

Impact of the Early Hearing Detection and Intervention Program on the Detection of Hearing Loss at Birth—Michigan, 1998-2002

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The objective of this study was to evaluate the impact of the Early Hearing Detection and Intervention (EHDI) program on the detection of hearing loss (HL) at birth in Michigan. Using EHDI surveillance data for 1998-2002, we calculated screening, referral, and evaluation rates, as well as the rate of enrollment into early intervention (EI) services. We determined that during the 5-year study period, screening rates increased from 22.8% to 92.1%, referral rates declined from 4.7% to 2.8%, and the mean age (and range) at diagnosis of HL decreased (and narrowed) from 6.49 months (range: 0.03-44.27) to 2.65 months (range: 0.07-10.67). The proportion of referred infants with reported re-screening or diagnostic evaluation results remains below 50.0%. Among those referred to EI services with known follow-up, enrollment in services was reported by 74.6%; of these, 48.6% enrolled by age 6 months. Our results suggest that EHDI has improved the detection of HL in the newborn period in Michigan; however, sub-optimal reporting threatens the validity of our findings. Continued development of EHDI programs, collaboration with EI providers, and mandated reporting may improve the quality of EHDI data and assure that newborns screened for HL receive appropriate follow-up services.

Key words: newborn, hearing screening, program evaluation

Hearing loss (HL) is estimated to occur in one to three out of every 1,000 live births and is an important cause of pediatric morbidity (Finitzo, Albright, & O'Neal, 1998; Morton, 1991; Prieve, et al., 2000). The etiology of permanent childhood HL is not fully understood, however, it is estimated that genetic causes account for up to 50% of cases. According to a review of the literature on childhood HL by the Joint Committee on Infant Hearing [JCIH], other risk factors include, but are not limited to maternal infections, congenital infections, neonatal mechanical ventilation, and other gene/environment interactions (JCIH, 1995; Morton, 1991). HL is associated with significant delays in speech and language development, and evidence suggests that early identification and the provision of appropriate intervention services by age 6 months can improve speech ability, language skills, and academic achievement of children with HL (Carney & Moeller, 1998; Ruben, 1991; Yoshinaga-Itano, Coulter, & Thomson, 2000; Yoshinaga-Itano, 2003; Zinkus & Gottlieb, 1980).

Screening newborns for HL according to high-risk criteria can result in approximately 25%-50% of newborns with HL being missed because the majority of these newborns have no clinical risk factors for HL (Doyle, Burgraff, Fujikawa, Kim, & MacArthur, 1997; Grandori & Lutman, 1996). The availability of easy-to-use screening technology and growing evidence regarding the importance of early identification has led to the promotion of universal newborn hearing screening (UNHS) as the only acceptable approach to identification of HL in newborns (JCIH, 2000). During the last 10 years, the majority of states in the United States have implemented Early Hearing Detection and Intervention (EHDI) programs, and by January 2004, a total of 38 states had passed legislation related to UNHS (National Center for Hearing Assessment and Management, 2004). Michigan is not among these states. Newborn hearing screening at birth is voluntary in Michigan, with the exception of infants born to mothers covered by Medicaid if they delivered in a hospital with over 15

Medicaid births per year; for these patients and providers, UNHS at birth was mandated on March 1, 2000.

Centers for Disease Control and Prevention (CDC) and state representatives developed seven national goals for EHDI programs (CDC, 2003a). The first three goals (frequently called the 1-3-6 plan) promote early diagnosis and intervention of children with HL by recommending UNHS by age 1 month, preferably before hospital discharge, diagnostic evaluation or re-screening of infants referred by age 3 months, and enrollment of infants diagnosed with HL into EI services by age 6 months. Goals 4 and 5 stipulate that children with late onset, progressive, or acquired HL be identified at the earliest possible time and that all infants with HL have a medical home that coordinates their medical services. The last two goals focus on the need for EHDI programs to implement comprehensive tracking and surveillance systems capable of monitoring and evaluating the impact of EHDI on the early detection of HL. Data from evaluations of existing EHDI programs and their surveillance and tracking systems are limited, but are needed to help inform the ongoing development of such programs. The objective of this study was to describe the first five years of the EHDI program at the Michigan Department of Community Health and evaluate its impact on the detection of HL at birth, in terms of screening, referral, evaluation, diagnosis, and enrollment into EI services, during 1998-2002.

