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Clinical audits to improve critical care: Part 1 Prepare and collect data

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ABSTRACT

Clinical audits are used to examine current practice, compare this with established best practice and implementing change, to ensure patients receive the most effective treatment. They are successful in improving the quality and safety of care provided, and thereby clinical outcomes. Clinical audits are ubiquitous throughout critical care practice, but without the necessary focus, engagement, preparation, method, evaluation and communication, they may be a waste of resources.

This article is the first of a two-paper series regarding audits in critical care. The article provides an overview of the structures and processes needed to prepare and collect data for clinical audits, to make them as effective as possible to improve patient outcomes. This is accomplished through a practical step-by-step guide, including links to valuable resources, which are relevant to all critical care clinicians planning on undertaking clinical audits.

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1. Introduction

For decades clinical audits have been integrated into local, national and international healthcare systems as a means to ensure that patients receive the most effective, up-to-date and appropriate treatment.¹ Clinical audits fit within the quality improvement domain, and involve measuring performance and comparing this with established best practice.^{2–4} Aspects of clinical care are selected and systematically evaluated against explicit, defined criteria.⁵ The purpose of clinical audits is to identify areas needing improvement, thereby directing the implementation of education, research and quality improvement strategies to improve patient care and outcomes. Clinical audits need to be undertaken within a continuous, cyclical framework, such as the Deming Cycle⁶ (plan, do, study, act). Following the initial audit cycle, data associated

with the pre-defined criteria are collected again to evaluate the success of interventions aimed at improving care, and to inform future innovations.

Clinical audits in Australia are recommended by the Australian Commission on Safety and Quality in Healthcare,⁷ where they fit within the priority designed to promote safe, high-quality health care driven by information. Internationally, the majority of health-care institutions recommend, and government agencies instruct, that clinical audits are performed regularly.⁷ However, clinical audits are not consistently effective in improving practice quality and patient outcomes.

In a Cochrane systematic review⁸ it was the extent to which clinical audits lead to small but important improvements in professional practice was demonstrated. However, the effectiveness of the audit depends upon baseline performance, the personnel undertaking the audit, the frequency the audit is repeated, and the feedback method.⁸ Other authors have highlighted the importance of data quality; i.e., the accuracy, completeness, relevance, reliability, timeliness, and validity or making sure the data are 'fit for purpose'.^{9,10} The methods used to conduct and communicate clin-

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Table 1
Organisations providing resources on-line to support the undertaking of clinical audits of critical care practice.

Australian Commission on Safety and Quality in Healthcare http://www.safetyandquality.gov.au/national-priorities/australian-safety-and-quality-framework-for-health-care/ iSixSigma [®] http://www.isixsigma.com/tools-templates/control-charts/a-guide-to-control-charts/
National Health and Medical Research Council Guidelines (Australian Government) http://www.nhmrc.gov.au/guidelines-publications
National Institute for Health and Clinical Excellence (United Kingdom) http://www.nice.org.uk/
Scottish Intercollegiate Guidelines Network http://www.sign.ac.uk
United Kingdom Healthcare Quality Improvement Partnership http://www.hqip.org.uk/public/cms/253/625/19/191/HQIP-Guide-to-Ensuring-Data-Quality-in-CA-Reviewed%202011.pdf?realName=Zmh8bl.pdf
United Kingdom National Health Service: Institute for Innovation and Improvement http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/statistical_process_control.html
United Kingdom National Health Service: Clinical Governance Support Team https://www.bsuh.nhs.uk/EasySiteWeb/GatewayLink.aspx?allid=424764

ical audits influences the way in which the data can be used to influence the clinical practice improvement cycle.³

Critical care is a unique, interdisciplinary, high-intensity, and high-risk healthcare environment. Adverse events and serious errors are common because of patient and environmental complexity,^{11–13} and are estimated to cost \$853,000 USD per Intensive Care Unit (ICU) annually.¹³ Many of these adverse events and errors are considered preventable, with the consistent, timely application of evidence-based practice.^{14,15} Clinical audits, as a quality improvement initiative, are frequently used in critical care to promote the application of evidence-based practice.¹⁶ However, if incorrectly developed, clinical audit programmes can be ineffectual and a waste of resources.¹⁷

This is Part One of a two-paper series regarding clinical audits in critical care. The aim of this article is to provide an overview of the skills and resources needed to prepare and undertake clinical audits, to make them as effective as possible to improve patient outcomes. It will provide a step-by-step guide to:

- 1) Identify appropriate audit topics;
- 2) Engage relevant stakeholders;
- 3) Develop appropriate methods and audit criteria;
- 4) Determine effective sample sizes;
- 5) Develop reliable data collection tools; and
- 6) Establish consistent data collection procedures.

