Cervical Screening in General Practice: Changes to self-collection eligibility and the intermediate risk pathway

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Acknowledgement of Country

- *We recognise the traditional custodians of the land and sea on which we live and work. We pay our respects to Elders past and present*

Learning Objectives

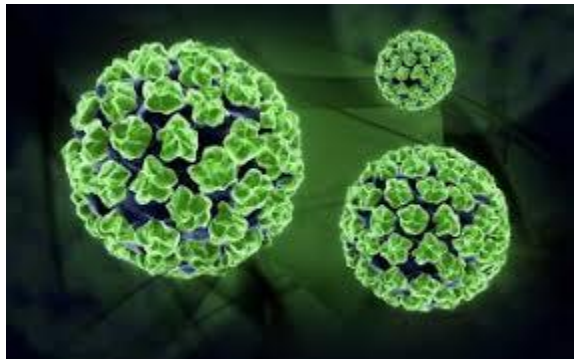
- Be aware that self-collection eligibility policy changed on 1 July 2022 and discuss self collection exclusions according to National clinical guidelines
- Discuss what changes were made to the intermediate risk clinical pathway in February 2021 including changes to referral recommendations
- Utilise appropriate referral pathways including when participants should be referred on to specialists

Disclaimer:

- *Although we refer to 'women' in this presentation, cervical screening is relevant for anyone with a cervix, including trans- and gender diverse people*

What we will cover…

- Overview of the National Cervical Screening Program (NCSP)
- Changes to self collection eligibility and the Intermediate Pathway
- Practical aspects of offering self-collection
- Case presentations
- Q&A



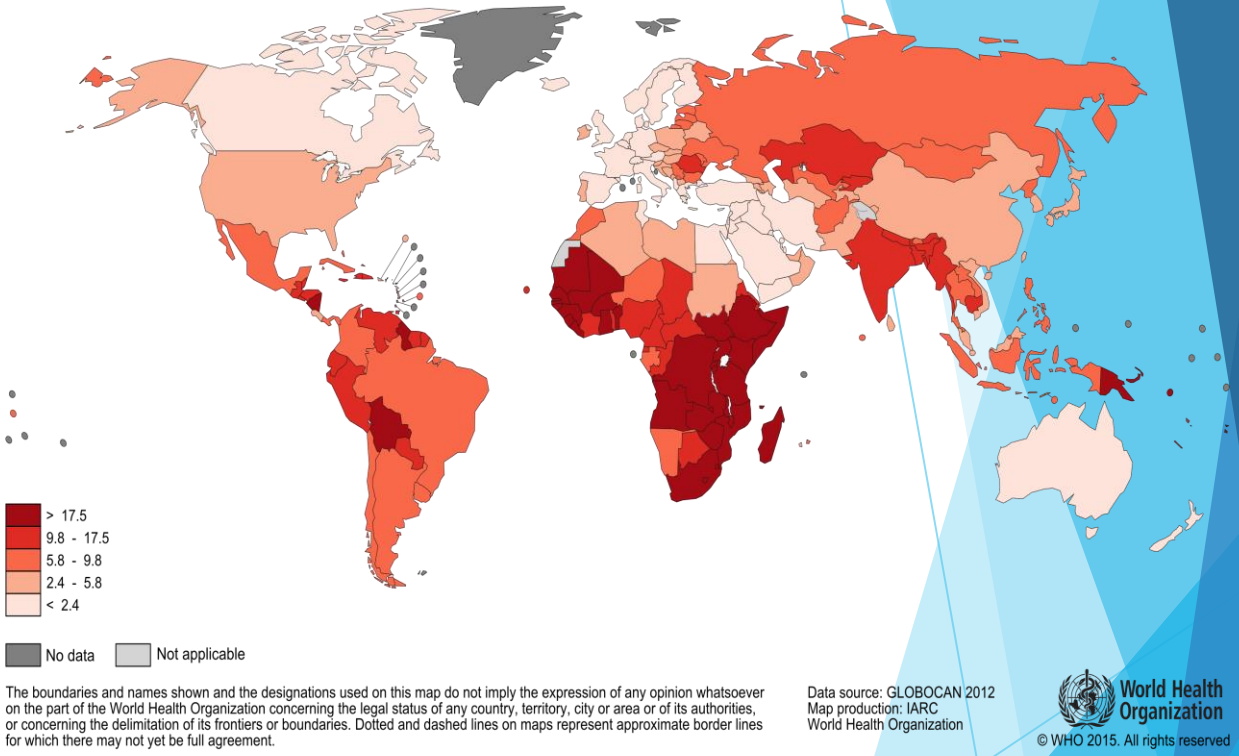
Cervical Screening Renewal – where are we now

