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Overview of the CDC Cervical Cancer (Cx3) Study: An Educational Intervention of HPV Testing for Cervical Cancer Screening

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Abstract

Background—The recommended screening interval when using the Papanicolaou (Pap) and human papillomavirus (HPV) test (co-testing) is 5 years. However because providers are reluctant to extend the screening interval, we launched a study to identify barriers to appropriate use of the co-test and to implement an educational intervention to promote evidence-based screening practices. This article provides an overview of the study including the multi-component intervention and participant demographics.

Methods—The study was conducted in 15 clinics associated with 6 Federally Qualified Health Centers (FQHCs) in Illinois. Each clinic received HPV tests to administer with routine Pap tests among enrolled patients ($n = 2,246$) and was assigned to a study arm: intervention arm ($n = 7$) received a multi-component educational intervention (small media, academic detailing, and website) for providers and printed educational materials for patients, and control arm ($n = 8$) received printed copies of general guidelines. Clinic coordinators ($n = 15$), providers ($n = 98$), and patients ($n = 984$) completed baseline surveys to assess screening practices.

Results—Providers reported an average age of 41.3 years and were predominately female, non-Hispanic, and white. Patients reported an average age of 45.0 years and nearly two-thirds were Hispanic or black. Of the 2,246 patients, 89% had a normal co-test. Lessons learned from the study included the importance of buy-in at a high level in the organization, a champion provider, and a clinical coordinator devoted to the study.

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Author Disclosure Statement

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Conclusion—Materials from this study can be adapted to educate providers and patients on appropriate use of the co-test and encourage extended screening intervals as a safe and effective practice.

Introduction

Based on the central role that persistent carcinogenic human papillomavirus (HPV) plays in the development of cervical cancer, HPV testing has been added to cervical cancer screening practices. HPV testing with the Papanicolaou (Pap) test (called co-testing) for women age 30–65 years is a recommended option for cervical cancer screening by all national organizations.^{1–4} From 2003 to 2012, most guidelines recommended extending the screening interval to 3 years for women with negative co-test results (normal Pap and negative HPV) because of the low risk of cervical precancer and cancer. In 2012, guidelines were revised to recommend extending the interval to 5 years for women age 30–65 years. Cost-effectiveness studies have demonstrated that the increased screening interval for women with negative co-tests (estimated to be about 90% of those screened) offsets the additional cost of the DNA test.^{5–7} However, annual screening, regardless of screening strategy, remains the common practice throughout the United States and across provider specialty.^{8–10} Studies in managed care settings examining the acceptability of the co-test strategy for screening found that both providers and women were amenable to the longer intervals once they understood the role of HPV in the development of cervical cancer.^{11,12}

To date, no studies have examined provider and patient acceptance of co-testing with longer screening intervals in a low income population. The Centers for Disease Control and Prevention (CDC) launched the CDC Cervical Cancer (Cx3) Study—a multi-component educational intervention to identify facilitators and barriers to guideline-consistent use of the co-test in an underserved population. The primary objective of this study was to determine whether an educational intervention would lead to increased willingness of providers and patients to extend the cervical cancer screening interval for women with negative co-tests and *decrease* cervical cancer screening visits to clinic sites for average risk women. This is contrary to most social marketing campaigns and patient education interventions that advocate annual Pap tests.

The purpose of this article is to give a detailed overview of the Cx3 Study and lessons learned once implemented in the field.

Methods

Study participants

The Cx3 Study selected Federally Qualified Health Centers (FQHCs) because the client base is predominately low income and under- or uninsured. Recruitment of FQHCs occurred through the CDC's National Breast and Cervical Cancer Early Detection Program (NBCCEDP).¹³ The Illinois program was chosen based on high Pap volume, high follow-up rate, and elevated cervical cancer incidence rates in their state compared with national rates. FQHCs that partnered with the Illinois Breast and Cervical Cancer Early Detection Program and reported high volume Pap testing with a multispecialty team were chosen for the study.

