Contributing authors

Professor Peter O'Leary (Centre for Population Health Research, Curtin University)

Associate Professor Vincent Williams (School of Biomedical Sciences, Curtin University)

Professor Jim Codde (Health Services Planning Unit, South Metropolitan Health Service)

Ms Christine Fletcher (WA Cervical Cancer Prevention Program, Women and Newborn Health Service)

Professor James Semmens (Centre for Population Health Research, Curtin University)

Clinical acknowledgements

The WA Cervical Cancer Prevention Program especially acknowledges the professional clinical expertise and input by:

Professor Yee Leung (School of Women's and Infants' Health, University of Western Australia)

Clinical Professor Greg Sterrett (Anatomical Pathology, PathWest)

Associate Professor Graeme Boardley (Midwifery, Nursing & Patient Support Services, Women and Newborn Health Service)

Ms Natalie Williams (Department of Nursing and Midwifery Education Research, Women and Newborn Health Service)

The WA Cervical Cancer Prevention Program records grateful appreciation to the above members of the Synopsis Review Committee, whose work and dedication has made this synopsis possible.
Foreword

The WA Cervical Cancer Prevention Program (WACCPP) was established in 1992 as part of the National Cervical Screening Program and is one of the six programs that reside within the Women’s Health Clinical Care Unit (WHCCU) in the Women and Newborn Health Service. The WACCPP is committed to increasing the number of credentialed nurses and midwives as Pap smear providers to deliver cervical screening services throughout Western Australia. Pap smear providers play a critical role in women’s health as they:

- enhance and complement existing cervical screening services
- ensure that Western Australian women have access to high quality cervical screening services
- increase women’s access to female health care providers (as the majority of nurses and midwives are female)
- assist women in overcoming barriers that prevent them from participating in regular cervical screening

The cervical screening synopsis was developed with valuable input from women’s health care providers and professional organisations in WA and was endorsed by the WACCPP in 2013. The purpose of this document is to:

- support health care providers in their delivery of cervical screening services
- guide clinical practice in accordance with the National Health and Medical Research Council guidelines Screening to Prevent Cervical Cancer: Guidelines for the Management of Asymptomatic Women with Screen Detected Abnormalities
- promote best practice standards
- be used as a quality assurance reference

The WHCCU adopts a holistic approach to promote the health and wellbeing of WA women. Through collaborative relationships we strive to improve women’s health, particularly for vulnerable women who are at most risk for cervical abnormalities. We hope that the distribution and use of this document will assist the WACCPP in reaching these goals.

Paula Chatfield
Director
Women’s Health Clinical Care Unit
Women and Newborn Health Service

Assoc Prof Jonathan Rampono
Chair
Women’s Health Clinical Care Unit
Women and Newborn Health Service
## Contents

Contributing authors ................................................................................................................. 1
Clinical acknowledgements ........................................................................................................ 1
Foreword..................................................................................................................................... 2
Contents ..................................................................................................................................... 3

1. Executive summary ............................................................................................................... 4

2. Aetiology of cervical cancer ................................................................................................. 5

3. Pathogenesis of cervical cancer .......................................................................................... 7

4. Prevention of cervical cancer ............................................................................................... 8

   4.1 Human papillomavirus vaccine .................................................................................... 8
   4.2 Cervical screening ........................................................................................................ 9
   4.3 National Cervical Screening Program Policy .............................................................. 9
   4.4 National Cervical Screening Program Policy on pregnancy ...................................... 10

5. Classification of cervical abnormalities ............................................................................. 11

6. Credentialing as a Pap smear provider .............................................................................. 13

   6.1 Health practitioner registration .................................................................................... 13
   6.2 Essential education and training .................................................................................. 13
   6.3 National competency standards for nurse Pap smear providers ................................ 14

7. Performing a Pap smear ...................................................................................................... 15

   7.1 Positive outcomes of Pap smears ................................................................................ 15
   7.2 What are common errors in Pap smear preparation? .................................................. 15
   7.3 The Pap smear assessment .......................................................................................... 16
   7.4 The Pap smear examination ......................................................................................... 16
   7.5 Completing the Pap smear pathology form .................................................................. 18
   7.6 Management of women with screen detected cervical abnormalities ..................... 19
   7.7 Referral of women with screen detected cervical abnormalities ................................ 19
   7.8 Interpretation of Pap smear reports .......................................................................... 20

8. Result follow-up and notification........................................................................................ 23

9. References............................................................................................................................ 24
1. Executive summary

Cervical cancer is a worldwide health issue and is one of the most preventable of all cancers. Since the introduction of the Papanicolaou (Pap) smear as a cervical screening tool, up to 90% of squamous cell carcinomas have been prevented. Human papillomavirus (HPV) infection is well-established as the principal cause of 99.7% of cervical cancer cases. There are many different subtypes of HPV that can infect the anogenital tract, but two HPV subtypes known as type 16 and 18 are responsible for 70% of all cervical cancer cases worldwide. HPV vaccines that prevent HPV type 16 and 18 infections are now available and have the potential to reduce the incidence of cervical and other anogenital cancers.