- **2017**: 2-yearly Pap tests → 5-yearly CST (HPV) tests
- **Feb 2021**: change to intermediate risk recommendations (where HPV non 16/18 is detected)
- **July 2022**: change to self-collection eligibility

website https://www.cancer.org.au/clinical-guidelines/cervical-cancer-screening

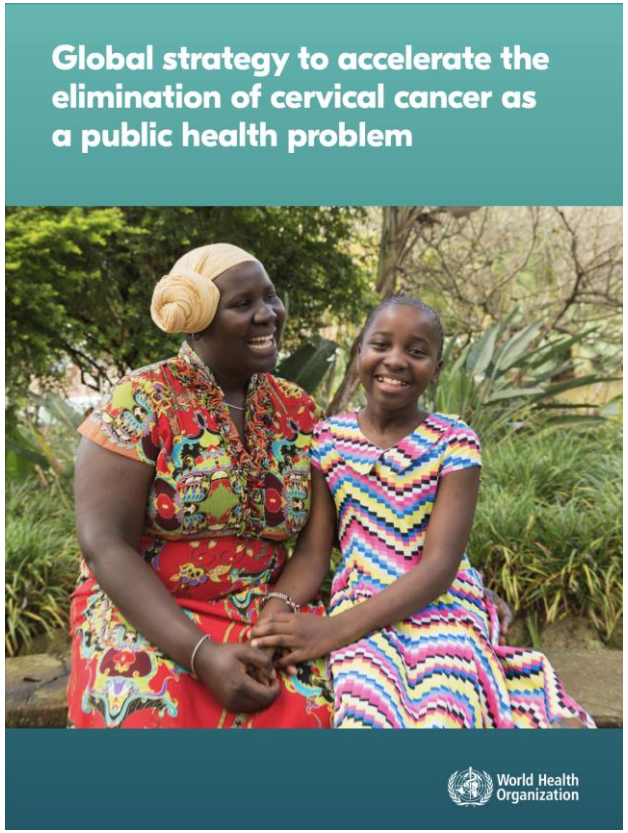
Cervical Cancer

- 4th most common cancer & cause of cancer deaths in women worldwide
  - 604,127 cases in 2020
- Burden not equal globally
  - Sig variation in incidence & mortality globally
  - Nearly 90% deaths in 2018 were in low & middle income countries



Bray et al 2018, https://gco.iarc.fr, WHO. Global strategy to eliminate cervical cancer as a public health problem 2020, AIHW 2021

Self-Collection Pathway



- Australia is on track to be the first country to eliminate cervical cancer by 2030
  - 14th most common cancer in females in Australia
  - 913 new diagnoses & 237 deaths in 2021
- → Inequities in the current program related to socio-economic status, remoteness, indigenous status
- In Australia 72% of women who develop cervical cancer are under or never screened (AIHW 2020)
- WHO target – 70% women screened for HPV at least twice in their lifetime. Australia's current screening rate is 52%
- Self-collection provides an opportunity to reverse the decline in overall screening participation rates and to reduce long standing inequities in participation

https://www.mja.com.au/journal/2021/215/8/self-collection-hpv-screening-game-changer-elimination-cervical-cancer#13

Under-screened or never-screened patients

In Australia 80% of cervical cancer are in never screened or under-screened patients. Groups more likely to be under-screened include:

- Aboriginal and Torres Strait Islander women
- Women from culturally and linguistically diverse backgrounds, including those who have experienced female genital mutilation – these patients may prefer to access screening from migrant and refugee services.
- People who identify as lesbian or bisexual or who are same-sex attracted.
- People who identify as transgender and have a cervix.
- Women who have experienced sexual abuse or assault.
- Women who experienced sexual activity (or abuse) before age 14.
- Women with a disability.

