vmia
Risk Management and Insurance

The Internal Audit of Clinical Areas Project

INFORMATION KIT FOR CLINICAL EXPERTS

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Contents

This document provides an overview of the approach for an internal audit of a clinical area.

Your involvement as a clinical expert is mainly:
- The review of clinical processes/protocols prior to the internal audit
- The conduct of the internal audit onsite
- The preparation of a summary of findings for the auditor to include in their report.

Part A: Stages of the Internal Audit of Clinical Areas

1. Conducting the internal audit

An internal audit is conducted in several stages as outlined below:

A. Planning internal audit
   a. Select the internal audit team
   b. Develop and agree on internal audit plan detailing: scope, approach, communication strategy and requirements
   c. Plan and prepare to access necessary documentation for off-site and onsite review
   d. Plan and prepare any required site visits
   e. Plan and prepare meeting with relevant managers and staff of clinical area

B. Conducting internal audit
   f. Internal Auditor reviews the 'offsite documentation'
   g. Onsite facilities tour, staff interviews, electronic data system review (e.g. incident register), patient health record audit with internal auditor and clinical expert
   h. Meeting between the internal auditor/s and the operational/unit manager of the clinical area to discuss key findings and emerging issues

C. Developing internal audit report
   i. Internal auditor prepares internal audit report with input from clinical expert
   j. Circulate draft report for staff input regarding findings and recommendations. The feedback submitted by manager to internal auditors to be incorporated into final report
   k. Report signed off by organisational representative of internal audit
   l. Report submitted to the audit committee

D. Implementation of internal audit findings
   m. Allocation of organisational responsibilities to address recommendations
   n. Reporting of implementation progress to quality committee
   o. Re audit to determine if improvement

2. The internal audit clinical tool (IACT)

The clinical internal audit is assessing evidence against an agreed number of criteria from the internal audit clinical tool (IACT). The criteria in the tool describe best available practice and are developed based on a review of relevant literature, clinical guidelines and expert consensus. The IACT is divided into 4 sections:

1. Quality Systems Evaluation – a review of the implementation of the main quality systems in the clinical area (e.g. risk, incidents, credentialing).
   (Note: the internal auditor will lead the audit in this section but may seek advice from clinical experts in some areas.
2. Clinical Process Evaluation- a review of the documents that support the effectiveness of clinical processes in the clinical area.
   (Note: the clinical expert will generally review the clinical processes documentation in this area against the criteria described in the tool).
3. Clinical Data Review – a review of patient related data monitored and analysed by the organisation for quality improvement purposes in the clinical area
   (Note: the clinical expert and the internal auditor will generally review the data used for quality improvement. Remember it is the type of data used, not the results of the data that are of interest).
4. Patient Record Review – a review of patient medical records for appropriate clinical processes required in all patients and, specific clinical processes required in defined sub populations.
   (Note: the clinical expert will generally review the patient file data with the assistance of a staff member of the organisation who is eligible to be rostered on in the clinical area. The staff member will assist the clinical expert with file navigation and answering process and protocol questions).

The internal auditor will, with the guidance of the organisation in advance of the onsite visits, define the scope of the audit and the criteria that will be examined. Not all parts of the tool will be used in every internal audit. The scope of the internal audit will depend on the amount of assurance or evidence the organisation already has about the effectiveness of procedures and the control of risks in the area.

Part B: Key Areas of involvement for the Clinical Expert

3.1. Meet with the internal auditor prior to the internal audit

Internal auditor and clinical expert to meet to clarify responsibilities and timelines for offsite and onsite audit components. The clinical expert needs to be clear about which parts of the tool and which criterion they will be examining in offsite and onsite internal audit stages. The timelines for report writing and report format need to be agreed.

3.2. The clinical expert's role in the offsite document review

The clinical expert will be sent clinical procedures and protocols related to the clinical area and should review them for the criteria listed in Part 2 of the tool. Generally this involves making a judgement as to whether the policy/protocols are comprehensive and references evidence/best practice and making notes accordingly. The specific criterion in Part 2 of the tool should be used to guide the analysis of this documentation.

3.3. The clinical expert's role in the onsite internal audit visit

Generally the onsite visit will start with an introductory meeting with key staff to: outline the intended approach to the internal audit, tour the clinical area facilities and confirm details such as access to date and any interim and end of visit meetings. It may be valuable for the internal auditors to meet with you just before this meeting to clarify responsibilities for the various section of the audit.

After the introductory meeting the internal audit team will generally meet with relevant staff to discuss section one and two of the audit tool. Prior to the visit the internal audit team may have reviewed some of the documentation related to the criteria in the audit and already prepared some questions for the staff. You may be asked by the internal auditor to examine some of the clinical procedures in section two prior to the visit and note any questions or clarification you require to understand the clinical procedures.

Part 3 may be undertaken jointly by you and the auditor to determine the type of data used to monitor the quality of services in the clinical area.

Part 4 of the internal audit involves a review of patient records and will be led by you. A member of the nursing staff normally rostered on the unit will be made available to assist you with navigating the patient files.

Recording internal audit evidence

The internal auditor will at the commencement of the internal audit discuss with you, respective responsibilities for recording evidence for each criterion within the scope of the audit.

