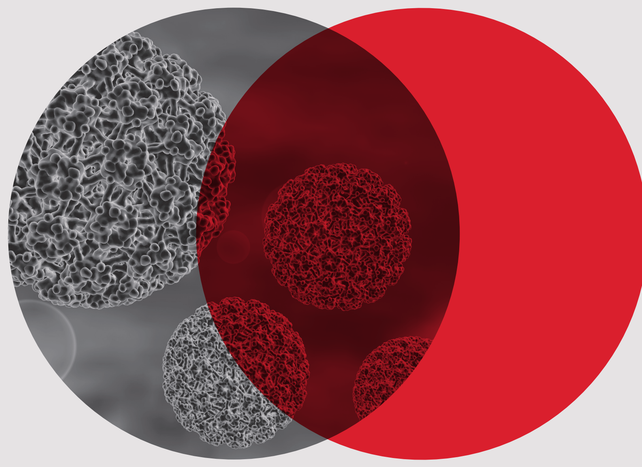
RCPAQAP Cervical Screening Test Result Survey



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Background

Analysis was performed on participant submissions of Cervical Screening Test Result (CSTR) across the first two surveys of 2018. The analysis for these surveys is provided in an additional poster. The analysis highlighted areas of variable performance, particularly across selected clinical scenarios. In response to the variability of CSTR responses, the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) distributed a SurveyMonkey™ to gather additional data across a further 15 case scenarios.

Objective

To provide a review of CSTR submissions from Australian participants external to the RCPAQAP External Quality Assurance program with the goal to test various facets of the *Guidelines for the management of screen-detected Abnormalities, Screening in Specific populations and investigation of abnormal vaginal bleeding*[1] and to provide timely and educational feedback to cytology laboratories reporting within the renewed National Cervical Screening Program implemented on 1st December 2017.

Methods

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. Participants were provided with clinical notes, partial human papilloma virus (HPV) genotyping result and cytomorphology result for fifteen cervical screening test scenarios and were asked to provide a CSTR in the categories of low, intermediate and higher risk for significant cervical abnormality, unsatisfactory for evaluation or other which allowed a free-text response. Analysis was performed against the target CSTR risk category as determined by the RCPAQAP Cytopathology.

Results

Twenty-five participants of the survey were from laboratories that primarily performed cervical cancer screening, two participants were from laboratories that primarily assessed liquid based cytology (LBC) preparations of patients being managed by a gynaecologist and six participants performed both types of assessment. The CSTR responses from thirty-three individuals for each of the fifteen cervical screening test scenarios were analysed. The RCPAQAP notes the reference to 'Reflex' cytology in most scenarios should have been more appropriately described as 'Co-test' and this terminology has been rectified for feedback purposes. Variation in CSTR was evident for all fifteen cases. Most variation was seen where clinical histories indicated symptoms and previous low-grade abnormality, non-cervical malignancy and reflex liquid based preparations were unsatisfactory for assessment (Table 1).

Recommendations

To extend *Guidelines for the management of screen-detected Abnormalities, Screening in Specific populations and investigation of abnormal vaginal bleeding*[1] to include co-test and non-screening scenarios in Table 3.2 Reporting of cervical screening result and to include co-test and symptomatic examples in the Sample cervical screening reports supplement. To extend the intermediate risk category recommendation to include co-test for test of cure and previous adenocarcinoma in situ scenarios.

Conclusions

Analysis of the submitted CSTR for the SurveyMonkey™ has re-affirmed the large variability between participants across various clinical scenarios. Inconsistencies between laboratories would result in confusion amongst clinicians and variable management of patients.

Further education or guideline enhancements may be required to harmonise laboratory practice. It should be noted the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for Laboratories Reporting Tests for the National Cervical Screening Program (First Edition 2017)* are currently under review. A/Prof Marion Saville and Prof Ian Hammond are also working to identify a process whereby clarifications to the *Guidelines for the management of screen-detected Abnormalities, Screening in Specific populations and investigation of abnormal vaginal bleeding*[1] can be made with regards to non-screening episodes and symptomatic thresholds.

Participant enquiries may be sent to the RCPAQAP cytopathology@rcpaqap.com.au for consideration by guideline co-authors. The RCPAQAP will delay the assessment of participant CSTR and continue to monitor the performance of Australian laboratories closely and provide timely feedback.

