Early Hearing Detection and Intervention
Hearing Screening and Follow-up Survey

Reinstatement with Change

ICR 0920-0733

Section A

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A Justification

A.1. Circumstances Making the Collection of Information Necessary

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. As part of these efforts the Center is actively involved in addressing the early identification of hearing loss among newborns and infants. 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] Studies have shown that children with a delayed diagnosis of hearing loss can experience preventable delays in speech, language, and cognitive development.[3 - 5] To ensure children with hearing loss are identified as soon as possible, many states and United States (U.S.) territories have implemented Early Hearing Detection and Intervention (EHDI) programs and enacted laws related to infant hearing screening. The majority of these EHDI programs have adopted the "1-3-6" plan, which consists of three core goals: 1) screening all infants for hearing loss before 1 month of age, 2) ensuring diagnostic audiologic evaluation before 3 months of age for those who do not pass the screening, and 3) enrollment in early intervention services before 6 months of age for those identified with hearing loss.

Federal support for identifying children with hearing loss began with the Children's Health Act of 2000, which authorized federal programs to support EHDI activities at the state level. Since then, funds have been distributed to states via cooperative agreements from the CDC and grants from the Health Resources and Services Administration (HRSA). States are using these federal monies to enhance EHDI programs and develop corresponding tracking and surveillance systems. These systems are intended to help EHDI programs ensure infants and children are receiving recommended hearing screening, follow-up, and intervention services.

The mission of the CDC-EHDI team is for every state and U.S. territory to have a complete EHDI tracking and surveillance system that will help ensure infants and children with hearing loss achieve

communication and social skills commensurate with their cognitive abilities. As part of this mission the CDC-EHDI team, in collaboration with representatives of state and U.S. territorial EHDI programs, developed seven National EHDI Goals that reflect the “1-3-6 plan” and address integration with the medical home (coordinated care by a medical provider) and development of tracking and surveillance systems to minimize loss to follow-up (Attachment 3). Many of the defined performance indicators for these goals involve obtaining data related to the number of children screened for hearing loss, referred for and receiving follow-up testing (e.g., diagnostic audiologic evaluation) and enrolled in early intervention services. The purpose of the revised survey (Attachment 4B) is to obtain annual state data on the performance indicators in a consistent manner, which is needed to assess progress towards meeting the National EHDI Goals. In addition, the availability of these data will better enable the CDC-EHDI team to provide technical assistance to states and respond to questions by the general public, policy makers, and Healthy People 2010 officials.

The CDC-EHDI team is therefore requesting Reinstatement with Change to the previously approved ICR (0920-0733)for an additional 3-year approval period for this data collection because it is responsible for distributing federal funds to states and U.S. territories for the development of EHDI tracking and surveillance systems and for providing evidence of the effectiveness of these programs. This data collection is based on the following three components of the Public Health Service Act: 1) Act 42 USC 241, Section 301, which authorizes “research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.” 2) 42 USC 247b-4, Section 317 C, which authorizes the activities of the National Center on Birth Defects and Developmental Disabilities, including the programs related to EHDI. This section was created by Public Law 106-310, also known as “the Children’s Health Act of 2000.” This portion of the code has also been amended by Public Law 108-154, which is also known as the “Birth Defects and Developmental Disabilities Prevention Act of 2003”; and 3) 42 USC 247b-4 Section 399 M, which specifically authorizes CDC’s role in EHDI (Attachment 1).

The Directors of Speech and Hearing Programs in State Health and Welfare Agencies (DSHPSHWA) previously distributed a survey annually (for calendar years 1999 – 2004) to EHDI programs (Attachment

5). At DSHPSHWA's request, CDC-EHDI provided assistance with the analysis of this data. This survey requested aggregate data about the number of infants screened for hearing loss, referred for and receiving follow-up testing, and who were enrolled in early intervention services. Although some of the EHDI benchmarks were included on the now retired DSHPSHWA survey, responses to the survey were not standardized due to some ambiguities in the phrasing of the questions. This was especially apparent in regards to data reported about the number of infants referred for and receiving recommended follow-up services (e.g., diagnostic testing and early intervention), as states have used different methods to calculate this information. The result of this was variability within the data reported by states and territories, which has made it difficult to assess overall progress in meeting the National EHDI Goals. This prompted the need for a new survey or Information Collection Request (ICR) that included clearly stated questions that require standardized responses. Specifically, standardized information related to when and how many infants receive follow-up services at different stages of the EHDI process was needed to help assess progress related to the National EHDI Goals and answer questions asked by policymakers and the public.

Following discussions with DSHPSHWA about the need for standardized data, it was agreed that CDC-EHDI would be better equipped to develop a new survey tool to replace the DSHPSHWA survey. When this original CDC EHDI ICR was approved by the Office of Management and Budget (OMB) in October 2006 (Control #: 0920-0731), DSHPSHWA was no longer surveying states. Additionally, DSHPSHWA and states, such as Colorado, supported the original ICR (Attachments 6 and 7). As with the original OMB approved EHDI ICR, representatives of state and U.S. territorial EHDI programs will be requested to complete this ICR. No educational efforts are anticipated to be needed for respondents to be able to complete this mildly revised ICR, as states and U.S. territorial EHDI programs already maintain such data for their own internal uses.

