What is it like practicing in Australia as a CytoScientist now that HPV primary screening program has been introduced?

Grace Tan

VCS Pathology

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Greetings from Melbourne's 6th lockdown

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Overview

- Introduction – Renewal
- Pre-Renewal
- Renewal
- Beyond Renewal

Renewal National Cervical Screening Program (NCSP)

- Commenced in 2011
- Review the policy and operation of the NCSP
- Report evaluation released and recommendations by MSAC in April 2014
- Interim Renewal Plan endorsed by AHMAC in September 2014
- Approval in 2015-16 Commonwealth Budget
- Implementation to start ~~1 May~~, delayed to 1 December 2017

Changes to the NCSP

NCSP	Pre-Renewal	Renewal
Primary Screening Test	Pap (Conventional/LBC)	HPV Nucleic Acid Testing Partial Genotyping (HPV 16/18)
Reflex	N/A	LBC (manual or image-read)
Age	18 - 69 years	25 - 74 years
Screening interval	2 years	5 years (3 years if immunosuppressed)
Co-testing	Test of cure	Test of cure Symptomatic DES-exposed
Self-collection	No	Yes (Under or never-screened women)
Register	State based	National

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Pre-Renewal

- Prior to 1 May
- Between 1 May to 1 December 2017

Preparation for Renewal – Prior to 1 May 2017

Pre-analytical

- Clinical Education
- Collection/Transport
- Specimen Triaging for testing
- Sharing of specimens between the Molecular and Cytology Laboratories

Preparation for Renewal – Prior to 1 May 2017

Analytical

- Equipment (Molecular)
  - HPV testing platforms – validation / verification of instruments
- Equipment (Cytology)
  - T5000 Autoloaders
  - TP Review Scopes
  - TP Image Processor
  - BD Surepath Prepmate
- Processes
  - Generate picklists for vial retrieval
  - Retrieve vials from the Molecular Laboratory after HPV testing
  - Using the LIS to track and trace the samples

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Preparation for Renewal – Prior to 1 May 2017

Post-analytical

- Storage of samples – 1 month post processing
- Disposal of samples
- Combined reporting
- Quality Assurance
  - Molecular – 2000 HPV tests per month
  - Cytology

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Preparation for Renewal – Prior to 1 May 2017

- Laboratory integration with NCSR
- Quality System
  - Documentation of new processes (pre to post analytical)
- Implementation of Workforce Plan
  - Preparing staff for Renewal
  - HR counselling
  - Cross-training to establish a pool of multi-skilled staff in all areas
  - Retention of skilled staff
  - Redundancy Plan

Pre-Renewal between 1 May to 1 December 2021

Challenges in the laboratory

- Workforce
  - 50 Scientists --> 40 Scientists (natural retention)
  - Contracted staff left to find permanent positions
  - Difficulty in recruiting new staff
  - Low morale – fear of losing job
  - Increased absenteeism
  - Increased TAT up to 2 – 3 weeks

Pre-Renewal between 1 May to 1 December 2021

Challenges in the laboratory

- 1 May 2017 – Government subsidy on medicare rebate for LBC to help reduce turnaround times
  - 95% conventional pap vs 5% LBC (1000 to 1500 samples a day)
  - Equipment
    - TP Autoloaders to handle the increased LBC samples
    - Review Scopes
    - TP Imaging System
  - Staff training on Review Scopes (50% staff performing TP)
    - Steep learning curve
    - Endocervical rates dropped – education on screening for endocervical component
    - Unsatisfactory rates increased
    - Lysis samples increased
  - Insufficient review scopes for all staff
    - Staff roster 4 hours each session
    - 6 to 10 am, 10 am to 2 pm, 2 to 6/8 pm
    - Staff not doing TP will screen conventional pap

Prior to 1 December 2017

Outcome of moving from pap to LBC

- November – 15% conventional pap versus 85% LBC
- All staff were trained to performed LBC
- TAT reduced to 4 days

Decision made to Go / No Go dependent on NCSR readiness

- Communication to staff on new laboratory structure for Renewal
- Redundancies
  - Staggered
  - First round application for voluntary redundancies
  - Spill and fill – application for available positions
  - Second round redundancies for unsuccessful applicants
- Retention of skilled staff (modelling for reduced test numbers in yrs 3-5)
- Multiskilling of staff

