About the companion website

This book is accompanied by a companion website:
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The website includes:
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Preface

The editors are delighted to present the second edition of *Pediatric Urology: Surgical Complications and Management*. Since the first edition was published in 2008, pediatric urology has advanced in terms of our understanding of disease processes and technology. However, it is incumbent on any clinician undertaking pediatric urology practice to be able to maintain and sustain a safe, high quality and outcome oriented practice. While recognizing and managing complications of surgical interventions is important, it is imperative that prevention of these complications is also recognized. The second edition aims to address these issues.

The general format of the textbook has been changed to include some case-based discussions and a summary “dos and don’t’s” take-home message for nearly every chapter. Where applicable, certain “tips and tricks” to maximize efficiency and minimize the risk of complications has been included. With the IT age, online videos demonstrating the techniques where appropriate also form an added feature of the online second edition.

There have been substantial updates to chapters and new chapters have been added based on feedback received from the first edition.

The editors believe that the second edition will be useful for practicing pediatric urologists, urologists in training, pediatric surgeons or indeed any surgeon undertaking office or specialist pediatric urology.

We are indebted to our contributors who have been very supportive in submitting such high quality chapters and within the tight deadlines required. The efforts of Jane Andrew and Rachel Wilkie at Wiley cannot go unrecognized and without whose assistance this book would have been a mere pipe dream.

Finally, as always, we are very grateful to our families who have stood by us and supported us by giving us the time to be able to undertake this worthwhile project.

PG, MK, DW
March 2015
PART I

Principles of Surgical Audit
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 reassure 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).
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 been 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 organisation, and bad outcomes should be investigated. It is not uncommon that high mortality or other clinical indictor 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.

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**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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CHAPTER 2
Evaluating personal surgical audit and what to do if your results are not “as expected”

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KEY POINTS
• Audit is the comparison of surgical results against a previously defined and accepted standard
• Published results may be better than the normal surgeon’s
• Complexity specific audit is important
• Dealing with outlying performance can be ‘directive’ or ‘collaborative’ depending on the surgeon
• Surgeons are responsible for ensuring satisfactory quality of care

Introduction
Any well-conducted audit should give information about systems and outcomes related to patient care. Data collection that generates new information about patient outcomes should be classified as research; to be regarded as audit, results need to be compared against a previously-defined and accepted standard. Often an audit will demonstrate satisfactory outcomes and this in itself may be a useful finding which should be of interest to patients, clinicians, managers, commissioners and regulators of health care. It is hoped that structured and regular audit data collection will lead to ongoing improvements in quality as described in Chapter 1. On occasions, audit results will be unacceptable and it is essential that this is recognized and acted upon.

Presentation and analysis of data
Effective audit requires clarity of purpose. When an audit is conceived the clinical question should be clearly stated and the data required to generate an answer should be defined. It is also important to be sure about the outcomes with which you will compare yourself, and there may be a number of options. Data on mortality or complication rates may be available from pooled national or regional registries [1–4]. Results of specific series of cases may be published through peer review journals for individual hospitals or individuals, but these outcomes may often be better than the “norm” because of submission and publication bias. False reassurance might be gained from comparing outcomes with outdated historical results; in cardiac surgery in the UK, a widely-accepted risk adjustment algorithm, the EuroSCORE [5], has been used to benchmark hospitals and surgeons in recent years. This was developed in a multi-center study in Europe in 1997 and improvements in overall quality of care in the UK are such that it no longer reflects current practice [6]. This concept of “calibration drift” for cardiac surgery has been seen in both the UK and the USA and is important to take into account when using benchmarking for audit [7].

It is possible to compare outcomes between units or surgeons simply by using “crude” or non-risk-adjusted data. Cardiac surgeons have focused on mortality as it is
a robust primary end point. In pediatric urology, mortality is not frequent enough to provide a meaningful measure; more appropriate endpoints need to be developed and this is a challenge for the profession.

Using non-risk-adjusted data has simplicity and transparency on its side but it is not embraced with enthusiasm by the majority of surgeons. It is clear that there are quite marked differences in patient characteristics between different units in cardiac surgery, and this variability is probably greater between surgeons who have different subspecialist interests [8]. These issues apply to other areas of surgery. Many surgeons are concerned that any attempt to produce comparative performance using non-risk-adjusted data will stimulate a culture whereby higher-risk patients are denied surgery to help maintain good results – so-called risk-averse behavior. In order to make data comparable between individual surgeons and units there have been a number of attempts to adjust for operative risk in cardiac surgery [9–12]. Other specialties will need to develop appropriate methodology and ideal tools should be accurate numerical predictors of observed risk (i.e. be calibrated correctly) and the ability to discriminate appropriately across the spectrum of risk (i.e. accurately differentiate between lower- and higher-risk patients).

