

SCHOOL OF POPULATION HEALTH



Participant Information Sheet

Study title

The human papillomavirus in men study (HIMS)

Names of researchers

Dr Helen Petousis-Harris
Associate Professor Mark Thomas
Associate Professor Nikki Turner
Mr Adrian Ludlam
Dr Peter Saxton

Department of General Practice
and Primary Health Care
School of Population Health
Cnr Morrins and Merton Rd
Glen Innes
www.health.auckland.ac.nz

The University of Auckland
Private Bag 92019
Auckland
New Zealand,

Helen Petousis-Harris
Telephone: 64 9 373 7599
extn 82078
Email: h.petousis-
harris@auckland.ac.nz

Hello, Kia ora, Talofa lava, 您好,

We are a multi-disciplinary group of researchers from the University of Auckland conducting a scientific study at this clinic. The study is being run by Dr Helen Petousis-Harris, Director of Immunisation Research and Vaccinology at the Immunisation Advisory Centre (IMAC), the University of Auckland.

We are investigating human papillomavirus (HPV) infection among New Zealand males. Currently there is very little information on HPV infection among men, men's awareness about HPV. This study aims to change this and we would like your help.

In summary:

- This study is voluntary.
- This study is anonymous.
- We will ask you to complete: an oral rinse, an anal swab, and a short questionnaire.
- Results of the HPV testing conducted in this study will not be provided to you or your healthcare provider.
- You will be compensated with a NZ\$20 Westfield shopping voucher for completing all study procedures.

This study is voluntary

Participation is entirely voluntary. If you decide to take part, you can withdraw at any point before all procedures are completed and you will not be required to undertake any procedures you do not wish to. You will be asked to provide verbal consent to participate in the study and at the start of each procedure. You may revoke your consent at any point during the study procedures.

Participation or non-participation in this study will not affect the care you receive from your healthcare provider in any way.

This study is anonymous

Your name will not be on any study material or forms, and any specimens or information you provide will not be traceable to you. The results of your HPV testing and the information provided on your questionnaire will not be given to your healthcare provider, nor will it be put on your medical records.

Upon completion of the study the information and samples you provided cannot be traced back to you, therefore if you wish to withdraw your information and data from the study at a later date this will not be possible. Data will only be presented as grouped sets; no data from a single individual will be presented.

Who can participate?

If you identify as male and were born biologically male, are aged between 16 and 49 years, are able to speak and read English, and live in Auckland then we invite you to participate in this study.

If you agree to take part today, you will be offered a \$20 Westfield shopping voucher as compensation for your time once you have finished the study procedures.

Disclosure of Sexual Orientation

We aim to recruit equal numbers of both heterosexual men and gay, bisexual and takatāpui men, therefore the healthcare provider will also ask you about the sex of your recent sexual partners to gain this information.

If you do not wish to disclose this information to your healthcare provider then you may not wish to participate in this study. You do not have to provide a reason for not participating in this study to your healthcare provider. Participating or not participating will not affect the care you receive from your healthcare provider. Furthermore, any information that you disclose to your provider will be treated confidentially and will not adversely affect the care you receive in any way.

What is human papillomavirus (HPV)?

HPV is a virus that is sexually transmitted. In males it can infect the mouth and throat, the penis and the anus. It is easily transmitted by direct skin-to-skin contact.

The majority of HPV infections are transient and go away without causing any health problems or symptoms. HPV is the cause of genital warts and some people with HPV will develop these. In rare cases, after ongoing and persistent infection with certain types of HPV, infection can result in the development of cancer at the site of infection (head and neck, penis, and anus).

Who is at risk from HPV?

HPV is the most common sexually transmitted infection worldwide. Most men become infected with HPV at some point in their lives. Anyone who has had sexual contact or plans to at some point in their lives is at risk of acquiring HPV infection. Increasing numbers of partners increases the risk of getting HPV, but the virus is so common it may be acquired after having only a single lifetime partner. The levels of HPV infection have also been found to vary between certain groups of men and also between countries.

What will I be asked to do?

We will ask you to complete three study procedures:

Oral rinse and gargle: your healthcare provider will provide you with a measure of mouthwash and ask you to rinse it in your mouth for 30 seconds; they will then ask you to gargle it for 5 seconds and expel it into the collection vial. The mouthwash used will contain a very small amount of alcohol.

