PAPANICOLAOU (PAP) SMEAR

**Key words:** Pap, Pap smear, Papanicolaou smear, cervical screening, cervical cancer, National Cervical Screening Program, NCSP, cervical cancer prevention, human papillomavirus, HPV, Pap smear in pregnancy, Pap smear report, cytology screening, colposcopy, Thin-Prep, SurePath, liquid-based cytology

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**Note:** Changes to Australia’s National Cervical Screening Program will occur 1 May 2017. For details, see [http://www.cancerscreening.gov.au/](http://www.cancerscreening.gov.au/)

**AIM**

- To guide staff on the procedure of collecting a Pap smear, ensuring high quality specimen collection, and assisting to reduce the incidence of, and mortality from, cervical cancer.

**BACKGROUND INFORMATION**

Australia has the second lowest cervical cancer rate in the world amongst countries with comparable cancer registration systems. This has been largely attributed to the implementation and success of the National Cervical Screening Program (NCSP) in 1991.¹ Cervical cancer is a largely preventable disease, as shown by a study in Victoria, where over 80% of women who developed invasive squamous cell cervical cancer in 2012 had no screening history or a lapsed screening history recorded in the Victorian Cytology Register.² According to the Australian Institute of Health and Welfare (AIHW) Cervical Screening in Australia 2012-13³: in 2011 there were 801 new cervical cancer cases diagnosed and in 2012 there were 226 deaths from cervical cancer.

Where Indigenous status data is collected, Aboriginal and Torres Strait Islander women are shown to have more than twice the cervical cancer rate and four times the mortality rate than that of non-Indigenous women.³ Reasons for the increased incidence and mortality rates among this population include lower cervical screening rates, and increased prevalence of residence in a remote location, as higher
mortality is demonstrated in women residing in remote areas, where access to medical treatment could potentially be an issue.³

Each Australian state and territory, as part of the National Cervical Screening Program, has a Cervical Screening Register, which keeps a confidential record of all cervical cytology, histology and more recently human papillomavirus (HPV) DNA results, taken on women residing within the jurisdiction. Unless the woman actively declines (the opt-off rate is less than 1%) it is compulsory for all laboratories to forward test results to the Register. The Register functions as a safety net, where women identified as overdue for routine cervical screening are provided a reminder in the form of a letter. Information held in the Register also supports women with screen detected abnormalities that are overdue for their follow-up. In this case letters are directed to health care providers in the first instance. Other uses of Register information include statistical analysis and monitoring of cervical screening participation.⁴

Recent data has shown HPV is detected in 99.7% of cervical cancer cases¹. HPV is spread during sexual activity, which includes any genital-skin to genital-skin contact. Infection with one or more types of HPV through adulthood is extremely common (peaks in young adulthood), but most healthy people will clear the virus within one³ to two years. In up to 10% the infection remains,³ and in rare cases where the virus persists and is undetected, it can lead to cervical cancer, although this may take up to 10-15 years from viral acquisition to develop.¹,³ While virtually all cervical cancers are positive for HPV, other associated co-factors may include smoking, HIV co-infection, herpes simplex virus,⁵ multiparity (specifically >5 full-term pregnancies), young age at first full-term pregnancy, oral contraceptive use, and immune suppression³.⁶

In 2007 Australia introduced free national HPV vaccination.⁴,⁶ Although initially for girls, the Program now recommends vaccination to girls and boys in their first year of high school (aged 12-13 years),⁶ with the Gardasil vaccine.

Gardasil® and Cervarix®, the two HPV vaccinations available in Australia, have been shown to prevent acquisition of two HPV types that have oncogenic potential, HPV 16 and 18.⁵ HPV types 16 and 18 have been found in over 70% of cases of cervical cancer, thus vaccination could prevent these cases.³,⁶ As HPV vaccination does not protect against all HPV types, vaccinated women should continue having Pap smears.⁶

Gardasil® also offers protection from two non-oncogenic types of HPV, 6 and 11, which are responsible for the majority (90%) of genital wart lesions⁶ and for some low grade squamous intraepithelial lesion Pap smear results. Gardasil® is licensed for use in females aged 9-45 years and males aged 9-26 years,⁶ and the duration of immunity has been demonstrated up to nine years post vaccination.⁶ Cervarix® has
been approved for use in women aged 10-45 years. Women older than 26 should be provided with information to make an informed decision regarding the cost and benefit of vaccination.