In addition to the appropriate use of risk adjustment, some units have found graphical techniques of presenting outcomes data useful to monitor performance. Various techniques, such as cumulative summation or variable life-adjusted display plots, have been used to help analyze results and detect trends or outlying performance at an early stage. These curves may be adapted to include predicted mortality to enable observed and expected mortality to be compared. These techniques are well described by Keogh and Kinsman [2]. More recently, interest is developing for measuring outcomes using statistical process control charts, which are widely used in the manufacturing industry. These charts use units of time, typically months when institutions are under scrutiny and the outcome of interest is mortality, and display actual mortality against expected mortality using control limits to define acceptable and unacceptable performance [12].

The use of funnel plots is becoming popular as a way of displaying hospital or individual mortality [13]. These are simply a plot of event rates against volume of surgery, and include exact binomial control limits to allow excessive mortality to be easily detected. They give a “strong visual display of divergent performance” [14]. They have been used to analyze routine data to define clinical case-mix and compare hospital outcomes in urology [15]. These methods have been used in the UK to display mortality rates to patients and the public [16].

Classical statistical techniques may be used to compare individual outcomes with a benchmark. When analyzing data from an individual hospital or surgeon it is probably appropriate to select 95% confidence intervals such that if significant differences are observed, there is a 1 in 20 probability that these are due to chance alone. Things become more difficult when many hospitals or surgeons are compared to a national benchmark. In the UK, there are over 200 cardiac surgeons and any comparison of the group against the pooled mortality. Using 95% confidence intervals with this group would raise a high probability of detecting outlying performance due to chance alone because of multiple comparisons, and it is appropriate to adjust for this. The choice of confidence intervals will always end up as a balance between ensuring that true outlying performance is detected without inappropriately creating stigma for surgeons with satisfactory outcomes [17]. It may be useful to select different confidence limits for different purposes. Tight limits may be appropriate for local supportive clinical governance monitoring; one hospital in northwest England launches an internal investigation into practice if a cardiac surgeon’s results fall outside 80% confidence limits but wider limits of 99% have been used to report those surgeon’s outcomes to the public [18].

**Dealing with outlying performance**

Detecting clinical outcomes that fall outside accepted limits does not necessarily indicate substandard patient care. However, any analysis which causes concern should trigger further validation of the data if appropriate. Then, if indicated, there should be an in-depth evaluation of clinical practice which may include analysis of subspecialty, case mix and an exploration of the exact mechanisms of death or complications. This process may lead to reassurance that practice is satisfactory. Ideally, this should be initiated by the clinician concerned who should be keen to learn from the experience to improve their practice. An excellent example comes from
pediatric cardiac surgery: a surgeon had concerns about his mortality outcomes following the arterial switch operation (which is complex, technically challenging, congenital surgery) [19]. He studied his outcomes in detail using CUSUM methodology and determined that things were worse than he would have expected from chance alone. He then underwent retraining with a colleague from another hospital with excellent outcomes, adapted his practice, and subsequently went on to demonstrate good outcomes in a further series of consecutive cases.

On occasions, the process of investigating outlying outcomes may be difficult for the individual hospital or surgeon involved. The investigation may raise significant methodological questions about the techniques of analysis and subsequent examinations. The cause of substandard results may be difficult to detect but may relate to failures in the systems of care in the hospital or department, or failures in the individual [17–23].

Clinical governance is an individual, departmental and hospital responsibility. Whist the onus should be on the individual with unsatisfactory outcomes to investigate and change their practice, they may need support, advice and direction from their clinical and managerial colleagues. Over recent years, the roles of different organizations in clinical governance are becoming clearer. Most hospitals should now have increasingly effective management structures for promoting quality improvement and detecting suboptimal performance.