As with the original ICR approved in 2006 (0920-0733), evaluation for the mildly revised ICR will consist of two components. The first component is the overall survey response rate and item-specific completion rates. In addition, the number of questions asked by respondents about how to complete the revised ICR

will serve as another indicator of user acceptability. The second component for evaluation will involve the use of the data reported by states and U.S. territories. This will include standard indicators such as whether the information is made available to the public, referenced in presentations, and used in published EHDI-related articles. Additional indicators include determining through discussions within the CDC-EHDI team whether the reported data is being used effectively to identify systematic areas of loss to follow-up. Data from the original ICR has been used for a variety of activities, for example, online posting of data for public and professional access, presentations and projects, as a source of information for technical assistance to CDC-funded states, and publications. It is anticipated that the data collected through the mildly revised ICR would be used in the same way and because of further increased data quality, would be of even greater utility to the government and the public.

A.2. Purpose and Use of the Information

As with the original ICR the overall purpose of this revised ICR is to consistently gather the aggregate data required to assess progress toward the National EHDI Goals. The collected data will continue to be used in four key ways. First, it will be used to determine annual rates of hearing screening, referral for further diagnostic testing, loss to follow-up, incidence of hearing loss in infants, and enrollment in early intervention. These data will assist in determining if infants and children are receiving recommended EHDI related services in a timely fashion. The information is intended to be made available through presentations, articles related to EHDI programs and infant hearing loss, and online at: www.cdc.gov/ncbddd/ehdi. Second, the data will be used to determine rates of loss to follow-up within different stages of the EHDI process. Aggregate information about maternal race, ethnicity, education, and age will be used to help determine whether rates of loss to follow-up are correlated with any of these demographic variables. This information is anticipated to continue to be important in developing methods to help minimize loss to follow-up so all children receive recommended hearing-related services in a timely manner. Third, the data will be helpful in determining whether state tracking and surveillance systems are capturing essential information related to follow-up services, identification, and enrollment in early intervention (National EHDI Goal 6). It will also be used by CDC-EHDI to identify areas in state and territorial EHDI systems that may require additional modification. This is anticipated to be helpful in

providing technical support to funded states as well as for assessing the impact of federal initiatives related to hearing loss in infants and children. Fourth, the requested data will aid in efforts to determine the prevalence of differing degrees of hearing loss (e.g., mild, severe, profound, etc) among infants and children.

Information provided by this revised ICR also has the potential to be used for other purposes. These include quality improvement activities by state and territorial EHDI programs (e.g., identifying areas within the EHDI processes that could benefit from further development) and providing requested data for Healthy People 2010, Objective 28-11 on newborn hearing screening, evaluation, and intervention (Attachment 8). In addition, the aggregate data will continue to be made available online to other state and federal agencies, organizations, and the general public.

The accuracy of these data are regarded as suitable for the stated purpose and intended uses. Although some states and U.S. territories may not be able to answer every question on the ICR, the information will nonetheless be important in determining overall progress toward the National EHDI Goals, including the development and status of EHDI tracking and surveillance systems.

If these data are not consistently available on an annual basis it will be difficult, if not impossible, to determine whether infants and children are receiving recommended services and how EHDI programs are progressing towards achievement of the National EHDI Goals. This situation is anticipated to severely limit the ability of CDC and other state, federal, and private agencies to ensure infants and children with hearing loss are identified and enrolled in intervention services as early as possible.

A.3. Use of Information Technology and Burden Reduction

In order to reduce the burden on respondents and improve data quality this survey will continue to be made available for completion via a secure website. The continued inclusion of automatic checks to help minimize data errors and the convenience of being able to complete and submit the ICR via the internet

should continue to help ensure a minimal level of burden. Financial costs will continue to be minimized because no mailing fees will be associated with responding to this survey.

As with the original ICR data quality with the revised ICR should remain high because it will continue to feature several error checks that have to be satisfied before the survey can be finalized and submitted. As before there will also be no need to reenter the data into a separate database at CDC, which will decrease the potential for data entry errors. This system has and should continue to help ensure a complete data set that will provide the information needed to generate the statistics (e.g., annual rates of hearing screening) required to assess progress related to the National EHDI Goals and address questions from the public and other stakeholders.

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 attempting to collect some information from state EHDI programs; however, these surveys did not provide the standardized, high-quality data needed to measure progress towards National EHDI Goals, Healthy People (particularly Objective 28-11, attachment 8), and NCBDDD's Program Assessment Rating Tool goal. HRSA also relies on the EHDI related data collected by CDC to help assess progress. In addition, DSHPSHWA no longer surveys state EHDI programs and instead relies on the EHDI related data collected by CDC.

Thus, there were no previous or current collections that provide the data needed by CDC, state EHDI programs, and other stakeholders. With encouragement and input by stakeholders, including DSHPSHWA and the CDC EHDI Data Committee, CDC developed the original ICR that was approved by OMB in October 2006 (0920-0733). This ICR provided a standardized way to compile state data and generate national-level statistics. The proposed revised version of the ICR was also developed with input from DSHPSHWA, state EHDI programs, and the CDC EHDI Data Committee.

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

Not applicable as small businesses are not part of the respondent universe.

