



Invited review article

Clinical quality improvement and medicine[☆]

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1. Introduction

Medical practice is facing many pressures, all requiring ever-higher standards and better 'quality' in the provision of clinical care. Medicine is not alone in facing such forces, and it may be appropriate to apply the methodology used in other disciplines to address this issue;

common problems are generally amenable to common solutions.

The 'quality' approach was initially applied to health care in the USA, presumably because of the accent on market forces and the relationship with market share. In recent years, other health care systems have invested in this approach, applying lessons learned from management disciplines and the aviation industry. The Institute of Medicine's report on health care quality noted that 'every system is perfectly designed to obtain the results it gets' [1]. The European Union has thus far not included quality as a formal item on its agenda; however, with increasing mobility of patients and health professionals, there is

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pressure for legislative action addressing risk management and quality improvement. The development of a European approach to ensure the highest quality standards, free movement in the European Union, as well as the medical devices industry, are all areas that are raising interest. Overall, it behooves the individual clinician to be aware of developments in the area.

2. Quality in industry...and in health care

Deming originated the movement for increased emphasis on quality; he was an American statistician who turned the postwar Japanese manufacturing industry into the world-beating entity that we are all familiar with today. He developed the approach illustrated in Fig. 1, where each step of the production process was reviewed and redesigned with a view to improving the quality of the end product [2]. This approach was subsequently applied to services, with equally good effect. The attraction of using this approach in the business world lies in the concept that better products and services are more likely to retain customer loyalty, which will result in increased market share, leading to improved profitability. There are many drivers to quality improvement (Table 1); many of these forces apply irrespective of the health care system within which clinical care is provided.

Batalden et al. [3] described how Deming's approach is applicable to health care, noting that social and community needs also need to be considered in this setting. The application of a 'systems approach' to organisational systems, as advocated by Senge [4], is being promoted by the Institute of Medicine 2001 Report [1] to produce a leap in health care quality. Health care is provided in many settings and within different systems, which implies that there are difficulties in addressing the whole. Senge described 'systems thinking' where the focus is on the 'big picture'. He also described the 'tragedy of the commons', whereby

common areas of importance tend to be neglected, as all players focus on their own particular area and interests, resulting in failure of the whole, to the detriment of the common good. The understanding of these concepts and their application should lead to a systems overview with global recommendations that will benefit the common good.

Batalden et al. [3] applied this global overview to health care, as illustrated in Fig. 2, which shows the various levels of patient care from a systems approach. Each level is important as it has its own impact upon the outcome. For example, the environment provides the 'ground rules' within which care is provided, via legislation, health care policy and social systems. The macro-organisation refers to the organisational entity that care is provided in, i.e., the health care system. Micro-systems refers to the level at which clinical care is provided, whether it is within a clinic or hospital ward. The individual care given, the patient system and self-care system describe the innermost levels of individual care. Each level is amenable to different approaches. Industrial focus has moved from 'quality' to 'quality assurance' and, more recently, to 'quality improvement', where the organisation or system continuously reviews its practices to improve quality. Garvin [5] noted the importance of the strategic perspective, with the impact of quality being considered in decision making at the highest levels. He asserted that quality improvement would not occur spontaneously and that it required nurturing as it would also take years to produce results. It should certainly not be expected to yield short-term gains. Other 'management' concepts that have been applied to health care, include 'Total Quality Management' (TQM), as developed by Feigenbaum [6]. This approach seeks to focus all areas within an organisation on quality improvement. He defined TQM as '...an effective system for integrating the quality-development, quality maintenance and quality-improvement efforts of the various groups in an organisation so as to enable marketing, engineering, production, and service at the most economical levels which allow for full

