Acceptability of human papillomavirus self-sampling for cervical-cancer screening in under-screened Māori and Pasifika women: a pilot study

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ABSTRACT

AIM: To assess whether self-sampling for cervical-cancer screening is acceptable to New Zealand women.

METHODS: Māori, Pacific and Asian un- or under-screened women aged 30–69 years were asked to: 1) examine three self-sampling devices; 2) complete a questionnaire on demographics and experiences with the devices; and 3) take a self-sample. Samples were tested 'off-label' using the cobas® 4800 human papillomavirus (HPV) test (Roche Diagnostics NZ).

RESULTS: Thirty-one Pacific, 12 Māori, nine Asian and four women of other ethnicities participated (mean age, 39.5 years). Before trying any devices, 78% indicated a preference to self-sample, compared to 22% who preferred a physician-collected sample (PCS). After trying a device (HerSwab™, 91%; Delphi Screener™, 14%; cobas Swab, 13%; 12.5% used >1 device), fewer women (66%) preferred to self-sample next time, fewer (16%) preferred a PCS, while 18% expressed no preference. One of 32 samples with valid results (35 were tested) was positive for HPV 'other' oncogenic types.

CONCLUSIONS: This was the first New Zealand study to invite women, including Māori women, to take a self-sample for cervical-cancer screening. The pilot study suggests that un- and under-screened women generally find self-sampling acceptable and all sample types are suitable for use with the cobas HPV test.

In Aotearoa/New Zealand, there are long-term major ethnic inequalities in cervical-cancer screening, incidence and mortality, with Māori and Pacific women having lower screening and higher incidence and mortality rates than European New Zealanders.[1–5]

Reasons for low participation include cost, whakamā (embarrassment/shyness), tapu (sacred/taboo), access, models of care (eg, a lack of cultural appropriateness), and discomfort.[5–9] Actions to reduce these barriers have been undertaken; however, there has been little change in screening coverage.[2,10] Thus, novel strategies for increasing screening participation are needed.

Persistent infection of the cervix with any of 14 oncogenic human papillomavirus (HPV) genotypes can cause cervical cancer and its precursor lesions.[11] DNA testing for oncogenic types of HPV is more sensitive than cytology for the detection of high-grade lesions,[12] and is now recommended by the World Health Organization for early detection.[13] Therefore, primary HPV testing, rather than cytology, is being introduced in several countries,[14] and New Zealand will transition to HPV primary screening in 2021.[15]

One advantage of HPV-based screening is that, unlike cytology-based screening, it is possible for women to take a sample themselves. Internationally, offering

self-sampling has been shown to increase screening uptake,[16–21] but no New Zealand studies where women have taken a self-sample have yet been published. The study was undertaken to examine the acceptability of self-sampling in Māori, Pacific and Asian women, who have known low screening rates.[4] This pilot study aimed to: 1) examine the acceptability of self-sampling among un- and under-screened Māori, Pacific, and Asian women; 2) enquire about the level of comprehension of the instructions for self-sampling devices; 3) develop laboratory methods for processing cobas® *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG) swabs, Herswab™ and the Delphi Screener™ through the cobas 4800 HPV test; and 4) contribute ethnic-specific data to enhance the design of a national randomised controlled trial of the acceptability of self-sampling.

Methods

In New Zealand, cervical screening is recommended in women aged 20–69 years, but because the prevalence of HPV infections in women <30 years is high and most infections clear without causing cervical abnormalities, the usefulness of HPV testing in these women is limited.[22,23] Women aged 30–69 years who had ever been sexually active and who had not had a hysterectomy were therefore recruited. Eligible women were identified by Porirua Union and Community Health Service (PUCHS). Initially, recruitment was through mail, but this was replaced by recruitment through PUCHS nurses' community outreach and home visits, a presentation at a community health promotion meeting, and at the regular screening clinics. The number of women who were invited to participate was not recorded but feedback from the clinic staff indicated that the number of participants was determined by the availability of nurses rather than by the willingness of women to participate. Any woman who attended a screening clinic and was interested in and eligible for the study was enrolled when the nurses had sufficient time available.

