Getting started with the model for improvement: introduction and understanding variation

Although the case for quality in hospitals is compelling, doctors are often uncertain how to achieve it. This article forms the first part of a series providing practical guidance on getting started with a first quality improvement project.

Introduction

The case for ensuring quality in health care is evident, but practical steps necessary to achieve it may not be. Several frameworks to aid quality improvement are widely used in this and other industries. This series describes one approach, developed within a health-care institution, which is applicable to any quality improvement endeavour (Britto et al, 2006). The methodology is based on the work of W Edwards Deming, an American engineer and statistician whose techniques proved transformative to Japanese manufacturing industry recovering after World War II. The approach pioneered by Deming has firm foundations in engineering, statistics and psychology.

Deming emphasizes that would-be improvers must have both quality improvement skills and expert subject domain knowledge. If, as Batalden and Davidoff (2007) have argued, all members of the health-care team have a duty to undertake quality improvement, all need quality improvement skills too. This series provides doctors with enough quality improvement know-how to lead a team to the successful conclusion of their first project.

This first article introduces the model for improvement, then considers how to set an aim for a project and also how to chart progress towards this. The second article looks at design of interventions and at the processes of iterative testing to determine if each intervention does indeed move the project towards its goal. In the final part, issues of psychology are discussed, before a final section on next steps to consider after successfully completing a first project. The *Case study* outlines a fictional quality improvement project, which will be continued throughout the series to illustrate the concepts described in each part.

When getting started in quality improvement, a supportive infrastructure within the institution is of considerable benefit (Mandel et al, 2009). If available, insight from an experienced quality improvement coach or consultant at the outset helps to set the project on the right lines. Aspects likely to benefit from such wisdom include setting a project's scope, goals and measures, drawing control charts, and team composition. If quality improvement training sessions are offered to employees, these may be invaluable, not least by creating an opportunity for enthusiasts from disparate backgrounds to meet and share ideas. If such support is not available, try to discuss the project at an early stage with a colleague who has quality improvement experience.

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Quality improvement case study

In a recent inspection by regulators, St Elsewhere University Hospital NHS Foundation Trust was noted to have poor outcomes for heart disease patients. The board makes improvement in this field a strategic priority, and a senior consultant cardiologist is tasked with the problem.

The cardiologist understands that the overall objective is to improve cardiac care, but believes this aim is too ill-defined to direct a project. In consultation with the Trust executive and senior clinical leaders, she decides to focus on myocardial infarction, a common clinical issue. Her team asks a question: what outcome is most important to patients and their families after myocardial infarction? All agree survival is key. They discuss the most appropriate measure to guide the project. While some argue that mortality at 12 months post-myocardial infarction is most meaningful, this measure is impractical since many patients are not followed up in their clinic this far out. Indeed, some will be lost to follow up much earlier, including the sickest who are referred out for cardiac surgery.

The team appreciates that post-myocardial infarction care is a well-researched field with many therapies proven in large, randomized controlled trials. All are unanimous that patient- and family-perceived outcomes will be improved by reliably offering a group of evidence-based interventions. The bundle could include early revascularization and particular drugs. The easier-to-measure process measure of bundle compliance is chosen over the outcome of mortality. The team believes that the hospital already does pretty well, but appreciates that some components get overlooked occasionally.

The key project control chart is created. On the vertical axis is plotted the percentage of patients receiving all appropriate therapies. Weeks are marked off on the horizontal axis. A retrospective audit yields 12 months of data to set a baseline. The team are disappointed that only 30% of cases have full bundle compliance currently. The team leader is relieved, however, that early revascularization rates are already excellent thanks to the Trust's new intervention suite. She resolves to keep watch on these rates as a balancing measure, but will not include angioplasty in the project. The team has been warned to contain costs, but the drugs needed are relatively inexpensive. The project's specific aim is therefore set as:

'To increase the proportion of troponin-positive patients receiving all of anti-platelet medications, beta-blocker, statin and angiotensin-converting enzyme inhibitor (if indicated) at first clinic follow-up, to greater than 90% by June 2013.'

