PRESENTATION TITLE

NATIONAL CERVICAL SCREENING PROGRAM
2017

Presenter:  Dr Fiona Douglas
With very grateful thanks to: Dr Lynne Davies, Ms Alison Lang
and the NPS for original material which I have augmented
New 2016 Guidelines are live. Can be found at:  

The guidelines can be downloaded as a whole, or in shortened form that contains only the recommendations, using the links at the bottom of the guidelines home page.

A ‘Cervical cancer education module’ is now available, in advance of more detailed training modules that will be rolled out when they have been fine-tuned. This module is quite detailed and covers a number of scenarios.  
It can be found at:  
OTHER RESOURCES

This report is updated annually

_Women’s cancers and cancer screening in the Northern Territory_  Zhang X, Condon J, Douglas F, _et al._ NT Dept Health 2012
A current project will update this during 2017

Partner newsletters and updates are circulated periodically. Register to receive these using the email address below. Information is also posted on the website

OVERVIEW

- Screening program, not management and follow-up of abnormalities
- Context for the Renewal
- Prevention of HPV disease and cervical cancer
  - Primary and secondary prevention programs
- The renewed National Cervical Screening Program
  - The changes - HPV, testing and conceptual change
  - Particular issues
  - Practicalities
  - Challenges
CERVICAL CANCER - TYPES

- Squamous cell carcinomas form 68% of cervical cancers

- Adenocarcinomas (arising from glandular cells in the cervical canal) now make up ~22% of cervical cancers

- Adenosquamous and other cervical cancers make up the remaining 10%

- Some rare, aggressive cervical cancers don’t appear to have a pre-invasive stage.
  (eg: Small and large cell neuro-endocrine carcinoma, clear cell carcinoma).

CHANGE IN CANCER INCIDENCE BY TYPE

Figure 4.3: Incidence of carcinoma of the cervix (squamous cell carcinoma, adenocarcinoma, adenosquamous carcinoma and other carcinomas) in women aged 20–69, 1982 to 2012

Source: AIHW Australian Cancer Database 2012. Data for this figure are available in Table A6.3.
GROUPS AT HIGHER RISK OF CERVICAL CANCER

- Under-screened or never screened
- Older women
- Smokers
- Also
  - Immunosuppressed
  - Young age of 1st full term pregnancy
  - Higher number of full term pregnancies
  - DES-exposed in utero
  - Using OCP >= 5 years
THE LINK BETWEEN HPV AND CERVICAL CANCER

Persistent infection with oncogenic human papillomavirus (HPV)
Types 16 or 18 cause most cases of cervical cancer

- HPV transmitted through genital skin-to-skin or mucosa-to-mucosa contact
- HPV infections are transient and usually clear without intervention within 1-2 years
- HPV may also be latent (return later)
- High grade abnormalities (CIN 3) > 1/3 will progress to invasive cervical cancer within 10–20 years

Gravitt PE. J Clin Invest 2011;121:4593-9; Trottier H, Franco EL. Vaccine 2006;24:S4-S15
TYPE OF HPV AND RISK OF HIGH GRADE CERVICAL CHANGE

PREVENTING CERVICAL CANCER

- **PRIMARY PREVENTION** – prevents vaccine HPV types from infecting cells
  - **VACCINATION** – currently quadrivalent
    - HPV types 16, 18 plus two others that cause genital warts

- **SECONDARY PREVENTION** – early detection of HPV infection to enable effective treatment before malignant change

- **CERVICAL SCREENING**
  - Pap testing, or the new Cervical Screening Test (CST) from December 1
## NT HPV VACCINE COVERAGE BY DOSE NUMBER

### Aged 15 years in 2015 (born in 2000)

<table>
<thead>
<tr>
<th></th>
<th>Gardasil dose number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
</tr>
<tr>
<td>Aboriginal</td>
<td>88%</td>
</tr>
<tr>
<td>Neither Aboriginal nor TSI</td>
<td>105%</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td></td>
</tr>
<tr>
<td>Aboriginal</td>
<td>75%</td>
</tr>
<tr>
<td>Neither Aboriginal nor TSI</td>
<td>90%</td>
</tr>
</tbody>
</table>

Personal communication: Dr Ros Webby, National HPV Vaccination Register data as at 28 Feb 2017
HPV VACCINE EFFECT: HIGH-GRADE HISTOLOGY BY YEAR

Includes CIN2, CIN3, ungraded CIN; glandular dysplasia, AIS

Cervical screening in Australia 2014-15 AIHW 2016; NT CSR unpublished data, 2017
SCREENING - STILL ROOM FOR IMPROVEMENT?