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Renewal Challenges

- Specimen Triage
  - Primary HPV – reflex cytology
  - Symptomatic co-tests
  - Test of cure
  - LBC only
  - Ineligible test requests from practitioners (requiring follow up phone calls, further education)
    - Conventional pap smears
    - Under 25 years old – NCSR reported more than 500 CST from under 25 performed per week
    - Co-test for asymptomatic patients, lack confidence in HPV testing
    - Invalid reasons for co-test – e.g. dyspaereunia, discharge, contact bleeding

Renewal Challenges

- Molecular → Cytology Laboratory
  - Sharing of specimens
  - Tracking of specimens between the laboratories
  - Identifying vials to enable easier retrieval for cytology
    - Colour coding of TP caps
      - LBC only
      - Positive HPV → Reflex cytology
      - Co-testing
      - Urgent
      - Other tests, e.g. Chlamydia / Gonorrhoea

Colour coding of TP vial caps

Urgent

CST + CT/NG

Co-test

Positive HPV

LBC only

CST + CT/NG
Aliquot taken

Co-test + CT/NG

Urgent – Positive HPV

Urgent LBC only

Co-test positive HPV

Repeat HPV

Renewal NCSP
– New management guidelines / Recommendations

Laboratory Information System (LIS) Implementation

- Transition from existing State/Territory Registers
  - NSWPTR – updated process
  - VCSR (VIC/SA) – until August 2019
- NCSR
  - Request for histories – not available on 1 December
  - Transmission of results – CST / Histology
  - Fully transitioned in August 2019

Renewal NCSP – New management guidelines / Recommendations

LIS Implementation

- Decision support system that relies on the history from the register ingested into LIS
- Rules for allocating test
  - Biopsy confirmed High Grade – TOC
  - Coded for symptomatic co-test
- Rules for reasons for HPV tests
- Rules for reasons for cytology tests
- Rules for suggested recommendations for reports

HPV test collection method	1 Practitioner-collected sample		2 Self-collected sample		
HPV test specimen site	0 Not stated	1 Cervical	2 Vaginal	3 Other gynaecological site	
Reason for HPV test	1 Primary screening HPV test	2 Follow-up HPV test (Repeat HPV test after intermediate risk result or unsatisfactory test)	3 Co-test i. Test of cure ii. Investigation of signs or symptoms iii. Other, as recommended in guidelines	4 Other	
HPV test result—oncogenic HPV [1]	U Unsatisfactory	0 Oncogenic HPV not detected	1 HPV 16/ 18 detected [2] i. Type 16 detected ii. Type 18 detected iii. Type 18/45 detected	2 Oncogenic HPV (not 16/18) detected[3] i. One or more of the following types detected: 31, 33, 45, 52, or 58 ii. One or more of the following types detected: 35, 39, 51, 56, 59, 66, or 68	
HPV test type [4]	1 Qiagen i. Hybrid Capture II	2 Roche i. cobas 4800 ii. cobas 6800 iii. cobas 8800	3 Abbott i. m2000 ii. Alinity m	4 Becton Dickinson i. Onclarity	5 Cepheid i. Xpert
	6 Hologic i. Cervista ii. Aptima	7 Seegene i. Anyplex	8 Genera i. PapType	9. Euroimmun i Euroarray	999 other

Specimen Type / Site, Reason for Cytology test

Cytology specimen type	A0 Not stated	A1 Conventional smear	A2 Liquid based specimen	A3 Conventional and liquid-based
Cytology specimen site	B0 Not stated	B1 Cervical	B2 Vaginal	B3 Other gynaecological site
Reason for cytology test	1 Reflex LBC cytology after detection of oncogenic HPV in primary screening HPV test	2 Cytology after detection of oncogenic HPV in self-collected sample	3 Reflex LBC after detection of oncogenic HPV in Follow-up HPV test	
	4 Cytology at colposcopy	5 Co-test i. Test of cure ii. Investigation of signs or symptoms iii. Other, as recommended in guidelines	6 Other	P Conventional Pap test to screen for cervical cancer precursors

