Tailoring Gynecologic Cancer Education for Health Care Providers

Information Collection Submitted Under
OMB No. 0920-0800 (generic)

Focus Group Testing to Effectively Plan and Tailor
Cancer Prevention and Control Communication Campaigns

Supporting Statement Part A

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Abstract

CDC is requesting approval for an information collection under a currently approved generic clearance (OMB control number 0920-0800, "Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns"). Information will be collected through focus groups to plan, develop, tailor, and disseminate gynecologic cancer-related health messages and materials targeted to health care providers, namely resident primary care physicians and their supervisors. One focus group (Group A) will be conducted with 20 participants who have not been exposed to messages and materials developed through CDC's *Inside Knowledge: Get the Facts about Gynecologic Cancer* campaign. Qualitative information will be collected to better understand respondents' knowledge, behavior, attitudes, and practices related to the 5 main types of gynecologic cancer. Focus group findings will be used to inform the development of educational modules for this audience. An additional focus group (Group B) will be conducted with 20 resident physicians and their supervisors after exposure to the draft educational modules. Participants in Group A will not necessarily be excluded from Group B, but the two groups will be independent and recruitment for each will be separate. Qualitative findings from the second focus group will be used to assess the clarity, salience and appeal of the educational materials and to make adjustments in content or format, if needed.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC), submits this new information collection request as part of a previously approved generic clearance (OMB control number 0920-0800, "Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns").The information collection for which approval is sought is in accordance with CDC's mission, as described by Section 301 of the Public Health Service Act (PHSA, 42 U.S.C. 241).

The prevention and control of gynecologic cancers is one of the focus areas within DCPC. Each year, nearly 81,000 women in the United States are diagnosed with and nearly 28,000 women die from one of the five main types of gynecologic cancer: uterine, ovarian, cervical, vulvar, and vaginal (USCS, 2010). In response, DCPC plans to continue awareness activities as specifically authorized by the Gynecologic Cancer Education and Awareness Act of 2005, Section 247b-17 of the PHSA, also known as Johanna's Law.

CDC received first-time congressionally mandated funding in fiscal year 2006 to develop, implement, and evaluate a national gynecologic cancer awareness campaign, *Inside Knowledge: Get the Facts About Gynecologic Cancer*. CDC's *Inside Knowledge* campaign educates women and health care providers about the signs and symptoms, screening tests (if available), prevention strategies, and risk factors associated with the five main types of gynecologic cancer: cervical, ovarian, uterine, vaginal and vulvar. The primary audiences for this initiative consist of women of all ages, races, and ethnicities as well as health care providers.

The central messages of *Inside Knowledge* are—

- There are several types of gynecologic cancers.
- When gynecologic cancers are found early, treatment is most effective.
- Pay attention to your body and know what is normal for you. Gynecologic cancers have warning signs.
- If you notice any unexplained signs or symptoms that last for two weeks or longer, see a doctor right away.
- Get a Pap test regularly to screen for cervical cancer.
- Get the HPV vaccine, if you are 11–26 years old.
- If you are diagnosed with a gynecologic cancer, see a gynecologic oncologist—a doctor who has been trained to treat cancers of a woman's reproductive system.

As mandated by Congress, CDC continues to produce materials to educate women and health care professionals about the five main gynecologic cancers. Development of some educational materials has been informed by focus groups with women ages 40-60 (OMB No. 0920-0800). To date, campaign materials for the public consist of a robust library of patient education resources including print and broadcast public service announcements (PSAs), posters, fact sheets, and brochures, many of which are available in English and Spanish. These materials can be found at www.cdc.gov/cancer/knowledge and www.cdc.gov/spanish/cancer/knowledge/ .

