

Risk Management in Clinical Areas:

THE ROLE OF INTERNAL AUDIT

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Contents

Introduction	2
Background	3
The principles of internal audit	4
The practice of internal audit in clinical areas	5
Summary	7
Useful resources and links	8
References	9

Introduction

High profile failures in healthcare delivery internationally resulting in harm to patients have highlighted the need for health services to develop more rigorous internal methods for identifying and managing significant clinical risks. This document outlines the use of internal audit as a method to review the management of significant risks in clinical areas and programs in health services. Internal audit of a clinical area involves the health service initiating a comprehensive review of processes and practice undertaken by an independent internal audit team with appropriate clinical expertise.

Internal audit is a robust, objective and proactive method for organisations to gain assurance on their management of key risks. While internal audit has traditionally been used to provide assurance on financial management and risks the approach is now applied more broadly to other significant risks in organisations. Recent trials of the approach through a VMIA funded project have indicated the value of this approach in a variety of health service settings in gaining assurance and advice on the management of significant clinical risks.

Background

A key responsibility of a healthcare organisation is obtaining assurance about the control and management of significant risks. This includes assurance about the management of clinical risk in the range of services delivered by the organisation. Traditional approaches to gaining assurance in clinical areas have focused on two main sources of assurance gained from external bodies, such as accreditation agencies and professional bodies, or internal assurance, from activities conducted by management and clinical staff such as clinical audits and policy and procedure reviews.

The limitations of existing forms of assurance, such as accreditation (Duckett 2016), have led health care organisations to seek additional forms of assurance on the management of clinical risks. 'Targeting Zero' a 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). 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.'

While these recommendations might at first glance appear contradictory with the former recommending external review and the latter recommending internal assessment, the process of internal audit satisfies both these recommendations. Internal audit is an activity that is initiated internally by the organisation in response to their need for assurance on the management of significant risks. The organisation will then generally engage an internal audit team comprising qualified internal auditors and appropriate independent experts, such as senior clinicians, to undertake the review. The internal auditors will then report internally to the board via the audit committee. So while internal audit is initiated and managed internally by the organisation it uses an internal audit team who are independent from the area under review in order to provide objectivity. The principles of internal audit and the methodology as applied in clinical areas are outlined in the next sections.

The principles of internal audit

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). Internal auditors are defined in this document as qualified internal auditor working in line with the international standards of internal auditing. Core principles underpin the professional practice of internal auditing and require the following from the internal auditor and the internal audit practice:

- Demonstrates integrity.
- Demonstrates competence and due professional care.
- Is objective and free from undue influence (independent).
- Aligns with the strategies, objectives, and risks of the organization.
- Is appropriately positioned and adequately resourced.
- Demonstrates quality and continuous improvement.
- Communicates effectively.
- Provides risk-based assurance.
- Is insightful, proactive, and future-focused.
- Promotes organizational improvement

(The Institute of Internal Auditors 2016)

One of the key questions for those with clinical backgrounds is how does internal audit differ from the comprehensive program of clinical audits that are undertaken in healthcare services?

Table One outlines the key differences between the two approaches.

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)

The risk based selection of areas for internal audit may be in contrast to compliance requirements that may influence the selection of areas for clinical audit. Additionally clinical audits are generally narrow in focus, for example a clinical audit of pain relief in emergency department or the appropriate use of prophylactic antibiotics in surgery, whereas internal audit can be much broader in scope and encompass a review of multiple aspects within a clinical area.

The practice of internal audit in clinical areas

The internal audit of clinical areas requires the input of senior managers responsible for clinical areas or units into the internal audit planning and review process. The clinical input into the internal audit of clinical areas is outlined in key stages below.

Prioritising internal audits

The first step in developing a program of internal audits for 2-3 years involves the prioritisation of organisational risks to inform the selection of internal audits to be included in the program. The input of senior managers of clinical areas in identifying significant clinical risks is integral to this.

The priority of internal audits can be assessed through the development of a set of criteria that can be used to rank potential audits. Potential criteria can include:

- The importance of the program to the organisation's objectives
- The risk rating identified in the risk register or identified through internal audit function
- Coverage by other assurance and review or external reporting functions
- The potential benefits of an audit
- Any relevant finding, reports, recommendations from other internal or external reviews, accreditation or audit
- The length of time since any previous internal or external audit

(Australian National Audit Office 2012)

In the clinical area additional information will inform the selection of internal audits including:

