Acceptability of self-collecting vaginal samples in HPValidate and attitudes to self-sampling as a choice in future cervical screening

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December 2023

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EXECUTIVE SUMMARY

> **KEY IMPLICATIONS**
> - Experience of self-sampling is overwhelmingly positive among those who complete a test within a primary care setting.
> - From an acceptability perspective, all three devices used in HPValidate could be considered for future use.
> - Ethnic inequalities in experiences are likely and this may result in variations in choice of self-sampling.

Background and Aims

- If HPV self-sampling is offered in the NHS cervical screening programme, it will be important to ensure the test is acceptable.
- With multiple self-collection devices on offer, some may be more acceptable than others.
- This acceptability study was carried out within HPValidate, a larger study designed to establish the accuracy of self-sampling compared to clinician taken samples.
- We had four aims:
  - *Assess acceptability of using a self-sampling device offered in General Practice*
  - *Measure differences in acceptability between three self-sampling devices*
  - *Explore differences in acceptability by socio-demographic background*
  - *Establish preferences for future testing options*

Methods

- A sample of 2320 women (48%) participating in HPValidate was recruited via GP practices in England.
- Participants completed a survey shortly after completing their self-sample.
- Items assessed overall experience, discomfort, unpleasantness, anxiety, embarrassment, worry about hurting themselves, relaxedness and confidence.
- We also assessed attitudes to being offered a choice of self-sampling vs. clinician screening in the future.

Results

- Overall experience was considered excellent (75.5%) or good (22.7%) by most participants.
- Very few participants reported that they felt a lot of or severe discomfort (1.1%) or that the test was moderately or very unpleasant (2.2%).
- After adjusting for socio-demographic factors, the Evalyn brush was associated with increased odds of reporting 'any discomfort', 'any anxiety' and 'any worry' (about hurting oneself) compared to the FLOQSwabs, but numbers reporting negative outcomes were still low.
- After adjusting for device, some socio-demographic subgroups reported more negative experiences with self-sampling. Notably, women from Asian backgrounds were significantly more likely to report discomfort, unpleasantness, anxiety, embarrassment and worry about hurting themselves.
- Those who had been attending for their first screening test were more likely to report discomfort, unpleasantness, anxiety, embarrassment and worry about hurting themselves than those with previous screening experience.
- Just over half of participants said they preferred the self-test (54.6%), 13.7% said they preferred the test done by a nurse or doctor and 31.7% had no preference or were not sure or didn't know yet.

BACKGROUND

A number of systematic reviews have confirmed that self-sampling for human papillomavirus (HPV) is generally acceptable to women and is often preferred over clinician sampling (Nelson et al, 2017; Yeh et al, 2019; Nodjikouambaye et al, 2020). It has the potential to increase screening participation in under-screened women (Arbyn et al, 2018; D Gennaro et al, 2022). A number of countries have already introduced self-sampling as a choice at the point of invitation for screening, including Australia, Sweden and the Netherlands.

Fewer studies have explicitly compared self-sampling devices. One large Finnish study found similar acceptability for lavage and brush devices (Karjalainen et al, 2016). More recently, a trial in Belgium found similar levels of discomfort reported by women using a plastic brush (Evalyn device) and a cotton swab (De Pauw et al, 2021). By contrast, a qualitative study of Muslim women in London found a swab was more acceptable than a lavage device (Szarewski et al, 2009). A study in Norway found acceptability was higher for the Evalyn brush compared with the FLOQSwabs (Leinonen et al, 2018). This piece of work adds to the existing literature on HPV self-sampling acceptability by comparing three self-sampling devices in the UK context, among women attending for cervical screening (as opposed to screening non-attenders).

The current acceptability sub-study was carried out with participants in HPVValidate, a clinical validation study, to address the secondary research question "How acceptable are the sample devices for participants to use?" HPVValidate was primarily designed to establish the accuracy of self-sampling compared to clinician taken samples for detecting HPV when tested in laboratories commissioned to provide cervical screening services for the NHS Cervical Screening programme (a report summarising the main findings from HPV validate is available here). Participants in the study were asked to complete a self-sampling test during their visit to the GP for cervical screening, or at colposcopy. Three different devices used were FLOQSwabs (Copan), Evalyn Brush (Rovers Medical) and Aptima Multitest Swab (Hologic). See Figure 1.

Figure 1: The three different devices used by women in HPVValidate

FLOQSwab (Copan)   Evalyn Brush (Rovers Medical)   Aptima Multitest Swab (Hologic)

https://phescreening.blog.gov.uk/2021/04/28/cervical-screening-self-sampling-study/

The sub-study was carried out with women who had completed their self-sample at their GP surgery, alongside their routine cervical screen. Participants in the colposcopy arm of HPVValidate were not asked to complete a survey.

The aims of this sub-study were to:
1. Assess *acceptability of using a self-sampling device offered in General Practice*
2. *Measure differences in acceptability between three self-sampling devices*
3. *Explore differences in acceptability by socio-demographic background*
4. *Establish preferences for future testing options*

METHODS

Procedure

Participants were asked to complete a self-sample before having their standard screening test. Immediately after both tests were complete, the participant was asked to fill out the questionnaire electronically. Questionnaires were completed on the Survey Monkey platform and accessed using a link on a device that was handed to women in the surgery. The option to send a survey link to an individual's personal device was made available part way through the data collection period. This approach avoided the need for management of paper surveys and data entry. It also meant responses were confidential and not accessible to the sample taker or anyone else in the GP surgery. Questionnaire data were collected anonymously and were available to the behavioural science researchers at KCL/QMUL. Three bespoke links were used, one for each self-sampling device, allowing the KCL/QMUL research team to link the survey data with the appropriate device.

Surveys were collected between June 2021 and July 2023. Consent for completion of the survey was included in the HPValidate study consent form. The survey was approved by research London-Stanmore Research Ethics Committee as part of the wider HPValidate study (ref: 20/LO/1009).

Survey items

The survey started with eight items assessing how women felt about the self-sampling test they had just completed. These items were taken from previous studies that have explored self-sampling experience (Waller et al. 2006; Landy et al 2021) and included overall experience, discomfort, unpleasantness, embarrassment, anxiety, worry (about hurting themselves) relaxedness and confidence (that they had done the test correctly). Responses to each item were made on a 4-point scale. Our ad-hoc analysis plan was to dichotomise responses at the mid-point, except for if this resulted <10% in the smallest category. Since very few participants indicated negative responses, most items were recoded to represent the extreme versus any other response: 'excellent' versus 'good/fair/poor' experience; 'any' versus 'No discomfort' and 'any' versus 'not at all' unpleasant, embarrassed, anxious, worried (about hurting themselves). Relaxedness and confidence were dichotomised at the mid-point i.e. 'not at all/slightly' versus 'moderately very'.

A free-text box was provided to allow additional comments about their experience.

Participants were also asked about their experience of the written instructions that they were given to help them complete the self-test. This included rating how easy the instructions were to understand as well as a free-text box to record additional comments.

After the user experience questions, participants were asked about their preference for cervical screening "Comparing the self-test with your cervical screening (the 'smear test' done by a nurse or doctor), which do you prefer?" with the following response options: prefer the self test; prefer the test done by a nurse or doctor; no preference; not sure; this is my first cervical screen so I don't know yet. Participants were also asked which they would choose "if offered a choice between doing a self-test at home or having your cervical screening done by a nurse or doctor" with the response options: I would do the self-test at home; I would go for cervical screening with a nurse or doctor; not sure; I wouldn't have screening.

Socio-demographic questions were included assessing age, highest educational qualification, marital status, ethnicity and sexual orientation. Number of previous cervical screens and experience of colposcopy were also assessed. Since the survey was collected anonymously, it was not possible to link responses to any clinical data collected for the wider HPValidate study.

