

**A systematic narrative review of quality
improvement models in health care**
(in support of NHS Quality Improvement Scotland)

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Headline findings

- The wide range of initiatives aimed at improving quality in health care organisations includes programmed approaches that build on models and tools first used in industry. Foremost among these are: TQM/CQI, BPR, rapid cycle change, lean thinking and Six Sigma.
- These approaches have been variously adopted since the early 1990s by many health care organisations in the UK and elsewhere, but there is little uniformity in nomenclature or in the content of programmes, and many organisations have used a combination of tools and approaches eclectically and variably over time.
- This systematic narrative review examines evidence for the success of these approaches, and explores the lessons that have been learned about effective implementation.
- In part because of variations in implementation, and in part because of the methodological challenges of studying any complex intervention, there is limited evidence available to assess how effective these approaches are in health care (or, indeed, in industry). Data on the cost-effectiveness of such approaches are largely lacking.
- However, a wide range of studies *do* provide insight into the experiences of implementing these quality improvement approaches in different health care settings, and broad lessons can be drawn about the potential for successful adoption in health care.
- No matter what model or approach to quality improvement is used, the broader literature on organisational change in health care, together with the studies reviewed in this report, suggest that there is a broad set of ‘necessary, but not sufficient’ conditions that need to be in place for successful implementation.
- ‘Necessary, but not sufficient’ conditions include: provision of the practical and human resources to enable quality improvement; the active engagement of health professionals, especially doctors; sustained managerial focus and attention; the use of multi-faceted interventions; coordinated action at all levels of the health care system; substantial investment in training and development; and the availability of robust and timely data through supported IT systems.

- The studies reviewed in this report show that although the models vary in their emphases and underlying principles, the different models have considerable similarities in implementation. *Importantly, there is no one right method or approach that emerges above the others as the most effective.*
- The success or otherwise of implementation depends crucially on the interaction between the local context and the approach as it is applied.
- This means that using any of these programmed approaches to quality improvement requires (at least):
 - recognition of the generic characteristics of all health care organisations that make quality improvement particularly challenging in this field, *and*
 - careful consideration of local circumstances to determine the model or approach that provides the 'best fit' locally (however imperfect), *followed by*
 - application in the local context in a programmed and sustained way, which may include considerable *adaptation* of the approach to suit the local circumstances and to respond to emerging developments.
- The implementation of quality improvement programmes places key responsibilities not only on front line clinicians planning and making changes to patient care but also on middle and senior managers in key supporting roles.
- Managers need to be actively involved with quality improvement for both symbolic and practical purposes: to ensure that quality improvement activities are aligned with the strategic objectives of the organisation and are resourced effectively; to address system barriers to changes; to embed effective practice into routine processes; and to ensure that the organisation makes full use of the external resources available to support local quality improvement.

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Executive summary

“Most quality improvement interventions work some of the time, but rarely live up to the dramatic claims made for them in their early stages. Success is contingent upon multiple factors, including the manner of implementation in each setting and specific local contextual factors.” (Locock 2003: 56)

Reviewing quality improvement interventions

Recognition of actual and potential deficits in quality in health care in the past two decades has prompted health care organisations to introduce a wide range of initiatives and programmes. Many of these approaches have drawn on quality improvement models which originated outside health care. This systematic narrative review seeks to understand what approaches exist, their relative strengths and weaknesses when used to inform quality improvement in health care, and their potential for application in the organisations that make up NHSScotland.

Making sense of the quality improvement literature

The quality improvement literature is large and sprawling. In part, this reflects the very broad range of activities and interventions aimed at quality improvement in health care. This review focuses on those strategies adopted at organisational level, with a particular emphasis on:

- Total Quality Management (TQM)/ Continuous Quality Improvement (CQI)
- Business Process Reengineering (BPR)
- The Institute for Healthcare Improvement (IHI)’s rapid cycle change
- Lean thinking
- Six Sigma

The review considers each of these approaches individually, while recognising that the models are not always well defined and that health care organisations often draw on a range of tools and principles from different approaches. After reviewing the background and evidence for each of the five models, the review considers the evidence internationally on five system-wide multi-model approaches that stood out in the literature because of the descriptive and evaluative work that has accompanied their implementation. These are Jonkoping County (Sweden), Kaiser Permanente and the VA QUERI initiative (the US), the ‘Organising for Quality’ case successes (Europe/US), and the IHI’s ‘100,000 Lives Campaign’ and related quality and safety initiatives (world wide).

The nature of evidence on quality improvement interventions

There is a growing consensus that quality improvement initiatives or programmes like TQM, BPR or lean thinking are best understood as complex interventions that are introduced into complex and diverse ‘social worlds’. This means that the types of

research methods used to understand and evaluate quality improvement initiatives need to shed light on the interaction between the intervention and its context. Traditional experimental research methods like randomised controlled trials have a limited role in this respect but the review was able to draw on a wide range of studies of quality improvement in health care that use diverse social science methods (e.g. observation, semi-structured interviews and action research). These studies provide informative explanatory analysis “*discerning what works for whom, in what circumstances, in what respects and how*” (Pawson et al 2005: S21). These studies therefore have much to say on implementation, but data on the cost-effectiveness of quality improvement interventions are almost completely absent..

Approach to the reviewing task

The search for relevant studies covered a wide range of sources including key databases, websites of government bodies, health policy organisations and research centres in the UK and worldwide, key medical, health services research and wider management journals in the field of quality improvement, and a search of the publications of key individuals writing in the field of quality improvement in health care. Synthesis of the studies was carried out in accordance with the broad principles of realist review: seeking to understand the key strengths and challenges of using these quality improvement approaches in health care organisations.

The full draft report was reviewed by six reviewers with expert knowledge of the field (three from health care organisations and three from academic institutions) to ensure completeness and validity of interpretation, and the final draft was revised in the light of reviewers’ comments.

The review findings

The five models are described and evaluated separately in order to bring out some important conceptual differences between them. In practice, however, distinctions between the models are not always clear-cut: there are many areas of overlap, with many of the approaches employing very similar tools and techniques. In implementation, health care organisations have tended to apply a combination of tools and approaches in a piecemeal and eclectic way.

What the models do have in common is that they all require the same broad set of ‘necessary, but not sufficient’ conditions for successful implementation. These conditions emerge strongly from the studies reviewed in this report as well as from the broader literature on health service change. They include: the active engagement of health professionals, especially doctors; the active participation of middle and senior managers, and the support of board members; the use of multifaceted interventions and sustained action at different levels of the health care system; the alignment of quality improvement activities with the strategic goals of the organisation; and the embedding of quality improvement as an integral part of the everyday work of all staff (rather than as the responsibility of a separate directorate or team).

Effective quality improvement work – whatever the model that structures this work – also needs to be supported by robust IT providing timely local data, and requires significant investment in staff training and development.

Five key models for quality improvement

1: Total Quality Management (TQM)/Continuous Quality Improvement (CQI)

The approaches TQM and CQI are often used interchangeably. Developed in Japan in the 1950s, their use in health care increased in the 1990s. Key components include an emphasis on quality improvement as an *ongoing* activity aimed at continuous improvement focused on the needs of internal and external customers. Quality improvement is data-driven and is led by managers but carried out by ‘empowered’ cross-functional teams. Although TQM/CQI has been widely adopted in health care (in name at least), there have been significant problems in embedding the core approach in health care organisations. In particular, TQM/CQI has had little impact on the work of medical staff.

2: Business Process Reengineering (BPR)

Classical BPR emerged in the US in the 1990s. It emphasised a radical ‘clean break’ approach to organisational change, but has rarely been implemented to its full extent, whether in health care or in other settings. Two substantial three-year NHS re-engineering pilots in the 1990s produced only modest changes. The enduring legacy of BPR has been its emphasis on the importance of examining and redesigning processes: this (together with TQM/CQI) has contributed to a range of more recent redesign initiatives in the UK (and internationally) around patient-centred care (e.g. redesigning care pathways).

3: Institute for Healthcare Improvement (IHI) and rapid cycle change

Rapid cycle change is based on Langley’s Model for Improvement which asks three questions: What are we trying to accomplish? How will we know that a change is an improvement? What changes can we make that will result in improvement? These questions are put into action by front-line staff through Plan-Do-Study-Act cycles (PDSAs), which provide a framework for repeated short-cycle small-scale tests of change linked to reflection. PDSA cycles have been widely used in the initiatives promoted by the US Institute for Healthcare Improvement, and particularly in quality improvement collaboratives (e.g. the National Primary Care Collaborative in the NHS). They enable low-risk tests of change based on the proposals of front line staff and may therefore encourage useful staff engagement in quality improvement. As yet, however, there is only limited evidence in the peer-reviewed literature in terms of changes in outcome or practice patterns from the rapid cycle change approach and quality improvement collaboratives. It is likely that ongoing work at various sites will begin to address these evidence gaps.

4: Lean thinking

Lean thinking was developed by Toyota in the 1950s. It emphasises streamlining processes to provide what the internal or external customer wants with minimal wasted time, effort or cost. The approach uses a range of tools including 5S or CANDO (a series of five steps to enable workforce teams to look at the environment they work in and to start to identify the blocks in current processes) alongside ‘value stream mapping’ (to remove any unnecessary steps in a process). Lean thinking approaches have been applied in health care settings with some success in reducing waste. The approaches appear to be particularly useful in streamlining processes in support departments rather than mainstream clinical services. Wholesale application has not yet been demonstrated in health care settings.

5: *Six Sigma*

Six Sigma is the newest of the five approaches: it has been used in industry since around 1980 and in health care only in the last decade. Six Sigma uses a structured approach (DMAIC – Define Measure Analyse Improve Control) and statistical tools (e.g. statistical process control) to identify variations in a process and to distinguish between ‘chance’ (or ‘common cause’) variation and assignable (or ‘special cause’) variation. Six Sigma has been applied to a limited extent in health care, and has some potential for wider application. However, the approach does require statistical expertise (to provide advice and direction on statistical approaches and analysis) alongside reliable local data collection. There has been increasing use of a combination of lean thinking and Six Sigma in the NHS (Lean Six Sigma) in recognition of the need to streamline many health care processes (through lean approaches) before the more exacting tools of Six Sigma can be applied.

Conclusions

Health care organisations share a range of generic characteristics that make them particularly challenging for quality improvement programmes: complex care processes; multiple stakeholders; long-standing inter- and intra- professional ‘turf wars’; an emphasis on individual proficiency rather than team-working; a history of challenging relationships between managers and health professionals; varying standards of data and infrastructure support for data collection/analysis; and a long history of successive top-down reorganisations and change programmes. These characteristics need to be borne in mind when considering which approaches to quality improvement will have greatest application in health services.

Importing quality improvement techniques from outside health care may have the benefit that the tools and approaches have been tested to some degree, but the complexity of health care and the contingencies of the particular local and organisational circumstances can combine to overwhelm these potential advantages.

Nonetheless, the accumulated knowledge from more than two decades of research, evaluation and experience has highlighted that, whatever quality improvement methods or approaches are used, there are core conditions that need to be met. Health care organisations need to:

- Apply methods consistently over a sufficiently long timescale with demonstrated sustained organisational commitment and support;
- Involve doctors and other health professionals in a wide team effort while providing adequate training and development;
- Seek active involvement of middle and senior managers, the board (including non-executive directors) and, most obviously and visibly, the chief executive;
- Integrate quality improvement into the organisation’s other activities (so that it is part of the organisation’s strategic plans and priorities, targets etc);
- Tailor the selected methods to local circumstances;
- Create robust IT systems that enable the measurement of processes and impacts, iteratively refining the approaches used;
- Acknowledge – and ameliorate as far as possible – the impact of competing activities/changes.

The review of the models and system-wide approaches shows that there are strong commonalities between them: although they may have different emphases, many share similar underlying objectives, and the distinctions between the approaches are often blurred in practice. Moreover, each of the approaches and the data used to underpin them can be used either to *enable* quality improvement by ‘inspiring and developing’ or to *mandate* quality improvement through ‘policing, punishing and rewarding.’

Despite the many insights into implementation that can be drawn from the studies, it remains hard to assess the overall impact of specific programmes in individual organisations or to make comparisons of approaches across a range of studies. What is clear from this review and from the broader literature on organisational change is that there is no one ‘right’ quality improvement method. Instead, successful implementation may be more about the interaction between any given programme and its implementation in the local context. This suggests that the following inter-linked processes are important:

- the thoughtful consideration of local circumstances and selection of the approach (or combination of approaches) that is the ‘best fit’ (however imperfect) for the local organisation;
- the adaptation of the approach so that it best reflects the local circumstances at the outset and responds to emerging developments as implementation unfolds; and
- the careful and sustained application of the approach in a way that is congruent with current knowledge on key considerations in change management in health care.

Thus quality improvement programmes – of whatever hue – will place simultaneous responsibilities on front-line health professionals and on managers at all levels. Managers need to be actively involved with quality improvement for both symbolic and practical purposes: to ensure that quality improvement activities are aligned with the strategic objectives of the organisation and are resourced effectively; to address system barriers to changes; to embed effective practice into routine processes; and to ensure that the organisation makes full use of the external resources available to support local quality improvement.

