INTENTION OF WOMEN TO RECEIVE CERVICAL CANCER SCREENING IN THE ERA OF HUMAN PAPILLOMAVIRUS TESTING

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Abstract

Cervical cancer screening and prevention has been one of the great success stories in public health, but is at a critical juncture. Awareness of the essential role of HPV infection in the genesis of cervical cancer, coupled with knowledge of the limitations of cytology has led to a re-visioning of the screening paradigm, towards the use of primary hr-HPV testing for cervical cancer screening instead of cytology. Use of HPV testing could result in significant changes for screening programs including a later start to screening, extended screening intervals, and use of a test for a sexually acquired infection. These changes may have unintended consequences on a woman’s willingness to participate in cervical cancer screening. In this dissertation, we explore the potential impact of use of HPV testing for primary screening on women’s intentions to be screened for cervical cancer, and outline a plan to guide the change from cytology to HPV testing, using findings from the analyses.

Methods: At study exit, a sample of participants from a randomized trial of primary hr-HPV testing in Canada were invited via email to complete an electronic questionnaire based in Theory of Planned Behaviour, which determined women’s intentions to be screened for cervical cancer if: a) hr-HPV was used instead of Pap smears b) HPV based cervical cancer screening was
offered only every 4 years and c) HPV based cervical cancer screening started after 25 years of age. Demographic data, sexual history and smoking rates were assessed, and scales for attitudes about hr-HPV testing, perceived behavioural control and direct and indirect subjective norms were created.

Item correlation for scales was calculated to determine item agreement. Univariate analyses compared demographics and scale responses of women who intended to be screened for cervical cancer with HPV to those who did not. All demographic data and scales that were significantly different (p<0.1) were included in a stepwise logistic regression model to determine predictors of intention to be screened for cervical cancer with HPV.

**Results:** 2016 email invites were sent to women and 981 completed the entire survey for a response rate of 48.7%. There were no demographic and risk behavior differences between survey respondents and non-respondents. Eighty-four percent of women (826/981) responded that they intended to attend for HPV-CCS which decreased to 54.2% with an extended screening interval, and decreased further to 51.4% with a delayed start of age 25. There were not significant differences in demographics, sexual or smoking histories between women who intended to be screened for cervical cancer with HPV and those who did not intend. Women who intended to be screened with HPV were significantly more likely to report positive attitudes toward HPV testing, report positive perceived behavioural control, describe positive influence of direct and indirect subjective norms, and express confidence in their decisions and abilities to communicate their HPV status with partners. In logistic regression modeling,
predictors of intentions to undergo screening were attitudes (OR 1.22; 95% CI 1.15, 1.30), indirect subjective norms (OR 1.02; 95% CI 1.01, 1.03) and perceived behavioural controls (OR 1.16; 95% CI 1.10; 1.22).

**Discussion:** Although women expressed intentions to be screened for cervical cancer with HPV, intentions decreased substantially when coupled with the extended screening interval and delayed screening start. Use of primary HPV testing may optimize the screening paradigm, but programs must anticipate women’s potential responses and concerns with program changes, such as extended intervals and delayed program starts, and should ensure robust planning and education to mitigate any negative impact on screening attendance rates. Using Kotter’s eight step model and integrating key findings from this study, essential elements to successfully implement this change are outlined.
Dedication

For McKerron, Lauchlan and Ian
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CHAPTER 1: Introduction

Cervical Cancer and Human Papillomavirus

Cervical cancer screening using cervical cytology (the Pap smear) has been an extremely successful public health intervention, achieving reductions in cervical cancer incidence of up to 80% where practiced effectively (1). However, the Pap smear was introduced over 50 years ago, and studies have now proven that, despite its substantial contributions, as a screening tool it has significant limitations. Data from some jurisdictions indicate that cervical cancer rates have reached a nadir, and meta-analyses indicate that the sensitivity of a single Pap test to detect cervical intraepithelial neoplasia (CIN) or invasive cervical cancer is less than 60%(2).

There is now ample evidence that infection with high-risk types of the human papillomavirus (hr-HPV) is a requisite step for the development of cervical cancer and its precursors (3;4). Of the over 100 subtypes of human papillomavirus, fifteen of these, including types 16 and 18, are high risk types and are known to be the necessary causes of cervical cancer(3). HPV is primarily acquired through sexual contact, but unlike other sexually acquired infections, HPV is exceedingly prevalent, and the cumulative lifetime prevalence of HPV in women is over 75% (5). It is a highly transmissible virus, and the majority of
women acquire cervical HPV infections with at least one type of HPV within 2 to 5 years after initiating sexual activity (6). Usually, however, HPV is a transient infection; over 90% of women clear incident cervical HPV infections within 2 years of acquisition (7;8). Women who do not clear HPV infections are at risk for developing persistent HPV infections and, potentially, pre-cancerous cervical lesions (CIN1, CIN2, CIN3) which may then progress to cervical cancer if not treated (9). Every year in British Columbia, more than 500,000 women are screened for cervical cancer through the cervical cancer screening program, more than 5,000 are treated for CIN2/3, and 100 develop HPV16/18 related cervical cancers (10). Although the overall rates of cervical cancer may appear low, these are only achieved because of extensive, sustained efforts with screening and treatment, of several thousands of women with pre-cancerous lesions using ablative and excisional therapies.

As a primary screening tool, cross-sectional studies have shown that hr-HPV testing has higher sensitivity and negative predictive value (NPV) for CIN2 or worse (CIN2+) detection than either the conventional Pap smear or liquid based cytology (LBC), albeit with lower specificity and positive predictive value (PPV) (11-16). In recognition of this, one approach for screening would be to use hr-HPV testing as a single primary screening test, with cytology reserved only for triage of women having a positive test. This is particularly relevant for vaccinated populations, where, especially following the advent of HPV vaccination, we can expect to see a degradation of the performance characteristics of cytology, including a reduction in the positive predictive value of cytology (17). HPV testing
in this setting has screening performance characteristics that would make it an ideal primary screening test for cervical cancer.

To examine these concepts, several large, international randomized controlled trials (RCT) are being conducted in Europe and Canada to evaluate HPV testing as part of primary cervical cancer screening (13;18-25). With the exception of the Finnish Randomized Public Health Trial and phase 2 of the New Technologies for Cervical Cancer Screening (NTCC) trial in Italy, these trials compared combined HPV and cytology testing and cytology alone as the primary screening intervention. Phase 2 of NTCC, the Canadian HPV Focal Trial and the Finnish trials are comparing HPV versus cytology as the primary screen, with follow up cytology. These trials all examine clinically relevant endpoints of CIN2+ and CIN 3+. Data from these trials show that use of hr-HPV as a primary screen improves detection of CIN2+, and also prevents more cancer than cytology (26-28).

Cervical cancer screening programs across jurisdictions in Canada and Europe are now poised to make a substantial paradigm shift to consider the use of hr-HPV testing as the primary screen for cervical cancer(29-31). However, successful screening programs should consider factors beyond attributes of the screening test. To date, emphasis on use of hr-HPV testing in cervical cancer screening has focused on diagnostic accuracy and clinical outcomes of the screening modalities. There are other, broader considerations that should be examined. Introduction of primary HPV testing would be a paradigm shift in a long established screening program which for many women is a rite of passage.
Use of HPV testing as a primary screen could lead to changes in both the timing of testing and implications of positive test results, which would have impacts on the acceptability, uptake and ultimately the success of the screening program.

Experiences with colorectal cancer screening have demonstrated that implementation of screening tools should be considered in a broad sense, beyond the sensitivity and disease detection capabilities of the screening protocol. Colorectal cancer is the second most common cause of cancer death in Europe, Australia and the United States, and screening interventions have proved to be effective in reducing colorectal cancer mortality (32). Screening consists of faecal occult blood testing followed by colonoscopy, if warranted. Colonoscopy is a relatively invasive procedure, where a thin fibre-optic camera is inserted into the rectum and then into the large bowel. The clinician can then visualize both the rectal and bowel tissue and biopsy if any areas of concern are noted. In order for colonoscopy to be completed successfully, patients must complete bowel preparation in advance. Many patients find this uncomfortable and inconvenient. Combined, both the bowel preparation and the actual colonoscopy can be an unpleasant experience for patients, and has led to challenges with acceptance of colorectal screening. In a comprehensive review, although rates for surgery for colorectal cancer have increased in the United States, up to 20% of individuals with abnormal faecal occult blood testing did not proceed to colonoscopy after initial screening (32). When explored in further detail, patients were reluctant to undergo colonoscopy due to discomfort with the bowel preparation, as well as anxiety with the test, anticipation about pain and
complications. Women in particular articulated embarrassment and feelings of vulnerability. Suggested actions included development of improved bowel preparation processes as well as focusing on comfort during the procedure and providing comprehensive education to alleviate anxiety in order to improve the uptake rate of colonoscopy. The importance of client education and knowledge about the value of colonoscopy were identified as key opportunities to improve uptake and finally physician recommendation was a critical factor in influencing the uptake of colonoscopy.

Practitioners and policy makers need to be mindful that simply because a screening intervention is effective clinically, this is not sufficient to ensure successful acceptance and implementation. However, screening for colorectal cancer has been successful in many countries, demonstrating that even if a screening intervention itself is of some concern for clients, they can be successfully adopted and utilized in a health care system to improve health outcomes, when attention is paid to the potential client issues. As colorectal screening has shown, program implementation with consideration of broader issues can lead to a high acceptability of the procedure and screening intervention. Thus, careful reflection of the broader implications of moving to hr-HPV testing as a primary screen for cervical cancer on the structure and acceptability of cervical cancer screening is essential; to anticipate how the change in the test used might impact on this long established screening program.
HPV testing has specific elements that, if employed, will impact on the structure and delivery of cervical cancer screening. Because hr-HPV testing offers improved sensitivity for detecting precancerous lesions, a negative test offers greater assurance to clinicians and screening participants that they are not at risk for developing cervical cancer in the near future. Recent reviews by Dillner (14) have proposed that screening intervals for hr-HPV negative women could be extended to five years, yet still offer effective and safe screening for cervical cancer precursors. If hr-HPV testing were offered in British Columbia, women who have been accustomed to receiving annual screening may be advised and possibly limited to cervical cancer screening every five years.

In addition, hr-HPV testing is based more in the true natural history of cervical cancer dysplasia and lesions, and screening with hr-HPV may permit a delay in the age at which women begin to be screened for cervical cancer. HPV is an exceedingly prevalent infection, and the majority of women clear the infection on their own. However, in women who do not clear their infections, there is a risk for development of precancerous cervical lesions and possibly cervical cancer. Given the prevalence of HPV, particularly in young women, testing for cervical cancer using HPV in women under 25 will identify an extensive number of lesions that will most likely regress, and thus limit the value of the screening test by diminishing the test’s specificity. For hr-HPV testing to be useful, it should detect primarily persistent, as opposed to transient lesions. To minimize false positives, cervical cancer screening using hr-HPV testing likely will
be delayed until after age 25 and possibly even later, to ages 30, which is more aligned with current European practices.

The final challenge of the shift to HPV testing is that from an oncological to a communicable disease paradigm. Cytology identified cellular changes associated with precancerous lesions in the transition zone of the cervix. In contrast, HPV testing identifies the infection that precipitates these changes in the transition zone. However, HPV itself is an infection that is sexually acquired. Despite the fact that the infection is highly prevalent, use of hr-HPV testing as the screen for cervical cancer will require practitioners to provide women, many of whom have been in monogamous relationships, with information that they are infected with a sexually acquired virus. Even though the virus may have been acquired many years prior, doubtless this will offer significant challenges both for practitioners and for patients. Since practitioners will be counselling women about a sexually transmitted infection, they will need to manage the anxiety, guilt and shame that may follow.

Since cervical cancer screening using cytology is one of the most established and integrated health services screening programs, clinicians, researchers and policy makers should systematically examine potential impacts, both positive and negative, of a change from cytology to hr-HPV testing on attendance for and uptake of cervical cancer screening. As one of the most effective types of screening, it is essential to determine if the switch from cytology to hr-HPV testing has negative effects on the uptake rate for cervical cancer
screening. If that occurs, policies, education and interventions to attenuate any projected uptake reductions will be required.

Context for research question

British Columbia is the western-most province of Canada, with a population of 4 million. Health care in the province is publicly funded, and cancer care in the province is centralized with one agency, the British Columbia Cancer Agency, primarily responsible for establishing screening guidelines and for service delivery of cancer care throughout the province. The cervical cancer screening program of the BCCA is one of the longest established screening programs. Over 750,000 Pap screens are conducted in the province yearly, and one central laboratory analyzes all Pap smears.

In British Columbia, all recommendations for cancer screening and cancer care are made by the British Columbia Cancer Agency (BCCA) Tumour Group, an interdisciplinary panel of appointed experts, who review recommendations based on advice from focused task groups. Currently, the British Columbia Cancer Agency recommends that women be screened for three years annually using cytology, and then every two years, if the initial three screenings are negative. Even with these recommendations, many women still are screened yearly. As British Columbia begins to consider a change from cytology to hr-HPV testing, a comprehensive examination of the impact of such a change specifically on women’s intention and willingness to be screened for cervical cancer is required.
CHAPTER 2: Study roles, responsibilities and chronology

This dissertation has two parts: secondary analysis of a survey conducted as part of the HPV FOCAL trial and a plan for change to implement cervical cancer screening based on HPV testing. The HPV FOCAL trial is a randomized trial based in British Columbia with the primary objective of comparing the efficacy of cytology to hr-HPV testing as the primary screen for cervical cancer. The Doctorate of Public Health candidate, Dr. Gina Ogilvie, is co-principal investigator for the HPV FOCAL trial. HPV FOCAL trial is funded by Canada’s national health research agency, the Canadian Institutes for Health Research.

