The audit process: Part III – Closing the loop

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ABSTRACT

The audit process fills the gap between policy and practice. Providing audit results and constructive feedback to those audited, correcting practice where improvements are required and re-testing to ensure that standards are now being met are important final steps in "closing the loop" on the audit process. In this third and final component of the audit process, suggestions for managing the post-audit follow-up are discussed.

Key Words
Audit; infection control; quality; patient safety; closing the loop; risk management; risk level matrix.

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INTRODUCTION

Identifying and analysing infection risks associated with health care is an integral part of a successful infection prevention and control (IP&C) program. Monitoring and reviewing are essential components of this process. The audit process identifies new risks, analyses risks against established norms and effectively implements risk management activities. Key elements of this process are communication and consultation. An interactive exchange of information between IP&C, management, health care workers and other stakeholders provides the basis for increased awareness of the importance of IP&C, identification of risks before they arise and prompt management of risks as they occur.

In Part I of this series, *The Audit Process: Part I Pre-audit Preparation* (1), the need for process audits in IP&C and the initial preparation that is required was discussed. In Part II, *The Audit Process: Part II Setting the Audit Criteria*, discussion focused on choosing audit criteria or elements, designing a data collection form or tool and validating the audit tool (2). In this final instalment in the series, the execution of the audit and actions to be followed after carrying out the audit are described.

METHODS

Once an IP&C audit has been administered, the results of the audit are assessed or scored. Both a verbal and a written report are prepared in a timely manner. A meeting with stakeholders to develop an action plan for improvement will ensure departmental commitment to the action plan, address the implications of deficiencies and suggest timelines for completion. Following the audit, modification of practice and subsequent demonstration of improvement in practice through re-auditing "closes" the audit "loop" (Figure 1). This cycle is repeated until the chosen criteria are fulfilled, outcomes are satisfactory and deficiencies are addressed.

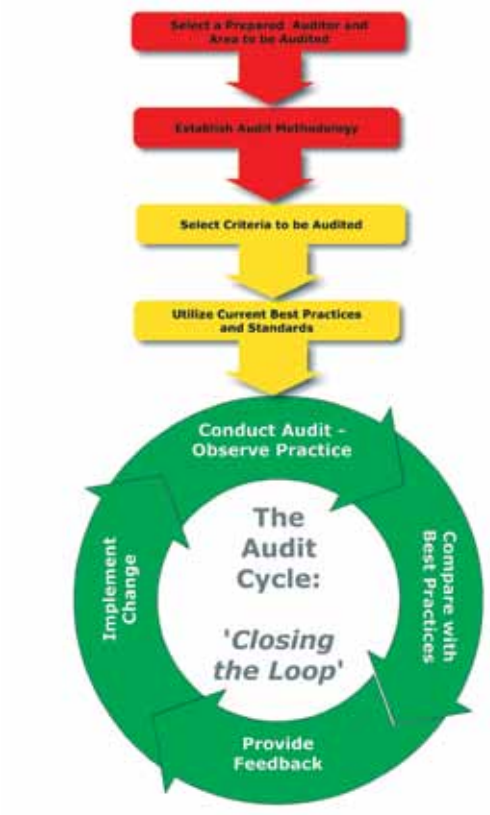
Conducting the audit

Prior to conducting the audit, IP&C advises the area manager that a formal audit of their work area is to be conducted and a meeting is arranged to review the audit process (3).[3] Auditing practice is accomplished with document review, staff interviews and observational tours (see Part I of this series, *Pre-Audit Preparation*, for more information) (1).

