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Abstract

Background

Human papillomavirus (HPV) self-testing was introduced in Aotearoa New Zealand in September 2023, with the potential to improve screening access and reduce inequities for priority populations: Māori, Pacific, and those overdue for screening by ≥2 years (underscreened). To contribute towards informing this change, we tested the implementation of offering the self-test opportunistically in primary care (with a take-home option) with follow-up by a central nursing team.

Methods

Trained general practice clinicians offered HPV self-tests to eligible people aged 30-69 years who attended for any reason between November 2021 and September 2023. Six clinics were selected for high proportions of priority populations. The central team reminded participants to return samples (if tested at home), and notified and managed HPV results via telehealth.

Results

Of 9,292 potentially eligible people, 37.9% (n=3,524) were self-tested. A lower rate of self-testing was seen in all priority populations: 34.7% in Māori and 36.3% in Pacific vs. 40.4% in European/Other ($p<0.01$, $p<0.05$, respectively), and 32.2% in underscreened vs. 52.3% in those <6 months overdue (due) ($p<0.001$). In the 16.8% of participants who took self-test kits home (n=635), 61.1% (n=388) returned a sample. Priority populations were more likely to take a test kit home: 22.2% of Māori and 20.0% of Pacific vs. 12.1% of European/Other, and 21.5% of underscreened vs. 11.7% of due (all $p<0.001$). Although a similar return rate was seen in Māori (64.3%) vs. European/Other (70.3%), fewer Pacific (51.1% vs. 70.3% in European/Other; $p<0.05$) and underscreened (48.7% vs. 89.4% in due; $p<0.001$) returned their sample. HPV was detected in 9.5% of 3,524 returned results. Follow-up testing rates were high (96.4% for cytology; 92.8% for colposcopy).

Conclusions

Opportunistically offering HPV self-tests in primary care engaged priority populations in cervical screening. Intensive support is required to achieve high rates of sample return (if tested at home)

and follow-up where HPV was detected. Opportunistic offer of HPV self-testing in primary care should be considered as an important component of a broader strategy to increase equitable participation in cervical screening, with more focus needed for Māori, Pacific and those who are underscreened.

Trial registration

This study did not reach the ICJME or WHO criteria for clinical trial registration.

Key words

Cervical screening; human papillomavirus (HPV); self-sampling; at-home testing; primary care; Māori health, Pacific health; health inequity.

Manuscript

Background

In Aotearoa New Zealand, cervical screening is organised centrally through the National Cervical Screening Programme (NCSP) and delivered mainly through primary care. Access barriers to cervical screening are well documented and include opportunity costs for preventative care, primary care out-of-pocket visit costs, accessibility issues, cultural safety and travel (1). Government equity initiatives have been in place for decades, with the most recent funding free cervical screening for groups at higher risk of cervical cancer; however, access barriers remain (2). Priority populations, those with the highest cervical cancer burden, include Māori (the Indigenous population), Pacific (those with Pacific Island origins), those who are overdue by ≥2 years (underscreened), and those living in areas associated with high socioeconomic deprivation. For Māori, underlying system-level barriers also contribute to health inequities (3, 4).

The New Zealand Ministry of Health | Manatū Hauora commissioned three local research groups to undertake implementation studies to directly inform the design and development of the HPV primary screening programme. HPV self-testing was novel in the New Zealand setting at the time of our research, as was the opportunity to expand the opportunistic offer of cervical screening through the use of a self-test. Our findings and insights, alongside that from our colleagues (5) and international programme experience (particularly Australia), were relayed in real-time to policy makers and the NCSP, which informed both the decision to move to a programme with primary offer of a self-test and guidelines for the management of HPV triage to support equitable participation (6, 7).

The programme changed from a liquid-based cytology (LBC) programme, with recall and screening delivered through general practice (in place at the time of our research), in September 2023 to HPV self-tests, to be taken in the clinic offered as an option alongside a clinician-taken sample with

cytology triage of HPV Other detected results and direct referral to colposcopy of HPV 16/18 (8). In the programme change, opportunistic offers and take-home self-tests are at the discretion of the practitioner rather than routine practice. The NCSP eligibility age range (changed prior to HPV screening) is 25-69 years and the standard screening interval changed from 3 years in the cytology-based programme to 5 years for people with an HPV not detected result (8). The revised NCSP anticipated improved screening access to reduce longstanding and unacceptable inequities (8). New Zealand and international studies show that the self-test can increase participation for priority populations who experience the most barriers to screening (1, 9, 10, 11, 12, 13, 14).

Nearly nine months after the programme change, self-testing was the option used for 80.7% of tests (15). Overall cervical screening coverage in New Zealand increased from 66.9% in September 2023 to 73.6% in March 2025 (16). While screening coverage for all ethnicities increased, disparities persist for Māori (67.1%) and Pacific (71.7%) versus European/Other (81.5%) (16). Furthermore, 18.9% of those tested were un- or underscreened (15). With the known barriers to primary care access, a move to self-testing without significant change to the programme delivery model may not maximise the potential to improve participation and timely follow-up in priority populations who would benefit the most. A risk remains that mortality inequities may increase if priority populations have less access to self-testing than populations with lower risk of cervical cancer (17).