Methods

Study Population and Data Source

The study is based on Michigan's EHDI Surveillance System (described below) and live birth certificates (Vital Records) data for 1998-2002. Performance measures (e.g., screening, referral, and evaluation rates; age at diagnosis; and enrollment into EI services) were calculated from EHDI surveillance records, which are restricted to children who are Michigan state residents and born during January 1, 1998 –December 31, 2002. Vital Records data were used to determine annual live births for the study period. A case of HL was defined as hearing impairment of any symmetry (unilateral or bilateral), type (conductive or sensory), and degree (mild, moderate, or severe) reported to the EHDI program by evaluating audiologists or physicians.

EHDI Surveillance System

The EHDI Surveillance System is a passive reporting system that has been in place since January 1, 1998 and captures hearing screening data for live born infants. Initial screening results, typically from screening at birth, for each newborn screened are reported voluntarily to the EHDI program by the persons performing the hearing screens, such as hospital nurses, audiologists, or hearing technicians, via an attachment to newborn metabolic disorder screening cards, hospital-generated line lists, or electronic birth certificates. EHDI program staff process these screen results and fax/mail referral notices for re-screening or diagnostic evaluation to healthcare providers, if applicable. Health care providers who perform re-screens or diagnostic evaluations, such as audiologists or physicians, also report their results to the EHDI program. The EHDI program collects data on the outcome of referrals to EI services directly from EI service providers. The

Michigan Department of Community Health's EHDI program developed all reporting forms and all reporting is being done on a voluntary basis.

Performance Measures

The following performance measures were calculated: 1) screening rates, defined as the percentage of live-born infants with a completed screen for HL at birth; 2) referral rates, defined as the proportion of infants screened who fail initial screenings (screen status at hospital discharge from one or more screenings) and are referred for outpatient re-screening or diagnostic evaluation; and 3) evaluation rates, defined as the proportion of infants referred for re-screening or diagnostic evaluation for whom evaluation results are reported to the EHDI program. We also report the number of infants diagnosed with HL, rate per 1,000 live births completely screened at birth, and the mean and range of age (months) at diagnosis of HL. Data on access to and enrollment in EI services are available for reported cases of HL born from 2000-2002. For this sub-population, we report the proportion of those enrolled in at least one service offered, the frequency of enrollment into select services, and the timeliness (by age 6 months) of enrollment. Because low reporting rates and variation in follow-up times limited our ability to make valid statistical comparisons across study years, we report annual performance measures for descriptive purposes only.

Human Subjects Review

This study was based on routinely collected surveillance data, which was de-identified for our research purposes; therefore, the protocol was exempted from Human Subjects Review.

