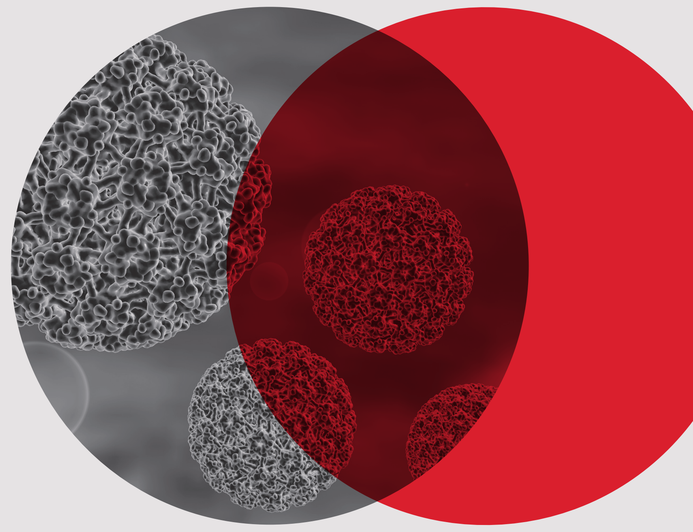
External quality assurance within the renewed National Cervical Screening Program – a preliminary analysis



Janelle Greaves, Elizabeth Phillips, Julia Pagliuso

The Royal College of Pathologists of Australasia Quality Assurance Programs Pty Ltd, St Leonards, NSW, Australia

Background

In December 2017 the National Cervical Screening Program (NCSP) transitioned from a two yearly morphology based screening test to a five yearly human papillomavirus (HPV) screening test with partial HPV genotyping and reflex liquid based cytology (LBC) triage. The renewal of the NCSP was based on recommendations by the Australian Medical Services Advisory Committee (MSAC) and founded on current evidence and best practice.

Objective

The Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) is committed to assisting Australian laboratories during the implementation of the new cervical screening test by providing timely feedback and peer review of Cervical Screening Test Result (CSTR) submissions to help identify areas of variable or poor performance in an external quality assurance (EQA) setting.

Methods

From 2018 ThinPrep and SurePath modules have been modified for Australian laboratories to align with the requirements of the renewed Australian cervical screening program. Each survey case now includes partial HPV genotyping together with clinical history. All case scenarios and target responses have been determined by members of the RCPAQAP Cytopathology Advisory Committee and all high grade abnormalities histologically confirmed. Participants are required to provide a CSTR according to Cancer Council Australia's National Cervical Screening Program: Guidelines for the Management of Screen-detected Abnormalities, Screening in Specific populations and investigation of abnormal vaginal bleeding[1].

Analysis was performed on participant submissions across the first two surveys of 2018, with responses triaged against morphology, clinical history, partial HPV genotyping and CSTR. The group response for each liquid based module was assessed against the target morphology and the target CSTR risk category. The RCPAQAP compared the outcomes of participant responses based on morphology as determined by the RCPAQAP 'Classification of Diagnostic Codes' with the CSTR as determined by the current guidelines[1].

Results

A total of four hundred and forty responses were analysed (ThinPrep n=330, SurePath n=110). For the purpose of this analysis, each LBC module was further divided into 'routinely reporting' and 'not routinely reporting' laboratories. The ThinPrep module returned an incorrect CSTR in 41 cases (12%) from 24 of the 33 enrolled participants (Table 1).

Table 1. Incorrect CSTR submission – Thinprep

Reporting status	Correct morphology	Incorrect morphology	Total
Laboratories routinely reporting	24	6	30
Laboratories NOT routinely reporting	10	1	11
TOTAL	**34**	**7**	**41**

The SurePath module returned an incorrect CSTR in 5 cases (4.5%) from 3 of the 11 enrolled participants (Table 2).

Table 2. Incorrect CSTR submission – SurePath

Reporting status	Correct morphology	Incorrect morphology	Total
Laboratories routinely reporting	3	2	5
Laboratories NOT routinely reporting	0	0	0
TOTAL	**3**	**2**	**5**

Comparison of target response rates showed variation between morphology and the equivalent CSTR. This was more evident where clinical histories indicated symptoms and previous low grade abnormality, and reflex liquid based preparations were unsatisfactory for assessment. (Tables 3–5). Clinical scenarios falling outside of the *cervical screening pathway* and the threshold criteria for 'symptomatic patients'
with subsequent LBC co-testing has been highlighted as an area of confusion for some participants. Case scenarios highlighted in **bold** indicate an incorrect morphological target response potentially impacting the corresponding CSTR. The target morphology and participant morphology responses have been omitted from this data as the gynaecological program is modelled around a rotation of 20 clinical scenarios throughout 4 surveys per year (5 cases per survey). All case scenarios have not been assessed by all participants at this stage.

Participant responses assessed against the RCPAQAP 'Classification of Diagnostic Codes' produced a major error rate of 1.8% (n=8) across combined ThinPrep and SurePath modules (Table 6). Of the 8 major errors, 4 participants returned a target CSTR, 3 returned an incorrect CSTR and one participant did not provide a CSTR. Comparison of the variable response rates between the submitted CSTR and the diagnostic code is of concern for future EQA assessment. The RCPAQAP Cytopathology Advisory Committee have agreed participants will continue to be solely assessed against diagnostic codes for 2018 with future assessment protocols to be developed.