Offering the HPV self-test opportunistically when people attend their GP clinic may reach more of those due for screening. Health survey data (2023-24) found that most (80%) New Zealand women (all groups) were enrolled with a primary care provider and visited a general practitioner (GP) at least once in the previous 12 months (74% for Māori and 70% for Pacific) (18). Following a pilot in six clinics (19), a large-scale evaluation within the English screening programme in ethnically diverse London general practices (YouScreen) found opportunistic offers of the HPV self-test in GP clinics to be feasible and acceptable (20).

In New Zealand, studies that directly offered the self-test in primary care did so alongside other invitation methods (14, 21, 22). To our knowledge, there has been no comprehensive quantitative exploration of implementation of opportunistic offers in New Zealand GP clinics.

In this current study, we explored offering HPV self-tests opportunistically to people due for cervical screening and attending their primary care clinic for any reason and included the option to take a test-kit home, with a central process to follow-up sample return and results. This is a novel approach, as New Zealand primary care providers do not uniformly offer opportunistic screening, at-home testing, centralised follow-up or standardised reminders. We tested a centralised nurse-led specialist co-ordination team as an alternative to general practice results management for future consideration in New Zealand. We explored real-world implementation processes, considering feasibility of opportunistic testing for clinic staff alongside the ability of the strategy to reach and be effective for priority underscreened populations.

Methods

Study design

This was a hybrid II implementation effectiveness research study using mixed methods and the RE-AIM evaluation framework to assess the introduction of a new screening test (23). The RE-AIM outcomes are planned to be reported elsewhere. This study offered HPV self-tests to people due for cervical screening and eligible for the HPV self-test who attended their GP practice clinic for any reason between November 2021 and September 2023, prior to the change in the national screening programme.

Aims and objectives

We aimed to trial an opportunistic screening pathway from the offer of HPV self-test through to at least the first follow-up test, where required. The objective of the study was to test the process of,

and response to (participation and test completion), an opportunistic offer of the self-test with centralised nurse-led follow-up.

Setting

A large metropolitan Primary Health Organisation (PHO) was selected for the study. In New Zealand, PHOs coordinate primary healthcare services to an enrolled population via general practices. PHOs are funded by the government to subsidise healthcare for their enrolled patients. The PHO partner for this study has 50 general practice clinics operating on a centralised, shared database, with enrolment of around 260,000, serves an ethnically diverse enrolled population disproportionately living in areas of high socioeconomic deprivation and low cervical screening coverage (30.8% in Māori and 30.5% in Pacific (personal communication from the PHO) vs. 59.8% and 57.9%, respectively (24), nationally in October 2021). In the PHO's service model, enrolled patients can attend any clinic across their network and cervical screening is provided free of charge to all. In most New Zealand GP clinics, there are variable out-of-pocket costs for cervical screening, unlike other cancer screening programmes.

Six clinics (five in south Auckland and one in west Auckland) were selected as they had high numbers of Māori, Pacific and underscreened people. Our study was conducted during the COVID-19 pandemic, with periods of lockdown restrictions that affected primary care clinic staffing levels and patient attendance.

Training/credentialling

Forty clinical staff (31 nurses, 9 GPs) were trained to offer HPV self-tests using specifically designed modules, an on-site training session and credentialling quiz. Ongoing support was available to clinicians from our team of cervical screening nurses (central nurses) via the co-ordination centre. The clinics were onboarded sequentially once staff were trained from November 2021.

Eligibility

Inclusion criteria were people aged 30-69 years, enrolled with the PHO and meeting the NCSP Clinical Practice Guidelines as eligible for self-testing (i.e. people with a cervix and due for cervical screening) (8). Exclusion criteria were total hysterectomy, history of cervical cancer, no longer residing in New Zealand, previous high-grade lesion and no test of cure, symptomatic (e.g. abnormal bleeding or discharge), or never been sexually active. Eligibility could change over time as people enrolled with another PHO or became ineligible for screening.

Participant recruitment

When people eligible for HPV self-testing (the potentially eligible cohort) attended a study clinic for any reason during the study period, a flag indicating NCSP eligibility appeared on their records on the practice management system (PMS) dashboard. This was a prompt for primary care clinicians, generally nurses, to offer the HPV self-test.

People interested in participating were given a study brochure and had their eligibility confirmed by credentialled clinic staff, which included clinical assessment questions related to the other self-test eligibility criteria (e.g. gynaecological symptoms, hysterectomy, cervical screening history). Eligible people who agreed to join the study provided informed consent (the participant cohort) and were recorded in the study IT system (see Study IT system below). An automated welcome text offering information and phone support was sent to all participants on the day of consent. The study brochure was developed based on findings from focus groups with Māori, Pacific, and Asian participants (13), and was available in te reo Māori, Samoan, Tongan and English. People who were eligible and chose to have a clinician-taken sample instead of participating in HPV self-testing were excluded from the study.

