

**FORMATIVE RESEARCH TO DEVELOP ZIKA TOOLS FOR HEALTHCARE
PROVIDERS**

Supporting Statement A

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Clinical recommendations for healthcare providers regarding Zika virus have evolved repeatedly as information on the virus has increased. The American College of Obstetricians and Gynecologists (ACOG) has revised its clinical guidance on Zika 11 times since January 2016. The frequency with which clinical recommendations have changed has required healthcare providers to regularly review and apply new guidance to their practice, emphasizing the importance of professional organizations' ability to rapidly and effectively communicate recommendation changes and to support providers. The survey of obstetrician-gynecologists, focus groups of healthcare providers, and survey of local health department CDC field assignees will provide information that can be used to improve the provision of clinical guidance and resources to healthcare providers and local health departments and to better facilitate communication among healthcare providers and with public health professionals.

While website data shows that ACOG's Zika guidance and resources are widely accessed, there is little feedback regarding providers' preferences on format and method of communication nor is there data on providers' application of the guidance. This formative research of a survey of obstetrician-gynecologists and focus groups of healthcare providers will help fill this knowledge gap and inform future development of tools and resources to support healthcare providers responding to Zika and similar emerging healthcare issues. Similarly, there has been no evaluation of the calls conducted by ACOG and the American Academy of Pediatrics (AAP) staff with Centers for Disease Control and Prevention (CDC) field assignees as part of the Local Health Department Initiative and data from such an evaluation would allow the program to be tailored to better fit the needs of field assignees.

The CDC has awarded funding to ACOG as a subaward (6NU38OT000167-04-06) through AAP to support Zika Response Project activities, and this includes conducting a survey of ACOG members and focus groups of healthcare providers to acquire qualitative and quantitative data on provider attitudes, experiences, and behaviors regarding Zika virus in order promote adherence to Zika-specific clinical guidance and ameliorate future responses.

2. Purpose and Use of Information Collection

Survey of Obstetrician-Gynecologists

The purpose of this survey (Att A) is to assess obstetrician-gynecologists' knowledge, attitudes, information sources, and behaviors regarding clinical management of Zika virus infection during pregnancy. The specific objectives are to: 1) assess gaps in healthcare provider knowledge; 2) assess provider use of resources and clinical guidance; 3) evaluate methods of communicating clinical recommendations to providers; and 4) better understand barriers to performing recommended patient counseling, laboratory testing, imaging, clinical assessment, and communication among providers.

The survey addresses the following domains:

1. Demographic information
2. Preferred sources and formats of clinical guidance and resources
3. Application of clinical guidance including barriers to applying guidance
4. Methods of communicating among provider types and barriers to communication

5. Preferred ways for ACOG to support providers
6. Attitudes regarding Zika

While not generalizable to all physician types, the healthcare community at large, or the public, results from the survey will be incorporated into the overarching AAP/ACOG Zika Response Project activities, such as educational sessions, webinars, scientific publications, and resources for patients and healthcare providers. Results will not state any prevalence estimates based on data. Results may be considered by ACOG, AAP, and the CDC to guide future dissemination of messaging and guidance for Zika response and future healthcare responses.

Focus Groups of Healthcare Providers

The purpose of the focus groups (Att F) is to better understand the behaviors and attitudes around Zika virus of healthcare providers who treat women of reproductive age and children: obstetrician-gynecologists, pediatricians, certified nurse-midwives, and nurse practitioners. The specific objectives are to: 1) better understand which sources and formats of resources and clinical guidance providers prefer and access most frequently; 2) assess providers' level of confidence in understanding Zika guidance and applying it to practice; and 3) better understand barriers to performing recommended patient counseling, laboratory testing, imaging, clinical assessment, and communication among providers. Potential participants for the focus groups will be screened during recruitment to ensure they meet the criteria for inclusion (Att G). The target audience is ob-gyns, pediatricians, nurse practitioners, and certified nurse-midwives; the screener will filter out candidates that don't meet those specifications.

