Title

Reactions of women underscreened for cervical cancer who received unsolicited human papillomavirus self-sampling kits

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EXPERIENCES AND REACTIONS AMONG UNDERSCREENED WOMEN WHO DID AND DID NOT RETURN UNSOLICITED MAILED HPV SELF-SAMPLING KITS FOR CERVICAL CANCER SCREENING

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Abstract

Objectives—To evaluate experiences and reactions after receiving an unsolicited human papillomavirus (HPV) self-sampling kit in the mail and identify psychosocial correlates of using kits.

Setting—Survey participants were underscreened women aged 30–64 years who were mailed HPV kits as part of a pragmatic trial at Kaiser Permanente Washington, a U.S. integrated health care system.

Methods—Six months after the HPV kit mailing, we invited kit returners and non-returners to complete a web survey that measured psychosocial factors (e.g., cervical cancer/HPV knowledge, attitudes toward screening), experiences, and reactions to kits. We compared responses between kit returners and non-returners.

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Results—Comparing 116 kit returners (272 invited) and 119 non-returners (1083 invited), we found no clinically significant differences in psychosocial factors. Overall, survey respondents showed knowledge gaps in HPV natural history (82% did not know HPV infection can clear on its own) and interpreting HPV test results (37% did not know an HPV-negative result indicates low cancer risk). Kit returners found kits convenient and easy to use (>90%). The most common reason for non-return was low confidence in ability to correctly use a kit, although many non-returners (49%) indicated they would consider future use. Women reported low trust in HPV testing to identify women at high risk for cervical cancer (52% in returners, 42% in non-returners).

Conclusions—Screening programs could improve uptake and acceptability of HPV self-sampling through outreach materials that emphasize the high efficacy of HPV testing for cervical cancer screening and educate patients about how to interpret results.

Keywords

Human Papillomavirus DNA Tests; Early Detection of Cancer; Surveys and Questionnaires; Cervical cancer screening; Embedded research; Pragmatic randomized trial

Introduction

Women who never or rarely attend Pap screening are at increased risk for cervical cancer.[1–3] Pap screening barriers include sociodemographic factors (e.g. race/ethnicity),[4] poor health status,[5,6] logistical difficulties,[7,8] embarrassment,[8,9] and fear of abnormal results.[8,9] Recently expanded U.S. cervical cancer screening guidelines include primary HPV screening (i.e., HPV alone) as an additional recommended option for women aged 30–65 years.[10] With primary HPV screening, samples for HPV tests (unlike Pap tests) can be self-collected with comparable accuracy to clinician-collected samples.[11] HPV self-sampling (HPV-SS) is an emerging option that may address known Pap screening barriers.

Numerous studies have shown that women find HPV-SS acceptable,[12] and mailing HPV-SS kits directly to underscreened women in an organized screening program increases screening rates compared to traditional invitations or reminders for Pap screening.[11] However, little is known about women's reactions to receiving unsolicited HPV-SS kits in the mail, their preferred screening options, future screening intentions after receiving a kit, and how much their willingness to use an HPV-SS kit may be impacted by psychosocial factors such as HPV/cervical cancer knowledge, trust in HPV-SS results, or trust in their physician.[13–15] Better understanding these factors can help healthcare systems optimize mailing HPV-SS kits as a cervical screening outreach strategy.[16–19]

Our objectives were to: (1) measure potential psychosocial correlates of HPV-SS uptake among underscreened women who were randomized to receive a mailed HPV-SS kit as part of a pragmatic trial within a U.S. healthcare system; (2) compare correlates between women who returned and did not return HPV-SS kits; (3) characterize experiences with HPV-SS kit use; (4) identify reasons for non-return; and (5) characterize women's reactions to receiving kits, including screening preferences, future intentions, and trust in HPV-SS.

Materials and Methods

Study population and setting

We conducted this study among women randomized to the intervention arm of the Home-Based Options to Make screening Easier (HOME) pragmatic trial (ClinicalTrials.gov ID:NCT02005510).[20] HOME evaluated whether direct mailing of HPV-SS kits to underscreened women increases cervical cancer screening uptake and cervical pre-cancer detection/treatment compared to usual care. Trial design has been discussed in detail elsewhere.[20] Briefly, from 2014–2017, 16,590 underscreened women (>3.4 years since last Pap) aged 30–64 years with a primary care provider at Kaiser Permanente Washington (KPWA, a large integrated healthcare system in Washington State) were randomized to a control arm (usual care consisting of annual patient reminders to attend Pap screening and ad-hoc outreach by clinics), or an intervention arm (usual care plus a mailed, unsolicited HPV-SS kit and reminders). Kits included an invitation letter, a research information sheet, instructions, two Dacron-tipped swabs, a collection tube, and a pre-paid return envelope to the KPWA lab. HPV test results were entered into the electronic health record (EHR) and provided to women's primary care teams for appropriate follow-up. The study protocol was reviewed and approved by the KPWA Institutional Review Board.

Eligibility and recruitment

From January-July 2015, we mailed survey invitations six months after trial randomization. We used the EHR to identify and recruit women in two groups based on kit return status (hereafter called "kit returners" and "non-returners"). The target sample size (100 per group; 200 total) was determined based on study resources; we estimated 80% power to detect between-group mean scale score differences as small as 0.4 standard deviations. We excluded women who opted out of EHR review after receiving a kit, were undergoing diagnostic follow-up, or were invited to participate in a qualitative interview after an HPV-positive kit result.[19]

We invited women to complete a 5–10-minute web survey about their experience with a "health screening kit" mailed six months prior. The letter included a survey URL, personalized access code, cash incentive, and a toll-free number to request a paper survey or opt out. We randomized women 1:1 to one of two cash incentives: $5 pre-incentive only or $2 pre-incentive plus $10 post-incentive after survey completion. A paper version was mailed if the web survey was not completed within six weeks. We mailed invitations weekly until we reached the target sample size. In total, 1355 invitations were mailed: 272 to kit returners and 1,083 to non-returners. The web survey was hosted on Qualtrics (Provo, UT).

Data collection

Personal Characteristics—We assessed sociodemographic characteristics, health status, length of health plan enrollment, and time since last Pap through EHR data.

Survey Data—Supplemental Figure 1 outlines the order of survey constructs. Unless otherwise noted, item responses used a 5-point Likert scale format. We adapted items from validated questionnaires when possible.[21–29]

The first section measured constructs hypothesized to be correlates of underscreening: knowledge of HPV/cervical cancer (seven items; yes/no response scale);[21] perceived risk of HPV infection and cervical cancer (two items);[30] perceived barriers to Pap testing, (physical, emotional, and structural issues, 11 items), [22,23] and trust in physician recommendation for new health technologies and medical care (two items).

