PART A
Request for OMB Review and Approval

Title of Project: A Survey of the Knowledge, Attitudes and Practice of Medical and Allied Health Professionals Regarding Fetal Alcohol Exposure 0920-0692

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A Survey of the Knowledge, Attitudes and Practice of Medical and Allied Health Professionals Regarding Fetal Alcohol Exposure

Supporting Statement

SECTION A: JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

Maternal prenatal alcohol use is one of the leading, preventable, causes of birth defects and developmental disabilities. Children exposed to alcohol during fetal development can suffer a wide array of disorders, from subtle changes in I.Q. and behaviors to profound mental retardation. These conditions are known as fetal alcohol spectrum disorders (FASDs). The most severe condition within the spectrum is fetal alcohol syndrome (FAS), which involves disorders of the brain, growth retardation, and facial malformations.[1,2]

Physicians and other health practitioners play a vital role in diagnosing FAS and in screening women of child-bearing age for alcohol consumption and drinking during pregnancy. In Diekman's, et al 2000, study of obstetricians and gynecologists, only one fifth of doctors surveyed reported abstinence to be the safest way to avoid the adverse outcomes associated with fetal alcohol exposure.[3] Importantly 13% of doctors surveyed were not sure of levels of alcohol consumption associated with adverse outcomes.[3] One of CDC's multifaceted initiatives in combating alcohol-exposed pregnancies is the education and reeducation of medical and allied health students and practitioners.

In fiscal year 2002, the Centers for Disease Control and Prevention (CDC) received a congressional mandate to develop guidelines for the diagnosis of FAS and other conditions resulting from prenatal alcohol exposure; and to incorporate these guidelines into curricula for medical and allied health students and practitioners [Public Health Service Act Section 317K (247b-12) b and c] (See Appendices A-1, A-2).

In response to the second congressional mandate listed above, CDC proposed five national surveys of health providers. In August of 2005, OMB approved these five surveys under control number 0920-0692. The purposes of the surveys are to assess, among various health care provider groups, their knowledge, attitudes, and practices regarding the prevention, identification, and treatment of FASDs. These health care provider groups are pediatricians, obstetrician-gynecologists (OBGYNs), psychiatrists, family physicians, and allied health professionals. To date, three of the five surveys have yet to be conducted – the survey of allied health professionals, the survey of family physicians, and the survey of pediatricians[1].

The results of the surveys will help to inform further development of model FASD curricula to disseminate among medical and allied health students and professionals nation wide using a variety of formats including computer interactive learning applications, workshops and

[1] Under separate cover, the American Academy of Pediatrics used the pediatrician survey to survey a sample of their Fellows in 2003. Findings from this survey were published in 2006 (see Appendix K). The pediatrician survey contained in this package could be repeated in order to provide more current information regarding pediatricians' knowledge, attitudes, and practices surrounding this topic.

conferences, Continuing Medical Education credit courses, and medical and allied health school grand rounds and clerkships. Consistent with OMB's previous terms of clearance, CDC does not expect the results to be generalizable to the larger populations of the professional organizations from which the samples were drawn. Instead, the survey results will provide necessary information to further develop and refine educational materials for medical and allied health students and practitioners and to evaluate their effectiveness.

Periodic surveys of practicing health care providers and medical and allied health students provides vital information regarding the state of current practice behaviors and pedagogical constructs offered in medical education programs. Reliable and valid estimates of health care provider knowledge, attitudes and practice regarding fetal alcohol exposure is critical to identifying gaps in knowledge and essential for developing education programs that are current, timely and contain state of the science information. These efforts are directed at accomplishing Health and Human Services Healthy People 2010 maternal, infant and child health objectives 16-18 [4], which address increasing abstinence from alcohol and illicit drug use among pregnant women and reducing the occurrence of fetal alcohol syndrome.