The HPV vaccine does not prevent persistent infection or cervical abnormalities in women who are already infected with these HPV types prior to vaccination. Thus, the decision to vaccinate women who have already initiated sexual activity needs to be on an individual basis following a thorough discussion of the benefits, risks and cost.

Note: Gardasil® and Cervarix® are pregnancy category B2 (not recommended for use in pregnancy). If the woman has not completed the three dose course, remaining doses should be delayed until after pregnancy.

Cervical cancer complicating pregnancy occurs in about 0.05% of pregnancies. Pregnant women with low-grade cytologic abnormalities should be managed in the same way as for all women with low-grade squamous abnormalities. If a pregnant woman is found to have a high-grade lesion she will require early referral for colposcopy examination which is considered safe in pregnancy, to exclude the presence of invasive cancer.

Cervical screening in WA is the responsibility of physicians, nurses and midwives. The Department of Health WA Operational Directive (OD) 0555/14: Guidelines for the Credentialing of Pap Smear Providers recommends that nurses and midwives, registered with the Nursing and Midwifery Board of Australia, who perform cervical screening, apply for credentialing as a Pap Smear Provider (PSP). See OD 0555/14 for credentialing application details. The process of credentialing ensures quality assurance of smear taking and recognition of one’s skills and contributions to cervical screening. Pap smear provider courses are available through KEMH/WNHS: DNAMER (internal staff) and Sexual and Reproductive Health WA (formerly Family Planning WA).

**PROCEDURE: PERFORMING A PAP SMEAR**

**EQUIPMENT**
- Bi-valve speculum (plastic or metal)
- Jar containing fixative solution
- Cervex-Brush® / Cytobrush® / Spatula
- Cotton wool (optional)
- Water based lubricating gel
- Sponge holding forceps (optional)
- Kidney dishes
- Sheet
- Examination gloves
- Torch or extension light
- 1 glass slide – labelled with the woman’s full name (surname & given name) in pencil (ink will dissolve due to the fixative)
### PROCEDURE

