Practice Patterns related to Opioid Use during Pregnancy and Lactation

New Information Collection Request

Supporting Statement: Part A

Submitted by:

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Submitted: 8-24-2016

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Goal of the study: This survey is aimed to assess obstetrician-gynecologists' (OB/GYNs) 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.

Intended use: Reliable data on OB/GYNs' practices during prenatal and postpartum visits regarding maternal opioid abuse (e.g., screening procedures, prenatal and postpartum practice patterns) is needed to determine current knowledge, opinions, and practices and to identify potential barriers to effective treatment (e.g., barriers to screening and treatment, clinical preparedness, and resources needed).

Methods to be used: A survey will be administered to a nationally representative sample of the OB/GYNs using a combination of electronic and paper mailing protocols. The initial survey will be administered by email with access to a full online survey. To non-responders, a follow-up mailing of a full paper version of the survey will be sent 3 - 4 months after the initial contact, and for those who do not respond to the full paper survey, a final mailing with a shortened paper version of the survey will be sent six weeks later.

How the data will be analyzed: Summary statistics will be calculated, such as the mean, median and standard error for continuous and ordinal data, and frequencies for categorical data. Chi-square tests will be used to assess differences between subgroups (e.g., Maternal and Fetal Medicine vs. OB/GYN, rural vs. urban, percentage of Medicaid patients vs. private insurance).

PART A. JUSTIFICATION

A.1 Circumstances making the collection of information necessary

The proposed information collection request (ICR) is classified as a new data collection, seeking approval for 1 year. This study is a collaborative effort between CDC and the American College of Obstetricians and Gynecologists (ACOG) Research Department staff in an effort to reduce respondent burden and strengthen the quality of the overall effort.

The use of various psychoactive substances such as marijuana, opioids (illicit abuse or non-medical abuse of prescription opioids), and many other illicit drugs during pregnancy increases the risks for health and social problems for both mother and infant. Substance use during pregnancy may cause perinatal death, low birth weight, an increased risk of preterm birth, and an increased risk of maternal depression (Hudak et al., 2012; Patrick et al., 2015; Passey et al., 2014). Over the past decade, the incidence of neonatal abstinence syndrome (NAS), most commonly a consequence of maternal opioid use during pregnancy, has steadily increased (Patrick et al., 2015). The results of recent studies indicate that 4.5% of pregnant US women between 15 and 44 years of age have disclosed that they have recently used illicit drugs (Hudak et al., 2012) and 10.9% of pregnant US women have indicated that they have used marijuana in the past year (Ko et al., 2015).

Obstetrician-gynecologists (OB/GYNs) are the principal health care providers for women and provide preconception, pregnancy, and postpartum care to optimize a woman's health and that of her infant and child. OB/GYNs deliver 85% of the 4 million births in the U.S. annually. For many women, and some at-risk women in particular, prenatal visits may be the only time they routinely see a physician. Thus, OB/GYNs are well situated to screen for substance use (alcohol, tobacco and drugs) and to treat or encourage cessation of substance use during pregnancy; several committee opinions are relevant on this topic (ACOG, 2008, 2011a, 2011b, 2011c, 2012).

This data collection request aims to address a knowledge gap in the clinical knowledge, attitudes, and practices of OB/GYNs regarding screening for and treatment of maternal opioid use (illicit abuse or non-medical abuse of prescription opioids) surrounding the time of pregnancy. Findings will be used to inform future recommendations and educational interventions. Authority for CDC to collect this data is granted by Section 301 of the Public Health Service Act [42 U.S.C. 241] (**Att 1**).

A.2 Purpose and use of the information collection

The purpose of the proposed information collection is to improve screening for and treatment of maternal opioid abuse during pregnancy by:

(1) Assessing a national sample of OB/GYNs on their clinical 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, and the barriers they face
(2) Describing provider barriers to screening and treatment
(3) Making recommendations about essential clinical training, supports, and resources

The *practical utility* of the information to be collected is to identify areas for provider education, training, resource allocation, etc. to reduce barriers to screening and treatment while increasing clinical preparedness.

