REQUEST FOR OMB REVIEW

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

SUPPORTING STATEMENT

PART B: COLLECTIONS OF INFORMATION
EMPLOYING STATISTICAL METHODS

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B.1. Respondent Universe and Sampling Methods

Selection Criteria for State. From the universe of all states in the U.S., one state was to be selected for this pilot project to study the impact of introducing HPV testing as an adjunct to Pap testing in the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). There were three criteria for a state to be considered eligible for selection as the demonstration state. Based on national NBCCEDP data from 2004, each state had to (1) have completed over 1000 Pap tests during 2004, (2) have over 90% completed follow-ups in 2004, and (3) have a high state ranking of incidence of invasive cervical cancer.

Eleven NBCCEDP state programs met these criteria and were invited to submit a letter of interest addressing the following areas:

- Interest in HPV and this project
- Previous research experience
- Professional educational efforts around cervical cancer screening
- Race and ethnic distribution of program participants
- Other programs affiliated with the program (i.e. WISEWOMAN)
- Describe the providers in the program including a master list

Of the 11 state programs, 2 programs were not interested and 9 replied. A committee from DCPC reviewed all 9 letters and requested a follow-up call with 2 states where more details were obtained. Illinois was selected as the demonstration state due to several unique features including (a) its work with WISEWOMAN, (b) an active cervical cancer task force, (c) an electronic data system that included other state programs, (d) the American Society for Colposcopy and Cervical Pathology president who worked with the NBCCEDP (Dr. Leslie S. Massad), and (e) the NBCCEDP team was very enthusiastic and eager to work on this project.

Selection Criteria for Sites. Within the state of Illinois, the universe of sites is all Federally Qualified Health Centers (FQHC) and FQHC look-alikes in the state of Illinois. The FQHC's were selected as the universe because the client base was most similar to NBCCEDP clients and because the sliding fee scale available to patients would provide the greatest likelihood that study sample patients would remain in the clinic over three years of follow-up regardless of continued eligibility in NBCCEDP (low income and uninsured). There are approximately 50 FQHC's and FQHC look-alikes in the state of Illinois. From this, 4 FQHC's and 2 hospital-based FQHC look-alikes were identified as providing a high volume of screening Pap tests to NBCCEDP clients.

Table B.1-1 summarizes the characteristics of the sites that were selected for participation in this pilot study. In total, 6 health care systems were selected, representing a total of 18 clinics. Two FQHC systems and one hospital-based system were allocated to each arm of the study. Intervention and control arms were matched on geographical location (urban, rural), racial/ethnic diversity, hospital versus non-hospital, provider specialty mix, and patient volume. The intervention arm thus includes 10 clinics representing 39 Pap providers and the control arm includes 8 clinics representing 31 Pap providers.

Table B.1-1. Participating Clinics, Providers and Average Number of Eligible Pap Patients per month

Intervention	# clinics	# Pap Providers	Paps per month*	Area	Type of sites	Predominate group
A	5	20	240	urban	Clinic-based	Hispanic
B	4	14	95	rural	Hospital-based	White
C	1	5	25	urban	Clinic-based	Black
Control						
A	3	13	250	urban	Clinic-based	Hispanic
B	4	13	65	rural	Clinic-based	White
C	1	5	40	urban	Hospital-based	Black

* Average number of screening Paps performed for women age 35-60 years.

Selection Criteria for Clinic and Providers. All 18 clinics will participate in the study. All providers who perform routine screening Pap tests within these selected clinics will be included in the study. We estimate the number of Pap providers to be about 70.

Selection Criteria for Patients. Within the selected health care sites, all patients who meet the eligibility requirements will be invited to enroll in the study over a period of 12 months (or until 8,000 HPV tests have been conducted). To be eligible, women must be between the ages of 35 and 60, and must be coming in for a regular screening Pap test. Women coming into the office for surveillance of previous abnormal screening test will not be eligible for the study because the purpose of the study is to look at the effects of the intervention on women with normal screening results. Enrolling women at age 35 instead of age 30 was selected to match the NBCCEDP lower age limit in Illinois. The upper age limit was selected so that follow-up is completed before women become Medicare eligible. Patients who enroll will receive an HPV DNA test in addition to the Pap test. They will also receive the educational materials (intervention arm only). A subsample of patients (n=2,600; 1,300 in each arm) will also be asked to complete a baseline and 2 follow-up surveys. The subsample of patients who will receive the patient survey will represent all eligible patients who are accrued into the study during a defined period of time until an adequate sample has been recruited (see sample size discussion below).

