Practice Patterns related to Opioid Use during Pregnancy and Lactation

Supporting Statement: Part B

Submitted by:

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PART B. STATISTICAL METHODOLOGY

In collaboration with the Centers for Disease Control and Prevention (CDC) investigators from the Maternal Health Team in the Division of Reproductive Health, the American College of Obstetricians and Gynecologists (ACOG) Research Department's staff will develop a single point in time survey to assess obstetrician-gynecologists' knowledge, attitudes, and practices regarding screening for and treatment of maternal opioid use (illicit abuse or non-medical abuse of prescription opioids) surrounding the time of pregnancy. Data will be analyzed to assess OB/GYNs' practices during prenatal and postpartum visits regarding maternal opioid abuse (e.g., screening procedures, prenatal and postpartum practice patterns) and to identify potential barriers to effective treatment (e.g., barriers to screening and treatment, clinical preparedness, and resources needed).

B1. Respondent Universe and Sampling Methods

B1.1 Target Respondents

The proposed sample is intended to be nationally representative. The respondent universe is ACOG's membership, which comprises almost 95% of board-certified OB/GYNs in the United States. ACOG is separated into eleven districts, of which 10 are geographic regions encompassing the entire United States and Canada, with District 10 representing the US Military. All ACOG Fellows have a current medical license, are Board certified in obstetrics and gynecology, and are in medical practice focused on women's health. There are approximately 31,614 practicing Fellows of ACOG. There are an additional 5,313 Junior Fellows in Practice, which means that they meet all the requirements to be a Fellow of the College except that they are not yet Board certified.

Potential survey respondents will be randomly drawn from the ACOG membership list of Fellows. The sample is selected through a quasi-randomized process. The population is stratified by district and a random sample is taken from each district. Within each district, each Fellow has an equal probability of selection into the sample. If contact information for dissemination of the initial survey is out of date or incorrect, the sampled individual will be replaced through the same randomized sampling.

The survey will be sent to 1,500 practicing Fellows (including Junior Fellows) of ACOG. It is expected that 600 OBGYNs caring for pregnant women will respond to this survey for a 40% response rate. Of these 600 respondents, it is expected that 420 will respond to the full length survey first presented in the initial contact and through 4 follow-up reminders. It is anticipated that an additional 180 will respond to a short survey that will be sent after all other reminders (see B2. Procedures for the Collection of Information).

The sample size of 1,500 initially selected Fellows (including Junior Fellows) was determined by resources available to administer the survey and expected response rates from previous surveys conducted by ACOG in which a combined electronic paper / mailing protocol has typically resulted in a response rate of at least 40% (Stark, L.M. et. al.; Manuscript in preparation). In this study, this response will yield a sufficient sample size to detect a difference in proportions of less than 5%. All analyses will be conducted in SPSS. Statistical significance will be set at $P \leq 0.05$. Exact P-values will be reported whenever possible. Ninety-five percent confidence intervals and odds ratios will be computed where appropriate.

Initial analyses will focus on differences among respondents based on demographic variables. Subsequent analyses will focus on the relationships among non-demographic questions of interest (e.g.,

the relationship between knowledge and training or between screening and intervention), after controlling for any significant effects identified in the demographic analyses. Data will only be presented in aggregate; no personal identifiers of survey respondents will be used.

B2. Procedures for the Collection of Information

The survey will be administered by a combined electronic and paper mailing protocol. The initial survey administration will be by email with an introductory cover letter (**Att 3a**) to orient survey respondents to the study, provide a date by which responses should be made and a link to a full online survey. The full online survey will be administered through Real Magnet (© 2015) (**Att 4a**). Recipients may request a paper survey (**Att 4b)** to be mailed to them at any time. Four follow-up email reminders will be sent approximately at week 4, 7, 10 and 13 (**Att 5)**.Those who do not respond after the 4 follow-up-email reminders will be sent a mailing with the following materials: the cover letter for full paper survey (**Att 3b),** a paper version of the full survey (**Att 4b)**, and pre-paid coded return envelope at 16 weeks. Those who still have not responded after having receiving the full paper survey will receive a final mailing with a cover letter and a short survey (**Att 6**), and a return envelope at week 22. ACOG will assign an identification number to track respondents versus non-respondents to maintain anonymity of responses overall. See **Figure B2** for a detailed timeline.

ACOG will develop a data entry system and codebook and enter data after the last mailing deadline has been reached. Electronic data will be downloaded from Real Magnet (© 2015) to a Microsoft Excel file. ACOG will enter responses from the paper survey into a Microsoft Excel spreadsheet which will then be combined with the downloaded spreadsheet of electronic responses from Real Magnet (© 2015). Excel files will be converted into an SPSS data file for statistical analysis with a coded identification number, gender, years of practice, race, board certification and geographic location for Fellows who were sent the survey. This allows ACOG to compare the basic demographic characteristics of respondents and non-respondents. An initial data analysis will be performed to screen for highly implausible answers (e.g. Fellows who completed residency training at age 8), inconsistent answers (e.g., contradictory responses to similar questions), and to check randomly selected survey items for data entry accuracy.

