The Renewed National Cervical Screening Program

"Implementing the Changes"

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What are the changes

- **5 yearly HPV test, partial genotyping**
- **Reflex liquid based cytology triage**
- **Age 25 – 69**
- **Exit HPV testing age 70 – 74**
- **HPV vaccinated and unvaccinated**
- **Invitation and Reminder system**
- **Self testing for underscreened women**
What am I talking about today

- What is the Renewal
- What are the outcomes of the MSAC review
- What does this mean for you
- What are the some of the issues
- What is the Renewal Implementation Project
National Cervical Screening Program

The Pap smear

Age 18+

Every 2 years

Stop at age 69

Register reminder system
# Cervical Cancer in Australia

Incidence and mortality rates of cervical cancer: selected countries-2012

<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>
<td>Canada</td>
<td>6.3</td>
<td>1.7</td>
</tr>
<tr>
<td><strong>Australia</strong></td>
<td><strong>5.5</strong></td>
<td><strong>1.6</strong></td>
</tr>
<tr>
<td>New Zealand</td>
<td>5.3</td>
<td>1.4</td>
</tr>
<tr>
<td>Finland</td>
<td>4.3</td>
<td>1.0</td>
</tr>
</tbody>
</table>

Source: GLOBOCAN 2012
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
• **National HPV Vaccination Program**

• **Reduced cervical abnormalities**
  – 70% reduction in HPV infections in women <25yr
  – Reduction in HSIL in <18yrs and 20-24yrs

• **Reduction 90% Genital Warts in women**

• **Public perception re ‘screening’ may change**
The aim of the Renewal is:

- Ensure the success of the program continues

- All women, HPV vaccinated and unvaccinated…….

- Access to a cervical screening program based on current evidence and best practice.
Renewal activities:

- Assess the evidence for screening pathways
  - Tests
  - Interval
  - Age range
- Determine a cost effective pathway
- Improve national data collection & registers
- Improve quality and safety monitoring
- Assess feasibility & acceptability of renewed program
• Any potential changes to the Program must achieve equal or better outcomes for women

• Evidence review
  o Sally Lord: NHMRC Clinical Trials Group, USyd

• Effectiveness modeling and economic evaluation
  o Karen Canfell: Lowy Institute, UNSW

• Additional research papers & requested information
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
MSAC recommendations

• 5 yearly cervical screening
  – Primary HPV test with partial genotyping
  – Reflex LBC triage
  – HPV vaccinated and unvaccinated women
  – Age 25 to 69 year
  – Exit testing 70 to 74 years
MSAC recommendations

• Self collection of an HPV sample
  – Under screened and never screened women only
  – Facilitated by nurse or medical practitioner
  – Or on behalf of a medical practitioner
  – Who also offers mainstream cervical screening
MSAC recommendations

• **Invitations** and reminders to be sent to women
  – 25 to 69 years of age

• **Exit** communications to be sent to women
  – 70 to 74 years of age

• To ensure effectiveness of the program

• **Delisting** of current MBS items
  – 6/12 month transition
15% ↓

Fewer cases of cervical cancer

Fewer deaths from cervical cancer
19th September 2014

Australian Health Ministers Advisory Council (AHMAC)

Endorsed
Draft Interim Implementation Plan
• Take an LBC sample from the cervix and send to lab for testing
• If HPV+ve ---- Cytology on the same sample: no additional visit
• You will receive a report with HPV +/- cytology status, level of risk, including a single recommendation for action

For example:
HPV 16 +ve, recommend colposcopy (+ cytology result)
HPV +ve, Cytology HSIL, recommend colposcopy
HPV +ve, Cytology pLSIL, recommend repeat testing in 12 months
HPV –ve, recommend repeat testing in 5 years
• 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

• The doctor will receive a report with HPV +/- cytology status, level of risk including a single recommendation for action

• Women will receive results from their doctor in the usual way: active communication

• Test results will be recorded by the cervical registry
Estimated Volume changes / year

- Pap tests ~ 2.4M to 0
- HPV tests ~ 55K to 1.3M+
- LBC tests ~ ? to 340K
- Colposcopies ~ 82K to 102K
What does this mean for laboratories?