B.1.B. Response Rate and Statistical Power

Clinics and Providers. In total, 18 clinics and an estimated 70 providers will be included in the study. Given their promise to participate in this demonstration study, we expect that we will have 100% response rates to clinic and provider surveys at baseline and over the follow-up period.

Patients. Based on data regarding the volume of routine screening Pap tests conducted per month in the study clinics among women within the study age range, we estimate that the volume of HPV tests to be distributed (n=8,000) is approximately equal to the number of women who are likely to enroll in the study during a 12 month period. This is consistent with the study goal of 1 year of intervention and 3 years of follow-up. We believe that this length of time is sufficient to achieve a change among providers in their screening attitudes and behaviors.

We will obtain electronic billing data for all 8,000 women to examine screening intervals. However, a sample of 8,000 women is more than is required to detect changes in patient attitudes and behaviors regarding screening intervals. Thus, not all women enrolled in the study will be asked to complete the patient surveys. Based on power estimates presented in Table B.1-2 and expected response rates over the three-year follow-up, a subset of 2,600 patients will be surveyed at baseline. We estimate that 90% of these women will be Pap normal and HPV negative and thus eligible for extended screening intervals. In addition, an 80% attrition rate is expected from baseline to first follow-up, and from first to second follow-up. Thus the total number of completed surveys anticipated in each wave is as follows: 2,600 (baseline); 2,340 (eligible for extended interval analysis), 1,872 (first follow-up); 1,498 (second follow-up). The sample of patients will be evenly divided between intervention and control arms.

Sample Size and Power. Power analysis was conducted to determine the number of patients to be sampled for the patient surveys of attitudes, beliefs and behaviors regarding screening intervals and HPV testing. As shown in Table B.1-2, a sample of 750 patients in each arm of the study with complete data over the three year study period will yield a power of .9 or greater to detect a 0.1 difference between the intervention and comparison groups in attitudes, beliefs and behaviors toward HPV testing and extending the Pap test screening interval to 3 years among women who are Pap normal and HPV negative.

Table B.1-2: Sample size and power estimates

Number of providers per study arm	Number of patients per provider	Total patients per study arm	Power
30	12	360	0.745
30	14	420	0.792
30	15	450	0.824
30	20	600	0.870
30	25	750	0.915
30	30	900	0.929
30	35	1050	0.961

To calculate the sample size and power we can write the following about the outcomes:

Let P_0 = Average prevalence of support for extending the Pap test screening interval among the comparison group (without intervention), and
Let P_1= Average prevalence of support for extending the Pap test screening interval among the intervention group.

We assume that P_0=0.2 and P_1=0.3. i.e. we are looking for a 0.1 difference in the average prevalence of support for an extended screening interval between the intervention and comparison groups. In order to determine the sample size for the number of providers and patients per provider that we need to sample, and the corresponding power, we ran different simulations with different sample size scenarios. We generated N normal random variables with a mean of 0.3 and a standard deviation of 0.075 for the N providers in the intervention arm and N normal random variables with a mean of 0.2 and a standard deviation of 0.075 for the N

providers in the control arm. For each provider in each study arm we generated M uniform random variables for the provider's M patients. We then applied the provider's probability of recommending an extended interval to generate a success/failure data for each of the patients (we compared the patient's probability to its provider's probability). We ran this simulation 1,000 times. We then did a logistic regression (using PROC GENMOD) with the simulated data and determined if the coefficient associated with the variable arm (study group) was statistically significant (two-tailed, alpha = 0.05). In doing this logistic regression, we took account of the correlation of the responses within providers by using provider as a "cluster" variable.

B.2. Procedures for the Collection of Information

Participant Recruitment. In the proposed study, information will be collected from approximately 70 clinical care providers, 18 clinic coordinators, and a sample of 2,600 patients.

