

Clinical Governance Framework

Excellence in Service and Outcomes



Health
Pathology

Creating better health and justice systems
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Review

This policy will be reviewed by 06/11/2024.

Risk

Risk Statement	The NSW Health Pathology Clinical Governance Framework addresses the following risks: <ul style="list-style-type: none"> • Non-compliance with relevant NSW Health Policy and legislation • Failure to meet relevant Standards
Risk Category	Clinical Care and Patient Safety

Further Information

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Version History

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1.0	28/02/2018	Clinical Governance Quality & Risk Committee	11/12/2017	Linda Sorum	High	New framework
2.0	07/11/2023	Director, Clinical Governance	06/11/2023	Linda Sorum	High	Reviewed – No changes made

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Message from the Chief Executive



To deliver our purpose of creating better health and justice systems we must work together to provide world-class care for patients and customers in a safe working environment.

Integrated clinical governance systems are fundamental to providing quality, customer-focused care and services.

We must commit to delivering excellence - whether it is in the laboratory, hospital, collection centre or in the community.

The *NSW Health Pathology Clinical Governance Framework* delivers on the directions outlined in our strategic plan to provide:

- appropriate and timely access to services in rural, regional and metropolitan areas;
- quality, patient-centred, customer-focused services;
- innovative models of service delivery and practice.

It informs and guides us on our journey to lead through innovation and excellence. However, the framework is just a starting place. It is dynamic and will respond to changes informed by feedback so that it will remain relevant and successful.

Dr Don Berwick, internationally renowned authority on healthcare quality and improvement, recommended the following patient safety strategies to senior leaders in the NHS, United Kingdom¹:

- Place the quality of patient care, especially patient safety, above all other aims.
- Engage, empower, and hear patients and carers at all times.
- Foster whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work.
- Embrace transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.

I invite all NSW Health Pathology staff to take on this commitment to excellence as we work to ensure our organisation is truly exceptional and is one that makes a difference in people's lives.

Tracey McCosker
Chief Executive,
NSW Health Pathology

Introduction

Purpose

The *NSW Health Pathology Clinical Governance Framework* ensures NSW Health Pathology (NSWHP):

- is a leader in innovation and collaboration
- maintains its reputation for excellence in pathology and forensic services and outcomes
- provides services that encompass the internationally recognised quality domains (Figure 1)
- meets its statutory requirements relating to clinical governance.

Figure 1



Background

Clinical governance is a framework through which “... organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.”²

It encompasses the integrated systems, processes, leadership and culture that are at the core of providing safe, effective, accountable and patient-centred healthcare and is underpinned by continuous monitoring and improvement.

Good clinical governance is:

- participatory
- consensus orientated
- accountable
- transparent
- responsive
- effective and efficient
- equitable and inclusive
- follows the rule of law.

(*Australian Commission on Safety & Quality in Health Care (ACSQHC) National Standards*).³

In practice it requires:

- leadership, teamwork, patient-centredness and robust data
- strong and effective partnerships with shared accountability and responsibility between the Board, Executive, managers and health professionals
- transparent responsibility and accountability for maintenance of clinical care standards that are effectively communicated throughout the health organisation
- staff knowledge and capability in safety science and quality improvement
- active participation from all staff in evaluation and improvement of processes and practice
- a cohesive program of action to ensure systems are in place and being continually improved that:
 - operate at all levels of the organisation
 - provide an environment that fosters quality and excellence
 - monitors quality
 - provide regular reports to a Board that monitors quality
 - minimise risk and identify deficiencies in quality
 - effectively address deficiencies identified.

The need for, and principles of, clinical governance apply equally in pathology as they do in other areas of healthcare. Providing quality services requires collaborative working relationships between pathologists, clinical scientists, scientists, technicians, other laboratory staff and professionals from across the health and justice settings.

The National Pathology Accreditation Advisory Council's (NPAAC) policy for accreditation and uniform standards of practice in pathology laboratories throughout Australia provides a strong foundation for assurance of quality of our pathology services. These standards focus on staff competence, supervision, and technical and procedural quality control including participation in external proficiency testing programs. This focus promotes reliable and safe laboratories. However, comprehensive clinical governance requires additional activities that extend and complement NPAAC requirements.

Performance

To deliver on the intent of the Framework a Patient Safety & Quality Operational Plan will clearly articulate our patient safety and clinical quality priorities, interventions, enablers and measurement strategies.

Guiding Documents/Standards

The Framework aligns with:

- *NSW Health Pathology (NSWHP) Strategic Plan 2014-2018*
- *NSW Health Pathology Strategic Risk Management Framework*
- *NSW Health Patient Safety and Clinical Quality Program-PD2005_608*
- *National Pathology Accreditation Advisory Council (NPAAC) Standards and Guidelines*
- *Australian Commission for Safety and Quality in Healthcare (ACSQHC) National Standards*
- *AS ISO 15189 Medical Laboratories – Requirements for Quality and Competence*
- *AS/NZS ISO 9001:2016 Quality Management Systems*

- AS ISO/IEC 17025 Laboratory Accreditation (testing and calibration laboratories)
- TGA IVD Medical Devices Regulatory Framework
- TGA Licencing where applicable.

Definitions

Customer: patients, clinicians, Local Health Districts (LHDs), Specialty Health Networks (SHNs), NSW Police Force, State Coroner, Local Government agencies and other key external customers.

Just Culture: a culture that is both fair to staff who make errors and effective in reducing safety risks.

Quality Assurance: maintaining and monitoring the quality of health care and services by constantly measuring the effectiveness of the organisations that provide it. This is achieved through audits and accreditation and guided by relevant standards, policy and legislation.

Quality Improvement: systematic and continuous actions that lead to measurable improvement.

High Reliability Organisation: a high reliability organisation (HRO) is an organisation that has succeeded in avoiding serious accidents or incidents despite operating in a highly complex and risky environment. Weick and Sutcliffe⁴ describe the five principles of HRO's as:

1. Preoccupation with failure
2. Reluctance to simplify
3. Sensitivity to operations
4. Commitment to resilience
5. Deference to expertise.



