Request for OMB Review and Approval

Survey of Knowledge, Attitudes and Practice Management Patterns of Obstetricians Regarding Stillbirth Pregnancy Outcomes

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December 19, 2006

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A Survey of Knowledge, Attitudes and Practice Management Patterns of Obstetricians Regarding Stillbirth Pregnancy Outcomes

Supporting Statement

Justification

1. Circumstances Making the Collection of Information Necessary

Stillbirth (intrauterine fetal death or fetal demise) is one of the most common adverse outcomes of pregnancy, and yet it remains one of the least studied outcomes, particularly from a population-based perspective. In the U.S., it is estimated that 7 stillbirths occur for every 1000 live births, accounting for approximately 1% of all pregnancies and about one half of all perinatal deaths (1, 2). The true incidence of fetal death in the U.S. is unknown because systematic, ongoing, population-based monitoring of this outcome has been lacking. Although fetal deaths are by law a reportable event in most states, it has been well documented that fetal deaths, and in particular early fetal deaths, are under-reported to vital records (3, 4). Furthermore, with few fetal death surveillance programs in this country, it has not been possible to adequately document temporal prevalence trends of stillbirth outcomes, thereby limiting efforts to better identify causal relationships. Ongoing surveillance of stillbirths is needed in order to devise and conduct adequate population-based epidemiologic studies into stillbirth risk factors and causes, including environmental influences.

The challenges in conducting stillbirth surveillance and research include heterogeneous reporting practices of stillbirth occurrence in terms of completing a fetal death certificate, incomplete and inaccurate recording of data in the medical record, no national accepted standard definition of stillbirth, and no standardized postmortem fetal death evaluation protocol. These factors make data compilation from multiple sources difficult to interpret.

Although many risk factors have been identified and associated with stillbirth, most, if not all, of these factors are non-specific and are associated with adverse pregnancy outcomes in general rather than stillbirth. Therefore, population-based surveillance activities are essential to better identify and characterize an at-risk population for stillbirth, both in terms of mothers and fetuses at risk (5). Likewise the heterogeneity of risk factors for stillbirth along the spectrum of gestational age, as well as potential interactions of risk factors, is unknown. Equally alarming is the fact that upwards of three-fourths of all stillbirths lack an identifiable cause (6), due in large part to inadequate and incomplete evaluation of fetal deaths, lack of and inconsistent use of post-mortem protocols and incomplete documentation of potentially relevant information.

The Metropolitan Atlanta Congenital Defects Program (MACDP) was established in 1967 as a population-based birth defects registry to monitor prevalence and trends of birth defects in the metropolitan Atlanta area (counties of Fulton, Dekalb, Cobb, Gwinnett and Clayton). MACDP is administered by CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD). As with most birth defect surveillance programs,

stillbirths having an identifiable malformation are included in the registry; however, stillborn fetuses without identifiable malformations have not been routinely monitored. In an effort to overcome the knowledge gaps relative to fetal deaths, occurrence of stillbirth and associated causes, the Metropolitan Atlanta Stillbirth Surveillance Project will establish a surveillance program to monitor fetal deaths in the 5-county metropolitan Atlanta area.

Population-based etiologic studies of stillbirths are essential for the identification of mothers and fetuses at risk for stillbirth, and ongoing monitoring of this outcome is needed to establish reliable and accurate registries for conducting such studies. Although fetal deaths are a reportable event in Georgia and other states, evidence suggests that these events are under-reported in vital registries (8). Furthermore, the recorded data in these registries are often unreliable, nonspecific and inaccurate for conducting etiologic studies. In fact, only 8% of respondents in a national random survey of Fellows in the American College of Obstetrics and Gynecology believed that state and national data collected on fetal deaths were reliable. (7)

The proposed survey of obstetricians will be conducted among those practices serving the population of the MACDP 5-county area. It is designed to measure the attitudes and knowledge of obstetricians about stillbirths in their practice and in general, their attitudes regarding importance of accuracy and completeness in documentation and reporting and to assess the heterogeneity of stillbirth evaluation procedures. The results of this survey will help to identify relevant knowledge gaps in conducting stillbirth surveillance. This knowledge will be used to develop and implement a targeted educational strategy to improve case reporting and data quality.

