

The Renewed National Cervical Screening Program 2019

Common Questions and Cases



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Preventing cervical cancer Australia

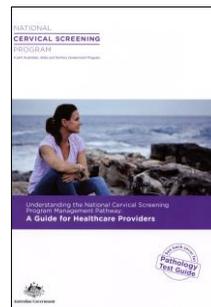
- National HPV vaccination program
- The National cervical screening program



The New National Cervical Screening Program

1st December 2017

- Primary HPV testing with partial genotyping and cytology triage
- Commencing at age 25 years
- Every 5 years
- Exit HPV test 70-74 years, can continue on Medicare
- Self testing for under-screened women



NATIONAL CERVICAL SCREENING PROGRAM:

Guidelines for the management of screen-detected abnormalities, persisting in specific populations and investigation of abnormal vaginal bleeding



Management guidelines

- 2016 Guidelines
http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening
- 2016 Guidelines online education - scenarios
http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening/E-learning



Population screening

Complex Public Health program – Issues relevant at a time of great change

- Ethical issues in population screening: balance of benefits and harms
- *"The ethical imperative with all medical interventions is to endeavour to ensure that potential benefits will outweigh harm. This is particularly so of screening. If a patient asks a doctor for help the doctor is obliged to do his or her best to help but ... (if) the doctor initiates a screening program there is a presumption that this must benefit the patient"*

https://wiki.cancer.org.au/policy/Principles_of_screening#Ethical_issues_in_population_screening_balance_of_benefits_and_harms



Population screening

Complex Public Health program – Issues relevant at time of great change

- A program should, at the very least, be able to demonstrate evidence of an overall benefit to the community
- And a minimum of risk that certain individuals *may be disadvantaged* by the program
- Not only is it important that information on the effectiveness of screening programs be available, it should also be disseminated widely

https://wiki.cancer.org.au/policy/Principles_of_screening#Ethical_issues_in_population_screening_balance_of_benefits_and_harms

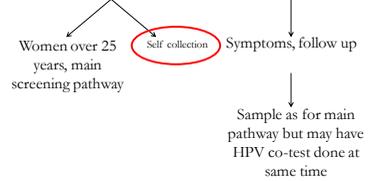


Issues that have arisen in first year...

- Self collection
- National Cancer Screening Register (NCSR)
- HPV testing in practice
 - screening versus non-screening
 - older women
- HPV testing
 - a little more detail



SCREENING VS. NON SCREENING



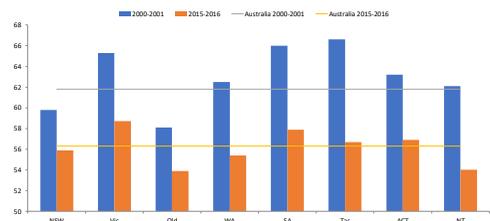
Why self collection?

- Major issue with screening programs – RECRUITMENT
- Acknowledged as part of major review undertaken
- Participation has fallen by 50% in the last 10 years



PARTICIPATION IN CERVICAL SCREENING

PERCENTAGE OF ELIGIBLE WOMEN BY STATE



Sources: Data taken from AIHW Cervical screening publications:
 - Cervical screening 2015-2016
 - Cervical screening in Australia 2000-2001 and 1999-2000

Self collection

- Recognised solution for women who won't screen
- Possible now there are reliable HPV tests
- NOT for cytology e.g. Solopap



Self collection option

- Aged 30-74 years
- Women who have not screened for 2 years longer than recommended interval
 - 4 years in the first round
 - 7 years future

MEDICARE RESTRICTED!!



Self collect

- Screening samples only
- Directed by Primary Care Giver
- To be done in clinic
- Not to be taken home
- NOT posted



SELF COLLECTING DEVICE RED TOP FLOQ SWAB



Self-sampling Instructions Cervical Swab Sampling Tool



Self collected HPV tests

- The availability of self collection in the screening program has been limited
- Each individual testing laboratory must validate the collection method
- VCS only laboratory with accreditation for most of 2018



Self collect validation study

- Individual lab validation requires a study protocol and ethics approval with the collection of dual samples (self collect plus Dr collect) from 200-300 women
 - DHM and FPNSW undertook study, March – June 2018
 - 223 women
 - Excellent correlation
 - Approved by NATA, TGA and testing is now being performed at DHM in Sydney



Self collect data

		CLINICIAN COLLECT (cervical)		
		hrHPV+	hrHPV-	TOTAL
SELF COLLECT (vaginal)	hrHPV+	30	5	35
	hrHPV-	0	188	188
	TOTAL	30	193	223

Sensitivity = 100% Specificity = 97%
 Concordance = 98% Kappa = 0.910 (95%CI 0.833-0.988)

Source: Validation of Patient-Collected Vaginal Swabs for Use in the Roche cobas® 6800 HPV Assay



Ms AJ 35 year old



- Known patient usually comes with her children
- Presents with infected finger
- Classic paronychia
- Note she hasn't ever had cervical screening
- Ask about it
- Flatly refuses
- Suggest self sampling
- Treat paronychia
- Give her brochure re self sampling and ask her to return