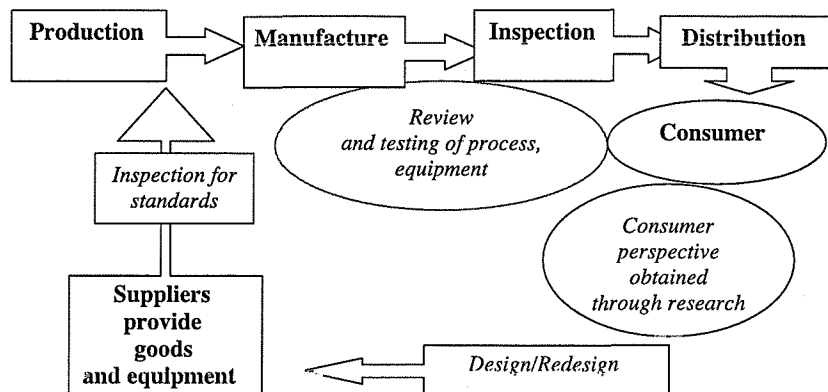


Fig. 1. W. Edwards Deming Out of the Crisis [2].

Table 1
Drivers to quality improvement

- Demanding ‘customers’ who have rising expectations, as well as better standards of living. They expect better outcomes, similar to those experienced when consuming commercial services.
- Ageing populations who are making more demands upon their health services
- Increased government scrutiny
- Increased liability suits
- Funding: competition for this /loss of market share
- Developments in biotechnology and information technology are having a profound influence on the way health care is delivered.
- Chief executive officer focus on quality
- Restart situation, e.g., moving to a new site

customer satisfaction’. Table 2 lists the steps in a TQM approach; they can usefully be applied as a framework for application to health care (after Moss [7]).

3. TQM described

3.1. Making customers’ needs a priority for everyone

Implied in this statement is the perception that the whole system is geared up to patient needs. This means that all organisational levels (administrative, clinical, maintenance, cleaners) within the health care system keep this focus. It also links up with the second step.

3.2. Defining quality in terms of customer needs

A TQM defines quality in terms of customer needs; when applied to health care, this means ‘through the patients’ eyes’, an approach that has its proponents [8–15]. Delbanco [8] considered patients to be ‘expert witnesses’ to the health care process, with their perspective enriching the doctor–patient relationship, acting as a

Table 2
Characteristics of total quality management/continuous quality improvement

- (1) Making customer’s needs a priority for everyone
- (2) Defining quality in terms of customer needs
- (3) Recognising internal customers and suppliers
- (4) Focusing on process rather than on individual performance
- (5) Using sound measurement
- (6) Promoting effective teamwork and removing barriers
- (7) Understanding that the process is continuous

screening test uncovering areas for improvement. This approach has been advocated to drive organisational change and improvement [15]. The main concerns with using this approach are that patients are not qualified to assess technical care [16] or reproducibility and reliability [17]. No relationship was found between patient satisfaction and an external assessment of clinical care quality [18], implying that there has to be a clear distinction between the two. Studies addressing stakeholders’ viewpoints regarding aspects of care found agreement that the crucial element was clinical skill [19]. There was disagreement about other aspects, especially the importance of effective communication of health-related information. This was borne out by Nelson [20], who identified other important aspects of care. Asking patients direct questions about what happened, rather than how satisfied they were with treatment, may elucidate the problems facing them [14,17,21,22]. Patients’ expectations also vary consistently with ethnicity and educational level, with the more educated having higher expectations [23–25]. Many organisations and systems are now using these concepts to formally assess patient care. Some countries, including the United Kingdom and Malta, have introduced patient charters in an effort to lay down ground rules as a basis for improvement [26]. The degree of service accessibility to patients and continuity of care have also been highlighted as important in patient surveys [27].