The only other similar survey we are aware of was conducted at the national level among Fellows in the American College of Obstetrics and Gynecology (ACOG). (7) This study utilized a short survey to assess physician practice patterns and opinions concerning intrauterine fetal demise (IUFD) with 17 multiple-choice and 5 Likert-scale items. Similar items and topics will be used in our survey; however, many questions will be tailored around our stillbirth surveillance activities to identify barriers for educational targeting. The sample of respondents who completed the ACOG survey was not representative at either the national or county levels, so the extent to which the practice patterns and opinions observed in this previous study apply to obstetricians in the MACDP 5-county area is unclear.

The Centers for Disease Control and Prevention (CDC), an Agency of the Department of Health and Human Services, is authorized to collect this information under provisions of the FY 2005 Appropriations Bill (P. L. 108-792) and under Sections 317C and 301 of the Public Health Services Act (42 U.S.C. 247b-4 and 42 U.S.C. 241, respectively). Specifically, funding has been appropriated “to support the development of a pilot project to expand existing birth defect surveillance systems to include fetal death data at the Iowa Department of Health and the Metropolitan Atlanta Congenital Defects Program.” (Attachment A -1)

2. Purpose and Use of Information Collected

The stillbirth surveillance project is a pilot project designed essentially to assess the feasibility of expanding the existing birth defects surveillance programs in Atlanta (MACDP). The purpose of the MACDP stillbirth surveillance project is to: (1) evaluate and devise a strategy to expand the population-based birth defects surveillance system (MACDP) to include existing records on fetal deaths in this population; (2) initiate ongoing monitoring and reporting of stillbirths in this study population, and provide baseline data on stillbirth occurrence in the population served by MACDP; (3) serve as a registry for etiologic studies regarding fetal deaths; (4) serve as a resource for education and information in devising, implementing and evaluating fetal death prevention strategies; (5) serve as a resource for estimating and developing service needs for grieving mothers and families..

The purpose of this survey is to gather information regarding knowledge, attitudes and practice patterns relating to stillbirths among obstetricians practicing in the 5 county area monitored by MACDP . There is no nationally accepted definition of what constitutes a stillbirth, and no universal guidelines exist for systematic and uniform post-mortem evaluation. This survey is specific for MACDP obstetric practices and will help to qualify local understanding of knowledge and attitudes relative to stillbirth occurrence and identify the varying protocols and procedures, if any, used to evaluate these outcomes. This information will then be used to develop educational strategies designed to raise awareness regarding the need for stillbirth surveillance and emphasize the importance of post-mortem evaluation with accurately recorded data. Implementation of such strategies will ultimately improve the quality of data in the medical record that can be abstracted for surveillance purposes. More specifically, the survey contains measures to assess the following:

1. The *knowledge* content areas of the survey will assess obstetricians' understanding of what constitutes a stillbirth. Questions will ask what gestational and/or weight cut-off values best define a fetal death, as well as what clinical criteria they use to distinguish a fetal death from an early neonatal death. This information will help to identify areas where misclassification of outcome status may be occurring. The importance and types of support offered to families in the aftermath of a stillbirth will also be assessed.
2. The *attitudes* content areas will assess obstetricians' overall perception regarding the importance of stillbirth in individual practice as it relates to their patient population as well as the importance of stillbirth evaluation in identifying causes. Questions will also gauge attitudes toward the importance of a national research agenda on stillbirths and the need for surveillance of this outcome. The importance of this outcome to each individual practice will be determined as well as the importance of accurate, reliable and timely information on stillbirth occurrence. This information will aid in developing strategies to increase awareness regarding the public health burden of this outcome and the importance of appropriate evaluations in determining causally associated risk factors.
3. The *practice* content of the survey will consist of questions to better define the procedures obstetricians utilize in the evaluation of stillbirth occurrence. Questions will ask how often and under what conditions autopsy consents are obtained. What, if any, alternative procedures are offered in the event of refusal. Questions will also gauge how often placental evaluations, cytogenetic testing,

gross fetal exams and other tests such as radiographs are obtained. This information will help determine the varying evaluation protocols used in the MACDP area and help in devising a strategy to promote more uniformity in stillbirth evaluation.

A survey targeted specifically at obstetricians practicing in the MACDP area will prove useful in a variety of ways. First, it will help in determining with specificity what practice strategies are being employed and are unique to obstetricians in the MACDP 5-county area, thereby allowing CDC to tailor awareness and educational strategies for improving surveillance data specific for MACDP. It will also help to promote awareness and serve as a foundation and reference point for educational strategies at each facility in the future.