NSWHP Clinical Governance Framework

NSWHP is responsible for patient safety and clinical quality relating to services provided by our laboratories, staff and contractors. Most NSWHP patients are also patients of Local Health Districts (LHDs) and/or Specialty Health Networks (SHNs) as part of a shared care role. The primary focus of clinical governance can be summarised as assuring patient safety and minimisation of clinical risk whilst continuously improving service quality and maintaining patient-centredness. The NSW Health Patient Safety and Clinical Quality Program⁵ directs that NSW health entities meet the following Standards and core functions of clinical governance:

Standards

1. Health services have systems in place to monitor and review patient safety
2. Health services have developed and implemented policies and procedures to ensure patient safety and effective clinical governance
3. An incident management system is in place to effectively manage incidents that occur within health facilities and risk mitigation strategies are implemented to prevent their reoccurrence
4. Complaints management systems are in place and complaint information is used to improve patient care and clinical services
5. Systems are in place to periodically audit a quantum of medical records to assess core adverse events rates
6. Performance review processes have been established to assist clinicians maintain best practice and improve patient care
7. Audits of clinical practice are carried out and, where necessary, strategies for improving practice are implemented.

Core functions

1. Structural establishment
2. Incident management
3. Incident Information Management System (IIMS) implementation
4. Complaints management
5. Death reviews
6. Continuous Quality Improvement (CQI) support
7. Communication training
8. Policy development
9. Clinician performance review
10. Reporting
11. External reports.

Other functions include:

1. Management of individual performance issues
2. Integrated risk management.

Key Attributes

- Recognisably high standards of care
- Leadership and Safety-II thinking⁶
- Transparent responsibility and accountability for those standards
- A constant dynamic of improvement
- Effective linkage with corporate governance
- Effective linkage with customers.

Guiding Principles

The following principles will guide effective clinical governance systems and are informed by the NSW Health Patient Safety and Clinical Quality Program⁵:

Excellence in customer experience – commitment to providing a positive, quality customer experience at all touchpoints.

Openness, transparency and accuracy – errors are reported and acknowledged without fear of inappropriate blame, and patients and their families are told what went wrong and why. Reporting, reviews and decision making are underpinned by transparency and accuracy.

Emphasis on learning and continuous improvement – the system is oriented towards learning from its mistakes and extensively employs improvement methods for this.

Obligation to act – the obligation to take action to remedy problems is clearly accepted and the allocation of this responsibility is unambiguous and explicit. This is underpinned by strong staff engagement and leadership where ownership of systems and processes is promoted and practiced by all staff who actively participate and contribute their expertise and experience.

Accountability – the limits of individual accountability are clear. Individuals understand when they may be held accountable for their actions and accountability and ownership is displayed by all staff.

Just culture – individuals are treated fairly and are not blamed for the failures of the system.

Appropriate prioritisation of action – action to address problems is prioritised according to the available resources and information and is directed to those areas where the greatest improvements are possible. This is informed by proactively collecting and sharing critical information and rigorous measurement of performance and progress. Robust data is effectively understood and informs decision making, risk management and strategies for improvement.

Teamwork – teamwork is recognised as the best defence against system failures and is explicitly encouraged and fostered within a culture of trust and mutual respect. The team includes consumers who are effectively engaged.

Roles and Responsibilities

To achieve excellence in quality and reliable patient centred, customer focused services NSWHP employees must:

- Take ownership and accountability for the quality and safety of the services provided
- Commit to partnering with customers to facilitate effective engagement and participation
- Regularly evaluate performance to identify areas for improvement

NSW Health Pathology Board

Leads the commitment by NSWHP to provide world-class quality care and services safely by:

- Setting a clear vision and strategic direction and leading a 'just' organisational culture that drives consistently high-quality care and facilitates effective staff and consumer engagement and participation
- Ensuring the Board membership has the necessary skill set, composition, knowledge and training to actively lead and pursue quality and excellence in healthcare
- Understanding key risks and ensuring controls and mitigation strategies are in place
- Reviewing reports, and monitoring NSWHP's progress on safety and quality performance
- Endorsing the clinical governance framework, ensuring robust clinical governance structures and systems across NSWHP are effectively supported and staff are empowered to provide high-quality care that is designed in collaboration with staff and consumers where appropriate.
- Working in partnership and sharing responsibility with the Chief Executive for the implementation, monitoring and evaluation of clinical governance systems.
- Regularly seeking qualitative and quantitative information about the status of the quality and safety of care processes and outcomes in all services. This information should be sought beyond the purposes of audit and accreditation

NSW Health Pathology Strategic Leadership Team

Is accountable for the safety and quality of care and services provided by NSWHP with key responsibilities being to:

- Establish and maintain the clinical governance framework and use the processes within the framework to drive improvements in safety and quality
- Ensure efficient allocation of resources that delivers on the organisation's vision for quality and safety
- Ensure robust and transparent reporting, analysis and discussion of the safety and quality of care occurs regularly, informed and supported by qualitative and quantitative data, committee structures and clinician engagement
- Create a safe and open culture that encourages, supports and empowers staff to speak up and raise concerns and to report any event or circumstance that could have resulted, or did result, in unnecessary harm to a patient
- Foster a 'just' culture of safety, fairness, transparency, learning and improvement that empowers and supports staff to understand and enact their roles and responsibilities
- Elevate quality of care and services within the organisation, ensuring the voice of the customer is at the centre of core business and that the organisation remains focused on continuous improvement



- Delegate the implementation, review, measurement and evaluation of operational quality and safety performance to relevant clinical leaders
- Ensure all staff (clinical and non-clinical) are supported in their involvement in quality activities
- Regularly report to the board on clinical risks, care processes and outcomes, areas for improvement and progress towards excellence across all NSWHP clinical services
- Ensure that recommended changes and improvements in safety and quality are put into practice
- Review feedback (compliments and complaints) received to identify areas of excellence and those requiring improvement
- Regularly evaluate clinical governance systems to ascertain their effectiveness

Clinical Leaders, Managers and Laboratory Supervisors

Are required to:

- Understand the challenges and complexity of providing consistently high-quality care and services
- Lead and support their staff through a culture of safety, transparency, accountability, teamwork and collaboration
- Provide a safe environment for customers and staff that supports and encourages productive partnerships between different clinical groups and between clinicians and patients
- Provide useful performance data and feedback to their staff and relevant committees and engage clinicians and others to identify and take appropriate action in response
- Proactively identify, monitor and manage areas of key clinical risk and lead appropriate escalation and response where patient safety is compromised

- Be skilled in staff management, foster productive and open cultures, and promote multidisciplinary teamwork
- Ensure staff are clear about their roles and responsibilities, are supported with resources, standards, systems, knowledge and skills development, and are accountable for the care and services they provide
- Expect and drive action in response to managing clinical risks and improving care
- Foster and support quality improvement
- Operate within relevant Standards for accreditation
- Operate within obligations as Approved Pathology Practitioners where applicable.

Clinical leaders must be alert to preventing errors and harm to patients by ensuring that clinical teams work more effectively so that individuals are taking fewer decisions in isolation; be clear about the skills and competencies needed in each area of service; and take action to change things to make them better.