Screening recommendations

- Recommend cervical cancer screening for all asymptomatic women (**including pregnant women**) with a cervix, aged 25 to 74 years, who have ever been sexually active, including those who:
  - have had intimate sexual skin-on-skin contact.
  - have sex with women.
  - identify as male or non-binary.
  - are no longer sexually active.
  - have received the HPV vaccination.
  - are in a monogamous relationship.
  - use condoms.
- Start screening at age 25 years.
- Screen every 5 years if oncogenic HPV is not detected.
- Invite asymptomatic patients aged > 70 years to have an "exit test" and discontinue screening if negative for HPV.

Screening – Additional considerations

- **Sexual activity (or abuse) at a young age** (before 14 years) -A single cervical screening test (CST) may be considered, for asymptomatic patients 20 - 24 years who experienced their first sexual activity before 14 years and did not receive the HPV vaccine prior to exposure.
- **Immune-deficient -** Offer cervical screening test (CST) every 3 years to patients who are:
  - HIV positive.
  - solid organ transplant recipients.
- Consider 3-yearly screening for patients:
  - with congenital (primary) immune deficiency.
  - who are being treated with immunosuppressant therapy for autoimmune disease.
  - who are allogeneic bone marrow transplant recipients treated for graft versus host disease.

Screening – Additional considerations

- **Diethylstilboestrol (DES)-exposed patients**
- For patients exposed to DES in utero, recommend annual co-test and colposcopic examination of the cervix and vagina indefinitely.
  - Daughters of women exposed to DES in-utero do not have an increased risk of cervical cancers or pre-cancers. They should be screened with routine cervical screening test (CST) at 5-year intervals.
- **Pregnant patients**
- Offer cervical screening test (CST) at any stage of a patient's antenatal care if they are due or overdue.
  - Offer self-collection, as it provides opportunity for screening patients who may otherwise not be screened because of barriers to speculum examination.
  - If clinician collected sample, the cervical broom is recommended for pregnant patients to collect a cervical screening specimen. Do not use the endocervical brush.

Emotional and Cultural Barriers

Embarrassment about the procedure

Cultural issues (related to circumstances, beliefs, background and inequities in society)

Reluctance to screen after a negative past experience e.g. pain or discomfort

Past history of sexual abuse or sexual violence

Fear of cancer diagnosis / treatment

Confidentiality concerns

Practical Barriers

- Time constraints, including availability of childcare
- Intending to have a test but not getting around to doing it or forgetting when the test is due
- Concerns about cost
- Language issues
- Lack of transport
- Physical, social or practical barriers associated with a disability
- Weight-related barriers (obesity)
- Personal preference for choice of healthcare provider

Barriers in Knowledge

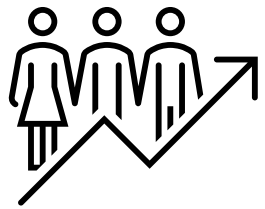
Some women may lack of knowledge about:

- the purpose of a Cervical Screening Test
- the role of screening in prevention
- the risks of cervical cancer
- who needs to be tested
- the accuracy of the test
- available screening options including self-collection

Self-Collection – Addresses Barriers to Screening

It's a game changer! And….

- Most screening participants described the experience of self-collection positively and reported a greater sense of control over their health. [1]
- Sensitivity of HPV PCR testing for detection of CIN 2 or worse is similar for clinician and self-collected samples[2]



1. Creagh NS, Zammit C, Brotherton JML, et al. Self-collection cervical screening in the renewed National Cervical Screening Program: a qualitative study. *Med J Aust* 2021; 215: 354–358.

2. Arbyn M, Smith SB, Temin S, et al; Collaboration on Self-Sampling and HPV Testing. Detecting cervical precancer and reaching under-screened women by using HPV testing on self samples: updated meta-analyses. *BMJ* 2018; 363: k4823.

Assess suitability for self collection

Self-collection is not suitable if the patient requires a co-test, e.g.:

- is symptomatic e.g., is experiencing abnormal bleeding.
- requires Test of Cure follow-up after treatment for HSIL.
- follow-up after certain screen-detected abnormalities (eg glandular abnormalities after normal colpo)
- treated for adenocarcinoma in situ (AIS)
- has been exposed to diethyl-stilbestrol (DES) in utero.
- has had a total hysterectomy with past history of high-grade squamous intraepithelial lesion (HSIL).