Finally, so that quality improvement work contributes to its own evidence base, it is essential to put in place some form of ongoing evaluation (both qualitative and quantitative): *“in a sense we should view every quality improvement programme as a kind of experiment, and design it to be ‘auto-evaluative’ so that the programme itself produces information about its own effectiveness.”* (Walshe and Freeman 2002: 87).

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Introduction

The growing focus on quality of health care in the past two decades (Batalden and Stoltz 1993; Ferlie and Shortell 2001; Ham et al. 2003; Teasdale 2008) has led to much debate about how quality is defined and about whether and how health systems can be organised so that quality is an integral component of care. There is increasing recognition that quality in health care is complex and multi-faceted; this is demonstrated in the influential definition from the Institute of Medicine* which identifies six dimensions through which the overall concept of quality is expressed:

- Safety
- Effectiveness
- Patient-centredness
- Timeliness
- Efficiency
- Equity

Although there is broad agreement about the inclusion of these dimensions, it is well recognised that quality of health care is not a static concept: it depends on such factors as whose perspective is taken, the timescale over which it is examined, and the purpose of any measures applied (Chin and Muramatsu 2003; Currie et al. 2005):

“Quality is a term which defies precise definition... [it] is a contested concept, and is defined by individual actors according to their particular experiences, value systems, and deeply held assumptions.” (Sutherland and Dawson 1998: S20-21).

Different professional groups have different views on what constitutes quality or a good outcome of health care (Davies et al 2006) and equally problematic are consumer definitions of quality in health care, whether as patients or relatives, carers or taxpayers.

Despite these ongoing debates, recognition of the actual and potential deficits in quality in health care has prompted the introduction of a wide range of diverse initiatives and programmes which aim to address these challenges. Many of these approaches have drawn on quality improvement models which originated outside health care. A growing body of literature describes and analyses the experience of applying these models in health care settings. This systematic narrative review has been commissioned to understand what approaches exist, their relative strengths and weaknesses when used to inform quality improvement in health care and their potential for application in an organisation like NHSScotland.

* Crossing the Quality Chasm: A New Health System for the 21st Century. Institute of Medicine, Washington DC: National Academy Press, 2001

In reviewing this literature, three key issues will be addressed¹:

- What models exist for quality improvement in health care particularly at organisational level?
- What evidence is available on their usefulness, effectiveness and potential application in a system such as NHSScotland?
- How can NHSScotland learn from this literature and what are the implications for NHS QIS in the development, dissemination and implementation of its conceptual framework?

Making sense of the literature on quality improvement interventions

The literature on quality improvement in health care is large and sprawling; in part, this is a reflection of the very broad range of activities and interventions that can be classed as aimed at quality improvement. These interventions have been classified in many different ways (see for example Leatherman and Sutherland 2008; World Health Organisation Europe 2008). For example, interventions can be categorised by their primary focus (e.g. interventions aimed at patients or interventions aimed at medical products and technologies) or by the level of the health system at which they are directed (e.g. interventions directed at commissioning bodies or interventions directed at individual health professionals). Interventions may be categorised according to the extent to which they seek to *enable* quality improvement by ‘inspiring and developing’ or to *mandate* quality improvement by ‘policing, punishing and rewarding’ (World Health Organisation Europe 2003).² The approach used in this review is to take what the Health Foundation’s Quest for Quality and Improved Performance Programme (QQIP) categorises as organisational interventions (Leatherman and Sutherland 2008) and to draw from the literature the main programmed approaches to quality improvement that have been used in health care settings in the past twenty years (Box A) in order to explore how they have been used and to what effect.

Box A: The main programmed approaches to quality improvement

- Total Quality Management (TQM)/ Continuous Quality Improvement (CQI)
- Business Process Reengineering (BPR)
- The Institute for Healthcare Improvement (IHI)’s rapid cycle change
- Lean thinking
- Six Sigma

These five approaches are those which predominated as the main organisation-level programmed approaches in the literature reviewed. Our focus on organisation-level approaches means that quality improvement interventions which operate at a different level are not to the fore in this review. For example, we do not focus on micro-level approaches to quality improvement (e.g. approaches to the revalidation of individual health professionals) or on macro-level approaches to quality improvement (e.g. national systems of financial incentives or national accreditation of whole

¹ As requested by NHS Quality Improvement Scotland in the commissioning brief.

² In practice, many health care systems use both. These functions may be combined in the same body or programme which can cause problems (e.g. the conflict between data collection for learning and data collection for judgement, the impact on health professionals’ willingness to report ‘near misses’) (Wallace et al 2001; World Health Organisation Europe 2003).

organisations). However, the focus in this review on these five organisation-level programmed approaches does inevitably mean that the review touches briefly on a range of other approaches to quality improvement which are subsumed within or overlap with the programmed approaches, but which have their own substantial bodies of literature that cannot be covered here. For example, many redesign and rapid cycle change approaches look at *clinical pathways*; the ‘bundles’ (combinations of tasks based on best practice) used in safety initiatives are an example of *evidence-based practice*; *learning organisations* (a major theme in the quality improvement literature in the past decade) may emerge as an outcome of the application of these programmed approaches.

Four of the approaches covered in this review were developed in industry and have since been applied in health care settings (i.e. TQM/CQI, BPR, Lean thinking and Six Sigma). Their effectiveness in industrial settings is disputed and they have attracted controversy and critique in their own right (see for example Tuckman 1994; Zbaracki 1998; Kaboolian 2000; Kelemen 2000; Sorge and van Witteloostuijn 2004; Learmonth 2008; Messner et al. 2008). Their adoption in health care settings has been the subject of ongoing debate in the literature, although it has been argued that with the increasing use of these approaches, the debate is now largely about how best to translate and adapt them rather than about whether to use them at all (World Health Organisation Europe 2003).

These approaches have been applied in many different ways: the ‘brand’ names and their key components are not always well defined and the names are often used by different organisations to describe a whole range of different activities that might not conform to the approach as originally defined by its pioneers. Many quality improvement programmes borrow tools and principles eclectically from a range of approaches and indeed some distinct hybrids are developing (e.g. Lean Six Sigma: NHS Institute for Innovation and Improvement undated). Moreover, some approaches are being combined in bespoke configurations to underpin system-wide initiatives (McCannon et al. 2006; McCarthy and Blumenthal 2006; Andersson-Gare and Neuhauser 2007).

Despite these complexities, this review uses the five approaches listed in Box A as a starting point for exploring the literature. For convenience these approaches will be referred to by the terms ‘approach’ or ‘model’ but, in keeping with the observations already made, these terms should be interpreted loosely rather than as references to well-defined and discrete entities. After explaining the background and evidence for the five main models we then examine the evidence in support of five system-wide multi-model approaches that stand out in the literature for the descriptive and evaluative efforts that have been made alongside their implementation.

The nature of evidence on quality improvement interventions

Having identified the type of quality improvement interventions the review will address, the next issue concerns what evidence the literature provides as to their effect in health care settings. There is a growing consensus (e.g. Macfarlane et al. 2004; Walshe 2007; Bate et al. 2008) that quality improvement initiatives or programmes like TQM or rapid cycle change are best understood as complex interventions that are introduced into complex and diverse ‘social worlds.’ Viewing quality improvement

initiatives in this way has implications for the choice of research method and for the conclusions that can be drawn from research studies in this field (Pawson et al. 2005).

As complex interventions, quality improvement initiatives are critically influenced by the contexts into which they are introduced and by the processes of implementation in those contexts (Ovretveit 2004; Walshe 2007): “*the interventions depend for their results on the conditions that surround and interact with the QI [quality improvement] intervention and that help or hinder the intervention, often by affecting the ‘depth of implementation.’*” (Ovretveit 2004: 16-17).

This means that the types of research methods used to understand and evaluate quality improvement initiatives must be able to shed light on how context and implementation interact in particular organisations. Traditional experimental research methods like randomised controlled trials are unlikely to illuminate these processes because they are designed for a different purpose (Ovretveit and Staines 2007; Berwick 2008; Crump 2008; Lindenauer 2008): “*randomised controlled trials, and the scientific paradigm of which they are a part, systematically obscure the conditional interaction that we need to understand*” (Ovretveit 2004:17). Indeed, traditional systematic reviews focused on RCT evidence are likely to be forced to conclude that there is limited evidence to support any of the existing quality improvement approaches (Health Evidence Network 2006; Lindenauer 2008).

Taking a wider perspective on what counts as knowledge and evidence, however, we can see that there are in fact many helpful studies using more diverse social science methods (e.g. observation, semi-structured interviews, action research). These studies provide different kinds of data and enable some informative explanatory analysis: “*discerning what works for whom, in what circumstances, in what respects and how*” (Pawson et al 2005: S21).

In this review, therefore, we draw on a wide range of studies that emerge from and utilise varying methodological approaches. We use these studies to provide insight into the strengths, weaknesses, applicability and use of particular quality improvement approaches. Taken together, these enable lessons to be learned about what has worked in some settings and may be useful (with appropriate modification to suit local circumstances) in other settings. However, a weakness of the literature on quality improvement methods is that there is little discussion of – or evidence on – the costs of implementation (Jarlier and Charvet-Protat 2000). Reference is sometimes made to broad notions of the direct and indirect costs of quality *failures* (e.g. litigation, delayed discharge, length of stay prolonged by avoidable complications, duplication of tests) (Merry and Wing 1993), and many quality improvement interventions have as one of their stated objectives to reduce costs through greater efficiency (Hurst 1995). However, there is little reference to the costs of introducing and carrying out (and indeed evaluating) quality improvement programmes themselves. Where evidence is available, it is limited and contradictory (Hurst 1995). Quality and safety are seen as inherently ‘good things’ and so the issue of costs is largely overlooked (Hurst 1995; McDonnell et al 2006; Landefeld et al 2008). This is an important area for further work, although it is well acknowledged (e.g. Brennan et al 2005) that measuring and analysing costs and savings from quality improvement programmes does present complex challenges.

Approach to the reviewing task

The search for studies of the main programmed approaches to quality improvement that have been applied in health care settings had several inter-related components: a search of key databases (including Health Management Information Consortium, Cochrane); a search of the websites of relevant government bodies, health organisations and research centres in the UK and worldwide (including (in the UK), the Nuffield Trust, the King's Fund, the Health Foundation, Quality Improvement Scotland, Audit Scotland, the NHS Institute for Innovation and Improvement, the National Institute for Health Research) and (outside the UK) the World Health Organisation, the National Institute of Clinical Studies and the Institute for Healthcare Improvement); a search of key medical, health services research and wider management journals in the field of quality improvement; and a search of the publications of key individuals writing in the field of quality improvement in health care. The reference lists of retrieved papers and reports were reviewed for further relevant material and the search was supplemented by the authors' existing knowledge of major recent reports and reviews in the field.

In synthesising this broad material for the purposes of this narrative review, the research team was guided by the review's three questions and by the broad principles of realist review (Pawson et al. 2005): drawing on a wide range of material in order to arrive at a better understanding of the experience of using quality improvement approaches in health care settings. The material was read and discussed by the team to assess what the literature shows about the strengths and challenges of each model and to extract the key findings from the reported experience of applying the models in health care. Further discussion and reading across enabled a synthesis of the common themes and the implications for quality improvement in health care.

The full draft report was reviewed by six reviewers with expert knowledge of the field (three from health care organisations and three from academic institutions) to ensure completeness and validity of interpretation; the final draft was revised in the light of the reviewers' comments.

The review findings

The review that follows will firstly consider in turn the main programmed approaches/models of quality improvement applied in health care settings that emerged from the literature (see Box A above). For each model, a summary account is offered comprising a description of the approach, its historical and theoretical roots, and its main methods, together with a review of the empirical evidence of its use in health care settings, with an outline of any strengths, opportunities and challenges. Each of these models has a corresponding 'Technical Appendix' which contains a fuller explanation of the model and further details of the empirical studies on which the summary review of that approach is based.

Having reviewed the five models, the review will then consider what emerged from the literature on major case studies of health care systems where a strategic system-wide approach to quality improvement has been used incorporating diverse models and methods. These case studies demonstrate further the range of hybrid approaches to quality improvement alluded to earlier. The Discussion section will 'read across'

the models and case studies of health care systems to bring out similarities and differences, to draw together key findings and to consider the implications.

Five models of quality improvement

The five models reviewed here are described separately for convenience and in order to bring out the differences between them. However, as the individual accounts acknowledge, and as the later case studies show, in practice the distinctions between the models are not clear-cut in practice. There are many areas of overlap and in health care organisations the models have been applied piecemeal and in combination with other tools and approaches in a range of hybrids.

Core conditions for successful implementation

What the models *do* have in common is that, despite their differences in origin or in emphasis, they all require the same broad set of conditions to be met. These are summarised in Box B.

