

CFPlus. Summary of the literature review

STUDY*	COUNTRY OF STUDY	STUDY CHARACTERISTICS	OUTCOMES AND FINDINGS
RCTs			
• Harper et al, ¹⁷ 2002	US	<ul style="list-style-type: none"> 103 women who required a colposcopy underwent randomization of the HPV sampling technique Agreement between clinician-directed and self-sampling techniques for high-risk types of HPV was measured 	<ul style="list-style-type: none"> All self-directed samples were equivalent to clinician-directed samples for all CIN disease states High-risk HPV was detected by self- and clinician-directed methods in 83% of the women with CIN2 or CIN3 94% of participants accepted self-sampling for their yearly cervical screening
• Bais et al, ¹⁶ 2007	Netherlands	<ul style="list-style-type: none"> All women who do not attend cervical cancer screening programs were included: those who received a device for high-risk HPV testing (self-sampling group, n=2546) vs those who received an extra recall for conventional cytology (control group, n=284) Self-sampling responders with positive results for high-risk HPV were invited for cytology and colposcopy 	<ul style="list-style-type: none"> Active response was higher in the self-sampling group than in the control group (34.2% vs 17.6%; <i>P</i><.001) Self-sampling responders with positive high-risk HPV results were less likely to have a prior screening history than screening participants were (<i>P</i><.001) High-risk HPV prevalence was similar (8.0% vs 6.8%; <i>P</i>=.11), but CIN2 or higher yield was higher in self-sampling responders vs the control group (1.67% vs 0.97%; OR=2.93, 95% CI 1.48-5.80; <i>P</i>=.0013) Costs per CIN2 or higher lesion detected via self-sampling were in the same range as those calculated for conventional cytological screening (€8836 vs €7599)
• Giorgi Rossi et al, ¹⁸ 2011	Italy	<ul style="list-style-type: none"> Nonresponding women aged 35-64 (N=2480) in 3 programs in Rome, Florence, and Teramo Study split into 4 arms: 2 control groups that received a standard recall letter to do either a Pap test (first group) or HPV test (second group) at the clinic; third group received letters that offered an HPV self-sampler to be requested by telephone; and the fourth group received self-samplers directly at home 	<ul style="list-style-type: none"> Compliance with standard recall was 13.9% Offering an HPV test at the clinic had a non-significant effect on compliance (n=616, RR=1.08; 95% CI 0.82-1.41) Self-sampler requests had the poorest performance: 8.7% (RR=0.62; 95% CI 0.45-0.86) Direct mailing of the self-sampler had the highest compliance: 19.6% (RR=1.41; 95% CI 1.10-1.82) This effect on compliance was observed only in urban areas of Florence and Rome (n=438, RR=1.69; 95% CI 1.24-2.30) but not in Abruzzo (n=178, RR=0.95; 95% CI 0.61-1.50), a prevalently rural area
• Lazcano-Ponce et al, ¹⁹ 2011	Mexico	<ul style="list-style-type: none"> Women of low socioeconomic status aged 25-65. Participants from 540 medically underserved, predominantly rural communities 12330 women randomly allocated to HPV screening and 12731 to cervical cytology Primary end point was CIN2 or higher, detected by colposcopy 	<ul style="list-style-type: none"> HPV prevalence was 9.8% (95% CI 9.1%-10.4%) and abnormal cytology rate was 0.38% (95% CI 0.23%-0.45%) Relative sensitivity of HPV testing was 3.4 times greater (95% CI 2.4-4.9) Positive predictive value of HPV testing for CIN2 or higher was 12.2% (95% CI 9.9%-14.5%) compared with 90.5% (95% CI 61.7%-100%) for cytology Because women at these sites will be screened only a few times in their lives, the high sensitivity of HPV screening is of paramount importance
• Szarewski et al, ²⁰ 2011	UK	<ul style="list-style-type: none"> 3000 women randomly selected from persistent nonresponders (ie, those who had not responded to at least 2 invitations to attend for screening in a primary care trust in London between June 2009 and December 2009) Women randomized to receive either an HPV self-sampling kit or another invitation to attend for cervical cytology 	<ul style="list-style-type: none"> Total response in the self-sampling group for screening was 10.2% vs 4.5% women who attended for cytology screening (statistically significant [<i>P</i><.0001]) Of the 8 women who had positive HPV test results, 7 attended for a cervical test and had a concurrent colposcopy; 3 of them (43%) had CIN2 or higher, with 1 having an invasive cancer (stage 1b) and 1 having CIN3 The relatively high yield of abnormalities found is consistent with that expected among hard-to-reach and relatively high-risk women
• Virtanen et al, ⁷ 2011	Finland	<p>Non-participants in cervical cancer screening in 2008 in Espoo, Finland, were randomized to receive a self-sampling kit (1130 women) or a reminder letter (3030 women)</p>	<ul style="list-style-type: none"> Participation rate in self-sampling arm (29.8%) was statistically significantly higher than in the reminder-letter arm (26.2%) (adjusted RR for participation of 1.13) Total participation in Espoo in 2008 rose substantially after the 2 interventions from 64.0% to 75.4% Participation was lowest among young age groups and immigrants after the primary invitation and after interventions
