

Supporting Statement A

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

OMB # 0920-0955

Revision

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification “Revision.” The length of data collection requested for Office of Management and Budget – Paperwork Reduction Act (OMB-PRA) approval is three years. 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 1**). The Early Hearing Detection and Intervention Pediatric Audiology Links to Services (EHDI-PALS) advisory group reviewed the telepractice section of the originally approved survey (see **Attachments 3 and 3a, noted as Annual Survey Review**) and has added 2 additional questions to the revised survey (see **Attachments 4, 4a**) to specifically find out what telepractice system a clinic has in place. We anticipate the additional questions will give state EHDI coordinators valuable information in connecting regions with resource shortage with clinics that have the proper telepractice system in place. This will reduce the burden of resource shortage in certain regions of the U.S.

Background

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 Act, renewed in 2010, all U.S. states and territories have implemented Early Hearing Detection and Intervention (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 2011 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 35%, although varying from 7% to as high as 98% in some states. The high rate in certain states 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 previously.

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 EHDI coordinators can use to verify and quantify the true distribution of the pediatric audiology resources in a state.

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 (DSHPHWA), and 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.

With the originally approved EHDI-PALS data collection (OMB # 0920-0955), a survey based on standard of care practice was developed and administered to 892 audiologists to quantify the pediatric audiology resource distribution within the U.S. and how often providers report diagnostic hearing test results to their EHDI state jurisdiction. Both ASHA and AAA, being members of the EHDI-PALS workgroup, disseminated two requests through association e-newsletters and e-announcements to all pediatric audiologists requesting them to complete the approved EHDI-PALS survey. We originally anticipated 1500 audiologists would complete the survey during the initial year. As of 9-23-2013, 892 audiologists have read through the purpose statement and completed the survey. Response rate is 59% (892/1500) which is far better than a typical survey response rate of 30%. Since this method has proven very effective in reaching out to pediatric audiologists, the same survey announcement and data collection method will continue to be used.

We propose to add 2 additional questions to the originally approved EHDI-PALS survey (original survey, **Attachments 3, 3a**; revised survey, **Attachments 4, 4a**). From data collected from 892 facilities, we can already delineate the zip code areas and geographic regions that have a dearth of audiology facilities. For example in Iowa, both the northwest and southeast corner of the state lack pediatric audiology facilities. Parents who reside in these areas typically have to drive over 100 miles to reach the closest facility. The EHDI-PALS advisory group reviewed the telepractice section of the originally approved data collection and has added 2 additional questions to specifically find out what telepractice system a clinic has in place. We anticipate the additional questions will give state EHDI coordinators valuable information in connecting regions with resource shortage with clinics that have the proper telepractice system in place. This will reduce the burden of resource shortage in certain regions of the U.S.

Facilities do sometimes change their clinical service or hours of operation. For example, a facility may have acquired new hearing screening equipment and will be able to offer hearing screening to young children. To keep the facility service up to date when parents and physicians search for a suitable facility, we will send a reminder to all 892 facility contacts requesting that they review their previous survey answers on a yearly basis. Out of the 892 audiologists, we expect 800 audiologists will review their survey answers. This is in addition to the continuing data collection for audiologists who have not yet completed the survey.

1.1 Privacy Impact Assessment

I. Overview of the Data Collection System

As with the originally approved data collection (OMB # 0920-0955), this data collection is intended to target only pediatric audiologists who provide services to children age 5 and younger. State EHDI coordinators, AAA, and ASHA will continue to request through association e-newsletters or e-announcements to pediatric audiologists around the country to complete the revised survey (see **Attachments 4, 4a**) through the secured internet portal, EHDIPALS.org. The notification message to audiologists who have not filled out the survey will contain a short summary of the purpose for the survey, the EHDI-PALS website address, and where the survey is located on the website.

Those 892 audiologists who have completed the originally approved survey (see **Attachment 3, 3a**) from last year will be notified by a brief e-mail (see **Attachment 6**) to remind them to review their previously submitted survey answers since their contact e-mail has been stored in the secured website. This brief e-mail alert will be auto-generated by EHDI-PALS workgroup member, University of Maine. (see **Attachment 6**). After an audiologist completes the approved survey or the yearly review, the types of services a facility can offer 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. 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. EHDI-PALS workgroup member, 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 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