HPV FOCAL began recruitment in late 2007, and recruitment of 28,000 women was completed in April 2012. By January 2010, ~2000 women who had been randomized to the safety check arm had completed the trial. As part of exiting the trial, women were invited to complete a survey on a variety of topics, including acceptability of self-collection, experience in the clinical trial and their intentions to receive cervical cancer screening based on HPV testing. The investigator team of HPV FOCAL designed and implemented the survey. For this dissertation, the Doctorate of Public Health candidate analysed survey data relevant to intentions to receive cervical cancer screening using HPV.
CHAPTER 3: Literature Review

Substantial changes in health care programs require health policy to provide the foundation for the change, leadership and engagement from the system to support the program, from practitioners, as advocates and experts to deliver the intervention and from the patients, who ultimately must accept and make the decision to be screened. Evidence shows that all of these elements must be aligned in order for a program to be successfully implemented. For purposes of this dissertation, the focus will be on one of these elements: the factors that facilitate acceptability and intention to be screened for women for cervical cancer using hr-HPV testing. Ultimately however, for system change to be effective, the broader elements of policy, system support and practitioner engagement must all be aligned and working in concert to achieve the paradigm shift.

As part of this inquiry, we examined the scientific literature broadly to determine women’s experiences and concerns about HPV testing as well as the impact of the proposed use of hr-HPV testing on women’s intentions and uptake of cervical cancer screening services. Following this, to specifically align with our focused research question, we conducted a systematic literature review to determine if there is any evidence that: i) extension of the screening interval ii) delay of screening initiation and iii) use of a test for a communicable disease
have an impact on intentions or actual attendance for cervical cancer screening in North American women.

**Search Methods**

The search was conducted using standard search procedures in ‘PubMed’, a free database maintained by the U.S. National Library of Medicine and the National Institutes of Health that accesses MEDLINE and other biomedical databases. PubMed was searched using the key words ['attitude' OR 'knowledge' OR 'acceptability' OR 'intention'] AND human papillomavirus (HPV). Given the rapid pace of development for HPV testing, the search was limited to studies published from 2002 until December 2011 and to English language studies. Key words 'screening', 'cervix', 'vaginal smears' were not used for this search, since use of these words might limit search results unnecessarily, given the nascent nature of this field.

**Inclusion and exclusion criteria**

Both qualitative and quantitative studies that surveyed or interviewed females who routinely attended cervical cancer screening (> =15 years of age and <= 70 years of age) about their knowledge of and/or attitudes towards the use of HPV testing and/or intentions to screen if hr-HPV testing was used for cervical cancer screening were included. Studies using a variety sampling techniques, including random digit dialing, convenience, clinic based, venue based and population-based also were included. Studies that were completed in person, by mail, telephone-based, or online also were included. There was no
restriction for study inclusion based on country where the study was conducted, as long as the study was published in English.

As outlined earlier, although the role of practitioners, policy and systems are critical elements in success of a change in implementing screening programs, for purposes of this dissertation, the focus is on acceptability and intentions to be screened from the perspective of women. Thus, studies that assessed attitudes of practitioners, peers or policy makers as were studies that examined attitudes to the HPV vaccine alone (and not HPV testing) or to attitudes about HPV in men were not included.

Criteria for inclusion included:

1. Participants: Female
2. Age: 15-70 years
3. Study Objective: Examine women’s attitudes towards OR acceptability of HPV testing as a primary method for cervical cancer screening; To examine women’s intentions to be screened for cervical cancer with hr-HPV testing
4. Analysis technique: Qualitative or quantitative

Using ‘PubMed’ and following the search strategy listed above, the following results were obtained:

Key words: ‘attitude’ OR ‘knowledge’ OR ‘acceptability’ OR ‘intention’: 489,771 articles
In the end, 483 articles were identified through the search strategy and sixty-eight articles were selected for review: None of the studies examined extension of cervical cancer screening from annual or bi-annual screening.

I. Intention and willingness to be screened with HPV-DNA

In a qualitative study of Hispanic women aged 18 to 60, Vanslyke et al. (34) used focus groups with women from community-based organizations to discuss cervical cancer, HPV testing and prevention. Fifty-four women were recruited, and seven focus groups with 5 to 11 participants each were conducted in both English and Spanish. Data analyses were not based on pre-specified frameworks, but were derived from the data. For this phenomenological study, the researchers transcribed and translated all the focus groups and underwent translation verification. Two researchers read the transcripts and organized data to identify themes related to cervical cancer and Hpv testing. Data was coded and then the team met to come to consensus on the coding scheme and identify major themes. Vanslyke found that there was a range in willingness for women to participate in HPV DNA testing. Responses ranged from an intention to be screened for cervical cancer to a belief that there is no need for HPV testing. Those who intended to be screened for cervical cancer said they wanted to know how to get treatment, while those who were unsure or unwilling said they were
reluctant to receive a cancer or HPV diagnosis. Participants also expressed concern about the meaning and implications of a positive test. Regardless of a women’s perspective on HPV testing, all stressed the need for expressed consent regarding the meaning of the test.

Strengths of this study include the broad age range of the participants included, which mirrors the majority of women who seek and are recommended for cervical cancer screening. Women who often do not attend for screening (Spanish speaking, low income) specifically were recruited for this study, which can help broadly inform approaches to improve recruitment into screening for women known to be at higher risk for cervical cancer. By employing a focus group methodology, participants are encouraged and supported to explore broader conceptualization than with individual interviews. This study deliberately explored a very important area that will inform future programming for cervical cancer screening with the question ‘How would you feel about being tested for HPV?’ However, this exploratory study of the phenomena of HPV testing did not develop nor test a theoretical or conceptual framework for understanding HPV testing. The authors identified their findings as a foundation for future areas of future research and examination.

As part of an omnibus survey from the National Centre for Social Research conducted between November 2006 and February 2007, 994 women aged 25-64 women in Britain were asked about acceptance of HPV testing. Specifically, they were asked how likely they would be to accept an HPV test if offered one at their next cervical cancer screening appointments. Overall, 70% of
women said they were willing to accept HPV testing as cervical cancer screening. In multivariate modeling, screening attendance, Caucasian ethnicity and talking to friends about female health issues were significant predictors of intention to receive hr-HPV testing for cervical cancer screening (35).

This study relied on an existing national recruitment methodology for a population based survey and is not based in a specific theoretical model. The survey explored a broad range of health questions, and included specific questions about HPV screening based on five point Likert scales. Variables relevant to cervical cancer screening attendance and uptake, including age, ethnicity and education level, were available on all participants. It also included the precise target range for cervical cancer screening. However, the study was limited by reliance on the pre-existing items in the survey. In addition, the author’s commented that specific minorities (6% vs. UK population of 8%) were under-represented, limiting their ability to examine detailed differences between specific ethnic minorities. As ethnicity is an important predictor of cervical cancer screening in general, this study could have provided very useful information for policy makers, given the existing differences in screening uptake in different cultural and ethnic groups.

In Huang’s evaluation of 865 older women aged 50 to 80 who were educated about HPV (including the fact that it is sexually transmitted), 64% indicated an interest in HPV testing (33). This study did not look at extended HPV testing intervals, but participants indicated a willingness to have Pap testing every three years rather than ever year if they had a previous negative HPV test.
Over 75% said they would have more frequent Pap testing after a positive HPV test.

The study was embedded in and thus benefitted from an established, well-designed community-based cross-sectional study. The study was designed to evaluate cancer perceptions in women from four racial and ethnic groups (white, Latina, African American and Asian). Participants were recruited from a wide range of primary care clinics in San Francisco and offered questionnaires in multiple languages to ensure a broadly representative sample. A limitation of this study was that it did not include women outside the health system. The authors also did not describe a theoretical framework for their survey. These findings are very relevant for the proposed research, as they offer important information on HPV testing in an older cohort. That said, the very specific ethnicity of the participants will offer some limitations to generalizability of findings.

Kwan (36) developed an intervention with the goal of reducing HPV-related stigma in the Chinese community. In a randomized controlled trial of HPV message testing, Kwan applied different foci for messaging around HPV, varying information and stress on prevalence, sexual acquisition and risk for cancer in women older than 18. Participants were assigned to read information about HPV from one of three theme groups, and completed a survey before and after the informational intervention. Prior to receiving the educational intervention, 90% of the 294 ethnic Chinese women who participated stated they would receive HPV testing. After messaging, overall, 97% stated they would get HPV
testing as part of cervical cancer screening. The increase in positive intention to participate was significant (p<0.05), and this was found across all three arms.

The study provided insights about women’s intentions to receive high risk HPV testing both pre and post HPV education. It used items that showed good reliability, and the survey instrument was pilot tested and revised. Sample size calculations were clearly presented, and the rationale for statistical analyses was cogent. There were some limitations to this study. No theoretical framework for study design and approach was presented. Also, the study only included women who could read Chinese, which could limit generalizability of study findings to literate women. The study recruited solely from the Family Planning Association of Hong Kong for birth control. This would bias findings towards women who potentially had more sexual partners and were not in steady relationships, which would potentially limit the generalizability of the findings to a broad screening population.

II. Impact of a positive HPV test

Waller et al. (37) conducted a web-based survey of 811 female students in the United Kingdom. They were asked to imagine that they received a positive HPV test and then answered a series of questions regarding stigma, shame and anxiety (in keeping with experience of other positive STIs). Stigma, shame and anxiety were significantly lower when women were aware that HPV is a highly prevalent virus (p<0.05). Knowledge that HPV is sexually transmitted was associated with higher levels of stigma and shame, but not anxiety (p=0.001).
Lack of awareness of the prevalence of HPV, but awareness of its sexually acquired nature was associated with high scores for stigma and shame.

Strengths of this study include use of a survey that is based on established theories and was adapted from previous instruments and qualitative work. The method of distribution and recruitment model was highly appropriate for the age of the participants. However, because only women under the age of 30 were recruited it would be challenging to generalize findings of this study to a broad screening population.

In our literature search, four studies were identified in the past five years that examined women’s willingness to be screened with hr-HPV instead of cytology. No studies were completely consistent with our parameters. In general, most reported that the majority of women were willing to receive HPV testing for cervical cancer screening. No studies looked at an extension of screening intervals or delayed screening, but included studies that assessed the acceptability of hr-HPV testing. Studies tended to explore particular subgroups, such as women over the age of 50 or women of Chinese background, and only one aimed to recruit a broad screening population. Women expressed the need to consent for the test and information regarding implications of a positive test. Messaging was an important aspect of test acceptability, and a focus on high prevalence of hr-HPV was key to acceptance of HPV testing and decreased stigma of HPV infection.

Only one study explicitly examined the impact of positive HPV testing in the setting of a screening program. In this study, shame and stigma were
assessed in the context of a positive HPV test in low risk women. Some critical findings for HPV education emerged. Women who were aware of the very high prevalence of HPV were less likely to report high levels of stigma, shame and anxiety. However, women who were only aware of the sexually transmitted nature of HPV had high levels of stigma and shame. This is likely related to the ongoing stigma that sexually acquired infections have in our society.

No studies explored consequences of extended screening intervals on acceptability and intentions to receive screening with hr-HPV nor on delayed initiation of screening. These are particularly important areas, as findings in related settings contrast regarding the implications of delayed and extended cervical cancer screening. In a study of Pap screening (not HPV testing), Sirovich reported that women preferred to be screened annually, and 69% reported that they would try to continue to receive annual screening, even if advised for extended screening by their physicians. Women in this survey also believed that any extension in screening was based on cost constraints, not about best practice (38). In one study, women reported that they were willing to have extended cytology screening if they had a previous negative test. This indicates that women need to be assured regarding accuracy of their screening results, in order to accept extended intervals. The contradictory findings confirm the need for further research into the implications of extended screening intervals for women and educational interventions needed to effectively support these changes.
**Perceptions and psychosocial reactions to an HPV diagnosis**

In qualitative and quantitative studies women reported a wide range of emotions and psychosocial reactions to receiving an HPV diagnosis. These reactions included anxiety, fear, distress and anger in response to a positive HPV test. Women described anxiety about the impact of HPV results on their relationships, expressed concern about the need to disclose their results to their sexual partners and highlighted the importance of informed consent for HPV testing. Some women also felt empowered, because they could take action to mitigate the consequences of the infection (39).

In an Australian study, women were anxious, distressed and confused by the diagnosis of HPV (40). In an additional study of British women, McCaffery found that much of the distress for HPV testing related to stigma for sexually acquired infections, and that this transcended cultural groups. McCaffery described ‘strong negative emotional responses’ to positive HPV tests. Women were concerned about the source of infection, and impact of a positive result on relationships, implications on mistrust, infidelity and promiscuity (41). While Hispanic women also reported potential anxiety and distress with an HPV positive result, this same group also reported a wide range of acceptance for HPV testing, from willingness to receive an HPV test to reluctance(34).

In a study of adolescents and how they process HPV results, there were four key dimensions for young women as they defined the personal meaning of positive HPV results. Despite similar education, young women framed a positive HPV test result as either an STI or a cancer result. Young women who labelled
the HPV result as an STI reported much guilt, shame and stigma. Perceived risk for cancer was influenced by an adolescent’s framing of the health risk and perceptions of control. Stigma and shame were prominent components of the personal meaning that young women applied to positive HPV results. In particular, adolescent women were more likely to understand an HPV infection compared to an abnormal Pap smear as stigmatizing, and expressed concern about social rejection. Specifically, adolescents endorsed the belief that adolescents who had HPV infections would be perceived as promiscuous and likely co-infected with other sexually transmitted infections(42).

In Waller’s study of university students, she found that awareness of HPV infection was associated with higher levels of stigma and shame (43). In this study, however, increased awareness of HPV did not lead to greater anxiety, perhaps because women who were aware of HPV were less focused on the HPV and cancer link compared to women with less knowledge about HPV. At the same time, Waller noted that women reported lower stigma and shame scores when they were informed about the high prevalence of HPV.

