ALBERTA HEALTH SERVICES and the UNIVERSITY OF CALGARY
IMPLIED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: HPV Self sampling in Indigenous, newcomer, rural and remote populations

FUNDER: Alberta Health - Cancer Research for Screening and Prevention (CRSP) Program Fund

PRINCIPLE INVESTIGATOR:

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INTRODUCTION

The Cervix Self-Screening Pilot Project is coordinated by AHS' Alberta Cervical Cancer Screening Program (ACCSP). The Cervix Self-Screening Pilot is testing different ways the program can best get people to test for the human papillomavirus (HPV) which causes cervical cancer.

HPV is a very common sexually transmitted virus. More than 70% of sexually active people will have an HPV infection at some time in their lives. Infection with HPV usually has no signs or symptoms. For most people, the body can get rid of the virus; in some cases, the virus stays in the body. If a high-risk type of HPV virus stays in the body for many years, changes in the cells of the cervix can happen which may lead to cervical cancer. When cervical cancer is found early, it can easily be treated.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to test new ways for people to get tested for cervical cancer. Some of the new ways are: The ACCSP will mail a letter for people to order a kit, or mail a kit directly, or provide a kit at a healthcare office where patients self-collect samples. Right now, cervical cancer screening uses a Pap test done by healthcare providers in their offices. Mailing a dry sample to laboratory for testing is not currently Health Canada approved. For this pilot study, you will collect your own sample in an area you choose and send the sample to laboratory via Canada Post. Research shows that self-collection is a trusted way for cervical cancer screening.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

In this pilot study, 5,000 people will take part in this Alberta-wide study through the ACCSP. We are recruiting women and people with a cervix who identify as **Indigenous, newcomer or live in the rural and remote** areas of Alberta. In addition to being part of these populations, the participants must also meet the following study eligibility criteria: between 25-69 years, have a cervix, have been sexually active, no previous abnormal Pap results, and no cervical cancer.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

By giving a sample, you are consenting to being part of this study.

If you are part in the pilot study, the research team will give you a cervical cancer self-screening kit with instructions on how to perform self-collection. The kit will include information about HPV and cervical cancer screening, instructions on how to self-collect, a swab to perform the collection with, a tube to place the swab in after collection, and finally, a pre-paid postage envelope which will be used to send the sample to the lab for testing. At the lab, the testing team may review your past cervical cancer screening records to make sure they are providing the right recommendation. The ACCSP will send you a result letter 4-6 weeks after the lab gets your sample (see section below on test results). You will be asked to complete a short survey about your experiences with the collection process so that we can make improvements to the information you are provided with and the testing procedure.

HOW LONG WILL I BE IN THIS STUDY?

Taking part in this study will take a total of about 45 minutes, including survey.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

Swirl of the swab (long Q-tip) in your vagina for 20 seconds is needed and should not hurt.

ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?

For the pilot, the sample you collect is just as accurate as a healthcare provider taken sample and the results from the test will be mailed directly to you. By taking part, you are screening for cervical cancer with a test that is very good at finding the virus that causes cervical cancer so that early treatment can be provided. Depending on your results, you may not need a cervical cancer screening test for 3-5 years.

WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?

You can continue to get Pap tests for cervical cancer screening. Your health care will not be impacted if you choose not to take part in this study.

CAN I STOP BEING IN THE STUDY?

At any point in time if you want to stop being part of the study, please email accsp@ahs.ca OR call 1-877-727-3926.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

For the pilot, 4-6 weeks after lab gets your sample, you will receive a letter in the mail with your results.

A normal result means no high-risk types of HPV were found in your sample. This means your risk of developing cervical cancer is very low. You may not need cervical cancer screening for 3-5 years.

An abnormal result means that a high-risk type of HPV virus was found in your sample. It does not mean that you have cervical cancer. It means that your risk of cervical cancer is higher, and you need more tests.

- An abnormal result where HPV 16 or HPV 18 are found in your sample means: You will get a phone call about the referral to colposcopy (special cervix exam). You will also get a result letter in the mail.
- An abnormal result where other high-risk strains of HPV are found in your sample means: You will get a phone call about next step. You will also get a result letter in the mail.

WITHDRAWAL OF STUDY DATA

The result of the pilot test is used as part of your health care, which cannot be removed from your Alberta Health Records (Netcare).

You have until March 31, 2026 to inform us if you wish to remove your test data from the study report. Please contact accsp@ahs.ca OR call 1-877-727-3926.

For the survey, you have 2 weeks after you finished the survey to let us know if you want your data to be removed by emailing accsp@ahs.ca. After this time, the survey data will be anonymized for analysis and can no longer be removed.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will not be paid for taking part in this study.
The cervix self-screening is a free test. You do not need to pay.

WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

Yes, the ACCSP follows the rules of the *Health Information Act* and only accesses information related to your care. The program will not access any other health information or results. No personal or identifiable information will be shared outside of the program.

The study team will only see aggregated (added up, no identifying) information.

HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?

Data from this study will be kept per AHS records retention (keep) policy. Currently, cytopathology samples are retained for 5 years; study data are retained for 25 years.

Aggregated (added up, no identifying) data for this study may be shared with other researchers for future studies that are unknown at this time. Laboratory may store swabs collected during the pilot per lab protocol for future validation purposes. Any data shared with other researchers will not include your name or other personal identifying information. Any future use of this research data is required to undergo review by a Research Ethics Board.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

Any biospecimens (e.g., tissue, blood, urine) obtained will be stored, discarded or destroyed per usual laboratory processes.

We will protect the confidentiality of your information to the extent possible. Your name and other identifying information will be on the biospecimens you provide so that we can provide result information. Any identifiable study information can only be accessed by the clinical and program teams who have health care responsibilities.

WHOM MAY I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact the research team at accsp@ahs.ca or call 1-877-727-3926 with any questions or concerns about the research or your participation in this study.

Conjoint Health Research Ethics Board (CHREB):
If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the standard medical care you receive.
- If you decide to take part, see withdrawal from study on page 3.

AGREEMENT TO PARTICIPATE

Your decision to provide a sample and answer survey questions will mean you agree to take part in this study. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time.