3. Use of Information Technology and Burden Reduction

The administration of the survey will not employ automated, electronic, mechanical or other technological collection techniques. Montano et al. found that clinicians prefer a mailed survey for a number of reasons. (9) A hard copy survey, sent by mail, is much more convenient and feasible for a health care practitioner engaged in a busy practice to complete. 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.

As respondents return the surveys, a data management system will track the mailing dates for the questionnaires and postcards. Flags will be set to initiate follow-up mailings and reminder postcards (Attachment G). The receipt of a completed questionnaire, or receipt of the post-card indicating that the provider will not participate (three-part post card, Attachment F), will be logged into this computerized control system. Electronic progress reports will be generated from this system on a weekly basis. This will reduce respondent burden by ensuring clinicians are contacted at appropriate time points and are not sent excessive mailings. In addition, the system will track respondents to ensure that those 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) and will not be used to link participants' responses to their identities (see section A 10).

4. Efforts to Identify Duplication and Use of Similar Information

A search of the literature revealed only one similar survey conducted by the National Institute of Child Health and Development in 2001. This was a national random mailed survey sent to a sample of Fellows of the American College of Obstetricians and Gynecologists. The results of this survey were published in 2003 and described the practice patterns in the management of stillbirth. The sample of respondents who

completed the ACOG survey was not representative at either the national or county levels, so the extent to which the practice patterns and opinions observed in this previous study apply to obstetricians in the MACDP 5-county area is unclear.

In addition, as part of our planning efforts to implement stillbirth surveillance activities, two workshops have been held to explore and discuss the many issues involved in conducting surveillance on stillbirths, including data sources, quality and completeness and need for evaluation. The second meeting consisted of several clinicians affiliated with facilities served by MACDP, and the general consensus was there is likely wide variability in stillbirth management practices in the MACDP area. No one was aware of any attempts to qualify and quantify this variability. Each workshop, titled the *Metropolitan Atlanta Stillbirth Surveillance Workshop*, was sponsored by NCBDDD at CDC. Each workshop was attended by experts in the field of stillbirth management and/or research, including epidemiologists, clinicians, and public health officials (Attachments K and L).

5. Impact on Small Businesses or Other Small Entities

There should be very minimal impact on the health practitioner's practice attributable to the administration of this survey. A major objective in developing the survey was to ensure that it was concise and could be completed as expeditiously as possible. Physician respondents can complete the survey on-site before, during or after clinic hours, or they can complete it off-site. We worked diligently with experts in survey development and methodology at Battelle on developing a survey that included the minimum number of questions necessary to capture the content areas. In addition there are no record keeping requirements as part of this survey.

6. Consequences of Collecting the Information Less Frequently

The survey is not intended to be administered on an ongoing, repeated basis. The consequences of not collecting this data include delayed and inadequate improvements to the MACDP surveillance program, thereby limiting the utility of the surveillance data. Not collecting this data will also limit our ability to devise effective awareness and educational strategies.

7. Special Circumstances

This request for OMB approval fully complies with the regulation. No special circumstances apply

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

A. 60 Day Federal Register Notice

A 60 day notice was published in the *Federal Register* on December 13, 2005 (Attachment B). No comments from the public were received in response to this notice.

B. Consultation with Individuals Outside of the Organization

CDC contracted and consulted with Battelle Centers for Public Health Research and Evaluation (CPHRE), in the development of the survey sampling plan, as well as plans for the construction, distribution and collection of the survey responses. The principal contacts are:

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This consultation began in September 2005 and will continue until the survey is administered and the data collected.

The survey content was also developed through informal consultation with several clinical and public health experts in stillbirth research. Opinions and suggestions were requested from the following individuals regarding appropriate content to be covered in the survey that would produce the most meaningful data in meeting our objective. These individuals were:

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Marion Willinger represented NICHD in the informal discussions regarding the development of the survey. She discussed the burden of a 17-item survey that the National Institute of Child Health and Development (NICHD) conducted in 2001. The NICHD survey took approximately 15-20 minutes to complete. Our survey is of similar length, and we estimate it will take 15 minutes or less to complete

9. Explanation of Any Payment or Gift to Respondents

Each respondent will receive a $50 dollar incentive enclosed, as cash, with the survey (Attachment C), cover letter (Attachment D) and three part post-card (Attachment F) to encourage timely completion and return of the survey. Obtaining high survey response rates is particularly difficult for busy professionals like physicians. However, there is clear and consistent evidence that monetary remuneration significantly increases response rates in most surveys and that the amount of the incentive is positively correlated with the response rate (9, 11-13, 19, 20).