Clinic and provider recruitment. All providers within participating clinics will be informed by clinic staff that their clinic is participating in the Cx3 Study. All providers that perform Pap testing will be requested to complete a provider survey at four points in time (a baseline survey prior to study implementation and annual follow-up surveys at 1, 2, and 3 years following study implementation). Clinic staff will distribute the baseline and follow-up surveys to providers. The cover letter for the baseline provider survey (Attachment D1a), the cover letter for the follow-up provider survey (Attachment D2a), and the first page of the baseline and follow-up surveys constitute the informed consent. They describe how the survey data will be used, by whom, and describe the steps to protect the privacy of the data. They also clearly indicate that participation in the survey is voluntary.

Patient recruitment. Patient enrollment and consent will be the responsibility of clinic staff. Staff serving in this capacity will be trained by Battelle to perform this function. The staff will personally approach eligible women when they arrive at the clinic for their scheduled Pap test. Using the patient recruitment script (Attachment E1a), the clinic staff member will notify the woman that the clinic is participating in the Cx3 study and that she may be eligible for the study. If the woman meets the study eligibility criteria, she will be invited to enroll in the study. If she is not eligible, she will be thanked for her time and informed that her provider will see her as soon as possible for her scheduled appointment. If she is eligible, the staff member will hand her a copy of a consent form (Attachment E1b, if the patient was selected to be surveyed; Attachment E1c, if the patient will not be surveyed) to read in English or Spanish, as she prefers. The staff person will answer any questions she has about the form or the study. The consent form gives consent for the HPV test and review of medical and billing records. The consent form also asks patients whether or not they are willing to allow the CDC to store their HPV specimen for up to 10 years after the end of the study for possible future testing. If not granted, CDC will destroy the specimens submitted to the CDC HPV lab at the end of the study. In addition to the patient, the staff member will sign the consent form. A copy of the consent form will be provided to the patient, another will be kept in the medical record, and a third copy will be provided to Battelle. After the consent form is signed, the staff member will complete the patient enrollment form (Attachment E1d). If the woman is selected for the patient survey, contact information for the woman will be recorded on the enrollment form to allow Battelle to conduct the follow-up surveys. The completed enrollment forms will be faxed to Battelle for data entry.

Provider and Patient Interventions. The study will implement clinic-focused interventions and patient-education materials, to be delivered, in combination, to the clinics in the intervention group. The clinics in the control group will be given clinical practice guidelines that describe the algorithm for using the HPV DNA test along with the Pap test as part of routine cervical cancer screening. The clinic-focused intervention will include provider training for clinicians and clinical staff, focusing on both person-level skills building and systems-level office changes (e.g., reminder systems). The patient-focused intervention will include providing patient's with an educational brochure (Attachment E3) and a bookmark (Attachment E4).

The objectives of the provider training sessions are to:

1. Provide clinicians and clinical staff with the most current information about the natural history of HPV and development of cervical cancer screening;
2. Provide succinct and tailored messages to motivate clinicians and clinical staff to actively encourage and endorse HPV DNA test with the Pap test as the main mode of cervical cancer screening among their patients;
3. Motivate clinicians to engage in cervical cancer screening conversations with their patients, especially about the new guidelines of using HPV as an adjunct and the potential implications it would have on being HPV positive, possible further surveillance, and in the majority of cases, extension of screening intervals; and
4. Motivate and facilitate staff to review their office systems and to modify their systems to improve clinicians' ability to: (a) identify patients due for cervical cancer screening; (b) identify patients that are not due for cervical cancer screening (HPV negative, cytology negative women); (c) remind clinicians to discuss cervical cancer screening with patients, and (d) track cervical cancer screening among patients.

The clinicians and clinic staff in each clinic will receive three types of educational interventions:

- ***Grand Rounds***. Grand-rounds style CME which will encourage all providers who are conducting Pap testing at these sites to attend. The guest speakers at these grand rounds will consist of two speakers to discuss the guidelines that incorporate HPV testing as part of the Pap test and the importance of extending the screening interval from a risk and cost perspective. If at all possible, the grand rounds will allow for an interactive session.