The focus groups address the following domains:

1. Preferred sources and formats of clinical guidance and resources for providers and resources for patients
2. Attitudes regarding Zika
3. Application of clinical guidance including barriers to applying guidance
4. Patients' behaviors and adherence to recommendations
5. Methods of communicating among provider types and barriers to communication
6. Lessons learned from Zika to guide responses to future health crises

While not generalizable to the national full population, or the healthcare community at large, qualitative and quantitative results from the focus groups will complement the data acquired from the survey and will be incorporated into the overarching AAP/ACOG Zika Response Project activities, such as educational sessions, webinars, and resources for patients and healthcare providers. Results may be considered by ACOG, AAP, and the CDC to guide future dissemination of messaging and guidance for Zika response and future healthcare responses.

Survey of Local Health Department CDC Field Assignees

The purpose of the survey (Att I) is to evaluate the effectiveness of the calls conducted with CDC field assignees to local health departments and ACOG and AAP as part of the Local Health Department Initiative in order to modify the program in the future, if necessary, to better meet assignees' needs. The specific objectives are to: 1) assess how helpful assignees found the calls and call follow-up, 2) better understand field assignees' use of ACOG and AAP guidance and resources before and after the calls, 3) better understand the frequency with which assignees communicate with local ACOG and AAP staff

and providers and any barriers to communication, and 4) gather input for how future calls could be improved.

The survey addresses the following domains:

1. Demographic information
2. Usefulness of information provided before the call
3. Timing and content of the call
4. Usefulness of information provided after the call
5. Behaviors performed by assignees as a result of the call
6. Communication between assignees and ACOG or AAP staff or local providers
7. Preferred sources and formats of resources

While not generalizable to all CDC field assignees, results from the survey will be used to evaluate field assignees' perceived helpfulness of the calls and call follow-up and can be used to better tailor similar future initiatives to assignees' needs.

3. Use of Improved Information Technology and Burden Reduction

For the survey of obstetrician-gynecologists, the population of Fellows and Junior Fellows is stratified by district and a proportionate, random sample is taken from each district. Individuals who received a different survey from ACOG within the past year are excluded from selection to avoid survey fatigue. Within each district after these exclusions, each Fellow or Junior Fellow has an equal probability of selection into the sample. The survey is online and is transmitted via email to reduce respondent burden. Sampled individuals will be able to complete the survey at their leisure, and will answer only questions about themselves and their practice. A paper survey will only be sent if a selected individual does not complete the online survey after 4 weeks. Both the online and paper surveys employ skip logic to reduce participant burden.

The focus groups and recruitment for them will be conducted online to eliminate the need for potential participants to travel. Participants will type responses during the focus groups, which will create a transcription in real time, eliminating the need for transcription from audio files.

The survey of local health department field assignees will be conducted entirely online. Individuals will be able to complete the survey at their leisure, and will answer only questions about themselves and their experiences with the Local Health Department Initiative. The survey employs skip logic to reduce participant burden.

4. Efforts to Identify Duplication and Use of Similar Information

Informal needs assessment data from ACOG members has been collected by reviewing clinical questions emailed by members or submitted during webinars. In June 2017, ACOG conducted a survey of members to evaluate the ACOG Zika toolkit that had been distributed in April 2017. The survey evaluated members' use of materials included in the toolkit, but did not evaluate their broader experiences, practices, or attitudes regarding Zika. ACOG, the only national association of obstetrician-gynecologists, is not currently and has no plans to conduct other surveys on Zika.

While much has been published regarding Zika research and clinical recommendations, a review of literature shows very limited published research on healthcare provider attitudes regarding their understanding of the disease and application of clinical guidance. Yeung et al. surveyed physicians in obstetrics and gynecology, neonatology, and pediatrics in Singapore in 2016 to assess their knowledge of Zika management, transmission prevention, and other clinical aspects. The survey focused on physicians' clinical understanding of Zika and did not measure their attitudes on aspects such as perceived barriers or communication among provider types, domains that the survey of ACOG members and provider focus groups will explore (Yeung et al.). Gathering data specifically from ACOG members will allow ACOG to tailor resources to fit members' preferences and needs.

The Local Health Department Initiative connecting CDC field assignees with ACOG and AAP staff is a new program and no previous evaluations have been completed.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection. However, the respondents of the survey of ACOG members may be obstetrician-gynecologists who work in small office practices, which will be indicated by their responses to demographic questions.

