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Survey of Women's Interest in Home Human Papilloma Virus Testing

by

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LIST OF ABBREVIATIONS

Papanicolaou Smear	is equivalent to:	Pap smear
		Pap test
		Cervical cytology
Last Pap test 3 years ago or less		Last Pap < 3 years
Last Pap test greater than 3 years ago		Last Pap > 3 years
Screened	is equivalent to:	Last Pap < 3 years
Unscreened	is equivalent to:	Last Pap > 3 years
Human Papilloma Virus		HPV
United States Preventive Services Task Force		USPSTF
National Committee for Quality Assurance		NCQA
Health Plan Employer Data and Information Set		HEDIS
Kaiser Permanente Northwest		KPNW
Hybrid Capture 2 Test		hc2
Odds Ratio		OR
95% Confidence Interval		95% CI

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ABSTRACT

Background: Cervical cancer is a leading cause of cancer deaths in women worldwide with over 200,000 deaths yearly. Screening programs with regular repeated Papanicolaous (Pap) smear testing by a medical provider and early treatment of cervical pathology have reduced cervical cancer mortality in developed countries. Despite effective early detection of cervical cancer by Pap smear testing, in the United States approximately 20% of eligible women with commercial insurance and 35% of women with Medicaid insurance do not take advantage of this lifesaving test. Human Papilloma Virus (HPV) has been determined to be the causative agent of cervical cancer and testing for the presence of HPV DNA is a newer diagnostic technique which supplements traditional Pap smear testing. The use of self-collected HPV testing as a primary screening test for cervical cancer has been suggested as a method that might reach women who do not come to clinics for Pap tests.

Objective: In an effort to understand the potential benefit of home screening for HPV a survey was developed to evaluate unscreened women's interest in the use of a proposed at-home self-collected test for HPV and their willingness to obtain follow up testing if they test positive for HPV.

Method: Cross-sectional survey of adult women, ages 24-69, who were overdue for Pap test screening based on current guidelines, recruited from two Kaiser Permanente primary care clinics in suburban Vancouver, Washington.

Results: Surveys were collected from a convenience sample of 779 women. After excluding women with a history of hysterectomy, age outside study range, and missing answers, a total of 576 surveys were analyzed. 45 (7.8%) of the women surveyed reported their last Pap test was more than 3 years ago, which is delayed by current screening recommendations.

Six significant barriers to timely Pap testing were found on univariate analysis: "timely Pap not important to me" ($p<0.001$), "dislike of pelvic exam prevents Pap test" ($p<0.001$)), "past history of adverse event causes emotional barrier to pelvic exam" ($p<0.001$), knowledge of recommended Pap screening interval ($p=0.004$), "difficult to schedule time for Pap" ($p=0.02$), and "not worried about cancer" ($p<0.001$).

After logistic regression analysis, women who reported their last Pap greater than 3 years ago (unscreened women) indicated they were "more likely to do an at-home self-collected HPV test than come in to the clinic for a Pap test" (Odds Ratio [OR] 2.3, 95% Confidence Interval [CI] 1.02-5.06, $p=0.045$) versus women who reported last Pap less than 3 years ago (screened women). Women who indicated "dislike of pelvic exams prevents Pap testing" were strongly associated with "more likely to do at-home HPV test" (OR 9.5, 95% CI 4.4-20.2, $p<0.001$). "Difficult to schedule time for a Pap test" was also strongly associated with being "more likely to do an at-home HPV test" (OR 2.3, 95% CI 1.5-3.5, $p<0.001$).

Although attaching low importance to a timely Pap test was associated with delay in Pap testing ($p<0.001$), it was not associated with "more likely to do a home test than clinic Pap test" ($p=0.38$).

A majority of women, 98% of screened and 91% of unscreened, indicated they would return for further testing if an at-home self-collected HPV test was reported positive (p=0.01).

Conclusions: Cervical cancer screening rates in women who avoid timely Pap testing due to the powerful barrier of pelvic examination, and in women with the logistical barrier of time to arrange a clinic Pap test, could be increased by the addition of mailed at-home self-collection HPV testing. It is less clear if self-collection, even when conveniently done at home, will significantly increase screening among women who assign lesser importance to regular Pap testing. The low survey response rate of unscreened women also suggests that at-home self-collection will only incrementally increase screening in this unscreened population.

INTRODUCTION

Despite effective cervical cytology (Papanicolaou or Pap test) screening programs for early detection of pre-invasive and invasive cervical cancer, not all women are screened as recommended. Women who delay Pap tests longer than the recommended 3 years or who do not obtain Pap tests have reasons why they do not receive recommended cervical cancer screening.[1,2] These unscreened women are a difficult population to access and are at greater risk for invasive cervical cancer than regularly screened women. [2,3,4,5] Different approaches are needed to increase screening among unscreened women. This study is a clinic based cross-sectional survey of a large health maintenance organization's women members to determine their attitudes about screening and a proposed new approach to screening: an at-home, self-collected vaginal sample to be mailed to a laboratory for Human Papilloma Virus (HPV) testing. The purpose of the survey is to determine if unscreened women are more likely to participate in at-home self-collected screening than clinic based Pap testing and to compare their response to that of screened women.

BACKGROUND

Prior to the introduction of the Pap test in 1941 and the institution of screening in developed countries, cervical cancer was the most common cause of cancer and cancer deaths among women worldwide.[6-9] With over 200,000 annual deaths worldwide, cervical cancer is still a leading cause of cancer deaths among women in developing countries where high mortality is due to lack of organized and effective screening and

treatment programs.[10,11] In the United States, where effective cervical cancer screening programs are a major component of women's health care, more than 10,000 cases of invasive cervical cancer are diagnosed yearly. Despite available screening and treatment, an estimated 3700 American women still die annually from a disease that is usually curable if detected at an early stage.[12]

Despite a lack of randomized, controlled trials of cervical cancer screening, multiple observational studies have shown that invasive cervical cancer and death rates fell dramatically, as high as an 80% decline in mortality in Iceland, after institution of nationwide screening programs.[13,14] Cervical cancer screening has traditionally been conducted using the Pap test (conventional cervical cytology) where cells from the transformation zone of the cervix are sampled by a collection device, deposited upon a glass slide with fixative applied, and then scanned for abnormalities by a trained cytotechnologist. Despite its demonstrated success, the Pap test is not without its limitations. Sensitivity and reproducibility are low, with a range reported from 55% to 80% for high grade lesions.[7,15-19] Sampling errors, where existing abnormal cells are either not collected or the slide is inadequately prepared, account for part of the false negatives. The remainder is from detection error, where the slide is not analyzed correctly. Detection error rates have been documented at 5% to 10%.[20] Application of new technology with liquid preparation smears and computerized optical scanning of slides decreases sampling and detection errors, but even with this technology a one time Pap smear may miss abnormal cells.[7] Fortunately, the low sensitivity of cervical cytology is offset by the fact that cervical cancer is typically a slow growing malignancy, taking years to reach invasive and metastatic stages.[20] Repeated screening

done at regular intervals may effectively counteract the inherent low sensitivity of the screening test.