- ***Web-based access to CME, podcasts, and articles***. CDC or subcontractor will give all study participants access to a website that is a repository of widely available web-based programs for CME, podcasts that will stress the screening interval issues in more detail, and peer-reviewed articles. An outline of the material to be included in the study web site is provided in Attachment D3.

- ***Academic detailing***. Provider training to target clinicians and clinical staff, and will be conducted in two separate sessions of approximately 3 hours total duration. The two sessions will be scheduled to accommodate the clinic schedule, but will be held with no more than 1 month between them. The modules to be included in the academic detailing are summarized in Table B.2-1.

Table B.2-1. Clinic-focused Intervention Modules and Objectives

SESSION 1	
Module	**Objectives**
I: Cervical Cancer and HPV Epidemiology and Natural History	1. Review Cervical Cancer and Cervical Cancer screening statistics 2. Briefly review cervical cancer screening modalities , with some evidence of efficacy and pros/cons of each 3. Review natural history of HPV and cervical cancer development 4. Review the concept of risk in cervical cancer and risk prediction
II: Review Current Guidelines, Discuss the implications of a less than annual Pap test, and Enhance Skills for HPV and Pap Screening Conversations with Patients	1. Review current management guidelines for abnormal cytology (GIVE ASSCP Guidelines) 2. Review USPSTF cervical cancer screening recommendations, American Cancer Society screening guidelines, and American College of Obstetric screening guidelines for average risk patients (Provide copies of ASCCP, ACOG, ACS guidelines, and USPSTF) 3. Review Adolescent guidelines 4. Provide tools for effective patient-clinician and patient-clinical staff HPV testing and cervical cancer screening conversations that result in a shared screening decision (hand out counseling sheet) 5. Key messages (based upon common patient attitudes, beliefs, social influence, and barriers/facilitators regarding cervical cancer screening) to motivate clinicians and clinical staff to actively encourage and endorse cervical cancer screening among their patients (Leave CDC patient brochures, and screening interval card with clinician/ office staff)
III: Role-Playing for Cervical Cancer Screening Conversations with Patients	1. Provide opportunities for clinicians and clinical staff to practice conversational techniques for HPV testing and cervical cancer screening to include patients who are identified as (a) HPV positive, normal cytology; (b) HPV negative, positive cytology; and (c) HPV positive, abnormal cytology and discuss the appropriate screening interval
SESSION 2	
Module	**Objectives**
IV. HPV Vaccine	1. Role of HPV 16/18 in precancerous and cancers 2. Current ACIP recommendations 3. Current ACS Recommendations 4. Discuss current practice and pros and cons of HPV vaccine 5. Discuss role of HPV vaccine among HPV exposed women
V: Office Reminder Systems for cervical cancer Screening with extended screening intervals	1. Engage clinicians and clinical staff in a discussion to review their existing office-based Pap test tracking system and to generate potential improvements or alternate solutions 2. Provide clinical staff with options for office-based reminder systems for cervical cancer screening that can be separate for other annual reminders 3. Reach group consensus about office system changes that fit best within their clinic structure
VI. Reemphasize the HPV adjunct testing guidelines	

The curriculum and materials used for the provider training (e.g., training curriculum and handouts) were reviewed by clinicians and subject matter experts. Clinicians and clinical staff will receive the complete curriculum with presentations and resources (handouts) in hard copy form. Modules will be presented by peers at all clinics and participants will receive continuing education credit. The patient education materials will be given to the clinicians and clinic staff in the training sessions, as tools they can use to initiate and discuss HPV testing as part of adjunct cervical cancer screening with patients.

Data Collection Procedures. There are 5 primary data collection activities proposed. These include:

- Clinic surveys, monthly for 1 year, that record resources associated with participating in the study
- Provider surveys, baseline plus 3 follow-ups at 12, 24 and 36 months, to assess knowledge, attitudes, beliefs, and screening practices
- Patient surveys, baseline plus 2 follow-ups at 18 and 38 months, to assess knowledge, attitudes, beliefs, and screening behavior
- Electronic billing data and chart review to assess clinic use, screening intervals, and follow-up to a positive diagnosis for 4 years from the date of study enrollment
- HPV DNA test collection from enrolled patients with timely reports of test results back to provider

As discussed in Section B.4 (Tests of Procedures or Methods to be Undertaken), the provider and patient surveys were pre-tested with 9 providers and 9 patients for clarity of instructions and question wording, and to assess the average length of time it took to complete each survey.