• Virtanen et al, ²¹ 2011	Finland	<ul style="list-style-type: none"> One municipality (Espoo) of the Finnish screening program After initial invitation, non-attenders randomized to receive a self-sampling kit (2397 women) or another invitation (reminder letter) (6302 women); one-fourth (1315 women) of the reminder-letter group received a self-sampling kit as a third intervention 	<ul style="list-style-type: none"> The adjusted RR for participation by self-sampling as a second intervention in comparison with the reminder-letter arm was 1.21 (95% CI 1.13-1.30) Total attendance increased from 65% to 76% by self-sampling and from 65% to 74% with a reminder letter Combining the interventions (reminder letter and then self-sampling) increased total attendance from 63% to 78% Self-obtained samples more often had HPV-positive test results than provider-obtained ones did (participants after primary invitation and reminder letter), 12% to 13% vs 7% Self-sampling is a feasible option in enhancing the attendance at organized screening, particularly with the addition of a reminder letter
• Wikström et al, ²² 2011	Sweden	<ul style="list-style-type: none"> 4060 women in Sweden aged 39-60 who were non-attendees for Pap test screening for ≥6 y Study group was offered a self-sample device or a recommendation to attend cytological screening; the control group was recommended to attend cytological screening 	<ul style="list-style-type: none"> Participation rate was 39% (771 out of 2000) in the self-sampling group and 9% (188 out of 2060) in the conventional cytology group (<i>P</i><.001) The number of histological CIN2 or CIN3 alterations detected was 0.4% (8 out of 2000) among women offered self-sampling devices and 0.07% (3 out of 4060) in women offered Pap tests The OR for offering self-sampling and HPV testing instead of Pap tests for detection of CIN2 or CIN3 was 5.42 (95% CI 1.30-31.8) Offering self-sampling devices followed by a high-risk HPV test was considerably more effective for detection of histological CIN2 or CIN3 lesions in comparison with offering Pap tests in a midwife clinic to women who do not regularly attend organized screening
• Gök et al, ²³ 2012	Netherlands	<ul style="list-style-type: none"> 26409 non-attending women were randomly assigned to receive a vaginal brush device for high-risk HPV testing by the hybrid capture II method (self-sampling group [n=26145]) or a re-invitation for regular cytology-based screening (recall control group [n=264]) Self-sampling responders with positive test results for high-risk HPV were invited for a physician-taken scrape for cytology and blinded high-risk HPV testing. If cytology results were abnormal, women were referred for colposcopy 	<ul style="list-style-type: none"> Response rate in the self-sampling group was significantly higher compared with the recall control group (30.8% vs 6.5%; <i>P</i><.001) Concordance rate between high-risk HPV detection in self-samples and corresponding physician-taken cervical scrape samples was 68.8% Among women with CIN2 and CIN3, the concordance rates for high-risk HPV positivity between both samples were 95.5% and 93.8%, respectively Adherence at baseline to cytology triage of self-sampling women with positive results for high-risk HPV (89.1%) and colposcopy referral of those with abnormal cytology results (95.8%) was high CIN2, CIN3, and carcinoma yields were 1.5%, 1.0%, and 0.1%, respectively, in self-sampling responders Therefore, offering self-sampled vaginal material with a brush device for high-risk HPV to non-attenders increases attendance to screening, yields high-risk HPV test results that are in very good concordance with those of physician-taken scrapes in women with CIN2 and CIN3, and are effective in detecting CIN2 and CIN3
• Sancho-Garnieret al, ²⁴ 2013	France	<ul style="list-style-type: none"> 22785 women aged 35-69 from very-low-income populations around Marseille who had not responded to an initial invitation for a free Pap test One group randomized to receive a second invitation for a free Pap test; second group was offered a free self-sampling kit for HPV testing 	<ul style="list-style-type: none"> Only 2.0% of women attended for the Pap test; 18.3% of women returned the self-sample for HPV testing (<i>P</i>≤.001) The detection rate of high-grade lesions (CIN2 or higher) was 0.2% in the Pap test group and 1.25% in the self-sampling group (<i>P</i>=.01) Offering self-sampling increased participation rates, and HPV testing increased the detection of cervical lesions (CIN2 or higher) Low compliance to follow-up in the self-sampling group reduces the effectiveness of this screening approach in non-attending women and must be carefully managed

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STUDY*	COUNTRY OF STUDY	STUDY CHARACTERISTICS	OUTCOMES AND FINDINGS