Various experts and professional organizations have recommended screening for cervical cancer at prescribed intervals. The U.S. Preventive Services Task Force (USPSTF) "strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix". Onset of screening should be "within 3 years of onset of sexual activity or age 21" and continue through age 65, and the screening interval should be "at least every 3 years" after at least 2 normal annual Pap smears.[21] The American Cancer Society and American College of Obstetricians and Gynecologists have similar recommendations but recommend annual screening under age 30 with intervals lengthened to every 2 to 3 years after age 30 if 3 consecutive negative Pap tests.[22,23] There is no consensus among organizations for the age at which to stop screening. Ages 65 and 70 are typically mentioned, but an individual woman's risk factors need to be considered in determining an individual's appropriate screening interval and age to discontinue. All the above recommendations are for average risk women. Several large studies have shown that the risk of extending the screening interval from 1 to 3 years after 3 consecutive negative Pap smears is low, with excess risk of 3 cancers per 100,000 screened estimated in one study.[22,24,25] The USPSTF also concluded there is insufficient evidence to recommend for or against new technologies such as liquid-based cytology, computerized re-screening, or HPV testing for primary screening.[21]

Clinical performance information is collected by the National Committee for Quality Assurance (NCQA), a private non-profit organization that measures and reports

performance in health care plans. Its data set, called the Health Plan Employer Data and Information Set (trademarked HEDIS), sets the standard by which health plans are compared.[26] The following table reports cervical cancer screening rates from the NCQA Year 2005 report "The State of Health Care Quality".[27]

Table 1: Cervical Cancer Screening: Insurance and Medicaid Rates, 2000-2004*

Year	Commercial	Medicaid
2004	80.9	64.7
2003	81.8	64.0
2002	80.5	62.4
2001	80.0	61.1
2000	78.1	59.9

*Estimates % of women aged 21-64 who were enrolled in a health plan and who had at least one Pap test in the past three years.

These HEDIS data show minimal variation in screening rates of commercially insured women and only slight improvement for women on Medicaid over the past 4 years. This raises the question whether further incremental improvement, even among commercially insured women, will be possible unless there is a dramatic change in screening tests or implementation strategies to bring in underscreened women to obtain the proven screening tests.

Multiple studies of women with invasive cervical cancer have shown that a major limitation to the prevention of invasive cervical cancer is not inherent weakness of the screening test or inadequate treatment of early disease, but rather the lack of screening – not ever being screened or not being screened frequently enough.[4,5,15,16] For example, one study of 481 Connecticut women with invasive cervical cancer showed 28.5% had never had a Pap test and 23.5% had not had a Pap test in the 5 years prior to diagnosis.[4]

A Kaiser Permanente study from Oakland, California found 60% of 642 women with invasive cervical cancer had not had a documented Pap smear in the 36 months prior to diagnosis, despite at least one primary care clinic visit by 75% of the unscreened women (with Kaiser insurance for at least 30 months).[5] Review of 2000/2001 cancer data from Kaiser Permanente Northwest (KPNW) also showed that a disproportionate number of women with invasive cervical cancer came from their Cervical Cancer Registry group of women who failed to have recommended Pap tests.[28] These various studies have shown that a majority of invasive cervical cancers will be found in women who are not previously screened or are delayed past the recommended screening interval.

In addition, among health plan enrolled women there is a tendency for some women to be over screened while other women are under screened. A review of Kaiser Permanente NW data from 1998-2002 shows that "among routinely screened women, 36% were estimated to have received annual cervical smears, versus 22% every second year, 13% every third year and 29% less frequent screening".[29]

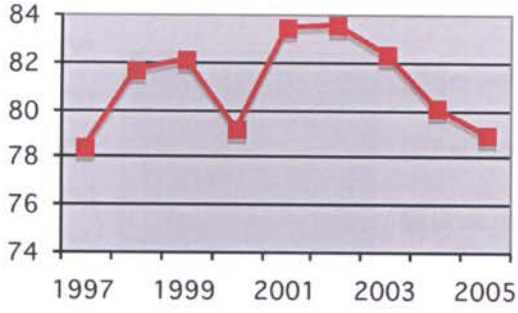
These data highlight that if morbidity/mortality from invasive cervical cancer is to be further reduced among women in developed countries, it is important to design screening programs to reach women who have never been screened or who have screening delays.

Registries can be used to monitor screening. In 1996 a managed health care delivery system instituted a centralized system for tracking breast and cervical cancer prevention services delivered to women members. This registry, named the "Safety Net", also includes an outreach component to members to encourage at risk members to receive

these prevention screening services. The cervical cancer screening "Safety Net" inclusion criteria are women ages 21-64 (age lowered from 69 after 3rd quarter 2005) who were continuously enrolled in the health plan for the preceding 3 years and have not had a documented Pap test during the preceding 3 years.[3,30] Women with documented hysterectomy are excluded. Racial and ethnic demographics for members of the Safety Net Registry are not determined, although the surveyed characteristics for the health plan enrolled women are 91% White/Caucasian, 3.8% Hispanic origin, 3.6% Asian, 1.5% African American, and the remainder "Other". [31]

Figure 1 below shows the percentage of eligible women screened from the years 1997 through year 2005. The mean screening rate for these years was 81%. Of note, the screening rate reached a high point in year 2002 (83.5%) and has declined since. A decline in screening was also seen in the national HEDIS data shown in Table 1. This raises a question whether declining Pap screening rates is a national trend or just a variation.

Figure 1: Percentage of Safety Net women screened[28,30]



Efforts to increase screening have included "in-reach" (clinic visit) efforts by staff to remind and schedule Safety Net women for a Pap test in addition to "out-reach"

reminder letters sent to women in the first year of inclusion in the Safety Net. A study of the Safety Net population has shown that outreach letters sent after the first year of a member's Safety Net inclusion were not efficient in improving screening rates.[3] After tracking the Safety Net population over several years an in-depth analysis of the Year 2000 Safety Net Registry demonstrated a population of women who remained in the Safety Net and appeared to be unresponsive to both in-reach and out-reach efforts.[28]

At the beginning of year 2000 there were 95,747 Pap smear eligible women. Of these women, 20,750 (22%) had no documented Pap within the past 3 years and were listed in the Safety Net. They were distributed through all age ranges. Figure 2 shows what happened to the 20,750 women over a year's time. By the end of 2000, 4,411 (21% of Safety Net women) were removed from the list due to documentation of exclusions such as age and hysterectomy. Pap tests were completed on 5,336 women (26% of Safety Net). By the end of 2000, 11,003 (53% of Safety Net, or 11% of total eligible women) were still unscreened and remained on the Safety Net list.

Figure 2: Outcome of Safety Net members at the end of year 2000 (n=20,750)

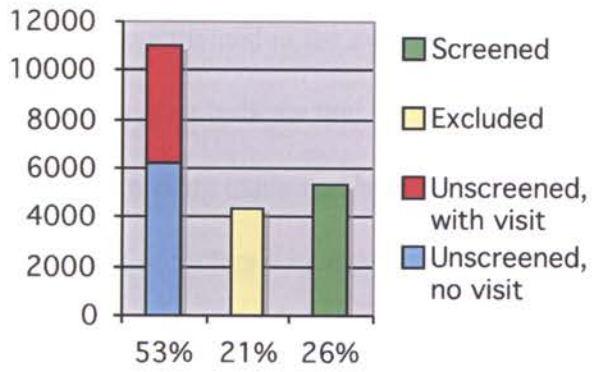
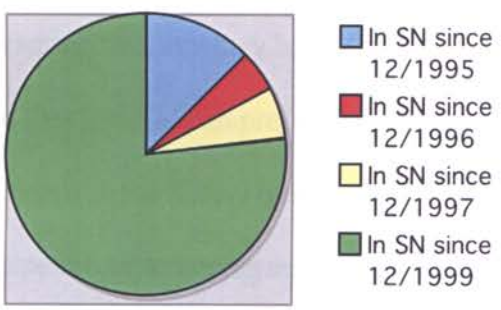


Figure 3 of the Year 2000 Safety Net Registry shows how long members remained in the registry with no documented Pap test. 13% remained in the registry since 1995, 5% since 1996 and 6% since 1997. Thus 24% (4,763) of women in the Safety Net Registry remained in the registry continuously, and without a Pap test, for 6 years or longer.

Figure 3: Length of time enrolled in Registry for no documented Pap test
(Year 1998 incomplete data and not graphed)



Despite comprehensive insurance coverage and efforts to remind them of the need for Pap test screening, 11,003 or 11% of all eligible KPNW enrolled women (53% of Safety Net) failed to complete nationally recommended cervical cancer screening and 24% of them remained in the overdue cervical cancer screening registry for multiple years. These data indicate that there are significant barriers to screening for many women that are not explained by cost.