2. Purpose and Use of Information Collected.

The National Center on Birth Defects and Developmental Disabilities (NCBDDD) partners with four FASD Regional Training Centers (RTCs) to develop, implement, and evaluate training for medical and allied health students and practitioners regarding FASDs. These centers are university-based. They develop training programs to be implemented in their own schools as well as other universities in their regions. These RTCs also provide continuing education training for practicing health care professionals.

The RTCs have used and will continue to use the findings from these surveys to tailor their training programs for specific types of students and health care providers. In addition, CDC's FAS Prevention team will use the results of one of these surveys, in particular the OBGYN survey, to evaluate training materials that were developed in collaboration with the American College of Obstetricians and Gynecologists (ACOG) in 2006 (see Appendix J).

To date, two surveys (the OBGYN and psychiatrist surveys) have been deployed. The results of both of these surveys are currently being analyzed.[2]

Collectively, the five surveys will gather estimates of health care provider knowledge regarding the epidemiology of fetal alcohol exposure and estimates of health care provider knowledge regarding alcohol use during pregnancy. More specifically, the surveys assess provider estimates of the prevalence of FAS and related conditions in the United States, the dysmorphology associated with these conditions, and neurological and behavioral problems associated with fetal alcohol exposure. Further, the study includes assessments of the extent of provider training regarding the diagnosis and treatment of FAS and other prenatal alcohol-related disorders and assesses the types of training and support materials preferred by health practitioners. Information gathered through these surveys will inform and further guide CDC's FAS Prevention Team's efforts surrounding training of medical and allied health students and practitioners.

[2] The OBGYN survey was amended and was submitted as a change request (83-C) for nonsubstantive changes to the survey in May 2007. The change was approved on July 9, 2007. The amended version of the survey is attached as Appendix D.

Each survey, generally, consist of the following three elements:

- The *Knowledge* content areas of the survey instrument will assess the understanding of the FASD epidemiology; definitions for binge (number of drinks containing alcohol consumed per occasion) and frequent (number of drinks containing alcohol consumed per week) drinking for pregnant women; pregnancy trimesters in which occasional drinking is considered safe; and the diagnostic criteria, facial dysmorphia, sequelae and secondary disabilities associated with FASDs. Additional questions ascertain training received in any venue on the diagnosis of FAS, knowledge of the biomedical processes that result in FASDs, selecting appropriate tools to screen and diagnose FAS and other prenatal alcohol-related disorders, risk factors and intervention for secondary disabilities, and screening and diagnosing women for high risk drinking.

- The *Attitudes* content areas assess the perception of stigma associated with an FAS diagnosis; whether rates of FAS are found at similar rates in all socio-economic, ethnic and cultural groups; the perception of alcohol as a teratogenic agent; and attitudes regarding long range results for persons living with these conditions. Also included are questions to assess perceived competence in identifying children/persons with possible FAS or other prenatal alcohol-related disorders; diagnosing FAS; managing treatment of children/persons with FASDs; screening women for drinking during pregnancy; identification of barriers to the diagnosis and treatment of these conditions; and preferences for clinical education and support materials.

- The *Practice* content areas of the survey consist of the use of FAS diagnostic schema in clinical practice and type of FAS diagnostic schema. Also included are questions to assess provision of patient education regarding the risks associated with drinking during pregnancy and factors contributing to why some providers do not make the diagnosis of FAS in practice.

The resulting estimates garnered from these surveys will be used to identify gaps in knowledge regarding FASDs with respect to demographic and provider practice characteristics. In addition, the results of these surveys will be used to modify and improve existing training programs for medical and allied health students and practitioners and aid in the further development of such training programs.

3. Use of Improved Information Technology and Burden Reduction

The administration of the survey will not employ automated, electronic, mechanical or other technological collection techniques. Montaño, et al. (1998) found that clinicians prefer a mailed survey for a number of reasons.[5] First, a hard copy mailed survey is much more convenient and feasible for a health care practitioner engaged in a busy practice. A mailed hard copy survey removes the constraints of necessitating the use of electronic equipment, for example computers or telephones for lengthy time intervals. The mailed survey can be completed in successive periods, at different times during the day or night, allowing for necessary business or personal interruptions. Surveys conducted by computer or telephone require uninterrupted blocks of time

to complete which may be difficult to negotiate around patient scheduling or personal responsibilities.