Procedure for self collection

- **Self-collected sample**
- A self-collected sample is taken from the vagina (not the cervix). It can be tested for the presence of the human-papillomavirus (HPV) but not cytology (cervical cell abnormalities).
- Where self-collection is chosen, patients attending an in-person consultation should be encouraged to collect their sample while still at the clinic, as sample collection is considered more likely in this context.
  - a clinician can assist collection of the vaginal swab (eg tremor, low vision, other disability) and still classify it as self collected on the request form
- However, with the aim to maximise participation in cervical screening, collection of the sample can occur in any setting that the healthcare provider believes is appropriate, including in the context of a telehealth consultation.

Self-Collection Highlights

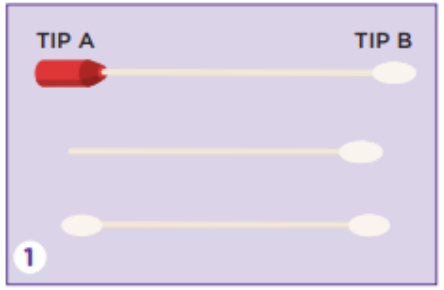
- Self-collection HPV test an option for all who are eligible for screening
  - women and people with a cervix, aged 25 to 70-74, who have been sexually active
  - → Vaginal swab to detect oncogenic HPV DNA
  - use dry swab from the lower vagina without need for speculum examination
- HPV is being shed from the cervix, can be found on the vaginal walls
  - → Not cervix sample, cannot perform reflex LBC / cytology

Australian Government

NATIONAL CERVICAL SCREENING PROGRAM
A joint Australian, State and Territory Government Program

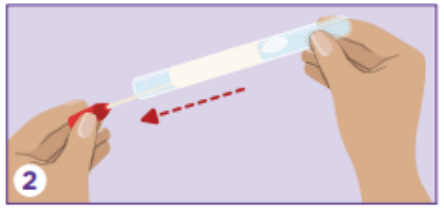
Cervical Screening Test: How to take your own sample

This guide will help you collect your own vaginal sample for cervical screening. If you're unsure about anything or have any questions you can talk to your healthcare provider.



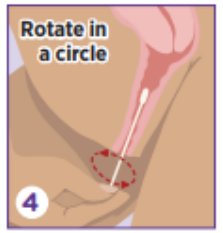
1. Before starting

- Your healthcare provider will provide you with a private space to collect your sample. This could be behind a screen or in a bathroom. You'll then receive a package. Inside is a swab. Your swab may look different to those pictured here.
- Before you open the package make sure you know which end of the swab can be held (Tip A), and which end is for taking the sample (Tip B). If you are unsure which end is which, ask your healthcare provider for advice.
- Make sure your hands are clean and dry, get yourself in a comfortable position and lower your underwear.



2. Preparing the swab

- Twist the cap and remove the swab from the packaging.
- Make sure not to touch Tip B that will be inserted to collect the sample.
- Do not put the swab down.

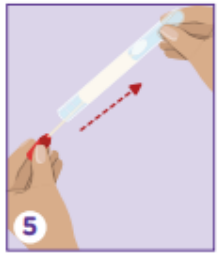


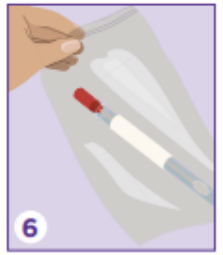
3. Inserting the swab

- Use your free hand to move skin folds at the entrance of your vagina.
- Gently insert Tip B into your vagina a few centimeters.
- The swab may have a line or mark on it showing you how far to insert.

4. Taking the sample

- Rotate the swab gently for 10-30 seconds (in any direction). This may feel a bit uncomfortable but should not hurt.





5. Storing the sample

- Still holding Tip A, gently remove the swab from your vagina.
- Place the swab back into the packaging with Tip B going in first.
- Screw the cap back on. Get dressed and return the package to your healthcare provider.

6. Sending the sample

- The sample will be sent to a pathology laboratory for HPV testing.
- The results of the test will be sent to your healthcare provider.

