

**CDC'S CERVICAL CANCER STUDY (CX3)
AN INTERVENTION PILOT STUDY OF HPV IN
ILLINOIS NBCCEDP**

SUPPORTING STATEMENT

PART A

Revision, OMB No. 0920-0814

April 27, 2012

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Abstract

The Centers for Disease Control and Prevention (CDC) requests OMB approval for a one-year Revision of a currently approved collection. Approval is requested in order to complete the project as described in the original Information Collection Request.

In 2009, OMB approved the first three years of data collection for CDC'S Cervical Cancer Study (Cx3) An Intervention Pilot Study of HPV in Illinois NBCCEDP (OMB No. 0920-0814; exp 6/30/2012). The study is being conducted in 15 clinics in the state of Illinois. A total of 2,246 women who visited one of the participating clinics for a scheduled Pap test were recruited for the study. Patients who agreed to participate in the study received an HPV DNA test in addition to the Pap test (co-test). Clinics were assigned to one of two study arms. Clinics in the intervention arm administered the HPV DNA tests to eligible patients, along with a multi-component educational intervention involving both providers and patients. Clinics in the comparison arm administered the HPV tests but patients and providers did not receive the educational intervention.

The purpose of the study is to examine whether or not there is an increase in the cervical cancer screening interval to 3 years for women in the target age range with a normal Pap test and a negative HPV DNA test. Primary goals of the study are to: (1) assess whether provider and patient education will lead 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 (Phase I) of the study, the following data collection efforts were completed: a provider baseline survey was administered to providers at the participating clinics who routinely perform Pap testing before beginning patient recruitment; a patient baseline survey was administered to a sample of patients during their initial clinic visit prior to the patient's HPV test; a monthly clinic survey was administered to all participating clinics during the first year of patient recruitment to obtain information regarding resources associated with participating in the study; and a provider follow-up survey was administered to clinic providers 12 months following study initiation. In addition, 18 months following the initial clinic visit, a patient follow-up survey is being administered to patients who completed a baseline survey.

Approval is currently being requested to continue data collection during Phase II of the study. These data collection activities include: continuing administration of the patient follow-up survey 18 months following the patient's initial clinic visit to assess changes in knowledge, attitudes, beliefs, and behavior regarding cervical cancer screening; administration of a provider follow-up survey 36 months following study initiation to assess changes in knowledge, attitudes, beliefs, and behavior regarding cervical cancer screening practices; and conducting qualitative interviews with providers to identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. An additional source of data for the analysis includes patient medical and billing records, which will be reviewed by contractor staff to

provide information necessary to determine whether or not HPV co-testing leads to extended screening intervals for women with negative results (and to determine what type of follow-up care was provided to women with positive HPV test results). This data collection presents no burden to clinic staff.

A.1. Circumstances Making the Collection of Information Necessary

Background

This is a request for a one-year Revision of a currently approved collection (OMB No. 0920-0814; exp 6/30/2012). The Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Center for Disease Control and Prevention (CDC), requests permission from the Office of Management and Budget (OMB) to continue the data collection associated with a pilot study to determine whether Pap test screening intervals increase with the addition of HPV testing along with Pap testing in women over 30. Because this is a pilot study, the results of the study will not be generalizable to entire U.S. population. However, the outcomes of the study can be used to inform policies on reimbursement of the HPV DNA tests for CDC's national screening program.

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) is the only organized national screening program in the U.S. that offers breast and cervical cancer screening to underserved women (<http://www.cdc.gov/cancer/nbccedp/about.htm>). To improve access to screening, Congress passed the [Breast and Cervical Cancer Mortality Prevention Act of 1990](#), which guided CDC in creating the NBCCEDP. Currently, the NBCCEDP funds all 50 states, the District of Columbia, 5 U.S. territories, and 12 American Indian/Alaska Native tribes or tribal organizations to provide screening services for breast and cervical cancer. Since 1991, NBCCEDP-funded programs have served more than 3.9 million women and diagnosed 2,856 invasive cervical cancers, and 136,837 premalignant cervical lesions, of which 41% are high-grade. However given limited resources, less than 10 percent of the eligible population receives screening. The current cervical cancer screening standard in the NBCCEDP is 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 3 years.

Based on the central role of persistent, carcinogenic human papillomavirus (HPV) in cervical cancer, HPV testing has been introduced into cervical cancer screening. HPV testing with the Pap test (called co-testing) for women over 30 years of age is a recommended option for cervical cancer screening by national organizations (Saslow, 2002; ACOG, 2009). Because of the high sensitivity to detect cervical cancer, those that test negative are at an extremely low risk of developing cancer and therefore can safely extend the screening interval regardless of screening history (Cuzick J, 2006; Arbyn M, 2006; Mayrand MH, 2007; Naucler P, 2007, Bulkman N, 2007). The current guidelines recommend that any woman who has negative tests (Normal Pap and Negative HPV) would automatically move to a 3-year screening interval (Saslow, 2002; ACOG, 2009). Cost-effectiveness studies have shown that additional costs associated with introducing the HPV co-testing are offset by an increase in the screening interval among women with negative co-tests (estimated to be about 90%) because of the low risk of cervical precancer

and cancer (Mandelblatt JS, 2002; Goldhaber-Fiebert JD, 2008; Bistoletti P, 2008). However, in the Program (Benard, 2011) and throughout the United States (Yabroff,2010; Saraiya, 2010; Roland, 2011), the common practice across provider specialty regardless of screening strategy is an annual screen.

