Feasibility and acceptability of telehealth and contactless delivery of human papillomavirus (HPV) self-testing for cervical screening with Māori and Pacific women in a COVID-19 outbreak in Aotearoa New Zealand

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ABSTRACT

AIM: To determine the feasibility and acceptability of a telehealth offer and contactless delivery of human papillomavirus (HPV) cervical screening self-test during the 2021 COVID-19 Level 4 lockdown in Auckland, New Zealand.

METHODS: A small proof-of-concept study was undertaken to test telehealth approaches in never-screened, due or overdue Māori and Pacific women enrolled in a local Primary Health Organisation (PHO). Study invitation, active follow-up, nurse-led discussions, result notification and a post-test questionnaire were all delivered through telehealth.

RESULTS: A sample of 197 eligible Māori and Pacific women were invited to take part, of which 86 women were successfully contacted. Sixty-six agreed to take part. Overall uptake was 61 samples returned (31.8%) and uptake of all contactable women was 70.9%. Six of the 61 HPV self-tests (9.8%) were positive, all for non 16/18 types, and were referred for cytology. Three had negative cytology results, and three with positive cytology results were referred for colposcopy.

CONCLUSION: The offer of HPV self-testing during COVID-19 lockdown was both feasible and highly acceptable for Māori and Pacific women. Importantly, HPV self-testing via telehealth and mail-out, alongside other options, offers a potential pro-equity approach for addressing the impact of deferred screens due to COVID-19 and other longstanding coverage issues.

Nearly 200 cases of cervical cancer are reported annually in Aotearoa New Zealand, with incidence and mortality rates in Māori and Pacific women more than two folds higher than in NZ European women.1,2 Cervical cancer incidence and mortality are strongly linked to being never screened or under-screened. The most recent review of cancer cases found only 12% of women aged 25–69 with cervical cancer in the years from 2012 to 2017 had been adequately screened.3 There is considerable inequity in cervical screening coverage rates between ethnic groups, with coverage for Māori, Pacific and Asian women substantially lower than for other women.4

Self-testing reduces a range of barriers to screening.5–7 Our research and other local studies have demonstrated that self-testing is acceptable, improves participation in screening and will improve equity if well implemented.8–10 We have shown that very overdue and never-screened Māori, Pacific and Asian women were more likely to accept offer of a mailed self-test kit than the same offer in a clinic and, further, that these groups of women have a strong preference for a mailed self-test method of delivery.11,12

Telehealth is the utilisation of information systems and technology to deliver healthcare, and aims to address challenges of health systems by increasing healthcare access and quality.13 The Outpatient Telehealth Trial at Waitematā District Health Board (WDHB) reported that reasons why patients chose telehealth outpatient appointments...
were to: reduce travel, save time, save money and shorten waiting times.14 Most patients saw telehealth consultation as a positive change.14

Telehealth has particular relevance to cervical cancer screening. Self-collected human papillomavirus (HPV) samples can facilitate continued screening during care disruptions, and can also be used to accelerate catch-up screening as we move out of pandemic-related crisis care. Participants can be supported via telehealth to self-test safely in their homes, and screening results can be discussed in subsequent virtual visits. This will reserve the limited in-person visits for those needing follow-up cytology, colposcopy or treatment.

Even though telehealth seems compelling, it is not always acceptable or accessible for patients. Over half of the participants in the WDHB telehealth trial declined the offer of telehealth appointments due to a lack of confidence with computers, or not having internet access or a space suitable to take a call.14 This highlights that a shift to telehealth may exacerbate inequities; however, with proper consideration these can be reduced or eliminated. The aim of our current study is to provide evidence on the impact of telehealth on cervical screening during the COVID-19 lockdown.

Methods
Study design and participant eligibility
Our research team planned to initiate a metro-Auckland implementation science study in 2021 in the context of likely ongoing COVID-19 outbreaks, testing different offer approaches, including: Phase 1) an opportunistic offer in primary care clinics (when people attend primary care for another reason they can be identified as eligible and offered a self-test); and Phase 2) a nurse-led telehealth invitation with mailed kits in partnership with Total Healthcare Primary Health Organisation (PHO), via the Tamaki Health general practice clinics. During the August 2021 Delta COVID-19 outbreak, we brought forward a modified Phase 2, proof-of-concept, that included contactless pick up and drop off to determine whether Māori and Pacific women would find it acceptable to be approached, and undertake a self-testing, in a COVID-19 lockdown.