Clinical leaders, managers and laboratory supervisors must encourage all staff to report adverse incidents, errors and near misses that could have resulted in avoidable patient harm, and ensure they are documented in the NSW Health incident information management system (IIMS). Incidents must be escalated where appropriate, investigated and used to enhance systems and processes across the organisation to improve patient safety.

All NSW Health Pathology Staff

All staff are required to:

- Uphold the RITE Values of NSWHP:
 - Respect
 - Integrity
 - Teamwork
 - Excellence
- Provide high-quality care in their services as a priority
- Go beyond compliance to pursue excellence in care and services
- Speak up and raise concerns and issues, promoting a culture of transparency
- Regularly update their skills and knowledge to provide and support the best care and services possible
- Actively monitor and improve the quality and safety of their care and services
- Share information and learnings regarding clinical safety, reporting any event or circumstance that could have resulted, or did result, in unnecessary harm to a patient
- Work within Standards and Policy
- Contribute to a culture of safety, transparency, teamwork and collaboration and accept shared personal responsibility for the quality and safety of clinical care and services provided by NSWHP.

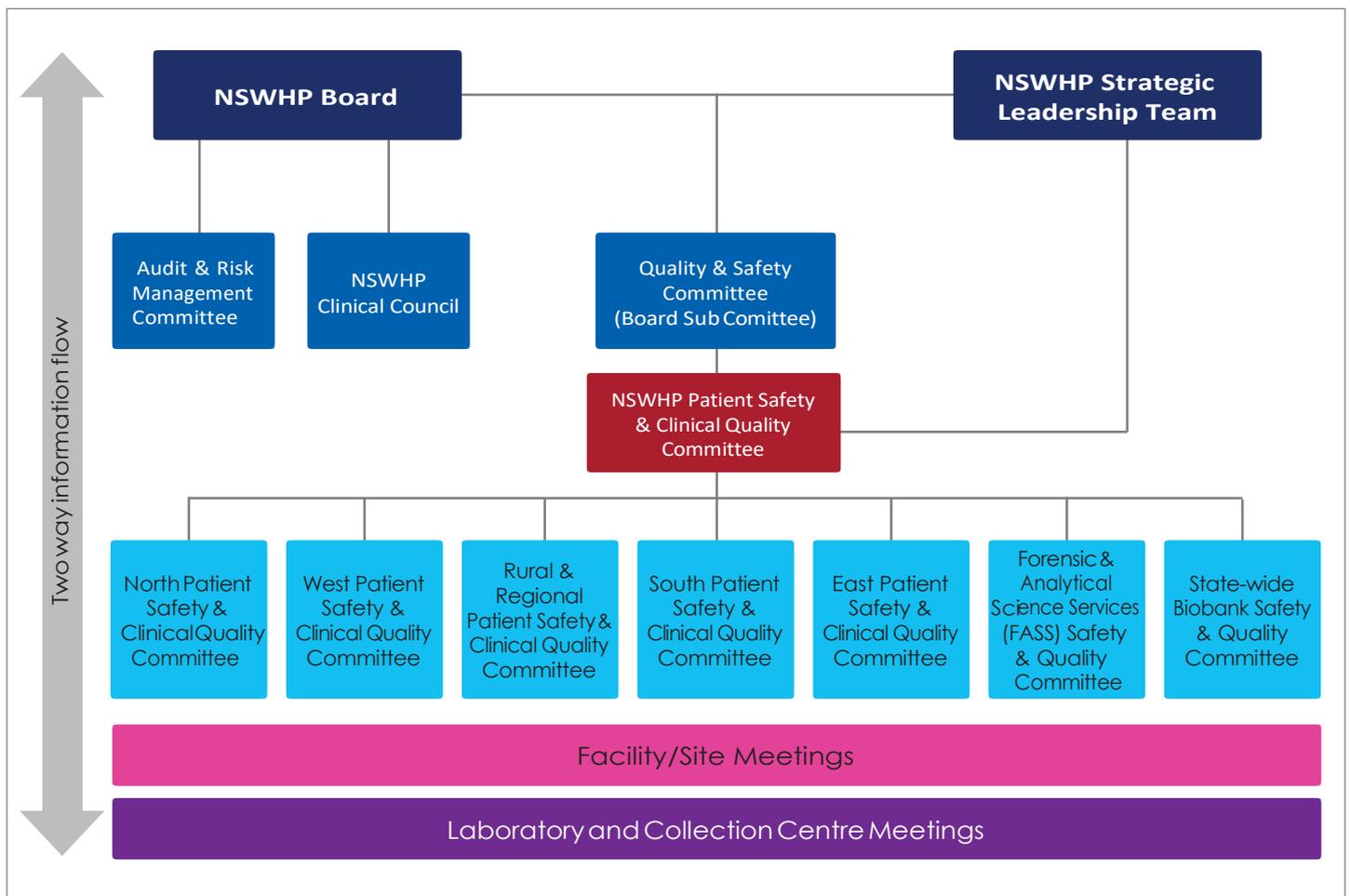
Clinical Governance Framework Reporting Structure

High reliability organisations with robust clinical governance have patient safety and clinical quality included in the organisation's governance committees' terms of reference and relevant meeting agendas.

This defines reporting lines and documents relevant actions so that transparency and collaboration are supported.

It also enables quick and efficient recognition when performance is exceptional and action when not meeting expectations. NSWHP has a transparent committee structure and reporting lines in place (see Figure 2 below).

Figure 2: Clinical Governance Structure



Quality Improvement

Quality improvement in healthcare has been defined as the “combined and unceasing efforts of everyone — healthcare professionals, patients and their families, researchers, payers, planners and educators — to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development”⁷

Quality improvement draws on a wide variety of methodologies, approaches and tools. However, many of these share some simple underlying principles, including a focus on:

- understanding the problem, with a particular emphasis on what the data tell you
- understanding the processes and systems within the organisation – particularly the patient pathway and whether these can be simplified
- analysing the demand, capacity and flow of the service
- choosing the tools to bring about change, including leadership and clinical engagement, skills development, and staff and patient participation
- evaluating and measuring the impact of a change.⁸

Improvement in the safety and quality of services relies on staff at all levels of the organisation building their skills and abilities in innovation and improvement, and seeking support to undertake activities to improve care. Building capability in organisations with a safety culture requires a workforce that is capable of analysing quality and safety data and delivering improvement.

NSWHP will build the QI capability of its staff based on the Kaiser Permanente model represented by the triangle in Figure 3 (page 14). This model recognises the need to have a range of knowledge across an organisation, with a relatively small number of experts, but with all staff understanding at least the essentials of quality.