Anal swab: your healthcare professional or practice nurse will insert a wet swab 3-5cm into the anal passage and rotate it as it is withdrawn for about 10-15 seconds, placing pressure onto the walls of the anal passage. This should not feel uncomfortable nor be painful.

Questionnaire: we will ask you to self-complete a short 5 minute questionnaire and then return it to a secure drop-box. The questionnaire will ask you about your knowledge of HPV prior to the study and your feelings about some statements.

All specimens collected from the procedures will be sent directly to the laboratory for testing.

Study compensation

By taking part in this study you will be offered compensation for your time in the form of a NZ\$20 equivalent voucher (Westfield). This compensation will only be provided upon the completion of all study procedures as stated above.

Where will the findings be published?

The research team will report the overall proportion (“prevalence”) of participants found to have certain types of HPV infection, and whether this varied by groups of respondents such as by age group or by sexuality. We will also report how many individuals agreed to take part in this study as a proportion of all those who were invited (the “response rate”). The research team will report these findings in academic presentations and journal articles. The overall findings will also be discussed with groups who were consulted about this study, such as HIV and sexual health clinicians, GPs, the New Zealand AIDS Foundation and Body Positive.

Will I get my results?

We will not be able to give you back the results of the HPV test. This is due to two reasons: firstly the HPV test we are using is still new and **not clinically validated** and therefore is not accurate enough to be able to say a test is positive beyond doubt. Secondly the study is anonymous and we are unable to link the result from the laboratory back to you. It is not possible to determine whether you are at risk of developing HPV-related cancer from a single positive HPV test.

Can I get my samples returned to me for disposal?

We will not be able to return specimens collected in the study to participants. The study is anonymous and therefore we are unable to link a specimen back to the participant it was taken from. If you have cultural concerns regarding the collection, storage and destruction of specimens that you provide, you may wish to discuss this with your family, whanau, hapu and iwi before consenting to this study.

Data storage and destruction

After the specimens are tested for HPV, they will be stored at LabPlus laboratory for a period of up to 6 years for further testing of HPV types and sexually transmitted infection if funding for this is later acquired. The laboratory will then destroy the specimens by incineration. The anonymous questionnaires will be stored securely at the Department of General Practice and Primary Health Care at the University of Auckland and will only be accessible by the research team. These will be stored for 6 years and then destroyed. Information from the questionnaires will be electronically stored for a minimum of 6 years for future analysis. The electronic data will be stored securely with password protection and firewalled.

Risks

It is possible that the health professional may notice other medical conditions affecting your oral or anogenital area during the specimen collection process, for example anal warts. You may then be referred for examination and treatment for any suspected abnormalities. However it is important to understand that you are not being medically examined. If you are concerned about a health issue affecting your oral or anogenital areas, or would like a routine health screen for these areas, please make an appointment with your healthcare provider.

Who paid for this research?

Funding for this research was provided by the Health Research Council (HRC) of New Zealand. Funding for staff time was also provided by the University of Auckland and the NZAF Fellowship.

Where can I get more information about HPV?

If this study has raised questions or concerns about HPV you can find extra information on the NZ HPV Project website: <http://hpv.org.nz>. Your healthcare provider has also been given pamphlets and other material with information regarding HPV, please take some copies for your reference.

Who can I contact if I have concerns about the research?

For queries regarding concerns with the research or its procedures, please contact:

Principle investigator:

Dr Helen Petousis-Harris,
Dept. General Practice and Primary Health Care,
Faculty of Medical and Health Sciences
University of Auckland
Private Bag 92019, Auckland 1142.
Ph: 64 9 373 7599 extn 82078
Email: h.petousis-harris@auckland.ac.nz

Head of department:

Professor Felicity Goodyear-Smith
Dept. General Practice and Primary Health Care,
Faculty of Medical and Health Sciences
University of Auckland
Private Bag 92019, Auckland 1142.
Ph: 64 9 923 2357
Email: f.goodyear-smith@auckland.ac.nz

For any queries regarding ethical concerns you may contact:

The Chair
Health and Disability Ethics Committees
Ministry of Health
Freyberg House
20 Aitken Street
PO Box 5013
Wellington
6011
Ph: 0800 4 ETHICS

Email: hdecs@moh.govt.nz - please include the study reference number 15/NTB/5 in your email

PROVISIONALLY APPROVED BY THE NORTHERN B HEALTH DISABILITY ETHICS COMMITTEE
ON 11/02/2015 for (3) years, Reference Number 15/NTB/5