In in-depth interviews with women following HPV diagnoses, Daley et al. described five themes in their emotional responses: stigma, fear, self-blame, powerlessness and anger(44). As a consequence of their HPV diagnosis, women reported reactions often associated with stress, including loss of sleep, loss of appetite and problems focusing on activities of daily living, but were they still were able to disclose their results to partners.
In another study of Hispanic men and women, Fernandez found that women had a range of reactions to HPV positive results, from fatalistic to stoic. Their responses focused primarily on the link of HPV with cancer, and thus their responses reflected responses to a perceived ‘cancer’ diagnosis, as opposed to an STI diagnosis or results of a screening test to be investigated further. Women also focused on the impact on their families and economic consequences of a cancer diagnosis. When discussing partners’ reactions, women said that their partners would be angry, question their fidelity and quite possibly may abandon them. Women framed this in the machismo of Hispanic men, and most felt that their partners would believe the women had been unfaithful; few male partners would worry about the diagnosis being a reflection of their own potential infidelity (45).

Canadian women from Ontario associated an HPV diagnosis with stigma, infidelity and immorality (46). They described a reluctance to receive results and to share results with those around them. However, their anxiety about the implications of results did not appear to deter women from having HPV tests, and they welcomed the opportunity to have a screening test that provided more definitive results for them and their practitioners which could more accurately guide their follow up procedures. As with previous studies, women highlighted the need for confidentiality and also the opportunity to consent and control their access to the test results.
In another study of women who received positive HPV test results, Waller noted reactions of shock, confusion, distress about the diagnosis (47). These reactions were centred on the sexually transmitted nature of the virus, and the potential source of the virus from their partners. When women experienced a persistently positive HPV result a year later, women’s anxiety was heightened, as women realized that there may not be a resolution to the infection, and they may require further investigation and treatment. At this point, women described concerns about cancer, fertility and again focused on the sexually transmitted nature of the infection and its potential impact on their relationships. They also expressed disappointment that the infection had not cleared on its own, as they had hoped, and so were realizing that the infection was more serious than they initially believed. Disclosing results in this study created comfort for some women, as they found reassurance and support in their friends and family. However, for others, disclosure was not helpful, because their support networks were unaware of HPV, or women felt guilty that they had potentially infected their partners.

In a study with co-testing for HPV and cytology, women with abnormal Pap smears who also were HPV positive reported higher levels of anxiety, distress and concern compared to women with abnormal or normal smear results(48). The anxiety rates were higher when women perceived themselves to be at higher risk for developing cervical cancer. In their follow up study 6 months later, the authors found a diminished level of anxiety in the women who were positive, but these women still had heightened level of concern about the test results(49). Specifically, predictors of heightened concerns were associated
mainly with ongoing worries about developing cancer, as well as HPV status, history of abnormal smears and sexual health concerns.

In this literature review, we examined published data to determine if there is any evidence that demonstrates if i) an extension of the screening interval ii) delay of screening commencement and iii) use of a test for a communicable disease has an impact on intentions to participate in cervical cancer screening in North American women. Despite widespread use of cervical cancer screening, and its position as a central pillar in routine health maintenance, there has been relatively little work conducted on the impact of changing screening modality. This literature review has demonstrated that a preliminary body of work has been conducted on acceptability of the HPV vaccine and considerable work has been done on women’s knowledge, attitudes towards HPV testing as well as their experiences receiving HPV results both theoretically and in reality. However, few researchers have taken the next step to deliberately and methodically apply a theoretical framework and inquire from women as to whether they would continue receiving this important health intervention when paradigms shift. This is a concerning omission, as the focus of research seems to have been primarily on the diagnostic accuracy and characteristics of the new testing intervention with little consideration of how these new tests will impact the use of cervical cancer screening broadly. Research is urgently needed, as the clinical data confirming the utility of hr-HPV for screening expands, to ensure that implementation of this change in screening modality is conducted in an effective and patient centred fashion.
Need for studies situated in Behavioural Models

Future studies in this field should be grounded in established theoretical models that examine health care seeking in individuals, such as the Theory of Planned Behaviour or Health Belief Model (50). Research should be focused in particular on use of hr-HPV testing in screening paradigms (as opposed to case finding or follow-up of abnormal cytology). Implications for asymptomatic, low risk women are different from women who report symptoms or have abnormal test results. Both qualitative and quantitative work should be conducted. Population based studies that examine key elements such as intention to receive screening if hr-HPV testing is used and the potential impact of extended screening intervals should be conducted. These population-based quantitative studies should include a broad range of women who both participate and do not participate in cervical cancer screening. Women should be asked how a change in testing modality would impact their future intentions to participate in screening. Qualitative work should examine women’s perceptions around hr-HPV testing and their concerns and worries about extended screening intervals and use of a test for sexually acquired infections. Women also should be asked how educational programs and clinicians can best allay their fears about the use of hr-HPV testing. There should also be deliberate examination of populations known to have low rates of cervical cancer screening (aboriginal women, immigrant women, African-American women) to determine if this shift in screening modality can enhance their participation in screening programs.
One of the main limitations of previous studies regarding the acceptability and impact on intentions of a new screening paradigm is that they were not grounded in models of health behaviour. Ultimately, information from the proposed research will be used to inform program and policy planning for implementation of a new screening program. It is prudent and advantageous and will improve the rigour of findings if inquiries are based on established theoretical models. By using a framework, planners can move beyond intuition and develop programs that are based on a more refined understanding of health behaviour.

Several reviews have shown that interventions based on theories were more effective than those not based on a theoretical framework. Thus, considering theories from the start of planning programs designed to promote health seeking behaviours will likely to improve their success.

No single theory dominates health promotion research and education on health behaviour. Several prominent theories are used to understand why individuals participate in behaviours that promote health, such as cancer screening. Using theoretical foundations, researchers can better parse out both the behaviour and the specific elements that underpin behaviours. Broadly, theories can be understood as explanatory or change theories, which focus on different aspects of behaviour, but contribute in complementary way to planning. In a recent systematic review, the most frequently used theories used for examining health promotion are social learning theory, theory of planned behaviour and the health belief model.
The theory of planned behaviour (TPB) is a well-described theory of human behaviour and has been used extensively to look at screening health behaviours, such as mammography (51). It is based on Ajzen’s and Fishbein’s Theory of Reasoned Action (TRA), which is particularly valuable to describe behaviours that are under an individual’s volitional control. The theory of planned behaviour, and its predecessor TRA describes intention as the most proximate predictor of behaviour. In turn, three specific elements predict intentions: attitude towards the behaviour, perceived behavioural control and subjective norms to the behaviour. Initially, with TRA, Ajzen and Fishbein described attitude toward the behaviour in question as well as the subjective norms to the behaviour (an individual’s belief about how people they care about will view the behavior in question.) To predict someone’s intentions, knowing these beliefs can be as important as knowing the person’s attitudes. As the TRA was developed, Ajzen added an additional dimension, perceived behavioural control, to capture an individual’s ability to control the behaviour. This new theory was named the Theory of Planned Behaviour (51).

For purposes of this study, we will use theory of planned behaviour to examine the behaviour of interest - ‘attending for cervical cancer screening in the era of HPV testing’, and women’s intentions to be screened for cervical cancer screening if HPV testing is used. Specifically, this study will examine women’s attitudes to cervical cancer screening with HPV, subjective norms related to cervical cancer screening using HPV and a woman’s belief ability to control her attendance for cervical cancer screening (Figure 1). Information derived from the
proposed study can offer critical insights to clinicians and policy makers as they consider essential program elements for introduction of hr-HPV testing as the primary screen for cervical cancer in an organized North American screening program.
CHAPTER 4: Methods

Objectives: We determined intentions of Canadian women to attend cervical cancer screening in the era of HPV testing. We conducted secondary analyses using exit survey data obtained from participants who were part of a large clinical trial in a Canadian provincial cervical cancer screening program. Among women who had completed the trial, we determined intentions to attend for cervical cancer screening in the era of hr-HPV as a primary screen for cervical cancer(52).

Primary Objective: Determine variables that predict intentions to undergo HPV testing instead of having Pap smears for cervical cancer screening

Survey instrument: The survey, developed by the investigative team of HPV FOCAL prior to the dissertation, was based on Theory of Planned Behaviour (TPB) (53). For purposes of clarity, we will outline how the investigative team created the survey.

In keeping with the principles of TPB, study items were developed from a thorough literature review and elicitation interviews and feedback from content
experts in the field. Surveys were drafted and reviewed by a Theory of Planned Behaviour expert Racheal Powell) and then pilot tested on ten women in the target demographic. Revisions were reviewed by principal investigators, investigative team and the TPB expert. A final version of the survey was piloted and finalized. All items used seven point Likert scales (Appendix 1).

The survey is divided into six parts (Appendix I.):

I. Attitudes

II. Subjective Norms

III. Perceived Behavioural Control

IV. Attitudes and Intentions

V. Self-collection for HPV

VI. Involvement in HPV Focal study

For purposes of this evaluation, findings from parts I-IV were used. The primary research question is ‘What variables predict a woman’s willingness to be screened for cervical cancer with HPV testing instead of a Pap smear? (PI19)). We further examined this topic and determined how the following additional factors would influence willingness to undergo cervical cancer screening using HPV testing:

- Cervical cancer screening using HPV testing would only be done every 4 years instead of yearly and
- Cervical cancer screening using HPV testing would only be done every 4 years and start after 25 years of age.

**Participants:** Participants were recruited through the HPV FOCAL trial in British Columbia, Canada (Figure 2). HPV-FOCAL is a randomized, controlled, three-armed study conducted in British Columbia (52) that has recruited 28,000 women aged 25-65 through the province’s population based cervical cancer screening program. There are three trial arms: control, safety check and four year intervention arm. In the control arm, liquid based cytology (LBC) was conducted at entry and two years, and combined LBC and high risk HPV testing (hr-HPV) at four years among those with initial negative results. In the two year safety check arm, hr-HPV testing was conducted at entry and LBC at two years in those with initial negative results. Finally, with the four year intervention arm, hr-HPV was conducted at entry and combined hr-HPV and LBC at four years among those with initial negative results. Women aged 25 to 65, registered with the health insurance plan for the province, who received care from participating family physicians (FP) for routine cervical screening were eligible. Exclusion criteria were: history of histologically proven CIN2 or worse requiring treatment in last five years; history of histologically proven invasive cervical cancer; Pap smear within the preceding twelve months; no cervix; pregnant; HIV positive or on immunosuppressive treatments; or unwilling or unable to provide informed consent.
Figure 1 HPV FOCAL: a three-armed, RCT over a 4 year period.
Recruitment: HPV FOCAL trial recruitment was completed March 2012. As of August 31, 2012, 28,000 women were enrolled as study participants: over 4000 women had exited the trial. Women were invited to participate in the randomized trial in one of two ways. The first approach was when women presented for cervical cancer screening and were deemed eligible to participate by their family physicians (FP). The other method of recruitment was when women were pre-identified as being due for screening from the provincial cervical cancer screening program. For the pre-identified, the FP office sent eligible women a study package that included invitation letter, study information pamphlet and appointments for their cervical screening test and also provided them with the opportunity to contact, or be contacted by study staff to learn more about the trial and decide on participation. All participants were consented by their FPs and asked to complete demographic and epidemiologic questionnaires as part of trial recruitment. As part of their consent, women allowed researchers to contact them to participate in other studies (Figure 2).

At study exit (which for this study included only women allocated to the two year safety check arm – Figure 2), women were mailed end of study questionnaires via email using fluid survey’, an online web-based survey tool that complies with Canadian privacy laws. Women were sent two additional reminders to complete the end of study survey, which included data on overall study participation, attitudes toward self-collection as well as attitudes about the future of cervical cancer screening (Appendix).
**Sample Size:** In the survey, women were asked if they intended to receive cervical cancer screening if HPV testing was used instead of Pap screening. Assuming 75% of women agreed with the statement of intention to receive hr-HPV testing(35), with a sample size of 1000, our 95% confidence interval around the estimate will be ± 2.7%.

**Data Entry:** At study exit, all women who had email addresses were sent invitations to complete surveys. Surveys were completed on ‘fluid surveys. Data entered by participants were stored at fluid surveys and then were automatically populated into an Excel spreadsheet when required for analysis. Data were then converted from Excel spreadsheet to SAS for analysis.
CHAPTER 5: Analyses

Survey response rate: Response rates were determined based on the standard definitions from the American Association for Public Opinion Research(54). This survey is defined as a ‘list based survey’ where the investigators have a sampling frame of email addresses for specifically named persons. As all women were participants in the HPV FOCAL trial, there are no women in ‘unknown eligibility’ category. Respondents fell into the following categories (Figure 3):

Eligible, Non-interview

- Non-contact: Email bounced back as incorrect
- Refusal: Email did not bounce back, survey not completed
- Logged on: Clicked through link, did not complete any items
- Break off: started survey, did not complete enough information to use responses

Returned questionnaire

- Complete: survey completed
- Partial: completed partially with sufficient information to use responses
Surveys responses were reviewed for completeness. In the case of duplicate complete surveys, the first complete survey was used and the second survey was discarded. Minimum response rate (RR1) was calculated according to the American Association for Public Opinion Research. RR1 is the number of complete surveys divided by the number of returned questionnaires plus eligible non-interview. Demographic characteristics of survey non-respondents was available from epidemiological data from the larger clinical trial (Table 1), so we were able to compare non-responders and responders for mean and median age, education, cultural background, sexual history and smoking history. Continuous variables were compared with Student’s t-tests, categorical variables were compared with Chi-square and with Kruskal-Wallis tests to compare medians, as appropriate.