Partnering with Patients

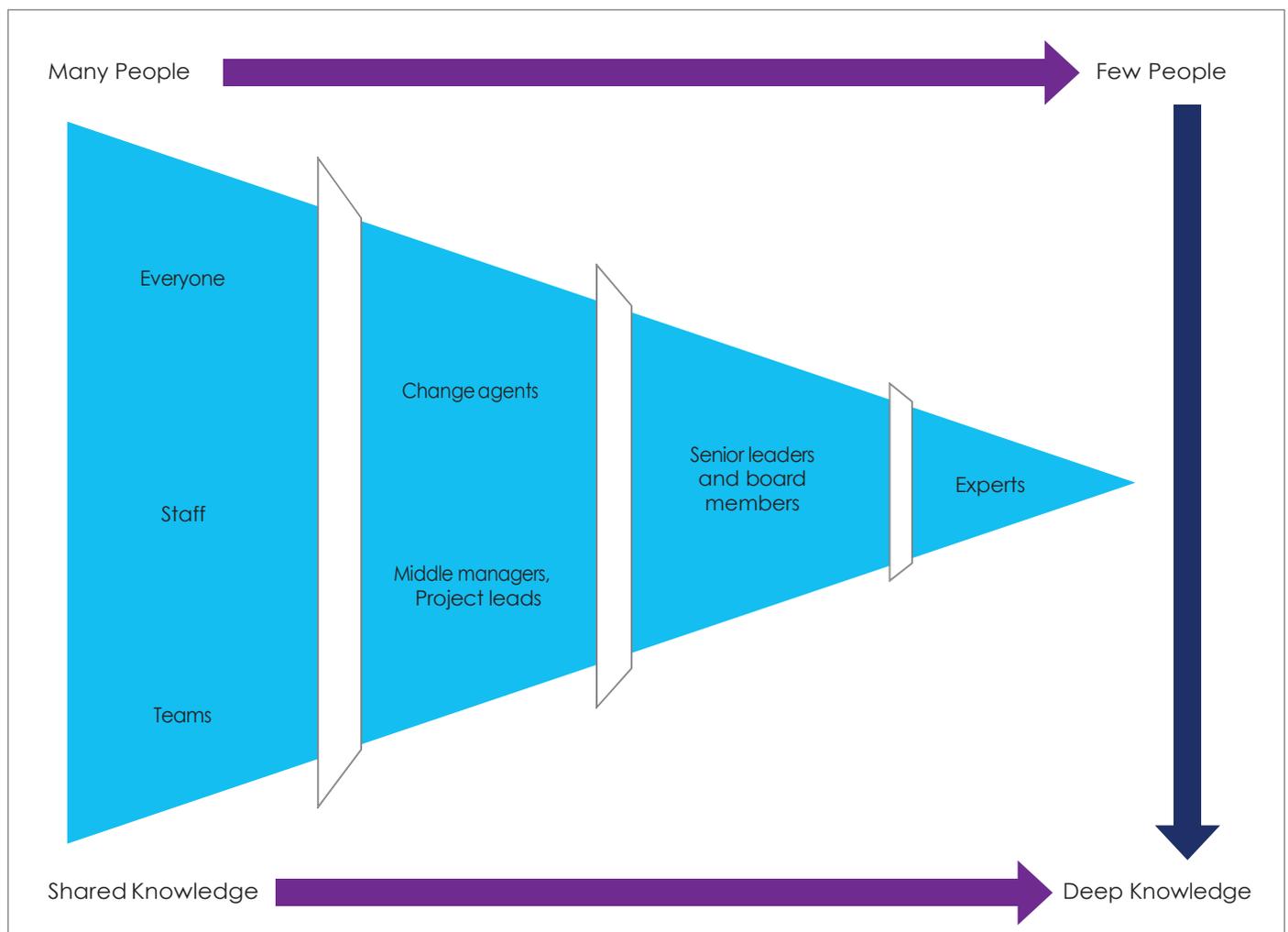
Partnering with patients to ensure that patients, family and carers are an integral part of our health care teams is essential to providing safe, quality care. There is growing recognition that the safety and quality of care can be enhanced by engaging with patients, family and carers to improve health outcomes, the patient and staff experience, as well as safety and performance indicators.

The Australian Commission for Safety & Quality in Healthcare, [National Standard 2, Partnering with Consumers](#) provides the framework for NSWHP’s active partnership with our consumers. The intention of this Standard is to create a health service that is responsive to patient, carer and consumer input and needs.

Clinical Risk Management

Robust risk management in health care requires the effective identification, analysis and management of organisational risks and adverse events, including clinical risks, which are inherent in the provision of health care services. The governance and oversight of clinical risk is supported by Clinical Governance functions including monitoring and reporting of patient safety and quality indicators and the clinical incident investigation process. The Clinical Governance Quality and Risk Committee oversees the delivery of risk management, clinical governance and quality strategic priorities.

Figure 3 Amended from source: Kaiser Permanente⁹



All NSWHP services are required to implement locally based risk management systems, or to enhance their existing risk management systems, in line with the [Risk Management - Enterprise-Wide Risk Management Policy and Framework – NSW Health PD2015 043](#), [NSWHP Enterprise Risk Management Framework NSWHP CG 002](#) and [Enterprise Risk Management Procedure, NSWHP PR 026](#).

Incident Reporting and Management

All NSWHP clinical incidents are investigated in accordance with [NSW Health Incident Management Policy, PD2014 004](#) and [Critical Incident Management Procedure NSWHP PR 021](#).

NSW Health staff are required to report all identified clinical incidents and near misses in the State-wide electronic Incident Information Management System (IIMS).

NSWHP's system to manage incidents is based on the following principles:

- Openness about failures – incidents are reported and acknowledged without fear of inappropriate blame. Patients and their families/support persons are offered an apology and told what went wrong and why
- Emphasis on learning – the system is oriented towards learning from mistakes and consistently employs improvement methods for achieving this

- **Obligation to act** – the obligation to take action to remedy problems is clearly accepted and the allocation of this responsibility is unambiguous and explicit
- **Accountability** – the limits of individual accountability are clear, individuals understand when they may be held accountable for their actions
- **Just culture** – individuals are treated fairly
- **Appropriate prioritisation of action** – action to address problems is prioritised and resources directed to those areas where the greatest improvements are possible
- **Cooperation, collaboration and communication** – teamwork is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust and mutual respect

Open Disclosure

Following a patient safety incident, timely discussions with patients and/or their support person/s must occur in an open and honest manner. NSWHP works in collaboration with LHDs/SHNs and other partner organisations such as NSW State Coroner and Department of Justice NSW, where formal open disclosure is required. NSWHP staff participate, where appropriate and agreed, in open disclosure meetings related to incidents involving errors in pathology. NSWHP conducts the open disclosure independently when appropriate e.g. in relation to collection centre incidents.