The above estimate includes the number of facilities who have already completed the originally approved survey in EHDI-PALS from last year. Both ASHA and AAA, being members of the EHDI-PALS workgroup will continue to disseminate a request through association e-newsletters or e-announcements to all pediatric audiologists to complete the EHDI-PALS survey. Over the past year, this method has proven very effective in reaching out to our target respondents, pediatric audiologists who provide audiologic services to children age 5 and younger. During the initial year of our data collection, we originally estimated 2000 audiologists would read through the purpose statement to decide whether or not to complete the survey, and about 1500 audiologists would actually complete the survey. After 9 months of data collection, 892 audiologists have completed the survey. The data collected allowed us to see the facility distribution throughout the majority of our states, including Puerto Rico and a few territories. Although we are close to our original target, we still lack comprehensive data for a few states especially California, Texas, Alaska and Montana. Both California and Texas have the largest population of pediatric audiologists while Montana and Alaska are known to be sparsely distributed with medical resources. It is imperative that we continue our effort because the percent of infants loss to diagnostic follow up in Texas continues to register 74%, Montana 81% and Alaska 44% in 2011.

Although the facility contact person’s name and e-mail will be collected, this information will only be accessed and used by EHDI coordinators so that they can contact the person if an error

is noted in their data. Besides the EHDI coordinators, EHDI-PALS workgroup member, University of Maine Centre for Research and Evaluation, will also have access to the facility contact so they can generate an auto e-mail alert to remind facility contacts to review their survey answers on a yearly basis. A password will also be required for access. 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 what telepractice system the facility is equipped to 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 purpose of this ICR 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. 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. The collected data will be used in the following ways:

- Sections 5 to 13 of the survey will inform CDC-EHDI team and state EHDI programs the number of audiology facilities equipped to provide hearing test, hearing aid and rehabilitative services for infants and young children.
- The types of audiologic services each facility can offer will be made available for parents, pediatricians, and family physicians in a searchable directory designed according to natural internet searching behavior of a user (i.e., by types of services, state, zip code, and distance).
- Since EHDI-PALS went live in April 2013, in 5 months the website registered 2513 hits to the searchable facility database.
- Over the past 9 months, from data collected from section 5 to 13, we can already delineate the zip code areas and geographic regions that have a dearth of audiology facilities. For example in Iowa, both the northwest and southeast corner of the state lack pediatric audiology facilities. Parents who reside in these areas typically have to drive over 100 miles to reach the closest facility. This probably is the main reason for Iowa's loss to follow up rate.

- The EHDI-PALS advisory group reviewed the telepractice questions in section 11 and have added 2 more questions to find out specifically what telepractice system a clinic has in place. We anticipate the additional questions will give state EHDI coordinators valuable information in connecting regions with audiology resource shortage with clinics that have the proper telepractice set up. This will reduce the burden of resource shortage in certain regions of the U.S.
- Section 4 of the survey allows CDC-EHDI team and state EHDI programs to quantify the rate of facilities 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.
- From preliminary data collected, we are able to discern approximately 40% of pediatric audiology facilities in Texas report only one third of their newly identified hearing loss cases to Texas EHDI program, while in Iowa over 95% facilities consistently report newly identified pediatric hearing loss cases to Iowa EHDI program. This data has proven to be valuable to EHDI programs in doing outreach.
- The findings from this survey will be compiled as downloadable reports for state and territorial EHDI programs to build capacity, conduct quality improvement activities and provide data for Healthy People 2010 objective 28-11: newborn hearing screening, evaluation, and intervention.
- Data collected from the survey will also be used by CDC-EHDI team in combination with U.S. census bureau's household income data to study whether economic factors may also play a part in contributing to loss to follow up rate for certain geographic areas.
- Preliminary data suggested that in Indiana household income appears to predict the odd ratio of a child loss to follow up. With every \$10,000 decrease in household income, the odds of a child lost to follow up increases by 20%.

In conclusion, it is imperative for us to continue data collection because if audiology facility distribution data are not available it will be difficult, if not impossible, for CDC and state EHDI programs to continue the surveillance and tracking effort as stated by Early Hearing Detection and Intervention Act of 2010. Not to mention the elimination of a useful tool for providers and parents to ensure infants who have failed hearing screening received timely diagnosis and follow up.

