ORIGINAL ARTICLE

Acceptability of unsupervised HPV self-sampling using written instructions

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Objectives The study measured the acceptability of self-sampling for human papillomavirus (HPV) testing in the context of cervical cancer screening. Women carried out self-sampling unsupervised, using a written instruction sheet.

Setting Participants were women attending either a family planning clinic or a primary care trust for routine cervical screening.

Methods Women ($n = 902$) carried out self-sampling for HPV testing and then a clinician did a routine cervical smear and HPV test. Immediately after having the two tests, participants completed a measure of acceptability for both tests, and answered questions about ease of using the instruction sheet and willingness to use self-sampling in the future.

Results The majority of women found self-sampling more acceptable than the clinician-administered test, but there was a lack of confidence that the test had been done correctly. Significant demographic differences in attitudes were found, with married women having more favourable attitudes towards self-sampling than single women, and Asian women having more negative attitudes than women in other ethnic groups. Intention to use self-sampling in the future was very high across all demographic groups.

Conclusion Self-sampling for HPV testing was highly acceptable in this large and demographically diverse sample, and women were able to carry out the test alone, using simple written instructions. Consistent with previous studies, women were concerned about doing the test properly and this issue will need to be addressed if self-sampling is introduced. More work is needed to see whether the demographic differences we found are robust and to identify reasons for lower acceptability among single women and those from Asian background.

INTRODUCTION

Self-sampling methods are used increasingly for a variety of purposes, including diagnostic tests for sexually transmitted infections such as gonorrhoea and chlamydia[1] and screening for bowel cancer using faecal occult blood testing.[2] In recent years, there has been growing interest in the possibility of using self-collection methods to obtain samples for testing for human papillomavirus (HPV) in the context of cervical cancer screening.

The causal link between HPV and cervical carcinoma is now well established,[3] and there is ongoing debate about introducing HPV testing into cervical screening programmes. In the USA, HPV testing is recommended for women aged 30 years and over,[4] and is approved as a method of triaging women with borderline or mildly abnormal cytology.[5] There is also growing interest in the use of HPV testing as a primary screening tool.[6,7]

HPV testing opens up the possibility of self-sampling in cervical screening. Although the major application of this method is likely to be in developing countries with poor screening infrastructure, it might also allow established screening programmes to reach women who have traditionally been missed due to concerns and embarrassment about the intrusive nature of smear tests. Uptake of cervical screening is currently high in England and Wales (over 80%),[8] but there is some evidence that it is lower among women in less-educated and some ethnic minority groups[9,10] and it appears to be decreasing in younger age groups.[11] Self-sampling may potentially help to increase uptake in these hard-to-reach groups, but the success of any self-sampling programme would depend on the method being feasible and acceptable to the target population.

Although there is a sizable literature examining the efficacy of HPV self-sampling devices, there is less research on acceptability. Overall, studies with colposcopy patients,[12,13] as well as women attending for routine cervical screening[14–16] in a range of countries including North America,[12,15,17,18] Mexico,[19] Europe[13,14,20,21] and Gambia,[22] have found self-sampling to be at least as acceptable as clinician-administered sampling for HPV. One exception is a recent Canadian study which found that over half of participants preferred the clinician-administered test.[16] However, no studies of this type have been carried out in Britain, and many previous studies have a variety of limitations. Some have asked women hypothetically about self-sampling, without giving them the chance to try the test.[23] Others have used participation in testing as a proxy for acceptability, but without directly assessing women's experiences of carrying out the test.[22] Importantly, in many studies women have carried out the test under medical supervision and/or received detailed verbal instructions from a clinician.[12,14,15,19,22] High acceptability in this situation cannot be generalized to a 'real life' situation where a woman might be sent the test kit to do the test in her own home, on the basis of only written instructions. With one exception,[19] sample sizes in acceptability studies have been relatively small, and measures of acceptability often rely on response to a single item, or are poorly described.[14,16,17,20]

We sought to overcome these limitations using a British sample. In a large and demographically diverse sample, this

study compared women's attitudes to self-sampling for HPV testing with their attitudes to a smear and HPV test carried out by a clinician. The primary aim of the study was to find out whether self-sampling would be acceptable to women if carried out on their own, with only a written instruction sheet and no additional information from clinicians. The same attitude questions were asked about self-sampling and the clinician-administered tests so that comparisons could be made between the two testing methods.

MATERIALS AND METHODS

The recruitment of participants and clinical methods used for HPV testing and cytology are described in detail elsewhere.[24] All women taking part in the clinical trial of self-sampling described by Szarewski *et al*. were asked to complete a series of psychological measures including one relating to test acceptability, which is the focus of this paper.