The second section used a skip pattern based on whether the woman remembered 1) receiving a kit, and 2) using the kit and returning it. A picture of the kit was included as a memory aid. Women who did not remember receiving a kit were skipped to the end. We asked kit returners about their experiences (10 items, 8 from a previous study[25] and 2 new items) with the kit itself (instructions, ease of use), including physical (pain, discomfort) and emotional (embarrassment) responses, and feelings about the HPV-SS modality (trust, confidence, convenience). Exploratory factor analysis[31] supported a single factor (eigenvalue=4.47; all factor loadings >0.3). Cronbach's alpha was 0.88, indicating high internal consistency. We assessed reasons for not returning a kit with seven statements covering similar domains to kit returner experience questions, based on items from a previous study.[25] In addition, we identified additional reasons among open-ended responses. Two investigators (CM and RLW) independently reviewed each response before reaching a consensus.

The third section asked women who remembered receiving a kit about three constructs: perceived efficacy of HPV-SS kits to detect HPV infection and women at risk of developing cervical cancer (2 items); intentions to use kits in the future or recommend to others (2 items);[25] and screening preference (1 item),[29] with four response options: Pap, HPV-SS kits, both (no preference), or neither.

Data analysis

Using chi-square tests, we compared personal characteristics between survey responders and non-responders by kit return, and personal characteristics between kit returners and non-returners who completed the survey. For personal characteristics comparisons, we used the EHR to define kit return.

For the following comparisons of psychosocial correlates, we used women's self-reported status to define kit returners and non-returners because we were interested in women's subjective experiences based on their own recall. To compare HPV/cervical cancer knowledge between kit returners and non-returners, we combined responses into an additive index (higher score indicates more correct responses) and compared scores by group using a chi-square test. For women with one (n=17) or two (n=6) missing or "prefer not to answer" responses, those responses were coded as incorrect. Women with more than two missing or "prefer not to answer" knowledge items were dropped from the index (n=2). We estimated mean scale scores to compare perceived risk of HPV/cervical cancer and physician trust by kit return and used two-sided *t*-tests to test for differences.

Because our perceived barriers to Pap screening questions encompassed different structural and emotional barriers rather than a single underlying theoretical construct, we evaluated

each item's association with kit return individually. We compared item responses by kit return using chi-square tests or Fisher's exact test for comparisons with cell sizes <5.

To compare HPV-SS reactions, we compared mean scores for perceived efficacy of HPV-SS kits and future HPV-SS intentions by kit return using t-tests. We used chi-square tests to identify significant differences in reported screening preference between kit returners and non-returners.

Analyses were conducted using Stata 15 (College Station, TX).

Results

Survey response was 43% among kit returners (116/272) and 11% among non-returners (119/1,083). One returner and four non-returners opted out of EHR review after receiving a survey invitation and were excluded from EHR comparisons. Among returners, survey respondents were more likely to be White, non-smokers, and have a longer duration of KPWA enrollment than non-respondents (Table 1). Among non-returners, survey respondents were more likely to be non-smokers than non-respondents. Overall, most survey respondents were non-Hispanic, white, and 50–64 years of age.

Potential correlates of HPV-SS kit uptake

Self-reported kit return—Self-reported kit return was mostly concordant with EHR data. Five women reported returning a kit with no record in the EHR, and one woman reported not returning a kit despite one documented in the EHR. The following comparisons use self-report to define kit return for a total of 120 kit returners and 115 non-returners.

Knowledge—Knowledge scores were similar between kit returners and non-returners (Table 2). Most (89%) knew HPV is sexually transmitted and can be asymptomatic (90%), were aware of the link between HPV and cervical cancer (96%), and knew that a positive HPV test does not necessarily indicate cancer (94%). However, most women did not know HPV infection can resolve without treatment (82%), or that most sexually active women will get HPV (69%), and 37% were not aware that HPV-negative tests indicate low cervical cancer risk. Kit returners were more likely than non-returners to know HPV infection can be asymptomatic (95% vs. 85%) and that an HPV-negative test indicates low cancer risk (63% vs. 52%).

Perceived risk—Overall, respondents perceived themselves at low risk for cervical cancer, and even lower risk for future HPV infection; no difference by kit-return (p=0.94, Table 2).

Physician trust—Most women trusted their provider's medical judgment (60%) and recommendations about new technologies (73%, Table 2). Kit returners were slightly less likely than non-returners to say they trusted their doctor's judgment (53% vs 67%) or recommendations about new technologies and treatments (68% vs 79%).

Perceived Pap barriers—There were few differences between kit returners and non-returners. Most women believed Pap screening is needed in the absence of symptoms (85%)

or sexual activity (72%), and agreed that the benefits of screening outweigh the difficulties (76%) (Table 3). Over half (56%) found Pap tests embarrassing. Most said they intended to get a Pap test despite not always getting around to it (72%), and 42% reported difficulties fitting Pap tests into their schedule. More kit non-returners than returners worried about Pap results (31% vs 20%), found them embarrassing (61% vs. 51%), and worried that Pap tests are painful (30% vs. 22%).

Kit returner experiences

Kit returners were positive about their experiences (Table 4). Most believed the instructions were easy to follow (95%); the kits were easy to use, (94%) convenient (98%), and painless (86%); and swabs were easy to insert (95%). Fewer (70%) were confident they had gotten a good sample, and just over half (58%) said they trusted HPV-SS results.

Reasons for non-return

Among non-returners, 94 (82%) said they remembered receiving a kit in the mail. Of these 94 women, 87 (93%) chose at least one of seven listed reasons for non-return and/or wrote in an open-ended response. Listed reasons included being unsure they could use the kit correctly (38%), not wanting to insert the swab (20%), being embarrassed to use the kit (14%), not trusting kit results (13%), not finding it convenient to use the kit (10%), finding the instructions confusing (9%), and fear that using the kit would be painful (9%). Additional reasons identified in open-ended responses included forgot/did not get around to it (17%) and low perceived risk due to sexual behavior (11%).

Reactions to HPV-SS kits

Perceived efficacy—Kit returners were significantly more confident than non-returners about HPV-SS efficacy ($p<.01$, Table 5). More than half of kit returners believed kits effectively detected HPV infection or identified women at high risk for cervical cancer, compared to roughly 40% of non-returners.

Future screening intentions—Most kit returners (89%) said they would use a kit in the future and would recommend HPV-SS to a friend (79%) (Table 5). Scores were higher among kit returners than women who did not use the kit ($p<.01$), but 49% of non-returners expressed a willingness to try a kit in the future.