- Areas of higher volume
 - minimum three years through-put data for clinical service areas to identify volumes: e.g. average total inpatient days, average number of patients, average length of stay per patient, growth trend
- Areas of higher risk
 - minimum three years incident reporting for each clinical service area to identify frequency of adverse events
 - minimum three years claims data for hospital and state-wide (VMIA) to identify emerging/high potential risk areas
 - complaints and patient satisfaction data to identify frequencies and trends by clinical service area
- Other evidence, policy directives or guidelines such as:
 - National Safety Goals
 - Coroners' reports
 - Clinical Registry Reports
 - Statement of Priorities indicators
 - My Hospital reports
- Consultation with clinical staff

Selecting the internal auditor

Senior managers of clinical areas will provide input into the selection of the internal audit team to conduct the internal audit at the organisation. While the manager responsible for internal audit in the organisation will assess the credentials of the internal audit professional, the clinical manager will need to either specify or assess the credentials of the clinical expert included in the internal audit team. Key considerations when assessing the clinical expertise include:

- must be independent to the organisation i.e. not employed or engaged in any activity within the organisation
- Have relevant specialist qualification in clinical area
- Have relevant clinical/management experience in clinical area
- Undertaken previous internal audits or have undertaken clinical audits in clinical area
- Knowledge of current standards and practice guidelines relevant to clinical area.

The practice of internal audit in clinical areas (continued)

Defining the scope of the internal audit

The internal audit is conducted by measuring processes and practice against audit criteria, explicit statements that define what is being measured objectively through the internal audit process. Internal auditors will discuss with the organisation the appropriate criteria to be included in the internal audit. Where no internal audit tool with established criteria exists, preliminary work will need to be undertaken to identify suitable criteria. Recommendations from standards and clinical practice guidelines can be used to develop criteria for the internal audit of clinical areas. Where no suitable clinical guidelines exist for developing criteria, prioritising evidence from literature and generating criteria based on professional consensus may assist.

The project funded by VMIA to undertake internal audits in clinical areas has generated a generic internal audit tool that may be adapted to any clinical area. The generic internal audit tool and versions created for emergency services and maternity services can be found in the reference section of this document.

The generic internal audit tool comprises criteria that are grouped in four sections:

1. Quality Systems Evaluation – a review of the implementation of the main quality systems that underpin service delivery in the clinical area (e.g. credentialing or incident systems).
2. Clinical Process Evaluation- a review of the documents that support the effectiveness of clinical processes in the clinical area (e.g. assessment and clinical management procedures)
3. Clinical Data Review – a review of the type of patient related data routinely monitored and analysed by the organisation for quality improvement purposes in the clinical area.
4. Patient Record Review – a review of patient medical records for appropriate clinical processes required in all patients in the clinical area (e.g. initial assessment and discharge) and specific clinical processes required in defined sub-populations (e.g. for an internal audit of maternity services it might be management of women with prolonged labor or for an emergency department it may involve review of the management of a patient with altered conscious state) .

The internal audit can be tailored to meet the needs of the organisation by selecting which criteria will be included in the internal audit. Defining the scope of the internal audit will be guided by the following factors:

- Applicability of the criterion to the service profile
- Known high risk areas
- Areas for which no other source of assurance was available (e.g. accreditation, clinical audits, external review processes)
- Budget available for internal audit

Preparing staff

Senior managers of clinical areas are essential in preparing and involving clinical staff in the internal audit of the clinical area. Clear communication regarding the purpose and process of internal audit prior to the internal audit is important in assisting staff to understand that internal audit is an internally generated activity designed to improve patient care. Clinical staff may be involved in the fieldwork either through providing a tour of the clinical area, discussing clinical processes with the internal auditors or assisting the clinical expert navigate the patient files as part of the patient file audit. The involvement of clinical staff in the internal audit provides a valuable opportunity for the clinical expert to share their knowledge of best practice approaches.

Summary

The internal audit of clinical areas provides a valuable tool for organisations to use in the in depth review of a clinical area that informs the management of risks and the areas for improvement. The key points summarised are:

- Clinical risks are significant risks for healthcare organisation that require similar levels of assurance as other key risks
- The prioritisation of internal audits to be conducted requires the identification of significant areas of clinical risk via input from managers in clinical areas
- The conduct of an internal audit in a clinical area requires the appointment of an internal audit team with access to relevant clinical expertise and an appropriate internal audit tool to guide the process
- The involvement of clinical staff in the internal audit provides a valuable opportunity for learning and exchange of knowledge

Useful resources and links

- Internal audit clinical tool (IACT)
- emergency and urgent care centres Internal audit clinical tool ED/UCC IACT
- Maternity Services Internal audit clinical tool (MATIACT)
- VMIA Risk Based Approach to Internal Audit in the Healthcare Setting: Clinical Risk Assurance for Boards and Audit and Risk Committees (background for internal audit staff)
- Information kit for clinical experts

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