2.1. Privacy Impact Assessment

(i) Why the information is being collected

As with the original data collection, the purpose of this data collection is to:

1. Identify and quantify the audiology facility resources in the U.S. Facility data will be compiled into a distribution map. This map will be shared with the EHDI coordinators and accessible by password in the EHDI-PALS website. The map will reveal the facility distribution pattern across zip codes and geographic regions so EHDI coordinators are better informed whether one of the reasons for their state's loss to follow up is due to distance parents have to drive in order to reach the nearest facility and where to allocate resources. **(Project impact on a state level)**
2. Quantify the rate of facilities 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. **(Project impact on a state level)**
3. Collect data to reveal the type of follow up services a facility can offer. This information is compiled into a searchable directory 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. **(Project impact on a population level)**
4. In addition the data collected from the survey will be used by CDC-EHDI team in combination with U.S. census bureau's household income data to study whether economic factors may also play a part in contributing to loss to follow up rate for certain geographic areas. **(Project impact on a state and federal level)**

(ii) Intended use of the Information

As with the original data collection, the survey data will inform CDC-EHDI team of the following:

- The number of audiology facilities that can provide hearing tests, hearing aids and other rehabilitative services for infants and young children.
- The zip code areas and geographic regions that have a dearth of audiology facilities and whether this may be one of the reasons contributing to the state's loss to follow up rate.
- The number of facilities not reporting test results and diagnosis to the EHDI program by state. This is the loss to documentation rate when children have received follow up but providers fail to report the result to EHDI programs.

Participation in the survey is voluntary. 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. 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:

- 1) Facility type, facility address, phone number, and hours of operation.
- 2) Is the facility equipped to perform hearing tests, hearing screenings, hearing aid fittings and/or cochlear implant services.

3) Types of insurance accepted and interpreter services available.

Collected raw data will reside in a secure website accessible by password only. While names and email contacts of respondents will be known, respondents are not asked for personal information about themselves or about the infants they have seen. A contact person's name and e-mail is collected in the event an error is noted so that the EHDI coordinator can alert the facility contact to correct the error. Secondly, an auto generated e-mail reminder will be sent to the facility contact person so they can review their survey answers annually. This is to ensure the facility information is kept up to date for the benefit of parents and physicians. The contact person's name and e-mail can only be accessed by the state EHDI coordinators and University of Maine Center for Research and Evaluation staff who maintain the password-protected website and database.

A.3. Use of Information Technology and Burden Reduction

In order to reduce the burden on respondents, this survey will continue to be made 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. As with the original data collection, 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. The data will also remain up to date because an auto-generated e-mail will be sent to the facility contacts to remind them to review the survey answers annually.

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' clinical services. 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 is 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 and state EHDI programs. Thus CDC-EHDI team has collaborated with the EHDI-PALS workgroup to develop this updated survey.

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. In order to reduce the burden on respondents, this survey will continue to be made 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.

A.6. Consequences of Collecting the Information Less Frequently

If the requested data collection is not conducted and audiology facility distribution is not known, it will be difficult, if not impossible, for EHDI programs to continue tracking and surveillance which is mandated by all 56 state, district and territorial law and federal Early Hearing Detection and Intervention Act of 2010 (section 399M of the Public Health Service Act 42 USC 280g). The lack of the type 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 will 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

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- A. A copy of the agency's 60-day Federal Register Notice is attached (**Attachment 2**). The notice, as required by 5 CFR 1320.8 (d), was published on November 1, 2013 (volume 78,

number 212, pages 65653-65654). No 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 about the infants they have seen.

Survey respondents will be asked for information about the facility's capability and capacity to provide audiologic care for children age 5 and younger only, such as:

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

Participation in the survey is voluntary and respondents are advised that only facility information will be posted in a database accessible by parents, physicians, and EHDI coordinators in the EHDI-PALS website. All survey data are treated in a secure manner and are not disclosed. Facility manager or administrator's contact information will be available to the state EHDI coordinators and University of Maine, Center for Research and Evaluation staff who maintain the database 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 (see **Attachment 5**).

A.10.1. Privacy Impact Assessment Information

- A.** All survey respondents are 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 are advised that only the facility information portion is 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 about the infants they have seen. All collected facility data reside in a secure website accessible by password only. The name and e-mail contact of each facility is collected so that in the event an error is noted in the facility data, the EHDI coordinator can alert the facility contact to correct the error. Secondly, an auto-generated e-mail reminder will be sent to the facility contact person so they can review their survey answers annually. This is to ensure the facility information is kept up to date for the benefit of parents and physicians. The contact person's name and e-mail can only be accessed by the state EHDI coordinators and University of Maine Centre for Research and Evaluation staff who maintain the password-protected website and database.
- 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 Centre for Research and Evaluation staff and EHDI coordinators and a password is required.