• Broberg et al, ²⁵ 2014	Sweden	<ul style="list-style-type: none"> • Women (8800) aged 30-62 were randomly selected among women without a registered Pap test in the past 2 screening rounds in Sweden • 800 women were offered a high-risk HPV self-test, 4000 were randomized to a telephone call (reported previously), and 4000 constituted a control group (standard screening invitation routine) 	<ul style="list-style-type: none"> • Results were based on intention-to-treat analysis, and cost-effectiveness was calculated as marginal cost per cancer case prevented • Total response rate in the self-testing arm was 24.5%, significantly higher than in the telephone arm (18% [RR= 1.36, 95% CI 1.19-1.57]) and the control group (10.6% [RR= 2.33, 95% CI 2.00-2.71]) • All 9 women who tested positive for high-risk HPV attended for a cervical test and colposcopy • From a health care sector perspective, the intervention will most likely lead to no additional cost
• Sultana et al, ²⁶ 2014	Australia	<ul style="list-style-type: none"> • Women aged 30-69 for whom there is no record of a Pap test (never screened) or the last recorded Pap test was between 5-15 y ago (underscreened) • iPap trial 	<ul style="list-style-type: none"> • Primary outcome is the proportion of women who return an HPV self-sampling kit for those in the self-sampling arm, and notification of a Pap test result for women in the Pap test arm at 3 and 6 mo after mail-out • Secondary outcome is the proportion of women with positive test results who undergo further investigations at 6 and 12 mo after the mail-out of results • The iPap trial will provide strong evidence about whether HPV self-sampling could be used in Australia to improve participation in cervical screening for never-screened and underscreened women
• Cadman et al, ²⁷ 2015	UK	<ul style="list-style-type: none"> • 6000 non-attenders for screening in Newcastle upon Tyne, UK • Primary objective was to determine whether non-attenders were more likely to respond to (group 1) a postal invitation (including kit to collect a self-sample) or (group 2) respond to another invitation for cytology screening • Secondary objective was to determine whether women with abnormal test results would attend for follow-up 	<ul style="list-style-type: none"> • 411 (13%) responded to the intervention (247 [8%] returned a self-sample; 164 [5%] attended for cytology) compared with 183 (6%) who attended for cytology: RR= 2.25; 95% CI 1.90-2.65 (comparator arm) • Of those with positive test results for high-risk HPV (32 [13%]), 19 (59%) subsequently attended cytology screening • Of those in the intervention group who attended cytology screening without returning a high-risk HPV self-sample (n= 164), 5% (n=8) were referred for colposcopy and all attended • In the comparator group, 8 out of 9 who were referred for colposcopy attended • Therefore, nonresponders are statistically significantly more likely to respond to a postal invitation to return a self-collected sample than a further invitation for cytology screening. However, a little more than half followed up for positive HPV test results
• Racey et al, ²⁸ 2015	Canada	<ul style="list-style-type: none"> • 818 eligible women from a small rural community in southwestern Ontario • Women aged 30-70 who were overdue for cervical cancer screening randomized to receive 1 of the following: an at-home self-collected HPV kit, a reminder invitation for Pap testing, or the standard-of-care opportunistic screening • The first 2 groups were also asked demographic and screening history questions. Women randomized to first group were asked about acceptability 	<ul style="list-style-type: none"> • 335 women received a self-collected HPV testing kit; 331 received a reminder letter; and 152 received standard of care • In the HPV self-collection group, 21% (70 of 335) returned the sample and questionnaire and 11% (37 of 335) opted to undergo Pap testing • In total, 32% of women in the HPV self-collection group, 15% (51 of 331) in the Pap invitation group, and 8.5% (13 of 152) in the standard-of-care group were screened • Women who received the self-collected HPV kit were 3.7 (95% CI 2.2-6.4) times more likely to undergo screening compared with the standard-of-care group • In the HPV self-sampling arm, 80% (56 of 70) said they would be very likely to choose self-collected sampling in the future • Providing self-collected sampling for HPV testing was more effective than sending reminder letters to increase screening coverage in under-screened women
• Sewali et al, ²⁹ 2015	US	<ul style="list-style-type: none"> • 63 Somali immigrant women aged 30-70 who had not undergone cervical cancer screening within the past 3 y were randomly assigned to a home HPV test group (intervention) or a clinic Pap test group (control) 	<ul style="list-style-type: none"> • Test completion rates were measured at 3 mo • Participants in the HPV test group were 14 times more likely to complete the test compared with those in the Pap test group ($P= .0002$) • Women who reported having friends or family members to talk about cancer screening were approximately 3 times more likely to complete any screening test than those who did not ($P= .127$) • Participants who reported residing in the US longer were more likely to complete a screening test ($P= .011$)
