Community Grants Hub Health Research Grants Application

Prepared by the Australian Centre for the Prevention of Cervical Cancer

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Australian Centre for the Prevention of Cervical Cancer

Contents

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Executive Summary

This executive summary provides an overview of the key findings and implications of the SCoPE2 study, which assessed the accuracy of human papillomavirus (HPV) self-collection methods for cervical screening within the National Cervical Screening Program (NCSP).

The study aimed to assess the accuracy and efficacy of HPV testing on self-collected samples compared to those collected by healthcare practitioner. Findings revealed that self-collected samples were as sensitive and specific in detecting cervical disease (CIN2+) as samples collected by healthcare practitioner. Five HPV assays were assessed during this project and all these assays were listed with the Australian Register of Therapeutic Goods (ARTG) and met the National Pathology Accreditation Advisory Committee Requirements for Laboratories Reporting Tests in the NCSP. The swab (Copan FLOQSwab 552C.80) is also listed on the ARTG for self- collection.

The aim of this study was to assess whether the method (swab, vaginal collection, and HPV assay) was accurate in combination.

Self-collection refers to a swab being used by a person with a cervix to collect a sample from their vagina. This sample can then be tested for the presence of the HPV as part of the NCSP. Previously these samples had to be collected by a healthcare practitioner, who had to insert a speculum into the vagina so that they could see the cervix to collect a sample. Self-collection has been available in the Australian NCSP since the move to primary HPV testing in December 2017 but only became universally available in July 2022.

The study also demonstrated use of the new MSwab liquid, a safer and more efficient method (compared with other self-collection methods) for sample processing. This new method addresses the challenges of increasing test volumes, with self-collection volumes going from a few hundred a month to over 30,000 annually since July 2022. Due to the swab, HPV assay, and collection site (vagina) all being accepted within the Australian NCSP, there were few challenges faced by this project, with the only minor issue being that it took seven months to recruit the 400 participants but this was not outside of the normal range, especially with the lingering effects of the COVID19 pandemic restrictions in hospital settings.

The study demonstrated the improved efficiency of processing tests, with more than 30,000 HPV tests conducted using the newly validated MSwab method at the Australian Centre for the Prevention of Cervical Cancer (ACPCC) to date.

The accreditation agency (NATA) reviewed this new self-collection method using three different commercial HPV tests and approved it for use in the Australian NCSP. Additionally, the study's success has extended beyond Australia, supporting laboratories in New Zealand to adopt self-collection methods for their cervical screening programs.

Overall, the SCoPE2 study has provided robust evidence supporting the accuracy, safety, and efficiency of a new self- collection method, paving the way for its widespread use for cervical screening.

Background

Self-collection is the process by which a swab can be used by a person with a cervix to collect a sample from their vagina. This sample can then be tested for the presence of HPV as part of the NCSP. Previously these samples had to be collected by a healthcare practitioner, who had to use a speculum inserted into the vagina so that they could see the cervix to be able to collect a sample. Self-collection has been available in the Australian NCSP since the move to primary HPV testing in December 2017 but was initially limited to only those people who were under- screened or never-screened and who refused a healthcare practitioner-collected sample. At that time there weren't any approved self-collection methods from commercial HPV assay manufacturers. Therefore, a protocol was developed by the ACPCC and assessed in a clinical trial called SCoPE in 2016. The method involved using a swab that was collected by the patient, sent to the lab dry, and then resuspended in a liquid called ThinPrep prior to processing. ThinPrep is flammable and isn’t available in the volume used for self-collection (5 ml), so requires a lot of manual work to process.

In November 2021, a change was announced for the NCSP. It meant that, from July 2022, everyone would have the choice to use self-collection for routine screening. More people were expected to use self-collection once this change started. However, lab methods for processing these samples weren't ready for the increase in test volumes. The existing protocol using ThinPrep wasn't easy to adapt to the increased number of tests because of the manual nature of the process. To overcome this problem, the SCoPE2 project commenced. It looked at different ways to process self-collected samples, including new lab equipment, different collection devices, and a different liquid (MSwab) for testing.

Objectives

The objectives of the study were to:

- determine if self-collected vaginal samples are as accurate in detecting cervical disease as samples collected by healthcare practitioner from the cervix using the new method: and
- validate a different liquid for testing (MSwab media) to determine if there were better ways to handle more tests

To achieve these objectives, we aimed to:

- recruit 400 women to participate in the study;
- from each participant, collect one practitioner-collected sample and two self-collected samples, using different collection devices;
- process the self-collected samples on five different laboratory machines, are resuspending in MSwab liquid; and
- compare the HPV results against any biopsy samples from participants to identify the presence of cervical disease.

Outcomes

From the 400 participants, 58 participants had cervical disease (CIN2+), and 342 participants did not have cervical disease.

The study demonstrated that self-collected samples were as sensitive for cervical disease as the healthcare practitioner-collected samples. The self-collected samples were also shown to have equivalent specificity (which looks at false positive results) as the healthcare practitioner-collected samples, when the HPV test results that caused the patient to go for a colposcopy were assessed.

The results from this study show that the method of laboratory processing using MSwab liquid is accurate and effective.

Evaluation

The SCoPE2 study has demonstrated a safe, effective, and efficient way to process high numbers of self-collected samples for the Australian NCSP. It adds more evidence on the accuracy of self-collection for cervical screening and confirms that the new method using MSwab liquid is just as good as the previous one using ThinPrep.

The processing of self-collected tests at the ACPCC has become more efficient because of this study, allowing samples to be tested in the lab faster than before. This is crucial, given the significant increase in self-collected samples, with more than 1,000 swabs being received by the laboratory on some days. Following approval by NATA (the Australian laboratory accreditation body), self-collection using the method developed in SCoPE2 began as part of the NCSP at the ACPCC in October 2023. Over 30,000 HPV tests have been processed using this method so far. Moreover, the use of a safer liquid that's easier to transport and use (because it's not flammable or toxic) makes the laboratory safer for staff.

Additionally, this study has helped laboratories in New Zealand use this method for self-collection as part of their cervical screening program.