Feasibility of self-collection of specimens for human papillomavirus testing in hard-to-reach women

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Despite the availability of cytology screening programs in developed countries, women who are of lower socioeconomic status may not make full use of these programs.\(^1\)\(^2\)\(^3\) As a result, these women experience higher rates of cervical cancer than women in the general population.\(^4\)\(^5\)\(^6\)

Screening tests that use patient-collected samples may increase the rate of cervical cancer screening in populations that are historically underscreened.\(^7\)\(^8\) Unlike Papanicolaou smears, which require a clinician to collect the specimen, women can directly obtain a cervicovaginal sample by intravaginal insertion of a swab, tampon or cytobrush.\(^9\) These self-collected specimens can then be used to screen for the presence of human papillomavirus types of high oncogenic risk (herein referred to as high-risk HPV), and women whose test results are positive for high-risk HPV can then be encouraged to seek further testing (e.g., Pap smear, colposcopy). In order to examine the feasibility of self-collection of specimens for HPV testing as a part of cervical cancer screening, we offered self-collection of specimens to women in Vancouver’s Downtown Eastside.

**Methods**

**Study population**

The study population included sexually active women over the age of 16 who were homeless or had unstable housing in Vancouver’s Downtown Eastside (a region characterized by high rates of drug-related mortality and homelessness\(^10\)), who were involved in the sex trade or who had a history of alcohol or drug abuse. Women were recruited to the study from November 2004 to October 2005 by outreach nurses using a standardized recruitment statement in women’s centres, shelters and alleys. Self-collection of specimens for HPV testing is not a standard part of cervical cancer screening; thus, all women were advised to have a Pap smear within 1 year. Participants were given a diagram that illustrated how to obtain a cervicovaginal specimen. They were instructed to insert a Dacron swab intravaginally, rotate it 3 times and place it in a specimen tube containing specimen transport medium (Digene Corporation). Women were asked to collect the specimen immediately at the closest washroom or private location and to return it to the nurse. Samples were transported to the British Columbia Centre for Disease Control within 24 hours of collection. They were analyzed for the presence of high-risk HPV DNA using the Digene HPV test, as per manufacturer’s instructions.

Ethical approval for the study was obtained from the Ethics Board at the University of British Columbia.

**Data sources and analysis**

We searched the database of the Cervical Cancer Screening Program at the British Columbia Cancer Agency (where all Pap smears in British Columbia are processed) in order to

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determine the recent cervical cancer screening practices of participants. In addition, we obtained self-reported data about the frequency of Pap smear testing in the general population of British Columbia from the Canadian Community Health Survey.11

Descriptive analysis of the study population included willingness to provide a self-collected specimen and whether nurses were able to recontact women who tested positive for high-risk HPV. We compared the rate of participation in cervical cancer screening programs among study participants and the general population of British Columbia using self-reported data from the Canadian Community Health Survey and aggregate data from the Cervical Cancer Screening Program. We also compared the frequency of Pap smear testing between participants and the general population of British Columbia. We determined the prevalence of high-risk HPV among participants and performed bivariate analyses of categorical variables by comparing the characteristics of women who tested positive with those who tested negative for high-risk HPV. Variables that were significant (p < 0.05) in the bivariate analysis were included in a multivariable elimination logistic regression procedure to achieve a best-fit final model. We used this final model to calculate adjusted odds ratios to identify factors associated with high-risk HPV status. An odds ratio greater than 1 indicates characteristics that are associated with high-risk HPV infection.

**Results**

Overall, 296 women were invited to participate in the study from November 2004 to October 2005. Of these, 152 (51.4%) agreed to participate. Participants had a median age of 39 years as compared with a median age of 40 years for women who participated in the provincial cervical cancer screening program.13

All of the participants provided a self-collected specimen for analysis of HPV status; 1 specimen was lost during accession and analysis, leaving 151 for analysis. Of the 151 participants with specimens available for analysis, 43 tested positive for high-risk HPV (28.5%, 95% confidence interval 21.5–36.1). Of these, 28 (65.1%) were aged 35 to 44 years, 20 (46.5%) were of Aboriginal ancestry, 29 (67.4%) had unstable housing, 28 (67.4%) were single, 26 (60.5%) had ever had a Pap smear, and 26 (60.5%) agreed to participate in the study from November 2004 to October 2005.

**Table 1:** Sociodemographic and behavioural characteristics of women who provided a self-collected specimen for human papillomavirus (HPV) status testing

