

The new NPAAC standard: Requirements for supervision in the clinical governance of medical pathology laboratories (Fifth edition 2018)

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NPAAC Standards (1)

- Purpose: **to reduce the risk of patient harm from pathology testing**
- TGA
- Australian Commission for Safety and Quality in Healthcare

NPAAC Standards (2)

- Strategy: **Shift from a compliance focus to a risk based approach**
- Acknowledgement of
 - Community expectations of protection from risk
 - Improve return on effort
- NATA, ISO aligned with risk based approach

NPAAC peak documents

- Requirements for Medical Pathology Services

Second edition 2018

WHAT

- Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories.

Fourth edition 2018

WHO

Pathology services have changed 2007 – 2019

- Volume, centralized testing, networks, POC, new technologies
- Pathology as an essential service. Leeds 2016
- Centrality to healthcare innovation Personalised medicine, screening, AMS
- Pathology as an end to end clinical service, including a test. Stewardship, Open disclosure

Consumer expectations have changed 2007-2019

- Consumer literacy
- Value of pathology My Health Record
- Awareness of potential harm Leeds, Theranos, PSA testing in SA

Community expectation of best practice and governance

- Healthcare
- SA Pathology review 2016 by ACSQHC of PSA testing failure
- On 3 March 2016, a patient contacted the Executive Director, SA Pathology and senior management via an email titled “Being on ‘Death Row’ for 30 days” which explained his anxiety on receiving an inaccurate SA Pathology test
- **Recommendation 1:** Formal apology and implementation of lessons learnt
- That SA Pathology issue a public apology for distress and anxiety experienced by the patients because of the inaccurate PSA testing, and provide regular updates to the community on the implementation of lessons learnt from the incident and the new measures introduced to assure the quality control of clinical testing in SA Pathology laboratories.
- Other sectors

Accountability

- “Accountability is a key component of healthcare reforms.”
R Deber, Healthcare Policy 2014
- Dr Patel, SA Pathology reviews 2016.
<http://www.sapathology.sa.gov.au/wps/wcm/connect/sa+pathology+internet+content+new/content/news/prostate+cancer+screening+review>
- “A top down management process although identified on paper and allocated to pathologists and scientists carries no accountability or responsibility.”
- “...significant governance failings of senior staff. Many senior staff in management positions are not familiar with their responsibilities and to who they are accountable. Equally they do not have in place an appropriate escalating communication response procedure to deal with significant abnormal results.”
- “SA Pathology’s complaint handling, open disclosure, governance and accountability systems during this period were totally inadequate.”

Revision of the Standard to be fit for purpose in 2018

- Strengthen accountability
- Embed responsibility for risk management
- Align laboratory categories with current models of practice
- Emphasize the need for a skilled workforce
- Clear Standards

Principles of the 2018 Standards

- Medical practitioner is the designated person accountable for the provision of a medical pathology service
- Clear delegation process
- Supervision delegated to staff with appropriate training, qualifications, scope of practice and CPD for testing.

G Laboratory

- The role of clinical scientists.

- *2007 Standard:*

GX/GY laboratories operate “under the direction, control and full time supervision of a supervising pathologist or senior scientist who is expert in the group, or groups, (of tests)

S1.3 Where a GX or GY laboratory is supervised by a senior scientist there must also be a pathologist present during normal working hours of the laboratory.

- *2018 Standard:*

Designated person...where responsibility for full time on site supervision of Pathology testing may be delegated to other Pathologists with relevant Scope of Practice. These pathologists may further delegate supervision of specific testing to Clinical scientists with relevant scope of practice.

Pathologists and clinical scientists play complementary roles in the delivery of pathology services.

Accountability **to users (referrers, the community)** rests with the medical practitioner.

- Training and qualification
- Registration, mandatory professional indemnity insurance
- APP undertaking
- ACSQHC, SA Pathology Review 2016 Clause 80.

ACSQHC Review of serious failures in reported test results for prostate specific antigen (PSA) testing of patients by SA Pathology

- 80. Responsibility to maintain quality in Australia lies with the supervising pathologist as the 'Approved Pathology Provider' under a formal agreement with the Health Insurance Commission stating they take personal responsibility for the rendering of services. It is vital that pathologists, the only medically qualified staff in a pathology laboratory, fulfil their bridging role for clinicians by ensuring that pathology services fulfil their clinical objective. This is done by remaining in close contact with both the laboratory and the clinicians which it serves. In discharging these vital obligations a pathologist must be supported by the administrative structure of the laboratory, ideally with each supervising pathologist represented at all senior administration meetings. This was not the case at SA Pathology.

S Laboratory

- Heterogeneity of services
- Revised Standard seeks to restore the requirement of specialised testing
- Implementation issues - response
 - Removal C4.3(i) “in house IVDs must not be used”
 - Include RTAC qualification

M Laboratory

- Medical practitioner led POC and other testing

Conclusion

- Purpose of the Standard is to reduce the risk of harm to patients from pathology testing by responding to community expectations for best practice and governance.
- Standards written to assist practices identify risks, strengthen accountability and reporting lines, to reinforce the crucial role of all laboratory professionals
- NPAAC's commitment to clear communication.