After completing the above items, participants were given the opportunity to answer eight additional questions assessing how they would feel about being offered a choice between self-sampling and clinician collected sampling. The full survey is available here: *https://osf.io/txawj*

RESULTS

Summary of participants who completed the survey

Of the 4839 women who completed a self-sample within the primary screening arm of HPValidate, 2323 (48%) also completed a survey (see Supplementary Figure S1). Three cases were excluded because their self-reported age was outside the screening eligible age (i.e. <24 or >65 years). Data for 2320 participants has been included in the analyses. Sample characteristics are shown in Supplementary Table S1.

The majority of the survey participants had used the Evalyn brush (n=1184) or the FLOQSwabs (n=1017); far fewer had used the Aptima Multitest swab (n=119). This was in part due to study design which meant the target sample was smaller for the Aptima Multitest. There was also a much lower survey completion rate among participants using the Aptima Multitest (12%) compared to those using the Evalyn brush or FLOQSwabs (62% and 53% respectively). This may have been partly due to people not being offered the survey at some surgeries because of wifi connection problems, but may also reflect the differing populations.

The sample characteristics of women who used each of the three devices are shown in Supplementary Table S1. There were significant differences between the groups using each device in terms of age (p<.001), marital status (p=.003), ethnicity (p<001), education (p=.006) and level of screening experience (p<.001).

Acceptability of using a self-sampling device offered in General Practice

A full break-down of responses for each of the eight acceptability items is presented in Table S2.

Across all participants who completed a survey (regardless of device), the majority felt their experience was excellent (75.5%) or good (22.7%). Very few women considered their experience to be fair or poor (2.1%).

Most women reported 'no discomfort at all' (79.4%) and felt doing the test was 'not at all unpleasant' (82.7%). Very few women reported that they felt a lot or severe discomfort (1.1%) or that the test was moderately or very unpleasant (2.2%).

Similarly, most women said they were 'not at all' embarrassed (92.2%), anxious (73.5%) or worried about hurting themselves while doing the test (82%). Few women reported that they felt moderately or very embarrassed (1.1%) or moderately or very anxious (3.2%) while doing the test, or that they were moderately or very worried about hurting themselves (2.3%).

Just over half said they were very relaxed (54.1%) while doing the test, with 12.4% saying they did not feel 'at all relaxed' or were only 'slightly relaxed' while taking the test. Just over a third felt 'very confident' that they had done the test correctly (39.2%), 45% were 'moderately confident' and 15.6% reported that they did not feel 'at all confident' or were only 'slightly confident' that they had done the test correctly.

Acceptability by device

Table S2 also shows the unadjusted percentages of women responding to each option for each of the eight acceptability items by device used.

As shown in Table 1, after adjusting for age, marital status, education, ethnicity and screening status, the device used was associated with reporting of discomfort, anxiety and worry (about hurting themselves). Participants using the Evalyn brush were at increased odds of reporting 'any discomfort', 'any anxiety' and 'any worry', compared with those who used the FLOQSwabs. There were no differences across devices for overall experience, unpleasantness embarrassment, feeling relaxed or confident.

Women were also given the opportunity to leave additional comments about their experience. Of the 504 participants (22%) who recorded a comment about their experience, the most common themes related to finding the test easy or simple to complete, mentioned by 30% of those who left a comment. Generally positive comments about self-sampling (e.g. "Great idea"), were also given by 30% of those who left a comment. Almost a quarter questioned whether they had completed the test properly and/or the accuracy of the results compared to a clinician take sample. See Table 2 for a summary of the comments (overall and by device) and Table S5 for example comments within each theme.

Table 1: Differences in acceptability items by device

	Unadjusted	Adjusted [a]
Excellent experience [$\chi^2(2)$, p-value]	*4.45, p=.108*	*2.13, p=.345*
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	1.07 (0.88-1.29)	1.05 (0.86-1.28)
Aptima Multitest; OR (95% CI)	0.68 (0.45-1.03)	0.76 (0.50-1.16)
Any discomfort [$\chi^2(2)$, p-value]	*5.50, p=.064*	*8.65, p=.013*
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	**1.25 (1.02-1.55)***	**1.38 (1.11-1.71)****
Aptima Multitest; OR (95% CI)	1.42 (0.91-2.22)	1.27 (0.80-2.01)
Any unpleasantness [$\chi^2(2)$, p-value]	*1.24, p=.538*	*1.39, p=.500*
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	0.90 (0.72-1.13)	0.95 (0.76-1.20)
Aptima Multitest; OR (95% CI)	0.80 (0.74-1.36)	0.73 (0.43-1.26
Any embarrassment [$\chi^2(2)$, p-value]	*9.40, p=.009*	*5.35, p=.069*
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	0.74 (0.54-1.02)	0.83 (0.59-1.15)
Aptima Multitest; OR (95% CI)	**1.78 (1.02-3.11)***	1.07 (0.95-3.05)
Any anxiety [$\chi^2(2)$, p-value]	6.85, p=.033	9.94, p=.007
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	**1.29 (1.07-1.56)****	**1.37 (1.12-1.67)****
Aptima Multitest; OR (95% CI)	1.18 (0.77-1.81)	1.10 (0.70-1.70)
Any worry [$\chi^2(2)$, p-value]	8.73, p=.013	14.28, p<.001
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	**1.38 (1.11-1.72)****	**1.52 (1.21-1.90)*****
Aptima Multitest; OR (95% CI)	1.11 (0.67-1.82)	0.99 (0.59-1.65)
Moderately or very relaxed [$\chi^2(2)$, p-value]	4.20, p=.123	4.20, p=.123
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	**1.34 (1.04-1.73)***	1.23 (0.95-1.61)
Aptima Multitest; OR (95% CI)	0.70 (0.43-1.16)	0.77 (0.46-1.29)
Moderately or very confident [$\chi^2(2)$, p-value]	2.94, p=.230	1.13, p=.597
FLOQSwabs (ref)		
Evalyn; OR (95% CI)	1.07 (0.85-1.35)	0.99 (0.78-1.26)
Aptima Multitest; OR (95% CI)	0.70 (0.44-1.13)	0.77 (0.47-1.26)

[a] adjusted for age, marital status, education, ethnicity[b] and screening experience
[b] Ethnicity is entered as a binary variable ('any White background' or 'any other ethnic background')
ref=reference category, OR=Odds ratio, 95% CI=95% Confidence Interval
Significant at * p<.05; **p<.01; ***p<.001

Table 2: Summary of free-text comments about experience

	Overall n=504	Evalyn brush n=274	FLOQSwabs n=207	Aptima Multitest n=23
	n (%)	n	n	n
Test was easy to do/simple	149 (29.6)	88	56	5
Test was quick	34 (6.7)	24	10	0
Test was painless/no discomfort	60 (11.9)	38	20	2
Felt reassured by the nurse	48 (9.5)	25	22	1
Comments on the device (e.g. red line)	32 (6.3)	22	9	1
Comments about the position needed	6 (1.2)	2	3	1
Comments about the procedure (including how it felt)	45 (8.9)	33	11	1
General positive comment about self-sampling	153 (30.4)	90	55	8
Comments about the test improving screening uptake	29 (5.8)	16	13	0
Questioning correct completion/accuracy of self-test	115 (22.8)	54	55	6
Future preferences to complete test at home	20 (4.0)	9	11	0
Other (including comments about research)	58 (11.5)	25	30	3

Experience of using the instructions

As part of considering acceptability, we explored satisfaction with the instructions that women had been provided with to support completion of the self-test. The majority of women felt that the instructions were 'very easy' or 'quite easy' to understand (79% and 19% respectively). Very few participants said they found the instructions 'not very easy' or 'not easy at all' to follow (1.3%). After adjusting for socio-demographic factors, participants who used the Evalyn brush were slightly less likely to say that they found the instructions 'very easy' to follow compared to those who used the FLOQSwabs (OR=0.71, CI:0.57-0.88). There was no significant difference between the FLOQSwabs and the Aptima Multitest.

