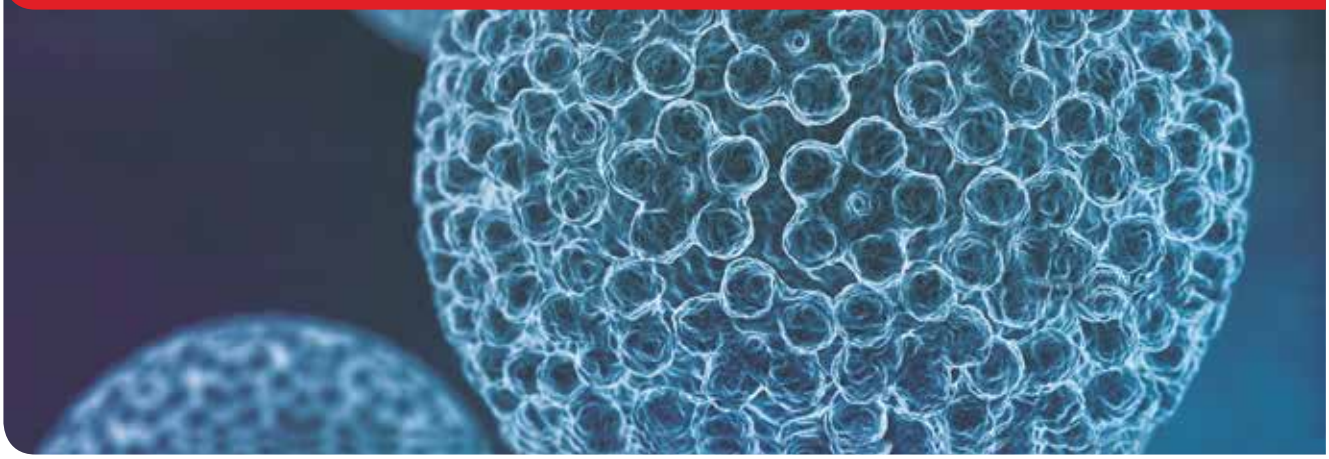
Abbott Pathology

Human Papillomavirus (HPV)



Pap smears are to be replaced by HPV testing from May 1st, 2017. Women are currently advised to have a Pap test every two years to screen for cervical cancer but the new recommendation is to be tested for HPV every 5 years. HPV testing is currently rebated on the Medicare Benefits Schedule (MBS) as a test of cure where a patient has previously received treatment for abnormal lesions of the cervix within the last two years. It is predicted that the HPV test will reduce the mortality of cervical cancer by a further 15 per cent.

In Australia we currently have a two pronged approach to the prevention and early detection of cervical cancer: the HPV Vaccination Program and the National Cervical Screening Program (NCSP). Australia introduced the HPV Vaccination Program in 2007. Initially the program was only for females aged 12 - 13 years but the program added males of the same age to the program in 2013. The HPV vaccine offers a new, complementary tool to improve the control of cervical cancer. It does not eliminate the need for cervical cancer screening even for vaccinated women as they will still be at risk from other high risk types.

