NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

PERFORMANCE MEASURES FOR AUSTRALIAN LABORATORIES REPORTING CERVICAL CYTOLOGY

(Third Edition 2015)

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The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate standards and initiate and promote guidelines and education programs about pathology tests.

Publications produced by NPAAC are issued as accreditation material to provide guidance to laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a risk to public health and patient safety.

Scope

The *Performance Measures for Australian Laboratories Reporting Cervical Cytology* is a Tier 4 document and must be read together with the NPAAC Tier 2 document *Requirements for Medical Pathology Services*, all Tier 3 documents and Tier 4 document *Requirements for Gynaecological (Cervical) Cytology*. The Tier 2 document is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

The *Performance Measures for Australian Laboratories Reporting Cervical Cytology* sets out the Standards of Performance Measures that describe the key elements of the day-to-day performance of a laboratory reporting cervical cytology.

The reporting of cervical cytology specimens remains predominantly a human endeavour and therefore inherently reflects a degree of subjectivity. Hence, the quality of the service must be accountable and the level of error must be minimised to ensure the safety of women, which is paramount. In Australia, the National Cervical Screening Programme actively encourages asymptomatic women to take part in regular preventive health checks. The majority of these women never achieve a health gain from being screened because they were never destined to develop cervical cancer. By participating in screening, they expose themselves to some risks, particularly those relating to the investigation and management of abnormal screening tests. The encouragement of women to screen regularly brings with it a responsibility to ensure that the standards of the screening programme are optimal and not harmful to women. Furthermore, the effectiveness of screening in reducing the incidence of cervical cancer is partially determined by the degree of accuracy achieved in reporting the cervical cytology specimens. The Performance Measures set minimum standards for this degree of accuracy.

Abbreviations

AIS	Adenocarcinoma in situ
CIN	Cervical intraepithelial neoplasia
HGA	High-grade abnormalities
HPV	Human Papillomavirus
HSIL	High grade squamous intraepithelial lesion
LBC	Liquid based cytology
LSIL	Low grade squamous intraepithelial lesion
NATA	National Association of Testing Authorities, Australia
NHMRC	National Health and Medical Research Council
NPAAC	National Pathology Accreditation Advisory Council
PPV	Positive predictive value
QAP	Quality Assurance Program
RCPA	Royal College of Pathologists of Australasia
RCPA QAP	Royal College of Pathologists of Australasia Quality Assurance Program
STI	Sexually transmitted infection

Definitions

Abnormal report	means all technically satisfactory reports which were not negative.
Double smear	means double smears received from one woman are counted as a single specimen.
High grade abnormality	means squamous and glandular cervical lesions: HSIL (CIN 2, CIN 3 and CIN 2-3), AIS, mixed adenosquamous carcinoma in situ and malignancy. Reports of CIN 1 to 2 should be graded as CIN 2 and included as a high grade abnormality. It excludes reports of ungraded CIN or inconclusive report (i.e. those that raise the possibility of a high grade abnormality but where a specific diagnosis is not possible).
High grade intraepithelial abnormality	means CIN 2, CIN 3, CIN 2-3, cervical adenocarcinoma in situ and mixed adenosquamous carcinoma in situ. Reports of CIN 1 to 2 should be graded up and included as a high grade intraepithelial abnormality. Inconclusive reports which raise the possibility of a high grade abnormality and reports of ungraded CIN should be excluded.
Low grade abnormality	means squamous and glandular cervical lesions: LSIL (atypia, HPV effects, CIN 1) or cervical glandular atypia.
Malignancy	means carcinoma (squamous, glandular and mixed adenosquamous) and other malignancies.
Negative specimen	means those specimens in which no abnormal cells were detected plus smears in which benign reactive and/or inflammatory cellular change was reported. Reports of atypia and/or HPV effect are not considered negative.
Non-screening (diagnostic)	means a diagnostic test that is used to classify people as having or not having disease, where there is an indication disease may be present e.g. signs (visually abnormal cervix, etc.) or symptoms (abnormal bleeding, excess pain, etc.). This classification is also used for specific tests taken after treatment to ensure effectiveness of treatment.
Possible high grade abnormality	means those cases in which there are abnormal cells present which suggest the possibility of a high grade abnormality, but in which a confident cytological diagnosis cannot be made. (Previously, this was referred to as inconclusive).
Possible low grade abnormality	means those cases in which there are abnormal cells present which suggest the possibility of a low grade abnormality, but in which a confident cytological diagnosis cannot be made.

Satisfactory specimen	means, for the purposes of this document, a specimen for which a report of Negative or Abnormal smear can be issued.
Screening	means testing of apparently healthy people who are at risk of developing a certain disease. Screening tests can predict the likelihood of someone having or developing a particular disease.
Specimen (slide)	means any tissue or fluid from a patient that is submitted to the pathology service for testing.
Unsatisfactory specimen	means the opposite of Satisfactory specimen. Smears which lack an endocervical component are not considered technically unsatisfactory solely because of the absence of an endocervical component.

Introduction

This document represents a revision of the 2006 *Performance Measures for Australian Laboratories Reporting Gynaecological Cytology*.

A standard has been defined by Muir Gray as 'a subjective judgement of a level of performance that *could* be achieved'. The Performance Measures in this document describe achievable levels of performance for key quantifiable criteria of relevance to a laboratory. Some laboratories may perform to a higher level of performance than described by these recommended standards.

This revision has been undertaken as part of the National Pathology Accreditation Advisory Council (NPAAC) document review cycle using current data but noting the implementation of the Human Papillomavirus (HPV) vaccination programme. The incidence of cervical disease will decline because of this programme but no data was available to set realistic new standards. These standards apply to cytology used as a primary screening test. With the anticipated changes to screening recommendations as part of the Cervical Screening Renewal these standards will continue to apply during any implementation period. [1,2]

Key changes to the Performance Measures include -

i) While laboratories will still be required to submit data to the Royal College of Pathologists of Australasia Quality Assurance Program (RCPA QAP) twice each year, the due date for Performance Measures 1 and 2 (which describe the profile of cytology reporting) will now be March of the following year. This change has been made so that there is adequate provision of time to receive data from the Pap test registers.

ii) The recommended standard for Performance Measure 3b, which describes the proportion of cytology specimens reported as a possible high-grade abnormality that must be confirmed on cervical histopathology, which is performed within six months, as having a high-grade intraepithelial abnormality or malignancy, has been changed to be at least 40%. This change has been made because when the original percentage was set at 33%, this was done using the best information available at that time. There is now a number of years of data collected by the RCPA QAP which shows that 40% is an achievable and realistic rate.[3] A higher correlation is desirable for optimal patient outcomes.

iii) The recommended standard for Performance Measure 4, which describes the accuracy of negative cytology reports, has been changed to not more than 7%. This change has been made because after review of current data collected by the RCPA QAP, it would seem beneficial to lower the previous standard of 10%. Data has been collected over a number of years which show that this is an achievable and realistic rate.[3] A lower false negative rate is desirable for optimal patient outcomes.

iv) Previous editions have not explicitly detailed the actions that are needed to ensure public safety when Performance Measures are not met. This omission has now been rectified by the inclusion of a new chapter that also outlines the consequences of repeated failure to meet the Performance Standards.

The standards outlined in this Performance Measures document apply to all laboratories, irrespective of their annual volume of specimens. While reporting of annual data to the

RCPA QAP is required, a laboratory can measure its performance against the recommended standards on a quarterly or half-yearly basis, thus giving it maximum opportunity to rectify any problems. In the absence of a detailed and well-documented investigation of non-compliance with the recommended standards, it is unacceptable for a laboratory to assert that it has not consistently reached the recommended standard because of a small volume of specimens.

Continued reporting of Performance Measures is required following amalgamation of laboratories for the separate entities prior to the amalgamation, after a laboratory discontinues gynaecological cytology reporting or ceases operating entirely, to enable the reporting of all Performance Measures.