Descriptive analyses of demographic characteristics of the survey respondents were performed, including mean and median age, marital status, education, sexual history, ethnicity and smoking history (Table 2). For all scale variables, definitions were listed in Table 3 and in the list of definitions. Participants’ intentions to be screened with HPV for cervical cancer (PI19>4) as well as overall rates of intentions to be screened every four years (IN21 >4) and intentions to be screened every four years after the age of 25 (IN23>4) were also calculated with 95% confidence intervals for descriptive analyses. Intentions to be screened with HPV for cervical cancer (PI19) were examined based on five-year age strata.
Overall attitude toward having an HPV test instead of Pap screening (A1) was assessed with four items which were summed to form an attitude scale. Attitudes to having an HPV test instead of Pap screening were assessed along with an extended screening interval (A20) and an extended screening interval and delayed start at the age of 25 (A22). All attitude scales were anchored in the same direction, so no recoding was needed. Item analysis using Cronbach’s α was conducted to determine internal consistency of scales. If internal consistency was achieved for the scale (Cronbach’s alpha >0.5), a composite variable was created for analyses (55).

For direct measures of subjective norms, 3 items (SND2-SND4) were assessed for consistency, and summed if Cronbach’s α was >0.5. If item correlation was <0.5, then subscales based on the combination of SND2, SND3 or SND4 were created, and item correlation conducted. To create the normative belief score for the model for indirect norms, the belief score was multiplied by the score for motivation to participate in the named activity(55). For indirect norms, the Likert scales of 1-7 that measure normative belief (Family Physician - SNI5, Friends - SNI7, Spouse/Partner - SNI9, BC Cancer Agency - SNI11) were re-coded to a scale of -3 to +3. With this recoding, positive score indicates that overall, the individual experiences pressure from the individual/group named in the item to participate in the activity. To then create the item, the normative belief was multiplied by motivation to comply, thus creating 4 indirect measures (SNI5XSNI6, SNI7XSNI8, SNI9XSNI10, SNI11XSNI12). The internal consistency of indirect subjective norm items was assessed by Cronbach’s
alpha. In the case of indirect norms, if there was low internal consistency, each item was examined individually, and subscales based on combinations of 2 or 3 of the indirect items were created. This is because the indirect norm of family physician influence may not necessarily be correlated with that of the influence of a friend or spouse. Based on these analyses, either a combined scale or individual items was finalized for the model.

Perceived behavioural control, consisting of 4 items (PBC15-18), was assessed for consistency as well. If they had low internal consistency, we re-examined to create subscales, likely based on self-efficacy and control. Based on these evaluations, items were summed, either as two subscales or as an overall scale for PBC.

In addition to the usual Theory of Planned Behaviour measures and variables, an additional variable of ‘contacting partners’ was created for this analysis. One of the unique aspects of cervical cancer screening with HPV is that HPV is a communicable disease. Several studies have shown that women’s concerns about HPV testing are related to stigma around sexually acquired infections, implications of infidelity and the impact of positive HPV results on relationships with partners (41). Thus, there may be an expectation that sexual partners should be advised of an individual’s HPV status. This expectation may influence a woman’s willingness to participate in cervical cancer screening, due to concerns about the need to disclose results of a communicable disease with partners. Two items assessing impact of needing to inform a partner about HPV status on decision to receive screening were included to determine whether the
communicable disease/STI element of HPV would impact on a woman’s willingness to have this test. These two items (CP13; CP14) were assessed for internal consistency and depending on score, were summed and included as an independent variable in the analyses.

Item analysis using Cronbach’s α was conducted to determine internal consistency of the composite scales, and scales with Cronbach’s α >0.5 were considered for the analysis (Table 3).

A logistic regression model was created to predict factors associated with women’s intentions to be screened for cervical cancer with HPV testing. The focus for the multivariate model was the dependent variable ‘intention to have HPV testing (PI19)’.

On consultation with the provincial cancer policy leads, respondents were dichotomized into intend to screen for cervical cancer with HPV (PI19>4) and do not intend to screen for cervical cancer with HPV (PI19<=4). Provincial cancer agency leads felt this dichotomization would best capture the characteristics of women who would intend to be screened for cervical cancer. Demographic characteristics between the two groups were compared overall and between five year age strata, with Chi-square and Student’s t-test as appropriate (Table 4). Psychological scales that achieved an item correlation with Cronbach’s α >0.5 were first assessed to determine if any were multicollinear. We used a Pearson correlation coefficient to determine how strongly the psychological variables were related to each other. If two variables were collinear (>0.8), based on judgment of the perceived role of the variable in impacting the analysis, the less influential variable was removed (Table 5).
Following this determination, overall scale scores and mean scores with standard deviations for scale results between those who intended to screen and those who did not (PI19) intend to be screened were calculated. Mean results with standard deviations between scales that had acceptable agreement (Cronbach’s alpha >0.5) and not collinear were compared using Student’s t-test.

The main research question for this proposal is *What variables predict women’s intentions to undergo HPV testing instead of Pap testing for cervical cancer screening?* with the model dependent variable of PI19 *I would be willing to have an HPV test to screen for cervical cancer instead of a Pap smear.* Thus, for the model, IN21 and IN23 were not included as they looked at the same issue as PI19, but with the added element of extended screening and delayed start. As well, the corresponding attitudes scales for IN21 and IN23, which are A20 and A22, were also excluded from the model. All demographic and scale variables that achieved p<0.2 in the univariate and bivariate analyses, and variables that were believed by the investigators to be important in predicting women’s decisions to attend screening based on the comprehensive literature review that preceded questionnaire development were entered into the stepwise logistic regression model.

Given the large sample size and relatively small number of variables considered in the analysis, we conducted a direct logistic regression analysis and entered all variables that achieved a p<0.2 into the model at the same time. Demographic data (mean age, marital status, cultural background, educational background, number of male sexual partners, smoking history) and psychological
scales [attitudes (A1), direct subjective norm (SND2-4), indirect subjective norm (SNI5-12), contacting partners (CP13-14), perceived behavioural control (PBC15-18)] where appropriate into the model. Analyses were performed using SAS Logistic. For the model, the model Chi-square, R squared and adjusted R squared as well as regression coefficients, Wald statistics, odds ratios for the significant variables with 95% confidence intervals were calculated to identify variables associated with a women’s intention to screen for cervical cancer with HPV.
CHAPTER 6: Results

Survey recruitment commenced May 1\textsuperscript{st}, 2011 and finished September 30\textsuperscript{th}, 2011. In May 2011, 2459 women had exited the safety arm of HPV FOCAL, and 2016 had email addresses. These 2016 women were all sent invitations to participate in the survey (Figure 3) and represent the eligible population. 1035 were eligible but were not surveyed. 478 emails were returned or bounced back, so these women were ‘non-contact’. 72 replied that they did not want to participate, so were ‘refusals’. 191 individuals logged onto the survey, but did not start it, and 294 started the survey but did not complete it with sufficient information to use the survey. 981 returned and completed the survey. The overall response rate (RR1) is 48.7\% (981/2016).

Responders and non-responders did not differ significantly in their socio-demographic characteristics (Table 1). In particular, age, education level, cultural background, sexual history, smoking history and ethnicity were not different between survey responders and non-responders. Survey respondents had a mean age of 45.1 (SD 10.1); the age range of respondents was 25 to 65 years of age (Table 2). Over 85\% of women had more than high school education, and 56.1\% reported five or fewer sexual partners in their lives. The majority of women were Caucasian, black or South Asian background; 2.4\% of women were
aboriginal. Six percent of women were current smokers and 36.1% had smoked at some time in their lives. 84.2% (95% CI 81.9; 86.5) intended to be screened for cervical cancer with HPV. However, willingness to be screened with an HPV test instead of Pap smear decreased substantially when women were provided with parameters around extended intervals and a delayed start. Willingness to be screened with HPV test instead of Pap smear for cervical cancer screening decreased from 84.2% to 54.2% (95%CI 51.1; 57.3) when women were advised about an extended screening interval of four years, and decreased further to 51.4% (95%CI 48.3; 54.5) when women were advised about a delayed start of screening at age 25.

Scale consistency was assessed for each construct (Table 3). Overall attitudes (A1), attitudes to extended screening interval (A20) and attitudes to extended screening interval and delayed starts (A22) all had Cronbach’s alpha of > 0.9, indicating excellent agreement. The indirect subjective norms scale (SNI5-SNI12), assessing the impact of individuals and organizations on women’s decisions to attend screening also had excellent agreement at >0.8. Perceived behavioural control items (PBC15-18) and contacting partners items (CP13-CP14) both showed good agreement at >0.6. In contrast to the other scales, direct subjective norms had less robust agreement between the items. SND2 (Most people who are important to me would think that I should/should not have an HPV test) and SND3 (People who are important to me would expect me to have an HPV test to screen for cervical cancer) showed moderate agreement at
0.5. However, SND2/SND4 and SND3/SND4 were poorly (0.103) or not at all correlated (-0.045). Thus, only the SND2/3 scale was included in the analysis.

Of 981 women who completed surveys, 826 (PI19) intended to be screened for cervical cancer with HPV tests instead of Pap smears (84.2%)(Table 4). There were no significant differences between the mean age, age strata, marital status, education level, sexual history, cultural background or smoking history of women who intend to be screened with HPV tests instead of Pap smears for cervical cancer (p>0.05). Across age strata, women over the age of 65 had the highest rates of intention to be screened for cervical cancer with HPV (n= 8, 100%) and women aged 55-59 reported the lowest rate (n=116, 81.0%). However, there was no significant difference across all age strata for intention to be screened with HPV for cervical cancer (p=0.542).

Unlike women who were willing to be screened for cervical cancer with HPV (PI19), there were significant differences between women who were willing to be screened with HPV when there was an extended interval between HPV tests and those who were not (IN21). Never married and divorced women were more likely to disagree with an extended screening interval, while common law and married women were more likely to agree with testing with an extended screening interval. Chinese and aboriginal women were more likely to disagree with an extended interval. Women with less education were more likely to disagree with an extended screening interval, while women with advanced university degree were more likely to agree with the extended interval. When a delayed start to screening in addition to extended interval (IN23), education
levels were still significantly different between women who were willing to undergo screening with an HPV test compared to those who were not.

The rest of the analyses will focus primarily on women’s overall willingness to be screened with HPV for cervical cancer (PI19). Univariate comparisons between composite scales for women who were willing (PI19 > 4) or not willing (PI19 ≤ 4) to be screened for cervical cancer with HPV tests showed significant differences (Table 6). Overall, women who were willing to be screened with HPV tests had significantly higher attitudinal scores (A1), indicating their belief that HPV testing was more accurate, safe, protective and acceptable than Pap smears (p<0.01). They were significantly more likely to report the influence of direct subjective norms (SND2-3) on their decisions, with the belief that most who are important to them would think they should have an HPV test, and would expect them to have an HPV test (P<0.01). Women who intended to be screened with HPV were significantly more likely to report the influence of indirect subjective norms as well (SNI5-SNI12), including the opinions of family physicians, friends, spouse or partner and the British Columbia Cancer Agency as important in their decision making (p<0.01). Women who were more likely to intend to be screened with HPV testing also reported significantly higher rates of perceived behavioural control (PBC15-18) (p<0.01). The role of contacting partners was also significantly different between women who intended to be screened with HPV and those who did not (CP13-14). Women who intended to be screened reported greater comfort sharing results
with their partners and were more likely to say that partners would be understanding of their HPV results (p=0.05).

Psychological variables were reviewed for collinearity (Table 5). No variables used in these analyses had p>0.8 on correlation testing, indicating that the variables are measuring non-collinear constructs. Based on univariate analyses of psychological scales, the following variables were put into the model:

- **Dependent variable:** - (PI≤4 vs PI>4)
- **Independent variables:** Psychological scales for attitude (A1); direct subjective norms (SN2-3); indirect subjective norm (SNI); perceived behavioural control (PBC15-18); and contacting partners (CP13-14).

Since no demographic characteristics were significantly different in univariate and bivariate analyses and based on review of all the variables, no demographic variables were entered into the model.

Table 7 shows the regression coefficients, Wald Chi-square statistics, odds ratios and 95% confidence intervals for odds ratios for variables in the model. According to the Wald criterion, overall attitudes, indirect subjective norms and perceived behavioural control were associated with women's intentions to be screened for cervical cancer with HPV instead of Pap smears. Odds ratios and 95% confidence intervals confirmed that positive attitudes regarding the value of HPV testing (OR 1.2; 95%CI 1.1, 1.3) positive indirect subjective norms (OR 1.02; 95% CI 1.01, 1.03) and positive behavioural control (OR 1.16; 95%CI 1.10, 1.23) all significantly predict women’s intentions to be
screened with HPV testing. The model adjusted R-squared is 0.436, indicating that 43.6% of the variance in the model can be accounted for by these variables.
CHAPTER 7: Discussion

Although almost entirely preventable, cervical cancer remains an important cause of morbidity and mortality for women worldwide (56). In high income countries, such as Canada, due to extensive investments and efforts with cytology, colposcopy, ablative and excisional treatments have led to a reduction in cervical cancer morbidity and mortality in these settings (1). The need to explore implementation of improvements in primary and secondary prevention of cervical cancer should be a priority for health policy leaders and clinicians. One of the newest innovations, HPV testing, has potential to contribute to improved outcomes since it is grounded in the relatively recent awareness of the virus’ role as the etiology of cervical cancer, and also has impressive attributes as a screening tool. However, prior to introduction of this new technology for screening, broader considerations should be included in deliberations regarding the inclusion of this new screening tool, including women’s experiences. An existing body of literature provides preliminary results of explorations of HPV testing as part of cervical cancer screening and the experience of women receiving HPV test results.

Previous work indicates that in many settings, women report anxiety, distress, and shame when they receive positive HPV results(43;47;57). Women also report concern about communicating test results to sexual partners, and
about stigma and shame associated with having a sexually transmitted infection (44;45). Although these results are illustrative, many of these findings were generated as part of a theoretical exercise or as part of co-testing screening with cytology and did not necessarily link the impact of these emotions of receiving an positive HPV result with impact on women’s intentions to be screened for cervical cancer. It is particularly important for researchers and planners to take the next step to fully articulate the impact of these psychosocial concerns with the intended outcome of taking a screening test, to determine if a switch in technology could be detrimental on the uptake rates of cervical cancer screening. To address this, using the theoretical framework of Theory of Planned Behaviour, we assessed the intentions of almost 1000 Canadian women who participated in routine cervical cancer screening to be screened for cervical cancer with HPV-DNA instead of Pap smears. These data will be used towards a broader implementation plan for HPV based cervical cancer screening in the province of British Columbia.

