PART B 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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B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The five surveys are self-administered questionnaires consisting of nominal, ordinal and interval/ratio scales, designed to capture knowledge, attitudes and practice behavior regarding fetal alcohol exposure and practitioner characteristics. The questionnaires are constructed for mail distribution. The surveys consist of questions in modular format covering the following content areas: FASD epidemiology and dysmorphology; risk drinking; diagnosis and treatment of FASDs; training experience and training needs; and provider background information. No personal identifying information such as name or identification numbers is requested. The survey will be distributed by Federal Express mail. Each questionnaire will be mailed with a letter of explanation (Appendix H) and a stamped, self-addressed envelop for returning the questionnaire.

1. Respondent Universe and Sampling Methods

Universe

The sampling frame from which we will draw our sample will be the total active membership lists of each professional health care practitioner organization. The professional organizations that will be targeted are: the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), the American Medical Association, and the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN). The table below lists the sampling frame size, the sample size, and expected response rate for each professional organization.

Table 5: Estimated Size of Respondent Universe and Proposed Study Sample

Survey Title	Organization Providing Sampling Frame	Number of Possible Respondents (i.e., total membership)	Sample Size	Response (60%)
Survey of Pediatricians	AAP	34,000	1500	900
Survey of Obstetrician- Gynecologists	ACOG	45,000	1500	900
Survey of Psychiatrists	AMA	66,000 (psychiatrists)	1500	900
Survey of Family Physicians	AAFP	55,000	1500	900
Survey of Allied Health Professionals	AWHONN	22,000	1500	900
	Total		7,500	4,500

Methods

CDC IRB clearance has been obtained for the surveys. After achieving Office of Management and Budget clearance, the plan is to administer the surveys to health care practitioners through selected professional organizations: the American Academy of Family Physicians (AAFP); the American College of Obstetricians and Gynecologists (ACOG); the American Medical Association (AMA), the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), and the American Academy of Pediatrics (AAP). [In the context of a different NCBDDD project, the American Academy of Pediatrics has published findings from a similar survey they administered to pediatricians in 2003⁸ (appendix K). Thus, we will administer the survey to a different sample of AAP pediatricians and compare the results with the study conducted earlier.]

Selection Criteria, Sampling, Response Rate

Approximately 1500 participants will be selected from each organization's active membership lists. Utilizing computer generated (SPSS or SAS) stratified and systematic random sampling procedures, efforts will be made to select respondents representative of sex, race and age strata consistent with practitioner population parameters. Further, only currently practicing professionals involved in direct patient care will be selected. These criteria will be made clear to each professional organization participating in the survey.

We expect to achieve approximately 60% completion and response rate. Diekman, et al 2000 administered a similar survey, using similar methods to obstetrician-gynecologists and achieved a 60% response rate. The AAP-sponsored survey of pediatricians discussed previously achieved a 55% response rate.⁸ The psychiatrist survey (the only survey from this package completed to date) achieved a 41% response rate. While this is generally considered low, the contractor who administered the survey, Battelle Memorial Institute, has indicated that it is actually quite a respectable response rate considering no incentive was provided to the respondent. In addition, the cover letter was sent from the Director of NCBDDD rather than a professional organization working directly with the respondent audience (psychiatrists). The respondents might have felt that a survey coming from CDC was less relevant to them than others they might receive. Other surveys we are conducting (e.g., the survey of obstetrician-gynecologists) is being addressed to the respondent from the American College of Obstetricians and Gynecologists (ACOG). In addition, as indicated above, ACOG has achieved a 60% response rate in the past with a very similar survey. Thus, we expect to achieve approximately a 60% response rate on the remaining surveys, provided that we work directly with the professional organization(s) affiliated with each professional group.

2. Procedures for the Collection of Data

We propose to use a printed survey delivered via express mail. Federal Express is our preferred express mail provider. The survey will be sent by Federal Express since this usually is given directly to the clinician rather than being filtered by office staff. The initial questionnaire mailing will be followed by a reminder postcard after one week, a second mailing to non-respondents at four weeks, a third mailing at week seven, and a fourth and final mailing at week ten. A study-specific computerized tracking and reporting system has been designed to monitor

all phases of the study. The database will hold all respondent information and track the study's progress through all phases. The data management system will track the mailing dates for the questionnaires and postcards, and flags will be set to initiate follow-up mailings and reminder postcards. The receipt of a completed questionnaire, or a refusal, will be logged into this computerized control system. From this system, electronic progress reports will be generated on a weekly basis. This system will reduce respondent burden by ensuring clinicians are contacted at appropriate time points and are not sent mailings too many times. In addition, this system will track respondents to ensure that the ones who have responded are not contacted with reminders. Bar codes containing participant ID numbers will be printed on surveys and signature postcards. Reading of these barcodes upon receipt of signature postcards and surveys will be used to record participants' final dispositions (complete, ineligible, letter undeliverable, refusal, etc).