In 1991, the Australian Government accepted recommendations made by the Screening Evaluation Steering Committee to the Australian Health Ministers’ Advisory Council (AHMAC) and implemented the Organised Approach to Preventing Cancer of the Cervix, now known as the National Cervical Screening Program (NCSP). The NCSP operates as a joint program of the Australian, and state and territory governments. The Australian cervical screening program recommends a 2-yearly screening interval for asymptomatic women, has adopted standardised quality assurance guidelines for the management of screen detected abnormalities and established Pap smear registries in every state and territory.

The WA Cervical Cancer Prevention Program (WACCPP) is the State funded component of the NCSP, and is responsible for the management and operation of the statewide cervical screening program. The WACCPP aims to reduce the incidence and mortality attributable to cervical cancer. The Program achieves this through support of existing health care systems and the implementation of appropriate strategies to enhance women’s participation in cervical screening.

Important Disclaimer

All information and content in this material is provided in good faith by the WA Cervical Cancer Prevention Program, Women’s Health Clinical Care Unit, WA Health, in collaboration with the Centre for Population Health Research, Curtin University, and is based on sources believed to be reliable and accurate at the time of development.
2. Aetiology of cervical cancer

The National Institute of Health Consensus Conference on cervical cancer stated, “cervical carcinoma is the first solid tumour to be shown to be virally induced in essentially every case.” Results from a large international collection of cervical tumour specimens have identified the human papillomavirus (HPV) DNA to be present in 99.7% of all cases\(^1\). There are more than 100 types of HPV, with 40 types affecting the anogenital region. Among the anogenital HPV infections, there are both low risk (LR) HPV and high risk (HR) HPV types. LR HPV is non-oncogenic and often causes genital warts, with types 6 and 11 causing 90% of these incidences\(^2\). It is well recognised that infection with HR HPV oncogenic types is a necessary, although not sufficient cause of virtually all cervical cancer cases\(^3-8\). HR HPV types 16 and 18 alone are responsible for 70% of cervical cancer incidences\(^9\).

In Australia, 637 incidences of cervical cancer were diagnosed in 2008 and 131 women died from this in 2007\(^10\). This is approximately 9 new cases and 2 deaths per 100,000 women, respectively\(^10\). In 2010, for every 1,000 women screened, 9 women had a histologically confirmed high-grade cervical abnormality, providing health care providers an opportunity to treat women before possible progression to cancer\(^10\).

There are two main types of cervical cancer, namely squamous cell carcinoma (SCC) and adenocarcinoma\(^10, 11\). SCC arises in cells in the ectocervix, with the majority of cases being detected in the transformation zone (the ectocervix and endocervix junction) (Figure 1)\(^10, 11\). Adenocarcinoma arises from mucus producing cells adjacent to the transformation zone or in the endocervical canal\(^11\). Across Australia in 2007 SCC comprised 63.4% of all cervical cancer cases, followed by adenocarcinoma (24.9%), adenosquamous (3.9%) and all other cervical cancers (7.9%)\(^12\).

**Figure 1.** Female reproductive organs, endocervix, ectocervix and transformation zone.
The development of squamous cervical carcinoma is related to both host and viral characteristics such as viral oncogenicity, inadequacy of the patient’s immune system response and any associated risk factors which may include\textsuperscript{2,13-16}:

- multiple sexual partners
- a partner with multiple previous or current sexual partners
- young age at first sexual intercourse
- persistent infection with a high risk (HR) HPV type e.g. HPV 16 or HPV 18
- cigarette smoking

There is evidence that cofactors contributing to the progression of adenocarcinoma, including those with HR HPV, are different from those that contribute towards progression to squamous cell carcinoma\textsuperscript{17}. Adenocarcinomas have been associated with different associated risk factors such as\textsuperscript{17}:

- obesity
- sero-positivity for Herpes simplex virus type 2 (HSV-2)
- endogenous hormonal factors such as parity and exogenous hormone use such as the oral contraceptive
3. Pathogenesis of cervical cancer

Human papillomavirus infection is a common sexually transmitted infection with approximately 11.4% of the female population estimated to be infected worldwide\(^\text{13, 18}\). Molecular testing has demonstrated that over 99.7% of cervical cancers are positive for HPV DNA\(^1\). Transmission of HPV to the anogenital region primarily occurs through microabrasions in the epithelium\(^\text{19}\). Most HPV infections are transient regardless of the age of the woman\(^\text{19}\), with approximately 50% of HPV infections spontaneously clearing within 8 months of initial infection and 90% being cleared within 2 years\(^\text{20-22}\).

