

# Quality improvement; part 1: introduction and overview

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## Learning objectives

By reading this article you should be able to:

- Explain the context in which quality improvement methods are being translated into healthcare
- Recognise that there are several structural frameworks for quality improvement methods
- Explain how quality improvement methods are different from clinical audit or empirical research
- Identify and overcome some frequent barriers to successful quality improvement.

## Editor's key points

- Quality improvement (QI) methodology differs from that of clinical audit or empirical research.
- Quality is most often defined in terms of the six domains of safety, clinical effectiveness, patient centredness, timeliness, efficiency, and equity.
- Many frameworks for improvement methodologies exist; common ones include the model for improvement, lean, and Six Sigma.
- QI training programmes that include experiential learning by doctors in training are best placed to achieve improvements in clinical outcomes.

- Executive sponsorship is considered crucial for the effectiveness and sustainability of QI programmes.

## Background

'Every system is perfectly designed to get the results it gets'.

The source of this quote is in question; it has been variously attributed to Arthur Jones, Paul Batalden, or W. Edwards Deming.<sup>1</sup> What is not disputed is the realisation that improvement in patient outcomes is dependent upon improving the systems that exist to provide healthcare. This is the first in a series of three articles in *BJA Education* on quality improvement (QI).

QI uses a range of techniques and methods translated from other industries to improve the quality of patient care whilst driving down costs. This is encapsulated in the Institute for Healthcare Improvement's Triple Aim<sup>2</sup> of improving the patient experience of care (including quality and satisfaction), improving the health of populations, and reducing the per capita cost of healthcare. There have been a number of political drivers for enhanced QI capability across the National Health Service (NHS). Berwick<sup>3</sup> reflected upon the recommendations within Francis's<sup>4</sup> report (into the scandal of patient mistreatment at Stafford Hospital), saying: 'Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all healthcare professionals, including managers and executives'.

National planning (such as the Five Year Forward View of NHS England<sup>5</sup>) and local commissioning arrangements have incentivised the adoption of best practice and innovation to improve performance against certain defined targets, and the

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NHS Outcomes Framework<sup>6</sup> sets out improvement priorities, such as reducing pressure ulcers or catheter-related bloodstream infections. Furthermore, national collaboratives, such as the Perioperative Quality Improvement Programme<sup>7</sup> and Getting It Right First Time,<sup>8</sup> are helping to systematise a common approach in pursuit of improvements in the quality of patient care.

A problem encountered hitherto in the NHS has been that ‘... managers see a clinical problem that they don’t understand. Doctors see a “system problem” and hope that managers will sort it out’.<sup>9</sup> For the quality of care to improve, it is imperative that clinicians understand and engage with QI as part of their daily work.

## Quality and QI

Traditional notions of quality have been driven by the context: tangible product features (e.g. conformity to specification, fitness for use, or value for price paid) in manufacturing, and intangible elements that must be experienced in the case of service industries. Defining quality, therefore, arises from the construction of meaningful outcome measures that can be quantified and tested.

There is no single universal definition of quality. The Institute of Medicine<sup>10</sup> has described quality in healthcare as being safe, effective, patient centred, timely, efficient, and equitable. The NHS Next Stage Review Final Report<sup>11</sup> focused upon three principal descriptors of quality: *safety, experience of care, and effectiveness of care*. These are now represented amongst the Care Quality Commission’s *key lines of enquiry*<sup>12</sup> in healthcare regulation.

QI is a broad term that describes the systematic use of a range of tools and techniques to improve patient care and associated healthcare processes continuously. QI is sometimes described as ‘the combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning)’.<sup>13</sup>

Another definition includes, ‘... improvement as better patient experience and outcomes achieved through changing provider behaviour and organisation through using a systematic change method and strategies’.<sup>14</sup> Although there are many different QI methods and tools, it is not yet clear that any one method is superior. There are some philosophical features, however, that are common to all: (i) clear and consistent distributed leadership from system level to patient level, with the adoption of a single QI method across an organisation; (ii) suitable investment in staff training to appreciate QI methodology and the nature of systems; (iii) choosing of appropriate measures and using of the right data to understand variation; (iv) inclusion and engagement of staff in suggesting ideas for improvement, and encouraging them to participate in the process; (v) engagement of patients and other stakeholders in the process from the outset; (vi) using structured, controlled tests of change in order to learn and improve; and (vii) the establishment of a continuous learning system to coordinate improvement efforts.