Because of the slow uptake of providers to move to a longer interval, the NBCCEDP has been hesitant to reimburse for the HPV co-test on a national level. With already limited resources, if providers are not willing to lengthen the screening interval according to guidelines then adopting HPV co-testing would not be cost effective. Therefore, this pilot study is an educational intervention to determine facilitators and barriers to appropriate use of the HPV co-test including extending the screening interval. Studies in managed care settings with the HPV co-test strategy for screening found that both providers and patients were acceptable to the longer intervals once they understood the role of HPV (Castle, 2009; Katki, 2011). Currently, there have not been studies that have examined the acceptance of HPV testing with longer screening intervals in a low income, uninsured population. This pilot study is necessary to inform standards for providing cervical cancer screening to women served by the NBCCEDP and essential with the changes in healthcare reform.

This data collection is authorized under section 301 of the Public Health Service Act (42 U.S.C. 241). The authorizing legislation is included as Attachment A.

Privacy Impact Assessment

The current request will involve the continuation of data collection from providers and patients in the 15 clinics in the state of Illinois that were recruited to participate in the study. In Section B (Collections of Information Employing Statistical Methods) of the Supporting Statement, details are provided regarding the types of data that will be collected and the methods that will be used. All patients included in the study will be at least 30 years of age. No children under the age of 13 will be involved in the study.

Overview of the Data Collection System

During Phase II of the study, the data will be collected from several sources. These include (1) an 18-month follow-up survey will be administered to assess changes in patient's knowledge, attitudes, beliefs, and behavior regarding cervical cancer screening; (2) a 36-month follow-up survey will be administered to assess changes in provider's knowledge, attitudes, beliefs, and behavior regarding cervical cancer screening practices; and (3) qualitative interviews will be conducted with providers to identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. Additional data will be obtained from a review of patient medical and billing records, which will be conducted by contractor staff. These data sources will provide the information necessary to determine whether or not HPV co-testing leads to extended screening intervals for women with negative results. The medical records of all women with a positive test outcome (i.e., abnormal Pap and/or positive HPV) will also be reviewed to determine what type of follow-up care was received.

CDC's Cervical Cancer Study (Cx3 Study) Follow-up Provider Survey (Attachment C1) will be

administered to clinic providers 36 months following study initiation. In addition, CDC's Cervical Cancer Study (Cx3 Study) Follow-up Patient Survey (Attachment D1) will be administered 18 months following patient enrollment. Administration of the 18-month follow-up patient survey was begun during Phase I of the study and will continue during Phase II (for patients who were recruited during the end of the recruitment period). The patient and provider follow-up surveys will be administered as mail surveys. The study contractor, Battelle, will conduct the mailing, track the responses, and enter and analyze the data. Finally, using the Provider Formative Research (Focus Group) Moderator Guide (Attachment C2), qualitative interviews will be conducted with providers at the conclusion of the study to identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. These qualitative interviews will be conducted three years following study initiation (between October 1, 2012 and March 31, 2013). They will be conducted as individual or group interviews at each clinic (depending on the preference of clinic staff). The one-year extension will allow the follow-up activities to be completed.

Items of Information to be Collected

The data to be collected in Phase II of the study will provide information regarding patient and provider knowledge, attitudes, beliefs, and behavior regarding cervical cancer screening. Responses to the follow-up survey questions will be compared with responses to the baseline surveys that were administered prior to study initiation. Names, addresses, and phone numbers of respondents are necessary in order to conduct the follow-up surveys. These data were obtained at the time of study enrollment. Survey data are identified only by a unique respondent identifier and are stored separately from Information in Identifiable Form (IFF). In the case of the survey data, IFF information is limited to date of birth (month/year).

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

There are no websites with content directed at children under 13 years of age or any other segment of the public.

A.2. Purpose and Use of Information Collection

The overall goal of the intervention is to increase patient and provider awareness of cervical cancer screening guidelines and intervals, thereby directly impacting the regularity of cervical cancer screening among women participating in the project. The educational intervention component of this pilot project provides opportunities to foster a change in the attitudes, beliefs, and practices of patients and providers through behavior change reinforcement and knowledge acquisition. The proposed outcome objective aims to increase cervical cancer screening intervals to 3 years for women who present a normal Pap test and a negative HPV DNA test. In essence, this objective is designed to decrease patient cervical cancer screening visits to clinic sites, a concept that is contrary to what past social marketing campaigns and patient education interventions sought to communicate: to have a Pap test annually. A majority of primary care and women's health providers are aware of these changes in guidelines and some are fearful that, among other reasons, they may lose patients to attrition with increased screening intervals, or

miss valuable opportunities to screen rarely or never screened women who rarely make office visits. It is vital that the advantages of the use of the HPV DNA test, such as higher sensitivity to identify cervical neoplasia, and the cost-effectiveness of co-testing be communicated to providers and patients alike, using culturally appropriate and evidence-based methods. They also need to understand that the aim is to reduce the frequency of the Pap test but not the annual well woman visit.

Public programs and studies that incorporate health communication and education strategies targeting patients and providers are vital if new testing strategies are to be adopted. Knowledge regarding HPV transmission, the relation between HPV and cervical disease, treatment and management, as well as the impact on clinical practice are necessary for both patients and providers, and have been recommended as future research initiatives (Wright, et al, 2004). This pilot project in Illinois will not only incorporate the provider as a central component to knowledge acquisition in the community, but will also study the adoption and adherence to new screening guidelines by patients and providers among a diverse population, and will observe the effects of behavior change through evidence-based educational interventions.