Participants were also offered the opportunity to comment about the written instructions, with an open box provided. Of the 2320 women completing the survey 279 recorded a comment about the instructions (12.0%). Comments predominantly described the instructions as easy to follow, but there was some indication that the instructions were not used by all participants. Some reported completing the self-sample based on verbal instructions from the nurse. See Table 3 for a summary of the comments (overall and by device) and Table S6 for example comments within each theme.

Table 3: Summary of free-text comments about the instructions

	Overall n=279	Evalyn brush n=137	FLOQSwabs n=129	Aptima Multitest n=13
	n (%)	n	n	n
Instructions were clear/easy to follow	96 (34.4)	52	42	2
Comments on the pictures/illustrations	41 (14.7)	26	15	0
Comments on text including structure and length	37 (13.3)	22	12	3
Explained by nurse (not given instructions)	67 (24.0)	35	28	4
Comments about specific instructions				
How far to put swab?	*16 (5.7)*	*2*	*14*	*0*
Confusion over wording instructions i.e. 'click'/ 'snap'	*25 (9.0)*	*8*	*17*	*0*
How much swab/circles?	*6 (2.2)*	*2*	*3*	*1*
Instruction inconsistent with experience, inc. position	7 (2.5)	7	0	0
Recommendation to improve instructions	10 (3.6)	2	7	1
Other (including comments about research)	13 (4.7)	4	6	3

Differences in overall experience and acceptability by socio-demographic background
Socio-demographic differences in overall experience of using the self-sample are presented in Table 4. After adjusting for device used, participants were less likely to report an excellent experience if they were from older age groups (40-49 years, 50-59 years or 60+ years) compared to those aged 30-39 years. Participants from Asian and Black ethnic backgrounds were less likely to report an excellent experience than those from white backgrounds (p<.05 and p<.01 respectively). Excellent experience was reported more often in sexual minorities.

Percentages and 95% confidence intervals for each acceptability item by socio-demographic characteristic are shown in Table 5. After adjusting for device used, there were a number of significant differences (see Tables S3 and S4). Most notably, women from Asian backgrounds were more likely to report discomfort (p<.001), unpleasantness (p<.01), anxiety (p<.05), embarrassment (p<.001) and worry about hurting themselves (p<.001) compared to women from white backgrounds. Women from Black backgrounds were also more likely to report worry about hurting themselves compared to women from white backgrounds (p<.05).

Women from the youngest age group (25-29 years) and oldest group (60+ years) were more likely to experience discomfort than women aged 30-39 years (p<.05 and p<.01 respectively). Separated, divorced or widowed women were less likely to report any anxiety (p<.05). Women with low/mid-level qualifications were less likely to find the test at all unpleasant and those with mid-level qualifications were also more likely to report discomfort (p<.05).

Compared to women who had been screened 3+ times, those who were attending for their first screening test or who had only been once before, were more likely to report anxiety (p<.01 and p<.05 respectively), embarrassment (p<.01 and p<.05 respectively) and worry about hurting themselves (p<.001 and p<.05 respectively). Women attending for their first screening test were also more likely to report discomfort (p<.001) and unpleasantness (p<.01). Women who had been referred to colposcopy in the past were less likely to report any anxiety (p<.01), embarrassment (p<.01) or be at all worried about hurting themselves (p<.01).

Finally, women in the oldest age group (60+) were more likely to feel moderately or very confident that they had done the test correctly, compared to women aged 30-39 years (p<.05). Women from Asian backgrounds were less likely to report feeling moderately or very relaxed while completing the test and less likely to feel moderately or very confident that they had completed the test properly compared to women from white backgrounds (p<.001).

Table 4: Overall 'experience' by socio demographic characteristics

	Poor/fair %	Good %	Excellent %	OR (95% CI) for an excellent experience[a]
Age group				
25-29 years (n=384)	1.2	19.5	79.3	1.07 (0.78-1.46)
30-39 years (n=705)	2.4	19.1	78.4	Ref
40-49 years (n=621)	1.7	24.6	73.6	**0.77 (0.60-0.99)***
50-59 years (n=414)	2.4	26.1	71.5	**0.68 (0.52-0.90)****
60+ years (n=132)	3.1	31.1	65.9	**0.52 (0.34-0.77)****
Marital Status				
Single (n=527)	2.1	21.1	76.9	1.15 (0.91-1.45)
Married/civil partnership/cohabiting (n=1523)	2.1	23.4	74.6	Ref
Separated/Divorced/Widowed (n=182)	1.6	21.4	76.9	1.12 (0.76-1.61)
Educational level				
Low-level (n=274)	2.2	23.0	74.8	0.90 (0.66-1.22)
Mid-level (n=636)	2.2	23.4	74.4	0.88 (0.71-1.10)
High-level (n=1286)	2.1	21.6	76.3	Ref
Ethnic background				
Any White background (n=1992)	2.0	21.6	76.5	Ref
Mixed ethnic background (n=57)	0	22.8	77.2	1.08 (0.58-2.03)
Any Asian Background (n=104)	3.9	31.7	64.4	**0.58 (0.38-0.88)***
Any Black background (n=60)	5.0	38.3	56.7	**0.44 (0.26-0.74)****
Other (n=34)	0	32.4	67.6	0.67 (0.32-1.41)
Sexual Orientation				
Heterosexual/Straight (n=2087)	2.0	23.2	74.8	Ref
Gay, Lesbian, Bisexual, other (n=125)	0.8	13.6	85.6	**2.00 (1.20-3.33)****
Screening Status				
Today is my first screen (n=200)	2.5	23.5	74.0	0.97 (0.69-1.36)
Been once before (n=246)	1.6	22.4	76.0	1.05 (0.76-1.43)
Been twice before (n=191)	1.6	20.9	77.5	1.14 (0.80-1.63)
Been 3+ times before (n=1563)	2.1	22.8	75.0	Ref
Experience of colposcopy				
No (n=1752)	2.0	23.2	74.7	Ref
Yes (n=514)	2.1	21.6	76.3	0.75 (0.37-1.49)

ref=reference category, OR=Odds ratio, 95% CI=95% Confidence Interval
Significant at * p<.05; **p<.01; ***p<.001
[a] *Compared to those who reported poor, fair or good. Adjusted for device used. Poor and fair have been combined for reporting due to very small numbers.*
Sample numbers are smaller than n=2320 due to missing demographic data.