A.6. Consequences of Collecting the Information Less Frequently

As with other state health reporting to Federal agencies (e.g., Department of Education/Special Education, Title V MCH Block Grant, immunizations, etc), and the original ICR, states and territories will again be requested to complete this ICR on an annual basis for several reasons. They report each year's birth and death data (i.e., Vital Statistics) annually. By using these established intervals, we will continue to minimize the burden to the respondent by employing a clear reporting schedule that states and territories already use to report data. Collecting data annually will also enable more expeditious tracking and analysis of trends over time.

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. This request fully complies with the regulation.

1) Respondents will not be asked to make copies of any documents;

2) Respondents do not need to retain records;

3) This data collection is designed to produce valid and reliable results that can be generalized to the universe of study;

4) This data collection does not include the use of a statistical data classification that has not been reviewed and approved by OMB;

5) This data collection does not include a pledge of confidentiality that is not supported by appropriate authorities; and

6) This data collection does not involve requiring respondents to submit proprietary trade secrets or other confidential information.

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

In addition to internal review, CDC-EHDI solicited input on data collection efforts from outside reviewers in two ways: (A) public comment in response to a *Federal Register Notice* and (B) experts in early newborn hearing screening. These opportunities for feedback are discussed below.

A. 60-Day Federal Register Notice: The 60-Day notice was published in the Federal Register on *May 11, 2009* (Attachment 2*)*. No public comments were received.

B. Consultations with Individuals Outside of the Organization: Several efforts were made during the development of the original ICR to consult with persons outside the agency to maximize the quality and utility of this collection and ensure that it provided essential information.

i. Regarding development of the original ICR a meeting was held in June 2004 with representatives from other federal agencies (e.g., HRSA, the National Institutes of Health, and the Department of Education), DSHPSHWA and state EHDI programs to discuss data related issues, including the need, availability, method, and frequency of collection. Participants agreed that aggregate level data was required in order to determine progress towards the National EHDI Goals. HRSA, DSHPSHWA, and states again provided input related to the minor changes that are now being proposed for the revised ICR.

ii. DSHPSHWA allowed the CDC EHDI team to use their retired 2004 survey as a model for the design of the original CDC EHDI ICR and provided significant input during the development of the original ICR. DSHPSHWA also provided input for the minor changes that are being proposed for the revised ICR.

iii. Representatives of four state EHDI programs (e.g., Colorado, Nebraska, New Jersey, and Wyoming) reviewed a draft version of the revised ICR that included the proposed minor changes and provided comments.

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iv. Key data items recommended by the CDC-EHDI Data Committee for collection continue to be included in the revised version of the ICR.

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

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

A.10. Assurance of Confidentiality to Respondents

The CDC Privacy Officer reviewed the original ICR and determined that the Privacy Act was not applicable to this data collection. Survey respondents will continue to provide information based on their roles as directors of state and territorial EHDI programs. While names of respondents will be known, respondents will not provide personal information about themselves or any personally identifiable information about infants screened for hearing loss. Each survey respondent will provide aggregate-level data about infants screened for hearing loss within the state or territory represented by the respondent. Respondents will also provide information about the state or territory's methods for defining hearing loss and how it tracks screening and follow-up activities. Participation in the survey will continue to be voluntary and respondents will be advised that CDC plans to post state-specific aggregate data on the CDC-EHDI website, which is accessible to the public, and in publications (for a representative publication, see the October 2003 MMWR article, Infants Tested for Hearing Loss - United States, 1999-2001).

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 (Attachment 9).

A.11. Justification for Sensitive Questions

As with the original ICR the revised version will request aggregate, non-identifiable data, including demographic information, which has already been collected by states and U.S. territories for other

purposes. Key demographic variables, including maternal race, ethnicity, and age, are needed to better describe and analyze the resulting data. As with the original the revised ICR does not include any sensitive questions.

A.12. Estimates of Annualized Burden Hours and Costs

A. Burden Hours for Respondents

A total of 57 respondents will be asked to complete the revised ICR each year during the 3-year requested data collection approval timeframe. Based on findings from the original ICR it is estimated that the burden for individuals to read through the survey and decide whether or not to complete it is 10 minutes per person (see Attachment 4A).. The 10 minute calculation was based on feedback received in pre-tests with 5 individuals and confirmed by the experience with the survey since the original OMB-PRA approval.

It is expected that 50 of the 57 potential respondents will complete the survey (see Attachment 4B) and therefore incur an additional burden of up to 4 hours per respondent (see table A.12-1). However, based on feedback from consulted experts about the length of time required to complete the original ICR it is anticipated that it will only take some respondents a few minutes to complete the revised ICR. This is because states often have already gathered and compiled the requested data for their own internal uses. Nevertheless, the more conservative time estimate of 4 hours per response from each of the 50 anticipated participants is shown in the Table below. This estimate is identical to the time estimate for the original OMB-PRA approved estimate from 2006-the only change is the estimated number of respondents.

A.12 – 1 Estimates of Annualized Burden Hours

Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
EHDI Program State Program Coordinators Contacted	57	1	10/60	10
EHDI Program State Program	50	1	4	200

Coordinators who return the survey				
Totals	57			210

12. B. Annualized Cost to Respondents

The hourly wage for respondents was estimated using budget information provided in the annual reports for those states and territories with funding from the CDC-EHDI program. Based on this information the average annual salary for the director of a state EHDI program is estimated to be $52,000. This salary divided by 40 hours per week results in an estimated hourly wage of $27.00 for an EHDI Program Director. The total estimated cost burden on all survey respondents is $5,670 (210 x 27.00). The average cost per respondent is estimated to be $99.47 (5,670 / 57).