Box B: Necessary but not sufficient conditions for successful implementation of quality improvement initiatives

- Quality improvement activities aligned with the strategic objectives of the organisation and integrated into the organisation's other activities
- Quality seen as an integral part of everyday work and as the responsibility of all staff (i.e. not handed over to a separate unit or directorate)
- Recognition that quality improvement takes a long time to be firmly established in an organisation
- The active engagement of health professionals and in particular doctors
- Belief among staff that they as well as patients will benefit from the changes
- Strong leadership from clinical, administrative and political leaders at different levels of the health system and a clear vision to guide the programme
- Sustained and active participation in quality improvement activities by board members and senior managers
- The use of multifaceted interventions and sustained action at different levels (i.e. individual, team, organisation, the wider health care system)
- Substantial investment in training and development (e.g. in project management and facilitation of change as well as in clinical skills required for new roles)
- Support from a designated team of change agents to provide skills and knowledge and to maintain momentum
- Robust and timely data of different kinds (quantitative and qualitative)
- Resources (e.g. finance, staff cover, training, IT systems) to support quality improvement
- Substantial training and support for health professionals and other staff using IT in new ways

Sources: derived from a range of quality improvement and organisational change studies. See for example: Pollitt 1996; Ovretveit 1997; Ferlie and Shortell 2001; Grimshaw et al. 2001; Locock 2001; Ham et al. 2003; Greenhalgh et al. 2004; Touati et al. 2006; Dickinson and Ham 2008; Ward et al. 2008.

This means that whatever quality improvement approach or combination of approaches is used, it is unlikely to be successful unless these conditions are satisfied. The set of conditions listed in Box B emerges strongly from the quality improvement studies on which this review is based and is also derived from what the generic literature on organisational change in health care concludes about critical factors for successful organisational change (e.g. Ferlie and Shortell 2001; Ham et al. 2003; Greenhalgh et al. 2004; Dickinson and Ham 2008). This set of conditions should be borne in mind as an important backdrop when reading through the accounts of the individual models and case studies. The conditions are included here to sensitise the reader to these essential underpinnings of successful implementation, issues to which the report will return in its concluding sections. The conditions are deliberately couched in broad terms because they need to be regarded firstly as necessary but not sufficient, and secondly as broad descriptors of what in practice will need to be locally-tailored interpretations and adaptations of them. The issue of the fundamental need to tailor quality improvement activities to local context is discussed further in the Discussion section.

Against this background, the five models will first be discussed in turn followed by the accounts of system-wide quality improvement.

1. Total Quality Management (TQM)/Continuous Quality Improvement (CQI)

“An integrated, corporately-led programme of organizational change designed to engender and sustain a culture of continuous improvement based on customer-oriented definitions of quality” (Joss and Kogan 1995:37)

The terms Total Quality Management (TQM) and Continuous Quality Improvement (CQI) are often used interchangeably (Gustafson and Hundt 1995). TQM/CQI was developed by the US statistician Deming in Japan in the 1950s and became more prominent outside Japan from the late 1980s and from the early 1990s in health care (Gann and Restuccia 1994; Schiff and Goldfield 1994; Trisolini 2002). It has been suggested that TQM/CQI was in part a reaction by Deming to Taylor’s ‘Scientific Management’ of the 1910s and 1920s and its perceived emphasis on profit-driven management rather than on quality (Schiff and Goldfield 1994).

There are few analytical or comprehensive definitions of TQM/CQI and the approaches tend to be defined by a list of characteristics held to be essential for their implementation (Box C). Indeed some authors (e.g. Shojania and Grimshaw 2005) argue that in practice TQM and CQI have become not so much specific interventions as more general approaches to improving quality: different organisations use different approaches under an overall heading of TQM/CQI.

[Box C overleaf]

Box C: Key tenets of TQM/CQI

1. TQM/CQI strongly emphasises leadership and the need for management involvement on project teams (both to provide leadership and to enable managers to understand the work processes)
2. TQM/CQI sees quality improvement as a normal and integrated ongoing activity within the organisation (not a one-off project)
3. TQM/CQI focuses attention on systems rather than individuals and emphasises continuous improvement and avoiding mistakes before they happen ('getting it right first time') rather than on inspection.
4. TQM/CQI emphasises the importance of measurement: data are a key tool for the analysis of variability in work processes and outputs.

Other features of TQM/CQI include:

- The concept that quality is the end result of complex but understandable processes that either enhance or detract from quality;
- The notion that as 'goods' or 'services' move along a process, different stakeholders and 'customers' emerge;
- A focus on these internal and external customers with whom one works in cooperation to meet their needs and enhance their satisfaction with goods and services;
- The continuous improvement and redesign of care processes by encouraging alternate cycles of change followed by relative stability;
- The concept that most people are intrinsically well motivated to work hard and do well;
- The emphasis on empowered cross-functional teams to identify and solve quality improvement problems for and by themselves.

Sources: Arndt and Bigelow 1995; Pollitt 1996; Grol et al 2007

One of the key principles of TQM/CQI is the importance of measurement: data are a key tool to analyse variability in work processes and outputs. A range of tools is used in TQM/CQI including statistical process control (SPC), cause and effect diagrams and the Plan-Do-Study-Act cycle (Roberts 1993; Gann and Restuccia 1994; Arndt and Bigelow 1995; Lilford et al 2003).

TQM/CQI appears to have been widely used, at least in name, in health care in Europe and in the US: there are numerous published papers describing its application in hospitals and in individual departments. The Technical Appendix gives details of some of these. It is difficult to categorise and evaluate the large number of projects and programmes that claim to be carrying out TQM/CQI: many hospitals adopt some of the principles of the approach and apply the approaches in a piecemeal way:

"The hospitals studied used a variety of methods and systems to assure and improve quality, but there was little awareness of, or emphasis on, a

disciplined scientific approach to quality improvement in the sense of running small scale experiments...It appeared that any activity could be renamed a quality project, and could then be eligible for resources.” (Ovretveit 1997: 227).

Reviews of published research (e.g. Shortell et al 1998; Ovretveit 2000) conclude that there is limited evidence about whether TQM/CQI works and whether it is more or less successful than other quality improvement approaches. In part this is because of the difficulty of defining what is done under this overall ‘heading’: although this is true of each of the five main approaches, TQM/CQI is more susceptible to being used as a general ‘catch-all’ label than lean thinking or Six Sigma for example. In addition, in common with the other approaches, it is difficult to assess whether reported improvements are attributable to, or merely contemporaneous with, the TQM/CQI interventions (Shortell et al 1998).

Interviews with 19 prominent CQI thinkers and activists in the US in the mid 1990s found that the basic principles of CQI had yet to diffuse deeply through most health care organisations especially on the clinical side: many doctors were sceptical about the approach or did not know about it, few patients were involved (despite the emphasis on ‘consumer’ definitions of quality) and not all senior leaders were directly involved in the CQI projects running in their organisations (Blumenthal and Kilo 1998). As in the US, European hospitals introducing TQM/CQI found that it was very difficult to secure doctors’ leadership and involvement (Ovretveit 1997). There was a lack of emphasis on producing demonstrable results and many employees viewed work on quality as separate to their everyday work, in part because quality approaches were largely being applied to more peripheral activities (e.g. diagnostic and administrative support services).

What the studies suggest is that there is evidence of some successes when TQM principles are applied to some administrative processes and support services (e.g. discharge processes, recruitment, medical records) that more closely resemble those in other industries (Arndt and Bigelow 1995) and that in Europe at least, both small hospitals and large complex hospitals had more difficulties introducing TQM than did medium sized hospitals (around 2000 employees) (Ovretveit 1997).

A major and well-respected evaluation of TQM in the NHS (Joss and Kogan 1995) comprised evaluation of TQM at a range of NHS units in 8 health authorities from 1990-1993. The researchers carried out around 750 interviews with staff at 38 different hospitals and community service units: a purposive sample that aimed to provide a broad cross-section of approaches and levels of sophistication at the time of the study. In concluding they found that many cost savings resulted but that there were significant problems: a lack of a corporate approach to quality; measurement was patchy and often crude; few doctors were involved; other structural changes were in conflict with TQM structures; and TQM activities were poorly integrated with other activities like audit. The researchers found that the organisations that appeared to have made more progress with TQM shared a number of key characteristics (Box D) including a strong focus on training individuals in the tools and techniques of process improvement, and providing sufficient funding for the programme both at the start and throughout the three year period of its implementation. A third key influencing factor was the extent to which TQM made sense to, and was accepted by,

the front-line staff who were expected to carry out its principles in their daily activities.

Box D: Characteristics of NHS organisations that made progress with TQM

- A strong focus on process improvement
- Attention to robust data collection and analysis before making changes
- Attention to cost and waste reduction as well as to improving patient satisfaction
- Attention to organisational-wide issues through cross-functional activity
- A move away from strong dependence on technical and professional definitions of quality to more holistic and patient-centred definitions
- A strong emphasis on providing training and support for individuals in the tools and techniques of process improvement
- The establishment of quality improvement structures including groups and teams at middle management and front line staff levels
- Realistic start-up funding and sustained funding over the three years
- Senior management understanding of and commitment to TQM
- An emphasis on engaging the active commitment of front line staff to carrying out TQM as part of their daily working practices

Source: Joss and Kogan 1995

Although TQM/CQI itself may not have permeated directly into many health care organisations, there was certainly a significant drive in the 1990s in the NHS and elsewhere around clinical audit as a means to quality improvement (Johnston et al 2000), and many health professionals were made aware of quality improvement approaches and principles through these developments on audit.

In summary, the strengths of TQM/CQI are that: it emphasises determining and meeting the needs and wishes of patients or customers; it aims at a holistic approach to quality improvement based on identifying the underlying causes of poor performance; it emphasises fact-based management and scientific methodology and may therefore be culturally compatible with the values of health professionals; and it emphasises the need to improve quality on a daily basis (Shortell et al 1998). However, significant challenges have also been identified, particularly in adopting TQM in the public sector (Morgan and Murgatroyd 1994). It is argued that much of the literature on TQM/CQI is based on assumptions that do not apply in many organisations, particularly in health care: the assumptions that decision-making in hospitals is a technical rational process; that managers have hierarchical control over technical core processes; and that there are no significant conflicts between the needs of internal and external customers (Bigelow and Arndt 1995). It is also argued that most models of TQM start from the assumption that the staff are naïve about most matters of quality, when in fact many health care professional and technical staff already view technical quality as of prime importance and may therefore be resistant to what appears to be a patronising approach (Joss 1994). Further weaknesses of TQM/CQI (which are also shared by other quality improvement approaches) are that it seeks to achieve what is in effect wholesale cultural change but appears to underestimate how long such change takes to achieve in practice, thus raising

unrealistic expectations on the part of organisations and health care funders (Counte and Meurer 2001). Like other approaches, it is also highly demanding in time and money: the work needed to redesign systems of care is very labour-intensive and prolonged (Blumenthal and Epstein 1996; Trisolini 2002).

The literature suggests that TQM/CQI is most likely to be successful when it is integrated into the organisation's structures and processes and not seen as a separate activity or one-off project (Shortell et al 1998; Jackson 2001) and when senior managers and physician leaders are actively involved in the TQM/CQI programme on an ongoing basis (Gann and Restuccia 1994; Carman et al. 1996; Ovretveit 1997; Weiner et al. 1997; Trisolini 2002).

2. Business process reengineering (BPR)

The classic definition of business process reengineering (BPR) is:

“...the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical, contemporary measures of performance, such as cost, quality, service, and speed.”
(Hammer and Champy 1995: 32)

BPR emphasises radical rethinking: starting afresh and designing processes anew from the ground up. The key question is ‘*Why do we do what we do at all?*’. Then, if a process or stage in a process adds no discernible value, it is removed. BPR, as originally conceived, is an ‘all or nothing’ approach which eschews incremental changes that leave basic structures and processes intact. Despite some common themes, like a strong focus on the customer, its proponents argue that it cannot be equated with other quality improvement programmes (e.g. TQM/CQI) which aim for incremental improvement of *existing* processes.

Other key themes of BPR are that:

- Change is driven from the top by a visionary leader who sets the direction for the requisite radical rethinking;
- Organisations should be arranged around key processes, not around specialist functions;
- Tasks and functions are aggregated and narrow specialists are replaced by multi-skilled workers in self-managed teams which are collectively responsible for designing work processes and delivering performance.

In its application in health care, BPR has evolved in different ways but in practice it has always been applied partially rather than comprehensively (Willcocks et al. 1997; Packwood et al. 1998). Indeed, some authors distinguish between *business* reengineering (strategic redesign of the whole organisation) and *process* reengineering (applied to key processes only). The literature notes that there is considerable confusion about whether and how patient-focused care, with its emphasis on redesigning processes around the patient, differs from BPR (Hurst 1995; Newman 1997; Arndt and Bigelow 1998; Powell and Davies 2001); one author suggests that patient-focused care is a health care variant of BPR (Edmonstone 1997).