Health care providers are another key target audience for the *Inside Knowledge* campaign, and their knowledge is essential to appropriate screening, referral, and treatment of gynecologic cancers (Cooper et al, 2013, Rim et. al, 2011). Health care providers may influence women to take early preventive action against these cancers, for example, or may play a central role in identifying patient risk behaviors or recognizing symptoms. However, practicing health care providers may not recognize or acknowledge their knowledge gaps related to gynecologic cancers. Strong and appropriate messages for physicians are needed to complement the messages that are developed for the public, so that physicians are well-equipped to address the concerns and questions of their patients.

To address the need for effective public health practice related to gynecological cancers, DCPC is developing a series of educational modules for health care providers, specifically medical residents. Such educational modules will strengthen existing, foundational knowledge among health care providers and increase their capacity to communicate about the five gynecologic cancers. The messages in these modules are intended to complement the information on risk factors, symptoms, and prevention strategies (if any) that were developed in previous *Inside Knowledge* activities. The modules will focus on educating health care providers about evidence-based recommendations for clinical care (e.g., the current cervical cancer screening recommendations, lack of evidence for routine ovarian cancer screening, the need to send women with suspected or diagnosed ovarian cancer to a gynecologic oncologist, family history and genetic counseling and testing recommendations) and basic information about all five gynecologic cancers (e.g., risk factors and symptoms). The modules will be made available for incorporation into the medical residency curriculum since that is the optimal way to improve physician behavior. Physicians undergo many levels of training, including undergraduate medical education (“medical school”), graduate medical education (“residency”) and continuing medical education (CMEs) for practicing physicians. Different materials may be needed at each of these stages and should be tailored to physician expertise, competency, and level of training.

To inform the development of educational materials for resident physicians and their supervisors, CDC plans to conduct focus groups with members of the target audience. Formative evaluation is often conducted during the development of health-related messages and materials to glean valuable information about the target audience's knowledge, attitudes, beliefs, and needs for information. CDC requests OMB approval to conduct two focus groups with health care professionals. The first group will involve respondents who have not been exposed to messages and materials developed in conjunction with CDC's *Inside Knowledge* campaign. The second focus group will involve respondents who have been exposed to draft educational modules designed for potential application in the medical residency curriculum. Based on feedback from focus groups, the educational messages/modules may be refined.

Privacy Impact Assessment

Overview of the Data Collection System

Health care providers will be asked to participate in in-person focus groups at one participating site. Respondents will be current physician residents and their supervisors at a collaborating academic medical institution. CDC's data collection contractor will work with the site to recruit a convenience sample of respondents for this qualitative information collection, who will be recruited from the enrollment lists of the residency program of interest at the collaborating academic medical institution and the supervisors affiliated with the program.

Audiotapes and transcripts of the focus groups will be made and will be maintained for twelve months from the focus group date.

Items of Information to be Collected

Two focus groups will be conducted. The first focus group will take place prior to exposure to any *Inside Knowledge* materials and will focus on elucidating existing knowledge gaps, attitudes, beliefs, behavioral intent and current practices regarding gynecologic cancers. The attached focus group guide (Appendix A) will be used to guide the discussion between the independent focus group guide moderator and the participants. Findings will be used to appropriately plan for the development of the gynecological cancer modules.

CDC's contractor will work with CDC scientists and academic collaborators to tailor key *Inside Knowledge* themes for delivery to the target audience. The draft educational modules developed through this process will be presented to physician residents at the collaborating medical center.

The second focus group discussion (see Appendix B) will take place approximately 1-3 months after the first focus group (and after exposure to the educational materials) and will ask about continued knowledge gaps, attitudes, beliefs, behavioral intent, current practices regarding gynecologic cancers, and the appeal, saliency, and likely uptake of the draft modules. Insights gained from these focus groups will assist in the development and/or refinement of *Inside Knowledge* messages and disseminated through the educational modules.