Screening preferences—Most kit returners preferred HPV-SS to Pap tests; 66% preferred HPV-SS over Pap; and 21% stated they liked both equally (Table 5). Despite not having used a kit, 30% of non-returners preferred HPV-SS to Pap testing.

Discussion

By surveying underscreened women who received a mailed, unsolicited HPV-SS kit in a pragmatic trial, we found that knowledge of and perceived risk for HPV and cervical cancer, physician trust, and perceived Pap screening barriers did not differ between kit returners and non-returners. Although knowledge about HPV and its association with cervical cancer was generally high, both groups' showed some knowledge gaps about HPV testing and natural

history. Kit users were highly positive about their experiences and would use them again but were not as confident about trusting HPV-SS results. Non-returners lacked confidence in using HPV-SS kits and trust in the test, but half expressed willingness to use a kit in the future. To our knowledge, this is the first survey of women receiving unsolicited HPV-SS kits in a U.S. healthcare system.

As countries transition to primary HPV screening, HPV/cervical cancer knowledge has been identified as a crucial factor in women's acceptance of HPV screening.[32] Women's knowledge of the epidemiology and natural history of HPV was somewhat limited, as the majority of surveyed women did not know that most sexually active women will be infected with HPV over their lifetime, or that HPV can clear on its own. There was also a lack of clarity among surveyed women on the clinical relevance of a negative HPV test. The observed gaps in knowledge of HPV natural history and the meaning of negative HPV tests could adversely impact reactions to HPV screening (including HPV-SS) in the future. Underscreened women in our study also reported low perceived risk of cervical cancer, consistent with other studies.[33] Kit returners and non-returners reported the same low level of perceived risk, suggesting that it is unlikely that perceived risk is driving choices in this population.

Surveys conducted in countries with organized screening programs found the most powerful predictors of Pap underscreening[23] were structural/logistical factors (e.g., forgetting to make an appointment[15] and scheduling difficulties)[13] and emotional factors (e.g., embarrassment).[14,15] These factors were commonly cited by both kit returners and non-returners in our study.

Similar to other studies using convenience samples and in a trial context,[12,14,15,34] kit returners were accepting of kits, found them to be convenient and were not embarrassed to use them, suggesting that HPV-SS kits helped address some logistical barriers to Pap screening. Physician trust was high among both kit returners and non-returners. When implementing their HPV-SS program, Australia emphasized continued clinician engagement.[35,36] Our results indicate that physicians could be important as endorsers and educators in future efforts to increase HPV-SS kit uptake.

Significantly more kit returners than non-returners believed HPV-SS is efficacious; this difference could have influenced women's decisions about using the kit. Compared to other studies of unsolicited mailed HPV-SS kits, women in our survey reported lower levels of trust and confidence. Two surveys conducted within large-scale trials of unsolicited mailed HPV-SS kits in Australia[14] and Finland[13] found roughly 80% of kit returners believed they had collected a sample correctly, compared to 70% in our study. The Finnish survey found 78% percent of kit returners trusted test results,[13] compared to 58% in our study. Nonetheless, most kit returners in our study indicated they preferred HPV-SS to Pap screening and would use and recommend kits in the future. Additionally, a relatively high proportion of non-returners also reported a preference for HPV-SS and intended to self-sample in the future, indicating that many non-returners are still open to the idea of HPV-SS. Future research should focus on ways to increase women's trust in HPV self-sampling kits.

In previous surveys of HPV-SS kit non-returners, the most common reasons for non-return had to do with women's screening eligibility (e.g., prior hysterectomy). The EHR facilitated identification and exclusion of women with recent Pap tests, hysterectomy, or pregnancy. Additional study strengths included recruiting non-returners and asking a broad range of questions to enable robust comparisons with kit returners.

As with similar surveys,[14,15] the response rate among non-returners was low (11%). We attempted to engage non-returners through mailed invitations, reminder calls, and cash incentives, but a large population of women remain unresponsive to Pap reminders, HPV-SS kits, or survey invitations. Responses from non-returners who participate in a survey may not be representative of women who are less engaged with the healthcare system. Open-ended responses revealed several additional reasons for non-return (e.g. forgetting and low perceived risk) that could be targeted in future outreach efforts. It is likely that we underestimated the frequency of these reasons by not including them as pre-specified choices. Women in our study were mostly non-Hispanic, white, and residing in urban areas; all were insured and received screening reminders. Therefore, our results cannot be generalized to all racial and ethnic groups, rural populations, or uninsured women. Individual-level data on socioeconomic barriers to screening like income[37] and education[38] were not available for our study. We waited 6 months post-randomization to mail survey invitations. This allowed us to purposively sample kit returners and non-returners, ensuring recruitment did not interfere with the HOME trial's primary outcome measures, and provided an adequate sample size among non-returners, but also meant subsequent (post-kit) experiences, like receiving test results, knowledge-seeking, or inaccurate memory could have influenced women's responses. Our survey excluded most women with positive HPV-SS results because they had been invited to participate in an interview to learn about their experiences.[19] Interview invitees with positive HPV-SS results were similar to kit returners invited to the survey with respect to age, race, and screening history.[19] Interviewees reported intense feelings and emotions upon receiving positive HPV-SS results. Including these women in the survey would possibly have resulted in lower overall levels of trust and confidence among kit returners, although when asked similar questions, interviewees reported similar levels of trust and preferences for HPV-SS to kit returners in our study.[19]

Conclusions

Cervical cancer screening outreach efforts involving HPV-SS should emphasize the accuracy and reliability of self-collected samples and educate women about the high screening efficacy of HPV testing. More research is needed on ways to increase trust and confidence in HPV testing and HPV-SS kits. Women's trust in physicians suggests that physicians may play an important role in educating women and encouraging HPV-SS. The low survey response rate among kit non-returners highlights the need for continued research on new ways to engage underscreened women in screening and research. The heterogeneity in response to mailed HPV-SS kits reported in similar international trials[11] underscores the importance of research on barriers and facilitators to HPV-SS uptake. With several countries (including Australia[35,36] and The Netherlands[39]) now offering HPV-SS for underscreened women as part of their national cervical cancer screening programs, our results suggest potential targets for education and outreach.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

