IDEA) requires all states to provide appropriate early intervention programs for all infants and toddlers with disabilities. Most children in Part C-funded early intervention programs are enrolled based on the fact that they exhibit significant delays from normal development. Infants and toddlers who are DHH often do not exhibit measurable delays in language, cognitive, or social skills until they are 18-24 months of age. Even though federal regulations provide for serving children who have “established conditions that are likely to lead to developmental delays,” only 5 of the 51 state plans for Part C provide an operational definition of how children who are DHH would qualify for such services (White, 2006). Of greater concern, CDC (2013) reported that in 2011, state EHDI coordinators were only able to document that 63% of infants and toddlers who the EHDI program had identified as being DHH were enrolled in Part C programs, and only 68% of those could be documented as having been enrolled before 6 months of age.



Photo courtesy of NCHAM

Goal 4 Infants and children with late onset or progressive hearing loss will be identified at the earliest possible time.

In describing hearing loss, the terms “late-onset” and “progressive” are frequently used together, which may lead to some people assuming that they are synonyms for the same condition. ***They are not.***

In describing hearing loss, the terms “late-onset” and “progressive” are frequently used together, which may lead to some people assuming that they are synonyms for the same condition. They are not. A progressive hearing loss is one that gets worse over time, whether the hearing loss is congenital or late-onset. The term “late-onset hearing loss” should only be used when normal hearing was present at birth and a permanent hearing loss occurred later.

The Joint Committee on Infant Hearing (JCIH, 2007, p. 899) recommends that:

Infants who pass the neonatal screening but have a risk factor should have at least one diagnostic audiology assessment by 24 to 30 months of age. . . . All infants should have an objective standardized screening of global development with a validated assessment tool at 9, 18, and 24 to 30 months of age. . . . Infants who do not pass the speech-language portion of a medical home global screening or for whom there is a concern regarding hearing or language should be referred for speech-language evaluation and audiology assessment.

In 2004 (the latest data available), only 14 states were collecting risk indicator information from “all hospitals,” and 17 states were collecting it from “some hospitals.” Eight states reported that they received risk indicator data for $\geq 85\%$ of all births. In many cases, the state EHDI program reports the presence of the risk indicator to the child’s PHCP and/or parent and takes no further action. States that were collecting risk factor data reported that they tried to do audiologic monitoring for 57% of the children that had risk indicators. Unfortunately, they were only able to complete “at least one audiologic monitoring during the first year of life” for 40% of those children where an attempt was made (NCHAM, 2013f). In a recent review of the literature, Beswick, Driscoll, and Kei (2012) found

surprisingly little good evidence about costs or benefits of monitoring children who pass a newborn hearing screening test but have one or more of the risk factors for hearing loss. They called for more large-scale, population-based research to assist with the development of evidence-based guidelines for monitoring the hearing status of children who have passed newborn hearing screening.

Clearly, detection of late-onset hearing losses should be a part of a comprehensive EHDI program. Although more work is needed to determine how this can be done most efficiently, recent research suggests that screening with OAEs is a viable alternative. Eiserman et al. (2008) reported results by lay screeners for more than 4,000 children in Early Head Start programs in four states using portable OAE equipment. A hundred and seven children (23.6 per 1,000 screened) were determined to have fluctuating conductive hearing losses requiring medical and/or audiologic treatment, and seven children (1.54 per 1,000 screened) were diagnosed with permanent hearing loss, including four who had passed their newborn hearing screening test. Foust et al. (2013) and Bhatia et al. (2013) reported on separate screening programs in which portable OAE equipment was used in federally funded clinics serving low-income and uninsured children in metropolitan areas. Foust and colleagues reported 3.55 children per 1,000 identified with permanent hearing loss based on 846 children screened, and Bhatia and colleagues reported 2.45 children per 1,000 identified with permanent hearing loss based on almost 2,000 children screened. These studies provide good evidence that OAEs are a viable tool for hearing screening of infants and young children. In its latest national survey of physicians, NCHAM (2013g) found that 29% report that they are doing hearing screening of infants and young children in their offices, and 66% of these report using OAE equipment as a part of their screening protocol.