The central tenet in all QI methodologies is that there is an emphasis upon using carefully chosen measures to understand the variation within a system to then remove unwarranted variation, and then to improve system performance through a series of iterative tests of change. In all

methodologies, a contextually appropriate solution is arrived at that correctly addresses the specific problem being addressed.

## QI strategies

There are many different tools that can be applied in the context of QI, and these are generally used within the context of broader frameworks, such as the model for improvement.<sup>15</sup>

### Model for improvement

This model is based upon three fundamental questions that frame the improvement efforts:

- (i) *What are we trying to accomplish?* The aim of the improvement programme is defined with as much clarity as possible.
- (ii) *How will we know that a change is an improvement?* Improvement is defined and measured in relation to a clear baseline or current state, for which specific metrics can be chosen.
- (iii) *What changes can we make that will result in improvement?* Ideas for change based upon a clear understanding of the problem can be tested in a controlled fashion.

Well-chosen measures are simple and unambiguous, and should be easy to use. A characteristic set of measures might include a measure of process, a measure of outcome, and a countermeasure (to look for unintended consequences).

The changes proposed are tested sequentially using plan, do, study, and act (PDSA) cycles (Fig. 1). This allows for small tests of change in a controlled fashion. The learning from each cycle is used to refine the next test of change. It is important to appreciate that there are no ‘failed’ PDSA tests—the outcome of a trial creates valuable learning that further increases the understanding of the system.

The model for improvement is very versatile and has been widely adopted in healthcare settings for improvement purposes.

### Lean thinking

The guiding principle behind the lean theory<sup>16</sup> is the removal of waste. The founding father of lean thinking, Taiichi Ohno, described seven major wastes: *overproduction, waiting, conveyance, processing, inventory, motion, and the correction of defects*. Lean methodologies are particularly useful when looking at systems in an end-to-end way and considering how the flow of work could be improved. There are five key elements to lean thinking:

- (i) *Identify value.* What really matters to the patient (or other system user)?
- (ii) *Identify the value stream.* How do we organise the process of care such that the patient experiences only steps in the process that add value?
- (iii) *Create flow.* How do sequential steps in the process flow from one to another without delays, errors, or duplication?
- (iv) *Create systems that pull.* Systems should be responsive and operate only to pull patients through according to demand.
- (v) *Strive for perfection.* No system is perfect, and continuous, systematic improvement efforts should be unceasing.