[NSW Health Open Disclosure Policy, PD2014_028](#) sets out the minimum requirements for implementing open disclosure within NSW Health facilities and services and describes when open disclosure is required. It also defines the two stages of the open disclosure process (clinician disclosure and, where indicated, formal open disclosure), outlines key steps, and outlines the roles and responsibilities for NSW Health staff in relation to open disclosure.

The objectives of Open Disclosure are to:

- Establish a culture which supports open communications between patients, their support person(s) and clinicians after a patient safety incident
- Ensure that communications with and support for all affected patients, their support person(s) and health service staff occur in a timely and empathic manner
- Ensure that all NSW Health Services have a consistent process for open disclosure

Open disclosure is an intrinsic part of the complaints management and incident management process. Open disclosure capability building, monitoring and reporting is a clinical governance function.

Complaints Management

Complaints are managed as per [NSW Health Complaint Management Policy, PD2006_073](#), adhering to the following principles:

- Complaints are assessed by considering risk factors, the known facts, the wishes of the complainant and accountability of staff
- All complaints are dealt with in a manner that is effective, complete, fair to all parties and provides just outcomes
- Complaint information is openly communicated while protecting confidentiality and personal privacy
- All complaints are recorded to enable review of individual cases, to identify trends and risk and report on aggregated complaint information
- Complaint management policy, practices, and data are regularly evaluated and the information is used to improve services.

Complaints to NSWHP are received at many points across the organisation and from a number of different sources including the Health Care Complaints Commission (HCCC) and the Incident Information Management System (IIMS). Complaints received by NSWHP are acknowledged and recorded. An investigation is conducted and recommendations developed and actioned as required. Feedback is provided to the complainant at their discretion and to relevant clinical areas. Complaint data is analysed, trended and reported to applicable committees. Learnings are shared across the organisation.

Customer Engagement

NSWHP engages and collaborates with its customers to deliver excellence in patient safety and clinical quality.

The NSWHP Stakeholder Engagement Framework provides guidance on membership and or consultation on relevant committees, improvement projects and investigations.

(For patient specific engagement see [Partnering with Patients](#), p.11)

Complaints or Concerns about Clinicians

NSWHP has processes in place to ensure that the requirements of [PD2006 007 – Complaint or Concern about a Clinician – Principles for Action](#), and [GL2006 002 – Complaint or Concern about a Clinician – Management Guidelines](#) are met.

Research and Innovation

Research and innovation lie at the heart of NSWHP's efforts to create better health and justice systems. As a result, it is positioned at the forefront of new diagnostic tests and technologies, forensic analysis methods, and models of service delivery. It is the governing structures and systems that help support a culture of research and encourage innovative thinking, driving NSWHP to achieve its vision to 'deliver excellence in service and outcomes'.

Improving patient health outcomes and delivering a customer-focused service is at the heart of all our research and innovative endeavours. Research and innovation is an integral component of NSWHP's core business and as such will be integrated into existing pathology and forensic governance and organisational structures. The [NSWHP Research and Innovation Framework](#) articulates governance and guides activities.



Quality Assurance

The Institute of Medicine's report *To Err is Human – Building a Safer Health System*¹⁰ states "Regulatory and related mechanisms, such as licensing, certification, and accreditation, set explicit performance standards for patient safety and service delivery and help to define minimum performance levels. The process of developing and adopting standards also helps to form safety and experience expectations for consumers and customers".

NSWHP will comply with all relevant national and State legislation, Standards and organisational policy.

Background

Pathology is one of the most highly regulated medical specialties in Australia and has the most longstanding and advanced accreditation program for medical laboratories in the world. The Royal College of Pathologists of Australasia (RCPA) has "driven the implementation of a quality framework that is unparalleled internationally"¹¹

Components of this include:

- The National Pathology Accreditation Advisory Council (NPAAC)
- A laboratory accreditation system established in 1984 by the National Association of Testing Authorities (NATA) in conjunction with the RCPA to promote a uniform approach to assessing and fostering high quality pathology services
- The Royal College of Pathologists of Australasia (RCPA), Quality Assurance Programs Pty Ltd, provides external Quality Assurance (QA) (proficiency testing) programs for medical laboratories
- Compulsory Continuing Professional Development (CPD) for RCPA Fellows
- Institution of the Commonwealth's Quality Use of Pathology Program as part of a Memorandum of Understanding between the profession and the Australian Government.

Accreditation of pathology laboratories is a mandatory pre-requisite for payment of Medicare benefits for pathology services. This is to ensure value for money from government expenditure and an assurance to the Australian community that laboratories providing services under the Medicare arrangements are meeting the minimum standards that underpin patient safety and quality of pathology services.

[Health Insurance \(Accredited Pathology Laboratories – Approval\) Principles 2002](#) sets out the specifics of pathology accreditation and its requirements. Laboratories seeking to provide services that are eligible for Medical Benefit rebates are expected to meet the specified quality standards expressed in the accreditation materials developed and maintained by NPAAC, a ministerially-appointed Council. Laboratories are accredited for the kind of services they provide and any extensions to their scope of services are subject to additional assessment and approval. A continual lifting of the bar in the applicable standards has ensured significant and continuous improvements in the quality and reliability of medical pathology services in Australia over the past 30 years.

National

Department of Health

National regulation of pathology is overseen by The Medical Benefits Division (MBD) of the Commonwealth Department of Health, whose mission is to improve the health outcomes of Australian residents by providing policy advice to government and program management that



will support and improve access to hearing, private medical, hospital and allied health services that are safe, cost effective and clinically effective.

The Primary Care, Analytics and Pathology Branch is responsible for supporting access to high quality, safe, efficient and clinically effective primary care and diagnostic services, through the Medicare Benefits Schedule (MBS). In regard to pathology the Branch is responsible for:

- Pathology quality management through ensuring laboratories are accredited to NPAAC Standards in order to be eligible for MBS rebates
- Supporting other initiatives and reforms that improve the quality of pathology services.

Department of Human Services – Medicare – Health Insurance Act 1973

[The Health Insurance Act 1973](#) enables eligible pathology services to be billed, provided laboratories have the appropriate authorities/accreditations in place as outlined in:

- Part I – Preliminary 16A – Medicare benefits in relation to pathology services
- Part IIA – Special provisions relating to pathology voters.

Approved Pathology Authority (APA)

Annual approval of APA by the Australian Minister for Health is required to enable NSWHP access to the Medicare Benefits Schedule (MBS) system.