By way of background, Performance Measures were first developed for cervical cytology in 1996 as part of the establishment of quality assurance standards by the then National Cervical Screening Programme. Initially they were voluntary but they became a compulsory part of National Association of Testing Authorities/ Royal College of Pathologists Australasia (NATA/RCPA) inspections of laboratories in July 1999. A review of these standards was subsequently undertaken in 2004. The name was changed to Performance Measures, and the document was published in 2006.

The revision of 2006 was evidence-based using data which had been collected over the preceding years as part of the National Cervical Screening Programme. This data was derived from both state-based Pap test registers and from the Australian Institute of Health and Welfare.[4] In particular, Performance Measure 2b was set using the known incidence of histologically confirmed high grade disease (Appendix B).

Since 1 July 1999, NATA/ RCPA inspections of laboratories have included assessment against the mandated standards. At an operational level, the system has worked as follows:

- Laboratories enrol in the Performance Measures module of the RCPA Cytopathology Quality Assurance Program and are provided with data collection forms for a calendar year.
- The laboratory returns the completed data collection forms to the RCPA office by mid-October of the following year.
- The RCPA Cytopathology Quality Assurance Program compiles a national report on the Performance Measures and this is supplied to each laboratory, along with data relevant to the laboratory in question.
- As part of the NATA/ RCPA triennial inspection of laboratories, the inspectors review the data for the laboratory in question.

While there has been a trend towards amalgamation of laboratories in Australia there are still some small-volume laboratories in operation and many of these are achieving the Performance Measures set in the previous edition (2006). It was decided not to impose a minimum annual number of specimens at this time.

Compliance with the Performance Measures has been facilitated by the existence of cervical cytology registries in all States and Territories. The cervical cytology registries assist laboratories with data relevant to the Performance Measures; for much of Australia, this allows independent verification of some of the data submitted by the laboratory to the RCPA Cytopathology Quality Assurance Program. Notwithstanding the assistance of the cervical cytology registries, each

laboratory is responsible for the accuracy of the data it submits to the RCPA Cytopathology Quality Assurance Program.

This document must be read within the national pathology accreditation framework including the current versions of the following NPAAC standards:

Tier 2 Document

- *Requirements for Medical Pathology Services*

All Tier 3 Documents

Tier 4 Document

- *Requirements for Gynaecological (Cervical) Cytology*

In addition to these standards, laboratories must comply with all relevant state and territory legislation (including any reporting requirements).

In each section of this document, points deemed important for practice are identified as either 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or laboratory facility that is required before a laboratory can attain accreditation — Standards are printed in bold type and prefaced with an 'S' (e.g. **S2.2**). The use of the word 'must' in each standard within this document indicates a mandatory requirement.

- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Note that when Comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. Where a Commentary contains the word '**must**' then that commentary is considered to be **normative**.

Please note that any Appendices attached to this document may be either **normative** or **informative** and should be considered to be an integral part of this document.

All NPAAC documents can be accessed at: http://www.health.gov.au/npaac

While this document is for use in the accreditation process, comment from users would be appreciated and can be directed to:

The Secretary	Phone:	+61 2 6289 4017
NPAAC Secretariat	Fax:	+61 2 6289 4028
Department of Health	Email:	npaac@health.gov.au
GPO Box 9848 (MDP 951)	Website:	http://www.health.gov.au/npaac
CANBERRA ACT 2601		

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1. Performance Measures and Standards

All Performance Measures apply to conventional Pap smears and liquid-based cytology specimens. Where multiple slides or samples constitute a specimen, count this as only one case. All measures are to be based on the report that was issued to the referring practitioner.

The original report of a specimen report issued to the practitioner is to be used and not the amended report.

Profile of Cytology Reporting

Performance Measure 1

S1.1 The number of specimens reported as 'unsatisfactory' must not be less than 0.5 per cent or be more than 5 per cent.

C1.1(i) If the incidence falls outside the Performance Measure range, this **must** be reported to the RCPA QAP by March in the following year.

C1.1(ii) Unsatisfactory specimens are defined in the National Health and Medical Research Council (NHMRC) guidelines[5].

Performance Measure 2a

S1.2 Laboratories must provide the proportion of all technically satisfactory specimens reported in the categories: negative, definite high-grade abnormality and possible high grade abnormality.

C1.2(i) This **must** be reported to the RCPA QAP by March in the following year.

C1.2(ii) This standard provides information about the reporting profile for laboratories that do not have a substantial proportion of their specimens collected by general practitioners and nurses (e.g. hospital-based laboratories).

C1.2(iii) No recommended numerical standards have been set due to the varying case-mix that laboratories may receive. Nevertheless, a laboratory reporting specimens that are almost solely collected by specialists would be expected to reach at least the abnormality rates recommended for Performance Measure 2b (S1.3).

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 3a

Proportion of cytology specimens reported as a definite high-grade intraepithelial abnormality where cervical histopathology, taken within six months, confirms the abnormality as a high-grade intraepithelial abnormality or malignancy.

S1.6 At least 65 per cent of cytology specimens reported as a definite high-grade intraepithelial abnormality must be confirmed on cervical histopathology, which is performed within six months, as having a high-grade intraepithelial abnormality or malignancy.

C1.6(i) This **must** be reported to the RCPA QAP by October in the following year.

C1.6(ii) The range of cervical histopathology encompassed by Performance Measure 3a is restricted to high-grade intraepithelial abnormality (namely CIN 2, CIN 3, AIS, and mixed adenosquamous carcinoma in situ) and cervical malignancy. Where multiple histopathology reports fall within the six-month period after the cytology report, the case **must** be compared with the highest grade of abnormality in the histopathology reports.

S1.7 Where cervical cytology and histopathology are performed on the same day, the case must be included if it is otherwise eligible for Performance Measure 3a.

Performance Measure 3b

Proportion of cytology specimens reported as a possible high-grade abnormality where cervical histopathology, taken within six months, confirms the abnormality as a high-grade intraepithelial abnormality or malignancy.

S1.8 At least 40 per cent and no more than 65 per cent of the cytology specimens reported as a possible high-grade abnormality must be confirmed on cervical histopathology, which is performed within six months, as having a high-grade intraepithelial abnormality or malignancy.

C1.8(i) This **must** be reported to the RCPA QAP by October in the following year.

C1.8(ii) The range of cervical histopathology encompassed by performance measure 3b is restricted to high-grade intraepithelial abnormality (namely CIN 2, CIN 3, AIS, and mixed adenosquamous carcinoma in situ) and cervical malignancy. Where multiple histopathology reports fall within the six-month period after the cytology report, the case **must** be counted against the most abnormal histopathology report.

S1.9 Where cervical cytology and histopathology are performed on the same day, the case must be included if it is otherwise eligible for Performance Measure 3b.

Accuracy of Negative Cytology Reports

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.

2. Achieving the Performance Measures and Standards

(Refer to Standard 2, Standard 3, Standard 6 and Standard 7 in *Requirements for Medical Pathology Services)*

The quality of the service must be accountable and the level of error must be minimised to ensure the safety of patients.

S2.1 If any of the Performance Measures are not met, the Laboratory must undertake an investigation, including an internal review of specimens and slides, directed towards investigating the outlying measure as outlined in Appendix E. These actions must be documented.

C2.1 The internal review **must** be completed within two months.

S2.2 If the internal review of specimens (slides) reveals the cause for the failure of compliance, corrective action must be undertaken and documented.

C2.2 This documentation **must** be provided to the accreditation body within three months.

S2.3 If the internal review fails to reveal the cause for the failure to comply with the Performance Measures, independent external expert advice must be obtained.

C2.3(i) This advice **must** be sought immediately.

C2.3(ii) The Laboratory **must** obtain advice relating to technical and quality issues which will enable them to comply with the Performance Measures.

C2.3(iii) This advice **must** be obtained and implemented and documentation provided to the accreditation body within three months.

C2.3(iv) During the following twelve months, the Performance Measures **must** be monitored every three months.

S2.4 If any subsequent Performance Measures are not met at the end of twelve months, an independent external review of the specimens (slides) must be undertaken and documented.

C2.4(i) The purpose of the external review is to ensure patient safety.