High participation in screening is required for the NCSP to achieve its major objective of reducing cervical cancer incidence, morbidity and mortality

Current participation rates:

- 2-yearly ~58%
- 5-yearly ~83%

At present, 80% of Australian women with cervical cancer are lapsed or never screeners

% participation in cervical screening in the NT (age standardised)

GROUPS LIKELY TO BE UNDER SCREENED

- Aboriginal and Torres Strait Islander women
- Women living in areas of low socio economic status, rural or remote locations
- Older women
- Women from culturally and linguistically diverse (CALD) backgrounds
- Women with a history of sexual trauma and or domestic violence
- Women with disabilities
- Women who identify as lesbian, gay, bisexual, transgender or intersex (LGBTI)
- Transgender men
THE NEW PROGRAM

Video
BRAVE NEW WORLD – CONCEPTUAL CHANGES

- Screening tests can identify:
  - Early disease eg mammography and breast cancer screening
  - Pre-disease eg Pap test and cervical screening
  - Disease risk marker eg HPV test and cervical screening
- What is the new paradigm?
  - The new program will use two tests:
    - Primary test – the Cervical Screening Test (CST) that identifies a disease risk marker
    - Secondary test – a reflex liquid-based cytology (LBC) test that identifies pre-disease and determines clinical management
- What does this mean?
  - Screening results will be reported as a woman’s risk of developing significant cervical abnormalities within the next five years
### A SNAPSHOT OF THE CHANGES

<table>
<thead>
<tr>
<th>Program features</th>
<th>Current</th>
<th>Renewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary screening test</td>
<td>Pap test</td>
<td>HPV test</td>
</tr>
<tr>
<td>Reflex test</td>
<td>N/A</td>
<td>Liquid based cytology</td>
</tr>
<tr>
<td>Age range</td>
<td>18 to 69 years</td>
<td>25 to 74 years (with exit test)</td>
</tr>
<tr>
<td>Screening interval</td>
<td>Two yearly</td>
<td>Five yearly</td>
</tr>
<tr>
<td>Self-collection</td>
<td>No</td>
<td>Yes, for certain groups only</td>
</tr>
<tr>
<td>Screening results</td>
<td>Cervical...</td>
<td>Risk of significant cervical abnormalities</td>
</tr>
<tr>
<td>Invitation system</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Register</td>
<td>Jurisdictional</td>
<td>National*</td>
</tr>
</tbody>
</table>

It is estimated these changes will prevent an additional 140 cases of cervical cancer per year.
WHY HPV TESTING IS REPLACING PAP SMEARS

- A significant (15-20%) false-negative rate associated with Pap tests required more frequent screening to minimise failure to detect disease
- The negative predictive value of HPV with partial genotyping is >99% for significant cervical pathology within five years
- Compared with cytology, HPV testing provided 60–70% greater protection against invasive cervical cancers
- Significantly reduced incidence of adenocarcinomas when HPV testing is used (78% of these are due to HPV 16 & 18)
- Assigns risk of high-grade change based on detection of causative agent, rather than managing according to cell changes that are less specific for risk of cervical cancer

Renshaw AA, Lezon KM, Wilbur DC. Cancer Cytopathology 2001;93:106-10
Dr Guglielmo Ronco, Prof Joakim Dillner, MD, K Miriam Elfström, MPH, Sara Tunesi, PhD et al
Lancet 2014;383:524-32
AND WHY PARTIAL HPV GENOTYPING

WHAT ABOUT LIQUID-BASED CYTOLOGY?