A.12 – 2 Annualized Cost To Respondents

Type of Respondents	Total Burden Hours	Hourly Wage Rate	Respondent Cost
Contacted (n = 57)	10	27.00*	$270
Complete (n = 50)	200	27.00*	$5,400
Total			$5,670

*Based on an estimated yearly salary of $52,000

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

There are no capital or maintenance costs to survey respondents.

A.14. Annualized Costs to the Federal Government

As with the original ICR Costs associated with this data collection are the result of the CDC-EHDI program personnel time involved in the design and distribution of the survey and the analysis of the collected data. The individual responsible for these tasks is a member of the CDC-EHDI team. Below costs for staff time dedicated to this survey are based on compensation at the GS 13 level (i.e., approximately $83,000). These costs are summarized in Table 1 below. Based on the original version of the ICR, the time required by the designated CDC-EHDI team member to conduct this survey, which will consist of contacting states primarily by email, is estimated to be 10 hours. Based on an average annual salary of approximately $83,000, or $40.00 per hour, the cost of conducting this survey will be $400 annually. The time required to prepare the data for analysis, again based on experience from conducting

the original ICR, will be approximately 8 hours, resulting in a cost of $320 annually based on the same average salary of $83,000. Data analysis is estimated to require 80 hours resulting in annualized analysis costs of approximately $3,200.

The time spent revising the original ICR required an estimated 60 hours and was coordinated by a member of the CDC-EHDI team. The average annual salary of this individual was equivalent to a GS 13 (i.e., approximately $83,000). This resulted in an estimated development cost of $2,400. The costs associated with these updates are not anticipated to be incurred again during the requested three year life of this annual data collection because no changes to the survey are planned during this period. Also, no additional developmental costs related to this survey are anticipated during the next three years. Approximately 25 hours were spent preparing the renewal application for OMB, which resulted in a cost of $1,000 based on an average annual salary of $83,000.

Based on the calculations described above, the total government costs over the 3 year approval period requested is $15,160. Divided by 3 years, the estimated annual cost is $5,053 (see Table 1 below).**Table 1. Estimated Annual Cost to Conduct EHDI Surveys**

Task	Cost
Labor Costs	
Survey Development (one time costs)	$2,400
OMB Application (one time costs)	$1,000
Survey Administration ($400 per year X 3 years)	$1,200
Data Preparation ($320 per year X 3 years)	$960
Data Analysis ($3,200 per year X 3 years)	$9,600
Total Costs for 3 Years	**$15,160**
Annual Estimated Costs	**$5,053**

*Labor Costs include Fringe and Benefits

A.15. Explanations for Program Changes or Adjustments

Minor changes are proposed to the original ICR that was approved by OMB in October 2006 (0920-0733). These proposed changes for the revised ICR have been made in response to feedback from respondents and requests for additional information from state and national partners. These minor changes are

intended to make the ICR easier to complete and further improve the quality of the data that is collected. These changes include revising the wording of some questions, splitting the previously combined questions about the number of infants that died and parents refused into two separate questions, adding a question about how many infants with hearing loss are receiving only monitoring services, simplifying the table for reporting type and severity of hearing loss data, and expanding the demographics section to include additional data items. These proposed changes for the revised ICR are explained in more detail below.

ICR Part 1 (Screening, Diagnosis, and Intervention)

- Hearing Screening Section:
  - Changed the wording of a data field from "Total Occurrent Births Reported by Vital Records" to "Total Occurrent Births According to Vital Records." This was done to clarify that this data field is requesting the number of births according to Vital Records.
  - Added two fields so respondents can now report the "Total Occurrent Births at Military Facilities According to Vital Records" and the "Total Occurrent Births at Military Facilities for which Hearing Results were Reported to the EHDI Program." These fields were added in response to requests from respondents because military facilities are not required to report hearing screening results and respondents did not have a standard way to account for this situation in the previous ICR.
  - Added the word "Documented" to the data field "Total Screened," so in the revised ICR it would appear as "Total Documented Screened." This was done to make it clear that respondents should report data for those infants that were documented as being screened as opposed to estimated data.
  - Added the word "Documented" to the data field "Total Not Screened," so in the revised ICR it would appear as "Total Documented Not Screened." This was done to make it clear that

respondents should report data for those infants that were documented as not being screened as opposed to estimated data.

- Separated the “Infant Died / Parents Declined Services” field into two separate fields (i.e., one data field for “Infant Died” and one data field for “Parents Declined Services”). This was done so that it will be possible to report the number of infants not screened due to infant death and the number not screened due to parents declining services, which is information that has been requested by partners. This change will also enable more detailed analysis of the data that is reported.

- Separated the Unknown / Missed fields into two separate fields (i.e., one data field for “Unknown” and one data field for “Missed”). This was done so that it will be possible to report the number of infants not screened due to being unknown and the number not screened due to being missed, which is information that has been requested by partners. This change will also enable more detailed analysis of the data that is reported.