Table 5: Percentages and 95% confidence intervals for acceptability items by socio-demographic characteristics

	Any discomfort % (95% CI)	At all unpleasant % (95% CI)	At all anxious % (95% CI)	At all embarrassed % (95% CI)	At all worried % (95% CI)
Age group					
25-29 years (n=348)	25.3 (21.0-30.1)	18.7 (14.9-23.1)	29.9 (25.3-34.9)	11.5 (8.5-15.3)	21.0 (17.0-25.6)
30-39 years (n=705)	19.4 (16.7-22.5)	17.9 (15.2-20.9)	27.7 (24.5-31.1)	6.7 (5.0-8.8)	19.9 (17.1-23.0)
40-49 years (n=621)	16.7 (14.0-19.8)	15.1 (12.5-18.2)	26.1 (22.8-29.7)	8.2 (6.3-10.7)	17.6 (14.8-20.7)
50-59 years (n=414)	20.0 (16.5-24.2)	16.7 (13.4-20.6)	24.2 (20.3-28.5)	5.8 (3.9-8.5)	17.6 (14.3-21.6)
60+ years (n=130)	30.8 (23.5-39.2)	19.2 (12.3-26.9)	27.7 (20.7-36.0)	9.2 (5.2-15.6)	16.9 (11.4-24.4)
Marital Status					
Single (n=527)	23.1 (19.7-26.9)	17.8 (14.8-21.3)	27.5 (23.9-31.5)	8.5 (6.4-11.3)	20.9 (17.6-24.6)
Married/civil partnership/cohabiting (n=1522)	19.6 (17.7-21.7)	17.2 (15.4-19.2)	27.1 (24.9-29.4)	7.0 (5.8-8.4)	18.1 (16.3-20.2)
Separated/Divorced/Widowed (n=180)	20.0 (14.8-26.5)	13.3 (9.1-19.1)	19.4 (14.3-25.9)	10.0 (6.3-15.3)	17.2 (12.4-23.4)
Educational level					
Low-level (n=273)	19.0 (14.8-24.1)	12.8 (9.3-17.3)	26.7 (21.8-32.3)	9.5 (6.5-13.6)	16.5 (12.5-21.4)
Mid-level (n=635)	18.0 (15.2-21.1)	14.8 (12.2-17.8)	26.3 (23.0-29.9)	9.1 (7.1-11.6)	18.6 (15.7-21.8)
High-level (n=1267)	22.1 (19.9-24.5)	18.8 (16.7-21.0)	26.6 (24.2-19.1)	6.6 (5.3-8.1)	19.2 (17.1-21.4)
Ethnic background					
Any White background (n=1991)	19.8 (18.1-21.6)	16.9 (15.3-18.6)	26.0 (21.4-27.9)	7.1 (6.0-8.3)	18.0 (16.4-19.8)
Mixed ethnic background (n=57)	17.5 (9.6-29.6)	14.0 (7.0-25.6)	21.1 (12.3-33.4)	7.0 (2.3-17.2)	8.8 (3.4-19.4)
Any Asian Background (n=104)	33.7 (25.3-43.2)	27.9 (20.1-37.2)	35.6 (27.0-45.2)	22.1 (15.2-31.1)	31.7 (23.6-41.2)
Any Black background (n=59)	32.2 (21.6-44.9)	13.6 (6.8-24.8)	37.3 (26.1-50.1)	11.9 (5.6-22.8)	27.1 (17.4-39.7)
Other (n=33)	18.2 (8.2-34.8)	18.4 (11.2-28.7)	33.3 (19.7-50.5)	6.1 (0.7-20.6)	21.2 (10.4-38.0)

Table 5 (continued): Percentages and 95% confidence intervals for acceptability items by socio-demographic characteristics

	Any discomfort % (95% CI)	At all Unpleasant % (95% CI)	At all anxious % (95% CI)	At all embarrassed % (95% CI)	At all worried% (95% CI)
Sexual Orientation					
Heterosexual/Straight (n=2085)	20.4 (18.8-22.2)	17.0 (15.5-18.7)	26.4 (24.6-28.4)	7.4 (6.4-8.6)	18.4 (16.8-20.1)
Gay, Lesbian, Bisexual, other (n=125)	22.4 (15.9-30.5)	17.6 (11.9-25.3)	27.2 (20.1-35.6)	9.6 (5.4-16.2)	20.8 (14.6-28.8)
Screening Status					
Today is my first screen (n=200)	30.5 (24.5-37.2)	25.0 (19.5-31.5)	34.5 (28.3-41.3)	14.5 (10.2-20.1)	28.0 (22.2-34.6)
Been once before (n=245)	23.7 (18.8-29.4)	18.8 (14.4-24.2)	31.4 (25.9-37.5)	11.8 (8.3-16.5)	22.0 (17.3-27.7)
Been twice before (n=191)	20.9 (15.7-27.3)	16.2 (11.6-22.2)	28.3 (22.3-35.1)	3.7 (1.6-7.5)	20.9 (15.7-27.3)
Been 3+ times before (n=1561)	18.8 (17.0-20.9)	16.0 (14.2-17.9)	25.1 (23.0-27.3)	7.0 (5.9-8.4)	17.0 (15.2-18.9)
Experience of colposcopy					
No (n=1750)	21.0 (19.2-23.0)	17.9 (16.2-19.8)	28.4 (26.3-30.6)	8.8 (7.6-10.2)	20.0 (18.2-21.9)
Yes (n=513)	19.1 (15.9-22.7)	15.0 (12.2-18.4)	21.2 (17.9-25.0)	4.5 (3.0-6.7)	14.2 (11.5-17.5)

95% CI=95% Confidence Interval
'Any' includes participants who indicated slightly, moderately or very
Sample numbers are smaller than n=2320 due to missing demographic data.
Percentages shown are unadjusted. Logistic regression for between group differences, adjusting for device used, are presented in Table S3.

Table 6: Percentages and 95% confidence intervals for feeling relaxed and confidence that they had completed the test properly by socio-demographic characteristics

	% moderately or very relaxed (95% CI)	% moderately or very confident (95% CI)
Age group		
25-29 years (n=348)	84.8 (80.6-88.2)	86.2 (82.2-89.5)
30-39 years (n=705)	88.2 (85.6-90.4)	83.3 (80.3-85.8)
40-49 years (n=621)	87.4 (84.6-89.8)	84.4 (81.3-87.0)
50-59 years (n=414)	91.8 (88.7-74.1)	87.2 (83.6-90.1)
60+ years (n=130)	93.8 (88.1-97.0)	92.3 (86.3-95.9)
Marital Status		
Single (n=527)	87.3 (84.2-89.9)	83.5 (80.1-89.9)
Married/civil partnership/cohabiting (n=1522)	88.2 (86.5-89.7)	85.5 (83.6-87.2)
Separated/Divorced/Widowed (n=180)	91.1 (86.0-94.5)	89.4(84.0-93.2)
Educational level		
Low-level (n=273)	87.9 (83.5-91.3)	83.2 (87.2-87.1)
Mid-level (n=635)	88.0 (85.3-90.3)	85.0 (82.0-87.6)
High-level (n=1267)	88.6 (86.7-90.2)	86.3 (84.3-88.1)
Ethnic background		
Any White background (n=1991)	88.9 (87.4-90.2)	85.9 (84.3-87.4)
Mixed ethnic background (n=57)	93.0 (82.8-97.7)	94.7 (85.1-98.8)
Any Asian Background (n=104)	74.0 (64.8-81.5)	73.1 (63.8-80.7)
Any Black background (n=59)	84.7 (73.3-92.0)	79.7 (67.6-88.1)
Other (n=33)	84.8 (68.6-93.8)	72.7 (55.6-85.1)
Sexual Orientation		
Heterosexual/Straight (n=2085)	88.3 (86.9-89.7)	85.4 (83.8-86.8)
Gay, Lesbian, Bisexual, other (n=125)	90.4 (83.8-94.6)	87.2 (80.1-92.1)
Screening Status		
Today is my first screen (n=200)	82.5 (76.6-87.2)	82.0 (76.1-86.7)
Been once before (n=245)	84.1 (78.9-88.2)	86.1 (81.2-89.9)
Been twice before (n=191)	86.4 (80.8-90.6)	84.3 (78.4-88.8)
Been 3+ times before (n=1561)	89.8 (88.1-91.2)	85.7 (83.8-87.3)
Experience of colposcopy		
No (n=1750)	87.6 (86.0-89.1)	85.0 (83.3-86.6)
Yes (n=513)	90.3 (87.4-92.5)	85.4 (82.0-88.2)

95% CI=95% Confidence Interval
Sample numbers are smaller than n=2320 due to missing demographic data.
Logistic regression for between group differences, adjusting for device used, are presented in Table S4.