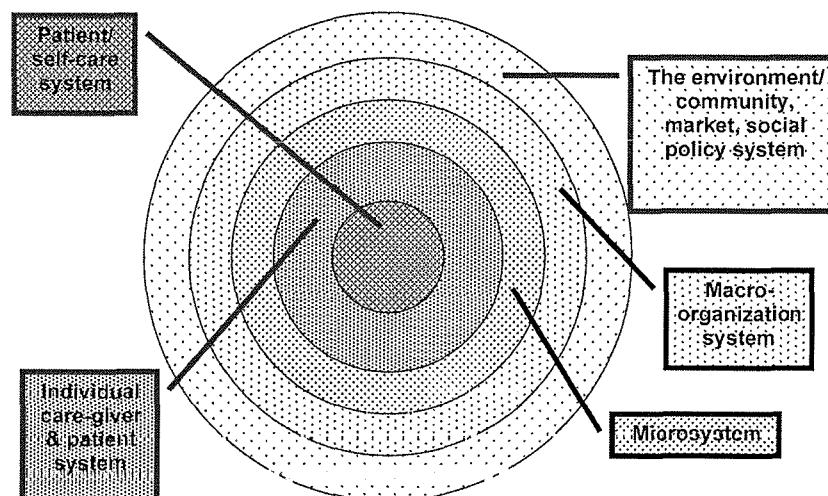


Fig. 2. Systems approach to medicine [3].

3.2.1. Methodology of understanding patient experiences and expectations

Patient experiences may be studied using various methods including SERVQUAL, a tool developed to assess service quality. It compares service users' expectations and perceptions of the service provided to them [28–32]. The information gained may then be used to identify where action is required for improvement. The underlying concept is that there are many interfaces between what should ideally be provided and what end-users perceive is being provided for them. Identifying the 'gap' may facilitate quality improvement initiatives. The Picker Institute Europe [33] has conducted various studies assessing patient satisfaction issues. More recently, they are exploring how patient needs can be met and comparing different countries' experiences. How policymakers should respond is an issue that is also being addressed and is likely to be of widespread interest. There has been little research regarding the outcome of such initiatives but, at the very least, they may result in patient-oriented professionals with more satisfied patients who may be more likely to comply with medical advice and, therefore, have better clinical outcomes.

3.3. Recognizing internal customers and suppliers

Many providers come together to provide a service; the contribution of each and every one of them therefore becomes vital in the service chain, which is made up of internal customers and users supplying one another, ultimately supplying the external customer. For example, the *internal customers* of laboratory and radiology departments are physicians who expect them to provide prompt and accurate results so they can treat their patients, who are the *external customers*. Each stakeholder has different motivators that need to be addressed in order to obtain the best possible outcomes.

Maslow [34] described a hierarchy of human needs motivating behaviour ranging from *extrinsic*, material needs (e.g., food, shelter) to *intrinsic*, more spiritual needs associated with personal satisfaction. He noted that monetary compensation is only effective for satisfying an extrinsic need. Satisfiers of intrinsic needs may be strong motivators in particular circumstances, e.g., the participation in providing a high level of care may be a strong motivator in health care. If internal customers are dissatisfied, the quality of service provided is likely to be less than optimal; conversely, internal customer delight (where they have high levels of satisfaction) is associated with a high level of service provision.

3.4. Focusing on process rather than individual performance

3.4.1. Industry and system quality

TQM takes the approach that, for quality to improve, the whole process has to be looked at in a holistic manner,

rather than relying upon individual performance. This requires consideration of different facets of the process, including people, information and change management. Information technology has the potential to facilitate accurate capture of clinical data, enabling better information exchange, data monitoring, provision of electronic information for 'just in time' care and better planning.

A zero defects approach has been advocated in which systems are designed to prevent error, aiming at 'zero defects' and fitness for purpose [35,36]. This approach is taken further in Motorola's Six Sigma approach, where the maximum tolerated error limits of a process are specified and adhered to [37,38]. Imai [39] suggested that 'complaints should be treasured' and used as 'improvement triggers'. Edvardsson et al. [40] advocated a focus on process rather than individual performance in explaining poor quality. Oakland [41] noted the importance of process capability, i.e., ensuring the capacity of the process to deliver outcomes within defined standards, all this taking place within a system that is 'mistake-proofed' and continually reviewing itself. More recently, a systems approach linking suppliers and customers has been advocated [42].