6. Consequences of Collecting the Information Less Frequently

The surveys and focus groups involve one-time data collection. Data will be used to identify successful aspects of the Zika response as well as challenges and barriers faced in understanding and applying clinical recommendations. Without the data from these surveys and focus groups, feedback from healthcare providers and field assignees would not be available to understand knowledge gaps and to improve future responses to Zika.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

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

The Federal Register notice was published for this collection on July 18, 2016, Vol. 81, No. 137, pp. 46680. No public comments were received.

9. Explanation of Any Payment or Gift to Respondents

Participants in the Survey of Obstetrician-Gynecologists and Survey of Local Health Department CDC Field Assignees will not receive incentives.

Focus group participants will be offered an incentive. Incentive amounts are industry standard set by recruitment professionals based on extensive market experience with a variety of provider types. Higher amounts are offered to provider groups that are more challenging to recruit. Incentive amounts are set to encourage responsiveness and full participation from each audience target within the

timeline. Lower incentives would not generate the same level of responsiveness and would make recruitment efforts more challenging, requiring more extensive efforts and thus longer recruitment times and higher recruitment cost investment.

Incentives offered to each group are as follows:

- Obstetrician-gynecologists: \$300 each
- Pediatricians: \$300 each
- Obstetrician-gynecologists and pediatricians in geographic areas most impacted by Zika (Florida, Texas, New York, and California): \$300 each
- Certified nurse-midwives: \$200 each
- Nurse practitioners: \$200 each

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.

Personally identifiable information will be collected, but CDC/ ACOG will keep this information private and secure to the extent permitted by law. For the survey of ACOG members and local health department CDC field assignees, electronic data will be downloaded and stored in spreadsheets on secure, restricted-access servers at ACOG. Any paper data that might be obtained would be stored in locked cabinets in a designated and secure office area at ACOG for up to 5 years. To protect the confidentiality of responses, identifying information will be separated from responses and each participant's responses will be assigned an identification number. The key matching identification numbers to identifying information will be maintained by ACOG Research staff until the completion of the study, at which point it will be destroyed.

For the focus groups, demographic data for participants will be collected in the recruitment screener and conveyed by APCO to ACOG Immunization staff along with other qualitative and quantitative data, but all data will be reported in aggregate and de-identified. ACOG Immunization staff administering the project will not have access to participants' personally identifiable information.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The survey of ACOG members, focus groups, and survey of local health department CDC field assignees were all submitted for IRB review and received approval. The IRB letters of approval are included as Attachments E, H, and L.

Sensitive questions will not be asked.

12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 835 hours. The ACOG Zika Virus Survey was estimated by Qualtrics to take 10 minutes to complete. The Zika Virus Focus Group Recruitment Screener consists of 16 questions, none of which should require more than 30 seconds to answer, thus it is estimated to take 8 minutes to complete. Based on the screening criteria and scheduling requirements, it is anticipated that approximately 25% of individuals screened will ultimately be scheduled to participate in a focus group. The four Zika Virus Focus Groups will be held for 90 minutes each. The Local Health Department Field Assignee Survey on Zika was estimated by Qualtrics to take 15 minutes to complete.

Exhibit 12.A Annualized Burden Hours

BURDEN HOURS

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Obstetrician-gynecologists	ACOG Zika Virus Survey	4,000	1	10/60	667
	Zika Virus Focus Group Recruitment Screener	120	1	8/60	16
	Zika Virus Focus Groups	30	1	90/60	45
Pediatricians	Zika Virus Focus Group Recruitment Screener	120	1	8/60	16
	Zika Virus Focus Groups	30	1	90/60	45
Certified Nurse-Midwives	Zika Virus Focus Group Recruitment Screener	40	1	8/60	5
	Zika Virus Focus Groups	10	1	90/60	15
Nurse Practitioners	Zika Virus Focus Group Recruitment Screener	40	1	8/60	5
	Zika Virus Focus Groups	10	1	90/60	15
Local health department field assignees	Local Health Department Field Assignee Survey on Zika	22	1	15/60	6
Total		4,422*			835

*25% of the individuals who take the screener will also participate in the focus groups. To avoid double counting those individuals, the total would be 4,342.

