Assessment of a Training Program to Improve Continuity of Care for Children and Families Affected by Fetal Alcohol Spectrum Disorders (FASD)

NEW

Supporting Statement Part A

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

- Intended use of the resulting data: The purpose and use of the assessment data will be to assure that specific information is conveyed and understood by participants.

- Methods to be used to collect: Up to ten clinics will be recruited for each of three years to participate in the curriculum (total 30 clinics for the project period). The curriculum uses a Train-the-Trainer model whereby attending physicians at developmental continuity clinics receive in-depth training and then facilitate training of first year pediatric residents in their own clinics. Assessment of the curriculum will be conducted using pre/post test data that will be collected through paper-and-pencil surveys for in-person training of attending physicians and through a secure online platform (Qualtrics) for resident trainees as well as the overall program assessment by attending physicians. Notes of a final project debriefing conference call of attending physicians also will obtained.

- The subpopulation to be studied: The target population is attending physicians who oversee first year pediatric resident training as well as the first year pediatric residents. It is anticipated that approximately 10 attending physicians will participate each year (total 30 for the project period) and approximately 25 pediatric residents per clinic will participate annually (total 750 for the project period). All participation is voluntary.

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

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This new Information Collection Request is submitted to the Office of Management and Budget (OMB) for approval of 3 years. 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) (Attachment 17). Background. Prenatal exposure to alcohol and other teratogens can have serious neurodevelopmental impact including Fetal Alcohol Spectrum Disorders (FASD). 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 an FASD are rarely recognized at birth by hospital staff. Further, at later ages, these children may be overlooked or misdiagnosed (Chasnoff, et al., 2015) since presenting concerns overlap with several other developmental conditions. 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 the child's 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 the pediatricians' role, the AAP, with CDC funding, has developed a curriculum and 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 manifestations of FASD in pediatric primary care settings to expedite diagnostic referrals, and 3) caring for affected children and their families in the pediatric medical home. The proposed activity builds upon formative research with attending physicians and residents initiated in 2020 (see OMB No. 0920-1154, "American Academy of Pediatrics Resident Training in Developmental Continuity Clinics (part 3)).

The curriculum is presented in two phases using a train-the-trainer model. Phase one is a one-day, in-person (or virtual if necessary), train-the-trainers session for attending physicians who oversee medical resident training in pediatrics. This training is organized around four presentations by experts in identification, diagnosis, and care of children with FASD and their families. Pre/post-test assessments are obtained for each presentation (**Attachments A1 – A8**). An overall assessment of the training is obtained at the end of the one-day training (**Attachment 9**). For phase two, the trainer attending physicians implement a curriculum of continuing medical

education activities with their first-year pediatric residents. The curriculum contains both required and optional activities that residents complete with support and facilitation from the attending physicians. Required activities are to view three pre-recorded video presentations then participate in discussions of the materials with the participating clinic's attending physician trainer. A pretest assessment is conducted prior to viewing all three videos (**Attachment 12**). A post-test assessment of knowledge change is conducted after the resident has viewed all three videos (**Attachment 13**). There is no assessment of optional activities. Clinics are allowed flexibility in implementing the curriculum. The required pre-recorded presentations may be viewed individually or in a group setting. Discussions with attending physicians may be individual, at regular staff meetings, during educational sessions (e.g., Lunch & Learns), or during off-site events (e.g., retreats). Overall assessment of the curriculum and its implementation is obtained from attending physicians (**Attachment 10**) and residents (**Attachment 14**) after all curriculum activities are completed. Finally, a debriefing conference call is held with all attending physicians after all clinics have implemented the curriculum (**Attachment 11**).

The target population is attending pediatricians who oversee first year pediatric resident training as well as the first-year pediatric residents. Approximately ten clinics will be recruited for each of three years to participate in the curriculum (total 30 clinics for the project period). It is anticipated that approximately 1 attending physician from each clinic will participate each year (total 30 for the project period) although additional physicians are welcome to participate; and approximately 25 pediatric residents per clinic will participate annually (total 750 for the project period). Participant clinics will be self-selected and recruited by emails sent to members of the AAP and notice in AAP newsletters (**Attachment A15b**). Potential participants also will complete a recruitment application (**Attachment A15a**). While 10 or less clinics are anticipated to participate in the project each year, the project will be expanded to accommodate additional clinics if needed. There are no selection criteria for type of clinic (e.g., university-based vs private practice), geographic location, or population served (e.g., Medicaid). All participation is voluntary.