The study was conducted from September to November in a geographically defined area of Auckland. The study population was Māori and Pacific women aged 30–69 years who were enrolled in a Local Doctors Tamaki Health Clinic (Total Healthcare PHO), who had a recorded address in one suburb of West Auckland, and who were due or overdue for cervical screening, or who had never been screened. Inclusion was determined from the most recently available routine data-match lists, matching the PHO enrolled population and National Cervical Screening Programme (NCSP) register data. Ethnicity data source was PHO data, prioritised as outlined in the New Zealand Ethnicity Data Protocols for the Health and Disability sector.15

Exclusion criteria were: (i) have or previously had cervical cancer; or (ii) had a history of a previous high-grade cytology result and not attended colposcopy or not complete a “test of cure” according to NCSP guidelines; or (iii) had gynaecological symptoms; or (iv) had a total hysterectomy; or (v) had never had sex; or (vi) invited/participated in previous HPV studies; or (vii) had another reason for exclusion (for example terminal illness or not eligible for New Zealand healthcare); or (viii) had contact details missing.

The initial exclusion check was performed at the data matching stage with a further check for eligibility on telehealth consultation.

The study, including data access, was approved by the New Zealand Health and Disability Ethics Committee (21/STH/141), the National Kaitiaki Group (NKG) and the NCSP.

The research topic was identified by the Hei Āhuru Mowai (the National Māori Cancer Network) and by health district Pacific leaders as significant.27 For this and prior foundational studies a range of consultation was undertaken, including with local Māori provider forum, the Iwi–DHB Partnership Board and the National Kaitiaki Group. The foundational work also included testing and development with eligible wahine Māori, and feedback is continuously sought from participants. The work is undertaken with the support of a Māori-led steering group and advisors, including Hei Āhuru Mowai members and the Chair of the National Screening Unit National Māori Monitoring and Equity Group. Four of the authors of this paper are Māori and one is Pacific.

Invitation and recruitment
The first contact with potentially eligible participants was through a text message with an invitation to take part. Interested participants were asked to reply with a “yes” and those not interested with a “no”. All those who responded with a “yes” had a nurse-led telehealth contact (offer of contact via phone or Zoom
Video Communications, Inc. (2020). The nurse-led discussions involved a second exclusion screen, discussion about the study and HPV self-sampling, informed consent, options for drop off and pick up of samples, interpretation and approach to HPV results.

**Single round of active follow-up**

Non-responders to the initial text were moved into a single round of active follow-up which involved a phone call attempt.

**Self-test kits**

The self-test kit contained a single blister-packed sterile Copan FloQ (5EO89N Copan, Italy) and an information sheet, instructions, and a laboratory form and labels. These materials were modified from our prior studies.1,6

**Contactless delivery model**

Due to delayed or limited courier service during the Level 4 lockdown, the self-test kits were delivered by study staff to participants’ residential address (mail-box) and completed tests picked up by the same method.

**Screening status definition**

Screening due is defined as ±6 months from the due date and overdue as >6 months from the due date.

**HPV testing**

All samples were tested for oncogenic HPV types using the BD Onclarity HPV Test (Becton, Dickinson and company, Franklin Lakes NJ, USA (BD)), a Polymerase Chain Reaction (PCR) test which amplifies targets in the E6 and E7 oncogenes of the HPV virus. It detects all 14 high-risk types of HPV (and individually genotype groups according to the following organisation: 16, 18, 45, 31, 51, 52, 33+58, 35+39+68, 56+59+66); and reports grouped as HPV16, HPV 18 or HPV Other (12 other non-16/18 oncogenic types). The Onclarity HPV test has a CE IVDD mark for HPV self-sampling using this collection device, and samples were processed at IANZ accredited PathLab Tauranga (Pathology Associates Ltd).