Table 1. Participant SurveyMonkey™ results

Scenario	Participant Responses: Low	Inter	Higher	Unsat	Other	Total Responses	Target CSTR
Clinical notes: 42 years old. PCB. **HPV DNA test result:** Oncogenic HPV types not detected. **Cytology result:** Negative, endocervical cells present.	26				7 — 6 responses: Low risk but symptomatic requires investigation. 1 response: No risk assigned (symptomatic).	33	**No risk assigned** (Investigation of abnormal bleeding)
Clinical notes: 52 years old. Test of Cure last year. First followup. **HPV DNA test result:** Oncogenic HPV types (not 16/18) detected. **Cytology result:**Negative, endocervical cells present.	1	25	3		4 — 4 responses: No risk assigned (ToC).	33	**Intermediate risk** Refer to Flowchart 10.1[1]. Co-test in 1 year.
Clinical notes: 32 years old. Previous LSIL. **HPV DNA test result:** Oncogenic HPV types not detected. **Cytology result :** Negative, endocervical cells present.	32	1				33	**Low risk** Refer to Flowchart 20.1[1]
Clinical notes: 42 years old. Previous biopsy confirmed AIS. **HPV DNA test result:** Oncogenic HPV types not detected. **Cytology result :** Negative, endocervical cells present.	4	21	3		5 — No risk assigned (annual co-test)	33	**Intermediate risk** Refer to Flowchart 11.4[1] No risk assigned acceptable Co-test in 1 year.
Clinical notes: 28 years old. Previous LSIL. **HPV DNA test result:** Oncogenic HPV types (not 16/18) detected. **Cytology result :** Low grade squamous intraepithelial lesion.		12	21			33	**Higher risk** Refer to Flowchart 20.1[1]
Clinical notes: 25 years old. History of CIN3 **HPV DNA test result:** Oncogenic HPV types (not 16/18) detected. **Cytology result:** Low grade squamous intraepithelial lesion.		26	4		3 — 2 responses: No risk assigned (ToC). 1 response: History too vague, could be Higher or Intermediate.	33	**Intermediate risk** Refer to Flowchart 10.1[1]. Co-test in 1 year.
Clinical notes: 42 years old. Biopsy CIN3. **HPV DNA test result:** Oncogenic HPV types 16/18 detected **Cytology result :** Unsatisfactory		1	31	1		33	**Higher risk** Refer to Flowchart 10.1[1]
Clinical notes: 68 years old. PMB. **HPV DNA test result:** Oncogenic HPV types not detected. **Cytology result:** Endocervical adenocarcinoma.			29		4 — Malignant/abnormal finding	33	**Higher risk*** Refer to Table 3.2[1]
Clinical notes: 33 years old. IMB. **HPV DNA test result:** Oncogenic HPV types not detected. **Cytology result:** Low grade squamous intraepithelial lesion.	5	22	1		5 — 3 responses: Intermediate risk but requires further investigation. 2 responses: Refer for gynaecological assessment.	33	**No risk assigned** (Investigation of abnormal bleeding)
Clinical notes: 26 years old. PCB. **HPV DNA test result:** Test not completed for technical reasons. **Cytology result:** Unsatisfactory.				32	1 — Specialist referral due to symptoms.	33	**Unsatisfactory**
Clinical notes: 65 years old. PMB. **HPV DNA test result:** Oncogenic HPV types not detected. **Cytology result:** Endometrial adenocarcinoma.	5		6	1	21 — 15 responses: Malignant/Abnormal/Non-cervical abnormaility. 3 responses: No risk assigned. 1 response: Higher Risk. 1 response: Low risk. 1 response: Refer to specialist.	33	**No risk assigned** (Investigation of abnormal bleeding) Must be flagged as abnormal result requiring follow-up.
Clinical notes: 33 years old. Oncogenic HPV 1 year ago. **HPV D NA test result:** Oncogenic HPV types (not 16/18) detected. **Cytology result:** Low grade squamous intraepithelial lesion.		5	27			32	**Higher risk** Refer to Table 3.2[1]
Clinical notes: 55 years old. PCB. **HPV DNA test result:** Invalid result **Cytology result:** Negative, endocervical cells absent.			1	32		33	**Unsatisfactory**
Clinical notes: 35 years old. Previous LSIL. Concurrent biopsy -result pending. **HPV DNA test result:** Oncogenic HPV types (not 16/18) detected. **Cytology result:** Negative, endocervical cells present.		7	24		2 — No risk assigned.	33	**No risk assigned** LBC taken at the time of of colposcopy is not considered a screening test, but rather a part of the assesement process. Accordingly, an over-arching cervical screening report incorporating a risk statement is not required or appropriate in this setting. Refer Chapter 3[1]
Clinical notes: 25 years old. Routine. **HPV DNA test result:** Oncogenic HPV types (not 16/18) detected. **Cytology result:** Unsatisfactory.		12		21		33	**Unsatisfactory**

**In this scenario, No risk assigned (based on symptomatic management) would also be acceptable.*

Clinical notes: 52 years old. Test of cure last year. First followup.
HPV DNA test result: Oncogenic HPV types (not 16/18) detected.
Cytology result: Negative, endocervical cells present.

