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Self-collected vaginal swabs for HPV screening: An exploratory study of rural Black Mississippi women

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ABSTRACT

Objectives. To determine the post-procedure acceptability of self-collecting a vaginal swab for HPV testing among a highly impoverished and geographically isolated population of medically underserved Black women residing in the Mississippi Delta. Further, to test correlates of reporting that self-collection is preferred over Pap testing. Finally, to determine the prevalence of any of 13 high-risk HPV types among this population and the correlates of testing positive.

Methods. Eighty-eight women were recruited from two churches located in different towns of the Mississippi Delta. After completing a survey, women were provided instructions for self-collecting a cervico-vaginal swab and completing a post-collection survey. Specimens were tested for 13 oncogenic HPV types. Due to the exploratory nature of the study, significance was defined by a 0.15 alpha-level.

Results. Comfort levels with self-collection were high: 78.4% indicated a preference for self-collecting a specimen compared to Pap testing. Overall, 24 women (28.7%) tested positive for one or more of the 13 HPV types. Significant associations with testing positive were found for women having sex with females ($P = 0.09$), those never having an abnormal Pap ($P = 0.06$), younger women ($P = 0.10$), those with greater fatalism scores ($P = 0.006$), and those having less trust in doctors ($P = 0.001$).

Conclusions. Black rural women from the deep-south are generally comfortable self-collecting cervico-vaginal swabs for HPV testing. Given that nearly 30% tested positive for oncogenic HPV, and that fatalism as well a lack of trust in doctors predicted prevalence, a reasonable screening alternative to Pap testing may be community-based testing for HPV using self-collected vaginal swabs.

1. Introduction

Cervical cancer mortality is largely preventable if women and providers follow Pap-testing guidelines (Centers for Disease Control and Prevention and Department of Health and Human Services). The recently approved the Cobas® Human Papillomavirus (HPV) Test (to detect HPV types 16 and 18 and 12 other high-risk types) represents an additional screening method (Simon and American Cancer Society, 2014). These tests can be performed on vaginal swabs and evidence suggests that self-collection is easy to perform, provides privacy, and is less embarrassing and more comfortable than physician-collected samples (Igidbashian et al., 2011; Schmeink et al., 2011; Barbee et al., 2010; Arriba et al., 2010; Huynh et al., 2010; Anhang et al., 2005; Dzuba et al., 2002; Vanderpool et al., 2014).

The ability for women to self-collect vaginal swabs in a community setting raises the question of whether cervical cancer screening programs could transcend clinic boundaries. This may be useful in medically underserved areas, including rural counties isolated from services. However, taboos on genital self-touching and collecting vaginal swabs in public places may preclude this type of screening. This study sought to determine the post-procedure acceptability of self-collecting a vaginal swab for HPV testing among a highly impoverished and geographically isolated population of medically underserved Black women residing in the Mississippi Delta. The intent was to test this non-clinical method of screening among women who had not been recently screened. Further, the study tested possible correlates of reporting that self-collection is preferred over Pap testing. Also the study determined the prevalence of high-risk HPV types and the correlates of testing positive.

2. Methods

2.1. Study sample

Two churches located in different towns of the Mississippi Delta served as recruitment sites. Two female research assistants obtained

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permission and support from church ministers to recruit women after Sunday services. As opposed to the research assistants approaching women, women were told to find and talk with the research assistant after services to learn about the study. Because print information had been circulated relative to the study inclusion criteria, all women who presented themselves to the research assistant were eligible. In the course of five Sunday afternoon sessions (both churches combined) 88 women meeting the eligibly requirements volunteered and were enrolled. We limited the recruitment to five Sundays based on a need not to overstay our welcome at these churches.

Eligibility criteria were: 1) being 30–65 years old, 2) not having a Pap test in the past three years, 3) not currently pregnant, 4) never testing HPV-positive, and 5) sexual activity in the past 12 months. This final criterion was included based on evidence that the median time to HPV clearance in women is approximately 10 months (Winer et al., 2010). Also, regarding the criterion of never testing HPV-positive, we were content with reliance on women's self-report of this for two reasons: 1) HPV testing is a rare occurrence in the MS Delta and 2) asking permission to access women's medical records for this information would have led to a strong possibility of sample bias. Collectively, these criteria provided a sample of women at-risk of HPV infections that may have persisted to the point of undiagnosed cervical dysplasia or invasive cancer. The second criterion provided a sample of women who otherwise would be considered non-compliant with public health screening guidelines for cervical cancer. The third and fourth criteria were included to help ensure a relatively naïve sample regarding current medical care and past HPV. Recruitment occurred from March through June of 2015.