- Diagnostic Section:

  - Changed the heading “Normal Hearing” to “No Documented Hearing Loss” based on the recommendations of two audiologists on the CDC EHDI team that the phrase “No Documented Hearing Loss” was more accurate to describe infants found to have no hearing loss than the term “Normal Hearing.”

  - Changed the heading “Cases of Permanent Identified (ID) Hearing Loss” to “Documented Permanent Identified (ID) Hearing Loss.” This was done to make it clear that respondents should report data for those infants that were documented to have been diagnosed with a hearing loss.

  - Added the word “Documented” to the heading “No Diagnosis / Undetermined” so that it now says No Documented Diagnosis / Undetermined.” This was done to make it clear that respondents

should report data for those infants that were not documented to have received a diagnoses of either no hearing loss or hearing loss and those for one several reasons.

- Separated the “Infant Died / Parents Declined Services” field into two separate fields (i.e., one data field for “Infant Died” and one data field for “Parents Declined Services”). This was done so that it will be possible to report the number of infants with no diagnosis due to infant death and the number with no diagnosis due to parents declining services, which is information that has been requested by partners. This change will also enable more detailed analysis of the data that is reported.

- Separated the field “Unable to Contact / Unresponsive / Unknown” into three separate fields and revised the wording. These new fields include:

  - “Unable to contact”: Does not include any changes to the wording or intent from the original ICR. This change will make it possible to determine how many infants not passing the final screening did not receive a diagnosis due only to the reason of the parents / family being unable to be contacted, which is of interest to CDC and state and national partners.

  - “Unknown”: Does not include any changes to the wording or intent from the original ICR. This change will make it possible to determine how many infants not passing the final screening did not receive a diagnosis due to only the reason of being unknown, which is also of interest to CDC and state and national partners.

  - A new field based on the previous “Unresponsive” component has been created. This new field is called “Parent / Family Contacted but Unresponsive.” This new field was created based on feedback from respondents that indicated in at least some cases the state EHDI program is able to contact the parents and/or family of an infant not passing the screening but the parents and/or family are unresponsive and do not seek the recommended follow-up testing.

- Intervention Section

- Under the heading “Total Referrals to Part C EI, added the words “Referred and” to the field “Eligible for Part C” so that the revised version would be “Referred and Eligible for Part C.” This was done to clarify that this fields refers to infants that are referred for early intervention.

- Under the heading “Total Referrals to Part C EI, added the words “Referred and” to the field “Not Eligible for Part C” so that in the new version it would be “Referred and Not Eligible for Part C.” This was done to clarify that this fields refers to infants that are referred for early intervention that are not eligible for these services.

- Under the heading “Total Referrals to Part C EI, added the words “Referred but” to the field “Eligibility Unknown” so that in the new version it would be “Referred but Eligibility Unknown.” This was done to clarify that this field refers to infants that are referred for early intervention but it is unknown if they are eligible for these services.

- Added a new heading called “Monitoring Services,” which includes a new field named “Receiving Only Monitoring Services.” This field was added at the suggestion of respondents and is intended to account for instances when children with hearing loss are receiving only monitoring services as opposed to actual early intervention services. On the original ICR there was no way to report infants with hearing loss that were only receiving monitoring services.

- Added a new field called “Not Eligible for Services” to account for those infants with hearing loss that are not receiving early intervention because they are not eligible. This new field will help ensure the completeness of the early intervention data.

- Separated the “Infant Died / Parents Declined Services” field into two separate fields (i.e., one data field for Infant Died and one data field for Parents Declined Services). This was done so that it will be possible to report the number of infants with no intervention due to Infant Death and the number with no intervention due to Parents Declined Services, which is information that has been

requested by partners. This change will also enable more detailed analysis of the data that is reported.

- Separated the field “Unable to Contact / Unresponsive / Unknown” into three separate fields and revised the wording. These new fields include:
  - “Unable to contact”: Does not include any changes to the wording or intent from the original/current ICR. This change will make it possible to determine how many infants with hearing loss did not receive a early intervention due to only the reason of the parents / family being unable to be contacted, which is of interest to CDC and state and national partners.
  - “Unknown”: Does not include any changes to the wording or intent from the original/current ICR. This change will make it possible to determine how many infants with hearing loss did not receive a early intervention due to only the reason of being unknown, which is of interest to CDC and state and national partners.
  - A new field based on the previous “Unresponsive” component has been created. This new field is called “Parent / Family Contacted but Unresponsive.” This new field was created based on feedback from respondents that indicated in at least some cases the state EHDI program is able to contact the parents and/or family of an infant that has been diagnosed with hearing loss but the parents and/or family are unresponsive and do not seek recommended intervention services.
- Added a new heading called “Cases of Hearing Loss not included in the above “Intervention” Section (e.g., Cases of late onset hearing loss),” which includes four separate fields to capture intervention data about cases of hearing loss that were reported in the “Hearing Loss not included in above “Permanent Identified (ID) Hearing Loss” part of the Diagnostics section. These new fields were added to make it possible to determine the intervention status of these infants, such as those with a late onset hearing loss, which is of interest to CDC and state and national partners. These new fields for the revised ICR include:

- Total Enrolled in Part C EI: This new field was added to determine how many infants reported in the “Hearing Loss not included in above “*Permanent* Identified (ID) Hearing Loss” section are receiving early intervention services.
- Total Services from Non-Part C EI services: This new field was added to determine how many infants reported in the “Hearing Loss not included in above “*Permanent* Identified (ID) Hearing Loss” section are receiving Non-Part C early intervention services.
- No Intervention - Monitoring Only: This new field was added to determine how many infants reported in the “Hearing Loss not included in above “*Permanent* Identified (ID) Hearing Loss” section are receiving only monitoring services.
- No Intervention: Unknown: This new field was added to determine how many infants reported in the “Hearing Loss not included in above “*Permanent* Identified (ID) Hearing Loss” section have an intervention status that is unknown.