Participants

Women were recruited when attending for routine cervical screening at two centres: a large family planning clinic in central London (Centre A) and a primary care trust in west London (Centre B). Women who were due a routine screening smear, and who had not previously had ablative or excisional treatment of the cervix, were eligible to take part in the self-sampling trial and were identified either as they attended the clinic (Centre A) or from Prior Notification Lists (PNL) (Centre B). Due to the recruitment strategy used at Centre A, it is not possible to say what proportion of women agreed to participate, but at Centre B, all women listed in the PNLs of participating general practitioners (GPs) were contacted, and 11.5% took part. The centres were selected to be contrasting in terms of the demographic characteristics of the populations they serve, with Centre A serving a younger, more affluent and better-educated population.

Measures

Women completed a baseline survey prior to participation in the tests. Questions included simple items assessing sociodemographic characteristics. Immediately after the HPV and smear tests, women completed a second measure that covered attitudes to the clinician-administered tests and to the self-sampling. It also assessed intentions to use HPV self-sampling if it were offered to them in the future. The attitude items were rated on a four-point scale (see Table 3 for the wording of the items) and were based on those used in other studies.[19] Following receipt of their test results, women completed a measure of the psychological impact of the test results. These findings are published elsewhere.[25]

Procedure

After completing the baseline survey, all participating women took a self-sample for HPV testing using a cotton swab (Digene kit) and then had a clinician-administered HPV test and cervical smear. They carried out the self-sampling in a room on their own, using a written instruction sheet (available at http://www.ucl.ac.uk/hbu/scales.html). No further information was provided by clinicians. Women were asked to complete the acceptability measure immediately after the two tests.

RESULTS

A total of 920 women took part in the self-sampling study,[24] but 18 (2%) did not complete the acceptability questionnaire and the results presented are therefore for 902 women. The demographic characteristics of the participants are shown in Table 1, separately for the two recruitment centres. The two populations were very different so the overall sample included women from a range of age groups (mean age was 34 years) and socioeconomic background. The majority of women were white and working either full- or part-time. Over half had stayed in full-time education beyond the age of 18 years, and 27% were current smokers.

Acceptability of self-sampling

Responses to the acceptability questions about self-sampling are shown in Table 2. Fewer than 5% of women found the test embarrassing or reported anything more than mild discomfort or slight anxiety. The majority reported feeling 'very' or 'fairly' relaxed while doing the test, and few found the test unpleasant. Over 90% felt 'fairly' or 'very' confident that they had done the test properly. There was a small but significant difference in anxiety between the two centres ($\chi^2[3] = 8.27$, $P = 0.041$). More women at Centre A reported feeling 'not at all anxious' while carrying out self-sampling (77% versus 68%), while more women at Centre B reported feeling 'slightly anxious' (27% compared with 20%).

Women were asked how easy the self-sampling instructions were to understand. Overall, 87% found them 'very easy' and a further 12% found them 'fairly easy'. Importantly, there was no difference in women's understanding of the instructions by educational level.

Women were asked whether they would use HPV self-sampling again in the future, if it were offered. Responses were on a four-point scale (yes definitely, yes probably, probably not, definitely not). Fewer than 5% of women said that they probably or definitely would not use the test again. When asked whether they would rather carry out self-sampling at home or come into the clinic to have a clinician-administered test, 73% said that they would rather do the test at home.

Comparison of self-sampling and the clinician-administered test

A mean score was calculated for each of the acceptability questions for self-sampling and for the clinician-administered test, and these are shown in Table 3. Differences in scores were tested using paired samples *t*-tests. Although scores were similar for the two tests, significant differences were detected, with women finding self-sampling less embarrassing, less uncomfortable, less unpleasant and less anxiety inducing, and reporting that they were more relaxed while doing it. However, they were less confident that the test had been done properly compared with the clinician-administered test.