The *negative consequences* of not having the information would be a potential inability to identify issues that limit full and accurate development of ACOG guidance and accompanying training tools and resources for screening and treatment of opioid use during pregnancy.

The results will be disseminated in a report to ACOG members and in manuscripts, and will be used by CDC and ACOG to generate a list of recommendations to improve screening for and treatment of maternal substance abuse during pregnancy. The survey content domains are outlined below.

Prenatal & Postpartum Care. Care questions will assess participant's screening and treatment patterns for pregnant and postpartum patients as they relate to maternal substance abuse, including screening tools and treatment referrals.

Provider Beliefs and Attitudes. These questions will assess participant's beliefs and attitudes, as these may affect screening and treatment patterns. Questions include participant's attitudes on the importance of cessation versus cutting down of substances during pregnancy and/or lactation.

Barriers. These questions will assess potential barriers to screening and treating pregnant and postpartum patients for opioid abuse, including access to addiction specialist or an addiction treatment facility.

Clinical Preparedness. These questions will assess participant's beliefs and attitudes, as these may affect participant's confidence in treating patients with opioid abuse, assess barriers and facilitators to treatment, and identify potential resources, such as information or training, which may improve treatment.

Demographics. Demographic data will be used to describe the participant population overall and to assess whether knowledge, attitudes, and practices vary by demographic and/or practice characteristics, including whether respondent is an MFM Specialist, as their response may differ from OB/GYNS who are not MFM Specialists.

A.3 Use of improved information technology and burden reduction

The survey will be administered by a combined electronic and paper mailing protocol. Electronic surveys will be the primary mode of survey administration to reduce costs, transcription errors associated with data entry, and because health care providers are increasingly choosing to complete surveys online. There is also support that mixed-mode survey options improve response rates among physicians (VanGeest et al., 2007). Paper surveys will only be administered among non-responders to the electronic surveys. For those opting to complete the web-based survey, questions that are not applicable to a respondent based on an answer to a

previous question, will be automatically skipped. For those opting to complete the paper-copy survey, questions that are not applicable to a respondent based on an answer to a previous question, will be skipped via formatting and skip patterns. Both options are designed to minimize burden to the respondent and obtain data as efficiently as possible, including the use of response options in lieu of open-ended questions for most survey items.

A.4 Efforts to identify duplication and use of similar information

There are no national level data that are similar to those being proposed in this ICR. A Government Accountability Office (GAO) report published February 2015 states that currently there no federal efforts to field a survey to a national sample of OB/GYNs on clinical knowledge, attitudes, and practices regarding screening for and treatment of opioid use, such as those proposed by this information collection (GAO 2015). In addition, we confirmed there were no duplicated efforts via literature searches of electronic databases and discussions with other CDC programs and ACOG, which is the only national association for OB/GYNs, of previously conducted or currently underway. The current literature for opioid use is around physicians attitudes on treating pain; no literature was found on screening for and treatment of opioid use dependence (Table A.4-1).

Table A.4-1

Publication	Target audience and topic
Jamison RN, et al. Beliefs and attitudes about opioid prescribing and chronic pain management: survey of primary care providers. J Opioid Manag. 2014;10(6):375-382.	Focused on primary care providers' perception of prescribing opioids for patients with chronic pain. OB/GYNs not included.
Hagemeier NE, et al. Prescription drug abuse: a comparison of prescriber and pharmacist perspectives. Substance use & misuse. 2013;48(9):761-768.	Focused on prescribers and pharmacists perception of prescribing opioids for patients with chronic pain. Authors noted that prescribers include OB/GYNs but data not provided by specialty.
Wilson HD, et al. Clinicians' attitudes and beliefs about opioids survey (CAOS): instrument development and results of a national physician survey. J Pain. 2013 Jun;14(6):613-27.	Development of a survey tool to assess clinician's attitudes for prescribing opioids for patients with chronic pain. OB/GYNs not included.
Vijayaraghavan M, et al. Primary care providers' views on chronic pain management among high-risk patients in safety net settings. Pain medicine (Malden, Mass). 2012;13(9):1141-1148.	Focused on primary care providers' of HIV-infected parients and their perception of prescribing opioids for patients with chronic pain. OB/GYNs not included.
Keller CE, et al. Practices, perceptions, and concerns of primary care physicians about opioid dependence associated with the treatment of chronic pain. Substance abuse. 2012;33(2):103-113.	Focused on primary care providers' perception of prescribing opioids for patients with chronic pain. OB/GYNs not included.
Payne M, et. al. Primary care providers' perspectives on psychoactive medication disorders in older adults. The American journal of geriatric pharmacotherapy. 2011;9(3):164-172.	Focused on geriatric providers' perception of prescribing opioids for patients with chronic pain. OB/GYNs not included.