Part Two of the series will complete the guide to comprehensive clinical audits in critical care, across the remaining stages of data analyses, benchmarking, improvement implementation and re-auditing.

Throughout this article, resources from leading healthcare institutions are referenced to facilitate effective clinical audit development (see Table 1). Specifically, the United Kingdom (UK) National Health Service (NHS) Clinical Governance Support Team has developed simple criteria to ensure quality clinical audit structures and processes, which are relevant at a local level (see Table 2). These criteria form the basis for this step-by-step guide.

2. Step One: Identification of clinical audit topics

Prior to undertaking an audit there should be a clear understanding of why the audit is planned and necessary.¹⁰ Audits are most effective in areas where current practice and/or healthcare

Table 2
“The Top Dozen Criteria for “Good Local Clinical Audit” by Copeland (2005) p.16.

1.	Should be part of a structured programme
2.	Topics chosen should in the main be high risk, high volume or high cost, or reflect national health priorities
3.	Service users should be part of the clinical audit process
4.	Should be multidisciplinary in nature
5.	Clinical audit should include assessment of process and outcome of care
6.	Standards should be derived from good quality guidelines
7.	The sample size chosen should be adequate to produce credible results
8.	Managers should be actively involved in audit and, in particular, in the development of action plans from audit enquiry
9.	Action plans should address the local barriers to change and identify those responsible for service improvement
10.	Re-audit should be applied to ascertain whether improvements in care have been implemented as a result of clinical audit
11.	Systems, structures and specific mechanisms should be made available to monitor service improvements once the audit cycle has been completed
12.	Each audit should have a local lead

outcomes are poor.⁸ The balance is to ensure that the audit topic is in accordance with international and national priorities, as well as targeting local areas of clinical priority and interest.⁵ For example, while the reduction of ventilator-associated pneumonia in critical care has been identified as an international health priority by many institutions, it may not be an area of local need if current rates are very low. An interdisciplinary approach to assessing audit priority areas should include assessment of whether the practice is high volume, high risk, high profile or high cost.⁵ If these criteria are met, it will ensure high levels of interest by institutional management, clinicians, patients and family members.⁵

3. Step Two: Engagement of stakeholders

Identifying the area requiring improvement in the local critical care unit should be a collaborative process with engagement by local stakeholders, including interdisciplinary clinicians, patient and family representatives, safety and quality experts, and institutional management.¹⁸ Early engagement with local stakeholders will show benefits throughout the auditing process, safeguarding relevance and effectiveness.¹⁰ These stakeholders should be involved in all stages of the clinical audit, including the audit preparation, tool development, data collection, result dissemination and practice improvement planning.

It is also important to clearly identify a leader who is responsible for driving the clinical audit programme, to ensure overall programme integrity and timeliness.⁵ This clinical audit leader should have leadership skills including collaboration, emotional intelligence, advocacy, organisation, communication and mentorship,^{19,20} as well as a high profile within the organisation, in order to champion and link with organisational resources.⁵

4. Step Three: Audit method and criteria

The types of information collected in clinical audits that lead to systematic improvements are based upon the Donabedian Model.²¹ The Donabedian Model states information about quality of care can be derived from three categories: structure, process, and outcomes. For example, if the critical care unit leadership team is concerned about the incidence of catheter-related bloodstream infections, it is possible to audit the:

- Structure: clinical equipment available to support practice, such as the type of skin antisepsis and sterile drapes;
- Process: the skin decontamination and catheter insertion procedures; or the

- Outcome: the rate of catheter-related bloodstream infections per 1,000 catheter days.

Auditing all criteria will give a multi-dimensional description of the current clinical performance, in order to understand systems, draw connections, and focus improvement strategies across all factors.²¹ If necessary, choosing between these audit criteria should be made with the key stakeholders, taking into consideration available resources and known areas of concern.