There was a strong emphasis on BPR in the NHS in the 1990s: the Department of Health gave substantial financial support to two three-year reengineering pilot sites

(King's Healthcare Trust, London and Leicester Royal Infirmary) (Packwood et al. 1998), which were evaluated by independent evaluators (Packwood et al. 1998; Bowns and McNulty 1999; McNulty and Ferlie 2002). There was also a major BPR programme at the John Radcliffe Hospital in Oxford (Willcocks et al. 1997). Although the proponents of BPR strongly differentiate it from the incremental improvement of other quality approaches like TQM/CQI, NHS Executive policy documents on BPR published in the late 1990s appear to play down the emphasis on radical change and present a more modest vision of the potential of BPR:

“The fact is that BPR, developed in the late 1980s and 1990s, is but one approach to the management of change...It is the equivalent of going back to a blank sheet of paper and thinking out afresh what should be done. For the NHS, although the rethink will be radical, any widespread changes probably will have to be made in measured steps.” (NHS Executive 1997:1)

“It is worth restating the point that embarking on a radical look at the organisation with BPR does not necessarily imply that the change must be radical” (NHS Executive 1997: 10)

More recently, redesign has evolved in the NHS into a form that has been described as building on the earlier experience of the challenging and largely unsuccessful attempts at implementing BPR and combining the more gradual approach of TQM/CQI with the more radical organisation-wide perspective of BPR (Locock 2003). Redesign principles have underpinned a number of national initiatives sponsored by the Modernisation Agency in England (e.g. the Booked Admissions Programme) and more recently by its successor the NHS Institute for Innovation and Improvement. There is increased emphasis within this later approach to redesign on the need to address the human aspects of change, and to involve senior managers and clinicians in actively leading the redesign initiatives.

The evaluators who studied the two NHS BPR pilot sites in the 1990s found that although there were inevitable differences in the details of the experience at each site, at neither site was the radical reengineering vision realised in practice. Instead the initiatives went through several redefinitions and ended up being ‘watered down’ into more modest changes and more limited improvements. There were some pockets of change but no overall organisational transformation; change was patchy, difficult and took longer than anticipated (Leverment et al. 1998; McNulty and Ferlie 2002): *“In short, second order rhetoric gave way to first order impact”* (McNulty and Ferlie 2002: 272). Reengineering was varied in pace and rate in different parts of the hospital, with progress and effects very variable in different clinical settings: *“...the image of change...is more one of multiple processes at multiple levels, containing patterns of both change regression and progression, upward and downward spirals of momentum, plural interpretations and actions by individuals and groups, and mixed effects.”* (McNulty and Ferlie 2002: 273).

Further details of these studies and of the study of BPR at the John Radcliffe Hospital (Willcocks et al. 1997) are given in the Technical Appendix. A crucial factor affecting BPR implementation at each of the sites was resistance from medical staff, who retained a high degree of control over clinical work practices and made it very difficult for the reengineers (who lacked the medical staff's detailed specialty-specific

knowledge) to reshape these core processes over the short timescales available (Buchanan 1997; Willcocks et al. 1997; McNulty and Ferlie 2002). The lack of managerial control over health professionals and in particular medical staff and the contrast this presents with managerial power in some other types of organisation has been noted (Arndt and Bigelow 1998; McNulty and Ferlie 2002).

The researchers identified a range of other interconnected barriers to implementing BPR in health care systems like the NHS. These include the scope and complexity of patient processes and the challenge of carrying out radical redesign while continuing to provide a year-round service. In addition, radical innovation may be precluded by several factors: the range of multiple stakeholders with competing perspectives, the high visibility of the public sector to those stakeholders (e.g. to communities, the media and policy-makers) and a culture which tends to be evolutionary rather than revolutionary (Packwood et al. 1998; Bowns and McNulty 1999).

Experience in applying BPR in health care outside the UK was also very mixed. A nationwide study in the US found that reengineering did not appear to improve a hospital's overall cost position (Walston et al. 1999). A questionnaire study of more than 200 US and Canadian hospital chief executives (Ho et al. 1999) found that only around two-thirds of hospitals had attempted to measure the results of their BPR activities. The executives acknowledged that many employees were unconvinced about BPR and were concerned about job security; many executives thought that hospitals ought to carry out successful CQI activities before attempting the more intense activity of reengineering. Reengineering in a large Canadian teaching hospital had significant adverse effects on staff morale and motivation, with perceptions of decreased support from colleagues and supervisors and increased confusion about roles (Woodward et al. 1999). One of the facets of BPR is aggregation of tasks and streamlining of roles, but one US hospital found that the plan to reduce the number of job categories from 250 to 12 was particularly contentious for staff and prompted widespread concerns about job security; the hospital cancelled its reengineering programme in an attempt to restore staff morale (Trisolini 2002).

A range of redesign initiatives have emerged out of BPR and TQM (Locock 2001; Locock 2003), both in the NHS and internationally. These initiatives have shown some successes (e.g. Spaite et al. 2002; McGrath et al. 2008), but they share the common challenges of other quality improvement initiatives including the need for leadership by senior managers and clinicians and problems of sustaining improvements. Role redesign has its own challenges and requires attention to a range of human resources issues including remuneration, management and accountability arrangements and education and training needs (Hyde et al. 2005). Studies of NHS redesign initiatives suggest that the changes achieved have not been as extensive as intended (Locock 2003).

A key strength of BPR is its emphasis on processes and this may have contributed to the interest in many health care systems (including the NHS) in examining patient care pathways as part of patient centred care (Newman 1997; Powell and Davies 2001). Advocates of BPR argue that the scope of BPR's ambition may stimulate more creative and bold thinking about existing ways of organising care than other more incremental quality improvement methods (Hammer and Champy 1995). However, in its purest form, BPR appears to disregard organisational history and culture. In

contrast, much of the organisational literature emphasises these as pivotal in organisational change, particularly in a complex and highly politicised setting like health care (Pollitt 1996; Buchanan 1997; Willcocks et al. 1997; Leverment et al. 1998).

In addition, like TQM/CQI, BPR relies on a high degree of managerial power and control which may not apply in health care settings, particularly in relation to medical staff: “...many of the claims made on behalf of reengineering do not make sense for hospitals and...important assumptions underlying reengineering do not apply to hospitals” (Arndt and Bigelow 1998: 64). Other health service developments can also conflict with BPR. For example, the increasing emphasis on vertical structures of performance management and the shift towards increasing medical specialisation (McNulty and Ferlie 2002) (together with the programmes of undergraduate and postgraduate medical training that underpin such specialisation) are at odds with the horizontal structures and aggregated roles of BPR.

In summary, the literature suggests that the radical abrupt change of BPR is unlikely to be feasible or desirable in health care settings, but that redesign principles can be applied in more modest incremental ways.

3. Institute for Healthcare Improvement (IHI) and rapid cycle change

The rapid cycle change approach endorsed by the US Institute for Healthcare Improvement (IHI) has two components. The first is the Model for Improvement (Langley et al. 1996) which asks three questions:

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

The second component, by which these questions are put into action and tested in the clinical environment, is the Plan-Do-Study-Act (PDSA) tool which is adapted from Shewhart’s Plan-Do-Check-Act tool from the 1970s (Kilo 1998; Ketley and Bevan 2007):

Plan: Plan the change to be tested or implemented

Do: Carry out the test or change

Study: Study the data before and after the change and reflect on what was learned

Act: Act on the information and plan the next change cycle

The rationale for PDSA comes from systems theory and the concept that systems are made up of interdependent interacting elements and are therefore unpredictable and non-linear: small changes can have large consequences. Short-cycle, small-scale tests, linked to reflection, are seen as helpful because they enable health care teams to learn on the basis of action and its observed effects (Berwick 1998; Iles and Sutherland 2001). The approach is also valuable because the changes are not imposed: front line staff are closely involved in determining the problems and in suggesting and testing out potential solutions. This bottom-up approach increases the likelihood that staff will ‘own’ the changes, a key requirement for successful organisational change (Greenhalgh et al 2004).

The rapid cycle change model is similar to CQI in that it is systematic and data-driven, but unlike CQI it places less attention on flowcharting processes and extensive measuring: rapid cycle change calls for *sufficient* data to be collected to know if the change has resulted in an improvement (Meisel et al. 1998). Changes are tested on a small scale, permitting experimentation and discarding unsuccessful tests (a typical pattern might be testing a change with one practitioner and one patient in a single clinic – then moving on to three, then five and so on). It is argued that in contrast to large scale once-and-for-all implementation of grand designs (which often fail), numerous small cycles of change can successfully accumulate into large effects; for example, an intensive care unit could improve quality by working on a series of cumulative and linked PDSAs in different aspects of care at the same time e.g. respiratory care, medication use, and patient flow (Berwick 1998).

In contrast to large-scale approaches, PDSA changes are small (therefore controlling risk and disruption), take minimal time, and require little financial investment (in staff terms), with the majority of staff needing little formal training to proceed. PDSA changes are also advantageous as they are designed in context to fit that particular set of local circumstances: they therefore meet one of the key criteria for sustainable organisational change (Dopson and Fitzgerald 2005; Grol and Wensing 2005).

PDSA has been used as a tool in quality improvement in health care in the UK and elsewhere. PDSA cycles were used as one of the redesign techniques by the National Booking Team formed in 2001 to support local teams in implementing the NHS booking programme (allowing patients to choose the date and time of their outpatient appointment or hospital admission) (Neath 2007). Other Modernisation Agency initiatives also used PDSA cycles, for example, the Agency's *Ideal Design of Emergency Access (IDEA)* project in the NHS involving 10 regions from 2001-2003 (Walley and Gowland 2004). The IDEA project used process mapping, capacity and demand theory and 'lean thinking' and, the improvement work was based around PDSA improvement cycles using local teams.

The researchers found mixed success in using PDSA in the case study sites: some organisations stopped at the Plan-Do part of the cycle and did not progress beyond it, in part because of problems with data collection and in part because of a tendency to revert to traditional approaches of top-down change instead of using front line teams to assess the issues properly and to monitor the performance and impact of changes. Some managers were reluctant to relinquish control over PDSA activity to teams and there was sometimes conflict between the changes that teams wanted to make and the overall objectives of the organisation. There were further more generic problems in that single changes could displace problems onto another part of the system (e.g. the four hour target time in A & E achieved by the patient waiting on a medical assessment unit instead). Other studies (e.g. Bate et al. 2002) have found similar experiences of organisations only making partial use of the PDSA method. This is similar to findings that audit cycles may not be completed (Hearnshaw et al. 1998). Another study found that planning for change using PDSA methods by managers and clinicians working together could be a useful way for managers and clinicians to identify problems and potential solutions and to gain insights into each other's perspective (Thor et al. 2004). Further details of these studies are given in the Technical Appendix.

An Australian study found that PDSA methods could be useful in achieving small scale gains but that the methods could founder when dealing with more intractable systemic or bureaucratic problems (Newton et al. 2007) and these limitations of the method have been echoed by other authors (e.g. Young 2005). The NHS Clinical Governance Programme developed a modified version of the PDSA cycle for use when there was significant complexity and less agreement and certainty about cause and effect relationships. This version was called RAID: Review (analysis and understanding of the service) – Agreement (agreement of all staff and stakeholders with the recommended changes) – Implementation (testing the effects of the changes) – Demonstration (evaluation and monitoring) (Rogers 2006). This format suggests a move away from the rapid introduction of change through successive swift cycles; however this adaptation does not appear to have been widely adopted.

Rapid cycle change approaches have been used in a range of settings and are a key component of quality improvement collaboratives. Quality improvement collaboratives were largely developed and popularised by IHI, which in 1996 launched the Breakthrough Series of collaborative programmes to support local teams in quality improvement (Kilo 1998; Mittman 2004). Quality improvement collaboratives combine rapid cycle change (PDSA methods) and inter-organisational networking to share learning (Bate et al. 2002). NHS examples include the National Primary Care Collaborative implemented by the National Primary Care Development Team (Locock 2001; Knight 2004) and the National Patients Access Team (Locock 2001). In Scotland, the Scottish Primary Care Programme, based on the Model for Improvement and using rapid change cycles has involved almost half of the GP practices in Scotland in collaborative working to improve patients' access to primary care and to improve the outcomes for patients with long term conditions (Scottish Government Directorate of Health Delivery: Improvement and Support Team 2008).

There is only limited evidence on the impact of the collaborative improvement model in terms of changes in outcomes or in clinical practice (e.g. Kerr et al. 2002; Mittman 2004; Schouten et al. 2008). In common with other quality improvement initiatives, there are striking differences between organisations (Bate et al. 2002; Pearson et al 2005) and participation by organisations and by health professionals (in particular doctors) can be difficult to secure (Kosseff and Niemeier 2001; Gollop et al. 2004). Addressing aspects of care in collaboratives may expose wider long-standing problems that are difficult to address (e.g. staffing shortages in some specialties, Kerr et al. 2002); or differences in perspective between professionals from different health care sectors, (Newton et al. 2007). Experience across different countries and health systems suggests a range of factors that influence the success of collaboratives. These include: appropriate sponsorship (success is less likely if there is conflict between the sponsor's perspective and that of participants); appropriate choice of topic (complex or less familiar topics are less likely to succeed or to attract participants); the need for active involvement of senior managers and physicians; and alignment with the organisation's strategic goals (Kosseff and Niemeier 2001; Mills and Weeks 2004; Wilson et al. 2004).