ICR Part 2 (Type and Severity)

- Table Format: The format of this table has been changed so that the type of hearing loss (i.e., sensorineural, conductive, mixed, type unknown, and Auditory Neuropathy) now is positioned on the left side of the table instead of being listed along the top of the table. The laterality options (i.e., bilateral, unilateral, and laterality unknown) now are positioned along the top of the table in the revised version of the ICR. These changes were made in response to comments from some respondents that the table in the original ICR was somewhat confusing.
- Type Unknown: the option to report cases where the severity of hearing loss is known but the type (e.g., sensorineural or conductive) is unknown was added at the request of several respondents because they indicated they had several cases where the severity was known but the type was not. This was not possible in the original ICR.

- Auditory Neuropathy Severity: At the request of respondents fields have been added so that the severity (i.e., mild, moderate, severe, profound, and unknown) of cases of Auditory Neuropathy can now be reported. This was not possible in the original ICR.

ICR Part 3 (Demographics)

- Maternal Race Categories: The maternal race categories for "White" and "Black or African American" were broken down into the fields "White (Not Hispanic), White (Hispanic), White (Ethnicity Unknown). Black or African American (Not Hispanic), Black or African American (Hispanic), and Black or African American (Ethnicity Unknown" This was done to enable the differentiation of this maternal race data for Healthy People 2010, Objective 28-11.

- Screening Section

  - Added the field "Total Pass." This was done to increase the completeness of the demographic data so that the receipt of services regardless of age of receipt could also be assessed.

  - Added the field "Total Not Pass." This was done to increase the completeness of the demographic data so that the receipt of services regardless of age of receipt could also be assessed.

- Diagnostics Section

  - Added two new fields, "Normal Hearing" and Hearing Loss." This was done to increase the completeness of the demographic data so that the receipt of services regardless of age of receipt could also be assessed.

- Intervention Section

- **o** Added two new fields, “Total Enrolled in Part C” and “Total Services non-Part C.” This was done to increase the completeness of the demographic data so that the receipt of services regardless of age of receipt could also be assessed.

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

The table below shows the anticipated project time schedule for Years 1, 2, and 3 of this revised ICR.

A.16-1 Project Time Schedule*	
Activity	**Time Schedule**
Distribute surveys to respondents	1 - 2 months after OMB approval
Email Reminders (to increase response rate)	2 - 3 months after OMB approval
Provide phone support for survey completion	2 – 3 months after OMB approval
Download data from web application	3 - 4 months after OMB approval
Data management and validation	3 - 4 months after OMB approval
Initial Tabulation of Results	3 - 4 months after OMB approval
Data validation with states (as needed)	4 - 5 months after OMB approval
Final data analysis	4 – 6 months after OMB approval
Dissemination of results	6 – 7 months after OMB approval
REPEAT of all steps above for **Year Two** of Survey	13 - 24 months after OMB approval

REPEAT of all steps above for **Year Three** of Survey	25 - 36 months after OMB approval

**Note: This time schedule is dependent on if and when the ICR is approved by OMB and the amount of time taken by respondents to return the survey.*

Analyses Plan: As with the original ICR all information reported for the revised ICR will be at the aggregate level. Therefore, annual national and regional calculations will continue to be performed on the state-based aggregate data to determine a number of relevant statistics, including overall rates of children screened for hearing loss, identified with hearing loss, and enrolled in early intervention services. Prevalence rates of hearing loss per 1,000 infants screened and the frequency of differing types and severity of hearing loss will also be determined for all states and territories that provide data. All statistics will be calculated by CDC-EHDI personnel. A list of relevant statistics and an explanation of how they will be calculated is provided in the table below. Additional statistics may be generated as needed.

EHDI Aggregate Statistics (*state and national level*)	**Explanation of Calculations**
Percent screened for hearing loss	(# screened for hearing loss / # of occurrent births)*100
Percent screened for hearing loss (*according to Vital Records*)	(# screened for hearing loss / # of occurrent births as reported by Vital Records)*100
Percent screened for hearing loss (*excluding infant deaths and parents / family declining services*)	[(# screened for hearing loss / # occurrent births – *(# infant deaths* + # *parental & family refusals*) *100
Percent screened for hearing loss (*excluding infants born in military facilities*)	(# screened for hearing loss / # of occurrent births – (# births in military facilities according to Vital Records)*100
Percent not screened for hearing loss	(# not screened for hearing loss / # of occurrent births)*100
Percent not screened due to infant deaths	(infant died / total # of occurrent births) *100
Percent not screened due to parents / family declining services	(parents declined services / total # of occurrent births) *100
Percent not screened due to infants being missed	(missed / total # of occurrent births) *100
Percent not screened due to being unknown	(unknown / total # of occurrent births) *100
Percent total pass	(total # pass / total # screened) *100
Percent pass before one month of age	(pass before one month of age / total # pass) * 100
Percent pass after one month but before 3 months of age	(pass after one month but before 3 months of age / total # pass) *100
Percent pass after 3 months of age	(pass after 3 months of age / total # pass) *100
Percent total not pass	(total not # pass / total # not pass) *100