- Reflex LBC will be used to triage samples that are positive for oncogenic HPV
- HPV testing with LBC triage has equal specificity and a higher positive predictive value for CIN2+ and CIN3+ compared with the Pap smear when considered across all age groups.
- Using triage reduces referrals to colposcopy compared with HPV testing alone
- LBC triage should minimise unnecessary follow-up procedures

COMMUNICATING THE NCSP CHANGES

Key Information

<table>
<thead>
<tr>
<th>HPV and cervical cancer</th>
<th>Changes from 1 December 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing an explanation about the link between <em>persistent</em> HPV infection and cervical cancer:&lt;sup&gt;5-8&lt;/sup&gt;</td>
<td><strong>Cervical screening will be based on HPV testing.</strong> Cells in the sample will be studied for changes only if HPV is detected.</td>
</tr>
<tr>
<td>▶ Explain that HPV infections are usually cleared by the immune system in 1–2 years.</td>
<td>The sample collection procedure will remain unchanged from the woman’s perspective.</td>
</tr>
<tr>
<td>▶ HPV is very common</td>
<td><strong>The age to start cervical screening is now 25 years,</strong> continuing until 74 years of age.</td>
</tr>
<tr>
<td>▶ If the infection persists, it can lead to development of cervical cancer in some women after about 10-15 years.</td>
<td>Screening will only be required once every 5 years for women who have <em>oncogenic HPV not detected.</em></td>
</tr>
<tr>
<td></td>
<td>Self-collection is now an option for a select group of under-screened and never-screened women.</td>
</tr>
</tbody>
</table>

**Note:** *Despite the new screening age range, any woman of any age with symptoms (bleeding, pain etc.) should have cervical testing included as part of the diagnostic work-up. Co-testing needs to be requested as this is not screening.*
HOW TO TAKE A QUALITY CERVICAL SAMPLE

Very good video available

Transformation zone is not always visible

Location of TZ & squamocolumnar junction is influenced by -

- Age
- Menopausal status

And may inform your choice of sampling instrument

WHAT TO WRITE ON LAB REQUEST FORMS

In the clinical information section

- Routine cervical screening
- Self-collected vaginal swab, never screened or not screened for yrs
- Test-of-cure after high-grade abnormality treated in (mm/ yyyy
- Investigation unexplained symptoms: IMB or PCB or specify other symptoms

In the tests requested section

- CST or HPV +/- reflex LBC or cervical screening test
- HPV test for cervical screening
- HPV & LBC co-test
- HPV & LBC co-test
WHAT PEOPLE ARE TALKING ABOUT

- Extending the screening interval
- Delaying the start of screening until age 25
- Self-collection for some women
- Raising the upper age limit to 74
- New national register to replace current state and territory ones
EXTENDING THE SCREENING INTERVAL

The screening interval for primary HPV testing with partial genotyping will be recommended every 5 years (ONLY from after the first screen with the new test)

Compared to Pap smears, a longer screening interval is appropriate for HPV testing because it has:

- Very high negative predictive value (>99%), allowing for a longer screening interval
- Improved longitudinal sensitivity: the sensitivity of 5-yearly HPV testing for low-grade cervical abnormalities (LSIL) or worse (86.4%) is similar to 3-yearly cytology testing (85.94%)
- Reduces over-diagnosis and over-treatment of abnormalities that would regress

ROUTINE SCREENING TO START AT 25

Based on the evidence, women will commence screening at 25 years:

- HPV infections are common and transient
- Common cervical abnormalities usually resolve spontaneously
- **HPV vaccination** has reduced serious cervical abnormalities, and will continue to do so
- Cervical cancer in young women is rare
- Screening before 25 has not impacted cervical cancer incidence or mortality rates
- Investigating and treating common abnormalities may lead to a greater risk of pregnancy complications later in life

CERVICAL CANCER IN AUSTRALIA BY AGE

NEW CASES (LEFT)
DEATHS (BELOW)


ROUTINE SCREENING TO START AT 25

Concerns about women who experienced early sexual debut

➢ There is no evidence that these women are at higher risk

➢ Provision for a **single** HPV test between the age of 20 and 25 if sexual debut was:

  ➢ At age < 14 years

  ➢ Prior to HPV vaccination

➢ ‘Eligible for early test’ potential phrase for pathology forms
**SELF-COLLECTED SAMPLE FOR PRIMARY TESTING**

This is a vaginal sample, not a cervical sample

*Only* certain never-screened or under-screened women are eligible:

- Aged 30 years or over, **and**
- Have declined a clinician-collected sample, **and**
  - Have never participated in the NCSP, **or**
  - Are overdue for cervical screening by 2 years or longer
- Performed in health facility that offers conventional screening (ie not at home)
- Specificity comparable with clinician-collected sample, but sensitivity a bit less

Because a self-collected sample is vaginal not cervical, women at intermediate risk will need to return for a clinician-collected sample for LBC
HIGHER PROGRAM EXIT AGE

- The upper target age for cervical screening will stay at age 69
- However women aged 70-74 can safely exit the program if they have a further negative HPV test during this time
- Cervical cancer incidence in women > 60 years has reduced substantially over time
- New cases of cervical cancer still occur in women aged 70 and over

NATIONAL CANCER SCREENING REGISTER (NCSR)

- Instead of the previous state- and territory-based Pap test registers, the Australian Government has established the National Cancer Screening Register (the Register) to support delivery of the renewed NCSP and bowel screening programs.

- For the first time, the Register will have one record for each participant regarding their participation in cervical and bowel cancer screening to allow for ease of data access for health professionals, pathology laboratories and women.

- Once implemented, women can opt off the Register at any time. This means they will no longer receive invitations to screen or follow-up correspondence from the Register.
NATIONAL CANCER SCREENING REGISTER (NCSR)

- Invitation-based prompting to participate in cervical screening
- Invitations will continue to invite non-screeners 5-yearly unless woman opts off
- Medicare enrolment data to identify and invite target population
- NCSR will often need to be used to determine whether and when a woman is due for a screen
- Complex protocols for correspondence
- Less likely to have women lost to follow-up
- Opt out policies and processes will be different
CORRESPONDENCE CYCLE

Eg 7 years after initial invite → REMINDER

Eg 5 years and 3 months after initial invite → REMINDER

Eg 4 years and 9 months after initial invite → INVITATION

Eg 3 month before due date → INVITATION

Eg 3 months after due date → REMINDER

Eg two years after due date → REMINDER
RESULTS AND FOLLOW-UP

- A valid screening test result prompts one of only three actions
- Most of the complexity is at the lab level
- A single result will be issued, giving the risk category and including result of HPV testing as well as LBC if that was indicated
- Lab result will recommend the next action according to the risk category
- ‘2016 guidelines’ will inform clinical management of abnormalities and testing for special groups
- Transitioning women to the new program
SCREENING RESULTS - THE SCREENING CLINICAL PATHWAY

Cervical screening pathway for asymptomatic women

[Diagram showing the screening pathway with Oncogenic HPV test with partial genotyping leading to outcomes such as Reflex LBC, Repeat HPV test in 12 months, and others with specific actions like Routine 5-yearly screening, Retest for LBC only within 6 weeks, and Referral for colposcopic assessment.]
SCREENING RESULTS – SELF-COLLECTION PATHWAY

Same principles, but minor adjustments
## SCREENING RESULTS – RECOMMENDATION FOR ACTION

Recommendations are based on RISK of significant cervical abnormality within 5 years

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low risk of significant cervical abnormality = population risk</td>
<td>Recall in 5 years for routine cervical screening.100</td>
</tr>
<tr>
<td>Intermediate risk</td>
<td>Return for a 12-month repeat HPV test and (if required) LBC test, to determine if the HPV infection has cleared.100</td>
</tr>
<tr>
<td>Higher risk</td>
<td>Refer for colposcopy and assessment.100</td>
</tr>
</tbody>
</table>
CLINICAL GUIDELINES – “2016 GUIDELINES”

- Comprehensive document – covers special populations and management of women with abnormalities
  - Available on line
  - Able to be updated between review periods
  - Covers screening in special populations (eg: women who are immune-compromised, DES-affected, or have had a hysterectomy) as well as management of screen-detected abnormalities

- Test-of-Cure retained

- Internet-based education & training modules
  - One module freely available on line now
  - Series training modules accredited for CPD are in final trial stages
TRANSITIONING WOMEN TO THE NEW NCSP

- The type of last screening test determines the interval when next screening test is due
  - Last test was a normal Pap – next screen due at 2 years
  - Last test was a low risk screening HPV – next screen due at 5 years

