

Supporting Statement A

for

Early Hearing Detection and Intervention Pediatric Audiology Links to Services (EHDI-PALS) Facility Survey

New

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IRB Determination

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification “new” request. The length of data collection requested for OMB-PRA approval is one year. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) is making this request as authorized by the Public Health Service Act, Title 42 United States Code—The Public Health and Welfare, Chapter 6A—Public Health Service, Subchapter II—General Powers and Duties, Part A—Research and Investigations (see *Public Health Service Act, 42 USC Sec. 241* Attachment A).

Background

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at the Centers for Disease Control and Prevention (CDC) promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. Congenital hearing loss is a common birth defect that affects 1 to 3 per 1,000 live births, or approximately 12,000 children across the United States annually.^{1, 2, 3} Studies have shown that children with a delayed diagnosis of hearing loss can experience preventable delays in speech, language, and cognitive development.^{4, 5}

Since the passage of the Early Hearing Detection and Intervention (EHDI) Act, renewed in 2010, all U.S. states and territories have implemented EHDI programs and enacted state laws and regulations related to infant hearing screening and follow up. The “1-3-6” goal has been adopted by all EHDI programs, which consists of: 1) screening all infants for hearing loss by 1 month of age, 2) ensuring diagnostic audiologic evaluation by 3 months of age for those who do not pass the screening, and 3) enrollment in early intervention services by 6 months of age for those identified with hearing loss. The Early Hearing Detection and Intervention Act of 2010 (section 399M of the Public Health Service Act 42 USC 280g-1) authorizes “(1) Centers for Disease Control and Prevention..... conduct(s) applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems.” According to 2009 CDC-EHDI’s Hearing Screening and Follow-up Survey (HSFS, OMB No. 0920-0733), the national average loss to follow up/loss to documentation rate is 45%, although varying from 3.8% to as high as 82% in some states. This rate remains an area of critical concern for states and CDC-EHDI team’s goal of timely diagnosis by 3 months of age and intervention by 6 months of age.

Loss to follow up: Many state EHDI coordinators cite a shortage of pediatric audiology facilities as the main factor contributing to loss to follow-up. This claim has not been quantified in the literature or by any survey to date.

Loss to documentation: Although many states have legislation that requires providers to report children who have received needed follow up, none of the states are able to quantify the number of children who are lost to follow up due to the provider’s failure to report the follow up result.

Both the American Speech-Language-Hearing Association (ASHA) and American Academy of Audiology (AAA) maintain a database of audiology members searchable by audiologist’s name. Neither is searchable by the facility where the audiologist works. However, the natural search behavior of a parent, physician, or stakeholder is to search by facility or by the type of audiology

service a facility can offer. So parents, physicians and stakeholders are left with a non-user friendly resource. To compound the problem, many pediatric audiologists may be proficient evaluating children age 5 and older but are not proficient with evaluating infants or young children because managing infants and young children requires a different skill set. To date, there is no existing literature or database the EHDI coordinator can use to verify and quantify the true distribution of the pediatric audiology resource in a state.

Early Hearing Detection and Intervention- Pediatric Audiology Links to Services (EHDI-PALS) is a project conceptualized by the CDC-EHDI team with input from an advisory group of external partners. The EHDI-PALS workgroup has broad representation from ASHA, AAA, Joint Committee on Infant Hearing (JCIH), National Centre for Hearing Assessment and Management (NCHAM), Directors of Speech and Hearing Programs in State Health & Welfare Agencies (DSHPSHWA), Healthcare Resources and Services Administration (HRSA), University of Maine Center for Research and Evaluation, and Hands & Voices. Meeting since April 2010, the EHDI-PALS workgroup has sought consensus on the loss to follow up/loss to documentation issue facing EHDI programs. A survey based on standard of care practice was developed for state EHDI programs to quantify the pediatric audiology resource distribution within their state. The survey will also capture how often providers report diagnostic hearing test results to their EHDI state jurisdiction.