In response to the variability of CSTR responses, the RCPAQAP distributed a SurveyMonkey™ to gather additional data across a further 15 case scenarios. The SurveyMonkey™ was distributed to all enrolled Australian laboratories routinely reporting gynaecological cytology. Participation by all validating laboratory personnel was encouraged, however not mandatory and not part of RCPAQAP assessment. The analysis from the SurveyMonkey™ is provided in an additional poster.

Table 3. ThinPrep – laboratories routinely reporting

Clinical details	HPV partial genotyping	Target CSTR	Participant CSTR	Response Number
Oncogenic HPV 1 year ago	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	7
Previous LSIL	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	5
Oncogenic HPV 12/12 ago	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	3
Routine	Oncogenic HPV (not 16/18) detected	UNSATISFACTORY	INTERMEDIATE	3
IMB	Oncogenic HPV not detected	LOW	HIGHER	2
Routine	HPV 16/18 detected	HIGHER	UNSATISFACTORY	2
PCB	Invalid result	UNSATISFACTORY	No risk category given for women with signs/ symptoms.	1
PMB	Oncogenic HPV not detected	HIGHER	No risk category given for women with signs/ symptoms.	1
IMB	**Oncogenic HPV (not 16/18) detected**	**HIGHER**	**NON-CERVICAL**	**1**
Oncogenic HPV 12/12 ago	**Oncogenic HPV (not 16/18) detected**	**HIGHER**	**INTERMEDIATE**	**1**
Routine	**Oncogenic HPV (not 16/18) detected**	**HIGHER**	**INTERMEDIATE**	**1**
Routine	**Oncogenic HPV (not 16/18) detected**	**HIGHER**	**INTERMEDIATE**	**1**
Routine	**Oncogenic HPV (not 16/18) detected**	**HIGHER**	**INTERMEDIATE**	**1**
Routine	**Oncogenic HPV (not 16/18) detected**	**UNSATISFACTORY**	**INTERMEDIATE**	**1**
TOTAL				30

Table 4. ThinPrep - laboratories not routinely reporting

Clinical details	HPV partial genotyping	Target CSTR	Participant CSTR	Response Number
Oncogenic HPV 1 year ago	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	2
Previous LSIL	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	2
Oncogenic HPV 12/12 ago	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	2
PMB	Oncogenic HPV not detected	NON-CERVICAL	HIGHER	1
PMB	Oncogenic HPV not detected	NON-CERVICAL	LOW	1
PMB	Oncogenic HPV not detected	HIGHER	LOW	1
Routine	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	1
IMB	**Oncogenic HPV not detected**	**LOW**	**HIGHER**	**1**
TOTAL				11

Table 5. SurePath - laboratories routinely reporting

Clinical details	HPV partial genotyping	Target CSTR	Participant CSTR	Response Number
Oncogenic HPV 1 year ago	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	1
Previous LSIL	Oncogenic HPV (not 16/18) detected	HIGHER	INTERMEDIATE	1
Routine	Oncogenic HPV (not 16/18) detected	UNSATISFACTORY	INTERMEDIATE	1
Routine	**Oncogenic HPV (not 16/18) detected**	**HIGHER**	**INTERMEDIATE**	**1**
Routine	**Oncogenic HPV (not 16/18) detected**	**UNSATISFACTORY**	**INTERMEDIATE**	**1**
TOTAL				5

Table 6. Combined ThinPrep / Surepath morphology - Major error / Unacceptable responses*

Reporting status	Participant No.	Major error No.	Unacceptable No.
Laboratories routinely reporting	12	5	12
Laboratories NOT routinely reporting	3	3	2
TOTAL	**15**	**8**	**14**

* Major error: A significant deviation from the panel diagnosis that may have a significant adverse effect on patient management.
Unacceptable: A response which is considered to be a significant deviation from the panel diagnosis but not a major error.

Conclusion

An initial analysis of the submitted CSTR for the first two EQA surveys of 2018 has highlighted areas of variable performance, particularly across selected clinical scenarios. Further clarification and understanding of the guidelines[1] is required to ensure the correct CSTR is consistently reported to referring practitioners from all pathology providers. This preliminary analysis has highlighted some areas for clarification:

1. In which clinical scenarios are risk categories deemed applicable?
2. The term 'symptomatic' requires further definition to ensure 'reflex testing' or 'co-testing' is appropriately applied to case episodes.
3. Clinical scenarios falling outside the cervical screening pathway

Similarly, the RCPAQAP must ensure all future clinical histories and HPV partial genotyping provided with EQA survey material is clear and concise, with LBC identified as a co-test or reflex test. This will assist participants to more accurately report the CSTR.

Participant responses will continue to be assessed against the morphological classification as determined by the RCPAQAP 'Classification of Diagnostic Codes' with the target CSTR provided in Final Survey Reports for educational purposes only at this stage. The RCPAQAP will continue to monitor the performance of Australian laboratories during the implementation of the renewed NCSP and provide timely feedback. A more comprehensive analysis will be provided at the end of 2018 when all enrolled participants have submitted responses for all 20 case scenarios.

References

1 https://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening

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