Surveys were emailed to all participants who had completed participation in a randomized controlled trial. Not all invitees had functional email addresses, and not all invitees completed responses, leading to a response rate of 48.7%. Comparison of survey respondents and non-respondents showed that they were not significantly different on demographic characteristics (Table 1). Thus, findings are likely to be generalizable to the population of women who were part of the provincial screening program and participated in a large clinical trial. Of course, this study does not capture perspectives of women who did not attend for
cervical cancer screening. As this population remains a key consideration for cervical cancer prevention, further explorations into this group are urgently needed, to understand both opportunities to improve uptake with novel approaches with HPV and also to ensure there is improved engagement.

Survey construction, although not part of this dissertation, found that most of the items within scales, with the exception of direct subjective norms were highly consistent, and thus were reliably measuring the same construct (Table 3). However for two of the scales using the direct subjective norms items analyses found Cronbach’s alpha of <0.5. For SND3-4, Cronbach’s alpha was 0.103, and for SND2-4 there was actually negative correlation (-0.045). Scores were re-examined to ensure that re-anchoring was conducted accurately, and findings were confirmed. Thus, we are left to interpret reasons underlying poor correlation of some of these items. It is noteworthy that when item SND4 is included (‘I would feel under social pressure to have an HPV test for cervical cancer instead of a Pap smear’), correlation for the items was poor. This item probably is not correlated with the other two items for direct subjective norms. Women may not believe that ‘social pressure’ will influence their behaviours, but if specific named individuals or groups important to them wanted them and expected them to be screened for cervical cancer using HPV, that would influence their decisions.

One might not expect that indirect subjective norms from groups as divergent as family physicians, friends, spouse/partners and BC Cancer agency would correlate so well at >0.8. This finding indicates the importance that women
place on the opinions of these groups in their decision making for cervical cancer screening. There are limited available published data on attitudes of these groups towards screening for cervical cancer with HPV. In one study, Fernandez explored men’s reactions to a partner’s HPV infection (45). She found that men were concerned about uncertainty about the source of HPV infection and the implications of a positive HPV result for infidelity with their partners. Ultimately though, men were action oriented, and wanted to understand what they could do to support their partners to manage infections and take control of the situation. Further research on the attitudes and concerns of these influential groups and individuals to screening for cervical cancer with HPV is needed. As well, educational efforts for HPV screening should ensure that they are targeted not only at the women, but also at these seemingly broad groups, as they play a substantial impact on women’s decision around cervical cancer screening with HPV.

Overall, 84.2% of women intended to have cervical cancer screening with HPV instead of Pap screening (Table 2). In this analysis, no demographic characteristics were significantly different among women who intended to be screened with HPV. In particular, age, marital status, sexual history, smoking history, education and cultural background were not significantly different between women who intended to screen for cervical cancer with HPV and those who do not. There was also no difference between age strata for women who intended to be screened with HPV and those who did not. This is in contrast to several previous studies, which identified differing anxiety and concerns about
HPV and willingness to have HPV-based test depending on age (33; 48; 58), and cultural background (41). In particular, previous studies reported certain cultural groups identified concerns about the sexual nature of the infection, implications for fidelity and relationships and the need for disclosure (41; 45). Regardless, this has relevance for programming. One might expect women who have different educational or cultural backgrounds to be more or less reluctant to move to a different type of screening; particularly one with a communicable disease overtone, and that this ultimately could affect on willingness to be screened.

Our data highlight a very critical trend that should be a significant consideration for programs moving to HPV testing for cervical cancer screening. Because of improved sensitivity, high negative predictive value of HPV compared to Pap screening as well as risk for false positive HPV tests, cervical cancer screening using HPV should occur every 4-5 years, not annually as has been the case with Pap smears (45). However, in this study, when women are advised that the screening interval will be extended from one year to four years, many women are substantially less likely to intend to be screened with HPV. Their intention rates to be screened for cervical cancer with HPV drop from 84.2% to 54.2%. When advised that screening would not start until age 25, compared to current recommendations of age 18 or soon after sexual debut, their intentions to be screened remained low at 51.2%. It is very apparent from these findings that programming must focus around the natural history of HPV, added diagnostic capabilities of HPV testing and its negative predictive value, in order to reassure women about the safety of the extended screening interval, and to ensure high
acceptability of this improved method of cervical cancer screening. In addition, health systems are often poor at outlining the risk for over-screening. For cervical cancer, overuse of HPV testing could lead to unwarranted colposcopies and biopsies, and perhaps create iatrogenic illnesses. This is also an important message to share with women and the public.

Further research around why women are reluctant to have an extended screening interval is needed. In research on Pap smears, women were reluctant to have extended screening intervals; 69% of women reported that they would continue to receive annual screening, even if advised it was not required(38). In Sirovich’s survey, women believed that cost was driving intervals around screening, and similarly for HPV testing, women may interpret less frequent screening as a poorer quality screening program. There is likely a perspective that important precancerous lesions could be missed because of less frequent screening. Thus, there is a need for comprehensive education for women to improve their understanding about the rationales for internal change because of its poor sensitivity, and HPV testing has a higher sensitivity, thus decreasing the need for frequent screening. Similarly, changes in age of commencement for screening are based on an improved understanding of the natural history cervical cancer, as well as an increased awareness of the potential long-term consequences of treatment of precancerous lesions, including preterm labour and low birth weight infants, not on a desire to reduce access to screening (59). Messaging that clearly outlines the scientific as opposed to economic underpinning of this decision is needed.
**Logistic regression analyses**

Women who intend to be screened with HPV reported significantly more positive attitudes regarding HPV accuracy, safety, ability to protect health and acceptability than women who did not intend to screen. In addition, attitudes of specific groups and behavioural control emerged as significant predictors of an intention to be screened with HPV. This indicates that substantial efforts should be invested in ensuring women are aware of the diagnostic attributes of HPV testing, as this is a key element for women to understand the safety, accuracy and acceptability of HPV testing and thus intending to receive HPV testing. Similarly, education and awareness in particular groups who are influential for women (friends, family physicians, spouses and BC Cancer Agency) is important for planners, as these groups play a key role in women’s decision about screening with HPV. Finally, women need to feel that they can obtain HPV testing, should they desire it, and this is another significant predictor of intending to be screened with HPV.
CHAPTER 8: Study Limitations

Although this research provides important new information for program planning for HPV screening, there are limitations, which are related to limitations in the survey design and implementation as well as with the sample of women who completed survey.

Although the survey was designed with careful attention to the recommended methods for Theory of Planned Behaviour (51), it is possible that the survey did not assess appropriate variables relevant for predicting participation in cervical cancer and the factors that were important for intention to be screened for cervical cancer with HPV. Variables selected for analyses were based on initial consultation with experts, comprehensive literature reviews and pilot testing with eligible women. It is possible that some factors of importance were missed in this overview, and as such, some key elements in decision making for women were not included. One emerging theme that was not explored was the need for explicit consent to be screened with HPV for cervical cancer. Women have identified an expectation that clinicians’ will make sure they are aware that they are receiving an HPV test for cervical cancer screening (34;39;46). Although this issue potentially could be embedded in the items on perceived behavioural control (i.e. the concept of consent is embedded in control), perhaps it would
have been helpful to explicitly examine this in the survey. In addition, some women in the pilot group found the rigid structure of TPB survey awkward and this may have affected their response patterns.

Although this study assessed women's intentions to be screened for cervical cancer with HPV using a very large sample, some limitations should be considered as we apply findings to program decisions. Ultimately, to improve cervical cancer screening, programs should recruit all women in a population to engage in cervical cancer screening. As this study only surveyed women who had family physicians, were already engaged in cervical cancer screening and were part of a large randomized trial, the findings may not accurately characterize the concerns and experiences of women who have not been screened for cervical cancer. As the trial sample size is substantial (28,000) and women are recruited from the province, there is less concern about its generalizability to the sample of women who attend for screening. However, this study did not survey any women who do not have regular care providers, nor women who do not attend for screening. Thus, we may not be able to inform the program about how to improve participation in women who have never been screened for cervical cancer. This is particularly important, because HPV offers some innovative methods for screening, including self collection(60;61) and when used as part of screening programs can improve uptake in women who don't attend for cervical cancer screening(62;63). Future research should attempt to explore the attitudes of women who have not attended for screening, to ensure
that the use of HPV screening will not negatively impact on any efforts for engagement into screening.

In addition, although over 90% of women have had Pap smears at some time in their lives, we only surveyed women who had completed participation in a randomized trial. It is possible that the sample may be more educated than the population as a whole, thus we may potentially miss some specific concerns of women who are less educated. Only women with electronic mail addresses were eligible to complete surveys. Not all women who started the survey completed it. All of these may affect the generalizability of survey findings.
CHAPTER 9: Plan for change

Pap screening has been described as a rite of passage, and any proposed changes to this long established screening program will require careful deliberation and planning. Introduction of primary HPV testing would be a paradigm shift in the delivery of this long established screening program, since use of HPV testing would lead to changes in both the frequency of testing and the consequences of positive test results. Currently, the British Columbia Cancer Agency recommends that women be screened for three years annually using cytology, and then every two years if the initial three screenings are negative. Even with these recommendations, many women still choose to attend for screening every year. Because hr-HPV testing offers improved sensitivity for detecting precancerous lesions, a negative test offers greater assurance to the clinician and screening participant that they are not at risk for developing cervical cancer in the near future. Recent reviews by Dillner (14) have proposed that screening intervals for hr-HPV negative women could be extended to five years, yet still offer effective and safe screening for cervical cancer precursors. If hr-HPV testing were offered in British Columbia, women who have been accustomed to receiving annual screening would be advised and possibly limited to cervical cancer screening every five years. Findings from these analyses have identified in a large, representative sample of women who have participated in
cervical cancer screening, women’s key concerns in the shifting paradigm of cervical cancer screening, and in particular what factors are associated with an intention to be screened with HPV cervical cancer screening.

**Leadership Models**

To implement a large program change, relying on well-established models for change will help to provide a road map to ensure a successful evolution in the screening program. There are a wide variety of models of leadership theory in public health that could be used to help guide this change. Yukl (64) defines leadership as a process where ‘intentional influence is exerted over other people to guide, structure and facilitate activities and relationships in a group or organization.’ To lead change, Yukl focuses on a comprehensive understanding to detail the variety of reasons for resisting change which may include some of the following - lack of trust, belief change is not necessary, belief that change is not feasible, economic threats, relative high costs, fear of personal failure, loss of status and power, threat to values and ideals, and resentment to interference. He then outlines the characteristics and nature of the organizational culture, and then explores how leaders can act to change them. In his outlines for change, he focuses on leadership behaviours to create a vision, which includes broad consultation, identifying strategic objectives with wide appeal, identifying relevant elements in the old structure, clear linking to core competencies and evaluation of the vision. To implement change, Yukl outlines guidelines that align very well with Kotter’s eight step model(65). This includes 1) need for a sense of urgency,
2) Form a powerful guiding coalition, 3) create a vision 4) communication of a clear vision of the benefits, 5) identify both key supporters and resisters, building a broad coalition for change, filling key positions with change agents and empower them to act, 6) create a dramatic change to signal the shift in work and then work on the ground to help people deal with the change. He then identifies the need for 7) early successes and 8) monitoring and communicating progress.

Other theories offer a variety of different perspectives on leadership change, include Meadow’s system views with an exploration of system archetypes and implementing change based on the leverage points of a system(66). Johnson-Cramer (67) proposes managing change by defining system networks, identifying dominant beliefs and values in the system and then focusing change at the correct relational dimensions of the system network. An appreciative inquiry approach builds on organizational strengths, and by harnessing the previous successes of an entity, change can be catalyzed by championing the key aspects of success(68).

All of these previously mentioned approaches have proven track records for successful implementation of change, but Kotter’s eight step model for change is perhaps one of the most widely known models for change, and is highly applicable to this situation, due to its practicality and simplicity (65). It takes a step away from theory, and is a practice-based approach, grounded in action and engagement, and prescribes a step-by-step approach for creating success. By aligning with Kotter’s strategic approach, we can expect a high likelihood of success in our drive for change. This chapter of the dissertation will
further discuss the application of leadership theory and practices to successful implementation of a program change. Each step is described in relation to the model, and then steps that I will take to implement this substantial change in screening.

*Create a sense of urgency:* There is a need for government, clinicians and the public to understand the current limitations of cytology as the basis for cervical cancer screening, the risks and harms of over-screening, and the increasing evidence of the advantages of HPV testing compared to cytology. In particular, women and clinicians should understand that even with the increased intervals between screening and delayed start, HPV testing offers superior capability for detecting precancerous lesions. There is also a need for clear understanding that inappropriate use of HPV screening (i.e. using it in women under the age of 25 or using it too frequently) poses risks for women to be harmed by over-investigation of innocuous lesions which can lead to reproductive consequences in their future (59).

**Recommended action:** I will identify the key opinion leaders on cervical cancer screening and cancer prevention from the BC Cancer Agency. As well, I will identify respected leaders in women's health and public health from institutions such as the clinical practice leads from BC Women's Hospital and the Office of the Provincial Health Officer. These individuals will be educated and engaged regarding cervical cancer screening with HPV, and then named as key spokespeople for cervical cancer prevention for the province. I will prepare standard messaging around HPV testing, so that all spokespeople have a shared
set of messages. The key messages will include findings from international trials on the improved detection of cervical cancer with HPV, issues with the current technology used as well as findings from this analysis, that show that the majority of women intend to be screened for cervical cancer with HPV.

With any new development or research publications in the field of HPV testing, press releases will be sent to local and provincial media, and these spokespersons will be available to describe the significance of these findings, and advocate for HPV testing, and articulate the urgent need to evolve to this type of screening. I will also use any presentation at international conferences as an opportunity for local media to highlight new findings and results from international trials on HPV testing. Also, any publications on HPV testing from provincial scientists and clinicians will have press releases attached to them, so we can also capitalize on those opportunities.