[National Cervical Screening Program – How to collect your own vaginal sample for a Cervical Screening Test (health.gov.au)]

Requesting PATHOLOGY

To ensure appropriate testing done and appropriate clinical recommendations made:

- **Indicate if self-collected or clinician collected**
- If clinician collected sample for cytology following HPV detection on self-collected sample, write **“LBC only”**
- indicate if patient is **Aboriginal and/or Torres Strait Islander**
- Indicate other relevant past screening info / symptoms / relevant medical history eg immunosuppression

Self-collection Results

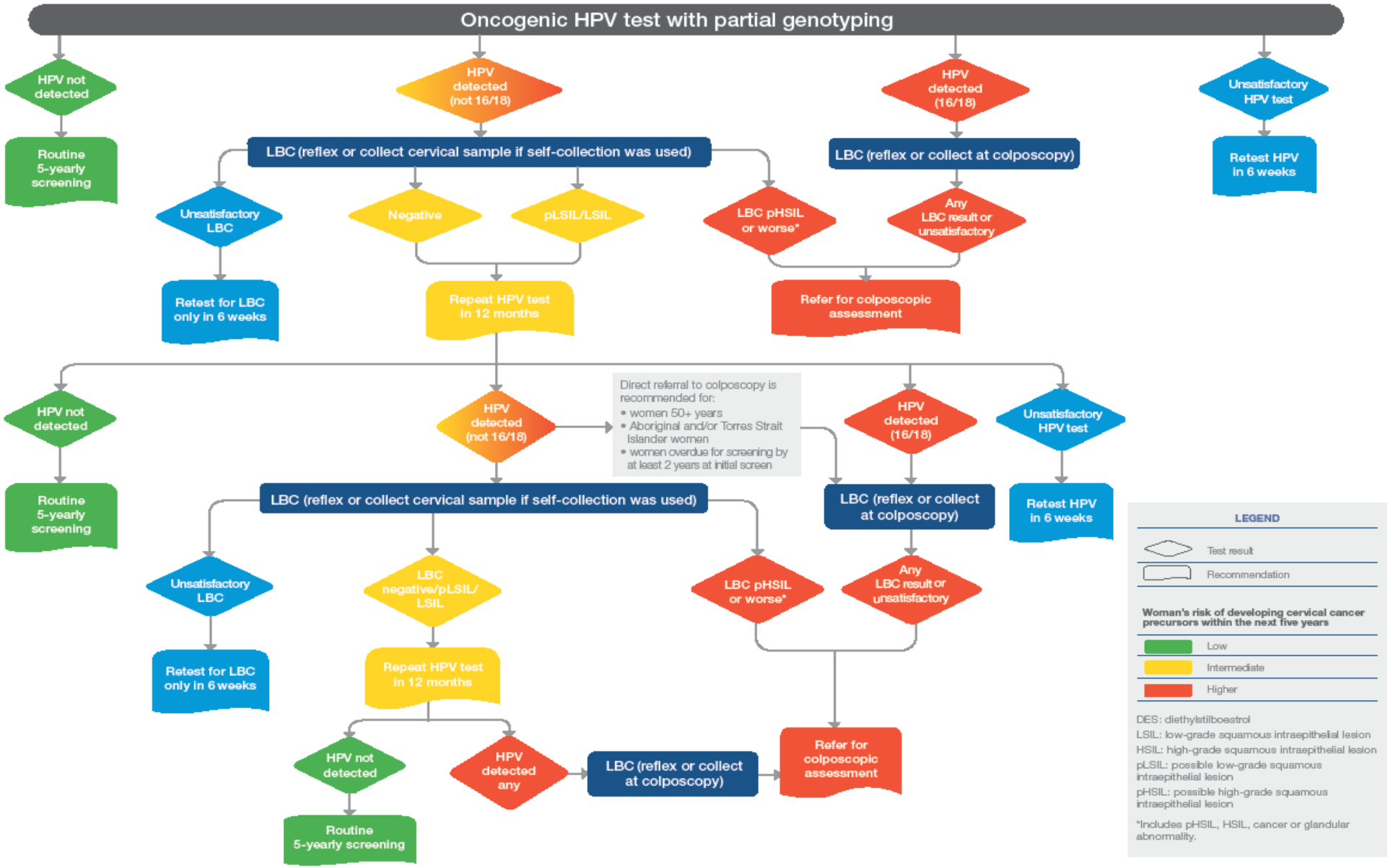
- **Self-collected vaginal sample test results**
- If the patient tests **negative for HPV** -> re-screen in 5 years.
- If the patient **tests positive for other oncogenic HPV types (non 16 or 18)**, (*expected in around **6-8%** of those attending for routine screening* -> recall for a clinician-collected sample for LBC and manage according to LBC results.
- If the patient **tests positive for oncogenic HPV types 16 or 18** -> Refer for colposcopy (*expected in around 2% of those attending for routine screening*.) Cervical sample for liquid-based cytology (LBC) will be taken at the time of colposcopy.