Participants were asked to: 1) examine three different self-sampling devices; 2) complete a questionnaire (see Appendix); and 3) take a self-sample with at least one device (of their choice). The questionnaire was completed face-to-face followed by self-sampling and cytology at the clinic. Participants were given a package that included a brochure on cervical cancer and HPV infections, and three self-sampling devices, with written and illustrated instructions from the device manufacturers. The three self-sampling devices were: i) HerSwab (Eve Medical), ii) Delphi Screener (Rovers Medical Devices), and iii) cobas CT/NG Swab (Roche Diagnostics NZ).

The questionnaire was developed for this study, based partially on the one used for a Delphi Screener study in the US.[24] The questionnaire inquired about: i) general information such as age, occupation and ethnicity; and, ii) experience with the devices. The women were asked to answer questions both before and after using the devices to assess whether their actual experiences matched their expectations, and whether their experiences changed their preferences. The questionnaire also inquired about the clarity of the instructions for each device. The questionnaire consisted of multiple choice and open-ended questions.

The self-samples were stored at room temperature for up to 48 hours before laboratory analysis and tested 'off-label' using the cobas 4800 HPV Test. Samples were prepared for testing according to the type of collection device. Delphi Screener: the vial containing cells in saline was vortexed for 30 seconds and 1mL of resuspended cells were transferred to an 8mL tube (Sarstedt GmbH) containing 2mL of PreservCyt® Solution, then vortexed again for 30 seconds. HerSwab: each brush was snapped into an 8mL tube containing 2mL of PreservCyt, then vortexed for 30 seconds. The cobas Swab was vortexed for 30 seconds.[25] All samples were tested according to the manufacturer's instructions, except as noted for the sample preparation.[26] The cobas 4800 HPV test detects all 14 oncogenic HPV types, genotyping HPV16 and HPV18 individually and pooling the 12 other oncogenic HPV types as "other high-risk".[26] HPV results were not used for clinical management. All women were offered cytology testing, as per usual care, which was carried out in accordance with national guidelines and standard operating procedures (data not shown).

Data are reported as prevalences, with the open-ended questions reported qualitatively. The study was approved by the New Zealand Central Health and Disability Ethics Committee (14/CEN/211).

Results

Fifty-six women completed the questionnaire (see Table 1 for demographics), the majority of whom only used one self-sampling kit (87.5%; n=49); three used all three kits and four used two kits. HerSwab was used by 51 participants, Delphi Screener by eight, and the cobas Swab by seven.

Table 1: Characteristics of participants.

	Number (%)
Ethnicity	
Pacific	31 (55.4)
Māori	12 (21.4)
Asian	9 (16.1)
Other	4 (7.1)
Age[#]	39.5 (20-61)
Occupation^	
Housewife*	18 (32.7)
Healthcare worker[$]	13 (23.6)
Education[‡]	6 (10.9)
Other	18 (32.7)
Number of kits used by each woman	
1	49 (87.5)
2	4 (7.1)
3	3 (5.4)
Kits used	
HerSwab	51
Delphi Screener	8
cobas CT/NG Swab	7

[#]Median (range), date of birth was missing for two women; ^Data were missing for one woman. Percentages do not equal 100% due to rounding; *Includes home-maker, housework and mother; [$]Includes nurse, caregiver and community health worker; [‡]Includes teacher, home base teacher and home educator. CT/NG: *Chlamydia trachomatis/ Neisseria gonorrhoeae*.

Preferences and expectations before and after self-sampling

Before trying any devices, 78.0% (n=39/50) of women said that they would prefer to self-sample next time they were due for screening, and 22.0% (11/50) said that they would prefer a physician-collected sample (PCS; six women did not answer the question). After trying a device, fewer women (65.9%; n=29/44) preferred to self-sample next time, fewer women (7/44) preferred a PCS, and 8/44 expressed no preference (12 women did not answer the question after trying a device).

Table 2 shows the participants' responses to general questions before trying any of the devices. Only one woman said that she would not go for a follow-up test after a positive result; she said that this was because she would think that she was healthy and did not need further testing.

Table 2: Participant responses to questions prior to trying self-sampling devices.