1.1 Privacy Impact Assessment

I. Overview of the Data Collection System

This data collection is intended to target only pediatric audiologists who provide services to children age 5 and younger. The information will be collected by EHDI coordinators, AAA, and ASHA via an internet portal available on a secure website. After the survey has been programmed into the secure website, EHDI-PALS.org, the CDC-EHDI project officer will notify all EHDI coordinators by e-mail. The notification message will contain the following:

- EHDI-PALS website address
- Where the survey tool is located in the website
- Sample e-mail to audiologists to complete the survey for EHDI coordinators' use

Both AAA and ASHA are workgroup members so official notification is not needed. After an audiologist completes the survey, the information will be electronically isolated into a secure database that is accessible by password only. Only EHDI coordinators, CDC-EHDI team and University of Maine Centre for Research and Evaluation will have password accessibility to the raw data. The CDC-EHDI team project officer will continue to collaborate with EHDI-PALS workgroup members to monitor the facility data, and will also encourage the EHDI coordinators to view and validate their state's facility data for any error or inconsistency in the secure website. The University of Maine Centre for Research and Evaluation will continue to be responsible for the analysis and maintenance of the data collected. The experience and knowledge of the individual(s) responsible for working with the data will include statistics, data architecture, geocoding, website programming, and maintenance.

II. Items of Information to Be Collected

The respondent universe is estimated based on ASHA 2010 audiology membership survey⁶. Published survey data (available in ASHA.org) revealed:

Potential Sampling Universe	
Work Setting of Audiologists	Estimated Number of Audiologists
School	885
Colleges and Universities	770
Hospitals	2499
Non-Residential Health Care	4884

Both ASHA and AAA, being members of the EHDI-PALS workgroup, have plans to disseminate a request through association e-newsletters to all pediatric audiologists to complete the EHDI-PALS survey. Pediatric audiologists who provide audiologic service to children age 5 and younger are our target respondents. It is estimated that potentially 2000 audiologists will read through the purpose statement of this survey located on page one to decide whether or not to complete the survey. It is estimated that 1500 audiologists will complete the survey. The survey will be available via a secure password protected website.

Although the survey will collect the facility contact person's name and e-mail, this information will be accessed and used only by EHDI coordinators' so that they can contact the person if an error is noted in their data. This information will be accessible by password only. General characteristics about the facility, such as facility address, phone number, hours of operation, disability accommodation, interpreter services, and types of insurances accepted will also be requested. Finally the type of diagnostic hearing tests, hearing aid services, cochlear implant services, vestibular services, and tele-practice services the facility is equipped with and can provide will also be requested. No information in identifiable form (IIF) will be transmitted to CDC.

III. Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

No website content directed at children under 13 years of age is involved in this information collection.

A.2. Purpose and Use of the Information Collection

The CDC's NCBDDD will fund this research to identify and quantify the audiology facility resources in the U.S. and help determine causes for loss to follow up/loss to documentation related to newborn and infant hearing screening. The findings will help the CDC-EHDI team and state EHDI programs quantify the number of facilities in each state who are not reporting test results and diagnosis to the EHDI program.

2.1. Privacy Impact Assessment

(i) Why the information is being collected

The overall purpose of this study is to identify and quantify the audiology facility resources in the U.S. Facility data will be compiled into a distribution map for CDC-EHDI team and state EHDI coordinators to visualize the geographic distribution of infants who are lost to follow up in relationship to the pediatric audiology clinic distribution. Since April 2010, the EHDI-PALS workgroup has sought consensus on the loss to follow up/loss to documentation issue facing EHDI programs. A survey based on standard of care practice was developed for state EHDI

programs to quantify the pediatric audiology resource distribution within their state. The survey will also capture how often providers report diagnostic hearing test results to their EHDI state jurisdiction.

(ii) Intended use of the Information

The survey will allow the CDC-EHDI team and state EHDI programs to quantify the number of facilities in each state who are not reporting test results and diagnosis to the EHDI program. This is the loss to documentation rate when children have received follow up but providers fail to report the result to EHDI programs. The survey will also inform CDC-EHDI team and state EHDI programs the number of audiology facilities equipped to provide hearing tests and/or hearing aid services for infants and young children. From this data, it will be possible to delineate the zip code areas and geographic regions that have a dearth of audiology facilities.

Parents and physicians will be able to use the data to identify and locate an appropriate pediatric audiology facility that is equipped to test infants and young children. In addition, the collected data will reveal the type of follow up services a facility can offer. This information will be compiled into a directory format in the EHDI-PALS website so parents and physicians can look for a facility that provides the type of service that matches a child's need.

