ORIGINAL ARTICLE

Human papillomavirus testing by self-sampling: assessment of accuracy in an unsupervised clinical setting

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J Med Screen 2007;**14**:34–42

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Accepted for publication 17 January 2007

Objectives To compare the performance and acceptability of unsupervised self-sampling with clinician sampling for high-risk human papillomavirus (HPV) types for the first time in a UK screening setting.

Setting Nine hundred and twenty women, from two demographically different centres, attending for routine cervical smear testing

Methods Women performed an unsupervised HPV self-test. Immediately afterwards, a doctor or nurse took an HPV test and cervical smear. Women with an abnormality on any test were offered colposcopy.

Results Twenty-one high-grade and 39 low-grade cervical intraepithelial neoplasias (CINs) were detected. The sensitivity for high-grade disease (CIN2+) for the self HPV test was 81% (95% confidence interval [CI] 60–92), clinician HPV test 100% (95% CI 85–100), cytology 81% (95% CI 60–92). The sensitivity of both HPV tests to detect high- and low-grade cervical neoplasia was much higher than that of cytology (self-test 77% [95%CI 65–86], clinician test 80% [95% CI 68–88], cytology 48% [95% CI 36–61]). For both high-grade alone, and high and low grades together, the specificity was significantly higher for cytology (greater than 95%) than either HPV test (between 82% and 87%). The self-test proved highly acceptable to women and they reported that the instructions were easy to understand irrespective of educational level.

Conclusions Our results suggest that it would be reasonable to offer HPV self-testing to women who are reluctant to attend for cervical smears. This approach should now be directly evaluated among women who have been non-attenders in a cervical screening programme.

INTRODUCTION

The National Health Service Cervical Screening Programme has stated that its target is to ensure that 80% of eligible women are screened. Although, overall, this target is being reached, it is recognized that uptake is not consistent throughout the population. In particular, women in inner city areas and from certain ethnic groups are not attending at high levels.[1] Among the reasons cited for the refusal to accept smear tests is the nature of the gynaecological examination itself, which may be embarrassing and culturally unacceptable to some women.[2,3] Specific concerns are that male staff may be present and that the examination will be painful. These issues need to be addressed if uptake of screening is to be improved. In this study, we aimed to assess whether women find screening more acceptable if women collected their own sample instead of a speculum examination carried out by a health-care professional.

To date, studies on human papillomavirus (HPV) self-sampling have been carried out mostly in women with abnormal smears, and a variety of sampling instruments have been used.[4–38] Most importantly, in the majority of studies, the women have taken their samples either under the direct supervision of a health worker, or with verbal instructions given at the time of the sampling. Such studies, therefore, cannot be taken to be representative of the envisaged scenario, in which women would be sent a sampling kit and asked to perform the test in their own home, without supervision. It is not known whether samples taken under such circumstances would be of comparable quality to those taken under supervision; this study attempts to approximate as closely as possible the scenario of self-testing in the home setting.

Most studies have focused thus far on the effectiveness of the self-test to detect the presence or absence of HPV. Few have incorporated measures of the acceptability of the test or assessed attitudes toward self-testing among the women to whom it is given. It has been found that not only do women have genuinely negative experiences either during the smear test or on receipt of their result,[39–41] but there is a general lack of awareness of the link between cervical cancer and HPV.[42,43] These studies have not asked women directly whether they find the test acceptable. This is because there has, up until now, been no alternative to which it can be compared. In the study described here, women were asked to perform a self-test as well as having a health professional carry out the test, and the acceptability of the two methods was compared. The women's stated intention to use the self-test in the future provides an indication of acceptability.

The objectives of this study were to compare the performance of self-sampling with physician sampling for high-risk HPV types, and to assess the acceptability of self-sampling for HPV for the first time in a UK screening setting.

METHODS

This prospective study was carried out between January 2001 and November 2004 at two investigating centres, the Margaret Pyke Centre, which is a large family planning clinic in central London, and Hounslow Primary Care Trust, in West London. Women who were due for a routine screening smear and who had not previously had ablative or excisional treatment of the cervix were eligible, and were either identified opportunistically (at the Margaret Pyke Centre) or from participating Feltham General Practitioners' (GPs) Prior Notification Lists (PNLs). In Feltham, all women listed in the PNLs of participating GPs were informed of the study and invited to contact the investigators if they were interested in attending a research smear clinic held on a particular day each week at a local clinic. The investigators were contacted by 11.5% and 99.2% of these consented to take part in the study. Women at the Margaret Pyke Centre were approached opportunistically in the waiting room, and it is not possible to say what proportion of these agreed to participate. All women received a patient information sheet explaining the study and provided written consent. Approvals were obtained from the Local Research Ethics Committees in Camden and Hounslow.

