

PART I

Principles of Surgical Audit

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CHAPTER 1

How to set up prospective surgical audit

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KEY POINTS

- Clinical audit is one of the keystones of clinical governance
- Audit can be conducted prospectively or retrospectively and robust data collected for patient benefit
- A well-performed audit can inform patients about surgical results and drive continuous quality improvement
- Data can be derived from local hospital statistics to nationally reported outcomes
- Paper based audit is time consuming and is being replaced by IT-based support to clinical care pathways

Introduction

Clinical audit is one of the “keystones” of clinical governance. A surgical department that subjects itself to regular and comprehensive audit should be able to provide data to current and prospective patients about the quality of the services it provides, as well as reassurance to those who pay for and regulate health care. Well-organized audit should also enable the clinicians providing services to continually improve the quality of care they deliver.

There are many similarities between audit and research but, historically, audit has often been seen as the poor relation. For audit to be meaningful and useful it must, like research, be methodologically robust and have sufficient “power” to make useful observations; it would be easy to gain false reassurance about the quality of care by looking at outcomes in a small or “cherry-picked” group of straightforward cases. Audit can be conducted retrospectively or prospectively and, again like research, prospective audit has the potential to provide the most useful data, and routine prospective audit provides excellent opportunities for patient benefit [1–4].

Much of the experience we draw on comes from cardiac surgery, where there is a long history of structured data collection, both in the USA and the UK. This was

initially driven by clinicians [1–7], but more recently has been influenced by politicians and the media [7,8]. Cardiac surgery is regarded as an easy specialty to audit in view of the high volume and proportion of a single operation (coronary artery bypass graft) in most surgeons’ practice set against a small but significant hard measurement endpoint of mortality (which is typically around 2%).

In the UK recently, increasing focus has been placed on national clinical audit. A Public Inquiry into the events at Mid Staffordshire NHS Trust found unsatisfactory care that had gone on for some time, despite the existence of data in the “system” that identified potential problems [9]. The UK Government’s response to these events has been to drive public reporting of outcomes down to the level of individual surgeons for 10 specialties, including gastrointestinal surgery, interventional cardiology and urology. These data were published in 2013, and the process has led to marked improvements in engagement with national clinical audit in the UK and has dramatically increased data quality and the utility of the audits [10,11].

Why conduct prospective audit?

There are a number of reasons why clinicians might decide to conduct a clinical audit (Box 1.1).

Box 1.1 Possible reasons for conducting clinical audit.

- As a result of local clinical interests
- As a result of clinical incident reporting
- To comply with regional or national initiatives
- To inform patients about surgical results and support choice
- To drive continuous quality improvement
- To comply with health care regulation
- To engage patients in decisions about their health care
- To provide public reassurance

As a result of local clinical interests

Historically, many audit projects have been undertaken as a result of local clinical interests. This may reflect interest in a particular procedure by an individual or a group, or may reflect concern about specific outcomes for a particular operation.

As a result of clinical incident reporting

The major disciplines that ensure high quality care and patient safety are clinical risk management and audit. Most health care organizations should have sophisticated systems in place to report and learn from adverse incidents and near misses [8]. Reporting is usually voluntary and investigated according to a “fair and just culture” but it is unlikely that all incidents that occur are reported. If an adverse incident is recorded, the record identifies that it has occurred but gives no indication of how often it has happened previously, and only limited indication of the likelihood of recurrence. A mature organization should have clear links between risk reporting and audit, and choose topics for the latter based on data from the former.

To comply with regional or national initiatives

Increasingly audits are being driven by organizations that exist outside a hospital. These may include audit led by professional societies, regulatory bodies or regional/national quality improvement and transparency initiatives.

To inform patients

Across the world health care is becoming more patient-focused. The modern health care consumer

will sometimes want to choose their health care provider on the basis of that hospital or surgeon's outcomes. Even if patients are not choosing between different hospitals, recent data from the UK suggest that patients are interested in outcomes of surgery by their doctors [13]. Patients' views should inform decisions about what to audit, and they may be interested in many areas which will be dependent on the planned operation but may include data on mortality, success rates, length of stay, the incidence of postoperative infection and other complications, and patients' experience data.