Recommendation
0 No recommendation
1 Rescreen in 5 years
2 Rescreen in 3 years
3 Repeat HPV test in 12 months
4 Co-test in 12 months
5 Retest in 6 weeks
6 Refer for colposcopic assessment
7 Test taken at time of colposcopy, no recommendation
8 Discharge from program
9 Other management recommendation
S Symptomatic—clinical management required
P Rescreen in 2 years

Renewal NCSP
– New management guidelines / Recommendations

LIS Implementation

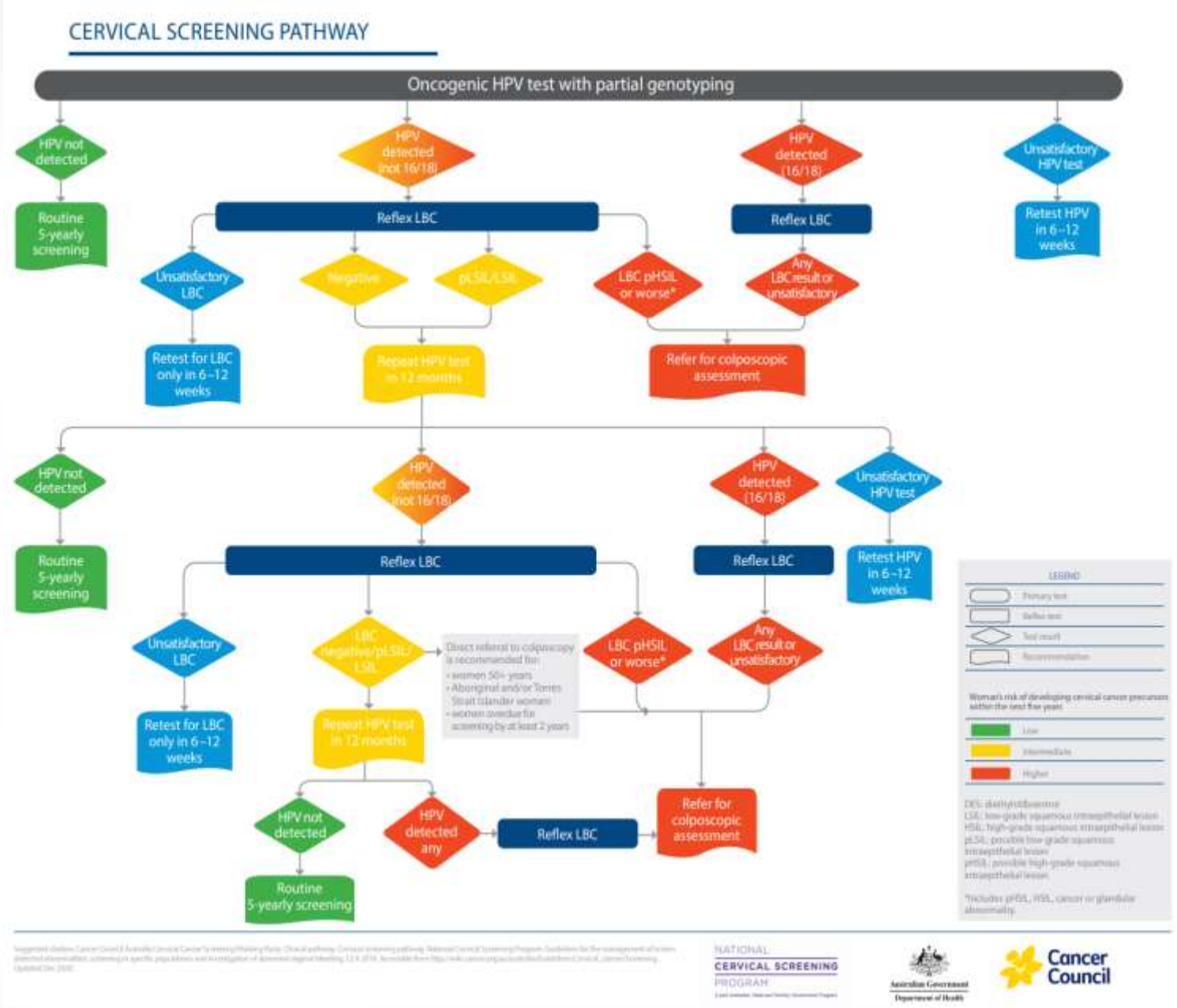
- Data Entry
  - Clinical coding to drive pathway for co-testing (clinical coding table)
    - PCB/PMB – co-testing
    - Suspicious cervix – co-testing
    - DES patients – co-testing
    - LBC only taken at colposcopy
    - Immune deficient to generate recommendation for 3 yearly repeat

