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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC at (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

CDC Cervical Cancer Study (CX3)(OMB No. 0920-0814, exp. 6/30/2012) – Revision - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is the only organized national screening program in the United States that offers breast and cervical cancer screening to underserved women. Current NBCCEDP screening standards for cervical cancer include an annual Pap test until a woman has had three consecutive normal Pap tests, at which time the Pap test frequency is reduced to every three years.

An alternative cervical cancer screening strategy involves administration of both the Pap test and a human papillomavirus (HPV) DNA test. Because persistent, carcinogenic HPV is strongly predictive of cervical cancer, this strategy, called HPV co-testing, can be used to identify women who should be screened frequently for signs of cervical cancer. HPV co-testing can also be used to extend the screening interval for women who are low risk, i.e., both cytology negative and HPV negative. HPV co-testing is recommended by national organizations, but health care providers have been slow to adopt it or to use the results of HPV testing to modify the frequency of cervical cancer screening with the Pap test.

CDC is currently conducting a pilot study in 15 clinics in Illinois to examine the effects of an educational intervention aimed at improving patient and provider understanding of HPV co-

testing (CDC Cervical Cancer Study (CX3)). The specific aims of the study are to: (1) assess whether provider and patient education leads to extended screening intervals for women who have negative screening results; (2) identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals; (3) track costs associated with HPV testing and educational interventions; and (4) identify the HPV genotypes among this sample of low income women. Secondary goals of the study are to: (1) assess follow-up of women with positive test results and (2) determine provider knowledge and acceptability of the HPV vaccine.

During the first three years of the study, each participating clinic was assigned to one of two study arms. Clinics in the intervention group administered the HPV DNA tests to eligible patients, along with a multi-component educational intervention involving both providers and patients. Clinics in the comparison group administered the HPV tests, but patients and providers have not received the educational intervention. A total of 2,246 women between the ages of 30 and 60 have been recruited into the study. Baseline information collection has been completed for an initial clinic survey, a 12-month follow-up clinic survey, a baseline provider survey, patient recruitment and enrollment, and a baseline patient survey.

Information collection was initiated for a 36-month follow-up provider survey and an 18-month follow-up patient survey. These activities were described in the original Information Collection Request.

In order to complete the study as planned, CDC requests one additional year of approval from OMB. Information collection will include completion of the 18-month follow-up survey for approximately 150 patients and completion of the 36-month follow-up survey for 70 providers. The final year of the study will also include focus groups with approximately 75 providers.

Information collected through follow-up surveys of patients and providers will be used to assess changes in knowledge, attitudes, beliefs and behavior regarding cervical cancer screening. Qualitative information collected during the focus groups with providers will be used to identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. Findings from the CX3 study will help inform NBCCEDP standards for primary cervical cancer screening, including reimbursement guidelines for the HPV DNA test.

Participation in the CX3 study is voluntary and there are no costs to respondents other than their time. OMB approval is requested for one year. Because the majority of information collection activities were completed in the first three years of the study, the estimated burden to respondents will decrease in the final year of OMB approval. The total estimated annualized burden hours are 135.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Patients	Follow-up Patient Survey	150	1	10/60
Providers	Follow-up Provider Survey	70	1	30/60
	Focus Group Moderator Guide	75	1	1

Kimberly S. Lane,
Deputy Director
Office of Science Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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