The findings from this survey also have the potential to be used for other purposes. These include quality improvement activities by state and territorial EHDI programs (e.g., identifying loss to follow up reasons that could benefit from continuous improvement effort) and providing data for Healthy People 2010, Objective 28-11 on newborn hearing screening, evaluation, and intervention.

Impact of Privacy on Respondents: As noted in section A.1. above, no IIF will be transmitted to CDC. The only IIF being collected (facility manager's name, email) will be accessed and used only by EHDI coordinators so that they can contact the person if an error is noted in their data. Collected raw data will reside in a secure website accessible by password only. While names of respondents will be known, respondents are not asked for any other IIF about themselves or about the infants they have seen. Respondents will be advised that only facility information will be posted in a directory accessible by parents and EHDI coordinators in the EHDI-PALS website. Therefore, the proposed data collection will have little or no effect on the respondent's privacy.

Survey respondents will be asked for information about the facility's capability and capacity to provide audiologic care for children age five and younger, such as:

- Facility address, phone number, and hours of operation
- Is the facility equipped to perform hearing tests, hearing screenings, hearing aid fittings and or cochlear implant services
- Types of insurance accepted and interpreter services available

Respondents will be informed that their participation in the survey is completely voluntary.

If audiology facility distribution data are not available it will be difficult, if not impossible, for EHDI programs to make an impact towards reducing the 45% loss to follow up/ loss to documentation rate. The lack of data is anticipated to severely limit the ability of CDC, state agencies, providers and parents to ensure infants who have failed hearing screening receive timely diagnosis and follow up.

A.3. Use of Information Technology and Burden Reduction

In order to reduce the burden on respondents, this survey will only be available via a secure password protected website. Placing the survey on the internet ensures convenient on-demand access by the audiologists. Financial cost is minimized because no mailing fee will be associated with sending or responding to the survey. The data quality will remain high because it will incorporate a pediatric standard of care algorithm to ensure the survey questions are logically constructed to truly reveal a facility's follow up service capability.

A.4. Efforts to Identify Duplication and Use of Similar Information

No other federal agencies collect this type of information. There have been other surveys conducted by non-governmental organizations regarding audiologists. Both ASHA and AAA maintain a database of all their member audiologists. ASHA has an on-line tool, the ProSearch, to help consumers identify audiologists who will provide services for young children. This on-line tool displays only the age group the audiologist serves rather than the facility the audiologist is affiliated with. AAA's on-line search tool displays only the audiologist's name. Whether the audiologist can and will see infants are not displayed. None have been found helpful to parents, physicians, or EHDI coordinators who need to know which facility is truly equipped to test an infant's hearing. Thus, there are no previous or current collections that provide the data needed by CDC, state EHDI programs, and EHDI stakeholders.

A.5. Impact on Small Businesses or Other Small Entities

According to the 2010 ASHA membership survey, there are 11,969 audiologists in the U.S. 50% (5,985) of these audiologists provide care in a non-residential health care facility. 44% (2,633) were owners of a private practice⁶. These privately owned audiology facilities can be considered small businesses. Some of these privately owned audiology facilities provide audiologic care for children age five and younger. The survey hopes to capture any facility capable of providing pediatric audiologic care, including privately owned audiology facilities. The surveys will be completed at the convenience of the participants and will not impact the participants' employers.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection effort and respondents will be asked to respond only once. If the requested data collection were not conducted and audiology facility distribution were not known, it will be difficult, if not impossible, for EHDI programs to make an impact towards reducing the 45% loss to follow up/ loss to documentation rate. The lack of data is anticipated to severely limit the ability of CDC, state agencies, providers and parents to ensure infants who have failed hearing screening receive timely diagnosis and follow up. The collection of this information would enable CDC-EHDI team to quantify:

- The number of audiology facilities that can provide hearing tests and/or hearing aid services for infants and young children.
- The zip code areas and geographic regions that have a dearth of audiology facilities.
- The number of facilities in each state who are not reporting test results and diagnosis to the EHDI program. This is the loss to documentation rate when children have received follow up but providers fail to report the result to EHDI programs.

