

Risk Based Approach to Internal Audit in the Healthcare Setting:

CLINICAL RISK ASSURANCE FOR BOARDS AND AUDIT AND RISK COMMITTEES

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Introduction

A key responsibility of a governing body is gaining assurance that significant risks to the achievement of strategic organisational objectives are being effectively managed. Governance assurance that a risk is being effectively managed may come in various forms. A common framework for viewing the different types of risk management and assurance within an organisation is the 'Three Lines of Defence' model.

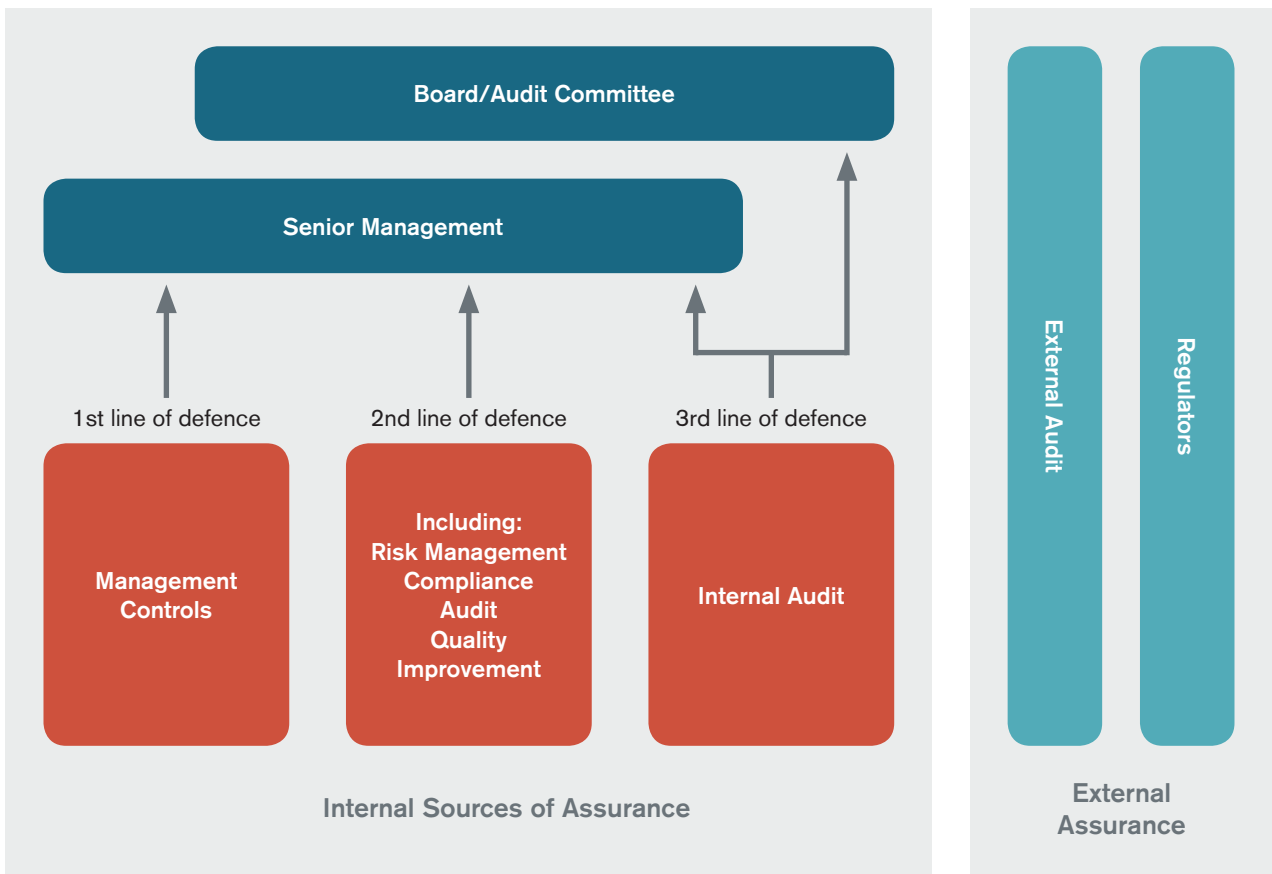


Diagram One: The lines of Defense in Risk Assurance (The Institute of Internal Auditors 2013)