Percent not pass before one month of age	(not pass before one month of age / total # not pass) * 100
Percent not pass after one month but before 3 months of age	(not pass after one month but before 3 months of age / total # not pass) *100
Percent not pass after 3 months of age	(not pass after 3 months of age / total # not pass) *100
Percent with normal hearing	(normal hearing / total not pass) *100
Percent with normal hearing before 3 months of age	(normal hearing before 3 months of age / total not pass) *100
Percent with normal hearing after 3 months but before 6 months of age	(normal hearing after 3 months before 6 months of age / total not pass) *100
Percent with normal hearing after 6 months of age	(normal hearing after 6 months of age / total not pass) *100
Percent with hearing loss	(hearing loss / total not pass) *100
Percent with hearing loss before 3 months of age	(hearing loss before 3 months of age / total not pass) *100
Percent with hearing loss after 3 months but before 6 months of age	(hearing loss after 3 months but before 6 months of age / total not pass) *100
Percent hearing loss after 6 months of age	(hearing loss after 6 months of age / total not pass) *100
Percent with no documented diagnosis due to audiologic diagnosis in process	(audiologic diagnosis in process / total not pass) *100
Percent with no documented diagnosis due to non-resident or moved out of jurisdiction	(non-resident or moved out of jurisdiction / total not pass) *100
Percent with no documented diagnosis due to infant death	(infant died / total not pass) *100
Percent with no documented diagnosis due to parents / family declining services	(parents declined services / total not pass) *100
Percent with no documented diagnosis due to parent / family unresponsive	(parents / family contacted but unresponsive / total not pass) *100
Percent with no documented diagnosis due to parents / family unable to be contacted	(unable to contact / total not pass) *100
Percent loss to follow-up / loss to documentation for diagnosis	(unknown / total not pass) *100
# Identified with hearing loss	Sum the reported # identified with hearing loss in each state & territory to yield a national level value
# Identified with hearing loss per 1,000 screened	(# identified with hearing loss / total # screened)* 1,000
Percent total referred for Part C* early intervention	(total referred for Part C early intervention / # with hearing loss) *100
Percent eligible for Part C early intervention	(eligible for Part C early intervention / # with hearing loss) *100
Percent not eligible for Part C early intervention	(not eligible for Part C early intervention / # with hearing loss) *100
Percent enrolled in Part C early intervention	(enrolled in Part C early intervention / # with hearing loss) *100
Percent enrolled in Part C early intervention before 6 months of age	(enrolled in Part C early intervention before 6 months of age / # with hearing loss) *100
Percent enrolled in Part C early intervention after 6 months but before 12 months of age	(enrolled in Part C early intervention after 6 months but before 12 months of age / # with hearing loss) *100
Percent enrolled in Part C early intervention after 12 months of age	(enrolled in Part C early intervention after 12 months of age / # with hearing loss) *100
Percent enrolled in non-Part C early intervention	(enrolled in non-Part C early intervention / # with hearing loss) *100

Percent enrolled in non-Part C early intervention before 6 months of age	(enrolled in non-Part C early intervention before 6 months of age / # with hearing loss) *100
Percent enrolled in non-Part C early intervention after 6 months but before 12 months of age	(enrolled in non-Part C early intervention after 6 months but before 12 months of age / # with hearing loss) *100
Percent enrolled in non-Part C early intervention after 12 months of age	(enrolled in non-Part C early intervention after 12 months of age / # with hearing loss) *100
Percent receiving no intervention services due to infant deaths	(infant died / # with hearing loss) *100
Percent receiving no intervention services due to parents / family declining services	(parents declined services / # with hearing loss) *100
Percent receiving no intervention services due to non-resident or moving out of the jurisdiction	(non-resident or moved out of jurisdiction / # with hearing loss) *100
Percent receiving no intervention services due to receiving only monitoring services	(monitoring services / # with hearing loss) *100
Percent receiving no intervention services due to parents / family contacted but unresponsive	(parents / family contacted but unresponsive / # with hearing loss) *100
Percent receiving no intervention services due to parents / family unable to contact	(unable to contact / # with hearing loss) *100
Percent loss to follow-up / loss to documentation for Intervention	(unknown / # with hearing loss) *100
Type and Severity	
Cases of unilateral hearing loss (total)	Sum the # of cases unilateral hearing loss cases reported by states and territories to yield a national level value
Cases of unilateral sensorineural hearing loss (total)	Sum the # of cases unilateral sensorineural hearing loss cases reported by states and territories to yield a national level value
Cases of unilateral sensorineural hearing loss by severity (i.e., mild, moderate, severe, and profound)	Sum the # of cases reported for each level of severity to yield national level data on type and severity of identified hearing loss
Cases of unilateral conductive hearing loss (total)	Sum the # of cases unilateral conductive hearing loss cases reported by states and territories to yield a national level value
Cases of unilateral conductive hearing loss by severity (i.e., mild, moderate, and severe)	Sum the # of cases reported for each level of severity to yield national level data on type and severity of identified hearing loss
Cases of unilateral mixed hearing loss (total)	Sum the # of cases unilateral mixed hearing loss cases reported by states and territories to yield a national level value
Cases of unilateral mixed hearing loss by severity (i.e., mild, moderate, severe, and profound)	Sum the # of cases reported for each level of severity to yield national level data on type and severity of identified hearing loss
Cases of bilateral hearing loss (total)	Sum the # of cases bilateral hearing loss cases reported by states and territories to yield a national level value
Cases of bilateral sensorineural hearing loss (total)	Sum the # of cases bilateral sensorineural hearing loss cases reported by states and territories to yield a national level value
Cases of bilateral sensorineural hearing loss by severity (i.e., mild, moderate, severe, and profound)	Sum the # of cases reported for each level of severity to yield national level data on type and severity of identified hearing loss
Cases of bilateral conductive hearing loss	Sum the # of cases bilateral conductive hearing loss cases reported by states and territories to