Difference scores between the two tests were generated for each participant on each attitude item so that the number of women who rated the two tests the same or differently could be calculated. The results of this analysis are shown in Figure 1. Fewer than 10% of women rated self-sampling higher than the clinician-administered test for embarrassment, discomfort, anxiety or unpleasantness and fewer than 10% were more relaxed when having the clinician-administered test than when self-sampling. However, in contrast, only 1.6% of women had a higher

Table 1 Demographic characteristics of the sample ($n = 902$)

Characteristic	Centre A, *n* (%) $n = 657$	Centre B, *n* (%) $n = 245$	All, *n* (%) $n = 902$
Age in years (mean, SD)	31.4 (7.8)	41.9 (11.0)	34.2 (9.9)
Age quartiles			
19–26 years	207 (32)	21 (9)	228 (25)
27–31 years	209 (32)	21 (9)	230 (26)
32–40 years	152 (23)	75 (31)	227 (25)
40 years and over	89 (13)	128 (52)	217 (24)
Martial status			
Married/living with a partner	331 (50)	165 (67)	496 (55)
Single	259 (39)	33 (14)	292 (32)
Separated	30 (5)	27 (11)	57 (6)
Divorced	9 (1)	9 (4)	18 (2)
(Missing)	28 (4)	11 (4)	39 (4)
Age of leaving full-time education			
16 years or under	47 (7)	144 (59)	191 (21)
17–18 years	83 (13)	36 (15)	119 (13)
19 years or over	492 (75)	61 (25)	553 (61)
(Missing)	35 (5)	4 (2)	39 (4)
Smoking status (current smoker)	185 (28)	56 (23)	241 (27)
(Missing)	16 (2)	0	16 (2)
Work status			
Working full-time	503 (77)	117 (48)	620 (69)
Working part-time	58 (9)	74 (30)	132 (15)
Not working	67 (10)	50 (20)	117 (13)
(Missing)	29 (4)	4 (2)	33 (4)
Ethnic group			
White	538 (82)	216 (88)	754 (84)
Black	14 (2)	9 (4)	23 (3)
Asian	22 (3)	8 (3)	30 (3)
Other	42 (6)	5 (2)	47 (5)
Do not wish to answer	10 (2)	3 (1)	13 (1)
(Missing)	31 (5)	4 (2)	35 (4)

confidence rating for self-sampling. In all, 56% were more confident that the clinician-administered test had been done properly, and 39% rated both tests the same.

When asked whether they found self-sampling or the clinician-administered test easier, 71% of women chose self-sampling.

Demographic differences in acceptability

A total attitude score was calculated for each test by adding together scores for embarrassment, discomfort, unpleasantness, anxiety, degree of relaxation (reverse scored) and confidence (reverse scored). Both scales had a possible range of 6–24, with a higher score indicating a more negative attitude. The scales showed internal consistency with Cronbach's α of 0.74 for the clinician-administered test and 0.75 for self-sampling. Differences in scores were examined by each of the demographic characteristics shown in Table 1. No differences were found by education, smoking status or work status. Attitudes to self-sampling did not vary by age, but younger women had significantly more negative attitudes towards the clinician-administered test than did older women ($F(3,882) = 6.05$, $P < .0001$). There were significant differences in attitudes to both tests by marital status. For the clinician-administered test, single women had the most negative attitudes ($F(3,843) = 3.18$, $P = 0.02$) but the effect was no longer significant when age was controlled for. Single and separated women also had the most negative attitudes towards self-sampling ($F(3,846) = 2.97$, $P = 0.03$), and the effect persisted when controlling for age. There were no differences in attitudes to the clinician-administered test by ethnicity, but there were for self-sampling. Asian women had the most negative attitudes (mean score = 9.10, 95% confidence interval [CI]: 8.10–10.11), while white women had the most positive attitudes (mean score = 7.90, 95% CI: 7.76–8.05). Differences between ethnic groups were significant ($F(4,849) = 2.71$, $P = 0.03$). There were no significant differences between the two centres for either of the attitude scores. Despite these variations in attitudes, there were no significant demographic differences in intention to use HPV self-sampling again in the future.

DISCUSSION

In this study of women who carried out HPV self-sampling using only written instructions and without supervision, the test was found to be highly acceptable and, for many women, preferable to a conventional speculum smear test. Fewer than 10% of women rated self-sampling more negatively than the clinician-administered test for any of the outcome measures, and mostly it was seen as the same or better. However, they were more likely to feel confident that the clinician-administered test had been done properly. This is in line with the findings of previous studies[15,19,23] but was unfounded in our study: none of the HPV samples were unsatisfactory, there was no significant difference in sensitivity between self-sampling and the clinician-administered test, and there was only a 2% difference in specificity.[24]