	Age <40 years n (%)	**Age ≥40 years n (%)**	**Total**[#]
Receive kit through post	12 (54.5)	10 (45.5)	22
Collect kit from clinic*	13 (44.8)	16 (55.2)	29
Automatically sent kit when due*[$]	8 (50.0)	8 (50.0)	16
Written to or phoned before kit sent*[$]	16 (48.5)	17 (51.5)	33
Other	0	1 (100.0)	1
Would attend follow-up if result positive^	19 (45.2)	23 (54.8)	42
Would not attend follow-up if result positive	0	1 (100)	1

[#]Totals exclude women who did not answer the question; *plus one woman with missing age; [$]one woman answered that she preferred to be automatically sent the kit and that she preferred to be telephoned first, so she has been included in both categories; ^plus two women with missing age.

Table 3: Participant responses to questions about the device(s).

Question	Response											
	HerSwab				Delphi Screener				cobas CT/NG Swab			
	Positive* n (%)	Negative# n (%)	Neutral/ Other n (%)	No comment/ answer n	Positive* n (%)	Negative# n (%)	Neutral/ Other n (%)	No comment/ answer n	Positive* n (%)	Negative# n (%)	Neutral/ Other n (%)	No comment/ answer n
Before using												
General impression	28 (68.3)	7 (17.1)	6 (14.6)	10	4 (50.0)	4 (50.0)	0	0	4 (100)	0	0	3
Ease of using	43 (89.6)	5 (10.4)	N/A	3	5 (71.4)	2 (28.6)	N/A	1	7 (100)	0	N/A	0
Ease of following instructions	44 (89.8)	5 (10.2)	N/A	2	5 (71.4)	2 (28.6)	N/A	1	6 (85.7)	1 (14.3)	N/A	0
Amount of discomfort expected	26 (53.1)	23 (46.9)	N/A	2	2 (28.6)	5 (71.4)	N/A	1	6 (85.7)	1 (14.3)	N/A	0
After using												
Anything unclear in instructions^	7 (14.3)	42 (85.7)	N/A	2	0	7 (100)	N/A	1	1 (14.3)	6 (85.7)	N/A	0
Ease of using	36 (92.3)	3 (7.7)	N/A	12	6 (85.7)	1 (14.3)	N/A	1	6 (100)	0	N/A	1
Were the instructions helpful	40 (95.2)	2 (4.8)	N/A	9	6 (85.7)	1 (14.3)	N/A	1	6 (100)	0	N/A	1
Amount of discomfort experienced during last cytology test	18 (46.2)	21 (53.8)	N/A	12	6 (85.7)	1 (14.3)	N/A	1	5 (83.3)	1 (16.7)	N/A	1
Amount of discomfort experienced using device	27 (62.8)	16 (37.2)	N/A	8	6 (85.7)	1 (14.3)	N/A	1	5 (83.3)	1 (16.7)	N/A	1
Worry had not done test properly^	20 (47.6)	22 (52.4)	N/A	9	3 (42.9)	4 (57.1)	N/A	1	2 (33.3)	4 (66.7)	N/A	1
Using device against religious or cultural beliefs^	0	43 (100)	N/A	8	0	7 (100)	N/A	1	2 (33.3)	4 (66.7)	N/A	1

Percentages in table are out of the number of women who tried the device and answered the question. Since seven women used more than one kit the total number of participants included in the table is 66.
*Positive includes favourable, very easy/easy, none/very little, somewhat agree/agree, and yes; #Negative includes unfavourable, difficult/very difficult, some/a lot, somewhat disagree/disagree, and no; ^In this question a negative is a good answer. CT/NG: *Chlamydia trachomatis/Neisseria gonorrhoeae*.

Participants' impressions of specific devices

Before using any of the devices the women's impressions of the devices were mostly positive (Table 3). Before using HerSwab, 76.6% (n=36/47) of women said that they would prefer to use HerSwab next time they need to be screened, compared to 23.4% (11/47) who said that they would prefer to have a PCS (four women declined to answer). After using HerSwab, 63.4% (n=26/41) of women stated that they would prefer self-sampling, compared to 7/41 saying that they would prefer to have a PCS and 8/41 stating no preference (10 women declined to answer). Before using Delphi Screener, 4/6 women said that they would prefer to self-sample next time, 2/6 said that they would prefer to have a PCS, and two women declined to answer the question. After using Delphi Screener, 6/7 stated that they would prefer self-sampling, and 1/7 said that they would prefer to have a PCS (one woman declined to answer). Finally, before using the cobas Swab, all six women said that they would prefer to self-sample next time (one woman declined to answer). After trying the cobas Swab, all of the women who answered the question (n=6/7) stated that they would prefer self-sampling next time. Reasons for preferring to use a self-sampling device, a PCS, or for having no preference (captured by open questions, after trying a device) are given in Table 4.

