He Tapu Te Whare Tangata:

Empowering Rural New Zealand

Pathway 2 Information and Consent Form - Ngāti Porou Hauora (NPH)

Locality – Tāirāwhiti
Principal Investigator – Professor Bev Lawton, Victoria University of Wellington (VUW) Centre for Women's Health Research
Local Co-Investigators – Frances King, Bobbie Cameron
Ethics Committee Ref - 20/NTB/311
HRC funded - 20/550
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You are invited to take part in a study to examine two different pathways of care for cervical screening and follow up. Both pathways will offer self-swabbing for the Human Papilloma Virus (HPV) as a cervical screening test instead of a cervical smear. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have.

You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people- whānau, friends, or healthcare providers. Feel free to do this.

Your participation in the study will be free (unless you are a non-resident in Aotearoa New Zealand, in which case you may incur a cost for any clinical care follow-up – for details see 'Who Pays for the Study' below on p.6).

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep. This document is 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages. Please ask any questions.

Note: If you would prefer a cervical smear or your GP advises a cervical smear you can still take part in the study by taking a self-test swab before you have your speculum examination.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Participation in this study is voluntary. If you do want to take part now, but change your mind later, you can pull out of the study at any time. Please note after the study has completed recruitment of participants, if the cervical screening programme has not changed, then the HPV self- test swab will not be available and your health centre will return to offer usual cervical screening care.

WHAT IS THE PURPOSE OF THE STUDY?

In Aotearoa New Zealand over the last 20 years the cervical screening programme using smears has reduced the number of women developing cervical cancer and dying from it. However, there are still a significant number of women who, for all sorts of reasons do not get a smear and are therefore at risk of having undetected abnormal cells which if left undetected could develop into pre-cancer and cancer. Māori women have a higher death rate from cervical cancer than other ethnicities. The purpose of the study is to try to improve cervical screening, and the pathway to getting diagnosis and treatment if it is required, by trialling alternative pathways of care for cervical screening and follow up.

HOW IS THE STUDY DESIGNED?

This study is a community randomised controlled trial comparing two pathways.

The two pathways being examined are **Pathway 1** and **Pathway 2**, being run within two primary care providers and their DHB's – Ngāti Porou Hauora in the Tairāwhiti DHB area, and Te Wairoa primary care providers in the Hawke's Bay DHB area.

Ngāti Porou Hauora has been randomised to offer Pathway 2 for the study's 1st 15 months (Feb 2021 - April 2022).

In **Pathway 2**, you will be offered a self-taken HPV swab instead of a cervical smear. If you accept, the swab will be sent as routine to the lab for testing and the result will be sent to the primary care clinician to inform you. Test results will usually be available 1 – 3 weeks after the test.

If the results shows high risk HPV then the doctor or nurse will follow the referral pathway as for an abnormal smear and arrange for you to have a follow up colposcopy appointment. If you need a colposcopy appointment you will be offered information, support and help with transport. <u>This is the pathway which you are being invited to participate in.</u>

In **Pathway 1**, a 'Point of Care' machine will be used in the health centre to process the swab test within one hour at the same visit and if required a colposcopy appointment will be made straightaway.

Ngāti Porou Hauora is one of two health providers who have approved that their primary care health centres/clinics participate in this study. Your primary care staff – manager, nurses, doctors and kaiawhina (community health workers) - are supporting and running this study.

The aims are:

- To compare two pathways of care on the timeliness and acceptability of cervical screening and where required, HPV diagnosis and treatment.
- To identify which of two cervical cancer prevention pathways of care are more acceptable and feasible to women and health care providers in rural Māori communities.

Participants in both pathways of care, will be offered a self-test swab for HPV, instead of a cervical smear. The HPV self-test is acceptable for Māori and is likely to be gold standard when the new HPV primary testing programme commences in NZ. Self-test swabs are tested for the Human Papilloma virus types which can cause pre-cancer changes on the cervix (neck of the womb). Precancerous cervical cell changes can be treated *before* becoming cancer.

You can take the self-test yourself at home or in the clinic. Your nurse, doctor or community health worker will explain in detail how to take the swab correctly and will make sure it gets tested. You can ask your doctor or nurse to take the HPV swab for you if you prefer, although most women do the swab themselves.

Note: If you would prefer a cervical smear or your GP advises a cervical smear you can still take part in the study by taking a self-test swab before you have your speculum examination.

This study is funded by the Health Research Council of New Zealand and we are working with the National Screening Unit (NSU) which co-ordinates the current cervical screening programme. Information about cervical screening and pathways of care from the results of this study will be used by the NSU to inform changes to their cervical screening programme to improve the outcome for New Zealand women and reduce inequities in health care.

This study has ethical approval from the Health and Disability Ethics (HDEC).