3.4.2. Medicine and systems quality—and adverse events

Quality and safety in health care have become a major concern for consumers, providers and managers. Yet, quality improvement will not occur with simple exhortations to try harder. Adverse events in any industry are seldom attributable to a single human error [43]. Most errors are due to a system or organisational failure rather than individual negligence. The 'Swiss Cheese model' of adverse event causation [44] (Fig. 3) introduces the concept that when an error occurs, a series of events would have aligned themselves, enabling the mishap to take place. An overview of the sequence of events leading up to this may enable system safeguards to be built in so as to prevent recurrences. In short, the system can be 'mistake-proofed'. However, this requires a change from the current 'blame culture', where adverse events lead to a search for the culprit who has caused the problem by his 'negligence'. This approach is very unlikely to reveal all of the relevant contributory

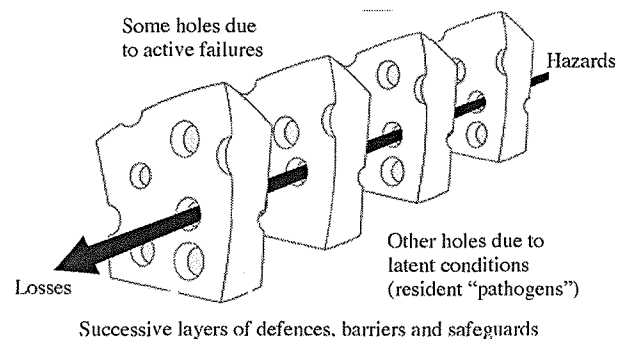


Fig. 3. The "Swiss cheese" model of accident causation (Reason et al. [44]). (Source: *Qual Health Care* 2001; 10: ii 21–5. Reproduced with permission from the BMJ Publishing Group.)

factors underlying an adverse event. On the contrary, it is more likely that causative factors will be hidden from evaluation. Moreover, the culture is based upon the adversarial tort-based legislative system currently in place in many countries. A change in culture is needed to move from a 'good–bad' culture to a 'good–better' one, with the eradication of 'naming, shaming and blaming', moving to one based on innovation and creativity to develop quality improvement in patient care.

Jarman [45] has noted the current conflict between medical audit, required to improve patient care, and current disciplinary procedures. The IOM report notes that a culture of safety is required, together with the introduction of a mandatory reporting system of near misses [1]. This requires a system change based on nonpunitive reporting of 'near misses' and making it unacceptable not to report potential errors. This approach has been implemented in the aviation industry [46] and is also being adopted by some national health care systems.

3.4.3. Evidence-based process improvement in industry and health care

At present, industry uses certification and performance indicators in order to standardise performance. In the main, health care has tended to rely on various measures, including audit, mortality and morbidity assessments, quality assurance certification and the legislative framework surrounding registration. The registration of doctors, dentists, pharmacists, nurses and paramedics at graduate and specialist levels ensures minimum standards, which the European Union has harmonised, although this is the subject of ongoing discussion. Ongoing/Continuing Medical Education (CME) has been used as a means of process improvement, although the evidence base concerning the impact of continuing medical education has not supported this for maintenance of state-of-the-art practice. Nevertheless, most systems are moving in this direction, with revalidation becoming part of the process in the American system and soon in the UK. In the longer term, European Union directives may make CME a formal requirement for ongoing registration in member states.

Guidelines have proliferated nationally and internationally, with various authorities releasing their own versions of adaptations for their particular area. Guidelines require enormous effort and resource allocation in terms of time to production, and they are not automatically transferable between systems and localities. They are obviously as good as the evidence they are based upon, implying that this needs to be made explicit, with regular updating to reflect the evidence base and evolving practice. The evolution of evidence-based guidelines requires that they be based upon a systematic review of the literature, use meta-analysis to assess the evidence base, and synthesise the information prior to making recommendations where the link to the literature and strength of the evidence is explicit. Guidelines

have been accused of promoting 'cookbook medicine' and of inadvertently raising the risk of litigation in specific situations where they may not be applicable or practicable. This has led to some ambivalence in their universal acceptance.