The results of this study will provide information regarding the extent to which providers are willing to extend the cervical cancer screening interval to 3 years for women in the target age range with a normal Pap test and a negative HPV DNA test. It will also provide information regarding whether provider and patient education will lead to extended screening intervals for women who have negative screening results. In addition, the study results will provide information regarding the level of knowledge regarding cervical cancer screening among low-income, underserved women—who represent the demographic most needy of highly sensitive screening methodologies that can increase the likelihood of detecting cervical dysplasia at less frequent screening intervals. The findings from this study will help inform standards regarding the HPV DNA test on a national level for cervical cancer screening in the NBCCEDP.

The National Breast and Cervical Cancer Early Detection Program, which was created in response to the Breast and Cervical Cancer Mortality Prevention Act passed by Congress in 1990, is both the first and thus far the only national cancer screening program in the United States. The NBCCEDP offers breast and cervical cancer screening to underserved women. Currently the program operates in all states, the District of Columbia, 4 U.S. Territories and 13 American Indian and Alaska Native tribal programs. Since 1991, NBCCEDP-funded programs have served more than 3.9 million women and diagnosed 2,856 invasive cervical cancers, and 136,837 premalignant cervical lesions. The agency is committed to the ongoing support of this national program. Without the information that will be gained from this study, the national screening program will have no information for informing standards regarding the HPV DNA test. Failure to set reimbursement policies could have a major impact on the efficient allocation of program resources to reach underserved women in the years ahead.

Privacy Impact Assessment Information. This study involves the collection of data that are needed to inform reimbursement policies for the NBCCEDP related to cervical cancer screening. Specifically, the study enrolled clinics and their physicians and patients into two study arms to compare outcomes associated with routine Pap testing coupled with HPV testing for women age 30-60 years coming in to the clinic for a regular screening Pap. Goals of the study are to: (1)

assess whether provider and patient education will lead 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; (4) identify the HPV genotypes among this sample of low income women; (5) assess follow-up of women with positive test results; and (6) determine provider knowledge and acceptability of the HPV vaccine.

In Phase II of the study, data will be collected from patients and providers. At the time of patient enrollment, a series of unique patient ID numbers were provided to each clinic participating in the study. Staff assigned a patient ID to each patient at the time of enrollment. Follow-up surveys are mailed by Battelle to patients using their pre-assigned ID. Responses are returned directly to Battelle for data entry. Clinic staff do not have access to the surveys or to the database containing individual responses. Provider follow-up surveys will be mailed directly to providers. Each provider will be provided with a postage-paid return envelope and instructed to send their completed survey to Battelle for data entry and analysis. Clinic staff will not have access to the surveys or to the database containing individual responses. Responses to the qualitative interviews will be aggregated and will not be associated with an individual provider.

In conducting the data analysis, data will be pooled across providers and patients. The survey data will be examined with univariate, bivariate and multivariate analyses, including analyses at both the provider- and patient-level. The unique ID system and the protocol for data handling were designed to protect the data being collected from accidental disclosure. To further ensure the confidentiality of the survey data, the project obtained a Certificate of Confidentiality (Attachment G3) from CDC. The IRB concluded that with this certificate in place, this project presents minimal risk to study participants. Documentation of CDC and Battelle IRB approval of the study is provided as Attachments G1 and G2.

A.3. Use of Information Technology and Burden Reduction

The provider and patient surveys will use hardcopy data collection methods, as was the case in the baseline and follow-up surveys conducted in the first three years of the study. In the case of the patient survey, a mail survey was selected because the patients recruited into the study consist of low income individuals (70% of the patients surveyed reported that they earned less than \$15 per hour) and access to computers could be problematic in this population. In the case of the provider survey, a mail survey was indicated as a preferred mode during early discussions with the clinics about their participation in the study. Mail survey for providers was preferred for ease of administration given the small number of clinics and providers involved.

CDC has contracted with Battelle Centers for Public Health Research and Evaluation to collect, manage, and analyze all data for this study. Information technology tools were used in two ways to reduce the burden of participation. For example, Battelle staff developed a survey tracking database that is being used to monitor the various data collection activities. This tracking database will let Battelle study staff know when to mail follow-up surveys and reminders.

A.4. Efforts to Identify Duplication and Use of Similar Information

In our efforts to find this information through consultation with medical care providers, researchers and a review of the literature, we were not able to address this issue of HPV DNA testing in a low income, uninsured group of women to inform standards for the NBCCEDP.

In 2002, the FDA approved the HPV DNA test with cervical cytology for cervical cancer screening in women 30 years of age and older. Since the approval, several organizations such as the American College of Obstetrics and Gynecologists and the American Cancer Society support HPV testing for use in combination with cervical cytology. A cost-effectiveness analysis has shown that additional costs associated with introducing HPV testing in conjunction with cytology could be offset by an increase in the screening interval among HPV-negative, cytology normal women because of the low risk of precancer and cancer (Goldie, 2004). However, in the United States, the common practice is annual cytology, either a Pap smear or liquid-based cytology. Some questions have been raised regarding the acceptability of longer screening intervals among those at low risk of disease. Several European prospective studies are examining the acceptability of HPV testing and increasing the screening interval. However, there are no current studies in the U.S. performed in a real-life setting among women who are racially/ethnically diverse.