Physician Perceptions on Opioid Therapy for Chronic Pain: https://www.scopeofpain.com/toolkit/documents/whitepaper.pdf	Focused on primary care providers' perception of prescribing opioids for patients with chronic pain. Included OB/GYNs.

The current survey has been reviewed by subject matter experts 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).

There have been at least two efforts to survey OB/GYNs on medication safety, funded by the National Center for Birth Defects and Developmental Disabilities; however, none focused on were on screening and treatment of opioid use. These efforts included a collaboration with the National Public Health Information Coalition and Harvard Opinion Research Program to conduct a survey of obstetric providers about Physician Views of Pregnancy-related Medication Safety, and a collaboration with the March of Dimes and RTI to conduct in-depth interviews with providers to better understand their clinical decision-making process when determining teratogenic risk of prescribing medication to both pregnant women and women of childbearing age. There are no current efforts to collect data by the National Center for Injury Prevention and Control as of the date of this submission (March 7, 2017) on physician knowledge, attitudes, and practices broadly or among OB/GYNs.

A.5 Impact on small businesses or other small entities

Data will be collected from OB/GYNs in the private- and public-sectors. The questions have been held to the absolute minimum required for the intended use of the data. The survey instruments will be presented in a clear and easy to complete format based on previous surveys and recommendations from survey methodology research. Sampled individuals will be able to complete the survey at their leisure, and will answer only questions about themselves and the practice at which they received the survey. The burden of participation in this survey for OB/GYNs will not affect the normal functioning of the entities in which they work.

A.6 Consequences of collecting the information less frequently

This information collection will be conducted one time.

A.7 Special circumstances relating to the guidelines of 5 CFR 1320.5

This ICR fully complies with the regulation of 5 CFR 1320.5.

A.8 Comments in response to the federal register notice and efforts to consult outside agency

Comments in Response to the FRN

The 60-day Federal Register Notice **(Att 2a)** was published in the *Federal Registrar* on March 31, 2016, Vol. 81, No.62, pp 18630 – 18631 One nonsubstantive public comment was received on April 4, 2016 CDC's standard response was sent (**Att 2b**).

Efforts to Consult Outside the Agency

CDC and ACOG are closely collaborating on this ICR (see section A1 – Background). CDC sought consultation on methodology and survey instrumentation outside of the agency from an ACOG substance abuse work group, which comprises of OB/GYNs with expertise in caring for women with substance use. No major unresolved problems were highlighted during consultation.

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.

A.9 Explanation of any payment or gift to respondents

Not applicable as no payment or gift will be offered to respondents.

A.10 Assurance of confidentiality provided to respondents

Upon initiation of the research contract, the CDC Office of the Chief Information Security Officer Privacy Act clearance determination was as follows:

While the Privacy Act is not applicable, the appropriate security controls and Rules of Behavior should be incorporated to protect the confidentiality of information, proprietary, sensitive, and Personally Identifiable Information (PII) the Contractor may come in contact with during the performance of this contract.

The compilation of individual responses for this study will only be used for research purposes. The sections below describe the protections in place to preserve privacy.

