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The Institute of
Internal Auditors
Australia

White Paper

Clinical Governance and Assurance

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Background

Purpose

This White Paper has been written to describe the concept of clinical governance based on existing Australian standards. It goes further by suggesting that existing standards would benefit from inclusion of more formal, holistic and proactive assurance as an integral component of clinical governance activities, and this should be recognised within the relevant standards.

Background

The Australian Commission on Safety and Quality in Health Care issued the 'National Safety and Quality Health Service (NSQHS) Standards' (2021a) which comprise:

- › Clinical Governance Standard

- › Preventing and Controlling Infections Standard
- › Comprehensive Care Standard
- › Blood Management Standard
- › Partnering with Consumers Standard
- › Medication Safety Standard
- › Communicating for Safety Standard
- › Recognising and Responding to Acute Deterioration Standard

The Clinical Governance Standard is one of the eight components of the NSQHS Standards. This White Paper addresses the Clinical Governance Standard (NSQHS Standards, p. 3).

Discussion

Issue

To be effective and safe, clinical practice must have strong governance, together with complementary assurance activities to independently validate clinical outcomes.

While health care practice has many assurance activities, the NSQHS Standards make passing comment on 'quality assurance' while remaining mostly silent on what this is and how it should be implemented.

History

The primary aim of the NSQHS Standards is to protect the public from harm and to improve the quality of health care. They provide an assurance mechanism to test whether relevant systems are in place to ensure a health care system meets expected standards of safety and quality. Since 2013, it has been mandatory for all Australian hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards (Australian Commission on Safety and Quality in Health Care, 2019b).

What is Governance?

Governance is a widely used business term that can mean different things to different people in different contexts. Its overall intention is to promote confidence with stakeholders that an organisation is achieving its purpose. There is a lot written about it. Discussion of governance

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often goes well beyond achievement of specific objectives to the way in which those objectives are achieved, taking into account the ethical performance of the organisation and its impact on its environment.

The term 'corporate governance' is generally applied to the way an organisation as a whole is governed, but considering how widely the term is used, it is surprising there is not more definitive information on holistic frameworks, capability maturity guidance, and the link between governance and assurance.

The governing authority of an organisation is ultimately responsible for an organisation's governance. The Institute of Internal Auditors (IIA) in its 'International Professional Practices Framework' (IPPF) refers to the governing authority as the 'board'. In a company, this will be the board of directors. In the public sector where there is no board of directors, governance arrangements are implemented by the head of the organisation such as the secretary, director-general or chief executive. Conceptually, a self-contained component of an entity is also an organisation and will, itself, have a governance process which is the responsibility of a group or individual.

The IPPF defines governance as:

The combination of processes and structures implemented by the board to inform, direct, manage and monitor the activities of the organisation toward the achievement of its objectives.

In discussing corporate governance, the ASX Corporate Governance Council (2019) has quoted Commissioner Mr Justice Owen in his report on the Australian Government HIH Royal Commission and has reminded readers that governance also "*encompasses the mechanisms by which companies, and those in control, are held to account*".

What is Clinical Governance?

In health care organisations such as hospitals and health services, there is generally a board with overall responsible for governance. This includes both enterprise corporate governance and clinical governance.

Clinical governance is defined as:

The set of relationships and responsibilities established by a health service organisation between its state or territory department of health (for the public sector),

governing body, executive, clinicians, patients, consumers and other stakeholders to ensure good clinical outcomes. It ensures that the community and health service organisations can be confident that systems are in place to deliver safe and high-quality health care, and continuously improve services.
(Australian Commission on Safety and Quality in Health Care, 2017, p. 2)

Clinical governance is the responsibility of the governing authority and is about managing clinical risks – it is aimed at achieving good clinical outcomes.

The Australian Commission on Safety and Quality in Health Care issued the NSQHS Standards. The primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health care. They supply an assurance mechanism to test whether relevant systems are in place to ensure a health care system meets expected standards of safety and quality. All Australian hospitals and day procedure services must be assessed through an independent accreditation process to determine whether they have effectively implemented the NSQHS Standards.

To be effective and safe, clinical practice needs to have strong governance, together with complementary assurance activities to independently validate clinical outcomes.

The NSQHS Standards are supported by the 'National Model Clinical Governance Framework' (Australian Commission on Safety and Quality in Health Care, 2017) to ensure patients and consumers receive safe and high-quality health care. It describes the elements essential for acute health service organisations to achieve integrated corporate and clinical governance systems. Through these systems, organisations and healthcare professionals and workers are accountable to patients and the community for continuously improving the safety and quality of their services.