Several studies specifically designed to test the effects of incentives on physician survey response rates have confirmed the importance of monetary remuneration. One study by Everett, Price, Bedell, and Telljohann found that response rates were 18% higher among physicians receiving remuneration (63% vs. 45%) (16). Another study by Tambor et al. (1993) found significantly more physicians responded when a $25 incentive was provided compared with a no incentive control group (62.0% vs. 18.3%) (21). A third study by Berk, Edwards, and Gay divided physicians into three groups: Group 1 received a monetary incentive on the initial mailing, Group 2 received a monetary incentive on a second mailing to non-responders, and Group 3 received no incentive (22). Response rates for the 3 groups were 63%, 50%, and 40%, respectively. Gunn and Rhodes (1981) and Weber, et al (1982) tested incentives of $0, $25 and $50, and found increased physician response rates for higher remuneration (23, 24). Similarly, Kasprzyk and colleagues tested incentives of $0, $15 and $25 found increased response with higher remuneration (27%, 75% and 81% respectively) (13).

We selected a remuneration amount of $50 for two reasons. First, studies have found that as the amount of remuneration increases, response rates also increase. Too small an amount is easy to ignore and may be insignificant particularly to clinicians whose salaries tend to be higher than many other professionals who are surveyed. A $50 remuneration is not likely to be ignored by a clinician. Montaño, et. al., (2003) provided $50 remuneration and obtained 81% response on a survey of physicians and non-physician clinicians of STD risk assessment and prevention practices (25). Second, this amount is near the optimal amount used by studies that have found positive associations between remuneration amount and response rate. Although two studies found greater response when doubling the amount of the remuneration, there is evidence that response rates drop when the remuneration approaches the respondent's salary (23, 24). In sum, the selected remuneration amount of $50 is large enough to not be ignored by the clinician, yet far enough below the typical salary to avoid being viewed as reimbursement for his or her time.

The reason we elected to mail cash incentives –rather than using an alternative form of payment such as checks or money orders -- is that research has shown that cash incentives improve survey response rates to a greater extent than incentives in the form of either checks or money orders (11). Further, focus groups with physicians indicated that physicians would be more likely to respond to a survey accompanied by a cash incentive than they would be to respond to a survey accompanied by some other form of payment such as a check (13).

We propose to prepay potential respondents because research has shown that prepayment (incentive mailed with the survey) is superior to post-payment (incentive mailed after return of completed survey) in improving response rates. Berry and Kanouse paid physicians $20 as an incentive with half of the respondents receiving payment with the initial mailing and the other half receiving a promise to be paid after they returned the survey. The response rate for those paid in advance was 78%, compared to 66% for those promised future payment (26). A physician survey conducted by Leung and colleagues yielded a similar pattern of results: The final response rate for physicians who received a cash incentive that accompanied the survey was 82.9%, compared with a 72.5% return rate for physicians who received a cash incentive of the same amount upon receipt of the completed questionnaire (10). Further, focus groups with physicians suggested that physicians would be more likely to respond

to a survey that included a cash incentive than they would be to respond to a survey for which the incentive would be provided at a later date (13).

10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this OMB application and determined that the Privacy Act does not apply to this data collection. CDC will obtain only de-identified response data.

The contractor, Battelle, will utilize names and addresses to mail the survey to prospective respondents, but this information will not be recorded on the actual surveys that are returned. We will ask participants for their zip codes, to allow confirmation that their office is located within the 5-county metro Atlanta area.

The contractor will assign a unique participant identification number to each prospective respondent. Only the Battelle program manager and program assistant will have access to the link between the respondent's name and participant ID number. The participant ID numbers will be used to re-send the surveys to non-respondents. 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 bar codes are used only to indicate which physicians have responded; they are not used to link the respondent to the survey. The response data from the survey will be maintained separately from the identifiable follow-up information. The final response data file will not have any bar coded information attached or incorporated, and the link between the participant ID number and the survey response data will be destroyed upon collection of all eligible surveys.