I will also seek opportunities at key professional conferences, such as the BC College of Family Physicians meeting, BC Pediatric Society meeting, BC Obstetricians and Gynecologists Society to present information on HPV testing and cervical cancer screening. Finally, I will arrange for these opinion leaders to present briefing notes and presentations for the Ministry of Health and the relevant Health Authorities, so that the funders will be aware of the need to move, and can be part of making this testing available. The expectation is that these efforts will create a sense of the need for HPV testing for the province, which will then lead to political and ultimately public support and expectation that
this type of testing is state of the art, and will be made available for all women in the province.

_Form a powerful coalition:_ Provincial leaders in cancer prevention, women’s health, sexual health and communicable disease prevention need to align in the province in a formal effort to support and engage around the use of HPV testing for cervical cancer screening. These leaders need to have a shared voice in the benefits of HPV testing.

_Recommended action:_ As part of the implementation of the HPV vaccine program in the province, I helped to create this broad coalition, which included BC Cancer Agency, BC Centre for Disease Control, BC Women’s Hospital, BC Children’s Hospital and the Office of the Provincial Health Officer. I will now re-engage this group of leaders to ensure they are informed of the shifting paradigm for cervical cancer screening, and to provide guidance for the province as it moves to this new paradigm of screening. Specifically, results from provincial studies, such as HPV FOCAL, recommendations from other jurisdictions such as Ontario and Quebec (29), as well as international recommendations from the European gynaecological society will be shared with this coalition (69). Findings from this study will also demonstrate the support of women in moving to this screening paradigm. In addition, key opinion leaders, such as gyne-oncologists, gynecologists, infectious disease specialists, family physicians, pathologists and other clinical specialists need to be part of the coalition for change. As described above, I plan to engage these individuals through opinion leaders in the province,
to ensure they can articulate the rationale for the change to HPV screening, as well as the benefits for individuals in the province.

Create a vision for change: Provincial leaders in the fields (BC Cancer Agency, BC Centre for Disease Control, BC Women’s Hospital and leading clinicians) need to articulate the benefits of this new screening program and formally adopt recommendations around HPV testing in the province. For example, creating a clear statement such as ‘No woman in British Columbia developing cervical cancer’ would be a vision that most could rally around and support.

Recommended action: As a publicly funded health system, vision for changes need to include the support of the Ministry of Health, which provides funding, as well as the BCCA, who will deliver and manage this service. Using the coalition, I will create a business case to support the move to HPV testing. This will likely require the support of a consultant, and needs to include a scientific rationale, as well as costing estimates, cost benefit analyses, implications for colposcopy and for surgical services. This document will also articulate how the new paradigm of screening will be implemented, and outline impacts on service provision at the local level. It will also include the risk for the province of not moving to HPV testing, which will include litigation for failing to identify precancerous lesions with cytology. The business case will also identify that women support this move, but that there needs to be substantial education to ensure women have positive attitudes around the safety, accuracy and acceptability of HPV testing. We will also be able to confirm that women are not
concerned about the communicable disease aspect of the testing modality, but can also demonstrate due diligence by flagging that the extended screening interval and delayed start is a concern for women. This will reassure the Ministry that the coalition has thought broadly about the impacts of this change. The critical aspect to this document is that it will be endorsed by the broad coalition, to ensure that the Ministry feels confident to move forward in the recommended direction.

Communicate the vision: With a shared, clear vision and concise actions, communication plans for their stakeholders and for the public can then follow. As the public relies substantially on their personal providers for health advice, it would be particularly important for the coalition to communicate the vision to the primary care providers, and ultimately for the primary care providers, with the support of the coalition to connect with their patients. The public also is increasingly proactive in seeking their own health information, and so use of reputable provincial websites, will be the foundation for any public messaging for a change in cervical cancer screening policy. Links with widely used and popular social media sites will also be part of an approved dissemination process. Consistent content, messaging and look that incorporates some of the key results from this research would be an important platform. The findings from this study will be particularly informative in this part of the plan for change, as we are informed as to the key areas of concern for women with this shifting paradigm, and can ensure any messaging specifically and accurately addresses those concerns.
**Recommended action:** Using similar methods as earlier described for establishing a sense of urgency, I will utilize local media, press releases, key opinion leaders, to ensure broad sensitization for the public and practitioners. However, I will now ensure the message is further nuanced, from the need to move to HPV testing, to one where the focus is on the benefits of HPV testing for the province. Key elements of these messages will include: evidence based practice; information from HPV FOCAL from BC; British Columbia leading the way in offering cutting edge and optimal technology; opportunity to decrease health care costs; opportunity to decrease over-screening; opportunity to prevent cancer.

Consistent content will be developed to be posted and communicated broadly on key provincial agency websites, including BC Cancer Agency, BC Centre for Disease Control, BC Women’s Hospital. I would also recommend the use of popular social media sites, such as Facebook to share information as well. In designing the messaging for the public, I will rely the findings from this study to direct the content of our messaging and to ensure we address some of the key concerns for women. As attitudes to HPV testing were most strongly associated with an intention to be screened with HPV for cervical cancer in our logistic regression analysis, I plan to communicate the accuracy, safety, and the ability of HPV to protect women’s health as the foundation for any messaging. I will also identify for women that their practitioners and BC Cancer Agency strongly endorse this approach to cervical cancer testing, and recommend that women be screened with HPV for cervical cancer. In addition, because women identified the
need for ease and control for HPV testing as another predictor of intention to be
screened with HPV for cervical cancer, I will communicate that HPV will be
funded as part of the provincial screening program and can be easily accessed
through their family physicians. Although concerns about contacting partners did
not achieve significance in the logistic regression modeling, I will also ensure that
messaging reassures women that HPV is a highly prevalent virus and infections
are common for all women. Because our data demonstrates a substantial
reduction in intention to be screened with HPV when screening intervals are
extended, I will include information on the improved ability of HPV to detect
relevant precancerous lesions compared to cytology. Women need to be aware
of the risks of overscreening, and that inappropriate use of HPV testing could
actually result in treatment and potential reproductive health consequences. I will
also communicate the reason for the extended screening, and focus on the
higher negative predictive value, and thus the need for fewer screens over a
lifetime.

 Remove obstacles: Obstacles for HPV testing can be both from the
communication perspective and from the administrative perspective. Some
individuals and groups will express concern about this shift. In particular, based
on the pilot results and initial reactions to HPV screening in other settings,
advocacy groups may be concerned that women are being ‘limited’ in accessing
their health care, because of the delayed start and extended interval. In Canada,
with a universal health care system, any perception of ‘reduced access to care’ is
viewed as a change driven by budgetary and not clinical elements. Key opinion
leaders who understand both the improved accuracy of HPV testing as well as
the potential harm with over screening will need to be quickly responsive to
concerns in the media and in the public.

Ensuring that clinicians can easily and seamlessly access HPV testing
and their results will be fundamental aspect to the success of the new screening
program. Fortunately, in BC, we have been offering over 20,000 HPV tests per
year as part of the HPV FOCAL trial at the centralized public health laboratory,
so it will be primarily an issue of scaling up. In addition, there are strategic
implementation approaches, such as starting with older women that can ease in
the system of HPV testing.

**Recommended action**: I will work to identify any high profile skeptics and
bring them into the coalition. These individuals will be able to articulate their
concerns to the opinion leaders in the province, and can have their issues
scientifically addressed. In many cases, individuals with concerns about a
change need assurances that the coalition and leaders are aware of their
concerns, believe they are serious, have reviewed them in detail and are taking
steps around monitoring and evaluation of the new change. As well, skeptics
often bring forward previously unidentified concerns and issues which will assist
in deployment. By proactively engaging with them, critical issues can be flagged
and solutions reached prior to implementation. Often, with careful stewardship,
skeptics can often become leading advocates of the change.

The other major obstacle for implementation will be costs for this new
testing paradigm. I will address this by leading the coalition to prepare a
comprehensive business case for the province. This will include rationale for the move, cost effectiveness and cost benefits of HPV testing, as well risks for the province if we remain with cytology. These risks broadly include over screening, as well as missed cases of cancer.

In other settings, laboratory infrastructure could be a substantial issue, but given that the HPV FOCAL trial has been implemented for over four years, with routine HPV testing with liquid-based cytology, many of the key elements are already in place, and simply require scaling up.

Create short-term wins: Early on in the screening, the team will need to search for the ‘medical narrative’ to highlight cases of cancer that have been prevented using HPV screening. In addition, women who have required enhanced screening with Pap smears as a result of false positive cytology may also be able to reduce their frequency of screening with the use of HPV testing. Cases such as these can be highlighted and communicated, to better provide concrete examples of the benefits of HPV screening for women in the province. Additional advantages of HPV testing, such as prevention of adenocarcinoma should be captured and highlighted broadly.

Recommended action: I will work with the BC Cancer Agency to identify practitioners and patients who have directly benefited from this switch to HPV testing. I will identify women who had previously required more intensive screening and who can now reduce their screening frequency, and assuming their willingness to participate, will ask them to share their story with the media to effectively create the medical narrative. I will also identify women who were 'Pap
negative’ but are HPV positive who received definitive treatment. This will be 
important, to demonstrate the cancer prevention benefits of HPV testing. With 
these success stories, the Ministry of Health will be invited to be part of the ‘good 
news’. Similarly, local opinion leaders will be invited to provide success stories 
with the new screening paradigm. In particular, some of the issues raised by 
women in this study, such as the extended intervals, will be highlighted as 
opportunities for both the women and the health care system.

   Build on the change: Building on examples from above, the guiding 
coalition can offer expanded guidance on how to further implement the use of 
HPV testing to streamline and improve cervical cancer detection. This may 
include use of self collected specimens in women who do not attend for 
screening, or better defining the age to stop screening for cervical cancer.

   Recommended action: To build on change, I will need to ensure that the 
coalition continues to meet and monitor the impact of the implementation of this 
change. By doing so, we can identify both ongoing issues and proactively 
directly address and resolve them. In addition, I will prioritize new opportunities with 
HPV testing, and work to implement small pilot projects to explore new forefronts.

   Anchor changes in the corporate culture: Finally, lessons learned from 
changing this well established screening program will be highly relevant to all of 
the agencies involved. These lessons will also have substantial international 
importance. A careful examination of how the change was managed, impacts of 
the change on screening and treatment rates, and also how the change could 
have been improved will be crucial. Any ongoing areas of challenge in the
acceptability of HPV screening will be important to analyze and steps taken to mitigate these remaining issues.

**Recommended action:** Anchoring the changes in the corporate culture will be central role for the guiding coalition. I will continue to lead this group on an ongoing basis to monitor the impact of the changes, through routine surveillance and evaluation processes. The coalition will also need to make a commitment to peer reviewed publications as well as publicly available reports, in order to ensure communication of its successes as well as lessons learned. Planned and routine engagement with local media to share the successes will be an ongoing priority of the guiding coalition as well.

**Required resources**

A comprehensive and thoughtful plan for change will require a committed champion as well as resources in order to effectively implement the change. Resources to pay for HPV testing and for clinicians will be a key element in any business case and analysis for the Ministry of Health, and the program will not move forward with this type of commitment from the Ministry. However, the leadership of this change effort will need to engage opinion leaders across provincial agencies such as the BC Cancer Agency, BC Centre for Disease Control, BC Women’s Hospital, Provincial health services authority laboratories and the Vaccine Evaluation Centre. As these agencies are mandated to offer provincial leadership, expertise and consultation to the Ministry of Health, no additional funds would be allocated to lead and participate in the process of this
transition. Clinicians and scientists would be expected, as part of their leadership roles in the province, to contribute to the effort of change.
CHAPTER 10: CONCLUDING REMARKS

Cervical cancer screening remains one of the greatest successes of modern medicine, but is at a critical juncture. Changing this rite of passage requires extensive planning and evaluation, but optimizing this screening paradigm is urgently required for the women and for our society, to more effectively detect pre-cancerous lesions, more efficiently use our scarce health care resources and to limit unnecessary procedures for women. This dissertation explores one focused aspect of this change, and examines the acceptability and potential impact of this change on the individuals at the centre of the screening program. Findings from this study will be of substantial importance to British Columbia, and in other settings with established cervical cancer screening programs, to ensure that the critical participants in screening, the women, are able to feel confident in any changes made.
FIGURES

Figure 1. Theory of Planned Behaviour (51)
Figure 2. HPV FOCAL – Clinical Trial flow chart (52)

*Survey participants all recruited from 2-year safety check arm
Figure 3. Study Flowchart and participant disposition

Recruitment May 1st 2011-September 30th 2011
HPV FOCAL participants completed study: n=2459
HPV FOCAL participants eligible (email address): n=2016

Eligible, Non interview n=1035

- Non-contact n=478
- Refusal n=72
- Logged on n=191
- Break off n=294

Returned Questionnaire n=981

Complete n=981
### Table 1. Comparison of demographic characteristics of survey respondents and survey non-respondents*