All sexually active women are at risk of HPV infection and it is estimated 75% will involve an oncogenic HPV type\(^\text{23}\). Sexual intercourse is the primary route of transmission of genital HPV infection\(^\text{18}\) and peak HPV prevalence has been identified soon after the onset of sexual activity in adolescence and early adulthood\(^\text{16, 24}\). The subsequent age-related decrease in prevalence reflects acquisition of immunity and monogamous relationships. The development of cervical cellular changes from the onset of genital HPV infection to the development of cervical carcinoma can take 10–20 years, although it has been reported that in some cases may only take 1–2 years post sexual debut\(^\text{5, 16, 25}\). The duration of the HPV infection is related to the HPV type, on average HR HPV infections last longer than infections with LR HPV. Research indicates that there is a causal relationship between HR HPV infection longevity and the likelihood that it will progress towards a precancerous lesion/carcinoma\(^\text{16, 19, 26-28}\). Approximately, 20-30% of women with persistent HR HPV infection (>12 months) will be diagnosed with a high-grade abnormality within 30 months\(^\text{22, 26}\).

The progression from HPV infection to cervical cancer may take approximately up to 5-15 years and can be summarised into four key stages: 1) HPV transmission 2) acute HPV infection 3) viral persistence and the development of a precancerous lesion, and 4) invasion through the basement membrane of the epithelium (carcinoma)\(^\text{16, 29, 30}\). Development of malignant lesions occurs through HR HPV DNA integrating into the host genome in infected cells\(^\text{31}\). Once this event occurs there is potential for the integrated viral genes to interfere with the normal mechanisms that control cell proliferation and destruction of “mutant cells” that can result in the proliferation of abnormal cells\(^\text{31}\).
4. Prevention of cervical cancer

4.1 Human papillomavirus vaccine

The development of prophylactic vaccines against human papillomavirus (HPV) infections is the most significant recent advancements in the prevention of cervical carcinoma\textsuperscript{32, 33}. HPV vaccination offers primary prevention against HR HPV types 16 and 18 that cause 70\% of this disease\textsuperscript{34-36}. HPV vaccines have been approved for use in over 100 countries, as the vaccine is safe, well tolerated and efficacious\textsuperscript{37}. In Australia there are two types of prophylactic vaccines that have been approved for use, namely Gardasil\textsuperscript{®} and Cervarix\textsuperscript{®}\textsuperscript{32, 33}.

Gardasil\textsuperscript{®}

In June 2006, the Therapeutic Goods Administration (TGA) approved the use of Gardasil\textsuperscript{®} (CSL Biotherapies/Merck & Co. Inc.) in Australia, for females aged 9 to 26 years and males aged 9 to 15 years\textsuperscript{38}. Gardasil\textsuperscript{®} is a recombinant, quadrivalent HPV vaccine that prevents infection with genital HPV types 6, 11, 16 and 18\textsuperscript{39}. The Australian Government covers the cost of this vaccine for girls aged 12 to 13 years, as part of the school based Immunisation Program\textsuperscript{38}. Gardasil\textsuperscript{®} has been reported to be 98\% effective at preventing cervical disease and external genital lesions when administered prophylactically to uninfected women (HPV DNA negative and HPV seronegative for relevant types)\textsuperscript{36, 40-43}. Gardasil\textsuperscript{®} is administered as an intramuscular injection (IM), given in 3 doses (0, 2 & 6 months)\textsuperscript{39}. Side effects may include injection site reactions, headaches, fever, nausea, dizziness and allergic reactions\textsuperscript{39}. Contraindications to this vaccine include hypersensitivity or severe allergy to yeast and prior allergic reaction to Gardasil\textsuperscript{39}.

Cervarix\textsuperscript{®}

The TGA approved the Cervarix\textsuperscript{®} vaccine in May 2007 (GlaxoSmithKline). Cervarix\textsuperscript{®} differs from Gardasil\textsuperscript{®} as it is a recombinant protein particulate bivalent HPV vaccine that prevents infection by HPV types 16 and 18\textsuperscript{44}. It is registered for use in females aged 10–45 years\textsuperscript{44}; however, the Australian Government does not support the cost of this vaccine. Cervarix\textsuperscript{®} has been administered and tested in clinical trials capturing approximately 40,000 females, and has consistently displayed high levels of efficacy (upwards of 98\%) in preventing precancerous lesions due to HPV types 16 and 18\textsuperscript{35}. Cervarix\textsuperscript{®} is administered as an IM injection given in 3 doses (0, 1 & 6 months)\textsuperscript{44}. The most common side effects include injection site reactions, headaches, gastrointestinal
symptoms, myalgia, arthralgia and allergic reaction\(^44\). Contraindications to the vaccine include pregnancy and a prior negative reaction to Cervarix\(^\circ\). Its use is cautioned in women who are either allergic to or have a sensitivity to latex\(^44\).

