

Frequently Asked Questions:

Who is conducting this study?

This study is a partnership between the University of Toronto and the Mount Forest Family Health Team.

Why was I contacted?

You were randomly selected to participate in this screening study as a patient of the Mount Forest Family Health Team who has not been in for a Pap test in more than 2 years. Your participation in this study is completely voluntary. You may refuse to participate and withdraw from the study. However, you will be unable to withdraw once you have mailed your swab sample and/or questionnaire. Whether or not you decide to participate will not in anyway impact the care or treatment that you will receive with the Mount Forest Family Health Team.

I don't want to be contacted anymore. Can you please remove my name?

Yes. If you would like to stop receiving information about the study, you can call the clinic and have your name placed on the 'do not contact' list. If you have already submitted a test, you will still receive the results of your test by mail.

What is this study about?

The purpose of this study is to determine if self-collected HPV testing is a way to screen for cervical cancer that works as well as, or better than, the current way of screening (Pap tests only). HPV testing is used to identify women who need to undergo Pap testing. We would like to see if women are willing to perform the test at home. The results from this study will be used to determine if HPV self-testing could be used in the future to improve cervical cancer screening.

Who can be involved in this study?

Women who are patients at the Mount Forest Family Health Team and who have not had a Pap test recently were randomly invited to participate. At the moment, only women invited are eligible; however, if you are interested in more information, we welcome all emails and phone calls. If you are interested in having an HPV test you can contact your doctor to discuss.

What will happen if I agree to participate?

First, you will be asked to collect a vaginal sample using the self-testing device by following the instructions provided. It will only take a few minutes to do the swab. You will then be asked to complete a 10 minute self-administered questionnaire. The questionnaire will ask you about your personal background, your cancer screening history, and your experience with the HPV self-test.

What are the Risk and Benefits?

There is a chance that collecting your own sample may make you feel uncomfortable. If at any point you feel pain you should stop, and we recommend you speak with your care provider about the reason for the pain.

Testing positive for HPV may make you feel uncomfortable or be stressful. *Your health care provider will tell you your results. This process is in place to maintain anonymity and confidentiality for all participants, and to ensure proper follow-up and care for those who test positive.*

Some of the questionnaire questions may make you feel uncomfortable. If you wish, you may refuse to answer certain questions.

A key benefit of participating is that you will learn whether you have a potentially important HPV infection, which is not currently routinely tested for. You may also learn that you do not have an HPV infection and therefore do not need to be re-tested for 3 years. This may lead to better care for you and other women in Ontario.

How will my identity and privacy be protected?

You will be assigned a unique code which will be used to label swab samples and questionnaire sheets. The unique code will track your questionnaire and test results. Your name will not be used at the laboratory. The study has been set up so that your information is anonymous when it is analyzed. Only HPV test results will be identified at the clinic when the unique code is matched to a participant to return their result.

Who will have access to my information?

You will receive a copy of your test results. Your primary care provider (doctor or nurse practitioner) will have access to your test results, but will not have access to questionnaire information. Only the research team will have access to data collected for this study. All data will be stored at the University of Toronto on a locked computer.

What will you do with my samples and information?

The data collected for this study will be stored on a password-protected computer in a locked office and analyzed to figure out what helps or blocks women from getting screened for cervical cancer. All questionnaires will be destroyed once answers have been entered into the computer and verified. Computerized data will be archived at the office of Dionne Gesink, University of Toronto for five years after the last manuscript is published. All swabs will be shipped to the Public Health Laboratory at the Ontario Public Health Agency and tested for HPV. You will be given your test results by mail. Your health care provider will receive a copy of your HPV test results. The Family Health Team and Laboratory will treat all information as private and confidential. All swabs will be disposed of after testing has been completed.

How long will it take to get my test results?

HPV testing is not a routine test and so it can take time to get the results back. Because this is a research study the results may take longer, however, you will always be contacted by mail with the results whether they are negative or positive!

What if I test Positive?

If you test positive for HPV, your results will be sent to you and your primary care provider. You will be notified by mail to contact the clinic and you will receive a phone call from your primary care provider's office. You will be asked to return for a follow up test; however, the responsibility for arranging an appointment is ultimately yours.

What if I test Negative?

If you test negative, you will be notified by mail and your results will be sent to your primary care provider. If you choose, you may contact your primary care provider's office to make an appointment to discuss this or any other issue with your doctor or nurse practitioner.

How will I learn about the results of this study and will they be published or presented somewhere?

We intend to present the results of this study to health care providers and communities after the data have been analyzed. It is also our intention to publish and make public presentations based on the results of this study. We will gladly send you a summary of the study findings at your request.

What if I have other questions?

If you have questions during the study, please feel free to ask! All questions can be directed to a member of the research team:

Project Assistant: Sarai Racey, sarai.racey@mail.utoronto.ca,

Dionne Gesink, Principle Investigator: Dionne.gesink@utoronto.ca

Or you can call the Mount Forest Family Health Team and ask to speak with Sarah at 519 – 323 – 0255

Questions about ethics can be directed to the University of Toronto Research Ethics Board: Ethics Review Office University of Toronto (416) 946-3273.