ORIGINAL ARTICLE

Analytical errors in pathology: a case study

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ABSTRACT

The Australian Government continues to be unsupportive of independent registration of the scientists through the Australian Health Practitioner Regulation Agency (AHPRA). They are satisfied with the controls of a Royal College of Pathologist, Australasia (RCPA), Registered Pathologist and National Association of Testing Authorities (NATA) accreditation.

In 2016 an investigation into one of the oldest private laboratories in South Australia was undertaken by the Australian Commission on Safety and Quality in Healthcare to ascertain the mishandling of a significant complainant from patients and clinicians. An experienced review team made five recommendations to improve the laboratory's infrastructure.

A major component of any professional registration is continuing education of staff and it is a requirement in both international and domestic standards. The review team made many references to the perceived lack of knowledge of the scientists in their report, but it does not form part of their recommendations. The Australian Government does not mandate independent registration of Healthcare scientists through AHPRA, which is an anomaly in the international community, and, as this report highlights, creates potential of risk to patients.

Keywords: Prostate Specific Antigen, Westgard Rules, Continuing Professional Education

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INTRODUCTION

In April 2016, a South Australian newspaper reported that there had been a medical misadventure at the state's largest private pathology laboratory, South Australia (SA) Pathology (1). This laboratory was established in the 1930's near the Royal Adelaide Hospital, and partnered with the existing hospital laboratories. It has evolved over the last 75 years and now includes training and research arms that support the healthcare system in South Australia.

SA Pathology performs a large range of clinical diagnostic tests, among them testing for levels of prostate specific antigen (PSA). PSA testing was initially described in America in the late 1980's and led to the development of a national Australian guideline for the monitoring of patients who had undergone radical prostate surgery (2). In 2015, SA Pathology used the Siemens ADVIA Centaur platform for this testing and, critically, this platform carries two alarms that inform staff that an assay is malfunctioning.

A report issued by the Australian Commission on Safety and Quality in Healthcare in October 2016 stated that these alarms were not being used by SA Pathology staff. *"The 10_x rule was no longer functioning*" and "*while the 4_{1s} rule was functioning, its reports were accepted despite the repeated warnings*" (4). As a consequence, the SA Pathology PSA test reports should have been considered unsafe as critical control measures may have violated two quality metrics and the review team identified that*; "…a lack of clinical expertise available when interpreting test results and examining the impact of quality assurance issues"* (4) may have contributed to this.

This is not unusual in a large laboratory which could be running hundreds of different chemistry tests on each of its analysers. The Barnes report for the British (UK) National Health Service (NHS) in 2014 concluded that the current quality assurance systems used in UK laboratories have gaps (5). This is not limited to the UK, a review of twenty-one large US academic medical centers showed that there is large variation in understanding and usage of quality control rules (6).

However, it wasn't until SA Pathology had received multiple (customer) complaints from clinicians and patients that the laboratory recognised the issue and began to act. At the beginning of February 2016 SA Pathology conducted an internal review. The problem was identified and confirmatory testing of the PSA assay with an external reference lab began at the end of the same month and released the following statement on its website as a Quality Improvement Program *"Whilst our PSA results have been highly accurate and reliable in the core range, we have moved to improve values below 0.15g/L, where some patients have required repeat testing"(7).*

Enquiries by reporters of the Adelaide Advertiser newspaper identified the truth of the confirmatory testing (1). An urgent review was commissioned by the Health Authority, which was convened in late April and its findings published on the 16th of July 2016 (4). The twenty-two page report, providing a comprehensive timeline of the issue, was conducted by a group comprising a senior clinical pathologist, a senior consultant urologist, a former Commissioner of the New South Wales Health Care Complaints Authority, and two members of the Australian Commission on Safety and Quality in Healthcare.

The report identified major deficiencies in analytical processes, governance and quality assurance of SA Pathology, which led to the following five recommendations:

Recommendation 1:	*Formal apology and implementation of lessons learnt*
Recommendation 2:	*New management structure for SA Pathology*
Recommendation 3:	*Immediately ensure appropriate pre-analytical, analytical and post-analytical quality control procedures are operational within SA Pathology which meet national standards and are reinforced and regularly audited*
Recommendation 4:	*National Accreditation to confirm that SA Pathology meets national laboratory standards.*
Recommendation 5:	*SA Pathology ensures that the Safety Learning System is fully implemented and that all incidents are logged in the Safety Learning System. Clinical staff are trained in open disclosure* (4).