It is important to note that HPV vaccines are designed to prevent initial HPV infection\(^33, 35, 36\). They are not a therapeutic vaccine, thus, the vaccine is most effective if given to females prior to the commencement of sexual activity\(^33, 35, 36\). Whilst vaccinating young girls before their sexual debut is consistently advised by current HPV vaccination guidelines, natural history studies indicate that all sexually active women may benefit from the vaccination\(^34-36, 41\). Research suggests that only women with confirmed current infections by both oncogenic HPV vaccine types will not benefit from the vaccination\(^45\).

Health care providers should assist women of all ages to make an informed decision when considering HPV vaccination\(^45\). Should the woman be over 25 years of age she may still be offered vaccination after a discussion about the risks and benefits to assist her in making an informed decision\(^45\).

Health care providers should emphasise the benefits of vaccination combined with the importance of continued cervical screening\(^45\).

### 4.2 Cervical screening

Australia’s cervical screening program operates as a joint program of the Australian Government and state and territory governments, targeting women aged 20-69 years\(^12\). The Australian cervical screening program, utilises the systematic application of a validated test to identify asymptomatic individuals in a population who may have cervical abnormalities\(^46\).

In Australia, the Pap smear, or ‘Pap test’ is used as the primary cervical screening tool. Pap smears identify early cellular changes in the cervix, which if left undetected and untreated may progress to cervical cancer\(^12\). A Pap smear can be a personally challenging procedure for a woman; therefore, as a Pap smear provider it is important that women participating in cervical screening are both psychologically and physically comfortable throughout the examination\(^47, 48\).

### 4.3 National Cervical Screening Program Policy

The National Cervical Screening Program (NCSP) recommends that all women aged 18 to 69 years, who have ever been sexually active, whether vaccinated or not, should
participate in 2-yearly cervical screening. This policy applies only to asymptomatic women. Symptomatic women require referral and further investigation. The Policy states\textsuperscript{12}:

- All women who have ever been sexually active (any genital-skin to genital-skin contact) should commence having Pap smears between the ages of 18 and 20 years, or one to two years after sexual debut, whichever is later.

- Pap smears may cease at the age of 70 years for women who have had two normal Pap smears within the last five years. Women aged 70 years and over who have never had a Pap smear, or who request a Pap smear, should be screened.

- Women with a past history of high-grade cervical lesions, or who are being followed-up for previous abnormal smears should be managed in accordance with the National Health and Medical Research Council (NHMRC) guidelines Screening to prevent cervical cancer: guidelines for the management of asymptomatic women with screen detected abnormalities\textsuperscript{49}.

4.4 National Cervical Screening Program Policy on pregnancy

Pregnancy is a time when women often have the greatest interest in their health and are more likely to participate in cervical screening if it is offered\textsuperscript{47, 48}. Opportunistic screening may be undertaken at the booking visit, unless there is a clinical reason, such as bleeding, which would prohibit performing the Pap smear\textsuperscript{12}. The Pap smear could then be performed at the follow-up visit.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists advised the NCSP that a Pap smear should be offered to every well pregnant woman (without symptoms of cervical cancer) who is due for cervical screening\textsuperscript{12}. Ideally screening would occur prior to 24 weeks; however, screening is safe beyond this gestation\textsuperscript{12}. Symptomatic pregnant women will need referral and further investigation\textsuperscript{12}.

Pregnant women with abnormal smear results should be managed in accordance with the NHMRC guidelines\textsuperscript{49}. 
5. Classification of cervical abnormalities

The Australian working party, using the Bethesda System as its basis, derived a unique Australian terminology system for squamous and glandular lesions called the Australian Modified Bethesda System (AMBS 2004, Table 1 and Table 2).

Table 1. The Australian Modified Bethesda System (AMBS 2004) for squamous abnormalities

<table>
<thead>
<tr>
<th>AMBS 2004</th>
<th>Incorporates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible low-grade squamous intraepithelial lesion</td>
<td>Non-specific minor squamous cell changes. Changes that suggest, but fall short of, HPV/cervical intraepithelial neoplasia (CIN 1)</td>
</tr>
<tr>
<td>Low-grade squamous intraepithelial lesion (LSIL)</td>
<td>HPV effect, CIN 1</td>
</tr>
<tr>
<td>Possible high-grade squamous intraepithelial lesion</td>
<td>Changes that suggest, but fall short of, CIN 2, CIN 3 or squamous cell carcinoma</td>
</tr>
<tr>
<td>High-grade squamous intraepithelial lesion (HSIL)</td>
<td>CIN 2, CIN 3</td>
</tr>
<tr>
<td>Squamous cell carcinoma</td>
<td>Squamous cell carcinoma</td>
</tr>
</tbody>
</table>

