Introduction

Healthcare and all aspects of surgery are dependent upon practices, pathways, teams, and individuals acting within and between systems in a complex organization. Improvements in the quality of healthcare, therefore, are reliant upon improving the systems within which teams and individuals work. Changing complex systems, that have dependent and interdependent components, is not easy and requires an understanding of the systems as well as the use of tried and tested methodologies for improvement. During the process of improvement there is a need for an iterative approach with careful attention and continuous measurements of performance. This topic area has expanded over the last few years and it is designed to complement research and training to establish real and sustainable changes and improvements in surgery. In this chapter a basic understanding of the terms and concepts that underpin quality improvement are provided and the key methodologies are described, and illustrated with real life examples and case studies relevant to surgical care.

Quality improvement

Definitions of quality

Over the last few years, terms such as ‘quality’, ‘safety’, and ‘human factors’ have become common parlance in medical practice. The official definitions of these are listed in Box 10.2.1. In essence, quality is simply how good we are at healthcare and it encompasses several domains: safety (avoiding harm), effectiveness (treating medical conditions), patient experience, efficiency (reducing cost and waste), and equity. These terms may also be worded from the patients’ perspective, and then quality becomes ‘making me better’ (effectiveness), ‘not harming me while you make me better’ (safety), ‘making it as pleasant as it can be for me’ (patient experience), ‘doing it for the least cost in terms of money and resources’ (efficiency), and ‘treating me the same regardless of my race, wealth, religion or any other personal or social factors’ (equity).

Historically, medicine has focused primarily on effectiveness using evidence-based medicine to find treatments that improve outcome from disease, but this is only part of the picture.

Box 10.2.1 Definitions of key terms in quality improvement

**Quality** is achieving the highest standard of care in four main areas; safety, effectiveness, efficiency and patient experience.¹
**Patient safety** is concerned with harm done to patients during treatment. This harm can either be from omission (a patient getting a pulmonary embolus from not receiving venous thromboembolism prophylaxis) or commission (development of a central line related infection).

**Effectiveness** is providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.²

**Efficiency** is avoiding waste, including waste of equipment, supplies, ideas, and energy.²

**Patient experience** is providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions. Care must also be delivered in a timely fashion.

**Quality improvement** is the process of improving all aspects of care given to patients. The three main areas are; education and training, research, and service improvement.

**Service improvement** (which may be used synonymously with quality improvement) is the process of systematically improving the standard of healthcare, within the four domains (patient experience, effectiveness, efficiency, and safety).

**Clinical audit** is the systematic and critical analysis of the quality of clinical care, including the procedures for the diagnosis, treatment and care, the associated use of resources and the resulting outcome and quality of life for the patient.³ Practically, this has been simplified to the audit cycle (see Figure 10.2.3).

**Human factors** refers to errors relating to non-technical skills. Technical skills are knowledge and practical skills. Non-technical skills are categorized as; communication, leadership, team work, decision making, situational awareness and coping with stress and fatigue.⁴

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**Quality improvement and clinical audit**

Knowing what quality really is, clarifies the definition of quality improvement. In its broadest sense quality is improving all aspects of care. Improving care does not happen by chance; it needs not only dedication, but crucially also a methodology that works. Clinical audit is an example of a quality improvement methodology and involves data collection of performance against an established standard, performing an intervention to improve performance, and then re-auditing the data to assess the effect of the intervention. While clinical audit has led to some important developments over the past two decades, there are also areas of healthcare where audit has not been sufficient to lead to real and sustained changes. More recently developed methods of quality
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improvement, including ‘the model of improvement’, have been used successfully to transform healthcare systems and other industries. The three stages of ‘the model for improvement’ will be discussed in the model for improvement section, illustrating these with clinical examples.