In the first year (2021) in-depth training for attending physician(s) will be held virtually. Subsequently, if COVID status allows, this training will be conducted in person at the AAP headquarters located in Itasca, IL. All resident trainings will be conducted at individual developmental clinics.

A.2. Purpose and Use of Information Collection

The proposed FASD pediatric resident training curriculum focuses on increased knowledge and awareness of children with FASD as well as development of clinical skills. To assess whether the project's presentations and other trainings activities meet these goals, information must be collected to assess changes in their knowledge of FASD, comfort in obtaining a prenatal history of alcohol exposure and understanding of providing care to children with FASD and their families. Presentation and program assessment surveys will be obtained to: 1) ensure that specific information is conveyed and understood by participants, 2) the curriculum increases confidence in providing clinical care, 3) solicit ongoing feedback regarding content, format, and delivery of project materials. This information collection will provide AAP and NCBDDD information regarding the effectiveness of the project as a whole and will assist with future program planning. Without this information collection, it

will not be possible to ascertain whether the proposed curriculum is effective in improving knowledge and clinical skills related to children with FASDs and their families.

No private information or personally identifiable data is collected from the attending physicians or residents. Email addresses are obtained for attending physicians to facilitate scheduling of the training, encourage return of surveys and provide continuing medical education (CME) credit. Email addressed are not obtained for residents with all reminders to return surveys provided by their attending physicians.

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

Assessment data will be collected through paper-and-pencil surveys for in-person training of attending physicians and through a secure online platform (Qualtrics) for resident trainees as well as the overall program assessment for attending physicians. Final program debriefing conference call notes are taken by AAP staff.

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

There are no similar data. Although formative work was conducted for development of the proposed curriculum (see OMB No. 0920-1154, "American Academy of Pediatrics Resident Training in Developmental Continuity Clinics), currently a pediatric resident training targeting identification, referral, and care of children with FASD 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. Therefore, we proposed to conduct ongoing monitoring and data collection over the next three years as the program continues to develop and expand.

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

Assessment of each learning component is needed since each session or activity targets a specific relevant topic. Overall program assessment surveys by both attending physicians and residents are needed to assess efficacy of as well as improve the program materials and curriculum. Information from the final debriefing call with attending physicians will provide information on the successes and challenges encountered across clinics and the various formats used by clinics to implement the curriculum (e.g., group vs. individual formats).

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

A.8a. A 60-day Federal Register Notice was published on March 8, 2021 Vol. 86, No. 43, pp. 13391-13392 (**Attachment 16**). CDC did not receive public comments related to this notice.

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CDC project staff collaborated with AAP on the session topics, session presentations, presentation assessments, program assessment, and program debriefing conference call guide. No major problems were identified that could not be resolved. CDC staff will attend the in-person (or virtual) training of attending physicians as well as the program debriefing conference call.

A.8b. AAP Staff and consultants

AAP staff and their consultants were involved in development of the proposed project and curriculum. AAP staff provided general administration of the project; Dr Smith provided medical oversight of the project; Dr. Broyles provided consultation on all aspects of assessment development, analysis and interpretation.

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

This collection of information does not involve any payment or gift to respondents. Attending physicians receive CME credit for participation.

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

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

Key agencies involved with the project include CDC and the American Academy of Pediatrics (AAP). All data are securely forwarded to AAP project staff.

Pre/post data will be obtained for each of 4 presentations for attending physicians. In addition, they will complete one overall assessment of their training, one overall assessment of the curriculum, and will participant in a project debriefing conference call with AAP at the end of the project. Email addresses are obtained for attending physicians to facilitate scheduling of the training, encourage return of surveys and provide continuing medical education (CME) credit. First year pediatric residents will complete one pre/post assessment for the pre-recorded video presentations and one overall program assessment. Email addressed are not obtained for residents with all reminders to return surveys provided by their attending physicians. In the first year (2021) the attending physician in-depth training will be held virtually. Subsequently, if COVID status

allows, this training will be conducted in person at the AAP headquarters located in Itasca, IL. All resident trainings will be conducted at the individual developmental clinic.

Since the attending physician training will be in person, the pre/post presentation assessment and the overall training assessment will be administered by paper-and-pencil. All resident pre/post assessments as well as the overall program assessment for attending physicians will be obtained electronically via a secure online platform (Qualtrics). Paper-and-pencil data are stored in locked files within secured file rooms at the AAP. Electronic data are stored on password-protected servers by the AAP. Data are identified by practice names rather than participant names and thus contain no personally identifiable information. For all assessments, pre and post training assessments are matched by 2-4 alphanumeric 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 summarize and aggregate data in the form of project 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.

