Section 1 **Core knowledge**

Chapter 1

Audit

There are various definitions available for audit but one of the most common is 'a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change'. Audit is so ubiquitous in healthcare that it is easy to forget that it is a relatively new innovation. The concept for audit was first mooted in the 1970s. With the publication of the 1989 White Paper 'Working for Patients: Medical Audit Working Paper No. 6', detailed plans for a comprehensive system of medical audit within the internal market were proposed. A massive drive to develop medical audit began. Protected funding was made available to support it. With the advent of clinical governance in the mid 1990s, audit is now firmly established as an integral part of healthcare delivery.

Audit can encompass managerial and financial components of the healthcare delivery process, but the most relevant to clinicians is clinical audit. Clinical audit is essentially a checking process to assess the quality and effectiveness of any aspect of healthcare delivery and making change or improvements where necessary. It is usually described as an audit cycle. The audit cycle encompasses identifying a clinical area or objective to be audited, agreeing the standard or benchmark for the audit (minimum level of acceptable performance), data collection that describes or measures current performance, analysing the results and identifying the areas for change or improvement and, lastly, re-auditing after the change has been implemented. Clinical audit can be retrospective or prospective. Retrospective audit is probably of most use in the event of critical incident (serious untoward incident resulting in severe morbidity or death) or when a complaint or litigation has arisen and a review of practice is required urgently. In the development of any clinical audit programme retrospective audit may have a role but, for audit to contribute meaningfully to improving quality of care, the majority of clinical audit should be prospective. Prospective clinical audit allows for accurate contemporaneous collection of data reflecting current rather than historical practice. Data is therefore more likely to be accurate in volume and detail.

Participation in clinical audit is a mandatory requirement for doctors at all levels. General Medical Council (GMC) recommendations are that all doctors 'must take part in regular and systematic audit' and that individual doctors must 'respond constructively to the outcome of audit' (General Medical Council, 2006).

Advantages of audit

As well as improving the quality of healthcare, clinical audit has other potential benefits:

- Improved multidisciplinary team working
- Improved working environment and greater openness to change

- Provides reassurance to patients and clinical staff that best practice standards are being met
- Can assist with the development of local guidelines or protocols
- Can reduce incidents, complaints and claims.

Choice of clinical audit

The choice of clinical audit should reflect national topics. Recommendations come from the Department of Health and the National Institute for Health and Clinical Excellence (NICE). Many of the Royal Colleges also provide advice on areas that should be audited and in some instances a selection of 'audit recipes' to facilitate audit. In addition, the choice of topics should be based on the traditional criteria of:

- High volume: frequent procedures or many patients or users involved
- High risk: the procedure or intervention may lead to harm to patients or users, staff or the organization
- High profile: causes of concern have already been identified, e.g. complaints and quality incidents
- High cost: activities that are costly in monetary terms or resources.

Clinical audit is a multidisciplinary process and therefore selection of topics should also look at those areas that can maximize the involvement of as many members of the teams delivering care as possible. Other factors that should be considered include:

- Is it practical to undertake the audit and who needs to be involved?
- Is the problem amenable to change?
- Is the subject a priority for the hospital, practice or service?
- Are national standards or recommendations available against which to benchmark?

The re-invigoration of clinical audit

Since 2006, following the Chief Medical Officer's report 'Good Doctors, Safer Patients', there has been a national drive to re-invigorate clinical audit. There are three main groups involved in this drive:

- NICE
- National Clinical Audit Advisory Group (NCAAG): established by the Department of Health to drive the re-invigoration programme and provide a national focus for discussion and advice on matters relating to clinical audit
- Healthcare Quality Improvement Partnership (HQIP): established in April 2008 to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales. It is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices (a coalition of national health and social care organizations).

HQIP has a contract with the Department of Health to manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP). This programme is a set of centrally funded national projects that use a common format to help individual trusts to collect audit data. The collected data is analysed centrally and trusts can then use this data to

help identify necessary improvements for patients. A wide range of medical, surgical and mental health conditions is already included in this programme; most notably the Paediatric Intensive Care Audit Network (PICANet) and the National Joint Registry (NJR).