Internal audit, the third line of defence, provides 'assurance on the effectiveness of governance, risk management, and internal controls, including the manner in which the first and second lines of defence achieve risk management and control objectives' (The Institute of Internal Auditors 2013). This VMIA publication provides an overview of the use of internal audit in clinical areas of a health service, in providing governing bodies with robust, objective data to inform their understanding of the control of significant risks. The document is intended to assist boards and audit and risk committees with the development of an internal audit program that accurately reflects the risk profile of their health service.

Background

Internal audit is defined as 'an independent, objective assurance and consulting activity designed to add value and improve an organisation's operations' (The Institute of Internal Auditors 2009). In theory, best practice internal audit approaches should 'direct their activities to the most significant risks of the entity and the controls in place to manage them' (Australian National Audit Office 2012). Contemporary internal audit programs in healthcare organisations have seen a move beyond just the management of financial risks to address other enterprise risks such as human resources systems and cybersecurity. However the evidence regarding risks related to the provision of health care services indicates that internal audit programs can be further refined in the healthcare setting to provide assurance on the management of risk that arise in relation to the delivery of health services.

The literature on health care quality and safety clearly demonstrates that health interventions carry significant risks to patients and consumers. Patients have a

'one in two chance of getting the right care, a 1:10 likelihood of being harmed in association with a hospital admission and a 1:50 possibility of system-induced death or major disability'

(Braithwaite and Coiera 2010)

The risks related to the delivery of a wide range of health care services from medical and surgical interventions in the acute hospital setting to pharmaceutical and allied health interventions in the community setting are referred to broadly as clinical risks. The increasing awareness over the last two decades of the role of the board in governing the quality and safety of healthcare services has highlighted the requirements of a board to

'monitor patient safety with the same rigour and attention they give to corporate and financial performance'

(Auditor General Victorian 2005).

Harm to patients, clients and residents represent significant healthcare organisational risks and require a similar degree of assurance regarding their management as financial risk. Some health service internal audit programs have begun to reflect healthcare specific risks through the development of internal audits of clinical governance systems and various healthcare processes such as theatre management. This document provides an overview of a comprehensive approach to the internal audit of higher risk clinical units that have undergone an initial pilot (Brown, Santilli et al. 2015) and a further trial in a range of settings as part of a VMIA funded project.

Existing Assurance Mechanisms in Clinical Areas

In clinical areas there are a range of controls to manage risks, and these can be categorised according to the three lines of defense model. The first line of defense, the day to day risk controls, are the responsibility of clinical managers who ensure risk controls are implemented in the form of policies, procedures and protocols in each unit/program to guide quality of care. The second line of defense, the oversight functions of the organisation to ensure risk management and compliance is usually exercised by quality reporting to quality, risk and human resources committees and undertaking local clinical audits. Clinical audit is the most common form of audit used in clinical areas to examine the gap between current practice and best practice and inform quality improvement strategies. Clinical audit has several significant differences in scope and intent from internal audit, the third line of defense, as outlined in the table one below.

Internal Audit	Clinical Audit
Examines clinical and non-clinical activity, systems and processes	Examines clinical processes and outcomes
Is carried out externally by independent professionals.	Is clinically led, and may be carried out by healthcare professionals and / or clinical audit staff
Selection of audit areas is risk based	Selection of audit areas may be driven by clinical interest and accreditation and only loosely related to significant risks
Assesses mechanisms of internal risk control within an organisation and feeds back into risk plans.	Measures defined area of clinical practice against agreed best practice standards
Internal audit programs are established over the medium term (3-5 years) with work-plans agreed annually.	May be an annual clinical audit program or audits may occur in response to an incident
Consistent approach according to Internal Audit Standards	Carried out in accordance with board approved clinical audit policy
Recipient of audit findings is the board	Recipient of audit findings is often internal committees or other interested internal parties e.g. unit manager

