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National
PATHOLOGY
ACCREDITATION
Advisory Council

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Consultation Phase Response Form for draft NPAAC Documents

Please complete and return this NPAAC Consultation Phase Response Form to the Secretariat by the requested date.

It would be appreciated if you could indicate whether the draft document is acceptable in its current form or not, and any potential regulatory costs associated with compliance to the proposed requirements.

Please note:

- The NPAAC Consultation Phase Response Form is in Word format to assist you in providing comments on the draft NPAAC document. To assist the Secretariat in collating responses, it would be appreciated if the template was not structurally modified.
- Adding extra table rows or pages is acceptable as required
- Responses can be forwarded to the NPAAC Secretariat via Email – npaac@health.gov.au and by post to NPAAC Secretariat, GPO Box 9848 (MDP 951), CANBERRA ACT 2601

FROM:

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RESPONSE:

Draft Document Name: Requirements for Laboratories Reporting Cervical Screening	
I consider the draft document acceptable in its present form	☐
I consider the draft document acceptable "as is" but I have proposed minor suggestions for improvement* **Please refer to my suggestion/responses overleaf*	☐
I do NOT consider the draft NPAAC document acceptable in its present form, and I have proposed various responses for consideration* **Please refer to my suggestion/responses overleaf*	X

SUGGESTION/RESPONSE OVERLEAF:

Page no.	S, G or C*	Issue/Item	Suggestion/Response:
4	S1.1	There is a requirement for supervision by a Pathologist or Senior Scientist with training and experience in HPV NAT. However, a laboratory that is proficient in NAT does not need specialized skills for HPV NAT testing as it uses the same or similar platform.	Amend to read: HPV NAT must be supervised either by a Pathologist or Senior Scientist with training and experience in NAT.
4	S1.5	The requirement for 60 abnormal LBC specimens per quarter to maintain competence will need to be reviewed over time as the prevalence of HPV vaccinated people in the community increases and the beneficial effect increases. The LBC test at Renewal will no longer be a screening test but a reflex diagnostic test. There is no other cytology diagnostic test which requires a minimum number of abnormal cases screened per person per quarter to maintain competency. It is a NATA requirement that competency be maintained, documented and proven through participation in external quality assurance programs and in-house quality review procedures. In addition other screening tests, funded by the Federal Government (Breast Screen and National Bowel Screening programs), have no minimum number of cytology and/or histology cases requiring reporting by participating pathologists, to maintain competency. Once again, competency is monitored through both internal quality audits and participation in external QAP.	Remove the requirement for a minimum of 60 abnormal LBC specimens per quarter. If minimum numbers are to be instituted, ensure the requirement is reviewed by formalizing the review date of the document.
7	S3.1	It is likely each pathology laboratory will have to adjust their request forms / requesting system (if electronic) to prompt the practitioner to state whether it is a screening specimen, self-collected specimen, repeat sample, specimen from a symptomatic woman or post treatment. Even then, it will be highly unlikely that this information will	The National Cervical Screening Program should advise practitioners of the information required by pathology to perform appropriate testing when they are sending out their communication about the changes. The training of Practitioners should come under the auspices of the Royal

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		be with the specimen. If this information is not provided the laboratory will have to spend time ringing practitioners to obtain the required information, placing a large burden on the laboratory.	College of General Practitioners or the Royal College of Gynaecologists and Obstetricians. Provision of required information by the GP/Specialist/Nurse Practitioner should be a requirement for the practitioner to receive MBS payment for taking the specimen. Only after other avenues are exhausted should the laboratory have to contact the practitioner directly.
4	S1.4	Cytology staff employed for examining LBC must hold a CT(ASC)	Include a clause for 'grandfathering' staff who have been practicing Gynae cytology for 30+ years who have not obtained a CT(ASC) qualification but continue to comply with laboratory competency evaluations and are a valued resource with regard to experience in the laboratory. These staff will likely be approaching retirement age and may not want to re-skill in another pathology discipline. Excluding them from Gynae Screening may see these competent, experienced staff redundant.
11	S5.4	The prevalence of HPV is not taken into account. The prevalence of HPV infection varies in different populations. Some ethnic groups and sex workers for instance have much higher rates of HPV infection than other groups. This will in turn mean some population groups will have higher rates of cervical cancer. This higher prevalence needs to be taken into account in assessing screening performance.	The prevalence of HPV infection in populations (and/or subgroups) should be used to predict and assess the adequacy of screening in those populations.