Goal 5 All infants with hearing loss will have a medical home.

The American Academy of Pediatrics advocates that all children should have access to health care that is accessible, family-centered, comprehensive, continuous, coordinated, compassionate, and culturally effective—often referred to as the Medical Home.

The American Academy of Pediatrics advocates that all children should have access to health care that is accessible, family-centered, comprehensive, continuous, coordinated, compassionate, and culturally effective—often referred to as the Medical Home (Jackson et al, 2013). It is clear that services for infants and toddlers with hearing loss would be much better if families of children who are DHH were connected soon after birth to a PHCP who is familiar with their circumstances, knowledgeable about the consequences and treatment of children who are DHH, and known and trusted by the family.

Unfortunately, according to state EHDI coordinators, this is not the case for many infants and toddlers with hearing loss. Shulman et al. (2010) reported that only 73% of coordinators said that hospitals in their state contacted the PHCP when a child did not pass the newborn hearing screening test. NCHAM (2013f) reported that the name of the PHCP who will care for the baby during the first 3 months of life was only known for about 75% of newborns discharged from the hospital. Furthermore, many PHCPs are not well informed about issues related to early

identification of hearing loss (NCHAM 2013g). This is not surprising given the rapid changes that have occurred in our knowledge about identification and treatment of children who are DHH during the last 15 years. It is unrealistic to expect all PHCPs to remain up to date about a condition that affects only about three babies per thousand. Thus, states must find ways of providing this information to PHCPs on an “as-needed” basis. The American Academy of Pediatrics is actively working with state EHDI coordinators to develop such informational materials, but much remains to be done. According to MCHB (2010), state Title V directors estimated that only 43.0% of children with special health care needs receive health care services in a setting that meets the minimal requirements for a medical home. State EHDI coordinators estimated that results about hearing screening tests were sent to the medical home for 73% of the births, but it is unclear how frequently these results reached the correct PHCP (Shulman et al., 2010). In fact, NCHAM (2013g) found that 46% of physicians said they never received information from the state EHDI program, and 68% reported that they never sent information to their state EHDI program.

Goal 6 Every state will have a tracking and surveillance system to minimize loss to follow-up.

CDC currently awards funding to 52 states and territories to assist with the development and enhancement of improved tracking and data management systems that can be linked with other state public health information systems. A recent survey of public health agencies concluded that information from EHDI programs was the child health information

most likely to be integrated with other health systems, but continued effort and improved coordination among agencies is still needed (Bara et al., 2009).

Loss to follow-up/loss to documentation remains a serious problem with state EHDI programs being unable to document the hearing status of 35%

of the newborns who do not pass the hearing screening test. Shulman et al. (2010) reported that hospitals report the results of hearing screenings to the state EHDI program using various methods, including paper forms, software developed specifically for this purpose, adaptations to the bloodspot screening cards, or electronic birth certificates. Some state EHDI programs mandate how reporting is to be done, but most allowed each hospital to choose which system they wanted to use. This means that only half the EHDI programs received screening results from all hospitals through a single method—the most common being a faxed or mailed paper form.

More systematic approaches, such as those used in other countries, would likely have better results. For example, well-established UNHS programs in the United Kingdom (UK National Screening Committee, 2013), Poland (Radziszdzska-Konopka, Niemczyk, Grzanka, & Owskiak, 2008), and the Netherlands (Nederlandse Stichting voor het Dove en Slechthorende Kind [NSDSK], 2007), report national screening rates of more than 95%, with loss to follow-up/loss to documentation

rates of less than 10%. It is interesting to note that low loss to follow-up/loss to documentation are achieved even though in England about 20% of the babies are not screened in the birth hospital, and in the Netherlands, 70% of the babies are screened at home . . . which would seem to be even more challenging for follow-up. Only four states in the United States (CA, IN, MA, and MI) reported loss to follow-up/loss to documentation rates of less than 10% in 2011 (CDC, 2013)

Eighty-five percent of EHDI programs received data about the screening outcomes of individual babies, which means that most state EHDI programs are able to assist in follow-up with individual families. Linkages with other public health data systems are also expanding, with 15 states reporting in a 2004 NCHAM survey that they had some type of linkage with newborn dried bloodspot screening programs, 13 with vital statistics, and 4 each with immunization registries and early intervention programs (NCHAM, 2013f; Shulman et al., 2010). As these linkages are refined and stabilized, it will eliminate duplication and will mean that services to these families can be better coordinated.