The investigation of unsatisfactory outcomes can be facilitated by appropriate clinical leadership, and different techniques may be necessary for different circumstances with the concept of “situational leadership” being useful to match the managerial intervention to the willingness and the readiness of the individual whose practice is being investigated [24]. Two examples make this point. A newly-appointed cardiac surgeon had three adverse outcomes following the same type of operation that, to colleagues, seemed to be due to a similar mechanism. Despite discussions, the surgeon involved had little or no insight into the problem. No confidence intervals for performance were crossed because of the small volume of cases involved but, due to the clinical concerns, the surgeon was subjected to forced but supportive retraining of his intraoperative techniques, which led to the reintroduction of full independent practice within a few months and excellent publicly-reported results for that operation several years later. This would be described in a situational leadership model as a “directive” approach. A second example is that of a senior surgeon with a low-volume mixed cardiothoracic practice who had a “bad run” of cardiac results, which again led to outcomes that failed to generate statistically-significant mortality outcomes. On his own initiative, he involved his clinical managers and launched an in-depth analysis of his practice. He detected that he was conducting very high-predicted-risk surgery despite lower volumes of surgery than some single specialty colleagues. He was also suspicious of a potential common mechanism of adverse outcomes in several cases of mortality and some cases of morbidity. Along with colleagues, he changed his referred practice to make it more compatible with low volume mixed cardiothoracic surgery and adapted his technique of surgery to avoid further problems. This again resulted in excellent subsequent outcomes. This would be described in a situational leadership model as a “collaborative” approach. From a managerial perspective, both examples led to satisfactory ends, but adopting the appropriate leadership style was important in reaching the desired conclusions. In addition to having some understanding of leadership intervention models, we would also recommend that clinical managers have expertise in having “difficult conversations”, understand some change management theory, and have the ability to use an understanding of their personality characteristics and those of their colleagues to maximize the benefits, and the downsides, of managerial interventions.

In addition to the roles of the individual and the hospital in ensuring satisfactory outcomes, other agencies should be acting to support the process. In the UK, the Chief Medical Officer produced a report, *Good Doctors, Safer Patients*, about regulation of health care, and now the General Medical Council has responsibility for professional regulation, but passes significant responsibilities down to employers [25–28]. Professional revalidation for all 230,000 doctors in the UK has now started, and should include data from clinical audit to give positive affirmation that good care is being delivered. It is suggested that professional societies should set clear, unambiguous standards for care, and recertification of doctors should be dependent on achieving those standards. Patient consultation as part of this report has suggested that patients are keen to see that satisfactory outcomes of treatment by their doctors form part...
of this process and this is now made available to the public from doctors working in 10 specialties [29,39].

UK cardiac surgeons have responded to this agenda by articulating clearly their responsibilities to patients and the public in their publication *Maintaining Patients’ Trust* [33]. These themes have been reiterated clearly by the recent UK public inquiry into the events at Mid Staffordshire NHS Trust [20].

This direction of travel in the UK is a long way from the culture in which most doctors were trained. It will be a challenge for professional societies and the profession to deliver on this agenda.

## Conclusion

Most audit projects will deliver results that demonstrate clinical practice is satisfactory. There is some evidence that scrutiny of results alone can contribute to improvements in quality. On occasions, audit will flag up concern about clinical processes or outcome, but it is important that the data and the methods are “fit for purpose”. Ensuring that satisfactory quality of care is given and demonstrated is the responsibility of all involved in health care delivery, including individual practitioners, employers, commissioners, professional societies and regulators.

## DOS AND DON’TS

**Do**

- Act rapidly if audit data suggest results are not as expected
- Ensure that data quality issues are resolved without unnecessary delay
- Configure an improvement plan involving colleagues, the wider multidisciplinary team and organizational management
  
  *Ensure that patient safety and outcomes remain the primary consideration in all actions*

**Don’t**

- Assume that poor outcomes are due to data quality issues
- Derive false reassurance on quality by benchmarking against a time-expired clinical standard
- Try to act on poor outcomes without engaging colleagues and the organization
- Underestimate the importance of excellent clinical leadership in optimizing the quality of clinical outcomes for patients

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CHAPTER 3
A critical assessment of surgical outcomes

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KEY POINTS
• Outcomes between units or surgeons can be compared using non-risk-adjusted data; for example cardiac surgeons focus on mortality; while simple it may lead to risk averse behavior amongst surgeons
• In pediatric urology, mortality is not frequent enough to use as a meaningful end point for comparison
• Other techniques to analyze data include cumulative summation or life-adjusted display plots, statistical process control charts, funnel plots and classical statistical techniques with a benchmark

Introduction
In 1979, Lewis Thomas said: “There is within medicine, somewhere beneath the pessimism and discouragement resulting from the disarray of the health care system and its stupendous cost, an undercurrent of almost outra-geous optimism about what may lie ahead for the treatment of human disease if only we can keep learning” [1]. If he was concerned about the disarray and cost of the health care system in 1979, he would be disappointed today. Since 1979, health care costs have been rising at a much higher rate than the consumer price index, yet biomedical and technological research has been extremely productive [2]. In an attempt to control health care costs, an unfortunate consequence would be loss of new knowledge and innovation. Evidence suggests that around 40% of health care cost is due to waste or is non-value added to the patient, and reducing this waste should be the primary goal of health care providers [3].

As health care providers we can apply evidence-based medicine to provide the highest quality care to our patient population at the lowest possible cost.

Evidence-based medicine (EBM) was initiated by many in the medical field and is the critical evaluation of the current literature to obtain the best evidence and apply it to clinical practice. It is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients [4]. We, as health care providers, can apply this evidence to provide value (quality/cost) to the patients we treat.