Clinic surveys. Clinics that have agreed to participate in the study will be asked to complete a survey monthly during the first year of the study. The survey requests information about the clinic patient population and practice characteristics, as well as the staff time associated with participating in the Cx3 Study. Battelle staff will send the survey and cover letter to the on-site coordinator for completion. The cover letter, signed by the CDC study leader, emphasizes the importance of survey completion by every participating clinic. Upon completion of the survey, the on-site coordinator will return the survey to Battelle for data entry. Attachment C contains four documents:

1. cover letter for initial clinic survey (Attachment C1a),
2. initial clinic survey (Attachment C1),
3. cover letter for follow-up surveys (Attachment C2a), and
4. follow-up clinic survey (Attachment C2).

Provider surveys. Providers will be requested to complete a provider survey at four points in time: baseline, 12 months, 24 months, and 36 months. Battelle will send the surveys in a batch to the on-site coordinator for distribution. Clinic staff will approach the providers to request that they complete the survey. Each provider will be provided with an envelope and instructed to seal the envelope containing their completed survey and return it to Battelle for data entry. Clinic staff will not have access to the surveys or to the database containing individual responses.

Attachment D contains:

1. cover letter for baseline provider survey (Attachment D1a),
2. baseline provider survey (Attachment D1),
3. cover letter for follow-up surveys (Attachment D2a),
4. follow-up provider survey (Attachment D2), and
5. outline for the planned intervention for those providers in the intervention arm of the study (Attachment D3).

Patient surveys. Beginning in month 2 of the study, all patients will be asked to complete the patient survey, until a total of 2,600 patients have been surveyed. These selected patients will be asked to complete a patient survey at three points in time: baseline, 18 months, and 40 months. The trained clinic staff member who enrolls each patient into the study will also be responsible for distributing and collecting the baseline survey from her. Clinic staff will give the baseline survey and survey envelope to the patient and ask her to complete the survey and, when completed, seal the survey in the envelope provided and return to clinic staff. Bar-coded labels will be affixed to the baseline patient survey and the survey envelope. When the patient returns the completed and sealed survey, the staff person will provide her with the $5 incentive. The on-site coordinator will forward the completed and sealed surveys to Battelle for data entry.

Using the contact information provided on the patient enrollment form, Battelle staff will be responsible for directly distributing (via mail) and collecting the follow-up surveys. Each survey packet mailed will include a cover letter, a hardcopy survey, a stamped and addressed envelope, and $5. Responses will be returned directly to Battelle for data entry. Completed follow-up surveys will at no time be handled by clinic staff. An initial postcard to tell patients to expect the follow-up survey will be sent two weeks in advance of the survey (to identify bad addresses) and a thank you/reminder postcard will be sent two weeks after the survey is mailed. Non-respondents will receive a follow-up phone call at four weeks after the mailing date. Attachment E contains:

1. patient recruitment script (Attachment E1a),
2. patient consent form with patient survey (Attachment E1b),
3. patient consent form without patient survey (Attachment E1c),
4. patient enrollment form (Attachment E1d),
5. patient baseline survey (Attachment E1),
6. initial postcard (Attachment E2a),
7. cover letter for patient follow-up surveys (Attachment E2b),
8. reminder postcard (Attachment E2c),
9. script for reminder phone call (Attachment E2d),
10. patient follow-up survey (Attachment E2),
11. patient brochure (Attachment E3), and
12. patient bookmark (Attachment E4).