Systematic reviews			
• Stewart et al, ³⁰ 2007	NA	<ul style="list-style-type: none"> • 25 studies were identified in systematic search of MEDLINE, EMBASE, Cochrane Library, and other sources for evidence related to the efficacy and feasibility of HPV DNA self-collection 	<ul style="list-style-type: none"> • Concordance between samples collected by patients and clinicians was reasonably high in most cases • Women in many countries across various age ranges were successful in collecting samples for HPV DNA testing • In 4 studies, the quality of the cytology from patient samples was as good as clinician samples • The studies that examined acceptability found that women were generally very positive about collecting their own samples, although some concerns were noted • No study evaluated the effect of HPV DNA self-sampling on screening participation rates, early detection, survival, or quality of life
• Racey et al, ³¹ 2013	NA	<ul style="list-style-type: none"> • 10 studies were reviewed (8 from Europe and 2 from North America) to determine to what extent providing self-collected HPV testing increases screening participation in women who were never screened or underscreened for cervical cancer 	<ul style="list-style-type: none"> • Of the 10 studies, 9 employed a randomized design • In all studies, the relative compliance with HPV self-collected testing compared with Pap testing was significantly greater than 1.0 ($P< .01$) • The overall relative compliance was 2.14 (95% CI 1.30-3.52). There was large heterogeneity of screening compliance between studies for both HPV self-testing and Pap testing • HPV self-collected testing statistically significantly improved the participation of women who did not routinely attend cervical cancer screening programs

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Non-experimental studies			
• Pengsaa et al, ³² 1997	Thailand	<ul style="list-style-type: none"> • Questionnaire study • 552 rural women were trained and motivated to use a self-scraping device • After 1 wk, the same women were reexamined by gynecologists using the routine scraping method. Acceptance of the self-scraping device was evaluated 	<ul style="list-style-type: none"> • For self-scraping samples, 13 cases were suspicious for malignancy • For physician-obtained samples, 11 cases were suspicious for malignancy • No false-negative cases were found • In detection of inflammation, self-scraping method was less accurate than examination by a physician • The device was accepted by the women who participated in the study • In the rural areas of developing countries, where medical personnel are not often available, the self-scraping method can be applied
• Chang et al, ³³ 2002	Taiwan	<ul style="list-style-type: none"> • Prospective study • 1194 women were prospectively registered from September 1997 through September 1999 • Compared HPV detection in self-obtained swabs with physician-obtained cervical swabs from the same patients that were analyzed using hybrid capture II assay 	<ul style="list-style-type: none"> • 144 (12.1%) of self-test samples and 155 (13%) of physician-obtained samples had positive results for oncogenetic-associated HPV • The sensitivity of cervical precancer or cancer detection using self-obtained HPV testing was higher (96.3%) as compared with the Pap test (79.2%) ($P < .02$) • The detection correlation of the HPV test between the self-obtained method and physician-obtained method was 93% • It can be used in early identification of high-risk women with cervical precancer and cancer especially in underserved populations
• Dzuba et al, ³⁴ 2002	Mexico	<ul style="list-style-type: none"> • Prospective study • 1069 women aged ≥ 20 y who were eligible for coverage through the Mexican Institute of Social Security provided a self-collected vaginal sample for HPV testing and underwent a Pap test. Afterward, each woman was interviewed about her experience or opinion regarding the 2 procedures 	<ul style="list-style-type: none"> • 93% experienced sufficient privacy with the routine Pap test • 98% reported that privacy was acceptable with the self-sampling • Pap test consistently provoked more discomfort, pain, and embarrassment than self-sampling did • 68% of the women with a test preference chose self-sampling because it is more comfortable (71.2%) and causes less embarrassment (55.8%) • Preference for this method was positively associated with monthly household income
• Forrest et al, ³⁵ 2004	UK	<ul style="list-style-type: none"> • Questionnaire and survey • 200 women of Indian, Pakistani, African-Caribbean, and white British origin were recruited in Manchester, UK • Questionnaire included items on attitudes toward self-sampling and intention to use the test 	<ul style="list-style-type: none"> • Willingness to try to use the test was high • Women did not foresee religious or cultural barriers to self-sampling • Women were concerned about doing the test properly • Concern was greatest in the Indian and African-Caribbean groups • Concern about doing the self-sampling procedure correctly must be addressed if women are to feel confident about the test results and reassured by negative test results