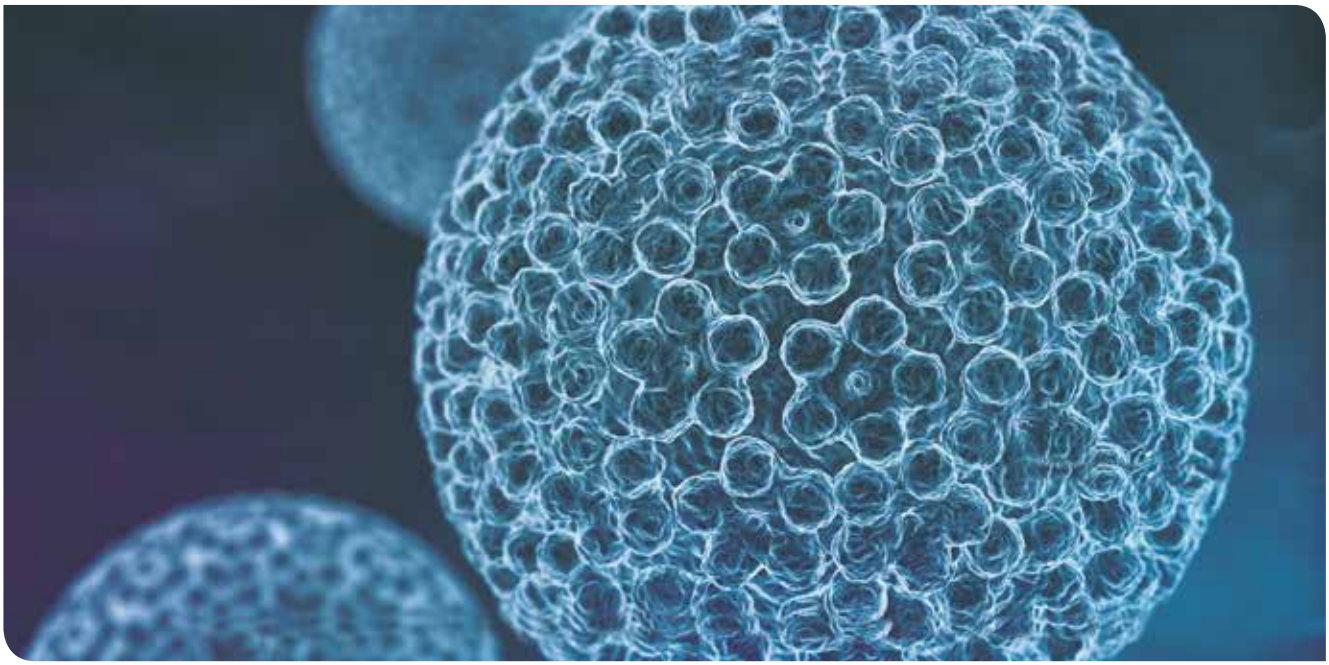
Changes to the current system

But why change the NCSP if it is so successful? The answer is new technologies, new scientific evidence and an overdue review of the current NCSP. These changes now mean that women would have their first screening for cervical cancer at 25 and would be tested only every five years, rather than every 2 years by Pap. This is because an HPV test every five years is even more effective than, and just as safe as, screening with a Pap test every two years.

The 38-page MSAC submission document also made recommendations to the criteria expected from an HPV test for a population screening test.

These are as follows:

1. To be able to provide partial HPV genotyping including HPV16, HPV18 and possibly HPV45 as well as a pooled result for other high risk HPV genotypes;



2. To be able to enable a reflex liquid-based cytology examination in the event of a positive HPV test result;
3. To be appropriately validated against the guidelines developed by Meijer et al 2009;
4. To be validated to perform within the reference test range; and
5. To be approved by the Therapeutic Goods Association under the IVD regulatory framework.

There are more than 100 known HPV genotypes of which 80 are fully sequenced. They are typed by assigning a sequential number based on the order of discovery. Fourteen genotypes are considered a high risk to developing cervical cancer and these are: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68. Genotypes 16 and 18 are the most common genotypes and make up 70% of cervical cancers. Genotypes 6 and 11 are low risk genotypes and cause ~95% of genital warts.

Dorovitch Pathology currently use the Roche cobas HPV test for detection of 14 high risk HPV genotypes. The test specifically detects HPV 16 and HPV 18 while simultaneously detecting the 12 other high risk genotypes. The cobas HPV test contains a full process/internal control which minimises the risk of a false negative result for each patient. Coupled with the unique contamination control measure (AmpErase), these are considered critical design features. This is particularly relevant for HPV testing of Australian women in a primary screening environment with a five year screening interval. This full process control design ensures that a negative HPV sample is not caused by lack of cellularity (sample adequacy) or inhibition. According to NPAAC guidelines, a negative patient result must be accompanied by an internal control result.

08 8159 7900
abbottpathology.com.au

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Specialist Diagnostic Services, ABN 84 007 190 043 APA No. 000042, trading as Dorevitch Pathology. DP0510 17.10.17