2.2. Procedures

All study procedures were approved by the Office of Research Integrity at the sponsoring university. Women were informed that the study involves four sequential tasks: 1) providing written informed consent, 2) answering questions in a short survey, 3) self-collecting a vaginal specimen, and 4) completing a brief post-collection survey. Thus, women began by completing a paper-and-pencil survey instrument prior to receiving instructions for specimen collection. Survey questions collected demographic and health information, as well as beliefs about sexual health and HPV. Next, research assistant read aloud a specimen collection instruction sheet, before providing a hard copy. Women took the instructions into church restrooms. The instructions included an illustration showing the insertion of the swab into the vagina and the rotating motion of the swab to collect an adequate specimen. After self-collecting, women then swirled the collection brush 40 times in a specimen vial containing Preservecyt®, a fixing solution. They then sealed the specimen vial, placed it in a pre-labeled bag, and returned the sealed bag. Last, women completed a post-survey regarding their self-collection experience. Women received $20 to compensate their time. Samples were stored in a temperature-controlled environment (30 °F or −1 °C) until they were shipped on dry ice to the participating university laboratory.

2.3. Pre-collection measures

These measures included basic demographic variables and various measures such as women's history of Pap testing, ever having HPV or other sexually transmissible infections, whether friends or family members were diagnosed with cervical cancer, and the number of male sex partners (past 12 months). Two scale measures were included. A 6-item scale assessed fatalism relative to cervical cancer (obtained Cronbach's alpha = 0.80). A sample item from that scale is, "Getting cervical cancer is beyond my control."

Also, a 5-item scale assessed trust in doctors (obtained Cronbach's alpha = 0.82). A sample item from that scale is, "I trust doctors' judgment about my medical care."

2.4. Post-collection acceptability measures

After women self-collected the vaginal swabs, they were asked five questions via paper-and-pencil survey (response options were "yes" and "no" unless otherwise specified): 1) Did you feel that you understood the directions for collecting the specimen?; 2) On a 5-point scale with 5 being "comfortable" to 4 being " somewhat comfortable," to 3 being "slightly comfortable" to 2 being "neither comfortable nor uncomfortable," to 1 being "uncomfortable"; 3) Did you experience any pain during the collection process?; 4) Did you experience any bleeding during the collection process, and 5) Would you be more likely to do this test on a regular basis compared to having a regularly scheduled Pap test?

2.5. Laboratory analysis

HPV was detected by Polymerase Chain Reaction analysis. Cellular DNA was extracted from the swabs using a Qiagen DNA extraction kit. The DNA was extracted from BSC cells as an extraction control with every 20 samples (Chaturvedi et al., 2005). HPV DNA was amplified and genotyped using the Roche reverse line blot system (Chaturvedi et al., 2005; Gravitt et al., 1998). This assay used the extended-spectrum and biotin-labeled L1 consensus (PGMY09/11, amplicon 450 bp) and biotin-labeled β-globin primers (PC04, GH20, amplicon 250 bp). Samples demonstrating the 450 bp L1 amplicon were genotyped using the 37 types contained on the reverse line blot: the 13 high-risk HPV types were16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. Any bands more intense than the low β-globin band intensity were scored as positive.

2.6. Data analysis

To identify correlates of indicating that self-collection is preferred over Pap testing bivariate tests of association (chi-squared tests or independent groups *t*-tests) were conducted. To identify correlates of testing positive for HPV bivariate tests of association were applied to nine single-item measures and the two scale measures. Because of the exploratory nature of this study, a less conservative standard was used to define significance ($P < 0.15$) and effect size estimates were calculated for dichotomous outcomes (using the risk ratio) and continuous outcomes (using the percent relative difference).

3. Results

Average age of the sample was 46.5 years (standard deviation = 9.0 years). All women identified as non-Hispanic Black. A monthly household monthly income of less than $2000 was reported by 40.9%, with 28.4% reporting incomes between $2000 and $3000, and 30.7% reporting incomes above $4000. Just over one-half of the sample (55.7%) indicated not having children who lived with them, 22.7% reported having one child living with them, and the remainder had two or more living with them. Less than one-half (44.3%) were married at study enrollment.

3.1. Acceptance of the self-collection process

Only one woman of the 88 enrolled, reported she did not understand the directions for self-collecting the specimen. When asked "how comfortable were you with collecting the specimen," 35.2% selected the option of "comfortable," 19.3% selected "somewhat comfortable," 22.7% selected "slightly comfortable," 13.0% selected "neither comfortable nor uncomfortable," and 8.0% selected "uncomfortable." Seventeen percent reported experiencing some pain during the collection process, and 12.5% reported bleeding during the collection process. A majority (78.4%) reported they would you be more likely to do this test on a regular basis compared to having Pap tests.