HPV	human papillomavirus
HER	electronic health record

REFERENCES

1. Janerich DT, Hadjimichael O, Schwartz PE, et al. The screening histories of women with invasive cervical cancer, Connecticut. Am J Public Health 1995; 85: 791–794. [PubMed: 7762711]
2. Kinney W, Sung H-Y, Kearney KA, et al. Missed Opportunities for Cervical Cancer Screening of HMO Members Developing Invasive Cervical Cancer (ICC). Gynecol Oncol 1998; 71: 428–430. [PubMed: 9887244]
3. Sung HY, Kearney KA, Miller M, et al. Papanicolaou smear history and diagnosis of invasive cervical carcinoma among members of a large prepaid health plan. Cancer 2000; 88: 2283–2289. [PubMed: 10820350]
4. White A Cancer Screening Test Use — United States, 2015. MMWR Morb Mortal Wkly Rep; 66 Epub ahead of print 2017. DOI: 10.15585/mmwr.mm6608a1.
5. Kiefe CI, Funkhouser E, Fouad MN, et al. Chronic Disease as a Barrier to Breast and Cervical Cancer Screening. J Gen Intern Med 1998; 13: 357–365. [PubMed: 9669564]
6. Datta GD, Colditz GA, Kawachi I, et al. Individual-, neighborhood-, and state-level socioeconomic predictors of cervical carcinoma screening among U.S. black women: a multilevel analysis. Cancer 2006; 106: 664–669. [PubMed: 16378349]
7. Catarino RR, Vassilakos PP, Royannez-Drevard II, et al. Barriers to Cervical Cancer Screening in Geneva (DEPIST Study). J Low Genit Tract Dis 2016; 20: 135–138. [PubMed: 26735148]
8. Glasgow RE, Whitlock EP, Valanis BG, et al. Barriers to mammography and pap smear screening among women who recently had neither, one or both types of screening. Ann Behav Med 2000; 22: 223. [PubMed: 11126467]
9. Limmer K, LoBiondo-Wood G, Dains J. Predictors of Cervical Cancer Screening Adherence in the United States: A Systematic Review. J Adv Pract Oncol 2014; 5: 31–41. [PubMed: 25032031]
10. Curry SJ, Krist AH, Owens DK, et al. Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement. JAMA 2018; 320: 674–686. [PubMed: 30140884]
11. Arbyn M, Smith SB, Temin S, et al. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. BMJ 2018; 363: k4823. [PubMed: 30518635]

12. Nelson EJ, Maynard BR, Loux T, et al. The acceptability of self-sampled screening for HPV DNA: a systematic review and meta-analysis. Sex Transm Infect 2017; 93: 56–61. [PubMed: 28100761]
13. Virtanen A, Nieminen P, Niironen M, et al. Self-sampling experiences among non-attendees to cervical screening. Gynecol Oncol 2014; 135: 487–494. [PubMed: 25284037]
14. Sultana F, Mullins R, English DR, et al. Women's experience with home-based self-sampling for human papillomavirus testing. BMC Cancer 2015; 15: 849–849. [PubMed: 26536865]
15. Bosgraaf RP, Ketelaars PJW, Verhoef VMJ, et al. Reasons for non-attendance to cervical screening and preferences for HPV self-sampling in Dutch women. Prev Med 2014; 64: 108–113. [PubMed: 24736093]
16. Darlin L, Borgfeldt C, Forslund O, et al. Comparison of use of vaginal HPV self-sampling and offering flexible appointments as strategies to reach long-term non-attending women in organized cervical screening. J Clin Virol 2013; 58: 155–160. [PubMed: 23867008]
17. Wikström I, Stenvall H, Wilander E. Attitudes to self-sampling of vaginal smear for human papilloma virus analysis among women not attending organized cytological screening. Acta Obstet Gynecol Scand 2007; 86: 720–725. [PubMed: 17520406]
18. Tranberg M, Bech BH, Blaakær J, et al. HPV self-sampling in cervical cancer screening: the effect of different invitation strategies in various socioeconomic groups - a randomized controlled trial. Clinical Epidemiology. Epub ahead of print 23 August 2018. DOI: 10.2147/CLEP.S164826.
19. Tiro JA, Betts AC, Kimbel K, et al. Understanding Patients' Perspectives and Information Needs Following a Positive Home Human Papillomavirus Self-Sampling Kit Result. J Womens Health 2018; 28: 384–392.
20. Winer RL, Tiro JA, Miglioretti DL, et al. Rationale and design of the HOME trial: A pragmatic randomized controlled trial of home-based human papillomavirus (HPV) self-sampling for increasing cervical cancer screening uptake and effectiveness in a U.S. healthcare system. Contemp Clin Trials 2018; 64: 77–87. [PubMed: 29113956]
21. Waller J, Ostini R, Marlow LAV, et al. Validation of a measure of knowledge about human papillomavirus (HPV) using item response theory and classical test theory. Prev Med 2013; 56: 35–40. [PubMed: 23142106]
22. McQueen A, Tiro JA, Vernon SW. Construct Validity and Invariance of Four Factors Associated with Colorectal Cancer Screening across Gender, Race, and Prior Screening. Cancer Epidemiol Prev Biomark 2008; 17: 2231–2237.
23. Waller J, Bartoszek M, Marlow L, et al. Barriers to cervical cancer screening attendance in England: a population-based survey. J Med Screen 2009; 16: 199–204. [PubMed: 20054095]
24. Groeneveld PW, Sonnad SS, Lee AK, et al. Racial Differences in Attitudes Toward Innovative Medical Technology. J Gen Intern Med 2006; 21: 559. [PubMed: 16808736]
25. Kahn JA, Bernstein DI, Rosenthal SL, et al. Acceptability of human papillomavirus self testing in female adolescents. Sex Transm Infect 2005; 81: 408–414. [PubMed: 16199741]
26. Anhang R, Nelson JA, Telerant R, et al. Acceptability of Self-Collection of Specimens for HPV DNA Testing in an Urban Population. J Womens Health 15409996 2005; 14: 721–728.
27. Waller J, McCaffery K, Forrest S, et al. Acceptability of unsupervised HPV self-sampling using written instructions. J Med Screen 2006; 13: 208–213. [PubMed: 17217611]
28. Mitchell S, Ogilvie G, Steinberg M, et al. Assessing women's willingness to collect their own cervical samples for HPV testing as part of the ASPIRE cervical cancer screening project in Uganda. Int J Gynecol Obstet 2011; 114: 111–115.
29. Litton AG, Castle PE, Partridge EE, et al. Cervical Cancer Screening Preferences among African American Women in the Mississippi Delta. J Health Care Poor Underserved 2013; 24: 46–55. [PubMed: 23377716]
30. Gerend MA and Shepherd JE. Predicting human papillomavirus vaccine uptake in young adult women: comparing the health belief model and theory of planned behavior. Ann Behav Med 2012; 44: 171–180. [PubMed: 22547155]
31. Floyd FJ, Wideman KF. Factor Analysis in the Development and Refinement of Clinical Assessment Instruments. Pyschological Assess; 7: 286–299.
32. Patel H, Moss EL, Sherman SM. HPV primary cervical screening in England: Women's awareness and attitudes. Psychooncology 2018; 27: 1559–1564. [PubMed: 29521462]