Future preferences for self-testing

Women were asked to compare the self-test with their cervical screening (as completed by the nurse or doctor) and say which they preferred. Just over half of participants said they preferred the self-test (54.6%), with 13.7% saying they preferred the test done by a nurse or doctor. The remaining 31.7% had no preference, were 'not sure' or selected 'this is my first screen so I don't know yet'. Preference was not associated with the device that the participant had used.

When asked which they would choose in the future if they were offered a choice between doing a self-test at home or having cervical screening done by a nurse or doctor, the majority said they would prefer a self-test at home (69.1%), 18.7% would prefer screening done by a nurse or doctor and 12.2% were not sure. Future choice was not associated with the device that was used.

We also asked women how they would feel about being offered a choice between self-sampling or clinician taken sampling (see Table 4). Most felt that they would like to be offered a choice (85%), felt a choice made sense to them (86%) and felt that being offered a choice would improve cervical screening for them (72%). Overall, 12% said they would not want a choice and half felt that would want a recommendation to do either self-testing or have a clinician test (48%). A detailed exploration of these items will be reported elsewhere (Marlow et al. Under review).

Table 7: Descriptives for attitudes towards being offered a choice between a self-test at home or a clinician-taken sample

	% strongly/somewhat agree (95% confidence interval)
Being offered a choice between self-testing and clinician testing for cervical screening makes sense to me (n=2207)	86.3 (84.8-87.7)
I would like to be offered a choice between self-testing and clinician testing for cervical screening (n=2208)	84.9 (83.3-86.3)
Offering a choice between self-testing and clinician testing would improve cervical screening for me (n=2205)	71.7 (69.8-73.5)
I would prefer to have a recommendation to do either self-testing or clinician testing rather than having to make a choice myself (n=2206)	48.3 (46.2-50.4)
If I was given the choice between self-testing and clinician testing for cervical, I would assume it was a way of saving the NHS money (n=2204)	41.6 (39.5-43.6)
I would find it difficult to choose between self-testing and clinician testing for cervical screening (n=2203)	22.8 (21.1-24.6)
I would feel worried about being offered a choice between self-testing and clinician testing for my cervical screening (n=2201)	15.1 (13.6-16.6)
I would not want to be offered a choice between self-testing and clinician testing for my cervical screening (n=2199)	12.4 (11.1-13.8)

Items presented with the following instruction *"In the future, the NHS Cervical Screening Programme might offer you a choice between using a self-test at home, or going for your cervical screening appointment with a nurse or doctor (we call this 'clinician testing'). Thinking about this, please tell us how much you agree or disagree with the following statements."*

CONCLUSIONS & IMPLICATIONS

Very few women reported negative attitudes to the self-sampling test, regardless of device, suggesting that those who complete a self-sample for cervical screening will likely have positive experiences. This is consistent with findings from a previous UK-based acceptability study of women > 18 years who used self-sampling (Waller et al. 2006), with both studies suggesting that >90% report no embarrassment while doing the test, >79% report no discomfort and >82% report no unpleasantness. In studies exploring barriers to cervical screening done by a sample taker, embarrassment (29%) and worry about the test being painful (21%) are some of the most frequently endorsed barriers (Waller et al. 2009). This work within HPValidate contributes to evidence suggesting the experience of self-sampling is unlikely to be considered embarrassing or to cause discomfort and could overcome some prominent barriers to engagement with cervical screening.

HPValidate used three different devices for self-sample collection. Two of these, the FLOQSwabs and Aptima Multitest are similar – both using a long swab. The Evalyn brush consists of plastic casing which the brush sits within (see Figure 1). We found that participants using the Evalyn brush were more likely to report 'any discomfort', 'any anxiety' and 'any worry' (about hurting themselves), compared with those who used the FLOQSwabs. However, experience was positive overall across all three devices.

Just over a third felt very confident that they had done the test correctly (39%). Previous studies have suggested a wide range in the proportion of women who report feeling confident about completing a self-sample (27-95%; Waller et al. 2006; Landy et al. 2022). The free-text comments suggest that for many women in HPValidate the nurse helped them to feel confident about their ability to collect that sample. Though most described the instructions as easy to understand, the free-text responses indicated examples of confusion about specific wording used and conflicts between descriptions and experience. The GP-practice setting for this work meant that nurses were able to clarify confusion and offer reassurance. Careful consideration is needed to support women with information materials designed to help them to take their own home-based samples, particularly for the first time.

Exploring the free-text comments sheds further light on the experience of taking a self-sample. Many described the test as easy and quick but there was widespread questioning of whether they had completed it properly and whether the test could be as accurate as the one completed by the nurse. While the potential to complete the test at home and reduced need to attend a GP and ultimately reduce burden on GPs was mentioned as a potentially positive aspect of self-testing, some women said they would prefer to continue visiting the nurse for the test which gave them the opportunity to discuss concerns and felt like a more thorough examination.

There were ethnic differences in acceptability of self-sampling, with Asian women more likely to report negative experiences. This warrants further investigation to understand why this might be. This also suggests that fewer women may choose self-sampling in some geographical areas where there are larger South Asian populations.

METHODOLOGY LIMITATIONS

The HPValidate design meant that devices were used at surgeries in specific areas (determined by the laboratories). This explains the sociodemographic differences in the populations using each device as a result of geographic variations.

The smaller numbers using the Aptima Multitest, and a lower response rate in this group, means wider confidence around the estimates provided for this device.

Free-text comments suggest that in some cases the sample-takers helped women to complete the self-sample. It is difficult to know how frequently this was the case and the impact this had on experience, but may influence how likely the findings are to be reflected in experience when completing a home-based self-sample.

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Figure S1: Study Flow diagram
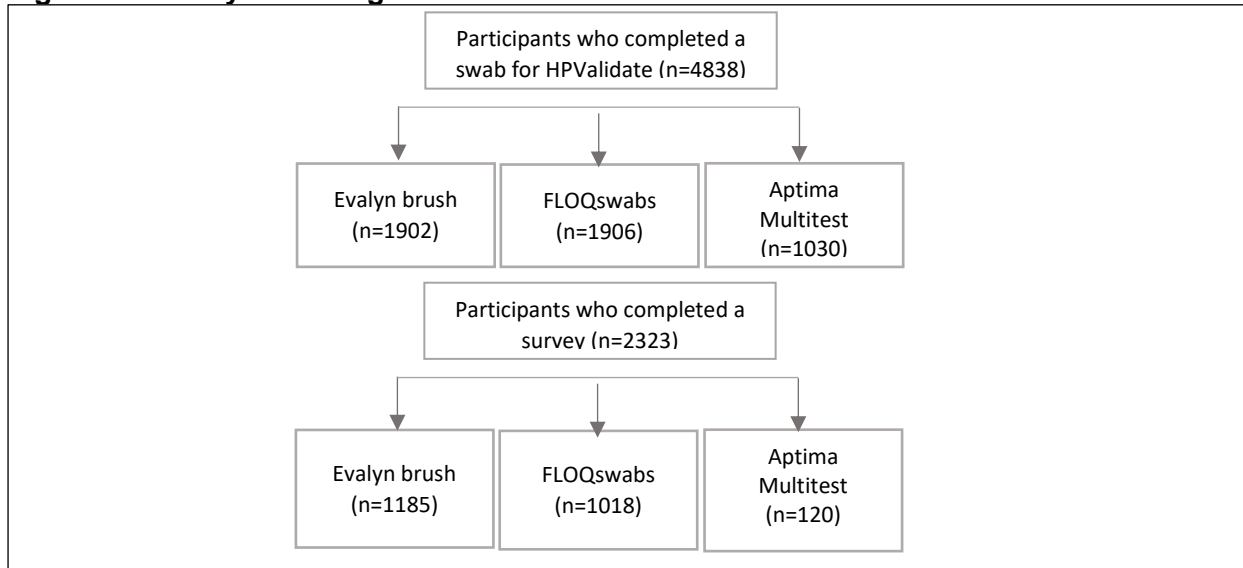
Note: Three participants were excluded prior to analyses due to ineligible age