The strengths of rapid cycle change are that it can draw on the ideas and ingenuity of local staff and can enable low-risk testing of changes in the clinical setting. Thus it can help to secure commitment to changes and to embed them in everyday routines. It can also be scaled up or scaled down to address different types of quality issues (e.g.

small processes in one clinic waiting room or the operation of a suite of theatres). However, as in all bottom-up change initiatives, there may be conflict between the changes that local individuals or teams want to make and the organisation's strategic objectives (Savage and Scott 2004; Walley and Gowland 2004). Problems can also arise where changes identified in one department are thwarted because of wider processes (e.g. cross-departmental processes) that are less amenable to rapid cycle testing. Experience in health care settings also shows that teams may be unable or unwilling to carry out the full cycle of Plan-Do-Study-Act and may therefore risk jumping to premature 'solutions' or fail to benefit from the full potential of the approach. In particular, the well-documented problems with obtaining robust data in health care threaten to jeopardise the principle of accurate and timely measurement of the impact of changes and subsequent review on which the approach relies. Although as yet there is only limited evidence in the peer-reviewed literature in terms of changes in outcome or practice patterns from the rapid cycle change approach and quality improvement collaboratives, it is likely that ongoing work at various sites will begin to fill these evidence gaps.

4. Lean thinking

'Lean thinking' was developed by Toyota in the 1950s based largely on the work of Deming (Institute for Healthcare Improvement 2005). The Toyota Production System aimed to achieve waste reduction and efficiency while simultaneously improving product quality and led to Toyota increasing its competitive edge by using fewer employees to produce more cars with fewer defects (Westwood and Silvester 2006). The principles behind the Toyota Production System have led to a set of ideas that are commonly grouped under the rubric 'lean thinking' (or sometimes just 'lean'), although the variants are not an exact application of the Toyota model. The core idea in lean thinking is the need to provide what the internal or external customer wants, i.e. to provide '*value*' to the customer, with minimal wasted time, effort and cost. Those actions or processes which do not create value need to be identified and modified or eliminated (showing strong similarities with BPR approaches). Removing any 'waste', it is claimed, will lead to additional capacity and hence enhanced performance. Table A lists lean thinking categories of waste with health care examples.

Table A: Lean thinking categories of waste and health care examples

Lean thinking category of waste	Health care examples
Correction (defects)	Adverse drug reactions Readmission because of inappropriate discharge Repeating tests because of incorrect information
Waiting	Waiting for doctors to discharge patients Waiting for test results
Transportation	Central equipment stores rather than ward based stores for commonly used items
Overprocessing	Asking patients for the same information several times
Inventory	Waiting lists Excess stock in stockrooms
Motion	Unnecessary staff movement to obtain

	information or supplies
Overproduction	Requesting unnecessary laboratory tests Keeping beds or slots free 'just in case'

Adapted from NHS Institute for Innovation and Improvement: Going lean in the NHS (2007)

Lean thinking uses a range of tools to identify core processes and to develop them so that the system flows efficiently. These tools are described in more detail in the Technical Appendix. They include: 5S or CANDO (a series of five steps to enable workforce teams to look at the environment they work in and to start to identify the blocks in current processes e.g. lack of supplies, defective equipment); rapid improvement events or *kaizen* (five day intensive workshops to analyse current processes and identify changes needed); and value stream mapping (analysing current processes to generate ideas for process redesign). Lean thinking also uses other quality improvement tools (e.g. Plan-Do-Study-Act rapid change cycles, Six Sigma) in analysing processes and redesigning them. There is increasing use in the NHS of a hybrid approach combining lean thinking and Six Sigma and this is discussed in the section below on Six Sigma.

The NHS Modernisation Agency and its successor the NHS Institute for Innovation and Improvement have endorsed the use of lean thinking principles in their approach to service redesign in the NHS for several years and produce a range of tools to assist hospitals in redesigning processes in line with lean thinking. Lean thinking is also endorsed by the US Institute for Healthcare Improvement (IHI) as one way that health care organisations can reduce waste and improve processes and outcomes and increase patient and staff satisfaction.

In terms of evidence, there are reports from the US and the UK (e.g. Institute for Healthcare Improvement 2005; Radnor et al. 2006; Papadopoulos and Merali 2008; Radnor and Walley 2008) of substantial reductions in waste in health care organisations, with lower inventory levels, reduction in waiting time to first appointment or to diagnosis following tests, and people and supplies travelling shorter distances. A study that used two years activity data from two health care communities, and extensive observation of activities over a six week period by seven researchers to identify patient flows that could be used to re-design treatment processes around the patient using lean principles, found that there was potential to reduce some queues by redesigning processes, and that waiting times in A & E were to some extent attributable to capacity imbalances rather than capacity shortages (Walley 2003). However, despite considerable activity in some areas (e.g. national programmes in NHSScotland supported by the Scottish Government's Improvement and Support Team; Scottish Government Directorate of Health Delivery (2008)), overall implementation in health settings has so far been relatively limited. A review of the use of lean thinking in public sector organisations in the UK, including two health organisations (Radnor et al. 2006; Radnor and Walley 2008) found that there were few examples of organisations using the full lean thinking approach (rather than a handful of the tools) and that most health care organisations were using lean only in individual support departments (e.g. pathology, radiology). The one organisation (Bolton Hospitals NHS Trust) reported to have attempted to apply lean thinking principles across the whole hospital had mixed results (Fillingham 2007).

Lean thinking has several strengths. It encourages staff to look at processes in a customer- or patient- focused way, which fits well with other policy initiatives. Its main focus (on value for the customer) can be addressed in conjunction with other tools and approaches; and it is seen as a bottom-up change process, which is more conducive to staff involvement. Moreover, lean can assist in identifying and addressing different types of ‘waste’ in processes and thus make health care delivery more streamlined and more pleasant for patients and for staff.

However, lean is also challenging in health care for several reasons: its ‘just-in-time’ thinking requires that demand can be accurately predicted, which may be hard in some health care fields (e.g. psychiatric and emergency care), and making processes ‘lean’ is difficult in health care settings when many patient pathways are complex and when current processes are department- or specialty- based. Like other quality improvement approaches, lean thinking in health care faces the challenge of defining ‘the customer’ when there are multiple internal and external customers, whose interests may conflict. A particular challenge for implementing lean thinking is that many staff are suspicious of the concept: lean thinking is perceived to emphasise cost cutting and staff reduction (‘lean and mean’). Indeed one NHS Confederation document explicitly advises that applying lean methods cannot be used as a short term crisis measure to balance budgets, and warns that *“long experience suggests that lean initiatives rarely succeed unless staff employment is guaranteed in advance”* (Jones and Mitchell 2006:21).

In summary, on the evidence available to date, lean thinking may provide a useful approach to looking at processes in organisations and particularly in streamlining processes in individual support departments (e.g. pathology, radiology). 5S type tools may help with initial ‘ground-clearing’ prior to more detailed examination of processes or prior to implementing other quality improvement approaches. More wholesale application may only be feasible in particular types of organisation: *“lean is most suited to organisations with high volume, repeatable tasks that allow greater standardisation and integration, supported by a less hierarchical management structure that allows empowerment and engagement of the workforce”* (Radnor et al 2006: 5).

5. Six Sigma

Six Sigma has been used in industry since around 1980 but started to be used in health care from around 2000 (Antony et al. 2007b). The term is said to derive from the physicist Shewhart’s observation in the 1920s that three sigma (standard deviations) from the mean is the point where a process requires correction; Six Sigma is therefore used to denote ‘perfection’ and is usually defined for practical purposes as achieving a rate of only 3.4 defects per million (Wears 2004; Young et al. 2004). The definition of a defect within a health care process is inherently problematic and in practice when Six Sigma is used in health care the tendency is to adopt a broader and more pragmatic approach to measurement than in traditional Six Sigma. The broad intention is to increase the reliability of a process or system of care. If a process or system of care is fully reliable it will deliver care in the same way to all eligible patients every time they need it. If this care is evidence-based, then every patient receives optimal care (regardless of who actually delivers that care, when or where).

Six Sigma aims to eliminate defects and reduce variation in a processes in order to improve output and outcomes from the system (Westwood and Silvester 2006). The key methods to achieve this are statistical tools and analysis to identify the root cause of variation. Six Sigma identifies two causes of variation: ‘common’ or ‘chance’ causes that result in minor fluctuations in the data, and ‘special’ or ‘assignable’ causes that result in the data showing an unusual pattern (compared to that normally displayed by chance causes) and to which a cause can be assigned (Naslund 2008; Taylor and Shouls 2008). In Six Sigma, the aim is primarily to address the second type of variation (i.e. special or assignable causes of variation), although if a process has a significant amount of common variation (i.e. it is inherently unstable), then action may be needed to change the process itself (Naslund 2008).

A crucial differentiator of Six Sigma from other quality improvement methods is intensive technical training and coaching by experienced so-called ‘master black belts’ (Proudlove et al. 2008). Six Sigma offers a structured approach to get to the root causes of problems using the DMAIC methodology (Define Measure Analyse Improve Control); further details on this and other techniques are given in the Technical Appendix. This methodology guides practitioners through problem-solving steps and gives a structure for the use of tools like process mapping and statistical process control.

Statistical process control (SPC) is a key tool used in Six Sigma; SPC can also be used independently of a Six Sigma approach. SPC uses statistically based rules to interpret any unusual patterns in plotted data of events or other system parameters. SPC charts enable *retrospective analysis* of the state of the process, but also *prospective analysis* that allows dynamic monitoring to detect any shifts in the process (Taylor and Shouls 2008). In health care quality improvement, SPC control charts can be used to visualise and analyse organisational processes over time to determine whether the process is stable and predictable or whether there is unwarranted variation (Thor et al. 2007). Interventions can then be designed to address the variation. Six Sigma also uses other tools like the ‘theory of constraints’: a step by step process to examine bottlenecks in a system (Hines et al 2004; Young et al 2004).

The use of Six Sigma in health care is relatively recent. Outside the UK, hospitals have achieved costs savings and improved efficiency in a range of areas including length of stay, waiting times, distribution of supplies and time to diagnosis (Revere et al 2004; van den Heuvel et al 2005). In the NHS, the Modernisation Agency set up a Six Sigma pilot project in 2004 to test its viability in the NHS. This was in part a response to concerns that few hospitals were carrying out measurement as part of their quality improvement initiatives, despite the Agency’s promotion of the PDSA approach (with its strong emphasis on measurement as part of the improvement cycle).

More recently there has been increasing pragmatic use of a combination of lean thinking and Six Sigma (Hines et al. 2004; Antony et al. 2007b), although there is no widely accepted common or integrated methodology (Proudlove et al. 2008). The NHS Institute for Innovation and Improvement has designed an integrated Lean Six Sigma approach (NHS Institute for Innovation and Improvement 2007) with the intention that organisations can draw on a range of tools and make use of facets of

both approaches: “*If we can use Lean methods to identify our value streams at a macro level, we increase the potential to design better basic processes that are more likely to benefit from Six Sigma...Lean Six Sigma gives us the opportunity to get the basic processes right (through Lean) then take the variation out of the process (Six Sigma)*” (NHS Institute for Innovation and Improvement undated p11).

The Modernisation Agency’s pilot Six Sigma project involved 50 staff in 14 projects across England. The evaluators found a range of barriers to Six Sigma implementation (Proudlove et al. 2008):

- Many of the projects were isolated from wider quality improvement programmes or the organisation’s strategic objectives
- Staff strongly disliked the Six Sigma jargon
- The rigorous DMAIC methodology was challenging to apply
- The Six Sigma approach seemed to ignore cultural and interpersonal factors
- Many of the existing processes were very unstable and required radical redesign rather than adjustment

However, studies have reported quality improvements in health care when Six Sigma tools are applied to particular processes e.g. reducing turnaround time for pathology specimens (Westwood and Silvester 2006).

Studies that have looked at the use of statistical process control (SPC) in health care have found that SPC has the potential to improve a range of processes at the individual patient level (e.g. in an individual patient’s control of their diabetes) and at the organisational level (e.g. bed occupancy, medication errors), but that effective use of SPC depends on the existence of a number of conditions which are difficult to achieve in a typical health setting (e.g. high quality routine data, statistical expertise, robust and comprehensive IT infrastructure) (Thor et al. 2007). Application of SPC also has some significant risks: “*in the worst case scenario, incorrect application of SPC could lead to erroneous conclusions about process performance and waste time, effort and spirit and even contribute to patient harm...To apply SPC is, paradoxically, both simple and difficult at the same time. Its power hinges on correct and smart application, which is not necessarily a trivial task*” (Thor et al 2007: 390). A recent review of quality improvement tools (Health Evidence Network 2006) concluded that statistical process control was effective but that it requires greater skills and training than other approaches and that it is crucially dependent on good quality data, which is often lacking in health care (Leatherman and Sutherland 2003; Audit Commission 2004; Guven-Uslu 2006).

