

RESEARCH METHODS

Embedding clinical audit into everyday practice: Essential methodology for all clinicians

Sue Skull^{1,2}

¹Child and Adolescent Health Service, Department of Research, Perth Children's Hospital and ²Division of Paediatrics and Child Health, University of WA, Perth Children's Hospital, Perth, Western Australia, Australia

Clinical audits should underpin everything we do as clinicians – to constantly evaluate and improve our day-to-day clinical practice. Errors in practice, suboptimal practice or inefficiencies can occur in any part of our health-care system, despite the training and best intentions of health-care professionals. Audits examine how clinical care is being provided and whether benchmarks are being met, and identify opportunities for improvement. Detection of problems is greatly improved when audits of practice are undertaken, ideally regularly, and as part of a continuous process of quality improvement. Audits also make ideal entry-level research projects for students and trainees through to senior clinicians. Despite a willingness to undertake audits, and improvements in both undergraduate and postgraduate training, not all clinicians have had formal teaching in audit methodology, and a refresher can also be helpful. This short overview covers basic clinical audit methods, discusses key facilitators for embedding audit into every day practice, and references additional resources to guide clinicians wanting to take up the challenge of regularly and efficiently undertaking audits.

Key words: audit; clinical; methodology.

What Is a Clinical Audit?

Whilst a baseline survey describes an issue or practice before standards for performance have been set, by contrast, a clinical audit is a type of survey examining actual practice or activity against established or desired standards of practice. The aim is to improve clinical care and outcomes by describing practice and whether it meets accepted criteria from a clinical guideline or an explicit benchmark,¹ and if not, make practical recommendations for practice change. In health-care settings, clinical audits are part of clinical governance, which aims to ensure that patients receive the best quality care.² Following implementation of recommendations, further monitoring is used to confirm an improvement in health-care delivery. An audit that is repeated (multiple times depending on requirements), as part of a (continuous) quality improvement (QI) process is referred to as a clinical audit cycle (Fig. 1).² Some of the benefits of undertaking a clinical audit are shown in Table 1.

What Makes a Good Clinical Audit Question?

An audit topic must have potential to improve practice or policy and be able to measure some aspect of practice against a benchmark or desired standard. Ideally choose a topic based on high-

risk, high-volume or high-cost problems; national clinical audit or service frameworks; or institution-based set priorities.³ In addition, consider available resources, staff availability and required sample size to answer primary objectives before finalising a question. If large in scope, a multidisciplinary team of relevant stakeholders including community members may be required over an extended period. An inclusive approach is far more likely to result in a meaningful topic, appropriate design, successful conduct and ultimately result in change in policy or practice. By contrast, a question for a student project that is smaller in scope due to time and resource constraints will need to be carefully framed to remain feasible.

What Approval Is Required to Undertake Clinical Audit?

Whilst all clinical audits require consideration of ethical and scientific issues, the National Health and Medical Research Council and New Zealand Ministry of Health's National Ethics Advisory Committee allow different levels of ethical review according to the risk involved. Factors that may trigger the need for higher level ethical review include^{4,5}:

- Where the activity potentially infringes the privacy or professional reputation of participants, providers or organisations.
- Secondary use of data – using data or analysis from QI or evaluation activities for another purpose.
- Gathering information about the participant beyond that which is collected routinely.
- Testing of non-standard (innovative) protocols or equipment.
- Comparison of cohorts.
- Randomisation or the use of control groups or placebos.

Correspondence: Associate Professor Sue Skull, Division of Paediatrics and Child Health, University of WA, Perth Children's Hospital, 5E 2.008, 15 Hospital Avenue, Nedlands, WA 6009, Australia. email: sue.skull@uwa.edu.au

Conflict of interest: None declared.

Accepted for publication 25 June 2020.