Electronic billing data and chart review. At the time of study enrollment, patients are asked to give consent for study personnel to access their medical and billing records. Billing records will provide the information necessary to answer the primary study question, namely does HPV as an

adjunct to Pap testing with provider and patient education lead to extended screening intervals for women with negative results. Clinic staff will provide Battelle with information about clinic visits for a period of 3 years beginning with the date of study enrollment. The information that will be requested includes (1) name of the provider seen during each office visit, (2) date of the visit, (3) whether or not a Pap test was performed, and (4) whether or not the visit was for a wellness checkup. The chart review will support the secondary study question of what type of follow-up is received by HPV positive women. Chart reviews will only be conducted for women with a positive test outcome (i.e., abnormal Pap and/or positive HPV). More detail about the information that will be collected during the chart review is provided in Attachment F.

HPV DNA testing. As described more fully in the Laboratory Protocol (Attachment G), each patient enrolled in the Cx3 Study will receive an HPV test in addition to her scheduled Pap test. The specimen for the Pap test will be collected, shipped, tested, and reported in accordance with the usual procedures in place in the clinic. A second specimen will be collected by the provider during the exam for shipment and testing at the CDC HPV laboratory. Clinic staff will be responsible for labeling and shipping the specimen. CDC lab staff will provide the results (positive or negative) to Battelle via LUNA. Battelle will merge the test result data from LUNA with patient names and prepare a laboratory report for each patient. Battelle will send the reports to the clinic/provider. The clinic/provider will inform the patient of the results of the HPV test following their standard reporting procedures. Any follow-up suggested by the test results will also be arranged for and completed by the clinic according to their standard procedures. As part of the study, clinics will receive additional HPV tests to use for follow-up purposes. The CDC HPV lab will also conduct HPV typing on the specimens but these results will only be provided to Battelle and not to the clinic/provider. If patients consent to long-term storage of their specimen, CDC will store the specimens submitted to the CDC HPV lab for a period of up to 10 years.

Battelle staff will produce a series of unique patient ID numbers for each clinic. Clinics will be sent bar-coded labels to be used to identify all data collection forms, as well as the HPV test that will be shipped to the CDC HPV lab. Staff will assign a patient ID to each patient at the time of enrollment and affix this ID to the consent form, the HPV test tube, the patient chart, and the baseline survey.

LUNA will be used to (1) store patient eligibility information, (2) store Pap test results, and (3) track HPV shipments. To protect patient confidentiality, LUNA will not contain personal identifying information. Clinic staff will complete the patient enrollment form (Attachment E1d) manually and fax the completed form to Battelle for data entry. Battelle will <u>not</u> enter the patient enrollment data into LUNA. Identifying information will be kept in a separate data file that will be available only to authorized project staff.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

Every effort will be made to maximize the response rates to the provider and patient surveys. Multiple methods studies, reviews and meta-analyses have been conducted to determine which factors lead to an increase in response rates to mail surveys. Preliminary notification, multiple follow-ups with respondents, monetary and non-monetary incentives, use of Express Mail or first

class stamped envelopes and appropriate salutations have positive effects on response rates while sponsorship or endorsement, use of personalization techniques in mailings, and length of questionnaires, have shown inconsistent effects on response rates. The approaches that we will use to maximize the response rates to the provider and patient surveys are described below.

Provider Surveys. Health care providers who spend most of their time on direct patient care are a particularly difficult group to survey. Many medical practices have administrative personnel assigned to sort through mail and telephone messages and only pass on to physicians those most in need of his/her direct attention. Consequently, surveys of practicing physicians generally result in lower response rates than surveys of other groups of respondents, including other professionals. Nevertheless, reviews of survey methods clearly point to a number of procedures that improve response rates among physicians.

In a previous study, Battelle worked with the American Cancer Society and CDC to conduct focus groups with primary care physicians to obtain their input about strategies for maximizing response to physician surveys. There was clear consensus among these physicians that: (1) the survey should be sent by Express Mail because it gets the physician's attention and is unlikely to be screened by office staff; (2) a substantial monetary incentive should be provided; (3) the monetary incentive should be sent with the survey; (4) the reputation of CDC among physicians is good, and therefore the cover letter for CDC studies should clearly indicate that the study is being conducted by CDC.

