The Royal College of Pathologists of Australasia
ABN 52 000 173 231

Durham Hall 207 Albion Street Surry Hills NSW 2010 Australia
Telephone 61 2 8356 5858 Facsimile 61 2 8356 5828

RCPA
The Royal College of Pathologists of Australasia

Guideline

Subject:	**Managing cervical cytology performance measures in the transition period to the renewed Australian National Cervical Screening Program**
Approval Date:	April 2019
Review Date	April 2020 (and annually until rescinded)
Review By	Cytopathology Committee
Number:	3/2019

Background
The renewed Australian National Cervical Screening Program (NCSP) began on 1 December 2017*, bringing an end to cervical cytology using the Papanicolaou (Pap) smear as the primary screening test for cervical neoplasia. The quality assurance of the pre-renewal test was underpinned by the NPAAC Performance Measures for Cervical Cytology and the NATA RCPA Laboratory Accreditation Program. These measures rely on prospectively collected follow-up data and still have to be completed for Pap smears taken up to 1 December 2017. This document aims to provide guidance to laboratories providing Performance Measures in this transition period. **This document should now be followed rather than Appendix E of the NPAAC Performance Measures and will serve as guidance in this area for NATA technical assessors and committees in this transition phase of the NCSP.** Liquid based cytology (LBC) Performance Measures in the renewed NCSP have not yet been set.

Laboratories providing cervical screening within the framework of the NCSP have undergone huge changes in the last few years. These include significant staffing changes, laboratory technical and instrument changes, as well as information technology changes with report structure, and interface with the National Cervical Screening Register (NCSR). These changes have influenced laboratories prior to the renewed NCSP. This is on a background of declining incidence of oncogenic Human Papillomavirus (HPV) types following broad scale HPV vaccination. It is important however that despite these structural and reporting changes the Australian community can be assured that laboratories continue to deliver safe levels of service in cancer screening.

Assessment of outlying performance and ongoing performance monitoring
Laboratories are required to continue submission of Performance Measure data relating to cases prior to renewal, including those laboratories that are no longer participating in cervical screening post renewal. Of particular note in this regard is Performance Measure 4 which requires 30 months follow up. When Performance Measures are not met, laboratories should satisfy themselves that they have identified the source of outlying results. A pathway of investigation is set out in the NPAAC Performance Measures for Cervical Cytology document in Appendix E (See appendix below).

Recent changes to the NPAAC document Appendix E relate to the removal of the requirement for extensive rescreening of Pap smears, replaced with ensuring that timely HPV testing has been undertaken in affected women, (see below).

Performance Measures 2b (see Appendix 2)
The individual Performance Measures have differing levels of significance but overall detection of high-grade lesions, as evaluated in Performance Measure 2b, is probably of the greatest clinical significance and importance in underpinning the effectiveness of the program. Whilst there are a number of potential reasons why a laboratory may not meet this performance measure, such as screener performance and demographic differences, in this transition period

*The New Zealand Cervical Screening Program is currently being reviewed and this position statement may only be relevant in part

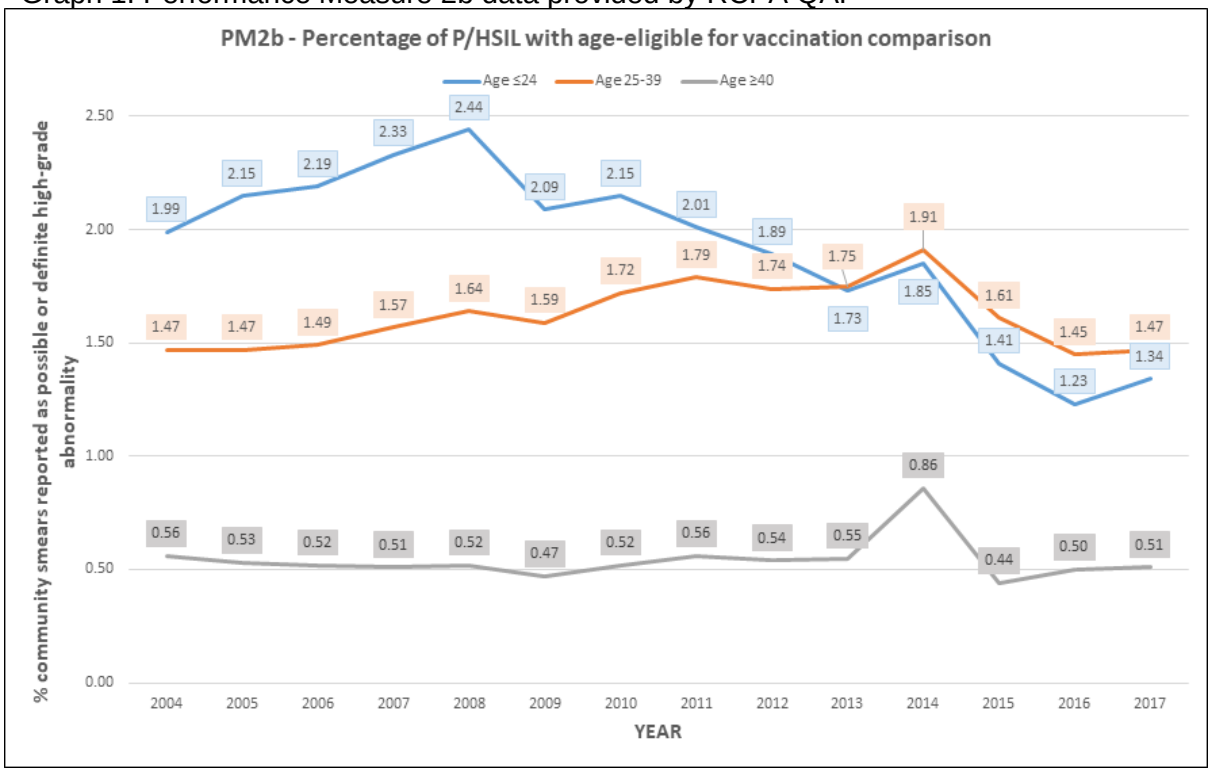
there are additional influences potentially impacting performance. These include the increasing impact of vaccination, changes to staffing levels and roles, job insecurity, the need for cytology staff to be involved in other aspects of the management of the Renewal such as building new IT connection to the NCSR, and the delayed implementation of the NCSP.