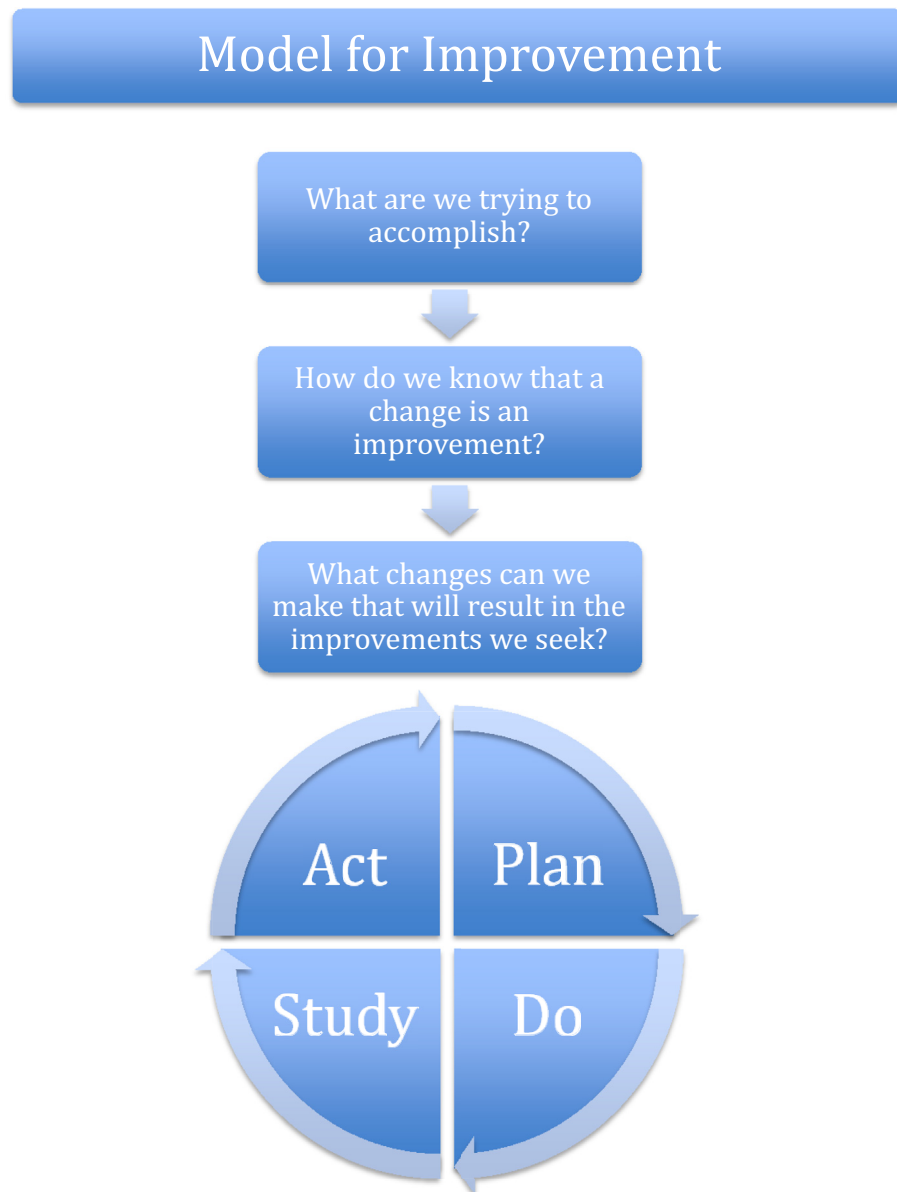


Fig 1 Model for improvement.

The Toyota Motor Corporation is arguably the most complete adopter of lean thinking; indeed, this has been codified in terms of the Toyota Production System (TPS). Few health-care systems have managed to introduce lean thinking on a scale approaching the TPS, with the exception of the Virginia Mason Medical Center,<sup>17</sup> who have transformed not only their processes of clinical care, but also their entire management philosophy around lean principles. Their concept of quality is summarised in the equation:

$$\text{Quality} = \text{appropriateness} \times \frac{(\text{outcomes} + \text{service})}{\text{waste}}$$

### Six sigma methodology

The aim of Six Sigma methodology<sup>18</sup> is to reduce variation in a system using the define, measure, analyse, improve, and control methodology. In this case, improvement efforts are often focused upon a single step in a process, in order to refine and standardise, before moving on to other areas of variation. Six Sigma approaches are best suited to improving single steps in a process that are prone to unacceptable variation.

### Theory of constraints

This approach seeks to identify the rate-limiting step in a system, and concentrate upon removing the bottleneck.<sup>19</sup> This method is particularly well suited to improving throughput in a system.

There are many other ways in which QI methodologies can be described; however, the underlying principle is that sustainable improvement can only be brought about following a clear understanding of the nature of the system.

## QI, audit, and research

Clinical audit and scientific research have methodologies that are well understood by the healthcare community. Audit has a focus upon meeting specific assurance targets or standards, and is often sporadic, retrospective, and limited in scope. Failure to complete the audit cycle (and hence introduce an improvement) is common. When this does occur, the results of any change are typically presented in terms of before and after the change.

Scientific research, by contrast, is about the generation of new knowledge, and is conducted according to the scientific method in which the starting point is equipoise. Studies have strict inclusion and exclusion criteria, and translation of the findings to the general population is made only after the research activity is completed. Traditional research studies are generally held to be more powerful by the inclusion of large subject numbers, and evidence of the superiority of one treatment over another, or the establishment of correlation or causality, is determined at the end of a study by manipulation of often batched data, using a set of widely accepted statistical tools.

Improvement science represents a different paradigm, which has translated a number of approaches that are familiar to those in other industries, which are often not familiar to practicing clinicians. Although high-quality healthcare demands that patients are treated as individuals, improvement science recognises that care is delivered through a series of processes that form a system. Improvement of a system requires a different set of tools—regardless of whether that system is in a factory or a healthcare setting.

Deming's 'Theory of Profound Knowledge'<sup>15</sup> explains a philosophical basis for improvement science:

- (i) Appreciation of a system: how different elements interact with one another.
- (ii) Understanding of variation: most variation in a system is 'common cause'; the rest is 'special cause'. They are statistically distinct from one another and require different solutions to control them.
- (iii) Theory of knowledge: learning from the results of controlled tests of change; information and learning not the same.
- (iv) Human side of change: the psychology of engagement and creating change.

An audit may form the baseline from which a QI project then takes off—focusing upon improvement rather than assurance. True QI activity is continuous, not sporadic (improvement is not a finite event—it must be continuously pursued), and data collection is almost always prospective rather than retrospective.