Accountability:

- Compliance with reporting notifications of changes as outlined in APA Application: Part 9 – Notice of Matters Affecting Approval of Premises
- Compliance with Part¹² – Agreements, arrangements or contract of employment with Approved Pathology Practitioners
- Compliance with Part 13 – No inducement to use services.

Accredited Pathology Laboratory (APL)

Three-yearly renewal of laboratories APL status is required and is subject to NATA certification of accreditation compliance for the scope of testing sought, with the appropriate laboratory category determined by the functionality and supervision arrangements of the laboratory. It is essential that each laboratory holds APL status to meet requirements for participation in the Medicare program.

Accountability:

- Compliance with Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002 in regard to the provision of reliable results and risks of misdiagnosis.

Approved Pathology Practitioner (APP)

Not every pathologist is required to hold APP status granted by the Australian Minister for Health. However, it is essential that there are sufficient APPs within a laboratory to comply with the APP undertakings in regard to supervision of provision of pathology services.

Accountability:

- Responsibility is undertaken for personal supervision in regard to training, skills and qualifications
- Responsibility for methodology and quality control.

Approved Collection Centres (ACC)

ACCs are specimen collection centres which have been approved by The Department of Human Services, Medicare.

Accountability:

- Compliance with Guidelines for Approved Pathology Collection Centres
- Charges payable for premises are at market value.

The National Pathology Accreditation Advisory Council (NPAAC)

[NPAAC](#) is a ministerially-appointed Council established in 1979 by an Order made by the Governor-General (known as an Order in Council) that sets out NPAAC's role, structure and function.

NPAAC advises the Australian, State and Territory health ministers on matters relating to the accreditation of pathology laboratories. NPAAC plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices. NPAAC is comprised of representatives from all states and territories, nominees from peak professional bodies and The Department of Health.

Accreditation to NPAAC Standards

In 1986, the Australian Government introduced a compulsory accreditation system for pathology. Pathology laboratories must be accredited for the services they provide for patients to participate in the Australian Government Medicare program. In order to be accredited, a pathology laboratory must meet specified quality standards developed and maintained by NPAAC. AS ISO 15189 *Medical laboratories – Requirements for quality and competence* is amongst sources of materials from which NPAAC Standards draw. Audits against these standards and guidelines are conducted by NATA. NATA audit assessment reports are considered by the Department of Human Services in determining laboratory – APL applications.

The Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002 set out the specifics of pathology accreditation and its requirements. The Principles include a Schedule that lists accreditation materials (or the standards) that relate to the actual process.

The minimum standard of care expected in pathology is set down in the [NPAAC Standards](#):

Document Hierarchy System for NPAAC Standards

Tier 1 – The Principles

Tier 2 – Requirements for Medical Pathology Services

Tier 3A – Requirements for the Supervision of Pathology Laboratories

Tier 3B – Requirements for Good Medical Practice in all Pathology Laboratories

Tier 4 – Specialised technical publications, intended to specify requirements in Pathology Laboratories undertaking testing in specific areas of pathology.

National Association of Testing Authorities (NATA)

The medical testing accreditation program is administered by NATA in conjunction with the RCPA. Currently NATA is the only body recognised by the Australian Government to accredit medical pathology laboratories in Australia. Regardless of whether Medicare is claimed or not accreditation is a TGA requirement for approved use of in-house in vitro diagnostics (IVD's) and is assessed against the NPAAC Standards. NATA also assesses pathology and forensic medicine laboratories against [AS ISO 15189 Medical laboratories – Requirements for quality and competence](#). NATA accredits other laboratories including NSWHP Forensic and Scientific Services to [ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories](#).

All providers of Medical Pathology Services must be aware of and have access to [NPAAC Standards](#) and to the current international Standard [AS ISO 15189 Medical laboratories – Requirements for quality and competence](#). There is intended overlap between these Standards.

Australian Commission on Safety and Quality in Healthcare (ACSQHC) National Safety & Quality Health Service (NSQHS) Standards first and second edition

NSQHS Standards have well-defined criteria, actions and achievement outcomes. While pathology laboratories are not required to be assessed against the NSQHSS, by using them as a resource tool alongside the NPAAC mandatory standards, NSWHP will be able to ensure that the necessary monitoring and actions are taken to improve services, risk management, clinical quality and patient safety. In addition NSWHP has roles and responsibilities to assist LHDs/SHNs to meet these standards.

The second edition was published in November 2017. LHD/SHN assessment to the second edition will commence from 1 January 2019.

National Safety and Quality Health Service Standards | Safety and Quality

The primary aims of the [NSQHS Standards](#) are to protect the public from harm and to improve the quality of health service provision. They provide a quality assurance mechanism that tests whether relevant systems are in place to ensure minimum standards of safety and quality are met, and a quality improvement mechanism that allows health services to realise aspirational or developmental goals.

The First Edition Standards that are particularly relevant to pathology are:

-  1. Governance for Safety and Quality in Health Service Organisations which describes the quality framework required for health service organisations to implement safe systems.
-  2. Partnering with Consumers which describes the systems and strategies to create a consumer-centred health system by including consumers in the development and design of quality health care.
-  3. Preventing and Controlling Healthcare Associated Infections which describes the systems and strategies to prevent infection of patients within the healthcare system and to manage infections effectively when they occur to minimise the consequences.
-  5. Patient Identification and Procedure Matching which describes the systems and strategies to identify patients and correctly match their identity with the correct treatment.
-  6. Clinical Handover which describes the systems and strategies for effective clinical communication whenever accountability and responsibility for a patient's care is transferred.
-  7. Blood and Blood Products which describes the systems and strategies for the safe, effective and appropriate management of blood and blood products so the patients receiving blood are safe.
-  9. Recognising and Responding to Clinical Deterioration in Acute Health Care which describes the systems and processes to be implemented by health service organisations to respond effectively to patients when their clinical condition deteriorates.

The Second Edition Standards particularly relevant to pathology are:

-  [Clinical Governance \(PDF 113KB\)](#)
-  [Partnering with Consumers \(PDF 110KB\)](#)
-  [Preventing & Controlling Healthcare-Associated Infection \(PDF 106KB\)](#)
-  [Communicating for Safety \(PDF 107KB\)](#)
-  [Blood Management \(PDF 101KB\)](#)
-  [Recognising and Responding to Acute Deterioration \(PDF 104KB\)](#)

Department of Health – Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is part of the Health Products Regulation Group (HPRG) in the [Australian Government Department of Health](#). TGA is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products and applying a risk management approach to ensure acceptable standards of quality safety and efficacy when necessary.