The limited number of recommendations from this review of SA Pathology compares unfavorably to reviews of similar incidents in other laboratory services. A review of cellular pathology governance at Sherwood Forest Hospitals NHS trust by the Royal College of Pathologists in 2013 led to 57 recommendations (9). New Zealand Ministerial inquiries into the

under-reporting of cervical smears led to 46 recommendations (10), and the Health and Disability Commissioners report into PSA testing procedures at Gisborne Hospital, which encompassed administrative and clinical practices, provided 16 recommendations (11). These investigations resulted in fundamental changes to pathology services in those countries.

One of the common findings in these investigations was to highlight the lack of staff education regarding the issue at hand. In Australian laboratories, there is no legal requirement for technical staff to hold a practicing license or seek any continuing professional development (CPD) to maintain employment, as the Australian Government doesn't believe that medical scientists sufficiently influence patient outcomes to warrant it.*"The success of the National Australian Testing Agency (NATA)/ Royal College of Pathologist, Australasia (RCPA) laboratory accreditation scheme has given Australia one of the best pathology sectors in the world and the government's view is there is no evidence that scientist registration is required"* (12). In the recent National Pathology Accreditation Advisory Council Requirements (NPAAC) for Supervision in the Clinical Governance of Medical Pathology Laboratories: **S1.1"** *Every laboratory must be under the direction and control of a designated person who is a medical practitioner and who is responsible for and accountable for the clinical governance of the medical pathology services provided by the laboratory"* (13). The Pathologist has sole responsibility for supervision of the laboratory in Australia, NATA have the responsibility for the assessing the laboratory compliance with international standards and providing nationally recognised accreditation. These mechanisms seem to have been inadequate in this case, as observed by this comment by the review team: "*It appears that there was little understanding within SA Pathology of the clinical use to which the low level tests could be put and little appreciation of potential harm to patients*" (4). Given the above, were the number and type of recommendations resulting from the review of SA Pathology due to the vague nature of the incident, or the review parameters?

DISCUSSION

The central document that was analysed in this article was the Australian Commission on Safety and Quality in Health Care "*Review of serious failure in reported test results for PSA testing of patients by SA Pathology"*. It is a twenty-two page document released in July 2016 following three months of investigation into SA Pathology (4). An experienced team of clinicians and safety experts was assembled and charged with gaining information through meetings and interviews with key stakeholders, general observation of laboratory practices, and a review of all materials relating to the PSA testing incident. They had access to all stakeholders, including patients, clinicians, laboratory staff, SA Pathology Executive team members, and key members of the South Australian Healthcare departments. "*The terms of reference for this review ask it to "advise on improvements required relating to clinical governance systems and processes, incident management, professional standards and accountability within SA Pathology"* (4). The published recommendations were as follows:

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* (4). This first recommendation was made in response to the lack of general disclosure given by SA Pathology following its discovery of inaccurate results. That discovery only resulted in communicating the unsafe test reports to referring clinicians. Sikaris *et al* recognised that this level of communication complied with the principle of open disclosure but critically added the need for a public apology stating: *"Although somewhat belated, the review recommends that an apology should now be offered"* (4).

In both the UK and New Zealand there is a robust system for open disclosure of incidents through those countries regulatory authorities: The Health and Care Professions Council (HCPC) in the UK and the Medical Sciences Council of New Zealand (MSCNZ). In Australia, laboratory accreditation is provided by the National Association of Testing Authorities (NATA) and its findings are not available to the public. Following an exhaustive search of both the SA Pathology (14) or the NATA website (15) the author could find no reference to the incident or any subsequent indications to the public that the review findings had been implemented.

Recommendation 2: New management structure for SA Pathology. The Program Director of South Australia Statewide Clinical Support Services engage an appropriately qualified and experienced person to implement an organization structure for SA Pathology that: aligns appropriately skilled staff placement with the operational needs of the service; provides adequate clinical expertise to monitor and inform the production of results; clearly defines the responsibilities and accountabilities of staff; and ensures the requirements of referring clinicians are reflected in the work rules of the service (4). Dr Sikaris made this observation of the management of SA Pathology: "During the review it became apparent that the structure of the organization did not provide sufficient clinical input and management accountability at appropriate levels" (4). In a concurrent review of the Governance and Management of SA Pathology by Dr. Peter Flett, a former Director General of Health in Western Australia, areas of concern were identified within the management structure of SA Pathology (16):

- A top down management process, which is identified on paper and allocated to pathologists and scientists but carries no accountability or responsibility.
- A horizontal management structure termed "Directorates" that identify senior pathologists and senior scientists as line managers, who cover all twelve laboratory sites, but they are confined and work one site. Hence management is off site and distant.
- A central large automated department is identified in each of the three metropolitan laboratories which is managed by a scientist, but the pathologists do not have active management influence within this area.