Results

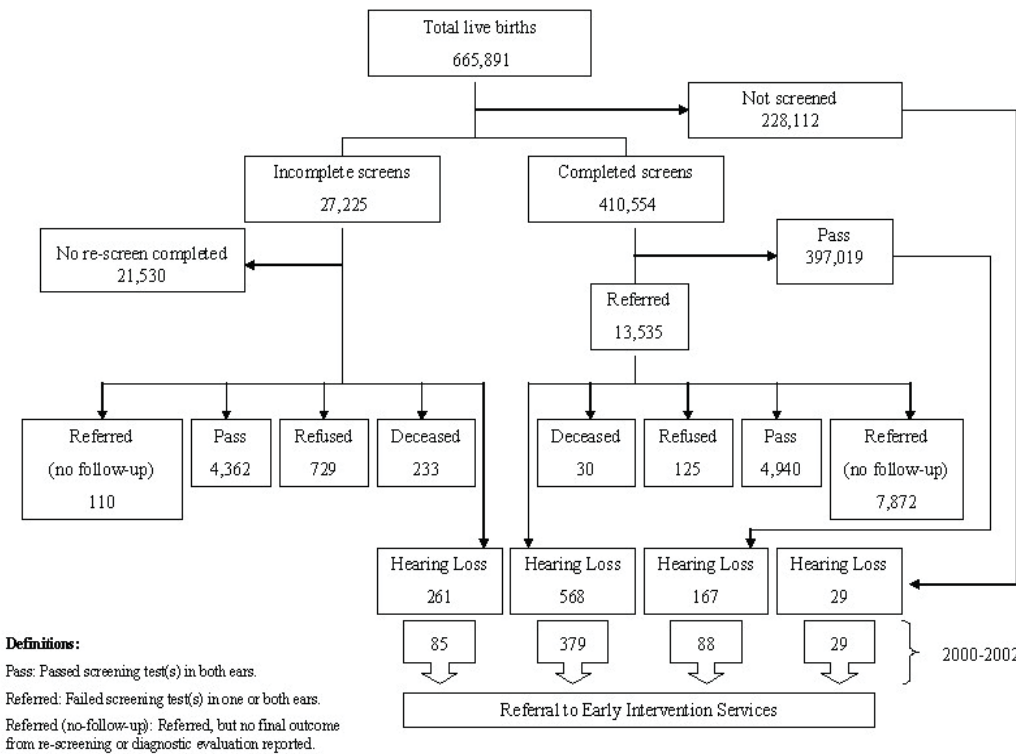
Performance Measures

Figure 1 summarizes the flow of EHDI data for 665,891 live born infants during 1998-2002, in terms of number of newborns screened, referred, evaluated, diagnosed, and referred to EI services. From 1998-2002, a hearing screen was attempted on at least 65.7% (437,779 of 665,891) of all live-born infants, and was completed before hospital discharge for 93.8% (410,554 of 437,779) of those attempted. The majority, 79.1% (21,530 of 27,225) of the infants with attempted, but incomplete hearing screens at birth, did not go on to have a complete hearing screening performed on an outpatient basis. Infants were screened with one or both of two automated screening tools: one that measures otoacoustic emissions (OAE) and the other auditory brainstem responses (ABR), with the majority, 75.0%, screened with ABR technology (this proportion did not vary across study years). Infants who did not pass the screening test(s) in one or both ears often have screening repeated before hospital discharge; however, only final screening results are reported to EHDI.

As depicted in Figure 1, the EHDI Surveillance System captured 1025 cases of HL during the study time period: 735 among infants screened before hospital discharge (568 screened and referred at birth + 167 screened with pass results at birth), resulting in a rate of 1.79 cases per 1,000 live births completely screened at

Figure 1. Flow of EHDI data for 665,891 live-born infants: number of newborns screened, referred for re-screening, evaluated, diagnosed, and referred to early intervention services – Michigan, 1998-2002

Table 1 summarizes the number and percentage of live-born infants screened at birth, referred for HL by age 3 months during 1998-2002 in Michigan. In 1998, the first year of the implementation of EHDI, approximately 22.8% of live-born infants were screened for newborn HL at birth and 4.7% of these newborns failed in one or both ears and were referred for further evaluation. Among the infants referred in 1998, evaluation results were reported for 38.9%; 68 cases of HL were diagnosed among these infants, and just 22 (32.3%) were diagnosed by age 3 months. Over the next few years, the proportion of live-born infants being completely screened at birth has increased from 22.8% to 92.1%, and referral rates have declined from 4.7% to 2.7%. However, evaluation rates - the percentage of infants referred for whom full hearing evaluation results were reported to EHDI - have remained below 50.0%.



Definitions:
 Pass: Passed screening test(s) in both ears.
 Referred: Failed screening test(s) in one or both ears.
 Referred (no follow-up): Referred, but no final outcome from re-screening or diagnostic evaluation reported.

As depicted in Table 1, approximately 10.0% (568 of 5,660) of the infants with known evaluation results were diagnosed with HL during 1998-2002. Among the infants screened and referred at birth with evaluation results reported who were diagnosed with a HL, 56.3% (320 of 568) were diagnosed by age 3 months. Specifically, age at diagnosis for infants screened and referred at

birth was known for 531 of the 568 diagnosed with a HL during 1998-2002 and showed a steady decline. Specifically, the mean age in months at diagnosis of HL was 6.49 (range: 0.03-44.27), 5.04 (range: 0.00-49.33), 4.59 (range: 0.00-37.17), 4.19 (range: 0.13-26.73), and 2.65 (range: 0.07-10.67) for 1998, 1999, 2000, 2001, and 2002, respectively.

