The Renewed National Cervical Screening Program:
Key information for Health Professionals

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Overview: National Cervical Screening Program

The National Cervical Screening Program (NCSP) is for HPV vaccinated and unvaccinated ASYMPTOMATIC women who have commenced sexual activity. It also provides advice about the management of symptomatic women.

Key changes

- Start screening at age 25 (sexually active only)
- Finish screening with an exit test from age 70-74
- 5 yearly primary Human Papilloma Virus (HPV) testing with partial genotyping and Liquid-Based Cytology (LBC) triage
- Self-collection of a vaginal HPV sample for under screened women aged 30 years and over
- Women with symptoms (bleeding, discharge, pain) at any age are eligible for co-testing (both HPV and cytology) regardless of when their last cervical screening test was performed.

Key messages

- An HPV test every 5 years is more effective, just as safe, and is expected to result in a significant reduction (24%-36%) in incidence and mortality from cervical cancer in Australian women, compared with the program it replaces which is based on 2 yearly Pap smears.
- The renewed Program is expected to improve the rate of detection of precursors of both adenocarcinoma and squamous cell cervical cancers which are caused by persistent infection with oncogenic HPV types.

Test procedures

- Take your cervical sample in the same way: insert a speculum, visualise the cervix and sample from the transformation zone. Transfer the cellular material into a liquid-based medium. **Do not prepare a glass slide.**
- The primary (first) test will be for 14 oncogenic HPV types known to be associated with the development of invasive cervical cancer.
- This test will separately identify oncogenic HPV types 16 and 18 which cause 70-80% of cervical cancer and 12 other oncogenic HPV types known as oncogenic HPV (not 16/18).
- All samples in which oncogenic HPV is detected will have cytology performed on the same cervical sample. This is known as reflex Liquid Based Cytology (reflex LBC) and the laboratory will carry out cytology without needing a specific request from you.
- Cervical Screening Test (CST) – is an HPV test and any reflex LBC test done on cervical cells in a liquid-based sample.

Key recommendations

- Women with a negative CST (no oncogenic HPV detected) result should re-screen in 5 years
- Women with oncogenic HPV types 16/18 detected should be referred directly for colposcopy
- Women with other oncogenic HPV types (not 16/18) detected will be triaged according to the reflex LBC result and screening history
- Women who do not have oncogenic HPV detected on a self-collected sample should re-screen in 5 years
- Women with an unsatisfactory CST result (HPV or LBC) should return in 6-12 weeks for a repeat HPV or cytology.
Background: HPV and cervical cancer

- HPV is critical in the pathogenesis of cervical cancer and the risk of developing cancer increases significantly with persistent HPV infection.
- Genital HPV infection is usually transient and most often asymptomatic. Anogenital HPV infections are transmitted mainly by skin-to-skin or mucosa-to-mucosa contact during sex. It is highly contagious and most people acquire infection within a few years of becoming sexually active.
- There are about 40 genital HPV types, 14 are classified as oncogenic as they are associated with anogenital cancer, including squamous and adenocarcinoma of the cervix. HPV types 16 and 18 cause 70-80% of cervical cancers.
- However, while HPV is an extremely common genital infection, anogenital cancer is a rare outcome of its acquisition because most infections are cleared and progression from any persistent infection to invasive cervical cancer is generally slow.
- The immune system clears the virus within one to two years in the majority of those with genital HPV infection.
- Persistent infection with oncogenic HPV (especially type 16) is associated with a significantly elevated risk of developing high grade cellular abnormalities of the cervix.
- It is estimated that persistent HPV infections and pre-cancer are established within 5-10 years from less than 10% of new infections. Invasive cancer occurs rarely in a small portion of women with pre-cancer over decades.
- Prior to implementation of HPV vaccination, cervical HPV infection was common in young sexually active women.
- After the introduction of vaccination, Australia experienced rapid falls in rates of cervical infections with vaccine included oncogenic HPV types, in anogenital warts and in histologically confirmed HSIL.

