Renewal of the National Cervical Screening Program
Changing environment

- New scientific knowledge on the development of cervical cancer.
- New international and local evidence for cervical cancer prevention and screening.
- New technologies
  - liquid-based technology
  - computer assisted image analysis
  - HPV DNA tests
- 2007 - National HPV Vaccination Program
Aim

The Renewal aims to ensure the success of the program continues and all Australian women, human papillomavirus (HPV) vaccinated and unvaccinated, have access to a cervical screening program that is based on current evidence and best practice.
Objectives

1. Assess the evidence for the effectiveness of screening tests and pathways, the screening interval, age range and commencement for both vaccinated and non-vaccinated women.

2. Determine a cost-effective screening pathway and program model.

3. Investigate options for improved national data collection systems and registry functions to enable policy, planning, service delivery and quality management.

4. Assess the feasibility and acceptability of the renewed program for women.
Milestones

- November 2011 - Renewal Steering Committee’s inaugural meeting
- March 2013 – Partner Reference Group meeting
- May 2012 - Public Consultation on the Renewal methodology
- June 2013 – Public Consultation on the draft Review of Evidence
- October 2013 – Renewal to be considered by Economic Subcommittee (ESC) of MSAC
- November 2013 – Renewal to be considered by MSAC
- Mid 2014 – Renewal to be considered by the Standing Committee on Screening
Phase 1

- Review of evidence, effectiveness modelling and economic evaluation.
  - Phase 1 is being undertaken through the Medical Services Advisory Committee (MSAC).
  - Principal role of MSAC is to advise the Australian Minister for Health on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures.
  - Information on MSAC - [www.msac.gov.au](http://www.msac.gov.au)
<table>
<thead>
<tr>
<th>Primary Question</th>
<th>Comparator (Current program)</th>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary screening test</strong></td>
<td>Conventional cytology</td>
<td>Conventional cytology</td>
<td>LBC</td>
<td>HPV DNA testing</td>
</tr>
<tr>
<td><strong>Age range</strong></td>
<td>Women aged 18-69 years</td>
<td></td>
<td>Women aged 25-64 years</td>
<td></td>
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<tr>
<td><strong>Interval</strong></td>
<td>2 yearly</td>
<td>3 yearly (aged 25-49) and 5 yearly (aged 50-65)</td>
<td></td>
<td>5 yearly</td>
</tr>
<tr>
<td><strong>Triage options</strong></td>
<td>As per NHMRC Guidelines</td>
<td>As per NHMRC Guidelines</td>
<td>Reflex HPV DNA testing</td>
<td>Co-test LBC OR Reflex LBC</td>
</tr>
<tr>
<td><strong>Additional technology</strong></td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td>With and without automated image analysis</td>
</tr>
<tr>
<td><strong>Exit strategy</strong></td>
<td>Must have two normal cytology tests within the last 5 years</td>
<td></td>
<td>HPV DNA test at age 64 years</td>
<td></td>
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<tr>
<td><strong>Self collection</strong></td>
<td>N/A</td>
<td></td>
<td>N/A</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Call-recall system</strong></td>
<td>N/A</td>
<td></td>
<td></td>
<td>YES</td>
</tr>
</tbody>
</table>
Conventional Cytology at IARC intervals

- **Conventional Cytology**
  - **Negative Cytology**
    - Recall for routine screening
  - **p/d LSIL**
    - Non-exception women
      - Repeat cytology in 12 months
    - Exception women
      - Refer to colposcopy
  - **HSIL**
    - Refer to colposcopy

Current NHMRC Guidelines
Conclusions: Conventional Cytology at IARC intervals

- Cervical cancer is very rare below 25 years
- HPV vaccination should almost eliminate the risk of cervical cancer in young women
- There are limited comparative data on the age at which to start and stop screening
- Extending interval from 2-3 years is unlikely to alter incidence or mortality rates
- The majority of cervical cancer cases in women aged 65 and over are in women who do not have a history of negative Pap smear results.
LBC at IARC intervals

LBC

Negative Cytology
- Recall for routine screening

p/d LSIL
- Non-exception women
  - Repeat cytology in 12 months
- Exception women
  - Refer to colposcopy

