Towards 2017: the new National Cervical Screening Program

Drs Siobhan Bourke and Lara Roeske
Liaison Physicians
VCS Pathology

Assisted ably by Dr Jo Mountford & Ms Lyndal Ritchie

• VCS: Core Business
  – VCS Pathology
  – Victorian Cervical Cancer Registry
  – National HPV Vaccination Registry

• www.vcspathology.org.au
• www.vcs.org.au
• www.compasstrial.org.au
Running of workshop

• GP activity 1
• Talk/presentation
• GP activity 2

• Possible splitting of group:
  1. Victorian practitioners interested in recruiting for COMPASS
  2. Cases

Learning Objectives

• 1. The GP will have the resources to explain the new NCSP
• 2. The GP will be prepared for the practical & clinical changes of the NCSP in 2017
• 3. The GP will confidently deal with the changes in the NCSP ensuring patient safety.
Activity 1
Put the HPV in order of risk of causing cervical cancer: high, intermediate, low

• Is a VERY common STI
  – The most common viral STI

• Life time 80% plus genital HPV (some studies suggest over 90%)

  ~ 200 types
  ~ About 50 genital types
  ~ 13-14 high risk genital types

Five yearly cervical screening using a primary HPV test with partial genotyping and reflex LBC triage, for HPV vaccinated and unvaccinated women 25 to 69 y.o, with exit testing for women up to 74 y.o.

Vaginal HPV sample (self or clinician collected), facilitated by physician or cervical screening nurse; for an under screened or never screened woman.

Delisting of current MBS items – 6 to 12 month transition.
### International comparisons

Incidence of cervical cancer and mortality, selected countries 2008

<table>
<thead>
<tr>
<th>Country</th>
<th>Incidence per 100,000 Women (ASR)</th>
<th>Mortality per 100,000 Women (ASR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>6.6</td>
<td>1.9</td>
</tr>
<tr>
<td>USA</td>
<td>5.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Finland</td>
<td>3.7</td>
<td>0.9</td>
</tr>
<tr>
<td>UK</td>
<td>7.2</td>
<td>2.0</td>
</tr>
<tr>
<td>Australia</td>
<td>4.9</td>
<td>1.4</td>
</tr>
<tr>
<td>New Zealand</td>
<td>5.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Sweden</td>
<td>7.4</td>
<td>1.8</td>
</tr>
</tbody>
</table>

Source: Glocan 2008, International Agency for Research on Cancer

### In Victoria 2009

![Graph showing incidence and mortality rates per 100,000 women in Victoria from 1982 to 2009. The incidence rate decreased from 10 in 1982 to 4 in 2009, while the mortality rate decreased from 0.9 in 1982 to 0.1 in 2009.]

VCCR statistical report 2011
If it ain’t broke, why fix it?

• We always talk about the Australian cervical screening program as one of the best in the world?

• So why did they decide to do this?

Several factors

• Vaccine effectiveness
• Testing technologies
• Better test- patient safety
• Lessening HSIL which is deskillling scientists
• Cost effectiveness
• Less invasive - reduced number of screening episodes
• Underpinning this is an explosion in scientific knowledge
VACCINE EFFECTIVENESS

National notified coverage

As held at Sept 2011. Excludes consumers who have opted off.
Fall in cervical HPV prevalence in young women 18-24yrs

Figure 1. Differences in human papillomavirus (HPV) genotypes between pre-vaccine and post-vaccine populations. *P < 0.05 for differences in percentages between groups. Abbreviations: C, combined 3-dose sets; including 16, 18, 11, 6, 19-941, 40-8, 93.6.

1HGA • 10/02/2012 08:12 • Lusardi et al

Figure 2. Incidence of high-grade cervical lesions in millions. Squares denote incidence of high-grade squamous intraepithelial lesions (HGSIL) in the months of nine diagnoses within a 3-month period per 1,000 women treated. Lowermost smoothing indicates average incidence in the months of diagnosis. The vertical bars, within each month of the HGSIL incidence, denote the median of human papillomavirus vaccination.

Warts

Presentations with warts in women by age group - July 2004 to end June 2011

6 month periods since July 2004

Pers Com Dr Tim Read MSHC Oct 2012

Warts

Presentations with warts in men and women <21 years, and MSM all ages, July 2004 to end June 2011

Vaccination program commences

Figure 1: Proportion of patients aged <21 years, diagnosed as having genital warts by risk group compared with MSM of all ages. MSM, men who have sex with men; men <21 years excluded MSM, and non-residents excluded.

TESTING TECHNOLOGIES

Technologies

- Pap smear
  - Conventional cytology
  - Liquid-based cytology (LBC)
  - Image-read LBC

- HPV DNA/mRNA testing
  - Plethora of emerging technologies
  - Performance benchmark established (HC2™ Qiagen)*

DNA technologies

• PCR for HPV DNA
• Detecting (the results will show)
  – 16, 18 +/- 45,  
  – “other” HR HPV
  • These others account for just under 30% of the Australian cervical cancers. They do not carry as great a risk of cervical cancer as 16 & 18

Stratification of risk

• NB Activity one
High risk HPV (High)

- 16 & 18
- Identified risk of 15-20% to cause HSILs in ten years for 16
- Identified risk of 10-12% to cause HSILs in ten years for 18

- these are worth following up if detected, regardless of cytology- i.e. in the absences of high grade squamous intra-epithelial lesions

- 16 & 18 cause glandular or adenocarcinoma. This is not easily detected on cytology.