Your role in relation to reviewing evidence to satisfy criterion in the tool will be one of either:

A. Assisting the internal auditor with reviewing the evidence and forming an opinion about the adequacy of the evidence.

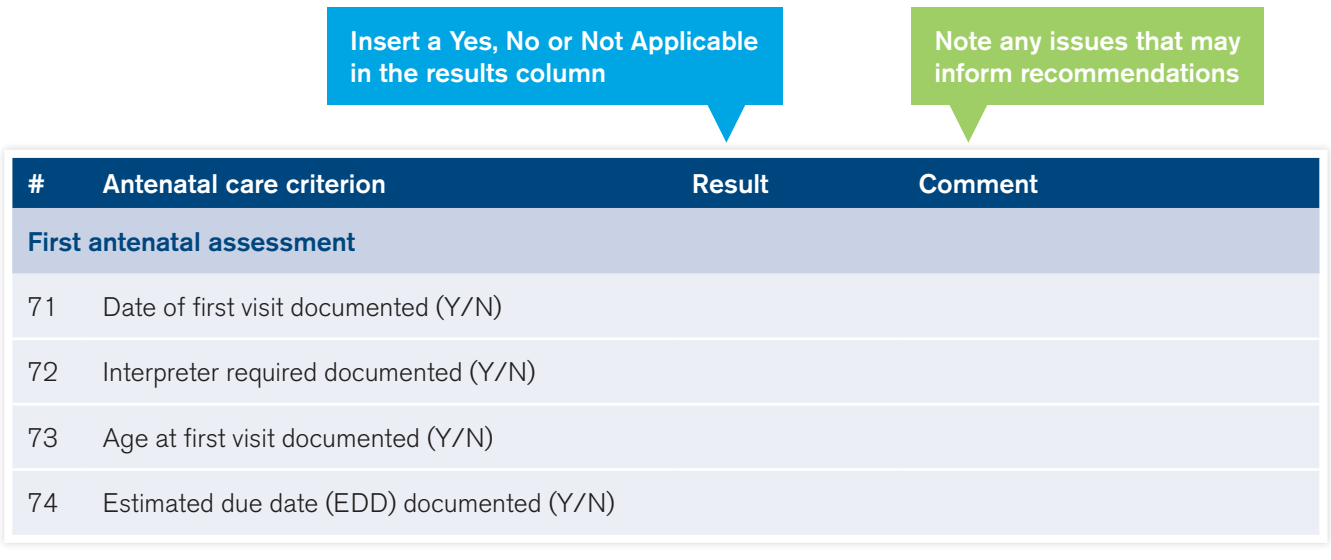
   For example Criterion 3 in the tool relates to the credentialing requirements of staff . The internal auditor may seek your input into the appropriateness of various training undertaken by staff.

B. Undertaking the review of documents yourself and recording the information for the internal auditor. This would occur in section 2 which contains criterion related to the review of documents outlining clinical processes in the clinical area.

   For example, Criterion 27 would involve reading clinical area procedures or protocols supporting the initial assessment of antenatal care. You can use the list of elements required in the document in the tool (e.g. specification of types of assessment undertaken) and make notes about whether the document contains these elements and whether they reflect best practice.

C. Undertaking the review of patient files Section 4 will be the largest area of the audit that you will be involved with. This will require two steps in recording information.

   Step 1: for each patient the result related to each of the criterion for that patient needs to be entered into the results column of the data collection sheets. The result is usually a yes, no or not applicable (See diagram 1).



#	Antenatal care criterion	Result	Comment
First antenatal assessment			
71	Date of first visit documented (Y/N)		
72	Interpreter required documented (Y/N)		
73	Age at first visit documented (Y/N)		
74	Estimated due date (EDD) documented (Y/N)		

Diagram 1: Example of file review data collection sheet

Part B: Key Areas of involvement for the Clinical Expert (continued)

Step 2: The data related to each criterion will then be aggregated from all files into a summary aggregate data on the internal audit tool (see example diagram 2). The tool contains room for recording severity rating for each finding and any recommendations as shown below.

For each of the aggregate criterion results demonstrating a significant omission of care the clinical expert (with the assistance the internal auditor if required) needs to make a severity rating. The severity rating rates the issue, which is usually either an omission in care or a documentation failure, in terms of the risk it represents to the organisation and the urgency with which it is required to be addressed

The rating scale used needs to be confirmed by the internal auditor but would generally follow the form of high, medium and low ratings based on consideration of the following criteria:

- likelihood of the error to potentially cause significant harm
- the likelihood to expose the health service to successful litigation
- urgency with which it needs to be addressed by the organisation

These sheets can form the basis of your draft report to the internal auditor on Part 4 of the tool.

Note the severity rating and any recommendations

#	Antenatal care criterion	Total no. of patients who meet criteria (Numerator)	Total number of patient files examined (Denominator)	Percentage (Numerator/ Denominator x 100)	Assessment of severity rating (high, medium and low) and recommendations
First antenatal assessment					
71	Date of first visit documented				
72	Interpreter required documented				
73	Age at first visit documented				

Diagram 2: Example of record of aggregate results of file reviews in tool

4. Writing the report

After the onsite visit the internal auditor will be writing a draft report of the internal audit to present to the management team. The internal auditor will include information derived from the evidence you collected in the parts of the audit that you were involved in. Generally the internal auditor will ask you for a summary report for the areas you were collecting the evidence. You can use the headings in the tool for example antenatal care, first stage of labour, postnatal care to format your report. You can use the notes you developed from the review of documents and from the patient file reviews to develop a draft report.

For example looking at the area of initial assessment you might make the following comments based on the finding in section 2: clinical document review and the section 4: patient file review (as reflected in diagram 2)

> *Initial antenatal assessment*
>
> *Clinical protocols related to this area contained insufficient information regarding the expectations in relation to the exact types of physiological parameters to be collected at initial assessment. This was also reflected in the patient file review where a review found there was an inconsistent collection of the physiological data ranging with 33% of records recorded had a blood pressure documented at initial assessment.*

5. Support

The internal auditor is in charge of coordinating the audit and will provide you with advice and support as you need. Organisations will also make available nursing staff to assist you in navigating your way through the patient files for section 4 of the tool