As the current performance is rather poor on the team's chosen all-or-none score, they agree to keep charts for each key bundle component separately too.

To be continued

Even if a hospital has no track record with quality improvement, there are many external resources, notably the extensive websites of both the Institute for Healthcare Improvement (www.ihi.org) and the Institute of Medicine (www.iom.edu).

The model for improvement

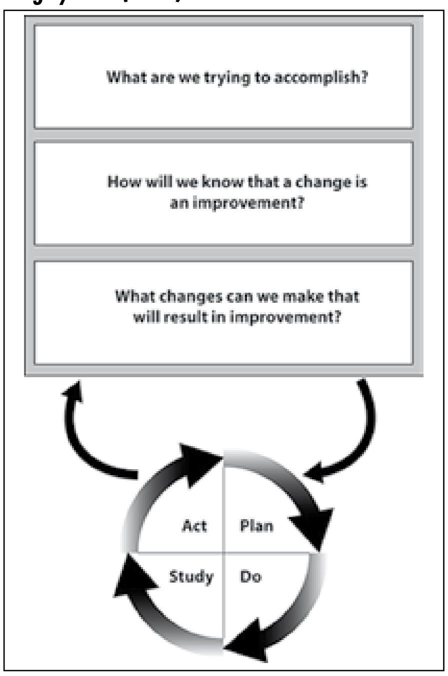
Every system is perfectly designed to achieve the results it achieves (Berwick, 1996). The corollary of this statement is the basis for quality improvement: to achieve improvement, the system needs to be changed; increased effort or attention alone will not achieve substantial or lasting results.

The model for improvement is a construct to guide thinking in quality improvement efforts (*Figure 1*; Langley et al, 1992). The model focuses the minds of 'improvers' on those elements that are vital to success. Three questions are asked:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What changes can we make that will result in an improvement?

Fundamental to the model is the concept of 'small tests of change', meaning an iterative process of trying out interventions which perturb the system. For example, in a project to reduce 'no shows' at an outpatient clinic, you could try reminding patients of their appointment by telephoning 1 day beforehand. As discussed in the next article, these tests do not always have the expected results and, for this reason, are initially put into place on only a temporary basis. In this example, perhaps patients hate the disturbance of being telephoned. Failures should not dishearten, however, since they represent opportunities for an open-minded quality improvement team to learn more about the system on which their efforts are focused. The discipline of the 'plan-do-study-act' (PDSA) cycle ensures that these opportunities are maximized (Shewhart, 1931).

Figure 1. The model for improvement. After Langley et al (1992).



Setting the aims of a quality improvement project

What does 'quality' mean?

While it is inarguable that health care should be 'excellent', it can be difficult to define exactly what this means in practice. This conundrum relates to the first question posed by the model for improvement: what are we trying to accomplish? In the case of bowel surgery, we could be most interested in surgical site infection, hospital length of stay or return of bowel function. If we want to improve quality within a particular domain, it is vital that we can quantify it (e.g. infection rate, hospital stay length or time to first bowel transit).

Quality in health care is heavily dependent on who is judging, but the only truly important observer is the patient. Where disagreement or uncertainty reign, this perspective enlightens. Including patient representatives within the project team is the best way to achieve this. The chosen target for quality improvement may not be the same in every hospital. Taking the above example further, perhaps one colorectal unit has a long length of stay after bowel surgery, while another is more preoccupied with anastomotic leaks.

