

Quality in Practice

The internal audit of clinical areas: a pilot of the internal audit methodology in a health service emergency department

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Abstract

Quality problem or issue: Governing bodies of health services need assurance that major risks to achieving the health service objectives are being controlled. Currently, the main assurance mechanisms generated within the organization are through the review of implementation of policies and procedures and review of clinical audits and quality data.

Initial assessment: The governing bodies of health services need more robust, objective data to inform their understanding of the control of clinical risks.

Choice of solution: Internal audit provides a methodological framework that provides independent and objective assurance to the governing body on the control of significant risks.

Implementation: The article describes the pilot of the internal audit methodology in an emergency unit in a health service. An internal auditor was partnered with a clinical expert to assess the application of clinical criteria based on best practice guidelines.

Evaluation: The pilot of the internal audit of a clinical area was successful in identifying significant clinical risks that required further management.

Lessons learned: The application of an internal audit methodology to a clinical area is a promising mechanism to gain robust assurance at the governance level regarding the management of significant clinical risks. This approach needs further exploration and trial in a range of health care settings.

Key words: health care, clinical governance, risk

Introduction

A key responsibility of a governing body is gaining assurance that significant risks to the achievement of strategic objectives are being effectively managed. Risk assurance at a board level is gained through a variety of mechanisms including management and committee reports, external audits and internal audits.

Internal audit has been defined as ‘an independent, objective assurance and consulting activity designed to add value and improve an organisation’s operations’ [1]. Internal audits in health care organizations have been widely used in providing assurance to boards regarding the robustness of the various financial controls in place to manage

financial risks and ensure financial objectives are met. 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’ [2].

It is well established in the literature that health care 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’ [3]. It is logical then that the board would welcome a similar degree of assurance regarding the management of clinical risk as financial risk.

Internal audits of clinical areas are distinct from clinical audits. Clinical audits are generally led by programme area staff and may only be loosely related to significant risks. The results of the clinical audits are often delivered to quality committees or area managers. In contrast, the internal audit of a clinical area is based on the assessment of significant risks to the organization, carried out independently by accredited internal auditors according to international internal audit standards and the objective findings are reported to an audit committee. Internal audits are often described as the third line of defence in risk management, with the first line being day-to-day operational controls and procedures to guide care and manage risk in each area of the organization and the second line of defence being the organization-wide risk management and compliance functions [4].

The attention paid to clinical governance over the last two decades in response to high-profile safety and quality failures in health care has highlighted the requirements of health boards to 'monitor patient safety with the same rigour and attention they give to corporate and financial performance' [5]. While extending the internal audit methodology to the clinical area makes sense theoretically, there has been little evidence of its application in the clinical areas to date. It appears the main barrier to widespread use of internal audit in clinical areas is the lack of existing guidelines, internal audit tools in this area and the availability of the combined audit and clinical expertise credentials required for undertaking an internal audit of a clinical area. This discussion paper outlines the initial findings and recommendations of a project undertaken to trial a framework and accompanying tools and resources in a pilot of the internal audit of a clinical area undertaken in the emergency department of a health service.

Methods

The objective of the project was to develop a framework, guidelines and toolkit for a systematic approach to the internal audit of clinical care areas within the health care setting. These objectives were met through a four-stage process.

Stage 1: literature review

A review of relevant international literature resulted in the identification of one article [6] that was directly relevant to this project and a number of other publications that provided background information on internal audit standards. A detailed discussion of the literature review methodology can be found in Hutchinson *et al.* [7].

Stage 2: development of a theoretical framework

The framework was informed by the literature review with the additional information gained through consideration of relevant legislation, standards, policies and consultation with key stakeholders. The framework [8] identified the differences in the key processes and responsibilities of an internal audit of a clinical area compared with that of traditional areas. Internal audits carried out in clinical areas require the involvement of clinical managers in the internal audit planning process to identify risks and plan individual internal audits. It is also suggested the responsibility for oversight of clinically related internal audit recommendations may sit better with the quality committee than, as with traditional internal audits, with the audit committee. The identification of clinical areas for internal audit relies on a mature risk assessment process based on the review of data such as incidents, complaints as well as peer-reviewed literature and external reports such as coroner's reports.

Stage 3: guidelines and resources

This stage involved development of practical guidelines and an internal audit template to assist the implementation of an internal audit of clinical areas. These resources were developed through a review of grey literature on internal audit guidelines, health care accreditation standards, clinical audit guidelines and tools and consultation with key stakeholders.