All providers within the clinics who were part of the NBCCEDP and routinely performed cervical cancer screening were eligible for the study. Women coming into the clinics for routine well women exams were eligible if they were between the ages of 30 and 60 years at the time of enrollment and scheduled for a regular screening Pap test but were excluded if they had an abnormal Pap test in the last year, a history of cervical cancer, or a hysterectomy. Women did not have to be part of the NBCCEDP to participate in the study. The CDC Institutional Review Board approved this study.

Study design

Six FQHCs with 15 individual clinics were enrolled in the study by August 2009. Each clinic was assigned to one of two study arms: intervention ($n = 7$) or control ($n = 8$). The intervention and control arms were matched on clinic attributes including racial/ethnic characteristics of the patient population, provider specialty, and patient volume. Clinics in both groups received free HPV tests and hard copies of clinical practice guidelines. Additionally, clinics in the intervention group received a multi-component educational program, including provider and patient education materials designed for this project. Ninety-eight providers were enrolled in the study from August 2009 through March 2010 and 2,246 women were enrolled in the study from October 2009 through May 2011.

At the time of the woman's examination, two samples of exfoliated cervical cells were collected. The first used the clinic's routine sampling method for cytology diagnosis. The second sample was collected using the HC cervical sampler (Qiagen, Inc.) and sent to the CDC HPV lab for the Hybrid Capture 2 High Risk HPV DNA test (Qiagen, Inc.) The HPV test results were sent to the provider who was responsible for informing patients of the results following their standard reporting procedures.

Intervention

Educational materials for the intervention arm were developed based on qualitative data collected from 6 providers in Illinois who participated in a 2-hour face-to-face interview to discuss screening practices and barriers to guideline-consistent intervals. A recurring message in the interviews was the reluctance of the woman to return for her well-woman exam and other screening tests if she was not coming in for an annual Pap test. Therefore, our messages included the importance of other medical procedures that were not linked to the Pap test.

Provider Intervention—Providers in the intervention arm were offered three types of intervention over 9-months.

- Grand Rounds continuing medical education (CME) events were held in August 2009 at all intervention arm clinics and led by leaders in women's health. Discussion included the screening 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.
- Four, one-hour academic detailing sessions were offered in September 2009 through June 2010. The four modules were presented at all clinics in the

intervention arm and providers received CME credit for their participation in the trainings. The content and tools distributed at the four academic detailing sessions are summarized in Table 1.

- Providers were given access to a password-protected website that contained a repository of CME programs, CDC-developed podcasts on the recommended intervals for cervical cancer screening, and relevant peer-reviewed articles.

Patient intervention—A patient brochure and bookmark emphasizing the co-test and the extended screening interval were developed for the study in both English and Spanish.¹⁴ The 22-page educational brochure was written at a sixth grade reading level.¹⁵ These materials were distributed to patients in the intervention group after they completed the baseline survey.

Data collection

Enrolled patients consented to have their medical and billing records accessed by study personnel for a period of 40 months following the date of study enrollment (Table 2). The main outcomes were to determine (1) whether a woman who had a normal Pap test and a negative HPV test returned for her routine well woman exam, and (2) whether this exam included screening tests according to guidelines. In addition, medical records will be used to determine the type of follow-up care received by women with HPV positive test outcomes.

Other study variables were gathered from surveys of clinics, providers, and patients (Table 2). Clinic coordinators at each of the 15 participating clinics were surveyed three times: (1) at baseline to request information about the clinic patient population and practice characteristics; (2) monthly for 11 months to request staff time associated with study; and (3) at 12 months to assess changes in HPV practice and systems interventions. Coordinators at participating clinics distributed baseline surveys along with a \$50 cash incentive to providers. The surveys assessed knowledge, attitudes, beliefs, and practices regarding cervical cancer screening.¹⁶ Roland et al. provides greater detail on the baseline survey results, we list only a summary of the demographic variables.¹⁶ Follow-up surveys at 12 and 36 months are also planned. A sample of patients ($n = 984$) were asked to complete a baseline survey to assess knowledge, attitudes, beliefs, and behavior regarding cervical cancer screening.¹⁷ Only a summary of patient demographics are presented in this paper. Staff at participating clinics distributed the baseline survey to patients prior to the patient's HPV test. Patients were given a \$5 cash incentive for participating. The 12-page patient survey was written at an eighth-grade level and was self-administered in English and Spanish. A 15-month follow-up survey is planned.