Interestingly, this deficiency identified in SA Pathology mirrors the deficiency identified in the PSA testing issue at Gisborne Hospital in 2003 which reported that: "*Communication between all levels of management and technical staff must be improved. Problems will recur if there is a continuation of the dysfunctional relationship evident in the past*" (11). It is worth noting that SA Pathology had a Quality Manager in position since 2009 and NATA would have conducted multiple periodic inspections to ensure compliance with International Organisation for Standardisation (ISO) 15189 standards. As part of the Flett review of SA Pathology a new, more conventional structure, was adopted in 2018 that included a Training Manger as an important addition. A laboratory without a dedicated Training Manager means that this responsibility is added to those of the Quality Manager.

Recommendation 3: *Immediately ensure appropriate pre-analytical, analytical and post- analytical quality control procedures are operational within SA Pathology which meet national standards and are reinforced and regularly audited. It is the role and responsibility of the senior management of a pathology service to see that policies, procedures and practices are in place that ensure staff understand the quality control*

system in use, and that staff understand their role in relation to quality control including reporting requirements. This review recommends that an immediate review is undertaken to ensure appropriate quality control procedures are operational within SA Pathology and staff are regularly assessed to ensure their understanding and compliance with quality control procedures (4).

It would be reasonable to assume that all training and competency documents would have been available to the review team as stated in ISO 15189 standard: ***5.1.6 Competence assessment***. *Following appropriate training, the laboratory shall assess the competence of each person to perform assigned managerial or technical tasks according to established criteria. Reassessment shall take place at regular intervals. Retraining shall occur when necessary* (17). Competency assessment documents are required for every test system (any process within the laboratory that produces a result) and are required to be reviewed following any change to the standard operating procedure. Therefore, all chemistry staff using the Siemens ADVIA Centaur must have had an annual competency document that recorded compliance with the six parts of full competency described in the standard:

a) direct observation of routine work processes and procedures
b) performance of equipment maintenance and function checks
c) recording and reporting of examination results
d) review of quality control records
e) assessment of problem solving skills
f) examination of specially provided samples e.g. proficiency testing samples

These records are explicitly stated in the NATA guidance for its assessors. Critically, the inadequacy of competency documentation appears to be a universal issue, as noted by Chittiprol *et al: "The most common areas of deficiencies among all the agencies include: testing personnel qualifications and competency evaluation"* (18). Throughout the report references are made about the apparent lack of knowledge of SA Pathology surrounding the PSA test among the staff at SA Pathology with a urologist interviewed by the review team stating that *"when he called SA Pathology he spoke to a scientist who appeared to have no understanding of the clinical implications of the inaccurate low level tests"*(4).

These observations, and the fact that NATA accreditation had been awarded to SA Pathology, appears conflicted. The third recommendation highlights a serious flaw concerning training and competency and, we contend, an underlying issue of CPD in Australian laboratory staff is being ignored. This is not uncommon and was identified in New Zealand following the incidents in Gisborne: *"Staff therefore had to ask for training opportunities and these were frequently declined"* (11).

The Therapeutic Goods Administration (TGA) of Australia released a Safety Advisory note in August of 2016 regarding a number of PSA testing kits that were showing errors.(19) This would constitute an excellent opportunity for education within a laboratory and in many other countries there is a requirement for CPD for medical scientists. A nationwide CPD scheme does exist for members of the Australian Institute of Medical scientists (AIMS) but is voluntary. Therefore, there is no mechanism to assess whether this important information reached the bench level staff. Due to the lack of any requirement for CPD, employers do not commit resources nor provide time for staff to complete these elements, despite this being an ISO 15189 requirement which states: **5.1.8 Continuing education and professional development**. *A continuing education programme shall be available to personnel who participate in managerial and technical processes. Personnel shall take part in continuing education. The effectiveness of the continuing education programme shall be periodically reviewed. Personnel shall take part in regular professional development or other professional liaison* (17).

International accreditation standards require staff education and records of training whenever a laboratory introduces a new test or changes the procedure around an existing one. This can be as simple as calling a huddle or as elaborate as giving an off-site presentation. In any case competency documents must be modified appropriately to reflect changes and the events recorded as CPD by the staff. Due to the fact that it is not a requirement for staff in Australia there was no mention made of this in Sikaris' report nor is it required of a NATA inspection, despite it being explicit in the ISO 15189 standards which NATA uses as its basis for accrediting Australian laboratories.