Table S1: Characteristics of the sample, overall and by device

	Overall (n=2320)	Evalyn brush (n=1184)	FLOQSwabs (n=1017)	Aptima Multitest (n=119)	Between device difference
Age in years (mean; SD)	41.14; 10.6	42.10; 10.53	40.07; 10.63	40.63; 10.28	
Age group (n; %)					
25-29 years	348 (15.0)	146 (12.3)	184 (18.1)	18 (15.1)	$\chi^2(10) =$
30-39 years	705 (30.4)	349 (29.5)	325 (32.0)	31 (26.1)	**29.27,**
40-49 years	621 (26.8)	329 (27.8)	251 (24.7)	41 (34.5)	**p=.001**
50-59	414 (17.8)	241 (20.4)	156 (15.3)	17 (14.3)	
60+	130 (5.6)	71 (6.0)	54 (5.3)	5 (4.2)	
Missing	102 (4.4)	48 (4.1)	47 (4.6)	7 (5.9)	
Marital Status (n; %)					
Single	527 (22.7)	232 (19.6)	260 (25.6)	35 (29.4)	$\chi^2(6) =$
Married/civil partnership/cohabiting	1522 (65.6)	823 (69.5)	628 (61.8)	71 (59.7)	**19.64,**
Separated/Divorced/Widowed	180 (7.8)	89 (7.5)	84 (8.3)	7 (5.9)	**p=.003**
Prefer not to say/Missing	91 (3.9)	40 (3.4)	45 (4.4)	6 (5.0)	
Educational level (n; %)					
Low-level	273 (11.8)	153 (12.9)	110 (10.8)	10 (8.4)	$\chi^2(6) =$
Mid-level	635 (27.4)	331 (28.0)	285 (28.0)	19 (16.0)	**18.06,**
High-level	1267 (54.6)	639 (54.0)	547 (53.8)	81 (68.1)	**p=.006**
Missing	145 (6.3)	61 (5.2)	75 (7.4)	9 (7.6)	
Sexual Orientation (n; %)					
Heterosexual/Straight	2085 (89.9)	1067	913 (89.8)	105 (88.2)	$\chi^2(4) =$
Gay, Lesbian, Bisexual, other	125 (5.4)	68 (5.7)	51 (5.0)	6 (5.0)	*2.98,*
Missing	110 (4.7)	49 (4.1)	53 (5.2)	8 (6.7)	*p=.562*
Ethnic background (n; %)					
Any White background	1991 (85.8)	1084	837 (82.3)	70 (58.8)	
Mixed ethnic background	57 (2.5)	19 (1.6)	30 (2.9)	8 (6.7)	$\chi^2(10) =$
Any Asian Background	104 (4.5)	27 (2.3)	62 (6.1)	15 (12.6)	**142.92,**
Any Black background	59 (2.5)	19 (1.6)	31 (3.0)	9 (7.6)	**p<.001**
Other	33 (1.4)	2 (0.2)	21 (2.1)	10 (8.4)	
Missing	76 (3.3)	33 (2.8)	36 (3.5)	7 (5.9)	
Screening Status (n; %)					
Today is my first screen	200 (8.6)	69 (5.8)	115 (11.3)	16 (13.4)	$\chi^2(8) =$
Been once before	245 (10.6)	121 (10.2)	114 (11.2)	10 (8.4)	**30.04,**
Been twice before	191 (8.2)	97 (8.2)	86 (8.5)	8 (6.7)	**p<.001**
Been 3+ times before	1561 (67.3)	840 (70.9)	644 (63.3)	77 (64.7)	
Missing	123 (5.3)	57 (4.8)	58 (5.7)	8 (6.7)	
Experience of colposcopy (n; %)					
Yes	513 (22.1)	284 (24.0)	205 (20.2)	24 (20.2)	$\chi^2(4) =$
No	1750 (75.4)	876 (74.0)	784 (77.1)	90 (75.6)	*7.27,*
Missing	57 (2.5)	24 (2.0)	28 (2.8)	5 (4.2)	*p=.122*

Note: All demographic data was missing for n=53 women. These women have not been included in the demographic analyses. Missing includes those who selected prefer not to say or were unsure.
Significant at * p<.05; **p<.01; ***p<.001

Table S2: Descriptives for all acceptability items overall and by device (Unadjusted)

	Overall (n=2320)		Evalyn brush (n=1184)		FLOQSwabs (n=1017)		Aptima Multitest (n=119)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Overall experience (n; %)								
Excellent	1745	75.2 (73.4-76.9)	902	76.2 (73.7-78.5)	763	75.0 (72.3-77.6)	80	67.2 (58.4-75.0)
Good	526	22.7 (21.0-24.4)	258	21.8 (19.5-24.2)	231	22.7 (20.2-25.4)	37	31.1 (23.5-39.9)
Fair	4	1.9 (1.4-2.6)	21	1.8 (1.1-2.7)	22	2.2 (1.4-3.3)	2	1.7 (0.1-6.3)
Poor	4	0.2 (0-0.5)	3	0.3 (0-0.8)	1	0.1 (0-0.6)	0	0.0 (0-3.8)
Discomfort (n; %)								
No discomfort at all	1841	79.4 (77.7-81.0)	922	77.9 (75.4-80.1)	829	81.5 (79.0-83.8)	90	75.6 (67.2-82.5)
Mild	454	19.6 (18.0-21.2)	253	21.4 (19.1-23.8)	176	17.3 (15.1-19.8)	25	21.0 (14.6-29.2)
Quite a lot	18	0.8 (0.5-1.2)	7	0.6 (0.3-1.2)	8	0.8 (0.4-1.6)	3	2.5 (0.5-7.5)
Severe discomfort	7	0.3 (0.1-0.6)	2	0.2 (0-0.7)	4	0.4 (0.1-1.0)	1	0.8 (0-5.1)
Unpleasantness (n; %)								
Not at all unpleasant	1919	82.7 (81.1-84.2)	986	83.3 (81.0-85.3)	832	81.8 (79.3-84.4)	101	84.9 (77.3-90.3)
Slightly	350	15.1 (13.7-16.6)	180	15.2 (13.3-17.4)	157	15.4 (13.3-18.8)	13	10.9 (6.4-17.9)
Moderately	40	1.7 (1.3-2.3)	13	.1 (0.6-1.9)	23	2.3 (1.5-3.4)	4	3.4 (1.0-8.6)
Very unpleasant	11	0.5 (0.3-0.9)	5	0.4 (0.1-1.0)	5	0.5 (0.2-1.2)	1	0.8 (0-5.1)
Embarrassment (n; %)								
Not at all embarrassed	2139	92.2 (91.0-93.2)	1107	93.5 (91.9-94.8)	930	91.4 (89.6-93.0)	102	85.7 (78.2-91.0)
Slightly	156	6.7 (5.8-7.8)	66	5.6 (4.4-7.0)	76	7.5 (6.0-9.3)	14	11.8 (7.0-18.9)
Moderately	21	0.9 (0.6-1.4)	8	0.7 (0.3-1.4)	10	1.0 (0.5-1.8)	3	2.5 (0.5-7.5)
Very embarrassed	4	0.2 (0-0.5)	3	0.3 (0-0.8)	1	0.1 (0-0.6)	0	0 (0-3.8)
Anxiety (n; %)								
Not at all anxious	1706	73.5 (71.1-75.3)	844	71.3 (68.6-73.8)	775	76.2 (73.5-79.7)	87	73.1 (64.5-80.3)
Slightly	539	23.2 (21.6-25.0)	300	25.3 (22.9-27.9)	212	20.8 (18.5-23.5)	27	22.7 (16.0-31.0)
Moderately	67	2.9 (2.3-3.7)	36	3.0 (2.2-4.2)	26	2.6 (1.7-3.7)	5	4.2 (1.6-9.7)
Very anxious	8	0.3 (0.2-0.7)	4	0.3 (0.1-0.9)	4	0.4 (0.1-1.0)	0	0 (0-3.8)