Barriers, or factors which prevent screening, have been described in four categories: lack of knowledge, economic constraints, cultural or belief systems, and logistical issues.[6] The cost of medical care, lack of medical infrastructure and access to care, and social customs and religious beliefs are included in these categories. In addition, the

physical and emotional barrier of the pelvic examination is a major deterrent to some women due to embarrassment, discomfort, and intrusive memories as a result of prior sexual trauma.[32,33]

A recent study in Chicago, Illinois evaluated barriers to Pap testing among 148 women recently diagnosed with invasive cervical cancer. Women who self reported they had never been screened were more likely to be Hispanic, recent immigrants, less educated, and uninsured. Cultural and belief system barriers also included lack of family support, lack of knowledge about cervical cancer risk, fatalistic attitudes, and not wanting to know they had cancer.[1] A study evaluating a Hispanic population found that low English proficiency is a barrier to Pap testing.[34]

Women in the Safety Net Registry have been studied to determine barriers to their participation in screening and they have consistently revealed more numerous and intense barriers to cervical cancer screening than women with recommended interval screening. [28,2] Embarrassment and discomfort associated with the pelvic exam, mistrust, pessimism (I don't want to know if something is wrong), and logistical (such as cost, convenient appointment time) barriers were reported. Many significant barriers reported were due to misinformation (not needing screening because of feeling healthy; the cure being worse than the disease; perceptions that the tests are inaccurate).[2] Among these women there were "very low correlations between patient socio-demographics and barrier scores."[2] The authors suggested that to reach this group of women with delayed screening "an individualized, patient centered intervention" is needed with approaches tailored to women's individual barriers.[2] In-reach efforts (advice given at time of a primary care appointment to obtain needed

screening service) were not effective due to fewer medical visits by Safety Net women.[35]

Due to the difficulties of establishing traditional Pap smear screening programs in developing countries and improving screening rates in developed countries, new approaches to cervical cancer screening are being considered. One approach that has potential to overcome barriers to Pap testing is self-sampling for HPV testing. HPV virus is found in 99.7% of cervical cancer cases and studies over the past two decades have established that genital HPV is a necessary, but not sufficient, causative agent of cervical cancer.[36-38] There are over 30 DNA types of genital HPV with 10-15 types causing cervical cancer. Most HPV infections are transitory and resolve spontaneously within one year. The oncogenic types, however, are more likely to persist for over one year. In susceptible women the high risk virus types establish a chronic carrier state and promotes malignant transformation of the cervical epithelium.[36] The infection progresses from HPV infection of the squamous epithelial cells of the cervix, to high grade pre-invasive lesions, and finally to invasive cervical cancer.

Once it was established that HPV is a necessary agent for development of cervical cancer, and that women who are chronic carriers of high risk type HPV are high risk, it became feasible to use HPV testing as a cervical cancer screening strategy.[39-42] Type specific HPV DNA testing is now clinically available as an adjunct in cervical cancer screening (Hybrid Capture 2 Test by Digene –"hc2").[43] DNA testing is highly sensitive for the targeted HPV types with reported sensitivity of 96% to 100% for high grade lesions compared to reported conventional cytology sensitivity of 43.5% to 77% [44-47] A

negative predictive value of 99% has been demonstrated with a single negative HPV DNA test.[32,48] The hc2 test was initially FDA approved for management of women with cytology testing classified as "atypical squamous cells of uncertain significance" (ASCUS). It is now also approved for primary screening in women over 30 years old in conjunction with cytology.[43] The sensitivity and negative predictive value of screening in combined testing has been described as close to 100%.[49]

Although the hc2 test is currently approved only for use in conjunction with cervical cytology, primary screening with HPV testing has been suggested.[40,44] One study of 7932 women identified a negative predictive value of 100% among a subgroup of 1225 women with both negative cytology and negative HPV DNA. With a median follow up of 30 months, no detectable high grade lesions were found in this group.[44] Given demonstrated high negative predictive values, it has been suggested that HPV testing could be a good initial primary screening test, particularly in areas which are low in resources and where traditional screening cytology programs are difficult to implement.[40,44,50] Although HPV DNA testing is not currently approved for primary cervical cancer screening alone, it appears likely at some point this will occur given the higher sensitivity of HPV testing for high grade invasive cervical lesions compared to conventional cytology.

If a clinician collected cervical swab for HPV is an accurate method of screening to identify high risk women, it raises the question of whether patient collected testing can be an equally effective alternative. In previous years, studies have evaluated various methods for patient self-collection of cervical cell samples for cytologic screening. These studies have shown that self-collected cytology samples are not useful due to low

sensitivity and negative predictive value.[32] Different conclusions have been drawn, however, in the multiple studies where patient collected HPV sampling has been tested.[32,33,51-55] In a series of 3 studies where the detection of high risk HPV from self collected swabs, or tampon samples, was compared to clinician obtained specimens, self collection methods were equivalent to clinician collected HPV samples. Women also found self collection an acceptable method for use as a yearly screen".[51,56,57] One study of 1415 unscreened South African women compared patient collected vaginal sampling to cervical cytology (Pap) and clinician obtained HPV samples. In this study the sensitivity of patient collected sampling was equal to that of the Pap test (66.1% versus 67.9%) but less sensitive than clinician obtained HPV sampling (66.1% versus 83.9%). Specificity of both patient collected and clinician collected HPV tests was slightly lower than Pap tests for high-grade disease (82.9% and 84.5% versus 87.7%).[53]

Another study evaluated multiple techniques to detect cervical neoplasia in an underserved province in China.[50] One of the detection techniques was self collection for HPV. This study showed a lower sensitivity (83%) for HPV detection by self-collected sample than the 95% sensitivity of the clinician directed HPV test with similar specificity.[50]

A published meta-analysis of twelve self-collection studies found an overall sensitivity in six similar studies of 74% (95% CI 61% - 84%) and specificity of 88% (95% CI 83% - 92%) for HPV compared to clinician obtained samples.[55] In four studies where women were recruited at referral clinics the sensitivity increased to 81% (95% CI 65% –91%) and specificity to 90% (95% CI 80% - 95%).[55] Experts believe that self-collected samples give reasonable results and may be useful in low resource

areas and with unscreened populations.[58] Participants in self-collection studies uniformly found the methods acceptable and preferable to clinician obtained samples.[32] Mailing self-collected samples from home has not been extensively researched, but one study comparing the efficacy of various lengths of time of tampon sample collection found mailed tampon samples to be highly technically feasible.[57]

A model for the use of self-collected vaginal swabs is testing for sexually transmitted diseases (STD). In particular, testing by vaginal self-sampling for *Chlamydia trachomatis* has been extensively researched in the U.S. and has been found to be highly accurate and patient preferred over clinician obtained sampling.[59,60] Clinic based patient collected vaginal swab tests for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* were recently FDA approved.[61] A recent study found these vaginal swabs comparable in sensitivity and specificity to clinician obtained endocervical swabs and more sensitive than urine samples.[59] Since these tests are particularly useful for screening of asymptomatic women, it is anticipated they will become widely used.[59,62-64] Home self-collection with mailed return of a urine sample to a testing laboratory has also been researched and was found to be a feasible and acceptable method of screening for recurrent chlamydial infections.[65,66] These STD testing models demonstrate success in the U.S. of methods similar to proposed at-home self-collection HPV testing.

Self-collected sampling for HPV uniquely addresses many of the identified barriers to traditional Pap testing encountered by women in developed countries including the U.S. The cultural sensitivities, embarrassment and discomfort of the pelvic examination can be avoided. In addition, if self-sampling occurs in the home by mailed sampling kits, most logistic issues of transportation, time off work, child care, and

appointment scheduling can be avoided. Depending on the cost of the test and co-pays, financial barriers may also be reduced. Thus, when there are no gynecologic conditions necessitating a pelvic examination, a mailed, at-home self-collection testing method might be successful in increasing screening among unscreened women with little loss of test sensitivity and specificity as compared to Pap testing.