C2.4(ii) The external review will be conducted at the expense of the Laboratory.

C2.4(iii) The nature and extent of the external review will be determined and coordinated by the accreditation body.

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Appendix A Cytology Code Schedule (Informative)

Cytology Code Schedule below is the recommended format to be reported to cervical registries.

CYTOLOGY CODE SCHEDULE

SPECIMEN	**Type**	AØ Not stated	A1 Conventional smear	A2 Liquid based specimen	A3 Conventional and liquid based specimen
	Site	BØ Not stated	B1 Cervical	B2 Vaginal	B3 Other gynaecological site

CYTOLOGY	**S**	**Squamous Cell**	**E**	**Endocervical**	**O**	**Other/Non-cervical**
	SU	Unsatisfactory for evaluation e.g. poor cellularity, poor preservation, cell detail obscured by inflamation/blood/degenerate cells	**EU**	Due to the unsatisfactory nature of the smear, no assessment has been made	**OU**	Due to the unsatisfactory nature of the smear, no assessment has been made
	S1	Cell numbers and preservation satisfactory. No abnormality or only reactive changes	**E-**	Not applicable: vault smear/previous hysterectomy	**O1**	No other abnormal cells
	S2	Possible low-grade squamous intraepithelial lesion (LSIL)	**EØ**	No endocervical component	**O2**	Atypical endometrial cells of uncertain significance
	S3	Low grade LSIL (HPV and/ or CIN 1)	**E1**	Endocervical component present. No abnormaltity or only reactive changes	**O3**	Atypical glandular cells of uncertain significance – site unknown
	S4	Possible high-grade squamous intraepithelial lesion (HSIL)	**E2**	Atypical endocervical cells of uncertain significance	**O4**	Possible endometrial adenocarcinoma
	S5	High-grade squamous intraepithelial lesion (HSIL) (CIN II/ CIN III)	**E3**	Possible high-grade endocervical glandular lesion	**O5**	Possible high-grade lesion non-cervical
	S6	High-grade squamous intraepithelial lesion (HSIL) with possible microinvasion/ invasion	**E4**	Adenocarcinoma – in-situ	**O6**	Malignant cells – uterine body
	S7	Squamous carcinoma	**E5**	Adenocarcinoma – in-situ with possible microinvasion/invasion	**O7**	Malignant cells - vagina
			E6	Adenocarcinoma	**O8**	Malignant cells – ovary
					O9	Malignant cells – other

RECOMMEND	**RØ**	No recommendation	**R4**	Repeat smear 6 months	**R8**	Referral to specialist
	R1	Repeat smear 3 years	**R5**	Repeat smear 6-12 weeks	**R9**	Other management recommended
	R2	Repeat smear 2 years	**R6**	Colposcopy/biopsy recommended	**RS**	Symptomatic – clinical management required
	R3	Repeat smear 12 months	**R7**	Already under gynaecological management		

Appendix B AIHW Cervical Screening in Australia Report 2008-2009 (Informative)

High-grade abnormality detection by state and territory

In 2009, the high-grade abnormality detection rate varied across states and territories, between 7.4 and 15.1 women aged 20-69 years per 1,000 women screened (Table 4.6).

Table 4.6: High-grade abnormality detection rate, by state and territory, women aged 20-69 years, 2009

	NSW	Vic	Qld	WA	SA	Tas	ACT	NT	Australia
AS rate	8.3	7.5	7.5	9.3	7.7	10.4	7.4	15.1	8.1
95% CI	8.0-8.5	7.3-7.8	7.2-7.8	8.9-9.7	7.2-8.2	9.4-11.4	6.5-8.3	13.5-16.8	8.0-8.2

Note: Age-standardised (AS) rate is the number of women with a high-grade abnormality detected by histology per 1,000 women screened age-standardised to the Australian population at 30 June 2001.

Source: AIHW analysis of state and territory cervical cytology register data.

Appendix C Age Standardisation (Informative)

The percentage of specimens reported as abnormal is age dependent. Younger women have a higher percentage of specimens reported as abnormal, than older women. Therefore while performance measure 2b requires that 0.7 per cent of technically satisfactory specimens collected by general practitioners and nurses be reported as definite or possible high-grade abnormalities (HGA), it is conceivable a laboratory would not reach this recommended standard if its specimens came from women with a very skewed age distribution.

Age standardisation removes the effects of differences in age on a summary statistic. In the hypothetical examples provided in this Appendix, the summary statistic is the overall percentage of HGAs for the laboratory (refer cell A in the bottom row of the table). This summary statistic is a crude percentage, rather than an age-standardised percentage.

Direct age-standardisation involves the following three steps:

i) Calculate the age-specific percentage for each five-year age group (column D in table).

ii) Calculate the expected number of cases in each five-year age group by multiplying the age-specific percentages (column D) by the corresponding standard population for that age group (column E), giving you the expected number of cases (column F).

iii) Sum the expected number of cases in each age group (cell H). Divide this sum by the total of the standard population (cell G) and multiply by 100. This is the age standardised percentage (cell I).

To calculate the age-standardised percentage for your own laboratory using the Excel spreadsheet available from the QAP, you would only need to fill in the numbers in columns B and C. Results for women whose age is unknown are excluded from the data set.

The age standard is consistent with the Australian Institute of Health and Welfare which uses the 2001 Australian population as the standard population for age standardisation in its publications.

Hypothetical example 1:

Laboratory X has a reasonably typical age profile for its community-based specimens, with 34 per cent of its specimens from women aged <35 years.

Age Group (yrs)	No. of community specimens reported as HGA [B]	Total no. of community specimens reported [C]	Age-specific percentage reported as HGA [D = (B/C) x 100]	Australian 2001 Standard Population [E]	Expected no. of HGAs in the Australian 2001 Standard Population [F = D x E]	Age standardised percentage reported as HGA
10-14	0	9	0.00%	1,353,177	0	
15-19	70	4,618	1.52%	1,352,745	20,562	
20-24	150	4,217	3.56%	1,302,412	46,366	
25-29	142	5,737	2.48%	1,407,081	34,896	
30-34	90	7,540	1.19%	1,466,615	17,453	
35-39	65	7,559	0.86%	1,492,204	12,833	
40-44	48	6,159	0.78%	1,479,257	11,538	
45-49	36	6,118	0.59%	1,358,594	8,016	
50-54	15	6,336	0.24%	1,300,777	3,122	
55-59	12	5,736	0.21%	1,008,799	2,118	
60-64	5	3,748	0.13%	822,024	1,069	
65-69	4	1,953	0.20%	682,513	1,365	
70-74	2	1,690	0.12%	638,380	766	
75-79	1	1,774	0.06%	519,356	312	
80-84	0	1,286	0.00%	330,050	0	
85+	0	700	0.00%	265,235	0	
Total	**640**	**65,180**	**0.98%** [A]	**16,779,219** [G]	**160,416** [H]	**0.96%** [I =(H/G)x100]

Conclusion: Age standardisation has made little difference to the proportion of community-based specimens reported as HGA for Laboratory X, changing the crude percentage from 0.98 per cent (cell A) to an age-standardised percentage of 0.96 per cent (cell I).

Hypothetical example 2:

Laboratory Y has an atypical age profile for its community-based specimens, with 20 per cent of its specimens coming from women aged <35 years. However, Laboratory Y has very similar age-specific percentages for HGA to Laboratory X (refer column D).