Patient safety

The chasm between the best possible healthcare in the National Health Service (NHS) (which may be defined in the hypothetical setting as the application of the best available evidence, by the perfectly trained clinical team functioning within a seamless system for 100% of the time) and what actually happens in practice in hospitals and within the NHS is enormous. This gap is well recognized and although hospitals and clinical teams are attempting to reduce it, closing the chasm and increasing safety is critical. One method, initiated in 2001, was the creation of the NHS National Patient Safety Agency, which is a body that investigates safety incidents within healthcare and proposes solutions to improve safety. This is essential as repeated studies show that 10–20% of patients admitted to hospital experience errors in their care that can result in harm (i.e. an adverse event), and of those, up to a further 10% may die from such errors. In this setting, an adverse event is defined as an unintended injury that results in temporary or permanent disability, death, or prolonged hospital stay that was caused by the system of healthcare rather than the patient’s disease. This statistic holds true for surgery as well. A study of ten surgical units in The Netherlands documented some 881 unintended events over a 3 month period. The consequences of the events were analysed and these included suboptimal care, inconveniences to patients, extra interventions, prolonged hospital stays, and physical and mental injury.

The surgical safety checklist

The translation of the risk of experiencing an adverse event while in hospital to population data demonstrates the scale of the problem. In the UK, there are 3 million hospital admissions per year, meaning that approximately 300,000 patients may suffer unintended events each year as a result of error, leading to significant morbidity and mortality. The challenge to staff within the health service, therefore, is to consider how these adverse events can be prevented and to take action to change systems to improve safety. One of the best examples of a system change that can reduce adverse events in surgery is the introduction of the surgical safety checklist. This demonstrated a 36% reduction in mortality following its introduction (Box 10.2.2).

Box 10.2.2 The surgical safety checklist
In a landmark study, Atul Gawande and colleagues trialled a simple 20-point checklist to be used perioperatively as well as preoperative briefings and training for staff on the use of these tools. The study was conducted in eight hospitals in eight cities, four in the developed world and four in the developing world. Over 7000 operations were observed, half using the checklist and the other half as a control. In the group where the checklist was being used the reduction in mortality was 46% and in morbidity was 36%. Both of these were highly statistically significant results. As the authors point out in their discussion, the exact impact of the checklist is difficult to untangle as there were almost certainly other factors that influenced the outcome. First, the use of preoperative and postoperative briefings have been shown to improve communication and improve efficiency and, in addition, the findings may have been subject to the Hawthorne effect, an improvement in performance due to subject’s knowledge of being observed. Despite these potential pitfalls the magnitude of the effect cannot be ignored.


**Human factors**

**Adverse events**

When surgical adverse events are analysed in detail, the factors contributing to them are overwhelmingly related to human error (72.7%), followed by systematic organizational failings (16.1%); technical errors are the smallest group (5.7%). The terms used to encompass human error within an organizational setting are nowadays referred to as ‘human factors’ or ‘non-technical skills’, and these include communication, leadership, team work, decision making, situational awareness, and coping with stress and fatigue. Recognition of the need for excellence in human (non-technical) factors among surgeons, who traditionally focus on the acquisition of technical skills, is a significant advance in healthcare and in the attempt to reduce human error and improve healthcare systems. The widespread use of methods that mitigate human factors error (such as the surgical checklist) have huge potential for reducing adverse events in surgery.
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Communication

Effective communication underpins the other human factor domains and is fundamental to workplace safety and efficiency. There are checklists or aide-mémoires designed to improve and formalize communication within clinical teams with the aim of maximizing the accuracy of information transfer. An example of this is the situation, background, assessment, and recommendation (SBAR) communication tool (Box 10.2.3).

While this tool was developed in the aviation industry, and used within the military, it has now been adapted for healthcare where the effective (or ineffective) use of a structured communication can be a matter of life and death.

Box 10.2.3 Situation, background, assessment, and recommendation—the communication tool recommended to improve hand over in clinical teams

The SBAR (situation, background, assessment, and recommendation) tool was developed to formalize communications and help both the sender and the receiver to transmit meaning accurately. It consists of four parts.

