GenIC Clearance for CDC/ATSDR

Formative Research and Tool Development

Supporting Statement A

American Academy of Pediatrics Neurodevelopmental ECHO (Extension for Community Health Outcomes)

OMB # 0920-1154

Supporting Statement Part A

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- Goal of the study: The purpose of this information collection is to monitor the AAP neurodevelopmental Extension for Community Health Outcomes (ECHO) project. The intent of the project is to improve pediatrician capacity for identification and care of children with neurodevelopmental disorders, particularly prenatal exposure to alcohol, in the medical home.

- Intended use of the resulting data: Customer satisfaction information will be used to monitor any incorporation of presented materials or suggestions from ECHO sessions into participating pediatric practices. Feedback also will inform any needed changes in topics, procedures or other aspects of the program. The purpose and use of the session satisfaction data will be to assure that specific information is conveyed and understood by participants for each monthly session, ongoing improvement and refinement of sessions and used inform subsequent neurodevelopmental ECHO projects.

- Methods to be used to collect: Data will be collected through secure email and will include monthly chart reviews, a monthly session satisfaction survey, one overall program satisfaction survey at the end of the project period and one overall debriefing conference call at the end of the project.

- The subpopulation to be studied: The target population is actively practicing pediatricians.

- How data will be analyzed: Quantitative descriptive analyses are planned for the chart reviews. Qualitive data will be obtained from the session and program satisfaction surveys as well as the debriefing conference call.

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LIST OF ATTACHMENTS

Attachments A1-A4: Instruments
Attachment A1: Monthly chart review form
Attachment A2: Monthly session satisfaction survey
Attachment A3: Overall program satisfaction survey
Attachment A4: Overall debriefing conference call guide

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted the Office of Management and Budget (OMB) for approval of 1 year. The request is submitted by National Center of Birth Defects and Developmental Disability (NCBDDD) at the Centers for Disease Control and Prevention (CDC) as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

Background. Fetal Alcohol Spectrum Disorders (FASDs) are the result of prenatal exposure to alcohol. FASD is an umbrella term that encompasses several, more specific, diagnoses. These conditions are associated with lifelong physical and neurodevelopmental abnormalities, including growth problems and prenatal brain damage, which may lead to developmental, behavioral and neurocognitive impairments (Stratton, et. al, 1996; Turchi, et al., 2018). Infants with a FASD are rarely recognized at birth by hospital staff. Further, at later ages, these children may be overlooked or misdiagnosed (Chasnoff, et al., 2015). While there is no cure for FASDs, early identification and intervention can mitigate adverse effects (Streissguth, et al., 2004).

In *Bright Futures*, the American Academy of Pediatrics (AAP) suggest routinely obtaining prenatal alcohol exposure history for all pediatric patients (Hagan, et al., 2017). The AAP also recommends developmental monitoring and screening for all patients for behavioral and neurodevelopmental issues. Finally, pediatricians are typically the first clinician that parents turn to when developmental or behavioral issues arise. Given these roles, pediatricians are critical in the process of early identification, referral and ongoing care in the medical home of children with FASDs and their families.

To facilitate and strengthen pediatricians' role, with CDC funding, the American Academy of Pediatrics (AAP) established a neurodevelopmental ECHO training program. ECHO stands for Extension for Community Health Outcomes. The AAP Neurodevelopmental Screening ECHO is a tele-mentoring program that leverages video conference technology to connect a multidisciplinary team of specialists with primary care providers in local communities. This ECHO will include actively practicing pediatricians. The project aims to build a bi-directional learning community whereby a faculty team and all participants will provide guidance aimed at improving the quality of care provided to children and youth affected by neurodevelopmental and neurobehavioral disorders, with an emphasis on children with an FASD. . The intent of the project is to improve pediatrician capacity for identification and care of children with neurodevelopmental disorders, particularly prenatal exposure to alcohol, in the medical home.

The one hour ECHO sessions occur monthly for 9 months. Each session includes 1) introduction with review of purpose and procedures, 2) a short didactic session on selected topics and 3) case presentation with faculty and participant discussion of clinical care. Included in the session are six faculty members with expertise in diagnosis and care of children with neurodevelopmental disorders and their families as well as up to 15 participant pediatricians. The 15 participant pediatricians are selected by a brief application to the AAP. All participation is voluntary. The ECHO program will be conducted for a one year period.

A.2. Purpose and Use of Information Collection

The project will be monitored using three instruments: monthly chart reviews for 8 months to monitor incorporation of presented material or suggestions (20 charts per month), monthly session satisfaction survey, one overall program satisfaction survey and one overall debriefing conference call. The purpose and use of the session satisfaction data will be to assure that specific information is conveyed and understood by participants for each monthly session, ongoing improvement and refinement of sessions and used inform subsequent neurodevelopmental ECHO projects. No private information or personally identifiable data is collected. Instruments are provide in **Attachments A1-A4**.

A.3. Use of Improved Information Technology and Burden Reduction

All data will be collected secure email.

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

There are no similar data. The AAP neurodevelopmental ECHO is unique and not conducted by other organizations, so ongoing monitoring data is needed as the program develops.

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

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

Monthly chart review data and session satisfaction surveys are needed because the didactic presentation topics and cases presented change each month. Only one overall program satisfaction survey will be used.

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

This request fully complies with the guidelines of 5 CFR 1320.5.

A.8. Project Staff and Expert Consultation

CDC Project Staff

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CDC project staff collaborated with AAP on the session topics, session presentations, the chart review instrument as well as the session and program satisfaction instruments. No major problems were identified that could not be resolved.