The contractor or the professional organization administering each survey will conduct the following activities:

- Assign a data base manager and program assistant to coordinate administration of the survey.
- Obtain mailing labels from CDC FAS Survey Working Group.
- Administer the survey by express mail.
- A participation identification number will be assigned to all potential participants. These identifiers will be used to re-send surveys to non-respondents. Only the Battelle program manager and program assistant will have access to the link between participant names and identification numbers.
- Procedures to decline participation in the survey will be incorporated into the letter of introduction mailed to potential respondents. A code for those health practitioners who chose to decline will be established to prevent subsequent mailings to those individuals.
- Ensure that the response rate conforms or exceeds the range specified above (80%) and is adequate to provide the statistical power needed to infer results to the larger population of practitioners utilizing a first and reminder mailings. Four mailings will be necessary in some cases.
- Develop a data analysis plan that includes computer SAS and SPSS software.
- Enter data into computer software programs and maintain data base.
- Conduct the analysis of data.
- Comply with CDC rules regarding anonymity and confidentiality of the data.
- Provide reports of the national data analysis and 4 region-specific reports for the four Regional Training Centers.
- Release the data sets to the CDC upon completion of the reports.

As mentioned above, 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, members of the American College of Obstetricians and Gynecologists (ACOG) Collaborative Ambulatory Research Network (CARN) are being invited to participate in the survey. CARN is comprised of a group of 1,567 practicing ACOG Fellows and Junior Fellows who have agreed to complete 4-5 surveys throughout the year. CARN is designed to be a representative sample of ACOG membership. The demographics of the CARN group closely resemble those of the larger member population. For this survey, 1,000 members will be sampled. Responses will be private to the extent

allowable by law. Physicians will not be asked to provide any personal identifying information on the survey, but will be assigned a number that will be associated with the survey that is mailed to them. This numbering system is used to track which surveys have been returned.

3. Methods to Maximize Response Rate and Deal with Non-Response

Though mailed surveys are the cheapest and sometimes most efficient form of data collection, this format has a number of advantages and disadvantages. Advantages include accessibility, reduction of bias, and anonymity. The mailed survey can reach a wide geographic distribution of respondents at low cost. The absence of an interviewer reduces biased answers that might result from the personal characteristics of an interviewer and provides greater anonymity to respondents. The disadvantages of mailed surveys include: careful question construction, no opportunity for probing, no control over who actually completes the questionnaire and low response rate. Questions must be carefully constructed so that the meaning is clear and explicit. If questions are not clear enough for the respondent to make an informed choice among response categories, then the validity of measures is called into question. Without an interviewer conducting the encounter with the respondents, there is no opportunity to probe for additional information regarding content areas and no opportunity to ascertain if the desired respondent is actually completing the questionnaire. Putting these concerns aside, the most important disadvantage of mailed questionnaires is the low response rate.

Questionnaires mailed to respondents using the simple, stamped return envelop method without

Questionnaires mailed to respondents using the simple, stamped return envelop method without follow-up generate a 20 to 40% response rate.¹¹

Methods to enhance response rate include: brief questionnaire format and follow-up mailings utilizing confidential lists of respondents. The initial survey will be sent to clinicians via Federal Express. Packets will be sent via priority US mail to clinicians with PO Box addresses since Federal Express does not deliver to these addresses. This mode of mailing has been demonstrated to result in higher response rate than first class mail. ¹⁰ The packets will include a cover letter, survey, stamped, self-return signature response postcard (with space to indicate a reason for ineligibility), stamped self-return envelope. The cover letter will be either printed on CDC letterhead and signed by the Director of NCBDDD (as was the case in the survey of psychiatrists) or will be on the organization letterhead and personalized from the professional organization working most closely with the respondent audience (e.g., from the American College of Obstetricians and Gynecologists for the survey of obstetrician-gynecologists. The letter will emphasize that the survey seeks clinician input in order to help CDC and provider organizations develop clinical training materials, and aid in the development of model FAS curricula for medical and allied health schools. The letter will also contain an 800 toll number for the recipient to call in case the packet does not reach the intended provider. This number will be located in the contractor/professional organization office responsible for the survey mailings. Because it is important to ensure that the clinician, rather than the office manager, completes the questionnaire, we will ask each participating clinician to sign the signature postcard attesting to the fact that he/she completed the survey instrument. The signature postcard is also designed for an ineligible clinician to indicate that he/she is no longer practicing or see women who are at risk of having an alcohol-exposed pregnancy, or physicians and other health care professionals who no longer treat persons affected by fetal alcohol exposure. The signature postcard will also provide an easy method for someone opening the package to inform us that the clinician is

deceased or moved. We have found that when clinicians have moved or are ineligible or deceased, such a postcard is more likely to be returned than an entire survey packet. We will not be able to offer incentives for providers to complete the survey at this time. Copies of the survey cover letter and signature postcard are included in the appendix.

A reminder postcard (see appendix I) will be sent via first class mail to all sampled clinicians one week after the initial packet mailing. It is expected that the first mailing and reminder postcard will result in return of about 33% of the questionnaires. A copy of the reminder postcard is included in the appendix. The reminder postcard thanks the respondent if they already replied to the survey and offers the respondent the chance to call if they never received the survey, if they misplaced the survey and require a new copy, or if they have any questions.