Table 1. Number and percentage of live-born infants screened at birth, referred, evaluated, and diagnosed for hearing loss by age 3 months, by year – Michigan, 1998-2002

Year	Live Births N	Screened*		Referred†		Evaluated‡		Diagnosed§		Diagnosed by Age 3 Months	
		N	%	N	%	N	%	N	%	N	%
1998	133,649	30,508	22.83	1,447	4.74	564	38.98	68	12.06	22	32.35
1999	133,429	63,290	47.43	2,242	3.54	1,110	49.51	121	10.90	69	57.02
2000	136,048	90,971	66.87	3,007	3.30	1,272	42.30	138	10.85	82	59.42
2001	133,247	106,555	79.97	3,561	3.34	1,561	43.84	123	7.88	69	56.09
2002	129,518	119,230	92.06	3,278	2.75	1,153	35.17	118	10.23	78	66.10
Total	665,891	410,554	61.65	13,535	3.29	5,660	41.82	568	10.03	320	56.33

*Screened - infants with a completed screen for HL at birth

†Referred - infants screened that fail initial screenings (screen status at hospital discharge from one or more screenings) and are referred for outpatient re-screening or diagnostic evaluation

‡Evaluated - infants referred for re-screening or diagnostic evaluation for whom evaluation results are reported to the EHDI program

§Diagnosed - infants screened and referred at birth with evaluation results reported who received a diagnosis of HL

Early Intervention Services

A total of 581 cases of HL reported to EHDI during 2000-2002 were referred to EI services: 379 (65.2%) of whom were screened and referred at birth and an additional 202 cases (34.8%) who were not part of referral population because they either were not screened at birth ($n = 29$), were incompletely screened ($n = 85$), or passed initial screening ($n = 88$; acquired HL, temporary conductive HL, later-onset permanent HL, or false negatives). (Figure 1)

Table 2 depicts the status and timeliness of enrollment into EI services. EI service providers returned a follow-up form to EHDI for 382 of 581 (65.7%) referred during 2000-2002. Of those with known enrollment status, approximately 74.6% enrolled in at least one intervention service offered. Among enrollees for whom a date of enrollment was specified, nearly half, 48.6%, were enrolled by 6 months of age. Parental refusal of EI services was documented for approximately 29.9% (29/97) of non-enrollees. Reasons for non-enrollment could not be determined for the remaining 70.1% (68/97) of families due to lost to follow-up.

The frequency of enrollment into specific EI services for those diagnosed with HL by year of birth is summarized in Table 3. The proportion of those enrolled in EI services for whom a coordinating interventionist is reported was higher in 2002 (36.4%) than in 2000 (10.0%). The majority (57.2%) of families enrolled had an audiologist coordinating their care during 2000-2002. Medical evaluations with otolaryngologists were reportedly received by an average of 62.1% of enrollees from 2000-2002. Evaluations with ophthalmologists and genetic counselors were less commonly reported.

The proportion of children enrolled in EI services for whom a hearing aid or cochlear implant was recommended is not known. However, nearly half (47.4%) of families enrolled in EI services reported that their children had been fit with hearing

aids, and 2.3% of families reported their children had cochlear implants. On average, 53.3% of those with HL born from 2000-2002 were enrolled in Parent-Infant communication classes. More families in 2001 (55.6%) and 2002 (42.4%) as compared with those in 2000 (25.8%) were given a Resource Guide containing information about obtaining medical and educational services for their children. The majority of families, however, did indicate enrollment in the state-funded Children with Special Health Care Services Program: approximately 56.8% of those born from 2000-2002.