Figure 1: HPV to cervical cancer
HPV testing is more effective and safe

Starting to screen at age 25 is safe for Australian women

- Cervical cancer is extremely rare in women under 25. The best protection against these extremely uncommon cancers arising in women aged under 25 years is the HPV vaccination, as these cancers cannot be prevented by screening. Screening women aged under 25 years regularly since 1991 has had no impact on the incidence and mortality of cervical cancer in this age group. Notably the main impact of the program has been on the rate of squamous cancer in women aged 25 years and older.

- The changing cervical screening environment has been prompted by the impact of HPV vaccination. HPV vaccine coverage in Australia is increasing with coverage for girls aged 15 in 2015 being 86, 83 and 78% for doses one, two and three respectively. The benefit of the HPV vaccine includes documented reductions in the prevalence of cervical pre-cancerous lesions now extending to women in their late 20s.

- The International Agency for Cancer Research (IARC) recommends that cervical screening commence at the earliest at age 25, because 'there is minimal benefit and substantial harm in screening below age 25.' Most countries with organised screening programs commence screening at age 25 or 30 years, and have achieved cervical cancer incidence and mortality rates that are similar to Australia.

- This approach will reduce the harms associated with screening younger women, in particular, reducing the side-effects of over investigation and treatment including pain, bleeding and infection. Evidence links treatment of the cervix with a small but important increased risk of preterm delivery. Therefore, the later age to commence screening protects women from long term complications associated with future pregnancies as a result of over diagnosis and treatment.

- **Women at any age with possible symptoms of cervical cancer (pain, bleeding, discharge) should have a co-test (diagnostic cytology and HPV testing) and appropriate referral.**

- Young women who commence sexual activity prior to 14 years of age and who did not receive the HPV vaccine before this may have a cervical screening test between the ages of 20-24 years.

Screening every 5 years is more effective and is safe for Australian women

- Several studies have demonstrated the increased sensitivity of the HPV test and that the likelihood of developing a significant cervical abnormality, cervical intraepithelial neoplasia grade 3 (CIN 3) or cervical cancer within 5-6 years of a negative HPV test is low and less than the likelihood of developing cervical intraepithelial neoplasia grade 3 (CIN 3) or cancer within two years of a negative Pap test.

- A recent meta-analysis of four randomised controlled trials of primary HPV testing has demonstrated that HPV based screening provides greater protection against the development of invasive cervical cancers (including both squamous cell carcinoma and adenocarcinoma) than cytology based screening, even when HPV testing is performed at longer screening intervals.

- Women should be assured that a five-yearly cervical screening test is safer and more effective than a two-yearly Pap test.

- Women with a negative cervical screening test result should be told that they are extremely unlikely to develop a significant abnormality of the cervix or cancer in the next five years, at which time they will receive a reminder to return for repeat screening.
Patient education: Explaining HPV to women

Tips
- Normalise the infection: HPV has been referred to as the ‘common cold of sexual activity’.
- Avoid using terminology such as ‘pre-cancerous’ and ‘oncogenic’ as it causes anxiety and is usually inaccurate.
- If you have any queries please call the Victorian Cytology Service on 03 9250 0300 and ask to speak to a Liaison Physician.

Key messages
- Most patients with genital HPV will not develop high grade cervical abnormalities, as the virus usually clears by itself. However, when cervical cancer occurs, HPV is found in virtually all cases.
- Some types of HPV may be more difficult for the body to clear naturally.
- Long-term infection with these HPV types can increase risk of high grade cervical abnormalities, which may lead to cervical cancer. Treatment for abnormalities caused by the HPV infection may be required.

What is genital HPV?
- HPV is a virus that is passed on by genital skin-to-skin contact during sex.
- It is extremely common in men and women who have ever had sex.
- Some types of HPV cause genital warts, but most HPV infection does not cause any symptoms at all.
- HPV is usually cleared by the body’s immune system in one to two years.
- Occasionally HPV remains inactive in cells and can be re-activated in later life. HPV infections identified in testing may not have been recently acquired.

HPV transmission
- The virus enters the body through tiny breaks in genital skin; it is not spread via blood.

Treatment of HPV
- Treatment of the virus itself is not needed as the body’s immune system usually clears the infection. Antibiotics do not treat HPV infection.

Re-infection
- You are highly unlikely to be re-infected with the same type of HPV, as your body will usually develop immunity to it. However, you can be infected with other types of HPV.