Results

Of the 2,246 patients who had both HPV and Pap tests, 2,002 (89.1%) had a normal Pap test and a negative HPV test.¹⁸ These women will have a chart review at 40 months to determine if well-woman exams were performed and what screening tests occurred. The HPV test was positive in 162 (7.2%) women. (Data not shown.)

At the time of the baseline survey, HPV test use varied among providers at the study clinics. Most of the providers were using the HPV test for management after an abnormal Pap test (ASC-US) (91%) and fewer were using HPV for co-testing (39%).¹⁶ Most of the clinics (66%) had at least one provider who could conduct colposcopies on site. In the case of abnormal test results, most clinics relied on a combination of systems for follow-up including verbal prompts, mail and telephone reminders. Only one clinic did not have any reminder system in place. (Data not shown.)

A sample of the provider and patient characteristics are provided in Table 3. The average age of the providers was 41.3 years at the time of study initiation. Almost 70% of the providers were from the Chicago area. Approximately three-quarters of the providers were female and the majority were non-Hispanic (94%). With respect to race, 55% reported that they were white, 20% reported that they were black, and 25% reported that they were Asian. The average age of the patient sample at the time of recruitment was 45.0 years. Nearly one-third of the patient sample reported that they were Hispanic, and 26% that they were African American. Nearly one-third of those surveyed (31%) were born outside of the U.S, 26% were born in Mexico, and 28% reported that they normally speak Spanish in the home.

Lessons learned

By choosing to conduct the study in FQHCs, we were able to operate in a real-world setting and at the same time observe the nuances associated with conducting this type of research. This information is extremely important, as most studies are conducted in a research setting with little ability to be transferred to ongoing clinical practice. We learned that it is important to get buy-in at a high level in the organization so that when operational changes need to be made (for example, sending a reminder letter to a woman with negative tests to return in 3 years and not annually as was most of the clinic protocols) it can be disseminated efficiently and effectively. It is also important to identify a champion provider who can help gain momentum for the study and emphasize the importance of participating. We also learned that having a full-time clinical coordinator devoted to the study is key, since adding additional responsibilities for office staff who are already overburdened is not the most efficient model.

Discussion

This study was developed to identify barriers to appropriate use of the co-test, and to implement an educational intervention to promote evidence-based screening practices. This article provides a detailed overview of the study including the multi-component intervention and brief participant characteristics. Additional information on the lessons learned is also an important contribution to the literature in conducting this type of study in the field. The lack of a physician recommendation for cancer screenings is one reason why women report not being screened.¹⁹ One interventional strategy to disseminate evidence-based, provider-oriented interventions (provider assessment and feedback and provider reminders)²⁰ is academic detailing.²¹ Multiple studies in the literature have used these techniques to improve recruitment for screening but very few interventions have been introduced to address how to screen at the appropriate intervals (in this case, to decrease screening when

not recommended). This study provided multiple evidence-based strategies to encourage providers to follow recommendations, including placing current screening guidelines in charts, discussing reimbursement codes, offering current literature on co-testing, and office-based materials (small media, examples of client reminders, discussions regarding system interventions). Additionally, podcasts were developed by professional experts in their communities covering recommended follow-up. Despite these efforts, the practice of annual screening may be difficult to change even after newer guidelines have recommended less frequent screening.

The impetus for this study was to understand the barriers with co-test use and the extension of the interval between screenings in the underserved population. To improve cervical cancer screening among medically underserved women, Congress authorized the CDC to develop the National Breast and Cervical Cancer Early Detection Program (nBCCEDP) in 1991.¹³ The NBBCCEDP is a comprehensive public health program that helps low-income, under- and un-insured women gain access to breast and cervical screening services. Before the 2012 revision to the USPSTF screening guidelines,²² the NBBCCEDP reimbursed for the HPV test for management of cervical cancer, but not as a co-test²³. Therefore, this pilot study was also designed to provide feedback to the national program on facilitators and barriers to appropriate use of the co-test including screening intervals. This information is now even more useful, as the NBBCCEDP began reimbursing for the co-test in July 2012 and will be using the outcomes of this study and the materials developed to help providers and patients adopt new recommendations.