Closely related to the development of tracking and data management systems is the implementation of systematic evaluation and quality assurance programs. Systematic evaluation and monitoring of the state EHDI program is an area where more work is needed.

Goal 7 All states will have a system to monitor and evaluate progress towards the EHDI goals and objectives.

Closely related to the development of tracking and data management systems is the implementation of systematic evaluation and quality assurance programs. As visualized in the CDC national goals, an EHDI advisory committee in each state should assist with developing and maintaining the EHDI system. Almost all states have an EHDI advisory committee that meets at least quarterly and has representation from diverse stakeholders, including audiologists, parents of children with hearing loss, PHCPs, and early intervention providers. These committees have made good progress

in overseeing the development of educational materials for PHCPs and parents. Coordinators in 78% of the states reported that they had good to excellent materials for educating parents about the states' EHDI programs. More work is needed in developing materials to educate PHCPs about EHDI and to educate parents of children who are DHH about communication options where only 53% and 56%, respectively, of EHDI coordinators said that they had good to excellent materials. Shulman (2010) reported that 83% of the states had developed materials in languages other than English.

One of the strongest rationales for providing a medical service is if it is recognized as the medical/legal “standard of care.” Arguably, UNHS programs have now achieved that status.

Systematic evaluation and monitoring of state EHDI programs is an area where more work is needed. NCHAM (2013f) found that states were using a variety of methods to gather information about the EHDI program, but only 18 states reported that a systematic evaluation of their state’s EHDI program had been completed during the last 5 years. Interestingly, 10 of these 18 evaluations were internal evaluations conducted by state EHDI program staff, and only 8 resulted in a written report.

Making progress toward achieving EHDI goals presumes that there is adequate funding to sustain the program. Unfortunately, most EHDI programs are on somewhat tenuous financial footing. NCHAM (2013f) found that almost two-thirds of the resources for operating EHDI programs came from the MCHB grants and CDC cooperative agreements that are viewed by Congress as temporary sources of support. Only 17% of the financial resources for state EHDI programs came from state appropriations, and only six states provided more than half of the resources for their EHDI program from nonfederal sources. Shulman (2010) reported that 42% of EHDI coordinators were unsure whether the program could be continued if federal funding were to be discontinued.

Improving Newborn Hearing Screening Programs

The following section discusses several issues about the operation of newborn hearing screening programs that are often overlooked.

Recognizing Newborn Hearing Screening as the Standard of Care

One of the strongest rationales for providing a medical service is if it is recognized as the medical/legal “standard of care.” Arguably, UNHS programs have now achieved that status, and hospitals

and state departments of public health are exposing themselves to significant liability risks if they are not operating effective hearing screening programs for all newborns.

Marlow (1996) was one of the first to suggest that newborn hearing screening was becoming the actual medical/legal standard of care in the United States:

Every medical and allied health practitioner and every hospital administrator should be keenly aware that they are held to a hypothetical standard of care whenever their professional conduct is being evaluated legally. . . . Definition of a standard of care is complicated by the fact that it is not usually articulated in a specific, identifiable form, and it may be subject to clarification on a case-by-case basis should legal actions arise.

Even though there have not yet been court cases that definitively establish newborn hearing screening as the legal standard of care, health care providers and hospital administrators should be aware that newborn hearing screening seems to meet each of the following guidelines that have been used in the past for establishing a practice as the standard of care.

