



Cervical Screening Self-Test Study

He Taonga, He Tapu

Participant Information Sheet

What is this study for?

This study is to find out about different ways to offer a self-test for cervical screening to women, so that more women get checked to prevent cervical cancer. In the self-test, women use a swab to sample their vagina to find out if they have the human papillomavirus (HPV). HPV is a virus spread by skin-to-skin contact and some types are linked to cervical cancer. Testing for HPV is now the primary test in the National Cervical Screening Programme, with the option of self-testing. The self-test is safe and effective for cervical screening.

What am I being asked to do?

Making a choice about having a cervical screening self-test is your decision. This self-test is being offered as part of a research study so you will need to provide your consent if you choose to participate. We will then provide you with a kit and instruction sheet to do the test yourself. If you have any questions, a member of the study support team can call you.

Is doing the HPV test myself right for me?

It's your choice. Women can now choose how they do a cervical screening test as part of the National Cervical Screening Programme (NCSP). Many people find doing the self-test easier than getting a smear with their nurse or doctor. A self-taken vaginal swab is just as good as a clinician-taken sample for detecting HPV. If you have had a hysterectomy, or previously had an abnormal smear result, ask the study nurse whether the self-test is right for you. If you have had the HPV vaccine, you can still take part in the study. If, at any time, you wish to opt out of self-testing and have a smear test, talk to the study nurse or your own doctor or nurse.

How will I find out the results of my self-test?

You will receive your results from the cervical screening study team two or three weeks after your test. If your test results show you do not have HPV, you don't have to do anything else. Your nurse or doctor will let you know when you are due for your next cervical screening test. You will have the option of answering some short questions about your experience being offered the self-test.

What if my test results show I have HPV?

A test result that shows you have HPV does NOT mean you have cervical cancer. The study nurse will talk more about what the test results mean. Depending on the result, you might need to have a follow up cervical smear test, or a visit to a specialist (a colposcopy at a hospital clinic, which is a simple procedure to look at your cervix). There will be no charge for any follow up tests.

We strongly recommend that you complete the follow up tests to look for any cell changes that might need treatment. We will talk with you about the follow up tests and answer all your questions. We can talk with you and your whānau / family if you want us to. The study nurse can also arrange help so you can get to the clinic.

More about the HPV self-test

The self-test is a very accurate test to check for HPV and can identify people who may need further testing at an earlier stage than the previous smear screening test. You don't need to know where your cervix is to do the test. HPV lives in the genital area instead of just the cervix, so taking your sample from the vagina will pick up whether HPV is present. Testing for HPV is now the primary test in the National Cervical Screening Programme, and for most women self-testing in a health clinic will be an option. The new self-test does not check for other sexually transmitted infections (STIs) such as chlamydia or HIV.

More about HPV

HPV is very common. Four out of five people will have HPV at some time in their lives. Some types of HPV stay in the body for a long time. For most people, having HPV does not cause any problems. Your body gets rid of the virus by itself. Having HPV doesn't mean that your partner is being unfaithful to you. You could still have HPV even if you are in a long-term relationship with one partner, not currently having sex or have not had sex in a long time.

You can find out more about how HPV is linked to cervical cancer here www.hpv.org.nz

How is HPV Treated?

There are treatments for cell changes to your cervix caused by HPV. This is why it is important for you to have follow up tests if your results show you have one of the types of HPV that can cause cervical cancer. Treatment happens at a hospital clinic and is successful at stopping cell changes from becoming cervical cancer.

National Cervical Screening Programme

You can find more information about cervical screening and follow up your tests online at www.timetoscreen.nz

Everyone who participates in this study will be invited back for another cervical screening test when they are next due. If you have unusual bleeding, pelvic pain, or discharge, please talk with your doctor or nurse - don't wait for your next screening test.

Who is doing the study?

The study is a joint project between Te Whatu Ora – Waitematā, Te Toka Tumai Auckland and Counties Manukau districts, Tāmaki Health and Total Healthcare PHO.

Withdrawing from this study

Being part of this study is your choice. You can choose not to take part, or to withdraw from the study at any time. Your care won't be affected in any way. If you withdraw from this study, we will keep the information we have collected up until the time of your withdrawal. We will not collect any new information after that.

Privacy and confidentiality

Your test results will be shared with your usual nurse or doctor to make sure you get the correct follow-up. Other people who will have access to information that identifies you (your name, date of birth or address) are study team staff (to track participants and complete study assessments) and laboratory staff (to process and report your screening tests). You have the right to access and correct your information. In the same way as with previous cervical screening results, your name and test results will also be held on the National Cervical Screening Programme Register and one of the laboratory registers (TestSafe / Éclair).

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Your test sample will be stored by the laboratory for the usual amount of time (for quality checking). To keep your information confidential during the study, you will be identified by a code so that your name will not be used on the study documents.

People and providers working with or for the study sponsor (about 20 people) may have access to coded information for the purposes of this study. Although all efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed, even with coded information. The risk of people accessing and misusing your information is very small. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you. De-identified data may be available for use in future related research.

Participants will have the option to receive a summary of the overall study results when available.

ACC statement

It is not likely that you will get injured in this study. If you did, you would be eligible to apply for compensation from ACC just the same as if you were injured in an accident at work or at home. You would have to put in a claim to ACC, which might take some time to be assessed. If your claim was accepted, you will receive funding to help you recover. If you have private health or life insurance, you may wish to check with your insurer that taking part in the study won't affect your cover.

Further information

Thank you for thinking about being part of the study. If you have any further questions, or complaints about the study, you can contact:

Dr Karen Bartholomew

Lead Researcher for this study

email: Karen.Bartholomew@waitematadhb.govt.nz mobile: 021 211 5629

Māori Cultural Support Contact

AUCKLAND AND WAITEMATĀ

He Kāmaka Waiora

phone: 09 486 8900 (ext 42324).

COUNTIES MANUKAU

Te Kaahui Ora Māori Health

email tekaahuiora@middlemore.co.nz

This study has received ethics approval (21/STH/141) and approval from our Te Whatu Ora district Māori Research Review Committee.

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

Phone: 0800 555 050

Email: advocacy@advocacy.org.nz

Website: www.advocacy.org.nz

Te Whatu Ora
Health New Zealand

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