Improvement science focuses upon the specific solutions to specific problems, and whilst spread to other sites is often feasible, widespread applicability is not a guiding principle behind any given QI project. In contrast to empirical research, QI activity takes place in the 'real world', in which exceptions do not constitute exclusion criteria. Rather, the observed variation is recognised as a result of a common cause or a special cause, and these are addressed in different ways.

In contrast with research, improvement science is less concerned with the generation of new knowledge (except as it pertains to the understanding of a system), but rather the improvement in the way a system operates. Improvement methodology often requires 'just enough' data to demonstrate a variation (although there are still statistical rules that must be followed).

## Organisational context

QI initiatives can take place at a team, organisational, or system level. It follows that there will be different influences and strategies involved in change at these different levels.

### Clinical team level

QI activities at this level are frequently 'homegrown' initiatives responding to a local need, such as improving analgesia after certain types of operations, introducing an enhanced recovery programme, or streamlining throughput through an operating suite. Such projects may come about after a baseline audit or may come about in response to an index adverse event, and the QI initiative will generally have been developed from first principles.

### Organisational level

These tend to be larger-scale projects, typically crossing clinical areas, and will be allied to certain key strategic goals of the organisation or clinical network. Such projects will typically have clear executive sponsorship and will characteristically have project teams drawn from a variety of areas. Some of the project elements may well represent 'off-the-shelf' solutions that have been shared between organisations as examples of best practice. Typical examples may include addressing venous thromboembolism risk assessment or introducing a care bundle for the timely treatment of sepsis.

### System level

Such programmes are much larger in scale and will usually carry the sponsorship of a national body, such as the NHS England or a Royal College. Projects on this scale require local leadership; however, the local-leadership task is mainly concerned with implementing the set tools and protocols in tandem with numerous other organisations, rather than creating an original improvement project. Examples include the Matching Michigan project and the National Emergency Laparotomy Audit.

## Teaching and training QI skills

QI methodology now features in the core curricula for undergraduate and postgraduate medical training, with the support of the General Medical Council and The Academy of Royal Colleges. Reaching all levels of the medical profession has so far been challenging, to say nothing of other staff groups within healthcare. Much of the literature describes initiatives aimed at junior doctors, and training strategies can be categorised by approach.

### Formal (didactic) training

This approach can offer a defined curriculum to an entire cohort of learners, and can take the form of face-to-face or

web-based teaching, mixing didactic teaching with experiential learning. Teaching can take place over a restricted timescale, and there can be reasonable confidence that meaningful learning will occur. An example of a web-based resource is the IHI Open School, which confers credibility to the process through a certificate of completion. This form of teaching reliably leads to increases in learner knowledge.<sup>20</sup>

### Clinician participation in QI projects

This is an increasingly popular method for teaching QI skills to junior doctors. Indeed, it is a requirement of the UK Foundation Programme that each junior doctor 'manages, analyses and presents at least one quality improvement project and uses the results to improve patient care'.

This style of teaching allows each learner to explore an improvement idea with the support of a more senior or experienced mentor, and QI projects are frequently chosen to reflect the concerns of those working on the frontline. The peripatetic nature of junior-doctor rotations means that, with fresh eyes, they can question inefficient systems and act as 'change agents' for good practice. The scale of these learning programmes is varied, and attempts to create national, regional, or even organisation-wide systems for support have achieved some success.

Large-scale projects, such as the Learning to Make a Difference<sup>21</sup> programme of the Royal College of Physicians, reported encouraging levels of participation following its pilot in London; however, there is still patchy uptake amongst trainees. Another national programme is the National Medical Director's Clinical Fellow Scheme, which provides very high-quality support to doctors at registrar level, who are characteristically attached to a body, such as NHS England. This training model will only ever reach a very small proportion of all doctors in training, and represents the most intensive end of the QI training spectrum.

At a more local level, many hospitals have offered a programme of structured QI training and mentorship for doctors in training, who tackle QI projects of their own choosing.<sup>22</sup> Despite encouraging early successes, the issues of sustainability, protected time, and continued enthusiasm have hampered full-scale adoption.

Improvement projects designed by others to improve the quality of clinical care provided by junior doctors.

In this model, the learning of QI expertise is a by-product of participation in a wider project, often directly aimed at the juniors themselves<sup>23</sup> (i.e. the target population are the junior doctors themselves, rather than a patient group).

