The Renewed
National Cervical Screening Program

Women’s Health Regional Webinar Series

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School of Women’s and Infants’ Health: University of Western Australia
Suggested learning outcomes

- Understand the main changes to the renewed National Cervical Screening Program (NCSP)
- Understand the management of screen – detected abnormalities

- Confidently discuss the benefits of cervical screening with your patients
- Effectively promote and contribute to the delivery of the renewed NCSP
LEARNING OBJECTIVES FOR TODAY

- Why are we changing from Pap test to Primary HPV screening?
- Why all sexually active women should participate in the NCSP, including HPV vaccinated women
- Understand the recommended changes to the NCSP and be able to explain/reassure your patients
- Understand the initial management of cervical screening test results
• Why are we changing from Pap test to Primary HPV test screening?
  • Why all sexually active women should participate in the NCSP, including HPV vaccinated women

• Understand the recommended changes to the NCSP and be able to explain/reassure your patients
• Understand the initial management of cervical screening test results
Cervical screening in Australia

- 1991 NCSP Policy:
  - 2-yearly (Pap test)
  - 18 to 69 years
  - Registry reminder

- Participation:
  - 2-yearly 58%
  - 5-yearly 83%

- 50% reduction in incidence & deaths

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<table>
<thead>
<tr>
<th>Country</th>
<th>Incidence per 100,000 women</th>
<th>Mortality per 100,000 women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>7.4</td>
<td>1.9</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>7.1</td>
<td>1.8</td>
</tr>
<tr>
<td>USA</td>
<td>6.6</td>
<td>2.7</td>
</tr>
<tr>
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<td>6.3</td>
<td>1.7</td>
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</tr>
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<td>5.3</td>
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</tr>
<tr>
<td>Finland</td>
<td>4.3</td>
<td>1.0</td>
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Source: GLOBOCAN 2012
Renewal of the NCSP

Why

- **New knowledge** on the development of cervical cancer.
- **New evidence** for cervical cancer prevention and screening
- **New technologies**
  - liquid-based technology
  - computer assisted image analysis
  - HPV tests
- **2007 - National HPV Vaccination Program (girls)**
- **2013 - National HPV Vaccination Program (girls + boys)**

- Current NCSP is **intensive** compared to other countries
Development of cervical cancer due to HPV infection

- Normal
- Add HPV (30% incidence)
- 5 weeks

Prevent HPV infection (Vaccine)

- LSIL
- 2% in 5 years
- E1-7, L1,2

Detect/Treat HPV/CIN
- PAP smear, HPV testing
- Destructive therapy

- HSIL
- E6, E7

Cancer
- 10-20 years
- E6, E7

98% over 5 years
MSAC Outcomes

Application No. 1276 – Renewal of the National Cervical Screening Program

Sponsor/Applicant/s: Standing Committee on Screening

Date of MSAC consideration: MSAC 61st Meeting, 3-4 April 2014
• Cervical Screening Test (CST)
• HPV test with partial genotyping (16/18)
  – Reflex Liquid Based Cytology (LBC) triage
• Five year screening interval
• Start at age 25 years
• Exit at 70–74 years
• All sexually active women-HPV vaccinated or not
• Self collection: never-screened and under-screened
• Invitation & reminders to screen: National Register
Primary HPV screening program will lead to:

Up to 30% ↓

Fewer cases of cervical cancer

Fewer deaths from cervical cancer
Other benefits

- Less frequent testing
- Fewer tests overall

For women aged 25 – 69

26 → 10 tests in lifetime
Now

• Pap smear
• 2 yearly
• Start 18 years
• End 69 years

• Reminders

December 2017

• Cervical Screening Test
  – Oncogenic HPV test
• 5 yearly
• Start 25 years
• End 70-74 years

• Invitations/Reminders

• Self-collection
LEARNING OBJECTIVES FOR TODAY

• Why are we changing from Pap test to Primary HPV test screening?