The 'National Model Clinical Governance Framework' (Framework) builds on the NSQHS Standards and provides more information. It:

- › Defines clinical governance.
- › Provides the context for clinical governance being an integrated component of corporate governance.

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- › Describes the key components of a clinical governance framework based on the NSQHS Standards.
- › Discusses the role of culture in supporting good clinical governance.
- › Outlines the roles and responsibilities of, and essential partnership between, patients and consumers, clinicians, managers, and governing bodies such as boards in implementing effective clinical governance systems in health service organisations.

The NSQHS Standards and Framework make passing comment on ‘quality assurance’ but are mostly silent on:

- › The concept of ‘assurance’.
- › Assurance activities in a health care setting.
- › Who delivers assurance.
- › What assurance decision-makers should receive.
- › Standards for performing assurance activities in a health care setting.

There is also a ‘User Guide for Governing Bodies’ issued by the Australian Commission on Safety and Quality in Health Care (2019b).

What are Health Care Related Risks?

At a strategic level, risks associated with delivering health care are:

Strategic risk	The likelihood of internal or external events affecting an organisation’s ability to reach its objectives – strategic risks include financial, governance, change management project management and reputation risk.
Operational risk	The likelihood internal processes, people or systems will fail in a way that disrupts business operations – operational risks include clinical, business disruption, cyber-attack, documentation, errors or negligence in credentialing, financial, fraud, human error and workforce risks.

Performance risk	The likelihood internal processes, people or systems will fail in a way that affects an organisation’s ability to meet its obligations – performance risks include accreditation, compliance, legal, quality, safety, regulatory and work health safety risks.
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At a more granular level, health care risks may be:

Acute risk	A hazard, danger, loss or injury may affect a patient’s health.
Assurance risk	Oversight of clinical activities may not be effectively structured to provide adequate assurance.
Behavioural health risk	Risk factors that individuals have the most ability to modify may not be addressed.
Biomedical risk	Risk factors influenced by health may carry direct and specific risks for patients.
Clinical governance risk	Minimising risks and harm to patients that may not be addressed by: <ul style="list-style-type: none"> › Identifying what can and does go wrong during care. › Understanding the factors influencing this. › Learning lessons from adverse events and poor outcomes. › Ensuring action is taken to prevent recurrence. › Putting systems in place to reduce risks.
Clinical workforce risk	Supply of professional clinical workforce may be insufficient to cope with demand.
Communication risk	Clinical risk and outcomes may not be adequately communicated to individuals.
Confidentiality risk	Confidential patient data may be released accidentally or deliberately.
Credentialing risk	Academic qualifications and clinical practice history of a health care professional may not be properly verified.
Documentation risk	There may be inadequate official papers or written material that provides proof of clinical activities.
Exploitation risk	Vulnerable individuals may have treatment performed against their will or treatments withheld without their knowledge.

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Facility accreditation risk	A health facility environment may not be adequately controlled to maintain independent accreditation.
Financial sustainability risk	Clinical treatment may become too expensive to be financially sustainable.
Lessons learned risk	Lessons from the past may not be captured to improve future outcomes.
Patient safety risk	Prevention of errors and adverse effects to patients may not be optimised.
Physical risk	Physical health of individuals may be compromised.
Privacy risk	Privacy of individuals may be breached.
Quality risk	Adverse patient outcome may occur due to quality control that fails to meet specified quality requirements.
Safe environment risk	A health care facility environment may not be fit-for-purpose or adequately prepared for unexpected eventualities.
Sentinel risk	Risk of preventable occurrences involving physical or psychological injury to patients may not be effective.
Training risk	Health care professionals may not be adequately trained to effectively and safely perform their roles.

What Does a Clinical Governance Model Look like?

The Clinical Governance component of the NSQHS Standards states:

Leaders of a health service organisation have a responsibility to the community for continuous improvement of the safety and quality of their services, and ensuring that they are patient centred, safe and effective.

A properly structured governance model includes the systems for clinical governance designed to ensure accountability, good outcomes and continuous improvement. Shown below are the 'systems', while 'processes' complement systems and refer to 'how' this is achieved.

Governance, Leadership and Culture

Leaders at all levels in the organisation set up and use clinical governance systems to improve the safety and

quality of health care for patients.