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>ADDITIONAL INFORMATION</th>
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</thead>
<tbody>
<tr>
<td><strong>1</strong> Preparat *ion</td>
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<tr>
<td><strong>1.1</strong> Inform the woman:</td>
<td>Prior to examination the provider should ensure:</td>
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<tr>
<td>- the purpose and importance of screening</td>
<td>- the woman has been given enough information to ensure an informed decision, which may include declining examination and/or screening.</td>
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<td>- the follow-up required for positive and negative results (including counselling and support services)</td>
<td>- verbal permission is obtained to conduct the procedure</td>
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<tr>
<td>- the incidence of false negative and false positive findings</td>
<td>- privacy is ensured, and suitable covers are provided during examination</td>
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<tr>
<td>- risks associated with screening including risks of treatment should it be required</td>
<td>- understanding of the role and benefits of the WA Cervical Screening Register (CSR), including the required and automatic transmission of results from laboratories to the CSR unless the woman declines (“opt-off” system)</td>
</tr>
<tr>
<td>- any significant implications (medical, social, financial) of screening.</td>
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<tr>
<td><strong>1.2</strong> Ensure a chaperone is available to attend irrespective of provider gender.</td>
<td>The chaperone signs the “Chaperone” stamp which is placed in the woman’s medical record after the examination.</td>
</tr>
<tr>
<td><strong>1.3</strong> Position the patient.</td>
<td>The supine position is usually the best, with knees bent and letting the knees fall apart. The left lateral position may be used if the cervix is difficult to visualise e.g. an older woman with a lax anterior wall.</td>
</tr>
<tr>
<td><strong>1.4</strong> Confirm patient identification and cervical screening history, complete relevant details on the pathology request form, and label the frosted section on the glass slide with a</td>
<td>Place a patient identification sticker on the container that will hold the glass slide. See Clinical Guideline, O&amp;G, Patient Administration: <a href="#">Patient Identification</a>.</td>
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<tr>
<td>PROCEDURE</td>
<td>ADDITIONAL INFORMATION</td>
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<tr>
<td>pencil⁸ with the woman’s full name (surname &amp; given name).</td>
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<tr>
<td>2 Speculum insertion</td>
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<tr>
<td>2.1 Refer to Clinical Guideline, O&amp;G, Vaginal Procedures: Speculum Examination.</td>
<td>Provides instruction about performing a speculum examination.</td>
</tr>
<tr>
<td>3 Taking the Pap Smear</td>
<td></td>
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<tr>
<td>3.1 1. Insert the speculum.</td>
<td>Offering the woman a choice of positioning or self-insertion of the speculum may help reduce feelings of vulnerability and powerlessness.⁹</td>
</tr>
<tr>
<td>2. Inspect the cervix. Note if the squamous columnar junction (SCJ) is visible and whether the cervix appears normal, a variation of normal, or abnormal.</td>
<td>Moisten and warm the speculum. This may be done with warm water or a lubricant. Lubricant may interfere with collection⁸ however a small amount of water-soluble lubricant on the speculum does not reduce the quality of Pap smears and probably does not affect microbiologic results provided it is used sparingly¹⁰ and contact with the cervix is avoided.⁸</td>
</tr>
<tr>
<td>3.2 If unable to locate the cervix:</td>
<td>If the lateral vaginal walls are bulging inwards, consider using a larger speculum or use of a condom over the speculum (cut off the reservoir of the condom)⁸.</td>
</tr>
<tr>
<td>• ask the woman to lift her buttocks and place a rolled towel under them, or place her clenched fists under her buttocks⁸.</td>
<td></td>
</tr>
<tr>
<td>• withdraw the speculum, and palpate the position of the cervix with a gloved hand, moistened with water (not lubricant)⁸. Reinsert the speculum in the direction of the cervix.</td>
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<tr>
<td>• Use a different size speculum</td>
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<tr>
<td>PROCEDURE</td>
<td>ADDITIONAL INFORMATION</td>
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<tr>
<td>4 Pap smear collection: GYNAECOLOGY</td>
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</table>
| 4.1 Take the smear from the ectocervix and the endocervical canal using implement(s) appropriate for the woman (Cytobrush®, Cervex-Brush®, spatula). It is recommended a Cytobrush® should be used in conjunction to the Cervex-Brush® in the following circumstances:  
  - Premenopausal women who have undergone surgery for a previous cervical abnormality e.g. cone biopsy  
  - Women whose previous smears have shown no endocervical cells  
  - Post-menopausal women in order to increase likelihood of collection of endocervical cells.  
  - Where the SCJ is not visible. | The Cervex-Brush® is used to collect both endocervical and ectocervical cells, and is the preferred implement for most women. The Ayres Spatula is not commonly used or recommended unless more effective instruments are unavailable. An optimal Pap smear sample has:  
  - Sufficient mature and metaplastic squamous cells to indicate adequate sampling from the transformation zone  
  - Sufficient numbers of endocervical cells, which indicate the upper limit of the transformation zone was sampled, ensuring screening for adenocarcinoma and its precursors.  |
| 4.2 Using the Cervex-Brush® | If a large ectropian is present, ensure that a sample of cells is collected from beyond the border of this area as well.  |
| - Insert the centre of the brush into the endocervical canal  
- Rotate the brush 3-5 times in the same direction, keeping bristles in contact with the ectocervix, ensuring the SCJ, if visible, is sampled.  
- Transfer the cellular material onto the glass slide by sweeping the brush in one direction on one end of the side, turn the brush over and repeat the motion on the other end of the slide (note that if using the Cervex-Brush® in conjunction with... |
<table>
<thead>
<tr>
<th>PROCEDURE</th>
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<tbody>
<tr>
<td>the Cytobrush only transfer cellular material on one end or one side of the slide, reserving the remaining end/side of the slide for Cytobrush cellular collection. Place the glass slide into a patient labelled jar with fixative solution.</td>
<td></td>
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</tbody>
</table>

**4.3 Using the Cytobrush**

- Gently insert the brush into the cervical os.
- Gently rotate the cytobrush one quarter of a turn in the endocervical canal.
- Roll the cytobrush on one end or one side of the slide. Place the glass slide into a patient labelled jar with fixative solution.
- It is recommended that the Cytobrush not be inserted out of vision of the cervical canal. More rotations drive the desired cells deeper into the bristles and they may not be transferred to the glass slide.

**4.4 Using the Spatula**

- Place the end of the spatula in the cervical os.
- Rotate the spatula three times keeping the shoulder of the spatula in contact with the ectocervix and ensuring the SCJ, if visible, is sampled.
- Wipe spatula on one end or one side of the labeled slide. Place slide into jar with fixative solution.
- If a large ectropion is present, ensure that a sample of cells is collected as well from beyond the border of this area.