In all three models, learner satisfaction is generally positive, and pre- and post-course tests of learner knowledge have usually demonstrated improvements. This is perhaps unsurprising. Altered learner behaviours, however, have not been commonly measured, and crucially, there is only limited evidence that any of these teaching endeavours have led to improved patient-level outcomes.<sup>13</sup>

### Barriers to QI uptake

#### Lack of senior leadership

It is a consistent finding that executive sponsorship of QI is a prerequisite for success. Change is often hard to make and even harder to sustain. Senior leaders are vital in helping to

maintain the constancy of purpose that is required to make QI successful.

#### Engagement of patients and staff

There is a human dimension to any change. Improvements that draw on the enthusiasm, ideas, and buy-in from patients and staff are more likely to be successful and sustainable.

#### Uncertainty and lack of support

One of the challenges of undertaking QI work is bridging the knowledge and skills gap between enthusiastic juniors who are keen to undertake QI projects, whilst under the supervision of more senior clinicians who may not themselves have the requisite QI knowledge to offer meaningful support.

#### Poor choice of quality indicators

QI endeavours will be limited by poor metrics or poor data collection. Ideally, the measures chosen should be specific and fit for the purpose of improvement. It is often expedient to try to use routine data that are already being collected, without considering whether better measures could be used.

#### Lack of discipline

It is often tempting to reach for a solution before the problem in question is fully understood. The central tenet of QI is that the right solution will only be brought about if there has been a systematic approach to understand the issue first.

#### Misunderstanding

Many clinicians will not have had exposure to improvement science during their training, and fail to appreciate the paradigm differences between QI, audit, and research. Batching of before-and-after data and an inappropriate search for a significant P-value are frequent pitfalls.

#### Prejudice

There is still a persistent view amongst some clinicians that 'patients are not like products on an assembly line' and that the lessons learned from other industries are not translatable to healthcare. Improvement science needs to be understood by clinicians as a valid discipline.

#### Overreach

It is often tempting to expand the project beyond its original remit. This not only leads to lack of focus and extra work, but also a deviation from the original aims and metrics, which may not prove valid for the 'drift'.

### The future

Improvements in the clinical care of patients will depend increasingly on a shared understanding of the complexity of the systems involved, and there is a growing acceptance of Deming's<sup>24</sup> maxim that 'Quality is everyone's responsibility'. The challenge is to bridge the skills and knowledge gap in the clinicians of today and of the future.

**Table 1** Useful resources and further reading

Resource	Comments
BMJ Open Quality ( <a href="http://bmjopenquality.bmj.com">http://bmjopenquality.bmj.com</a> )	An online platform upon which QI projects can be hosted and ultimately published
Faculty of Medical Leadership and Management ( <a href="https://www.fmlm.ac.uk">https://www.fmlm.ac.uk</a> )	Hosts a number of QI resources and commentaries
The Health Foundation ( <a href="http://www.health.org.uk">http://www.health.org.uk</a> )	A charitable organisation publishing many evidence-based commentaries and reports on quality improvement and related issues
Institute for Healthcare Improvement Open School ( <a href="http://www.ihio.org/education/IHIOpenSchool/Pages/default.aspx">http://www.ihio.org/education/IHIOpenSchool/Pages/default.aspx</a> )	An online, self-directed series of training modules on improvement science, patient safety, and leadership
NHS Improvement ( <a href="https://improvement.nhs.uk/improvement-hub/">https://improvement.nhs.uk/improvement-hub/</a> )	Improvement tools, techniques, and shared learning from across healthcare
Royal College of Anaesthetists, <i>Raising the Standard: A Compendium of Audit Recipes</i> ( <a href="https://www.rcoa.ac.uk/system/files/CSQ-ARB-2012_0.pdf">https://www.rcoa.ac.uk/system/files/CSQ-ARB-2012_0.pdf</a> )	Audit recipe book with an introductory section on improvement science
<b>Further reading</b>	
<i>Making Hospitals Work</i> (Baker M, Taylor I. <i>Lean Enterprise Academy</i> , 2009)	A practical, step-by-step introduction to improvement methodology for hospitals
<i>Patient Safety and Healthcare Improvement at a Glance</i> (Panesar SS, Carson-Stevens A, Salvilla SA, Sheikh A. Chichester: John Wiley & Sons, 2014)	An illustrated guide to QI methodology with real-world examples
<i>The Toyota Way</i> (Liker JK. New York: McGraw-Hill, 2004)	A detailed description of the Toyota Production System—the foremost exponents of lean management

## Declaration of Interest

None declared.

## MCQs

The associated MCQs (to support CME/CPD activity) can be accessed at [www.bjaed.org/cme/home](http://www.bjaed.org/cme/home) by subscribers to BJA Education.

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