HPV and sexual history
- People can have HPV for a long time without ever knowing it. It may have been acquired many years ago.

Condoms and HPV
- Condoms offer limited protection against HPV as they do not cover all of the genital skin. However, they do provide excellent protection against infections such as chlamydia and are recommended in new sexual relationships.

Young sexually active women should see their Health Professional for:
- A chlamydia test each year
- Contraceptive advice for heterosexual and bisexual women.
HPV testing is safe

- The new cervical screening test looks for the Human Papillomavirus (HPV).
- HPV is so common that most sexually active people will be infected at some stage, as HPV is spread through genital skin to skin contact during sex.

90% of women will have HPV in their lifetime
90% of men will have HPV in their lifetime

- HPV usually has no symptoms and is cleared from the body naturally. Occasionally it causes serious disease.

98% of people infected with genital HPV will clear the virus naturally within 5 years

- Some types of HPV have the potential to cause cervical cancer.

There are 14 HPV types that cause 99% of cervical cancers. The HPV test looks for these 14 types.

It then takes 10-20 years on average for this cell change to potentially become cancerous

- Occasionally HPV remains inactive in the cells and can be re-activated in later life. It’s important to continue to have tests into your 70s even if you’ve been with the same partner or haven’t been sexually active for many years.

- If we find HPV is present, the cells of the cervix will be automatically re-examined for any changes.

- Depending on the type of HPV and the cell changes found, you might need immediate further testing or a repeat test in 12 months to confirm the virus is no longer present in the cervix.

30% more cases of cervical cancer will be prevented with the new national Cervical Screening Program compared with the Pap Smear Program
#### Desktop aid: A risk-based approach to managing asymptomatic women

<table>
<thead>
<tr>
<th>Risk of significant cervical abnormality</th>
<th>Cervical Screening Test (CST) Result</th>
<th>Recommended management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Oncogenic HPV not detected</td>
<td>Routine 5-yearly CST</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Oncogenic HPV detected (not 16/18) with negative, possible LSIL or LSIL cytology</td>
<td>Repeat CST in 12 months</td>
</tr>
<tr>
<td></td>
<td>Oncogenic HPV (any type) persisting at 12 month repeat following initial oncogenic HPV (not 16/18)</td>
<td>Refer for colposcopic assessment regardless of cytological result</td>
</tr>
<tr>
<td>Higher</td>
<td>Oncogenic HPV 16 &amp;/or 18 detected with any cytology result</td>
<td>Refer for colposcopic assessment regardless of cytological result</td>
</tr>
<tr>
<td></td>
<td>Oncogenic HPV 16 &amp;/or 18 detected with unsatisfactory cytology</td>
<td>Refer for colposcopic assessment. Repeat cytology to be performed at time of colposcopy</td>
</tr>
<tr>
<td></td>
<td>Oncogenic HPV detected (not 16/18) detected with possible HSIL or HSIL cytology</td>
<td>Refer for colposcopic assessment at the earliest opportunity, ideally within 8 weeks</td>
</tr>
<tr>
<td></td>
<td>Oncogenic HPV detected (any type) with glandular abnormalities including adenocarcinoma-in-situ on cytology</td>
<td>Refer to a gynaecologist with expertise in suspected malignancies or a specialised gynaecological oncologist</td>
</tr>
<tr>
<td></td>
<td>Invasive squamous cell carcinoma (SCC) or adenocarcinoma</td>
<td>Refer to a gynaecological oncologist or gynaecological cancer centre for urgent evaluation, ideally within 2 weeks</td>
</tr>
<tr>
<td>-</td>
<td>Unsatisfactory HPV or cytology</td>
<td>Repeat sample 6 to 12 weeks after dealing with any remediable problem</td>
</tr>
<tr>
<td>-</td>
<td>Oncogenic HPV detected (not 16/18) with unsatisfactory cytology</td>
<td>Repeat Liquid Based Cytology (LBC) in 6 to 12 weeks</td>
</tr>
</tbody>
</table>
Instructions: Taking an effective Cervical Screening Test

Sampling instruments

| Cervical sampler broom | Cervex-Brush Combi | Endocervical brush | Plastic Spatula |