• **Why all sexually active women should participate in the NCSP, including HPV vaccinated women**

• Understand the recommended changes to the NCSP and be able to explain/reassure your patients

• Understand the initial management of cervical screening test results
Papillomaviruses

4 main groups in man:
- skin warts (HPV 1, 2)
- EV associated (HPV 5, 8)
- genital warts (HPV 6, 11)
- genital cancers (HPV 16, 18)

IARC, IBSCC and multicentric studies (N=3045 + HPV negative 264 (7.98%))
Ian Frazer AC

1991-2005
Developed the first vaccine for HPV

2006
Australian of the Year

2007
National HPV Vaccination Program – girls

2013 - boys
HPV types
6 & 11
16 & 18
National (Australia) HPV 3-dose vaccination coverage for females turning 15 years of age in 2012
Fall in cervical HPV prevalence in young women 18-24yrs (pre vaccine n=202, post vaccine n=1058)

Tabrizi and Brotherton et al. *Lancet Infect Dis* 2014
*Online 6 August 2014*
Vaccine impact in Australia
Females, early twenties

- HPV infections: 77%↓
  *Tabrizi S/Brotherton J et al JID 2012*

- Confirmed HSIL: 21%↓

- Warts: 73%↓
  *Smith M et al JID 2014*
• Why all sexually active women should participate in the NCSP, including HPV vaccinated women

  – Gardasil contains HPV 6, 11, 16, 18
  – 16/18 responsible for 70% of cervical cancers
  – Other oncogenic HPV types (12) not in Vaccine

• All sexually active women should be screened !!
LEARNING OBJECTIVES FOR TODAY

• Why are we changing from Pap test to Primary HPV test screening?
• Why all sexually active women should participate in the NCSP, including HPV vaccinated women

• **Understand the recommended changes to the NCSP and be able to explain/reassure your patients**
• Understand the initial management of cervical screening test results
Now

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- Self-collection
What sample should you collect for a cervical screening test?

- Liquid based cervical specimen only
  - Conventional Pap smear not accepted!!

- Laboratories will provide
  - detailed instructions
  - appropriate consumables
  - so that the sample satisfies requirements both of the HPV test and LBC, should this be required.
Collecting a ThinPrep Sample

*Broom-Like Device Protocol*

1. **3 to 5 rotations of broom**
2. **Crush 10 times on base of vial and swirl**
3. **Cap vial**
4. **Record patient details**
BD SurePath™ Sample Collection Method for Rover’s® Cervex-Brush® With Detachable Head

1. Collect
   1. Insert into endocervical canal. Rotate broom five times in a clockwise direction.

2. Drop
   2. Drop detachable head of device into BD SurePath™ vial.

3. Send
   3. Place cap on vial and tighten. Send BD SurePath™ vial to lab for processing.
What should you expect from the lab report?

• An overall cervical screening risk assessment
  - Low risk
  - Higher risk
  - Intermediate risk

• A statement of test(s) performed and the results
  - HPV test result including any LBC result

• A recommendation for follow-up/action
  - Taking account of screening history and clinical notes
What does this mean for women?

- Will be invited to have a screening test every 5 years
- Will still need a speculum vaginal examination
- A sample will be taken from her cervix and sent to lab
  - If cytology needed – no additional visit to GP
- Women will receive results from their doctor
  - active communication
- Test results: kept by National Cancer Screening Registry
• New - screening test  
  HPV
• New - screening interval  
  5 years
• New - starting age  
  25 years
• New - finishing age  
  74 years
• New - self-collection
• New - National Cancer Screening Register

NEW CHALLENGES
• Is the HPV test as good as the Pap test?

• Is the later starting age >25yr safe?

• Is the 5 year screening interval safe?

• What is self-collection?
Why are we changing to oncogenic HPV testing with partial genotyping and reflex LBC?

Is it safe?
• **More sensitive** than cytology
• **Earlier detection** of high grade lesions
• **Prevents more** cervical cancer
• **+ Potential** to reduce invasive adenocarcinoma

• Allows for individual risk based assessment
  – Partial genotyping improves risk stratification
• **A negative oncogenic HPV test is protective for at least 5 years**
Why has the recommended age for commencing screening been raised to 25 years?

Is it safe?
Three-year average cervical cancer incidence (with 95% CIs), by all ages and histological type, 1982-2010

Three-year average cervical cancer incidence (with 95% CIs), by age and histological type, 1982-2010

• **25 years of screening women under 25 years of age**
  • no impact on incidence of cervical cancer in this age group

• **Systematic literature review**
  • No evidence for screening effectiveness in other countries

• **Very low incidence of cervical cancer in these women**
  • Expected to decline further due to HPV vaccination

• **IARC recommendation**
  • Do not screen women under age 25 years
Why has the screening interval been extended from two years to five years?