**Results management and follow-up**

Any invalid results were recorded, and a repeat test was offered to the participant.

Negative test results were provided to the women via text message, with advice to return for a routine cervical screen in five years, consistent with the Australian HPV self-test pathway and the proposed NCSP clinical pathway for primary HPV screening with self-testing. The Patient Management System (PMS) was updated with the appropriate recall interval.

HPV positive results were communicated via a telehealth contact (offered phone or zoom contact). In partnership with local colposcopy units, participants who tested positive for HPV16 or 18 were referred directly to colposcopy. Follow-up for participants who tested positive for any of the 12 other oncogenic HPV types involved a shared decision-making process including the options of a home visit for cytology test (followed DHB guidelines for home visit and Personal Protective Equipment (PPE) use), or a follow-up cytology test at the general practice clinic (protections as per COVID-19 guidelines at the time).

**Post-test questionnaire**

All participating women were asked to complete a post-test questionnaire. The questionnaire link was sent to women with negative results via text message during result notification, and to positive women following a discussion. Questions included how participants found being offered the self-test in lockdown, including their comfort with the decision they made about the self-test, the amount of information provided about the test, whether women found the self-sample acceptable, how they might prefer to be tested in the future,11,12,16 and any other comments about self-testing. Questionnaire results were analysed descriptively and reported as proportions, free text was coded and analysed thematically.

**Statistical analysis**

Data was analysed using STATA 12.0 (Statacorp, USA). Descriptive analyses were used to describe the proportion of participating women by age, ethnicity, screening status and HPV results.

**Results**

Routinely available data-match reports between PHO and NCSP Register identified 24,558 women due, overdue or never-screened for cervical screening (see Figure 1).

Data matching identified 816 Māori and Pacific women aged 30–69 years, enrolled with Tamaki Health and living in a specific suburb in West Auckland. Participants from our two previous studies were excluded (n=497). Exclusion of women who had hysterectomy, recent smear, had
Figure 1: Data matching and applying inclusion/exclusion criteria.

- **Inclusions**
  - Māori and Pacific women
  - Age 30–09 years
  - Enrolled with Tamaki Health clinic
  - Living in specific suburb in West Auckland

All potential eligible Tamaki patients
N= 24,559

Exclusion (n=497)
Participants of our two previous studies

All potential eligible for the study
Post-Inclusions (N=810)

- **Exclusion (s) N=122**
  - Hysterectomy (n=3)
  - Recent smear (n=1)
  - High Grade history (n=65)
  - Not eligible for NZ Healthcare (n=2)
  - Had no contact details (n=21)

All potential eligible for the study
N= 319

Total Eligible (N=167)

- Māori Women  
  n=86

- Pacific Women  
  n=111
high grade history, were not eligible for New Zealand health services, and had no contact details identified 197 women as eligible for the study; of which 86 (43.7%) women were Māori and 111 (56.3%) were Pacific women (Figure 1).

The demographic characteristics of all eligible participants (n=197) are shown in Table 1. The median age of the participants was 43 years (interquartile range 35–51 years; Table 1). More Māori participants were overdue (69.8% vs 48.6% Pacific women) and fewer were due for screening (24.4% vs 45.0% Pacific women). The proportion who were never screened was similar in both the Māori and Pacific groups. The time gap since a previous screen was up to 12 years for Māori women and up to 16 years for Pacific women, and a greater proportion of Māori women had their screens overdue by >10 years (8.1 % vs 2.7% for Pacific women) (data not shown).

**Self-test offer and follow-up**

Among the 197 women who were identified as eligible and invited to participate in the study, 35 women (18.0%) replied to the initial text indicating their interest to take part (Appendix 1). Three women declined participation. Text messages were not delivered to nineteen women due to incorrect contact details. Women who did not respond to the initial text message (n=140) were followed up, of whom 26 indicated their interest and 17 declined. Ninety-two women (65.7%) did not respond to any contact attempts. Overall, 66 women responded either through the initial text or follow up contact (33.5%) and had telehealth-led conversations with the Research Nurse. The average duration of the call with the research nurse was 3–5 minutes, with three calls lasting more than 10 minutes. Five women were excluded as they did not meet the study criteria (had previous hysterectomy n=4; recent smear n=1). In terms of participation, the overall response rate was 37.1%. The overall sample uptake was 34.3% and uptake of those contactable was 70.9%. Of note, no participants elected for a zoom telehealth appointment, all preferred phone contact.