Table S2 (continued): Descriptives for all acceptability items overall and by device

	Overall (n=2320)		Evalyn brush (n=1184)		FLOQSwabs (n=1017)		Aptima Multitest (n=119)	
	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)	n	% (95% CI)
Worry about hurting self (n; %)								
Not at all worried	1884	81.2 (79.6-82.7)	934	78.9 (76.5-81.1)	852	83.8 (81.4-85.9)	98	82.4 (74.5-88.2)
Slightly	382	16.5 (15.0-18.0)	220	18.6 (16.5-20.9)	143	14.1 (12.1-16.3)	19	16.0 (10.4-23.7)
Moderately	41	1.8 (1.3-2.4)	24	2.0 (1.4-3.0)	16	1.6 (0.9-2.6)	1	0.8 (0-5.1)
Very worried	13	0.6 (0.3-1.0)	6	0.5 (0.2-1.1)	6	0.6 (0.2-1.3)	1	0.8 (0-5.1)
Relaxedness (n; %)								
Not at all relaxed	42	1.8 (1.3-2.4)	13	1.1 (0.6-1.9)	29	2.9 (2.0-4.1)	0	0 (0-3.8)
Slightly	246	10.6 (9.4-11.9)	113	9.5 (8.0-11.4)	111	10.9 (9.1-13.0)	22	18.5 (12.5-26.5)
Moderately	777	33.5 (31.6-35.4)	424	35.8 (33.1-38.6)	317	31.2 (28.4-34.1)	36	30.3 (22.7-39.0)
Very relaxed	1255	54.1 (52.1-56.1)	634	53.5 (50.7-56.4)	560	55.1 (52.0-58.1)	61	51.3 (42.4-60.1)
Confident done correctly (n; %)								
Not at all confident	56	2.4 (1.9-3.4)	18	1.5 (0.9-2.4)	38	3.7 (2.7-5.1)	0	0 (0-3.8)
Slightly	305	13.1 (11.8-14.6)	158	13.3 (11.5-15.4)	122	12.0 (10.1-14.1)	25	21.0 (14.6-29.2)
Moderately	1050	45.3 (43.2-47.3)	538	45.4 (42.6-48.3)	461	45.3 (42.3-48.4)	51	42.9 (34.3-51.8)
Very confident	909	39.2 (37.2-41.2)	470	39.7 (36.9-42.5)	396	38.9 (36.0-42.0)	43	36.1 (28.1-45.1)
Ease of understanding instructions (n; %)								
Very easy	1840	79.3 (77.6-80.9)	930	78.5 (76.1-80.8)	828	81.4 (78.9-83.7)	82	68.9 (60.1-76.5)
Quite easy	448	19.3 (17.8-21.0)	241	20.4 (18.2-22.7)	175	17.2 (15.0-19.7)	32	26.9 (19.7-35.5)
Not very easy	22	0.9 (0.6-1.4)	8	0.7 (0.3-1.4)	11	1.1 (0.6-2.0)	3	2.5 (0.5-7.5)
Not easy at all	10	0.4 (0.2-0.8)	5	0.4 (0.1-1.0)	3	0.3 (0.1-0.9)	2	1.7 (0.1-6.3)

Table S3: Logistic Regressions for each acceptability item by socio-demographics (adjusted for devise used)

	Any discomfort OR (95% CI)	At all unpleasant OR (95% CI)	At all anxious OR (95% CI)	At all embarrassed OR (95% CI)	At all worried OR (95% CI)
Age group					
25-29 years	**1.43 (1.05-1.94)***	1.05 (0.75-1.46)	1.14 (0.86-1.51)	**1.78 (1.14-2.77)***	1.10 (0.80-1.51)
30-39 years	Ref	Ref	Ref	Ref	Ref
40-49 years	0.82 (0.62-1.09)	0.83 (0.62-1.11)	0.91 (0.71-1.16)	1.24 (0.82-1.88)	0.75 (0.64-1.12)
50-59 years	1.02 (0.75-1.38)	0.93 (0.67-1.28)	0.81 (0.62-1.08)	0.88 (0.53-1.47)	0.84 (0.61-1.12)
60+ years	**1.83 (1.20-2.77)****	1.10 (0.68-1.77)	0.99 (0.65-1.50)	1.45 (0.75-2.82)	0.81 (0.49-1.33)
Marital Status					
Single	1.25 (0.99-1.60)	1.04 (0.80-1.35)	1.05 (0.84-1.31)	1.19 (0.82-1.71)	1.23 (0.96-1.58)
Married/civil partnership/cohabiting	Ref	Ref	Ref	Ref	Ref
Separated/Divorced/Widowed	1.04 (0.70-1.53)	0.74 (0.47-1.15)	**0.66 (0.45-0.97)***	1.46 (0.86-2.48)	0.95 (0.63-1.44)
Educational level					
Low-level	0.83 (0.59-1.15)	**0.63 (0.43-0.93)***	1.00 (0.74-1.34)	1.57 (0.99-2.49)	0.82 (0.58-0.89)
Mid-level	**0.78 (0.61-0.99)***	**0.75 (0.57-0.97)***	0.99 (0.79-1.23)	**1.49 (1.05-2.12)***	0.79 (0.48-1.29)
High-level	Ref	Ref	Ref	Ref	Ref
Ethnic background					
Any White background	Ref	Ref	Ref	Ref	Ref
Mixed ethnic background	0.89 (0.44-1.78)	0.81 (0.38-1.74)	0.80 (0.42-1.53)	0.89 (0.31-2.50)	0.47 (0.19-1.20)
Any Asian Background	**2.16 (1.41-3.32)*****	**1.92 (1.22-3.01)****	**1.70 (1.12-2.59)***	**3.30 (1.99-5.47)*****	**2.37 (1.53-3.67)*****
Any Black background	**1.99 (1.13-3.49)***	0.78 (0.37-1.67)	**1.80 (1.05-3.09)***	1.57 (0.69-3.55)	**1.85 (1.03-3.34)***
Other	0.96 (0.39-2.37)	1.13 (0.46-2.80)	1.61 (0.77-3.40)	0.65 (0.15-2.81)	1.49 (0.63-3.51)
Sexual Orientation					
Heterosexual/Straight		Ref	Ref	Ref	Ref
Gay, Lesbian, Bisexual, other	1.12 (0.72-1.73)	1.04 (0.65-1.68)	1.03 (0.69-1.55)	1.76 (0.98-3.16)	1.15 (0.74-1.80)
Screening Status					
Today is my first screen	**1.98 (1.42-2.75)*****	**1.75 (1.23-2.48)****	**1.66 (1.21-2.27)****	**2.10 (1.35-3.27)****	**2.05 (1.46-2.88)*****
Been once before	1.36 (0.99-1.87)	1.21 (0.86-1.72)	**1.39 (1.04-1.86)***	**1.77 (1.15-2.73)***	**1.41 (1.01-1.96)***
Been twice before	1.15 (0.80-1.67)	1.02 (0.68-1.53)	1.19 (0.85-1.66)	0.5 (0.23-1.09)	1.31 (0.90-1.91)
Been 3+ times before	Ref	Ref	Ref	Ref	Ref
Experience of colposcopy					
No	Ref	Ref	Ref	Ref	
Yes	0.88 (0.68-1.13)	0.81 (0.62-1.06)	**0.67 (0.53-0.85)*****	**0.49 (0.32-0.78)****	**0.65 (0.50-0.86)****

ref=reference category, OR=Odds ratio, 95% CI=95% Confidence Interval. **Significant at * p<.05; **p<.01; ***p<.001**