HSIL
- Refer to colposcopy

Current NHMRC Guidelines
LBC with HPV triage

- LBC
  - Negative Cytology
    - Recall for routine screening
  - p/d LSIL
  - HSIL
    - Refer to colposcopy
  - Positive HPV
    - Option A: Repeat cytology in 12 months
    - Negative cytology
      - Recall for routine screening
    - Positive cytology
      - Refer to colposcopy
    - Option B: Refer to colposcopy
      - Negative cytology
        - Recall for routine screening
      - Positive cytology
        - Refer to colposcopy
Conclusions: LBC

- LBC provides no statistically significant difference in the ability to detect high grade cervical abnormalities or to exclude women without high grade cervical abnormalities compared to conventional cytology.
- LBC reduces the rate of unsatisfactory smears in comparison with conventional cytology.
- Automation-assisted image analysis detects as many high grade lesions as conventional cytology, and may detect more.
HPV test

- Negative HPV
  - Recall for routine screening
- Positive HPV
  - Reflex LBC

  - Negative HPV
    - Repeat HPV and cytology in 12 months
      - Negative both
        - Recall for routine screening
      - Positive any
        - Refer to colposcopy
    - Positive any
      - Refer to colposcopy
  - p/d LSIL
    - Option A: Repeat HPV and cytology in 12 months
      - Negative both
        - Recall for routine screening
      - Positive any
        - Refer to colposcopy
    - Option B: Refer to colposcopy
  - HSIL
    - Refer to colposcopy

HPV with LBC reflex
HPV test

- Negative HPV
  - Recall for routine screening
- Positive HPV (other types)
  - Reflex LBC
- Positive HPV (16, 18, 45)
  - Refer to colposcopy

- Negative HPV
  - Repeat HPV and cytology in 12 months
- p/d LSIL
  - Option A: Repeat HPV and cytology in 12 months
  - Option B: Refer to colposcopy
- HSIL
  - Refer to colposcopy

- Positive any
- Negative both
  - Recall for routine screening
- Positive any
  - Refer to colposcopy
HPV with LBC co-testing

- LBC and HPV test
  - Negative both
    - Recall for routine screening
  - Negative cytology + Positive HPV
  - p/d LSIL + Negative HPV
    - Repeat both in 12 months
    - Option A: Repeat both in 12 months
    - Option B: Refer to colposcopy
  - p/d LSIL + Positive HPV
    - Option A: Repeat both in 12 months
    - Option B: Refer to colposcopy
  - HSIL and any HPV result
    - Refer to colposcopy
  - Positive any
    - Refer to colposcopy
Conclusions: HPV testing

- HPV based screening strategies detect at least as many high grade cervical abnormalities as cytology based screening strategies.
- HPV testing alone (without triage) for primary screening increases that number of women referred to colposcopy for further investigation.
- Among unvaccinated women, the balance between increased detection of precancerous cervical lesions and increased colposcopy referral for HPV testing alone is more favourable in women over 30 years.
- HPV and cytology co-testing does not demonstrate a clear advantage over HPV testing alone.
Conclusions: HPV testing

- The accuracy of HPV self-collection varies for different types of sampling devices and HPV tests.
- HPV self-collection has a moderate to high ability to detect high-grade abnormalities and comparably high ability to exclude women without high-grade abnormalities compared to clinic HPV testing.
- HPV self-sampling increases screening participation rate for women who do not attend for cervical screening or who are under-screened and warrants consideration for women in these groups.
Need for Modeling

- A modelled analysis is necessary to explore the potential long-term benefits and trade-offs of implementing new screening strategies in the Australian setting.

- Most of the evidence review relates to population groups who have not been vaccinated for HPV, and that data integration and modelling has been undertaken to apply this evidence to the Australian context where the national HPV vaccination program has been in place for six years.
Phase 2

- Data systems and quality management
  - A review of the national data collections and registry functions will be undertaken.
  - A quality management plan for the NCSP will be developed.
Phase 2

- Program acceptability
  - Assess the feasibility and acceptability of a renewed program for women, health professionals, pathology providers and industry.
Conclusion

• Australian women, HPV vaccinated or unvaccinated, will have equitable access to a safe, efficient, cost-effective screening program which maximises benefits and minimises harms and is based on the best available evidence.
The Renewal Steering Committee is consulting with and seeking input from a wide range of NCSP partners, including health professionals, scientists and consumers, through a Partner Reference Group.

If you would like to be added to the Partner Reference Group email list, please email: CervicalRenewal@health.gov.au
Further information

- Further information on the Renewal may be found on the cancer screening website: www.cancerscreening.gov.au

- To contact the Renewal Project Team Email: CervicalRenewal@health.gov.au