Figure B2. Survey Timeline

Week	Item	Detail
1	Initial Contact Email	• Introductory letter • Online link to full survey • Due date
4	Reminder email 1	• Reminder letter • Online link to full survey • Due date
7	Reminder email 2	• Reminder letter • Online link to full survey • Due date
10	Reminder email 3	• Reminder letter • Online link to full survey

		• Due date
13	Reminder email 4	• Reminder letter • Online link to full survey • Due date
16	Paper Mailing	• Cover letter • Postage-paid coded return envelope • Full paper survey
22	Final Paper Mailing	• Cover letter • Postage-paid coded return envelope • Short Survey

B3. Methods to Maximize Response Rates and Deal with Non-Response

ACOG worked with CDC investigators to develop final surveys, which will include a full survey and a short survey for non-responders. The questions have been held to the absolute minimum required for the intended use of the data and to ensure adequate response rates. The surveys will be presented in a clear and easy to complete format, based on previous surveys and recommendations from the ACOG survey methodologists. Sampled individuals will be able to complete the survey at their leisure, and will answer only questions about themselves and their practice. The introductory cover letter and follow-up reminders will assure potential respondents that their answers will be maintained in a secure manner, and that results will only be released in summary form to ensure confidentiality.

The availability of web-based and paper-based forms, flexible windows for completion online, and follow-up email reminders will help to maximize response rates. This combined electronic and paper mailing protocol will typically result in a response rate of at least 40% (600 response out of 1500 sampled) (Stark, et al.; manuscript in progress).The full survey is expected to provide 420 responses and the short survey is expected to provide another 180 responses. The short survey only captures information on clinician screening and management practices of their pregnant patients regarding opioid use. This limited information is still useful and thus captured on the short survey. However, information on clinicians' knowledge and attitudes, only captured on the full survey, regarding care of women using opioids during pregnancy is needed to understand the percentage of clinicians following ACOG recommendations, whether barriers are restricting care of pregnant women, and areas of improvement and intervention. Use of the short-survey in addition to the long survey is recommended by ACOG methodologists to increase the response rate and to capture critical information. The responses to the short survey can be used to examine whether non-respondents differ from respondents.

ACOG has demographic information regarding the gender, age, and primary state of residency of non-respondents. These demographic characteristics for non-respondents and respondents will be compared using Chi-squared tests, and all statistically significant differences between these groups will be reported. Final data presented will be unweighted survey responses. Prior research has shown that nonresponse bias is minimal among physician groups compared to other groups (Kellerman and Herold, 2001).

B4. Test of Procedures or Methods to be Undertaken

The full survey was reviewed by subject matter experts for question wording and appropriate and adequate response options. CDC shared the draft with internal reviewers who have worked on substance use and/or pregnancy within other CDC programs (National Center for Injury Prevention and Control and National Center for Birth Defects and Developmental Disabilities). The web-based survey was pilot tested with a sample of 5 ACOG Fellows, and the paper survey was pilot tested with two OB/GYNs who work at CDC. Feedback from the pilot test was incorporated into the final surveys.

B5. Individuals Consulted on Survey Content and Statistical Aspects of Data

The survey has been reviewed by subject matter experts on opioid abuse from the CDC's Prescription Drug Overdose Epidemiology and Surveillance Team in the National Center for Injury Prevention and Control (Matthew Gladden, PhD and Michele Bohm, MPH). Subject matter experts on prescription drug safety for pregnant women from CDC's Treating for Two Program within the National Center for Birth Defects and Developmental Disabilities (Emily Petersen, MD; Jennifer Lind, PharmD; Meghan Frey, MPH, Suzanne Gilboa, PhD; Cheryl Broussard, PhD) have also reviewed this survey. ACOG research staff (Mike Powers, PhD; Jay Schulkin, PhD) developed the sampling strategy and data collection and statistical methodology for this study.

ACOG is responsible for sample selection, data collection, data cleaning, and preparing the final analytic datasets that are to be delivered to CDC; data analysis and preparation of reports will be a collaborative effort between CDC and ACOG. The CDC project officer (Jean Ko) will be responsible for receiving and approving contract deliverables.

REFERENCES

Kellerman, S.E., Herold, J., 2001. Physician response to surveys. A review of the literature. Am. J. Prev. Med. 20 (1), 61–67.

Stark, L.M., Power, M.L., Schulkin, J. Trends in a Representative Sample, A Review of Collaborative Ambulatory Studies, 1997-2015 (manuscript in progress)