Before any tests, women were asked to complete a questionnaire which collected demographic and psychosocial information.[44] As described in detail below, the women were then given the self-sampling HPV test kits, followed by samples taken by a doctor or nurse for the cervical smear test and clinician HPV test.

The women were also asked to fill in a questionnaire immediately after testing. This included specific questions regarding the procedural acceptability of the HPV test that the doctor/nurse performed and the HPV self-test. Women were asked which of the two methods they found more acceptable as well as questions about the self-test instructions and intentions to use the test in future.

A third questionnaire was posted to participants one week after they had received the results of their smear and HPV tests. This was designed to investigate the psychological impact of both the smear result and the HPV result. Results of this aspect of the study have been published elsewhere.[42,45]

Diagnostic tests

Women were provided with written instructions detailing how to carry out the self-sampling test. They were advised that the doctor or nurse could not help them or answer questions relating to the performance of the self-test. This ensured that the woman only had access to the same resources as at home, i.e. written information and not an expert. She was then left alone to carry out the procedure.

Following the self-test, a cervical smear and a clinician HPV test were taken on the same visit by the doctor or nurse. The sampling order was always therefore:

(1) Self-sampling HPV test using a cotton swab (Digene kit);
(2) Cervical smear test for cytology using a pointed spatula and endocervical brush;
(3) Clinician HPV test using the Digene Cervical Sampler brush as provided in the Digene Hybrid capture II (HCII) specimen transport medium kit (this HPV test was taken with the speculum *in situ*).

The threshold for a positive cytology result is presented by referral practice, i.e. referral for colposcopy is recommended after a smear showing mild dyskaryosis or worse.[46] In general, since HPV test positivity is not graded, a positive HPV test is used as a criterion for colposcopy referral. Results are then presented for high-grade disease alone, and for all grades of disease.

HPV testing was carried out using the Digene HCII test for both clinician and self-samples. Results were recorded in relative light units (RLU) compared with a 1.0 pg/mL standard. A positive HPV result was defined as a value greater or equal to the standard threshold of 1.0 pg/mL. Staff in the cytology, histopathology and molecular biology laboratories were blinded to other results.

If cytology results, on the same day as the HPV tests, were unsatisfactory, results were used from the repeat cytology where available. Median time for repeat cytology was 78 days (interquartile range [IQR] 69–108). The 12 remaining unsatisfactory cytology results were not included in estimates of cytology accuracy.

Reference tests

Women with either an abnormal cervical smear or a positive HPV test result were offered colposcopy, with biopsy as appropriate as the reference test. In addition, a randomly selected 5% sample of women who tested negative on all three tests were asked to attend for colposcopy, to ascertain whether any disease could be missed by all the tests. A previous study has indicated that this is sufficient verification to ascertain whether any disease was likely to have been missed in the triple negative group.[47]

Histopathology was carried out at the Imperial Cancer Research Fund (Cancer Research UK) laboratory and reported by two histopathologists. Where there was disagreement, a decision was reached by consensus. All colposcopies were carried out by the same colposcopist (AS). Low-grade disease on histopathology was defined as cervical intraepithelial neoplasia (CIN) 1 or less (i.e. including borderline and HPV changes). High-grade disease was defined as CIN 2 and CIN 3 (there were no cases of adenocarcinoma *in situ* or invasive cancer).

Statistical analysis

Comparison of sensitivity and specificity between the self HPV, clinician HPV and cytology tests used paired comparisons for women with and without disease. Two disease levels were used: (i) high-grade disease, (ii) low- and high-grade disease, as determined by reference tests. The 95% confidence intervals (CIs) were calculated using the Wilson method for estimates of sensitivity, specificity, positive predictive value (PPV), negative predicative value (NPV) and for differences between paired test results for sensitivity and specificity. The 95% CIs for comparisons of unpaired proportions for sensitivity and specificity used the Newcombe method for unpaired samples (CIA 2.1.1, Trevor Bryant). Comparisons of PPV and NPVs for the two tests and CI were not calculated since, as Leisenring *et al*[48] have pointed out, for a paired study design these outcomes are correlated, so there is no simple method of estimation of variance of test statistic. All other statistical analyses were undertaken in STATA v9.0.