Overview of the data collection system

The survey will be administered by a combined electronic and paper mailing protocol. A total of 1500 ACOG members who are randomly selected will receive an email introductory cover letter (**Att 3a**) inviting them to participate in the online survey (**Att 4a**) or to request a full paper survey (**Att 4b)**. Four follow-up email reminders will be sent at approximately three week intervals (**Att 5**). If no response is received after all four e-mail reminders, a follow-up mailing

of a paper cover letter and full paper version of the survey will be sent (approximately 3 - 4 months after the initial contact) (**Att 3b and 4b**). A final mailing with a shortened version of the introduction and survey (2 pages) will be sent six weeks later to ACOG members who did not respond to any of the previous contact attempts (**Att 6**).

The short survey captures useful but limited information on screening and management practices regarding women using opioids. Additional 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.

Electronic surveys will be administered through Real Magnet (© 2015), which collects data from responses as well as tracks responders. Electronic data will be downloaded from Real Magnet (© 2015) to a Microsoft Excel file once time at the end of the survey period. ACOG will enter responses from the paper survey into a Microsoft Excel spreadsheet which can be combined with a downloaded spreadsheet of electronic responses. No PII is collected on the data collection instruments. CDC will not have access to information in identifiable form (IIF) at any time.

Respondents will not be re-contacted after the survey, even if there are unclear data elements.

Items of information to be collected

The survey will capture basic demographics of the respondent and his or her clinical practice.

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. ACOG will maintain local respondent PII; only de-identified data will be transmitted to CDC. Resulting reports and journal articles will be presented in the aggregate and disseminated via peer-reviewed publications, presentations, and/or fact sheets.

As part of study, ACOG will maintain respondent PII that will include: name, year of birth, gender, mailing address and email address. ACOG staff will protect the privacy of participant data and survey response by assigning a unique identification number (UID) to each participant. No PII is collected on the data collection instruments. To ensure the anonymity of the survey data, this UID will be the only identifier associated with a subject's responses and will be maintained by ACOG. CDC will receive a de-identified dataset. Resulting reports and publications regarding this study are to be reported in aggregate and will ensure individuals cannot be identified. CDC will not obtain PII nor will CDC will have access to any file linking the names and addresses of respondents with their UID. CDC will obtain a de-identified dataset with UID and a dataset codebook from ACOG. ACOG will maintain ownership of the data.

Completion of a survey will be considered consent. Respondents will also be informed that all individual answers will be kept private and data will be analyzed and reported in aggregate form only.

Planned control

Paper documentation, such as the hardcopy full and short survey, will be stored in a designated and secured office area at ACOG (physical control). Research data kept online will be kept secure and confidential on password-protected, restricted access servers at ACOG (technical and administrative controls). De-identified data will be kept secure and confidential on password-protected, restricted access servers at CDC (technical and administrative controls).

A.11 Institutional Review Board (IRB) and justification for sensitive questions

CDC determined that this project is research and will contribute to generalizable knowledge. Human subjects are involved, however CDC will not be in contact with any respondents nor will it receive any personally identifiable information. Thus, CDC IRB review is not needed. ACOG has sought local IRB determination and/or approval; it was determined to be IRB exempt. Survey procedures only includes adults and does not involve information that could reasonably be considered damaging to the participants financial standing, employability or reputation. Questions are focused on provider clinical practices and are not expected to be sensitive. Respondents will be reminded that the survey is voluntary and that they are not required to answer any questions to which they would prefer not to respond.

A.12 Estimates of annualized burden hours and costs

We estimate that the full survey, capturing all desired information on clinician knowledge, attitudes, and practices, will take on average 10-15 minutes to complete; the upper estimate of 15 minutes was used to estimate the annualized burden hours for the full survey. The short survey, capturing only clinician practices related to screening and management, is estimated to take 5 minutes in total. These estimates are based on the amount of time five ACOG members not familiar with this project needed to complete the surveys.