**Self-testing kit and test results**

The time range for sample pick-up was 4 to 7 days. The results processing was batched, and the average time to receive results was between 2 to 17 days, due to concomitant COVID-19 test surge laboratory processing in Tauranga. Fifty-five HPV test results were negative. HPV other positive tests were seen in three Māori (positivity rate 11.1%) and three Pacific women (positivity rate 8.8%). All six women completed cytology tests, of which three returned negative cytology results.
Pro-equity in this context refers to proactive diagnostic delays. The number of people potentially at risk of cancer/bowel cancer screening. Twenty-one women provided free text comments about their experience of being offered the self-test, which were overall very positive about the self-testing process and their experiences (See Table 2). Their responses were coded into four thematic areas: (1) empowerment; (2) convenient, easy; (3) comfortable space; and (4) doing it yourself/no health professional involved.

Discussion

The modified version of the telehealth component of the HPV self-testing during the COVID-19 lockdown was found to be both feasible and highly acceptable to Māori and Pacific women in Aotearoa New Zealand. COVID-19 has impacted on the delivery of preventative healthcare across the world, particularly face-to-face activity such as primary care, cytology based cervical screening, breast and bowel cancer screening. In Aotearoa New Zealand, there were alert level changes where screening activity was paused (initial Alert Level 4) in 2020 and reduced throughout 2021, particularly in Auckland (Alert Level 2–4 and COVID-19 Protection Framework Orange and Red settings). Some estimates suggest that reductions in screening to a half or a third of usual levels, creating a backlog of deferred screens thereby increasing the number of people potentially at risk of cancer/diagnostic delays. Like many other COVID-19 impacts, delays are likely to have a disproportionate impact on Māori and Pacific populations, unless specific pro-equity approaches are taken.

Pro-equity in this context refers to proactive explicit policies, processes or interventions to address known causes of inequity, for example fast tracking referrals where diagnostic delay is a known cause of cancer inequity. HPV self-testing with telehealth and contactless delivery offers a mechanism to continue screening women even in lockdown or restrictions on face-to-face healthcare, and also to reach more women as part of addressing deferred screens. A similar approach was taken in Victoria, Australia in COVID-19, via telehealth appointments with general practitioners and referral for a mailed kit to the Australian Centre for Cancer Prevention. In the Netherlands, self-sampling has been offered as an alternative to a clinician examination since November 2020. Preliminary data suggest that while the number of tests collected by clinicians has remained low during the COVID-19 pandemic, the volume of self-screened samples has doubled, and overall screening participation has largely recovered to pre-pandemic levels.

There was already clear evidence from our research and other Aotearoa specific studies that HPV self-testing can enable increased participation and equity. This study provides evidence that extending such an approach using telehealth during a COVID-19 outbreak and in the context of an ongoing pandemic is acceptable, as it provides a relatively high level of participation and is a positive experience for women. This further reinforces our previous randomised community trial findings that participants, particularly Māori women preferred, and were more likely to participate, in home-based mail-out screening.

Our previous study mailed directly to all potentially eligible women (a different population of very overdue or never-screened participants), with a relatively modest uptake of 12% (15% for Māori, and 9% for Pacific), with associated population study limitations of the inability to determine contactability and eligibility for exclusions (e.g., previous hysterectomy, symptoms). This suggested that mail-out was a critical model for delivery, but that a “mail-out to all” approach may not be the optimal approach. Our colleagues from a Northland based study reported 23% of women to be uncontactable and uptake levels for Māori, and 9% for Pacific), with associated population study limitations of the inability to determine contactability and eligibility for exclusions (e.g., previous hysterectomy, symptoms). This suggested that mail-out was a critical model for delivery, but that a “mail-out to all” approach may not be the optimal approach. Our colleagues from a Northland based study reported 23% of women to be uncontactable and uptake levels for all contactable women of 42% and 50.8% for Māori and Pacific women. The current small study found that 56% of potential participants were uncontactable leading to overall uptake of 34.3%, but uptake among contactable was high at 70.9%. To improve the pro-equity approach, future approaches should extend beyond telehealth to support