This study had many strengths including enrolling over 2,000 low-income, un- and under-insured patients in the setting of FQHCs across a diverse population of urban and rural clinics in Illinois. Research among FQHC patients and providers allows for understanding the access and barriers to care among the underserved. These facilities and their staff provide care regardless of a person's insurance status, income, or ability to pay, and they are a large, essential component of the U.S. healthcare safety net for people who otherwise have limited options to access essential care.²⁴ Additionally, the multi-level assessment of the clinics, providers and patients provides details to understand how practices, attitudes and beliefs will change over time including the increase in the 3- to 5-year screening interval. This study also has the capacity to follow women with positive test results since they will have medical chart review through the 40 months. Additionally, the educational intervention that was developed gives the rationale for using all of the strategies for cervical cancer screening including longer intervals regardless of the method to screen.

As a demonstration study in one state, our results may not be generalizable to all. However, when we examined the racial and ethnic distribution of this study population in Illinois, it was very similar to the NBBCCEDP racial and ethnic distribution. Since most of the clinics in our study did not have research experience, we faced challenges such as longer-than-expected patient enrollment, no data collection on the women who refused to participate (which does not allow us to calculate a response rate for patients), and limited staff time at one of the health centers to conduct the survey portion of the study.

Conclusion

While many studies are aimed at introducing new technology, very few are focused on introducing new technology coupled with evidence-based strategies that emphasize less but more-efficient screening. When complete, the Cx3 Study will provide a wealth of information on current trends in screening and effective approaches for encouraging guideline-adherent cervical cancer screening. These findings on practices and attitudes regarding HPV testing and screening interval extension are very timely with all national organizations recommending co-testing and extended screening intervals. Additionally, the management guidelines are being updated with a focus on triaging women with specific high-risk HPV types²³; thus, as the science advances, conveying this information to providers and patients will be essential to encouraging the most effective patient care. The information on the harms of over-testing—which may lead to over-diagnosis and overtreatment—is only useful to the extent that it is understood and accepted by providers and patients. CDC has produced several materials to educate providers and patients on the appropriate use of the co-test, and these materials may be adapted over time to meet the changing needs of the population and the latest science.

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Table 1

Content of Academic-Detailing Component of the Provider Intervention for the Cx3 Study, 2009-2010

Session title	Content	Tools distributed
I: Updates and Guidance	1.Cervical cancer and HPV: epidemiology and natural history 2.Cervical cancer screening guidelines 3.Resources for additional training	Cervical cancer screening guideline summary sheet, ASCCP algorithm booklets, password to website, patient brochures, recommended reading (hard-copy articles)
II: Physicians' Perspective and Office Management	1.Physician perspective on changes to screening guidelines 2.Conversations with patients about HPV and cervical cancer 3.Office management and tracking system	ASCCP algorithm wall posters, Cx3 study poster, Qiagen HPV materials, billing and reimbursement code sheet, risk stratification chart, examples of client reminders, AHRQ Your checklist for health brochure
III: Patient Management and Guidelines	1.Overview of ASCCP guidelines 2.Algorithms for patient management 3.Algorithms for special populations	ASCCP algorithms, ASCCP online modules (CME), example letters to send to patients for follow-up, recommended reading
IV. HPV Vaccine	1.HPV vaccine 2.Review of cervical cancer screening guidelines	Web resources from CDC

ASCCP, American Society of Colposcopic and Cervical Pathology; CDC, Centers for Disease Control and Prevention; CME, continuing medical education; Cx3, CDC's Cervical Cancer Study; HPV, human papillomavirus.