NB: The swab is not currently licenced for vaginal HPV screening but it is validated for cervical screening in Aotearoa New Zealand and for vaginal HPV screening overseas.

WHO CAN TAKE PART IN THE STUDY?

Women aged between 25 and 69 years old who are due for a cervical smear and are registered patients with Ngāti Porou Hauora health centres and Queen Street Practice (Wairoa) will be eligible for this study

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you agree to be a participant in this study you will be offered a self- test for HPV – that is a self-taken vaginal swab. This will be offered by your usual doctor, nurse or a community health worker who have had additional training in this self-test method in this study. This person will explain how you take the swab and you can take your own swab in your own bathroom or bathroom facility on a marae or community centre or you can choose to have your nurse or doctor take the swab in the health care centre or clinic.

As a participant in **Pathway 2**, your self- test will be sent to the laboratory and the results will come back to the ordering health worker (doctor or nurse). Your doctor or nurse will contact you with the results as soon as they can by text or phone or in person.

If you get a positive result for high risk HPV (about 10% of women) you will be given all the information you need with support from your health worker. A positive result DOES NOT mean cancer. A positive result indicates the detection of the virus that can cause changes that can cause cervical cancer but if detected early it can be treated. A referral letter will be sent as usual for an appointment for follow up which is called a colposcopy (so that any cell changes can be detected and treated early) at your local DHB hospital or outreach clinic. Your health worker will offer you support for this appointment, including the usual cervical screening support with a voucher towards travel costs or transport.

If you get a negative result (about 90% of women) you will not need another cervical screening test for 3 years.

Copies of your swab test results will be sent by a secure method (encrypted) to the senior researcher at Victoria University of Wellington and then de-identified (made anonymous) before analysis for this study. If you needed further investigation with a colposcopy, copies of those results will also be sent to the senior researcher and then de-identified before analysis.

WHAT WILL HAPPEN TO MY SWAB SAMPLE?

Your HPV swab will be sent to the lab for testing and will be stored and then disposed of in the standard process for any swab testing in the lab.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study your health practitioner will record information about you and your study participation. This includes the results of HPV tests taken. Your health information will be kept as normal by your health practitioner in the NPH health centre where you are registered.

The screening HPV test results will not be sent to the National Cervical Screening Register (NCSP) but if you need a colposcopy the subsequent results will be put on the register and the NCSP will have your NHI number. The NCSP will get a list of participating women from the researchers so that the register can flag these women as part of a research study.

The Victoria University of Wellington research team will have your NHI number on a secure restricted data base (password protected) along with your study-code number. The NHI number is needed for two reasons:

- so the research team can match information from Ministry of Health databases on ethnicity and deprivation index when the study findings are analysed;
- to ensure clinical safety for follow up of your results as a backup for the health care centre.

The data will be kept for 10 years on a password protected database as per HDEC regulations at Victoria University of Wellington.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

Although every effort will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified.

This research includes basic information such as for example your ethnic group, geographic region, age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

De-identified data from this study could be used for future research by the same research group related to the current study and will not be shared with other research groups.

If you are due your cervical smear and your HPV test is negative, the National Cervical Screening Programme (NCSP) will have your results but will not be able to follow up the results and care. As a result you will likely receive reminders that you are due your smear. **You will have undertaken HPV screening as part of this research project** and you will be given a card with these details.

At the end of the study you will be re-registered by your primary care provider onto the NCSP register to ensure you receive a reminder when your next screening test is due – most likely in 2024.

If you are unsure please talk to your primary care provider.

An HPV test as a screening test is a better test than a cervical smear but like any tests there can be false results - however this is unlikely.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

The HPV self-test has been shown to be acceptable to Māori in a previous trial, and it is likely to be gold standard when the new HPV primary testing programme commences in NZ.

The possible benefit of the study to participants is

- the offer of an alternative way to have a cervical screening test with an HPV self-test which gives the benefits listed below:
    - HPV testing provides an accurate way of telling if a high-risk type of HPV is present in a woman's cervix. It helps to detect those women who need further assessment and those who don't.
    - The HPV test detects whether HPV genetic material (DNA) from any of the types of HPV most commonly associated with cervical cancer is present.
    - A negative test result indicates a woman is unlikely to be at risk of developing cervical cancer in the next five years.

- A positive HPV test means a woman has high-risk HPV and she should be assessed for cell changes or monitored to see that the infection goes away and that she does not develop abnormal cells.
- A positive HPV test DOES NOT mean that a woman has cancer, but it does mean that it is important she has follow-up investigation called colposcopy so any cell changes can be found and treated early.

Colposcopy is a procedure where the gynaecologist examines the cervix with magnification. Colposcopy can detect pre-cancer changes and treatment can be done to prevent these pre-cancer cells turning into cancer.

Pathway 2 uses the usual pathway to colposcopy which requires the doctor or nurse to write a referral letter to the local DHB to refer the woman for colposcopy. The appointment will be sent to the woman at her address.