Participants in HPV self-collection studies have been recruited in various ways. Several studies recruited women who underwent colposcopy for abnormal cytologic findings.[51,54,57,67] Other studies recruited women at time of appointments for routine gynecologic or primary care.[52,56,68] The Shanxi Province and South African studies recruited women in underserved areas where there were only limited cervical screening programs.[50,53] By participation in these studies, the women demonstrated they were motivated to seek care and were willing to undergo a pelvic examination. Women in these studies may represent a different population, with different or fewer barriers to testing, than women in the U.S. who are unscreened. None of the reviewed studies specifically recruited participants from a registry of unscreened women. It is unclear if the self-collection testing that was acceptable to study participants will be acceptable to unscreened women, particularly women with health insurance who have not taken advantage of available Pap testing services within the recommended screening interval. It might also be the case that unscreened women will have a higher interest in self-collection testing than the women studied, particularly if self-collection can be done at home with a testing kit received and returned by mail.

An additional concern that has not been addressed by published studies is whether unscreened women who successfully complete screening using a self-collection test

will follow up with further testing and treatment if a self-collected screening test is positive for high risk HPV. It may be difficult to explain to women, especially those who avoid traditional testing, that a positive HPV test puts them at higher risk for, but does not diagnose cervical abnormalities or cancer. For a conclusive diagnosis they must still undergo pelvic examination and further testing.

Interest in self-collection testing among Safety Net Registry members was initially evaluated when a brief anonymous questionnaire was included in the annual 2003 KPNW Prevention Committee's outreach reminder letter sent to Safety Net Registry women who were new to the registry in the previous year. A stamped, addressed return envelope was included. There was no identifying or demographic information other than membership in the Safety Net Registry. Results are as follows.[69]

Figure 4: 3460 surveys mailed to Safety Net members with 226 (6.5%) returned.

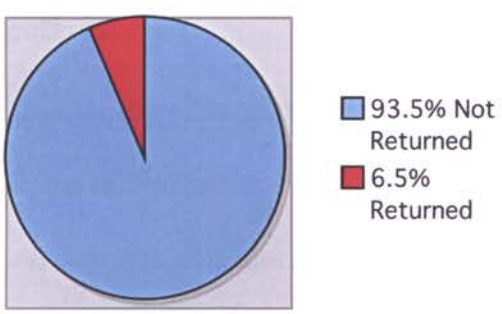
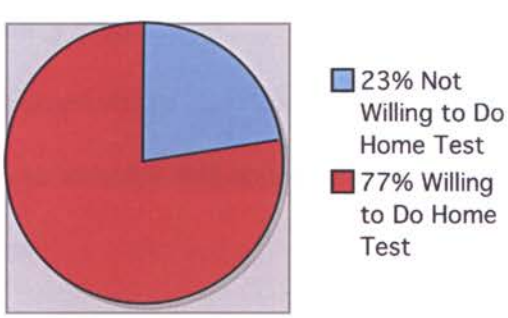


Figure 5: 175/226 Safety Net respondents willing to return self-collected HPV test.



The very poor response rate of this survey, despite its brevity and ease of return, was consistent with the known difficulty of accessing this population of unscreened women. Of the respondents, however, 77% indicated, both by check-off and many written comments, a strong interest in at-home self-collection testing.

Cervical cancer screening in the U.S. faces a dilemma. Unscreened women have been shown to be at higher risk for invasive cervical cancer, while at the same time screening rates remain flat at approximately 80% and 65% for women with commercial and Medicaid health insurance, respectively.[4,5,27] Current health industry and public health efforts have not significantly changed screening rates in recent years. New strategies are needed to effectively address barriers to cervical cancer screening.

METHODS

Objectives

The purpose of this study is to compare screened and unscreened women's interest in at-home self-collection HPV testing and their willingness to proceed with further medical care if an at-home self-collected HPV test is positive, and to identify the association between barriers to Pap testing and women's interest in at-home self-collected HPV testing.

Primary Hypothesis

Women with a last Pap test more than 3 years ago will indicate they are more likely to do an at-home self-collection HPV test than women with a last Pap test 3 years ago or less.

Secondary Hypothesis

Women with a last Pap test more than 3 years ago are less likely to agree to further testing and treatment if the self-collected HPV test is positive than women with a last Pap test 3 years or less.

Study Design and Study Population

The study is a cross-sectional survey utilizing a written questionnaire. The study subjects were recruited from enrolled women members of KPNW, a nonprofit health maintenance organization of approximately 487,000 members located in the Portland,Oregon and Vancouver,Washington area. Participating clinics for the survey were the Clark County clinics of Cascade Park and Salmon Creek. Ethnic/racial composition is 93% white/Caucasian and the remainder of the population is distributed among a variety of multi-ethnic groups including Hispanic origin (3%), various Asian populations (1.5%), African American (1%), Hawaiian/Pacific Islander (0.8%), and Native American (0.4%).[31]

A screening program for secondary prevention of cervical cancer is an integral part of health care for women enrolled in KPNW. All enrolled women members have coverage for screening at the cost of a co-pay which is typically $10 to $20. KPNW screening rates are typically 75-81% of the eligible enrolled population. Year 2005 3rd quarter screening rates at Cascade Park and Salmon Creek were 80.8% and 80.7%.[30] Women are identified when they reach three years from the time of last documented

Pap test and are then tracked by a cervical cancer screening registry named the "Safety Net".

Survey

A 27 question survey was developed to gather information on women ages 24 through 69 about their interest in at-home self-collection HPV testing and other information. Survey questions included hysterectomy status so that women with prior hysterectomy could be excluded from the study. Self report of last Pap test was also queried. A series of 12 questions were asked about barriers for obtaining timely Pap testing, and then a series of 7 questions asked about attitudes towards at-home self-collection testing. Demographic information was also obtained. Education level was used as a surrogate for socioeconomic status and income. English as the primary language was used as a surrogate for ethnicity given the already known ethnic/race composition with dominant white Caucasian members (93%). The survey was pilot tested on approximately ten women and revised based on their comments. It was found to be acceptable in the wording of questions, the instructions for completing, and the length of time needed to complete it. The survey and study plan received approval from both the Kaiser Institutional Review Board (IRB) and Oregon Health and Science University (OHSU) IRB. A copy of the survey and the cover letter to participants is included in the Appendix.

Survey Distribution

A total of 1000 surveys, with pencils and collection boxes, were given to receptionists at the Cascade Park and Salmon Creek primary care outpatient clinics in June, 2005. Reception areas targeted were Primary Medical Care, Radiology, Lab,

Nurse Treatment, Optometry, and Urgency Care. The receptionists were given verbal as well as printed instructions to ask each adult women ages 24 through 69 to fill out the anonymous survey while waiting for their appointments. Participants were given the option of returning the completed survey by mail or placing it in a collection box located in each reception area. The length of the study was 3 weeks, or with complete distribution of the clinic area allotment of surveys, whichever came first. Refusals were not tracked given the multiple receptionists involved and their other duties.

Sample Size Estimation

This study is powered to detect a 20% difference in proportion of at-home self-collected HPV testing between the screened and unscreened groups. The unscreened KPNW population is approximately 20% of eligible women. However, they seek medical care less frequently and it is likely that only 10% of the returned surveys will come from unscreened women. Assuming that 50% of screened women will indicate they are more likely to do an at-home self-collected HPV test, it takes 522 women altogether to detect a 20% difference with 80% power in a two-tailed test at 0.05 significance level by using the method in Hulley et al. (1981)[70]

Statistical Methods

Outcome Variables

The primary outcome variable was "I am more likely to do a home test than a clinic Pap test." Interest in at-home self-collection HPV testing was also assessed by five other related outcome variables. All responses were answered on a 5 point scale. Responses to "strongly agree" and "agree" were collapsed to Agree and coded as "1".

