SULLIVAN NICOLAIDES PATHOLOGY

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Cervical screening test: self-collection update

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- Australia is on track to be the first country in the world to eliminate cervical cancer by 2035.
- Human papillomavirus (HPV) self-collections account for over 20 per cent of testing at SNP, with numbers rising.
- Meta-analysis data shows equivalent accuracy between self- and clinician-collected specimens for detecting HPV.

The World Health Organization (WHO) officially launched a global strategy to accelerate the elimination of cervical cancer as a public health initiative in November 2020 (elimination is defined as fewer than four cases per 100,000 women per year). Australia is on track to become the first country in the world to achieve elimination by 2035. Improved screening rates, together with the 2017 transition to highly sensitive HPV testing and the National HPV vaccination program, are important steps towards achieving this goal.

A high uptake of self-collection for tests

The new five-year cycle for cervical cancer screening is advanced. It has been well over 12 months since the introduction of the expanded eligibility criteria for self-collection of specimens for testing. Healthcare services involved in cervical cancer screening are experiencing the expected significant increase in participation numbers, together with the very new phenomenon of enthusiastic uptake of self-collection – something we are also seeing at SNP. In the year before the expanded eligibility criteria, self-collections comprised less than one per cent of our cervical screening tests (CSTs). They now comprise over 20 per cent, in line with National Cervical Screening Program (NCSP) numbers, and we expect that figure to continue to rise.

Encouraging participation from under-screened populations

The NCSP decision to expand self-collection was based on the need to improve screening rates and achieve equity in cervical cancer screening outcomes for all eligible Australians. As 70 per cent of cervical cancers occur in unscreened and under-screened populations, removing the barrier of a traditional speculum-collected test gives healthcare providers an important new tool to encourage participation from these populations. Under-screened populations need to be actively encouraged into the program. These groups include Aboriginal and Torres Strait Islander peoples; culturally and linguistically diverse communities; LGBTIQ+; people with disability; people with history of sexual violence; people from low socio-economic backgrounds; and people over 70 years of age.

Consider low vaginal swabs as another option

With meta-analysis data showing equivalent accuracy of PCR results for self- and clinician-collected specimens, patients who are hesitant or mistrust the test can be reassured. In addition, self-collection offers privacy and self-direction to the participant. Clinician-collected low vaginal swabs are another option for those reluctant to undergo speculum examination but are unable to perform self-collection.

Patient eligibility for self-collection

Those who present for their first CST, who are pregnant or who are being followed up for previous positive HPV results are all eligible for self-collection. Groups of people who require co-testing with liquid-based cytology (LBC) preparations are not eligible for self-collections.

Note: it is important to remember this is not a new test, and participants are only entitled to **one Medicare-funded CST every five years**. Offer self-collection **only** when the participant is due for screening.

Before offering self-collections, please check your patient's eligibility via the National Cancer Screening Register (NCSR). To learn more, visit **ncsr.gov.au** and search for 'NCSR portal'.

If a self-collection is performed outside NCSP guidelines, no Medicare rebate is available, and an account will be issued to the patient.

Which swab to use?

SNP recommends and supplies the NPAAC-validated red-top dry FLOQSwabs®. The Roche COPAN 552C.80 swab is another option, but it must be suspended in ThinPrep® solution immediately after collection. A potential downside in using this swab is the risk of confusion with clinician-collected CSTs. In all instances, self-collected specimens must be clearly labelled as self-collections to ensure proper specimen processing.

Reflex testing of self-collected samples and results

Participants who choose self-collection must be fully informed that if HPV is detected, a reflex LBC cannot be performed.

- Around two per cent of tests will be positive for HPV 16/18 and these participants must be referred directly for colposcopy.
- A further 11 per cent of tests will be positive for HPV not 16/18 and these participants will need to return to their healthcare provider for a clinician-collected sample.

For LBC triage, the result informs the next management step. If there is evidence of pHSIL or HSIL, then the participant is referred for specialist gynaecologist assessment; otherwise, they must return for repeat HPV testing in 12 months.

New publication: CST quick reference guide

View our CST fact sheet covering Medicare eligibility, cervical cytology collection devices, and the routine CST screening pathway online at **snp.com.au/cst**

Hard copies are available on request.

References

Inturrisi F, Aitken CA, Melchers WJG, et al. Clinical performance of high-risk HPV testing on self-samples versus clinician samples in routine primary HPV screening in the Netherlands: An observational study. Lancet Reg Health Eur. 2021;11:100235. Published 2021 Nov 9. doi:10.1016/j.lanepe.2021.100235.

C4: NHMRC Centre for Research Excellence in Cervical Cancer Control. 2021 Cervical cancer elimination progress report: Australia's progress towards the elimination of cervical cancer as a public health problem.