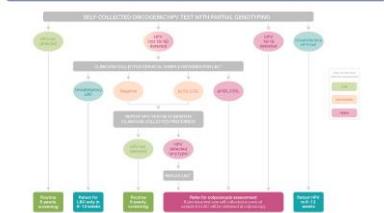


Ms AJ 35 year old

- Returns 2 weeks later
- Provide her with FLOQ swab and directions
- She takes sample in the bathroom
- Send it off to the lab



Screening pathway for self-collected samples




Ms AJ 35 year old

- Positive for other, non 16/18
- Needs to return to you for cytology sample
- Happy to do
- Visualize cervix, take LBC
- Report: negative, recommend repeat 12 months time
- NCSR will follow-up



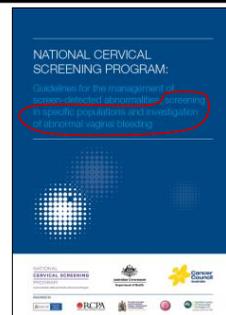
NCSR

- Numerous delays
- State data transfer completed Mid 2018
- But functionality has been poor
 - patient histories
 - recruitment
 - 25 year olds invitation letter
- Follow-up OK

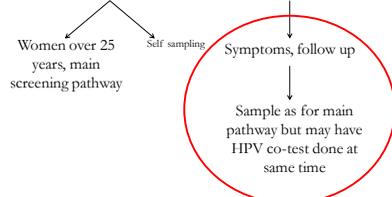


NCSR

- Clinical interface still planned for 2020
- Bowel screen to be included 2019
- Because of Medicare linkage have identified large numbers of unscreened women
- Important role is provision of data to monitor program



SCREENING VS. NON SCREENING



Co-testing

- HPV and LBC ordered at same time
- Concerns re too much co-testing?!



Why co-test?

- Why was co-testing included?
 - false negative HPV tests
- data from US
 - co-testing recommended, not an organised screening program
 - approx. 6% negative HPV with known high grade abnormality
 - less than Pap smear



Ms JS 46 year old

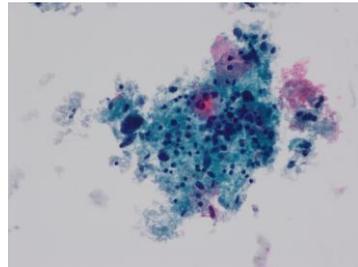


- Clinical notes
 - last pap smear 10 years ago
 - history of post coital bleeding
 - abnormal uterine bleeding
 - polyp anterior lip
 - bulky uterus
 - SYMPTOMATIC
 - co-test for symptoms and signs requested by GP



HPV DNA test

- | | |
|----------------------|--------------|
| - HPV 16 | Not Detected |
| - HPV 18 | Not Detected |
| - HR HPV (not 16/18) | Not Detected |

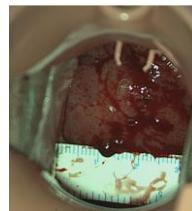


CST

- | | |
|---------------------|------------------------------------|
| - Risk Category | * HIGHER RISK |
| - TEST RESULTS | PCR for Oncogenic HPV and Genotype |
| - HPV16 | Not Detected |
| - HPV18 | Not Detected |
| - HPV(not 16/18) | Not Detected |
| - Cytology Category | * Squamous Cell Carcinoma |
| - Specific Findings | Endocervical component is present |
| - Recommendation | Refer for colposcopic assessment |



This whole field is exophytic tumour, 3cm at least



- Patient has a clinical stage 2B, 4-5cm tumour on palpation with left parametrial involvement
- Chemotherapy and radiotherapy only at this stage

Routine cervical screening using primary human papillomavirus (HPV) testing: Early observations from the renewed National Cervical Screening Program

Dorothy A Machak, Jennifer M Roberts, Suzanne M Garland, Julia Thutler, Adèle Richards, Ian Chambers, Terri Seewann, Annabelle Farnsworth

- Data from DHM Sydney, Australia
- First 6 months
- Submitted for publication

Reasons for referral among 195,606 samples received for HPV testing, and overall HPV positivity among valid tests

Reason for HPV test	Sample received		β-globin positive (valid) tests		Any Oncogenic HPV		HPV16/18		Other oncogenic HPV only (not 16/18)	
	n (%)	n (%)	n	%	n	%	n	%	n	%
Primary screening	157,700 (80.6)	157,542 (99.9)	12,099	8.1	3,653	2.2	9,246	5.9		
Non-screening	37,906 (19.4)	37,843 (99.8)	7,900	20.9	1,406	4.2	6,294	16.6		
Follow-up for previous LSIL	6,118 (16.1)	6,096 (99.6)	2,106	34.6	380	6.2	1,726	28.3		
Co-test for previous AIS	49 (0.1)	49 (100.0)	4	8.2	1	2.0	3	6.1		
Co-test for previous HSIL	9,682 (25.5)	9,672 (99.9)	1,708	17.7	532	5.5	1,176	12.2		
Co-test for symptoms/signs	12,703 (33.5)	12,685 (99.9)	1,954	15.4	324	2.6	1,630	12.9		
Co-test for other, indication unknown	9,354 (24.7)	9,341 (99.8)	2,128	22.8	369	4.0	1,759	18.8		

Machak et al. Routine cervical screening using primary HPV: early observations from the renewed cervical screening program.