Univariate logistic regression was used to identify possible risk factors potentially associated with positive self or clinician HPV results. A multivariate logistic regression model was fitted to take into account potential confounding factors. The risk factors age, centre, current smoker, contraceptive method and age of leaving full-time education were

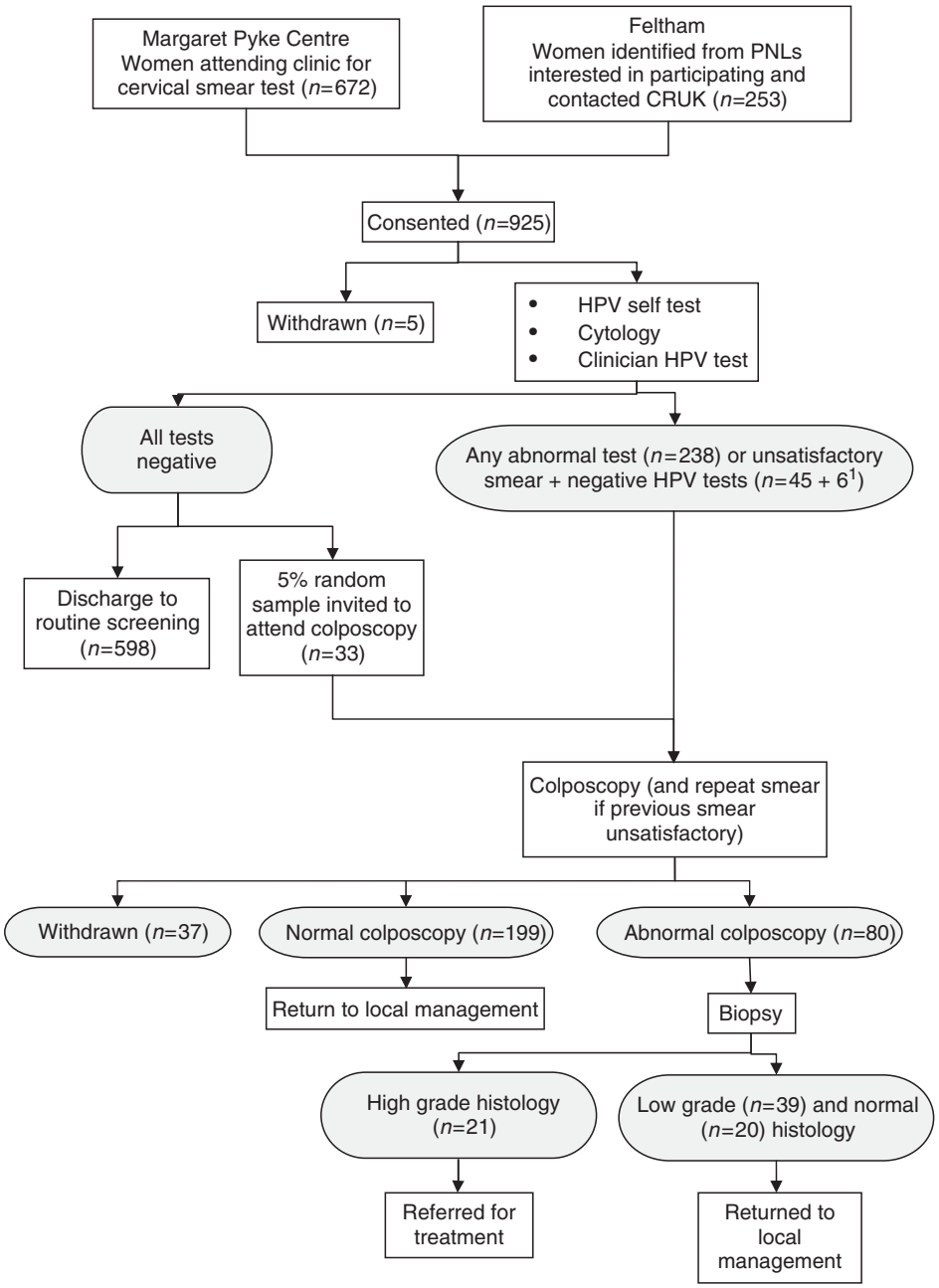
considered. Age was treated as a continuous variable after checking that there was an approximately linear relationship between age and estimates of log odds ratio. All other variables were treated as categorical variables. Analysis was done separately for each HPV test. Relationships are expressed as odds ratios (ORs) and 95% CIs for each risk factor, with significance assessed by *P* values computed from Wald statistics.