Burden Hours

ACOG will send survey to an initial sample of 1,500 Fellows. Based on previous surveys fielded by ACOG to their members, ACOG estimated to have approximately a 40% response rate, or 600 returned surveys (420 full surveys, 180 short surveys). See **Table A.12-1** for total burden hours.

Table A.12-1. Estimated annualized burden hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
OB/GYNs non caring for pregnant women	Practice Patterns related to Opioid Use during Pregnancy and Lactation – Full Survey	420	1	15/60	105
	Practice Patterns related to Opioid Use during Pregnancy and Lactation – Short introduction and	180	1	5/60	15

	survey				
				Total	**120**

Cost to Respondents

The cost to respondents was calculated using the national median hourly rate for physicians in the US according to the most recent data on the U.S. Bureau of Labor Statistics' website, which at the time of OMB clearance preparation was for November 2015 (U.S. Bureau of Labor Statistics' 2014). These labor rates may vary across states, but these variations are not expected to result in significant differences in costs to respondents. Table A.12-2 exhibits the annualized costs as they relate to each of the surveys to be completed. The table below summarizes the estimated annualized burden costs.

Table A.12-2. Estimated annualized cost to respondents (physicians)

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours	Hourly Physician Wage Rate	Total Costs
OB/GYNs caring for pregnant women	Practice Patterns related to Opioid Use during Pregnancy and Lactation -- Full Survey	420	1	15/60	105	$93.74	$9,842.70
	Practice Patterns related to Opioid Use during Pregnancy and Lactation – Short introduction and survey	180	1	5/60	15	$93.74	$1,406.10
				Total	120		$11, 248.80

A.13 Estimates of other total annual cost burden to respondents or record keepers

There are no costs to respondents other than their time.

A.14 Annualized cost to the federal government

The cost of the 2-year contract with ACOG is $45,000 which includes operational costs. The annualized cost to the federal government is approximately $51,105.33, which includes the 2-year contract with ACOG and CDC staff time to oversee and collaborate on the project. The total over two years is $102,210.66, which includes the cost of the 2-year contract with ACOG. See **Table A.14-1.**

Table A.14-1. Estimated annualized cost to federal government

Expense Type	**Expense Explanation**			**Annual Costs (dollars)**
Federal government staff salaries	Project lead	GS-13	.05 FTE	$4,360.95
	Project staff	GS-13	.02 FTE	$1,744.38
Contract with ACOG				$45,000
TOTAL				**$51,105.33**

*Salary estimates were estimated from 2015 Federal Pay Rates (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2015/general-schedule/)

A.15 Explanation for program changes or adjustments

This is a new collection of information.

A.16 Plans for tabulation and publication and project time schedule

A 1-year OMB clearance is requested to cover all data collection activities. **Table A.16-1** below outlines the project time schedule after OMB approval. Study data will be released in two formats: cleaned datasets and final reports. The final datasets will be formatted as de-identified restricted-use files. The final report will include a study overview, work plan, and a summary of scientific findings.

Table A.16-1. Project time schedule

Activity	**Timeframe after approval**
Online mailing to ACOG Fellows and reminders	1 month
1st postal mailing to non-respondents	4th month
2nd postal mailing (letter and short survey) to non-respondents	6th month
De-identified and cleaned dataset and codebook	7th month
Data analysis completed	9th month
Final report	12th month

Analysis plans include conducting descriptive analyses that describe the current screening and treatment practices for substance use during pregnancy of ACOG members and identify potential barriers to effective treatment. Summary statistics, such as the mean, median and standard error for continuous and ordinal data, and frequencies for categorical data, will be calculated. Chi-

square tests will be used to assess differences between subgroups (e.g., Maternal and Fetal Medicine vs. OB/GYN, rural vs. urban, percentage of Medicaid patients vs. private insurance).

A.17 Reason(s) display of OMB expiration date is inappropriate

The OMB approval date will be displayed on all surveys.

A.18 Exceptions to certification for Paperwork Reduction Act submissions

This collection is not requesting any exceptions from OMB Form 83-I.

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