• Anhang et al, ³⁶ 2005	US	<ul style="list-style-type: none"> • Survey • 172 low-income, inner-city, minority women after they underwent an gynecologic examination and self-collection of a sample for HPV DNA testing 	<ul style="list-style-type: none"> • Desirable characteristics of self-sample were as follows: ease of use (69%), less painful procedure (62%), "could do it myself" (56%), and privacy (52%) • Most of the participants (57%) reported that there was nothing they did not like about self-sampling; however, most (68%) preferred the clinician-collected test • Characteristics of those who were more likely to prefer self-sampling: recruited through an STD clinic (57%) vs cancer screening clinic (24%); college education (43%) vs less educated (26%); non-Hispanic (49%) vs Hispanic (28%)
• Kahn et al, ³⁷ 2005	US	<ul style="list-style-type: none"> • Prospective study • 121 females aged 14-21 attending a hospital-based teen health centre; mean age was 17.8 y and 82% were black 	<ul style="list-style-type: none"> • Acceptability of and preferences for self- and clinician-testing were assessed at baseline and 2-wk visits • Scores were significantly lower for self-testing than clinician-testing on the acceptability scale and 3 subscales measuring trust of the test results, confidence in one's ability to collect a specimen, and perceived effects of testing ($P < .01$)
• Karwalajtys et al, ³⁸ 2006	Canada	<ul style="list-style-type: none"> • Questionnaire study • 307 women in Ontario aged 15-49 who were due for a 1-y visit and a new sample of women aged ≥ 50 visiting their family physicians for cervical screening 	<ul style="list-style-type: none"> • Among women aged 15-49, prevalence of HPV was 20.8% (64 of 307) in the vaginal sample group and 17.6% (54 of 307) in the cervical specimen group • Among the women aged ≥ 50, prevalence was 9.9% (15 of 152) in the vaginal sample group and 8.6% (13 of 152) in the cervical specimen group • κ for agreement between sample collection methods was 0.54 for the younger women and 0.37 for the older women (both $P < .001$). • Nearly half of the women preferred self-sampling or had no preference
• Waller et al, ³⁹ 2006	UK	<ul style="list-style-type: none"> • Questionnaire study • 902 women attending either a family-planning clinic or a primary care trust for routine cervical screening • Women carried out self-sampling unsupervised, using a written instruction sheet, and then a clinician did a routine cervical test and HPV test 	<ul style="list-style-type: none"> • Most women found self-sampling more acceptable but lacked confidence that the test had been done correctly • Differences in attitudes were found: married women had more favourable attitudes toward self-sampling than single women did; Asian women had more negative attitudes toward self-sampling than other ethnic groups did • Intention to use self-sampling in the future was very high across all demographic groups
• De Alba et al, ⁴⁰ 2008	US	<ul style="list-style-type: none"> • Prospective study • 1213 Hispanic women in California • Health workers distributed self-collection kits to Hispanic women in the community. Participants collected an unsupervised vaginal sample at home or in the place and time of their preference 	<ul style="list-style-type: none"> • 662 (55%) of participants had Pap tests and the first 386 of these also had a physician-collected samples for HPV retesting • Using physician collection as the criterion standard, self-collection had a sensitivity of 90% and specificity of 88% for identifying high-risk HPV • Compared with physician samples, self-samples had comparable sensitivity for identifying low-grade lesions or higher in the Pap test (50% vs 55%; $P = .45$) but lower specificity (94% vs 79%) • Overall experience with self-sampling was reported as excellent or very good by 64%, and only 2.6% reported having a poor or fair experience
• Soisson et al, ⁴¹ 2008	US	<ul style="list-style-type: none"> • Prospective study • 878 Appalachian women recruited in Utah • 775 were able to submit a self-test sample and a provider-collected sample. Each specimen was assessed for cytologic abnormalities and for high-risk HPV infection 	<ul style="list-style-type: none"> • Both the provider-collected samples (869 of 878 [99%]) and the self-collected specimens (771 of 775 [99%]) provided sufficient material for cytologic analysis • There was sufficient cellular material (DNA) for HPV testing in 724 of 834 (87%) provider-collected samples compared with 690 of 736 (94%) self-collected specimens ($P < .04$) • Endocervical cells were found in 654 of 869 (75%) of the provider-collected samples, compared with 103 of 771 (13%) of the self-collected specimens ($P < .001$) • 142 (19%) women had high-risk HPV DNA detected; of these women, 28 (20%) had HPV detected on the provider-collected specimen only, 51 (36%) on the self-collected specimen only, and 63 (44%) on both specimens • The self-sampling device was sufficient to obtain an adequate number of epithelial cells for cytologic and HPV testing