CDC will not be privy to the last names, mailing addresses, telephone numbers or email addresses of any of the focus group participants. These individuals will be recruited from the enrollment lists of the residency program of interest at the collaborating academic medical institution and the supervisors affiliated with the program (see recruitment form, Appendix C). Anyone enrolled in the residency program of interest would be eligible to participate in either focus group and potential participants will be recruited during a telephone interview. We will telephone eligible participants until we reach the target number of participants for each focus group (n = 20). No personal identifying information used in the recruitment process will be linked to the data collected in the focus group discussions. Thus, no personal information in identifiable form will be collected by CDC. Data from Focus Groups A and B will not be linked with each other and will only be analyzed in aggregate. Every focus group participant will be advised that all information he or she provides during the focus group will be kept private, unless otherwise compelled by law.

Identification of Web Site(s) and Web Site Content Directed at Children Under 13 Years of Age

No Web-based data collection methods will be used and, thus, there is no Web content directed at children under 13 years of age.

A2. Purpose and Use of the Information Collection: for what purpose the information is to be used

The purpose of this clearance request is to conduct formative evaluation activities needed to tailor *Inside Knowledge* messages for delivery in gynecological cancer educational modules for medical residents.

The *Inside Knowledge* campaign requires focus group testing with health care professionals so that the campaign efforts may be directed in the most efficient and audience-appropriate manner. These focus groups will differ from previous *Inside Knowledge* focus groups of health care professionals in that a more tailored audience (medical residents and their supervisors) will be included so as to understand physician behavior and information needs. CDC's objective is to support the dissemination of *Inside Knowledge* information and messages to a key audience: health care professionals. The materials to be developed will be appropriate for use in the medical school curriculum or physician continuing education.

CDC will not be collecting information in identifiable form.

A3. Use of Improved Information Technology and Burden Reduction

Electronic data collection methods have limited applicability to focus groups, other than audio-taping discussions. However, whenever possible, DCPC staff will employ electronic technology to collect and process data in order to reduce respondent burden and aid in data processing and reporting efficiency.

Efforts have been made to design items that are easily understandable, not duplicative in nature, and least burdensome. In all instances, the number of items posed will be held to the minimum required in order to elicit the necessary formative or materials-testing data.

A4. Efforts to Identify Duplication and Use of Similar Information

Based on a division- and federal-wide review, CDC has determined that the planned data collection efforts are specific to CDC-defined objectives and do not duplicate any other current or previous data collection efforts related to the *Inside Knowledge* campaign.

A5. Impact on Small Businesses or Other Small Entities

The information collection will have no impact on small businesses or other small entities.

A6. Consequences of Collecting the Information Less Frequently

Formative evaluation is a critical stage in the development of sound educational materials. Formative evaluation, often encompassing concept, message, and materials testing activities, is essential in pre-testing materials to evaluate aspects such as appeal, saliency, clarity, cultural appropriateness and readability/understandability. If a concept and/or a message is not tested, then resources could be expended without necessary attention and preparation paid to the overall communication objective. Forgoing testing can also increase the likelihood of unintended consequences from physicians not being provided with the appropriate level of information, which could have a negative impact of the quality of medical care to women. Finally, if materials are not tested with the intended audience, a poor execution strategy could weaken a sound concept. For these reasons, additional focus groups with medical residents are needed.

There are no legal obstacles to reducing the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. The activities outlined in this package fully comply with all guidelines of 5 CFR 1320.5.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A8.a Federal Register Notice

This data collection is being conducted using the Generic Information Collection mechanism under the following generic approval (OMB control number 0920-0800, “Focus Group Testing to Effectively Plan and Tailor Cancer Prevention and Control Communication Campaigns”). As required by 5 CFR 1320.8(d), a notice for public comments was published in the Federal Register on August 17, 2011 (Vol. 76, No. 159, pages 51035-51036). One public comment was received and acknowledged. The comment was not specific to the information collection described in the current request.