Table 2 Perceptions of self-sampling between centres

	Centre A, *n* (%) *n* = 657	Centre B, *n* (%) *n* = 245	All, *n* (%) *n* = 902
Embarrassment			
Not at all embarrassed	626 (95.3)	229 (93.5)	855 (94.8)
Mildly embarrassed	25 (3.8)	12 (4.9)	37 (4.1)
Very embarrassed	2 (0.3)	0 (0.0)	2 (0.2)
Discomfort			
None at all	550 (83.7)	195 (79.6)	745 (82.6)
Mild discomfort	85 (12.9)	40 (16.3)	125 (13.9)
Quite a lot of discomfort	17 (2.6)	5 (2.0)	22 (2.4)
Severe discomfort	0 (0.0)	1 (0.4)	1 (0.1)
Anxiety			
Not anxious at all	504 (76.7)	164 (66.9)	668 (74.1)
Slightly anxious	130 (19.8)	65 (26.5)	195 (21.6)
Fairly anxious	15 (2.3)	10 (4.1)	25 (2.8)
Very anxious	4 (0.6)	2 (0.8)	6 (0.7)
Unpleasantness			
Not unpleasant	568 (86.5)	214 (87.3)	782 (86.7)
Mildly unpleasant	76 (11.6)	24 (9.8)	100 (11.1)
Fairly unpleasant	5 (0.8)	2 (0.8)	7 (0.8)
Very unpleasant	4 (0.6)	1 (0.4)	5 (0.6
Degree of relaxation			
Not relaxed at all	9 (1.4)	2 (0.8)	11 (1.2)
Not very relaxed	16 (2.4)	13 (5.3)	29 (3.2)
Fairly relaxed	296 (45.1)	118 (48.2)	414 (45.9)
Very relaxed	330 (50.2)	111 (45.3)	441 (48.9)
Confidence test done properly			
Not confident at all	5 (0.8)	4 (1.6)	9 (1.0)
Not very confident	39 (5.9)	7 (2.9)	46 (5.1)
Fairly confident	377 (57.4)	138 (56.3)	515 (57.1)
Very confident	232 (35.3)	92 (37.6)	324 (35.9)

*n*s vary slightly due to missing data. Percentages are calculated using the whole sample so may not add up to 100

Table 3 Acceptability of the two tests (mean scores on a scale of 1–4)

Feeling during the test	Clinician-administered test	Self-sampling	*t*-test for differences
Did you feel embarrassed?	1.50	1.05	$t = 19.68$, df = 892, $P < 0.0001$
Did you feel any discomfort?	1.77	1.19	$t = 22.97$, df = 892, $P < 0.0001$
Did you feel anxious?	1.63	1.29	$t = 12.54$, df = 892, $P < 0.0001$
Did you find the test unpleasant?	1.64	1.14	$t = 19.33$, df = 892, $P < 0.0001$
Are you confident that the test was done correctly?	3.92	3.29	$t = 28.41$, df = 888, $P < 0.0001$
How relaxed were you?	3.06	3.44	$t = -14.13$, df = 883, $P < 0.0001$

Degrees of freedom vary between tests because of missing data

Despite the concern about self-sampling, the majority of women said that they would use it again in the future if offered it, and expressed a preference for carrying out self-sampling at home rather than attending the clinic to have a health professional do the test. Though consistent with one German study,[21] this is in contrast to the views expressed by women in a US study, who said they would rather have a conventional smear test if self-sampling meant that they would have to forego their annual gynaecological check-up.[12] In a more recent US study, although women found self-sampling acceptable, the majority expressed a preference for attending for a smear test rather than doing the test at home, and this was particularly true among less-educated women.[15] The same has been found among adolescents in the USA.[18] The reason for our different findings is unclear, but may have something to do with the longer screening interval in Britain and the fact that smear tests are rarely carried out by a gynaecologist. This means that women in Britain may not use cervical screening as an opportunity to discuss other gynaecological concerns or to have any broader check-ups, as seems to be the case in the USA.

We failed to replicate the previous findings suggesting that acceptability of self-sampling decreases with lower socio-economic status (SES).[15] The reason for this is unclear, but in the US study, it is difficult to disentangle the effects of language and ethnicity from SES, as many of the least-educated women were from Hispanic background. In addition, this low SES Hispanic sample was drawn from a cancer screening clinic, whereas the better-educated women were recruited at a clinic specializing in sexually transmitted infections, and it is possible that this difference in context may have influenced the findings. We did, however, find some demographic variation in attitudes. Older women had