In prospective audits data are collected over time as events occur. They are generally preferred as they allow the real time accrual of data that reflect current rather than historical practice.⁵ Prospective audits are generally associated with greater accuracy and completeness, which increase the reliability of the data.⁹ However, prospective data collection may be difficult to accomplish if resources are scarce,²² or if a critical incident arises and urgent practice review is required.⁵ Retrospective audits may have a role in understanding historical benchmarks, in order to inform the development of an ongoing auditing programme.

Auditing criteria can be based on clinical practice guidelines,⁹ and used to assess whether recommendations are adequately applied in the individual critical care setting. For many common issues in critical care, clinical practice guidelines have been developed to inform practice, critiquing and summarising the best available evidence. If recent, these can provide a great starting point when selecting criteria for the audit. Clinical practice guidelines relevant to the topic area should be easily identified by: (i) reviewing recent health literature; (ii) accessing clinical guideline websites (see Table 1: National Health and Medical Research Council, National Institute for Health and Clinical Excellence, Scottish Intercollegiate Guidelines Network); (iii) reviewing local institutional guidelines; and, (iv) consulting with clinical colleagues and stakeholders. Additional quality-focussed resources are frequently included within these guidelines. For example, the Australian Commission on Safety and Quality in Healthcare provides²³ detailed information for best practice in improving handover procedures including checklists and toolkits, which may also form the basis of a clinical audit.

It is necessary to identify the best data source for each criterion under examination.⁹ In order to comprehensively describe an audit criterion it may be necessary to include a combination of data sources. These may include interviews and surveys with patients, families and staff, a review of patient records, and direct clinical observations.

During audit planning, it is necessary to discuss the audit programme with the local ethics or quality improvement manager. This is in order to ensure adherence to local institutional and national ethics requirements. This is especially relevant if it is planned to publish or present the results of the clinical audit outside of the hospital.²⁴ Individual hospital requirements for ethical governance of clinical audits vary between healthcare services; however, the general principles of respect, research merit and integrity, justice, and beneficence must be recognised.²⁴

5. Step Four: Sample size

Sample refers to the number of participants or events examined during the clinical audit, and involves a specific collection of the participants or events that are drawn from a wider population.⁹ It is essential that a sufficient sample size is collected to get an accurate description of the audited practice, to minimise the risk of under- or over-estimating the issue being audited. Table 3 provides sample size calculations that should be considered when the event being audited occurs around 50% of the time.⁹ Confidence intervals (CI) described in the table provide the level of certainty

Table 3

Recommended sample sizes to ensure accuracy (assuming event being measured happens about half of the time).⁹

Population	90% confidence ±5% accuracy	95% confidence ±5% accuracy	99% confidence ±5% accuracy
<30	All	All	All
30	27	28	29
50	42	44	47
100	73	79	87
150	97	108	122
200	115	132	154
250	130	151	182
300	142	168	207
350	153	183	229
400	161	196	250
450	169	207	268
500	176	217	286

that the results, including a range ±5% accuracy, will be correct, and clinicians can be confident in the ‘truthfulness’ of the data.^{9,25} In recommendations described in Table 3, the higher the CI (e.g., 99%), the more precise the results.⁹ The sample size recommendations within the higher CI categories should be used when an exact estimate of the criteria is required, for example, when a change in practice has significant financial or clinical implications.⁹

For example, if the audit team is interested in examining the hand-washing habits of visiting medical officers (VMOs) in the ICU, and around 50 VMOs visit regularly with about 50% compliance with hand hygiene, between 42 and 47 would need to be audited to get a true, accurate reflection of current practice in that population, and conducting the larger audit will improve the reliability of the data collected.

6. Step Five: Development of data collection tools

A data collection process, including a tool, is needed in order to collect relevant data to assess the audit criteria. This tool may be in the form of a questionnaire, survey, chart review, or a checklist. The data collection tool needs to be accurate, efficient and comprehensive.⁹ The terms used to describe these characteristics of data collection tools are reliability and validity. Reliability (or consistency) refers to the stability of the tool, no matter by whom, or how frequently, the data are collected.^{9,26} Validity refers to how comprehensively the data collection tool collects the relevant data to encompass the audit topic.^{27,28} In order to ensure reliability and validity of clinical audit data collection tools, several principles and processes need to be followed.