Table S4: Logistic Regressions for feeling relaxed while using the kit and confidence that they have competed the kit correctly (adjusted for devise used)

	Moderately or very relaxed OR (95% CI)	Moderately or very confident OR (95% CI)
Age group		
25-29 years	0.76 (0.52-1.10)	1.27 (0.88-1.82)
30-39 years	Ref	Ref
40-49 years	0.93 (0.67-1.29)	1.09 (0.82-1.47)
50-59 years	1.46 (0.96-2.22)	1.36 (0.96-1.93)
60+ years	2.00 (0.95-4.26)	**2.40 (1.22-4.72)***
Marital Status		
Single	0.95 (0.71-1.29)	0.87 (0.66-1.14)
Married/civil partnership/cohabiting	Ref	Ref
Separated/Divorced/Widowed	1.39 (0.81-2.38)	1.44 (0.88-2.36)
Educational level		
Low-level	0.91 (0.61-1.37)	0.77 (0.54-1.11)
Mid-level	0.93 (0.69-1.25)	0.89 (0.68-1.17)
High-level	Ref	Ref
Ethnic background		
Any White background	Ref	Ref
Mixed ethnic background	1.79 (0.64-5.01)	3.02 (0.94-9.75)
Any Asian Background	**0.39 (0.24-0.62)*****	**0.46 (0.29-0.72)*****
Any Black background	0.75 (0.36-1.56)	0.66 (0.34-1.26)
Other	0.84 (0.31-2.22)	0.46 (0.21-1.02)
Sexual Orientation		
Heterosexual/Straight		Ref
Gay, Lesbian, Bisexual, other	1.23 (0.67-2.27)	1.17 (0.68-2.00)
Screening Status		
Today is my first screen	**0.57 (0.38-0.85)****	0.78 (0.53-1.15)
Been once before	**0.61 (0.42-0.89)***	1.04 (0.70-1.53)
Been twice before	0.73 (0.47-1.14)	0.90 (0.59-1.36)
Been 3+ times before	Ref	Ref
Experience of colposcopy		
No	Ref	Ref
Yes	1.29 (0.93-1.79)	1.02 (0.78-1.35)

ref=reference category, OR=Odds ratio, 95% CI=95% Confidence Interval
Significant at * p<.05; **p<.01; ***p<.001

Table S5: Examples of free-text comments about experience for each coded theme

Test was easy to do/simple
"Very easy and simple to use"
"Surprised how easy it was"

Test was quick
"Very quick"
"A lot faster"

Less pain/discomfort
"Much less uncomfortable than nurse led swab"
"The self-test wasn't painful in anyway"
"I thought it was good, less uncomfortable than using a tampon!"

Felt reassured by the nurse
"Was reassured by the nurse and that helped me relax"
"Nurses were informative, compassionate & reassuring which made all the difference"
"My nurse was brilliant and very professional. She made me feel relaxed and comfortable"

Comments on the device
"The 'device' was a little difficult to retract once the process was complete and before removal"
"The swab is very thin and bendy and so difficult to insert"
"Bright pink / purple feels a little condescending"

Comments about the position needed
"Would be easier at home in a recline position"
"I only hesitated about how high my leg should be"
"A little more advice as to how to position yourself for the test would be good"

Comments about the procedure
"Just uncomfortable pulling it out"
"I tried to hurry too much so initially had the swab in the wrong place, which caused pain"
"The mild discomfort was when turning it 5 times just before the clicks"

General positive comments about self-sampling
"This was my first Smear and I definitely preferred doing it myself to having the nurse do it as the docs procedure was much more invasive"
"Positive experience, if it helps women manage their health it can only be a good thing"
"Much simpler than booking a test with the surgery. It saves time and I'm more likely to do it at home at the right time as I always delay booking the appointment otherwise"

Comments about the test improving uptake
"This would be brilliant if it happens and hopefully allow a lot more ladies to come forward for the test especially as they can take part privately. Hopefully will end the stigma surrounding smears"
"I think it is a great way to get people to test especially those who are nervous/ embarrassed to go to the doctors"

Questioning correct completion/accuracy of self-test
"I'd be nervous I hadn't done it correctly or damaged the specimen and so be anxious the results were wrong"
"I was just a little worried that I didn't do it right"
"I only put that I prefer the test done by a nurse as this is obviously a very new concept and I just wanted it to be correct"

Future preferences to complete test at home
"It was strange to do it in GP surgery even though I was there by myself but I guess to do this self-test at home, it will be more comfortable"
"If they send it out to you and you could drop it at the surgery, would save a lot of time. I would prefer to do the self test at home rather than in the surgery"

Table S6: Examples of free-text comments about the instructions for each coded theme

Instructions were clear/easy to follow
 "Very easy to understand and use"
 "They were clear to understand"

Comments on the pictures/illustrations
 "The diagrams made it seem more complicated than it was"
 "The graphics are not very clear and make the self swab appear more complicated"
 "I liked the graphics as this will be useful for people where English is not their first language or those who have difficulties with reading."
 "The pictures helped a lot having a visual opposed to written instructions. It just confirmed I was doing it right."

Comments on text including structure and length
 "Print was too small"
 "Larger numbers on the panels so it is easier to follow the steps in order for people with poorer eye sight"
 "Due to the creasing of the pamphlet. I read down the page as opposed to across, to begin with and then had to re read the steps."

Explained by nurse (not given instructions)
 "The nurse explained the process rather than reading the written instructions which I found helpful."
 "Nurse explained fully the process whilst showing me the instructions - if she hadn't done this I may have struggled"
 "The Nurse demonstrated how to use the test so I didn't read them myself."

Comments about specific instructions
 How far to put swab?
  "Would be good to highlight how deep to insert swab"
 "I would maybe make it clearer how far inside you should insert the swab - I was told not to insert too far, but maybe there could be a clearer line or colour difference on the swab to indicate how far to insert."
 Confusion over wording instructions i.e. 'click'/ 'snap'
 "The 'snap' instruction made me ask if I needed to snap the sample stick as you would with a pcr"
 "The last instruction was incorrect as you don't snap the swab. It should say click the lid back on."
 "I think you have to turn the lock thing a certain direction to hear the click. I faffed about turning it the wrong way without a clock for a while"
 How much swab/circles?
  "There was no instruction as to how long or many circles you should do"

Instruction inconsistent with experience, inc position
 "The manual demonstration indicated the brush would flay out but mine did not. I was not certain I had done the test correctly however the nurse reassured me that it does not tend to flay out"
 "For me it was better laid down than stood up"

Recommendation to improve instructions
 "It is worth mentioning that if you've ever inserted a tampon or self tested for an STI a then this will be very similar maybe to ease people"
 "A demonstration before where I could understand the mechanism of the device would have been useful"