Expectations for a reasonable practitioner under similar circumstances.

An often cited case in determining what constitutes a medical/legal standard of care was the 1898 Pike v. Honsinger case in which the Court of Appeals decision stated that:

A physician . . . impliedly represents that he possesses . . . that reasonable degree of learning and skill . . . ordinarily possessed by physicians in his locality. . . . [It is the physician’s] duty to use reasonable care and diligence in the exercise of his skill and learning . . . [he must] keep abreast of the times . . . departure from approved methods and general use, if it injures the patient, will render him liable.

Deciding what equipment to use and what protocol to follow is one of the first steps in setting up a newborn hearing screening program. The particular brand and type of equipment is not the primary determinate of whether a program will be successful.

The fact that newborn hearing screening is now being provided for over 98% of all newborns and have been successfully functioning in many parts of the United States for 15 years means that it would be difficult for any health care provider to successfully argue that UNHS programs should be viewed as experimental or unproven.

Support from governmental, professional, and advocacy groups. It is difficult to think of health care procedures that are not yet routinely implemented that have been endorsed by so many different authoritative groups ranging from the American Academy of Pediatrics to the National Institutes of Health to the March of Dimes—all of whom have concluded that UNHS is feasible to implement, results in earlier identification of hearing loss, and can be done with equipment that is accurate, practical to use, and economical.

Availability of appropriate technology to implement the practice. Ginsburg (1993) suggested that one of the criteria for establishing a standard of care:

... is when an inexpensive reliable device comes onto the market, the technology and concept of which have already been adopted by a group who specializes in the concept ... a guideline becomes a standard of care when the device behind the guideline is available and readily usable (p. 125).

Newborn hearing screening equipment is widely available, relatively inexpensive, and continually improving, which means that it easily meets Ginsburg's standard of being "available and readily usable."

Selecting Screening Equipment and Protocols

Deciding what equipment to use and what protocol to follow is one of the first steps in setting up a newborn hearing screening program. During the past 20 years, many different pieces of equipment have been successfully used in newborn

hearing screening programs—transient evoked OAEs, distortion product OAEs, and A-ABR. Each type of equipment has its proponents and detractors, but it is clear that the particular brand and type of equipment is not the primary determinate of whether a program will be successful.

In fact, the type and degree of hearing loss that is targeted by the screening program is much more important than the type and/or brand of screening equipment that will be used. This was demonstrated by Johnson et al. (2005), who evaluated how many infants are diagnosed with permanent hearing loss after passing a two-stage hearing screening protocol in which all infants are screened first with OAE, and some are screened with A-ABR. In this protocol, no additional testing is done with infants who pass the OAE, but infants who fail the OAE are next screened with A-ABR. Those infants who fail the A-ABR screening are referred for diagnostic testing to determine if they have permanent hearing loss. Those who pass the A-ABR are assumed to have normal hearing and are not tested further. The objective of this multi-center study was to determine if a substantial number of infants who fail the initial OAE and pass the A-ABR have permanent hearing loss at approximately 9 months of age.

Seven geographically dispersed birthing hospitals that had been successfully using a two-stage OAE/A-ABR screening protocol were included in the study. Almost 87,000 babies were screened at these hospitals during the period of the study. Infants who failed the OAE, but passed the A-ABR in at least one ear (1.8%) were enrolled in the study and invited back for a diagnostic audiologic evaluation when they were on average 9.3 months of age. Diagnostic audiologic evaluations were completed for 64% of the enrolled infants (1,432 ears from 973 infants). Twenty-one infants (30 ears) who had failed the OAE but passed the A-ABR were identified with permanent bilateral or unilateral hearing loss, with most of them (77%) having mild hearing loss.

The results of this study suggest that if all infants were screened for hearing loss using the two-stage OAE/A-ABR hearing screening protocol currently used in many hospitals, approximately 23% of those with permanent hearing loss at approximately 9 months of age would have passed the A-ABR with the presumption that they had normal hearing. This happens in part because most currently used A-ABR screening equipment uses a 35dBnHL click, which is best for identifying infants with moderate or greater hearing loss. Thus, program administrators should be certain they are using equipment and protocols that are appropriate for identifying the type of hearing loss they wish to target.