Age Group (yrs)	No. of community specimens reported as HGA [B]	Total no. of community specimens reported [C]	Age-specific percentage reported as HGA [D = (B/C) x 100]	Australian 2001 Standard Population [E]	Expected no. of HGAs in the Australian 2001 Standard Population [F = D x E]	Age standardised percentage reported as HGA
10-14	0	59	0.00%	1,353,177	0	
15-19	10	640	1.56%	1,352,745	21,103	
20-24	41	1,150	3.57%	1,302,412	46,496	
25-29	56	2,252	2.49%	1,407,081	35,036	
30-34	22	1,862	1.18%	1,466,615	17,306	
35-39	34	3,935	0.86%	1,492,204	12,833	
40-44	35	4,483	0.78%	1,479,257	11,538	
45-49	29	4,935	0.59%	1,358,594	8,016	
50-54	10	4,117	0.24%	1,300,777	3,122	
55-59	5	2,602	0.19%	1,008,799	1,917	
60-64	3	2,550	0.12%	822,024	986	
65-69	2	1,205	0.17%	682,513	1,160	
70-74	1	488	0.20%	638,380	1,277	
75-79	0	73	0.00%	519,356	0	
80-84	0	41	0.00%	330,050	0	
85+	0	7	0.00%	265,235	0	
Total	**248**		**0.82%** [A]	**16,779,219** [G]	**160,790** [H]	**0.96%** [I =(H/G)x100]

Conclusion: Age standardisation has made a substantial difference to the proportion of community-based specimens reported as HGA for Laboratory Y, changing the crude percentage of 0.82 percentage (cell A) to an age-standardised percentage of 0.96 per cent (cell I). This is because the age profile of women who are screened by Laboratory Y was unusually skewed towards the older population.

Because of age-standardisation, both Laboratory X and Laboratory Y have a figure of 0.96 per cent as their age-standardised proportion, whereas their overall crude percentages at 0.98 per cent and 0.82 per cent respectively are quite different. Their age-standardised percentages are identical because their five-year age percentages as shown in column D are very similar.

Hypothetical example 3:

Laboratory Z has 40 per cent of its specimens coming from women aged <35 years. The crude percentage of specimens reported as HGA does not reach the recommended standard for performance measure 2b.

Age Group (yrs)	No. of community specimens reported as HGA [B]	Total no. of community specimens reported [C]	Age-specific percentage reported as HGA [D = (B/C) x 100]	Australian 2001 Standard Population [E]	Expected no. of HGAs in the Australian 2001 Standard Population [F = D x E]	Age standardised percentage reported as HGA
10-14	0	3	0.00%	1,353,177	0	
15-19	4	746	0.54%	1,352,745	7,305	
20-24	14	2,661	0.53%	1,302,412	6,903	
25-29	32	3,513	0.91%	1,407,081	12,804	
30-34	19	3,546	0.54%	1,466,615	7,920	
35-39	13	3,472	0.37%	1,492,204	5,521	
40-44	7	3,264	0.21%	1,479,257	3,106	
45-49	6	2,915	0.21%	1,358,594	2,853	
50-54	3	2,261	0.13%	1,300,777	1,691	
55-59	5	1,617	0.31%	1,008,799	3,127	
60-64	1	1,157	0.09%	822,024	740	
65-69	1	676	0.15%	682,513	1,024	
70-74	0	217	0.00%	638,380	0	
75-79	0	47	0.00%	519,356	0	
80-84	0	16	0.00%	330,050	0	
85+	0	6	0.00%	265,235	0	
Total	**105**	**26,117**	**0.40%** [A]	**16,779,219** [G]	**52,994** [H]	**0.32%** [I =(H/G)x100]

Conclusion: Age standardisation has not improved the figures for Laboratory Z, reducing the crude percentage of 0.40 per cent (cell A) to an age-standardised percentage of 0.32 per cent (cell I). This is because the percentage of specimens reported as HGA by Laboratory Z was low for almost all five-year age groups (column D).

Laboratory Z did not reach the recommended standard for performance measure 2b because of the low rate of detecting HGA in each five-year age group, not because of an atypical age profile of women being screened.

Appendix D Data Requirements for Performance Measures for Australian Laboratories Reporting Cervical Cytology (Informative)

The following data is submitted annually by participating laboratories via an online data entry system administered by the RCPA QAP Cytopathology.

Part 1 – PERFORMANCE MEASURE 1 – *Profile of cytology reporting*

Proportion of cervical specimens reported as unsatisfactory

- *This measure is to be calculated on all cervical cytology specimens (conventional and liquid-based) received by your laboratory for the period January 1 to December 31.*
- *Where liquid based cytology (LBC) is performed in conjunction with a conventional smear, the data submitted should reflect the final combined report. Where LBC is performed without a conventional smear, the data submitted should be based solely on the LBC report.*
- *Where multiple slides are reported for the same episode, this counts as only one case.*
- *If an interim report was issued prior to a final result, then data submitted for this measure should be based on the final report issued. Where the final report was amended due to review or quality control screening, the final report rather than the amended report should be used.*

Number of specimens[1] received by laboratory. (B1)	**1.1**

Number of specimens reported by laboratory as technically unsatisfactory[2] for reporting. *(any record with SU, unless E>1, O>1)*	**1.2**

Percentage of specimens received that were reported as technically unsatisfactory.	**1%** *(1 = (1.2/1.1) x 100)*

[1] Count *double smears* received from one woman as a single specimen. Count a conventional and a liquid based smear received from one woman as a single specimen.

[2] Smears which lack an endocervical component are not considered *technically unsatisfactory* solely because of the absence of an endocervical component.

PERFORMANCE MEASURE 2a – *Profile of cytology reporting*

Reporting categories for all technically satisfactory cervical specimens reported by your laboratory

- *In calculating this measure, include all technically satisfactory specimens reported.*
- *Where multiple slides are reported for the same episode, this counts as only one case.*
- *If an interim report was issued prior to a final result, then data submitted for this measure should be based on the final report issued. Where the final report was amended due to review or quality control screening, the final report rather than the amended report should be used.*

Number of technically satisfactory specimens.	**2a.1**

Number of technically satisfactory specimens reported as negative[3]. *(any record with any of the following: S<2, E<2, O <2; not U or -)*	**2a.2**

Percentage of technically satisfactory specimens reported as negative.	**2a.3%** *(2a.3= (2a.2/2a.1) x 100)*

Number of technically satisfactory specimens reported as high-grade abnormality[4]. *(any record with any of the following: S>4, E>3, O>5)*	**2a.4**

Percentage of technically satisfactory specimens reported as high-grade abnormality.	**2a.5%** *(2a.5 = (2a.4 / 2a.1) x 100)*

Number of technically satisfactory specimens reported as possible high-grade abnormality[5]. *(any record with any of the following: S4, E3, O4, O5)*	**2a.6**

[3] *Negative* comprises those smears in which no abnormal cells were detected plus smears in which benign reactive and/or inflammatory cellular change was reported. Reports of atypia &/or HPV effect (definite or possible LSIL) are *not* considered negative.

[4] *High-grade abnormality* includes reports of HSIL (CIN 2, CIN 3), cervical adenocarcinoma in situ and carcinoma (squamous and glandular). Reports of CIN 1 to 2 should be graded as CIN 2 and included as a high-grade abnormality. Possible high-grade reports should be excluded and entered in 2a.6.

[5] *Possible high-grade abnormality* includes possible high-grade HSIL, possible high-grade glandular lesions and possible high-grade cases where cellular differentiation is not apparent.

Percentage of technically satisfactory specimens reported as possible high-grade abnormality.	**2a.7%** *(2a.7 = (2a.6 / 2a.1) x 100)*

Percentage of technically satisfactory specimens reported as high-grade abnormality or as possible high-grade abnormality.	**2a.8%** *(2a.8=[(2a.4+2a.6)/2a. 1]x 100)*

Number of technically satisfactory specimens reported as abnormal[6]. *(any record with any of the following: S>1, E>1, O>1)*	**2a.9**

Percentage of technically satisfactory specimens reported as abnormal.	**2a.10%** *(2a.10= (2a.9/ 2a.1) x 100)*

[6] *Abnormal* includes all technically satisfactory reports which were not negative (see definition of negative in footnote 3).