Second, while computers are accessible and usable for many persons, not all physicians and health practitioners, particularly older ones, feel comfortable with this technology. Moreover, clinicians educated 20 or more years ago are a primary target of this survey. Previous studies indicate that this group may not have benefit of the most current knowledge regarding fetal alcohol exposure and its consequences. Mailed surveys may be a way of reaching this group more efficiently than other methods.

Third, some physicians may feel that computer and telephone surveys do not offer complete confidentiality. Fear of computer hacking associated with computer identification and fear of telephone interviewers revealing personal telephone numbers via caller identification hardware may be a concern for some. In the context of other research on provider knowledge and practice regarding FAS, electronic administration of a survey was not an effective tool for recovering data.[6] For these reasons, the optimal choice to reach a diverse, but representative sample of clinicians, we propose the use of a printed survey delivered via Federal Express.

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

Our team of experts, made up of CDC and RTC staff, formed a Survey Work Group in December of 2003 and conducted exhaustive literature reviews regarding physician's surveys to ascertain knowledge, attitudes, and practice about fetal alcohol exposure. Some studies recovered were dated.[7] Reports based on two recent practitioner surveys were recovered.

a. Clarke M. Tough, SC. 2003. A National Survey Regarding Knowledge and Attitudes of Health Professionals about Fetal Alcohol Syndrome. Health Canada Final Report, January 2003.[6]

b. Shane T. Diekman, et al. A Survey of Obstetrician-Gynecologist on Their Patient's Alcohol Use During Pregnancy. ACOG. Vol 95, Number 5. May 2000.[3]

The findings of the Canadian survey, which targeted pediatricians, family physicians, psychiatrists, obstetrician/gynecologists and midwives, suggest that knowledge, attitudes and practice behavior regarding FAS varied significantly among the types of health care professionals. The American survey, Diekman, et al. 2000,[3] was assessed only of obstetricians and gynecologists. Information from a broader group of health care professionals in the United States is required to adequately inform the development of current training programs for health practitioners across the spectrum of providers.

The proposed surveys will assess the knowledge, attitudes and practice regarding fetal alcohol exposure among American health care providers. Additionally, the surveys described herein will provide information regarding the current state of practitioner knowledge regarding up-to-date recommendations, screening tools and diagnostic criteria, and binge and heavy drinking thresholds for pregnant women. With the evolving science, these recommendations, criteria and thresholds have changed. Thus, surveying health practitioners periodically will contribute to the process of keeping education programs in touch with practice behaviors in the field, aid in the

process of timely curricula modification, and facilitate a dynamic relationship between praxis and pedagogy.

5. Impact on Small Businesses or Other Small Entities

There has been very minimal impact on the health practitioner's practice attributable to the administration of these surveys. A major objective in developing the surveys was to insure that they were concise and could be completed as expeditiously as possible. The RTC Survey Work Group consisted of practicing physicians and research methodologists. The group worked diligently on developing the surveys to include the minimum number of questions necessary to capture the content areas. As a component of development of the project, we consulted with colleagues at the American Academy of Pediatrics and compared this survey to others where the burden is known. Based on the administration of similar surveys, we estimate each survey will take 25 minutes or less to complete.

6. Consequences of Collecting the Information Less Frequently

In recent years, a variety of educational courses and materials for health care professionals have been developed that address one or more aspects of FASD prevention, identification, and treatment. However, to date, no other group has developed a comprehensive set of FASD competencies for medical and allied health practitioners and students. The collection of data regarding FASDs from medical and allied health practitioners is essential to efforts to develop training programs for medical and allied health schools. Without the knowledge of what a broad range of health care professionals know about fetal alcohol exposure and how they use this knowledge, we are without an evidence base for the design of a set of core competencies for curricula to teach about this field. Furthermore, we must have periodic assessments of existing training-to-practice knowledge and behaviors to continually redress FASD curricula in medical and allied health schools. There are no legal obstacles to reduce the burden.