A8.b Efforts to Consult Outside the Agency

The following individuals outside the agency have been consulted on the development of this information collection request:

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A9. Explanation of Any Payment or Gift to Respondents

CDC engaged the contractor and medical consultants in residency programs in a discussion of appropriate incentives. Members of the target audience, medical school residents and their supervisors, have complicated schedules and many competing demands on their time. A key barrier to participation in voluntary activities is the need to reserve limited free time for a meal or snack. To eliminate this barrier (and to show appreciation), CDC's contractor will arrange for refreshments to be provided during the time of the focus group.

If the data collection contractor is unable to confirm at least 20 participants per focus group within a week of starting recruitment, CDC plans to recontact OMB for permission to offer a $35.00 gift card as an incentive. The gift card would be redeemable for refreshments at a local coffee shop at a time of the respondent's choosing. A coffee shop gift card of this denomination is consistent with the intent of removing a barrier to participation, and less than the value of cash incentives typically associated with focus groups involving health professionals.

A10. Assurance of Confidentiality Provided to Respondents

A. Privacy Act Determination

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) has reviewed this OMB submission and determined that the Privacy Act is not applicable. Respondents will be recruited via telephone by the data collection contractor, SciMetrika, LLC, using established lists of participants enrolled in a residency program at the collaborating academic medical institution.

B. Safeguards

Although respondent names and contact information may be used to schedule focus group participation, personal identifying information will not be linkable at any time to response data collected during focus group discussions. A minimum amount of demographic information may be retained in focus group notes for purposes of analysis, but will not be sufficient to identify respondents. Participants will be informed that focus groups will be audio-taped and transcribed, and that audiotapes will be destroyed after completion of each report on findings. DCPC staff, in conjunction with a communications contractor, will collect and evaluate the audience research data.

C. Consent

All information provided by respondents will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Informed consent will be obtained from respondents (Appendix D); they do not have to answer questions if they do not want to, their responses will be treated in a secure manner, and they can stop participating at any time. CDC has determined that the proposed activities do not require IRB review and approval.

D. Nature of Participation

The draft educational materials will be presented to primary care residents in the context of their graduate training program. This is the context in which the materials are designed to be delivered, i.e., the materials represent a mode of delivery of gynecologic cancer information

tailored for primary care physicians in training. There is no additional burden to respondents associated with exposure to the educational materials.

Participation in the focus group data collection is a voluntary activity. The voluntary nature of participation is stated in the consent form (Appendix D).

A11. Justification for Sensitive Questions

The majority of questions asked will not be of a highly sensitive nature. A portion of respondents could consider questions about race, ethnicity, or other demographic characteristics to be sensitive, although such questions are unlikely to be highly sensitive. Additionally, a portion of respondents may feel uncomfortable answering some questions about gynecologic cancer knowledge including symptoms, screening, and treatment. Asking such questions helps to identify knowledge gaps among providers. However, these questions are necessary to the purposes of this information collection - which include assessing gaps that need to be addressed in educational materials for the target audience. To minimize psychological distress, the moderator will inform participants that they do not have to respond to any questions they do not want to answer and they may stop participating at any time.

A12. Estimates of Annualized Burden Hours and Costs

A. The primary audience for this information collection is residents in primary care medicine. A secondary audience is residency supervisors, since their acceptance of the educational modules is critical to incorporation of the modules into the medical training curriculum. DCPC estimates that up to 40 respondents will be involved in 2 focus groups. Approximately 20 respondents will be involved in each focus group: 18 residents and 2 supervisors. The first focus group discussion will be based on questions in Appendix A: Focus Group Discussion Guide for Group A. The second focus group discussion will be based on questions in Appendix B: Focus Group Discussion Guide for Group B. The average burden for a focus group discussion will be 1 hour.

   Recruitment and scheduling will occur by telephone using the Respondent Recruitment Form (Appendix C). The average burden per response is 2 minutes. We estimate that the contractor will need to contact a total of 80 residents to schedule 36 residents for focus group participation. In addition, the contractor will contact approximately 10 supervisors to schedule the participation of 4 supervisors in focus groups.