In summary, Six Sigma and its associated tools enables prospective and retrospective analysis of variations in a process and can enable identification of unwarranted variation and the impact of subsequent interventions. However, its application in service environments brings additional challenges relating to data collection, complexity of processes, definition of what constitutes a defect and competing customer definitions of quality (Antony et al 2007a). In itself Six Sigma does not address the cultural or interpersonal aspects of quality improvement and it is limited further in that it looks at individual processes rather than taking a system-wide approach. To be effective, Six Sigma is dependent on high quality data and statistical expertise. Front line clinicians must therefore have access to appropriate systems and support (both technical and statistical) so that they can easily collect robust

appropriate data for analysis. Six Sigma may therefore be useful in analysing variation in relatively stable processes in organisations providing there are high quality data and robust ongoing support for clinical teams to enable them to collect, analyse and use the data effectively.

System-wide multi-model approaches to quality improvement

As the review of the five models has shown, in practice quality improvement models and their tools are used in a variety of ways. They are rarely applied singly or sequentially; what is more common in health care settings is to draw on combinations or hybrids of the main approaches. The second part of this review of quality improvement models applied in health care settings considers health care systems that stand out in the literature as particularly successful or integrated examples of system-wide approaches to quality improvement. The evaluations in the literature of these five system-wide approaches add to an understanding of the successful use of blended approaches in health care organisations and of the challenges encountered.

1. Jonkoping County, Sweden

Jonkoping's system is widely viewed as a useful model of the progressive implementation of methods for improving quality of health care outcomes through sustained activity over several years; indeed, at the end of 2005 (Staines, personal communication) it was selected by a panel of 10 international quality improvement experts as one of the top three health care locations that had made the most of quality improvement methods (Ovretveit and Staines 2007).

The Jonkoping County Council health care system covers 330,000 inhabitants and has over 9000 employees. Quality improvement (QI) work began in the early 1990s but accelerated in 1998 when an innovation and learning centre known as "Qulturum" was set up to provide leadership and training for local quality improvement projects and to supply 'learning helpers' for the bottom up part of the QI programme. Qulturum is staffed by 15-20 people who focus on QI activities; through a range of meetings and collaborative learning sessions the centre has trained senior executives, clinical leaders and health professionals in the science and techniques of quality improvement. In 2006 the County Council launched a system-wide training programme on microsystems thinking.³ Qulturum promotes a system-wide improvement strategy based on 3 principles (Bodenheimer et al. 2007):

- Learning is key to improvement
- Improvement must be broad (i.e. it must reach all patients in the system and encompass a wide variety of measures) and deep (i.e. it must involve as many people as possible at all levels of the system)
- Improvement must be both top-down and bottom-up: the County Council leaders and Qulturum set the top-down improvement priorities and the front

³ Addressing the design and functioning of clinical microsystems (e.g. a cardiovascular surgical care team, a neonatal intensive care unit) is intended to improve quality, safety and cost outcomes at the frontline of care: "*Ultimately the outcomes of the macrosystems can be no better than the microsystems on which they are formed.*" (Mohr et al 2004: ii35)

line caregivers decide on the best ways to implement or modify county-wide goals.

The Jonkoping quality improvement programme is based on a wide range of approaches (Andersson-Gare and Neuhauser 2007) including systems thinking, safety analysis models, epidemiological and outcomes research, collaborative inter-professional and chronic care models, and models for adult learning in relation to change and patient-centredness. Kaplan and Norton's balanced scorecard (Andersson-Gare and Neuhauser 2007) which focuses attention on multiple measures including cost containment is used at all levels of the system. Thus the Jonkoping programme encompasses elements from several of the models described earlier: the emphasis on systems, the focus on the customer and the use of collaborative models drawing on rapid cycle change.

The quality improvement programme in Jonkoping has achieved a number of improvements in access, waiting times, process redesign, teaching patients with chronic conditions self-management skills, radiology result supply times and patient safety improvements (e.g. decreased sepsis, fewer medication errors) (Bodenheimer et al. 2007; Ovretveit and Staines 2007). Changes trialled in JCC to improve access and reduce waiting times have been rolled out to other counties, with a reduction in median waiting time from 90 days to 7 days in 8 months (an improvement of 93%) (Strindhall and Henriks 2007). Researchers in one study concluded that Jonkoping has impressive QI infrastructure and substantial resources allocated for learning and improvement; learning and improvement had become a real part of everyday working life, with a positive attitude to QI seen in most departments and units (Ovretveit and Staines 2007). The County Council's results on several dimensions (e.g. clinical results, patient satisfaction and financial performance) compare very well with those of other Swedish counties (Andersson-Gare and Neuhauser 2007).

Factors which appear to have helped Jonkoping to achieve these successes (Andersson-Gare and Neuhauser 2007; Ovretveit and Staines 2007) include: a stable political and financial environment, widespread process and systems thinking, commitment to improvement and learning, and the County Council's clear and consistent motivating vision that goes beyond health care: "*a good life in an attractive county*". The County Council has organised all of its health care processes to fit a system map that it has drawn that defines the role of each process and its contribution to the system's mission. Priorities are communicated using a graphic representation referred to as 'the diamond picture' which is widely used to communicate the strategic areas for improvement (Ovretveit and Staines 2007). Jonkoping has benefited from continuity of senior leadership, complementarity of skills and effective teamwork: since the mid 1980s quality improvement has been led by the CEO and by the chief of learning and innovation (who has a wide QI expertise and network and experience as a national basketball coach). In the mid 1990s this senior management team was joined by the head of the department of internal medicine, who is seen in some ways as a representative of local physicians (Ovretveit and Staines 2007).

The programme at Jonkoping is widely perceived to be successful but there has been to date little measurement and there is therefore limited concrete evidence of better patient and clinical outcomes. Many units have proved reluctant to share data with other units. There is limited statistical support for teams and clinical IT systems are

limited (Ovretveit and Staines 2007). Improvement has been patchy across the area. The County leadership encourages – but does not force – health professionals to get involved, yet the involvement of physicians remains patchy (Ovretveit and Staines 2007). Some primary care centres and specialty departments have made significant progress but others have not engaged (Bodenheimer et al. 2007). On some indices (e.g. access to a GP) other counties have improved more rapidly than Jonkoping (Ovretveit and Staines 2007). Some managers have expressed concern at the poor cultural fit between ideas developed in the US (e.g. IHI’s Pursuing Perfection programme) and the Swedish context (Ovretveit and Staines 2007).

Jonkoping has a well-structured quality improvement programme which has benefited from stable and committed leadership, the support and input of international quality improvement experts and an uninterrupted period of development of around 10 years. Compared to nearly all other Swedish health systems which are described as being (like the NHS) in a state of continual reorganisation (Ovretveit and Staines 2007), Jonkoping has pursued an organisational strategy of continuous incremental improvement and no major reorganisation. That Jonkoping, despite these many advantages, continues to struggle with the substantial generic barriers to quality improvement in health care identified at the start of this review (e.g. lack of medical engagement, the challenges of measuring impact and effect) underlines how intractable quality improvement problems can be: *“this case illustrates how much energy, resources, dedication and consistency are needed to achieve measurably better patient outcomes in some departments. It also illustrates how much is still needed to reach system-wide outcomes improvements.”* (Ovretveit and Staines 2007: 82).

2. Kaiser Permanente

The Kaiser Permanente health system⁴ in the US has an organisation-wide approach to quality and safety improvement, with linked national and regional quality committees, programme-wide systems support and an Assistant Medical Director and Vice President in each region solely dedicated to quality improvement (Young 2007). Progress is evaluated through common metrics, and data on safety, service and efficiency can be evaluated nationally, by region or by individual medical centre (Chao 2007).

Quality improvement activities⁵ within Kaiser Permanente reflect aspects of the five models described earlier: customer focus, analysis and streamlining of processes, an emphasis on introducing good practice into routine care and on timely and robust data. Quality improvement activities include monitoring clinical performance, the care delivery systems and the quality of care and service experienced by patients, and systematically promoting evidence-based medicine and clinical best practices, while providing clinical and administrative support to enable health professionals to improve their performance. Process improvements have been put in place to improve

⁴ There has been considerable debate in the literature about the differences between Kaiser Permanente and the NHS (e.g. Feachem et al 2002, Talbot-Smith et al 2004). We include it here as an example of a system-wide approach to quality and safety improvement and in doing so (as with the other non UK examples we include in this review) do not intend to understate the contextual differences between US and UK health care organisations.

⁵ http://www.hmohelp.ca.gov/library/reports/med_survey/surveys/Appendex%20Statement%20Final%20Version.pdf (accessed July 2008)

communication and reduce errors at handover between health professionals. There is a comprehensive health information system that incorporates an advanced electronic health record. The Care Management Institute carries out research into medical best practice.

A national strategic five year safety plan was developed in 2000 based on thorough internal and external assessment;⁶ the plan is updated on an annual basis. In 2002 the Kaiser Permanente health system started a programme of organisational learning to promote teamwork and communication in high risk areas like surgery (The Commonwealth Fund 2004; McCarthy and Blumenthal 2006). Clinical leaders were taught safety-oriented principles and techniques adapted from the US Navy and from airline crew resource management training. Kaiser Permanente hospitals in California have adopted a range of practices all aimed at enhancing team working and communication and addressing identified 'human factors' issues in risk (e.g. poor communications across professional boundaries, omissions, preoccupation):

- Preoperative safety briefing: a one page checklist analogous to the pre flight checklist used on airlines;
- Multidisciplinary patient rounds to ensure that care plans are fully understood;
- Assertive and structured communication techniques to promote accurate situational briefings (e.g. 'scripted handoffs' enable recovery room nurses to care safely for postoperative patients and structured communication techniques enable more junior staff to report fetal distress effectively);
- A communication escalation policy defining how to forward safety concerns through the chain of command to avoid delays in responding to critical events;
- Team briefings before a procedure and debriefings following an adverse outcome;
- Critical event team training to enable staff to understand how their behaviour affects others and to develop their appreciation of teamwork in emergency situations. Simulations using mannequins are video taped for later discussion and debriefing.

Factors influencing the success of the quality and safety improvement system include the strong involvement of doctors as well as managers in leading the organisation and in determining its strategic goals, the integration of both inpatient and outpatient services, diagnosis, management and care, training and development for physicians who take on leadership roles, substantial investment in IT systems, and the employment of case managers to work intensively with high risk patients (Crosson 2003; Ham 2003; Tyndale-Biscoe 2004). The health system invests heavily in research and emphasises collaboration between clinicians and researchers (Lomas 2003).

It is difficult to reach firm conclusions when evaluating whole systems. Some evaluators have concluded that the NHS and other health care systems can improve the quality of their services by adopting some of the approaches adopted by Kaiser Permanente (e.g. with regard to the degree of integration between primary and secondary care, in relation to IT systems and to the level of involvement of doctors in the management and strategic development of hospitals) and indeed some pilot programmes have been developed in the NHS to explore Kaiser's approaches (Ham

⁶ www.opm.gov/insure/04/safety/kaiser.asp (accessed July 2008)

undated). Others have argued that the differences in structure, culture, remit and resources mean that even broad comparisons between Kaiser Permanente and other health systems like the NHS are misleading and of limited use (see for example Talbot-Smith et al. 2004). It may be that the lessons from quality improvement approaches at Kaiser Permanente could most easily and appropriately be followed by health systems that are directly and readily comparable.

3. VA Quality Enhancement Research Initiative and patient safety initiatives

The Veterans Health Administration (VA) in the US runs 157 medical centres and in 2004 cared for more than 5 million patients (Armstrong et al 2005). In the late 1990s in response to public and Congressional concerns about the quality of care provided by the VA (McCarthy and Blumenthal 2006), the VA created the Quality Enhancement Research Initiative (QUERI): an ongoing system-wide effort to improve performance and quality of care (Demakis et al. 2000; Kizer et al. 2000; Stetler et al. 2008). The VA set up new organisational structures and procedures to enable researchers and managers and other stakeholders to work together and to try out a range of well known interventions and models and also test new ones. The major redesign of organisational structures and policies included innovative IT systems, a new performance management/accountability programme, and linking research activities with clinical care to generate ‘real time’ knowledge (Feussner et al. 2000; Rubenstein et al. 2000; Stetler et al. 2008).

QUERI centres are disease or problem-focused (e.g. diabetes, chronic heart failure, mental health) and are either housed within one VA facility or organised ‘virtually’ across several sites (Stetler et al. 2008). QUERI centres have research, clinical and implementation research coordinators who make contact with local and national clinical and policy leaders. The centres are responsible for monitoring, understanding, evaluating and acting on emerging clinical research findings and implementing the research findings that impact on their patient group. They also carry out their own research activities, including preliminary efficacy/effectiveness studies of promising clinical/delivery system interventions, and developing and evaluating tools and measurements.

All work is carried out according to a six step process that has evolved since 1998:

1. Identify high risk/high volume diseases or populations
2. Identify best practices
3. Define existing practice patterns and outcomes across the VA and current variation from best practices
4. Identify and implement interventions to promote best practices
5. Document that best practices improve outcomes
6. Document that outcomes are associated with improved health-related quality of life

(Steps 4-6 usually co-occur within individual implementation projects.)