Renewal – Cytology

- NPAAC requirements
  - CTASC, Trainees (4 years to obtain qualification)
  - 60 abnormal viewed per quarter
  - Productivity
    - Not > 70 LBC (manual)
    - Not > 150 (imaged assisted)

Renewal – Cytology

- Except for TOC, all cases reflexed to cytology are HPV positive and are therefore, diagnostic
- Known HPV result → Overscreening
- Not all positive HPV tests will be abnormal on cytology
- Approximately 40% - 60% are abnormal (LSIL and above)
- Knowledge of guidelines – Composite reporting combining both HPV and cytology test results with recommendations and risk categories


CERVICAL SCREENING PATHWAY
Oncogenic HPV test with partial genotyping
HPV not detected
Routine 5-yearly screening
HPV detected (not 16/18)
Reflex LBC
Unsatisfactory LBC
Retest for LBC only in 6–12 weeks
Negative
pLSIL/LSIL
Repeat HPV test in 12 months
LBC pHSIL or worse*
HPV detected (16/18)
Reflex LBC
Any LBC result or unsatisfactory
Refer for colposcopic assessment
Unsatisfactory HPV test
Retest HPV in 6–12 weeks
HPV not detected
Routine 5-yearly screening
HPV detected (not 16/18)
Reflex LBC
Unsatisfactory LBC
Retest for LBC only in 6–12 weeks
LBC negative/pLSIL/LSIL
Repeat HPV test in 12 months
Direct referral to colposcopy is recommended for:
• women 50+ years
• Aboriginal and/or Torres Strait Islander women
• women overdue for screening by at least 2 years
HPV not detected
Routine 5-yearly screening
HPV detected any
Reflex LBC
Refer for colposcopic assessment
LBC pHSIL or worse*
HPV detected (16/18)
Reflex LBC
Any LBC result or unsatisfactory
Unsatisfactory HPV test
Retest HPV in 6–12 weeks
LEGEND
Primary test
Reflex test
Test result
Recommendation
Woman's risk of developing cervical cancer precursors within the next five years
Low
Intermediate
Higher
DES: diethylstilbestrol
LSIL: low-grade squamous intraepithelial lesion
HSIL: high-grade squamous intraepithelial lesion
pLSIL: possible low grade squamous intraepithelial lesion
pHSIL / possible high-grade squamous intraepithelial lesion
*Includes pHSIL, HSIL, cancer or glandular abnormality
NATIONAL CERVICAL SCREENING PROGRAM
Australian Government Department of Health
Cancer Council

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LEVEL 6 176 WELLINGTON PARADE
EAST MELBOURNE VIC 3002

Report No: 17V700780
EXAMPLE, ANN
DOB: 01/01/1980
Ref No: -
265 FARADAY STREET
CARLTON VIC 3053
Collected: 21/04/2017
Received: 21/04/2017
Printed: 27/04/2017

LOW RISK

CERVICAL SCREENING	**Low risk**
SPECIMEN	Cervical - PreservCyt Solution
TEST RESULTS	PCR for oncogenic HPV and genotype: HPV 16 - Not Detected HPV 18 - Not Detected HPV (not 16/18) - Not Detected
RECOMMENDATION	**Rescreen in five years**

A/Prof Marion Saville Director 21/04/2017

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Report No: 17V700785
EXAMPLE, ANN
DOB: 01/01/1980
Ref No: -
265 FARADAY STREET
CARLTON VIC 3053
Collected: 21/04/2017
Received: 21/04/2017
Printed: 27/04/2017

INTERMEDIATE RISK

CERVICAL SCREENING **Intermediate risk**

SPECIMEN Cervical - PreservCyt Solution

TEST RESULTS

PCR for oncogenic HPV and genotype:
HPV 16 - Not Detected
HPV 18 - Not Detected
HPV (not 16/18) - Not Detected

Liquid based cytology (LBC), Image Assisted:
NEGATIVE
There is no evidence of a squamous intraepithelial lesion or malignancy.
Endocervical component: Present.

