The NEW Renewed National Cervical Screening Program
‘Who, Why, What, How and When’

Is this the end of the Pap test?

IAN HAMMOND
Chair: Renewal Steering Committee
Chair: Steering Committee for Renewal Implementation Project
• 5 yearly HPV test, partial genotyping
• Reflex liquid based cytology
• Age 25 – 69
• HPV vaccinated and unvaccinated
• Exit HPV testing age 70 – 74
• Invitation and Reminder system
• Self testing for underscreened women
15% ↓

Fewer cases of cervical cancer

Fewer deaths from cervical cancer
What I am talking about today

• Current National Cervical Screening Program
• Why the Renewal
• HPV and cervical cancer
• Renewal process
• Options and Outcomes of MSAC review
• What does this mean for you
• Concerns: younger women and older women
• Opportunities for the future
Since 1991 in Australia:
- 50% incidence & mortality ↓
  - constant for past decade

Cervical Cancers
- squamous cell (~80%) 65
- adenocarcinomas (~20%) 25
- other (~<2%) 5 – no suitable screening test

Currently 80% of Australian women with cervical cancer are lapsed or never screeners.
Incidence of carcinoma of the cervix in women aged 20–69
1982 to 2008

Note: Rates age-standardised to the Australian population as at 30 June 2001.

Source: AIHW Australian Cancer Database.

Figure 6.4: Incidence of carcinoma of the cervix (squamous cell carcinoma, adenocarcinoma, and other carcinoma) 1982 to 2008.
National Cervical Screening Program

The Pap smear

Age 18+

Every 2 years

Stop at age 69

Reminder ‘safety net’
Endorsed by NHMRC
9th June 2005

Screening to Prevent Cervical Cancer:
Guidelines for the Management of
Asymptomatic Women with Screen Detected Abnormalities

Implemented
3rd July 2006
The National Health and Medical Research Council, however, recommended that the *screening interval* in Australia be reviewed as soon as possible to ensure that the National Cervical Screening Program is consistent with international best practice.

9th June 2005
Announcement of Renewal of the National Cervical Screening Program

“To assess the impact of the HPV vaccine, new technologies, age range, and screening interval on the Program”

A. Koukari PCC2009, March 2009
Why

- New knowledge on the development of cervical cancer.
- New evidence for cervical cancer prevention/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
Harald zur Hausen

1982
Demonstrated that HPV was the cause of cervical cancer

2008
Nobel Prize in Medicine
Papillomaviruses

4 main groups in man:
- skin warts (HPV1,2)
- genital warts (HPV6,11)
- EV associated (HPV 5,8)
- genital cancers (HPV16,18)

Courtesy Prof. Ian Frazer
Ian Frazer AC

1991-2005
Developed the first vaccine for HPV

2006
Australian of the Year

2007
National HPV Vaccination Program – girls

2013 - boys
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
What: is the aim of the Renewal

• 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.
How

• 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
Governance

Who is involved in Renewal

Standing Council on Health (NCSP policy)
Australian Health Ministers’ Advisory Council
Community Care and Population Health Principal Committee
Standing Committee on Screening (intergovernmental)
Renewal Steering Committee (expert)
Partner Reference Group (consumers, industry, health professionals and service providers)
Minister for Health (MBS listings)
Medical Services Advisory Committee
Public Consultation
# MSAC Process

## Expression of Interest stage

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>Initiation of process</td>
<td>Applicant submits Part A &amp; Aii</td>
</tr>
<tr>
<td>Technical Discussion Meeting</td>
<td>Dept</td>
</tr>
<tr>
<td>Initial meeting</td>
<td>Dept and applicant</td>
</tr>
<tr>
<td>Eligibility check</td>
<td>Dept, Applicant submits Part B</td>
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<tr>
<td>MBS Management Committee</td>
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## Determination of Approach to Assessment stage

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<tr>
<td>Proposed DAP</td>
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<td>Public notification of PASC agenda</td>
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<td>On consultation DAP, Dept seeks specific input from prof bodies, Applicant comment</td>
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<td>2nd Consideration by PASC</td>
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## Consideration of Evidence stage