Fig. 1 The clinical audit cycle.²

Table 1 Benefits of undertaking a clinical audit

Assess and improve quality and efficiency of patient care Uphold professional standards/facilitate professional development Identify and measure areas of risk Create a culture of transparency and quality improvement, where regular audit activity occurs Educate health professionals and keep up to date with evidence-based practice

- Targeted analysis of data involving minority/vulnerable groups whose data are to be separated out of that data collected or analysed as part of the main QI/evaluation activity.
- Unlikely to provide direct benefits to patients
- Involves the use, storage or preservation of an individual's body parts or bodily substances

If uncertain about the approval pathway, early discussion with ethics, research governance, clinical governance or safety and quality officers will avoid important negative consequences such as breach of confidence, or inability to obtain retrospective approval for publication. Discussion of requirement for consent is important. Whilst different sites may vary in their approach to audit approval, there are generally three levels at which ethical review can occur.³

1. Safety and quality/clinical governance approval: Many audits examine routinely collected, non-sensitive data, collected by staff normally caring for those patients and ultimately for internal use only. These very low risk projects are generally suitable for approval outside a Human Research Ethics Committee. For example, in Western Australia (WA), the Governance Evidence Knowledge Outcomes online application system for QI activities, under the clinical governance structure for public health service providers, enables committee review, real-time discussion and approval of simple online applications generally within 2–3 weeks. Results and recommendations are entered within the system by investigators and escalated as needed by the reviewing committee.

2. The low and negligible risk pathway: may be appropriate where risk remains low (e.g. minor discomfort) or negligible (e.g. inconvenience only) but individual consent may be required, for example, where collecting new data from focus group participants.
3. Human Research Ethics Committee approval will be needed for projects where participants usually provide consent, data may be sensitive, higher risk, not routinely collected, or from vulnerable or easily identifiable populations, particularly if intended for external use such as scientific publication or conference presentation.

Whilst the right to publication may be granted for any of these three levels of review, the correct pathway must be chosen in the first instance, as retrospective higher level approval will not be granted.

How Do I Develop My Question, Aims, Objectives and Benchmarks?

Following a review of the literature and discussion with stakeholders, a clear, answerable and worthwhile question must be stated, along with aims and objectives, and rationale for undertaking the project. Investigators should ensure there is a good fit with stakeholder needs and that there will be impact potentially on policy and practice. Use of the PICOT framework for articulating a question⁶ and SMART (Specific, Measurable, Achievable, Realistic and Timely) framework for an objective(s) is helpful. Define eligibility criteria. Clear objectives then facilitate identification of a standard or benchmark for comparison and inform development of the data collection instrument for the project. A benchmark may be a statement of best practice, or of the quality of care to be achieved, or a target for expected adherence, usually expressed as a percentage. A standard should be chosen based on a thorough literature review including local, state or national guidelines^{7–9} and careful examination of the level of evidence, and then justified in subsequent reports.³ A basic example is shown below:

Example

Aim

A statement of the project outcome or goal.

For example, are we meeting best practice standards for opportunistic vaccination?

Objectives

A focused step(s) with measurable outcomes describing how an aim will be achieved.

For example, for all patients attending clinic F for the period January–June 2020:

1. what proportion had their vaccination status recorded? Benchmark: 100%
2. with incomplete vaccination status according to the National Immunisation Register, what proportion received an opportunistic vaccination at the time? Benchmark: 100%

What Sample Size Is Needed?

The only way to get a 'true' estimate for the outcome of interest for your primary objective is to include the entire population of interest. Where this is not possible, due to time and resource constraints, a sample will need to be selected. Most often, this will require calculating a sample size for a single proportion. Online calculators can provide a starting estimate for discussion but getting advice from a biostatistician is recommended as other approaches may be needed.³ Allow a buffer for missing records or non-participation. The key pieces of information required to determine a sample size for a proportion are:

- An estimate of the true/expected proportion in the source population. How often are audit criteria expected to be met? Use the literature, do a pilot study or make an educated guess.
- Degree of confidence required (commonly 0.95, or 95%).
- Precision, or the amount of error you can tolerate (commonly 0.05, or 5%).
- The size of the population from which you plan to sample (not all calculators ask for this).

For example, if we estimate 90% will staff to comply with opportunistic vaccination policy, to provide an estimate of 90%, with a 95% confidence interval of 85–95% ($90\% \pm 5\%$), a sample size of 122 participants providing data is needed out of a population of 1000.³

What Sampling Method Is Best?

Choose and justify an appropriate sampling method to obtain your sample size whilst maximising the ability to generalise results to the wider population of interest (external validity). Ideally this is via simple random sampling from a listing of all relevant records. Where not feasible, consider the advantages and disadvantages of other methods³ such as systematic, stratified or cluster sampling, and obtain advice from a biostatistician or epidemiologist. Avoid convenience sampling wherever possible, as it is the method most likely to result in a non-representative study sample.