	yield a national level value
Cases of bilateral conductive hearing loss by severity (i.e., mild, moderate, and severe)	Sum the # of cases reported for each level of severity to yield national level data on type and severity of identified hearing loss
Cases of bilateral mixed hearing loss (total)	Sum the # of cases bilateral mixed hearing loss cases reported by states and territories to yield a national level value
Cases of bilateral mixed hearing loss by severity (i.e., mild, moderate, severe, and profound)	Sum the # of cases reported for each level of severity to yield national level data on type and severity of identified hearing loss
Cases of Type Unknown Hearing Loss (total)	Sum the # of cases type unknown hearing loss cases reported by states and territories to yield a national level value
Cases of Type Unknown Hearing Loss by severity	Sum the # of cases reported for each level of severity to yield national level data on the severity of identified cases of type unknown
Cases of Auditory Neuropathy/ Dyssynchrony (total)	Sum the # of Cases of Auditory Neuropathy/ Dyssynchrony cases reported by states and territories to yield a national level value
Cases of Auditory Neuropathy/ Dyssynchrony by severity (i.e., mild, moderate, severe, and profound)	Sum the # of cases reported for each level of severity to yield national level data on the severity of identified cases of Auditory Neuropathy/ Dyssynchrony
Demographics	
Hearing Screening by Maternal Age	Sum of the # of cases of Pass and Not Pass for each maternal age category (e.g., 15 – 19 years) / total # of occurrent births
Hearing Screening by Maternal Education	Sum of the # of cases of Pass and Not Pass for each maternal education category (e.g., less than high school) / total # of occurrent births
Hearing Screening by Maternal Ethnicity	Sum of the # of cases of Pass and Not Pass for each maternal ethnicity category (e.g., Hispanic or Latino) / total # of occurrent births
Hearing Screening by Maternal Race	Sum of the # of cases of Pass and Not Pass for each maternal ethnicity category (e.g., Hispanic or Latino) / total # of occurrent births
Diagnosis by Maternal Age	Sum of the # of normal hearing and hearing loss cases for each maternal age category / total # not passing the hearing screening
Diagnosis by Maternal Education	Sum of the # of normal hearing and hearing loss cases for each maternal education category / total # not passing the hearing screening
Diagnosis by Maternal Ethnicity	Sum of the # of normal hearing and hearing loss cases for each maternal ethnicity category / total # not passing the hearing screening
Diagnosis by Maternal Race	Sum of the # of normal hearing and hearing loss cases for each maternal race category / total # not passing the hearing screening
Intervention by Maternal Age	Sum of the # enrolled in Part C and non-Part C intervention for each maternal age category / total # identified with hearing loss
Intervention by Maternal Education	Sum of the # enrolled in Part C and non-Part C intervention for each maternal education category / total # identified with hearing loss
Intervention by Maternal Ethnicity	Sum of the # enrolled in Part C and non-Part C

	intervention for each maternal ethnicity category / total # identified with hearing loss
Intervention by Maternal Race	Sum of the # enrolled in Part C and non-Part C intervention for each maternal race category / total # identified with hearing loss

Part C*: Refers to Part C of the Federal Individuals With Disability Act. This section of the law provides for early intervention services for children aged 0-3 with disabilities, including hearing loss.

Generated statistics will be compared to data previously reported to CDC to assess state, regional, and national performance at different stages in the EHDI process (e.g., percent screened for hearing loss). Aggregate statistics will also be compared across states and territories. The titles of potential reports to be produced from the aforementioned analyses are listed in Attachment 10. Although the primary intent of this ICR is to generate aggregate state and national-level statistics on hearing screening, referral, receipt of follow-up testing, identification, and intervention, within-state subgroups, analyses will be performed as the data allow.

Data Management: To ensure the accuracy of the information submitted, the data will be inspected for outliers and subsequently compared to data reported in previous years. Respondents will be contacted via email and/or phone if any responses appear to be incomplete or do not correspond to other information reported. Please see Attachment 11 for a copy of this email request.

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

No such exemption is requested.

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

No exceptions apply to this data collection.

References

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3. Yoshinaga-Itano C. Early intervention after universal neonatal hearing screening: impact on outcomes. Ment Retard Dev Disabil Res Rev. 2003; 9(4):252-66.

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.