- › *Governance, Leadership and Culture*
- › *Organisational Leadership*
- › *Clinical Leadership*

Patient Safety and Quality Systems

Safety and quality systems are integrated with governance processes to enable organisations to actively manage and improve the safety and quality of health care for patients.

- › *Policies and Procedures*
- › *Measurement and Quality Improvement*
- › *Risk Management*
- › *Incident Management Systems and Open Disclosure*
- › *Feedback and Complaints Management*
- › *Diversity and High-Risk Groups*
- › *Healthcare Records*

Clinical Performance and Effectiveness

The workforce has the right qualifications, skills and supervision to provide safe, high-quality health care to patients.

- › *Safety and Quality Training*
- › *Performance Management*
- › *Credentialing and Scope of Clinical Practice*
- › *Safety and Quality Roles and Responsibilities*
- › *Evidence-Based Care*
- › *Variation in Clinical Practice and Health Outcomes*

Safe Environment for the Delivery of Care

The environment promotes safe and high-quality health care for patients.

- › *Safe Environment*

A point worthy of consideration is absence of reference to engagement with consumers of health care services as part of clinical governance. For contemporary clinical

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governance, particularly in the public sector, ‘consumer engagement’ or ‘partnering with consumers’ is an important consideration. While ‘partnering with consumers’ is a separate NSQHS standard (Australian Commission on Safety and Quality in Health Care, n.d.), it is increasingly seen as a requirement that consumers are involved in organisation governance. There is a growing body of evidence demonstrating improved patient outcomes and equity of access when consumers are involved in the design and governance of health care services.

Why is Assurance Also Necessary?

Assurance is a positive declaration intended to give confidence and improve the quality of information to aid informed decision-making. In some contexts, the term ‘assurance’ is applied to the whole process of being confident of achieving something and therefore includes considerations of design, resourcing and competence in addition to the traditional concepts of assurance information. It concentrates on the information provided to those who are governing the process to enable them to be assured the activity is designed and operating to achieve its objectives. This information should come from several sources.

The NSQHS Standards and the Framework mention ‘quality assurance’ in the context of:

- › Responsibility of Managers including Clinical Managers – *Ensure availability of data and information to clinicians to support quality assurance and improvement* (Framework, p. 13).
- › Responsibility of Governing Bodies – *Ensure availability of data and information to support quality assurance and review across the organisation* (Framework, p. 14).

However, neither document specifically mentions other forms of assurance, especially assurance independent of management.

The Framework sets the requirements for good clinical governance, but there also needs to be a range of objective clinical review and assurance activities which should consider the following:

Assurance

Evidence for the purpose of supplying an independent assessment of governance, risk management, and control processes for safe clinical practice.

Oversight

- › Board
- › Safety and quality committee
- › Audit committee

Self-Assessment and Compliance Monitoring Activities

- › Quality control and quality assurance
- › Other assurance activities, validations and evaluations
- › Peer review
- › Lessons learned
- › Community expectations

Independent Assurance Activities

- › Evaluations and management reviews
- › Financial audits
- › Internal audit
- › Investigations
- › Maturity assessments
- › Performance reviews
- › Special audits
- › Accreditation (external assurance independent of the organisation 3 Lines Model)

For the purpose of an independent assessment of governance, health services should be able to demonstrate existence of various oversight committees with a direct interest in clinical governance and assurance. In large health organisations, it is likely there are multiple committees that have oversight of safety / quality metrics / issues and multiple committees that review audit results. This in itself can be a risk due to possible duplication and unknown gaps. It can be useful to map committees and governance structures for the purpose of providing clarity for reporting and risk escalation pathways.

The ‘3 Lines Model’ (The Institute of Internal Auditors, Inc, 2020) shows where various assurance activities are positioned – the following example shows what this could possibly look like in a health care setting.