There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

- A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice Attachment 2*). The notice, as required by 5 CFR 1320.8 (d), was published on June 20, 2012 (volume 77, number 119, pages 37050 - 37051). Two non-substantive public comments were received in response to this notice.
- B. Consultations with Individuals Outside the Organization: Since December 2009, the CDC-EHDI team has collaborated with the EHDI-PALS workgroup on this data collection effort.

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A.9. Explanation of Any Payment or Gift to Respondents

There are no plans to provide any payment or gift to respondents.

A.10. Assurance of Confidentiality to Respondents

This submission has been reviewed by the NCBDDD Privacy Officer who has determined that the Privacy Act does not apply. Survey respondents will provide information based on their roles as facility manager or administrator. While names of respondents will be known, respondents are not asked for personal information about themselves or IIF about the infants they have seen. This IIF will be maintained at the specific facility and will not be linked to any data. Survey respondents will be asked for information about the facility's capability and capacity to provide audiologic care for children age 5 and younger. Such as:

- Facility address, phone number, and hours of operation.
- Is the facility equipped to perform hearing test, hearing screening, hearing aid fitting and or cochlear implant services.
- Types of insurance accepted and interpreter services available.

Participation in the survey is voluntary and respondents will be advised that only facility information will be posted in a database accessible by parents and EHDI coordinators in the EHDI-PALS website. All survey data will be treated in a secure manner and will not be disclosed. Facility manager or administrator's contact information will be available to the state EHDI coordinators only. A password is required to access this contact information

IRB Approval: IRB approval is not required for this data collection. It was determined that this project is not considered to be research and that no further action is required by CDC for human subjects protections in accordance with federal regulation for the protection of human subjects in research.

10.1. Privacy Impact Assessment Information

- A. All survey respondents will be informed that their participation is voluntary. Survey respondents will be asked for information about the facility's capability and capacity to provide audiologic care for children age 5 and younger. Respondents will be advised that only the facility information portion will be posted in a directory accessible by parents and EHDI coordinators in the EHDI-PALS website. While names of respondents will be known, respondents are not asked for personal information about themselves or IIF about the infants they have seen. All collected facility data will reside in a secure website accessible by password only. The name and e-mail contact of each facility is collected in the event an error is noted in the facility data so that the EHDI coordinator

can alert the facility contact to correct the error. The contact person for each facility can only be accessed by the state EHDI coordinators and password is required to access the information.

- B. No informed consent form is associated with this survey.
- C. This survey will be available via a secure password protected website which will be maintained by University of Maine Centre for Research and Evaluation. Survey raw data can only be accessed by the EHDI coordinators and a password is required. This project will not maintain any IIF. The legal authority to collect and maintain this data is granted by Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)).

A.11. Justification for Sensitive Questions

There are no items considered to be highly sensitive for respondents in this data collection. Collected data is about the audiology services each facility can provide. No demographic, race, ethnicity, or age question is asked. The license numbers of providers who are pediatric audiologists are requested; however, this is not a sensitive question, as the license numbers of all U.S. audiologists are publicly posted and obtainable from each state licensure board website, including suspended and revoked licenses. In addition to the state licensure boards, audiologists' license numbers are also publicly posted in the National Provider Identification directory in the Centers for Medicare and Medicaid website.

A.12. Estimates of Annualized Burden Hours and Costs

Both ASHA and AAA are members of the EHDI-PALS workgroup and have plans to disseminate a request through the association e-newsletter to all audiologists who provide services to children younger than 5 to complete the EHDI-PALS survey. The survey will be available via a secure password protected website. It is estimated that potentially 2000 audiologists will read through the purpose statement of this survey located on page one to decide whether or not to complete the survey. It is estimated that 1500 audiologists will complete the survey during the one year approval period. The survey will take 9 minutes to complete, with a total annual burden of 258 hours. There is no cost to respondents other than their time.