Publication of data assessing health care is currently being used in an effort to identify areas requiring improvement and to reward 'good areas', notably in the UK, which has introduced financial inducements related to performance data. However, the publication of data comparing clinical practice may lead to difficulties due to variable case-mix, the differing therapeutic options available within an area and the risks the operator is prepared to take. For example, surgeons who avoid high-risk patients will have lower mortality rates, but this will exclude higher-risk patients from potentially efficacious treatment, which is hardly the desired outcome. These considerations apply at both the individual and organisational levels. Other measures that have been used include patient involvement, feedback and audit. All of these have their proponents and detractors; none is a panacea, as noted above.

3.4.4. Standardising processes to excellence

Deming's original approach was to standardise a process by eliminating all unnecessary steps and variations with the ultimate goal of achieving excellence [47,48]. Health care equivalents include evidence-based clinical pathways, disease/symptom management programmes and standardised referral protocols. Evidence-based clinical pathways identify all possible outcomes against a time scale and relate this to the evidence base and agreed best practice in the field. Pathways require a multidisciplinary approach with shared notes as a communication tool, where the health care professional signs against the expected event. Free text is generally used to record variation from the pathway, which can be due to patient choice amongst other factors. Pathways are being used in both primary and secondary care. The approach requires a fundamental change in attitude in medical practice relating to putting the patient at the centre of care, and in attitudes towards ownership of clinical notes [49]. It allows ongoing review of current practice and thus facilitates improvement efforts, as well as enabling the rapid introduction of advances in practice based on research. Disease/symptom management programmes are similar, except that they may be targeted against specific symptoms, e.g., chest pain clinics/pathways or diseases, such as diabetes mellitus, hypertension, stroke, asthma and cancer. Chronic disease management is attracting much attention as it has the same theoretical possibilities for improved clinical and financial management. Standardised referral protocols aim to improve communication and reduce mistakes at interfaces of care, which are known to be prone to this, reconciliation of information on either side of the interface has been used to reduce medication errors. Electronic records that follow patients across

interfaces of care (primary, secondary and tertiary) are seen to have much potential to reduce error and to simplify patient care. In some systems, this is being used to enable seamless care, where patients are admitted to hospital without the need for reassessment. This approach also enables joint disease management programmes to be implemented.

3.5. Using sound measurement

3.5.1. Industry and sound measurement

Six Sigma [37] was developed by Motorola in the 1970s. This system assesses critical customer requirements using defined methodology. Measurement of process defects that affect important client requirements is the first phase, followed by analysis to determine possible improvement areas. The improvement phase is followed by a control phase using statistical process control (SPC) tools. Sigma is a statistical measure of standard deviation from the mean in a Gaussian distribution; one sigma represents a tolerance of 790,000 errors per million opportunities. Six sigma tolerates 3.5 defects per million. Industry is now applying this approach to services.

3.5.2. Health care and sound measurement

Variation in outcomes has become a focus within health care, with various indicators being developed. The main problem with this approach has been the identification of appropriate markers. An outcome indicator assesses the actual health care outcome of a process, e.g., the number of amputations that a diabetic population undergoes. A process indicator tries to assess the adequacy of the process of care, e.g., assessing the frequency with which neuropathy is

actively looked for in diabetics. Very often, surrogate indicators are used in place of monitoring actual outcomes, an example being the use of HbA1c measurement to assess diabetic control. The evidence base for using various measures is still very limited, and much effort is being made to find adequate indicators. Most process indicators in use are actually surrogates for outcomes, with a limited evidence base regarding their relationship to long-term clinical outcomes.

The problems associated with assessing variation in clinical practice are compounded by the tendency to focus on what is measurable, which may not necessarily be clinically important. 'Cooking the books' is not unknown in health care. Managers have been known to devise ways and means to evade transgressing required targets when these are measured (e.g., devising a waiting list for a waiting list so that patients do not 'wait' longer than predefined periods!). Benchmarking against best in class is being advocated as a means of identifying and improving practice. Some indicators are being collated nationally, then compared in pooled data to be used as international benchmarks enabling quality improvement efforts. Examples include mortality (inpatient), unscheduled readmissions following a visit to the A&E Department and unscheduled readmissions within 15 days [50]. This information enables better discharge planning, coordination of community care and long-term follow-up pathways; it is also being applied to clinical management [51].