This six step process reflects the thinking behind the PDSA cycle discussed earlier and the concept of small tests of change is also reflected in the four phase sequence pattern that quality improvement implementation efforts typically follow:

1. Single site pilot
2. Small scale, multi-site implementation trial
3. Large-scale, multi-region implementation trial

4. System-wide rollout

This sequence allows small-scale testing and refinement of interventions before they are then rolled out across multiple VA medical centres and clinics (Brown et al. 2008).

In 1999 the VA established its National Center for Patient Safety to provide local health care organisations and staff with tools, methods and initiatives to improve patient safety, drawing on human factors principles and experience from high reliability industries (McCarthy and Blumenthal 2006). Key components of the safety programme are:

- Distinguishing unintended errors (treated confidentially and non-punitively) from blameworthy acts (criminal, alcohol, substance or patient abuse or intentionally unsafe act)
- Encouraging reporting of adverse events and close calls (internal or external) – and including the reporter (confidentially) directly in the feedback loop
- Designing and providing training on easy to use root cause analysis tools and aids so that multidisciplinary teams can analyse reported safety events
- Adapting a systems engineering tool (FMEA –failure modes and effects analysis) to discover critical vulnerabilities in the system and to design and assess improvements that will reduce risks to patients
- Disseminating throughout the VA warnings about potential safety threats and lessons learned about effective system improvements
- Requiring local executives to reach agreement with incident investigation teams on remedies that will be taken to address identified vulnerabilities

Patient safety managers at 153 VA hospitals and patient safety officers at 21 VA regional headquarters participate in the programme.⁷

An evaluation of the VA quality improvement programme in 2000 (Jha et al. 2003) found that throughout the VA system, on 9 out of 17 quality of care indicators, the proportion of patients receiving appropriate care was 90% or more and on 13 indicators it was greater than 70%. Statistically significant improvements in quality had been achieved by the VA system from 1994-5 to 2000 in all nine indicators collected in all of those years. Among the developments the researchers noted were:

- Routine performance measurements were taken for high priority conditions like diabetes and coronary artery disease
- Managers had performance contracts and were therefore accountable for achieving these goals
- An external independent agency gathered and monitored data
- All VA medical centres now had critical process improvements e.g. an integrated comprehensive electronic medical record
- Performance data were made public and widely distributed e.g. within the VA, to veterans service organisations and Congress members.

The success of the VA quality improvement programme has been attributed to a range of factors including the stable patient population, a robust electronic health records system developed in collaboration with physician ‘champions’, the multifaceted

⁷ www.patientsafety.gov/ (accessed July 2008)

approach to system change driven by a central vision, investment in health services research, the linking of objectives to clearly quantifiable measures of access and quality that were monitored and reported regularly, and the clear delineation of accountability, with an integrated network of hospitals to review data and encourage improvement initiatives originating at local clinic level (Bevan et al undated; Kizer et al. 2000; Armstrong et al. 2005; Oliver 2007; Stetler et al. 2008).

4. Organising for Quality: the improvement journeys of leading hospitals in Europe and the United States (Bate et al/The Nuffield Trust 2008)

A major recent study (Bate et al. 2008) identified ‘leading’ hospitals in quality improvement in Europe and the US and explored in detail the processes by which these hospitals had achieved these successes in quality improvement. The hospitals in the study were selected from peer recommendations from quality improvement experts in the US and the UK, from surveys of quality awards and from other external forms of recognition for outstanding performance in quality improvement. Once the sites had been selected, the researchers then selected a high-performing micro-system (i.e. a particular department or clinical service) within each organisation by taking ‘soundings’ from staff at different levels of the organisation. The researchers therefore combined study of the top-level strategic management of the organisation with study of a micro-system and could therefore look at the interactions between the two. Study methods over an 18 month period included semi-structured interviews, informal discussions, observation of meetings and of clinical practice and review of internal and external documents (including reports of external reviews). In analysing the data from each case study site, the researchers identified for each organisation a ‘key theme’ of quality improvement within that organisation to which other factors appeared to be integrally connected (Table B).

Table B: Overarching theme in quality improvement at each study organisation

Hospital	Overarching theme in quality improvement
Royal Devon and Exeter NHS Trust, UK	Organisational identity: a shared sense of ‘who we are’ and ‘what we stand for’.
Peterborough and Stamford Hospitals NHS Trust, UK	Empowerment: granting power over decisions and resources to staff at different levels of the organisation.
King’s College Hospital NHS Trust, UK	Organisational citizenship: dedication to the common good.
Reinier de Graff Groep, Delft, Netherlands	Multi-level leadership: quality improvement leadership that is ‘distributed’, ‘multi-layered’ and ‘strategically collective’ across different parts of the organisation.
Children’s Hospital of San Diego, California, US	Mindfulness: heightened state of involvement and awareness, characteristic of ‘high reliability’ organisations.
Cedars-Sinai Medical Center, California, US	Organisational learning: the ability of an organisation as a whole to search for, retain and act on new knowledge.
Luther-Midelfort Mayo, Wisconsin, US	Socio-technical design: work systems designed to maximise productivity and quality of life.
Albany Medical Center, New York	Mobilisation: marshalling and organising resources including funding, physical assets, commitment and talents to achieve common goals.

Source: adapted from Nuffield Trust 2008: 3

The researchers found that each of these successful organisations had addressed in an integrated way six interrelated core challenges in quality:

- *Structural* – structuring, planning and coordinating quality efforts and embedding them within the organisational fabric;
- *Political* – negotiating the politics of change and securing agreement to common goals;
- *Cultural* – building shared understanding and commitment;
- *Educational* – developing formal and informal learning;
- *Emotional* – inspiring and motivating staff to want to join and sustain the improvement effort ;
- *Physical and technological* – developing a physical and technological infrastructure that enables service improvement.

Table C gives examples of some of the elements that addressing each of the challenges may involve.

Table C: The six core challenges in quality improvement

Core challenge	Examples of elements that formed part of addressing this challenge
Structural – structuring, planning and coordinating quality efforts and embedding them within the organisational fabric	<ul style="list-style-type: none"> • A formal strategy for QI and an implementation plan • Quality facilitators with expertise in a range of methods • A flat organisational structure that encourages bottom-up improvement initiatives • Data and monitoring systems for constant monitoring
Political – negotiating the politics of change and securing agreement to common goals	<ul style="list-style-type: none"> • Senior leaders with the ability to engage others with QI • Strong and active clinician involvement • Strong partnerships between internal staff and external stakeholders in the improvement process • Strong peer-to-peer communication
Cultural – building shared understanding and commitment	<ul style="list-style-type: none"> • A culture that places a premium on excellence and on patient-centred care • A culture of mindfulness that keeps staff alert to personal and group standards • A group/collaborative culture based on respect, trust and honesty • A culture of learning and innovation • A long-term culture that sees QI as an ongoing process
Educational – developing formal and informal learning	<ul style="list-style-type: none"> • Formal and informal learning in QI methods and in using them in practice • Experience-based learning (including learning from the experiences of patients) • Developing and testing new QI methods

	<ul style="list-style-type: none"> • Influential organisational leaders who champion reflective practice
Emotional – inspiring and motivating staff to want to join and sustain the improvement effort	<ul style="list-style-type: none"> • Clinical champions who can motivate their peers to engage in QI • Local quality activists driving improvement efforts through informal networks and through professional groups • Improvement campaigns to speed up improvement work
Physical and technological – developing a physical and technological infrastructure that enables service improvement	<ul style="list-style-type: none"> • Design of buildings and rooms to support and enhance patients’ and carers’ experience of care • Design and location of physical and technological systems (e.g. IT, medical equipment) to support and enable quality improvement

Source: adapted from Bate et al 2008: 178-185

A key factor was that, in addressing the six core challenges, each organisation had tailored the approaches they used to their particular organisational circumstances (e.g. their national and local context, organisational history, local networks, interest groups, resources etc). The researchers commented that these cases demonstrated that while quality improvement challenges are common across organisations, the most appropriate solutions are crucially dependent on each organisation’s circumstances: “...the universal but variable nature of QI systems...the same recurring common challenges but the infinite number of variations and permutations of attempted process solutions” (Bate et al 2008: 200).

This evaluation of hospitals leading the field in quality improvement in the US and Europe demonstrates that being effective in quality improvement can take a different form in different organisations: the key overarching theme defining quality improvement in each organisation (Table B) was subtly different from that of the other hospitals. What managers and health professionals leading quality improvement in each organisation had done was to take detailed account of the local context and to tailor the quality improvement approaches accordingly. The six core challenges they faced (Table C) echo the generic messages referred to at the start of the review (e.g. the need to engage clinicians, and the need to coordinate quality improvement activities and then embed them into the daily activities of the organisation), but all of the organisations had addressed these in locally-appropriate ways that fitted that context.

5. IHI’s 100,000 Lives Campaign and related initiatives

The 100,000 Lives Campaign

The Institute for Healthcare Improvement (IHI) 100,000 Lives Campaign was launched in December 2004 with a focus on patient safety as part of quality improvement activity and the specific objective of preventing 100,000 unnecessary deaths between January 2005 and June 2006 (McCannon et al. 2006). Five years previously, the Institute of Medicine had published an influential report on medical errors (Kohn et al. 1999), but action was still largely driven by mandates and by public reporting systems (Wachter and Pronovost 2006). The 100,000 Lives

Campaign aimed to take this work forward by focusing on front line workers ‘doing the right thing’ (Wachter and Pronovost 2006). The IHI campaign encouraged hospitals to adopt six evidence based interventions (Box E) selected because they addressed common problems, were known to reduce harm and death, had been used successfully in the past in a variety of health care settings (i.e. not in unique institutional circumstances) and did not require major capital investments (beyond the potential need to increase staff numbers) or IT system redesign (Gosfield and Reinertsen 2005; McCannon et al. 2006).

The IHI refer to their unit of quality improvement as a ‘care bundle’. A bundle is a set of (usually five) tasks to be carried out which, if completed, represent best practice in care delivery: *‘The power of a “bundle” is that it brings together those scientifically grounded concepts that are both necessary and sufficient to improve the clinical outcomes of interest; the focus of measurement is the completion of the entire bundle as a single intervention, rather than the completion of its individual components’* (IHI Prevention of Surgical Site Infection).⁸ This means that providing the bundle has a strong evidence base (i.e. that its combined components are an effective and appropriate distillation of current evidence on best practice), the implementation of the whole bundle should lead to improved patient outcomes. Execution of a bundle usually does not require special resources or prior training; what it requires is that practitioners ensure that the tasks are all carried out.

Box E: The six evidence-based interventions in the 100,000 Lives Campaign

- Deploy rapid response teams to patients at risk of cardiac or respiratory arrest
- Deliver reliable evidence based care for acute myocardial infarction including appropriate drugs and timely reperfusion
- Prevent adverse drug events through drug reconciliation at all transitions in care
- Prevent central line infections by reliably implementing a ‘bundle’ of evidence-based actions including hand hygiene, barrier precautions, skin antisepsis and appropriate care of the catheter site
- Prevent surgical site infections by reliably implementing a ‘bundle’ of evidence-based actions including no shaving, guideline-based timing and use of perioperative antibiotics and tight perioperative glucose control
- Prevent ventilator associated pneumonia by reliably implementing a ‘bundle’ of evidence-based actions including elevation of the head of the bed by 30 degrees, daily sedation ‘vacations’ and daily readiness-to-wean assessment

Sources: Gosfield and Reinertsen 2005; McCannon et al. 2006

The responsibility for the implementation of the changes rested largely with multi-disciplinary teams working in their own clinical areas. The campaign was supported however by infrastructure developed by the Institute over the previous 15 years to assist the rapid spread of effective health care interventions. This infrastructure is based on a set of key principles (McCannon et al. 2006): ensuring leadership commitment; stating clear aims; identifying and packaging proven ideas and practices

⁸ www.100kliveswashington.org/resources/SSI-summary.pdf undated

(i.e. care bundles); developing and executing a plan to communicate and implement the ideas; establishing a system for measuring progress; and establishing a process for refining the plan in response to learning during implementation (McCannon et al. 2006). Thus the campaign embodied the principles of effective quality improvement outlined in the introduction to this review and directly utilised the thinking behind the PDSA cycle as a meta-approach i.e. as an approach to evaluating and refining the campaign itself.

The campaign operated at three levels:

1. National level: IHI provided field staff, resources and learning events
2. Nodes: campaign nodes consisted of one or more health organisations that agreed to co-ordinate activity for a group of 50-100 hospitals and to provide more intensive local support
3. Individual hospitals or systems: individual hospitals or systems that joined the campaign had to implement the six interventions through a process of engaging all of the stakeholders, developing explicit plans, applying quality improvement methods and regularly reviewing performance.

The 100,000 Lives Campaign involved over 3000 US hospitals (representing over 80% of total US hospital discharges) (McCannon et al. 2006). There is considerable debate about the number of lives 'saved' by the campaign: although the campaign leaders estimated that by April 2006, more than 84,000 lives had been saved (McCannon et al. 2006), this figure has been disputed by others (e.g. Wachter and Pronovost 2006) on methodological grounds (e.g. difficulties in attributing effects to the campaign alone, insufficient data submitted by campaign hospitals).