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• Howard et al, ⁴² 2009	Canada	<ul style="list-style-type: none"> • Focus groups • 11 focus group interviews: each group had 5-9 women aged 35-65 who were married with children: 1 group had Canadian-born, English-speaking lower socioeconomic status women; 2 groups had recent immigrants to Canada (women who spoke Arabic, Cantonese, Dari [Afghani], Somali, or Spanish). One focus group was conducted in English, the others in the native language 	<ul style="list-style-type: none"> • Women generally perceived benefits of self-sampling and a small number thought they might use the method • All groups had some reservations: uncertainty over performing the sampling correctly; fear of hurting themselves; concern about obtaining appropriate material; and concerns about test accuracy • Women preferred testing by a health care professional because they were accustomed to pelvic examinations, it was more convenient, or they trusted the results • Perceptions of self-sampling for HPV were similar across cultures and pertained to issues of confidence in self-sampling and need for physician involvement in care
• Szarewski et al, ¹³ 2009	UK	<ul style="list-style-type: none"> • 3 focus group discussions • 28 women were recruited from a Muslim community centre following a talk given on cervical cancer and HPV. Topic discussions included cervical cancer screening, self-sampling, HPV testing, and a swab self-sampling kit vs a cervicovaginal lavage device 	<ul style="list-style-type: none"> • Participants expressed concern about not doing the test correctly, but thought self-testing might overcome barriers to screening for some women • HPV testing was thought to raise potentially difficult issues relating to trust and fidelity within marriages • There was limited enthusiasm for self-sampling in this group of Muslim women who had mostly attended for cervical screening; but if they were to perform self-testing, they preferred the swab kit over the cervicovaginal lavage device
• Gök et al, ⁴³ 2010	Netherlands	<ul style="list-style-type: none"> • Cohort study (the PROHTECT trial) • 28073 women who had not responded to 2 invitations to the regular cervical screening program • Noord-Holland and Flevoland regions of the Netherlands • December 2006 to December 2007 • 27792 women were assigned to the self-sampling group and invited to submit a self-sample; yield of CIN2 or higher in self-sampling responders was assessed 	<ul style="list-style-type: none"> • Compliance rate in the self-sampling group was significantly higher than in the control group (crude 26.6% vs 16.4%, $P < .001$; adjusted 27.5% vs 16.6%, $P < .001$) • The number of detected CIN2 or higher and CIN3 or higher lesions in self-sampling responders was 99 (1.3%) and 76 (1.0%), respectively • Self-sampling responders who had not participated in the previous round of screening (43%) had increased RRs of CIN2 or higher (RR = 2.04, 95% CI 1.27-3.28) and CIN3 or higher (RR = 2.28, CI 95% 1.31-3.96) compared with self-sampling women who had been screened in the previous round (57%) • Offering self-sampling devices to collect cervicovaginal specimens for high-risk HPV testing to women who did not attend regular screening is a feasible and effective method of increasing coverage in a screening program. The response rate and the yield of high-grade lesions support implementation of this method for such women
• Zehbe et al, ⁴⁴ 2011	Canada	<ul style="list-style-type: none"> • Questionnaire study • 49 community women aged 25-59 were recruited from a First Nation community of the Northern Superior region in northwestern Ontario • Women were provided a vaginal self-sample kit and answered a questionnaire • Self-collected samples were tested for integrity and HPV using optimized molecular biological methods 	<ul style="list-style-type: none"> • Of participants, 87.2% were amenable to future HPV screening by self-sampling • This finding was independent of age, educational level, and a previous history of abnormal Pap test results • The preferred way to learn about sexual health remained through interaction with health care professionals • Using a housekeeping gene, self-sample integrity was 96% • Using PCR-based Luminex typing, 28.6% of participants had positive HPV results, and 16.3% of participants were infected with a high-risk HPV type such as HPV type 16 • In this pilot study of First Nation women, self-sampling and HPV testing was well received and self-sample quality was excellent