Scoring the audit and setting targets for achievement

Audit criteria/elements are marked **Yes, No** or **Not Applicable (N/A)**. If a standard is not achievable because a facility does not use the equipment, or the practice is not undertaken in the facility, the option to score N/A (Not Applicable) will eliminate the element/statement from the audit. All audit criteria are given equal weighting

Figure 1: The audit cycle: Closing the loop



for scoring (4). Compliance scores are calculated by adding the total number of Yes responses, dividing this by the total number of Yes and No responses and multiplying this result by 100:

$$\frac{\text{Total number of 'yes'}}{\text{Total number of 'yes' and 'no'}} \times 100 = \%\ \text{compliance (compliance score)}$$

Achievement of a *target score* reflects the care or practices that are required to comply with the target. The compliance score indicates whether the area/department/service meets, exceeds or is deficient compared to best practice and national or provincial standards. Compliance less than the chosen target score requires follow-up. Management in collaboration with IP&C of each facility determines the target score for the IP&C audits in their facility. For example, a target score of 75% compliance is not appropriate for an audit dealing with reprocessing medical devices.

Summarizing audit deficiencies: The audit summary report

Rapid analysis of data and generation of timely reports are essential to improvement. Data are most useful when the time between data collection and reporting is short (5). Summarizing deficiencies captured by an audit that are not immediately addressed during the audit and sharing these with stakeholders affected by the audit are essential before an action plan is formulated.

Following the audit, both a verbal and a written report are prepared in a timely manner. At the completion of the audit and prior to leaving the area, the auditor gives an initial verbal report to the clinician/manager in charge of the area being audited, outlining any areas of concern as well as identifying good practice. A written report on the audit is then developed and given to the area clinician/manager for action within one week of completing the audit. The written report clearly identifies the deficiency areas requiring action. A well-written report guides decision-makers in the corrective action(s) required to address deficiencies. A separate report may be prepared for each audit tool used, or a single report might be completed for all audits done in a given time period. See Figure 2 for a sample audit summary report.

The audit summary report:

- states the time period during which the audit(s) occurred
- states the area audited and overall impression of the audit
- describes the audit process used (e.g., review of documents, interviews with staff, observational tours in the area)
- includes positive highlights as well as negative findings
- highlights any area that requires immediate response (i.e., if not corrected, the situation will have a negative impact on client/patient/resident care or on staff safety).

If an unsafe situation is detected that warrants work stoppage, the auditor takes this action and informs the manager immediately (e.g., construction without proper hoarding; unacceptable sterilization processes or practices used for reprocessing medical equipment).

Implementing change: Assigning level of risk and preparing an action plan

The auditor meets with the manager from the audited area within a week of completing the audit to discuss the summary report and to assign a risk level to each deficiency that will guide corrective action(s). The risk level is based on the negative impact and/or severity that a deficiency will have on client/patient/resident or staff safety and on the likelihood that an adverse event will occur or re-occur if uncorrected. Using the Risk Level Matrix (Figure 3) will help determine the urgency of the required corrective action(s) and level of administrative involvement that is required. Involving the manager from the audited area and working through the process of assigning a risk level to each deficiency assists the manager in understanding the importance of the deficiency and helps to gain their support

Figure 2: Sample Audit Summary Report

Auditor: _____ Date of Audit: _____ Area Audited: _____ Compliance Score: ___%

ELEMENT #	AUDIT DEFICIENCY	RECOMMENDED CORRECTIVE ACTION(S)	RISK LEVEL	AREA OF RESPONSIBILITY	REVIEW DATE	COMPLETION DATE	SIGNATURE

and input on how best to address the deficiency. Using this process helps to foster buy-in and accountability from others towards closing the loop on audit deficiencies.