As shown in Table 3, before using the device only 2/5 women who used Delphi Screener anticipated experiencing no or very little discomfort using the device, but after using it 6/8 said that they experienced no or very little discomfort.

The majority of the women said that there was nothing unclear in the instructions (Table 3). The only women who used HerSwab or the cobas Swab and thought

Table 4: Some of the participants' comments about the devices.

	Comments		
	HerSwab	**Delphi Screener**	**cobas CT/NG Swab**
Before using Favourable	"Small, colourful, appears easy" "Looks like it's easy to use, small, compact" "User-friendly"	"Awesome" "User-friendly" "Like a tampon"	"Easy" "Very easy" "Awesome"
Less favourable	"Ugh! The way it looks is off-putting" "Unsure/uncomfortable looking at this, but happy to have a go after this explained" "Hmmm!!! How does that work and will it collect what is needed?"	"Big" "Large and frightening"	N/A
After using For next screening test			
Prefer self-sample because…	Comfort and ease; being able to do it at home in own time; no appointment needed; convenience; no shame; privacy; less pain	"Easier"; "more comfortable"; "confidentially, privacy, and convenience"	"Easier"; "comfortable"; "privacy and convenience"; "rather do it myself"
Prefer cytology test because…	Self-sampling was painful; concern about not doing self-sampling correctly; cytology test would be done properly first time, is more thorough and more accurate	No comments given	N/A
No preference because…	"Will the swab indicate glandular cancers? I would like to alternate between self-testing and cervical smears" "Whichever one gives non-contaminated/ reliable result"	N/A	N/A
To return sample			
Prefer to use at home and mail to laboratory because…	Faster; more convenient; easier and saving time	No comments given	"Comfortable"
Prefer to use at home and take to clinic because…	Better hygiene; ease; tamper-proof	Sample won't get lost in mail; a lot easier, because sample can be dropped into clinic on way to an errand/work	"Flexibility"; "to make sure it gets to the clinic"
Prefer to use at the clinic because…	Ease; safety (including availability of help & sample being contamination-free); correctness of the procedure	Will not get contaminated	N/A
Have no preference because…	"This was a complete fail. The pink brush did not come out at all"	N/A	No comments given

Comments are either quotes (marked as such) or paraphrased for brevity. CT/NG: *Chlamydia trachomatis/Neisseria gonorrhoeae*.

that there was something unclear and who wrote a response, said that there were not enough instructions.

Some women said that they would worry that they had not done the test correctly: 47.6% (n=20/42) who used HerSwab, 3/7 who used Delphi Screener and 2/6 who used the cobas Swab (Table 3).

Preferences for where to self-sample

The majority of women who used HerSwab (38%, n=16/42) preferred to use it at the clinic, but only 1/7 who used Delphi Screener, and none who used the cobas Swab did so. The majority of women who used Delphi Screener (n=5/7) and who used the cobas Swab (4/6) said that they would prefer to use it at home and take the sample to the clinic, as did 29% (12/42) of women who used HerSwab. Twenty-four percent (n=10/42) of women who used HerSwab said that they would prefer to use the device at home and mail the sample to the laboratory in the future, as did 1/7 who used Delphi Screener, and 1/6 who used the cobas Swab. Ten percent (n=4/42) of women who used HerSwab said that they had no preference, while none who used Delphi Screener, and 1/6 who used the cobas Swab had no preference. Nine women who used HerSwab declined to answer the question, as did one who used Delphi Screener, and one who used the cobas Swab. Some of the (qualitative) reasons given for these preferences are given in Table 4.

Would the participants recommend using the self-sampling device to a friend?

The majority of the women would recommend using the device to a friend: 87.8% (n=36/41) who used HerSwab, 6/7 Delphi Screener and 6/7 the cobas Swab. However, 12.2% (n=5/41, 10 declined to answer) of women who used HerSwab, 1/7 (one declined to answer) Delphi Screener, and 1/7 the cobas Swab would not.