To order clinician resources, including the CST fact sheet and self-collection kits, please contact your Medical Liaison Manager.

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New MBS rebates for reproductive carrier screening, effective 1 November 2023

From **1 November 2023**, new Medicare rebates apply to reproductive carrier screening (RCS), covering cystic fibrosis (CF), spinal muscular atrophy (SMA) and fragile X syndrome (FXS).

Testing for females (CF/SMA/FXS) – MBS item 73451: covers the testing of a female who is planning a pregnancy or is already pregnant.

Subsequent screening for male partners (CF and/or SMA) – MBS item 73452: covers the testing of the reproductive partner of a female patient identified as a carrier of CF and/or SMA to determine the reproductive risk for the same condition.

These items are in addition to existing MBS items for CF (73348 and 73349) and FXS (73300) genetic testing in the setting of family history or clinical features.

Next steps

- Request RCS by using our **reproductive carrier screening request form**. A standard pathology request form may also be used – please include clinical notes.
- **Note**: if couples choose to test simultaneously, only the **female will be eligible** for the Medicare rebate, and an out-of-pocket fee of $385 will apply for the male partner.
  A separate request form is required for each patient.
- Genetic counselling is available at no additional cost for couples identified as carriers of the same autosomal recessive or X-linked condition that places them at higher risk of having an affected child.

Available resources for clinicians and patients:

- **RCS clinician guide**
- **RCS quick reference guide**
- **RCS patient course**: covers the general principles and different types of carrier screening, and is now an RACGP- and ACRRM-accredited activity for doctors.
  Access the course at **patientedu.sonicpathology.com.au**
- **RCS patient brochure**

Need help?

Our Medical Liaison Managers are available to assist:

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P 1300 767 284

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Prostate specific antigen (PSA) testing update

Key MBS changes from 1 November 2023:

- Screening interval increased to 2 years for patients with no family history and no previous prostate disease.
- New MBS item allows yearly screening for patients with significant family history (refer to Clinical Practice Guidelines table below).
- Free PSA can be added when total PSA >3 ug/L for men aged 50–69, or >2 ug/L for men with significant family history.
- Benign prostatic hypertrophy now no longer accepted as "previous prostatic disease".

Routine screening of men for prostate cancer

For men with no previous prostate disease and no family history of prostate cancer, the interval between routine PSA tests has increased from 12 months to 23 months (item 66655).

For men who have an increased risk due to family history (refer to Table 1.1 of Clinical Practice Guidelines below), the interval between successive routine PSA tests has been reduced from 12 months to 11 months.

Follow-up of an abnormal total PSA in men undergoing routine assessment

If a total PSA result on routine assessment falls within the ranges specified below, then follow-up testing should be carried out after 1–3 months. **Testing must include both total and free PSA measurement**. The following MBS criteria apply (item 66659):

- PSA >2.0 ug/L and ≤5.5 ug/L for patients at increased risk based on family history; or
- PSA >3.0 ug/L and ≤5.5 ug/L for patients at or over 50 years of age and under 70 years of age; or
- PSA >5.5ug/L but <10.0 ug/L for patients at or over 70 years of age

Testing for free PSA is limited to one episode within a period of 11 months. Any man whose total PSA is greater than the upper limits specified above, or where free PSA is less than 25 per cent, should be considered for referral for specialist management.

Testing of men with previously diagnosed prostate disease

The MBS definition of previously diagnosed prostate disease includes prostate cancer, prostatitis and premalignant conditions such as atypical small acinar proliferation, but excludes benign prostatic hyperplasia. For these patients, there are no specified time intervals between successive total PSA tests (item 66656).

For monitoring, there is a limit of four episodes of free PSA testing within a period of 11 months (item 66660).

Table 1.1 Clinical Practice Guidelines[1]

Level of family history of prostate cancer	Relative risk for prostate cancer death
1 first-degree relative	
Father diagnosed	1.8
Father diagnosed age <60 years	2.1
Father died	2.0
Brother diagnosed	2.8
Brother diagnosed age <60 years	3.3
Brother died	2.8
2 first-degree relatives	
Father and brother diagnosed	3.0
2 brothers diagnosed	6.3
Father and brother both died	6.9
3 first-degree relatives	
Father and 2 brothers diagnosed	9.7
3 brothers diagnosed	8.1

1. Prostate Cancer Foundation of Australia and Cancer Council Australia PSA Testing Guidelines Expert Advisory Panel. Draft clinical practice guidelines for PSA testing and early management of test-detected prostate cancer. Prostate Cancer Foundation of Australia and Cancer Council Australia, Sydney (2016).

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