**S—Situation:** A brief outline of the current state of the patient ('Mrs X is hypotensive and tachycardic')

**B—Background:** What has happened running up to this moment ('Mrs X is previously fit and well and had a laparoscopic cholecystectomy this morning')

**A—Assessment:** The state of play now. ('Her respiratory rate is 35, blood pressure 90/70 and heart rate is 130. I think she is in class III hypovolaemic shock, she has received 2 litres of crystalloid')

**R—Recommendation:** What the sender wants the receiver to do. ('Can you please come to ward 31 immediately as I think she needs to go back to theatre')

(N.B In Australia it is called, i-SBAR, the first i standing for introducing yourself.)

Adapted from the SBAR Toolkit, available from the Institute for Healthcare Improvement at: http://www.ihi.org/knowledge/Pages/Tools/SBARToolkit.aspx. The SBAR Toolkit was originally developed by Michael Leonard, Doug Bonacum, and Suzanne Graham at Kaiser Permanente of Colorado.

Situational awareness and decision making
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Situational awareness refers to the human facet of simply being aware and knowing what is going on around you. While this may seem very obvious, without situational awareness in surgery, serious mistakes may occur. One such example is the loss of situational awareness in theatre in a unilateral operation leading to wrong-side surgery.\(^{13}\) Decision making refers to the ability to process the available information and make an informed choice based on this. In reality, decision making is a continuous process of monitoring the environment, re-evaluating, and then making the appropriate decision.\(^{4}\) A classic medical example of where decision making goes wrong is ‘tunnel vision’. A clinician makes a diagnosis and sticks to that diagnosis, despite evidence (from tests and investigations) to the contrary. This can lead to major error, and yet if iterative processes and team working were in place, it is possible that such problems could be avoided.

**Stress and fatigue**

Coping with stress at work involves understanding that emergency situations affect our ability to function and take appropriate decisions. The development and use of systems such as the surgical safety checklist may mitigate against flawed thinking when under pressure by ensuring that basic standards of care are adhered to and that the whole team is involved in achieving the standards. As healthcare operates 24/7, all healthcare workers will at some point experience fatigue at work. This needs to be recognized and minimized as much as possible and, in addition to using safe systems, the use of safe and ‘humane’ shift patterns of work are essential to reduce the potential for harm that fatigue inevitably produces in individuals and teams.

**The model for improvement**

**The aim**

One of the most widely used methods for implementing change in healthcare, is the ‘model for improvement’.\(^ {14,15}\) This consists of three simple steps that are applied to achieve change in a system. The first is to be clear about the aim of the project, the second is to measure the process and outcomes, and finally there is the need to test for change (Figure \textbf{10.2.1}).\(^ {15}\) Ensuring that the aim of any project is clear is critical for it to be achieved. An aim should be specific in content and nature and also it should be realistic. For example, a clear aim will ask exactly what and where is the target of the project, for example, ‘what’ (how many patients have documented venous thrombo-embolism risk assessments) and ‘where’ (on the surgical ward 7B).
Measurement

Measurement is crucial to quality improvement and it is essential to measure the effects of implemented changes. The main measurements that can be made include measures of process, outcomes and of balance.

Process measures

Process measures (like the quality of weekend handovers or discharge summaries) may be used to assess part of the overall system that delivers care and, as such, they are not measures of clinical outcomes. Process measures, however, will be linked to and often associated with clinical outcomes, and by improving them it would be expected that a clinical outcome would improve. Although it may be hard to prove the association between an improvement in a process measure and clinical outcome, the links will usually be very plausible. For example, a better communicated handover between clinical teams will result in better patient care and, therefore, a reduced number of adverse events (clinical outcomes). This is plausible and may be explained because of accurate and timely exchange of information between key personnel at the hand over.