• Bosgraaf et al, ¹⁴ 2014	Netherlands	<ul style="list-style-type: none"> • Questionnaire study • 30 130 underscreened women in Netherlands • This study wanted to determine why nonresponders do not attend regular screening, and why they do or do not participate when offered a self-sampling device 	<ul style="list-style-type: none"> • The analysis was based on 9484 returned questionnaires (31.5%) with a self-sample specimen and 682 (2.3%) without • Participants' main reason for non-attendance to screening was that they forgot to schedule an appointment (3068 [32.3%]) • Their main reason to use the self-sampling device was the opportunity to take a sample during their own time-setting (4763 [50.2%]) • 30.9% of the women who did not use the self-sampling device preferred after all to have a cervical test completed instead • Important reasons for using a self-sampling device included convenience and self-control
• Chen et al, ⁴⁵ 2014	Taiwan	<ul style="list-style-type: none"> • Questionnaire study • 500 women attending hospital gynecologic clinics in central Taiwan from June to October 2012 	<ul style="list-style-type: none"> • 297 (59.4%) women had heard of HPV; of these, 69 (23%) had performed self-sampling for HPV and 234 (78.8%) considered cost a priority for HPV self-sampling • Likelihood of HPV self-sampling was determined by having had previous Pap testing, perceiving risk of cervical cancer to be high, being willing to perform self-sampling for HPV, having higher level of HPV-related knowledge, and considering cost to be a priority
• Galbraith et al, ⁴⁶ 2014	US	<ul style="list-style-type: none"> • Telephone survey • 199 women in North Carolina who had not had a Pap test in 4 y and who reported ≥ 1 indicators of economic hardship, such as being uninsured • HPV self-test kits were mailed to low-income, underscreened women their perceptions of self-testing and cervical cancer prevention were assessed 	<ul style="list-style-type: none"> • 55% of women were black; 74% reported annual household incomes of \leq \$20 000 • Trust in HPV self-testing was moderate to high, with 98% agreeing the mailed test was safe • 6% of women preferred HPV self-testing over the Pap test, but 75% had no preference • Trust in and preference for self-testing did not vary by race or income • Compared with white women, black women had lower HPV-related knowledge (OR = 0.46, 95% CI 0.23-0.92) and perceived lower cervical cancer risk in the absence of screening (OR = 0.44, 95% CI 0.22-0.86) • There were similar patterns of disparities for women with very low incomes ($<$ \$10 000) vs relatively higher incomes
• Mullins et al, ⁴⁷ 2014	Australia	<ul style="list-style-type: none"> • Random sample study; telephone survey • 3000 women aged 18-69 in Victoria, Australia • 2526 women answered the questions about self-sampling 	<ul style="list-style-type: none"> • 34.0% preferred to self-sample, 57.2% would not self-sample, and 8.7% were unsure • Preference for self-sampling was significantly stronger for women who had not had a Pap test for ≥ 3 y (64.8%, $P < .001$) or who had never had one (62.1%, $P < .001$) compared with those who were up to date with their Pap tests (27.0%) • Convenience and less embarrassment were key reasons given for self-sampling
• Reiter et al, ⁴ 2014	US	<ul style="list-style-type: none"> • Online survey • Lesbian and bisexual women aged 21-26 (N = 418) who completed an online survey in the autumn of 2013 	<ul style="list-style-type: none"> • A little more than half the women (51%) were willing to use an HPV self-test at home • Women were more willing to use an HPV self-test at home if they were older (OR = 1.16, 95% CI 1.03-1.30) or reported higher levels of worry about getting an HPV-related disease (OR = 1.28, 95% CI 1.01-1.63) • The most common concerns about HPV self-testing at home were using the test incorrectly (70%) and test accuracy (64%)

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STUDY*	COUNTRY OF STUDY	STUDY CHARACTERISTICS	OUTCOMES AND FINDINGS
• Vanderpool et al, ⁴⁸ 2014	US	<ul style="list-style-type: none"> • Exploratory study • 31 Appalachian women aged 30-64 who were overdue for cervical cancer screening were recruited from a primary care clinic in southeastern Kentucky 	<ul style="list-style-type: none"> • 26 of the 31 participants had negative test results for high-risk HPV; 5 of 31 had positive test results • All the women with negative test results declined nurse navigation to Pap testing, whereas 4 of the 5 women with positive test results accepted nurse navigation and received subsequent Pap tests (all results were normal) • Self-sampling for HPV testing was highly acceptable for all of these women
• Arbyn et al, ⁴⁹ 2015	Netherlands	<ul style="list-style-type: none"> • Review article 	<ul style="list-style-type: none"> • PCR-based assays, detecting high-risk HPV DNA, are as accurate on self-samples as on clinician-collected samples. HPV assays, based on signal amplification, are less sensitive and specific on self-samples • Opt-in procedures involving a request for a self-sampler might reduce response rates • An affordable device that can be included with the invitation to all non-attendees might have a stronger effect on participation • In 2016 the Netherlands was the first European country to switch to HPV-based cervical cancer screening, with cytology triage for those with positive HPV test results. This includes sending self-sampling devices to women who do not respond to an invitation for a Pap test by a GP