- Changing technologies
  - HPV testing + partial genotyping
  - LBC
  - Automated assisted image analysis
- Less cytology tests, more HPV tests
- Changes to reporting (HPV + Cyto)
- Changes to quality standards
- Register changes: one woman one record
- Workforce and practice changes
Proposed Cervical Screening Pathway

1. **Negative HPV**
   - Negative Cytology
   - p/d LSIL
   - Repeat HPV test in 12 months
   - Negative HPV
     - Test was negative (normal)
       - Recall for screening in 5 years
   - Any positive HPV
     - Indicated HPV infection - still present
       - Refer to colposcopy with reflex LBC result
   - HSIL
     - Indicated cellular changes present that may require treatment
     - Un satisfactory test for technical reasons
       - Retest within 6 weeks

2. **Positive HPV other types**
   - Reflex LBC
     - Negative Cytology
     - p/d LSIL
     - Repeat HPV test in 12 months
     - Negative HPV
       - Test was negative (normal)
         - Recall for screening in 5 years
     - Any positive HPV
       - Indicated HPV infection - still present
         - Refer to colposcopy with reflex LBC result
     - HSIL
       - Indicated cellular changes present that may require treatment
       - Refer to colposcopy with reflex LBC result
   - **Positive HPV 16, 18 +/- 45**
     - Unsatisfactory test
       - Retest within 6 weeks
Some issues

- Younger women < 25 yr
- HPV self collection
- Participation rates
Some issues

• Younger women < 25 yr
  • HPV self collection
  • Participation rates
Young women < 25 years of age

- HPV prevalent in young women and regresses
- Cervical cancer is very rare
- Screening has not decreased mortality
- HPV vaccination has reduced the risk of high grade abnormalities in young women
- Starting at 25yr reduces over treatment and minimises harms such as future pregnancy loss.
Some issues

- Younger women < 25 yr
- HPV self collection
- Participation rates
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 and HPV tests
- less cost effective than mainstream pathway.
- if HPV+ve will need separate visit for LBC sample

- only available to under or never screeners.
No of new cases cervix cancer per 100,000 women
Incidence NSW, QLD, WA & NT 2004 - 2008

Notes
2. Bars on the columns represent 95% confidence intervals.

Source: AIHW Australian Cancer Database.
Some issues

- Younger women < 25 yr
- HPV self collection
- Participation rates
Cervical screening rates for women vaccinated against human papillomavirus

Australia has a well established cervical screening program that currently recommends 2-yearly Pap tests for women aged 18 years (or 2 years after commencement of sexual activity, whichever is later) to 69 years. The program is supported by opt-out cervical cytology registers ("Pap test registers") in each state and territory that record the results of cervical cytology tests, cervical histopathology tests and human papillomavirus (HPV) DNA tests. The relatively high level of participation in Australia’s National Cervical Screening Program has led to halving of cervical cancer incidence and mortality rates.1

In April 2007, Australia initiated a national, publicly funded HPV vaccination program, using a three-dose schedule of a quadrivalent HPV recombinant vaccine that protects against HPV types 16 and 18 (which are responsible for 70%–80% of cervical cancer cases in Australia)2 and types 6 and 11 (which cause genital warts). The program vaccinates 12-year-old and 13-year-old girls in schools and included a catch-up vaccination program for 14–18-year-old girls in schools and 18–26-year-old women in community-based settings until the end of 2009. All communications provided to vaccinated women emphasised the need to continue having cervical screening tests every 2 years until their 26th birthday.

Abstract

Objective: To compare cervical screening rates for women vaccinated with a quadrivalent human papillomavirus (HPV) vaccine with those for unvaccinated women, to address concerns that vaccinated women may not be participating in cervical screening.

Design, setting and participants: Cross-sectional analysis of linked data from the Victorian Cervical Cytology Registry and the National HPV Vaccination Program Register for 20–29-year-old women in Victoria, Australia, for the period 1 January 2009 to 31 December 2011.

Main outcome measures: Screening participation rates for vaccinated and unvaccinated women.

Results: Participation in cervical screening during the 2-year period 2010–2011 was significantly lower in 20–24-year-old vaccinated women compared with unvaccinated women of the same age (37.6% vs 47.7%, a 10.1 percentage point difference [95% CI, 9.7–10.6]; P < 0.001) and significantly lower in 25–29-year-old vaccinated women compared with unvaccinated women of the same age (45.2% vs 58.7%, a 13.5 percentage point difference [95% CI, 13.1%–13.9%]; P < 0.001). Similar results were observed for participation during the 3-year period 2009–2011.

Conclusions: Despite education messages provided to young women, our results suggest that vaccinated women are being screened at lower rates than unvaccinated women in Australia. While some degree of undermatching of women in the study may have occurred, this cannot wholly explain our findings. Effective implementation of individual Healthcare Identifiers to health records, including registry records, is needed to prevent potential undermatching of individuals in future linkage studies. In the meantime, efforts to increase participation in cervical screening by vaccinated women are needed.

Data collection

The VCCR captures cervical screening results for all female residents of Victoria (a population of more than 2.7 million), including cervical cytology and cervical histopathology test results obtained directly from laboratories. Fewer than 1% of women "opted out" of the VCCR.3 The NHVPR...
Changes to cervical screening in Australia: applying lessons learnt

The potentially more effective new program will rely heavily on successful implementation.