**5 Pap smear collection: OBSTETRIC**

**5.2 Inform the woman that Pap smears can be performed in pregnancy.**

Women should be advised of the possibility of spotting or minor bleeding following collection and reassured that there is no risk to the fetus. Any heavy or sustained bleeding should be followed up. If
### PROCEDURE

| 5.2 | Collect the smear using the **Cervex-Brush**® brush as described above. |

**ADDITIONAL INFORMATION**

- Concerned about the amount of bleeding, the woman should contact her health care provider.
- **Do not use the Cytobrush**® in pregnancy (>10 weeks).

### 6 Follow up

- **6.1** Inform women of recommendations for [future screening frequency](#).

- **6.2** Inform women of the management if the Pap smear sample is unsatisfactory.
  - A smear may need repeating in 6-12 weeks if the sample is unsatisfactory.
  - In these situations, liquid based cytology collection may be offered as an adjunct to the repeat conventional Pap smear.

- **6.3** Advise the woman that the Cervical Cytology Coordinator Nurse at KEMH will review all Pap smear results, and a letter documenting the result will be sent, usually within 2-3 weeks, to the:
  - The woman herself
  - The woman’s General Practitioner

  The letter will advise of any follow up required.

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**Use of liquid based cytology (e.g. ThinPrep®, SurePath)**

If the Pap smear slide in fixative is also accompanied by a liquid based cytology sample, then this should be noted on the Pathology request form including the rationale (e.g. previous unsatisfactory result due to inflammation, sample is heavily blood stained, etc.).
**INTERPRETING REPORTS & RECOMMENDED MANAGEMENT**

Any abnormal symptoms not readily explained (e.g. post coital or intermenstrual bleeding or spotting) should be investigated regardless of Pap smear history or current result. Any abnormality noted upon visual inspection of cervix requires immediate colposcopy referral.

<table>
<thead>
<tr>
<th>PAP SMEAR REPORT</th>
<th>MANAGEMENT</th>
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<tbody>
<tr>
<td>Negative / within normal limits.</td>
<td>Repeat Pap smear in 2 years</td>
</tr>
<tr>
<td>Negative / within normal limits and no</td>
<td>Repeat Pap smear in 2 years</td>
</tr>
<tr>
<td>endocervical cells present.</td>
<td>Repeat Pap smear in 2 years</td>
</tr>
<tr>
<td>Negative with inflammation.</td>
<td>Repeat Pap smear in 2 years</td>
</tr>
<tr>
<td>Unsatisfactory</td>
<td>Repeat Pap smear in 6 – 12 weeks</td>
</tr>
<tr>
<td>Low-grade squamous intraepithelial lesion (LSIL)*</td>
<td>Repeat Pap smear in 12 months. If the woman is 30+ years, and has no negative cytology in the previous 3 years, either refer for colposcopy or repeat Pap smear in 6 months.</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Possible LSIL*</td>
<td></td>
</tr>
<tr>
<td>High-grade squamous intraepithelial lesion (HSIL)</td>
<td>Refer for colposcopy.</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Possible HSIL</td>
<td></td>
</tr>
<tr>
<td>Glandular abnormalities, including adenocarcinoma in situ</td>
<td>Refer for colposcopy, which should be performed by a gynaecologist with expertise in suspected malignancies or by a gynaecologist/oncologist.</td>
</tr>
<tr>
<td>Invasive squamous cell carcinoma (SCC)</td>
<td>Refer to a gynaecologist / oncologist</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Adenocarcinoma</td>
<td></td>
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</table>

* Two LSIL results (including possible LSIL) within a three-year timeframe, even if intervening negative results, requires colposcopy referral

**SPECIAL CIRCUMSTANCES**

- Abnormality in pregnancy – follow guidelines as for non-pregnant women. High-grade lesions require an early colposcopy referral to the KEMH colposcopy clinic.
- Immunosuppression (defined as a CD4 count of <400 in HIV positive women or transplantation with immunosuppressive therapy for >3 years) - refer for colposcopy at KEMH even if the lesion is a low-grade abnormality.
- Women exposed to diethylstilboestrol (DES) – annual cytological screening and colposcopy of the cervix and vagina performed in a specialist centre by an experienced colposcopist.
CERVICAL SCREENING RECOMMENDATIONS

The Australian National Cervical Screening Program recommends:

- Routine screening with Pap smears should be carried out every two years for women who have no symptoms or history suggestive of cervical pathology.3

- All women who have ever been sexually active (including any genital-skin to genital-skin contact) should commence having Pap smears between the ages of 18 – 20 years, or one to two years after first sexual activity, whichever is later.3