Almost any product for which therapeutic claims are made must be entered in the [Australian Register of Therapeutic Goods \(ARTG\)](#). The Medical Devices Branch is responsible for evaluating [medical devices, including in vitro diagnostic tests \(IVDs\)](#), and monitoring them throughout their lifecycle to ensure they continue to meet an appropriate level of quality, safety and performance.

A new regulatory framework for IVDs, as a subset of medical devices, using a risk based approach is currently being phased in with important implications and obligations for all pathology providers. NSWHP is regulated by TGA with regard to '[In-house IVDs](#)', which are 'pathology tests that have been developed (or modified) within a laboratory (or laboratory network) to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or be used in making decisions concerning clinical management.'

NSWHP is also regulated by TGA with regard to a range of other specific services related to therapeutic products, eg transplant donor screening.

Accountability:

- Compliance with regulations and access to monitoring by TGA
- Compliance with NPAAC Requirements for the development and use of in-house IVDs.

State

Legislation

The NSWHP Clinical Governance Framework has been developed to provide essential components of an effective and comprehensive clinical governance system under relevant NSW Legislation:

- *NSW Health Services Act (NSW) 1997*
- *Health Administration Act (NSW) 1982*
- *Public Health Act (NSW) 2010 (currently under review)*
- *Human Tissue Act (NSW) 1983*
- *Anatomy Act (NSW) 1977*
- *Coroners Act (NSW) 2009*
- *Radiation Control Act (NSW) 1990*
- *Biosecurity Act (NSW) 2015*
- *Health Records and Information Privacy Act (NSW) 2002*
- *Privacy and Personal Information Protection Act (NSW) 1998*
- *Government Information (Public Access) Act (NSW) 2009*
- *Health Care Complaints Act (NSW) 1993*
- *Health Practitioner Regulation National Law (NSW) (currently under review).*

Policy

Policy as it applies to health service delivery often requires the consideration of multifaceted issues and complex interrelationships between many people. Policy however is of no value if it is not implemented and regularly reviewed for currency. Regular monitoring of implementation and compliance with policy directives is essential. NSWHP has processes in place to ensure this occurs including the [NSWHP Policy Framework](#). Clinical policy is approved at the relevant governance committee.

NSW Ministry of Health (MoH)

Various [Policy Directives, Information Bulletins and Guidelines](#) established at State level are important in establishing a framework for clinical governance. These are available on the NSW Health Internet site and also via [NSWHP Intranet Policy Library](#).

Some of the documents that are pertinent to NSWHP with regard to clinical governance are:

- Patient Safety and Clinical Quality Program PD2005_608
- Incident Management Policy PD2014_004
- Complaint or Concern about a Clinician – Principles for Action PD2006_007
- Complaint or Concern about a Clinician – Management Guidelines–GL2006_002
- Open Disclosure Policy PD2014_028
- Complaint Management Policy PD2006_073
- Recruitment and Selection of Staff to the NSW Health Service PD2017_040
- Visiting practitioners and staff specialists Delineation of clinical privileges for policy for imp PD2005_497

- Lookback Policy PD2007_075
- Clinical Procedure Safety PD2014_036
- Clinical Handover – Standard Key Principles PD2009_060
- Accreditation of Pathology Laboratories in NSW Health PD2017_011
- System Purchasing and Performance, Safety & Quality Framework, NSW Health, August 2017
- Forensic Pathology – Code of Practice and Performance Standards PD2012_049

An annually reviewed Service Compact Agreement between the Secretary NSW Health and NSWHP outlines service obligations and performance requirements for NSWHP which are monitored and reported both internally and externally.

NSWHP

[NSWHP policy documents](#) are developed and implemented in the absence of a Ministry of Health (MoH) policy or where a remedy to a State-wide or local risk, or operational situation, is required.

Partner Organisations/Agencies

NSWHP works with a number of partner organisations and agencies engaging with key stakeholders. Interactions may be formal including membership of committees e.g. Patient Safety and Clinical Quality, Morbidity and Mortality, investigation teams and quality improvement projects. Informal and ad hoc interactions and collaboration occurs as required.

The NSWHP Clinical Council is a sub-committee of the NSWHP Board and functions as an external stakeholder reference group advising on strategies to maximise effectiveness of clinical engagement between NSWHP and Council member organisations.

The business of the Clinical Council will involve providing advice on clinical services strategies for NSWHP that support effective provision of patient care and forensic medicine services.

Local Health Districts (LHDs) and Specialty Health Networks (SHN)

Governance structures established between NSW Pathology and each LHD/SHN will monitor mutual performance through agreed performance measures, including clinical outcomes, and ensure improvements are made as required.

Accreditation background

Most NSWHP patients are also patients of LHDs/SHNs and NSWHP has a shared care role. Incidents and complaints relating to pathology aspects of patient care are often notified to the relevant LHD or SHN and will be documented in the LHD or SHN NSW Health Incident Information Management System (IIMS). Necessarily the investigation and response to incidents and complaints involving pathology will frequently need to be managed collaboratively between NSWHP and the LHD/SHN and are often led by the LHD/SHN.

LHDs and SHNs:

- Facilitate LHD/SHN specific quality improvement activities and mandatory State-wide requirements involving support from or participation by pathology
- Oversee patient complaint processes where pathology services are involved
- Coordinate Severity Assessment Code (SAC) SAC 1 privileged Root Cause Analysis (RCA) investigations with pathology issues in collaboration with NSWHP as per Incident Management Policy PD 2014_004

- Convene Medical and Dental Appointments Advisory Committee (MDAAC) meetings, assisting NSWHP with Senior Medical Officer (SMO) appointments.

NSWHP is not currently authorised to convene a privileged RCA as it is not established as a Public Health Organisation as defined in the *Health Services Act (NSW)*. Pathology related SAC1 incident RCA investigations will have NSWHP involvement and any RCA report with recommendations with NSWHP responsibility will have endorsement from both the LHD/SHN and NSWHP Chief Executives prior to submission to MoH.

Health Protection NSW

Reporting to the Chief Health Officer, Health Protection NSW is responsible for surveillance and public health response in NSW including monitoring the incidence of notifiable infectious diseases and taking appropriate action to control the spread of diseases. It also provides public health advice and response to environmental issues affecting human health.

NSWHP works with Health Protection NSW across a range of programs and situations. These include providing microbiology laboratory services in relation to identification and typing of bacteria, viruses and other agents causing communicable disease, microbiological testing of drinking water, clinical expertise and laboratory support in response to communicable disease outbreaks, and laboratory notification of notifiable conditions as required under the *Public Health Act (NSW) 2010*.

NSWHP has established a Director of Public Health Pathology position aimed at coordination and optimising NSWHP's support to Health Protection NSW.

