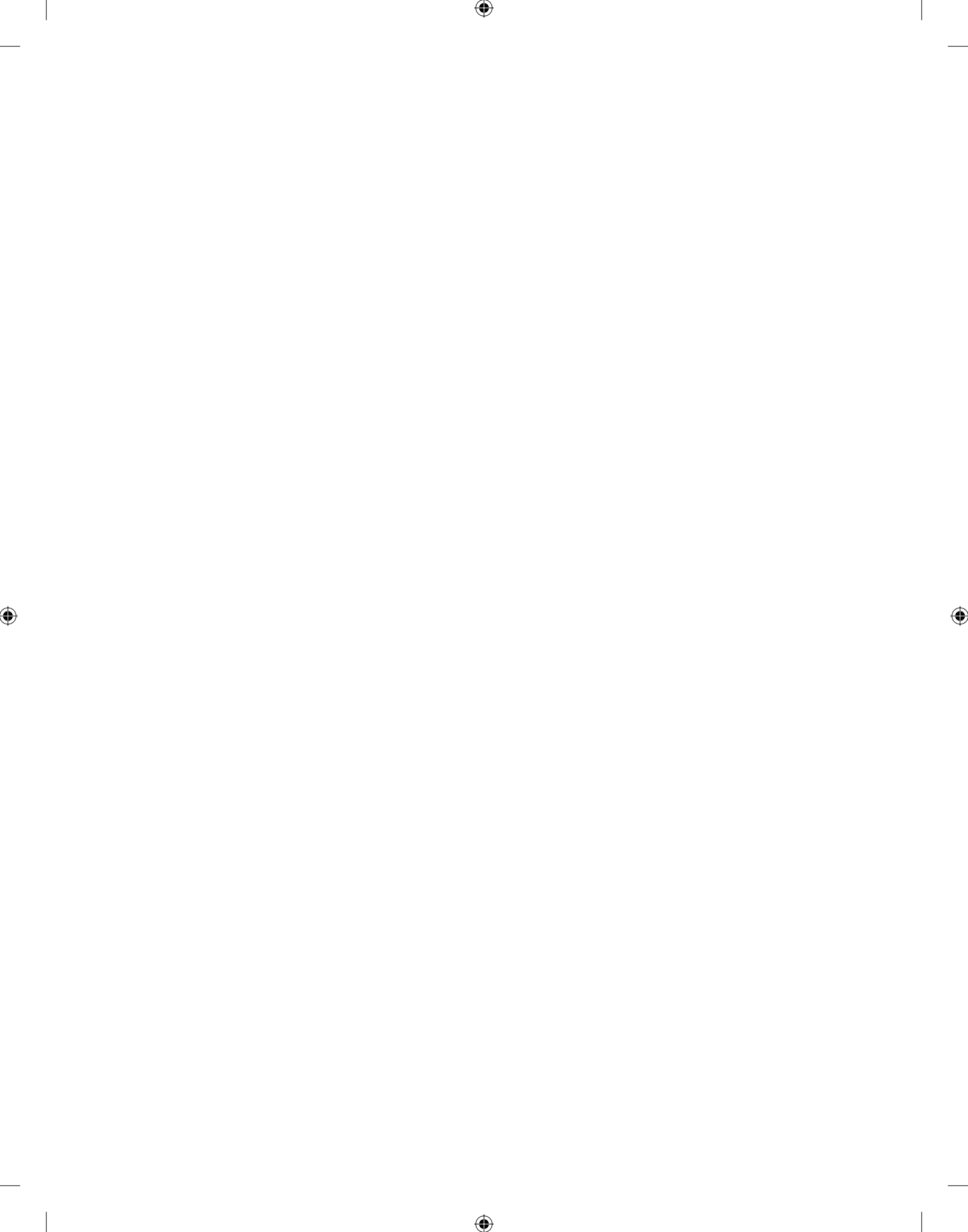


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# Principles of Surgical Audit



# 1

## How to Set Up a Prospective Surgical Audit

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### Key points

- Clinical audit can be prospective and/or retrospective.
- Audit information can be obtained from national, hospital, and surgeon-specific data.
- A clinical department benefits from a clear audit plan.
- Clinical audit improves patient outcome.