Discussion

Screening Rates

Screening rates have increased dramatically since the beginning of EHDI despite the fact that UNHS is not legislatively mandated in Michigan. We believe that the increase in screening rates during the first five years of EHDI is attributable to numerous factors. First, enhanced communication and collaboration between EHDI program staff and audiologists and pediatricians have increased awareness regarding the importance of UNHS. Second, the involvement of EHDI parent consultants in actively promoting UNHS by attending and conducting focus groups for parents, audiologists, and other healthcare providers helped to educate the community about the importance of UNHS and distributing the recommended guidelines for newborn hearing screening developed by the EHDI program. Third, to comply with the Medicaid ruling in March of 2000, hospitals statewide began to adopt UNHS protocols. Finally, during this time period, two non-profit organizations in Michigan awarded small grants to hospitals and other birthing centers for the purchase of newborn hearing screening equipment to promote UNHS. As of April 1, 2004, all 100 birthing hospitals in the state of Michigan had adopted UNHS policies, with the last hospital switching from risk factor-based screening of newborns to UNHS in March of 2004.

Although approximately 92% of live born infants were screened completely before hospital discharge in 2002, this screening rate remains lower than those reported by other states with a similar number of annual live births. For example, North Carolina, a state that legislatively mandated UNHS in 1999, reported a 99.4% screening rate at hospital discharge during 2002 [D. Carroll, personal communication, June 18, 2004]. This finding highlights the need for the EHDI program in Michigan, in the absence of legislatively mandated screening, to continue to focus on increasing screening rates by evaluating barriers to newborn screening, factors contributing to incomplete screens (as 79.1% of the infants with incomplete screens did not go on to have a complete hearing screening performed on an outpatient basis), and gaps and barriers in reporting of initial screening results.

Table 2. Status and timeliness of enrollment into early intervention services, by year – Michigan, 2000-2002

Enrolled									
Year	HL N	Form Received		Enrolled		Known Enrollment Date		Enrolled by Age 6 Months	
		N	%	N	%	N	%	N	%
2000	215	152	70.69	120	78.95	101	84.17	43	42.57
2001	200	135	67.50	99	73.33	88	88.88	36	40.91
2002	166	95	57.23	66	69.47	60	90.91	42	70.00
Total	581	382	65.75	285	74.61	249	87.37	121	48.59

Not Enrolled

Year	HL N	Refused		Lost to Follow-up	
		N	%	N	%
2000	32	11	34.38	21	65.62
2001	36	9	25.00	27	75.00
2002	29	9	31.03	20	68.97
Total	97	29	29.89	68	70.10

Table 3. Frequency of enrollment in early intervention services, by year – Michigan, 2000-2002

Educational Intervention	2000 N=120		2001 N=99		2002 N=66		Total 2000-2002 N=285	
	n	%	n	%	n	%	n	%
Educational Intervention								
Coordinating Interventionist	12	10.00	15	15.15	24	36.36	51	17.89
Audiological Intervention								
Coordinating audiologist	59	49.17	60	60.61	44	66.66	163	57.19
Monitoring every 3 months	7	5.83	6	6.06	16	24.24	192	67.37
Hearing aid fit	51	42.50	54	54.54	30	45.45	135	47.37
Cochlear implant	0	----	4	4.04	7	10.61	11	3.86
Communication Skills								
Parent-Infant program	60	50.00	55	55.55	32	48.48	152	53.33
Family Support								
Resource guide	31	25.83	37	55.55	28	42.42	96	33.68
Mental health services	6	5.00	10	10.10	6	9.09	22	7.72
Children Special Health Care Services	63	52.50	60	61.61	39	59.09	162	56.84
Family-to-Family support referral	6	5.00	4	4.04	10	15.15	20	70.17
Medical Intervention								
Coordinating physician	16	13.33	18	18.18	25	37.88	59	20.70
Otolaryngology evaluation	67	55.83	67	67.68	43	65.15	177	62.10
Ophthalmology evaluation	1	0.83	6	6.06	8	12.12	15	5.26

in the more recent years (2002 and 2001). However, we do not anticipate that the final evaluation rates will change our findings as infants referred in 1998 and 1999 have had three to four years of follow-up time and evaluation results have been reported for fewer than half of these infants. As a result of low reporting rates and lack of consistent reporting of the dates when re-screens are performed, we were unable to report on the proportion of referred infants who receive re-screening or evaluation by age 3 months, an important component of the 1-3-6 plan. Instead, we reported the proportion of newborns diagnosed with HL who were diagnosed by age 3 months. Low reporting rates also limited our ability to estimate the proportion of infants referred who actually received re-screening or diagnostic evaluations. The EHDI program needs to continue to work closely with health-care providers conducting re-screening to examine barriers to reporting and to help ensure that follow-up services are being obtained. We expect our follow-up rates to increase in the near future with the implementation of a new data system in June of 2004 which has automated the sending out of referral notices to providers.