High risk HPV (intermediate)

- 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
- They can be described as having an intermediate risk
- Identified risk of 3-5% to cause HSILs in ten years for “HR HPV other”
**BETTER TEST- PATIENT SAFETY**

*Longitudinal outcomes: HPV and cytology negative women*

![Graph showing incidence of CIN3+ per 10,000 over time since intake testing (months)]
Longitudinal outcomes:
HPV positive women

**Cumulative CIN3+ in 20,514 women (median age 34 years)**

Khan MI, Castle PE, et al. The elevated 10-year risk of cervical precancer and cancer in women with human papillomavirus (HPV) type 16 or 18 and the possible utility of type-specific HPV testing in clinical practice. *JNCI* 2005

Activity 2

- Predictive value
- Place in order of increasing predictive value.
- I.E. What is the likelihood of the result actually being true.
Answer activity 2

1. CERVICAL SAMPLE FOR HPV
2. SELF COLLECTED HIGH VAGINAL SWAB FOR HPV
3. TRADITIONAL CERVICAL SMEAR

New National Cervical Screening Program

Commence: 25 years sexually active

Screening interval: five yearly to 69 years

Screening test: HPV PCR and partial genotyping

Specimen: liquid based medium (Thin Prep™)

Exit test: between 70-74 years
Reflex testing

• When cytology or additional testing is required, reflex testing is done on same sample—this does not have to be ordered by the requesting clinician
New National Cervical Screening Program is to come into effect
Renewal

May 1st 2017

Compass RCT

- VCS and Cancer Council NSW are conducting a large RCT to:
  - Evaluate primary HPV in partially vaccinated population using updated testing technology
  - More focus on optimal management of HPV positive women
  - Specific evaluation of safety, effectiveness and costs in Australian context
  - Pragmatic trial/demonstration of concept
The Compass Clinical Trial

Woman attends for cervical screening
Practitioner collects LBC sample & consent
VCS Lab
Randomise

1/3 women 2.5 yearly cytology
2/3 women 5 Yearly HPV test

Where are the recruiting practices?
Compass details (Victorians only) or Cases

- Victorian GPs who participate in recruiting for the Compass Clinical Trial can gain 40 cat 1 CPD & QI. Women’s health points apply.
- To achieve this the GP must:
  - Attend a one hour long education session (this!)
  - Recruit, follow up and manage 20 eligible women
  - Complete a self reflection activity and evaluation

Compass

- A way to get for your patients, early access to HPV testing or better cytology at no cost
A JOINT INITIATIVE OF
THE VICTORIAN CYTOLOGY SERVICE
AND
CANCER COUNCIL NSW

The Compass trial

- Intended as a sentinel experience of the Renewed National Cervical Screening Programme.
- Compares the performance of cervical screening based on primary HPV testing with screening based on cytology
- Pilot recruited 5,000 women 2014
- Main trial need 121,000 women (14,000 recruited to date)
- As part of the main trial we are working with our participating GPs to understand the practical issues that might arise in a screening programme based on HPV testing
Main trial recruitment

- Main trial is underway and currently recruiting from Pap providers (mainly GPs and practice nurses)
- Currently mainly Victoria but some NSW areas involved

- Thinprep, liquid based cytology (LBC),
- Test request ‘cervical screening’
- Minimal extra time/paperwork required to organize trial involvement
- Ring liaison physicians if you have any problems or questions
The Compass Clinical Trial

Woman attends for cervical screening

Practitioner collects LBC sample & consent

VCS Lab

Randomise

1/3 women
2.5 yearly cytology

2/3 women
5 Yearly HPV test

COMPASS TRIAL FLOW CHART
The Pathology request form is same as the VCS usual form.
Consent form is the lower half of the request form.

Opt out of further research.
Result slip and wallet card for the woman

Your recent cervical screening test results indicate the presence of HPV infection.

Ms Anne Citizen
32 Tuer Stret
BRUNSWICK WEST VIC 3055

Brochures for results explanation- stapled to all results
Low Risk- HPV negative

Intermediate risk- HR HPV other
Preparing for Compass recruitment

- Sign the practice agreement and send to VCS -we have some here today to sign- PM or director. You can take it back to your practice if you don’t have the authority to sign or want to discuss it further with your practice.
- If further clinicians from your practice want to join Compass organise a practice visit or Webinar.
- Practice details to be logged with Bellberry Ethics (VCS completes this).
- Insurance details of participating clinicians.*
- Receive start up kit with consumables.

* The Compass trial is classified as a low risk trial – automatic coverage from insurance agencies- some want to know who of their members is recruiting and other don’t.
QI&CPD

✓ Session attended
  • Recruit 20 eligible patients
  • Complete recruitment and self reflection activity and evaluation and return to VCS
    – In your packs.

Thank you

Contact: Liaison Physicians
03 9250 0300

Organise practice visit or webinar
Angela Mitchell 03 9250 0300,
amitchell@vcs.org.au

www.compasstrial.org.au