7. Special Circumstances

The administration of this survey has no special circumstances and meets all guidelines outlined in 5 CFR 1320.5 pursuant to respondent's rights, confidentiality and anonymity.

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

8.A. 60 Federal Register Notice

A 60 day notice was posted in the Federal Register Notice and published in the *Federal Register* on November 26, 2007, page 65966, Volume 72 Number 226. One comment from the public in response to this notice was received and was responded to by the CDC OMB Office. [Please see Appendix B.]

8.B. Consultation with individuals outside of the organization

CDC consulted with FAS RTC principal investigators and staff in the development of this collection of information. These training centers are Meharry Medical College in Nashville, TN., Dr. Roger Zoorob, Principal Investigator; the University of Medicine and Dentistry of New Jersey in Newark, Dr. Michael Brimacombe, Principal Investigator; St. Louis University in Missouri, Dr. Mark Mengel, Principal Investigator; and the University of California at Los Angeles, Dr. Margaret Stuber, Principal Investigator. These individuals are well known in the field of medical education, as well as for their contributions to the fields of medicine, working with children with developmental disabilities, and family practice. Contact information for these individuals follows:

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9. Explanation of Any Payment or Gift to Respondent

No gifts or compensation will be given to respondents who complete the survey.

10. Assurance of Confidentiality

The CDC Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is applicable. Names and addresses will be used to contact respondents.

Personal identifying information will not be collected on the survey. All responses, including answers to questions regarding knowledge, attitudes and practices regarding fetal alcohol exposure will be considered private to the extent allowed by law. Clinicians will not be identified by name, or any other identifying information, on the survey instrument. No attempt will be made to connect responses with specific practices or sites.

Privacy and quality assurance procedures will be in place through-out the data collection process. A tracking and receiving system will be established to ensure privacy and improve efficiency in the collecting the data. An identification number will appear on the questionnaire to facilitate re-contact of non-respondents, only. An active list of potential respondents based on population based survey procedures will be established utilizing the identification numbers. After practitioners have either completed a survey, refused to participate, or are designated as a non-responder (after three attempts to contact), they will be removed from the active list. At this

time all links to the clinician will be destroyed. Clinicians will remain on the active list until one of the three outcomes is ascertained. After the process is completed for all persons receiving the survey, links to all clinicians will be destroyed. Only aggregate statistics such as percentages will appear in published reports.

11. Justification for Sensitive Question

The questionnaires do contain sensitive or intrusive questions. CDC will ask the respondents to supply race and ethnicity information. This information will only be used for cross-tabulating demographic information with FAS knowledge, attitudes, and practice variables to identify specific training needs for physicians and other health care professionals by demographic groups. Results from a similar pediatrician survey, sponsored by the American Academy of Pediatrics, were published in September 2006 in *Pediatrics*[8] (see Appendix K) and suggested that knowledge, attitudes, and practice regarding FAS vary by demographic characteristics, and consideration of these differences is important for the development of curricula for medical education.

12. Estimates of Annualized Burden Hours and Costs

12. A. Annualized Burden Hours

The annualized burden estimates are based on the administration of similar surveys and estimates of time required for practitioners to complete the survey. It is estimated that the survey will take approximately 25 minutes to complete. This estimate was based on previously conducted surveys similar in length and content published in 2000 by Diekman, Shane, et al [3]. Although previously we had hoped for an 80% response rate, we have adjusted our estimates to a 60% response rate based on actual results to date. Due to this adjusted expected response rate, we would like to increase our sample size to 1,500 providers within each group. At a response rate of 60%, this would yield 900 respondents. In terms of the actual annualized burden, it should be noted that an average of only one group of providers is surveyed per year. Therefore, the actual burden per year is only for one provider group (total of 375 hours). (See section A15 for a more detailed explanation of these program adjustments).