Recommendation 4: *National Accreditation to confirm that SA Pathology meets national laboratory standards, the service, as soon as practical, seeks independent assurance of technical competence through accreditation by the National Association of Testing Authorities (NATA) (4).*

NATA was established in 1947 and is a member of many international accreditation organizations. In order for any pathology laboratory to be approved by the Australian Government Department of Human Services (DHS) and to claim Medicare benefits, the laboratory must hold accreditation with NATA.*"NATA is the authority that provides independent assurance of technical competence through a proven network of best practice industry experts for customers who require confidence in the delivery of their products and services"* (15). In New Zealand prior to 2004, International Accreditation New Zealand (IANZ) held a similar position within the healthcare system as NATA does in the Australian Healthcare system today. *"Gisborne Hospital viewed IANZ as the 'primary watchdog for community safety' through its accreditation and assessment processes"* (11).

SA Pathology was established prior to NATA and has a close relationship with the South Australian Health system, so it can be assumed that SA Pathology must have maintained NATA accreditation for many years. Recommendation 4 appears to cast NATA assessments of SA Pathology in a critical light. NATA advises its assessors to audit, amongst other things, training and competence records. (20) The Sikaris review team would certainly have had access to the previous NATA reports, which would have provided them with a considerable amount of information. As it was in the report into the PSA testing errors in Gisborne, the authors make mention of reviewing the previous accreditation document and came to the following conclusion about laboratory accreditation: "*It is clear from subsequent events and investigations by International Accreditation New Zealand (IANZ), and from my investigation, that many of the concerns raised by previous assessments had a sequencing*" (21). The NATA Annual reports for 2016 or 2017 does not refer to the PSA test reporting discrepancies and customer complaint procedures. The assessors must have ratified the SA Pathology Chemical Pathologist directive to report PSA levels as low as 0.3ng/mL with the report mentioning that the manufacturers lowest checked value was much higher than this (4). It does not appear there was any documented additional education provided to laboratory staff about the clinical implications of the new testing criteria. This is require by ISO 15189 standards: **5.1.5** Training**, 5.1.6** Competence assessment, and **5.1.7** Reviews of staff performance (21) which state that: "*The effectiveness of the training programme shall be periodically reviewed"* and *"Retraining shall occur when necessary".* In the National Pathology Accreditation Advisory Council (NPAAC) is an Australian governmental ministerial advisory body responsible for publishing guidance for the pathology service. It explicitly mentions CPD standards in "*Requirements for Medical Pathology Services"*: **C6.1(ii)** "*All qualified staff involved in the provision of Medical Pathology Services must provide documented evidence of participation in continuing professional*

development commensurate with their role and responsibilities" (23).

In the NATA document provided to inspectors, they are required to address the following questions pertaining to each ISO standard; (23). Remedial training is required when staff work in unfamiliar areas of the laboratory, work out of hours or at weekends. It is also required for all staff, especially if competency is lacking or when a new test is introduced, and this training must be documented. However, in the latest "*Guidance to NATA assessors*" document this is conflicting as there appears to be no requirement for an inspection team to review training or competency documentation as the only instructions provided are as follows:

Staff training and competence (20)

As a routine aspect of every assessment visit, an appropriate range of tests or inspections should be witnessed to ensure that:

- staff are familiar with test/inspection methods and are capable of carrying them out;
- appropriate training and education has been provided;
- staff are appropriately supervised and technical direction is provided; and
- staff understand test/inspection principles and limitations according to their responsibility.

Standard laboratory practice is to run periodic quality control (QC) materials for every test that is conducted which is detailed in ISO 15189 standard **5.6.2** Quality control (17). This is done to confirm that the analyser is providing a result that reflects the known value of the QC sample. Typically, there are statistical biases built into the system as no test is completely accurate but varies regarding its sensitivity and specificity. However, the review team observed that: "*In SA Pathology it does not appear that bench level staff were able to assess the significance of potential warnings being generated by analytical systems*" (4). The analyser software provides the user with information aligned to these rules and if the test violates these conditions then it will alarm to bring it to the scientists' attention. The "Westgard rules" are used on most laboratory analysers that run multiple QCs and usually require manual input to disable. The report implies that the technical staff ignored a warning from an analyser for some time, before it came to the attention of a senior member of staff or clinician who was aware of these implications.

