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EXECUTIVE SUMMARY

NPAAC is the ministerially appointed Council established to advise Australian Federal, State and Territory Health Ministers on matters relating to the accreditation of pathology laboratories and to promote safe, reliable and uniform practice in pathology laboratories by the development of quality standards. Thus, NPAAC (the Council) takes the lead role in the continual improvement in the safety and quality of pathology services in Australia and recognises that pathology services underpin Australia’s safe, accessible, high quality, and sustainable healthcare system.

NPAAC reviews the risks to the safety of pathology services on a continual basis and makes adjustments to the pathology accreditation framework and its Strategic Plan where required. In the next three years, NPAAC intends to emphasise a risk based approach to standard setting and expects that this will be paired with accreditation processes based on the principle of risk management.

The priorities are outlined in four strategic objectives which address oversight of the pathology sector, the accreditation framework, NPAAC’s role in improving the value of pathology services to patient outcomes, and the conduct of NPAAC’s operations.

NPAAC reports to the Minister on the progress of the strategic plan at the conclusion of each calendar year.

**Strategic objectives for 2016-2019**

1. Oversight
2. Accreditation framework
3. A patient focus for the value of pathology services
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INTRODUCTION

**Our vision** is to be a world class standard setter and the trusted advisor to the Australian Government in relation to pathology accreditation, and the improvement of safety and quality in pathology services.

**Our role** is to advise Australian Federal and State and Territory Governments on all matters relating to the accreditation of pathology laboratories and to promote safe, reliable and uniform practice in pathology laboratories through the development and maintenance of quality standards, education and policy advice.

**Our mission** is to establish standards and processes which improve health outcomes for all Australians through the delivery of safe, high quality pathology services within a sustainable pathology sector.

**Our people** are recognised leaders in pathology, nominated by the peak bodies of Australian pathology and appointed by the Minister. Their work is supported by robust organisational systems and processes within the Australian Government Department of Health.

Membership includes representatives from all States and Territories, the Commonwealth and nominees from the following organisations:

- Australasian Association of Clinical Biochemists
- Australian Institute of Medical Scientists
- Australian Medical Association
- Australian Society of Microbiology
- Consumers Health Forum
- Human Genetics Society of Australasia
- Pathology Australia
- Public Pathology Australia
- Royal College of Pathologists of Australasia
OPERATING ENVIRONMENT

Australia’s pathology services are highly regarded by equivalent countries as being of high quality, accessible and efficient and the model is under examination where ever healthcare delivery reforms are underway. Particular respect is accorded because of an appreciation of Australia’s challenges of vast distance and an unevenly distributed population.

This success is the product of the partnership between the medically led pathology professions and the Australian Government’s regulatory framework. A unique feature of the Australian system is the volunteer workforce of 1000 pathologists and scientists who act as technical assessors for the independent pathology accrediting agency.

There are, however significant and new challenges to the continued provision of safe pathology services. These relate to

- the model of service delivery
- new technologies
- risks outside of the regulatory framework
- the regulatory framework
- patient safety strategies.

The model of service delivery has evolved over the last twenty years from a cottage industry to a highly consolidated and corporatised industry in which testing is centralised, where possible, to large multi-disciplinary laboratories. This change, driven by the need for both efficiency and consistency of services, has taken place in both private and public sectors to the exclusion of other models. A handful of specialist stand alone service providers remain. This has improved the risk profile of pathology service provision in that quality failures due to low volumes of testing and a dispersed and non-expert workforce have fallen. New risks have, however, appeared. Centralisation has resulted in longer turnaround times for some testing, and new systems have been required to address the risk of error associated with multiple handovers of specimens.

Recently, it has become apparent that the complex arrangements within some pathology networks have created strain in their governance frameworks. It has also become evident that the risks to quality known to accompany the commissioning of new laboratories are also seen where there is consolidation, by reorganisation or sale, of existing laboratories. This is most likely due to the introduction of new processes and changes in organisational culture.
New technologies are now entering clinical services. The highest profile of these is the genomic technologies which appear likely to pervade all areas of testing, and impact broadly on the diagnosis and management of illness. The successful implementation of genomic medicine, whereby value is unlocked for individual patients and for the Australian healthcare system as a whole, will depend entirely on the quality of the pathology services which will underpin it.

