NATIONAL

CERVICAL SCREENING

PROGRAM A joint Australian, State and Territory Government Program



CHANGES TO THE NATIONAL CERVICAL SCREENING PROGRAM (NCSP) FOR HEALTHCARE PROVIDERS

FROM 1 DECEMBER 2017:

- A five yearly Cervical Screening Test will replace the two yearly Pap test.
- Women who are already having Pap tests should have their first Cervical Screening Test when they are next due for a Pap test (this is usually two years after their most recent Pap test for those women with a normal screening history)
- Women who have ever been sexually active should have a Cervical Screening Test every five years
- Women will be invited to start cervical screening from the age of 25 and continue screening until they are 74 years
- Women who have been vaccinated against human papillomavirus (HPV) need to have regular cervical screening as the vaccine protects against some high-risk types of HPV, but does not protect against all oncogenic types
- Healthcare providers will still perform a vaginal speculum examination and take a cervical sample, but the sample medium is liquid-based for partial HPV genotyping
- The new Cervical Screening Test will be supported by a new National Cancer Screening Register that will send invitations and reminder letters to women when they are next due, and follow up letters when women have not attended further investigations or tests

The link between HPV and cervical cancer

Nearly all cervical cancers are caused by a HPV infection. HPV is easily transmitted via skin contact during sexual activity. It is extremely common in men and women who have ever been sexually active, with most people being infected with at least one type of HPV at some point in their life. While HPV infections are normally cleared naturally by the immune system, sometimes they cause cervical cells to become abnormal. The body is usually able to rid itself of HPV and the abnormal cells, but in some cases this doesn't happen and the abnormal cells develop into cervical cancer. The time from HPV infection to cervical cancer is usually 10-15 years.

What is the new Cervical Screening Test?

The Cervical Screening Test detects infection with human papillomavirus (HPV). Partial genotyping is used to determine the type of HPV into one of two groups: oncogenic HPV 16/18 or oncogenic HPV types other than 16/18 as a pooled result.

Reflex liquid-based cytology (LBC) is applied to all HPV positive samples and is used to triage women who test HPV positive for types other than 16/18.

Based on the test result:

- women who test negative for HPV will be invited to screen again in five years (low risk)
- women who test positive for high-risk HPV (types 16 and/or 18) are referred to colposcopy regardless of their reflex LBC result (higher risk)

- women who test positive for other types of HPV, the reflex LBC result is used to determine management as follows:
 - a possible or definite high-grade squamous intraepithelial lesion (HSIL) and/ or any possible or definite glandular abnormality will be referred to colposcopy (higher risk)
 - negative cytology or a possible or definite low-grade intraepithelial lesion (LSIL) will be referred for a repeat Cervical Screening Test in 12 months (intermediate risk)

Why are the changes taking place?

Between 2012 and 2014, the Medical Services Advisory Committee (MSAC) assessed an extensive range of clinical evidence and modelling of potential screening pathways. MSAC made a recommendation for the new Cervical Screening Test and pathway.

The New Cervical Screening Test and Pathway

- The new Cervical Screening Test every five years is more effective than and just as safe as, a Pap test every two years
- The new Cervical Screening Test and pathway is a risk-based approach to management of women participating in the program. Women are managed according to their risk of developing cervical cancer which is determined by the Cervical Screening Test results
- HPV testing for cervical screening is more sensitive than cytology (Pap tests) and detects the potential for progression to high-grade lesions earlier, thus preventing more cervical cancers
- The Cervical Screening Test detects infection with human papillomavirus (HPV). Partial genotyping is used to determine the type of HPV into two groups: oncogenic HPV 16/18 or oncogenic HPV types other than 16/18 as a pooled result
- If HPV is detected the laboratory will automatically, on the same sample, conduct a cytology test to determine if any cervical cell abnormalities are present. This assists in determining the person's risk rating and triaging for colposcopy

Cause of cervical cancer

Cervical cancer is a rare outcome of persistent infection with high-risk HPV types. Infection with a high-risk HPV type is necessary, although not sufficient, for the development of cervical cancer.¹ HPV types 16, 18 and 45 are most predominantly associated with cervical cancer, with types 16 and 18 detected in 70–80% of cases in Australia.² The time from HPV infection to cervical cancer is usually 10-15 years.

What do I say to women who ask about cervical cancer not caused by HPV?

More than 99% of cervical cancers are caused by HPV, which includes squamous cell and adenocarcinoma. A third type of cervical cancer is called neuroendocrine or small cell cervical cancer. These are often more aggressive, but account for less than 1% of cervical cancers. Neither the Pap test nor the new Cervical Screening Test effectively detects neuroendocrine cancers.

Cervical Screening Test

HPV testing for cervical screening is more sensitive than cytology (i.e. Pap tests) and detects the potential for progression to high-grade lesions earlier, thus preventing more cervical cancers.³

Screening using HPV testing also has the potential to improve detection of adenocarcinoma and its precursors.

While self-collection of samples is possible in some circumstances, it is not recommended for routine screening, as it is not as effective as clinician-collected screening.

Can women have the Cervical Screening Test now?

Yes, however the Cervical Screening Test will not be available on the Medicare Benefits schedule prior to 1 December 2017 and women will be responsible for the full cost of the test. Until 1 December 2017 women should be encouraged to have a Pap test and attend any follow-up when they are due.