The Standards for Reporting of Diagnostic Accuracy checklist for reporting of diagnostic test studies was followed,[49] and we report relevant items from the Quality Assessment of Diagnostic Accuracy Studies quality assessment tool.[50]

RESULTS

Of the 925 women who consented to participate in the study, five withdrew before having all tests taken. Thus, 920 women had all three tests on the same day. The median length of time between the screening tests and colposcopy was 63 days (IQR 49–84, range 1–276); it is unlikely that any abnormalities would alter in that time. The median length of time from date of screening test to receipt of cytology result was 38 days (IQR 28–49, range 9–147), while the median length of time from receipt of cytology result to colposcopy was 26 days (IQR 14–35, range 49 to 226). Figure 1 (flow chart) shows the study recruitment.

Women in the two centres differed considerably in terms of age of leaving full-time education and contraceptive use (Table 1). The majority at Feltham had left education at or before the age of 16 years, and were much less likely to be using hormonal contraception. There were also differences between the two centres in the percentage of women testing positive for HPV with both tests (10% positive with the clinician HPV test in Feltham versus 20% at Margaret Pyke). Figure 2 shows the age distribution of women by HPV test in



[1] 6 participants with unsatisfactory smear + negative HPV tests had repeat smear only (no colposcopy)

Figure 1 Study flowchart. ([1]Six participants with unsatisfactory smear + negative HPV tests had repeat smear only [no colposcopy])

Table 1 Characteristics and test results of participants by centre

	Feltham		Margaret Pyke		Total	
	%	(*n*)	%	(*n*)	%	(*n*)
Age left full time education						
16 years or under	58	(145)	7	(47)	21	(192)
17–18 years	15	(36)	13	(85)	13	(121)
19 years or over	25	(62)	73	(494)	60	(556)
Missing data	2	(5)	7	(46)	6	(51)
Current smokers	23	(57)	28	(187)	27	(244)
Missing data	0	(0)	4	(25)	3	(25)
Contraceptive use						
COC (Combined oral contraceptive pill)	13	(32)	51	(342)	41	(374)
Progestogen	7	(17)	17	(112)	14	(129)
Other*	80	(199)	30	(204)	44	(403)
Unknown	0	(0)	2	(14)	1	(14)
High-grade disease	1	(2)	3	(19)	2	(21)
Low-grade disease	2	(4)	5	(35)	4	(39)
Self HPV test positive	10	(24)	23	(153)	19	(177)
Clinician HPV test positive	10	(24)	20	(136)	17	(160)
Cytology (mild dyskaryosis and above)	4	(10)	6	(41)	6	(51)
Total	100	(248)	100	(672)	100	(920)

*All barrier and other methods grouped

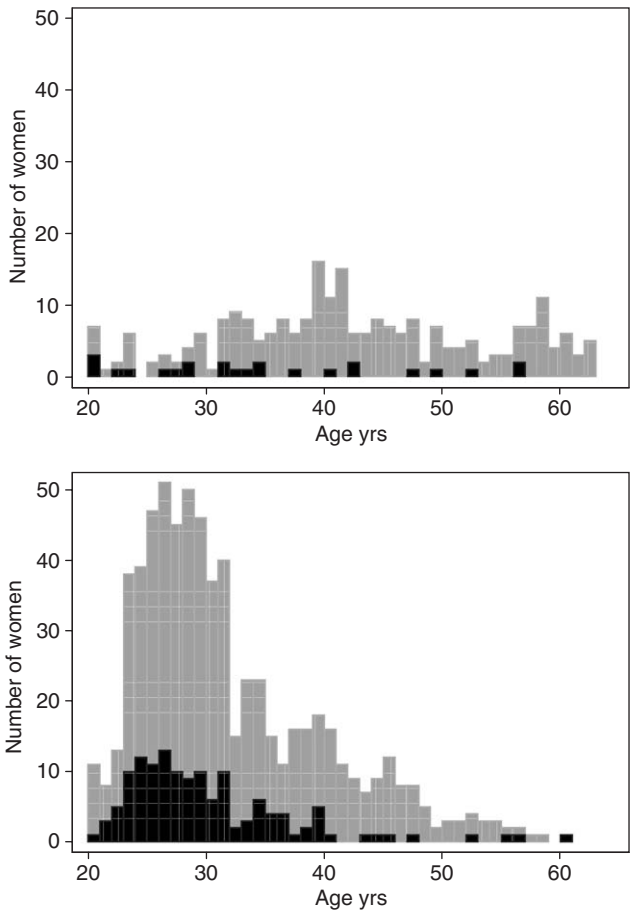


Figure 2 Age distribution of women by HPV result and centre. The age distribution of women by clinician HPV test result: positive HPV test results (black), negative HPV test (grey) for each centre, (A) Feltham (B) Margaret Pyke