Another example of why it is important to pay attention to selecting the equipment and protocol used in a newborn hearing screening program is the need to identify babies who present with Auditory Neuropathy Spectrum Disorder (ANSD). Such babies are a challenge to identify in newborn hearing screening programs, because they have normal or near normal OAEs but an absent/abnormal auditory brainstem response (ABR). Thus, a program that uses only OAE for screening would miss such babies. Although it does occur in well-baby nurseries, most babies with ANSD have spent time in the NICU. For this reason, the JCIH (2007) recommends ABR technology as the only appropriate screening technique for use in the NICU. Berlin et al. (2010) provide additional information about the diagnosis and management of children with ANSD.

Regardless of the screening technology used, program administrators also need to be thoughtful about the number of screening tests that are done for each infant. To keep refer rates low at the time of hospital discharge, many programs repeat screening tests a number of times if the baby doesn't pass on the first test. JCIH (2007, p. 903) cautions that "the likelihood of obtaining a pass outcome by chance alone is increased when screening is performed repeatedly." Because of this caution, many state EHDI programs have guidelines that babies should not be screened more than two or three

times before leaving the hospital. Although screening a baby too many times is often not an efficient use of the screener's time, it does little to increase the probability of obtaining "a pass outcome by chance alone." Nelson and White (2014) had testers who were DHH repeat OAE tests in their own ear 1,000 times to determine how often a pass result would be obtained for an ear that has moderate to severe permanent hearing loss. They found an average of one false negative result per 1,000 tests. Statistical probability calculations were then used to show that if the screening test was repeated three times for every baby in a state with 100,000 annual births, only 1 baby who is DHH would be missed and 300 babies who are DHH would be correctly identified. If every baby were screened 10 times, only 3 babies who are DHH would be missed. In short, the negative consequences of repeat testing with respect to babies passing the screening test by chance have been greatly exaggerated.

Does Hearing Screening Create Excessive Anxiety for Some Parents?

Many people (e.g., Nelson et al., 2008; Paradise, 1999) have suggested that UNHS creates unduly high levels of anxiety, worry, and concern for parents and might even interfere with parent-child bonding—particularly for parents of babies who fail the initial screen and are found on subsequent testing to have normal hearing (the false-positives from screening). Tueller (2006) found dozens of studies that had examined this issue, with most reporting that 4 to 15% of parents in the general population and 14 to 25% in the false-positive group experienced high levels of anxiety. The problem with most of these studies is that there was no explicit basis for comparison (i.e., were parents any more worried about their child's hearing than they were about other aspects of the child's development).

To more accurately assess whether the worry expressed by parents was unduly high, Tueller collected data from 191 mothers (split between those whose babies had passed the initial screening test and those who failed the initial test in the

Regardless of the screening technology used, program administrators also need to be thoughtful about the number of screening tests that are done for each infant.

Many people have suggested that UNHS creates unduly high levels of anxiety, worry, and concern for parents and might even interfere with parent-child bonding—particularly for parents of babies who fail the initial screen and are found on subsequent testing to have normal hearing.

hospital and passed a rescreen when they were 1-4 weeks of age). Data were collected when the baby was 1 week of age, and again at 6 weeks of age (which was after the time that babies received a rescreen if they failed the initial screen). Mothers were asked to rate whether they were “not at all, somewhat, moderately, or very worried” about the baby’s hearing, as well as 20 other aspects of infant development (e.g., irritability, sleeping habits, eyesight, etc.). When babies were 1 week old, 14.6% of the mothers reported that they were moderately worried or very worried about their child’s hearing (similar to what has been reported in other studies). But hearing was ranked 6th on the list of 21 items about which they might be concerned, and it was not statistically significantly different from 14 of the other items.