The use of the HPV DNA test in conjunction with cervical cytology is advocated based on the very high negative predictor value of the combined HPV DNA plus Pap test, usually 99.9 to 100 percent (Lorincz and Richart, 2003). The HPV DNA test has been proved to be reproducible, and is simple to perform (Ratnam, et al, 2000). One benefit to using HPV testing with cervical cytology for screening women is that it identifies not only women with concurrent cervical disease, but also those at risk of developing disease in the future (Wright, et al, 2004). Because of the large number of women with low-grade Pap tests who are HPV negative and thus at lower risk of cervical precancer and cancer, the opportunity is present to safely manage these women with a less intensive follow-up.

In recent studies it has been reported that conventional Pap tests are only about 50-60 percent sensitive in detecting high-grade CIN and cervical cancer, and are less sensitive for lower-grade lesions (Nanda, et al, 2000; Fahey, Irwig, and Macaskill, 1995). Because of this lower sensitivity, the Pap test needs to be repeated with great regularity to necessitate effectiveness. Because of occasional pathology misdiagnoses and consequential possible Pap test litigation, it is vital to have a screening test that can discriminate between patients with and without cervical neoplasia, and those patients that are at risk for developing disease (Lorincz and Richart, 2003). However, most women who develop cervical cancer do so because of lack of screening rather than errors in cytodiagnosis (Nanda, et al, 2000). The combination of HPV and Pap tests avoids the greatest number of invasive cervical cancer cases and deaths, measured biennially (Mandelblatt, et al, 2002).

Previous studies have indicated that multi-component interventions that target both the patient and provider have been successful in achieving objectives and goals for improved cancer screening coverage and increase in knowledge (Curbow, et al, 2004; Dignan, et al, 1994; Jenkins, et al, 1999; Taylor, et al, 2002; Dietrich, et al, 1989; Shelley, et al, 1991; Suarez, et al, 1993). A study published in 2006 implemented in rural Arkansas to influence primary care provider's cancer screening practices in medically underserved and rural areas cited using

academic detailing, which is physician education to assure accurate screening guideline knowledge; patient education to increase awareness of risk factors and regular screening; and patient generated screening questionnaires to prompt discussion between patients and providers to improve screening among the underserved. Academic detailing visits between the provider and a retired physician occurred every 6-8 weeks to reinforce expected behavior led to an increase in physician knowledge about cancer screening. For the patient education component, education centers were created in the waiting areas including brochures and a 45 minute video and patient interviews indicated increased knowledge led to increased intent to receive preventive cancer screening. Results from the education intervention for the physician found a 100% correct response rate upon post-testing from the academic detailing sessions with the physician educator. This study illustrates that the inclusion of health care providers is vital to reducing health disparities (Rutledge, et al, 2006). However, none of the studies cited above have examined the extent to which patient and provider education is effective in changing attitudes and behavior regarding HPV DNA testing in a low income, uninsured group of women. This pilot study is necessary to inform standards for providing cervical cancer screening to women served by the NBCCEDP.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequence of Collecting the Information Less Frequently

This request is for continuation of a one-time study that follows providers and patients in selected clinics for 3 years after enrollment. This information is essential to inform future CDC reimbursement policies for the NBCCEDP. The duration of the study is necessary to answer the study questions related to screening intervals. Specifically, the study will answer whether or not there is an increase in the cervical cancer screening interval to 3 years for women in the target age range with a normal Pap test and a negative HPV DNA test. Responses to patient and provider follow-up surveys will be compared to responses to the baseline surveys to assess changes in attitudes and behaviors related to cancer screening. This level of follow up is required to answer the study questions and complete the analyses described in Section A.16 (Plans for Tabulation and Publication and Project Time Schedule). There are no legal obstacles to reduce the burden.

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

This request fully complies with the regulations 5 CFR 1320.5.

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

A. The Federal Register Notice (Attachment B1) for the proposed data collection was posted in the Federal Register on February 17, 2012, Volume 77, pages 9660-9661. One comment was received from the American Cancer Society Cancer Action Network (Attachment B2), which expressed support for the study and recommended that the research questions should be updated to reflect recently revised guidelines from the American Cancer Society and the United States Preventive Services Task Force (USPSTF). In response to this recommendation, CDC revised question no. II.A.2 of the moderator’s guide for focus groups with providers (Attachment C2). All information collection based on this instrument will occur during the final year of the study (Phase II), as it was not fielded during the initial three years of the project (Phase I). CDC also considered incorporating the comment into the Follow-up Provider Survey (Attachment C1), which was fielded during Phase I and will continue to be used in Phase II. However, to avoid inconsistencies between follow-up surveys that were completed in Phase I, and follow-up surveys that will be completed in Phase II, CDC decided not to revise this instrument.

B. The study protocol, including the survey instruments, sampling plans, and data collection procedures were designed in collaboration with researchers at Battelle Centers for Public Health Research and Evaluation.

Four consultants provided input to CDC and Battelle in the development of the study protocol, data collection instruments and patient and provider intervention materials. The names, titles, telephone numbers, and email addresses of the consultants—along with their organizational affiliations—are provided in Table A.8 – 1.