Summary

- Primary screening, overall HPV positive rate 8.1%
- Non screening overall HPV positive rate 20.9%
 - symptoms or signs 15.4%
 - not classified 22.8%

Co test for symptoms or signs

...of cervical disease (cancer)

- Abnormal bleeding
 - post coital bleeding, intermenstrual, post menopausal
- Dyspareunia
- Discharge, unusual, red
- Abnormal cervix
 - suspicious, friable, hard, irregular

Ms CF 26 year old

- Presents – post coital bleeding
- Due for cervical screening test
- Take sample, order co-test (HPV and LBC)
 - request form – post coital bleeding
- Use opportunity for gynaecological check.
- Also order chlamydia/gonorrhoea



Ms CF 26 year old

- Laboratory: books patient in as "Symptomatic"
- RESULT:
 - Risk category – SYMPTOMATIC
 - oncogenic HPV Result – positive "not 16/18"
 - cytology negative
 - Recommendation – repeat 12 months
 - appropriate investigation of noted "symptoms and/or signs is advised"



Ms CF 26 year old

BUT

- Chlamydia test positive
- Cause of bleeding
- Treat



Ms CF 26 year old

- Even though HPV positive still classed as symptomatic, with "Intermediate Risk" report
- Investigation of symptoms & signs DOESN'T MEAN referral to GYNAECOLOGIST NECESSARILY
- Can be managed by you!



"False positive" HPV tests

- Over detection?
- HPV testing increased sensitivity, decreased specificity



Mrs PT 54 year old

- Has been seeing you regularly for years
- Has received a letter from National Cancer Screening Register (NCSR) saying she is due for cervical screening test?
- Has screened regularly with no abnormalities over last 20 years



Mrs PT 54 year old

- Cervical screening – no longer Pap smear
- HPV test
- LBC cytology – sample
- Explain if negative – won't need a test for five years

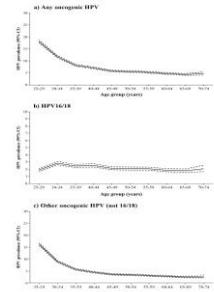


Mrs PT 54 year old

- Test result returns
- **HIGH RISK**
 - HPV 16 Positive
 - cytology negative
- Recommend colposcopy



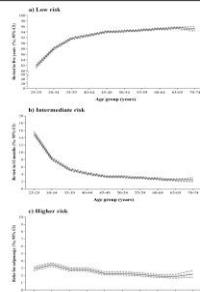
- Age-specific oncogenic HPV prevalence among 156,683 valid primary screening tests, women 25-74



Machakó et al. Routine cervical screening using primary HPV: early observations from the renewed cervical screening program.



- Age-specific risk classification and management recommendations from 156,683 valid primary screening tests, women 25-74



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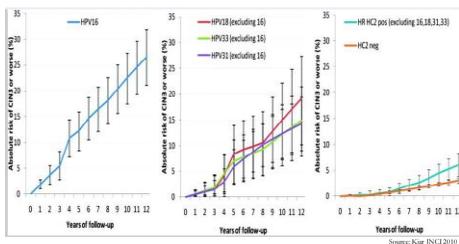


Mrs PT 54 year old

- What does this mean?
 - recently acquired infection?
 - latent infection?
 - has had for years and is non-active virus
 - why colposcopy?



Absolute risks of CIN3 or worse after infection with different high-risk human papillomavirus (HPV) types in women with normal cytological findings at baseline.



Source: Kjer JNCJ 2010



Mrs PT 54 year old

- COLPOSCOPY
- Atrophic cervix
 - Type 3 transformation zone - squamocolumnar junction not visible
 - No abnormality seen
 - Returns to you for advice on what she should do



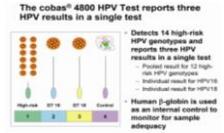
Invalid HPV testing – inhibited

- Why invalid?
- HPV testing
 - test can be inhibited by blood and other substances e.g. lubricant
 - the molecular reaction doesn't actually work
 - can be just one, just two or all three
 - no report can be issued



Invalid HPV testing – sample adequacy control

- Internal Cellular control present for each sample
- To detect where NO material is present
- Crucial in a screening program



New era of cervical screening

- Self Collect testing now available at Douglass Hanly Moir
- Routine patient management relatively straight forward
- But occasional more complicated patient “first do no harm”
- Be mindful of issues associated with screening programs: false negatives, false positives
- Patients must be kept informed
- Importance of monitoring



Thank you

Acknowledgments:

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Machalek et al. Routine cervical screening using primary HPV testing in early observations from the national cervical screening program.