Outcome measures
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There are many different outcomes that can be measured in healthcare, including clinical outcomes (e.g. rates of wound infection), patient-reported outcomes (outcomes described by patients themselves such as walking distance after a total knee replacement or patient experience and satisfaction with healthcare), cost-related outcomes (e.g. cost of improved life year gained), and observer-assessed outcomes (e.g. symptoms assessed by doctors). Selection of the right measures to assess any changes is often difficult and it is likely that a combination of outcome measures will be used to complement measures of process and balance. The chapter on research includes a detailed summary of each of these types of outcomes. Careful and accurate measurement will reveal the underlying complexity of a system and allow a deeper understanding of it and further the goal of improving it. As Peter Drucker said ‘if you can’t measure it, you can’t manage it’.¹⁶

Balancing measures

Balancing measures attempt to quantify the undesired or the side effects of any change. They are a crucial, but often forgotten, part of the programmes that implement change. Measures of the undesired effects provide data to understand the balance of the overall impact of the intervention. In the handover example (Box 10.2.4) between doctors using weekend handover stickers, a measure of balance would be time lost completing the handover, which may erode into time to complete technical tasks. An often cited example of a major change in the NHS that did not fully balance the impact of the change was the introduction of the 4-hour wait target in emergency departments in 2003.¹⁷ Although within 4 years the target was met successfully (98.5% of patients in the UK were seen within 4 hours in 2007), there was a lack of consideration of some of the unintended consequences and side effects of achieving this. For example, sick patients were removed from the safe environment of the emergency department to wards that were unable to provide the acute care.¹⁸¹⁹ As balancing measures were not collected it is difficult to truthfully comment on the success of the programme.

Box 10.2.4 Improving weekend handover: a junior doctor-led quality improvement project

The aim: what are we trying to accomplish

A group of F1 doctors realized that the weekend handover at their trust was not as good as it could be. When they were doing the weekend on call they were frustrated that the key information regarding patients had not been passed to them, which meant they were often reacting to events rather than preventing them. At the
same time as they were conceiving their plan, a significant amount of media attention was being paid to a Dr Foster report that highlighted a significantly higher mortality of patients at weekends and specifically highlighted poor handover as one of the causes.

They decided to try and improve weekend handover, and they used the model for improvement to help them. The aim was to ensure that 95% of surgical inpatients on two wards had a documented and adequate weekend handover plan in the patient’s notes.

Measurement: how do we know if our changes are an improvement?

Often this is one of the harder stages of an improvement project. The area being measured (the ‘metric’) can sometimes be hard to define, but in this case it was simple. On a Monday morning, the group would check the notes of all the patients on the ward. Clear definitions are important to allow the data to be consistent. In this case, the only patients included were ones that had been admitted before 5pm on the Friday and had stayed in until Monday. The notes were quickly reviewed to see if an adequate weekend handover had been documented (adequate was defined as a clear diagnosis and management plan as well as whether the patient needed daily review). This allowed one metric per week to be collected and plotted on a run chart (Figure 10.2.2). Six data points were collected before any changes were implemented.

Tests of change: the plan-do-act-study (PDSA) cycle

Once measurement was securely in place, the F1 doctors started devising their first test of change. They knew of a group in another hospital who had done a similar project successfully using a sticker that was filled in and then placed in the notes. They contacted the other team and their first PDSA used the sticker from the other hospital. As a result of local variations in practice, several modifications were made to the sticker (PDSA cycles), before the final one was agreed. Further PDSA cycles had to be conducted to work out how to get the stickers to the F1s, so they had them on Friday. For example, one PDSA was to give the stickers out during the F1 teaching at lunchtime. This sounded like a good idea, but in fact several teams wanted to fill most of the stickers out on the morning ward round, so other plans had to be made. The results in the run chart speak for themselves. After a series of PDSAs (marked with red arrows but in practice there were many more), the percentage of adequate weekend plans in the notes went from the baseline of 30% up to 95%. When analysed using a statistical process chart the change was significant.
Measurement also acts to provide continuity to the project. In the example (Figure 10.2.2), data regarding improving the handover between F1 doctors was collected weekly and, although it did not take long to collect the data, the very action of data collection brought the project back to the attention of the F1s. During periods when no changes were being made, the project’s drumbeat was the data collection.

Fig. 10.2.2
Run chart showing % of weekend plans documented in the notes. The red arrows refer to the plan–do–study–act cycles. The x-axis is the time period. Data was collected on a weekly basis for the 4 months the project was run.