The laboratory is required to record QC results, which may be done electronically, and are usually reviewed on a monthly basis by senior staff. The understanding of QC particular to any test system is one of the requirements of a competency assessment and these documents must be provided to accreditation inspectors if required. Once again this was highlighted by the review team "The clinical significance of the inaccurate low level PSA readings was not appreciated and action to investigate the cause was not pursued with any sense of urgency" (4). There are a number of ISO15189 standards that mention this practice such as:

4.9 Identification and control of nonconformities

The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes.

5.6.2.3 Quality control data

The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.

5.7.1 Review of results

The laboratory shall have procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results, and follow up with actions to address issues in a systematic and managed way, with closer monitoring in the implementation of any change in processes (17).

The review team's recommendation of seeking national accreditation with NATA appears redundant as SA Pathology was accredited by NATA at the time of the incident. The fundamental laboratory errors associated with PSA testing may have been missed by the previous NATA inspections but these reports are not publicly accessible. The NATA Annual reports for 2016 or 2017 do not refer to the SA Pathology PSA test reporting discrepancies and customer complaint procedures.

Recommendation 5: *SA Pathology ensures that the Safety Learning System is fully implemented and that all incidents are logged in the Safety Learning System. Clinical staff are trained in open disclosure. SA Pathology should cease using Q-Pulse as its exclusive incident reporting system and fully implement the state wide Safety Learning System (SLS) together with a program that ensures that staff understand how the system operates and the mandatory reporting requirements when clinical incidents are identified. SA Pathology should also review its open disclosure policy and how it will operate in the event of incidents involving patient results. SA Pathology should ensure that its systems allow for all relevant information to be provided to treating clinicians who will conduct the appropriate discussion with the patient (4).*

A standardised approach to safety is always desirable in a large organization as it reduces errors that might be easily be missed by divergent practices. The SLS was introduced into the South Australian Health system in 2010 and despite its use being a requirement of all organisations providing services on behalf of SA Health, it had not been adopted by SA Pathology at the time of the incident. They were still using Qpulse (24), which is a software solution for quality management, document control, and training and competency in use in many laboratories. The review team's recommendation for SA Pathology to surrender its use of Qpulse for incident reporting and adopting the universal SLS is sound. The approach would allow for more robust management of incidents by a team that are appropriately trained and unbiased, and it would also require little to no resource commitment from SA Pathology. This highlights another failure of SA Pathology management team to provide its staff with the required training that may have recognised this incident much earlier.

CONCLUSIONS

The 2015 PSA testing incident by SA Pathology was poorly managed by the executive of the organisation. There are many lessons that should be learnt from how it was handled that could have been implemented into the wider Australian pathology service. As it was in New Zealand fifteen years before however, it seems that the warning signs were not heeded. The Sikaris report found that neither of the regulatory controls in place were deficient, which contrasts with the findings of the review of the Gisborne Health Board which suggested that reliance on a single form of regulation would come with an element of risk. "*It is clear that accreditation by IANZ is no guarantee that all is well in the registered laboratory"* and " *It has become clear in the course of my investigation that, in light of IANZ's limited statutory role, this confidence may be misplaced*" (11).

An experienced and qualified team of specialists spent three months succinctly tying up all the issues in only five recommendations. They decided that the IT system was inadequate, the organisational chart needed review and, despite a recent accreditation inspection, that it needed to be accredited again. That does not appear to be the case here, as analytical errors definitely affected fifty patients. There were certain questions that went unanswered by the review team, namely:

- How Siemens was made accountable for this error.
- Was there any investigation of the other laboratories using the same reagent.

- Did they review the previous accreditation report.
- Were the required training and competency records made available.

The Australian Health Practitioners Regulatory Agency supports many healthcare professions, all of which require some evidence of CPD. If the medical scientists involved had been provided with education and training, then many of the errors that contributed to this incident may have been prevented. The contention that supervision by an RCPA-accredited pathologist and NATA accreditation are the necessary and efficient controls required by laboratories was clearly shown to be inadequate by the fundamental failings of both precautions. The certification project currently implemented by the Australian Institute of Medical Sciences is a positive step but needs more support from industry or legislation to be truly effective. Any framework must ensure that clinical decision-making be made more frequently with the full support of those performing the testing, and licensing of medical scientists and require participation in a CPD scheme should become mandatory.

"Accreditation ensures a public service will be delivered at a standard which is appropriate. This in turn underpins the confidence of the public which then gives the government credibility allowing them to make policies which are robust and achievable". ***Greg Palmer, Laboratory Manager of SA Pathology in the 2016 NATA Annual report.***

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