Is it safe?
Primary HPV screening
Longitudinal results for screen-negative women


Copyright ©2008 BMJ Publishing Group Ltd.
Primary HPV screening:
Pooled data on invasive cervical cancer outcomes from four European trials - 176,000 women

"At longer intervals] HPV-based screening provides 60—70% greater protection against invasive cervical carcinomas compared with cytology"

Effectiveness and Safety

Ronco et al, Lancet 2014
What is self-collection for cervical screening?
Self-collection for cervical screening?

• What is it?
• Why is it being offered?
• Who is eligible?
• How is it done?
• Where is it done?
80% cervical cancer occurs in women never screened or under-screened

(VCCR 2012)
• Self collection of vaginal sample for HPV test
  – Under screened and never screened women only
  – Facilitated by nurse or medical practitioner
    • Carried out at the practice not at home
  – Or on behalf of a medical practitioner
  – Who also offers routine cervical screening
HPV self-collection

- increased participation rate for never and under-screened
- not as effective as health professional collected sample
- more effective than the current Pap test
- accuracy varies for different sampling devices, HPV tests
- less cost effective than routine pathway.
- if HPV+ve will need separate visit for LBC sample

- only available to under or never screeners.
• National Cancer Screening Register
  – Linked to HPV register
  – Used to issue invitations/reminders
  – Full history from vaccination-diagnosis
  – Colposcopy and pathology data

• Monitoring and service improvement

• One woman = One record
Education and Training

• National Prescribing Service
  – On line education modules
  – Practical training modules
  – Train the Trainer module
  – (For all CST providers)

• Cancer Council Australia
  – On line education clinical scenarios
  – (For GPs, O&G specialists and others)

• Department of Health Australia
  – Cancer screening website, Publications
Now

• Pap smear
• 2 yearly
• Start 18 years
• End 69 years
• Reminders

December 2017

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• Invitations/Reminders
• Self-collection
• Why are we changing from Pap test to Primary HPV test screening?
• Why all sexually active women should participate in the NCSP, including HPV vaccinated women
• Understand the recommended changes to the NCSP and be able to explain/reassure your patients
• Understand the initial management of cervical screening test results
Endorsed by NHMRC

9th June 2005

Implemented

3rd July 2006
The 2016 Guidelines

NATIONAL CERVICAL SCREENING PROGRAM:

Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding
What should you expect from the lab report?

- An overall cervical screening risk assessment
  - Low risk
  - Higher risk
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- A statement of test(s) performed and the results
  HPV test result including any LBC result

- A recommendation for follow-up/action
  Taking account of screening history and clinical notes
Cervical Screening Test

Women’s Risk Based Assessment
(risk of women having a cervical cancer precursor or cervical cancer)

Low risk
(the majority of women)

Higher risk

Intermediate Risk
Cervical Screening Test
Women’s Risk Based Assessment

**Low risk**

HPV not detected

**ACTION:** REPEAT CST in 5 YEARS

**Higher risk**

HPV (16/18) detected
(with any LBC result)

OR

HPV (not 16/18) detected
(with LBC: pHSIL, HSIL or any glandular abnormality)

**ACTION:** REFER for COLPOSCOPY
CERVICAL SCREENING  LOW RISK FOR SIGNIFICANT CERVICAL ABNORMALITY

Specimen  Cervical – ThinPrep
Test results  PCR for oncogenic HPV and genotype
• HPV 16 – Not detected
• HPV 18 – Not detected
• HPV (not16/18) – Not detected

Recommendation: ???
CERVICAL SCREENING  LOW RISK FOR SIGNIFICANT CERVICAL ABNORMALITY

Specimen          Cervical – ThinPrep
Test results      PCR for oncogenic HPV and genotype
                  • HPV 16 – Not detected
                  • HPV 18 – Not detected
                  • HPV (not16/18) – Not detected

Recommendation: Re-screen in 5 years
CERVICAL SCREENING  
HIGHER RISK  
FOR SIGNIFICANT CERVICAL ABNORMALITY

Specimen  
Cervical – SurePath

Test results  
PCR for oncogenic HPV and genotype
• HPV 16 – Not detected
• HPV 18 – Not detected
• HPV (not16/18) – Detected

Liquid based cytology (LBC) manually read:
HSIL (high-grade squamous intraepithelial lesion)

Endocervical component: Present

Recommendation: ????
## Cervical Screening

**Higher Risk for Significant Cervical Abnormality**

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<th>Cervical – SurePath</th>
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**Test results**