Vaccination effect

It is acknowledged that the impact of vaccination has increased over time, with consequent reductions in high grade abnormality rates for younger vaccine eligible cohorts. However, the RCPA Cytology Advisory Committee with the NATA RCPA Laboratory Accreditation Program advise that laboratories who report cytology from a disproportionate number of women who were age-eligible for vaccination should in fact have a higher abnormality detection rate than other laboratories. This is because while the high-grade abnormality rate has been falling in these cohorts, the absolute rate remains higher than in older cohorts. Furthermore, any age dependent factors (including vaccination) are already corrected for in the existing reporting arrangements, as counts of abnormalities and denominators are entered in 5-year age bands and an age-standardised detection rate is calculated for each laboratory. Aggregated data for Australia for 2016 and 2017 (data collection years 2017 and 2018) is shown in Table 1 (Appendix 3).

If laboratories believe that they are screening samples from an unusually highly vaccinated group of young women, as a reason for a low detection rate of high-grade lesions, then they could compare their high grade detection rate among women 40 years and over with the results for the same age cohort from the rest of Australia. At the commencement of the National HPV Vaccination Program in 2007, girls and young women up to the age of 26 years were offered publicly funded HPV vaccination[i]. At the time of writing, the oldest of these women are 38 years. Therefore women 40 years and over were not in age cohorts offered publicly funded vaccination. Statistical advice should be sought to determine whether any difference in the laboratory rate, as compared to the National rate, is statistically significant.

Graph 1. Performance Measure 2b data provided by RCPA QAP



Regional variation

If laboratories consider a low rate of high-grade abnormalities in their population to be a reason for underperformance in Performance Measure 2b, then this hypothesis should be tested by comparing local rates of HPV detection in the renewed NCSP (reported by their

laboratory, or referral laboratory, or utilizing NCSR data) in comparison with national data. Statistical advice should be sought to design a valid comparison that also examines whether any detected difference is large enough to explain the difference in high grade detection rates in Performance Measure 2b.

Cytology slide rescreening
In addressing unexplained low detection rates for high-grade abnormalities, laboratories are no longer required to perform an exhaustive rescreen of all cases from the period in question. This is a significant difference from the approach prior to renewal. In this situation laboratories would work with NATA to establish whether additional follow up is required. The basis for this change in approach relates to the optimal outcome for women. HPV testing (see below) is considered more beneficial to women than rescreening previous cytology and issuing amended reports. Furthermore, the substantial change in laboratory staffing that has been undertaken to support renewal means that, for most laboratories, the number of remaining scientists is not sufficient to support large rescreening efforts.

Timely rescreening for women with potentially under-detected high-grade lesions
If a satisfactory explanation for the outlying Performance Measure cannot be identified, then the NCSP should be notified so that measures can be taken by the NCSP, supported by the NCSR, to identify affected women and determine whether they have subsequently participated in cervical screening based on HPV testing. Affected women who have apparently not yet been screened should receive targeted communication from the NCSP.

Performance Measure 4 (see Appendix 2)

The data for Performance Measure 4 is still required to be submitted for cases prior to renewal, including laboratories who are no longer participating in cervical screening post renewal. As Performance Measure 4 requires rescreening, laboratories not currently involved in NCSP need to maintain capacity for rescreening cytology. Performance Measure 4 requires 30 months follow up and is therefore ongoing until 2020.

Participants no longer participating in cervical screening but submitting data for Performance Measure 4 should contact the RCPAQAP cytopathology@rcpaqap.com.au prior to enrolment.

Documentation
Laboratories should document their investigatory pathway and actions taken, as this will be required by NATA.

APPENDICES

Appendix 1:

Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015) NPAAC document (informative) appendix E:

http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-perfmeas.htm

Appendix 2:

From NPAAC Performance Measures for Australian Laboratories Reporting Cervical Cytology (Third Edition 2015):

Performance Measure 2b

S1.3 Laboratories must provide the proportion of technically satisfactory specimens collected by general practitioners and nurses reported in the categories: negative, definite high-grade abnormality and possible high-grade abnormality, and abnormal.