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

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 reviewed this collection and determined that IRB approval is not required for this activity.

Sensitive Questions

No questions will be sensitive except for asking about race and ethnicity for residents (Attachment 12). These data will be used to describe the population of residents who participated in the curriculum. No comparative analyses will be conducted.

A.12. Estimates of Annualized Burden Hours and Costs

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

Participants will include attending physicians and first year pediatric residents from up to 10 developmental continuity clinics each year. It is anticipated that 10 attending physicians (representing 10 clinics) and approximately 25 first year residents from each clinic will participate each year (total 250 residents). Table SSA.1a provides a listing of the time burden per year. There are no costs to respondents other than their time.

Table SSA.1a. Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (minutes)	Burden in Hours
Pediatricians (Attending Physician)	Attending Physicians Screening & Diagnosis Pretest (A1)	10	1	10/60	2
	Attending Physicians Screening & Diagnosis Posttest (A2)	10	1	10/60	2
	Attending Physicians Treatment Across Lifespan Pretest (A3)	10	1	10/60	2
	Attending Physicians Treatment Across Lifespan Posttest (A4)	10	1	10/60	2
	Attending Physicians Overcoming Social Attitudes Pretest (A5)	10	1	10/60	2
	Attending Physicians Overcoming Social Attitudes Posttest (A6)	10	1	10/60	2
	Attending Physicians Educational Care Pretest (A7)	10	1	10/60	2
	Attending Physicians Educational Care Posttest (A8)	10	1	10/60	2
	Attending Physicians Training Program Assessment (A9)	10	1	15/60	3
	Attending Physicians Overall Program Assessment (A10)	10	1	20/60	3
	Attending Physicians Debriefing Guide (A11)	10	1	60/60	10
	Attending Physicians application (A15)	10	1	10/60	2
Pediatricians (Residents)	Resident Overall Effects & Prevalence Video Pretest (A12)	250	1	15/60	63
	Resident Overall Effects & Prevalence Video Posttest (A13)	250	1	15/60	63

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (minutes)	Burden in Hours
	Resident Overall Program Assessment (A14)	250	1	15/60	63
TOTAL		**870**			**223**

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 2020 National Occupational Employment and Wage Estimates." (See http://www.bls.gov/oes/current/oes_nat.htm.) (See Table 2 for details.)

Table SSA.12b Estimated Annualized Burden Costs

The total estimated annualized burden cost is $19,375.

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (in hours)	Avg. Hourly Wage	Burden Cost
Pediatricians (Attending Physician)	Attending physicians Screening & Diagnosis pretest (A1)	10	1	10/60	$88.74	$148
	Attending physicians Screening & Diagnosis Posttest (A2)	10	1	10/60	$88.74	$148
	Attending physicians Treatment Across Lifespan Pretest (A3)	10	1	10/60	$88.74	$148
	Attending physicians Treatment Across Lifespan Posttest (A4)	10	1	10/60	$88.74	$148
	Attending physicians Overcoming Social Attitudes Pretest (A5)	10	1	10/60	$88.74	$148
	Attending physicians Overcoming Social Attitudes Posttest (A6)	10	1	10/60	$88.74	$148

Type of Respondents	Form Name	Number of Respondents	Number of Responses	Burden per Response (in hours)	Avg. Hourly Wage	Burden Cost
	Attending physicians Educational Care Pretest (A7)	10	1	10/60	$88.74	$148
	Attending physicians Educational Care Posttest (A8)	10	1	10/60	$88.74	$148
	Attending physicians Training Program Assessment (A9)	10	1	15/60	$88.74	$222
	Attending physicians Overall Program Assessment (A10)	10	1	20/60	$88.74	$296
	Attending physicians Debriefing Guide (A11)	10	1	60/60	$88.74	$887
	Attending physicians application materials (A15a)	10	1	10/60		$148
Pediatricians (Residents)	Resident Overall Effects & Prevalence Video Pretest (A12)	250	1	15/60	$88.74	$5,546
	Resident Overall Effects & Prevalence Video Posttest (A13)	250	1	15/60	$88.74	$5,546
	Resident Overall Program Assessment (A14)	250	1	15/60	$88.74	$5,546
TOTAL						**$19,375**

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	$14,733
Cooperative Agreement	Cooperative Agreement (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

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