Self-test return

Participants were given a self-test kit with instructions (Supplementary file 1) and encouraged to take the sample in the clinic (the clinic collected cohort). However, taking a kit to complete at home was an option (the kit taken home cohort). These two cohorts combined form the self-tested cohort.

Home-collected samples could be returned to the clinic or a community laboratory collection centre. Additional test kits for invalid test results or by participant request were sent by courier. Participants with more than one test result (e.g. if the first result was invalid) are counted only once. Participants who took a kit home entered active follow-up, including a schedule of text message and phone call reminders to return the sample (Supplementary file 2). Text message wording was developed in consultation with Māori engagement staff.

HPV test

Completed samples, from swabs taken in clinic and at home, were transported dry and at ambient temperature to a single laboratory and processed using the BD Onclarity HPV molecular test (reporting 12 oncogenic HPV types, outputted to match the NCSP programme change as HPV 16, HPV 18 or HPV Other), which has a CE IVVD mark for HPV self-sampling with the Copan collection device and is accepted as a validated test by the NCSP. HPV test results were sent from the laboratory to the study IT system by HL-7 message, as well as to the PHO clinical lead, and the NCSP Register.

Central nurse-led co-ordination team

A central co-ordination and results management team was led by experienced cervical screening nurses, supported by Māori and Pacific engagement and administration staff. Central nurses provided training of clinic staff and oversaw HPV results management. Administration staff were responsible for the follow-up of kits taken home and sending new kits.

Results management

The central nurses communicated HPV test results to participants and managed all follow-up requirements according to the (at the time draft) NCSP guidelines (8). Participants with HPV not detected results were notified by text message. Participants with HPV detected results were informed by phone and a follow-up text message sent with links to further information/frequently

asked questions on the study website (Supplementary file 2). Participants with invalid test results were informed by phone and sent a new test kit.

Participants with HPV 16/18 were referred for colposcopy at the appropriate district hospital service with an offer of kaiawhina support (holistic practical and cultural support from a Māori staff member, e.g. with transport or childcare; different to Māori engagement staff) to attend appointments. Participants with HPV Other could choose to have a triage cytology (LBC) performed by their primary care provider or a central nurse (at a study clinic or their home). LBC samples were processed by the cytology service routinely used by participating clinics in accordance with NCSP standards. To reflect current NCSP guidelines (8), we included colposcopy data from participants referred with high-grade cytology findings and excluded low-grade referrals made under previous guidelines.

Study IT system

A bespoke web-based clinical software application was developed for this study. Two components were built into the primary care PMS: the patient dashboard (linked to NSCP PHO-level data) provided a prompt that a person presenting to the clinic was eligible for screening, and an advanced form enabled the eligibility and consent processes to be entered into the study database by GP clinic staff. Although most primary care PMS dashboards will flag eligibility to clinicians based on practice data, we developed our own software that displayed eligibility based on NCSP data for greater accuracy for people who may have been screened elsewhere in New Zealand and for the central co-ordination team to oversee study participants.

The co-ordination team recorded each step of results management and follow-up in the study database. HPV test results were received into the system via the HL-7 interface, which also enabled results and messages to be sent to the PHO clinical lead. Manual and automated text messages were sent from and messages from participants were received by the system.

Data collection

Data on the eligible cohort were obtained from the PHO and supplemented for screening status by NCSP Register data. Data on those who participated in the study were obtained from the study IT system. The study data was censored at 22 April 2024; HPV results received after this time were not included in this analysis. Clinical management of a small number of active study participants continued but was not relevant to the results presented here (i.e. to support participants until discharged from colposcopy).

Statistical analysis

Descriptive analysis was performed to present numbers and percentages overall and for individual subgroups. Univariable logistic regression was performed to compare the subgroups, and the effect size was presented using odds ratios (OR) and their corresponding 95% confidence intervals (CI) and p-values. A p-value of <0.05 was considered statistically significant. The analyses were conducted using Excel (25) and Stata 18 (26).

Variables

Ethnicity data in New Zealand is self-identified and people can identify with multiple ethnic groups; where participants identified more than one ethnic group, ethnicity was prioritised according to the New Zealand Health and Disability Ethnicity Data Standards: Māori > Pacific > Asian > European/Other (European/Other includes New Zealand European, other European, Middle Eastern, Latin American and African) (27).

Data on gender were not collected; eligibility to the NCSP is for “anyone with a cervix or vagina who has ever been sexually active” and aged 25-69 years (8).

Socioeconomic deprivation status was derived from the New Zealand Index of Deprivation for 2018 (NZDep2018) data. NZDep is an area-based measure of household and individual census data reported in deciles, although we report quintile data, where 20% of the population is represented by each category (28). We consider quintiles four and five to represent higher socioeconomic deprivation.