<table>
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<th>Characteristic</th>
<th>Group</th>
<th>Overall N (%)</th>
<th>Respondent N (%)</th>
<th>Non-Respondent N (%)</th>
<th>P-Value</th>
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<td>Overall Age, Recruitment</td>
<td>Mean (SD)</td>
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<td>981 45.0(10.0)</td>
<td>1035 45.3(10.2)</td>
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<td>Median (IQR) †</td>
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<td></td>
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<td>&lt;High School (Complete)</td>
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<td>11(1.1%)</td>
<td>20(2.2%)</td>
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<td>122(12.4%)</td>
<td>126(13.9%)</td>
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<td>311(31.7%)</td>
<td>273(30.2%)</td>
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<td>181(18.5%)</td>
<td>150(16.6%)</td>
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<td>178(20.1%)</td>
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</tr>
<tr>
<td></td>
<td>&gt;50</td>
<td>22(1.2%)</td>
<td>12(1.2%)</td>
<td>10(1.1%)</td>
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<tr>
<td></td>
<td>Missing</td>
<td>128</td>
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<td></td>
<td>0.2879</td>
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<td></td>
<td>Cultural background</td>
<td></td>
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<tr>
<td></td>
<td>Chinese</td>
<td>175(9.3%)</td>
<td>81(8.3%)</td>
<td>94(10.4%)</td>
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</tr>
<tr>
<td></td>
<td>Aboriginal</td>
<td>46(2.4%)</td>
<td>24(2.4%)</td>
<td>22(2.4%)</td>
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<tr>
<td></td>
<td>Caucasian and other</td>
<td>1667(88.3%)</td>
<td>876(89.3%)</td>
<td>791(87.2%)</td>
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<td>Characteristic</td>
<td>Group</td>
<td>Overall N (%)</td>
<td>Respondent N (%)</td>
<td>Non-Respondent N (%)</td>
<td>P-Value</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------</td>
<td>---------------</td>
<td>------------------</td>
<td>----------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Smoke, Now</td>
<td>Missing</td>
<td>188</td>
<td>923(94.1%)</td>
<td>784(92.6%)</td>
<td>0.1908</td>
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<tr>
<td></td>
<td>No</td>
<td>1707(93.4%)</td>
<td>912(94.1%)</td>
<td>795(92.6%)</td>
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<tr>
<td></td>
<td>Yes</td>
<td>121(6.6%)</td>
<td>58(5.9%)</td>
<td>63(7.4%)</td>
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<tr>
<td></td>
<td>Missing</td>
<td>188</td>
<td>923(94.1%)</td>
<td>784(92.6%)</td>
<td>0.4382</td>
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<tr>
<td>Smoke, Ever</td>
<td>No</td>
<td>1156(63.1%)</td>
<td>627(63.9%)</td>
<td>529(62.2%)</td>
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</tr>
<tr>
<td></td>
<td>Yes</td>
<td>676(36.9%)</td>
<td>354(36.1%)</td>
<td>322(37.8%)</td>
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</tbody>
</table>

*Pearson’s Chi Square
Student’s t-test
*Kruskal-Wallis
Table 2. Demographic characteristics of survey respondents

<table>
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<tr>
<th>Variable</th>
<th>Group</th>
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<tbody>
<tr>
<td></td>
<td>N (%)</td>
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</tr>
<tr>
<td>Overall</td>
<td>981 (100.0)</td>
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</tr>
<tr>
<td>Age, Recruitment</td>
<td>Mean age (SD) 45.1(10.1)</td>
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<td></td>
<td>Median age (IQR) 45.0(38.0, 53.0)</td>
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</tr>
<tr>
<td>Marital Status</td>
<td>Divorced 108(11.0%)</td>
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</tr>
<tr>
<td></td>
<td>Common Law/Married 689(70.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Never Married 112(11.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Widowed 7(0.7%)</td>
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</tr>
<tr>
<td></td>
<td>Did not Answer/Missing 65(6.6%)</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td>&lt;High School 11(1.1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High School (Complete) 122(12.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trade/College/University(Incomplete) 356(36.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>University graduate 311(31.7%)</td>
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</tr>
<tr>
<td></td>
<td>University Advanced Degree 181(18.5%)</td>
<td></td>
</tr>
<tr>
<td>Education: Combined</td>
<td>High School or Less 133(13.6%)</td>
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</tr>
<tr>
<td></td>
<td>More than High school 848(86.4%)</td>
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</tr>
<tr>
<td>Sexual Partners – Ever</td>
<td>0 1(0.1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 185(18.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 to 5 364(37.1%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 to 10 221(22.5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>11 to 50 198(20.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;50 12(1.2%)</td>
<td></td>
</tr>
<tr>
<td>Cultural background</td>
<td>Chinese 81(8.3%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aboriginal 24(2.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Caucasian and other 876(89.3%)</td>
<td></td>
</tr>
<tr>
<td>Smoke, Ever</td>
<td>No 627(63.9%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes 354(36.1%)</td>
<td></td>
</tr>
<tr>
<td>Intend to screen with HPV</td>
<td>P19&gt;4 826 (84.2%)</td>
<td></td>
</tr>
<tr>
<td>every four years</td>
<td>IN21 &gt;4 532 (54.2%)</td>
<td></td>
</tr>
<tr>
<td>Intend to screen with HPV</td>
<td>IN23&gt;4 504 (51.4%)</td>
<td></td>
</tr>
<tr>
<td>every four years starting at 25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>years</td>
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Table 3. Characteristics of scale items: Correlation by Cronbach’s alpha

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<tr>
<th>Screening Concepts: Composite variables</th>
<th>Scale Item</th>
<th>Cronbach’s alpha</th>
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<tr>
<td>Attitudes</td>
<td>A1</td>
<td>0.917</td>
</tr>
<tr>
<td>Attitudes for HPV testing every four years</td>
<td>A20</td>
<td>0.964</td>
</tr>
<tr>
<td>Attitudes for HPV testing every four years and after age of 25</td>
<td>A22</td>
<td>0.968</td>
</tr>
<tr>
<td>Subjective Norms: Direct</td>
<td>SND2-SND4</td>
<td></td>
</tr>
<tr>
<td>Subjective Norms: Direct 2/3</td>
<td>SND2-SND3</td>
<td>0.478</td>
</tr>
<tr>
<td>Subjective Norms: Direct 2/4</td>
<td>SND2 and SND4</td>
<td>-0.045</td>
</tr>
<tr>
<td>Subjective Norms: Direct 3/4</td>
<td>SND3-SND4</td>
<td>0.103</td>
</tr>
<tr>
<td>Subjective Norms: Indirect</td>
<td>SNI5-SNI12</td>
<td>0.823</td>
</tr>
<tr>
<td>Contacting Partners</td>
<td>CP13-CP14</td>
<td>0.633</td>
</tr>
<tr>
<td>Perceived Behavioural Control</td>
<td>PBC15- PBC18</td>
<td>0.626</td>
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Table 4. Univariate and bivariate comparisons between demographic characteristics of women who intend and do not intend to receive cervical cancer screening with HPV

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>Intend to screen with HPV; PI19 &gt;4 N (%)</th>
<th>Do not intend to screen with HPV; PI19&lt;=4 N (%)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td></td>
<td>826(84.2%)</td>
<td>155(15.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Age</td>
<td>Mean (Standard deviation)</td>
<td>44.9 (10.1)</td>
<td>45.1 (9.2)</td>
<td>0.8874</td>
</tr>
<tr>
<td>Age</td>
<td>25-29</td>
<td>67 (83.8)</td>
<td>13 (16.3)</td>
<td>0.542</td>
</tr>
<tr>
<td>Age</td>
<td>30-34</td>
<td>65 (86.7)</td>
<td>10 (86.7)</td>
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</tr>
<tr>
<td>Age</td>
<td>35-39</td>
<td>124 (86.1)</td>
<td>20 (13.9)</td>
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</tr>
<tr>
<td>Age</td>
<td>40-44</td>
<td>151 (82.5)</td>
<td>32 (17.5)</td>
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<td>Age</td>
<td>45-49</td>
<td>142 (84.0)</td>
<td>27 (16.0)</td>
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</tr>
<tr>
<td>Age</td>
<td>50-54</td>
<td>111 (81.6)</td>
<td>25 (18.4)</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>55-59</td>
<td>94 (81.0)</td>
<td>22 (19.0)</td>
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</tr>
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<td>Age</td>
<td>60-64</td>
<td>64 (91.4)</td>
<td>6 (8.6)</td>
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<tr>
<td>Age</td>
<td>65+</td>
<td>8 (100)</td>
<td>0 (0)</td>
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<td>Marital Status</td>
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<td>88(10.7%)</td>
<td>20(12.9%)</td>
<td>0.7427</td>
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<td>Common Law/Married</td>
<td>581(70.3%)</td>
<td>108(69.7%)</td>
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</tr>
<tr>
<td>Marital Status</td>
<td>Never Married</td>
<td>95(11.5%)</td>
<td>17(11.0%)</td>
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</tr>
<tr>
<td>Marital Status</td>
<td>Widowed</td>
<td>7(0.8%)</td>
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<td></td>
</tr>
<tr>
<td>Marital Status</td>
<td>Did not Answer/Missing</td>
<td>55(6.7%)</td>
<td>10(6.5%)</td>
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</tr>
<tr>
<td>Education</td>
<td>&lt;High School</td>
<td>9(1.1%)</td>
<td>2(1.3%)</td>
<td>0.6839</td>
</tr>
<tr>
<td>Education</td>
<td>High School (Complete)</td>
<td>105(12.7%)</td>
<td>17(11.0%)</td>
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</tr>
<tr>
<td>Education</td>
<td>Trade/College/University(Incomplete)</td>
<td>292(35.4%)</td>
<td>64(41.3%)</td>
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<tr>
<td>Education</td>
<td>University graduate</td>
<td>264(32.0%)</td>
<td>47(30.3%)</td>
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</tr>
<tr>
<td>Education</td>
<td>University Advanced Degree</td>
<td>156(18.9%)</td>
<td>25(16.1%)</td>
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</tr>
<tr>
<td>Education: Combined</td>
<td>High School or Less</td>
<td>114(13.8%)</td>
<td>19(12.3%)</td>
<td>0.6065</td>
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<td>Education: Combined</td>
<td>More than High school</td>
<td>712(86.2%)</td>
<td>136(87.7%)</td>
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<tr>
<td>Sexual Partners - Ever</td>
<td>0</td>
<td>1(0.1%)</td>
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<td>0.6869</td>
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<tr>
<td>Sexual Partners - Ever</td>
<td>1</td>
<td>155(18.8%)</td>
<td>30(19.4%)</td>
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<tr>
<td>Sexual Partners - Ever</td>
<td>2 to 5</td>
<td>315(38.1%)</td>
<td>49(31.6%)</td>
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<td>Sexual Partners - Ever</td>
<td>6 to 10</td>
<td>180(21.8%)</td>
<td>41(26.5%)</td>
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<tr>
<td>Sexual Partners - Ever</td>
<td>11 to 50</td>
<td>165(20.0%)</td>
<td>33(21.3%)</td>
<td></td>
</tr>
<tr>
<td>Sexual Partners - Ever</td>
<td>&gt;50</td>
<td>10(1.2%)</td>
<td>2(1.3%)</td>
<td></td>
</tr>
<tr>
<td>Cultural background</td>
<td>Chinese</td>
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<td></td>
<td></td>
</tr>
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<td>---------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>71(8.6%)</td>
<td>10(6.5%)</td>
<td>0.3236</td>
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<tr>
<td></td>
<td>Aboriginal</td>
<td>18(2.2%)</td>
<td>6(3.9%)</td>
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</tr>
<tr>
<td></td>
<td>Caucasian and other</td>
<td>737(89.2%)</td>
<td>139(89.7%)</td>
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</tr>
<tr>
<td>Smoke, Ever</td>
<td>No</td>
<td>527(63.8%)</td>
<td>100(64.5%)</td>
<td>0.865</td>
</tr>
<tr>
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<td>Yes</td>
<td>299(36.2%)</td>
<td>55(35.5%)</td>
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</table>
Table 5. Assessment of scale collinearity

<table>
<thead>
<tr>
<th>Variable</th>
<th>Age at recruitment</th>
<th>A1</th>
<th>A20</th>
<th>A22</th>
<th>SND2-3</th>
<th>SNI</th>
<th>PBC15-18</th>
<th>CP13-14</th>
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<tbody>
<tr>
<td>Age at</td>
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<td>0.09</td>
<td>0.11</td>
<td>0.13</td>
<td>0.11</td>
<td>0.07</td>
<td>0.05</td>
<td>-0.04</td>
</tr>
<tr>
<td>recruitment</td>
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<td></td>
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<td></td>
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<tr>
<td>A1</td>
<td>1.00</td>
<td>0.39</td>
<td>0.36</td>
<td></td>
<td>0.58</td>
<td>0.56</td>
<td>0.45</td>
<td>0.04</td>
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<td>1.00</td>
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<td>0.80</td>
<td>0.30</td>
<td>0.37</td>
<td>0.27</td>
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<td>A22</td>
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<td></td>
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<td>0.27</td>
<td>0.33</td>
<td>0.21</td>
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<td>SND2-3</td>
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<td></td>
<td>0.59</td>
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<td>0.38</td>
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<td>SNI</td>
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<td>1.00</td>
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<td></td>
<td>0.47</td>
<td>0.16</td>
</tr>
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<td>PBC 15-18</td>
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<td>1.00</td>
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<td>0.13</td>
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<td>CP13-14</td>
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<td>1.00</td>
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Table 6. Comparison of scale results between women intending to undergo HPV testing instead of Pap smear for cervical cancer screening

<table>
<thead>
<tr>
<th>Psychological scales</th>
<th>Mean score Overall (SD)</th>
<th>Intend to screen (PI19 &gt;4) Mean (SD)</th>
<th>Do not intend to screen (PI19&lt;=4) Mean (SD)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitudes to HPV testing (A1)</td>
<td>25.7 (3.7)</td>
<td>26.5 (2.4)</td>
<td>21.2 (5.7)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Subjective norms, Direct (SND2-3)</td>
<td>11.0 (2.6)</td>
<td>11.4 (2.3)</td>
<td>8.8 (2.6)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Subjective norms, Indirect (SNI5-12)</td>
<td>34.8 (31.9)</td>
<td>40.7 (28.9)</td>
<td>3.3 (28.8)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Perceived Behavioural Control (PBC 15-18)</td>
<td>23.4 (4.1)</td>
<td>24.1 (3.7)</td>
<td>19.6 (4.1)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Contacting Partners (CP13-14)</td>
<td>12.6 (2.2)</td>
<td>12.7 (2.2)</td>
<td>12.2 (2.6)</td>
<td>0.0555</td>
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</tbody>
</table>