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3 Lines Model of Assurance		
Line 1 Part of the line management structure <i>Business operations that own and manage risk</i>	Line 2 Part of the line management structure <i>Oversight functions that monitor risk</i>	Line 3 Independent of the line management structure <i>Assurance that risk is managed</i>
<p>Enterprise</p> <ul style="list-style-type: none"> › Strategic and operational planning › Change management › Clinical policies and procedures › Corporate policies and procedures › Jurisdiction policies and procedures › Delegations › Model of care (clinical service planning) › Project management › Performance reporting <p>Information Systems and Workflows</p> <ul style="list-style-type: none"> › Incident management system › Performance monitoring › Quality assurance reporting system › Research ethics <p>Quality Control</p> <ul style="list-style-type: none"> › Clinical quality control competency requirements › Standards of performance 	<p>Governance</p> <ul style="list-style-type: none"> › Corporate governance › Clinical governance › Fraud and corruption control › Annual attestations <p>Risk Management</p> <ul style="list-style-type: none"> › Enterprise risk management › Clinical risk management and patient safety › Incident management (root cause analysis) › Fraud and corruption control › Business continuity planning including pandemic planning › Work health safety › Security (non-ICT) › ICT governance, risk management, cybersecurity › ICT disaster recovery › Control effectiveness and continuous control monitoring <p>Compliance Management</p> <ul style="list-style-type: none"> › Legal and regulatory compliance › Policy compliance › Ethics and conduct › Privacy and information protection <p>Quality Assurance</p> <ul style="list-style-type: none"> › Clinical data governance › Clinical governance and standards activities › Clinical incident analysis › Clinical data and contract monitoring › Clinical quality assurance data and contract monitoring › Clinical quality assurance integrity of reporting › Clinical incident analysis › Project assurance › Research quality assurance 	<ul style="list-style-type: none"> › Evaluations and management reviews › Financial audits › Internal audit › Investigations › Maturity assessments › Performance reviews › Special audits 

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How Might Further Assurance Focus Help?

In health care organisations, consideration could be given to more formally defining the complete clinical assurance environment. This can ensure the range of assurance activities is adequate and operating effectively, while supplying validated assurance information to decision-makers. This could look like:

Governance, Leadership and Culture

Leaders at all levels in the organisation set up and use clinical governance systems to improve the safety and quality of health care for patients.

- > Governance, Leadership and Culture
- > Organisational Leadership
- > Clinical Leadership

Patient Safety and Quality Systems

Safety and quality systems are integrated with governance processes to enable organisations to actively manage and improve the safety and quality of health care for patients.

- > Policies and Procedures
- > Measurement and Quality Improvement
- > Risk Management
- > Incident Management Systems and Open Disclosure
- > Feedback and Complaints Management
- > Diversity and High-Risk Groups
- > Healthcare Records
- > Community Expectations

Assurance

Evidence for the purpose of supplying an independent assessment on governance, risk management and control processes for safe clinical practice.

Oversight

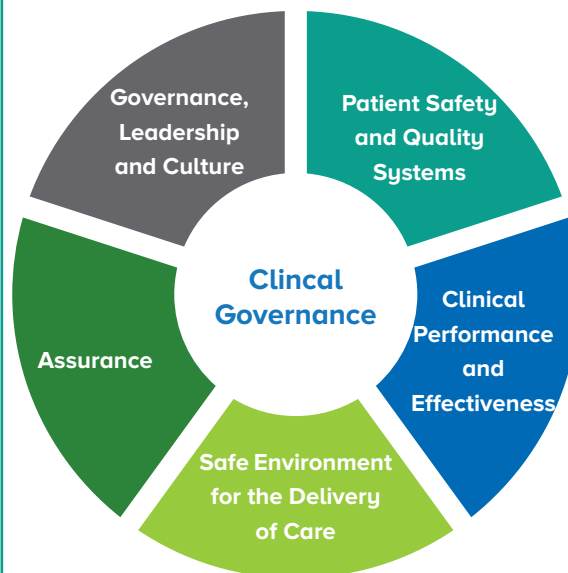
- > Board
- > Safety and quality committee
- > Audit committee

Self-Assessment and Compliance Monitoring Activities

- > Quality control and quality assurance
- > Other assurance activities, validations and evaluations
- > Peer review
- > Lessons learned

Independent Assurance Activities

- > Evaluations and management reviews
- > Financial audits
- > Internal audit
- > Investigations
- > Maturity assessments
- > Performance reviews
- > Special audits
- > Accreditation



Clinical Performance and Effectiveness

The workforce has the right qualifications, skills and supervision to provide safe, high-quality health care to patients.

- > Safety and Quality Training
- > Performance Management
- > Credentialing and Scope of Clinical Practice
- > Safety and Quality Roles and Responsibilities
- > Evidence-Based Care
- > Variation in Clinical Practice and Health Outcomes

Safe Environment for the Delivery of Care

The environment promotes safe and high-quality health care for patients.