A.8-1 Study Consultants

Year	Consultant	Agency/Organization
2007	George F. Sawaya, MD Associate Professor Phone 415-502-4090 sawayag@obgyn.ucsf.edu	University of California, San Francisco Departments of Obstetrics, Gynecology and Reproductive Sciences; Epidemiology and Biostatistics
2007	Allen J. Dietrich, MD Professor Phone: 603-653-3648 Allen.J.Dietrich@Dartmouth.edu	Dartmouth Medical School Department of Community and Family Medicine
2007	Shalini Kulasingam, PhD Assistant Professor Phone: 919-286-3399 kulas002@mc.duke.edu	Duke University School of Medicine Department of Obstetrics and Gynecology
2007 2008	Philip Castle, PhD, MPH Investigator Phone: 301-435-3976 castlep@mail.nih.gov	National Cancer Institute, NIH, DHHS Division of Cancer Epidemiology and Genetics, Hormonal and Reproductive Epidemiology Branch

A.9. Explanation of Any Payment or Gift to Respondents

Patients will be sent a \$5 monetary incentive and providers will be sent a \$50 monetary incentive to encourage their completion of the patient and provider follow-up surveys. There is clear and

consistent evidence that monetary remuneration significantly increases response rates to mail, telephone and face-to-face surveys, and experts on survey methods recommend their use (Dillman, 1978; Dillman 2000; Sudman, 1985). Church (1993) and Singer and colleagues (1999) have published meta analyses comparing the response rates of mail and interviewer-mediated surveys with and without monetary incentives. These studies have clearly shown that even a nominal gratuity increases response rates, and that the amount of the incentive is positively correlated with response rate (Kropf, et al., 1999; Hopkins and Gullickson, 1992; Fox et al., 1988; Harvey, 1987). Furthermore, combining other measures to increase response (e.g., sending advance letters, repeated follow-up with non-respondents) with monetary payments has been shown to produce higher response rates than payments alone or other types of incentives without payments (Collins et al., 2000; Yamarino, et al, 1991).

Previous research suggests that monetary incentives may be especially effective in recruiting low-income and minority respondents. For example, analyses by Singer, Van Hoewyk, and Maher (2000) indicate that a \$5 incentive paid to a random half of households in a random digit dialed telephone survey brought a higher percentage of low-education respondents into the sample. Patients recruited into this pilot study in Illinois include a high percentage of African American (32.6%) and Hispanic (32.1%) women. We feel that it will be particularly important to obtain a high response rate from these minority populations.

Finally, in addition to increasing survey response rates, a few studies have examined the impact of incentives on data quality (Shaw et al., 2001; Shettle and Mooney, 1999; Singer, et al, 2000). For example, experiments reported by Singer and associates (2000) indicate that promised and prepaid incentives reduce the tendency of older people and nonwhites to have more item missing data, resulting in a net reduction in item nonresponse. These studies suggest that offering an incentive may improve data quality in the sense that respondents who were provided incentives had less item-missing data and provided longer open-ended responses compared with respondents who were not provided incentives.

Cash payment was selected as the preferred incentive for both the patient and provider surveys. In addition, research indicates that mailing incentives along with the questionnaire raises response rates more effectively than promising an incentive upon receipt of a completed questionnaire (Dillman, 2000). Therefore, for the patient and provider follow-up surveys, Battelle will mail the incentive as part of the initial questionnaire mailing to further improve response rates.

The \$5 patient incentive and \$50 provider incentives were approved for the baseline and follow-up surveys that have been conducted to date. Several other CDC studies have provided a monetary incentive to respondents. For example, a recent study entitled “Preventive Cardiac Health Care Knowledge, Beliefs, and Behaviors in Female Carriers of Duchenne/Becker Muscular Dystrophy” (OMB No. 0920-0718) provided \$5 to each of 1,477 women who participated in a mail survey. These women were selected from mailing lists of the Muscular Dystrophy Association (MDA) or the Parent Project Muscular Dystrophy (PPMD) organization. Another CDC study entitled the “Arthritis Health Condition Effects Survey (ACHES)” (OMB No. 0920-0673) provided a \$5 incentive to individual who responded to a random digit dial telephone survey. Finally, the CDC study entitled the “Study to Explore Early Development

(SEED)” (OMB No. 0920-0741) involved incentives to families with young children, many of which included children with autism or other developmental disabilities. In this longitudinal study, incentives ranged from \$25 included in the enrollment packet, to \$30 included in questionnaire packets, to \$80 for clinic visits.

In other recent studies targeting physician and other medical office and hospital-based respondents, incentives have been provided as compensation for their time and inconvenience and in recognition of their contributions to the studies’ goals. Other examples include:

HPV Provider Survey: Knowledge, Attitudes, and Practices About Genital HPV Infection and Related Conditions (OMB No. 0920-0629)

- Sponsor: Division of STD Prevention, National Center for HIV, STD, and TB Prevention
- Incentive Payment: \$50
- Population: a national sample of 7,000 clinicians from 9 specialties
- Response Rate: 81%

Survey of Endoscopic Capacity at the State Level (OMB No. 0920-0590)

- Sponsor: Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion
- Incentive Payment: \$40
- Population: the universe of physician practices, ambulatory survey centers and hospitals that perform flexible sigmoidoscopy and/or colonoscopy to screen for CRC in 15 selected states
- Response Rate: 80%

A.10. Assurance of Confidentiality Provided to Respondents

In order to conduct both the provider and patient surveys, Battelle must maintain the link between both provider names and patient identifying information and their respective participant ID numbers. These links are used for tracking survey mailings, and to link responses to the baseline and follow-up surveys. While Battelle will have the capability to link responses to individual participants, this capability will only be present until data collection is completed. At that point, the tracking files will be destroyed and there will be no way to link responses to individuals. The link between identifying information and ID numbers will be stored securely and separately.