*Student’s t-test
Table 7. Multivariate Logistic Regression Analysis

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Regression co-efficient</th>
<th>Wald Chi-square statistic</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
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</thead>
<tbody>
<tr>
<td>Attitudes to HPV (A1)</td>
<td>0.2024</td>
<td>43.157</td>
<td>1.224</td>
<td>1.153;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.301</td>
</tr>
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<td>Indirect subjective norms (SNI5-12)</td>
<td>0.0222</td>
<td>27.018</td>
<td>1.022</td>
<td>1.014;</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td>1.031</td>
</tr>
<tr>
<td>Perceived behavioural control (PBC 15-18)</td>
<td>0.1471</td>
<td>26.259</td>
<td>1.158</td>
<td>1.095;</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>1.225</td>
</tr>
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<td>Leadership Model</td>
<td>Definition/ Focus</td>
<td>Foundation</td>
<td>Action</td>
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</tr>
<tr>
<td>------------------</td>
<td>------------------</td>
<td>------------</td>
<td>--------</td>
<td></td>
</tr>
<tr>
<td>Yukl (64)</td>
<td>Intentional influence is exerted other people to guide, structure and facilitate activities in a group or organization</td>
<td>Identify reasons for existing change: Lack of trust Change is not necessary Change is not feasible Economic threats Relative high costs Personal failure Loss of status or power Threats to values and ideals Resentment of interference</td>
<td>Create a vision from broad consultation Identify strategic objectives with wide appeal Link to core competencies Evaluate vision</td>
<td></td>
</tr>
<tr>
<td>Kotter (65)</td>
<td>Leadership defines what the future should look like, aligns people with that vision, and inspires them to make it happen despite the obstacles</td>
<td>Create a sense of urgency Form powerful coalition</td>
<td>Create a vision for change Communicate the vision Remove obstacles Create short term wins Build on the change Anchor changes in the corporate culture</td>
<td></td>
</tr>
<tr>
<td>Meadows (66)</td>
<td>Leverage points are places within a complex system where a small shift in one thing can produce big changes in everything</td>
<td>Places to intervene in a system: - Constants, parameters, numbers - Regulating negative feedback loops - Driving positive feedback loops - Material flows and nodes of material intersection - Information flows - Rules of the systems - Distribution of power over the rules of the system - Goals of the system Mindset or paradigm out of which the system arises</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Johnson-Cramer (67)</td>
<td>Organizational network analysis is a set of analytical tools to assess interaction patterns, which can affect change via power, diffusion of ideas and formation and maintenance of belief structures</td>
<td>Working through key culture carriers Uncover cultural brokers and marginalized perspectives Diagnose how culture fragments networks Assess diffusion of prescribed values, norms and practices Identify dominant beliefs and values</td>
<td>Design intervention targeting the right relational dimensions</td>
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<tr>
<td>Boje (68)</td>
<td>Appreciating what already works Discovery: appreciating what is Dreaming: Imaging what might be Designing: determining what should be</td>
<td>Delivering/Destiny: Creating the future</td>
<td></td>
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</tr>
</tbody>
</table>
Appendix 1

Study Questionnaire

Thanks for participating in the HPV FOCAL trial. We invite you to complete this on-line survey in order to help us to plan for the future of cervical cancer screening in British Columbia. We are conducting this survey to help understand women’s attitudes to screening for cervical cancer with HPV testing instead of Pap smears. This survey will take you about 10 minutes to complete, and all who complete the survey are eligible to win one of 5 iPODs. Please remember, your name, or any other personal identifiers are not linked with the questionnaire responses in any way.

Here is some background information for you to consider before you complete this survey.

The human papillomavirus (HPV) is a common virus that can infect the cervix (part of a woman’s womb). It is now known to be the cause of cervical cancer. Women develop HPV infections in the cervix after having sexual activity with a partner who is infected with HPV. However, HPV is so common that over 75% of sexually-active women will have an HPV infection of their cervix sometime during their life. Most women who find out they have an HPV infection in the cervix after the age of 30, were infected with HPV years before. Over 90% of women who are infected with HPV in the cervix get rid of the infection naturally. It is only women who have longstanding infections with certain types of HPV who may be at risk for developing cervical cancer. Women may not have known it in the past, but it is these same HPV infections that are the most common reason for abnormal Pap smears.

Right now in BC, women start cervical cancer screening once they become sexually active. We now know that testing for HPV infections in the cervix is more accurate than the Pap smear for predicting whether or not a woman will develop cervical cancer.

I. Attitudes

A1. Having an HPV test to screen for cervical cancer instead of a Pap smear would be:

<table>
<thead>
<tr>
<th>Accurate</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Inaccurate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>Unsafe</td>
</tr>
<tr>
<td>Protect my health</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>Harm my health</td>
</tr>
<tr>
<td>Acceptable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>Unacceptable</td>
</tr>
</tbody>
</table>

II. Subjective Norms
Direct

**SND2.** Most people who are important to me would think that I
Should 1 2 3 4 5 6 7 Should not have an HPV test to screen for cervical cancer instead of a Pap smear

**SND3.** People who are important to me would expect me to have an HPV test to
screen for cervical cancer instead of a Pap smear
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

**SND4.** I would feel under social pressure to have an HPV test to screen for
cervical cancer instead of a Pap smear
Strongly disagree 1 2 3 4 5 6 7 Strongly agree

Indirect

**SNI5.** My family physician would think that I should have an HPV test to screen
for cervical cancer instead of a Pap smear
Unlikely 1 2 3 4 5 6 7 Likely

**SNI6.** What my family physician thinks is important to me
Not at all 1 2 3 4 5 6 7 Very much

**SNI7.** My friends would think that I should have an HPV test to screen for cervical
cancer instead of a Pap smear
Unlikely 1 2 3 4 5 6 7 Likely

**SNI8.** What my friends think is important to me
Not at all 1 2 3 4 5 6 7 Very much

**SNI9.** My spouse/partner would think that I should have an HPV test to screen for
cervical cancer instead of a Pap smear
Unlikely 1 2 3 4 5 6 7 Likely
**SNI10.** What my spouse/partner thinks is important to me
Not at all   1  2  3  4  5  6  7    Very much

**SNI11.** The BC Cancer Agency would recommend that I should have an HPV test to screen for cervical cancer instead of a Pap smear
Unlikely   1  2  3  4  5  6  7    Likely

**SNI12.** What the BC Cancer Agency recommends is important to me
Not at all   1  2  3  4  5  6  7    Very much

**Contacting Partners**

**CP13.** If I had a cervical cancer screening result that showed I had an HPV infection, I would feel comfortable sharing the results with my partner(s)
Unlikely   1  2  3  4  5  6  7    Likely

**CP14.** My spouse would be understanding if I had an HPV infection
Strongly disagree   1  2  3  4  5  6  7    Strongly agree

**III. Perceived Behavioural Control**

**PBC15.** I am confident that I could have an HPV test to screen for cervical cancer instead of a Pap smear
Strongly disagree   1  2  3  4  5  6  7    Strongly agree

**PBC16.** For me to have an HPV test to screen for cervical cancer instead of a Pap smear would be
Easy  1  2  3  4  5  6  7    Difficult

**PBC17.** Whether or not I would have an HPV test to screen for cervical cancer instead of a Pap smear would be entirely up to me
Strongly disagree   1  2  3  4  5  6  7    Strongly agree
**PBC18.** How much control would you have over whether you had an HPV test to screen for cervical cancer instead of a Pap smear?

No control 1 2 3 4 5 6 7 Complete control.

**Preliminary Intention**

**PI19.** I would be willing to have an HPV test to screen for cervical cancer instead of a Pap smear

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

**IV. Attitudes and Intention**

Right now in BC, women start cervical cancer screening once they become sexually active. We now know that testing for HPV infections in the cervix is more accurate than the Pap smear for predicting whether or not a woman will develop cervical cancer, So, in BC, women would be screened every 4 years with HPV testing instead of every year with Pap screening

**A20.** Having an HPV test to screen for cervical cancer every four years instead of a Pap smear every year would be:

Accurate 1 2 3 4 5 6 7 Inaccurate
Safe 1 2 3 4 5 6 7 Unsafe
Protect my health 1 2 3 4 5 6 7 Harm my health
Acceptable 1 2 3 4 5 6 7 Unacceptable

**IN21.** I would be willing to have an HPV test to screen for cervical cancer every four years instead of a Pap smear every year

Strongly disagree 1 2 3 4 5 6 7 Strongly agree

With HPV testing, women would not need to be screened for cervical cancer until the age of 25, regardless of when they started being sexually active.

**A22.** Having an HPV test to screen for cervical cancer start after the age of 25 and every four years instead of a Pap smear every year after becoming sexually active would be:

Accurate 1 2 3 4 5 6 7 Inaccurate
Safe 1 2 3 4 5 6 7 Unsafe
Protect my health 1 2 3 4 5 6 7 Harm my health
IN23. I would be willing to have an HPV test to screen for cervical cancer after the age of 25 and every four years instead of a Pap smear every year after becoming sexually active:

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

V. Self Collection for HPV

*Testing with HPV may offer the opportunity for women to collect their own samples for cervical cancer screening by inserting a Q-tip into their vagina. This would mean women would not need to have a clinician take the cervical sample.*

SC24. Collecting my own sample for cervical cancer screening would be…

<table>
<thead>
<tr>
<th>Accurate</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Inaccurate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safe</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>Unsafe</td>
</tr>
<tr>
<td>Protect my health</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>Harm my health</td>
</tr>
<tr>
<td>Acceptable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>Unacceptable</td>
</tr>
</tbody>
</table>

SC25. I would be willing to collect my own sample/specimen for cervical cancer screening:

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Strongly agree</th>
</tr>
</thead>
</table>

VI. Involvement in the HPV FOCAL Study

*Please answer the following questions about your involvement in the HPV FOCAL Study*

ST26. As a participant in the HPV FOCAL Study, my knowledge of HPV and its relation to cervical cancer has improved

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>Strongly Agree</th>
</tr>
</thead>
</table>

ST27. My involvement in the HPV FOCAL Study has influenced my willingness to have an HPV test every 4 years, instead of a Pap smear every year
Strongly disagree  1  2  3  4  5  6  7  Strongly agree

Please include my name and phone number in the draw for an iPOD
Yes  No

Name
Phone number:
<table>
<thead>
<tr>
<th>Item number</th>
<th>Variable name</th>
<th>Survey description: survey items (positive orientation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>Attitudes to HPV testing</td>
<td>Having an HPV test to screen for cervical cancer instead of a Pap smear would be:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Accurate</td>
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<td></td>
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<td>• Safe</td>
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<td></td>
<td></td>
<td>• Protect my health</td>
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<td></td>
<td></td>
<td>• Acceptable</td>
</tr>
<tr>
<td>PI19</td>
<td>Intention to be screened for HPV</td>
<td>I would be willing to have an HPV test to screen for cervical cancer instead of a Pap smear</td>
</tr>
<tr>
<td>A20</td>
<td>Attitudes to HPV testing every four years</td>
<td>Having an HPV test to screen for cervical cancer every four years instead of a Pap smear every year would be:</td>
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<tr>
<td></td>
<td></td>
<td>• Accurate</td>
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<td></td>
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<td>• Protect my health</td>
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<td></td>
<td>• Acceptable</td>
</tr>
<tr>
<td>IN21</td>
<td>Intention to be screened for HPV every four years</td>
<td>I would be willing to have an HPV test to screen for cervical cancer every four years instead of a Pap smear every year</td>
</tr>
<tr>
<td>A22</td>
<td>Attitudes to HPV testing every four years and after age of 25</td>
<td>Having an HPV test to screen for cervical cancer after the age of 25 and every four years instead of a Pap smear every year after becoming sexually active would be:</td>
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<td></td>
<td></td>
<td>• Accurate</td>
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<td>• Acceptable</td>
</tr>
<tr>
<td>IN23</td>
<td>Intention to be screened for HPV after the age of 25 years and every four years</td>
<td>I would be willing to have an HPV test to screen for cervical cancer after the age of 25 and every four years instead of a Pap smear every year after becoming sexually active</td>
</tr>
<tr>
<td>SND2-</td>
<td>Subjective Norms: Direct 2/3</td>
<td>SND2. Most people who are important to me would think that I should have an HPV test to screen for cervical cancer instead of a Pap smear</td>
</tr>
<tr>
<td>SND3</td>
<td></td>
<td>SND3. People who are important to me would expect me to have an HPV test to screen for cervical cancer instead of a Pap smear</td>
</tr>
</tbody>
</table>
screen for cervical cancer instead of a Pap smear

| SNI5-SNI12 | Subjective Norms: Indirect | SNI 5/6. My **family physician** would think that I should have an HPV test to screen for cervical cancer instead of a Pap smear & What my family physician thinks is important to me  

SNI 7/8. My **friends** would think that I should have an HPV test to screen for cervical cancer instead of a Pap smear & What my friends think is important to me  

SNI 9/10. My **spouse/partner** would think that I should have an HPV test to screen for cervical cancer instead of a Pap smear & What my spouse/partner thinks is important to me  

SNI 11/12. The **BC Cancer Agency** would recommend that I should have an HPV test to screen for cervical cancer instead of a Pap smear & What the BC Cancer Agency recommends is important to me |

| CP13-CP14 | Contacting partners | CP13. If I had a cervical cancer screening result that showed I had an HPV infection, I would feel comfortable sharing the results with my partner(s)  

CP14. My spouse would be understanding if I had an HPV infection |

| PBC15-PBC18 | Perceived behavioural control | PBC 15. I am confident that I could have an HPV test to screen for cervical cancer instead of a Pap smear  

PBC 16. For me to have an HPV test to screen for cervical cancer instead of a Pap smear would be easy  

PBC 17. Whether or not I would have an HPV test to screen for cervical cancer instead of a Pap smear would be entirely up to me |
PBC 18. How much control would you have over whether you had an HPV test to screen for cervical cancer instead of a Pap smear?
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