Time since the last recorded due date for a screen (screening status) and age were calculated as at the date of attendance.

Screening status is categorised by the NCSP (29) as due (from >0 to <6 months after last recorded due date on the NCSP Register), overdue (from ≥6 months to <2 years after due date), underscreened (≥2 years since due date), and unscreened (no recorded screen date in New Zealand).

Results

Recruitment to the study

The population potentially eligible for study recruitment (i.e. those who attended a participating clinic and were due for screening at the time of attendance) was 9,292 (Figure 1). Of these, 3,771 enrolled with the study and received a self-test kit, giving an overall participation rate of 40.6% (Table 1). Participation rates did not differ by ethnicity. Significantly lower participation rates were seen in those who were under- and unscreened in New Zealand, and those living in areas associated with high socioeconomic deprivation than their respective comparator groups (Table 1).

Participant demographics

Priority populations were well represented (55.1%; Māori 13.7%, Pacific 41.4%) in the participant cohort. Most (68.1%) of the participants were ≥6 months overdue for cervical screening and more than a third (36.8%) were ≥2 years overdue (underscreened). Greater proportions of Māori and Pacific were underserved by standard screening practice (48.7% in Māori and 45.6% in Pacific were underscreened vs. 30.8% in European/Other). Most (65.9%) of the participant cohort lived in areas associated with high deprivation, with the highest proportions in Māori and Pacific (78.7% and 82.7%, respectively, vs. 52.1% in European/Other).

The participant cohort was generally similar to the potentially eligible cohort, with no statistically significant difference by ethnicity or socioeconomic deprivation; the only significant between-group differences were seen when analysed by each screening status (see Supplementary file 3).

Participants screened

Among the eligible people who received a self-test kit, 93.5% completed their test (n=3,524 of 3,771) and 37.9% of those potentially eligible people were screened (n=3,524 of 9,292) (Table 1). The self-tested people include both participants who took their sample in the clinic (n=3,136; 89.0%), and those who completed their self-test at home (n=388; 11.0%).

Of all screened participants (n=3,524), 13.5% were Māori, 40.0% were Pacific, 35.0% were underscreened, and 65.0% lived in areas associated with high socioeconomic deprivation. In the underscreened self-tested group (n=1,234), the mean time overdue was 5.4 years, and the maximum time was 28.1 years, and 35.3% of this group (n=436) were more than 5 years overdue, which is 12.4% of all self-tested participants. Of the underscreened self-tested group, 17.9% were Māori and 49.4% were Pacific. Of the Māori and Pacific underscreened self-tested groups, 81.0% and 84.6%, respectively, lived in areas associated with higher deprivation versus 55.7% of European/Other.

The proportion of self-tested people from the potentially eligible population was significantly lower in Māori (34.7% vs. 40.4%; OR 0.78 (95% CI 0.65, 0.94); p<0.01) and Pacific (36.3% vs. 40.4%; OR 0.84 (95% CI 0.71, 0.99); p<0.05) than in European/Other participants (Table 1). Significantly lower self-tested rates were also observed in un- and underscreened participants, and in those living in areas associated with higher deprivation quintiles than in each of the respective comparator subgroups (Table 1).

Self-test kits taken home

Overall, 16.8% of study participants (n=635 of 3,771) took a self-test kit home. A significantly higher proportion of Māori (22.2% vs. 12.1%; OR 2.07 (95% CI 1.39, 3.10); p<0.001) and Pacific (20.0% vs. 12.1%; OR 1.82 (95% CI 1.26, 2.62); p<0.001) participants took a self-test kit home compared with European/Other (Table 2). Significantly more underscreened (21.5% vs. 11.7%; OR 2.06 (95% CI 1.55, 2.75); p<0.001) and unscreened in New Zealand (16.9% vs. 11.7%; OR 1.53 (95% CI 1.10, 2.13);

p<0.05) participants took a kit home than those due for screening (Table 2). Significantly more participants living in the most deprived areas took a kit home than those living in the least deprived areas (19.4% vs. 13.6%; OR 1.54 (95% CI 1.26, 1.88); p<0.001).

Sample return of self-test kits taken home

Of the 635 participants who took a self-test kit home, 61.1% (n=388) returned it for testing (Table 2). The sample return rate in Māori was similar to that in European/Other (64.3% vs. 70.3%; OR 0.76 (95% CI 0.34, 1.70); Table 2), but was significantly lower in Pacific than in European/Other participants (51.1% vs. 70.3%; OR 0.44 (95% CI 0.21, 0.93); p<0.05; Table 2). Sample return rates were significantly lower in participants un- or underscreened versus those who were due (Table 2). Sample return rates were significantly lower in participants living in areas associated with the highest deprivation than those with the lowest deprivation (Table 2).