A zero defects approach, as advocated by Chassin, advocates the use of six sigma in health care [52,53]. Table 3 illustrates a comparison of sigma levels with examples. It is noteworthy that health care does not reach six sigma. Drug prescription may be amenable to this approach as it is

Table 3

Selected health care quality problems viewed as defects per million compared with quality performance in selected industries (from Chassin [53])

Sigma level	Defects per million	Selected health care examples	Selected industrial examples
6	3.4	–	Allied Signal: 3 model factories
		–	Publishing: one misspelled word in all the books in a small library
	5.4	Deaths caused by anaesthesia during surgery	–
5	10,816	–	2 Siebe plants in Italy and United Kingdom, making temperature controls for refrigerators.
	230	–	Airline fatalities
4	6210	–	Airline baggage handling. Restaurant billing
	10,000	1% of hospitalised patients injured by negligence	–
3	66,800	–	Publishing: 7.6 misspelled words per page in a book
	210,000	21% of ambulatory antibiotics for colds	–
2	308,000	–	–
	580,000	58% of patients with depression not detected or treated adequately	–
1	690,000	–	–
	790,000	79% of eligible heart attack patients who fail to receive beta blockers	–

a defined process that can be monitored and that has a high throughput; both attributes are prerequisites for success. Computerised prescription systems have been shown to reduce the error rate significantly [54].

3.6. Promoting effective teamwork and removing barriers

A TQM approach requires seamless teamwork, with reduced barriers dividing different levels of care. All of the ‘quality gurus’ advocate teamwork, with quality improvement teams [36] focusing on motivation by changing attitudes, behaviour and culture [35], with managerial responsibility for leadership [41] and good communication [55]. The importance of teamwork also applies to health care [49,56]; yet, medicine is characterised by its ‘tribal nature’ [56], with each profession living in its own world. Moss [56] noted the ‘disadvantage of the divided views and approaches to quality that are endemic within the NHS is that the potential capacity of any group alone to improve quality is limited’. The importance of identifying the different team roles and professional drivers acting is critical in identifying the motivation of different team members and colleagues, because consensus cannot be built by ignoring strong individual motivations. Blumenthal [57] and Berwick [58] noted that physicians need to move to the partnership approach inherent in TQM.

Culture is perceived to be an important driver of quality improvement in health care [59], with certain cultural attributes being linked with high quality [60], in particular linking in with organisational, corporate and wider cultural perspectives [59,61–63] (Table 4). Davies considered the role of cultural transformation and destination as a means of improving performance [59,61]. Aron and Headrick [64] noted that educating physicians prepared to improve care and safety is no accident: it requires a systematic approach starting from the early training years. ‘Medical schools and academic health centres are among the most important contributors to the culture of the practice of medicine’ and thus have a role to play in ‘upstream’ development’ (i.e., on the supply side) [64]. In this respect, the traditional compartmentalisation that starts from undergraduate training, with little interstudent contact during training, which is very competitive, is unlikely to facilitate the development of the team working skills required for quality improvement.

Table 4
Focus on effective teamwork and removing barriers—culture (after Newman [62] and Robbins [63])

• Attitudes to innovation	• Internal or external focus
• Risk-taking	• Uniformity or diversity
• Degree of central direction	• People orientation
• Patterns of communication	• Team orientation
• Outcome- or process-oriented	• Aggressiveness/competitiveness
	• Attitudes to change

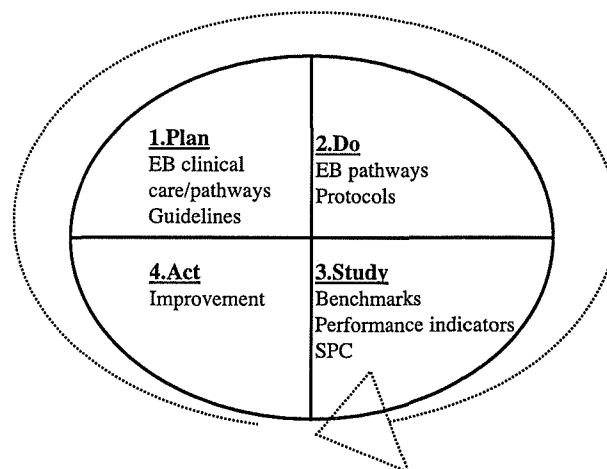


Fig. 4. Deming's PSDA cycle and health care; EB=evidenced-based; SPC=statistical process control.