HPV testing

A total of 57 samples were received for HPV testing from 56 women. Of these, 22 samples had been stored for more than seven days at room temperature, exceeding the acceptable limits for testing, and were therefore discarded. The remaining 35 samples (one woman used two devices) gave unremarkable HPV results with one of these positive for HPV 'other' oncogenic type. Three (8.6%) of the samples were invalid/failed. Both of the samples from the woman who provided two (one from HerSwab and one from Delphi Screener) were negative.

HerSwab samples frequently returned "failed" results from the cobas HPV test, which resolved on removal of the sampling brush head from the test tube. There were additional handling problems with HerSwab during the pre-analytical phase, caused by sample loss through drying due to no lid on the device; cross contamination was also a potential issue. The Delphi Screener provided a macroscopic bolus of cells and the lack of a swab device in vitro meant that no issues were encountered when processing on the cobas® X480 instrument. There were no issues with the cobas Swab.

Discussion

This pilot study, which examined the acceptability of self-sampling in un- and under-screened Māori, Pacific and Asian women in New Zealand showed that, in general, the participants were positive about the self-sampling devices, which is in accordance with the hui (of 106 under-screened Māori women) findings of Adcock et al.[6] The participants found the devices easy to use, but several were worried that they had not taken the sample properly. The majority of the participants used only one self-sampling kit, and the nurses always presented the devices in the same order (HerSwab, Delphi Screener, cobas Swab), which explains why the HerSwab device was used most often. Indeed, the design of the HerSwab presented technical difficulties and contamination risks that could affect any HPV testing system; future users need to be aware of this. To the authors' knowledge this is the first study to show the use of Herswab and Delphi Screener with the cobas HPV test, albeit with a modification of the US Food and Drug Administration approved protocol.

Before trying any devices, 78% of the women (n=46/59) said that they would prefer to self-sample, rather than have a PCS, next time they were due for screening, showing that these women largely found the idea of self-sampling to be an acceptable alternative to a PCS. However, after they had tried using a device 'only' 70% (n=38/54) preferred that

option. Adcock et al[6] found that 61% of their survey participants (397 under-screened Māori women) would prefer to self-sample rather than have a PCS. In contrast to the current study, a study of 197 low-income, recently screened women in New York City, US showed an increase in preference for use of a self-screen (rather than a PCS).[24] The difference between the results of the current study and those of Jones et al[24] may be because the participants in the current study were un- and under-screened, rather than recently screened women.

The decrease in preference for self-sampling that was found in the current study was accompanied by a decrease in the preference for a PCS (22%, n=13/59 before trying a device, and 15%, n=8/54 afterwards) and an 'increase' in the number of women who expressed no preference after trying the device (n=8/54; all eight used HerSwab), an option that unfortunately was not available in the questionnaire before trying the device. Six women did not answer the question before trying a device, compared with 12 afterwards. So, it is likely that after trying a device, women were more inclined to state no preference or not answer the question rather than that they changed their mind about which test they would prefer in the future.

The women in the New York study experienced less discomfort taking a self-sample than they had expected,[24] and the majority of women in Canadian,[27] British[28] and Australian[7] studies found self-sampling comfortable. In contrast, of the women who only used one device in the current study (n=49/56), the majority (70%; 28/40) experienced the same amount of discomfort as they had expected, and nine (23%; 9/40) experienced less discomfort than they had expected. Nine women did not answer the question both before and after trying a device.

The study found that 42% (n=22/52, four women did not answer the question) of women would prefer to receive the self-sampling kit through the post, but most (58%; 30/52) would prefer to collect the kit from a clinic. Slightly more of the women who preferred to receive the kit through the post were aged <40 years (55%; n=12/22), whereas slightly more of the women who preferred to collect the kit from a clinic were aged ≥40 years (55%; 16/29). Similarly, Adcock et al[6] found that 64% of their survey participants would be happy to receive a kit through the post. The majority (67%; n=33/49) of the women said that they would prefer advance notice by mail or telephone before having a self-sampling kit sent to them next time they were due for screening. Reasonable postal delays will not affect the validity of the HPV self-sample test as recent research has shown that dry-brush self-samples stored at room temperature for up to 32 weeks were stable for both human genomic material and HPV.[29] Overall, age did not seem to have a large influence on women's preferences for how to receive the kit, but the small numbers meant that other possible explanatory factors (such as ethnicity) were not able to be examined. The ongoing national randomised controlled trial of the acceptability of self-sampling is further investigating these preferences.