Of the participants who returned their samples for testing, more than half (61.1%; n=237 of 388) did so without reminder prompts from the central team, which began 3 weeks after a self-test kit was taken home. Fewer samples per week were returned thereafter, across all ethnicities; 23.2% of participants returned samples in the weeks that reminders were sent, and an additional 15.7% of samples were returned after all scheduled reminders were delivered. The median time from consent to sample return was 12.3 days (mean 45.9 days; range 1 to 526 days).

HPV test results

Of 3,524 HPV test results received, HPV was detected in 9.5% (Table 3). Of participants with an HPV detected test result, 16.7% were of HPV subtypes 16 or 18 (1.6% of all test results) and 83.3% were of HPV Other (7.9% of all test results).

The rate of invalid HPV results was 0.9% of all test results received (n=31 of 3,556). Most (71.0%) of participants with an invalid test result repeated the self-test and subsequently returned a valid result.

Management of participants with HPV detected results

Of the participants with an HPV Other result (n=280), the majority (96.4%) completed follow-up cytology (Table 4). Of the participants who completed cytology (n=270), most (70.4%) were performed by the central nurses, with the remainder (29.6%) by GP clinic nurses. Of the cytology performed by the central nurses (n=190), most (70.5%; n=134) were done in a GP clinic, with the remainder (29.5%; n=56) in participants' homes. Our small numbers suggests that home visits may be preferred by participants who were Pacific, aged 50-60 years, underscreened or living in areas associated with socioeconomic deprivation quintile 4, and that cytology with central nurses at a GP clinic may be preferred by participants who were Asian, aged 40-50 years or unscreened (Supplementary file 4). The median time from the date that participants were notified of their HPV Other result until the date of their completed cytology test was 7.0 days (mean 26.9 days; range 1 to 527 days in those with available data (n=261)); this included repeat sampling for participants who had invalid cytology results (n=10). The reasons for not completing cytology were study withdrawal (n=4), unable to contact the participant (n=3), and repeated non-attendance (n=3).

In participants whose HPV result was HPV 16/18 (n=56) and HPV Other with high-grade cytology findings (n=13), the majority (92.8%; n=64 of 69) were seen and discharged by the colposcopy service at study end or seen but not yet discharged (awaiting discharge (n=1) and awaiting repeat colposcopy and discharged by the central team back to GP (n=1)). In participants seen at colposcopy (n=64), the median time from the date that participants were notified of the recommendation for colposcopy until the date that they were first seen at colposcopy was 52.9 days (mean 79.4 days; range 6 to 425 days). The reasons that participants were not seen at colposcopy were repeated non-attendance (n=2), unable to contact participant (n=1), participant left the country (n=1) and deceased (n=1).

Discussion

Our study tested the implementation of routine opportunistic offer of HPV self-testing in primary care in New Zealand, with a focus on people who were Māori and Pacific, underscreened (due by ≥2 years), and those living in areas associated with high levels of socioeconomic deprivation. The option to take a test kit home was a key component of our approach, as well as having a central nurse-led co-ordination team to oversee results management instead of general practice.

Screening rate

The cohort of participants who completed an HPV self-test was ethnically diverse, with half comprising Māori and Pacific who are typically underserved by the national programme. There were also high proportions of other priority groups, such as those underscreened. Self-testing was completed by 37.9% of those potentially eligible (presenting to clinic and due for screening), with over 3,500 people, largely from priority populations, screened through the study.

Most cervical cancers in New Zealand are strongly linked to a history of being un- or underscreened and these groups need to be prioritised by screening programmes (30). In our study, 51.6% of self-tested participants were un- or underscreened, reflecting the profile of our eligible population. Importantly, more than 400 self-tests were from participants who were more than 5 years overdue, which accounted for 12.4% of all self-tested participants. These findings show the potential of opportunistic self-testing (including the option to take test kits home) to reach people who are currently underserved by the NCSP.

As with the YouScreen study (20), we also report that opportunistic self-test invitation was acceptable to the ethnically diverse primary care population. Two smaller trials of opportunistic in-clinic offer to underscreened people in Belgium and Australia both reported uptake rates of around 80% (31, 32).

In our study, of those who attended clinics and were due for screening, 37.9% were tested, demonstrating that the addition of an opportunistic offer of cervical screening to routine primary care practice is feasible. The initial stages of the study took place during the COVID-19 pandemic; the

response achieved in this challenging setting indicates that the opportunistic strategy has the potential to reach a large number of people. Our result compared favorably with a pilot of the YouScreen study in six London clinics that reported 20.8% of eligible people were offered kits, and noted feedback from some GPs of limited time in a consultation to offer the self-test (19). In our study, we estimate that the time taken for primary care clinicians to explain both the self-test and the study and for participants to complete the test was around 10-15 minutes. Now that the self-test is part of the national screening programme and as people gain experience with its use, we anticipate the time needed to introduce the self-test will lessen.