Researcher typically consider the face, content, criterion and construct validity of a tool to determine whether the tool will give meaningful results.^{26,27} The validity of data collection tools for use in clinical audits, can be greatly improved by ensuring the audit team involves experts across the necessary clinical and academic disciplines. This expert group, in addition to conducting a review of the literature during the early planning phase, needs to provide a critical review of the data collection tool for clarity and completeness. This will assist in achieving tool authenticity (i.e., all relevant criterion are included) and directness (i.e., not including irrelevant criteria) and thereby validity.²⁶

Reliability and consistency of the data collection tool can be increased through the use of clear definitions of the variables under examination.¹⁰ This is especially relevant in critical care, where clinical outcomes may have varying definitions, such as rates of ICU readmission, medication errors and pressure injury classification. A ‘data dictionary’ can be valuable, where each audit question has clear definitions of what data is required, from which source, and at what time. This is useful if multiple staff members will collect audit data, or to ensure a correct record of exactly how the audit

was carried out is available for later reference. High quality auditing templates are available within Table 1 online resources, to support the undertaking of clinical audits.

Reliability can also be improved by thoroughly training data collectors in the proper use of the data collection tool. This will ensure data accuracy and completeness, while minimising variation.²⁹ The training should include a comprehensive discussion regarding the goals of the audit, the definitions, sources and frequency of the data being collected, and a pathway for asking questions.²⁹

Prior to audit commencement, the trained data collectors should conduct a practice (pilot) audit by collecting data from a small sample of records, and then identifying, discussing and resolving discrepancies. Additionally, this pilot can examine face validity, utility (i.e., how practical tool is to use), and feasibility (i.e., how much time will be needed to undertake the audit).²⁶ Standardising the process before conducting the larger audit will make the outcome more reliable, through establishing inter-rater consensus. More detailed information on assessing inter-rater consensus when auditing patient records can be found in an article by Liddy et al.³⁰

Data collection tools for clinical audits previously used by critical care clinicians in other healthcare institutions are frequently available. These can be identified by a review of published peer-reviewed literature and at relevant local, national or international conferences and databases. Reliability and validity assessment of the data collection tool should have been previously conducted, reported and published. It is preferable to use a previously validated data extraction tool, even with some amendment, as long as it is relevant to the audit topic and appropriate to the local setting, rather than a completely new, untested tool.

7. Step Six: Data collection procedures

Data collection procedures for clinical audits need to encompass clinical, resource and institutional practicalities.¹² The timing of the data collection for the audit needs to ensure an accurate description of the audit topic.⁹ For example, undertaking a clinical audit of ICU staffing, but collecting data during a period of low activity, would not provide accurate data. Additionally, if completing a prospective audit involving patients, families and clinicians, it is important to choose a time when the potential participants are available, without putting undue burden on the clinical workforce.

It is important to consider ways to reduce potential errors associated with data collection, to improve data reliability. Wherever feasible, use two data collectors with different skills (e.g., one experienced clinician, one experienced data collector) to ensure data quality.⁹ Open and continuing discussion with the clinical audit leader during the data collection phase is also important to recognise potential issues with data quality.⁹ Consider the use of technology (e.g. computer prompts if a data field is left blank, or if an impossible value is entered) to minimise errors associated with data entry when transcribing from paper tools to electronic databases.

8. Conclusion

Clinical audits can be effective tools to promote best practice, improve patient and clinical outcomes, and reduce errors in the critical care setting,³¹ but their success relies on several characteristics. This first paper of this series has described the importance of identifying appropriate audit topics, engaging relevant stakeholders, developing appropriate methods and audit criteria, determining effective sample sizes, developing reliable data collection tools and establishing consistent data collection procedures. The second paper of the series will complete the guide to comprehensive clinical audits in critical care across the remaining stages of data

analyses, benchmarking, improvement implementation and re-auditing.

Authors' contributions

Conception and design of the study: all authors.

Acquisition of data, or analysis and interpretation of data: all authors.

Drafting the article and revising it critically for important intellectual content: all authors.

Final approval of the version to be submitted: all authors.

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