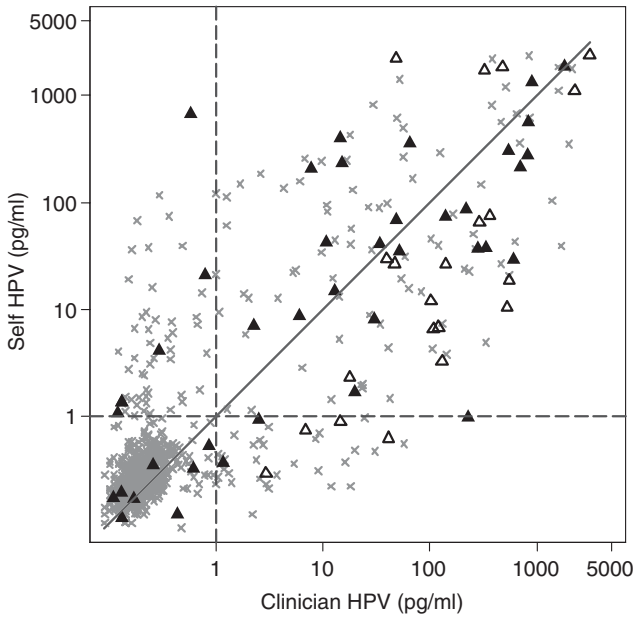


Figure 3 Scatterplot of self and clinician HPV values. HPV test values are shown for 918 women according to self and clinician HPV tests conducted on the same day: Δ, women with high-grade disease; ▲, women with low-grade disease; X, women without disease; -----, corresponds to the standard threshold value (1.0 pg/mL) for a positive HPV test result, and values on or above this line correspond to positive HPV test results; —, corresponds to the line of agreement where values for self and clinician HPV tests are equal

each centre. The women recruited at Margaret Pyke are younger: the median age of 29 years compared with 41 years at Feltham. A higher proportion of younger women have positive HPV results (Figure 2) similar to findings in other studies.[47] This difference in age distributions between the two centres explains the different percentages of women testing positive for HPV (Figure 2).

Figure 3 shows a scatterplot of HPV values from the self and clinician tests for each woman. The test threshold for positive test results is indicated by dotted lines. The test results are symmetrically distributed around the line of agreement for women with at least one positive result, suggesting that overall neither test gives consistently higher values. Of the women with a positive HPV result, 52% (112/214) had higher values on the self-test, while

48% (102/214) had higher values on the clinician sample. From Figure 3, the standard threshold for positive HPV results corresponding to 1.0 pg/mL appears to be an arbitrary value, and a threshold value of 2 or 3 would include a similar number of women with disease.

Figure 4 shows a receiver operating characteristic (ROC) plot of sensitivity and specificity at different threshold values for self and clinician HPV tests for women with high-grade disease. CIs are shown for test thresholds of 1, 4 and 10 pg/mL. The *a priori* test threshold for this study is 1 pg/ml and this graph is for exploratory purposes only, but it does suggest that the sensitivity of the self-test falls off faster at high thresholds than the clinician test. This difference arises from the higher values for the clinician HPV test compared with the self HPV test for women with high-grade disease, a pattern not seen for the total group of 214 women with positive HPV values (Figure 3). Choosing a different threshold based on these data is likely to introduce bias, which will overestimate values of sensitivity, particularly as there are fewer than 50 women with high-grade disease.[51]