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

Currently, EHDI-PALS has 892 facilities (as of 9-23-2013) in the database since the beginning of the originally approved data collection (OMB # 0920-0955). All 892 facilities' contact will receive

a brief e-mail from University of Maine to remind them to review their survey answers (see **Attachment 6**). It is estimated that approximately 800 audiologists will do so. It will take an average of 9 minutes per person to review the survey answers. Both ASHA and AAA are members of the EHDI-PALS workgroup and will continue to disseminate a request through association e-newsletters and e-announcements to all audiologists who provide services to children younger than 5 to complete the approved EHDI-PALS survey. The survey will be available via a secure password protected website. It is estimated that potentially an additional 400 new audiologists will complete the revised survey (see **Attachments 4, 4a**) which will average 9 minutes per respondent. The 9 minutes calculation is based on a previous timed pre-test with 6 volunteer audiologists.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Audiologists (completed OMB approved survey)	Annual Survey Review	800	1	9/60	120
New Audiologists	Revised Survey	400	1	9/60	60
	Totals				180

B. Annualized Cost to Respondents

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 \$72,800. This salary divided by 40 hours per week results in an estimated hourly wage of \$35.00. The total estimated cost burden on all survey respondents is \$6,300 (180 hours x \$35.00).

Estimated Annualized Burden Cost

Respondents	Form Name	Total Burden Hours	Estimated Hourly	Respondent Cost
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			Wage	
Audiologists (completed OMB approved survey)	Annual survey review	120	\$35.00	\$4,200
New Audiologists	Revised Survey	60	\$35.00	\$2,100
	Total	180	\$35.00	\$6,300

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

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 \$1,937.60. 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, result analysis 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.

Annualized Cost to Federal Government

		Task	Cost
Federal Government Personnel Costs	CDC Project Officer (GS-13 at 20% time)	Preparing OMB materials	\$484.40
	CDC Project Officer (GS-13 at 20 % time)	Survey review and consultation with programmer	\$484.40
	CDC Project Officer (GS-13 at 10 % time)	Consultation with programmers on data structure	\$242.20
	CDC Project Officer (GS-13 at 30 % time)	Result analysis	\$726.60
Total Annualized Costs			\$1937.60

A.15. Explanations for Program Changes or Adjustments

This is a revision of an existing data collection, OMB # 0920-0955, with an expiration date of 02/28/2014. The EHDI-PALS advisory committee suggested an additional 2 questions added to

section 11- telepractice so detailed information on the telepractice technology in place at the clinics can be captured. We anticipate the information will allow EHDI coordinators to connect audiology resource poor regions with clinics that can provide services through tele-technology. This will reduce the burden of resource shortage in certain regions of the US. Otherwise, there has been no revision, changes and adjustments to the project.

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

Sending our annual survey reminder and recruitment for new survey participants will begin within 1 month after OMB approval. The entire study is intended to be ongoing to support parents, state and territorial EHDI jurisdiction and to fulfill CDC EHDI team’s congressional mandate: Early Hearing Detection and Intervention Act of 2010 (section 399M of the Public Health Service Act 42 USC 280g). See Table A16 below outlines the project time schedule by activity.

Table A.16 Project Time Schedule

Project Time Schedule Year 1	
Activity	Time Schedule
Notify AHSA and AAA so the third national notification to audiologists to complete survey can begin	1 month after OMB approval
Notify University of Maine so they can auto-generate reminder e-mail to audiologists who have previously completed the approved survey	1 month after OMB approval
Monitor incoming facility data and analyze data	2 to 12 th month after OMB approval
Notify University of Maine so they can auto-generate reminder e-mail to audiologists who have previously completed the approved survey	12 th month after OMB approval

Project Time Schedule Year 2	
Activity	Time Schedule
Notify AHSA and AAA so the fourth national	13th month after OMB approval

notification to audiologists to complete survey can begin	
Monitor incoming facility data and analyze	14 to 24 th month after OMB approval
Notify University of Maine so they can auto-generate reminder e-mail to audiologists who have previously completed the approved survey	24 th month after OMB approval

Project Time Schedule Year 3	
Activity	Time Schedule
Notify AHSA and AAA so the fifth national notification to audiologists to complete survey can begin	26 th month after OMB approval
Monitor incoming facility data and data analysis	27 to 36 th month after OMB approval
Notify University of Maine so they can auto-generate reminder e-mail to audiologists who have previously completed the approved survey	36 th month after OMB approval

Analysis Plan:

At the conclusion of the 3 year survey period, EHDI-PALS workgroup members will collaborate with programmers to analyze data for the following:

- 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.
- Download and merge US Census Bureau's American Community Survey Household income tract data with EHDI-PALS facility data.
- Calculate the overall distance a household from a low income area needs to travel in order to access a clinic that accepts Medicaid.

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. _

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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>