Responses of "not sure", "disagree", and "strongly disagree" were collapsed to Disagree and coded as "0". The five other questions asked were: 1) I am willing to do and return this test, 2) I feel comfortable and confident to do this test, 3) Vaginal tampons are easy to use, 4) If a home test costs less than Pap test, I am more likely to do a home test, and 5) Assuming there is no medical problem, I prefer a home test.

The second main outcome variable of interest was "If I do a home test and am notified the test is positive, I will make an appointment and come in to the clinic for a pelvic exam and further testing." Responses were answered on a 5 point scale and were dichotomized for analysis. The responses "definitely/most likely will come in" were coded as "1." The responses "not sure/probably will not/definitely will not come in" were coded as "0".

Predictor Variables

The main predictor variable was the self-reported time of last Pap Smear test based on answers to the question "When was your last Pap Smear test?" The response of "3 years or less" (screened) was coded as "0". The responses "4 to 5 years ago" and "more than 5 years" were collapsed to "greater than 3 years" (unscreened) and coded as a "1". This variable was also an outcome variable in some analysis.

Secondary predictor variables were comprised of several known categories of barriers to Pap testing: knowledge, belief systems, logistical issues, and various aspects of pelvic examination. Knowledge, as assessed by the question: "How often should most women have a Pap smear done?" was dichotomized to every year (coded "0") and every 2-3/4-5 years (coded "1").

The belief system question "How important is it to you that you get a Pap test done as often as recommended?" was dichotomized to not important (coded "1") and moderate/very important (coded "0"). The remaining belief system variables were already dichotomous with responses of "Agree" (coded "1") or "Disagree" (coded "0"). The variables were "do not get Pap tests because I am not worried about getting cervical cancer", "if I have cancer changes on my cervix I don't want to know", and "if I have an abnormal Pap test, I will refuse further testing/treatment".

Respondents answered logistical and pelvic examination barrier questions on a 5 point scale. Responses to "strongly agree" and "agree" were collapsed to Agree (coded "1"). "Not sure", "disagree", and "strongly disagree" were collapsed to Disagree (coded "0"). The three logistic questions asked about difficulty getting a Pap test due to cost, transportation, and time. Pelvic exam questions were: 1) discomfort with the pelvic exam, 2) discomfort due to a male provider, 3) physical problem prevents Pap, 4) emotional problem due to difficult past experience prevents Pap and 5) dislike having a pelvic exam so much that it prevents me from getting a Pap test.

The socio-demographic predictor variables in this study were: age, education, smoking, English language, and gender of sexual partner. Age was entered as a continuous variable. Education was dichotomized into high school or less (coded "1") and past high school ("0"). Smoking was a dichotomous variable indicating whether or not a woman smoked (No=0, Yes=1). English was a dichotomous variable indicating whether English was the primary language in the home (Yes =0, No/some of the time =1). Sexual partner preference was broken down into three categories: male partner, female or both male/female partner, and never had a partner.

Data Analysis

Statistical analysis was performed by using SPSS 11 Graduate Pack for Mac OS X. Descriptive analysis was used to determine the mean and range for age, a continuous variable, and the number of valid responses and missing data as well as proportion for categorical variables.

Univariate association was determined by using the Pearson Chi-square and Fisher's Exact Test (when cell size <5) for five sets of predictor and outcome variables. A p-value of <0.05 was considered significant. The five sets of univariate analyses were the following:

1. Demographic differences between unscreened and screened women based on time of last Pap.
2. Association between barriers to Pap testing and time of last Pap (unscreened / screened).
3. Association between time of last Pap (unscreened / screened) and at-home, self-collection testing variables.
4. Association between barriers to Pap testing (predictor) and more likely to do at-home, self-collection testing.
5. Association between time of last Pap (unscreened / screened) and willingness to return for further testing.

Two multiple logistic regression models were built. The first model assessed the contribution of barriers to time of last Pap (unscreened / screened). The second model assessed the contribution of time of last Pap and various Pap barrier predictors on the main outcome variable "more likely to do at-home, self-collection testing." Predictor

variables were included in building the regression models if the univariate p values were determined to be <0.10. The demographic variables of age, education, and smoking were also included in the model building. The two final models were chosen by using a backward Stepwise selection method with p = 0.05 as the criteria to remove a variable. Final results are presented as Odds Ratio with 95% Confidence Intervals, and p-values. The Hosmer-Lemeshow Goodness of Fit test statistic was calculated with a value of >0.05 in support of a model.

RESULTS

Among the 1000 distributed questionnaires, 779 surveys were completed and returned. Six additional surveys were returned with only the first several questions answered and thus were not entered into the data base, resulting in a 78.5% overall response rate.

Among the 779 returned surveys, 154 women were excluded because of prior hysterectomy. Of the remaining 625 women, 2 women were excluded due to not answering the question "When was your last Pap smear test?" 41 women were excluded because their age was outside the target population. 6 completed surveys were excluded due to missing data from the outcome variable questions which asked about being more likely to do home testing and willingness to do further testing if a positive HPV test. Surveys with missing answers not related to the outcome variables were left in for analysis (81 or 0.6% missing responses out of a possible 12,672). Therefore, a total of 576 surveys were analyzed. Based on answers to the question

"When was your last Pap smear test?", these surveys were split into 2 groups: screened women (n= 531, 92%) and unscreened women (n=45, 8%).

Demographics

Demographic characteristics of the screened and unscreened women are shown in Table 2. They were similar in age distribution, education level, and English as primary language. Smoking, a known risk factor for cervical cancer, was reported by 10% more of the unscreened women although the difference is not statistically significant (p = 0.12). The total non-English speaking population was small (n=23, 4%), as well as the numbers of women preferring female/bisexual partners (n=9, 2%), and women never having a sexual partner (n=6, 1%). Therefore, these two variables were not included in further analysis.

Table 2: Demographic characteristics of subjects

Variable	Value	Unscreened N=45	Screened N=531	p-value
Age	Mean (range)	44.9 (24-69)	43.5 (24-69)	
Education	Past HS	84%	83%	1.00
Smoker	Yes	25%	15%	0.12
English	Yes	93%	96%	0.41
Sexual preference	Male partner	93%	98%	
	Female/ both male/female	2%	1.5%	
	Never	5%	.8%	

Totals do not always equal 100% due to missing data

Univariate analysis of barriers to Pap testing

Results of Pap test barriers are shown in Table 3. Five barriers to Pap testing were found by univariate analysis to be significantly associated with a delay in screening. Although unscreened women were less likely to consider a timely Pap test very important ($p<0.001$), 44% still rated the Pap test as very important. Their knowledge of the recommended screening interval also differed from screened women ($p=0.004$) with 56% of unscreened women incorrectly believing that Pap testing should be yearly, compared to 76% of screened women. Notably, 44% of unscreened compared with 9.5% of screened women identified dislike of the pelvic exam as an important barrier ($p<0.001$). Finding time to schedule an appointment ($p=0.02$) was also significantly associated with unscreened women compared to screened women. Although unscreened women were significantly less worried they would develop cancer compared to screened women ($p<0.001$), the proportions were small in both groups.

Table 3: Barriers to recommended Pap testing

		Unscreened N=45	Screened N=531	
Variable	**Response**	**%**	**%**	**p-value**
Knowledge of recommended Pap test interval	Yearly	56	76	0.004
Importance of timely Pap	Very important	44	78	<0.001
Co-pay deters Pap	Agree	20	12	0.20
Transportation difficult	Agree	4	2	0.21
Schedule time difficult	Agree	44	26	0.02
Discomfort with male provider	Agree	53	48.5	0.64
Dislike of pelvic exam prevents Pap test	Agree	44	9.5	<0.001
Physical problem prevents pelvic	Agree	7	7	1.00
Pelvic exam is emotionally difficult	Agree	24	6	<0.001
Not worried about cancer	Agree	16	3	<0.001
Don't want to know if cancer	Agree	7	1	0.03
Will refuse further tests if abnormal Pap	Agree	2	1	0.47

Association between barriers and delay in Pap testing

A logistic regression model was developed to further assess the association between barrier predictor variables and delay in Pap testing. The three demographic variables of age, education and smoking plus the five barriers identified in the univariate analysis were entered in the model.