Post-test questionnaire

Thirty-five women completed the post-test questionnaire (response rate 57.4%), of which majority (n=21) thought lockdown was a good time to be offered the self-test and 14 participants were neutral. All of the respondents reported that the information provided on self-testing was “about right”. Most women (n=28) were comfortable about their decision on self-testing, while seven were neutral. Nearly all women (n=31; 88.6%) indicated that when they were next due for cervical screening, they would prefer to get a self-test kit in the mail to do at home.

Twenty-one women provided free text comments about their experience of being offered the self-test, which were overall very positive about the self-testing process and their experiences (See Table 2). Their responses were coded into four thematic areas: (1) empowerment; (2) convenient, easy; (3) comfortable space; and (4) doing it yourself/no health professional involved.
#### Table 2: Feedback (free text comments) from women completing the post-test questionnaire.

<table>
<thead>
<tr>
<th>Theme</th>
<th>Feedback</th>
<th>Participant details (ethnicity and age band)</th>
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<tbody>
<tr>
<td><strong>Empowerment</strong></td>
<td>“Home test kits would be preferred option as it protects my mana as a wahine”.</td>
<td>Māori, 45–50 years</td>
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<td></td>
<td>“Being comfortable in myself doing the self-screening and not feeling embarrassed. Thank you for the opportunity of self-respect”.</td>
<td>Māori, 40–45 years</td>
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<td><strong>Convenient, easy</strong></td>
<td>“I thought it would be hard but it was very straight forward and it was convenient.”</td>
<td>Pacific, 30–35 years</td>
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<tr>
<td></td>
<td>“It was so easy.”</td>
<td>Pacific, 40–45 years</td>
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<td></td>
<td>“It was just a lot easier and simple.”</td>
<td>Pacific, 35–40 years</td>
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<td></td>
<td>“… much more achievable approach for busy mums.”</td>
<td>Pacific, 30–35 years</td>
</tr>
<tr>
<td></td>
<td>“It was stress-free, easy to do.”</td>
<td>Māori, 35–40 years</td>
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<tr>
<td></td>
<td>“it was easy and simple. I would recommend it to all.”</td>
<td>Pacific, 40–44 years</td>
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<tr>
<td></td>
<td>“This was a great experience, my wish is that this is available to all women, this will save lots of lives. It was easy, most women will do it.”</td>
<td>Māori, 50–53 years</td>
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<td></td>
<td>“Very simple process. Spoke to a few of my colleagues, they would be so interested in home self-testing.”</td>
<td>Māori, 35–40 years</td>
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<tr>
<td><strong>Comfortable space</strong></td>
<td>“Satisfied and did it at my own space and time.”</td>
<td>Māori, 40–45 years</td>
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<tr>
<td></td>
<td>“It was private.”</td>
<td>Māori, 30–35 years</td>
</tr>
<tr>
<td></td>
<td>Easier experience, felt more comfortable doing it from home.”</td>
<td>Pacific, 55–60 years</td>
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<td></td>
<td>“I was relaxed when I did the test at home.”</td>
<td>Pacific, 40–45 years</td>
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<tr>
<td></td>
<td>“It was ease of doing it at home in my own environment, easy to do and I am so proud of myself.”</td>
<td>Pacific, 50–55 years</td>
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<td></td>
<td>“It was easier for me to self-swab at home. I get quite anxious when its time for my smear and often leave it for the very last minute and it’s always been a painful experience except for the self-test which was uncomfortable but not painful.”</td>
<td>Pacific, 40–45 years</td>
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<td></td>
<td>“I am very comfortable doing this myself. I don’t like other people doing such a personal thing for me. Whist I have had children; I find smear tests to be very personal. Doing it myself makes me want to keep doing the checks.”</td>
<td>Māori, 45–50 years</td>
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<tr>
<td></td>
<td>“I talked to other women of my age who would like to do what I did.”</td>
<td>Pacific, 50–55 years</td>
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other options to reach uncontactable women, as previous research has highlighted this is likely to disproportionately affect Māori.8,11