In many settings genomic technologies will supplant older testing methods. They will provide new information and a scientific basis for treatment decisions, notably, in cancer and infectious disease. Testing of the human genome to diagnose or evaluate predisposition to an increasing number of diseases, and to promote wellness, is a more complex paradigm. Genomic literacy is uneven amongst both doctors and patients, and the understanding of the relationship between genomic findings and their predictive value in disease is rapidly evolving. This is an unstable and high risk environment for patient care, and complex ethical issues are unfolding. Genomic testing has also led an increase in cross border testing. Specimens are sent outside of the quality assured Australian framework by new channels and to new destination laboratories in centres of excellence across the world.

The regulatory framework cannot address all of the risk elements to patient safety related to pathology services. It cannot, for example, directly address workforce issues, which are a major concern for the sector, or the level of investment in laboratories and services. Non-Medicare services fall outside of its scope and it is noted that genomic testing is increasingly being offered in this unregulated setting, through medical consultations or directly to consumer. Given the identified risks to patient safety from the use of this new and immature therapeutic paradigm, the policy options warrant examination.

The thirty year old Australian pathology regulatory framework is now a mature compliance focussed framework and it has created a compliance culture in Australian laboratories. Regulators in all sectors are recognising the value of using a risk based approach to deliver the desired outcomes and in healthcare, these relate predominantly to patient safety and better health outcomes. A system to collect data on adverse events for patients will need to be developed, which would allow a strategic approach to minimising risk to patients from pathology services.

Lastly, the recent publication of a new report by The Institute of Medicine – Improving diagnosis in healthcare - has generated renewed international interest in the risk to patient welfare from either delayed or missed or wrong diagnosis. Although diagnosis is a complex collaborative process, pathology services play a central role, and it is clear that a focus is needed on interventions that address missed opportunities to reduce diagnostic error. It is likely that the design of these interventions will need to be specific to each country’s systems and processes.

In summary, the pathology services provided to the Australian public are of high quality. There is, however, a changing risk profile which must be addressed. In addition, there are opportunities to improve upon the value which pathology services contribute to patient health experience and these should not be missed.
STRATEGIC OBJECTIVES, RISKS AND STRATEGIES

Strategic objectives

OBJECTIVE 1. 
Oversight of the pathology sector
To protect the interests of patients by identifying and responding to significant risks in the sector.

OBJECTIVE 2. 
The accreditation framework
To maintain a robust accreditation framework to improve the practice of pathology.

OBJECTIVE 3. 
A patient focus for the value of pathology services
To lead and coordinate the improvement in value of pathology services to patient outcomes

OBJECTIVE 4. 
Collaboration and Transparency
To be collaborative in carrying out our mandate and to be transparent in our communication with stakeholders.

Potential Strategic Risks

- NPAAC failed to identify or respond to new and emerging risks to patient care.
- NPAAC’s standards were not sufficiently clear that the independent accreditation assessment body could not accredit against them in a correct and consistent manner, as NPAAC had envisaged.
- The alignment between NPAAC, as the standard setter and the independent accreditation assessment body was not sufficiently strong to support the achievement of NPAAC’s mission.
- NPAAC did not have sufficient access to accreditation data/information during the standard setting process which may have led to oversights in the Standards.
- NPAAC lacked the capabilities needed due to resource constraints.
- NPAAC did not communicate its activities sufficiently well, such that stakeholder support for its activities was diminished.

Risk Oversight and Management

Risk management will be overseen by NPAAC Council, and its subcommittees, the Strategy and Risk and Document Review Liaison Committees.

Performance Indicators

NPAAC will report its performance against its strategic plan to the Minister on an annual basis and when required.
OBJECTIVE 1.
Oversight of the pathology sector

To protect the interests of patients by identifying and responding to significant risks in the sector.

Australian pathology services are highly regarded as safe, accessible and efficient. The pathology sector is, however, in transition to a highly consolidated industry and new potential risks can appear during such transformations. NPAAC’s approach to the oversight of the sector will be to monitor changes, develop new Standards where required and provide advice to the Minister where policy may need to be reviewed.