Reference and further reading

http://www.hqip.org.uk (accessed 6 January 2011).

GMC (2006). *Guidance for Doctors. Good Medical Practice*. London: GMC.

Section 1 Core knowledge

Chapter 2

Care bundles

In 2004 the Modernisation Agency published '10 High Impact Changes for Service Improvement and Delivery'. By working with many clinical teams nationally, these 10 high impact changes for the delivery of healthcare were identified. The implementation of care bundles in the NHS was high impact change no. 6.

A 'care bundle' is a collection of interventions that, when implemented together, will achieve significantly better outcomes for patients, such as reduced mortality and morbidity and improved cost-effectiveness. They are used in specific clinical situations and aim to improve the consistency with which healthcare is delivered.

The features of a care bundle are as follows:

- All steps are necessary and each step must be performed to achieve success
- Each step is evidence-based (usually level 1 evidence)
- A bundle should include 3–5 steps. The chances of the bundle being carried out in full and being successful reduce with every step that is added
- The bundle must be completed in the same time and place continuum
- Each step of the bundle should be clearcut, being completed in a yes/no fashion
- The care bundle should be easily accessible by clinicians.

These features make care bundles distinct from checklists and guidelines.

Benefits of care bundles

The benefits of using care bundles are not only confined to patient outcomes. There are also benefits in terms of the following:

- **Service delivery**
  - Improved clinical governance procedures
  - Improved equity of care between patients
  - Faster delivery of care because of explicit agreement on therapies
  - Possibility of decreased length of stay
  - Possibility of decreased cost.
- **Patient experience**
  - Fewer complications
  - Fewer complaints
  - Fewer omissions of indicated therapy
  - Reduction in unnecessary length of stay and other risks of hospitalization.

- **Clinical outcomes**
  - Reduced morbidity
  - Improved outcomes if therapy is given more regularly
  - Treatment is based on agreed, evidence-based guidelines
  - Fewer adverse events
  - Fewer complications as prophylaxis regimens are administered more regularly
  - Links between outcomes and processes more evident.
- **Benefits for staff**
  - Clinical and managerial staff aligned to provide the best care for patients
  - A systematic approach to improve the delivery of healthcare is encouraged
  - Creative discussion between staff leads to new insights on care processes
  - Improved relationships between staff by stimulating dialogue.

(Source: http://www.ogc.gov.uk/documents/Health_High_Impact_Changes.pdf (accessed 6 January 2011)).

The use of care bundles originated from work in intensive care units in the USA. The advent of the International Surviving Sepsis campaign further popularized their use. This was a joint collaboration between the European Society of Intensive Care Medicine, the International Sepsis Forum and the Society of Critical Care Medicine to improve care and reduce the numbers of deaths worldwide from sepsis; the management principles underlying this campaign included care delivered as bundles. More recently a major UK study aimed to look at the use of care bundles outside of the intensive care setting (for diseases such as diarrhoea and vomiting, stroke, chronic obstructive pulmonary disease and heart failure). This study demonstrated a reduction in hospital standardized mortality rate consistent with other studies on the subject. The authors make the point that it is impossible to assume a causal relationship between introducing the targeted care bundles and the reduced mortality. However, the significant reduction in mortality occurred only at the site where the care bundles were predominantly used.

Further reading

Robb, E., Jarman, B., Suntharalingam, G. *et al.* (2010). Using care bundles to reduce in-hospital mortality: quantitative survey. *British Medical Journal*, **340**: c1234.

Section 1 Core knowledge

Chapter 3

Checklists

In the past 10 years there has been a huge increase in interest in ways to improve patient safety and reduce iatrogenic injury. The development of checklists in medicine is one such way. In the USA in 1999 the Institute of Medicine (a non-governmental organization whose purpose is to provide national advice on issues relating to health and medicine) published 'To Err is Human: Building a Safer Health System'. This report looked at medical errors in the USA. This was followed in 2001 by 'Crossing the Quality Chasm', which investigated further elements of the 1999 report. These reports were the inspiration for the widely publicized '100,000 lives campaign' in the USA, aimed at reducing hospital morbidity and mortality in a number of key areas, e.g. the prevention of central line infections and surgical site infections.