Sampling technique

For pre-menopausal women

Choose between:
- Cervical sampler broom: rotate 3–5 times plus (optional) Endocervical brush: insert ensuring that you can see the lower row of the bristles and make a quarter rotation
- Cervex-Brush Combi: insert central part of the brush into the os and rotate clockwise twice
- Spatula: rotate 1 or 2 times, taking care to keep contact with the ecto-cervix plus Endocervical brush: insert ensuring that you can see the lower row of the bristles and make a quarter rotation

For peri and post-menopausal women

Choose between:
- Cervical sampler broom: rotate 3–5 times plus Endocervical brush: insert ensuring that you can see the lower row of the bristles and make a quarter rotation
- Cervex-Brush Combi: insert central part of the brush into the os and rotate clockwise 2 times
- Spatula: rotate 1 or 2 times, taking care to keep contact with the ecto-cervix plus Endocervical brush: insert ensuring that you can see the lower row of the bristles and make a quarter rotation.

Lubricants

- Have the potential to interfere with the quality of screening tests
- Should be water soluble and carbomer free
- The current formulations of lubricant are approved for use:
  - KY Jelly (medical grade)
  - Astroglide (non-silicone based version)
  - Surgi-gel (not Surgi-gel Plus)
  - Surgilube
  - Glyde
  - Clinigel
- Applied very sparingly to the outer portion of the speculum taking care to avoid the tip of the speculum
- Luke-warm water to warm and lubricate the speculum presents the least risk to the quality of the sample.
Transferring cellular material into a ThinPrep vial

Cervical sampler broom or Cervex-Brush Combi
- Rinse the broom/brush as quickly as possible into the vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart.
- As a final step, swirl the broom vigorously to further release material.
- Do not leave any part of the sampling device in the fluid for ThinPrep.

Spatula (Plastic)
- Rinse the spatula as quickly as possible into the vial by swirling the spatula vigorously in the vial 10 times.
- Do not leave any part of the sampling device in the fluid for ThinPrep.

Endocervical Brush
- Rinse the brush as quickly as possible in the solution by rotating the device in the solution 10 times while pushing against the vial wall.
- Swirl the brush vigorously to further release material.
- Do not leave any part of the sampling device in the fluid for ThinPrep.

Don’t forget!
- Tighten the cap so that the black line on the cap passes the black line on the vial.
- Record the woman’s surname, first name and date of birth on the vial.
- Or apply ID label.
- Record the woman’s information and relevant medical history on the request form.
- There is no need to prepare a conventional slide.

Note:
SurePath samples
Instruments should be broken off and left in the fluid.

Pregnancy
Do not use the endocervical brush or Cervex-Brush Combi.

* Images supplied by Hologic (Australia) Pty Ltd
Visual Reference: Cervix Reference Card

This aid will assist you to identify a range of cervical appearances when undertaking cervical screening. If you are uncertain about the appearance of the cervix, we recommend you seek a second opinion.

Further investigation not required in asymptomatic women

- Nulliparous
- Eversion / ectropion
- Nabothian follicles
- Multiparous
- Atrophy

Consider further investigation

- Polyp
- Cervical wart

Should be investigated

- Mucopurulent discharge
- Cancer

Post-intervention - further investigation not required in asymptomatic women

- Intra Uterine Device (IUD)
- Stenosis
- Post treatment

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Health Professional’s guide: self-collection of HPV samples

Key points

- Self-collection is a vaginal swab taken by a woman for HPV testing
- The sample contains vaginal not cervical cells
- The vaginal HPV test is a sufficiently accurate test and includes partial genotyping for HPV 16/18
- LBC cannot be performed on the vaginal sample
- Self-sampling must be performed in a health care setting. It is not available as a home-based test or mail out kit
- The laboratory report will be sent to the practitioner, not the woman.

Key messages

- It is an alternative pathway to overcome barriers some women experience to having a clinician-collected cervical screening test.
- Women who are eligible for self-collection will benefit by participation in screening
- Women will also benefit by being reassured they are at low risk of cervical cancer if oncogenic HPV is not detected.

To be eligible for self-collection a woman must:

- Be aged 30 years or over
- Be more than 2 years overdue for screening, this currently means 4 years since last Negative Pap test.
- Decline (for whatever reason) a speculum examination.