33. Walsh JC. The impact of knowledge, perceived barriers and perceptions of risk on attendance for a routine cervical smear. Eur J Contracept Reprod Health Care 2006; 11: 291–296. [PubMed: 17484195]

34. Giorgi Rossi P, Fortunato C, Barbarino P, et al. Self-sampling to increase participation in cervical cancer screening: an RCT comparing home mailing, distribution in pharmacies, and recall letter. Br J Cancer 2015; 112: 667–675. [PubMed: 25633037]

35. Farnsworth A Self-sampling HPV testing versus mainstream cervical screening and HPV testing. Med J Aust; 204, https://www.mja.com.au/journal/2016/204/5/self-sampling-hpv-testing-versus-mainstream-cervical-screening-and-hpv-testing (2016, accessed 20 September 2016).

36. Smith M, Lew JB, Simms K, et al. Impact of HPV sample self-collection for underscreened women in the renewed Cervical Screening Program. Med J Aust; 204, https://www.mja.com.au/journal/2016/204/5/impact-hpv-sample-self-collection-underscreened-women-renewed-cervical-screening (2016, accessed 8 May 2016).

37. Calle EE, Flanders WD, Thun MJ, et al. Demographic predictors of mammography and Pap smear screening in US women. Am J Public Health 1993; 83: 53–60. [PubMed: 8417607]

38. Damiani G, Basso D, Acampora A, et al. The impact of level of education on adherence to breast and cervical cancer screening: Evidence from a systematic review and meta-analysis. Prev Med 2015; 81: 281–289. [PubMed: 26408405]

39. Ketelaars PJW, Bosgraaf RP, Siebers AG, et al. High-risk human papillomavirus detection in self-sampling compared to physician-taken smear in a responder population of the Dutch cervical screening: Results of the VERA study. Prev Med 2017; 101: 96–101. [PubMed: 28579497]

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Table 1:

Sociodemographic, health status, and cervical cancer screening history of underscreened women in a U.S. healthcare system who were invited to complete a survey 6 months after receiving an unsolicited mailed HPV kit, by kit return and survey response status

	Kit returners invited to survey					Kit non-returners invited to survey					All survey respondents
	Non-respondents n=155[a]		Respondents n=116		Non-respondents vs. Respondents	Non-respondents n=960[b]		Respondents n=119		Non-respondents vs. Respondents	Kit returners vs. Non-returners
Covariates[c]	**n**	**%**	**n**	**%**	**χ^2 p-value**	**n**	**%**	**n**	**%**	**χ^2 p-value**	**χ^2 p-value**
Age group (years)											
30–39	21	13.6	13	11.2	0.68	161	16.8	24	20.2	0.55	**0.03**
40–49	35	22.6	23	19.8		254	26.5	33	27.7		
50–64	99	63.9	80	69.0		545	56.8	62	52.1		
Race											
White	110	71.0	103	88.8	**0.01**[e]	689	71.8	86	72.3	0.80[e]	**0.02**[e]
Black/African-American	10	6.5	1	0.9		33	3.4	2	1.7		
Asian/Pacific Islander	14	9.0	6	5.2		86	9.0	13	10.9		
Other[d]	14	9.0	5	4.3		81	8.4	11	9.2		
Unknown	7	4.5	1	0.9		71	7.4	7	5.9		
Ethnicity											
Hispanic	6	3.9	3	2.6	0.15[e]	43	4.5	6	5.0	0.85	0.06[e]
Non-Hispanic	141	90.9	112	96.6		848	88.3	106	89.1		
Unknown	8	5.2	1	0.9		69	7.2	7	5.9		
Tobacco use											
Current	28	18.1	7	6.0	**0.02**	143	14.9	10	8.4	**0.01**	0.91
Former	28	18.1	19	16.4		183	19.1	20	16.8		
Never	86	55.5	76	65.5		459	47.8	75	63.0		
Unknown	13	8.4	14	12.1		175	18.2	14	11.8		
Body mass index (in kg/m^2)					0.46					0.15	0.21
<25	42	27.1	43	37.1		235	24.5	35	29.4		

	Kit returners invited to survey					Kit non-returners invited to survey					All survey respondents
	Non-respondents n=155[a]		Respondents n=116		Non-respondents vs. Respondents	Non-respondents n=960[b]		Respondents n=119		Non-respondents vs. Respondents	Kit returners vs. Non-returners
Covariates[c]	**n**	**%**	**n**	**%**	**χ^2 p-value**	**n**	**%**	**n**	**%**	**χ^2 p-value**	**χ^2 p-value**
25–29.9	39	25.2	28	24.1		195	20.3	20	16.8		
30–34.9	23	14.8	16	13.8		126	13.1	21	17.7		
≥35	34	21.9	19	16.4		237	24.7	31	26.1		
Unknown	17	11.0	10	8.6		167	17.4	12	10.1		
Charlson comorbidity score[f]											
0	118	76.1	93	80.2	0.64[e]	773	80.5	98	82.4	0.91[e]	0.90[e]
1	20	12.9	15	12.9		105	10.9	13	10.9		
2	8	5.2	5	4.3		51	5.3	6	5.0		
≥3	9	5.8	3	2.6		31	3.2	2	1.7		
Health Plan Enrollment Duration (years)[g]											
3.4–<5	38	24.5	24	20.7	**0.04**	194	20.2	20	16.8	0.29	**<0.01**
5–<10	44	28.4	20	17.2		297	30.9	45	37.8		
≥10	73	47.1	72	62.1		469	48.9	54	45.4		
Time Since Last Pap (years)[h]											
3.4 to <5	72	46.5	61	52.6	0.56[e]	326	34.0	50	42.0	0.34[e]	0.13[e]
5 to <10	37	23.9	27	23.3		220	22.9	25	21.0		
≥10	18	11.6	8	6.9		91	9.5	8	6.7		
No Prior Pap in EHR	28	18.1	20	17.2		323	33.7	36	30.3		

[a] One kit returner opted out of medical record review after receiving a survey invitation and was excluded.