Enthusiasm for checklists grew following the publication of the 'Michigan' or 'Keystone' paper. Peter Pronovost, an American intensivist at Johns Hopkins, devised a simple five-point checklist to accompany central line cannulation in an intensive care unit. He created the list after extensive literature review and he chose for the checklist the five points that were most likely to be effective in reducing line-associated infection. The checklist was therefore a standardized, evidenced-based tool. The use of the checklist was associated with a dramatic reduction in infection in the intensive care unit.

A checklist describes the key steps that must be carried out to ensure a procedure is completed safely. They can be procedure-specific for use by an individual, e.g. insertion of a central line, or process-specific for use by a team, e.g. the surgical safety checklist. They work by improving recall, and it has been suggested that the 'Hawthorne effect' (a tendency to perform better when an individual is being observed) may also play a part in their success.

The use of checklists in medicine has gathered momentum with the advent of the World Health Organization's second Global Patient Safety Challenge, 'Safe Surgery Saves Lives Campaign', launched in June 2008 to reduce the number of surgical deaths worldwide. The initiative has been led in the UK by the National Patient Safety Agency (NPSA). Probably the most widely used clinical checklist in the UK is the 'surgical safety checklist'. Since February 2010 it has been mandatory that a 'surgical safety checklist' be used for all surgical procedures. The aims of the surgical safety checklist include:

- Improved anaesthetic safety
- Reduced occurrence of wrong-site surgery
- Avoidance of surgical site infections
- Improved communication among the surgical team.

The surgical safety checklist comprises three components: sign in, to be completed before induction of anaesthesia; time out, completed before commencement of surgery; and sign out, completed before the patient leaves the operating theatre. Modified checklists, available on the NPSA website, have been produced specifically for radiological procedures, cataract surgery and obstetrics.

A study from the Netherlands recently published in the *New England Journal of Medicine* confirms that surgical safety checklists are effective in reducing surgical morbidity and mortality (de Vries *et al.*, 2010).

Checklists clearly have a role in improving patient safety; however, the provision of a simple tick box list is not enough; the use of checklists needs to be accompanied by a cultural change in that particular healthcare setting. Also, healthcare professionals need to be motivated to take part, e.g. when utilizing the surgical safety checklist any member of the theatre team can lead the checklist, and all members of the team need to feel empowered enough to challenge others. Audit is also an integral part of the process when using a checklist to ensure compliance and effectiveness.

Checklists may not be suitable for use in all aspects of medicine and even when they have proved to be useful in specific situations they may need to be modified in some circumstances, e.g. the use of a surgical safety checklist should not cause delay in emergency surgery.

Checklists clearly have an important role to play in patient safety but they are not a panacea. Peter Pronovost has warned of the risk of 'checklist overload', the creation of too many checklists, particularly if there is no clear benefit to patients. There is also the risk that checklists may lead to complacency and a false sense of security.

References and further reading

Bosk, C.L., Dixon-Woods, M., Goeschel, C.A. and Pronovost, P.J. (2009). Reality check for checklists. *Lancet*, **374**: 444–5.

De Vries, E.N., Prins, H.A., Crolla, R.M.P.H. *et al.* (2010). Effect of a comprehensive surgical safety system on patient outcomes. *New England Journal of Medicine*, **363**: 1928–37.

Haynes, A.B., Weiser, T.G., Berry, W.R. *et al.* (2009). A surgical safety checklist to reduce morbidity and mortality in a global population. (Safe Surgery Saves Lives Study Group.) *New England Journal of Medicine*, **360**: 491–9.

Section 1 Core knowledge

Chapter 4

Clinical dashboards

A clinical dashboard is a way of presenting information and data, and tracking changes about various aspects of healthcare delivery. The dashboard can be presented with visual displays, pie charts, etc., or simple Excel spreadsheets. The aims of using a dashboard are several: comparing local activity to national targets or standards, clinical governance and risk management.

The term dashboard comes from the analogy with the information provided on a car dashboard. On a car dashboard, red lights flash when there is cause for concern, so the clinical dashboard employs the same system. Thresholds are set using local or national figures where available. Areas where there is no cause for concern are marked as green, where action is required to improve or prevent further deterioration they are marked as amber, and areas that require urgent intervention are marked as red.