One approach to defining quality in the domain of interest is to consider a 'perfect' patient experience (*Table 1*). Both the six quality dimensions enumerated by the Committee on Quality of Health Care in America, Institute of Medicine (2001; *Table 2*) and also the Institute for Healthcare Improvement's triple aim (Berwick et al, 2008) can be useful too (*Table 3*). The relationship between quality and value deserves particular note. With rising health-care costs causing global concern, an entirely valid quality improvement aim is to do more work for the same (or less) money. It remains essential, however, that other appropriately defined measures of quality be maintained or improved to guarantee that cost cutting has not led to worsening of the care delivered. For exam-

Table 1. The 'perfect' emergency department visit

From a patient's perspective this list exemplifies an ideal experience of visiting an emergency department:
Quick and easy to reach emergency department
No wait to see clinician
All concerns adequately addressed
Investigations performed immediately
Results of tests received instantly
Treatment ordered and dispensed straight away
All questions answered
Follow-up visit (if required) booked expeditiously before leaving

Table 2. Institute of Medicine's dimensions of quality

Safe – preventing unintended harm in the provision of care
Effective – delivering care based on the best evidence to all, including not giving therapies to those who will not benefit from them
Patient-centred – providing care that is appropriate to individual needs and desires, and including the recipient in all decisions
Efficient – preventing waste of any kind
Timely – eliminating unnecessary delays
Equitable – ensuring all are treated equally and without discrimination, and that care does not vary according to the provider or location

From Committee on Quality of Health Care in America, Institute of Medicine (2001)

Table 3. Institute of Healthcare Improvement's triple aim

Care – improving the individual experience of care
Health – improving the health of populations
Cost – reducing the per capita costs of care for populations

From Berwick et al (2008)

ple, a hospital might try to undertake more tonsillectomy cases at lower cost by increasing the proportion performed as day cases. However, it would be essential to ensure that pain scores and postoperative bleeding are not negatively impacted.

Global and specific aims

Based on an in-depth analysis of what quality means in your area of interest, set a global aim for your quality improvement programme. This will be a lofty aspiration, such as 'improving safety'. A common beginner's error is to address too large a component of this in your first project. Failure in early efforts is personally dispiriting, and may sound a death knell for nascent quality improvement efforts within the department or even the organization. Successfully tackling a previously intractable problem, even an apparently small one, does much to foster the enthusiasm and resources needed to tackle larger issues. For a first project the focus must be limited to just one clearly definable piece of the global aim, known as a 'specific aim'.

A more circumscribed 'safety' aim might be to reduce sharps injuries among health-care workers. In settling on a specific aim, consider the timespan of the process and how often it repeats. If it takes months for effects of any perturbation to the system to be revealed, it will be impossible to perform and analyse multiple 'tests of change' within a practicable timeframe. Likewise there must be sufficient opportunities for intervention. For example, it will likely take many years to achieve improvement in an event that takes place on average just once or twice per month (or even more infrequently, such as wrong-site surgery at the individual hospital level).

Setting a SMART aim

Once the target of a quality improvement project has been established, the specific aim must be expressed in 'SMART' form (specific, measurable, actionable, relevant, time bound). A good SMART aim is critical to success and mandates careful consideration, plus review by an experienced 'improver' where possible.

It is important to state the project's goal unambiguously. This includes both a clear-cut (specific) definition for the aim and also quantification of the goal rather than a vague hope to improve (measurable). The specific aim must be sufficiently powerful to empower the team (actionable), and it must be firmly linked to the global aim (relevant).

Exactly how much improvement constitutes an appropriate aim? No one answer fits all projects. Increasing success rate to >90% from a much lower baseline (maybe 20–25%) may seem beyond a team's capability at first sight. However, a 'stretch' goal can be extremely motivating by implying just how inadequate the current state of affairs really is (Berwick, 1996). Sometimes there is an external beacon of best practice to inform the choice, while accepting that local differences may militate against fully emulating these. For instance, it would be laudable for an intensive care unit to aim to match the lowest central line infection rate in the literature. However, in a burns intensive care unit, where skin infection rates are understandably much higher than in most units, this is likely unrealistic.

Commitment to a deadline completes the SMART aim by ensuring that the project is time bound. Deadlines are more powerful when they carry external significance, such as a forthcoming inspection by regulators. Importance can be imbued to even an arbitrary time limit through stating it explicitly, and especially if you have promised a timeframe in which to announce results beyond the immediate team. Some routinely set 90-day goals for this reason (Mandel et al, 2009).