Self-Collection Highlights

Be aware…. Result risk categories:

- **HPV (not 16/18) detected from self-collected test -> (risk not determined until LBC performed on a clinician-collected sample)**
  - **pHSIL/HSIL** / glandular abn / invasive disease → **High risk result** → COLPOSCOPY
  - **Negative or pLSIL/LSIL** → **Intermediate risk result** → repeat HPV test in 12 mths

https://www.health.gov.au/sites/default/files/documents/2022/07/national-cervical-screening-program-understanding-the-national-cervical-screening-program-management-pathway.pdf



Suggested citation: Cancer Council Australia Cervical Cancer Screening Working Party. Clinical pathway: Cervical screening pathway. National Cervical Screening Program: Guidelines for the management of screen detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. CCA 2016. Accessible from http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening. Updated Dec 2020.

NATIONAL CERVICAL SCREENING PROGRAM

Australian Government Department of Health

Cancer Council

Supporting informed choice

- **Provide clear information about options available**
- **Discuss pros and cons including differences in management and follow-up of self-collection vs. clinician-collection**
- **If chosen, give step by step guidance about how to collect the sample and how results received**

Community HealthPathways

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Cervical Screening

Clinical editor's note

From 1 July 2022, all patients screening under the National Cervical Screening Program (NCSP) have the choice to screen using either a self-collected vaginal sample or a clinician-collected sample. Both screening options will still be accessed through a healthcare provider.

See Cancer Council Australia – National Cervical Screening Program Update.

Key links

National Cervical Screening Program Guidelines

Red Flags

- Persistent abnormal vaginal bleeding, even with a normal cervical screen result
- Invasion and/or atypical glandular cells (suspected or definitive) on liquid-based cytology (LBC)

Background

About cervical screening

Assessment

Negative CST does not exclude pathology

Arrange further assessment for a patient with symptoms (e.g., abnormal vaginal bleeding) or abnormal examination even if they have a negative cervical screening result.

1. Take a history.
2. Further assess any symptoms which may be due to reversible causes or indications for diagnostic co-test collection.
3. Check the routine screening recommendations.
4. Consider additional support for patients who are under-screened or never-screened.
5. Consider additional screening requirements for:
   - patients who experienced sexual activity (or abuse) at a young age (before 14 years).
   - immune-deficient patients.
   - diethylstilboestrol (DES)-exposed patients.
   - pregnant patients.
   - patients who have had a hysterectomy.
   - patients with cervical and vaginal atrophy.
6. Offer the patient a choice between a clinician-collected sample or a self-collected sample, if suitable. Explain sample collection procedure and obtain consent.
7. Perform examination if the patient selects a clinician-collected sample or the patient requires a co-test. Follow related protocol and consider a chaperone.
8. Take cervical sample using the appropriate collection technique if the patient selects a clinician-collected sample or the patient requires a co-test. On the pathology request form, include relevant clinical details to inform follow-up recommendations (e.g., previous CST result, immunosuppression, DES in-utero exposure).
9. If indicated (e.g., symptoms), arrange other investigations:
   - STI screening. Samples in liquid-based medium can be tested for:
     - Chlamydia

[HealthPathways Hunter New England (communityhealthpathways.org)]

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Password = p1thw1ys

Patient's previous cervical screening history

This may be accessed via the National Register.

- Practices using Best Practice, Medical Director, and Communicare can now integrate their practice systems with the National Cancer Screening Register to view their patient's cervical screening record directly within a patient record.
- All other users can access their patient's screening records via PRODA.
- For assistance accessing the National Register NCSR | Healthcare providers accessing participant data through the NCSR or ring **1800 627 701** or ask your PCIO to assist.

Summary

- **HPV testing with a self-collected sample is as accurate as HPV testing with a clinician-collected sample**
- Explain the options and pros and cons of self vs clinician-collected sampling to support informed choice
- LBC cannot be performed on a self-collected sample
- Anyone requiring routine screening or a follow up HPV test after an intermediate risk screening result is eligible for self-collection
- Anyone who requires a co-test is ineligible for self-collection
- Don’t forget the changes to the **intermediate risk pathway !**