At 1 week of age, mothers whose babies had failed the initial hearing screening test ranked hearing as the item about which they were most worried, but it was not statistically significantly different from 15 of the other items. But at 6 weeks of age (after the baby passed the hearing rescreen test), mothers ranked hearing as 8th on their list of possible concerns, and none of the mothers indicated that they were either moderately or very worried.

Tueller’s results suggest that mothers worry somewhat about lots of issues related to their new baby. If asked only whether they are worried about hearing, about 15% will say yes. But this is no different than the percentage who worry about other aspects of their child’s development (e.g., eating, sleeping, irritability, etc). Of course,

newborn hearing screening programs should educate parents about the screening process and why hearing and language development are important. However, there is no convincing evidence that the newborn hearing screening process causes parents to be unduly concerned about their baby’s hearing.

Complying with Federal Privacy Protection Laws

Successful EHDI programs share personally identifiable information about infants and young children among people who are responsible for screening, diagnosis, early intervention, family support, and medical home services. Many people involved with EHDI programs complain that Federal privacy laws (e.g., HIPAA, FERPA, Part C Privacy Regulations) make it impossible for EHDI programs to be successful (Houston et al., 2010). Most of these concerns are based on misperceptions or false information about the requirements of those laws. For example, HIPAA expressly allows for sharing of information among health care providers to facilitate health care services and for reporting information to public health programs. There is nothing in HIPAA that prevents screening program personnel from reporting screening results to other hospitals, state EHDI programs, pediatricians, or Part C early intervention programs. All of this can be done even if informed consent is not obtained from parents (NCHAM, 2013h). To help parents be full partners in the EHDI process, though, it makes sense to inform them prior to sharing information about their family with anyone in the EHDI system. Even though it is not legally required under HIPAA, one of the best ways to ensure that parents are well informed is to have a signed consent.

FERPA and Part C Privacy Regulations are more restrictive than HIPAA, but these regulations are not in force until an agency that is receiving federal funds provides services to the child. Thus in most cases, screening and diagnosis of hearing loss and referral to an early intervention



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program will be completed before the provisions of Part C Privacy Regulations or FERPA take affect. Once a child has been referred to Part C, information about that child cannot be given by the Part C program staff to the EHDI program, the audiologist who did the diagnostic evaluation, or a pediatrician—unless the parent provides informed consent. Effective strategies are listed in *Table 5*, and examples of the forms and documents being used by state EHDI programs to support many of these strategies are available from NCHAM (2013h).

Implementing these strategies requires strong interagency and personal relations among key stakeholders, including EHDI programs, Part C early intervention programs, the child’s pediatrician, and family support groups. Consistent training is usually needed at the community level to ensure that all stakeholders understand the importance of sharing information and helping families to be full participants in the process.

Data Management and Tracking

Arranging for a data and patient information management system is a task that is easy to procrastinate. The amount of information that needs to be managed continues to multiply as more and more babies are born. If a system is not in place when the screening program starts, program staff will soon be overwhelmed in piles of paper and yellow sticky notes. The importance of including an effective information management system in newborn screening programs has been emphasized by the JCIH (2007, p. 913):

Information management is used to improve services to infants and their families; assess the quantity and timeliness of screening, evaluation, and enrollment into intervention; and facilitate collection of demographic data. . . . [it is also] used in measuring quality indicators associated with program services.

Table 5 Effective Strategies for Complying with Federal Privacy Protection Laws

- 1 Coordinated consent forms that comply with the requirements of HIPAA and Part C Privacy Regulations can be used to streamline the referral process and relieve parents of the burden of completing similar forms for the same purpose.
- 2 Memoranda of agreement that designate EHDI programs as participating agencies of the Part C system are useful in those cases where EHDI is more than a primary referral source for child-find.
- 3 Parents should always be given copies of diagnostic evaluation reports, treatment plans, Individualized Family Service Plans (IFSPs), and signed consent forms. This enables the parent to provide information at-will and provides backup documentation for services the child is receiving.
- 4 Although not required by HIPAA, FERPA, or Part C Privacy Regulations, state laws that mandate reporting of screening, diagnostic, and early intervention information to EHDI programs and to the child’s pediatrician are often helpful.
- 5 The IFSP should include an option for parents to give permission for the document to be shared with EHDI staff, the child’s pediatrician, and other health care providers.