To drive continuous quality improvement

It has been shown quite clearly from cardiac surgery that structured data collection, analysis and feedback to clinicians improves the quality of outcomes. This has been detected both when data are anonymous and where named surgeon and hospital outcomes have been published [1–4]. The magnitude of this effect is large; in the UK, a system of national reporting for surgical outcomes was introduced in 2001 and has led to a 40% reduction in risk adjusted mortality [4]. The introduction of any drug showing a similar benefit would be heralded as a major breakthrough, but routine national audit has not been embraced by most surgical specialties. Simply collecting and reviewing data seems to drive improvement, but it is likely that the magnitude of the benefits derived and the speed at which improvements are seen can be maximized by developing a clear understanding of what data to collect and using optimal managerial structures and techniques to deliver better care. There is some debate about whether publicly disclosing health care outcomes encourages clinicians to avoid taking on high-risk cases [1,4,7,14,15], but recent experience from the UK certainly confirms that public reporting does drive compliance with national audit with all its inherent benefits.

To comply with health care regulation

Healthcare regulators have a responsibility to ensure that hospitals, and the clinicians working in them, are performing to a satisfactory standard. Whilst some assurance can be gained from examining the systems and processes in place within an organization, the “proof of the pudding” is in demonstrating satisfactory clinical results. This proof is important and can only come from

analyzing benchmarked outcomes data. Regulators of individual clinicians, such as the American Boards in the USA and the General Medical Council in the UK, are changing their emphasis so that it is becoming more important for clinicians to prove they are doing a good job rather than this being assumed. Routine use of structured outcomes data is now supposed to be in place and is included in the current proposals for professional revalidation in the UK (the process by which doctors now have to prove they are “fit to continue to practice” [16,17]).

To engage patients in decisions about their health care

As society becomes supported by better mobile devices and connectivity, people are looking to the internet to support many choices that they make, including choices about health care. It is vital that the medical profession and health care organizations accept this and provide patients and their carers with appropriate information to empower and engage them in the concept of “shared decision making” with their health care advisers.

To provide public reassurance

It is certainly true in the UK, but is possibly true more widely, that the trust that has traditionally been placed in the medical profession – and, indeed, medical professionals – is being eroded by repeated failure of clinical governance and increasing societal expectations. Maintaining a trusting relationship between an informed public and a trustworthy profession is in everyone’s best interests, and this can be supported by transparent clinical audit data.

What data can be used for audit?

Routine hospital data

Most health care systems are rich in data and poor in information. Medicare data in the USA and Hospital Episodes Statistics in the UK contain information about patient demographics, diagnoses, procedure, mortality, length of stay, day cases rates and readmissions. These information systems are developed for administrative or financial purposes rather than clinical ones, but may potentially contain much useful clinical data and will often have the capacity to

provide some degree of adjustment for case mix. In the UK this data has historically not been trusted by clinicians, but recently there has been increasing engagement between doctors and the data which is improving clinical data quality and increasing confidence. Many UK hospitals now have systems to benchmark their outcomes against national or other peer groups, to flag up areas of good practice, detect outlying performance and engage in quality improvement [18].

Ideally, hospitals should have clearly-defined systems in place to use the data: for example, they should regularly compare their outcomes for chosen procedures against an appropriately selected group of other hospitals. Significant “good” practice should be celebrated and shared with others inside and outside the organization, and bad outcomes should be investigated. It is not uncommon that high mortality or other clinical indicator rates may have a clear explanation other than that of “bad” clinical practice. The data may be incorrect, or there may be issues about classification or attribution that explain away an apparent alert, but structured investigation should improve the knowledge of both the organization and the clinician knowledge about their data systems and may lead to better knowledge that necessitates improvements in patient care.

Specialty-specific multi-center data

A number of surgical disciplines in the USA and the UK have embarked upon national programs to collect prospective disease- or operation-specific datasets. These are usually clinically driven and have benefits above routine hospital data in that a more useful dataset can be designed for specific purposes and, in particular, can look in more detail at subtleties of case mix and specific clinical outcomes in a way that is more robust and sensitive than that derived from routine hospital administration systems. Contemporary cardiac surgical datasets collect variables on preoperative patient characteristics, precise operative data and postoperative mortality, ICU stay, hospital stay, re-explorations, infection, renal failure, tracheostomy, blood usage, stroke rate and intra-aortic balloon pump use. The preoperative and operative data allow outcomes to be adjusted for case complexity to prevent comparison of “apples and oranges” by various algorithms such as the EuroSCORE [20]. Data for 10 such audits are now

published in the UK down to the level of individual surgeon [10,11].