Strategies

- Taking a risk based approach to the oversight of the sector based on evidence, and develop a capacity for timely response to emerging significant risks.
- Developing new Standards, providing clear advice to the accrediting agency and education to the sector where significant new risks arise.
- Developing a capability to collect, access and use data and information about the performance of Australian laboratories at accreditation, the prevalence of adverse events for patients deriving from, or contributed to, by pathology investigations.
- Developing a risk management framework with quality metrics, informed by accreditation data, to monitor the patient safety performance of the pathology sector and support the improvement of the pathology accreditation framework.

Outcomes

- Significant risks are identified at an industry level with a clear and consistent hierarchy of the level of risk to the interest of patients and reported to Governments.
- Oversight is proactive and proportionate, resulting in the protection of patients.
- The Standards and the accreditation assessment are aligned through a risk paradigm.
- NPAAC has access to accreditation data with which it can measure and monitor the accreditation framework.

Performance Indicators

- A risk register for the delivery of Pathology services in Australia is developed.
- Quality data/ metrics from the accrediting agency – e.g. the number of laboratories where accreditation has been withdrawn, the number of laboratories under active surveillance, the number of laboratories in which “Conditions” are placed on continuing accreditation, the Standards against which the “Conditions” were raised.
- A register of adverse events for patients resulting from pathology service provision which have entered the public domain.
OBJECTIVE 2. The accreditation framework

To maintain a robust accreditation framework to improve the practice of pathology.

Strategies

- Focusing the review and/or development of Standards on priority areas for patient safety and the stability of the sector using a consistent risk based approach.
- Ensuring that the Standards, advice and other materials set clear expectations for the independent accrediting body to identify risks to patient safety in individual laboratories and the sector as a whole.
- Reviewing relevant international and Australian standards, such as AS ISO 15189, having regards to evidence and ensuring that any adoption of potential requirements are appropriate for the Australian context through a thorough and consultative process.

Outcomes

- The accreditation framework is based on principles, rather than prescription, and allows a range of practices to achieve an outcome.
- Standards set out requirements which are clear and well understood by pathology laboratories and the independent accrediting agency and assist the accrediting agency to actively target risk in an efficient and proportionate manner.
- Reforms are developed in a consultative manner and are appropriate to Australian conditions.
- NPAAC’s Standards are fit for purpose.

Performance indicators

- Pathology laboratories are able to be in full compliance with the pathology accreditation materials and achieve accreditation.
- The cost benefit analysis of accreditation standards supports the pathology quality framework.
- A template to guide the preparation of Standards to ensure a consistent risk focus is developed.
OBJECTIVE 3. A patient focus for the value of pathology services.

To lead and coordinate the improvement in value of pathology services to patient outcomes

Strategies

• To engage and/or collaborate with other standard setting bodies and organisations related to patient safety to identify opportunities where the value of pathology services to patient outcomes can be enhanced.

• To partner with clinicians and consumers to share knowledge about initiatives focussed on pathology testing which improve outcomes for patients.

Outcomes

• A regular liaison is established with ACSQHC and relevant Standards are aligned.

• A workshop is held second yearly to promote discussion and implementation of initiatives focussed on pathology testing which improve outcomes for patients.

• A regular dialogue is established with consumer organisations to share knowledge about initiatives focussed on pathology testing which improve outcomes for patients.

Performance Indicators

• A regular meeting with ACSQHC is established to discuss pathology issues,

• A workshop, hosted by NPAAC, is held on a two yearly cycle and the workshop outcomes are promulgated to governments, the healthcare sector and consumer organisations.

OBJECTIVE 4. Collaboration and Transparency

To be collaborative in carrying out our mandate and to be transparent in our communication with stakeholders.

Strategies

• Actively engaging with stakeholders on key issues and changes to policies and practices, including clearly and effectively articulating expectations and the underlying reasons for decisions.

• Ensuring sufficient up to date, clear, accessible information on NPAAC’s framework and activities is in the public domain.

Outcomes

• NPAAC is clearly accountable for its performance in the context of its mandate, including how it gives due consideration to its statutory objectives in undertaking its functions.

• NPAACs engagement with external stakeholders is timely, credible, constructive and transparent and its communication is considered to be clear and effective.

Performance indicators

• Biennial stakeholder survey report.

• Regular meetings with key pathology and scientific stakeholders on matters relating to quality standards or improving pathology services.