Squamous abnormalities are classified into possible or definite low-grade squamous intraepithelial lesions (LSIL or HPV+/CIN 1), possible high-grade squamous intraepithelial lesion (where the presence of a high-grade abnormality such as CIN 2, CIN 3 or squamous cell carcinoma cannot be excluded), high-grade squamous intraepithelial lesions (HSIL, CIN 2 or CIN 3) and squamous cell carcinoma. The cervical cytology classification system assists the medical scientist and pathologist to classify the cervical cellular changes to allow appropriate follow-up recommendations and clinical management.

The classification of squamous intraepithelial lesions is characterised by abnormal cellular proliferation and maturation, together with nuclear atypia. In LSIL, the changes predominantly occupy the lower third of the epithelium and marked HPV cytopathic effects (koilocytosis) are often seen. In HSIL, the changes inhabit the lower two thirds of the epithelium (CIN 2), or the full thickness of the epithelium (CIN 3), and the nuclei are hyperchromatic and irregular. HSILs are also characterised by detectable high risk (HR) HPV DNA and chromosomal instability.
Although adenocarcinoma in situ (AIS) is defined as a preinvasive cervical lesion, natural history studies to confirm its potential to progress are lacking\textsuperscript{50}. AIS is much less commonly diagnosed than the corresponding squamous preinvasive lesions\textsuperscript{10}. No terminologies of glandular lesions with lower degrees of nuclear atypia have been established due to rarity in biopsies\textsuperscript{51-53}.

Table 2. AMBS (2004) for glandular abnormalities\textsuperscript{49}.

<table>
<thead>
<tr>
<th>AMBS 2004</th>
<th>Incorporates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atypical endocervical cells of undetermined significance</td>
<td>Non-specific minor cell changes in endocervical cells</td>
</tr>
<tr>
<td>Atypical glandular cells of undetermined significance</td>
<td>Non-specific minor cell changes in glandular cells</td>
</tr>
<tr>
<td>Possible high-grade glandular lesion</td>
<td>Changes that suggest, but fall short of, AIS or adenocarcinoma</td>
</tr>
<tr>
<td>Endocervical adenocarcinoma in situ</td>
<td>Adenocarcinoma in situ</td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td>Adenocarcinoma</td>
</tr>
</tbody>
</table>
6. Credentialing as a Pap smear provider

The WA Cervical Cancer Prevention Program (WACCPP) is responsible for the management and delivery of the Pap Smear Provider Initiative (PSPI). The PSPI encourages and supports nurses and midwives to credential as a Pap smear provider to increase the opportunity for women to access high quality cervical screening services throughout WA, especially in rural and remote areas. The credentialing process exists to support and ensure high-quality delivery of patient care. Credentialing promotes both the autonomy of an individual's practice and the advancement of nursing and midwifery through:

- increasing recognition of Pap smear provider practice by colleagues and other health disciplines
- increasing the public’s awareness of Pap smear provider skills and competencies

The process for credentialing includes submission of documentation to the WACCPP in support of these requirements. Further information can be found at http://www.health.wa.gov.au/cervical/healthprof/hp_become.cfm

6.1 Health practitioner registration

Credentialed Pap smear providers are required to be registered with the Nurses and Midwives Board, which is regulated by the Australian Health Practitioner Regulation Agency (AHPRA). AHPRA is responsible for the regulation of registration and accreditation of fourteen health professions across Australia.

For further information on health practitioner registration and accreditation, please visit: www.ahpra.gov.au

6.2 Essential education and training

To be eligible to credential, nurses and midwives need to have completed an educational program deemed appropriate by the WA Pap Smear Provider Credentialing Committee. For further information relating to approved education programs please contact the WACCPP on 13 15 56.
6.3 National competency standards for nurse Pap smear providers

The *National Standards for Nurse Pap Smear Providers* (1997) relate to the legal and ethical responsibilities for Pap smear providers, and includes accountability for clinical services.

The *National Standards for Nurse Pap Smear Providers* comprise eight competencies. These include:

- Demonstrate accurate knowledge for safe practice
- Protects the rights of individuals
- Recognises own ability and level of professional competence
- Acts to enhance the dignity and integrity of women
- Maintains a physical and psycho-social environment which promotes safety, security and optimal health care
- Acts to maintain the right of women to make informed decisions
- Integrates comprehensive health assessment and interpretive skills to achieve optimal care for women
- Collaborates with the health care team to achieve desired outcomes

For further information regarding the national competency standards for nurse Pap smear providers, please refer to Appendix A.
7. Performing a Pap smear

The Pap smear is a procedure in which cells are collected from the cervix, smeared onto a microscope slide, and sent to a pathology laboratory for cytological examination. Worldwide, the Pap smear is currently the most effective test to prevent squamous cervical cancer worldwide. Correct sampling technique increases the accuracy and adequacy of the smear sample, and decreases the risk of a false negative result\textsuperscript{54}.