This study provides further policy-relevant information for the NCSP on the utility of a text-based invitation with nurse-led telehealth and mail-out (courier, contactless) delivery model. Although the contactless option undertaken by the study team worked well in this small proof-of-concept study, courier delivery for a mailed option will be required for HPV self-test at scale. Most women (88.6%) reported that they preferred to receive posted HPV self-test kits when they are next due for a screen. This is very similar to our previous research that found home posting of kits to be feasible and acceptable, with 72.1% of women preferring to receive a mailed kit at home at their next screen.12

Our research team have developed the implementation science main study to test a clinic-based primary opportunistic offer in association with a telehealth model on the premise that a range of delivery options as well as active follow-up for both invitation and for positive results management are likely to be required to achieve equitable screening outcomes.25 This approach is consistent with the Waitangi Tribunal Hauora Inquiry report26 that outlined options as one of the five updated Te Tiriti principles, and is also consistent with the requirements for an equitable HPV primary screening programme outlined by Hei Āhuru Mowai, the national Māori cancer leadership group.27 The current roll-out of primary HPV screening in Aotearoa New Zealand is based around primary care delivery only, with the potential for mail-out options in the future. It is important to ensure that such an approach is appropriate and works for Māori women from a Te Tiriti perspective, and also for Pacific women and the perspective of those most impacted by current inequities.

The post-test questionnaire had a relatively high response rate, with the majority of women being comfortable with the self-testing offer in COVID-19 lockdown, feeling that they had sufficient information via telehealth to make a decision, and feeling positive about self-testing. This is consistent with our own prior work and that of our colleagues.5,8,9

Our study had a positivity rate of 10% (six women with HPV positive results), which was slightly higher than our previous study (6%),8 but similar to the Northland study (11%).10 Follow-up of HPV positive women, particularly where equity is a focus, remains a somewhat contentious issue nationally. Triage with cytology for HPV positive results is recommended in the proposed Aotearoa New Zealand clinical pathway, particularly due to the anticipated impacts on colposcopy services related to the higher sensitivity of HPV primary screening (higher volumes of women referred). The added step of cytology prior to colposcopy is intended to help manage colposcopy demand, with some limited case-by-case allowance to be referred straight to colposcopy. Hei Āhuru Mowai have outlined a rationale for Māori women with HPV, regardless of oncogenic type, to be referred straight to colposcopy, as a pro-equity approach, to reduce cost and time barriers and ensure women are not lost to follow-up.27

This small proof-of-concept sub-study showed that the offer of a HPV self-test for cervical screening via text with telehealth support and contactless delivery is acceptable to Māori and Pacific women in Aotearoa New Zealand. It was

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<tr>
<td>Doing it yourself / no health professional involved</td>
<td>“It was awesome to do it on my own way, more comfortable and better solution for myself and many other women.”</td>
<td>Pacific, 45–50 years</td>
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<td></td>
<td>“It was so much better having this done at home. I didn’t feel embarrassed and horrible having another person do it for me. I prefer this home testing above all.”</td>
<td>Māori, 30–35 years</td>
</tr>
<tr>
<td></td>
<td>“I’d love the other ladies to do it this way if there’s an option as I feel women would likely do it themselves.”</td>
<td>Pacific, 40–45 years</td>
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Table 2 (continued): Feedback (free text comments) from women completing the post-test questionnaire.
important to test this given the potential for novel interventions and telehealth to have equity positive or equity negative impacts, depending on how they are implemented and on a range of contextual factors. The study was also important given the current inequities in cervical cancer outcomes and screening coverage, and also the impacts of COVID-19 on cervical screening and primary care, which are likely to be unevenly distributed. These findings reinforce our previous research on the importance of mail-out as an option that participants strongly prefer, with important equity benefits. The findings also support the current main implementation science study which offers a range of options for a self-test, including opportunistically in clinic and via telehealth options.
COMPELING INTERESTS
Nil.

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REFERENCES


Appendix 1: Flow diagram showing the eligibility, recruitment and result management processes for self-testing.