• Cadman et al, ¹⁵ 2015	UK	<ul style="list-style-type: none"> • A mixed-methods design comprising a survey and 4 focus groups • Women aged 25-64 attending a Hindu temple in London. A total of 185 Hindu women completed surveys and 23 attended focus groups • Survey explored participants' opinions about cervical screening, HPV testing, and HPV self-sample collection devices 	<ul style="list-style-type: none"> • 75% of participants were screened within the past 5 y; 85% had attended college • Barriers to screening included the following: fear of pain or test results, embarrassment, screener's attitude, inconvenient appointment times, and difficulty arranging child care • Older and Indian-born women were less likely to attend for screening • Self-collected sampling had a mixed reception: women were not confident that their sample would be as good as a clinician sample and were concerned about the effects that a positive HPV test result might have on their relationships • Screening attendance in this highly educated group of Hindu women was slightly lower than in the general population (75% compared with 79% in the UK as a whole)
• Crofts et al, ⁵⁰ 2015	Cameroon	<ul style="list-style-type: none"> • Prospective study • 540 women (median age 43 y [range 30-65 y]) from Tiko (city) and Yaounde (low-income neighbourhood) in Cameroon 	<ul style="list-style-type: none"> • High acceptance of HPV self-sampling after information sessions about cervical cancer and HPV • Most women expressed no embarrassment, pain, anxiety, or discomfort (95.6%, 87.8%, 91.3%, and 85.0%, respectively) during the information sessions • Educational interventions on cancer and HPV were associated with high acceptability of HPV self-testing by Cameroonian women
• Montealegre et al, ⁵¹ 2015	US	<ul style="list-style-type: none"> • 2-stage cluster sampling; questionnaire study • 210 women ≥21 y recruited from 2 public ED waiting areas that primarily care for medically underserved populations 	<ul style="list-style-type: none"> • Acceptability of self-sample HPV testing was high (85% reported that they were willing to use the self-test if available) • Women's primary concerns were that sampling might not be done correctly (64%) and that they might not know how to perform sampling (39%)
• Montealegre et al, ⁵² 2015	US	<ul style="list-style-type: none"> • Prospective study • 100 immigrant women (most of them Mexican) who never or sporadically attend for Pap testing in Harris County, Texas • Participants self-collected a cervical sample for HPV testing; those with positive test results for high-risk HPV were referred for follow-up 	<ul style="list-style-type: none"> • Acceptability of self-testing for HPV was high; 99% were willing to use the self-test regularly • Of the 19% who had positive test results for high-risk HPV, 50% obtained clinical follow-up within 3 mo • Primary barrier to follow-up was difficulty obtaining health care coverage • While addressing critical barriers to primary screening, questions remain as to whether uninsured women who test positive for high-risk HPV are able to attend for clinical follow-up in the US
• Sultana et al, ⁵³ 2015	Australia	<ul style="list-style-type: none"> • 4 focus groups with 8-9 participants segmented by age (30-49 and 50-69 y) and screening history (never screened and underscreened) • Women evaluated acceptability, invitation letters, and the test kit for a trial of HPV self-sampling 	<ul style="list-style-type: none"> • Concept of HPV self-sampling had positive response • Appealing features of self-sampling were cost (free), convenience (home-based), and less discomfort (with a swab) than with a Pap test • Small kits that fit in mailboxes were preferred over post office parcel collection • Perceived barriers included concerns about test accuracy and lack of confidence that a home-based test would give the same results as a physician-administered test • Women wanted information on the timing of receipt of the results and information about the organization providing the test

CIN—cervical intraepithelial neoplasia, CIN2—cervical intraepithelial neoplasia grade 2, CIN3—cervical intraepithelial neoplasia grade 3, ED—emergency department, HPV—human papillomavirus, NA—not applicable, OR—odds ratio, Pap—Papanicolaou, PCR—polymerase chain reaction, PROTECT—Protection by Offering HPV Testing on Cervicovaginal specimens Trial, RCT—randomized controlled trial, RR—relative risk, STD—sexually transmitted disease, UK—United Kingdom, US—United States.

*Reference numbers correspond to those in Madzima TR, Vahabi M, Lofters A. Emerging role of HPV self-sampling in cervical cancer screening for hard-to-reach women. *Can Fam Physician* 2017;63:597-601.