7.1 Positive outcomes of Pap smears

As part of quality assurance measures it is important for a Pap smear provider to seek feedback from patients. Positive outcomes of a Pap smear may include\textsuperscript{47, 48}:

- a satisfactory cervical smear is obtained
- minor cell changes are detected early and appropriately managed
- the woman is given appropriate referral for the management of any abnormalities noted
- the woman and Pap smear provider decide the appropriate process for the notification of the Pap smear test results and this plan is adhered to
- the role and benefit of the Cervical Cytology Registry of WA are explained to the woman
- the woman expresses positive satisfaction with her Pap smear examination
- the woman knows when her next Pap smear is due
- the woman continues to participate in regular cervical screening

7.2 What are common errors in Pap smear preparation?

Pap smear providers are responsible for the correct preparation, fixation (preservation) and staining of specimens. Mistakes which may seriously interfere with the correct cytological interpretation of the slides may include\textsuperscript{47, 48}:

- use of slides which are not clean
- excess use of lubricants
- insufficient cells collected
- excessive blood associated with collection or menstrual cycle
- excessive inflammatory cells in cases where there is evidence of purulent discharge
- cells collected from the incorrect site i.e. vaginal walls instead of cervix
• incorrect application of cells onto slides
• time delay in applying fixation spray
• insufficient or excess fixation spray used to cover cells on the slide

7.3 The Pap smear assessment
Depending upon the clinical environment in which the Pap smear provider practises, the order of these steps may need to be altered to adapt to the woman’s requirements \(^{47, 48}\).

Obtain a thorough gynaecological or obstetrical history, particularly any:

• postmenopausal bleeding (PMB) or spotting
• postcoital bleeding (PCB) or spotting
• intermenstrual bleeding (IMB) or spotting
• abnormal vaginal discharge

Assessment of the woman prior to the Pap smear determines:

• the need for additional investigations
• the position to be adopted by the woman during the procedure
• the speculum size to be used
• ways in which to ensure the woman’s comfort (both physical and psychological) throughout the procedure
• need for referral

7.4 The Pap smear examination
Pap smear providers need to ensure women receive personal care that is sensitive, appropriate, and due regard is given to safety, comfort and dignity throughout the procedure. The steps below are suggested as a guide:

1. Explain the procedure, meaning of the test and results. Make a plan for Pap smear result notification
2. Position the woman comfortably. The supine position is usually best, with the knees slightly bent and falling apart. Cover the woman’s lower half with a sheet to create a sense of privacy
3. As the procedure is carried out, explain each step to the woman (if she desires)
4. Inspect external genitalia for any abnormalities

5. Moisten and warm the speculum with water. If lubricant is used, use it sparingly and avoid contact with the cervix

6. Gently part labia and slowly insert closed speculum at a posterior angle into the vagina. Observe the patient for signs of discomfort and encourage feedback throughout the procedure

7. Open speculum to allow visualisation of the cervical external os

8. If there is any difficulty in visualising the cervical external os;
   a. If the cervix is obscured by the lateral vaginal walls bulging inwards, consider using a larger speculum or applying a condom over the speculum (cut off the reservoir tip of the condom so you can sample the cervix) to support the lateral vaginal walls and offer better visibility
   b. Ask the woman to lift her buttocks slightly off the bed temporarily, and place either a rolled towel or ask her to place her clenched fists under her buttocks (this assists in the visualisation of a posterior cervix)
   c. Close and then reinsert speculum at an anterior angle (this assists in visualisation of an anterior cervix)
   d. If still unable to locate the cervix, close the speculum and withdraw it from the vagina. Palpate the position of the cervix with a gloved hand, moistened with water, preferably not lubricant. Once the position of the cervix has been located, reinsert the speculum into the vagina at the appropriate angle

9. Inspect the cervix for the following:
   - colour, size, shape
   - position
   - lesions
   - surface characteristics
   - squamocolumnar junction
   - discharge

   **Note:** if visual inspection of the cervix is abnormal, the woman requires specialist referral as soon as possible (regardless of the Pap smear result)
10. Take the Pap smear sample and other samples if necessary