- PCR for oncogenic HPV and genotype
  - HPV 16 – Not detected
  - HPV 18 – Not detected
  - HPV (not16/18) – **Detected**

Liquid based cytology (LBC) manually read:

- HSIL (high-grade squamous intraepithelial lesion)
  - Endocervical component: Present

**Recommendation:** Referral for colposcopic assessment
### Sample Cervical Report

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<th>HIGHER RISK FOR SIGNIFICANT CERVICAL ABNORMALITY</th>
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#### Specimen
- Cervical – SurePath

#### Test results
- PCR for oncogenic HPV and genotype
  - HPV 16 – **Detected**
  - HPV 18 – Not detected
  - HPV (not16/18) – Not detected

Liquid based cytology (LBC) manually read: Unsatisfactory

#### Recommendation: ???
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**Specimen**
- Cervical – SurePath

**Test results**
- PCR for oncogenic HPV and genotype
  - HPV 16 – **Detected**
  - HPV 18 – Not detected
  - HPV (not16/18) – Not detected

Liquid based cytology (LBC) manually read:
- Unsatisfactory

**Recommendation:** Referral for colposcopic assessment
- Repeat LBC at colposcopy visit
Intermediate risk
(risk is determined by combined HPV and LBC result)

HPV (not 16/18) detected
(with LBC negative or pLSIL/LSIL)

ACTION: Follow-up HPV test in 12 months
<table>
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<th>INTERMEDIATE RISK FOR SIGNIFICANT CERVICAL ABNORMALITY</th>
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**Specimen**  
Cervical – SurePath

**Test results**  
PCR for oncogenic HPV and genotype
- HPV 16 – Not detected
- HPV 18 – Not detected
- HPV (not16/18) – **Detected**

Liquid based cytology (LBC) manually read:
**There is no evidence of a squamous intraepithelial lesion or malignancy**
Endocervical component: Present

**Recommendation:** ???
## CERVICAL SCREENING

### INTERMEDIATE RISK FOR SIGNIFICANT CERVICAL ABNORMALITY

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Liquid based cytology (LBC) manually read:

**There is no evidence of a squamous intraepithelial lesion or malignancy**

Endocervical component: Present

**Recommendation: Repeat HPV test in 12 months**
Follow up of Intermediate risk women after initial cervical screening test result

**Women at Intermediate risk**

Follow-up HPV test in 12 months

At follow-up 12 month test
HPV detected (any type) with any LBC result
(= persistent HPV infection)
ACTION: REFER for COLPOSCOPY

At follow-up 12 month test
HPV not detected
ACTION: REPEAT CST in 5 YEARS
CERVICAL SCREENING PATHWAY

Oncogenic HPV test with partial genotyping

- HPV not detected
  - Reflex LBC
    - Unsatisfactory LBC
    - Repeat HPV test in 12 months
      - HPV not detected
        - Routine 5-yearly screening
      - HPV detected (any type)
        - Reflex LBC
        - Refer for colposcopic assessment
- HPV detected (not 16/18)
  - Reflex LBC
    - Unsatisfactory LBC
    - Repeat HPV test in 12 months
      - HPV not detected
        - Routine 5-yearly screening
      - HPV detected (any type)
        - Reflex LBC
        - Refer for colposcopic assessment
- HPV detected (16/18)
  - Reflex LBC
    - Any LBC result or unsatisfactory
      - Refer for colposcopic assessment
- Unsatisfactory HPV test
  - Retest HPV within 6 weeks

LEGEND

Primary test
- Reflex test
- Test result
- Recommendation

Woman’s risk of developing cervical cancer precursors within the next five years

Low
- Intermediate
- Higher

CERVICAL SCREENING  UNSATISFACTORY

Specimen  Cervical – ThinPrep
Test results  PCR for oncogenic HPV and genotype
  • HPV 16 – Not detected
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  • HPV (not16/18) – Detected

Liquid based cytology (LBC) image assisted: Unsatisfactory

Recommendation: ???
CERVICAL SCREENING  UNSATISFACTORY

Specimen  Cervical – ThinPrep
Test results  PCR for oncogenic HPV and genotype
  • HPV 16 – Not detected
  • HPV 18 – Not detected
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Recommendation: Repeat LBC in six weeks
The 2016 Guidelines

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Further information:

NCSP 2016 Guidelines

www.msac.gov.au
www.cancerscreening.gov.au

Email: Cervicalrenewal@health.gov.au