Data Variables

Choose and create variables for data collection by ensuring all the data required to answer each of the objectives are covered. Only collect what you need: do not collect data 'in case' it might be interesting as this wastes time and resources. A good process for literature and stakeholder review will ensure data are collected to enable comparisons with other similar studies. Include variables for case characteristics and a unique identifier for every record to enable de-identification and maintenance of data security. Ensure relevant definitions of outcome measurements and for case selection are clear in terms of person (or clinical factors), place and time. Other variables generally collected include those for recruitment and response rates, who is collecting the data, important subgroups, primary and secondary objectives, and potential confounders. Create a data dictionary describing the use and functionality of every variable³; this will enable future repeat audits to be done with ease and assist with database creation.

What Is the Best Survey Delivery Option?

Consider likely differences in response rate, representativeness and data quality for various survey delivery options. Choice depends on the resources available and the population of interest, and is worth discussing with an epidemiologist or experienced researcher. Retrospective data collection relies on the required data having been collected previously (e.g. in medical records). Whilst generally cheaper and easier, this approach almost always results in an incomplete data set or less rich data than would be ideal. Whilst more resource-intensive, prospective data collection is more likely to result in a complete, high quality data set and provide the opportunity to collect the exact data needed. Prospective data collection options for audits involving participants include phone (automated, in-person, or combination), text, email, face-to-face, standard mail and others. In addition, surveys may be self-administered or investigator administered. Each has relative advantages and disadvantages including time and level of training required, cost, outreach and response rate.³

Maximise the response rate to ensure validity of results.^{3,10,11} The response rate is the number of completed surveys, expressed as a proportion of the total number of eligible people approached/records selected. This final number should be greater than or equal to the estimated sample size. Aim for as close to 100% response rate as possible: non-responders or missing records could provide different or even opposite answers to data from responders or found records, potentially completely changing final results (response bias). To maximise response rates for a questionnaire, minimise effort involved in data collection: keep it as short as possible whilst answering the study objectives, have a logical flow of questions, from the least to most sensitive, and the general to the particular, and ensure the questionnaire is clear, simple, easy to read and well-presented. Pre-contact with relevant stakeholders can be helpful. Have a pre-determined process for chasing up missing responses and think carefully about timing.

Design your database using a data-entry package to ensure integrity, completeness and security of project data. For example, REDCap is free, relatively intuitive, stores data locally, allows multiple users and levels of security and is increasingly used by health service providers. Such packages also enable application of questionnaire skip logic, compulsory or unique variables, variable ranges, and mutually exclusive and collectively exhaustive options. Never use Excel as it has none of these capacities.^{3,10,11}

Pilot test the data collection instrument, delivery method and database entry prior to real data collection to iron out any unforeseen problems and ensure everything works as it should.

Train your study personnel and monitor performance, particularly for longer audits.

It is then time to obtain final audit approvals, and collect, enter, clean and analyse the data. Presentation of results generally includes response rate (number selected, eligible vs. 'out of scope', participated, completed),³ overall numbers for outcomes of interest (proportions, means, median), characteristics of participants (e.g. gender, age, comorbidities), condition (e.g. severity, duration etc) or practice (e.g. completeness, location, staff experience or training background). It may also be appropriate to examine variation in the outcomes of interest between different groups, or to examine the role of potential confounders. Different

approaches to analyses are required for repeat audits and should be discussed in advance with a statistician.³

Then comes the fun part – critical interpretation and development of recommendations for implementation. Beware over-interpretation of audit findings, particularly for repeat audits when examining associations between variables. Given each audit represents a ‘snapshot’ in time, with all variables measured at once, and multiple unmeasured factors potentially contributing to any difference seen, it is not possible to attribute results to a particular change in practice. Two variables can be associated, but this does not mean that there is a causal relationship. With an audit design, it is enough to describe a change in adherence without attributing the change to a particular cause.

In summarising audit data, it is usual to cover key outcomes (based on objective(s)), whether this was expected or not based on the current literature and why; if benchmarks were not met, what might the reasons be; strengths and weaknesses of the audit (e.g. response rate, timing), what the impact of findings are on current practice or thinking, and what changes might be suggested.

Activation of a pre-determined knowledge translation plan is required for audit completion.

Present the results to key stakeholders, seek their feedback and input to recommendations, and ensure these are implemented by designated people within a set time frame. Escalate results within and outside the organisation to all relevant areas to maximise efficiency and impact. For example dissemination may be via reports, writing new policy documents, clinical guidelines or peer-reviewed papers; meeting with other departments, executives or health service providers; or by developing education and training packages.