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

This collection of information does not involve any payment or gift to respondents.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Privacy Impact Assessment
This submission has been reviewed by the NCBDDD Privacy Officer, who determined that the Privacy Act does not apply. Activities do not involve the collection of individually identifiable information.

Privacy Impact Assessment

(i) Overview of the Data Collection System

An overview of the organization of the current project is helpful to understand the proposed data collection system. Key agencies involved with the project include CDC, and the American Academy of Pediatrics (AAP). All data are securely forwarded to an AAP ECHO consultant employed by AAP. At periodic intervals raw data are transferred to AAP.

Electronic data are stored on password-protected servers by ECHO consultant and AAP. Data are identified by practice names rather than participant names thus contain no personally identifiable information. The collected information and subsequent analyses will be stored

electronically for five years, at which time they will be destroyed. Access to raw data will be limited to project collaborators. CDC will receive only summarized, aggregate data in the form of evaluation reports, interim progress reports, and final project reports.

(ii) Items of Information to Be Collected

(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 request.

A.11. Institutional Review Board (IRB) and Justification of Sensitive Questions

I. IRB Approval.

This is non-research data collection. The NCBDDD Human Subjects Officer has reviewed this collection and determined that IRB approval is not required for this activity. AAP also has review this collection and determined that IRB approval is not required for this activity.

II. Sensitive Questions

No sensitive questions will be asked.

A.12. Estimates of Annualized Burden Hours and Costs

The information will be collected from the following types of respondents: Pediatricians

It is estimated that data collection will include 15 participants. The total estimated annual burden is 507 hours. (See Table 1 for details). There are no costs to respondents other than their time.

Table 1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (minutes)	Burden in Hours
Pediatricians	Chart Review	15	160	12/60	480
Pediatricians	Session satisfaction survey	15	8	5/60	10
Pediatricians	Program satisfaction survey	15	1	10/60	2
Pediatricians	Debriefing conference call	15	1	60/60	15
TOTAL					**507**

Estimates of annualized cost to respondents for the burden hours for collections of information were based on the mean hourly wage from the U.S. Department of Labor's "May 2014 National Occupational Employment and Wage Estimates." (See http://www.bls.gov/oes/current/oes_nat.htm.) (See Table 2 for details.)

Table 2. Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pediatricians	Chart Review	480	$84.33	$40,478
Pediatricians	Session satisfaction survey	10	$84.33	$843
Pediatricians	Program satisfaction survey	2	$84.33	$169
Pediatricians	Debriefing conference call	15	$84.33	$1264
TOTAL		**--507**		**$42,754**

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

There are no other annual cost burdens to respondents or record keepers.

A.14. Annualized Cost to the Government

The average annualized cost to the Government to collect this information is $97,804 for the OMB approval period that is requested (**Table 3**). It is anticipated that costs for the future years will be comparable to those shown, with appropriate adjustments for budget changes, inflation, and salary increases.

Table 3. Average Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Project Officer (GS-13, 0.05 FTE)	$5,752
	CDC Subject Matter Expert (GS-14, 0.05 FTE)	$6,981
	CDC Travel (2 persons; 1 trip each)	$2,000
	Subtotal, Direct costs	$14733
Cooperative Agreement or	Cooperative Agreements, Task orders, or Contracts for implementation or information	$83,071

Contract	management (including indirect costs)	
	TOTAL COST TO THE GOVERNMENT	$97,804

A.15. Explanation for Program Changes or Adjustments

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

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

Project ECHO sessions will begin soon after OMB approval is received. Content of the ECHO sessions didactic sessions are already developed and ready for presentation upon receipt of OMB approval.

Data will be summarized across respondents in all reports. For rating and categorical scales, the percent of each answer chosen compared to the total number of answers given will be reported per item. Open ended questions will be reviewed and summarized by themes. When applicable, qualitative and quantitative data will be synthesized to provide a more complete picture of the findings.

Table 4. Project Time Schedule

Activity		Timeframe
Identify and invite participants to trainings		Starts 1–2 months after OMB approval, ongoing
Conduct ECHO sessions	Conduct chart reviews	Starts 1–2 months after OMB approval, ongoing
	Conduct session satisfaction surveys	Starts 1–2 months after OMB approval, ongoing
	Conduct program satisfaction survey	Starts 9 months after OMB approval
	Conduct program debriefing conference call	Occurs 9 months after OMB approval
Analyze and Report Data		Annually

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

Expiration dates are displayed, no exception is sought.

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

There are no exceptions to the certification.

References

Chasnoff, IJ., Wells, AM, & King, L. (2015). Misdiagnosis and missed diagnoses in foster and adopted children with prenatal alcohol exposure, *Pediatrics*, 135(2), 264-270.

Hagan, JF, Shaw, JS & Duncan, PM (2017). *Bright Futures: Guidelines for health supervision of infants, children and adolescents* (4th edition). Elk Grove Village, IL: American Academy of Pediatrics.

Stratton, K.; Howe, C.; and Battaglia, F. 1996. *Fetal Alcohol Syndrome: Diagnosis, Epidemiology, Prevention, and Treatment.* Washington, DC: Institute of Medicine, National Academy Press.

Streissguth AP, Bookstein FL, Barr HM, Sampson PD, O'Malley K, Young JK.(2004). Risk factors for adverse life outcomes in fetal alcohol syndrome and fetal alcohol effects. Developmental and Behavioral *Pediatrics* 25(4):228-238.

Turchi RM, Smith VC, & AAP committee on Substance Use and Prevention, AAP Councile on Children with Disabilities. (2018). The Role of Integrated Care in a Medical Home for Patients With a Fetal Alcohol Spectrum Disorder. *Pediatrics*;142(4):e20182333