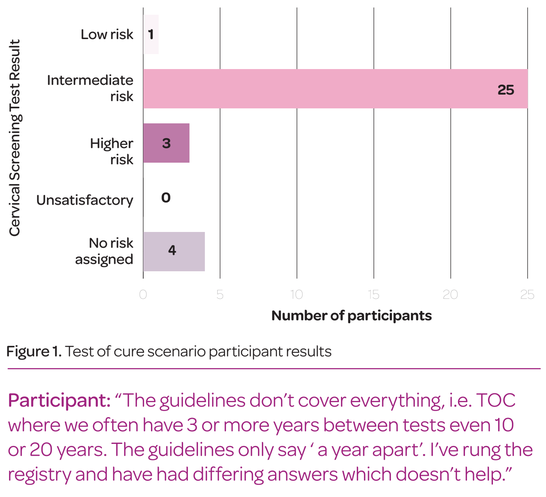

Figure 1. Test of cure scenario participant results

Participant: "The guidelines don't cover everything, i.e. TOC where we often have 3 or more years between tests even 10 or 20 years. The guidelines only say ' a year apart'. I've rung the registry and have had differing answers which doesn't help."

Test of Cure

Test of Cure* is considered part of the screening pathway. HSIL needs to be biopsy-confirmed to be on the Test of Cure pathway. Participant discrepancy is illustrated in one scenario (Figure 1).

Incomplete Test of Cure / Any combination of HPV (16/18) or pHSIL+	HIGHER RISK
Incomplete Test of Cure / Any combination of HPV (not 16/18) or pLSIL+	INTERMEDIATE RISK
Incomplete Test of Cure / Negative co-test	INTERMEDIATE RISK
Complete Test of Cure (two negative co-tests)	LOW RISK

It is noted that the guidelines require clarification in the screen-detected abnormalities pathway to include the Test of Cure subset of co-tests. The intermediate risk category in this scenario should align with a recommendation of repeat co-test in 12 months. Currently the recommendation for the intermediate risk category is solely for a repeat HPV test in 12 months.

**Test of Cure = Two negative co-tests at least a year apart. Test of Cure does not need to be restarted if >1 year.*

Clinical notes: 33 years old. IMB.
HPV DNA test result: Oncogenic HPV types not detected.
Cytology result: Low grade squamous intraepithelial lesion.

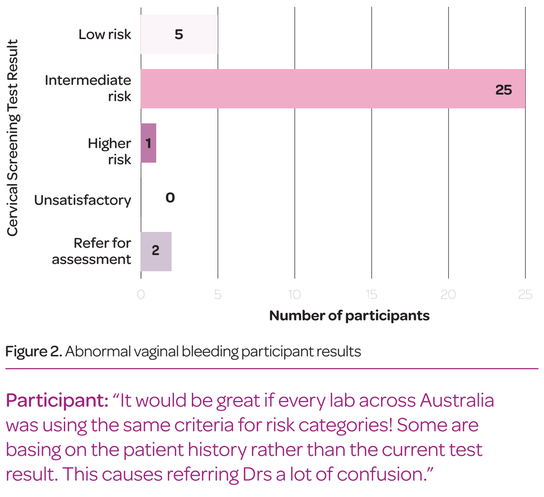

Figure 2. Abnormal vaginal bleeding participant results

Participant: "It would be great if every lab across Australia was using the same criteria for risk categories! Some are basing on the patient history rather than the current test result. This causes referring Drs a lot of confusion."

Abnormal vaginal bleeding

Women with symptoms such as abnormal vaginal bleeding are investigated outside of the screening pathway as a co-test. Participant discrepancy is illustrated in one scenario (Figure 2).

- Persistent post-coital bleeding, unexplained intermenstrual and post-menopausal bleeding require a co-test as initial investigation and referral for gynaecological assessment.
- Post-coital bleeding with co-test result of HPV detected and/or abnormal LBC requires referral for gynaecological assessment.
- Single episode of post-coital bleeding (pre-menopausal women) with negative co-test and clinically normal cervix does not require colposcopy.

The majority of these scenarios will have **'No risk assigned'** and referral for gynaecological assessment. Follow-up will depend on colposcopy and any histology results.

It is noted the guidelines require clarification in the abnormal clinical history scenarios and improved definitions of symptomatic thresholds. It is also noted the RCPAQAP target CSTRs were incorrect for these scenarios in 2018. These will be amended for 2019.

Acknowledgements

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References

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