Kits taken home

Although participants were encouraged to take the test in the clinic, a substantial proportion (16.8%) of participants chose to take the sample at home. Importantly, significantly more people in our priority groups of Māori, Pacific and underscreened took the self-test kit home than the respective comparator groups. At-home sampling (in-person offer or mail-out) as part of a range of approaches that potentially support participation for Māori is supported by other recent New Zealand studies (14, 21).

The sample return rate from kits taken home (61.1%) was considerably higher than return rates demonstrated by mail-out studies (14.0% achieved in an opt-out mail-to-all trial in the same metropolitan region (12), and international studies (mean 8.5%; range 1.5-17.5% (9)). One other small study reported a high rate of sample return from kits taken home from GPs (35 of 45 kits; 77.8%) (31). In our study, participants received an in-person explanation about the test, as well as an automated welcome text offering information and phone support, which may have enhanced sample return for people who took kits home. Many (61.1%) of the 388 participants who returned their sample did so promptly, prior to any reminders, a result consistent with findings from the UK study (20). The remainder of samples were returned after scheduled reminders (text messages and phone call attempts). In another recent New Zealand study, however, primary care clinicians

reported considerable extra work in follow-up of self-kits taken home (22), suggesting that the centralised and largely automated reminder approach in our study may be more efficient and reduce primary care burden. A large proportion (38.9%) of participants who took a test kit home did not return their sample, even after the full schedule of reminders. Further investigation of a centralised follow-up service model and additional strategies to encourage sample return are warranted.

Although more Māori, Pacific and underscreened participants and those living in areas associated with high socioeconomic deprivation than their respective comparator groups chose to take a test kit home, sample return rates were lower in each of these groups. These lower return rates, despite the relatively intensive schedule of follow-up reminders and support, highlight the need for further exploration of evidence-based strategies to understand the reasons for not returning a sample to ensure the programme has effective and equitable reach to these priority groups. Evaluations could include what return options are easiest for participants, the content of follow-up messages and the balance between additional contacts resulting in increased participation versus what might be considered intrusive. While our study recruited participants of all screening statuses, the self-tested rate in under- and unscreened participants who took a self-test kit home (48.7% and 50.9%, respectively) compared favourably with that from a previous study that recruited only un- and underscreened participants (14.0% combined) (12).

HPV positive results management

Our HPV positivity rate (9.5%) is in line with other New Zealand self-testing studies. The benefits of increased participation with self-testing can only be fully realised with accompanying high rates of follow-up in people with HPV detected results. Our commitment to support participants through the full diagnostic pathway resulted in very high rates of follow-up tests (96.4% of cytology and 92.8% of colposcopy). These rates are higher than reported in previous New Zealand self-testing studies (78.6% (14), 91.7% (12)) and most European and UK studies (80.6%) (33). Clear explanations and trusting empathetic relationships were described as critical to completion of the pathway for underscreened people (34). In our study, the rapport developed by central expert screen taker

nurses with participants, considered results management and communications, and the option of home visits for cytology are all likely to have contributed to the high follow-up completion rates**.** Our results demonstrate that even where people have previously disengaged with screening, an appropriately experienced and resourced team, including cultural support, can help most people with an HPV detected result to complete the diagnostic pathway. Our small numbers suggest that some groups (e.g. Pacific) may prefer home vs. in-clinic cytology; larger numbers are needed to draw firm conclusions. The NCSP contracts with Screening Support Services who can undertake home visits, including in the new primary HPV programme, and many include cultural support in their model of care. A recent review of support to screening services indicated their ability to be developed further to support improving access (35).

Strengths and Limitations

A key strength of this study is its location within busy clinics with ethnically diverse populations known to have low screening coverage. With more than half of the eligible cohort identifying as Māori or Pacific, a third underscreened and half living in areas associated with the most socioeconomic deprivation, the study was well targeted to populations who experience substantial barriers across the screening, diagnostic and treatment pathways.

Implementation was measured end to end, including monitoring of test kits taken home, sample return and completion of follow-up testing with centralised result management.

Respect for cultural values is an important aspect of successful engagement strategies that target specific groups, including Māori and Pacific, as is a diverse workforce. Our study team included Māori kaiawhina, and an engagement and call centre team, with the latter also including Pacific.

A limitation of our study was that in a busy real-world clinic environment, people who declined to participate in the study were not systematically recorded, despite the mechanism in the study IT system, so that we were unable to differentiate the people who were not offered from those who declined. While we were unable to provide an uptake rate based on offer, we ascertained

participant recruitment and screening rates from clinic presentation of eligible people during the study period.

Several factors impact on the ability to generalise from our findings. The demographic of the study population, though intentionally targeted, is very different to the overall New Zealand population. As our study clinics already incorporate opportunistic interventions into their patient consultation model, the study model was readily accommodated; this model may be more challenging for clinics with more traditional general practice models to adopt. In our study model, the central co-ordination team was responsible for results management and follow-up; if opportunistic offer was adopted without central co-ordination, and if self-test kits were taken home, general practice workload would increase. COVID-19 lockdown periods in 2021 and 2022 affected staffing levels and their ability to offer the test, and people's ability to attend their GP. Our study took place prior to the national roll-out of HPV self-testing, with the intent of informing the programme change; future studies may have different results.