- Women in the screening pathway with a normal last Pap test
  - HPV test (CST) replaces Pap test for all eligible women
  - From 1 December 2017, all Pap tests are replaced by HPV testing
  - HPV test (CST) due 2 years after last negative Pap test
  - Reflex LBC performed on any HPV sample with oncogenic HPV (any type) detected
LOCAL CERVICAL FOLLOW-UP SYSTEMS

- Likely to be much more important in remote areas than in more urbanised areas
  - No postal delivery to many areas
  - No culture of letters as effective communication
  - Mobile phones can be disposable items
  - Recurrent short- and medium-term population mobility
- Pan-organisation electronic records, possibly with standardised care plans
- Opportunistic screening
- Community education and screening events
PRACTICE SOFTWARE

- Major suppliers working with Commonwealth to incorporate new cervical screening program
- NCSR will eventually be accessible from software
- Check your software supplier’s plans and tell them what you want
- Most reminder schedules for women currently being screened will not change, BUT
  - Under 23s will not need screening until 25 years
  - Exit testing for women 70-74 years
- New screening interval happens only after the first new cervical screening test result
CARE PLANS

- Current care plans, or minor modifications will need to remain for women currently in screening program.

- After 1 December, women whose last test was a Pap test will still be due for screening at 2 years (unless they were under 23 at the time of the test).

- Complex protocol of actions for new NCSR for these women, so type, timings and target of communications from the NCSR may differ significantly from those used by the current NT Cervical Screening Register.

- New care plans will need to be developed for women having a screening test after 1 December, based on the risk categories.
RULE OF THUMB FOR DECEMBER 1

START HERE

Woman's age on 1 December 2017

If under 25 years:
- If normal, on screening path
- If abnormality follow-up:
  - High grade: colposcopy/biopsy etc
  - Test-of-cure: timing is unchanged, but need to request HPV & LBC co-test for test-of-cure
  - Low-grade: HPV test at 12 months unless colposcopy recommended

If 25+ years:
- If no prior Pap:
  - Screening due now
- If prior Pap test:
  - Screening due 2 years after Pap test

If under 23 at time of Pap:
- Screening due 2 years after Pap test

If 23+ years at time of Pap:
- Normal, so on screening path

Prepared by Fiona Douglas
May 2017
When new program commences, there will be only three actions after a satisfactory screening test:

- **Low risk of significant cervical abnormality**: Recall in 5 years for routine cervical screening.
- **Intermediate risk**: Return for a 12-month repeat HPV test and (if required) LBC test, to determine if the HPV infection has cleared.
- **Higher risk**: Refer for colposcopy and assessment.

- The Test-of-Cure remains the same
- Exit testing for women between 70 and 74
Follow-Up Assistance

- NCSR will be directly accessible to practitioners through an internet portal, though not immediately after 1 December.
- Call centre phone lines will be in place by 1 December.
- NCSR will be the primary source of women’s test history and follow-up with women’s records amalgamated.
- NCSR will expect to include colposcopy results for the first time.
- Plan to target never-screened, especially older, women.
MEDICO-LEGAL ISSUES
Risk management

- You need to keep documented evidence of:
  - Discussions about screening, including risks and benefits
  - Woman’s response to that discussion
  - Clinical procedures
  - Informing woman of results, discussion about them and recommended follow-up actions
  - All correspondence regarding management and follow-up of abnormal results
WHAT DO WE DO NOW?

- Upskill staff and keep yourself informed – resources available September/October
- Identify target groups for screening within practice
- Encourage unscreened/under-screened women to have a Pap test now and then keep screening according to the new program
- Advise women about the change
  - Waiting room notices and pamphlets when available
  - Next test will be at the current 2 year screening interval if their most recent test was a Pap test – the 5 years does not kick in until AFTER the first new test
  - Warn under-23s about upcoming changes to their eligibility for screening
- Encourage cervical screening in pregnancy
- Continue STI screening in young people
IN SUMMARY

- New evidence based test
- New evidence based protocols
- More accurate
- Less harm
- Will free up woman’s time
- Will (eventually) free up clinicians’ time
COLLECTING A QUALITY SAMPLE

Video