Royal College of Pathologists of Australasia (RCPA)

RCPA's constitution specifies its objectives regarding study, training, education, research, quality assurance and professional standards. The [full list of objectives](#) can be found in pages 3-6 of the RCPA constitution.

RCPA education programs are subject to accreditation by the Specialist Education Accreditation Committee of the Australian Medical Council (AMC) and Medical Council of New Zealand.

RCPA offers Fellowship for medical specialists in nine pathology disciplines and four post-Fellowship diplomas with another in Dermatopathology under development. It collaborates with the Royal Australasian College of Physicians to offer four joint programs and a new reciprocal program in Clinical Genetics and Genetic Pathology.

RCPA provides national leadership in a number of areas which impact on clinical governance, including:

- Training – setting standards in training/qualifications for specialist pathologists and clinical scientists (Fellowships – Pathologist and Faculty of Science)
- Endorsed structured reporting templates promoting best practice
- Continuing Professional Development – pathology-related activities only
- Reference materials – such as Pathology Information, Terminology and Units Standardisation (PITUS) and Best Practice Guidelines.

RCPA Quality Assurance Programs (RCPAQAP)

RCPAQAP offers Quality Assurance (proficiency testing) Programs in all disciplines of pathology and in other specialised programs, eg [Key Incident Monitoring & Management System \(KIMMS\)](#).

RCPAQAP is a world leading External Quality Assurance (EQA) provider, accredited to ISO 9001:2008-Quality Management Systems. Each Program is individually accredited by NATA and complies with the requirements of ISO/IEC 17043:2010 – *Conformity assessment-general requirements for proficiency testing*.

Standard S7.2 of NPAAC’s Requirements for Medical Pathology Services, states that:

‘The Laboratory must be enrolled, participate and perform to an acceptable standard in external proficiency testing programs that cover all test methods performed where such programs are available.’

The Standard further requires that ‘all staff performing Medical Pathology Services must participate in External Quality Assessment programs’.

RCPAQAP is the major provider of external proficiency testing programs to NSWHP and these programs are a critical element of our clinical governance.

Clinical Excellence Commission (CEC)

The CEC builds confidence in healthcare in NSW by making it demonstrably better and safer for patients and to make NSW Health a more rewarding workplace.

The Clinical Excellence Commission improves safety and quality in the NSW public health system by:

- Coordinating system-wide analyses of issues through audit and review
- Working collaboratively with clinicians, patients, managers and the community
- Implementing programs, projects and initiatives to address identified issues
- Convening the State-wide Directors of Clinical Governance Forum, in which the NSWHP Executive Director Clinical Governance and Quality is a participating member.

CEC and NSWHP work together in:

- Leadership programs
- Incident Management – using Incident Management Policy PD2014_004, Root Cause Analysis (RCA) and Incident Information Management System (IIMS)
- Patient safety programs
- Working groups
- Improvement education and programs.

Agency for Clinical Innovation (ACI)

ACI drives continuous improvement in the way care is provided to patients in the NSW Health system by working with clinicians, consumers and managers to design and promote better healthcare.

ACI works with NSWHP in achieving these objectives by:

- Service redesign and evaluation
- Specialist advice on healthcare innovation
- Initiatives including guidelines and models of care
- Implementation support
- Knowledge sharing
- Continuous capability building.



Blood and Marrow Transplant (BMT) Network

The BMT Network is part of ACI and provides governance to State-wide clinical improvement initiatives; delivers a State-wide quality management service and provides centralised education events for this specialised clinical service.

NSWHP interacts and collaborates with the BMT Network because it tests, stores and provides bone marrow for transplantation.

Health Education and Training Institute (HETI)

HETI has leadership responsibility for the education and training of clinicians and clinical support staff in NSW Health, including nursing and allied health staff.

HETI ensures that education and training:

- Supports safe, high quality, multi-disciplinary, team based, patient centred care
- Meets service delivery needs and operational requirements, and
- Enhances workforce skills, flexibility and productivity.

All staff within NSWHP are required to complete their mandatory training. There are differing requirements for mandatory training for non-clinical staff and clinical staff and these are set out on the [HETI website](#).

NSW Cancer Institute

The NSW Cancer Institute is the home of the NSW Cancer Registry (NSWCR) which maintains records of people diagnosed with cancer in NSW. The data captured within the registry provides useful insights into the impact of cancers, and how this has changed over time. NSWHP provides notification of new cancer cases as required under the *Public Health Act 2010*.

Australian Red Cross Blood Service (ARCBS)

The ARCBS is a division of the Australian Red Cross, funded by Australian, State and Territory governments of Australia to supply the community with safe, high quality blood and blood products. NSWHP receives blood and blood products from ARCBS to support the transfusion and related services it provides to LHDs/SHNs and some private facilities.

NSW Police Force

NSW Police Force has close links with NSWHP via the Forensic Chemistry and Forensic Biology DNA Sections of NSWHP Forensic & Analytical Science Service (FASS).

NSW Police Force requires analysis in regard to:

- Forensic Toxicology
- Drugs and Driving Toxicology
- Drug Toxicology
- Illicit Drugs Analysis
- Chemical Criminalistics
- DNA analysis and reporting of exhibits.

NSW State Coroner

NSWHP Forensic and Analytical Science Service (FASS) assists the Coroner in finding the answers to unexplained and unexpected deaths in NSW and provides information in relation to both natural and unnatural deaths. NSWHP Department of Forensic Medicine pathologists perform coronial post mortem examinations and provide advice, expert opinions and reports to the Coroner, at their direction regarding cause of death. NSWHP FASS Forensic Toxicology laboratory provides analytical chemistry services to the Coroner.

Credentialing and Scope of Practice

NSWHP has processes in place to ensure that relevant clinical governance issues, as set out in NSW Health's *Critical Actions Compliance Declaration*, are properly considered in the recruitment process. All position descriptions include a statement pertaining to their clinical governance roles and responsibilities.

Medical staff will be appropriately credentialed i.e. given appropriate clinical privileges, and will only operate within their approved scope of practice. This will be monitored and supported by managers. NSW Health is developing model scopes of clinical practice for all medical specialties recognised by Australian Health Practitioner Regulation Agency (AHPRA) including all pathology specialties. NSWHP will be guided by these model scopes of clinical practice in approving scopes of practice for its senior medical staff.

Nursing staff will hold current registration with AHPRA, operate within their scope of practice and complete all relevant competencies and mandatory training. This will be monitored and supported by managers

Scientific staff will operate within their scope of practice [Scope of Practice of the Scientific Workforce](#). This will be monitored and supported by managers.

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