How should women transition to the new screening pathway?

Most women will be due for their first Cervical Screening Test two years after their last negative Pap test. Women who are undergoing follow-up investigation or treatment should transition to the new screening pathway as outlined in the 2016 Guidelines found at <u>www.cancer.org.au</u>

Women under 25 years of age will be invited at 25 years of age for their first Cervical Screening Test.

How do I explain why women who have had the HPV vaccine still require cervical screening?

HPV types 16 and 18 cause more than 70% of cervical cancers in Australia.² The HPV vaccine protects against both these types; however, it does not protect against other oncogenic types of HPV known to cause cervical cancer. Therefore, vaccinated women are still at risk of cervical cancer from these other high risk HPV types and need to participate in regular cervical screening.

Screening interval

Due to the high negative predictive value of HPV testing, a screening interval of five years is safe for women who are HPV-negative.⁴

What do I say to women who want to screen more often than every five years?

The Cervical Screening Test is more effective at preventing cervical cancers than the Pap test. Cervical cancer usually takes 10 to 15 years to develop from an HPV infection, so it is very unlikely that cancer will develop in the five years following a negative Cervical Screening Test. Studies have shown that the chance of developing high-grade cervical abnormalities after a negative Cervical Screening Test is lower than the chance of developing them after a negative Pap test.⁵

Age range

Cervical cancer in young women (under 25 years of age) is rare, and screening has not changed the rates of incidence or mortality from cervical cancer in this age group. Commencing screening at age 25 will reduce the investigation and treatment of common cervical abnormalities that would usually resolve by themselves in women under the age of 25. In addition, the HPV vaccine has been shown to reduce cervical abnormalities in young women.

Sending an invitation for women to have a final HPV test between the ages of 70–74 years, rather than 64–69 years, is expected to reduce the incidence of cervical cancer by 4%, and mortality from cervical cancer by 7%.⁴

Women of any age with symptoms, such as unusual bleeding or spotting, will be able to have a Cervical Screening Test.

What do I say to women who are nervous about waiting until 25 to screen?

Screening women younger than 25 years has not reduced the number of cervical cancer cases, or deaths from cervical cancers, in this age group. Cervical cancer is rare in women younger than 25 years.

While HPV infection and cervical abnormalities are common in women younger than 25, both usually clear up without needing treatment. Treatment of these common abnormalities can increase the risk of pregnancy complications later in life.

What if I'm concerned that a woman engaged in sexual activity at a very young age?

For women who experienced their first sexual activity at a young age (before age 14) and had not received the HPV vaccine before this, a single Cervical Screening Test between the ages of 20–24 years could be considered on an individual basis.

How will women know when they are due for their Cervical Screening Test?

The new National Cancer Screening Register (NCSR) will provide an invitation, reminder and recall system to prompt women to book an appointment, supporting and promoting timely participation in cervical screening.

The new National Cancer Screening Register (NCSR)

The NCSR will be a national database of cancer screening records, including Cervical Screening Test results.

Data collected by the NCSR is protected by legislation and cannot be used for purposes other than to support the operations of the cervical screening program, inform ethics-approved research projects, and report on outcomes at a population level.

How will the NCSR support the NCSP?

The NCSR will support the NCSP by:

- inviting women to commence screening when they turn 25 years
- reminding women when they are due and overdue for cervical screening
- providing a woman's cervical screening history to laboratories for comparison with current results
- providing a 'safety net' for women who have positive test results and who have not attended further testing, by prompting them to have follow-up tests

Fees and the Medicare Benefits Schedule (MBS)

From 1 December 2017, new MBS numbers and fees for the Cervical Screening Test will commence. More detail on the MBS numbers to be provided closer to the commencement of the Cervical Screening Test.

What MBS items apply for Pap tests and LBC Pap tests prior to 1 December 2017?

A temporary change to the Medicare Benefits Schedule (MBS) is in place until 30 November 2017:

- A fee of \$28 for the Pap test
- A fee of \$36 for an LBC Pap test

Only one of the above items is claimable per woman, per screening episode. Liaise with your pathology provider about the cervical screening technologies they offer, and for advice about sample preparation.

Resources available for healthcare providers

Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding are available on the Cancer Council Australia wiki website: wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening

NPS MedicineWise has developed online training modules for the new Cervical Screening Test. Visit www.nps.org.au

The Cancer Council Australia is developing an online toolkit for healthcare providers on engaging with under-screened and never-screened women, due for release in October 2017.

References:

- 1. Bosch FX, Lorincz A, Munoz N, Meijer CJLM, Shah KV. The causal relation between human papillomavirus and cervical cancer. J Clin Path 2002;55(4):244-265.
- 2. Brotherton, Julia ML. How Much Cervical Cancer in Australia is Vaccine Preventable? A Meta-Analysis. Vaccine. 10 January 2008, Vol. 26, 2, pp. 250-25.
- 3. Cancer Council Australia Cervical Cancer Screening Guidelines Working Party. National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Sydney: Cancer Council Australia, 2016.
- 4. Commonwealth Government, National Cervical Screening Program Renewal: Evidence review, November 2013.
- 5. Dillner J, Rebolj M et al. Long-term predictive values of cytology and human papillomavirus testing in cervical cancer screening: joint European cohort study. BMJ 2008;337:a1754.