| Characteristic                                      | Positive n = 43 | Negative n = 108 | p value |
|-----------------------------------------------------|-----------------|------------------|---------|
| Age, yr, † median (min–max)                         | 35 (18–54)      | 41 (19–62)       | 0.007   |
| Education                                           | n = 43          | n = 108          | 0.025   |
| Completed high school                               | 32 (74.4)       | 59 (54.6)        |         |
| Completed trade, college or other                   | 11 (25.6)       | 49 (45.4)        |         |
| Ethnic background                                   | n = 43          | n = 104          | 0.24    |
| Aboriginal                                          | 20 (46.5)       | 54 (51.9)        |         |
| White                                               | 19 (44.2)       | 47 (45.2)        |         |
| Other                                               | 4 (9.3)         | 3 (2.9)          |         |
| Housing                                             | n = 43          | n = 107          | 0.43    |
| Unstable housing‡                                   | 29 (67.4)       | 79 (73.8)        |         |
| Stable housing                                      | 14 (32.6)       | 28 (26.2)        |         |
| Marital status                                      | n = 42          | n = 108          | 0.79    |
| Single                                              | 35 (83.3)       | 88 (81.5)        |         |
| Married                                             | 7 (16.7)        | 20 (18.5)        |         |
| Main source of income                               | n = 43          | n = 108          | 0.67    |
| Work                                                | 1 (2.3)         | 4 (3.7)          |         |
| Social, pension or disability                       | 42 (97.7)       | 104 (96.3)       |         |
| Sex trade in the 3 months before study recruitment  | n = 41          | n = 102          | 0.49    |
| Yes                                                 | 23 (56.1)       | 47 (46.1)        |         |
| No                                                  | 18 (43.9)       | 55 (53.9)        |         |
| Number of sex trade partners in the month before study recruitment | n = 43          | n = 108          | 0.029   |
| < 11                                                | 24 (55.8)       | 80 (74.1)        |         |
| ≥ 11                                                | 19 (44.2)       | 28 (25.9)        |         |
| Drug use                                            | n = 43          | n = 106          | 0.36    |
| Daily                                               | 29 (67.4)       | 63 (59.4)        |         |
| Less than daily                                     | 14 (32.6)       | 43 (40.6)        |         |
| Record of ever having a Pap smear§                 | n = 43          | n = 108          | 0.12    |
| Yes                                                 | 40 (93.0)       | 90 (83.3)        |         |
| No                                                  | 3 (7.0)         | 18 (16.7)        |         |
| Record of having a Pap smear in the 3 years before recruitment§ | n = 43          | n = 108          | 0.27    |
| Yes                                                 | 26 (60.5)       | 55 (50.9)        |         |
| No                                                  | 17 (39.5)       | 53 (49.1)        |         |
| Smoking                                             | n = 43          | n = 43           | 0.30    |
| Yes                                                 | 39 (90.7)       | 91 (84.3)        |         |
| No                                                  | 4 (9.3)         | 17 (15.7)        |         |

*Unless stated otherwise.
†Odds ratio 0.95, 95% confidence interval 0.91–0.99.
‡Unstable housing includes living on the street, in a shelter and staying temporarily with a friend.
§Data from the Cervical Cancer Screening Program, BC Cancer Agency.
Recent studies of the HPV vaccine confirm the need for ongoing cytology screening programs.6 Our findings suggest that women who do not participate in cervical cancer screening programs may be willing to provide a self-collected specimen.17 Future studies should include an examination of the rate of follow-up testing among women found to be positive for high-risk HPV. In addition, improved methods are necessary to enhance uptake of follow-up interventions.18 As well, given the high incidence of this preventable cancer in developing countries,16 self-collection of specimens for HPV screening could be offered as a component of reproductive health programs and could be administered by health care workers to improve access to cervical cancer screening. Follow-up using screen-and-treat methods could then be used to offer definitive treatment for women at risk for cervical cancer.20,21

This article has been peer reviewed.

Competing interests: None declared.

Contributors: Gina Ogilvie conceived the study (with assistance from Mel Krajden and Darlene Taylor) and its design (with assistance from all of the coauthors). She also supervised the study, conducted the data analysis (with Greg Hislop and Darlene Taylor) and prepared the manuscript. Mel Krajden supervised laboratory testing (with Judy Isaac-Renton). Juanita Maginley supervised the outreach team and specimen collection. Darlene Taylor assisted in coordinating the study. All of the authors revised the manuscript and approved the final version submitted for publication.

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Table 2: Participation of study participants and women in British Columbia in cervical cancer screening programs

| Variable | Study participants n = 151 | General population of British Columbia | Odds ratio (95% CI) | p value |
|----------|----------------------------|---------------------------------------|---------------------|---------|
| Never had Pap smear | 21 (13.9) | 608 (8.3)* | 1.8 (1.1-2.8) | 0.02 |
| Had a Pap smear in the 36 months before participation | 81 (53.6) | 5 023 (68.4)* | 0.5 (0.4-0.7) | <0.001 |

Note: CI = confidence interval.
*p = 7336. Data from the Canadian Community Health Survey, 2005.11
†p = 1 382 432. Data from the Cervical Cancer Screening Program, British Columbia Cancer Agency, 2005.13

Interpretation

We found that self-collection of specimens for HPV testing was feasible in women who did not participate in the provincial cervical cancer screening program. Over 50% of the women who were invited to participate in the study agreed to do so, which is similar to the participation rate of other studies in Vancouver’s Downtown Eastside.14 Study participants were significantly less likely than women in the general population to have ever had a Pap smear or to have had a Pap smear in the 3 years before recruitment, which suggests that this specimen-collection method is a feasible way to reach women who do not receive routine cervical cancer screening. In addition, the prevalence of high-risk HPV in our study was more than double that in the general BC population recently reported by the Cervical Screening Program (28.3% v. 13.9%), despite the fact that median age in the 2 groups was similar. This suggests that self-collection of specimens is feasible for women who are at high risk of cervical cancer.15 Self-collected specimens may not possess the same degree of diagnostic accuracy as clinician-collected specimens16; however, this limitation is outweighed by the increased uptake of HPV testing among hard-to-reach women.

confidence interval [CI] 21.2%–35.4%). In univariate and bivariate analyses, women who tested positive for high-risk HPV were significantly younger, less educated and reported having had more sex-trade partners than women who tested negative (p < 0.05, Table 1). In logistic regression modelling that included these 3 variables, women who were younger were less likely to be infected with high-risk HPV (adjusted OR 0.96, 95%CI 0.92–0.99). After HPV status was determined, the outreach team was able to recontact 81.4% (35/43) of the participants who tested positive for high-risk HPV. These women were referred for further testing.

Compared with the general population, significantly more women in the study group had never had a Pap smear in British Columbia (13.9% v. 8.3%, p < 0.05, Table 2). Of the participants, 53.6% (81/151) had received a Pap smear within the 36 months before study recruitment. This was significantly lower than both the rates in the BC general population, as determined from the self-reported survey data, and the data from the Cervical Cancer Screening Program15 (Table 2).
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