PERFORMANCE MEASURE 2b – *Profile of cytology reporting*

Reporting categories for technically satisfactory cervical specimens collected by general practitioners and nurses

- *This requires the same data as for 2a, but for this measure exclude all specimens collected by obstetricians, gynaecologists and all hospital based clinics.*

Number of technically satisfactory specimens collected by general practitioners and nurses.	**2b.1**

Number of technically satisfactory specimens reported as negative[7]. *(any record with any of the following: S<2, E<2, O <2; not U or -)*	**2b.2**

Percentage of technically satisfactory specimens reported as negative.	**2b.3%** *(2b.3 = (2b.2 / 2b.1) x 100)*

Number of technically satisfactory specimens reported as high-grade abnormality[8]. *(any record with any of the following: S>4, E>3, O>5)*	**2b.4**

Percentage of technically satisfactory specimens reported as high-grade abnormality.	**2b.5%** *(2b.5 = (2b.4 / 2b.1) x 100)*

Number of technically satisfactory specimens reported as possible high-grade abnormality[9]. *(any record with any of the following: S4, E3, O4, O5)*	**2b.6**

Percentage of technically satisfactory specimens reported possible high-grade abnormality.	**2b.7% (***2b.7 = (2b.6 / 2b.1) x 100)*

Percentage of technically satisfactory specimens reported as high-grade abnormality or as possible high-grade abnormality.	**2b.8%** *(2b.8=[(2b.4+2b.6)/2b.1] x100)*

[7] *Negative* comprises those smears in which no abnormal cells were detected plus smears in which benign reactive and/or inflammatory cellular change was reported. Reports of atypia &/or HPV effect (definite or possible LSIL) are *not* considered negative

[8] *High-grade abnormality* includes reports of HSIL (CIN 2, CIN 3), cervical adenocarcinoma in situ and carcinoma (squamous and glandular). Reports of CIN 1 to 2 should be graded as CIN 2 and included as a high-grade abnormality. Possible high-grade reports should be excluded and entered in 2b.6.

[9] *Possible high-grade abnormality* includes possible high-grade HSIL, possible high-grade glandular lesions and possible high-grade cases where cellular differentiation is not apparent.

Number of technically satisfactory specimens reported as abnormal[10]. *(any record with any of the following: S>1, E>1, O>1)*	**2b.9**

Percentage of technically satisfactory specimens reported as abnormal.	**2b.10%** *(2b.10 = (2b.9 / 2b.1) x100)*

See over for age-standardised rate of reporting definite or possible high-grade abnormality (item **2b**).

[10] *Abnormal* includes all technically satisfactory reports which were not negative (see definition of negative in footnote 7 above).

Age standardised rate of reporting definite high-grade abnormality or possible high-grade abnormality.

To calculate the age standardised rate:

1. Calculate age specific percentage for each five year age group (column D). This data should be provided by the relevant State or Territory Registers. Some laboratories may have to pool data from more than one Register.
2. Calculate the expected number of cases in each five year age group by multiplying the age-specific percentage (D) by the corresponding standard population for that age group (E), giving the expected number of cases (F).
3. Sum the expected number of cases in each age group to derive H. Divide this sum by the total of the standard population (cell G) and multiply by 100. This is the age standardised percentage (cell I)

Age Group (yrs)	No. of community smears reported as definite or possible high-grade abnormality	Total No. of community specimens reported [C]	Age specific percentage reported as definite or possible high-grade abnormality D=(B/C)x10	Australian 2001 Standard Population [E]	Expected No. of definite or possible high-grade abnormalities in the Australian	Age-standardised percentage reported as definite or possible high-grade abnormality
10-14				1353177		
15-19				1352745		
20-24				1302412		
25-29				1407081		
30-34				1466615		
35-39				1492204		
40-44				1479257		
45-49				1358594		
50-54				1300777		
55-59				1008799		
60-64				822024		
65-69				682513		
70-74				638380		
75-79				519356		
80-84				330050		
85+				265235		
TOTAL				16779219 [G]	[H]	**%** I=(H/G)x100 **2b**
Age standardised rate of reporting definite or possible high-grade abnormality:						

Notes:

1. An Excel spreadsheet is available from the QAP Office to help with this calculation. It may be obtained from the website www.rcpaqap.com.au/cytopathology or by phoning (07 3136 2595) or emailing the QAP Office (cytoqap@rcpaqap.com.au). **Data only needs to be entered into columns B and C of the spreadsheet to calculate the age-standardised percentage for your laboratory.**
2. Fully worked examples are provided in Appendix C.

Part 2 – PERFORMANCE MEASURE 3a – *Accuracy of reports predicting a high-grade abnormality.*

Proportion of cytology specimens reported as definite high-grade intraepithelial abnormality where cervical histology, taken within six months, confirms the abnormality as high-grade intraepithelial abnormality or malignancy.

- *This measure should be calculated on specimens, not on women.*
- *Include all cases, regardless of source (e.g. GPs, hospital clinics etc.).*
- *High-grade intraepithelial lesion includes both squamous and glandular cervical lesions HSIL (CIN 2, 3 and 2-3), AIS and mixed adenosquamous carcinoma in situ).*
- *Where multiple histology reports are available within the six-month period, the highest-grade report should be used.*
- *If an interim report was issued prior to a final result, then data submitted for this measure should be based on the final report issued. Where the final report was amended due to review or quality control screening, the final report rather than the amended report should be used.*
- *Where cytology and histology are performed on the same day, the case should be included.*

Number of specimens with a cytological report of definite high-grade intra epithelial abnormality.[11] (S5, E4).	**3a.1**
Number of specimens with a cytological report of definite high-grade intraepithelial abnormality and known cervical histology reported within the next 6 months.	**3a.2**
Cancer	**3a.3**
High-grade intraepithelial abnormality	**3a.4**
Low-grade abnormality[12]	**3a.5**
Negative/benign findings	**3a.6**
Unsatisfactory	**3a.7**
Percentage of specimens with a cytological report of definite high-grade intraepithelial abnormality where histology performed within 6 months confirms the lesion as high-grade intraepithelial abnormality or malignancy.*(Note: 3a.3+3a.4+3a.5+3a.6+3a.7 should = 3a.2)*	**3a%** *(3a = [(3a.3+3a.4)/3a.2] x 100)*

[11] Do not include cytology reports of ungraded CIN or possible high-grade abnormality. Reports that raise the possibility of an invasive lesion should also be excluded.

[12] Low-grade abnormality includes reports of LSIL (atypia, HPV effect, CIN 1) and cervical glandular atypia.

PERFORMANCE MEASURE 3b – *Accuracy of reports of possible high-grade abnormality.*

Proportion of cytology specimens reported as possible high-grade abnormality where cervical histology, taken within the next six months, confirms the abnormality as high-grade intraepithelial abnormality or malignancy.

- *This measure should be calculated on specimens, not on women.*
- *Include all cases, regardless of source (e.g. GP's, hospital clinics etc.).*
- *Possible high-grade abnormality includes possible high-grade intraepithelial abnormalities (both squamous and glandular cervical lesions HSIL (CIN 2,3 and 2-3), AIS and mixed adenosquamous carcinoma in situ) and possible cervical malignancies.*
- *Where multiple histology reports are available within the six-month period, the highest-grade report should be used.*
- *If an interim report was issued prior to a final result, then data submitted for this measure should be based on the final report issued. Where the final report was amended due to review or quality control screening, the final report rather than the amended report should be used.*
- *Where cytology and histology are performed on the same day, the case should be included.*

Number of specimens with a cytological report of possible high-grade abnormality.[13] (S4, E3)	**3b.1**
Number of specimens with a cytological report of possible high-grade abnormality and known cervical histology reported within the next 6 months.	**3b.2**
Cancer	**3b.3**
High-grade intraepithelial abnormality	**3b.4**
Low-grade abnormality[14]	**3b.5**
Negative/benign findings	**3b.6**
Unsatisfactory	**3b.7**
Percentage of specimens with a cytological report of possible high-grade abnormality where histology performed within 6 months confirms the lesion as high-grade intraepithelial abnormality or malignancy. *(Note: 3b.3+3b.4+3b.5+3b.6+3b.7 should = 3b.2)*	**3b%** *(3b= [(3b.3+3b.4)/3b.2] x 100)*

[13] Possible high-grade abnormality includes reports of possible intraepithelial abnormality or a malignancy (both squamous and glandular).

[14] Low-grade abnormality includes reports of LSIL (atypia, HPV effect, CIN 1) and cervical glandular atypia.