Examples of SMART aims might be:

'By February 2013, 75% of junior doctors employed in the Department of Paediatrics at Middletown NHS Foundation Trust will be trained to the Royal College of Paediatrics and Child Health's level 2 specification in child safeguarding.'

'Induction of anaesthesia will commence within 15 minutes of the scheduled time for all gynaecology cases in theatre 2 by the end of November 2014.'

Charting the progress of a project

Quantification of the target problem is central to quality improvement efforts. Without a sense of the scale of the problem, it is impossible to track progress toward a goal. To act as a basis for action, all stakeholders must accept that the findings are genuine. Data are often seen as tainted by the viewpoint of those collecting them. For example, a project on operating theatre efficiency could become mired in disagreements over whether the anaesthetist took too long to evaluate the patient, the surgeon was still on the ward round, the theatre nurses had not prepared the room, or the sterile supplies department did not have the instruments sterilized in time. To avoid this, get agreement in advance on a plan for unbiased data collection. Give careful consideration to asking a neutral party to perform this important task, perhaps an individual from the audit department. Data collected from an automated or computerized information system may also fit this bill by virtue of transparency.

Measures

The second question posed by the model for improvement asks how we will know that a change is an improvement. Lower morbidity or mortality, or perhaps more work done for the same cost, would be valid goals. Donabedian (1966) refers to these as 'outcome' measures.

Where the target process is very complex, or the time lag between change and any improvement is long, consider defining the project's goal in terms of a 'process' measure. This is something which all agree is necessary, if not in itself sufficient, to achieve the global aim. For example, if the long-term goal is to improve clinical outcomes for epilepsy as measured against some previously established and widely agreed standard, a first step might be to ensure high compliance with recording outcomes against this standard for all patients seen at the hospital's neurology clinic. As health-care workers typically feel more accountable for process than outcomes, Rubin et al (2001) argue that using process measures may be better for morale during the early phases of quality improvement efforts.

Careful monitoring of appropriate 'balancing' measures ensures that inadvertent adverse effects of the quality improvement project do not go unnoticed. An example would be in aiming to treat more patients without increasing cost. In this case the number of patients treated is the outcome, but total cost must also be observed as a balancing measure.

As Pronovost et al (2004) point out, establishing a measure can be one of the most challenging concerns in practice. Set out the terms of the measure in a written definition, and specify in advance exactly what will and will not be counted. For example, if looking at the cancellation rate for elective surgical cases, do you want to include both main theatres and also the day surgery unit? Get consensus from all stakeholders, as all need to agree on the meaningfulness of the definition (Jencks et al, 2000). Test out the measure for a period of time, as unexpected problems often come to light. Maybe, in the case of surgical cancellation rate, no one thought to include Saturday 'waiting list initiatives'.

Sometimes, from a project's outset, the team believes that multiple actions need to be performed together in order to achieve the desired outcome. This group of interventions is referred to as a 'bundle'. The approach has been highly fruitful in reducing rates of hospital-acquired infection. To reduce surgical site infection, for example, a bundle may include administration of appropriate prophylactic antibiotics in a timely fashion before skin incision, correct preoperative skin preparation, prevention of intraoperative hypothermia, and maintenance of tissue oxygenation throughout the perioperative period (Ryckman et al, 2009).

With the bundle approach the best final outcome is achieved only if all elements are in place for each patient, and hence partial compliance is not good enough. The important measure here is the proportion of patients for whom all components are used; if any elements are missed, a complete 'failure' is recorded for that patient. Nolan and Berwick (2006) describe this as an 'all-or-none' measure. Nevertheless complete reliance on an all-or-none measure from the outset may dishearten, as typically, at the start of a project, one or more elements are missed in almost all instances. Furthermore all-or-none measures do little to pinpoint exactly what went wrong in cases of failure – which of the components was the one missed? Instead therefore it is wise to consider elements individually too (as well as looking at overall bundle compliance in an all-or-none fashion) until the project reaches a more advanced stage and reliable application of each has become embedded in the system.