Consistent training is usually needed at the community level to ensure that all stakeholders understand the importance of sharing information and helping families to be full participants in the process.

An appropriate data management system depends on how the screening program is designed. In its simplest form, screening, diagnosis, and early intervention are each provided by a single source or homogenous group of sources. Infants flow seamlessly from the initial screening process to a diagnostic center and receive appropriate treatment or intervention (including family support). In this type of program, a data management system is relatively simple and straightforward. More commonly, however, the screening system has multiple screening sites, several diagnostic facilities, and many different providers who must be involved in the delivery of treatment, intervention, and family support services. Tracking infants through such a system, while challenging, is the only way to ensure that program goals are met.

Creating an effective data management system is one of the most challenging aspects of operating an effective newborn screening program. If all that was required was to count and report the total number of births, number of infants screened, and the number who passed and failed, data management would be easy. When all the other information necessary to follow-up and track babies is added, designing a data management system becomes much more complex. Even the simplest of programs generates an astounding amount of data that can quickly overwhelm the capacity of a poorly conceived data management system.

Implementing an effective and efficient newborn hearing screening program is more difficult than it sounds, and well designed and managed data management systems play important roles (see *Table 6*). The successful accomplishment of all of these purposes requires that the right data be collected in a timely manner, and that the data are reliable and valid.

Not only does a good data management system help ensure that babies and their families are receiving timely and appropriate services, but it also helps to document what has been accomplished, identifies areas that need improvement,

Table 6 Important Roles of a Well-Designed and Managed Data Management System

Role 1

A “safety net” to ensure that all babies are screened and identify those babies who need, but have not received, follow-up screening or testing.

Role 2

A communication tool that automatically generates emails or letters to parents, health care providers, and/or education programs about the results of screening tests, follow-up procedures needed, and/or reminders of upcoming appointments.

Role 3

A protocol management assistant that reminds screening program personnel about who should be tested and what procedures should be followed.

Role 4

A quality assurance/quality improvement tool that identifies facilities or screeners who are performing above or below acceptable standards, so that training and support can be efficiently targeted or superior performance recognized and rewarded.

Role 5

A system for documenting system performance, so that reports can be made to funding agencies, public officials, consumers, and lawmakers about what the program is accomplishing and areas where additional resources are needed.

Role 6

A basis for integrating data from various health-related programs, so that children and families can be provided with better and more efficient services.

Role 7

A tool for collecting data to be used for research about such things as the prevalence, incidence, etiology, comorbidity, predictability, and treatment of various conditions.

Creating an effective data management system is one of the most challenging aspects of operating an effective newborn screening program.

The current status of EHDI programs in the United States is like the proverbial glass that can be viewed as being either half full or half empty.

and provides information necessary for continued improvement and expansion. It is important that the creation and operation of such systems be done thoughtfully and carefully, because computer-based systems are capable of generating incredibly large amounts of data. If not done carefully, administrators of newborn screening programs may find themselves drowning in information but starving for knowledge. The key to success is to make sure that the purposes of a newborn hearing screening management system are thoughtfully considered by all stakeholders before a system is purchased or developed. Then the features and capabilities of the selected system must be carefully matched to those goals and purposes. The advice attributed to Mark Twain should be kept in mind:

“Data is like garbage. You’d better know what you are going to do with it before you collect it.”

- The fact that legislation or regulations related to UNHS have been approved in 43 states bodes well for the sustainability of these programs.
- Although not guaranteed for the long-term, federal funding continues to be available for all states to refine, expand, and improve statewide EHDI programs, and the Affordable Care Act covers hearing screening as a preventive service.
- There is substantial involvement and support from prestigious federal and professional organizations, such as MCHB, CDC, NIH, American Academy of Pediatrics, American Academy of Audiology, American Speech-Language-Hearing Association, and March of Dimes.
- Screening equipment and protocols continue to improve, and progress is being made on improving connections to diagnostic and early interventions programs and reducing the loss to follow-up/loss to documentation rates that have been so troubling for so long.