The estimates of odds ratio from the final model using a backward stepwise elimination are shown in Table 4. The Hosmer and Lemeshow test shows a good fit of the model (p=0.82).

Table 4: Estimates of odds ratio for barriers to Pap testing in a multiple logistic regression

Variable	OR (95% CI)	p-value
Dislike of pelvic exam prevents Pap test	5.59 (2.77 – 11.28)	<.001
Knowledge of recommended Pap test interval	2.25 (1.15 – 4.41)	0.02
Importance of timely Pap	4.55 (1.17 – 17.68	0.03
Not worried about cancer	4.02 (1.38 – 11.73)	0.01

In the multiple logistic regression model, the most significant barrier to timely Pap testing was dislike of pelvic exam. The odds in favor being unscreened for women who dislike the pelvic exam is 5.6 times the odds for women who didn't indicate dislike of pelvic exam (OR 5.6, 95% CI, 2.8-11.3, p<0.001). Other significant barrier predictors were difference in knowledge about recommended test interval (OR 2.3, 95% CI, 1.2-4.4, P=0.02), perceived importance of a timely Pap test (OR 4.6, 95% CI, 1.2-17.7, p=0.03) and not being worried about developing cancer (OR 4.0, 95% CI, 1.4-11.7, p=0.01).

Univariate analysis of at-home, self-collection HPV testing

Attitudes regarding at-home, self-collection HPV testing were compared between the screened and unscreened groups of women (Table 5). Unscreened women were found to be significantly more likely to do an at-home, self-collected HPV test than a clinic Pap test compared to screened women (69% vs. 35%; unadjusted OR 4.18, 95%

CI, 2.20 – 8.00, p<0.001). The questions and results for "prefer a home test" and "home test if costs less" were similar (p=0.02) and not used in further analysis.

Table 5: Agreement with statements about at-home self-collection HPV testing

	Unscreened N=45	**Screened N=531**	
Variable	**%**	**%**	**p-value**
Willing to do test	82	67	.06
Confident can do test	71	74	.83
Tampons easy to use	71	78	.39
Home test more likely	69	35	<.001
Home test if costs less	62	42	.02
Prefer home test	67	47	.02

Univariate analysis of Pap test barriers and at-home, self-collection HPV testing

Barriers to Pap testing were evaluated as predictors for being more likely to do an at-home self-collection HPV test (Table 6). Five significant associations were identified: the co-pay cost of a Pap test (p=0.01), difficult to schedule time for a Pap test (p<0.001), discomfort with a male provider (p<0.001), and dislike of pelvic exam prevents a Pap test (p<0.001). Although only a small number of women agreed with the statement "I am not worried about getting cervical cancer", this variable was also statistically significant (p<.001) and showed an association with home testing. These five barriers were included in further analysis using multiple logistic regression. The questions of physical and emotional difficulties related to pelvic examination were not

included in this analysis due to their similarity with the variable "dislike of pelvic exam prevents Pap". Knowledge of the recommended interval for Pap testing (p=0.27) and importance of a Pap test (p=0.38) were not predictive of home testing.

Table 6: Pap test barriers as predictors of a home test being more likely

		Agree: Home Test More Likely N=215	Disagree: Home Test More Likely N=361	
Variable	***Response***	*%*	*%*	***p-value***
Recommended Pap interval	Yearly	*72*	*76*	*0.27*
Importance of timely Pap test	Very important	*97*	*99*	*0.38*
Co-Pay deters Pap	Agree	*18*	*10*	*0.01*
Transportation difficulty	Agree	*2*	*2*	*1.0*
Difficulty to schedule time	Agree	*40*	*21*	*<.001*
Discomfort with male provider	Agree	*63*	*40.5*	*<.001*
Dislike of pelvic prevents Pap test	Agree	*28*	*2.5*	*<.001*
Not worried about cervical cancer	Agree	*8*	*1*	*<.001*

Association between home testing and last Pap and barriers

A logistic regression model was developed to assess the association between predictor variables on the primary outcome variable "more likely to do home test". An initial nine predictor variables were entered in the model including three demographic variables (age, education, and smoking), five barriers identified in the univariate analysis with $p<0.10$ (Table 6), in addition to the primary independent variable, time of last Pap (screened/unscreened).

The estimates of odds ratio from the final model using a backward stepwise elimination are shown in Table 7. The Hosmer and Lemeshow test shows a good fit of the model (p=0.77).

Table 7: Estimates of odds ratio for Home Test More Likely in a multiple logistic regression

Variable	OR (95% CI)	p-value
Last Pap (screened/unscreened)	2.27 (1.02 – 5.06)	0.045
Pelvic dislike prevents exam	9.47 (4.43 – 20.22)	<0.001
No worry of cancer	6.91 (1.85 – 25.80)	0.004
Time to schedule difficult	2.26 (1.48 - 3.45)	<0.001
Discomfort with male provider	1.91 (1.29 – 2.82)	0.001

Time of last Pap and four barriers remained in the final model. After controlling for the four barriers in the model, Last Pap remained significantly associated with a home test. The odds in favor of being more likely to do a home HPV test for unscreened women is 2.3 times the odds for screened women (OR 2.3, 95% CI, 1.02-5.06, p=0.045).

The strongest association with the outcome variable of "home test more likely" was shown by the predictor variable "dislike of pelvic exam prevents Pap test" (OR 9.5, 95% CI, 4.4-20.2, p<0.001) followed by the predictor variable "not worried about cervical cancer" (OR 6.9, 95% CI, 1.9-25.8, p=0.004). Other significant predictors were "difficult to schedule time" (OR 2.3, 95% CI, 1.5-3.5, p<0.001), and "uncomfortable with male provider" (OR 1.9, 95% CI, 1.3-2.8, p=0.001).

Univariate analysis of "Will do further testing if positive HPV test"

A secondary study question was to determine if women who do at-home self-collection HPV testing will proceed with necessary further testing if they have a positive HPV test. 91% of the unscreened women indicated they will complete further testing if a home collected test is positive compared with 98% of screened women (χ^2_1= 6.74, p=0.01).

The chi-square analysis showed a significant difference between the two groups, although the number of women who indicated they will not come for further testing is small (Table 8).

Table 8: Will make appointment for further testing if HPV test is positive

	Unscreened N=45 (#)	**Screened N=531 (#)**	χ^2	**P value**
Will come in	91%	98%	6.7	0.01
Will not come in	9% (4)	2% (9)		

DISCUSSION

The results of this cross-sectional survey of women enrolled in a health maintenance organization support the proposal that cervical cancer screening rates, which are consistently around 80% for women with non-Medicaid health insurance, will be increased by an alternative testing method, a vaginal sample self-collected at home and mailed to a laboratory for HPV DNA testing. 69% of unscreened women indicated they are more likely to mail in a self-collected sample than to go to a clinic for a Pap test, compared to only 35% of screened women.

This proposed home collected HPV test appears to be particularly well suited to remove several barriers to Pap testing experienced by unscreened women. In this study, the strongest associations with being unscreened were dislike of the pelvic examination, as well as considering Pap testing not important, and not being worried about developing cervical cancer. These findings are consistent with previous studies which have also found that the pelvic exam and misinformation about cervical cancer are associated with decreased screening.[2]

The only logistic barrier to Pap test screening found to be significant in univariate analysis was scheduling time for an exam. This time barrier did not remain a significant factor after controlling for other barrier variables. Financial and transportation barriers were not demonstrated. Unlike studies which have demonstrated socio-economic barriers to screening, there were no significant differences between the screened and unscreened women in the demographic characteristics of age, education level, tobacco use, or language.[1] This lack of association with demographic barriers was confirmed in the multiple regression model. The lack of socio-economic and other logistical barriers in this sample is not surprising, given the insured, ethnically homogenous, and educated population the women were recruited from.