The internal audit template for clinical areas was designed to address the following four internal audit domains:

- (i) Quality Systems Evaluation—a review of the implementation of organization-wide quality systems in the clinical area such as risk management and staff credentialling.
- (ii) Clinical Policy and Procedure Evaluation—a review of the procedures and protocols that support the effectiveness of clinical related processes in the clinical area.
- (iii) Clinical Data Review—a review of the type of patient-related data used for quality improvement purposes in the clinical area.
- (iv) Patient Record Review—a review of patient records for evidence of processes required in all patients (appropriate assessment, monitoring, discharge planning) and those required in high-risk sub-populations (e.g. those with altered conscious state in emergency).

Each of the four audit areas contains a number of criteria, explicit statements that define what was measured objectively through the internal audit process. There were four possible ratings for controls in place related to each criterion: effective, improvement opportunity, unsatisfactory and not applicable.

The design of the internal audit template allows customization for any specific clinical area. For the pilot the generic template was customized to be relevant to an Emergency Department through amendment of the criterion to reflect emergency patients and procedures.

Stage 4: pilot

The final stage involved a pilot of the internal guidelines and template in a clinical setting. A pilot was undertaken at an emergency department in a health service in Victoria, Australia, over a 2-day period in August 2013. The internal audit was undertaken by an internal audit team comprising an accredited internal auditor and an emergency physician.

The pilot internal audit planning process involved the identification of the appropriate scope of the internal audit, which resulted in the selection of a number of criteria from Domains 1, 2 and 4 of the template. The criteria were selected based on the known risk areas of the pilot health service where controls had not recently been reviewed by other assurance means. An internal audit report was developed by the audit team and presented to management for review before being submitted to the organization's audit and risk committee.

Findings

The internal audit report of the emergency department at the pilot health care organization found from 11 areas, 4 areas had unsatisfactory levels of control and 5 areas were rated as improvement opportunities.

The internal audit of Domain 1, review of quality systems, found improvement was needed in processes for credentialling and defining the scope of practice for medical staff as applied in the emergency services area. Weaknesses in the processes for incident reporting in this clinical area were also identified, which had the potential for

under-reporting of incidents and near misses and reducing the organization's ability to mitigate risks.

The review of Domain 2, clinical protocols and procedures, found significant deficiencies in the clinical documents that guided specific emergency management protocols. The review of patient files in Domain 4 revealed significant uncontrolled risks in the areas of documentation in patient files, monitoring and discharge planning.

A further measure for the success of implementing internal auditing to clinical areas is the acceptance at the board governance level. It was reassuring to find that the board of the pilot hospital had a high degree of acceptance for the report and moved to implement an improvement plan based on the recommendations from the audit report. The following quote from the health service board chair encapsulates the end-user acceptance.

'The clinical internal audit conducted on our emergency department has provided a greater level of assurance with regard to clinical governance responsibilities and importantly provided valuable information with regard to risk exposure. I am now provided with assurance that risk is being managed and that further risk treatments will be implemented.'

Conclusion/Discussion

The pilot of the internal audit of clinical areas undertaken in the Emergency Department of a health service revealed areas of risk that were either not adequately controlled or could be improved. It is worth noting that the pilot was undertaken at a service that had recently successfully undergone national quality and safety accreditation.

Accreditation generally examines the compliance of a service with a comprehensive set of quality and safety standards. Time and financial barriers mean that the accreditation process cannot systematically look at the application of standards in every clinical area. The limitations of relying solely on external methods of assurance are reflected in this statement by the National Advisory Group on the Safety of Patients in England [9].

'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 tools have been developed to assess the implementation of broad hospital-based quality management systems, which are useful to gauge the maturity of quality systems [10], these are not designed to address specific areas of clinical risk. Clinical audit is a mechanism used widely to drive quality improvement in specific clinical areas but may be subject to variable implementation of recommended clinical audit processes [11] and may be limited in scope.

Internal audit addresses some of the limitations and gaps in existing quality improvement methodologies through providing a systematic examination of the implementation of organization-wide quality systems and processes and evidence-based best practice standards in a specified clinical area. The pilot highlighted the differing capability of this approach to uncovering programme-level risk. In this way, internal audit may provide a more rigorous, comprehensive approach to the management of areas of significant clinical risk. Elements of a clinical audit can be incorporated into the internal audit and reduce the need for separate clinical audits.

The authors believe that the application of the internal audit approach to clinical areas has the potential to provide a powerful form of risk assurance to governance bodies of health care services. The approach could be applied selectively as part of the internal audit programme to areas of significant clinical risk within health services. The approach can be modified, where needed, to suit the existing governance structures and size of the organization through modifying the reporting pathway and scope of the internal audit.

This pilot provides encouraging evidence of the efficacy of applying internal audit standards in the clinical area and the need for further investigation of this approach in the health care sector. Further piloting is needed to test the robustness of the approach and tools in a variety of clinical settings and organizational contexts. The potential of the approach to provide useful information that can be aggregated at a sector level to identify sector-wide improvements to specific clinical areas would also be valuable to explore.

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