The action plan for implementing change is directed by the level of risk identified. The action plan and the timelines for its resolution must be realistic and appropriate to the priorities and resources available to the facility or area audited. The impact of deficiencies on staff and client/patient/resident safety will inform the action plan in terms of sequencing, level of involvement and timeline for resolution:

- *Sequencing* is the prioritization of corrective actions based on the level of risk identified for the deficiency. Deficiencies that have the greatest negative impact on client/patient/resident care or staff safety and are most likely to re-occur if not corrected (i.e., high or critical risk) will be first in the sequence for corrective action.
- *Level of involvement* is based on the risk level of the deficiency and may be an important factor in the successful resolution of the problem. Deficiencies with a higher level of risk are addressed by senior administration in a timely manner (Figure 3, Step 3).
- *Timeline for resolution* and the urgency of follow-up will depend on the level of risk and the resources available to the facility. If a critical or high risk deficiency is identified (i.e., continuation of the deficient practice will result in severe outcomes, such as an outbreak or death), the practice is stopped immediately, senior management is notified and the issue is resolved (Figure 3, Step 3).

See Figure 4 for a sample flow chart to guide the formation of an action plan and Figure 5 for a sample action plan worksheet.

Re-auditing: Closing the loop

Most auditing in health care is incomplete in that the audit loop is not closed. *Closing the loop* means that once an audit is completed and changes are advised or recommendations are made as a result of the audit, the effects of those changes are measured by re-auditing (6). Re-auditing can assess whether compliance scores are improving following remedial action(s) in order to evaluate the success of the action(s). Re-auditing may also be used to assess the impact of multiple IP&C interventions on outcomes when combined with outcome surveillance (e.g., measuring infection rates prior to the audit and following recommended interventions). Re-auditing should be repeated until the chosen criteria are fulfilled or practice is acceptable (7).

Often the prolonged nature of the audit cycle may make closing the loop difficult, particularly for items that may not be resolved completely within one month of the audit (e.g., items requiring construction, capital expenditures or significant resources, increased staffing levels, outside consultant review). In these cases, the auditor must have a process to ensure tracking and follow-up of the item until it is adequately addressed.

DISCUSSION

Process surveillance (evaluation of practice) constitutes an important aspect of an IP&C program. In the U.K., IP&C audits with feedback sessions to staff have been successful in raising awareness of areas requiring improvement, highlighting fundamental problems (e.g., unsafe sharps disposal, poor hand hygiene) and increasing staff education and training programs (4). The fact that IP&C interfaces with all departments in a health care setting and affects client/patient/resident care, quality of life and clinical outcomes, makes IP&C audits effective indictors of overall facility efficiency and safety.

In Part I of this series (1), we explored the rationale for doing IP&C audits and explained the audit planning process. In Part II (2), the development and validation of audit criteria were discussed. In this final component of

Figure 3: Action planning risk level matrix

STEP 1: Categorize the audit tool deficiency in terms of its impact on staff or patient safety and the likelihood of the impact occurring if corrective action is not taken.

IMPACT DEFINITIONS:

Extreme:
- ⇒ patient death related to infection or infectious disease
- ⇒ large/widespread environmental contamination
- ⇒ staff death related to infectious disease exposure
- ⇒ legal action

Major:
- ⇒ patient or staff suffers life-altering outcome related to infection or infectious disease exposure
- ⇒ infectious disease outbreak affecting large numbers of patients and staff
- ⇒ environmental contamination involving a high risk area or population
- ⇒ Canadian or provincial standards of practice breached
- ⇒ regional policy breached

Moderate:
- ⇒ deep or organ space infections substantially increased in number, severity or over time (from the usual pattern)
- ⇒ infectious disease outbreak affecting patients and staff
- ⇒ situation with potential for life-altering outcome to patient or staff related to infection or infectious disease exposure

Minor:
- ⇒ superficial or deep infections increased in number, severity or over time (from the usual pattern)

Insignificant:
- ⇒ no adverse patient or staff or system outcome
- ⇒ no change from historical pattern/incidence

LIKELIHOOD DEFINITIONS:

Almost Certain:
- ⇒ will happen again if recommendation/process not followed
- ⇒ known to happen regularly (common event)

Likely:
- ⇒ good chance of recurrence
- ⇒ has happened several times before
- ⇒ frequent occurrence published in the literature