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11	S5.4	At least 2000 screening specimens are required due to the low prevalence in the population. As a consequence of the expiry of the specimen collection medium at about 1 month, this will mean a test volume of 2000 screening specimens would be the minimum needed to fulfil this quality measure. There is no published evidence referred to in the document which justifies the need for minimum screening numbers. There will be some states/territories where HPV testing and LBC will therefore not be able to be performed by the public pathology service in that state/territory. Many if not most of the teaching hospital laboratories will be forced to cease their HPV testing/LBC services. This will adversely affect patients. It will mean that patients will have their access to screening reduced. Patients would have to have their specimens sent further for testing extending turn-around-times and/or they will be forced to pay a significant out of pocket payment to private providers. This is contrary to the aims of the screening program. While the intention to ensure appropriate screening quality is appreciated, this requirement will also exclude many public pathology laboratories currently providing high-quality services to tertiary referral women's hospitals. Due to the necessity of providing combined HPV/cytology reports and impracticality of splitting samples between laboratories, it will additionally be effectively impossible for laboratories excluded from HPV testing to perform reflex cytology examinations. Laboratories located at tertiary referral hospitals are responsible for the vast majority of Dysplasia Review meetings which are critical to appropriate patient	There should be no minimum screening test numbers required. Appropriate supervision and quality assurance programs (NATA/RCPA) are the more appropriate means of ensuring quality testing. If minimum screening test numbers are to be implemented, these should be determined in line with published evidence. If a published evidence base is not available, they could be determined by an independent body within a quality framework. If minimum numbers are required, it is important to state whether this also includes the test of cure patients who are a low prevalence population (under MBS Item 69418). There will be peaks and troughs in screening numbers due to the change from a two year to a five year program. It would be more appropriate to introduce any minimum numbers once this impact is known.

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		management when there is discordance between colposcopic findings and cytology. These essential case reviews will no longer be possible if pathologists providing these services are de-skilled by exclusion from the provision of HPV/cytology screening. Patient management will be compromised as a result. It should also be noted that the populations seen at tertiary referral women's hospitals are not representative of the wider screening population, containing a far higher proportion of symptomatic patients and women with a past history of abnormal screening tests. HPV prevalence is likely to be higher in such populations and it is unclear whether the 2000 minimum requirement takes this into account. The HPV detection rate is not the sole measure of screening test quality/accuracy and laboratories will additionally be participating in external QA and meeting NATA standards for operation. Ideally there should be no minimum screening numbers. If there is a justification for introducing the minimum numbers, there must be referral pathway strategies for HPV screening, to ensure that participating labs can meet an evidence-based minimum number of tests without being burdened with the cost of send-away tests. Otherwise, there is a potential risk of the test being performed by a small number of labs, creating monopolies and disadvantaging patients.	

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11	S5.4	HPV detection is a molecular test and does not need 2,000 samples per month for a lab to show adequate and accurate testing. Nearly all large modern, clinical pathology laboratories provide molecular pathology tests to detect pathogens and have accurate testing results. In Australia, they are also NATA/RCPA assessed. This molecular testing also includes tests that are mainly used for screening e.g. chlamydia and there are no minimum numbers specified for these tests.	.
11	S5.4	The expiry of the specimen collection medium needs to be reviewed. No statistical data or references have been provided to justify the minimum requirement of 2000 screening HPV cases per month. One justification given was due to the limited stability of the specimen. What data is available highlighting the limited stability of HPV in liquid based media? It is noted in one study[1] that when stored at 2-8°C HPV was able to be reliably extracted more than 2.5 years following collection. The cytology laboratories associated with large public hospitals service an increased segment of the population (compared with private laboratories) that is not considered to be screening; although some of the work is likely to be screening. Some may struggle to meet 2000 screening HPV tests per month. Is it appropriate that this screening number apply to tertiary referral centres? The exclusion of pap smears from public pathology laboratories will	HPV specimens should be from a period longer than one month (ie per quarter).

[1] Agreda PM, Beitman GH, Gutierrez EC, Harris JM, Kock KR, LaViers WD, Leitch SV, Maus CE, McMillan RA, Nussbaumer WA, Palmer MLR, Porter MJ, Richart GA, Schwab RJ, Vaughan LM. 2013, Long-Term Stability of Human Genomic and Human Papillomavirus DNA Stored in BD SurePath and Hologic PreservCyt Liquid-Based Cytology Media. J Clinical Microbiology **51**:2702-2705.

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		result in a reduction of training for Registrars and Scientists coming into the field.	
		Screening will be separated from histopathological testing. The effect of concentrating HPV and LBC test reporting in approximately 10 laboratories nationally will be to separate reporting of these tests from histopathology tests (Punch biopsies and LLETZ biopsies/Cone Biopsies), obtained as a consequence of these tests. This separation will be between different laboratories often over great distances.	
		Quality assurance using clinic-pathology procedures will become very difficult. Agreed colposcopy performance standards are not yet available. However it is highly likely that one of the requirements of the colposcopy quality protocol is that all discrepancies between HPV tests/triage cytology and subsequent biopsies be resolved at a clinic-pathologic conference. Bringing together triage cytology and biopsies will become difficult if not impossible for many of these discrepancies. It is not possible to perform rational resolution of cyto-histopathologic discrepancies at a face to face meeting between pathologist(s) and colposcopist(s) when one of the samples cannot be reviewed in real time. Repeating the LBC at colposcopy with biopsy would allow cyto-histologic correlation. However, this would require that the NPAAC standards allow laboratories to report LBC specimens taken at the time of colposcopy.	Clarification on this point is required.
13	S6.1	The requirement for a combined HPC NAT and LBC report will have costs incurred by pathology providers to adjust computing systems.	