3.7. Understanding that the process is continuous

Quality improvement is a slow, continuous process for which Deming developed the PDSA cycle (Fig. 4), consisting of a ‘planning phase’, followed by a ‘doing phase’, then a ‘study phase’ and finally an ‘acting phase’. This approach has been applied to clinical practice as shown. Deming's cycle has close parallels with Kolb's learning cycle [65], describing the learning process; the implications of this approach are that it should be efficacious in enabling development and improvement, as it coalesces reflective observation with active experimentation through concrete experience.

3.7.1. Learning improvement and medicine

For quality improvement to become part of the culture, there has to be a move towards educating for capability to face changing needs [66]. Industry incorporates skills in improvement methods as tools for improving the capacity of a process for ‘fitness for purpose’. Wilcock and Lewis [67] advocate teaching medical students and doctors quality improvement methodology as a core skill to ‘put quality improvement at the heart of health care’, by sustaining quality improvement throughout their careers. Doctors are required to have knowledge about their discipline, peer group and values to practice. For improvement to occur, there also has to be the acquisition and application of improvement tools. This requires knowledge of process or systems and their variation, cross-functional linkages within

Table 5
Capability and medicine [American Council for Graduate Medical Education (ACGME) General competencies required by physicians [68] (Feb 1999)]

• Patient care
• Medical knowledge
• Interpersonal and communication skills
• Professionalism
• Practice-based learning and improvement
• Systems-based practice

Table 6

Ten simple rules (taken from Crossing the Quality Chasm: A New Health System for the 21st Century [1])

-
- (1) Care is based on continuous healing relationships
 - (2) Care is customized according to patients' needs
 - (3) The patient is the source of control
 - (4) Knowledge is shared and information flows freely
 - (5) Decision making is evidence-based
 - (6) Safety is a system property
 - (7) Transparency is necessary
 - (8) Needs are anticipated
 - (9) Waste is continuously decreased
 - (10) Cooperation among clinicians is a priority
-

organisations, and how to work within them, as well as the psychology of change and its management. This approach is advocated by the American Council for Graduate Medical Education [68] (Table 5) and the European Federation of Internal Medicine (EFIM) [69].

4. Change management

For change to be brought about, a further understanding of the system the clinician practices in is required. Health care is a complex adaptive system, distinguished by its complexity [70]; there is no single controlling force to which it is subject. A variety of forces act upon it and it does not respond linearly. In addition, it is provided at various levels, at many sites and is subject to different systems, implying that change management is intricate and likely to be difficult and unpredictable.

The focus of this article is that of the clinical care provider; effective change at this level requires addressing various aspects, including people, processes, information and how change is to be implemented. Complex adaptive systems respond to simple rules that are explicit in giving direction and values [71]. This change process has discrete steps that first require the identification of the implicit value that is motivating people. This is followed by deconstruction of this current implicit value, which is then to be replaced by a new explicit value, constructed and supported so as to provide new, creative directions for practice. Transformational change can be introduced through understanding the motivating factors ('attractors') for providers and using these to enable development in the desired directions. The IOM Report [1] described different levels of transformational change and made recommendations to improve quality of care. It proposed 'Ten Simple Rules' (Table 6) for the clinician level (microsystem) that provide the basis for a paradigm shift in medical practice.

5. Conclusion

Clinical medicine is being affected by many industrial approaches that focus on process management and its

improvement. Whilst much progress has been made in various national spheres, what is lacking is a multidimensional, supranational approach linking up various centres, as well as rigorous project evaluation, international standard setting, public involvement and patient empowerment. The individual clinician needs to have an understanding of developments in the area so as to be proactive in quality improvement.

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