Run and control charts

The outputs of all complex systems vary over time. Think of weather: one knows what kind of conditions to expect in each month, but it is not possible to know if it will be sunny or dull on a particular April day next year. It is vital to differentiate inherent variation from that reflecting a genuine change. To continue the meteorological metaphor, is this just an unlucky (or lucky) year, or is there truly climate change? For quality improvement purposes, a real change is an opportunity to learn about the system, whereas intentionally changing the system in reaction to what is really random variation leads to instability and is referred to as 'tampering'. Statistical process control allows this distinction to be made. The methodology differs from familiar techniques used to analyse randomized trials, but provides an equally sound footing where learning derives from continuous feedback from a process. Unrecognized bias is a risk, but the frequency of repeated data points is better at detecting sustainability of any effects than a one-off comparison at the end of a standard clinical trial.

Plotting a chart is key. As Elting et al (1999) showed, visual display permits better and more rapid analysis of data by clinicians. Along the horizontal axis of a run chart equal intervals of time are marked. A measure of the system is plotted on the vertical axis for each time interval. The points are marked discretely and are not joined. When there are sufficient points to calculate it (typically 12 or more), a centreline corresponding to the median is added (*Figure 2*). Addition of a title and a key, as well as labelling of axes, is important for communication within and outside the team. Annotate interventions and other events as the team undertakes them. Mark also the desired direction of change.

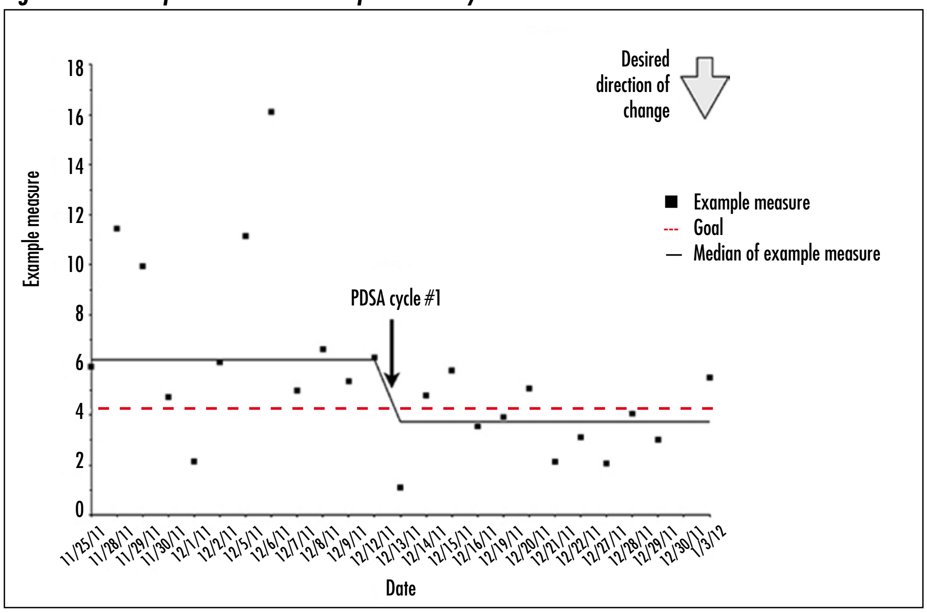
A genuine change in the system (a 'special cause') may be recognized on a run chart from three different patterns, which correspond to a low statistical likelihood that this is a chance event (*Figure 3*; Koutras et al, 2007):

- Shift: eight or more consecutive points all either above or below the centreline (points on the centreline neither make nor break a run; *Figure 3a*)
- Trend: six consecutive points all going up or all going down (*Figure 3b*)
- Alternating points: a zigzag pattern of at least fourteen points alternating up and down (*Figure 3c*).