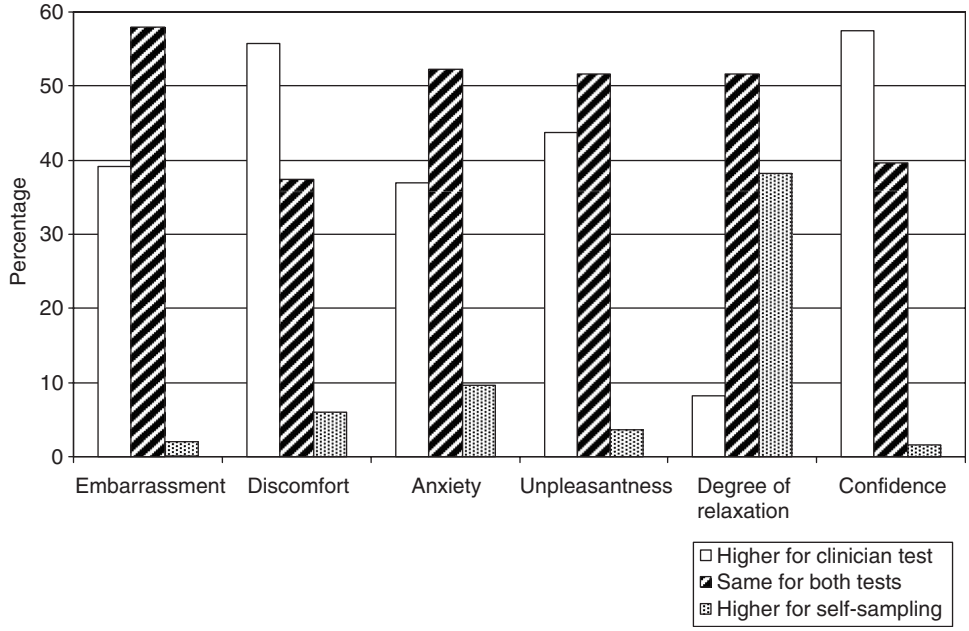

Figure 1 Comparison of women's experiences of self-sampling and the clinician-administered test

more positive attitudes to the clinician-administered test, which may well be due to greater previous experience of smear tests and a higher tolerance of the procedure. The ethnic differences indicate that self-sampling might be less acceptable to women from Asian background, which is important as this is one of the groups suggested to have low attendance at screening.[10] The finding is consistent with Forrest *et al.*'s study,[23] but should be treated with some caution as only 3% ($n = 30$) of our sample was Asian. However, it appears from our data that the provision of self-sampling may not help Asian women engage in cervical screening. The differences by marital status are more puzzling, although they are broadly consistent with the finding that single women have lower levels of cervical screening participation than married women.[9] In our analysis, the marital status differences in attitudes to the clinician-administered test were explained by age, but the differences in attitudes to self-sampling persisted when age was added to the model. This may be important given that screening participation in England is decreasing in younger women, so they might be a possible target for self-sampling. The fact that there were no demographic differences in intentions to use HPV self-sampling in the future, however, may indicate that small differences in attitudes would not be translated into behaviour.

This study benefited from a large sample and a high response rate among women taking part in the clinical trial of testing (98% of women in the trial completed the acceptability measure). The unsupervised setting in which self-sampling was carried out is comparable to a situation where women might be sent the test kit through the post, and the ease with which women seemed able to follow the instructions is very encouraging.

An important limitation of the study is that the women taking part were all attending for a smear test, so we were not able to assess the opinions of women who do not currently participate in screening. However, the very different demographic profiles of the two centres and the consistently high acceptability of self-sampling is encouraging. In the UK, low uptake of screening is associated with lower SES, but our findings suggest that acceptability is high across SES groups. This indicates that if self-sampling were introduced as a way of increasing screening uptake, it should not exacerbate existing social inequalities in screening participation, which is always a concern with new medical technologies. It is likely, though, that non-attenders for screening have other characteristics that might impact on their willingness to use self-sampling, and we cannot be sure what these might be. Given the possible application of self-sampling in targeting hard-to-reach groups, research with non-attenders should be a priority for the future. Self-sampling needs to be evaluated in the home-setting, particularly with women who do not attend for routine screening, to see whether this method is acceptable to under-screened women and can be carried out with confidence away from a clinical setting.

An additional limitation is the low participation rate in the trial at Centre B, and the unknown participation rate at Centre A. This makes the generalizability of the results more uncertain. It is possible that those who refused to take part would not be accepting self-sampling if it were offered outside a trial context.

Implications

This study indicates that self-sampling for HPV testing may be an acceptable alternative or adjunct to conventional smear tests, provided women can be reassured about the quality of the sample and the accuracy of the test results. Women from a wide variety of backgrounds were comfortable carrying out the test, found the written instructions easy to follow, and expressed a willingness to use the test at home in the future.

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