A strength of this pilot study is that it included Māori and Pacific women who have persistently low screening coverage rates and a high burden of disease.[1,3,30] The limitations of the study include the small sample size, which limits the reliability and generalisability of the findings. The number of women who were told about the study and invited to participate was unfortunately not recorded due to the large workload of the PUCHS nurses. The participants also included women who were younger than the target age range, and who were not of the target ethnicities.

Conclusions

This is the first study of HPV self-sampling for cervical-cancer screening in New Zealand and the first to include Māori women. Although the sample size is small, the pilot study suggests that un- and under-screened New Zealand women generally find self-sampling acceptable and, with appropriate laboratory validation, all sample types will be feasible for use with the cobas HPV test.

Appendix

The following questions were used in the study questionnaire.

These questions were asked before any devices were used:

1. If you were going to use a self-sampling kit for cervical screening would you prefer to receive the kit?

   (Answer options: through the post; collect it from a clinic (such as your family doctor); other—please specify.)

2. If you were going to use a self-sampling kit would you prefer to be?

   (Answer options: 'automatically' sent the kit when you were due to be screened; be written to or phoned first; other—please specify.)

3. Would you go for a follow up test with the doctor (or specialist) if your self-sampling result was positive?

These questions were repeated three times in the questionnaire so that women could answer them for each device that they tried:

Please answer these questions before you try the [device name]

1. What was your impression of the [device name]?
2. Please indicate how easy or difficult you think it will be to use the [device name]?

   (Answer options: Very easy; Easy; Difficult; Very Difficult.)

3. Please indicate how easy or difficult you think it will be to follow the user instructions?

   (Answer options: Very easy; Easy; Difficult; Very Difficult.)

4. Please indicate the amount of discomfort you think you will experience using the [device name]?

   (Answer options: Very little; Some discomfort; No discomfort; Very much.)

5. Please indicate which method you would prefer the next time you need to be screened?

   (Answer options: Smear test health professional; Use [device name] myself.)

Please answer these questions after you have tried the [device name]

1. Was anything not clear on the instructions for using the [device name]?

   (Answer options: Yes; No (If No, please go to Q.x).)

2. What was not clear?
3. Which method would you choose the next time you need to be tested, self-sampling with the [device name] or having a health professional take a specimen during a smear test?

   (Answer options: Self-sampling; Smear test by a health professional; No preference.)

4. Why would you prefer this?
5. If you could use the [device name] which would you prefer?

   (Answer options: Use [device name] at home and mailing the specimen to clinic; Use [device name] at home and bring the specimen to clinic; Use the [device name] at the clinic; No preference.)

6. Why would you prefer this?
7. Please indicate how easy or difficult it was to use the [device name]?

   (Answer options: Very easy; Easy; Difficult; Very Difficult.)

8. Please indicate how easy or difficult it was to follow the user instructions?

   (Answer options: Very easy; Easy; Difficult; Very Difficult.)

9. Please indicate the amount of discomfort you experienced during your last smear test (please leave blank if you have never had a smear test)?

   (Answer options: Very little; Some discomfort; No discomfort; Very much.)

10. Please indicate the amount of discomfort you experienced using the [device name]?

    (Answer options: Very little; Some discomfort; No discomfort; Very much.)

11. Please indicate whether you would worry that you had not done the test properly?

    (Answer options: Disagree; Somewhat disagree; Somewhat agree; Agree.)

12. Please indicate whether using the [device name] would go against your religious or cultural beliefs?

    (Answer options: Disagree; Somewhat disagree; Somewhat agree; Agree.)

13. Which method would you prefer the next time you need to be screened?

    (Answer options: Smear test by health professional; Use [device name] myself; No preference.)

14. Would you recommend using the [device name] to a friend?

    (Answer options: Yes; No.)

15. Do you have any last comments on the [device name] or the smear test?

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