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<tbody>
<tr>
<td>Assessment</td>
<td>Applicant Submission, Assessment Group</td>
</tr>
<tr>
<td>Assessment review</td>
<td>Assessment Group, Applicant comment</td>
</tr>
<tr>
<td>ESC evaluation</td>
<td>Focuses issues, prepares report, Applicant comment</td>
</tr>
<tr>
<td>MSAC appraisal</td>
<td>Deliberates, prepares advice and rationale</td>
</tr>
<tr>
<td>Minister</td>
<td>Notes MSAC Advice, Applicant advised, Report &amp; MSAC advice published</td>
</tr>
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## Implementation stage

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<td>Dept</td>
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<tr>
<td>Advice to Minister on item</td>
<td>Dept</td>
</tr>
<tr>
<td>Costing of item</td>
<td>Agreed across Depts</td>
</tr>
<tr>
<td>Advice to Government</td>
<td>Makes funding decision</td>
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<td>MBS listing</td>
<td>Dept</td>
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</table>
### Summary: Decision Analytic Protocol

<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>Primary screening test</td>
<td>Conventional cytology</td>
<td>Conventional cytology</td>
<td>LBC</td>
<td>HPV DNA testing</td>
</tr>
<tr>
<td>Age range</td>
<td>Women aged 18-69 years</td>
<td></td>
<td>Women aged 25-64 years</td>
<td></td>
</tr>
<tr>
<td>Interval</td>
<td>2 yearly</td>
<td>3 yearly (aged 25-49) and 5 yearly (aged 50-65)</td>
<td>5 yearly</td>
<td></td>
</tr>
<tr>
<td>Triage options</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>Additional technology</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td>With and without automated image analysis</td>
</tr>
<tr>
<td>Exit strategy</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>
</tr>
<tr>
<td>Self collection</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td>YES</td>
</tr>
<tr>
<td>Call-recall system</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
<td>YES</td>
</tr>
</tbody>
</table>
Evidence Assessment Team
Dr Sally Lord and team
NHMRC Clinical Trials Centre
University of Sydney

Effectiveness and Economic Modeling Evaluation Team
A/Professor Karen Canfell and team
Lowy Institute
University of New South Wales
Reflex LBC
Recall for routine HPV screening in 5/6 years

Negative HPV

Recall for routine HPV screening in 5/6 years

Repeat HPV test in 12 months

Negative HPV

Recall for routine HPV screening in 5/6 years

Repeat HPV test in 12 months

Negative HPV

Recall for routine HPV screening in 5/6 years

Repeat HPV test in 12 months

Negative HPV

Recall for routine HPV screening in 5/6 years

Positive any HR HPV

Refer to colposcopy

Option 3gA
p/d LSIL

Other HR HPV Positive

Reflex LBC

HPV 16/18 ± 45 Positive

Reflex LBC and refer to colposcopy

Option 3gB
p/d HSIL

Positive any HR HPV

Refer to colposcopy

Refer to colposcopy

Primary HPV testing with partial genotyping

## Results: Summary of outcomes (assumed screening ends at 64 years for new strategies)

<table>
<thead>
<tr>
<th>Main primary screening approaches</th>
<th>Unvaccinated cohorts</th>
<th>Cohorts offered vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of colposcopies and % change</td>
<td>% change treatments</td>
</tr>
<tr>
<td><strong>Current practice (predicted)</strong></td>
<td>81,300</td>
<td>-</td>
</tr>
<tr>
<td>Conventional cytology at IARC intervals</td>
<td>-22 to -12%</td>
<td>-23 to -13%</td>
</tr>
<tr>
<td>Manually-read LBC at IARC intervals</td>
<td>-17 to 20%</td>
<td>-22 to -4%</td>
</tr>
<tr>
<td>Image-read LBC at IARC intervals</td>
<td>-17 to 23%</td>
<td>-22 to -4%</td>
</tr>
<tr>
<td>HPV with LBC triage at 5-yearly intervals</td>
<td>-7 to 20%</td>
<td>-21 to -9%</td>
</tr>
<tr>
<td>HPV with partial genotyping and LBC at 5-yearly intervals</td>
<td>12 to 37%</td>
<td>-17 to -8%</td>
</tr>
<tr>
<td>Co-testing at 5-yearly intervals</td>
<td>6 to 33%</td>
<td>-15 to -4%</td>
</tr>
</tbody>
</table>