Setting up specialty-specific multi-center audit raises a number of challenges including defining clarity of purpose, gaining consensus, agreeing a dataset, securing resource, overcoming information technology and methodology issues, and clarifying ownership of data, information policies and governance arrangements [21]. In cardiac surgery there is now increasing international dialogue between professional organizations, moving towards the collection of standardized data to allow widespread comparisons.

Locally-derived data

Individual hospital departments will often decide to audit a specific theme that may be chosen because of clinical risk management issues, subspecialist interest or other concerns. In the UK National Health Service, dedicated resources for audit were historically “top sliced” from the purchasers of health care to generate a culture of clinical quality improvement, but commentators are divided about whether significant benefits have been realized from this approach [13]. In the early stages, large amounts of audit activity were undertaken, but there were significant failures in subsequently delivering appropriate change. To maximize the chances of improving care as a result of audit the following should be considered. Will the sample size be big enough to be useful? What dataset is needed? Will that data be accessible from existing hospital case notes or will prospective data collection be necessary? Is there an existing robust benchmark to which the results of the audit can be compared? How will the “significance” of the results be analyzed? Does conducting the audit have financial implications? Will the potential results of the audit have financial implications? Are all stakeholders who may need to change their behavior as a result of the audit involved in the process?

Techniques of data collection

Historically, the majority of audit activity was conducted from retrospective examination of case notes, which was labor intensive and relied on the accuracy and completeness of previously recorded data. There has subsequently been increasing use of prospective

data collection, much of which has been based on paper forms. This obviously improves the quality of data, but again requires time and effort from clinical or administrative staff for completion. The development of care pathways whereby multidisciplinary teams manage clinical conditions in predefined ways is thought to improve patient outcomes and will generate structured data that are readily amenable to audit. The use of modern information technology to support care pathways is the “holy grail” of effective audit – all data are generated for clinical use and the relevant subset of that data can then be examined for any relevant purpose. The care pathway can be adapted to include new or alternative variables as required. All data collection can be networked and wireless, assuming issues about data access, confidentiality and security are resolved. Maximizing benefits from this approach raises a number of challenges, including implementing major changes in clinical practice and medical culture.

Good practice in audit

A clinical department should benefit from a clear forward plan about its audit activity that should be developed by the multidisciplinary team in conjunction with patients and their carers. The audit activity should include an appropriate mix of national, local and risk management-driven issues and the specifics should depend on the configuration of services and local preferences. The plan should include thoughts about dissemination of results to users and potential users of the services. The multidisciplinary team should include doctors, professions allied to medicine, and administration staff. Adherence to the audit plan should be monitored through the departmental operational management structures. For the department to be successful in improving care as a result of audit there should be clear understanding of effective techniques of change management.

Arguments against audit

In the UK, audit has been an essential part of all doctors’ job plans for a number of years, but audit activity remains sporadic. In some specialties, such as those included in the NHS England transparency agenda,

comprehensive audit is being led by clinicians and driven by politicians and the media [10,11]. In other areas there remains little or no coordinated national audit activity. This may be due to a perceived lack of benefits from audit by clinicians along with failure to meet challenges in gaining consensus or difficulties in securing adequate resources. The experience from cardiac surgery and many other national audits in the UK is that structured national audit improves the quality of mortality outcomes [1–4]. It is likely that other issues, such as complication rates, are also reduced with associated costs savings, and as such effective audit may well pay for itself.

Conclusion

In modern health care, patients are increasingly looking to be reassured about the quality of care they receive, and doctors are being driven towards demonstrating their competence rather than this being assumed. Hospital departments should have a robust clinical governance strategy that should include “joined-up” clinical risk management and audit activity. There are strong arguments that structured audit activity improves the quality of outcomes and for these benefits to be maximized there should be involvement of multidisciplinary teams supported by high-quality operational management.

DOS AND DON'TS

Do

- Continually work to evaluate the quality of care you deliver for patients
- Develop a strategy for clinical audit which incorporates the relevant area of your practice and is methodologically robust
- Benchmark your practice against accepted best practice
- Develop a link between learning from risk management and your clinical audit program
- Develop links between clinical audit and departmental/individual reflective practice
- Evaluate your personal surgical audit and know what to do if your results are not ‘as expected’
- Be transparent about your audit program and your results of care

Don't

- Undertake an audit that is not methodologically robust
- Fail to implement changes resulting from an audit which demonstrates unsatisfactory processes or outcomes
- Derive false reassurance from benchmarking against time-expired clinical standards
- Assume that patients and the public have no interest in the outcome of care derived from your audit program.

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