C1.3 This **must** be reported to the RCPA QAP by March in the following year.

S1.4 The number of specimens reported as definite high-grade abnormality or possible high-grade abnormality (age-standardised to the Australian 2001 Standard Population) must not be less than 0.7 per cent.

S1.5 The number of specimens reported as abnormal must not be more than 14 per cent.

C1.5(i) Although Performance Measure 2b is a combined measure across both definite high-grade abnormality and possible high-grade abnormality reports, laboratories **must** report separate values for their definite and possible high-grade abnormality rates to the RCPA Cytopathology Quality Assurance Program. The collection of this data separately allows completion of Performance Measures 3a and 3b.

C1.5(ii) Restriction of Performance Measure 2b to specimens collected by general practitioners and nurses means this Performance Measure broadly represents the reporting profile of community specimens. This restriction adjusts for the varied case-mix that may occur if this Performance Measure was applied to laboratories with different proportions of their specimens originating from specialists.

Performance Measure 4

Proportion of women with a histological diagnosis of high-grade intraepithelial abnormality or malignancy having cells consistent with or suggestive of a high-grade abnormality identified on review of slides that were originally reported as negative within the preceding 30 months.

S1.10 Not more than 7 per cent of the women with a histopathological diagnosis of high-grade intraepithelial abnormality or malignancy must have cells consistent with a definite high-grade abnormality or possible high-grade abnormality identified on review of cytology slides that were originally reported as negative within the preceding 30 months.

C1.10(i) This **must** be reported to the RCPA QAP by October in the following year.

C1.10(ii) All slides where a negative final report was issued to the referring practitioner in the 30 months preceding the biopsy are to be reviewed. Cytology specimens reported as negative but amended to an abnormal result prior to the date of the histopathology **must** be included in the review.

C1.10(iii) Where cervical cytology and histopathology are performed on the same day, the case **must** be included if it is otherwise eligible for Performance Measure 4. Although there is evidence of a higher false negative rate for

Cervical cytology specimens repeated at short time intervals, this is considered to reflect mainly sampling problems rather than laboratory error and therefore should not disadvantage a laboratory in relation to Performance Measure 4.

C1.10(iv) Where multiple slides from the same woman are reviewed by one laboratory, the woman **must** be classified on the basis of the highest grade cytological appearance detected on the review.

C1.10(v) Review of the cytology slides **must** be performed in the knowledge that the woman has a subsequent histological diagnosis of high-grade intraepithelial abnormality or malignancy.

C1.10(vi) Laboratories **must** maintain records of all false negative reports preceding a histological diagnosis of high-grade intraepithelial abnormality or malignancy. The laboratory response to all false negative reports **must** be documented.

Appendix 3:

Table 1. Aggregated data for pHSIL and HSIL in Australia for 2016 and 2017 (data collection years 2017 and 2018)

2016

Age Group	No reported as HG (community)	Total	Age-specific % reported as HG
10-14 P/HSIL	0	34	**0**
15-19 P/HSIL	324	34622	**0.9**
20-24 P/HSIL	2436	157312	**1.5**
25-29 P/HSIL	4001	203392	**2**
30-34 P/HSIL	3479	216704	**1.6**
35-39 P/HSIL	2662	204781	**1.3**
40-44 P/HSIL	2040	210788	**1**
45-49 P/HSIL	1645	204698	**0.8**
50-54 P/HSIL	1269	187839	**0.7**
55-59 P/HSIL	1083	168475	**0.6**
60-64 P/HSIL	810	137483	**0.6**
65-69 P/HSIL	631	108621	**0.6**
70-74 P/HSIL	189	22217	**0.9**
75-79 P/HSIL	53	3139	**1.7**
80-84 P/HSIL	22	752	**2.9**
85+ P/HSIL	18	305	**5.9**
Total	20662	1861162	1.1

2017

Age Group	No reported as HG (community)	Total	Age-specific % reported as HG
10-14 P/HSIL	0	31	**0**
15-19 P/HSIL	268	25706	**1**
20-24 P/HSIL	1872	127766	**1.5**
25-29 P/HSIL	3218	172486	**1.9**
30-34 P/HSIL	2909	186835	**1.6**
35-39 P/HSIL	1988	178716	**1.1**
40-44 P/HSIL	1508	177495	**0.8**
45-49 P/HSIL	1093	179636	**0.6**
50-54 P/HSIL	811	158189	**0.5**
55-59 P/HSIL	655	144871	**0.5**
60-64 P/HSIL	421	118708	**0.4**
65-69 P/HSIL	329	92078	**0.4**
70-74 P/HSIL	113	20692	**0.5**
75-79 P/HSIL	36	2589	**1.4**
80-84 P/HSIL	18	564	**3.2**
85+ P/HSIL	51	475	**10.7**
Total	15290	1586837	0.96

[i] https://wiki.cancer.org.au/policy/Cervical_cancer/Policy_context