Finally, how can we best support a culture of clinical audit as part of routine practice?

- Have a responsive, efficient system for rapid review and approval of audit proposals.
- Embed clinical audit training in undergraduate and post-graduate clinical courses. For example, the University of Western Australia has developed online community modules in research methods that course coordinators from any clinical discipline can add to their courses to complement face-to-face teaching.
- Set up formal programmes with local universities for clinical students to participate in audits with health service providers, from community to tertiary hospital level.
- Encourage staff and students to undertake clinical audits. Reiterate benefits, including improved clinical practice and patient care, opportunities for presentation and publication, and improved research skills.
- Develop clinic databases and registries, to automate as much as possible the ability to conduct and repeat relevant audits.
- Keep research and audit as a regular agenda item for practice or departmental meetings.
- Maintain a list of previous audits, their year of conduct and suitability to repeat, along with future potential topics of interest, based on common conditions or current problems.
- Encourage presentation of audit results, and seek input to recommendations, their time frames, and the listing of suitable people responsible for ensuring implementation.

- Encourage research translation *via* publication and escalation of findings to all relevant stakeholders and health service providers, to ensure maximum impact and efficiency.

A culture of regular clinical audit and continuous quality improvement underpins a strong and safe health-care system. Learning basic audit methodology is both achievable and essential for all clinicians.

References

- 1 National Institute for Clinical Excellence. *Principles for Best Practice in Clinical Audit*, 208. Oxford: Radcliffe Medical Press; 2002 Available from: <https://www.nice.org.uk/media/default/About/what-we-do/Into-practice/principles-for-best-practice-in-clinical-audit.pdf> [accessed 15 Jun 2020].
- 2 Benjamin A. Audit: How to do it in practice. *Br. Med. J.* 2008; **336**: 1241–5.
- 3 Skull SA, Bear N, Hill K, ed. *Clinical Audit Handbook*, 1st edn. Child and Adolescent Health Service, Western Australia; 2019; 84. Available from: <https://cahs.health.wa.gov.au/Research/For-researchers/Research-Education-Program/Clinical-Audit-Handbook> [accessed 15 Jun 2020].
- 4 National Health and Medical Research Council. *Ethical Considerations in Quality Assurance and Evaluation Activities*. National Health and Medical Research Council; 2014; 5. Available from: <https://nhmrc.gov.au/about-us/publications/ethical-considerations-quality-assurance-and-evaluation-activities> [accessed 15 Jun 2020].
- 5 National Ethics Advisory Committee. *National Ethical Standards for Health and Disability Research and Quality Improvement*. Wellington: New Zealand Ministry of Health; 2019. Available from: <https://neac.health.govt.nz/system/files/documents/publications/national-ethical-standards-health-disability-research-quality-improvement-2019.pdf> [accessed 15 Jun 2020].
- 6 Tovey D. How to clarify a clinical question. *BMJ Best Practice*. 2020 June. Available from: <https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/how-to-clarify-a-clinical-question/> [accessed 15 Jun 2020].
- 7 *National Safety and Quality Health Service Standards*, 2nd ed. Sydney: Australian Commission on Safety and Quality in Health Care; 2017. Available from: <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-safety-and-quality-health-service-standards-second-edition> [accessed 15 Jun 2020].
- 8 *Clinical Care Standards*. Australian Commission on Safety and Quality in Health Care; 2019. Available from: <https://www.safetyandquality.gov.au/standards/clinical-care-standards> [accessed 15 Jun 2020].
- 9 *Ministry of Health Output Plan 2018/19*. New Zealand Ministry of Health; 2019. Available from: https://www.health.govt.nz/system/files/documents/publications/ministry_of_health_output_plan_2018_19.pdf [accessed 15 Jun 2020].
- 10 Skull S. Survey design and techniques. In: Skull S, ed. *Research Skills Seminar Series, Research Education Program*. Child and Adolescent Health Service; 2019. Available from: <https://cahs.health.wa.gov.au/Research/For-researchers/Research-Education-Program/Past-seminars> [accessed 15 Jun 2020].
- 11 Skull S. Data collection and management. In: *Research Education Program: Research Skills Seminar Series*. Child and Adolescent Health Service; 2019. Available from: <https://cahs.health.wa.gov.au/Research/For-researchers/Research-Education-Program/Past-seminars> [accessed 15 Jun 2020].