### 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].

*Pediatric Urology: Surgical Complications and Management.* Edited by Duncan T. Wilcox, Prasad P. Godbole and Martin A. Koyle.  
© 2008 Blackwell Publishing, ISBN: 978-1-4051-6268-5.

Much of the experience we draw on comes from cardiac surgery, where there is a long history of structured data collection, both in the United States and in the United Kingdom. This was initially driven by clinicians [1–3,5], but more recently has been influenced by politicians and the media [6,7]. 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 (CABG) in most surgeons practice set against a small but significant hard measurement end point of mortality (which is typically approximately 2%).

### Why conduct prospective audit?

There are a number of reasons why clinicians might decide to conduct a clinical audit as given in Table 1.1.

**Table 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
- To drive continuous quality improvement
- For health care regulation

### **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, this 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 have been driven by organizations that exist outside a hospital. These may include audit led by professional societies, regulatory bodies, or regional/national quality improvement initiatives.

### **To inform patients about surgical results**

Across the world, health care is becoming more patient-focussed. The modern health care consumer will sometimes look to choose their health care provider on the basis of that hospital or surgeon’s outcomes and, even if patients are not choosing between different hospitals, recent data from the United Kingdom suggests that patients are interested in outcomes of surgery by their doctors [9]. 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, and the incidence of postoperative infection and other complications.

### **To drive continuous quality improvement**

It has been shown quite clearly from cardiac surgery that structured data collection, analysis, and feedback to clinicians improve the quality of outcomes. This has been detected when data is anonymous [2,3] and where

named surgeon and hospital outcomes have been published [1,4]. The magnitude of this effect is large; in the United Kingdom 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 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 [1,4,7,10,11].

### **For health care regulation**

Health care regulators have a responsibility to ensure that hospitals, and the clinicians working in them, are performing to a satisfactory standard. While some assurance can be gained from examining the systems and processes in place within an organization, the “proof of the pudding is in the eating” and demonstrating satisfactory clinical results is important and can only come from analyzing benchmarked outcomes data. Regulators of individual clinicians, such as the American Boards in the United States and the General Medical Council in the United Kingdom, 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 included in draft proposals for recertification by the American Board of Thoracic Surgery and the Society for Cardiothoracic Surgery of Great Britain and Ireland and will follow to other specialties in time [12].

## **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 United States and Hospital Episodes Statistics in the United Kingdom contain data on patient demographics, diagnoses, procedure, mortality, length of stay, day cases rates, and readmissions. These information systems are developed for administration 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 casemix. In the United Kingdom, 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, flag up areas of good practice, detect outlying performance, and engage in quality improvement [13].

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 infrequent 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 organization’s and the clinician’s knowledge about their data systems and may lead to impressions that necessitate improvements in patient care.

### Specialty-specific multicenter data

A number of surgical disciplines in the United States and the United Kingdom 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 casemix 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, reexplorations, infection, renal failure, tracheostomy, blood usage, stroke rate, and intraaortic 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 [14].

Setting up specialty-specific multicenter audit raises a number of challenges including defining clarity of purpose, gaining consensus, agreeing a dataset, securing resource, overcoming information technology issues, and clarifying ownership of data, information policies,

and governance arrangements. In cardiac surgery, there is now increasing international dialogue between professional organizations to move toward 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 (NHS), dedicated resource for audit was 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 [9]. 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 casenotes 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 casenotes, which was labour 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 are thought to improve patient outcomes and will generate structured data that is readily amenable to audit. The use of modern information technology to support care pathways is the “holy grail” of effective audit – all data is 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. Variations on this theme are now available in many hospitals and it is these principles that underpin a major IT investment in the UK NHS [15]. Maximizing benefits from this approach raises a number of challenges including producing 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, professionals 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 United Kingdom, audit has been an essential part of all doctors' job plans for a number of years, but audit activity remains sporadic. In some high-profile specialties such as cardiac surgery, comprehensive audit has been led by clinicians and driven by politicians and the media. In other areas there has been little or no coordinated national audit activity. This may be due to a perceived lack of benefits from audit from clinicians along with failure to meet challenges in gaining consensus or difficulties in securing adequate resource. The experience from cardiac surgery 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.

### Summary

In modern health care, patients are increasingly looking to be reassured about the quality of care they receive and doctors are being driven toward 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.

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