Prevalence of HL at birth

The estimated prevalence of newborn HL reported here is comparable to the rate reported from other newborn populations screened at birth (Prieve, et al., 2000). However, there are several issues that threaten the validity of this estimate, including the number of referred infants who were lost to follow-up (7,872 of 13, 535), voluntary reporting, and the lack of a specific case definition for HL. Results of re-screens are known for fewer than half of newborns referred after the initial hearing screen; thus, the number of cases of HL diagnosed during the study period

Referral Rates

Referral rates declined steadily since the implementation of EHDI and, since 1999, have exceeded the goal referral rate of $\leq 4.0\%$ set by the JCIH (JCIH, 2000). These referral rates are also comparable to rates seen in other states with EHDI programs (CDC, 2003b). Low referral rates are an indication that screenings are being performed correctly and can save resources due to the referral of fewer false positives. A lower limit cut-off point for referral rates needs to be established, however, to avoid referral rates that are too low, resulting in an unacceptably high false negative rate.

Evaluation Rates

The proportion of referred infants with reported re-screening or diagnostic evaluation results remains low. As follow-up time increases, these proportions may be higher than those reported here, particularly for infants born

may not be representative of all newborns screened and referred at birth. Even when reporting occurs, report forms lack data required to report rates of HL by type, severity, and degree, thus necessitating the revision of these reporting forms.

Early Intervention Services

New and continuing collaboration between EI service providers and the EHDI program allowed us to describe enrollment in EI services among children diagnosed with HL born during 2000- 2002. As a result of incomplete reporting of the outcomes of referrals to EI services, it is not clear if all of the families referred actually made contact with EI service providers. Because enrollment into EI services is voluntary, it is difficult to comment on the significance of the frequency of enrollment into selected services we report here. However, among those with outcomes reported, approximately three-quarters enrolled in at least one service provided, with an otolaryngology evaluation as the most commonly reported service received. This finding is reassuring.

Study Limitations

The proportion of referred infants evaluated, mean age at diagnosis, proportion diagnosed by age 3 months, proportion enrolling in intervention services, and proportion enrolled by age 6 months are all threatened by differential follow-up time (amount of time since birth to date of data analysis: May 28, 2004). Comparing these proportions across years would lead to understatement of respective rates of such events. In particular, the 35.2% of referred infants evaluated in 2002 may increase as more follow-up time has elapsed. In contrast, as reports trickle in, the

mean age at diagnosis may be higher and the proportion enrolling in EI services by age 6 months may be lower than those we report here. Screening and referral rates, however, are not affected by differential follow-up.

Regardless of the impact of differential follow-up time, low reporting rates also may threaten the validity of our findings regarding age at diagnosis, proportion of newborns referred that were re-screened, and enrollment into EI services because data that are reported might not be representative of all those screened for HL at birth nor those diagnosed with HL during the study period.

Another limitation is that the data tracking system that captures EI service data is not linked with the surveillance system, which collects screenings results for those screened at birth. For this reason, we reported status of enrollment into EI services for all those reported with HL during 2000 – 2002 regardless of the timing of their initial hearing screening. Further development of EHDI tracking and surveillance systems would improve the ability of EHDI programs to assess where gaps exist in access or receipt of services for children diagnosed HL.

Public Health Implications and Recommendations

Our results suggest that EHDI has improved the detection of HL in the newborn period in Michigan; however, sub-optimal reporting by health-care providers threatens the validity of our findings. Continued development of EHDI programs may lead to earlier detection of HL in newborns and improve the overall quality of EHDI program data. Complete and accurate data from EHDI programs along with enhanced collaboration with EI service providers are needed to assure that newborns screened for HL receive the appropriate follow-up, including re-screening, diagnostic, and EI services.

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