[b] Four kit non-returners opted out of medical record review after receiving a survey invitation and were excluded

[c] Electronic Health Record covariates are measured as of HOME trial randomization

[d] Includes American Indian/Alaska Native/Native Hawaiian, More than one race, and Other race categories

[e] Used Fisher's Exact Test because cell size<5

[f] Calculated from a weighted index of 19 comorbid conditions

[g] HOME trial eligibility criteria required ≥3.4 years enrollment in health plan

[h] HOME trial eligibility criteria required >3.4 years since last Pap

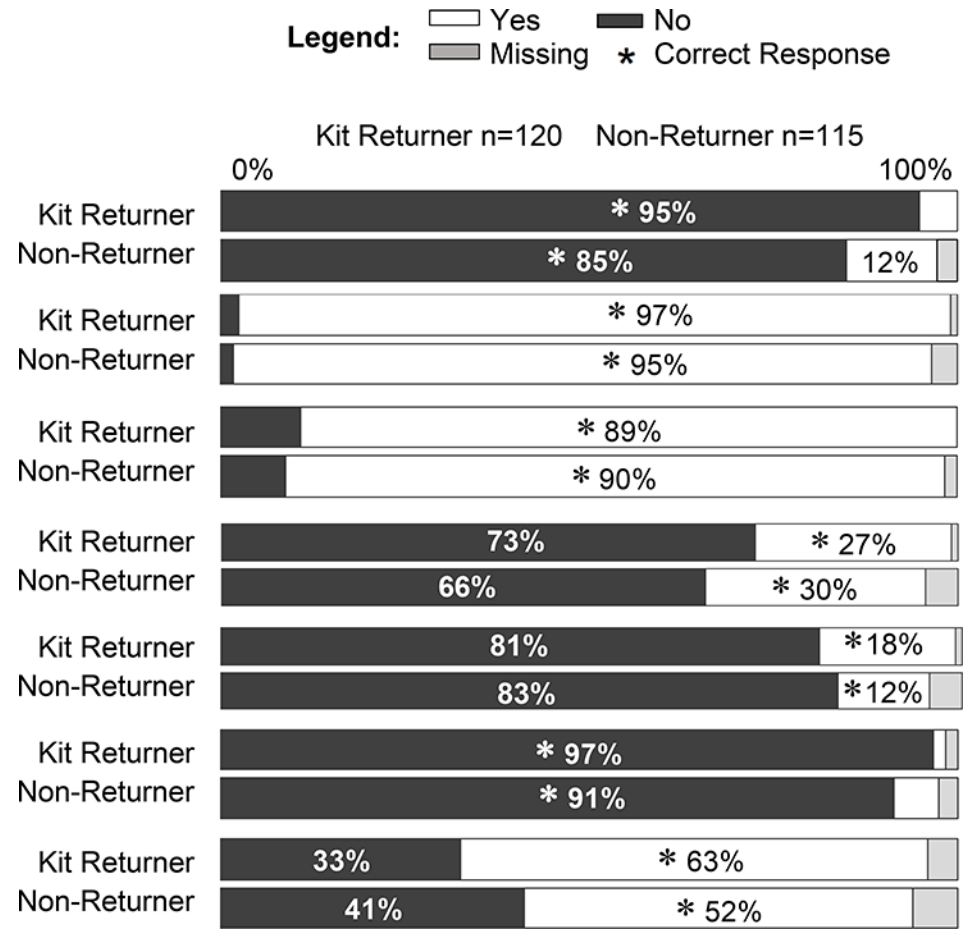
Table 2:

Scores and item responses for potential correlates of HPV self-sampling, by self-reported kit return

HPV/Cervical Cancer Knowledge

HPV/Cervical Cancer Knowledge Items

Prompt: Do you believe that...



"HPV always has visible signs or symptoms?"

"HPV can cause cervical cancer?"

"A person can get HPV from sexual contact?"

"Most sexually active people will get HPV at some point in their lives?"

"HPV infection can go away on its own without treatment?"

"A woman will definitely get cervical cancer if she tests positive for HPV?"

"A woman's risk of cervical cancer is low if she tests negative for HPV?"

Summary Knowledge Index *(missing items coded as incorrect)*	**Total knowledge items answered correctly**	**Kit Returner**		**Non-Returner**[a]	
		n	**(%)**	**n**	**(%)**

0–3 items correct	10	(8%)	9	(8%)
4–5 items correct	81	(68%)	83	(73%)
6–7 items correct	29	(24%)	21	(19%)
		p = 0.56		

Perceived Risk of HPV/Cervical Cancer

Perceived Risk Items

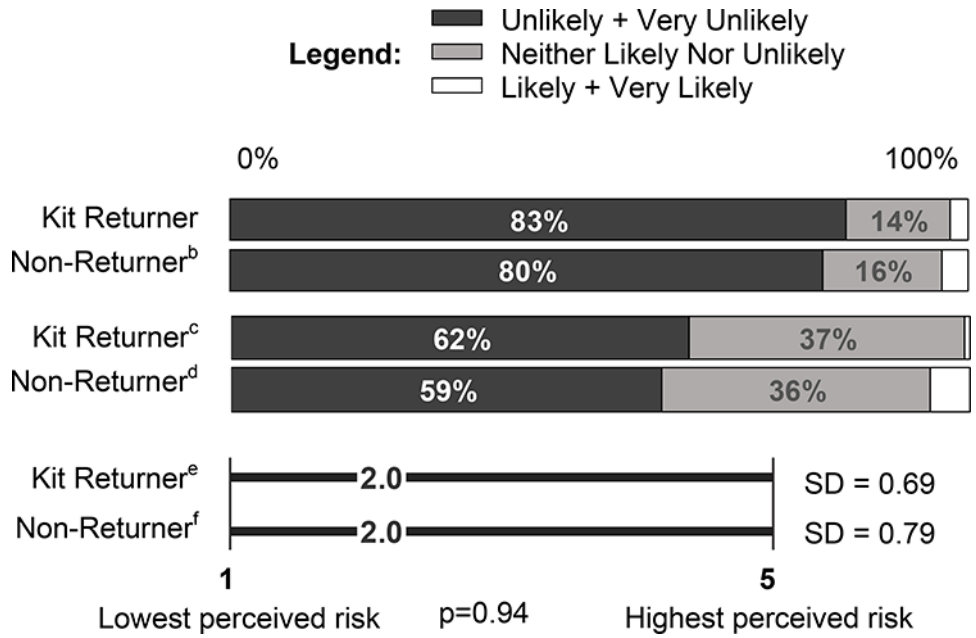
Prompt: How much do you agree or disagree with each statement?

"How likely is it that you will become infected with HPV?"

"How likely is it that you will get cervical cancer?"