Data will be treated in a confidential manner and will not be disclosed. Neither the names of respondents nor the institutions they represent will be identified in published reports or publicly available data. Completed paper surveys will be stored in locked file cabinets in Battelle offices. All electronic files are password protected and accessible only to authorized project staff. Measures to safeguard data are emphasized in written and verbal training procedures for project personnel. To protect the confidentiality of the provider survey data, the project received a Certificate of Confidentiality from CDC. The IRB concluded that with this certificate in place, this project presents minimal risk to study participants. Documentation of CDC and Battelle IRB approval of the study is provided as Attachments G1 and G2.

Privacy Impact Assessment Information.

A. This submission has been reviewed by staff in the CDC Information Collection Review Office, who determined that the Privacy Act does apply. The applicable System of Records Notice (SORN) is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems.

B. A Certificate of Confidentiality was received from the Associate Director for Science, CDC. This is authorized by section 301[d] under the Public Health Service Act. In addition, the contractor Battelle is using security controls to protect against unauthorized access, modification, destruction or disclosure of data through access control and authentication. Security controls will protect privacy and confidentiality of personal identifying information (PII) and personal health information (PHI) through technical controls, administrative controls and physical controls. Documentation of the Certificate of Confidentiality is included as Attachment G3.

Technical Controls. All data collected during performance of this study are stored in Battelle's SQL Server databases on Local Area Networks (LANs) behind firewalls. Each subject is assigned a unique subject ID that is the unique identifier on all analytic and survey data records, assuring that personal identifying information is not stored with the data and all analysts are blinded to the subject's identity. The link between personal identifying information and the assigned ID is stored in a separate secured database table with controlled access. Analytical data sets may be stored on analysts' PCs when they are working with the data. All Battelle PCs are currently Windows XP Professional, Service Pack 2 and access is controlled.

Physical Controls. All servers are located in secure controlled access areas. Physical access to Battelle offices during non-office hours requires possession of an electronic card. During office hours all visitors can only enter through a staffed reception area where they are logged in and must be escorted at all times while on the premises. Within each Battelle office are additional secure areas that have secured access at all times. All server rooms require 24-hours electronic card access. Each electronic card is programmed for a specific user and provides that user with access to all areas to which they are authorized. Battelle offices also have alarm systems monitored by professional security agencies that are activated when the offices are vacant. Authorized users have individual access codes and all access, including invalid attempts, are logged. In addition to these general security measures, sensitive material is stored in locked file cabinets when not in use. Only office administrators and staff authorized to work with these materials have keys to these file cabinets. Battelle staff are trained in these policies and periodically reminded of their importance. Battelle staff members are required to lock their computers when away from their desk using Windows XP Task Manager. Password-protected auto-locking is configured to activate after 10 minutes of inactivity.

Administrative Controls. Battelle's IT division maintains an intranet site on Cybersecurity Policies and Procedures that is accessible by all employees. This site includes staff responsibilities for protecting data and security requirements for protection of the network, PCs, mobile devices and the data residing on them. In addition, the IT division frequently sends emails to all staff reminding them of specific security issues, such as use of the internet, remote access, email safety, etc. Battelle is in the process of developing its own IT Security Awareness training.

SQL Server databases are backed up nightly to a folder on the server's hard drive and integrity is verified upon completion. The folder containing these full database backups is then backed up to tape as part of our network backup plan. The network backups provide nightly incremental backups and full backups on weekends for all data stored on Battelle LANs and WANs. Tapes are stored offsite at secure contracted facilities. Permissions to project databases are limited to staff members assigned to work on the project. Non-technical project staff can only access the data indirectly through applications and are authenticated by username and password when logging into the application. All PC-based files, folders, and applications are backed up nightly to a secure server in encrypted format using Connected DataProtector software. Laptops are backed up using this software when staff reconnects to the Battelle network. Files remain encrypted while stored and only the owner of the files and the IT administrator has the encryption key. Staff can elect to backup or restore files at any time in addition to the automatic backup. A Battelle technical staff member is responsible for transferring data to CDC and participating clinics in a secure manner and for receiving data from these agencies and securing it. Identifying information is always stored and transferred separately from analysis data. Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule.

C. Patients were recruited into the study by clinic staff when the patients visited the clinic for their scheduled Pap test. Patients who were eligible and who agreed to participate in the study were asked to sign a consent form (in either English or Spanish) providing permission for the HPV DNA testing. For those patients who were recruited into the survey arm of the study, the consent form also provided permission for the baseline and follow-up patient surveys. A copy of the consent form for patients who were surveyed is included as Attachment D1a. The consent language is repeated in the cover letter for the patient follow-up surveys (Attachment D1c). With respect to the provider follow-up survey, the consent language is included in the cover letter for the provider follow-up surveys (Attachment C1a). Completing the patient or provider follow-ups survey and returning it in the envelope provided will be taken as indication of consent. Consent for provider participation in the qualitative interviews to be conducted at the conclusion of the study will be obtained prior to the interviews (Attachment C2a). Participants in the interviews will be asked to read the consent form and to keep the copy for their records.

D. Participation in the provider follow-up survey and qualitative interviews is voluntary. The providers are informed of this in writing in the survey cover letter (Attachment C1a) and in the consent form for the qualitative interviews (Attachment C2a). Likewise, patient participation in the study is voluntary. The patient consent form (Attachment D1a) asked for their consent for the baseline and follow-up surveys. Specific language stating the voluntary nature of their participation is in the consent form. The follow-up surveys are being conducted by mail. The consent language is repeated in the cover letter for the patient follow-up surveys (Attachment D1c). Patients and providers are informed that their surveys will be identified only with their study ID number, that we will not identify any person who was in the study in any papers or reports, and that all responses will be kept private to the extent allowed by law.