The idea evolved from its use in obstetrics, and it is now a Royal College of Obstetricians and Gynaecologists' (RCOG) recommendation. The RCOG suggest four categories where data may be collected:

- Clinical activity
- Workforce
- Clinical outcomes
- Risk incidents/complaints or patient satisfaction surveys.

The development of clinical dashboards was a key recommendation from both Lord Darzi's major review of the NHS ('Next Stage Review'), published in June 2008, and the Health Informatics Review, published in July 2008.

Stages of development of clinical dashboards

A prototype phase began in April 2008 and aimed to provide 'proof of concept'. Three NHS organizations worked with NHS Connecting for Health to develop the first clinical dashboard 'prototypes'. The organizations involved were:

- Nottingham University Hospital (Urology dashboard)
- Homerton University Foundation Trust (A&E dashboard)
- Bolton Primary Care Trust (PCT) (GP practice and primary care dashboard).

Following this, a pilot phase was implemented in November 2009, which aimed to evaluate the potential benefits of using a clinical dashboard within a broader range of clinical settings across the UK. Across the 10 strategic health authorities in England, 24 dashboards were developed in hospital-based settings, general practice and other community-based clinical

teams. During this phase the core technical infrastructure necessary for implementation of dashboards was developed and collated into a 'toolkit' to facilitate a planned national roll-out.

Benefits of using a clinical dashboard

The pilot phase of development established that with well motivated local clinical leadership, dashboards can help staff to deliver accurate, contemporaneous information about healthcare delivery that can improve the quality of healthcare.

The benefits of using a clinical dashboard can be summarized as follows:

- Better information for clinical teams, presented in an easy-to-understand format with high visual impact
- Utilization of multiple sources of existing data, providing clinical information which is relevant across a multidisciplinary team
- Information provided in 'real time', facilitating immediate targeted decisions to improve patient care and avoiding delays by data cleansing processes
- Improved data quality through immediate, day-to-day visualization of data reinforces 'capture once, use many times' behaviours.

Challenges of a clinical dashboard

Clinical dashboards have proved to be an effective tool in the clinical governance process. However, the development of a clinical dashboard in any setting requires significant input to ensure the accuracy and quality of the information provided. The pilot project established that dashboards are not effective without clinical and executive level support or when data used to supply the dashboards was poor. Significant investment is required to achieve this. Therefore it has been suggested that each organization makes its own decision as to whether clinical dashboards are right for them and that, if they decide to proceed, local formal review is required to elucidate which clinical areas should be targeted.

Further reading

http://www.connectingforhealth.nhs.uk/systemsandservices/clindash/benefits (accessed 13 December 2010)

Section 1 Core knowledge

Chapter 5

Complaints procedure

A complaint can be defined as an expression of dissatisfaction requiring a response. Complaints are widespread in the health service. They can come from patients, relatives, carers or other healthcare workers.

The new shared complaints procedure for both health and social care came into force on 1 April 2009. It is structured around three main principles: listening, responding and improving. The premise for the reform was to give organizations the flexibility they need to deal with complaints more effectively and also encourage a culture that seeks and uses people's experiences to make services effective, personal and safe. This new complaints procedure represents a significant attempt to improve the management of patient, carer and public concerns in a complainant-centred manner.

The NHS Constitution

The NHS Constitution was published in January 2009 and states that every patient and carer has the right to:

- Have any complaint they make about NHS services dealt with efficiently and be properly investigated
- Know the outcome of any investigation into their complaint
- Take their complaint to the independent health service ombudsman if they are not satisfied with the way their complaint has been dealt with by the NHS
- Make a claim for judicial review if they think they have been directly affected by an unlawful act or decision by an NHS body
- Compensation where they have been harmed by negligent treatment.

The Health Act 2009 places a duty on NHS organizations to have regard to the NHS Constitution.

What do patients complain about?

Common reasons for complaints:

- Long waits: for appointments, investigations, therapies and operations
- Delays in treatment
- Cancellation of appointments and operations
- Poor or no communication
- Staff attitudes and bedside manners
- Environment: cleanliness, parking charges, food