12.B Estimated Annualized Costs

The cost to respondents was calculated using national mean hourly wages in the U.S. according to the most recent data on the website of the United States Department of Labor, Bureau of Labor, which at the time of OMB clearance preparation was for May 2016.

Exhibit 12.B. Annualized Cost to Respondents

Estimated Annualized Burden Cost

Type of Respondent	Form Name	Number of Respondents	Number of Total Burden Hours	Hourly Wages	Total Response Cost
Obstetrician-gynecologists	ACOG Zika Virus Survey	4,000	667	\$112.65	\$75,137.55
	Zika Virus Focus Group Recruitment Screener	120	16	\$112.65	\$1,802.40
	Zika Virus Focus Groups	30	45	\$112.65	\$5,069.25
Pediatricians	Zika Virus Focus Group Recruitment Screener	120	16	\$88.58	\$1,417.28
	Zika Virus Focus Groups	30	45	\$88.58	\$3,986.10
Certified Nurse-Midwives	Zika Virus Focus Group Recruitment Screener	40	5	\$49.23	\$246.15
	Zika Virus Focus Groups	10	15	\$49.23	\$738.45
Nurse Practitioners	Zika Virus Focus Group Recruitment Screener	40	5	\$50.30	\$251.50
	Zika Virus Focus Groups	10	15	\$50.30	\$754.50
Local health department field assignees	Local Health Department Field Assignee Survey on Zika	22	6	\$16.41	\$98.46
Total		4,422*	835		\$89,501.64

*25% of the individuals who take the screener will also participate in the focus groups. To avoid double counting those individuals, the total would be 4,342.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no costs to respondents other than their time.

14. Annualized Costs to the Government

Annual costs to the government for the Survey of Obstetrician-Gynecologists, Focus Groups of Healthcare Providers, and Survey of Local Health Department CDC Field Assignees are listed below by cost type. For cost by type per activity, refer to Request for genIC Approval, Federal Cost.

Expense Type	Expense Explanation	Annual Costs (dollars)
Costs to the Federal Government	ACOG Research staff salary	\$15,528
	ACOG Research staff fringe benefits	\$3,966
	Printing and postage for mailed survey of ACOG members	\$5,373
	Focus group contractor	\$89,500
	Subtotal, Direct costs	\$114,367
	Indirect costs	\$9,006
	TOTAL COST TO THE GOVERNMENT	\$123,373

15. Explanation for Program Changes or Adjustments

This is a new generic information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

All projects will be initiated as soon as OMB approval is received. All reports should be finalized by June 2018.

Survey of Obstetrician-Gynecologists	
<i>Activity</i>	<i>Timeframe After OMB Approval</i>
Send initial email invitation to participate in online survey	Immediately
Send weekly reminder emails to non-respondents	Weeks 2-9
Paper mailing of survey to non-respondents	Week 5
Survey closes	Week 10
Data de-identified, cleaned, and analyzed	Weeks 11-12
Prepare final report	Week 13

Focus Groups of Healthcare Providers	
<i>Activity</i>	<i>Timeframe After OMB Approval</i>
Begin participant recruitment	Immediately
Finalize recruitment and schedule focus groups	Weeks 2-3
Conduct focus groups	Week 4
Receive transcripts, review data	Weeks 5-6
Prepare final report	Week 7

Survey of Local Health Department CDC Field Assignees	
<i>Activity</i>	<i>Timeframe After OMB Approval</i>
Send initial email invitation to participate in online survey	Immediately
Send weekly reminder emails to non-respondents	Weeks 2-6
Survey closes	Week 7
Data de-identified, cleaned, and analyzed	Week 8-9
Prepare final report	Week 10

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCE

Yung CF, Tam CC, Rajadurai VS, et al. Rapid Assessment Zika Virus Knowledge Among Clinical Specialists in Singapore: A Cross-sectional Survey. PLoS Currents. 2017;9:ecurrents.outbreaks.44b19196298e01f3a6dcd4c09f235fa8. doi:10.1371/currents.outbreaks.44b19196298e01f3a6dcd4c09f235fa8.