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		The document does not clearly state whether it applies to all HPV tests and LBC tests regardless of whether they are taken for screening purposes, as repeat tests at colposcopy and as repeat tests during follow-up for previously positive tests. This needs to be clarified. Most labs servicing major hospitals will need to continue to offer a diagnostic gynaecological cytology service even if they no longer provide a screening service.	Clearly separate screening from diagnostic cytology.
13	S6.4	Good links to registry and access to results is essential. If public providers are unable to provide screening but are relied upon for cytology or more complicated testing, the screening results must be made available in real time. In the event of one report from two laboratories or send-aways, if must be made clear who has the responsibility for reporting to the national register.	Clarify reporting responsibilities to the register.
	Appendix A	The routine QC and QA and QAP systems of pathology laboratories should be sufficient to identify testing issues so that any HPV positivity that is outside the acceptable range would likely be population based. All molecular assays that will be used for HPV DNA have to meet the strict criteria in Section 4 including being approved by the TGA and meeting sensitivity and specificity criteria. Is Appendix A included because some laboratories will be doing molecular testing for the first time? Is it to detect PCR contamination?	Clarify the purpose of Appendix A.

POTENTIAL REGULATORY IMPACT INCLUDING COSTS, ASSOCIATED WITH COMPLYING WITH PROPOSED REQUIREMENTS

1. Do you expect that additional activities will be required in order for your laboratory to comply with the revised Requirements?

X Yes ☐ No

If Yes:

(a) What additional time do you estimate will be required to carry out the additional activities?

Public pathology providers will require additional time sourcing information about the specimen from practitioners, re-designing request forms, developing changes to the Laboratory Information System (for issuing one report and also linkages to the registry), and educating providers. Also time in reconfiguring processes so that one report can be issued.

(b) What additional staff to you estimate will be required to carry out the additional activities?

-

(c) What costs to you estimate will be incurred as a result of the additional activities?

Costs associated with (a). Also costs in sending tests away if the laboratory can no longer undertake screening.

(d) Will these costs be one-off or ongoing?

Request forms and LIS enhancements are one-off. Other costs identified in (a) (b) and (c) are ongoing.

The issue is not only about ongoing costs but the ongoing loss of other tests. If the practitioner can no longer send the screening specimen a public laboratory for testing they may also cease to send other tests to the public laboratories.

The requirements have the impact of substantially changing referral patterns in favour of private pathology providers. This is against principles of competition and beyond the remit of NPAAC.

Costs to government will be considerable if only private providers are able to provide screening due to funding disparity under Patient Episode Initiation Fees.

2. Do you expect that changes to existing processes/procedures or infrastructure will be required in order to comply with the revised Requirements?

X Yes ☐ No

If Yes:

(a) What additional time do you estimate will be required as a result of these changes?

Public pathology providers will require additional time to review the policies and procedures for pre-analytical, analytical and post-analytical processes.

(b) What additional staff to you estimate will be required as a result of these changes?

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(c) What costs to you estimate will be incurred as a result of these changes?

See above

(d) Will these costs be one-off or ongoing?

See above

Any additional general comments including any potential costs associated with compliance to the proposed requirements (please provide specific examples):

Promulgation of the standard in its current form will lead to consolidation of HPV testing laboratories. This will advantage private laboratories in terms of their profitability and share price. Private pathology providers charge patients for cervical screening tests and this limits access to patients if there is no public provider providing screening tests. The standards therefore need to be reviewed to ensure all women regardless of their ability to pay, have access to screening from a viable public sector as well as private sector involvement to ensure the ongoing success of this Commonwealth Government program.

In some states and territories, both public and private laboratories will be impacted by the minimum screening requirements. For example, in Tasmania both the public and private laboratories may not meet the requirements. This would negatively impact patients in terms of turn-around times. It would also jeopardise existing specialist review arrangements whereby the local pathologists and gynaecologists review discordant cases to optimize treatment outcomes for patients. Losing gynaecological screening services also negatively impacts the pathology provider's ability to provide non-gynae cytology services through the loss of experienced staff and challenges in recruiting appropriately skilled staff.

There would be a significant cost for both the requesting and source laboratories for send-aways. The amount of costs associated with specific activities mentioned above can be provided upon request.