Form Approved
OMB No. 0920-1154
Exp.: 01/23/2023

GenIC Clearance for CDC/ATSDR

Formative Research and Tool Development

Supporting Statement A

American Academy of Pediatrics Resident Training in Developmental Continuity Clinics

OMB #0920-1154

Supporting Statement Part A

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July 16, 2020

- Goal of the study: The purpose of this information collection is to refine an AAP project for training pediatric residents to identify, refer and care for children with prenatal exposure to alcohol or a fetal alcohol spectrum disorder.

- Intended use of the resulting data: Customer satisfaction information will be used to elicit feedback of training materials and the overall program. The purpose and use of the session satisfaction data will be to assure that specific information is conveyed and understood by participants for as well as ongoing improvement and refinement of materials, trainings and the overall program.

- Methods to be used to collect: Survey data will be collected through paper-and-pencil surveys for in-person training of attending physicians and by secure email for resident trainees.

- The subpopulation to be studied: The target population is attending pediatricians who oversee medical resident training and first year pediatric residents.

- How data will be analyzed: Quantitative and qualitive descriptive analyses are planned for the data.

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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. Prenatal exposure to alcohol and other teratogens can have serious neurodevelopmental impact including Fetal Alcohol Spectrum Disorders (FASDs). 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. This brain damage 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. Pediatricians are critical in the process of early identification, referral and ongoing care of children with FASDs. Through regular well-child appointments, addressing parental concerns and managing a family's pediatric medical home pediatricians are in a key position to obtain (and document) prenatal exposure history to alcohol and other drugs. Relatedly, their role in monitoring development enables them to identify issues early that in turn facilitates timely treatment, especially early intervention. It is important for pediatricians to

learn these skills early in their clinical training to make them routine throughout their clinical practice careers.

To facilitate and strengthen pediatricians' role, with CDC funding, the American Academy of Pediatrics (AAP) is piloting a program to provide first year pediatric resident trainees with strategies, tools and resources necessary for: 1) obtaining prenatal history of exposure to alcohol and other drugs for all their patients, 2) recognizing clinical manifestation of FASDs in pediatric primary care settings to expedite diagnostic evaluation referrals, and 3) caring for affected children and their families in the pediatric medical home.

The project will be conducted in two phases. Phase one is a one-day, in-person, train-the-trainers session for attending physicians who oversee resident training in developmental continuity clinics. Training will be provided by experts in identification, diagnosis and care of children with FASDs. For phase two, the trainer attending physicians will implement a curriculum of continuing medical education activities with their residents. The curriculum contains both required and option activities that residents complete with support and facilitation from attending physicians. It is estimated that five clinics will participate in the project which could include up to 10 attending physicians and 15 pediatric residents. Participant clinics are selected by a brief application to the AAP. All participation is voluntary.

A.2. Purpose and Use of Information Collection

Session, activity and program satisfaction surveys will be obtained to: 1) assess larger scale feasibility of the project, 2) ensure that specific information is conveyed and understood by participants, 3) solicit feedback regarding content, format and delivery of project materials and 4) understand participants' [attending physicians and resident trainees] experience with the program. In phase one, attending physicians will complete pre- and post-session surveys for each of four presentations plus one overall satisfaction survey for the entire training day and one overall program satisfaction survey at the end of the project (total 10 instruments). In phase 2, residents will complete a session satisfaction survey for the required activity and the overall program (total 3 instruments). In addition, residents can complete two optional activities that do not include satisfaction surveys. No private information or personally identifiable data is collected. Instruments are provide in **Attachments A1-A13**.

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

Survey data will be collected through paper-and-pencil surveys for in-person training of attending physicians and by secure email for resident trainees as well as the overall program evaluations for attending physicians.

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

There are no similar data. Currently a pediatric resident training targeting identification, referral and care of children with FASDs and their families does not exist at the AAP. Further it is a

novel project and we are not aware of such a training being 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

Surveys of each learning component are needed are needed since each session or activity targets a specific relevant topic. Overall program satisfaction surveys by both attending physicians and residents are needed to asses efficacy as well as improve program materials and curriculum.

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 by CDC.

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 AAP project staff.

Electronic data are stored on password-protected servers by AAP. Data are identified by practice names rather than participant names thus contain no personally identifiable information. Pre and post training surveys are match by 2-4 digit/letter codes chosen by the respondent (e.g., initials, random digits or words). 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.

Participant and AAP membership ID numbers are obtained to grant CME credit; however, these are not linked to data in any way, thus there is no sensitive or personally identifiable data. CDC does not receive this information.

(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 25 participants (10 attending physicians and 15 residents). The total estimated annual burden is 160 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	Attending physicians Screening & Diagnosis Pretest (A1)	10	1	10/60	2
Pediatricians	Attending physicians Screening & Diagnosis Posttest (A2)	10	1	10/60	2
Pediatricians	Attending physicians Treatment Across Lifespan Pretest (A3)	10	1	10/60	2
Pediatricians	Attending physicians Treatment Across Lifespan Posttest (A4)	10	1	10/60	2
Pediatricians	Attending physicians Overcoming Social Attitudes Pretest (A5)	10	1	10/60	2
Pediatricians	Attending physicians Overcoming Social Attitudes Posttest (A6)	10	1	10/60	2
Pediatricians	Attending physicians Educational Care Pretest (A7)	10	1	10/60	2
Pediatricians	Attending physicians Educational Care Posttest (A8)	10	1	10/60	2
Pediatricians	Attending physicians Training Program Evaluation (A9)	15	1	15/60	3
Pediatricians	Resident Overall	15	1	15/60	3

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (minutes)	Burden in Hours
	Effects & Prevalence Video Pretest (A10)				
Pediatricians	Resident Overall Effects & Prevalence Video Posttest (A11)	15	1	15/60	3
Pediatricians	Resident Overall Program Evaluation (A12)	15	1	15/60	3
Pediatricians	Attending physicians Overall Program Evaluation (A13)	20	1	20/60	4
TOTAL		**160**			**32**

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	Module feedbacks and program evaluation	32	$84.33	$2,698.56
TOTAL		**32**		**$2,698.56**

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 Contract	Cooperative Agreements, Task orders, or Contracts for implementation or information management (including indirect costs)	$83,071
	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

The project will begin soon after OMB approval is received. Content of the attending physician training, resident trainee videos and activities 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,
Attending physician 1-day training	3 months after OMB approval
Resident activities	4 months after OMB approval
Analyze and Report Data	8 months after OMB approval

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.

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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 Council 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