A.11. Justification for Sensitive Questions

Topics typically considered to be of a sensitive nature include sexual practices, alcohol or drug use, religious beliefs or affiliations, immigration status, and employment history. Several questions regarding sexual practices (e.g., number of sexual partners) are included in the patient surveys. These questions are necessary to determine the respondent’s risk of HPV. In addition, the follow-up provider survey involves the collection of information that may be considered sensitive by a portion of respondents, such as data regarding professional practices as they relate to professional guidelines. Thus, although some information may be considered sensitive by a portion of respondents, the information is required for the planned analyses and use of survey results. As described in Section A.10 (Assurance of Confidentiality Provided to Respondents), appropriate measures to safeguard respondent privacy have been instituted, including obtaining a Certificate of Confidentiality from CDC to protect the confidentiality of the survey data.

A.12. Estimates of Annualized Burden Hours and Costs

Approximately 70 providers at the participating clinics are expected to be sent the 36-month follow-up survey (Attachment C1), which is estimated to take 30 minutes to complete. A total of 984 patients completed baseline surveys at the time of their initial clinic visit, and these patients are being surveyed 18 months following study enrollment. Many of these patients will have completed their 18-month follow-up surveys during Phase I of the study (prior to June 30, 2012). We estimate that approximately 150 patient follow-up surveys will be conducted during Phase II of the study. We estimate that the patient follow-up surveys will take an average of 10 minutes to complete (Attachment D1). Finally, approximately 75 clinic providers (an average of 5 per clinic) will be asked to participate in a focus group interviews at the conclusion of the study to obtain qualitative information regarding the facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. Each focus group discussion will be scheduled for approximately one hour (Attachment C2). The estimated annualized burden for the data collection activities to be conducted during is the final one-year approval period (Phase II) is 135 hours.

A.12-1 Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	No. Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Patients*	Follow-up Patient Survey	150	1	10/60	25
Providers	Follow-up Provider Survey	70	1	30/60	35
	Focus Group Moderator Guide	75	1	1	75
Total					135

*For those patients who are scheduled to receive an 18-month follow-up survey after June 30, 2012.

The cost to respondents is shown in Table A.12 – 2. There are no costs to respondents other than their time to participate. Hourly wage rates were obtained for providers in Illinois using the mean wage for general and family practitioners. These rates were obtained on November 1, 2011 at the

following website: http://www.bls.gov/oes/current/oes_nat.htm. For patients, we assumed an hourly wage rate of \$10.25 (\$2 above the 2011 Illinois state minimum wage). Using these estimates, the total annualized cost to respondents for the first 3 years of the study is \$9,134.

A.12-2 Annualized Cost to Respondents

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Respondent Cost
Patients	25	\$10.25	\$256
Providers	110	\$80.71	\$8,878
		Total	\$9,134

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

The data collection entails no additional costs to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

This project has been fully funded by CDC. The project costs for Phase II of the study are shown in Table A.14-1. The costs include (1) contract costs for Battelle for data collection and analysis (analysis will extend beyond the OMB-approved data collection period), and (2) the cost of CDC staff involved in oversight and analysis. The total contract cost for carrying out the project is \$745,597 over the remaining project period. The CDC costs include personnel costs of Federal employees involved in oversight and analysis, estimated at \$71,989 (25% of an FTE at GS-13, 10% Grade 05 Commissioned Corps Medical Officer, 5% of a 3 FTEs at GS-13) Thus, the total cost to the government, including total remaining contractual costs, and annualized costs for CDC oversight, is \$817,586.

A.14-1 Annualized Cost to the Federal Government

	Remaining project costs, including data collection
Battelle Contract Costs	
Personnel	446,809
Data Collection materials/services	298,788
Total Contract Costs	\$745,597
CDC Costs	
CDC Oversight	\$71,989
Cost to Federal Government	\$817,586

A.15. Explanation for Program Changes or Adjustments

Due to a decrease in the number of instruments to be fielded in Phase II (the period of this Revision ICR), there will be an overall reduction in burden hours. The following instruments will be discontinued in Phase II: the Initial Clinic Survey, the Follow-Up Clinic Survey, the Baseline Provider Survey, the Patient Screening Script, the Patient Enrollment Form, and the Baseline Patient Survey. Information collection for these study components was completed in Phase I.

During Phase I, information collection was initiated for the Follow-up Provider Survey and the Follow-up Patient Survey. These information collections will be completed in Phase II. Finally, Phase II includes one new activity that has not been previously conducted: Focus Groups with Providers. The overall effect is a decrease in burden from 1,006 annualized hours in Phase I, to 135 annualized burden hours in Phase II.

A.16. Plans for Tabulation and Publication and Project Time Schedule

A. Tabulation Plan

Data Analysis. Data will be pooled across providers and patients. The survey data will be examined with univariate, bivariate and multivariate analyses, including analyses at both the provider- and patient-level. First, univariate analysis will be conducted on all items in the survey questionnaires. Second, bivariate analyses will be conducted to examine overall associations between key constructs. Third, multivariate analyses will be conducted in selected instances to determine the independent and mediating influence of factors. Tests of significance will be conducted with methods which adjust for clustering of participants within clinic and provider. Scale constructs will be computed with data from the patient and provider surveys. Prior to creating these indices, we will make appropriate transformations of the questionnaire scales to ensure that low values are indicative of low support and high values are indicative of high support for HPV and Pap outcome measures. The questionnaire responses will also be standardized (subtracting the mean and dividing by the standard deviation) to ensure that they are all on the same scale. Factor analysis will be conducted to examine factor structure and Cronbach's alpha's will be calculated. Inter-item correlations will be conducted on all items designed to be measuring these constructs, to ensure that convergent validity exists, yet items account for separate variances.