In Australia, the organised approach to preventing cervical cancer began over 20 years ago. This approach has been a great public health success story that has shown a significant reduction in screening participation in 20–24-year-old and 25–29-year-old vaccinated women compared with unvaccinated women in Victoria (37.6% vs 42.8% and 37.9% vs 42.8%, respectively).
“The potentially more effective new program will rely heavily on successful implementation”
Steering Committee for the Renewal Implementation Project

- Chair
- Standing Committee on Screening
- Population Health Policy
- Gynaecological Oncologist
- O&G - colposcopist
- General Practitioner
- Aboriginal & Torres Strait Islander General Practitioner

- Cytopathologist
- HPV scientist
- Nurse
- Epidemiologist
- Consumer
- NCSP Managers
- Renewal Project Manager
Steering Committee for the Renewal Implementation Project

• Small expert committee
• Engage broad range of stakeholders
  – Consultation
  – Working groups
  – Workshops
• Links with existing committees eg: NPAAC
• Specific implementation issues
  – Workforce, registers, guidelines etc
- Draft Interim Implementation Plan (SCRIP)
  - MBS items
  - Workforce + Practice Change
  - Quality and Safety
  - Registers
  - Communications and Information
MBS Items

- HPV tests
- LBC tests
- Pricing for HPV and LBC within the screening framework
- Involving:
  - Sponsors of HPV & LBC tests
  - Pathology sector
  - MBD & Pathology Services Advisory Committee
Workforce and Practice Change

• Consultations ongoing

• Information sought from:
  – Health Workforce Australia
  – Pathology Workforce Advisory Committee
  – Australian Society of Cytology

• Groups affected
  – Cytologists
  – Laboratories
  – Test collectors
  – Colposcopists
Quality and Safety

• QSMC established: Chair-Prof David Roder
• Quality Framework: draft developed
• NPAAC
  – Update cytology requirements and performance measures
  – Performance measures for HPV testing
• AIHW – data coding – histology/HPV testing
  data dictionary – annual monitoring report performance indicators
Endorsed by NHMRC

9th June 2005

Implemented

3rd July 2006
 Registers

• Register blueprint has been developed
• Register workshops
• **National Cervical Screening Register**?
  – Linked to HPV register
  – Used to issue invitations/reminders
  – Full history from vaccination-diagnosis
  – Colposcopy data
  – Monitoring and service improvement

• **One woman = One record**
Communication and Information

- Consultations ongoing
- Extensive consultation with many stakeholders
- Critical to the Implementation process
  - Health professionals
  - Pathology laboratories
  - NCSP Program Managers
  - Consumers
- Transition phase and beyond
Renewal
Implementation
Project

Project Management: Techniques and Tools
The major characteristics of a project:

- An established objective
- A defined life span with a beginning and an end
- Usually, the involvement of several departments and professionals
- Typically, doing something that has never been done before
- Specific time, cost and performance requirements
Project: Primary Objective

Establish the renewed National Cervical Screening Program by 1st May 2017 and maintain the current program until 1st May 2017
## Project Failure Rate

<table>
<thead>
<tr>
<th>Year</th>
<th>Successful</th>
<th>Failed</th>
<th>Challenged</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>29%</td>
<td>18%</td>
<td>53%</td>
</tr>
<tr>
<td>2006</td>
<td>35%</td>
<td>19%</td>
<td>46%</td>
</tr>
<tr>
<td>2008</td>
<td>32%</td>
<td>24%</td>
<td>44%</td>
</tr>
<tr>
<td>2010</td>
<td>37%</td>
<td>21%</td>
<td>42%</td>
</tr>
<tr>
<td>2012</td>
<td>39%</td>
<td>18%</td>
<td>43%</td>
</tr>
</tbody>
</table>

Standish International Inc, 2012
The top 5 factors found in successful projects are:

1. Executive Management Support
2. User Involvement
3. Project Management Expertise
4. Proper and Adequate Planning
5. Skilled Resources
The top 5 factors found in successful projects are:

1. Executive Management Support ✅
2. User Involvement ✅
3. Project Management Expertise ✅
4. Proper and Adequate Planning ✅
5. Skilled Resources ✅
Work Breakdown Structure

Phases, Activities and Tasks

Analyse Requirements

Develop the Program

Transition to the new Program
Link the task on line 24 with the task on line 12 and the task on line 23.
• Affected by the Project

• Affect the Project
Standing Committee on Screening

Steering Committee Renewal Implementation Project

Renewal Policy Implementation Plan

Register Plan

Project Management
Next Steps

Priority Activities

• **Register**: consider options for system capability

• **NPAAC**: standards and performance measures for LBC and HPV tests

• **Clinical Management Guidelines**
Until 2017

Business as usual!
George Papanicolaou
1883 – 1962

1928- Pap test developed

1943- Diagnosis of uterine cancer by the vaginal smear

1948- American Cancer Society “Pap smear is a valuable test”

2017 - time for change
Questions??????

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