In the case of a shift, it is appropriate to re-draw the centreline from the first point of the shift onwards. For a trend, the centreline is moved from the subsequent time interval. Strictly speaking, the reason for a change in the baseline ought to be known before the team agrees to shift it on the chart. Specifically, a quality improvement team may know they phased in a new process during that time period. Alternatively, on investigating a cluster of postoperative infections, infection control identifies a staff member present for all infected cases. He had an open skin infection from which the same organism is cultured.

A control chart looks similar to a run chart but its centreline is instead the arith-

Figure 2. An example run chart. PDSA = plan-do-study-act.



metic mean, and in addition upper and lower control limits corresponding to ±3σ (equivalent to ±3 standard deviations for a time series) are plotted (*Figure 4*). Control limits are similar to confidence limits but reflect variability in the process rather than in a distribution of data (Carey and Lloyd, 2001). Wheeler (2000) describes the steps of control chart construction with full mathematical details. The advantage of a control chart over a run chart is an additional means of detecting special cause variation: points outside the control limits. The above-mentioned rules for special cause variation still apply. Further different types of charts have been devised for special purposes and are reviewed by Wheeler (2000).

In all cases special cause variation must be investigated. It will likely provide learning about the properties of the system, and may point towards interventions that may be tested in your quality improvement project. This concept of deliberately perturbing the system through small 'tests of change' will be considered in a subsequent article. **BJHM**

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Batalden PB, Davidoff F (2007) What is "quality improvement" and how can it transform healthcare? *Qual Saf Health Care* **16**(1): 2–3

Berwick D (1996) A primer on leading the improvement of systems. *BMJ* **312**(7031): 619–22

Berwick DM, Nolan TW, Whittington J (2008) The triple aim: care, health, and cost. *Health Aff (Millwood)* **27**(3): 759–69

Britto MT, Anderson JM, Kent WM et al (2006) Cincinnati Children's Hospital Medical Center: transforming care for children and families. *Jt Comm J Qual Patient Saf* **32**(10): 541–8

Carey R, Lloyd R (2001) *Measuring Quality Improvement in Health Care.* American Hospital Association, Chicago

Donabedian A (1966) Evaluating the quality of medical care. *Milbank Mem Fund Q* **44**(3): Suppl 166–206

Elting L, Martin C, Cantor S, Rubenstein E (1999) Influence of data display formats on physician investigators' decisions to stop clinical trials: prospective trial with repeated measures. *BMJ* **318**(7197): 1527–31

Committee on Quality of Health Care in America, Institute of Medicine (2001) *Crossing the Quality Chasm – A New Health System for the 21st Century.* National Academies Press, Washington DC

Jencks SF, Cuerdon T, Burwen DR et al (2000) Quality of medical care delivered to Medicare beneficiaries: A profile at state and national levels. *JAMA* **284**(13): 1670–6

Koutras MV, Bersimis S, Maravelakis PE (2007) Statistical Process Control using Shewhart Control Charts with Supplementary Runs Rules. *Methodol Comput Appl Probab* **9**(2): 207–24

Langley GJ, Nolan KM, Nolan TW (1992) *The foundation of improvement.* API Publishing, Silver Spring, MD

Mandel KE, Muething SE, Schoettker PJ, Kotagal UR (2009) Transforming safety and effectiveness in pediatric hospital care locally and nationally. *Pediatr Clin North Am* **56**(4): 905–18

Nolan T, Berwick DM (2006) All-or-none measurement raises the bar on performance. *JAMA* **295**(10): 1168–70

Pronovost PJ, Nolan T, Zeger S, Miller M, Rubin H (2004) How can clinicians measure safety and quality in acute care? *Lancet* **363**(9414): 1061–70

Rubin H, Pronovost P, Diette G (2001) The advantages and disadvantages of process-based measures of health care quality. *Int J Qual Health Care* **13**(6): 469–74

Ryckman FC, Schoettker PJ, Hays KR et al (2009) Reducing surgical site infections at a pediatric academic medical center. *Jt Comm J Qual Patient Saf* **35**(4): 192–8

Shewhart WA (1931) *Economic control of quality of manufactured product.* Van Nostrand, New York

Wheeler DJ (2000) *Understanding Variation: The Key to Managing Chaos.* 2nd edn. SPC Press, Inc., Knoxville

Figure 3. Rules for special cause variation on a run chart. a. Shift. b. Trend. c. Alternating points.