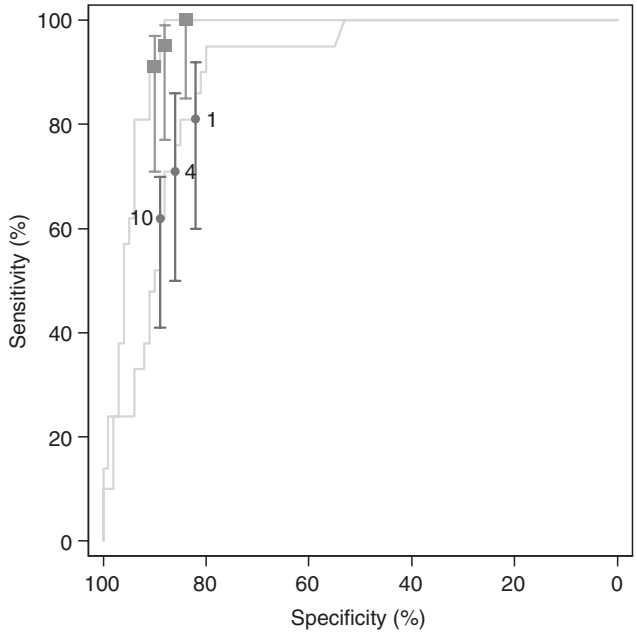


Figure 4 Receiver operating characteristic (ROC) plot of self and clinician HPV test thresholds for women with high-grade disease. ROC plots showing sensitivity and specificity across different thresholds for the self and clinician HPV tests. Sensitivity with its 95% CIs is shown for threshold values corresponding to 1, 4 and 10 pg/mL for self HPV (●) and clinician HPV (■) tests

Test adequacy

There were 61 unsatisfactory cytology smears while there were no unsatisfactory HPV tests (two HPV samples were lost). Thus, cytology has greater potential for requiring recall of women for repeat testing, with all the inconvenience and extra costs this entails.

Test accuracy for diagnosis of high-grade disease

Measures of test accuracy, sensitivity and specificity are compared for their accuracy to diagnose high-grade disease in all three diagnostic tests (Table 2). Sensitivity is compared for the 21 disease positive women and specificity for the 899 women without high-grade disease. The self HPV test gave high values for both sensitivity and specificity, although these were below the values for the clinician test. There is no statistically significant difference between these sensitivity values (19% difference, 95% CI of −0.2–40), but the CI is wide due to the low number of women with high-grade disease in the study. There is a marginally significant difference between the specificity of the self and clinician HPV tests (2% difference, 95% CI of 0.3–4). PPVs and NPVs are similar between the self and clinician HPV tests. There is no statistically significant difference in the sensitivity between cytology and either of the two HPV tests. The specificity of cytology is significantly higher than the specificity of the self HPV test (14% higher, 95% CI of 12–17) and clinician HPV test (12%, 95% CI of 9–14). The NPVs of cytology and the HPV tests are similar, but the PPV of cytology is higher than the PPV for the HPV tests and the CIs do not overlap.

Test accuracy for high- and low-grade disease

Although the primary purpose of this study was to assess the performance of the tests in women with high-grade disease, in practice it is interesting to look at the real-life situation of criteria which would lead to referral for colposcopy. It is recommended that women should be referred for colposcopy after a smear showing mild dyskaryosis or worse.[46] Since HPV tests are not graded, we assume referral for colposcopy after a positive HPV test.

Of the 920 women participating in this study, 60 were diagnosed with either low- or high-grade disease. Measures of test accuracy were calculated for all three tests to identify women with high- and low-grade disease (Table 3). The sensitivity of both HPV tests to detect high- and low-grade disease was much higher than that of cytology (self HPV test 29% higher, 95% CI 13–42; clinician HPV test 32% higher, 95% CI 16–45), whereas the specificity of cytology was

Table 2 Performance of the tests in women with high-grade disease

% (95% CI)	Self HPV test	Clinician HPV test	Cytology (mild dyskaryosis and above)*
Sensitivity	81% (17/21) (60–92%)	100% (21/21) (85–100%)	81% (17/21) (60–92%)
Specificity	82% (739/899) (80%–85%)	85% (760/899) (82–87%)	96% (853/887) (95–97%)
PPV	10% (17/177) (6–15%)	13% (21/160) (9–19%)	33% (17/51) (22–47%)
NPV	99% (739/743) (99–100%)	100% (760/760) (99–100%)	99.5% (853/857) (99–100%)

*12/899 women without high-grade disease had unsatisfactory cytology test results and were not included in calculations of estimates for cytology. There was no evidence of an association between unsatisfactory cytology results and either of the HPV test results

higher (self HPV test 12% lower, 95% CI 10–15; clinician HPV test 10% lower, 95% CI 8–13). Likewise, there was a higher PPV for cytology compared with the HPV tests. The NPVs appear very similar across all the tests.