- > Safe Environment

Note – Assurance is not part of the NSQHS Standards or the National Model Clinical Governance Framework

Note – Community Expectations are not part of the NSQHS Standards or the National Model Clinical Governance Framework

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What About Assurance Standards?

Another factor to consider is how assurance activities are performed in a health care setting. While there are NSQHS Standards, there is no guidance or formally issued assurance standards about how to audit against the NSQHS Standards. In particular, the evidence required and the criteria for conformance are not well-defined.

For Line 3 internal audits independent of management, the relevant standards would generally be the 'International Standards for the Professional Practice of Internal Audit' contained in the 'International Professional Practices Framework' (IPPF) issued by the Institute of Internal Auditors (IIA). Application of these standards requires:

- › Appropriate criteria for assessment (Internal Audit Standard 2210.A3 'Engagement Objectives').
- › Appropriate and sufficient resources (Internal Audit Standard 2230 'Engagement Resource Allocation').
- › Appropriate methodology (Internal Audit Standard 2240.A1 'Engagement Work Program').
- › Competent audit team members (Internal Audit Standard 1210 'Proficiency').

For Line 2 assurance activities, the relevant standards could be ISO 19011:2018 'Guidelines for auditing management systems' issued by the International Organization for Standardization (ISO). Once again, application of these standards has a number of preconditions including assessment criteria and competent auditors.

It is important that formal clinical assurance standards be prescribed for clinical assurance practitioners to:

- › Provide an Australia-wide accepted basis for the performance of clinical assurance activities.
- › Provide a uniform clinical assurance regime Australia-wide.
- › Provide an Australia-wide benchmark and criteria for establishing the quality of clinical assurance activities.

Conclusion

Summary

While health care practice has many assurance activities, the NSQHS Standards make passing comment on 'quality assurance' but are mostly silent.

The absence of more complete focus on assurance in the NSQHS Standards risks decision-makers making assessments without a full suite of assurance information, especially independently validated data from outside the line management structure. Incomplete information and deficient methodology risks management 'marking their own homework' or using inadequate assurance measures, and may detract from readiness for an independent accreditation process to determine whether the NSQHS Standards have been effectively implemented.

Without formal clinical assurance standards prescribed for clinical assurance practitioners, there is no basis to determine that a professional clinical assurance activity has been performed.

Conclusion

To be effective and safe, clinical practice needs to have strong governance together with complementary assurance activities to independently validate clinical outcomes.

Consideration should be given to more formally defining a health care organisation's assurance environment. This would strengthen data provided to decision-makers, providing a full suite of assurance information, especially independently validated data from outside the line management structure.



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Purpose of White Papers

A White Paper is a report authored and peer reviewed by experienced practitioners to provide guidance on a particular subject related to governance, risk management or control. It seeks to inform readers about an issue and present ideas and options on how it might be managed. It does not necessarily represent the position or philosophy of the Institute of Internal Auditors-Global and the Institute of Internal Auditors-Australia.

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He has made presentations on internal auditing in forums in Australia and internationally and has taught internal auditing in Australia and other countries. He co-authored the IIA-Australia publication 'Internal Audit in Australia' and co-authored 'Audit Committees – A Guide to Good Practice, 3rd edition' issued by AICD / AUASB / IIA-Australia. He contributed to 'Sawyer's Internal Auditing, 7th Edition' and co-authored the IIA-Australia publication 'Project Assurance'.

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About the Institute of Internal Auditors-Australia

The Institute of Internal Auditors (IIA) is the global professional association for Internal Auditors, with global headquarters in the USA and affiliated Institutes and Chapters throughout the world including Australia.

As the chief advocate of the Internal Audit profession, the IIA serves as the profession's international standard-

setter, sole provider of globally accepted internal auditing certifications, and principal researcher and educator.

The IIA sets the bar for Internal Audit integrity and professionalism around the world with its 'International Professional Practices Framework' (IPPF), a collection of guidance that includes the 'International Standards for the Professional Practice of Internal Auditing' and the 'Code of Ethics'.

The IIA-Australia ensures its members and the profession as a whole are well-represented with decision-makers and influencers, and is extensively represented on a number of global committees and prominent working groups in Australia and internationally.

The IIA was established in 1941 and now has more than 200,000 members from 190 countries with hundreds of local area Chapters. Generally, members work in internal auditing, risk management, governance, internal control, information technology audit, education, and security.

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