Table 2

Schedule and Methods for Measuring Variables in the Cx3 Study, 2009-2014

	Measures	Schedule		
		Initiation	12-15 months	36-40 months
Medical chart review – HPV negative tests	Completion and measures of a well woman exam (including Pap and HPV testing)			X
Medical chart review – HPV positive tests	Pap and HPV testing, diagnostic and treatment reports		X	X
Clinic survey	Patient and practice characteristics, staff time * and change in practices †	X	X	
Provider survey section				
Personal and professional characteristics	Race/ethnicity, age, sex, type of provider, clinical specialty, number of years providing clinical care	X		
Patient characteristics	Age and sex of patient population seen by provider	X	X	X
Cervical cancer screening practices	Volume of Pap tests performed, management on site, type of Pap test, reason for type of Pap test	X	X	X
Risk assessment management	Perceived importance of annual exams, tests conducted during annual exam	X	X	X
HPV test practices	Attitudes, beliefs and practice	X	X	X
Screening interval questions	Clinical vignettes to determine screening practices; attitude, beliefs and practices	X	X	X
HPV vaccine	Recommendations regarding use	X		
Education/guidelines	Guidelines followed for cervical cancer screening and management, receipt of CME for cervical cancer screening	X		
Patient survey				
Sociodemographic characteristics	Race/ethnicity, age, marital status, years of education, insurance status, country of origin, primary language	X	X	
Cervical cancer screening history	Number of visits to that clinic, lifetime number of Pap tests, frequency of getting Pap tests, abnormal Pap history, recommended Pap interval, previous HPV testing and result	X	X	
Risk factor assessment	Age at first intercourse, number of sexual partners, STDs, warts, smoking	X	X	
Knowledge and attitudes about cervical cancer screening	Knowledge and source of information regarding HPV and Pap tests, level of acceptance for getting an HPV test, level of acceptance for a 3-year screening interval, perceived barriers to an extended screening interval	X	X	
Cost of health care services	Direct and indirect costs associated with visits to the study clinic	X		

STD, sexually transmitted disease.

* Staff time was assessed every month to conduct cost of the intervention.

† Change in HPV test use or systems was assessed on the final survey (12 months).

Table 3

Personal Characteristics of Providers and Patients Who Completed the Baseline Survey for the Cx3 Study

Providers, 2009-2010	N	Percent or mean \pm standard deviation
Age		
Age at baseline, years	98	41.3 \pm 11.4
Location of clinic		
Chicago	68	69
Outside Chicago	30	31
Gender		
Male	23	23
Female	75	77
Hispanic or Latino origin		
Hispanic	6	6
Non-Hispanic	92	94
Race or racial heritage (respondent could check all that apply)		
White	51	55
Black or African American	19	20
Asian	23	25
Native Hawaiian/Pacific Islander	1	1
American Indian/Alaska native	1	1
Type of clinician		
Physician	65	66
Nurse practitioner	20	20
Certified Nurse Midwife	6	6
Physician's Assistant	7	7
Primary clinical specialty		
Family Medicine	35	36
Internal Medicine	8	8
Obstetrics/Gynecology	52	53
Pediatrics	1	1
Number of years providing clinical care		
Years at baseline	98	8.8 \pm 9.5

Patients, 2009-2011	N	Percent or mean \pm standard deviation
Age		
Age at baseline, years	984	45.0 \pm 7.5
Location of clinic		
Chicago	566	58
Outside Chicago	418	42
Race/ethnicity		
Hispanic	312	32
Non-Hispanic white	384	39
Non-Hispanic Black, African American	254	26

Patients, 2009-2011	N	Percent or mean \pm standard deviation
Non-Hispanic other/multiple races	26	3
Marital status		
Never married	176	18
Unmarried, living with partner	80	8
Married	430	44
Separated/divorced	250	26
Widowed	37	4
Highest level of schooling completed		
Elementary school	95	10
Middle school	83	9
High school, no diploma	122	13
High school diploma or GED	217	23
Some college or associate's degree	296	31
Bachelor's degree	89	9
Masters/doctoral degree	44	5

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