- This policy applies to women with no symptoms and normal Pap smear results who should be screened every two years. Women with abnormal Pap smear results should be managed in accordance with National Health and Medical Research Council Guidelines (NHMRC) guidelines: ‘Screening to Prevent Cervical Cancer: Guidelines for the Management of Asymptomatic Women with Screen-Detected Abnormalities’ (2005).3 Available at: http://www.nhmrc.gov.au/publications/synopses/wh39syn.htm

- Women aged 70 years and over who have had two normal smears in the previous five years may cease having Pap smears. Women over 70 years who have never had a Pap smear, or who request a Pap smear, should be screened.3

- Pregnancy: Offer a Pap smear to all pregnant women who are due to screen, up to at least 24 weeks gestation.11 Offer to perform a Pap smear up to at least 28 weeks, and for select women in the third trimester, if they are likely to have difficulty presenting in the postnatal period.8 This decision needs to be assessed on an individual case by case basis.

- Hysterectomy: Regular vault smears after hysterectomy should continue to be performed in the following circumstances14:
  - Women who have had a subtotal hysterectomy (cervix still in situ) should continue to have Pap smears at the recommended intervals.13, 14
  - Women who have had a total hysterectomy for benign reasons (e.g. menstrual problems or prolapse), with a history of normal Pap smears, histopathology of the cervix showed no neoplastic or premalignant changes, and who are asymptomatic - screening is no longer required.14
  - Women who have had a hysterectomy that has completely excised a high-grade lesion (CIN2-3/ACIS) - ongoing annual screening is reasonable for five years, then reverting to the recommended screening interval.14
  - Women who have had a hysterectomy for invasive gynaecological malignancy - ongoing screening recommendations are required to be at
the discretion of a Gynaecologist/Oncologist.¹⁴

- Women who have a history of LSIL on Pap smear or cervical biopsy and who returned to normal cervical cytology prior to hysterectomy - do not require vaginal vault smears unless symptomatic.¹⁴

- Women for whom the Pap smear history and/or the histology from the hysterectomy are unknown – obtain a baseline Pap smear from the vaginal vault at consultation. If normal, then further smears only as clinically indicated.¹³,¹⁴

- Women who have been treated for vaginal intraepithelial neoplasia (VAIN) - continue to have Pap smears or vaginal vault smears every one to two years or at the discretion of the treating specialist.¹⁴

- See RANZCOG C-Gyn 08: Cytological Follow-up After Hysterectomy.

REFERENCES / STANDARDS


REFERENCES / STANDARDS Cont.


National Standards – 1- Care Provided by the Clinical Workforce is Guided by Current Best Practice
5- Patient Identification and Procedure Matching

Legislation - Health Practitioner Regulation National Law (WA) Act 2010

Related Policies –
- Department of Health: OD 0555/14: Guidelines for the Credentialing of PAP Smear Providers (2014)
- KEMH Clinical Guidelines:
  - O&G, Patient Administration: Patient Identification
  - O&G, Vaginal Procedures: Speculum Examination, Swabs; LVS, HVS, ECS & Rectal
  - Gynaecology: Sexually Transmitted Infections;
  - Gynaecology: Gynaecological Cancers: Classification and Staging of Cervical Cancers

Other related documents –
- Australian Government: National Cervical Screening Program (includes patient brochures “In your language”); Cancer Australia: Cervical Cancer; Immunise Australia Program: Human Papillomavirus (HPV)
- Cancer Council Australia: Cervical Cancer Screening;
- Cancer Council WA: HPV Vaccination; & Cervical Cancer (patient information and support)
- Department of Health WA: Safety & Quality in Healthcare: Procedure Specific Information Sheets; NMHS: KEMH: Colposcopy and LLETZ (only available from WA Health Computers)
- Department of Health WA: WA Cervical Cancer Prevention Program
- FIGO Guidelines (2009): Revised FIGO Staging for Carcinoma of the Vulva, Cervix, and Endometrium
- Medical Services Advisory Committee (MSAC): National Cervical Screening Program Renewal (2014)
- Sexual and Reproductive Health WA (formerly Family Planning WA): Pap Smear Provider Course
- WNHS/KEMH: DNAMER: Continuing Professional Development: Pap Smear Provider Course (provides a pathway for WNHS/KEMH staff to become credentialled to perform pap smears on well women)

RESPONSIBILITY

Policy Sponsor
Nursing & Midwifery Director OGCCU

Initial Endorsement
November 2001

Last Reviewed
March 2016

Last Amended

Review date
May 2017 (National screening program changes due 1 May 2017)