11. Close the speculum and remove from the vagina

12. Offer the woman a tissue and panty liner if required

7.5 Completing the Pap smear pathology form

Accurate documentation is essential when delivering cervical screening services. The appropriate clinical management of the woman requires that the woman is uniquely identified. The following information will assist the examining laboratory to interpret the Pap smear and make clinical recommendations that are appropriate for each individual woman. These include:\n
- collector’s practice name
- collector’s practice address
- patient Medicare number
- cervical or vault smear
- unit/unique medical record number (UMRN)
- name (previous surname if applicable)
- date of birth
- address
- date of Pap smear
- date of last normal menstrual period (LNMP)
- previous abnormal smear results or treatment
- pregnancy (gestation)
- hormonal therapy: hormone replacement therapy, oral contraceptive pill, Implanon, Depo Provera etc
- hysterectomy
- abnormal symptoms such as postcoital bleeding (PCB) or spotting and intermenstrual bleeding (IMB) or spotting
- abnormal or suspicious appearance of the cervix
7.6 **Management of women with screen detected cervical abnormalities**

Women who are symptomatic need to be clinically managed in accordance with their presenting history and symptoms. Women who may require specific clinical management outside the NHMRC guidelines include those who present with symptoms such as:

- intermenstrual bleeding or spotting
- postcoital bleeding or spotting
- postmenopausal bleeding or spotting

Women with any of the above symptoms or any other signs or symptoms of concern should be immediately referred for further tests to a specialist gynaecologist so that their condition can be clinically assessed and an appropriate management plan formulated.

7.7 **Referral of women with screen detected cervical abnormalities**

The Pap smear provider must have knowledge of health care agencies and community resources available to women for follow-up care and treatment of cervical abnormalities. A diverse range of health care providers and resources available within the immediate locality need to be provided to the woman so that she has a range of options for her follow-up and treatment plan.

When a cervical abnormality has been detected, a letter of referral is sent to the patient’s nominated GP (or other medical provider) along with a copy of her Pap smear result.

A request for confirmation that the referral and Pap smear result has been received by the health care provider should be included in the letter. The patient should also be provided with a copy of the referral letter that was sent to her health care provider. It is the responsibility of the Pap smear provider to ensure that the referral is sent and received in a timely manner.

All steps taken to encourage the woman to attend for follow-up should be clearly documented in the woman’s record. For medico-legal reasons, the Pap smear provider must keep documented evidence of all correspondence relating to the follow-up of abnormal results.
7.8 **Interpretation of Pap smear reports**

The Pap smear provider should provide the woman with information regarding her cervical screening result. Should a cervical abnormality be detected, the Pap smear provider should assist the woman in understanding the meaning of her Pap smear result. The Pap smear provider should advise the woman clearly about her follow-up or treatment options to aid her in making an informed decision\(^\text{47, 48}\). The Pap smear provider then needs to make an appropriate referral based on the woman’s choice, and clearly document the outcomes of the consult.

**The Pap smear report**

The Pap smear provider will receive the Pap smear result within two to 14 days, depending upon where the specimen was collected and where it was examined. Pap smear report forms may differ in their format; however, they contain similar information. This section will also note whether it is a conventional Pap smear sample or a Thin Prep® sample. The information on a Pap smear report includes:

**Specimen:** Identifies the site of the cytology sample.

Possible explanations are:
- Slide Pap smear - Cervical
- Slide Pap smear - Vault

**Result:** Identifies if the result is negative or abnormal or not suitable for analysis.

Possible results include:
- Unsatisfactory
- Negative for intraepithelial lesion or malignancy
- Possible low-grade squamous intraepithelial lesion
- Low-grade squamous intraepithelial lesion
- Possible high-grade squamous intraepithelial lesion
- High-grade squamous intraepithelial lesion
- Atypical glandular cells
- Possible high-grade glandular lesion
- High-grade glandular lesion
Specific diagnosis:
A more detailed description of the result is given in this section of the report. Along with the report on the presence or absence of any cellular abnormality, the coexisting presence of specific microorganisms may be given. This part of the report also includes a comment on the presence or absence of an endocervical component.

National Health and Medical Research Council Recommendations:
Recommendations are according to the National Health and Medical Research Council screening to prevent cervical cancer: *guidelines for the management of asymptomatic women with screen detected abnormalities*

Unsatisfactory Pap smear
If a woman has an unsatisfactory smear she will be asked to have another Pap smear in approximately 6 to 12 weeks. The laboratory report should state why the Pap smear was unsatisfactory and may include reasons such as:
- the cells may be obscured by blood or inflammation / mucous
- there may not be enough cells on the sample to give an accurate assessment
- the cells may be atrophic and difficult to interpret
- the smear may not have been properly prepared
- the slide may have broken during transit to the laboratory

Atrophic smears can be difficult for the cytologist to interpret. Atrophic Pap smears commonly occur in postmenopausal and postnatal women, particularly if they are breastfeeding. These unsatisfactory Pap smears result from decreased oestrogen levels, which affect the quality of the cervical cells. It is recommended that if the Pap smear is unsatisfactory due to atrophic changes, the woman has a repeat Pap smear in 3 months after being treated with local oestrogen.