Self-collection should not be offered to:

- Pregnant women
- After total hysterectomy in women with a past history of a high-grade squamous intraepithelial lesion (HSIL)
- Women who have been exposed to diethylstilbestrol (DES) in utero
- Women under 30 years of age
- Women with symptoms (bleeding, pain or discharge).

Tips for supporting women to take a vaginal self-sample for HPV

- Women who are eligible for self-collection may be more anxious about cervical screening
- Reassure women in a sensitive and culturally appropriate manner about the test, use a visual guide (enclosed) to explain how the test is done
- It may be useful to show the woman the sampling device describing the soft-tip and red mark indicating they should insert the swab up to the red mark
- Tell women that taking the sample should not hurt
- Document the woman’s preferred method of contact and update her contact details
- Discuss and document women’s preferred method for receiving test results and how they will be followed up if HPV is detected.
**Oncogenic HPV not detected on self-collected sample**

- Women who do not have oncogenic HPV detected should be told their risk of developing cervical cancer is low.
- These women will be invited to re-screen in 5 years. Add a recall for a CST in 5 years.
- Let the woman know a clinician collected sample will be offered and encouraged at that time.
- Explain to women this avoids a second visit to collect cells from the cervix, as the vaginal sample does not allow cell changes in the cervix to be checked should this be necessary.
- Reassure women that a clinician collected sample provides effective protection against cancer of the cervix.

**Oncogenic HPV detected on self-collected sample**

- A small number of women will have oncogenic HPV detected. These women will be contacted by the practice to arrange a follow up visit.
- At the follow up visit the practitioner should:
  - EITHER:
    - For women with oncogenic HPV (16/18) detected, refer for colposcopy. This should not be delayed.
    - The cervical sample for cytology will be obtained by the colposcopist.
  - OR
    - For women with oncogenic HPV (not 16/18) detected, collect a sample from the cervix for reflex LBC. Explain to the woman that the cytology result will guide further management:
      - If the LBC test result is negative, possible LSIL or LSIL, the woman should be recalled in 12 months for a repeat HPV test (a clinician collected sample is preferred).
      - Tell the woman she must return in a year for a repeat HPV test and a sample will be taken from the cervix at that visit.
      - If the LBC test result is possible HSIL, HSIL or any glandular abnormality, refer for colposcopy preferably within 8 weeks.
      - *Tell the woman further investigation is required. The practice will contact her to organise an appointment at her earliest convenience, at this visit a referral to a specialist will be organised.*
Summary: Chlamydia testing in the context of the renewed NCSP

1. Test all young women and men who have ever had sex for Chlamydia every twelve months until the age of 30, then test selectively according to risk or request.

2. FPU (first pass urine) is an excellent test for Chlamydia. It does not need to be the first of the day and it does not matter when they last passed urine. Get the sample when your patient is there.

3. When undertaking cervical screening in women who are also eligible for a chlamydia test take the cervical sample as usual and transfer it to the liquid based medium and request a cervical screening test (CST) and chlamydia, ensure the woman has signed the Medicare assignment on the request form.

4. 1g stat oral dose of Azithromycin for uncomplicated Chlamydia infection is acceptable as this treatment is very effective. A test of cure is not recommended. Alternatively prescribe Doxycycline 100mg BD for one week. Advise no sex for one week.

5. Guidelines recommend the empirical treatment of patients with symptoms and any sexual contacts of positive cases.

6. Positive infections should be treated promptly, preferably the same or next day after a positive result.

7. Australian guidelines recommend re-testing at three months after a positive Chlamydia result.

8. Avoid re-testing for Chlamydia too early (one to two weeks after treatment) as false positive results may occur.

9. Chlamydia re-infection rates are high with most occurring in the four to five months after a positive result.

10. Level one evidence confirms that contact tracing for Chlamydia is effective in preventing transmission to partners and re-infection of the index case.

11. Patient delivered partner therapy (PDPT) for Chlamydia is an additional partner notification strategy that is effective and safe. PDPT increases partner treatment rates and reduces re-infection. This is legislated in the Northern Territory and Victoria only.