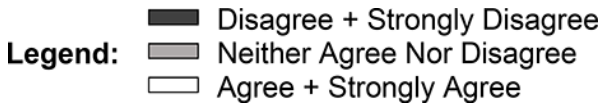
Mean Perceived Risk Scale Scores

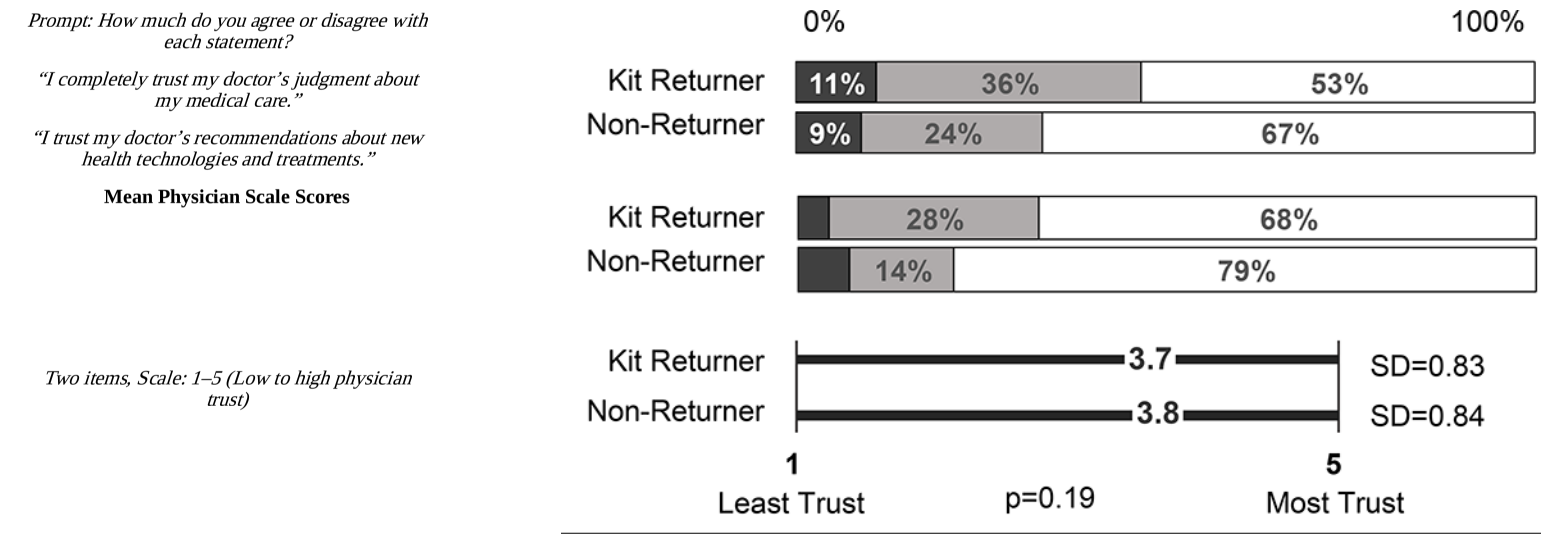
Two items, Scale: 1–5 (Low to high perceived risk)



Trust in Physician Recommendations

Physician Trust Items





HPV: human papillomavirus.

[a] Index was not calculated for 2/115 non-returners who answered <5 of 7 knowledge questions.

[b] Three respondents did not answer this question.

[c] Two respondents did not answer this question.

[d] Four respondents did not answer this question.

[e] Scale scores dropped for two respondents (<80% of items answered).

[f] Scale scores dropped for five respondents (<80% of items answered).

Table 3:

Perceived Pap barriers item responses, by self-reported kit return

Perceived Pap Barriers Items	Legend: Disagree + Strongly Disagree; Neither Agree Nor Disagree; Agree + Strongly Agree	p-value[a]
Prompt: How much do you agree or disagree with each statement?	Kit returner n=120 Non-returner n=115	
"Finding cervical cancer early gives you a better chance for a cure."	0% 100%	0.31[b]
"I am worried that a Pap test might find something wrong."	Kit Returner 98%	0.14
"The benefits of a Pap test outweigh any difficulty I might have getting it done."	Non-Returner 97%	0.79
"Pap tests are embarrassing."		0.33
"I worry that a Pap test will be painful."	Kit Returner 43% 37% 20%	0.06
"I only need a Pap test if I have symptoms."	Non-Returner 37% 31% 31%	0.10[b]
"I have had a bad experience with a Pap test in the past."		0.48
"I only need a Pap test if I'm sexually active."	Kit Returner 10% 13% 78%	0.99
	Non-Returner[c] 11% 15% 74%	
	Kit Returner 32% 18% 51%	
	Non-Returner[c] 25% 14% 61%	
	Kit Returner 62% 17% 22%	
	Non-Returner 46% 24% 30%	
	Kit Returner[c] 88% 9%	
"I trust Pap test results"	Non-Returner 81% 10% 9%	0.52[b]
	Kit Returner[c] 65% 13% 22%	
	Non-Returner[d] 64% 19% 18%	
	Kit Returner[c] 72% 14% 13%	
	Non-Returner[d] 72% 15% 13%	
	Kit Returner[c] 27% 70%	
	Non-Returner[d] 23% 71%	

Perceived Pap Barriers Items		Legend: Disagree + Strongly Disagree; Neither Agree Nor Disagree; Agree + Strongly Agree	p-value[a]
"I intend to get a Pap test when I am due for one, but I don't always get around to it right away"	Kit Returner[d]	16% 13% 71%	0.72
	Non-Returner[e]	13% 14% 73%	
"It is hard to fit a Pap test in with other commitments such as work or child care"	Kit Returner[c]	37% 16% 47%	0.23
	Non-Returner	42% 22% 37%	

[a] Chi-squared test unless noted

[b] Fisher's exact test (cell size <5)

[c] One respondent did not answer this question

[d] Two respondents did not answer this question

[e] Three respondents did not answer this question

Table 4:

Experiences with using HPV self-sampling kits

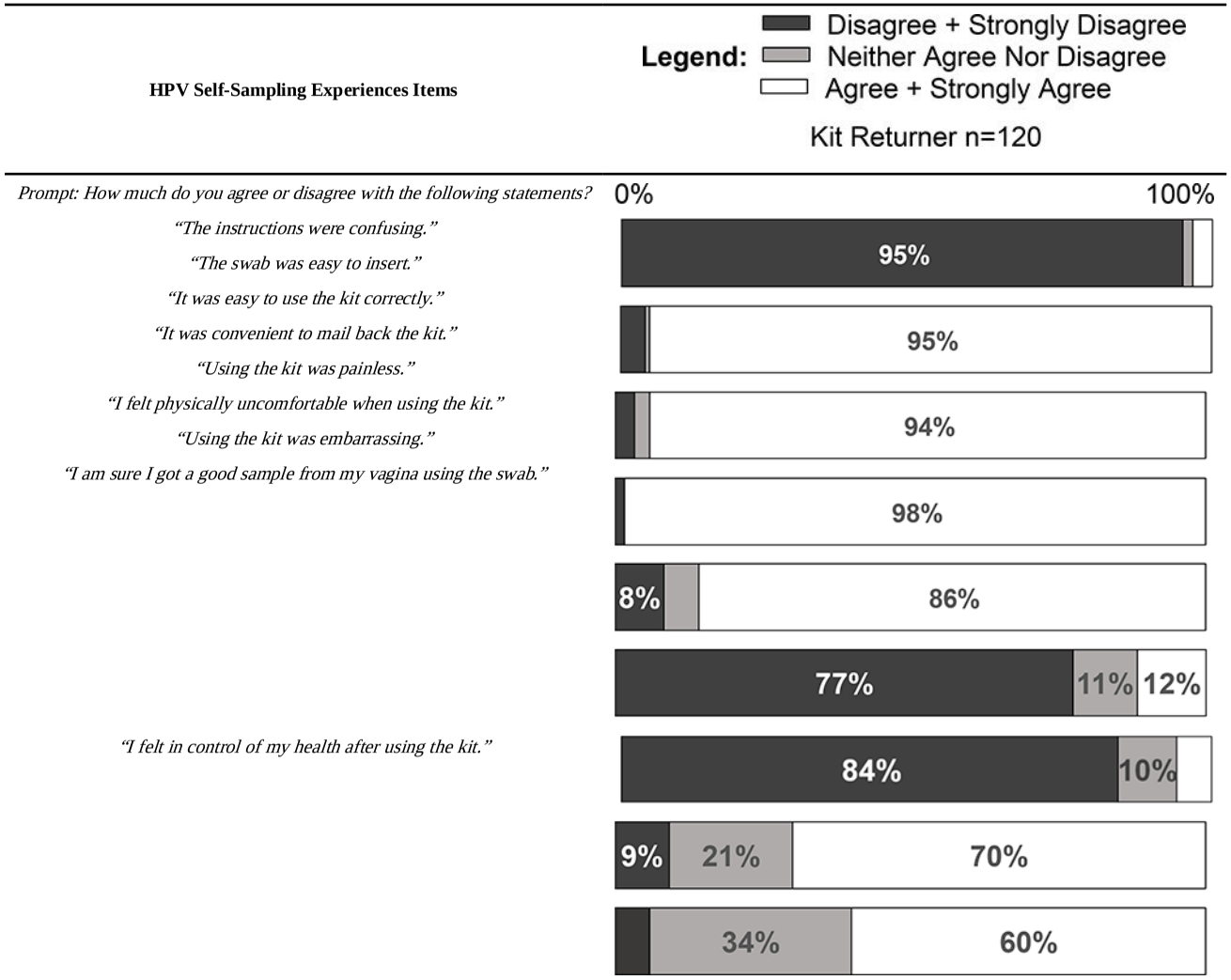
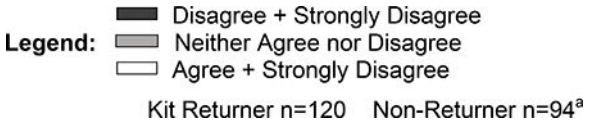


Table 5:

Scores and item responses for reactions to HPV self-sampling kits, by self-reported kit return

Perceived Efficacy of HPV Self-Sampling

HPV Self-Sampling Efficacy Items

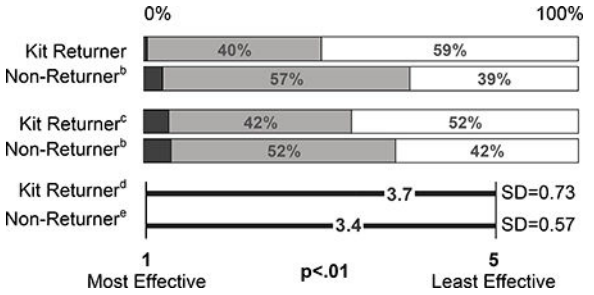


Prompt: How much do you agree or disagree with each statement? The HPV home screening kit is effective at...

":...finding HPV infection."

"...identifying women who are at high risk for cervical cancer."

Mean HPV Kit Efficacy Scale Scores
Two items, Scale: 1–5 (lower to higher perceived efficacy)



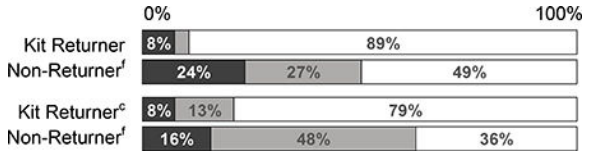
Future HPV Self-sampling Intentions

Future HPV Self-Sampling Intentions Items

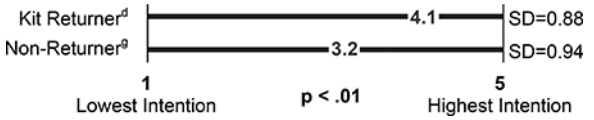
Prompt: How much do you agree or disagree with each statement?

"I would use an HPV home screening kit in the future."

"I would recommend an HPV home screening kit to a friend."



Mean Future Screening Intentions Scale Scores
Two items, Scale: 1–5 (lower to higher intention of HPV self-sampling)



Cervical Cancer Screening Preference

	Kit Returner	Non-Returner
	n=120	n=94[a]

		n	(%)	n	(%)
"Which type of cervical cancer screening test do you prefer?	Pap test in the clinic	13	(11%)	34	(36%)
	HPV kit used at home	79	(66%)	28	(30%)
	Both tests are good-I have no preference	25	(21%)	12	(13%)
	I do not like the Pap or HPV test	1	(1%)	9	(10%)
	Missing	2	(2%)	11	(12%)

HPV: human papillomavirus.

[a] 21 women who did not remember receiving a kit did not receive these questions.

[b] Three respondents did not answer this question.

[c] One respondent did not answer this question.

[d] Scale scores dropped for one respondent (<80% of items answered).

[e] Scale scores dropped for three respondents (<80% of items answered).

[f] Six respondents did not answer this question.

[g] Scale scores dropped for seven respondents (<80% of items answered).

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