PERFORMANCE MEASURE 4 – Accuracy of negative cytology reports

Proportion of women with a histological diagnosis of cervical high-grade intraepithelial abnormality or malignancy having cells consistent with or suggestive of a high-grade abnormality identified on review of cytology specimens which were originally reported as negative within the previous 30 months.

- *This measure involves rescreening of cervical cytology specimens originally reported as negative from women with a histological report of high-grade intraepithelial abnormality or malignancy. Negative smears reported within the previous 30 months should be reviewed.*
- *Cytology specimens reported as negative but amended to an abnormal result prior to the date of histology should be included in the review.*
- *Where cervical cytology and histology are performed on the same day, the case should be included.*
- *Where multiple slides are reviewed by one laboratory for the same woman, the most severe abnormality identified on review should be reported.*
- *Slides should be reviewed with the knowledge that the woman has a subsequent histological diagnosis of high-grade intraepithelial abnormality or malignancy.*

Number of women with histologically confirmed high-grade intraepithelial abnormality or malignancy in the year being interrogated, with any cervical cytology reported by your laboratory during the preceding 30 months.	**4.1**

Number of women with histologically confirmed high-grade intraepithelial abnormality or malignancy in the year being interrogated, with one or more negative cervical cytology reports *(any record with any of the following: S<2, E<2, O <2; not U or -)* in the preceding 30 months.	**4.2**

Percentage of women with a histological diagnosis of high-grade intraepithelial abnormality or malignancy with negative cervical cytology reported in the preceding 30 months by your laboratory.	**4.3[15]%** *(4.3 = [4.2/4.1] x 100)*

[15] This value was described as T/S in the 2003 NPAAC publication 'Performance Measures for Australian Laboratories Reporting Cervical Cytology'. Refer point h) on page 23.

Negative	**4.4**
Other abnormalities[16]	**4.5**
Possible high-grade abnormality[17]	**4.6**
High-grade abnormality[18]	**4.7**
Unsatisfactory	**4.8**
Slide unavailable for review	**4.9**

Percentage of women with a histological diagnosis of high-grade intraepithelial abnormality or malignancy with cells consistent with, or suggestive of, a high-grade abnormality identified on review of slides which were originally reported as negative. *(Note: 4.4+4.5+4.6+4.7+4.8+4.9 should = 4.2)*	**4%** *(4=[(4.6+4.7)/4.1]x100)*

[16] Other abnormalities include possible LSIL, LSIL, atypical endocervical cells of uncertain significance, and atypical glandular cells of uncertain significance.

[17] Possible high-grade abnormality includes possible high-grade squamous and possible high-grade glandular diagnoses.

[18] High-grade abnormality includes HSIL (CIN 2, CIN 2-3, CIN 3), AIS, mixed adenosquamous in situ and cervical cancer in cervical specimens.

Appendix E Explanatory notes on how to calculate Performance Measures and how to Investigate Outlying Data (Informative)

Performance Measure 1

Investigation of outlying data

a) Percentage of specimens reported as unsatisfactory is below the recommended standard (i.e. <0.5 per cent)

i) *What is the unsatisfactory rate among conventional specimens only?*

Calculate the unsatisfactory rate for conventional specimens only and ascertain whether it meets the recommended standard.

Occasionally a laboratory may not reach the minimum recommended standard if the dominant specimen type reported by the laboratory is liquid-based cytology specimens. This is considered an unlikely reason in and of itself to explain noncompliance, unless an extremely high proportion of all specimens reported by the laboratory were liquid-based specimens. One would still expect to see between 0.5 per cent and 5 per cent of conventional specimens reported as unsatisfactory.

Hypothetical example 1

Laboratory reporting 10,000 specimens per year

10 per cent of specimens are conventional specimens with 2 per cent unsatisfactory rate → 10,000 x 0.10 x 0.02 = 20 unsatisfactory specimens;

90 per cent of specimens are liquid-based cytology with 0.3 per cent unsatisfactory rate → 10,000 x 0.90 x 0.003 = 27 unsatisfactory specimens;

Total number (percentage) of unsatisfactory specimens = 47 (0.47 per cent)

ii) *What is the unsatisfactory rate for individual staff members?*

Calculate the unsatisfactory rate for each staff member who has authority to issue final reports. If a significant spread is evident, consider reviewing a series of consecutive specimens authorised by staff members with the lowest rates of unsatisfactory reports to determine if their threshold for a satisfactory specimen is appropriate.

iii) *Are time trends evident?*

Investigate the extent to which time trends or differences between staff members exist in relation to the two broad reasons for unsatisfactory reports, namely insufficient cells and obscuring of cells. Consider the merits of additional teaching sessions and in-house slide surveys.

b) Percentage of specimens reported as unsatisfactory is above the recommended standard (i.e. >5 per cent)

i) *Are there remediable external factors?*

Review the underlying reasons for the unsatisfactory reports, looking for remediable external factors. For example, an excess of broken slides may point to difficulties in the system of specimen transport to the laboratory. An excess of specimens solely comprising an endocervical component may relate to the provision of sampling instruments (e.g. only endocervical brushes supplied). Re-emphasising good specimen collection practices to referring practitioners may reduce the number of unlabelled specimens received by the laboratory or address other problems that some referring practitioners may be experiencing.

ii) *What is the unsatisfactory rate among average-risk specimens?*

Calculate the unsatisfactory rate for average-risk specimens only (i.e. exclude specimens collected from practices likely to have a high prevalence of sexually transmitted infections [STIs]) and ascertain whether the recommended standard is now met.

Infrequently, a laboratory may exceed the recommended standard if a sizeable proportion of specimens reported by the laboratory is from population groups known to have a high rate of STIs. This explanation is unlikely to account for >5 per cent unsatisfactory specimens unless the STI specimens constituted at least 20 per cent of all specimens reported by the laboratory and at least 20 per cent of the STI specimens were reported as unsatisfactory.[5]

Hypothetical example 2

Laboratory reporting 10,000 specimens per year

20 per cent of specimens from high-risk STI population where 20 per cent of specimens are unsatisfactory

→ 10,000 x 0.20 x 0.20 = 400 unsatisfactory specimens;

80 per cent of specimens from average-risk populations where 2 per cent of specimens are unsatisfactory

→ 10,000 x 0.80 x 0.02 = 160 unsatisfactory specimens;

Total number (percentage) of unsatisfactory specimens = 560 (5.6 per cent)

iii) *What is the unsatisfactory rate for individual staff members?*

Calculate the unsatisfactory rate for each staff member who has authority to issue final reports. If a significant spread is evident, consider reviewing a series of consecutive specimens authorised as unsatisfactory by staff members with the highest rates of unsatisfactory reports to determine if their threshold for a satisfactory specimen is appropriate.

iv) *Are time trends evident?*

Investigate the extent to which time trends or differences between staff members exist. Consider the merits of additional teaching sessions and in-house slide surveys.

v) *What is the unsatisfactory rate among specimens from non-pregnant women?*

Very infrequently, a laboratory may exceed the recommended standard if a high proportion of its specimens is collected from pregnant women. As in hypothetical example two above, a very large proportion of all specimens would need to be from pregnant women for this explanation to be cogent. Also, the proportion of unsatisfactory specimens from non-pregnant women would be expected to be within the recommended standard.

Performance Measure 2

The numerical standards for both Performance Measures 2a and 2b have been kept at the same levels as in the previous Performance Measures document of 2006. These are based on data collected by the Australian Institute of Health and Welfare and referenced in Appendix B. This data precedes the onset of the National HPV Vaccination Programme which will have a significant effect on the incidence of high grade cervical disease. This standard will be reviewed when the appropriate data become available.

Investigation of outlying data

a) Performance Measure 2b. Percentage of technically satisfactory specimens reported as definite high-grade abnormality or possible high-grade abnormality is below the recommended standard (i.e. <0.7 per cent).

i) *Is the overall rate of finding high-grade abnormalities satisfactory?*

National data indicate that the rate of histological diagnosis of high-grade intraepithelial abnormality has been stable between 2004 and 2007 at approximately 7.7 per 1,000 screened women but increased to 8.4 per 1000 between 2008 and 2011.