RECOMMENDATION **Repeat test in 12 months**

A/Prof Marion Saville Director 21/04/2017

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Report No: 17V700781
EXAMPLE, ANN
DOB: 01/01/1980
Ref No: -
265 FARADAY STREET
CARLTON VIC 3053
Collected: 21/04/2017
Received: 21/04/2017
Printed: 27/04/2017

INTERMEDIATE RISK

CERVICAL SCREENING	**Intermediate risk**
SPECIMEN	Cervical - PreservCyt Solution
TEST RESULTS	PCR for oncogenic HPV and genotype: HPV 16 - Not Detected HPV 18 - Not Detected HPV (not 16/18) - Detected Liquid based cytology (LBC), Image Assisted: Low-grade squamous intraepithelial lesion Endocervical component: Present.
RECOMMENDATION	**Repeat test in 12 months**

A/Prof Marion Saville Director 21/04/2017

DR GENERAL PRACTITIONER
MEDICAL CLINIC
LEVEL 6 176 WELLINGTON PARADE
EAST MELBOURNE VIC 3002

Report No: 17V700770
EXAMPLE, ANN
DOB: 01/01/1980
Ref No: -
265 FARADAY STREET
CARLTON VIC 3053
Collected: 21/04/2017
Received: 21/04/2017
Printed: 27/04/2017

HIGHER RISK

CERVICAL SCREENING	**Higher risk**
SPECIMEN	Cervical - PreservCyt Solution
TEST RESULTS	PCR for oncogenic HPV and genotype: HPV 16 - Detected HPV 18 - Not Detected HPV (not 16/18) - Not Detected Liquid based cytology (LBC), Image Assisted: High-grade squamous intra-epithelial lesion Endocervical component: Present.
RECOMMENDATION	**Refer to Colposcopic Assessment**

A/Prof Marion Saville Director 27/04/2017

NCSP Program Assurance Measures (PAM)

- PAM 1 – Unsatisfactory HPV and LBC
- PAM 2a – CST/Primary screening (Low, Intermediate, High risk)
- PAM 2b – Other/co-testing (Low, Intermediate, High risk)
- PAM 3a – % LBC specimens reported as HSIL with confirmed HSIL, AIS or cervical malignancy (within 6 months)
- PAM 3b – % LBC specimens reported as possible HSIL with confirmed HSIL, AIS or cervical malignancy (within 6 months)
- PAM 4 – % women with histological diagnosis of HSIL, AIS or cervical malignancy which were originally reported as low risk with a primary screening HPV NAT within the last 63 months

Internal Quality Measures

- 60 abnormal cases per quarter
- Internal 10 slide unknown sets
- Unsatisfactory rates
- Endocervical rates
- Correlation of LBC results with histology
- Review of negative cases with confirmed HG biopsies
- Circulation of interesting cases
- > 65% Concordance with pathologists
- Individual Proficiency Testing (RCPA QAP)?
- ASC CEC

Beyond Renewal

- NCSR – Issues resolved
  - Complete histories including colposcopy results
  - Incorrect recall of patients
- Cytology workforce
  - Reduced – 16 Cytologists (PT/FT)
  - Sustainability of cytology triage in the longer term is uncertain
  - Challenges in recruiting new staff
  - Years 3-5 reduced HPV testing and cytology workload