WHO PAYS FOR THE STUDY?

This study is funded by the Health Research Council of New Zealand and the participant's swab tests and follow up appointments are funded by the study. Thus it will not cost New Zealand resident / citizen participants anything. If your sway test is positive, as with current cervical screening services, Ngāti Porou Hauora will offer you support if needed as part of its healthcare services, including expenses to pay for, or provide transport, to your follow up appointment for further investigation.

If you are a non-resident in Aotearoa New Zealand you can still accept the offer the self-test swab for HPV. This test is funded by the study. However, if you have a positive high risk HPV result, a follow up colposcopy or further treatment as required will not be funded by the study or Ngāti Porou Hauora.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Participation in this study is voluntary. You are free to decline to participate or to withdraw at any time without experiencing disadvantage. You have the right to access information about your participation and you will be informed of any adverse or beneficial effects related to the study that may have an impact on your health. Your privacy and confidentiality will be protected as per the health and disability code.

WHAT ARE THE ALTERNATIVES TO TAKING PART?

If you would rather have a cervical smear you can have this as part of your normal care, and this would mean you will not be eligible to participate in this study. Your smear will be registered with the NSU as normal.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Participation in this study is voluntary. If you do want to take part now, but change your mind later, you can pull out of the study at any time. At this time, after recruitment of participants has been completed for the study, it is probable that the HPV self- test will not be available and your health care centre or clinic will return to offer usual care.

The study findings will be available about one year after the study recruitment has ended and the analysis is completed (around end of 2023). The research team and your doctors and nurses will make sure that all women who have been offered the self-test for HPV get a written copy of the summary of study findings and these also will be available for all staff and patients. No individual person will be identifiable in the study results and report (this is different from getting your own HPV test result which will be given to you about one to three weeks after the test is taken, and also entered in your medical records as part of usual cervical screening services).

The study de-identified data will be stored securely for 10 years at the Victoria University of Wellington.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Project Managers – Centre for Women's Health Research, Victoria University of Wellington

- Francesca Storey
  021 0237 5264 or Email: francesca.storey@vuw.ac.nz

- Jane MacDonald
  021 845 381 or Email: e.jane.macdonald@vuw.ac.nz

Acting Research Manager – Ngāti Porou Hauora

- Frances King
  021 861 426 or Email: frances.king@nph.org.nz

Primary Health Manager – Ngāti Porou Hauora

- Bobbie Cameron
  021 061 9632 or Email: bobbie.cameron@nph.org.nz

For Māori support from one of our Victoria University of Wellington team members, please contact:

- Anna Adcock, Research Fellow
  022 403 5515 or Email: Anna.adcock@vuw.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050 Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS Email: hdecs@moh.govt.nz

Consent Form: He Tapu Te Whare Tangata - Empowering Rural New Zealand

Please tick to indicate you consent to the following		
I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	
I understand that I can have more time to consider whether or not to participate in this study.	Yes ☐	
I have had the opportunity to involve whānau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐	
I consent to the research staff and the DHB cervical screening team collecting my information, including information about my health and test results.	Yes ☐	
I understand that the vaginal swab is an 'Off licence' use not yet validated for HPV testing in NZ using the technologies in this study but it has been validated overseas including in Australia, where it is part of their screening programme.	Yes ☐	
I understand that the HPV result will not be sent to the NCSP but other results if I need a colposcopy will be put on the register, as well as my NHI number. My name will be sent to the NCSP register by the research team as taking part in this research.	Yes ☐	No ☐
I am aware that my GP or current provider knows about my participation in the study, remains responsible for providing primary care during the study and will also be informed of any significant abnormal results obtained during the study and will inform me.	Yes ☐	
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	Yes ☐	

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes □	
I understand the compensation provisions in case of injury during the study.	Yes □	
I know who to contact if I have any questions about the study in general.	Yes □	
I understand my responsibilities as a study participant.	Yes □	
I wish to receive a summary of the results from the study.	Yes □	No □

As part of the study we also want to find out **the experiences of women who accept the HPV swab**. Our researchers may wish to contact you later to ask for your feedback and experience on the self-test and any follow up.

Are you happy to be contacted about this in the future? Yes □ No □

If yes, what is your phone number and / or email address:

_____

_____

Declaration by participant:
I hereby consent to take part in this study.

Participant's name (please print clearly): _____

Signature: _____ Date: _____

Declaration by member of health / research team:
I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

NHI of participant (OR patient sticker label on form): _____

Health worker / researcher name: _____

Signature: _____ Date: _____

Clinic: _____ Clinic telephone number: _____

PAGES 9 & 10 TO BE COPIED AND SENT TO DR EVELYN JANE MACDONALD
EMAIL ADDRESS: e.jane.macdonald@vuw.ac.nz