The first suggested investigation for a laboratory not meeting the recommended standard for Performance Measure 2b is to calculate the overall rate of 'predicted and confirmed' high-grade abnormality among women screened by the laboratory. This approach utilises a laboratory's performance on Performance Measures 2b, 3a and 3b to calculate the overall rate of high-grade abnormality potentially found due to the laboratory predicting a definite high-grade abnormality or possible high-grade abnormality on cytology, and these reports subsequently being histologically confirmed as a high-grade abnormality.

This is an attempt to make some allowance for a laboratory that may not be reporting 0.7 per cent of its specimens as definite high-grade abnormality or possible high-grade abnormality, but which has high positive predictive values associated with these types of cytology reports.

The artificiality of the 'predicted and confirmed' rate derives from the following sources:

a) Not all women who receive cytology reports of definite high-grade abnormality or possible high-grade abnormality undergo a cervical biopsy within six months.

b) The positive predictive value for all specimens (specialist as well as general practitioner/nurse) is being applied to general practitioner/nurse specimens. Despite these limitations, it is considered a useful first step for investigating outlying data.

The formula for calculating the 'predicted and confirmed' rate follows, and some hypothetical examples are provided.

Rate per 1,000 women screened = [percentage specimens reported as definite high-grade abnormalities (value 2b.5, from the Data Collection Form) multiplied by their positive predictive value (value 3a, from the Data Collection Form)] + [percentage specimens reported as possible high-grade abnormalities (value 2b.6, from the Data Collection Form) multiplied by their positive predictive value (value 3b, from the Data Collection Form)] x 1,000.

Hypothetical example 3

Laboratory with average values for specimens reported in 2011

Input data 0.93 per cent of technically satisfactory specimens collected by general practitioners and nurses reported as definite high-grade abnormality or possible high-grade abnormality (comprising 0.58 per cent reported as definite high-grade abnormality and 0.35 per cent reported as possible high-grade abnormality)

PPV for cytological predictions of definite high-grade abnormality = 74 per cent

PPV for cytological predictions of possible high-grade abnormality = 46 per cent

Overall rate = [(0.0058 x 0.74) + (0.0035 x 0.46)] x 1,000= 5.9 per 1,000 women screened

Comment: 70 per cent (5.9/8.4) of the national rate of high-grade abnormalities are potentially diagnosed through cytology reports of definite high-grade abnormality and possible high-grade abnormality among specimens collected by general practitioners and nurses for this laboratory.

(Note: the rate of histological high grade abnormality was 8.4 per 1000 women in 2011).

Hypothetical example 4

Laboratory that just reaches the recommended standards

Input data 0.70 per cent of technically satisfactory specimens collected by general practitioners and nurses reported as definite high-grade abnormality or possible high-grade abnormality (comprising 0.50 per cent reported as definite high-grade abnormality and 0.20 per cent reported as possible high-grade abnormality)

PPV for cytological predictions of definite high-grade abnormality = 65 per cent

PPV for cytological predictions of possible high-grade abnormality = 40 per cent

Overall rate = [(0.0050 x 0.65) + (0.0020 x 0.40)] x 1,000 = 3.9 per 1,000 women screened

Comment: 46 per cent (3.9/8.4) of the national rate of high-grade abnormalities are potentially diagnosed through cytology reports of definite high-grade abnormality and possible high-grade abnormality among specimens collected by general practitioners and nurses for this laboratory.

ii) *Is there a deficiency in knowledge or practice?*

Consider the merits of a careful review of the slides reported as negative in the 30 months preceding a histological diagnosis of high-grade abnormality (value 4.2 from the Data Collection Form) to identify any pattern in relation to laboratory false negative reports. It may be beneficial to have a number of staff members independently review these slides and to consider including staff from another accredited laboratory.

The advantages of this approach are twofold. First, while only a small number of slides will need to be reviewed, a systematic problem may become evident. Second, it may be possible to determine the extent to which laboratory false negative reports are occurring because of errors by the screening staff or, alternatively, by the pathologists.

iii) *Is the lower bound of high-grade abnormalities appropriate?*

Consider what proportion of all abnormalities reported by the laboratory are in the range of possible high-grade abnormality or definite high-grade abnormality.

Among all specimens reported as abnormal in 2011 that were collected by general practitioners and nurses, 16 per cent [(0.58 per cent + 0.35 per cent) / 5.89 per cent] were possible high-grade abnormality or definite high-grade abnormalities. If the laboratory's percentage is significantly lower than this, consider whether some of the reports issued at the upper end of the spectrum of low-grade abnormalities (i.e. CIN 1 reports) should be issued in the high-grade range. To assist in reaching this decision, calculate what proportion of women with CIN 1 cytology reports have subsequent high-grade histopathology. If this figure is close to the laboratory's performance for Performance Measure 3a, there may be under-calling of high-grade abnormalities.

iv) *What is the relative sensitivity for the detection of high-grade abnormalities by screening?*

Consider undertaking a review of consecutive specimens reported by the laboratory to identify the rate at which slides showing possible high-grade abnormality or definite high-grade abnormality are being missed at the time of original screening. It is not unexpected to find one or two missed possible or definite high-grade abnormalities per 1,000 slides reviewed.

The relative sensitivity of the original screening for the detection of high-grade or possible high-grade abnormalities can be calculated as (a+c)/ (a+b+c) from the classification shown in the following table. The review should encompass a volume of slides such that the value (a+b+c) should be at least 10, and preferably considerably higher.

	Final report high-grade or possible high-grade abnormality	Final report not high-grade or possible high-grade abnormality
Review opinion high-grade or possible high-grade abnormality	a	b
Review opinion not high-grade or possible high-grade abnormality	c	d

While no formal standards have been set for calculating relative sensitivity, values of 80 per cent or more may indicate very good performance. Sensitivity values of 50 per cent or less probably indicates poor performance, meriting a consideration of the risk to public health.

To minimise bias, it may be beneficial to include staff from another accredited laboratory in the review of the slides.

v) *What is the relative sensitivity for the detection of high-grade abnormalities for individual staff members?*

The review described in (iv) and the calculation of relative sensitivity could be undertaken for staff members with the lowest percentages of high-grade reports in the work they screen.

b) Performance Measure 2b. Percentage of technically satisfactory specimens reported as abnormal is above the recommended standard (i.e., >14 per cent)

i) *Where is the excess occurring?*

Calculate the ratio of the three broad types of abnormal cytology reports, being low-grade reports to possible high-grade reports to definite high-grade reports. Among all specimens collected by general practitioners and nurses in 2011 (n = 1,836,067 specimens), the ratio was 6.72:0.97:1.0 (3.94 per cent: 0.56 per cent: 0.58 per cent).

ii) *Is the boundary between low-grade abnormalities and negative appropriate?*

If the laboratory's percentage of specimens reported as low-grade abnormality is high, consider reviewing a consecutive series of specimens reported in the lower range of the low-grade reports to determine whether the boundary between low-grade abnormalities and negative is appropriate. It may be beneficial to have a number of staff members independently review these slides and to consider including staff from another accredited laboratory.

iii) *Is the boundary between low-grade abnormalities and negative appropriate for individual pathologists?*

The review described in (ii) could be undertaken for pathologists who have the highest percentages of low-grade reports in the specimens they report.

Performance Measure 3a

a) This Performance Measure measures the positive predictive value, which is the probability that a 'positive' cytology test is confirmed by further investigation as having disease.

b) Performance Measure 3a is restricted to cases where the cytology report was of high-grade intraepithelial abnormality; this reduces the likelihood that symptoms may have assisted in predicting the abnormality. Cytology reports of malignancy are deliberately excluded because of the high probability that abnormal symptoms and/or signs may have assisted the cytological diagnosis. If cytology reports of malignancy were included, then the recommended standard would need to be reset to a higher figure than 65 per cent.

c) The standard for Performance Measure 3b is less than for Performance Measure 3a. This acknowledges the fact that cytology reports of possible high-grade abnormality have less certainty about a prediction of disease than definite reports of high-grade intraepithelial abnormality.

d) Unlike Performance Measure 3a, Performance Measure 3b encompasses cytology predictions of either a possible intraepithelial abnormality or a malignancy.

e) It is considered unlikely that potential limitations of histopathology reporting would explain entirely why one laboratory failed to reach the recommended standard. Incomplete reporting of histopathology results to the Pap test registries will limit the accuracy and interpretation of this performance measure.