Estimates of Annualized Burden Hours					
Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Audiologists	Survey Introduction	2000	1	1/60	33
Audiologists	Survey	1500	1	9/60	225
	Totals				258

The hourly wage for respondents was estimated using ASHA's audiology member survey publicly available in ASHA website (ASHA.org). The average annual salary for an audiologist is averaged to be \$65,000. This salary divided by 40 hours per week results in an estimated hourly wage of \$31.25. The total estimated cost burden on all survey respondents is \$6,000 (192hr x \$31.25). The estimated cost per respondent who completes the survey is estimated to be \$4.69 (\$4,687.50 / 1000 respondents).

Annualized Cost To Respondents				
Respondents	Respondents Group	Total Burden Hours	Estimated Hourly Wage	Respondent Cost
Audiologists	Survey Introduction	33	\$31.25	\$1,031.25
Audiologists	Survey	225	\$31.25	\$7,031.25
	Total	258		\$8,062.50

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no capital or maintenance costs to survey respondents associated with this survey..

A.14. Annualized Costs to the Federal Government

The average annualized cost to the Federal Government to collect this information is \$1,835.40. The federal government personnel estimate is based on cost of the Project Officer, who is responsible for the management and oversight of the project (Table A.14). These figures include the costs of materials development, survey preparation, and consultation with programmers on the data structure. The survey will be administered through the EHDI-PALS website, which greatly reduces the administrative costs to the government.

Table A.14.

			Total
Federal Government Personnel Costs	CDC Project Officer (GS-13 at 10 % time)	Preparing OMB materials	\$1,276.80
	CDC Project Officer (GS-13 at 10 % time)	Survey preparation and consultation with programmer	\$319.20
	CDC Project Officer (GS-13 at 10 % time)	Consultation with programmers on data structure	\$239.40
			\$1,835.40

A.15. Explanations for Program Changes or Adjustments

This is new data collection; therefore, program changes and adjustments do not apply.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Recruitment for survey participants will begin within 1 month after OMB approval. The entire study will be completed within 12 months. See Table A16 below outlines the project time schedule by activity.

Table A.16 Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Program facility surveys into EHDI-PALS website	1 month after OMB approval
Notify EHDI coordinators, AHSA and AAA that facility survey is ready so notification to audiologists to complete survey can begin	2nd month after OMB approval
Monitor incoming facility data	At 3 rd , 4 th and 5 th month after OMB approval
EHDI coordinators, AAA, and ASHA send out 2 nd notification to audiologist to complete survey	At 6 th month after OMB approval
Monitor incoming facility data	At 8 th month after OMB approval
Review facility data and ensure auto reminder is sent out to audiologists to review their facility profile	At end of 1 st year after OMB approval
Collaborate with EHDI-PALS workgroup members and programmers to geocode data on a map	At end of 1 st year after OMB approval

Analysis Plan:

At the conclusion of the survey period, EHDI-PALS workgroup members will collaborate with programmers to geocode the facility addresses into longitude and latitude codes in order to position the facility on a map. The following data will be analyzed:

- The number of audiology facilities that can provide hearing tests and/or hearing aid services for infants and young children.
- The zip code areas and geographic regions that have a dearth of audiology facilities.

- The number of facilities in each state who are not reporting test results and diagnosis to the EHDl program. This is the loss to documentation rate when children have received follow up but providers fail to report the result to EHDl programs.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

No such exemption is requested. The OMB expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions apply to this data collection.

References

¹ Finitzo T, Albright K, O'Neal J. The newborn with hearing loss: detection in the nursery. *Pediatrics*. 1998 Dec; 102(6):1452-60.

² Van Naarden K, Decoufle P, Caldwell K. Prevalence and characteristics of children with serious hearing impairment in metropolitan Atlanta, 1991–1993. *Pediatrics*. 1999 Mar; 103(3):570-5.

³ Centers for Disease Control and Prevention. Hearing Screening and Follow-Up Survey 2009. <http://www.cdc.gov/ncbddd/hearingloss/index.html>

⁴ Yoshinaga-Itano C, Sedey AL, Coulter DK, Mehl AL. Language of early- and later-identified children with hearing loss. *Pediatrics*. 1998 Nov;102(5):1161-71.

⁵ Robinshaw HM. The pattern of development from non-communicative behavior to language by hearing impaired and hearing infants. *Br J Audiol*. 1996 Jun; 30(3):177-98.

⁶ American Speech-Language and Hearing Association. 2010 Audiology Survey- Private Practice. <http://www.asha.org>