Possible:
- ⇒ has happened a few times
- ⇒ has been reported in the region

Unlikely:
- ⇒ has only happened once or twice before
- ⇒ reported in the province or in Canada, not locally

Rare:
- ⇒ has never happened
- ⇒ reported in the literature

STEP 2: Using the Impact and Likelihood definitions above, assign a Risk Level to each element of the audit tool that indicates a deficiency

LIKELIHOOD	IMPACT				
	Insignificant	Minor	Moderate	Major	Extreme
Almost Certain	Moderate Risk	Moderate Risk	High Risk	Critical Risk	Critical Risk
Possible	Low Risk	Moderate Risk	High Risk	Critical Risk	Critical Risk
Likely	Low Risk	Moderate Risk	Moderate Risk	High Risk	High Risk
Unlikely	Low Risk	Low Risk	Moderate Risk	Moderate Risk	High Risk
Rare	Low Risk	Low Risk	Low Risk	Moderate Risk	Moderate Risk

STEP 3: Required action, level of involvement and action timeline will be based on the Risk Level

Critical Risk: STOP ACTIVITY!
- ⇒ Risk management must be informed to initiate senior administrative notification
- ⇒ Requires immediate written recommendations presented in person to Director and Manager
- ⇒ Written action plans with timelines must be set
- ⇒ ACTION TIMELINE: Immediate action required

High Risk: STOP ACTIVITY!
- ⇒ Risk management must be informed to initiate senior administrative notification as required Requires written recommendations, preferably presented in person to Director and Manager within 48 hours
- ⇒ Written action plans with timelines must be set
- ⇒ ACTION TIMELINE: 48 hours

Moderate Risk:
- ⇒ Written recommendations to Director and Manager
- ⇒ Written action plans with timelines set
- ⇒ ACTION TIMELINE: 3 months

Low Risk:
- ⇒ Written recommendations to Manager
- ⇒ Written action plans with timelines set
- ⇒ ACTION TIMELINE: 6 months or longer

STEP 4: Record the Risk Level on the Audit Summary Report (Figure 2)

the series, post-audit follow-up and re-auditing complete the audit process. Feedback of audit results has been identified as having the potential to change the practice of health care professionals (6). Involvement of staff throughout the audit process facilitates acceptance and completion of recommendations in a timely fashion (3). Sustaining improvement is achievable through continued monitoring, evaluation and reinforcement within a supportive environment, where staff are confident that the process will result in meaningful system changes without targeting individual performance.

Auditing IP&C practices in health care has been shown to raise IP&C standards when the audit program is well-designed with explicit, evidence-based criteria and multifaceted interventions. Audits are also an opportunity to highlight areas of excellence. Staff must be involved in both the audit itself and in the interventions, if barriers to change are to be overcome. Re-auditing after implementing interventions, correcting processes and educating and/or re-training staff to adjust behaviour is an important final step in closing the loop in the audit cycle.

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Figure 4: Recommendations and action plan process flow chart

1. **Prepare recommendations (Audit Summary Report):**
   - State corrective action(s) required
   - Priorize corrective actions based on Risk Level Matrix (Figure 3)
   - Base action on best practices and include references where available
   - Attach to summary report

2. **Present findings (Audit Action Plan):**
   - Meet with area manager, clinical department head and others who facilitate improvements
   - Involve key stakeholders in the completion of this action plan to ensure that:
     - there is departmental commitment to the action plan;
     - there is access to resources required to implement the action plan; and
     - audit results are communicated to a wider group.
   - Present scope of audit, audit findings, references consulted and recommendations

3. **Prepare action plan:**
   - Work with leaders to prepare an improvement action plan that includes:
     - assigned authority for completion of corrective action item(s);
     - timelines for completion; and
     - feedback from those observed.

4. **Follow-up:**
   - Determine process for tracking completion of action item(s)
   - Establish dates for follow-up audits
   - Maintain records of audits and follow-up
   - Report results to Infection Prevention and Control Committee and other departmental meetings