Thus, although the participant ID number is temporarily potentially linkable to the actual survey, this type of linking will not be done. All questionnaire data and the personal identifiers needed to locate potential participants will be stored in *separate* locked file cabinets in locked offices in a secured facility. All electronic files will be password controlled and only accessible to fully authorized employees.

All Battelle employees working on this project will receive extensive instruction on the importance of maintaining data in a secure manner at all times. Furthermore, all employees who work on this study will sign an Affidavit of Nondisclosure (Attachment H) affirming that they will not release, publish, or disclose any information. In addition, the contractor and CDC have an agreement that prior to delivering the final closed data file to CDC, all responder contact information, maintained separately from the response data, will be destroyed. The contractor further agrees to not disclose or provide the link between the response data and contact data.

CDC's IRB approval is attached (Attachment I).

11. Justification for Sensitive Questions

The questionnaire does contain sensitive questions. The respondents will be asked to describe the predominant racial /ethnic makeup of the patients they serve, and will be asked to indicate their own race or ethnicity. It is well documented that stillbirth occurs in disproportionately higher rates among certain racial/ethnic groups, and it is important to

assess whether reporting and evaluation practices vary, and to what extent, among differing racial/ethnic providers and the populations they serve.

Potentially sensitive questions also include questions related to the level of experience and preparation of the healthcare provider, their professional judgment and practice characteristics as well as potential discrepancies between the provider's personal practice and institutional policy or recommended practice. It is important to characterize how providers' understanding and management of stillbirth vary (if at all) with level of experience and to understand what sorts of professional judgments are being made relative to stillbirth evaluation. This knowledge will aid in developing targeted and specific educational and awareness strategies.

12. Estimates of Annualized Burden Hours and Costs

12.A. Annualized Burden Hours

The annualized burden hours are based on the administration of a similar survey and its estimate of time required for practitioners to complete the survey. It is estimated that the survey will take approximately 15 minutes to complete. This estimate is based on a previously conducted survey similar in length published in 2003 by Spong, et al. (7). Pilot testing of the survey among 8 CDC physicians also indicated that the survey will take only 15 minutes to complete. 600 obstetricians will be invited to participate in the survey; however, we anticipate a response rate of approximately 80%, yielding 480 respondents. We anticipate that it will take non-participants approximately one minute to read the survey directions and fill out the signature post card. In summary, the total burden for the proposed data collection is 122 hours.

Table A-12-1: Estimates of Annualized Burden Hours

Respondents	Number of Respondents	No. of Reponses per Respondent	Average Burden per Response (In hours)	Total Burden (Hours)
Obstetrician Non-Particpants	120	1	1/60	2
Obstetrician Participants	480	1	15/60	120
Total	600			122

12.B. Annualized Cost to Respondents

Annualized cost estimates to potential respondents are presented in Table A.12-2 and are based on mean (average) hourly wage estimates obtained from the U. S. Department of Labor, Bureau of Labor Statistics for Healthcare Practitioners (www.bls.gov/oes/2003/may/oes_29He.htm). The estimates for the physicians listed in the table were taken directly from the U. S. Department of Labor report. Costs are based on an estimate of ¼ hour survey completion time per respondent.

Table A-12-2: Annualized Cost to Respondents

Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Hourly Wage	Total Respondent Costs
Obstetrician Non-Participants	120	1	1/60	$86.86	$174
Obstetrician Participants	480	1	15/60		$10,423
Total	600				**$10,597**

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

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

14. Annualized Cost to the Federal Government

Costs to the Federal Government are based on estimates provided by the contractor who will be designated to carry out the majority of the data collection activities. CDC's Birth Defects Surveillance Team will contract with Battelle CPHRE. The contractor will administer the survey, collect the data, manage the data bases, and produce progress reports. Since 1987, CPHRE has been a part of CDC's effort to protect and promote public health through contracts and task orders with 12 different Centers, Institutes, and Offices at CDC. Diane Burkom, M.A. of Battelle (410-377-5660) will coordinate and administer the data collection activities for this project. Ms. Burkom produced the cost estimates based on staffing requirements, wages and expected expenditures of similar projects. Current plans are to conduct this survey once.