Overall cervical screening participation has improved since the NCSP programme change with HPV self-testing established as usual care, rather than offered opportunistically as a part of a research study. The challenge remains to improve uptake and timely follow-up in those from the most underscreened groups, and to improve vaccination and timely diagnosis and treatment, the other pillars of the World Health Organization's goal to eliminate cervical cancer (36). Although screening coverage rates in our partner PHO have increased from October 2023 to January 2025 (by 21.9% in Māori and 24.6% in Pacific), disparities remain by ethnicity (46.9% in Māori and 49.4% in Pacific vs. 53.6% in European/Other; personal communication from the PHO). Other strategies are needed to improve access to cervical screening for people who are not enrolled or rarely attend primary care, such as exploration of opportunistic offers of HPV self-testing by other services (e.g. hospitals, pharmacies) and in other settings (e.g. at community events, workplaces). As part of our larger HPV self-testing implementation study, we also evaluated other approaches to offer cervical screening,

including mailed self-test kits via telehealth and provision of self-tests at various community settings, planned to be published separately.

Conclusion

We report that a novel approach of opportunistically offering HPV self-tests in primary care, with at-home testing and support from a central co-ordination team, was feasible in a real-world primary care setting and engaged priority populations in cervical screening. High follow-up rates for cytology and colposcopy were achieved with dedicated, flexible and culturally appropriate support. Further work on additional strategies supporting kits taken home, particularly for priority groups, is warranted.

Declarations

Abbreviations

GP: general practice; HPV: human papilloma virus; LBC: liquid-based cytology; NCSP: National Cervical Screening Programme; OR: odds ratio; PHO: Primary Health Organisation; PMS: practice management system; 95% CI: 95% confidence interval.

Ethics approval and consent to participate

This study was approved by the New Zealand Health and Disability Ethics Committee (HDEC), reference number 21/STH/141. Data access was approved by the NCSP programme and by the National Kaitiaki Group, which oversees the use of data from wāhine Māori (Māori women) from the NCSP Register. The study was approved through localities research office approvals in the three Auckland districts where the study was conducted. A Māori data sovereignty assessment was conducted and approved as part of ethics and localities approval. A privacy and security assessment was conducted and approved. All individuals in the study provided informed consent. This study adhered to the Declaration of Helsinki.

Consent for publication

The photographs on the cover of the participant instructions (Supplementary file 1) are reproduced with permission and written informed consent was obtained for the publication.

Availability of data and materials

The data used and analysed during the current study contain identifiable individual patient information, including that of Māori. The data are not publicly available due to the data confidentiality and privacy restrictions and Māori data sovereignty considerations, but are available from the corresponding author on reasonable request and corresponding approvals.

Competing interests

The authors declare that they have no competing interests.

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Methodology: AM, KB, CB, JG, SS

Software: AM, JG, CN, LY

Validation: CN, LY

Formal analysis: LY, AM, CN, PSA

Investigation: SC, CB, GM, JK, DF, RM, JG

Resources: KB

Data curation: CN, LY

Writing - original draft: LY, CN, AM, KB, CB

Writing - review and editing: all authors

Visualisation: CN, LY, CB

Supervision: JG, SC, KB, PC, WB, CB, GM, RM, AM, DF, JK, KM, SS

Project administration: KB, AM, JG

Funding acquisition: KB

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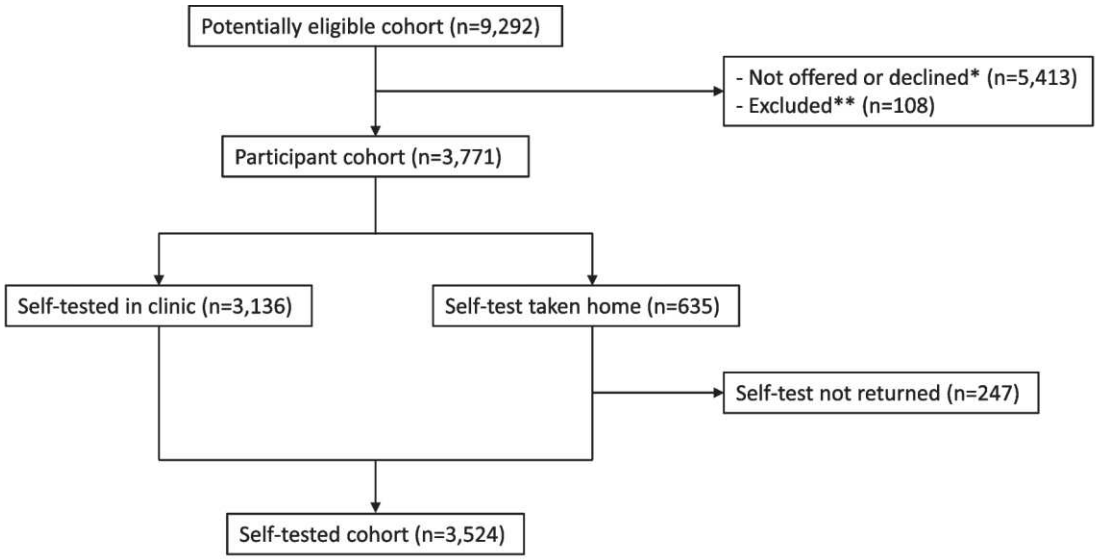
Figure 1.