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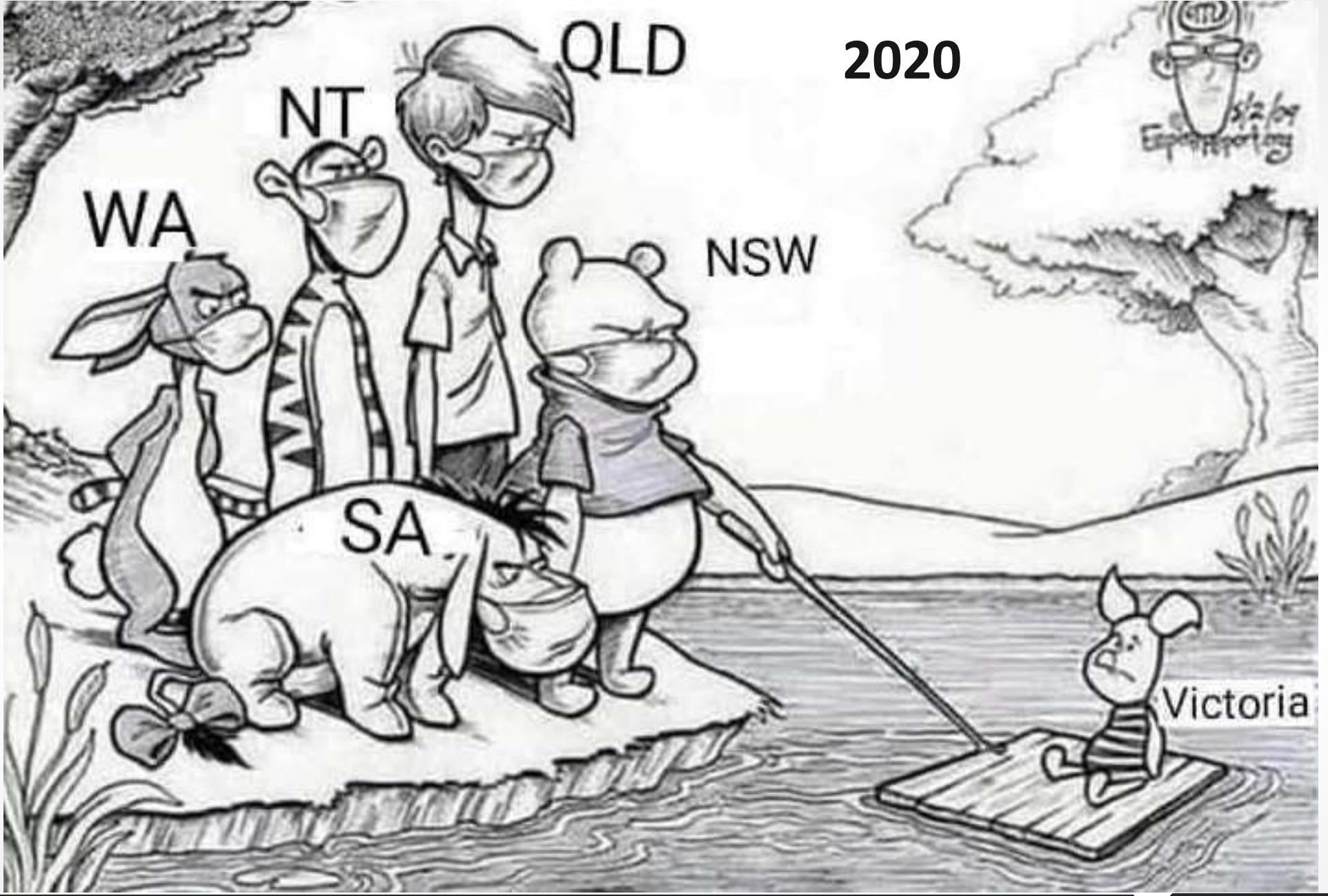
Beyond Renewal – 2020 / 2021