An unsatisfactory Pap smear due to inflammation may be caused by an infection such as Candida spp or Trichomonas. Pap smears may detect the cause of the inflammation; however, additional investigations should be undertaken to identify and treat the cause. Once the cause is treated, the woman should return within 3 months for a repeat Pap smear.
Negative Pap smear
A negative Pap smear result for asymptomatic women who have no history suggestive of cervical pathology would have a recommendation of repeat Pap smear in 2 years.

Possible or definite low-grade squamous intraepithelial lesion (LSIL)
This result indicates minor squamous cell changes that are often due to an acute infection with human papillomavirus (HPV). A woman with a Pap smear report of LSIL should be managed in the same manner, irrespective of whether the cervical abnormality is reported as possible or definite LSIL, and offered a repeat Pap smear in 12 months49.

Women aged 30 years or more with a possible or definite LSIL, without a negative Pap smear history in the preceding 2 to 3 years are managed differently. These cohorts of women need to have an immediate colposcopy or a repeat Pap smear within 6 months49. The reason for this management approach is two-fold: 1) health care providers may be concerned that an occult HSIL will remain undetected and progress to cancer, and 2) health care providers may be concerned that women will not comply with cytological surveillance49.

Possible or definite high-grade squamous intraepithelial lesion (HSIL)
Women with a possible or definite HSIL should be referred to a gynaecologist for colposcopic assessment and targeted biopsy49. This result represents suspected or definite changes commonly associated with a persistent HPV infection which, if left untreated, may progress to cervical cancer49.

Cervical glandular abnormalities
A Pap smear result reporting adenocarcinoma, endocervical adenocarcinoma in situ, possible high-grade glandular lesion, atypical endocervical or endocervical cells of undetermined significance, should be referred as soon as possible to a gynaecologist with expertise in colposcopic evaluation of suspected glandular malignancies, or a gynaecological oncologist49.
8. Result follow-up and notification

The National Pathology Accreditation Advisory Council (NPAAC) requires pathology laboratories that report cervical cytology process 90% of smears within 5 working days. The turnaround time for notification of Pap smear results can vary from 5 to 14 days depending on the location of the laboratory and Pap smear provider. The quick turnaround times support Pap smear providers in promptly following-up and treating screen detected cervical abnormalities. Laboratories are responsible for ensuring communication of Pap smear results, in writing, directly to the Pap smear provider. It is not the laboratories responsibility to notify a woman directly, or to provide them with a copy of their Pap smear result. The responsibility of communicating with a woman rests with the Pap smear provider. If you are not the primary health care provider for the woman, you should request a copy be forwarded to the woman’s nominated provider to promote continuity of care.

During the Pap smear consultation, the Pap smear provider must establish a mutually acceptable method of notifying the woman of her Pap smear result. Pap smear providers have a duty of care to the woman they provide cervical screening services to; therefore, they must have appropriate systems in place to review and follow-up all Pap smear results. The Pap smear provider is required to ensure that a woman is informed of her cervical test result and that the information is provided to her in a way that she understands. During this explanation it is a good time to advise the woman when her next Pap smear is due.

It is the woman’s responsibility to follow this advice and ensure that the Pap smear provider has her current demographic details (i.e. her most current address). In the event that the Pap smear provider is unable to contact or follow-up a woman, it is recommended that the Pap smear provider record all attempts made to contact her. For example the Pap smear provider should record the date and time the woman was phoned, if a letter was sent to her. Documentation of such attempts to contact the woman is an important risk management strategy.

The Cervical Cytology Registry (CCR) of WA also plays an integral role in reminding women when they are overdue for the next Pap smear and in following-up women that have had an abnormal Pap smear. It is important to understand that the CCR is not a ‘reminder service’ for health care providers. The CCR is a ‘safety net’ for women throughout WA and through direct mail will advise women and their health care provider when cervical screening tests are overdue. The ‘safety net’ is enacted in accordance with the WA Protocol of Actions for Reminder and Follow-up Letters (see Appendix B).
9. References


51. Sharpless K, O’sullivan D, Schnatz P. The utility of human papillomavirus testing in the
management of atypical glandular cells on cytology. Journal of Lower Genital Tract Disease.
2009; 13(2):72-78.


53. Zaino R. Symposium part I: adenocarcinoma in situ, glandular dysplasia, and early
invasive adenocarcinoma of the uterine cervix. International Journal of Gynecological

systematic review and meta-analysis. Lancet 354 (9192): 1763-70, 1999.;