Table One: Comparison of internal audit with clinical audit (modified from (Healthcare Quality Improvement Partnership 2012))

Existing Assurance Mechanisms in Clinical Areas (continued)

In addition to the three line of defense as internal sources of assurance the model describes external assurance mechanisms. In clinical areas these occur in the form of external audits (e.g. accreditation or external audits such as VMIA risk framework quality review) and reporting to funders or regulators (e.g. performance monitoring and reporting to department of health). Accreditation of health sector agencies provides the board with assurance that the organisation has met with an agreed set of minimum standards as outlined by national standards. Accreditation however does not necessarily provide assurance of high quality care and adequate management of risk in clinical areas. Many of the high profile failures that have occurred in health services have happened in services that have been accredited (Duckett 2016). In the wake of failings at the Mid Staffordshire Hospital Trust in the UK that saw high levels of preventable mortality and “appalling care” (Francis 2013), the National Advisory Group on the Safety of Patients in England (2013) advised:

‘...healthcare organisations should shift away from their reliance on external agencies as guarantors of safety and quality and toward proactive assessment and accountability on their own’.

A recent review of hospital safety and quality assurance in Victoria recommended that hospitals consider ‘initiating a program of regular external reviews of clinical units’ (Duckett 2016). The report promotes the use of external expert clinicians in clinical governance and improvement activities (Duckett 2016). The internal audit of clinical areas provides a third line of defence in the proactive assessment of clinical risk and provision of advice and assurance to the board through the use of a suitably qualified clinical expert as part of the internal audit team. The key features of the internal audit of clinical areas and the approach to incorporating this into a health service’s internal audit program is addressed in the next section.

Developing a risk based internal audit program

There are several key differences in developing a risk based internal audit program for healthcare that is inclusive of significant clinical risks compared to more traditional approaches. In the first instance the senior managers responsible for clinical areas will inform the identification of significant clinical risks to inform the risk based prioritisation of the organisation's internal audit program for the next period. Once the clinical area to be included in the internal audit program is identified the senior manager for the relevant clinical area (the internal audit manager) will work with the person responsible for the organisation wide internal audit program (head of internal audit) to inform:

- an annual internal audit work plan
- a detailed internal audit plan for the clinical area
- review the internal audit findings

The internal audit team contracted to undertake the internal audit must include the appropriate clinical expertise and access a suitable internal audit tool with relevant criteria to be assessed.

The normal accountabilities for internal audit in reporting to the board via the audit committee remain the same however the transfer from the audit committee to the board quality committee of the oversight of implementing internal audit recommendations is recommended for the internal audit of clinical areas. These accountabilities and responsibilities are summarised in the governance diagram below.