Table 1. Annualized Burden Hours

Survey Title	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours
Selected Survey Form	900	1	25/60	375

The OBGYN survey and psychiatrist survey have already been deployed. Thus, this revision request entails 1) the first-time deployment of the allied health professional survey and the family physician survey, 2) the iterative redeployment of the OBGYN and psychiatrist surveys, and 3) the deployment of the pediatrician survey which would serve as a comparison of

the AAP-sponsored, previously administered survey of pediatricians described above. Based on the findings of the OBGYN and psychiatrist surveys, which are currently being analyzed, the FAS Prevention Team might wish to re-assess these provider groups in future years. Provider education is a critical focus of efforts toward the prevention, diagnosis, and management of FASDs. Continuous insight into the knowledge, attitudes, and practices of professional groups working with women at risk for an alcohol-exposed pregnancy and with individuals who might have FASDs is necessary in order to tailor education and training activities.

12. B. Cost to Respondents

Annualized cost estimates to potential respondents are presented in Table 2 and are based on mean (average) hourly wage estimates obtained from the U. S. Department of Labor, Bureau of Labor Statistics for Healthcare Practitioners (http://www.bls.gov/oes/current/oes_nat.htm#b29-0000). The estimates for the physicians listed in the table were taken directly from the U.S. Department of Labor report. There are many varieties of allied health professionals including nurses, physician's assistants, occupational therapists, speech-language pathologists and so on. The average hourly wage estimate for allied health professional was obtained by averaging the hourly wage of nurses, physician's assistants, occupational therapists and speech-language pathologists. Costs are based on an estimate of 25 minutes per respondent to complete the survey. In terms of the actual annualized cost burden, it should be noted that an average of only one group of providers is surveyed per year. Therefore, the actual cost burden per year is only for one provider group (an average of $24,597).

Table 2: Annualized Cost Burden

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Average Hourly Wage	Average Respondent Costs
Selected Survey Form	900	1	25/60	$65.59	$24,597

13. Annualized Cost to the Respondents

There are no capital, start up, operation, or maintenance costs to respondents associated with this proposed collection of information.

14. Annualized Cost to the Government

Start up costs are based on estimates provided by the contractor who is currently involved in the administration and data collection activities for the psychiatrist survey and is anticipated to also administer and analyze the family physician survey. CDC's FAS Prevention Team has contracted with the Battelle Centers for Public Health Research and Evaluation (BCPHRE), a research organization of the Battelle Institute, to administer the surveys, enter the data into SAS and SPSS data bases, manage the data bases, analyze the data, and produce reports. Battelle produced the cost estimates based on staffing requirements, wages and expected expenditures of similar projects.

For other surveys within this package, the professional organization from which the sample is drawn and/or a contractor with whom CDC will collaborate, will carry out the administration and analysis of the surveys. For example, for the survey of obstetrician-gynecologists, administration of the survey is being conducted by the American College of Obstetricians and Gynecologists (ACOG). CDC has awarded $50,000 to ACOG under its larger cooperative agreement with NCBDDD, "Enhance Clinical Practices to Prevent Birth Defects and Developmental Disabilities and to Promote Health Among Women with Disabilities" to carry out these activities. Therefore, annualized cost to Government is $60,550.