The estimated burden to respondents is summarized in Table A12-A below.

Table A12-A: Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	Number of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Health Care Professionals-Medical Residents in Primary Care	Respondent Recruitment Form	40	1	2/60	1
	Focus Group Discussion Guide for Group A	18	1	1	18
	Respondent Recruitment Form	40	1	2/60	1
	Focus Group Discussion Guide for Group B	18	1	1	18
Health Care professionals-Supervisors	Respondent Recruitment Form	5	1	2/60	.5
	Focus Group Discussion Guide for Group A	2	1	1	2
	Respondent Recruitment Form	5	1	2/60	.5
	Focus Group Discussion Guide for Group B	2	1	1	2
	Total	**130**			**43**

The total number of responses is 130 and the total burden hours are 43. The adjusted average burden per response is 19.85 minutes.

B. All respondents will be health care professionals, specifically medical residents or their supervisors. Table A12-B presents the calculations for cost of respondents' time using mean hourly wages. Annual mean wage information is from the Association of American Medical Colleges (AAMC), specifically their 2013-2104 *Survey of Resident/Fellow Stipends and Benefits*
https://www.aamc.org/download/359792/data/2013stipendsurveyreportfinal.pdf and supervisor data is from the U.S. Department of Labor, Bureau of Labor Statistics Web site (http://www.bls.gov/ncs/ncswage.htm#Wage_Tables) specifically originating from the January 2007 National Compensation Survey, Bureau of Labor Statistics The total estimated annualized respondent cost is $1,131.

Table A12-B: Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	Number of Respondents	Total Burden (in hours)	Average Hourly Wage Rate	Total Cost
Health Care Professionals – Medical Residents in Primary Care	Respondent Recruitment Form	40	1	$24.52	$25
	Focus Group Guide for Group A	18	18	$24.52	$441
	Respondent Recruitment Form	40	1	$24.52	$25
	Focus Group Guide for Group B	18	18	$24.52	$441
Health Care professionals - Supervisors	Respondent Recruitment Form	5	.5	$66.59	$33
	Focus Group Guide for Group A	2	2	$66.59	$133
	Respondent Recruitment Form	5	.5	$66.59	$33
	Focus Group Guide for Group B	2	2	$66.59	$133
				Total	**$1,131**

A13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

None. There are no costs to respondents except their time to participate in the focus groups.

Table A14. Annualized Cost to the Government

The estimated average annual cost to the Federal government for the proposed focus group activities is $32,057. This figure encompasses the salaries of federal employees and communication contract costs.

Estimated Annualized Cost to the Government for conducting two focus groups	
Cost Category	Estimated Annualized Cost
Federal employee costs (10% FTE of 1 GS-13 @ $98,000/yr, 7.5% FTE of 2 GS-13 @ $98,000/yr)	$24,500
Contractual costs, including focus group moderator, participant incentives, transcription and analysis	$ 7,557
Total	**$32,057**

A15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments sought under this GenIC request.

A16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule
Table A16-1 presents the estimated timeline for conducting focus groups following receipt of OMB clearance. Information will be collected over approximately a 6 month time period and will not exceed the expiration of the originally approved generic clearance (11/30/2014).

Table A16-A: Estimated timeline for conducting focus groups

Activity	Time Schedule
Focus group testing- Group A	April- May 2014
Focus Group testing- Group B	May- June 2014
Analysis of focus group results	July- August 2014
Report Writing/Recommendations to CDC based on Findings	September- November 2014

Findings will be disseminated through presentations and/or posters at meetings and publications in peer-reviewed journals. All abstracts, poster presentations, and manuscripts will undergo CDC clearance review prior to submission to conferences or journals.

A17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB expiration date will be displayed.

A18. Exemptions to Certification for Paperwork Reduction Act Submissions

No certification exemption is being sought.

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