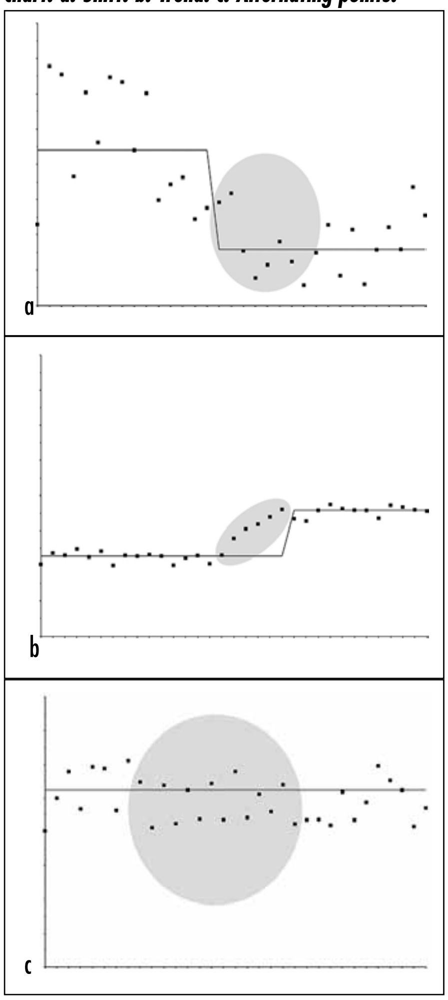
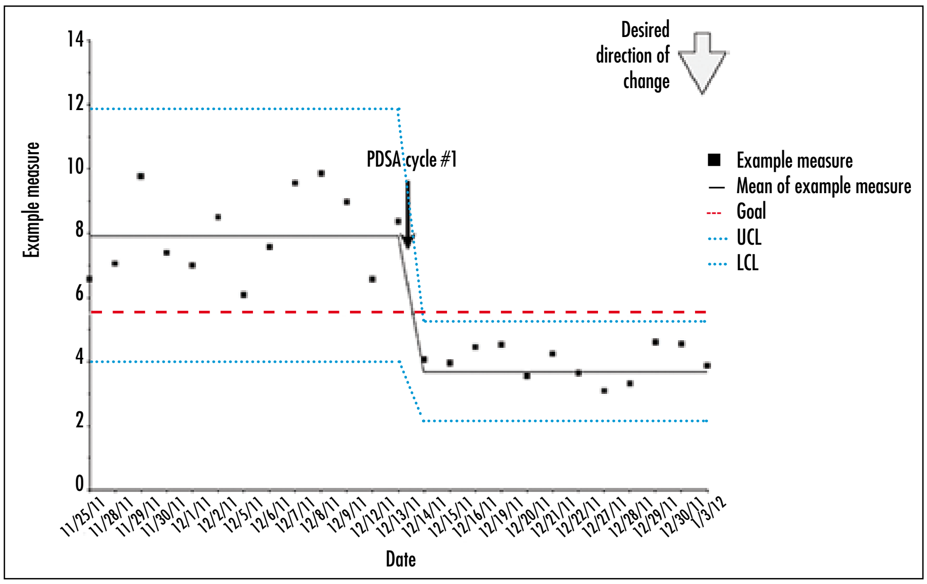


Figure 4. An example control chart. LCL = lower control limit; PDSA = plan-do-study-act; UCL = upper control limit.



LEARNING POINTS

- Quality improvement requires change in the system: increased effort or attention alone will not achieve substantial or lasting results.
- For a successful project, it is vital to define and quantify precisely the aspect of quality that the team agree is important.
- Always set a project aim that is specific, measurable, actionable, relevant and time bound.
- Plotting quality over time on a run or control chart is an essential component of leading a quality improvement project to successful conclusion.