Table 3: Governmental Costs*

Item / Activity	**Details**	***$ Amount***
CDC oversight of contractor and project	10% of time: GS-13 Health Education Specialist, Behavioral Scientist, or Epidemiologist	$ 10,000
Mailing List Labels from Organizations Each set of labels cost approx. $200 (Five each for 4 mailings)	[$200 x 4 mailing = $800] [$800 x 5 orgs] $4000	$4,000
Survey Development, programming tracking system, Battelle/contractor/organization IRB clearance	Services of a Project Director, Study Manager and Computer Programmer (250-300 hours) Word Processor and Data Prep staff (80-120 hours)	$40,000.
Print surveys, envelopes, letters and postcards	Direct cost of printing 5 versions of the survey for multiple mailings	$40,000.
Package assembly, FedEx and other mailing fees	Mail house services to assemble and send based on a maximum of 22,500 packets at $3.50 per mailing	$78,750
Open returns, update tracking, coding and keying data into data base	1500+ hours of labor	$85,000
Analysis and Report	75 hours of labor per survey version(5) totaling 375 hours of labor	$45,000.
Total		$302,750

***Costs are based on all five surveys, however, only an average of one survey of providers is conducted per year.**

15. Explanation for Program Changes or Adjustments

This is a revision. Previously, we assumed we would deploy all five surveys in one year. In actuality, it has been an average of one survey per year. Previously, we assumed it would take 30 minutes for a respondent to complete the survey, yet in practice, it is more accurate to estimate 25 minutes for completion of the survey. Previously, we had expected an 80% response rate and had thus used a sample size of 1,000. However, a response rate of 60% is more realistic and thus, we would prefer to increase the sample size to 1,500 to yield 900 respondents.

16. Plans for Tabulation, Publication and Project Time Schedule

A.16-1 Project Time Schedule

We anticipate beginning the project immediately following OMB clearance. Once the data is entered into the computer data base, data analysis will begin.

Data analysis plan

Exploratory analyses will be performed to investigate the relationships among the variables, and to identify data anomalies. The exploratory analysis will consist of calculating descriptive statistics or one-way frequencies of all knowledge/attitudes/practices and background information variables. The cross-tabulations of all knowledge/attitudes/practices variables will be with demographic variables such as age, race, gender, employment site, urban vs. rural practice, number of years in practice, and region of the country. Additional analysis between specific variables will be conducted for the purposes of tailoring and refining curricula and training materials for each group of respondents.

Association between all knowledge/attitudes/practices variables and demographic variables will be tested using Pearson's Chi-square tests for independence. The Pearson chi-square statistic for two-way tables involves the differences between the observed and expected frequencies, where the expected frequencies are computed under the null hypothesis of independence. A P-value less than 0.05 between a FAS variable and a demographic variable will be considered statistically significant. To test for the survey's internal consistency, Cronbach's alpha will be used as a numerical coefficient of reliability. Cronbach's alpha is an index of reliability associated with the variation accounted for by the true score of the "underlying construct." The construct is the hypothetical variable that is being measured. The alpha coefficient ranges in value from 0 to 1 and may be used to indicate reliability of a survey instrument. Reliability scores of .5 or higher are acceptable.[9]

Publications

Upon completion of the data collection, the team will collaborate on specific analysis plans, curriculum development, and curriculum dissemination. CDC will also publish findings in peer-reviewed journals.

Table 4: Project Time Schedule

Title	Activity	Time Schedule
Prepare and Print Surveys	Use master copies following IRB/OMB approval.	1 month after Clearance
First phase administration	Use membership lists, Send surveys via Federal Express mail and follow-up postcards	1 month after Clearance
Second phase administration	Use membership lists minus respondents who completed surveys, send surveys via Federal Express mail and follow-up post cards	2 months after Clearance
Third phase administration	Use membership lists minus respondents who completed surveys, send surveys via Federal Express mail and follow-up post cards	3 months after Clearance
Fourth phase administration	Use membership lists minus respondents who completed surveys, send surveys via Federal Express mail and follow-up post cards	4 months after Clearance
Data entry	Data manager will oversee the process	5 months after Clearance
Data analysis	Produce statistics	6 months after Clearance
Reports	Draft Reports	7 months after Clearance

Note: This project time schedule is for the first survey to be completed after OMB approval. Subsequent surveys will follow a similar schedule.

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

N/A

18. Exceptions to Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.

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