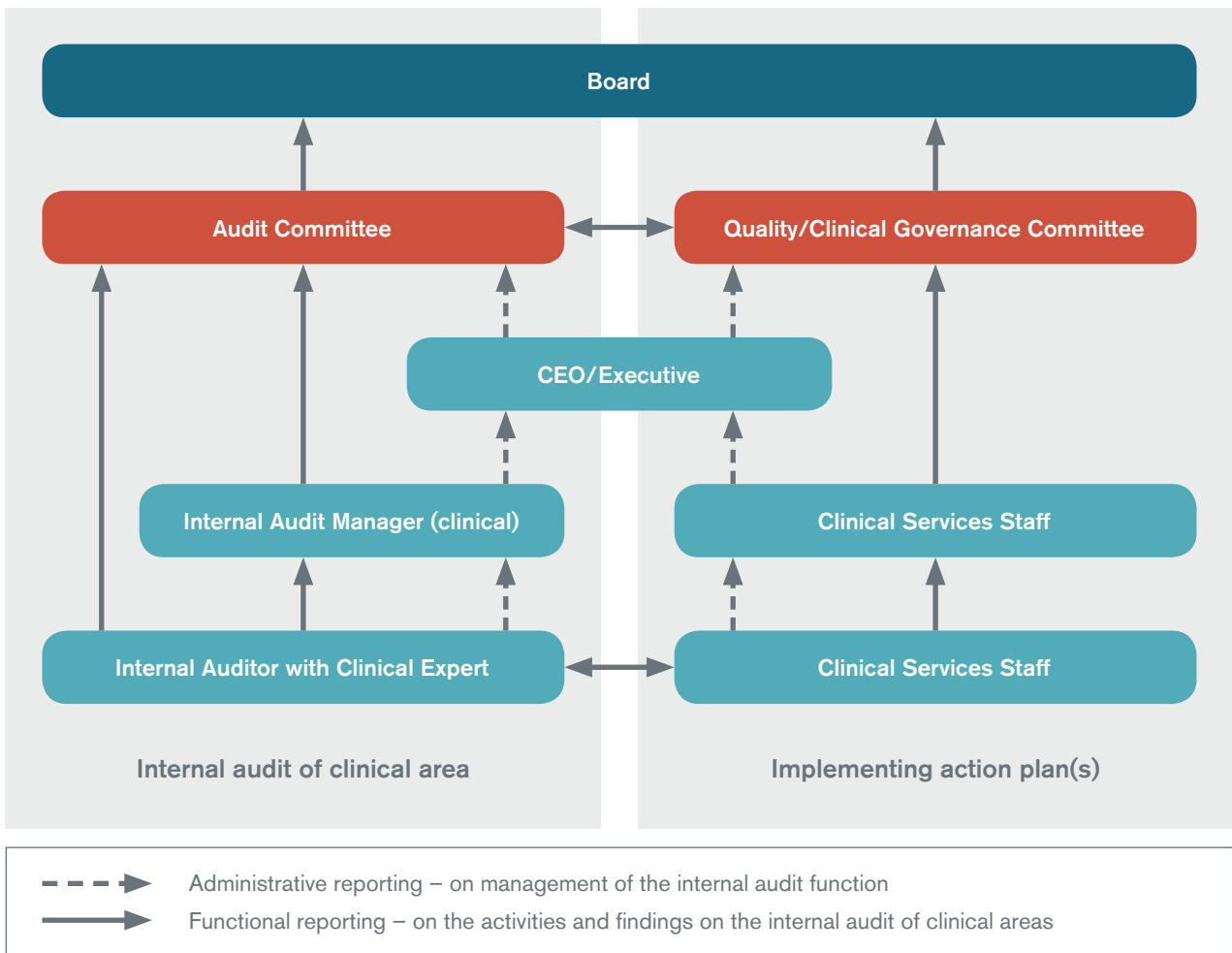


Diagram Two: Governance arrangements (modified from (INCITE information 2012)

Developing a risk based internal audit program (continued)

The key steps in developing a risk based internal audit program in an organisation that reflects the key clinical risks in healthcare are summarized in Diagram three below.



Diagram Three: Summary of key processes in the internal audit of clinical areas

Summary

This document has outlined the rationale and approach to the internal audit of clinical areas. The key messages are:

- The internal audit program of a health care organisation needs to reflect the significant risks associated with health care delivery
- Significant clinical risks require similar levels of assurance as other key risks
- The prioritisation of significant clinical risks and developing internal audit plans requires clinical input
- An internal audit of a clinical area requires the appointment of an internal audit team with relevant clinical expertise and an appropriate internal audit tool to guide the process

The project undertaken by VMIA to trial this approach in diverse settings in Victorian health services found the approach suitable and flexible to be tailored to the needs and budgets of both small and large services. Further information and resources developed by the project are provided under the resource heading.

Useful resources and links

- Internal audit clinical tool (ICAT)
- Emergency and Urgent Care Centres Internal audit clinical tool ED/UCC ICAT
- Maternity Services Internal audit clinical tool (MATICAT)
- Internal audit of clinical area guidelines
- VMIA Risk Management in Clinical Areas: The Role of Internal Audit (background for clinical staff)
- Information kit for clinical experts

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