Table A-14-1: Annualized Cost to the Federal Government

Item/Activity	Detailed Description	Cost (in dollars)
Develop sampling plan, survey content, mailing protocol	Battelle onsite labor w/ benefits (200-250 hours for project director, study manager and programmer), data prep staff (80 hours), survey development, Battelle IRB clearance, purchase of sample list, overhead **Total**	**54,128**
Develop, conduct, track and collect survey. Code and assemble data	1. Finalize survey and protocol Obtain Battelle IRB clearance 2. Purchase sample and load Into tracking system 3. Print materials 4. Assemble/mail/remail surveys 5. $50 incentive x 600 surveys 6. Collect, code data, enter into database, progress reports **Total**	25,000 4,000 6,000 10,000 30,000 25,000 **100,000**
CDC oversight of project	10% of time for GS-13 Medical Officer	**10,000**
	Total	**164,128**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We anticipate beginning the project immediately following OMB clearance and IRB approval. Battelle staff will administer the survey in three phases, including an initial mailing of the questionnaire, followed by a post card (Attachment G) after one week, and a second copy of the survey and a reminder letter to non-respondents at four weeks (Attachment E). Battelle will enter the survey data into a database and then create an analytic data set which will be delivered to CDC. Following receipt of the analytic data set, CDC staff will begin analyzing the data. The findings will be synthesized and published and will ultimately be used to develop awareness and training strategies to increase awareness of stillbirths as a public health concern and the importance of documenting relevant information for public health surveillance purposes in the 5-county metro Atlanta area.

Table A-16-1: Project Time Schedule

Activity	Time Schedule
Prepare, print and assemble survey packets for mailing	1-2 months after OMB approval

Distribute surveys to respondents	1-2 months after OMB Clearance
Follow up postcards to non-responders	2-4 months after OMB Clearance
Enter response data into database	5 months after OBM Clearance
Transfer closed data file to CDC	5-6 months after OMB Clearance
Analyze data and produce statistics	6 months after OMB Clearance
Draft and publish reports	7-8 months after OMB Clearance

Upon completion of the data collection, the team will collaborate on specific analysis plans and drafting of manuscripts.

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

No exception is being requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification are being requested.

B. Collections of Information Employing Statistical Methods

Battelle CPHRE developed a self-administered questionnaire consisting of nominal and ordinal scales, designed to capture knowledge, attitudes and practice management patterns regarding stillbirth pregnancy outcomes. The questionnaire is constructed for mail distribution.

The survey (Attachment C) consists of questions in modular format addressing the following areas: respondent demographic information, definition and case ascertainment, stillbirth surveillance research agenda, and professional education and self-evaluation.

1. Respondent Universe and Sampling Methods

The universe for this study is all physicians with a primary specialty of obstetrics who practice in one of the 5 MACDP counties: Clayton, Cobb, DeKalb, Fulton, or Gwinnett. All physicians listed in the current version of the American Medical Association (AMA) Masterfile with 1) a primary specialty of obstetrics and 2) a mailing address that falls within one of the 5 MACDP counties (Clayton, Cobb, DeKalb, Fulton, or Gwinnett) will be included in the sample. The sampling frame will cover almost 100% of the respondent universe: AMA has access to the medical licensure lists in all 50 states, DC, and the territories. Since all doctors must have a license to practice this results in the AMA Master File covering about 99 percent of practicing physicians in the U.S.

2. Procedures for Collection of Information

We propose to use a printed survey delivered via express mail. Express mail is usually delivered directly to the clinician rather than being filtered by office staff, and can help result in an 80% response rate (13). The initial questionnaire mailing will be followed by a reminder postcard (Attachment G) after one week and a reminder letter (Attachment E) and a second copy of the survey to non-respondents at four weeks. 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 (see section A10 for additional details).

Exploratory analyses will be performed to investigate the relationships among the survey variables, and to identify data anomalies. The exploratory analysis will consist of calculating descriptive statistics or one-way frequencies of all fetal death and background information variables. The cross-tabulations of all survey variables will be with demographic variables such as gender, practice type, number of years in practice, and county.

Association between all survey 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 survey variable and a demographic variable will be considered statistically significant.

Logistic regression will be employed to refine associations by controlling for potential confounders

Battelle will conduct the following activities pursuant to the program objectives listed above.