- Conventional Cytology (IARC)
  - 8-20% increase in incidence and mortality
- LBC manual + HPV triage (IARC)
  - up to 13% reduction in CxCa rates
- LBC image read + HPV triage (IARC)
  - up to 14% reduction in CxCa rates
- HPV strategies
  - up to 18% reduction in CxCa rates
- Increase exit age 64 to age 69
  - Improved mortality by 5-7%
## Other benefits

<table>
<thead>
<tr>
<th>Recommended lifetime screening tests now</th>
<th>Australia</th>
</tr>
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<tbody>
<tr>
<td>26% Percent reduction in screening tests</td>
<td></td>
</tr>
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<table>
<thead>
<tr>
<th>Recommended lifetime screening tests for primary HPV @5-yearly intervals in women 25-69 years</th>
<th>Australia</th>
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<tbody>
<tr>
<td>9 to 10</td>
<td></td>
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<table>
<thead>
<tr>
<th>Percent reduction in screening tests</th>
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<tbody>
<tr>
<td>62-65%</td>
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Additional papers

• Ronco et al – *Lancet*, Nov 2013
  • Pooled data of 4 large European RCT
  • **HPV screening = 60-70% greater protection against invasive cervical carcinomas compared with cytology**
  • Supports HPV-based screening from 30 yo and at least 5yr intervals

• Elfstrom *BMJ* 2014
  • increased sensitivity of HPV screening reflects earlier detection rather than overdiagnosis.
  • **support screening intervals of five years for such women.**

• Arbyn *Lancet Oncology* 2014
  • HPV sampling by a clinician should be mainstream.
  • **HPV self-collection - additional strategy to reach women not participating in regular screening program."**
  • self sampling - choice of test matters more than collection device ie Dacron swab not self-sampling devices.

  • Cervical screening at age 50–64 and the risk of cervical cancer over age 65
  • **Supports rethinking 65 yo exit to include older women**
MSAC Considerations

• Any potential changes to the Program must achieve equal or better outcomes for women.

• Natural history of cervical cancer

• Evidence – NHMRC Clinical Trials Group, Syd Uni

• Economic report – Lowy Institute, UNSW

• New research papers (Oct 13 to Feb 2014)

• Additional requested information

• See - MSAC Public Document (msac.gov.au)
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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
• 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 including a single recommendation for follow up (based on risk)

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

• The doctor will receive a report with HPV +/- cytology status including a single recommendation for follow up

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

• Test results will be recorded by the cervical registry
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.
Benefits and harms of cervical screening from age 20 years compared with screening from age 25 years

R Landy¹, H Birke¹, A Castanon¹ and P Sasieni*¹

¹Centre for Cancer Prevention, Wolfson Institute of Preventive Medicine, Bart’s and The London School of Medicine, Queen Mary University of London, Charterhouse Square, London EC1M 6BQ, UK
Older women

• Benefits of screening outweigh harms for 25 to 69 yo

• 70 to 74 yo are recommended to have an exit HPV test before leaving the cervical screening program.

• Older women, who are regular screeners will have a protective effect.

• Women > 69 years of age who have never screened or are lapsed screeners should be screened if they request a test.
HPV self-collection

- increased participation rate for never and under-screened
- not as effective 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.
Opportunities

• Less frequent testing, less cancers and more lives saved

• Better participation – invitations, recalls + targeted self-collect

• Future proofing cervical screening – HPV vaccinated cohort

• Improved registry functions: National Register?
  • One woman, one record

• Improved data collection – CALD, ATSI, colposcopy
Opportunities

• Improve evaluation:
  • National HPV Vaccination Program
  • National Cervical Screening Program

• Continued Leadership and Innovation
  • 1st HPV vaccine
  • 1st national HPV school based immunisation program,
  • 1st national cervical screening using primary HPV test
Next Steps

• Consultations

• Implementation Plan (SCRIP)
  • MBS items: Addition, Deletion + Transition
  • Registers
  • Workforce + Practice Change
  • Quality and Safety
  • Communications and Information

• Start Date: 2016 – until then 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”

2014- time for change?
What I have talked about today

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- Why the Renewal
- HPV and cervical cancer
- Renewal process
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Questions??????

Info:
msac.gov.au
cancerscreening.gov.au

Email:
Cervicalrenewal@health.gov.au