There was no statistically significant difference between the sensitivity of the self and clinician HPV tests. There was a small difference between the specificity of the self and clinician HPV tests which was just statistically significant (2.2% difference, 95% CI of difference of 0.2–4.3) with self-HPV having a lower specificity.

Comparison of test accuracy in different age groups

Figure 2 demonstrated the importance of age in the frequency of HPV positivity. Table 4 shows that the specificity of both HPV tests as a predictor of disease is significantly higher in women aged 30 years or above (7% difference, 95% CI 3–12 for the clinician HPV test) while maintaining similar sensitivity.

Colposcopy of the randomized triple-negative sample

Thirty-three women who tested negative on all three tests were randomly selected to attend for colposcopy, but only 16 (48%) attended. One of these women was found to have low-grade CIN on biopsy, while the rest of them had a normal colposcopy. This is congruent with previous studies that showed no significant disease is missed by the combination of cytology and HPV testing.[47]

Risk factors for positive HPV test results

Table 5 shows the results from univariate and multivariate logistic regression of risk factors for positive results with each HPV test.

In univariate analyses, contraceptive method and educational level were associated with a positive HPV result for both self-test and clinician test. Multivariate analysis indicated that none of these variables were strong predictors for a positive HPV result. Age was significantly associated with HPV positivity, with an OR decreasing by 6% per year for each test (95% CI 4–8). The results for the self and clinician HPV tests were broadly similar

Acceptability

The self-test proved highly acceptable to women at both clinics, with 73% of women stating that they would prefer to use the self-test at home rather than come to the clinic. Despite the demographic differences between the two populations, over 98% of women in both clinics reported that the instructions were easy to understand. A full report of the findings of the questionnaires on acceptability and perceptions is given elsewhere.[52]

DISCUSSION

This study is unique as it looks at both accuracy and acceptability of unsupervised self-testing and clinician HPV testing, compared with cytology, in a screening population in the UK.

We found no significant difference in sensitivity between the clinician and self HPV tests for women with high-grade disease, although the self HPV test missed four of the 21 women with high-grade disease and the clinician sample missed none. However, the low number of women with high-grade cervical neoplasia in this screening population limits the conclusions that can be drawn from comparisons of the sensitivity of these tests for high-grade disease. For women with high- and low-grade disease, we found that the sensitivity of the clinician and self HPV tests was rather similar. There was a marginal difference in specificity of 2%

Table 3 Performance of the tests in women with high- or low-grade disease

% (95% CI)	Self HPV test	Clinician HPV test	Cytology (mild dyskaryosis and above)*
Sensitivity	77% (46/60) (65–86%)	80% (48/60) (68–88%)	48% (29/60) (36–61%)
Specificity	85% (729/860) (82–87%)	87% (748/860) (85–89%)	97% (826/848) (96–98%)
PPV	26% (46/177) (20–33%)	30% (48/160) (23–38%)	57% (29/51) (43–70%)
NPV	98% (729/743) (97–99%)	98% (748/760) (97–99%)	96% (826/857) (95–97%)

*12/861 women without high- or low-grade disease had unsatisfactory cytology results

Table 4 Comparison of sensitivity and specificity of HPV tests in younger and older age groups (both high- and low-grade disease)

Age groups % (*n*/*N*) (95% CI)	Self HPV sensitivity	Clinician HPV sensitivity	Self HPV specificity	Clinician HPV specificity
20–29years	76% (32/42) (62–87%)	81% (34/42) (67–90%)	80% (270/339) (75–84%)	83% (280/339) (78–86%)
30 years plus	78% (14/18) (53–90%)	78% (14/18) (59–94%)	88% (459/521) (85–91%)	90% (468/521) (87–92%)
Difference between age groups*	2% (−21–24%)	−3% (−28–16%)	8% (4–14%)	7% (3–12%)