COVID-19 pandemic

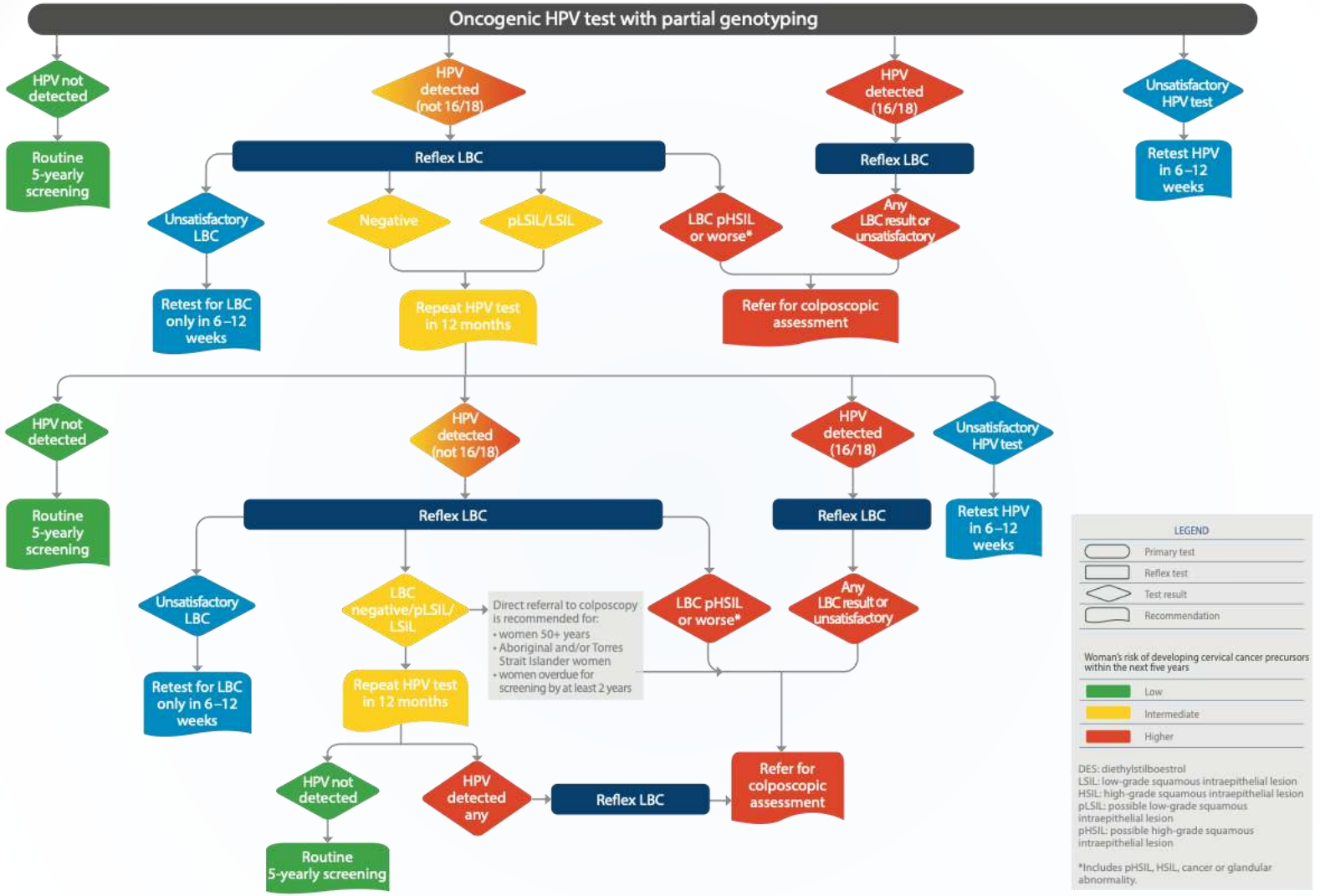
- Split Team roster arrangement
- 50% drop in CST -> fewer cytology cases
- Cytology staff redeployed to other duties – e.g. trained in phone calls, data entry, clinical coding
- Research – Dual stained cytology
- Multiskilling – Histology and Cytology preparation
- Quality – Audits
- Resilience in adapting to changes and learning new skills


2020
QLD
NT
WA
NSW
SA
Victoria

Beyond Renewal – 2021

- Updated NCSP Clinical Management Guidelines on women with intermediate risk
  - Following review of NCSP data for first 2 years
  - Effective 1 February 2021
  - Communication to staff
  - Communication / Education for healthcare providers
  - Update brochures / information on website
  - Update LIS to generate correct recommendation

CERVICAL SCREENING PATHWAY



Suggested citation: Cancer Council Australia Cervical Cancer Screening Working Party. Clinical pathway: Cervical screening pathway. National Cervical Screening Program: Guidelines for the management of screen detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. CCA 2016. Accessible from http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening. Updated Dec 2020.

NATIONAL CERVICAL SCREENING PROGRAM
A joint Australian, State and Territory Government Program

Australian Government Department of Health

Cancer Council

VCS Pathology

Future – Role of Cytoscientists

- No longer just screening
- Resilience to adapt to changes
- Multiskilling
  - Histology / Cytology
  - Molecular
  - Administrative duties
    - Phone calls
    - Histology coding
    - Quality
    - Audits
    - IT – user acceptance testing


PROTECT

Acknowledgements

- Professor Marion Saville
- Assoc Prof David Hawkes
- Staff at VCS Pathology

Thank you