It is now recognized that surgical outcomes vary by provider [5–7]. As such, surgeons and hospitals are being asked to provide evidence of the quality of care they deliver [8]. Social media is becoming more and more utilized by hospitals and medical professionals as a means of conveying general health information, sometimes even personalized help. Moreover, patients and their families are turning to the Internet and social media to make critical decisions about choice of surgeon and facility [9].

Surgeons have traditionally made therapeutic decisions based on personal experience, recommendations of surgical authorities and thoughtful application of surgical basic sciences. Evidence-based surgery emphasizes the need to evaluate properly the efficacy of diagnostic and therapeutic interventions before accepting them as standard surgical practice [10]. Evidence in clinical surgery, and especially in pediatric urology, varies in its quality.

Published research findings are sometimes refuted by subsequent evidence with ensuing confusion and
disappointment. Refutation and controversy is seen across a range of research designs [11]. There is also concern that false findings may be present in the majority of published articles. In a recent article in the *Journal of Urology*, Turpen et al. analyzed randomized controlled trials (RCTs) presented as abstracts at the 2002 and 2003 American Urological Association annual meeting and found that the current quality of reporting RCTs at urological meetings is suboptimal, and raising concerns about their use to guide clinical decision making [12]. Recently, De Sio et al. assessed the reporting quality of randomized and nonrandomized, controlled trials presented in abstract form at the European Association of Urology annual meeting over a 10-year period and determined the impact on subsequent publication. Unfortunately, they found that the reporting quality of European Association of Urology meeting abstracts did not improve in a decade. They stress the importance of improving the quality of abstracts following currently-available guidelines [13].

Pediatric urologists often make substantially different management decisions for similar clinical situations [14–16]. This variation in practice occurs in geographically close communities and is not always explained by differences in patient characteristics or preferences. More importantly, variation in management can be costly and often includes practices that are inconsistent with good evidence about optimal care [17,18].

Pediatric urologists should critically examine published evidence and then adjust their practices accordingly. The purpose of this chapter is to assist them in doing so.

The main elements that will be discussed are: (1) asking focused questions; (2) finding the evidence; (3) critical appraisal of the evidence; and (4) making a decision.

**Asking focused questions**

One of the fundamental skills related to finding the evidence is asking a well-built clinical question. To benefit patients and clinicians, such questions need to be both directly relevant to patients’ problems and phrased in ways that direct your search to relevant and precise answers. In practice, well-built clinical questions usually contain four elements (PICO: Population, Problem, Intervention, Comparison, Outcomes), summarized in Table 3.1. Included are some examples of asking these questions in pediatric urology [19].

By asking a concise and well-formed question it becomes straightforward to combine the terms needed to then query searching services such as PubMed.

**Finding the evidence**

You can now convert your PICO question into search words in a search engine such as PubMed as shown in Table 3.2.

<table>
<thead>
<tr>
<th>PICO</th>
<th>1: Patient or problem</th>
<th>2: Intervention (a cause, prognostic factor, treatment, etc.)</th>
<th>3: Comparison intervention (if necessary)</th>
<th>4: Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example 1</td>
<td>Adolescents diagnosed with varicocele and testicular size discrepancy</td>
<td>Would surgical varicocelectomy</td>
<td>When compared to nonsurgical treatment</td>
<td>Reduce the risk of febrile urinary tract infections</td>
</tr>
<tr>
<td>Example 2</td>
<td>Uncircumcised male infants diagnosed with SFU grade 4 hydronephrosis without vesicoureteral reflux</td>
<td>Would antibiotic prophylaxis</td>
<td>When compared to no antibiotics</td>
<td>Affect future fertility or sperm count</td>
</tr>
</tbody>
</table>

Table 3.1 PICO elements in asking clinical questions.
An analytic study attempts to quantify the relationship between the effect of an intervention or exposure (I) on the outcome (O).

Whether a researcher actively changes the intervention determines if the study is observational or experimental (Figure 3.1).

In the experimental study the researcher manipulates the exposure, such as in randomized controlled trials. If adequately randomized and blinded, these studies have the ability to control for most biases. This, though, depends on the quality of the study, design and implementation. Therefore, not all randomized trials are high quality [12].

In the analytical observational study the researcher simply measures the exposure or treatments of the groups. These include case–control studies, cohort studies, and some population cross-sectional studies. This is the bulk of studies published in the pediatric urological literature.

The type of study can generally be appreciated by asking three questions [21]:

1 What was the aim of the study?
   a To describe a population (PO question) – descriptive.
   b To quantify the relationship between factors – analytic.

2 If analytic, was the intervention randomly allocated:
   a Yes – RCT.
   b No – observational.