The plan–do–study–act cycle

The plan–do–study–act (PDSA) is the ‘doing’ bit of the model for improvement. It is as simple and intuitive as it sounds. Once measurement is in place and a suitable number of baseline points have been collected and examined, then it is possible to make system changes to improve practice. The PDSA cycle is initially done on a very small scale. For example, in the weekend handover project the initial test of change was to try out one sticker before a weekend with just one F1 (plan and do), then this F1 could feedback on the sticker (study) that would allow change and modification (act). The updated sticker was then re-tested on the same scale again by the F1 until s/he was happy with it. The next step was to try it on three F1s using the same feedback processes until they all agreed it was working, and then finally it was tested on a larger group of five F1s on two wards. This iterative process is crucial to quality improvement and an essential ingredient to develop and modify a solution to a problem before examining its impact on a large scale (i.e. start the tests small and scale them up when they are working). Multiple PDSA cycles are often needed to generate improvement (Figure 10.2.2).

The model for improvement is a tried and tested method for improving frontline care.20,21,22 The iterative approach with multiple small tests of change and continuous data collection contrasts starkly to clinical audit where data is collected only twice and only one intervention is attempted.
Quality improvement

Clinical audit

In 1989, the Department of Health highlighted the need for clinical audit in the white paper ‘Working for Patients’. It defined clinical audit as the ‘systematic and critical analysis of the quality of clinical care, including the procedures for the diagnosis, treatment and care, the associated use of resources and the resulting outcome and quality of life for the patient.’ This relatively sophisticated and complicated description has been simplified to the idea of the audit cycle (Figure 10.2.3). In practice, this means identifying a problem for which standards exist, collecting a large amount of data associated with it, performing an intervention, and then re-collecting the data at a later date (to close the audit loop).

Fig. 10.2.3
The audit cycle.

Although the use of the audit process has had some major impact and successes over the past two decades, particularly with nationally led projects, many aspects of it have also had a chequered history, particularly small-scale projects that are led by junior doctors. Retrospective analysis of audit (an audit of audits) has shown that only 5% resulted in any significant and lasting improvement. In addition, audit is not popular with junior doctors; 25% feel a negative personnel benefit of performing audit and a further 27% felt it was a waste of time. Also, it is rarely carried out properly, which is probably a major contributing factor to the lack of belief by junior staff in the process. There is also evidence to show that the audit loop is only ever completed in 20% of cases.

There are a variety of reasons why clinical audit may fail. Many clinical audits are done as a ‘tick box’ exercise, with little understanding of why the audit is being carried out. Large amounts of time are needed to extract meaningful data from notes and written records; this makes completion of the audit cycle difficult. However, the most significant problem is the lack of structure and support the clinicians running the audit have which limits their ability to do it properly and to use the data afterwards to make meaningful changes. Further to the above procedural problems, with audit there is a methodological flaw when
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looking at performance that only collects data on two occasions. This method is occasionally used in research as well where it is called an interrupted time series analysis. The two graphs in Figure 10.2.4 describe the potential inaccuracy associated with this method. Large grouped collections of data can hide real trends that can go against the conclusion drawn from looking at pooled data. Although the example shown is extreme, it would seem sensible to always display data over time to avoid this potential error.

Fig. 10.2.4
The danger of isolated interval data.

Conclusion

Recent recognition of the number and type of avoidable errors and unwanted events within healthcare has highlighted the need to better understand healthcare systems and how care is delivered. Methods to improve the quality of health systems differ from the traditional scientific ways of generating evidence, and require the consideration of non-technical skills as well as technical factors. The whole process of quality improvement, however, is not a separate part of healthcare and it runs through every aspect and involves every member of the healthcare team. Indeed, both undergraduate and postgraduate curricula require training in these methods and factors. It is anticipated that as healthcare professionals increase their understanding of these methods and skills and appreciate the wider context within which technical skills function, the number of unwanted adverse events will decrease, and safety increase. Clinical audit has played a part in understanding variation within clinical practice, but it seems the newer methodologies such as the model for improvement will become increasingly important in the transformation of healthcare. The chasm between the best possible care and what is currently provided to patients will be bridged by frontline clinicians working to improve the systems in which they work.

References


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