Barriers are associated with delayed Pap testing[1,2,35], but it is unclear if these same barriers are associated with willingness to do HPV at-home self-collection testing. This study found that the barriers which predicted being unscreened in this study were not consistently the same barriers which predicted a woman being more likely to do an at-home self-collection test. Dislike of pelvic exam was found to be a significant factor in both delay in screening and being more likely to do at-home self-collection testing.

44% of the unscreened women in this study indicated their dislike of a pelvic examination prevented them from obtaining Pap testing. This study provides evidence that self-collection testing will be an acceptable method of screening and could improve screening rates in women who avoid screening due to the pelvic examination.

Although discomfort with examination by a male provider was a predictor of an at-home self-collection test being more likely, it did not predict a delay in Pap testing. The implications of this are that if given the option, some women will choose screening by a self-collection method rather than a pelvic exam by a male provider. However, this by itself will not raise screening rates in women similar to this sample, as male providers were not a determining factor in being unscreened.

The logistic factor of difficulty finding time for an appointment was a predictor of both being unscreened, in univariate analysis, and more likely to do an at-home test. This study supports the proposal that at-home self-collection testing will meet the needs of women for whom time for testing is an important barrier to screening.

It is unclear from this study whether screening rates in those women who are unscreened due to "no worry about getting cervical cancer" or who "don't consider a timely Pap test to be very important" could be significantly increased by an at-home self-collection HPV test. Both of these misinformation barriers were significant predictors of being unscreened. "Not worried about cancer" was found to also be associated with an at-home test being more likely. However, the proportions of women in both the unscreened and screened groups for this variable were small (16% and 3%) and thus any effect on increasing a population's screening rate will be limited.

"Importance of a timely Pap test" was not a predictor of an at-home test being more likely, although it was a significant predictor of delay in Pap testing, with only 44% of unscreened women considering it very important. This is a misinformation barrier that may not be completely removed by offering an easier testing method. Women who have misconceptions about cervical cancer and screening and therefore attach less importance to regular Pap testing may be less likely to respond to self-collection programs and at-home mailed tests than women who avoid Pap tests due to the pelvic exam experience.

It will be of little value to provide a convenient at-home self-collection testing option if women who test positive do not arrange for further evaluation. The result of this survey provides reassuring evidence that a high proportion of both unscreened (91%) and screened (98%) women will obtain follow-up testing and treatment if an at-home collected sample tests positive for high risk HPV.

Limitations

A limitation of this study is the small proportion of the unscreened women included in this study. The proportion, if they had accurately represented the study population, should have included 20% from women who self-reported their last Pap test more than 3 years ago. Instead only 8% of women were from this unscreened group. This low proportion demonstrates how difficult it is to access unscreened women. It is consistent with the previously presented information describing fewer medical visits and also with the low response rate to the prior survey.[2,35,69] It cannot be determined in this study if the low percentage were due to decreased clinic visits in this group, inaccurate self-reporting of last Pap, inaccuracy of the KPNW screening rate, or a higher percentage of

unscreened women declining the survey invitation. While 69% of the unscreened study participants indicated interest in returning a home mailed test, an unanswered question is: What will the non-surveyed unscreened women do?

A second limitation is the lack of socioeconomic and ethnic diversity in the sample population. Higher cervical cancer risk and lower screening rates have been shown to be associated with populations of low socioeconomic status.[27,38] However, a previous study of screening barriers in the KPNW Safety Net population found there was a very low correlation between patient socio-demographics and barrier scores.[2] Despite the lack of diversity, response to barrier questions in this study were similar to previous studies where avoidance of pelvic examinations and beliefs regarding the importance of screening were found to be important barriers to Pap tests.[2,35] This suggests that this study's results could be generalizable to more diverse populations in regards to those specific barriers but be unlikely to generalize to diverse populations regarding the barriers of ethnicity, low education, low income and lack of health insurance.

Misclassification of dates of prior Pap tests is highly likely. The study of barriers to screening among Kaiser Safety Net women reported on discrepancy between self-reporting of last Pap and the health plan's database documentation of time of last Pap. The majority of women were correct in their self-reporting with errors of self reporting going in both directions[2,35] but inaccurate self-reporters were more likely to report having services more recently than they actually did.[71] This suggests that this study's unscreened group is smaller than the true number but it does not appear to be an important bias given the statistical significance found on multiple analyses.

Subject bias can be suspected from the cover letter and questionnaire. It was impossible to blind the respondents to the nature of the study. It was obvious that the intent of the study was to determine if women are interested in home testing. A systemic bias may exist to encourage women to respond in favor of home collection testing. However, the differential response of screened women in the questions "Home test more likely" versus "Prefer home test if no medical problem" suggests that women were not automatically answering yes to home testing without carefully considering it.

Response rates might have varied due to the multiple receptionists handing out the survey. Despite verbal and written scripting, the receptionists differed in their attitude, verbal invitation, and frequency of handing out the questionnaire. If they were busy, it was less likely they would request women to fill out the survey. This was particularly a problem in urgency care, which is the busiest area, but also the most likely to have a higher proportion of unscreened women. Despite the potential receptionist bias, it is unlikely this caused women to answer the survey differently with a systematic change in the results, but instead would have just decreased the numbers of members sampled.

Strengths

The most important strength of the study was the overall high response rate. The large number of completed surveys returned, the minimal missing responses, and comments from the receptionists handing out the surveys all indicate that women were interested in participating and the responses were accurate. Although the homogenous population was a limitation in terms of diversity, it was a strength in terms of controlling for demographic variation.

Assuming that HPV testing is eventually approved for primary screening, future research efforts should be directed at more ethnic and socio-economic diverse populations. For example, self-collection kits could be distributed at community sites such as grocery stores and studies done to evaluate the results of this approach. Actual randomized clinic trials could also be conducted on registries of unscreened women and compare their response to screened women.

CONCLUSION

Self-collection HPV testing removes the powerful barrier of pelvic examination in cervical cancer screening. If offered as a mailed, at-home vaginal sampling test, logistic barriers such as the time and transportation needed for a clinic visit are also removed. The results of this survey imply that screening rates in unscreened white/Caucasian educated women with medical insurance could be increased by an at-home self-collected HPV testing method. It is unknown if it is a method that could increase screening in other ethnic groups, particularly Hispanics, immigrants, and the poor, where barriers are more varied and numerous.

It is unlikely that implementation of a mailed self-collection testing program will be able to eliminate all barriers and dramatically increase screening rates in low risk populations such as the one studied. One barrier that may not be removed by use of a home self-collection model is the lesser importance ascribed to regular Pap testing as shown in this sample of unscreened women. The low proportion and known fewer medical clinic visits in the unscreened population suggests that response to a mailed self-collection test might be limited. If the actual response to a mailed self-collection

program is similar to an initial mailed survey response rate of 6.5% of the Safety Net (unscreened) registry, a health plan's screening rate might rise only by 1%.[69] If actual completed HPV test response rates are similar to this current survey's 8% unscreened response, (with 69% indicating interest in a self-collected test), then a health plan's screening rate could potentially increase by 5-6%.

Even if offered a simple, convenient method of screening, there will still be women who will not take advantage of it. Given the ease of the self-collection and mailing procedure, it can be hoped that women who are unresponsive to in and out-reach efforts will find it a method they don't refuse. The 91% response of unscreened women indicating they will come in for further testing if they test positive for a self-collected HPV test is encouraging and supports pursuing the concept of self-collection testing.

In summary, cervical cancer screening rates among unscreened insured women in the United States could potentially be incrementally increased by the addition of mailed at-home self-collection HPV testing. In particular, this method appears to be highly acceptable to women who are adverse to pelvic examination and women who find it difficult to arrange time for a clinic appointment. More research needs to be done on a more diverse sample of unscreened women. FDA approval for HPV primary screening as well as for self-collection and mailed test kits will be needed before this type of testing can be implemented for clinical use.