- Assign a data base manager and program assistant to coordinate administration of the survey.
- Obtain physician names and addresses from Medical Marketing Services (MMS), the vendor that maintains the AMA Masterfile.
- Deliver the survey by express mail.
- Assign a participant identification number 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.
- Incorporate procedures to decline participation in the survey 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%) utilizing reminder mailings.
- Enter data into computer software programs and maintain data base.
- Release the data sets to the CDC

3. Methods to Maximize Response Rates and Deal with Non-response

We will use several methods to enhance the response rate for our survey, including brief questionnaire format; use of express mail; use of a personalized introductory letter; use

of a financial incentive; signature postcard to identify ineligible respondents; and follow-up mailings to non-respondents.

- Brief questionnaire format: The questionnaire will take only 15 minutes to complete. This time estimate is based on the administration of a previously conducted survey that was similar in length (7) as well as pilot testing among CDC physicians.
- Use of express mail: The initial survey (Attachment C) will be sent to clinicians via express mail. Clinicians with PO Box addresses will receive the survey via priority US mail, since express mail carriers do not deliver to these addresses. This mode of mailing has been demonstrated to result in a higher response rate than first class mail (13).
- Personalized introductory letter: The survey packets will include a cover letter, survey, stamped, self-return signature response postcard, and self-return envelope. The cover letter (Attachment D) will be printed on CDC letterhead and personalized. The letter will emphasize that the survey seeks to better understand practice management patterns of obstetricians regarding stillbirths. Prior research has demonstrated that personalized letters have increased response rates (16 - 18).
- Financial incentive: Research has shown that survey response rates among physicians tend to be lower than the general population (15). Asch and colleagues found that surveys of physicians had a mean response rate of 54% compared to a 68% mean response rate among non-physicians. Prior experience has shown that surveys concerning physician attitudes about issues relevant to their practice of medicine can obtain response rates in the range of approximately 40-50% without monetary incentives. We therefore anticipate a higher response rate with a monetary incentive.
- Signature postcard: A three-part postcard will be included in the initial survey mailing (Attachment F). 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 deceased, such a postcard is more likely to be returned than an entire survey packet.

●Follow-up mailings: A reminder postcard (Attachment E) 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 45% of the questionnaires. A second mailing will be sent via express mail 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 cash incentive and reiterating the importance of their response. This letter will be printed on CDC letterhead and personalized. A copy of the second reminder letter is included in (Attachment E).

Other CDC studies – including *HPV Provider Survey: Knowledge, Attitudes, and Practices About Genital HPV Infection and Related Conditions* (OMB No. 0920-0629) and the *Survey of Endoscopic Capacity at the State Level* (OMB No. 0920-0590) – achieved a response rate of at least 80% using similar methods and levels of incentives.

4. Tests of Procedures or Methods to be Undertaken

The survey has been pilot tested among 8 internal CDC staff (including obstetricians) to ensure that each question reads well and is comprehensible and to ensure that the survey takes no longer than 15 minutes to complete. Suggestions from the pilot test were incorporated into the survey to improve readability and clarity. The survey took no

longer than 15 minutes in the piloting phase, and the revisions add no additional time for completing the survey.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Battelle CPHRE will be contracted to print and administer the surveys, and collect the data. Diane Burkom will lead the effort to administer the survey, collect and store the data.

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The analysis of the data will be conducted by the Birth Defects Surveillance Team at CDC. This aspect will be coordinated and conducted by CDC employees:

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List of Attachments

Attachment A: Authorizing Legislation

A1. FY 2005 Appropriations Bill (P. L. 108-792)

A2. Public Health Service Act, Section 317C (42 U.S.C. 247b-4)

A3. Public Health Service Act, Section 301 (42 U.S.C. 241)

Attachment B: 60-Day Federal Register Notice

Attachment C: Survey

Attachment D: Sample Letter to Providers

Attachment E: Sample Reminder Letter

Attachment F: Three-part Postcard

Attachment G: Sample Reminder Postcard

Attachment H: 30-Day Federal Register Notice

Attachment I: Affidavit of Non-disclosure

Attachment J: Letter of IRB Approval

Attachment K: List of Experts Attending the *Metropolitan Atlanta Stillbirth Surveillance Workshop – April 2005*

Attachment L: List of Experts Attending the *Metropolitan Atlanta Stillbirth Surveillance Workshop – July 2005*