A second mailing will be sent via Federal Express to non-respondents two to three weeks after sending the reminder postcard. The second mailing will include a cover letter reminding the clinician that he/she previously received the survey and reiterating the importance of their response. This letter will be printed on CDC letterhead and personalized. It is expected that this will increase the overall return rate to about 50%. A copy to the second reminder letter is included in the appendix.

A third mailing will be sent via Federal Express to all non-respondents two to three weeks after the second mailing. This should encourage another 5% of the original sample to return a completed survey, bringing the return rate to approximately 55%. A copy of the third reminder letter is included in the appendix.

A fourth mailing will be sent via Federal Express to all non-respondents two to three weeks after the third mailing. This should encourage another 5% of the original sample to return a completed survey, bringing the return rate to approximately 60%. A copy of the fourth reminder letter is included in the appendix.

4. Tests of Procedures or Methods to be Undertaken

The RTC Survey Work Group conducted a pilot study using a similar protocol and survey instrument with the help of the American Academy of Pediatrics in May-September 2003. Utilizing a standard multiple mailings format, of 1600 potential respondents, we received 879 completed surveys, a 55% response rate. Battelle has conducted a number of similar studies using the Federal Express, postcard and multiple mailings format in which 80% response rate was garnered. Based on the success of these studies, and the proposed similar methodology, we had hoped to also reach an 80% response rate. However, as discussed above in section B1, we are revising our expectation to a 60% response rate based on our experience thus far in administering these surveys.

5. Individuals Consulted on Statistical Aspects and Individuals Collection and or Analyzing Data

I) Designed the Data Collection Instruments

The workgroup was comprised of:

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II. & III. Collect and Analyze the data

The Battelle Centers for Public Health Research and Evaluation will be contracted to print and administer the surveys, collect and analyze the data. Diane Burkom will lead the effort to administer the survey. She will assign members of her staff to specific duties as outlined in section **B 2 and 3**.

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Specific to the obstetrician-gynecologist survey, conducted and analyzed by ACOG, Dr. Jay Schulkin and his colleagues will lead these efforts.

Jay Schulkin, PhD American College of Obstetricians and Gynecologists (202) 863-2504 jschulkin@acog.org

REFERENCES

- 1. Stratton, K., Howe, C., Battaglia, F., editors. 1996. *Fetal Alcohol Syndrome: Diagnosis, Epidemiology, Prevention and Treatment*. Institute of Medicine. National Academy Press. Washington, D. C.
- 2. 10th Special Report to Congress on Alcohol and Health. 2000. *Highlights from Current Research*. "*Prenatal Alcohol Exposure: effects on Brain Structure and Function*". U. S. Department of Health and Human Services: 285-299.
- 3. Diekman, S., Floyd, R.L., Decoufle, P., Schulkin, J., Shahul, E., Sokol, R.J., 2000. A Survey of Obstetrician-Gynecologist on Their Patients' Alcohol Use During Pregnancy. *Obstetrics and Gynecology* 95(5): 756-763.
- 4. U.S. Department of Health and Human Services. *Healthy People 2010*. 2nd *Edition*. Understanding Statistics and Improving Health and Objectives for Improving Health. Washington, DC: U.S. Government Printing Office, November 2000. www.healthypeople.gov/document/HTML/Volume2/16MICH.htm
- 5. Montaño, D.E., Kasprzyk, D., Phillips, W.R., John, L. 1998. *Evaluation of Physicians' Knowledge*, *Attitudes, and Practices Related to Screening for Colorectal Cancer*. Final Report to the American Caner Society.
- 6. Tough, C.M. 2003. *A National Survey Regarding Knowledge and Attitudes of Health Professionals about Fetal Alcohol Syndrome*. Health Canada Final Report, January 2003.
- 7. Morse, B.A., Idelson, B.K., Sachs, W.H., Weiner, L., Kaplan, L.C. 1992. Pediatricians' Perspectives on Fetal Alcohol Syndrome. *Journal of Substance Abuse*, 4:187-195.
- 8. Gahagan, S., Sharpe, T.T., Brimacombe, M., et al. 2006. Pediatricians' knowledge, training, and experience in the care of children with fetal alcohol syndrome. *Pediatrics*118(3):e657-e668.
- 9. Reynaldo, J., Santos, A. 1999. Cronbach's Alpha: A Tool for Assessing the Reliability of Scales. *Journal of Extension* 37(2).
- 10. Kasprzyk, D., Montano, D.E., St. Lawrence, J., Phillips, W.R. 2001. The effects of variations in mode of delivery and monetary incentive on physicians' responses to a mailed survey assessing STD practice and patterns. *Evaluation and Health Professions*, 24(1):3-17.
- 11. Nachmias, C.F., Nachmias, D. 1996. *Research Methods in the Social Sciences*. St. Martin's Press. New York.