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APPENDIX

June 2005

Dear Member,

As a Kaiser Family Physician and member of our Prevention Workgroup, I am interested in keeping you healthy. Currently I am working on research which looks at potential future ways of testing for cervical cancer.

I ask your help in completing this survey about your opinions of Pap smears and home testing. Results of this survey will contribute to our knowledge about women's preferences and it may influence further research on testing for cervical cancer.

This anonymous survey will take only about 6 minutes. The questions are sensitive and personal, but there is NO name, health record number, or any other identifying information asked for in this survey. If you are not interested in filling out the survey, just place it in the survey box or return it to the receptionist.

If you wish further information about this study or results you may contact me by calling 1-866-420-2244 and leaving me a message and your contact phone number or email.

Thanks for your help!

Carolyn Hokanson M.D.
Family Practice
Cascade Park Medical Office

Notice: Kaiser Permanente is committed to protecting health information about you. Federal laws also protect your privacy. All information that might let someone identify you will be kept private. This survey has no identifying information such as name, health record number or date of clinic visit. The collected survey forms will be destroyed at the end of the study. You may choose to answer this survey or not. If you choose not to, this will not affect your benefits. The results of the collected surveys will be shared with others. Individual survey results will not be shared. By filling out and returning this survey you agree that your survey answers will be used in medical research.

The following is a brief description of what this survey is about.

Cervical cancer is a common cancer. Without treatment it can kill women. The Pap Smear test, when done regularly, can find cancer early when it can still be cured.

Unfortunately, many women do not get regular Pap Smear tests because it involves a clinic visit and a pelvic examination.

Recently it has been discovered that a virus (HPV or Human Papilloma Virus) causes most cervical cancers. There is a test available that detects the presence of HPV types that can cause cervical cancer. It is currently used in certain circumstances such as when the Pap Smear results are unclear.

Perhaps in the future it may be possible for a woman to test herself for HPV by using a vaginal swab or tampon. A positive HPV would indicate a higher chance (greater risk) of developing cervical cancer. Further testing with a clinic visit and pelvic exam would then definitely be needed.

Because the questions are highly sensitive and personal, your privacy is important. You may fill out the questionnaire in the waiting room or, to ensure privacy, in the exam room. Or you may fill it out at home and mail it to me by using the attached envelope.

When finished, place the completed survey in the attached envelope, seal it, and put it in the survey collection box at the reception area. You may also give it to a staff member to put in the box.

Check the best answer for all the following questions or statements.

A Pap Smear test is when a health care provider takes a sample of cells from the cervix, which is the opening to the uterus. The cells are looked at under the microscope to find changes suspicious for cancer. Suspicious changes are then checked further with a biopsy. A Pap Smear may not be needed if you had a hysterectomy or you are over 70.

1. A hysterectomy is an operation in which a woman's uterus is removed. Have you had a hysterectomy?

( ) yes ( ) no

2. How often should most women have a Pap Smear done?

( ) every year ( ) every 2-3 years ( ) every 4-5 years

3. When was your last Pap Smear test? (give your best guess if you don't know)

( ) 3 years or less ( ) 4 to 5 years ago ( ) more than 5 years

4. How important is it to you that you get a Pap test done as often as recommended?

( ) not important ( ) moderately important ( ) very important

The following factors might influence getting a Pap test done.

5. Paying a co-pay makes it difficult for me to get a Pap test.

( ) strongly agree ( ) agree ( ) not sure ( ) disagree ( ) strongly disagree

6. Getting transportation to the clinic for a Pap test is difficult for me.

( ) strongly agree ( ) agree ( ) not sure ( ) disagree ( ) strongly disagree

7. It's difficult for me to schedule time to come to the clinic to get a Pap test.

( ) strongly agree ( ) agree ( ) not sure ( ) disagree ( )strongly disagree

8. I am uncomfortable with having a pelvic examination done.

( ) strongly agree (agree ( ) not sure ( ) disagree ( ) strongly disagree

9. I am uncomfortable having a pelvic exam/Pap done by a male provider.

( ) strongly agree ( ) agree ( ) not sure ( ) disagree ( ) strongly disagree

10. I dislike having a pelvic exam so much that it prevents me from getting a Pap test.

( ) strongly agree ( ) agree ( ) not sure ( ) disagree ( ) strongly disagree

11. I have a physical problem that makes it difficult or painful to have a pelvic/Pap exam. This can include problems such as being overweight, hip pain, arthritis, painful vagina or other kinds of health problems.

( ) strongly agree ( ) agree ( ) not sure ( ) disagree ( ) strongly disagree

12. It is emotionally difficult for me to have a pelvic exam because of difficult past experiences. This may include previous experiences such as sexual abuse, domestic violence, or a bad experience with a pelvic examination in the past.

( ) strongly agree ( ) agree ( ) not sure ( )disagree ( )strongly disagree

13. I do not get Pap tests because I am not worried about getting cervical cancer.

( ) agree with statement ( ) disagree with statement

14. If I have pre-cancer or cancer changes on my cervix, I don't want to know.

( ) agree with statement ( ) disagree with statement

15. If I am told I have an abnormal Pap test, I will refuse to get further testing or treatment.

( ) agree with statement ( ) disagree with statement

Questions about future testing methods

Some medical researchers have suggested a test should be developed so that a woman could do a test in the privacy of her own home. A test of this type would be a swab or tampon that could be inserted into the vagina, removed and placed in a collection tube. There would be clear instructions on how to do the test, and there would be a mailing envelope to send the sample to the lab for testing.

If a home test such as this ever becomes available, indicate your opinion about it.

16. I am willing to do this type of home test and return it by mail.

( ) strongly agree ( ) agree ( ) not sure ( ) disagree ( ) strongly disagree

17. I feel comfortable and confident that I am able to do a home test such as this.

( )strongly agree ( ) agree ( ) not sure ( ) disagree ( )strongly disagree

18. I find vaginal tampons easy to use.

( )strongly agree ( )agree ( )not sure ( )disagree ( )strongly disagree

19. I am more likely to do a home test like this than to come in to the clinic for a Pap test.

( )strongly agree ( )agree ( )not sure ( )disagree ( )strongly disagree

20. If a home test costs less than a Pap test at the clinic, I am more likely to do a home test.

( )strongly agree ( )agree ( )not sure ( )disagree ( )strongly disagree

21. Assuming there is no medical problem (such as vaginal discharge, pelvic pain, or need for birth control, etc), I would prefer doing a home test instead of coming in for a Pap test.

( )strongly agree ( )agree ( )not sure ( )disagree ( )strongly disagree

Assume you do a home test as described above, and you are notified the test is positive. It shows that the Human Papillomavirus (HPV) is present. (A positive test does not show you have cancer, but it does mean that you have a greater chance (higher risk) of having cancer or pre-cancer of the cervix.)

22. If I do a home test and am notified the test is positive, I will make an appointment and come in to the clinic for a pelvic examination and further testing (Pap Smear or exam of the cervix).

( ) definitely will come in (for further testing)
( ) most likely will come in
( ) not sure if I will come in
( ) probably will not come in
( ) definitely will not come in

Here are a few questions about your lifestyle. (fill in blank or check best answer)

23. How old are you? _____ years old

24. What is the highest educational level you completed?

( )elementary or middle school ( )some high school ( )high school
( )some education past high school ( ) completed college or higher

25. Do you smoke?

( ) yes ( ) no

26. What is your sexual preference with partners? Note: even if you have a same- sex partner, you may still be at risk for HPV / cervical cancer and you still need to have Pap tests.

( )male partner ( )female partner ( )both male and female partner
( ) have never had a sexual partner

27. Is English the primary language in your home?
( ) yes ( ) some of the time ( ) no

Thank you very much for your time! Put the completed survey in the envelope and then in the survey box at reception.