Investigation of outlying data

Positive predictive value of a cytological report of definite high-grade intraepithelial abnormality is below the recommended standard (i.e., <65 per cent)

i) *Is the percentage of specimens reported as high-grade abnormality high?*

Compare the laboratory's value (2b.5, from the Data Collection Form) for Performance Measure 2b with the national average. If the laboratory's value for 2b.5 is high and the recommended standard for Performance Measure 3a is not reached, this suggests the laboratory may be overcalling high-grade abnormalities on cytology.

ii) *Is there a problem area within the high-grade abnormalities?*

Consider the merits of a careful review of the slides reported as definite high-grade abnormality where the subsequent histopathology was reported either as negative or low-grade abnormality. Such a review may uncover a knowledge problem relating to false positive cytology.

Performance Measure 3b

Investigation of outlying data

Positive predictive value of a cytological report of possible high-grade abnormality is below the recommended standard (i.e., <40 per cent).

i) *Is the percentage of specimens reported as possible high-grade abnormality high?*

Compare the laboratory's value (2b.7, from the Data Collection Form) for Performance Measure 2b with the national average. If the laboratory's value for 2b.7 is high and the recommended standard for Performance Measure 3b is not reached, this suggests the laboratory may be overcalling possible high-grade abnormalities on cytology.

ii) *Is there a problem area within the possible high-grade abnormalities?*

Consider the merits of a careful review of the slides reported as possible high-grade abnormality where the subsequent histopathology was reported either as negative or low-grade abnormality. Such a review may uncover a knowledge problem relating to false positive cytology.

Note: Performance Measures 3a and 3b are to be calculated on specimens. Where a woman has multiple high-grade cytology reports issued by the same laboratory within the six months preceding cervical histopathology, the woman should be included on each such occasion.

Hypothetical example 5

Jan 2011 Cytology report of 'high-grade squamous intraepithelial lesion' by Lab X

Feb 2011 Cytology report of 'possible high-grade glandular lesion' by Lab X

May 2011 Cytology report of 'high-grade squamous intraepithelial lesion' by Lab Y

Jun 2011 Cone biopsy: CIN 3

Lab X would count this woman against Performance Measure 3a on the basis of the Jan 2011 cytology report, and against Performance Measure 3b on the basis of the Feb 2011 cytology report.

Lab Y would count this woman against Performance Measure 3a on the basis of the May 2011 cytology report.

Hypothetical example 6

Jan 2011 Cytology report of 'high-grade squamous intraepithelial lesion' by Lab X

Mar 2011 Cytology report of 'possible high-grade glandular lesion' by Lab Y

May 2011 Cytology report of 'squamous cell carcinoma' by Lab Y

Jun 2011 Target punch biopsy: adenosquamous carcinoma in situ

Aug 2011 Cone biopsy: microinvasive squamous carcinoma

Lab X would count this woman against Performance Measure 3a on the basis of the Jan 2011 cytology report and the June 2011 target punch biopsy report.

Lab Y would count this woman against Performance Measure 3b on the basis of the March 2011 cytology report and the Aug 2011 cone biopsy report.

Performance Measure 4

a) Performance Measure 4 may be an unreliable indicator of the accuracy of a laboratory's negative reports if a laboratory has not been operating for the full 30-month period. This is because the laboratory may have issued abnormal cytology reports in the period just prior to the histological diagnosis of a high-grade epithelial abnormality, but had not been able to issue cytology reports earlier in the 30-month period.

b) Performance Measure 4 may also be an unreliable indicator of the accuracy of a laboratory's negative reports because it relies, in the first instance, on self-review. It is conceivable that the reviewing staff member may not recognise the full spectrum of abnormalities. For this reason, RCPA/NATA assessors may wish to check the slides that were reported as negative.

c) If a laboratory consistently lodges a zero value for this performance measure, closer scrutiny by NATA may be required. Laboratories that have a zero result may have an independent expert check the specimen.

Investigation of outlying data

Review of cytology originally reported as negative but followed by a histological diagnosis of high-grade epithelial abnormality within 30 months reveals >10 per cent show evidence of missed high-grade abnormality.

i) *Is the percentage of specimens reported as high-grade abnormality low?*

Compare the laboratory's value (2b.5, from the Data Collection Form) for Performance Measure 2b with the national average. If the laboratory's value for 2b.5 is low, this suggests the laboratory may be not recognising high-grade abnormalities at the time of the original screening.

ii) *Is there a deficiency in knowledge or practice among the cytotechnologists or cytopathologists, or both?*

Consider the merits of a careful review of the slides that were reported as negative in the 30 months preceding a histological diagnosis of high-grade epithelial abnormality but which on review are considered to show missed abnormalities (values 4.3 and 4.4, from the Data Collection Form). This may help identify any systematic pattern in relation to laboratory false negative reports. It may be beneficial to have a number of staff members independently review these slides and to consider including staff from another accredited laboratory.

If a problem area is found on the review, determine the extent to which laboratory false negative reports are occurring because of errors by the screening staff or, alternatively, by the pathologists.

References

1. Brotherton J, Gertig D, Chappell G, et al. Catching up with the catch-up: HPC vaccination coverage data for Australian women aged 18-26 years from the National HPV Vaccination Program Register. *Commun Dis Intell* 2011;35:197-201.

2. Gertig DM, Brotherton JML, Saville M. Methods for measuring HPV vaccination coverage and the role of the National HPV Vaccination Program Register, Australia. *Sexual Health* 2011;8:171-178.

3. Shield P, Finnimore J, Cummings M, et al. Performance Measures for Australian laboratories reporting cervical cytology; a decade of data 1998-2008. *Pathology* 2010: 42: 623-628.

4. AIHW (Australian Institute of Health and Welfare) (2011), *Cervical Screening in Australia 2008-2009*, Cancer Series no. 61, AIHW, Canberra, ACT.

5. NHMRC (National Health and Medical Research Council) (2005). *Screening to prevent cervical cancer: guidelines for the management of asymptomatic women with screen-detected abnormalities*. Australian Government National Health and Medical Research Council, Canberra, ACT.

Bibliography

Australian Institute of Health and Welfare. Cervical Screening in Australia 2008-2009. *Cancer Series no. 61.* Australian Institute of Health and Welfare, Canberra, 2011

Brotherton J, Gertig D, Chappell G, Rowlands L, Saville M. Catching up with the catch-up: HPC vaccination coverage data for Australian women aged 18-26 years from the National HPV Vaccination Program Register. *Commun Dis Intell* 2011; 35: 197-201

Gertig DM, Brotherton JML, Saville M. Methods for measuring HPV vaccination coverage and the role of the National HPV Vaccination Program Register, Australia. *Sexual Health* 2011; 8: 171-178

NHMRC. Screening to prevent cervical cancer: guidelines for the management of asymptomatic women with screen-detected abnormalities. National Health and Medical Research Council, Canberra, 2005

Shield P, Finnimore J, Cummings M, Wright RG. Performance Measures for Australian laboratories reporting cervical cytology; a decade of data 1998-2008. *Pathology* 2010: 42: 623-628

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Members of the NPAAC Document Review & Liaison Committee (DRL)

Members of the National Pathology Accreditation Advisory Council (NPAAC)

Further Information

Other NPAAC documents are available from:

NPAAC Secretariat
Primary Care and Pathology Branch
Department of Health
GPO Box 9848 (MDP 951)
CANBERRA ACT 2601

Phone: (02) 6289 4017
Fax: (02) 6289 4028
Email: npaac@health.gov.au
Web: www.health.gov.au/npaac