Table Shells. Attachment F1 provides tables which summarize the measures that will be included in the provider and patient surveys in order to achieve the goals of the study. In addition to the patient and provider follow-up surveys, information will be obtained patient medical and billing records for each woman who received an HPV test to assist in the determination of the screening interval. In addition, patient medical records will be reviewed to provide information regarding the follow-up treatment provided to women with positive test results. The discussion below provides an overview of the analyses to be performed.

Descriptive characteristics. Examples of table shells that have been created to display the results of the analyses are included in Attachment F2. Table Shell 1 provides an example of the types of measures that will be used to describe the characteristics of the patients and providers, and to

compare these characteristics across the intervention and control sites. Significance of differences will be tested with Pearson chi-square for categorical measures and ANOVA for continuous measures. Analysis plans for each study goal are outlined below.

Assess whether provider and patient education will lead to extended screening intervals for women who have negative screening results. Examination of the intervention on extended screening intervals will apply two methods: logistic regression, and event history analysis. The initial models will run standard logistic regression with the dependent variable indicating whether the next Pap was conducted 30 months or more after the baseline Pap versus all other. This analysis will then be expanded to multinomial logistic regression where multiple outcomes can be examined. Four categories for the dependent variable will be defined in the initial analyses: (1) Pap conducted at 30 months or more; (2) Pap conducted at less than 30 months; (3) no follow-up Pap conducted; and, (4) lost to follow-up. Sensitivity analyses will be conducted by comparing the impact of outcome definition on estimates and study conclusions. In addition, event history analysis will be applied to examine the impact of the intervention on a continuous measure of months to next Pap. All of these methods will use patient-level data.

Identify facilitators and barriers to acceptance and appropriate use of the HPV test and longer screening intervals. These analyses add provider and patient survey data to identify factors which influence the acceptance and appropriate use of the HPV test and longer screening intervals. Table Shell 2 provides an example of the types of measures that will be used to examine differences in key constructs which might impact the appropriate use of the HPV test and the extension of the screening interval including knowledge, beliefs and attitudes at the baseline and the initial follow-up survey. Because the baseline patient- and provider-surveys are administered prior to the intervention training and the provision of guidelines to control sites, it is expected that there will be few differences between the control and intervention sites at baseline, and greater differences at follow-up. Significance of differences will be tested with Pearson chi-square for categorical measures and ANOVA for continuous measures.

Multivariate analyses of patient-level outcomes will be completed in two steps. First, bivariate associations will be calculated. Second, independent variables which had a significant bivariate association will be entered following a forward stepwise procedure. The analyses of screening intervals will apply the best models identified in the paragraph above for the first study goal. The method applied to models examining the acceptance and appropriate use of the HPV will depend on the structure of the dependent variable under consideration. Logistic regression will be used for categorical outcomes and linear regression for continuous outcomes. For each analysis where the intervention had a significant bivariate association with the outcome, further analysis will be conducted to see the impact of adding other bivariate significant independent variables into the equation including a measure indicating intervention site. Interactions between key constructs and treatment group will be considered. For instances where the analysis will focus on changes in repeated measures with patient-level data, either a generalized estimating equations approach or a generalized linear mixed models approach will be used.

Table Shell 3 provides examples of measures that will be used to examine the independent effect of constructs on lengthening the screening interval. The column under the heading *Bivariate Models* will present the estimate and significance level of models which include only the single

construct in the estimation model. Those constructs which are significant at the bivariate level will be considered for inclusion in the multivariate analysis. The estimates which are presented in the *Multivariate Model* column are only for those constructs which were found to have a significant independent effect.

In addition to the patient-level analyses outlined above, provider-level analyses will be conducted to examine changes in provider responses of constructs related to the acceptance and appropriate use of the HPV test and to extending screening intervals. Initial analyses will examine percent and mean distributions at baseline. Changes in provider responses to scales and the impact of the intervention will be examined longitudinally through the use of repeated measures ANOVA. Table Shell 4 provides an example of the presentation of repeated measures across three time points.

Assess follow-up of women with positive test results. Separate descriptive analyses will be performed for women with results in the following three categories: (1) HPV positive and Pap abnormal; (2) HPV positive and Pap normal; and, (3) HPV negative and Pap abnormal. With data from a medical chart review, the type of follow-up procedures along with the respective visit date and result will be examined and compared to the American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines. Table Shell 5 provides an example presentation of the distribution of follow-up tests and procedures performed for each of the three groups.

B. Publication Plan

Technical reports will be prepared to summarize project activities and the results of the data analysis. The results of the study will also be disseminated to various stakeholders through the publication of manuscripts in peer-reviewed journals and through presentations at professional meetings.

C. Project Time Schedule

A.16-1. Time Schedule

Activity	Date
Complete 18-month Follow-up Patient Survey	July 1, 2012 – January 31, 2013
Conduct 36-month Follow-up Provider Survey	October 1, 2012 – June 30, 2013
Conduct 36-month Interviews with Providers and Clinic Staff	October 1, 2012 – March 31, 2013
Data Analysis	July 1, 2013 – April 30, 2014
Publication of Results	January 1, 2014 – December 15, 2014

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

No exemption from display of expiration date is requested.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to certification are sought.

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