* We could not distinguish between people who were not offered to participate in the study from those who declined the offer.
** Reasons include women who have had a total hysterectomy, were not due for screening, or had symptoms.

Table 1. Demographics of the study population.

Demographic factor	Potentially eligible (n)	Participants				Self-tested				
		n	% of potentially eligible	OR (95% CI)		n	% of potentially eligible	OR (95% CI)		% of participants
Ethnicity										
Māori	1373	517	37.7	0.80 (0.70, 1.00)		476	34.7	0.78 (0.65, 0.94)	**	92.1
Pacific	3883	1562	40.2	0.90 (0.79, 1.09)		1409	36.3	0.84 (0.71, 0.99)	*	90.2
Asian	3309	1387	41.9	1.00 (0.85, 1.17)		1345	40.6	1.01 (0.86, 1.19)		97.0
European/Other	727	305	42.0	1.00		294	40.4	1.00		96.4
Age (years)										
30-39	3376	1238	36.7	1.00		1149	34.0	1.00		92.8
40-49	2441	1050	43.0	1.30 (1.17, 1.45)	***	985	40.4	1.31 (1.18, 1.46)	***	93.8
50-59	2012	929	46.2	1.50 (1.32, 1.66)	***	864	42.9	1.46 (1.30, 1.63)	***	93.0
60-69	1463	554	37.9	1.10 (0.93, 1.19)		526	36.0	1.09 (0.96, 1.24)		94.9
Screening status (time overdue for screening)										
Due (<6 months)	1065	564	53.0	1.00		557	52.3	1.00		98.8

Table 2. Self-test kits taken home and samples returned.

Demographic factor	Participants with a self-test kit	Self-test kits taken home				Samples (from home testing) returned			
		n	% of all self-test kits	OR (95% CI)		n	% returned	OR (95% CI)	
Ethnicity									
Māori	517	115	22.2	2.07 (1.39, 3.10)	***	74	64.3	0.76 (0.34, 1.70)	
Pacific	1562	313	20.0	1.82 (1.26, 2.62)	***	160	51.1	0.44 (0.21, 0.93)	*
Asian	1387	170	12.3	1.01 (0.69, 1.48)		128	75.3	1.29 (0.59, 2.83)	
European/Other	305	37	12.1	1.00		26	70.3	1.00	
Age (years)									
30-39	1238	194	15.7	1.00		105	54.1	1.00	
40-49	1050	169	16.1	1.03 (0.82, 1.29)		104	61.5	1.36 (0.89, 2.06)	
50-59	929	172	18.5	1.22 (0.98, 1.53)		107	62.2	1.40 (0.92, 2.12)	
60-69	554	100	18.1	1.19 (0.91, 1.55)		72	72.0	2.18 (1.30, 3.67)	***
Screening status (time overdue for screening)									
Due (<6 months)	564	66	11.7	1.00		59	89.4	1.00	

Table 3. HPV test results.

Demographic factor	Total HPV results	HPV not detected		HPV detected		Invalid
		n	%	n	%	n
Ethnicity						
Māori	476	404	84.9	71	14.9	1
Pacific	1409	1265	89.8	140	9.9	4
Asian	1345	1252	93.1	90	6.7	3
European/Other	294	258	87.8	35	11.9	1
Age						
30-39 years	1149	1015	88.3	129	11.2	5
40-49 years	985	890	90.4	92	9.3	3
50-59 years	864	795	92.0	68	7.9	1
60-69 years	526	479	91.1	47	8.9	0
Screening status (time overdue for screening)						
Due (<6 months)	557	499	89.6	57	10.2	1
Overdue (≥6 months to <2 years)	1147	1044	91.0	102	8.9	1
Underscreened (≥2 years)	1234	1113	90.2	117	9.5	4
Unscreened	586	523	89.2	60	10.2	3
Socioeconomic deprivation (NZ Dep 2018 quintile)						
5 (most deprived)	1615	1461	90.5	148	9.2	6
4	677	609	90.0	67	9.9	1
3 to 1 (least deprived)	1152	1036	89.9	114	9.9	2
Unknown	80	73	91.3	7	8.8	0
Total	3524	3179	90.5	336	9.5	9

Table 4. Completion rates of the first follow-up test.

Follow-up test	Required	Completed	
	n	n	%
Cytology	280	270	96.4
Colposcopy	69	64	92.8
Total	349	334	95.7