COMPASS TRIAL
A Randomised Controlled Trial of Primary HPV Screening

BACKGROUND

Primary HPV DNA testing has been reviewed and endorsed as a primary cervical screening method by the International Agency for Research on Cancer. A number of large scale randomised controlled trials of primary HPV DNA screening have found that HPV screening is more sensitive in detecting precancerous lesions than cytology-based screening and that it can safely be conducted at a longer interval (see fig 1). However to date there have been no specific trials that support primary HPV DNA testing for cervical screening in the Australian context.

Compass is a randomised controlled trial which aims to compare 2.5 yearly cytology-based cervical screening with 5-yearly primary HPV screening in Australian women aged 25-69 years. Researchers at VCS Inc. and UNSW Australia are about to commence a trial of 121,000 women with initial randomisation at 1:2. Eligible participants are women, aged 25-69 years, attending for routine screening at participating practices in Victoria.

Health practitioners will seek consent from eligible women to participate in Compass during a regular cervical screening consultation. At the beginning of the consultation practitioners will provide women with a study information sheet and ask them to sign a consent form. Only a liquid-based cytology (LBC) sample will be taken. This will be returned to VCS Pathology where randomisation will occur and samples will be analysed.

The recommended screening interval for women with negative (normal) results will be 2.5 years in the image-read cytology screening arm, and 5 years in the primary HPV testing arm. The laboratory reports, issued to practitioners, will specify the recommended management.

General Practitioners recruiting women for Compass will be eligible to take part in an Active Learning Module and earn QI&CPD program points.

For more information please contact one of the VCS Pathology Liaison Physicians on 03 9250 0300

Selected references:

COMPASS TRIAL FLOW CHART (SIMPLIFIED)

**Study Arm A**
Image Read LBC

- Unsat cytology
  - Repeat LBC in 6-12 weeks
- Negative cytology
  - Routine screening in 2.5 years-LBC
- p/d LSIL
  - Oncogenic HPV DNA testing
  - Repeat HPV test in 6-12 weeks
  - Routine HPV testing in 5 years
  - Other high risk HPV
  - HPV 16/18 positive
  - Image read LBC
- p/d HSIL
  - Colposcopy

**Study Arm B**
Oncogenic HPV DNA Testing

- Unsat HPV
  - HPV 16/18 positive
  - Randomisation 1:1
  - Image read LBC
  - Colposcopy
- Negative HPV
  - 10% return in 2.5 years for LBC Safety Monitoring
  - Dual Stained
  - Recommendation for follow up based on Dual Stain result
  - Recommendation for follow up based on LBC result

1. Possible/Definite
2. Liquid Based Cytology
3. High Risk/oncogenic
4. See Protocol for Compass for full flow chart.