To insure that the provider surveys will be delivered to the clinic providers, the survey packets for the baseline and follow-up provider surveys will be sent to the Clinic Coordinator. The Clinic Coordinator will be responsible for distributing the survey packets to providers and following up with non-respondents. The survey cover letter, which will stress the importance of the study, will be personally addressed to each provider. The letter will be printed on CDC letterhead and signed by the CDC study leader. The cover letter will give the respondents a toll-free telephone number to call if they have questions regarding the study. In addition to the provider survey and cover letter, the survey packet will contain a $50 incentive to complete the survey. Battelle has used these methods in several previous surveys of health care providers and they have been successful in achieving response rates in excess of 80%. Because the clinics have agreed to participate in the study and the providers have agreed to provide HPV testing to eligible patients, we expect that the response rate to the provider survey will be very high.

Patient Surveys. If a patient is selected for participation in the baseline and follow-up surveys, she will be asked to complete the baseline survey in the clinic prior to seeing the health care provider. Completed surveys will be returned to clinic staff in a sealed envelope. Completion of the baseline survey in the clinic, rather than mailing a survey to the patient's home, is likely to result in a high response rate.

The challenge will be achieving a high response rate to the patient follow-up surveys, which will be completed 18 and 40 months following study enrollment. In an effort to minimize loss to follow-up, we will obtain contact information for each patient to be surveyed and record the information on the patient enrollment form (Attachment E1d). In addition to recording the address and telephone numbers of the patient, we will also ask the patient to provide the name and telephone number of a friend or family member who will always know where to contact her,

in case she has moved and we are having trouble contacting her. Prior to mailing the follow-up surveys we will mail an initial postcard (Attachment E2a) to the patient to let know that she will be receiving a survey in the mail. We will send the postcards "Return Services Requested," so that the Post Office will let us know if the postcard is undeliverable. For those postcards that are undeliverable, we will call the contact numbers provided on the enrollment form in an effort to obtain a current address. If we are unable to get a current address from the information provided on the enrollment form, we will contact the clinic to obtain a current address (if the patient visited the clinic recently).

The surveys will be sent by First Class mail to the patient's home. The cover letter for the patient follow-up survey (Attachment E2b), which will stress the importance of the study, will be personally addressed to the patient. The letter will be printed on CDC letterhead and signed by the CDC study leader. The letter will give the respondents a toll-free telephone number to call if they have questions regarding the study. In addition to the patient survey and cover letter, the survey packet will contain a $5 incentive to complete the survey. Finally, reminder postcard (Attachment E2c) and reminder telephone call (Attachment E2d) will be used to encourage non-respondents to complete and return the survey.

B.4. Tests of Procedures or Methods to be Undertaken

The provider and patient baseline surveys were pilot tested to obtain an estimate of respondent burden, as well as to obtain comments and advice about the format, appropriateness and relevance of survey questions. The baseline provider survey was pilot tested with nine providers in the Atlanta area. The types of providers included in the pilot testing included obstetrician/ gynecologists, family practitioners, and nurse practitioners. Providers reported that, on average, the survey took 30-35 minutes to complete. The baseline patient survey was pilot tested with nine patients at a clinic in the Atlanta area. Patients were able to complete the survey in 15-20 minutes. Neither patients nor providers reported major problems in completing the survey. Minor modifications to the survey questions and response categories were made based on the feed-back received during the pilot tests.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Vicki Benard, PhD., of the Division of Cancer Prevention and Control, is the Principal Investigator and Technical Monitor for the study, and has overall responsibility for overseeing the design, conduct, and analysis of the study. She will also approve and receive all contract deliverables. Telephone: 770-488-1092.

The survey instrument, sampling and data collection procedures, and analysis plan were designed in collaboration with researchers at Battelle Centers for Public Health Research and Evaluation (CPHRE) under contract No. 200-2002-00573, Task Order No. 6 with the Centers for Disease Control and Prevention. Battelle will conduct data collection and will perform data analysis, in consultation with the CDC investigators.

Diane L. Manninen, Ph.D. [206-528-3140] has overall technical and financial responsibility for

the study at Battelle and led the Battelle effort to design this protocol. She will direct the overall data collection and analysis effort. She will also be responsible for writing the project reports.

Other CDC and Battelle personnel involved in designing the study protocol, development of the data collection instruments, data collection, and analysis include:

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