Conclusions

The current status of EHDI programs in the United States is like the proverbial glass that can be viewed as being either half full or half empty. Certainly the likelihood of an infant or toddler who is DHH receiving timely and appropriate services is better than ever. The substantial accomplishments of the last 25 years provide an excellent foundation for future progress:

- Ninety-eight percent of all newborns are now being screened for hearing loss prior to discharge, and all states and territories have formally established EHDI programs.

According to the national goals established by CDC, all children who are DHH should be diagnosed before 3 months of age. But we are still a long way from achieving the more modest goal set by Dr. Koop in 1990 that “no child [would reach] his or her first birthday with an undetected hearing loss.” To effectively identify children who are DHH and provide them and their families with the services they need, significant improvement must be made in the availability of pediatric audiologists, tracking and data management, program evaluation and quality assurance, availability of appropriate early intervention programs, and linkages with medical home providers.

In contrast to the early 1990s, there is now a solid research and experiential basis for addressing all of these issues, but it will continue to require the commitment and resources of state health officials, hospital administrators, health care providers, and

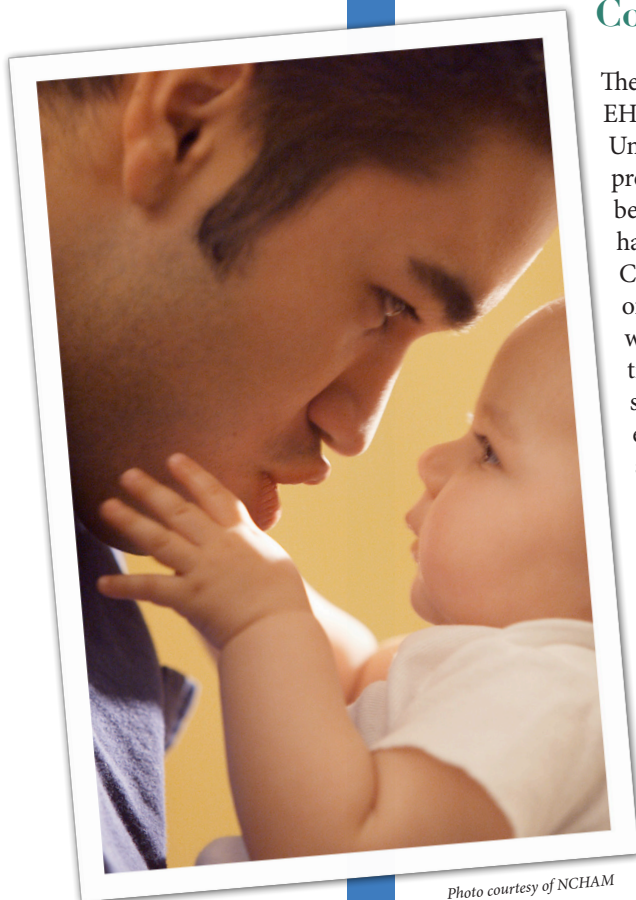


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The issues that need to be resolved are complex and will require stakeholders to continue working together over a sustained period of time.

parents. As pointed out by Wilson and Jungner (1968, pp. 7, 26):

“ . . . in theory, screening is an admirable method of combating disease . . . [but] in practice, there are snags . . . The central idea of early disease detection and treatment is essentially simple. However, the path to its successful achievement . . . is far from simple—though sometimes it may appear deceptively easy.

The issues that need to be resolved are complex and will require stakeholders to continue working together over a sustained period of time. As a result of continuing such work, infants and young children who are DHH will be able to acquire the “fundamental language, social, and cognitive skills that provide the foundation for later schooling and success in society” as foreseen almost 30 years ago in establishing the goals for *Healthy People 2000*.

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