*Unpaired proportions

Table 5 Logistic regression of factors leading to positive HPV test result

Risk factor	Self HPV test odds ratio (95% CI), *P* value	Clinician HPV test odds ratio (95% CI), *P* value
Logistic regression: univariate analysis (n = 920)		
Age (per year)	0.94 (0.92–0.96), $P<0.001$	0.94 (0.92–0.96), $P<0.001$
Centre		
Feltham	1	1
Margaret-Pyke	2.75 (1.74–4.35), $P<0.001$	2.37 (1.49–3.76), $P<0.001$
Current smoker		
No	1	1
Yes	1.55 (1.09–2.21), $P=0.014$	1.18 (0.81–1.72), $P=0.39$
Contraceptive method	Overall $P=0.005$	Overall $P=0.02$
Progestogen only	1	1
COC	1.78 (1.04–3.03)	1.25 (0.75–2.10)
Other	1.03 (0.60–1.78)	0.74 (0.44–1.27)
Age left education	Overall $P=0.001$	Overall $P=0.022$
16 years or under	1	1
17 to 18 years	1.26 (0.64–2.49)	1.20 (0.62–2.35)
19 years or above	2.28 (1.40–3.72)	1.85 (1.14–3.00)
Logistic regression: multivariate analysis (n = 855)		
Age per year ($n=855$)	0.95 (0.93–0.98), $P<0.001$	0.95 (0.92–0.97), $P<0.001$
Centre		
Feltham ($n=243$)	1	1
Margaret-Pyke ($n=612$)	1.67 (0.93–3.01), $P=0.09$	1.62 (0.90–2.94), $P=0.11$
Contraceptive method	Overall $P=0.48$	Overall $P=0.91$
Progestogen only ($n=121$	1	1
COC ($n=350$)	1.38 (0.79–2.45)	0.92 (0.53–1.58)
Other ($n=384$)	1.40 (0.78–2.52)	1.00 (0.56–1.76)
Current smoker		
No ($n=621$)	1	1
Yes ($n=234$)	1.36 (0.78–1.99), $P=0.11$	0.98 (0.66–1.46), $P=0.92$
Age left education	Overall $P=0.42$	Overall $P=0.64$
16 years or under ($n=192$)	1	1
17 to 18 years ($n=119$)	0.78 (0.38–1.66)	0.71 (0.34–1.48)
19 years or above ($n=544$)	1.15 (0.63–2.11)	0.88 (0.48–1.62)

(95% CI 0.2–4.3) between the self and clinician tests, in favour of the clinician test. Both HPV tests were at least as sensitive as cytology (equal for high grade, higher than cytology for all grades), emphasizing that this is a viable alternative when clinician-based cytology cannot be obtained. However, specificity was significantly lower for both tests as compared with cytology. The NPV of either HPV test is at least as good as that of cytology ($\geqslant$ to 99% for all tests). Cytology was unsatisfactory in 7% of women, whereas there were no unsatisfactory HPV tests.

On average, the RLU values for both types of HPV test were similar (Figure 3). HPV levels tended to be higher in the clinician samples for the 21 women with high-grade disease and, consequently, there is a higher sensitivity for the clinician HPV test in this group. However, the importance of this difference is unclear as no such difference in HPV levels, between the clinician and self-tests, was seen either in the 39 women with low-grade disease or the 154 women who were HPV positive but without disease. The self HPV test has slightly higher RLU values in women with negative HPV results, but this is not clinically significant and is over-emphasized in Figure 3 due to the log scale. Interestingly, some women had much higher values on the self-test than on the clinician sample, which raises the possibility of sampling having occurred from different genital areas.

There is no evidence that the women recruited through the clinic in a less socio-economically advantaged area (Feltham, Table 1) were less able to perform the self-test. Although more women at the Margaret Pyke Centre had positive HPV results, at each centre, a similar number of women tested positive by both self and clinician tests. In both centres, women found the instruction sheet easy to understand and the self-test highly acceptable.

Although there was low uptake in Feltham, this is not likely to have had an effect on the comparison of self and clinician HPV test results, as both samples were from the same woman. Though there were few women with disease, both the CIN rates and the HPV positivity rates are compatible with those of other screened populations.[47,53] Our results suggest that it would be reasonable to offer home HPV self-testing to women who are reluctant to attend for cervical smears. The sensitivity and NPVs of this test provide evidence that they would not be disadvantaged compared with women who attend for cytological screening. Other studies from our group have suggested that self-sampling would be acceptable to ethnic minority women.[54,55] This approach should now be directly evaluated among women who are non-attenders in the cervical screening programme.

ACKNOWLEDGEMENTS

This study was supported by Cancer Research UK. We thank the staff of the Margaret Pyke Centre and the Manor House Health Centre for their help and support. We thank Dr Hilary Buckley for histopathology review. We also thank the

general practices in Feltham which participated in the study, and the women who volunteered at both centres. HPV testing kits were provided by Digene Corporation.

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