Concerns have also been raised about the evidence base for one of the interventions (the use of rapid response teams) (Wachter and Pronovost 2006) and about the sponsorship of the campaign by a private organisation: *"...should a private organisation be setting a national agenda for change? Should this not be the role of organizations with better-defined roles in the health care system, organizations that are more fundamentally accountable to key stakeholders (including patients) and that have fewer opportunities for conflicts of interest?"* (Wachter and Pronovost 2006: 626).

Nevertheless, despite these significant concerns about the basis of the 100,000 Lives campaign (its sponsorship and the evidence base for the rapid response team intervention) and about whether the campaign did save as many lives as its supporters claim, there is widespread agreement that the 100,000 Lives Campaign was highly successful in raising the profile of patient safety in the US and more widely and that it generated significant social pressure for change (McCannon et al. 2006; Wachter and Pronovost 2006). In addition to the wide publicity, several other factors were thought to have contributed to the success of the campaign: its voluntary nature (which meant that participant organisations did not feel that they were simply complying with mandatory directives); the robust national infrastructure to support the campaign; and the use of a range of proven tools combined with a commitment to test out new approaches (McCannon et al. 2006; Wachter and Pronovost 2006).

The 5 Million Lives Campaign

The Institute for Healthcare Improvement launched the 5 Million Lives Campaign⁹ in December 2006 in order to address medically-induced injuries in health care (i.e. non-fatal harm) while continuing to address the causes of unnecessary deaths. This new campaign aims to protect patients from five million incidents of medical harm in the two year period from December 2006-December 2008 and the Institute aimed to enlist at least 4,000 US hospitals. The 5 Million Lives Campaign challenges US hospitals to adopt the six interventions from the 100,000 Lives Campaign (Box E above) together with six further interventions aimed at reducing harm to patients (Box F). Organisations are also encouraged to add their own changes in care to reduce harm to patients.

Box F: The six interventions in the 5 Million Lives Campaign

- ***Prevent harm from high-alert medications*** starting with a focus on anticoagulants, sedatives, narcotics, and insulin
- ***Reduce surgical complications*** by reliably implementing all of the changes in care recommended by the Surgical Care Improvement Project (interventions targeted at reducing complications of surgery e.g. surgical site infections, adverse cardiac events, deep vein thrombosis, pulmonary embolism)
- ***Prevent pressure ulcers*** by reliably using science-based guidelines
- ***Reduce Methicillin-Resistant Staphylococcus aureus (MRSA) infection*** by reliably implementing scientifically proven infection control practices
- ***Deliver reliable, evidence-based care for congestive heart failure*** to avoid readmissions
- ***Get Boards on board*** by defining and spreading the best-known processes to enable hospital Boards of Directors to become more effective in accelerating organizational progress toward safe care

Source: adapted from www.ihl.org (accessed July 2008)

By December 2007,¹⁰ the 5 Million Lives Campaign had enrolled over 3700 US hospitals (an increase of 600 hospitals since the end of the 100,000 Lives Campaign). There were Campaign field offices (nodes) in all 50 US states and around 150 mentor hospitals. The four UK sites involved in the Health Foundation's 'Safer Patients Initiative' (see below) also acted as exemplar sites, and additionally the campaign also enrolled other hospitals from outside the US, including hospitals in several other European countries, in Canada, New Zealand, Japan, India, Saudi Arabia and, most recently, Africa.

The Safer Patients Initiative in the UK

Led by the Health Foundation, the Safer Patients Initiative¹¹ in the UK began in 2004 with a four year pilot initiative in four hospitals (one in each of the four UK countries: Luton and Dunstable Hospital NHS Trust, Down Lisburn Health and Social Services Trust, NHS Tayside, Conwy and Denbighshire NHS Trust) to test ways of improving safety on a system-wide basis. All four sites followed a programme designed by the Institute for Healthcare Improvement which addressed five clinical areas and involved

⁹ www.ihl.org (accessed July 2008)

¹⁰ The 5 Million Lives Campaign's Fall Harvest: Reaping the harvest www.ihl.org (accessed July 2008)

¹¹ www.health.org.uk (accessed July 2008)

training staff in quality improvement and safety methods for safety. The programme established specific roles for the chief executives and the senior executive teams.

Although a full evaluation is not yet available, preliminary results suggest that all four pilot hospitals had on average reduced their number of adverse events by at least half (e.g. after one year NHS Tayside claimed to have reduced the adverse event rate from 70 events to 15 per 1000 patient days) and are developing a range of interventions to improve patient safety (e.g. structured communication and safety briefings in operating theatres, reconciliation of drug use, early warning systems to detect patients at risk of deterioration) (Hastings 2006; The Health Foundation 2008). In Scotland, these accomplishments have (in part) led to the formation of the Scottish Patient Safety Alliance (SPSA) who cite additional outcomes from NHS Tayside (70% decrease in ventilator acquired pneumonias and 50% reduction in MRSA bacteraemia in surgery (SPSA)¹²) and the Scottish Government has made a policy commitment to take forward this approach through the Scottish Patient Safety Programme (SPSP).¹³

Within the wider UK, the Safer Patients Initiative is now in its second phase (2006-2008) and has expanded to a further 20 UK hospitals which work in pairs and receive a tailored support package. This second phase aims to reduce the participating hospitals' mortality rates by at least 15% and adverse event rates by at least 30% across the two year period 2006-8. The programme covers ward care, perioperative and critical care, and addresses infection control, management of drugs and communication between staff and patients.

The IHI programmes use many of the quality improvement tools referred to earlier (e.g. process mapping, statistical process control) together with a range of safety tools and approaches, many of them drawn from 'high reliability' industries (e.g. aviation). Box G gives examples of safety tools and approaches.

Box G: Examples of safety tools and approaches used in IHI programmes

Prospective

- Structured communication between health professionals e.g. SBAR (situation, background, assessment, recommendation)
- M/EWS and SEWS (early warning scores) and rapid response teams to treat patients at risk of deterioration
- Probabilistic risk assessment, FMEA (failure mode and effects analysis – to determine potential failures and to assess the potential magnitude of their impact)
- Safety briefings, pauses, huddles (i.e. approaches designed to overcome handover issues and assess safety as practice happens)
- Walkrounds to detect potential risks and take preventive action
- Training using simulation devices
- Training based on human factors engineering (the study of human interactions with tools and the environment)
- Designing the physical environment to enhance safety
- Using 'high reliability design' principles to shape formal structures and

¹² www.patientsafetyalliance.scot.nhs.uk

¹³ www.patientsafetyalliance.scot.nhs.uk/programme/

informal practices

- IT-based interventions e.g. computer prompts
- Engaging patients in monitoring their care

Retrospective

- Retrospective case note reviews (identify adverse events and near-misses and means of prevention)
- Root cause analysis
- Incident/error reporting systems
- Significant event audit, confidential enquiries

Strong and enthusiastic narratives of success have attended the 100,000 Lives Campaign, the 5 Million Lives Campaign and the Safer Patients Initiative (e.g. McCannon et al. 2006; Wachter and Pronovost 2006; The Health Foundation 2008) and it is clear that the initiatives have generated significant publicity and raised the profile of patient safety issues. However, the rigorous peer-reviewed evaluation required to confirm these accounts is not yet available and therefore some caution is necessary in interpreting them. For example, the achievements reported have not been evaluated against comparator organisations which may have achieved similar harm reductions outside the initiatives. Caution is also needed in adopting the tools and approaches embraced by these initiatives (Box G): many of the newer tools (e.g. SBAR) have not yet been rigorously tested to determine their effectiveness, whether in health care or in other settings.

Discussion

In this concluding section, we draw together the findings from the review, situate them in the wider literature on quality improvement and organisational change, and consider the implications for various players within the NHS.

The health care backdrop

Before assessing what the evidence can tell us about the individual approaches to quality improvement, it is helpful to reflect on what we know about the broader context that makes health care organisations particularly challenging as a setting for *any* form of organisational change (Box H). While the details of these challenges may play out differently in specific local contexts, they all have the potential to impede, disrupt or derail application of *any* of the quality improvement approaches reviewed here.

Box H: Characteristics of health care organisations

- Complexity of care processes;
- Multiple existing standards, guidelines and protocols which are often poorly integrated;
- Multiple stakeholders (e.g. patients, communities, staff, media, politicians);
- Strong inter- and intra-professional boundaries, and the continued dominance of the medical profession (and unless their involvement is secured – which is challenging – quality improvement initiatives will remain peripheral and their

impact will be limited);

- Reluctance of many health professionals to engage in quality improvement activities;
- Limitations on the ability of managers to direct or control health professionals;
- Varying standards of data and infrastructure support for data collection and analysis;
- Contest and negotiation around what counts as ‘quality’ in health care and around the nature of ‘evidence’;
- Traditional patterns of education and socialisation that have focused on individual expertise and have not encouraged a team or system-wide approach;
- The ongoing impact (on staff, on structures, and on processes) of successive NHS reorganisations together with a history of top-down change approaches.

Sources: Ovretveit 1996; Pollitt 1996; Koeck 1998; Buetow and Roland 1999; Bate 2000; Batalden 2001; Ferlie and Shortell 2001; Fitzgerald et al. 2002; Ham et al. 2003; Leatherman and Sutherland 2003; McNulty 2003; Sheaff et al. 2003; Fulop et al 2005; Davies et al. 2006.

In particular, in relation to the NHS (although other health care systems have also been subject to similar developments to some degree), we would emphasise an issue that has dogged quality improvement initiatives in the past decade: the impact of successive reorganisations and top-down change initiatives. The ‘massive overhaul’ of the NHS since 1997, with the establishment of new organisations and processes in such areas as external inspection and oversight, performance evaluation and public reporting, payment reform and public engagement (Leatherman and Sutherland 2003) means that any quality improvement activity at local organisation level has jostled with the multiple, and at times competing, requirements of top-down initiatives. A key example is clinical governance:

“...[clinical governance] consists of an interlocking series of organizational arrangements and initiatives, planned and implemented with considerable discretion by local organizations, with the aim of improving quality, increasing safety and reducing variation in service delivery” (Wilkinson et al 2004: 106-7).

Since its inception in 1997, the clinical governance agenda has in practice been running parallel to the quality improvement agenda. Although conceptually they appear to share the same objectives and thus in principle many of the same structures and processes could be shared, in practice the emphasis in clinical governance has often been at the quality *assurance* end of the spectrum. Clinical governance has focused largely on risk avoidance, risk management and dealing with poor performance (Lugon and Scally 2000) rather than on *enabling* quality improvement. Many organisations have found these competing agendas hard to reconcile (e.g. Freeman et al 2002; Wilkinson et al 2004).

In summary, the challenges listed in Box H suggest a formidable array of complex generic contextual factors faced by health care organisations, none of which can be neglected as we consider which approaches to quality improvement will have greatest potential for application in health services.

Differences and similarities across the models

Reading across the models and system-wide approaches it is clear that there are some strong commonalities between them: the underlying objectives are often (but not always) similar, they often employ a similar array of tools (SPC, process mapping, local audits etc.), and there are often substantial overlaps in the ways in which they have been implemented in practice in health care organisations. However, it is worth exploring areas of divergence as well as convergence as a means of gaining a better grasp of the potential for each of the approaches.

There are differences across the approaches in the pace and degree of change envisaged: TQM/CQI aims at continuous incremental improvement, whereas classic BPR aims at a radical break with past practices. Rapid cycle change effects immediate changes to practice but initially on a small scale, seeing radical shifts as being the accumulation of numerous small changes. Moreover, there may be differences in the focus of attention: a criticism that has been levelled at Six Sigma, for example, is that it can lead to an undue focus on changing individual processes rather than taking a system-wide approach. The models also vary according to where they mainly try to effect change: in processes and systems (Lean, BPR), or in individual clinician behaviour and frontline activity (TQM/CQI, rapid cycle change).

The approaches can also vary according to what aspect of quality they address as their primary focus: to reduce variation (Six Sigma); to address harm (IHI's rapid cycle change); to address waste (BPR, Lean); or to enhance satisfaction (TQM, CQI). Such designations may over-simplify however: for example, TQM can be thought of as simultaneously addressing variation, waste and satisfaction; and rapid cycle change may be aimed as much at evidence-based care as at safety concerns.

Given the inter-linked nature of complex organisations, in practice each model proceeds by carrying out several secondary activities. These address the wider factors that might otherwise impinge adversely on their main area of concern. In this way TQM/CQI and rapid cycle change also contain elements of systems approaches such as reliable system design, value mapping (removing unnecessary stages in processes), and enhancing communication links between groups and units within the organisation. Similarly Lean and BPR also concentrate heavily on human factors, and the cultural and behavioural aspects of team-working, alongside their analyses of processes.

In these ways – for all their differences – the approaches do begin to resemble each other. Moreover, the same tools and interventions are commonly used across the approaches (e.g. process mapping in lean, BPR, and TQM), adding to how similar the different approaches appear. What is more, almost all of the approaches now rely heavily on measuring clinical activity through statistical process control (SPC) techniques. Most often these data are collected at the frontline and are used for either feedback on the effect of changes, or to gauge the success of the implementation process (compliance). Reliance upon measurement by frontline staff and the regular collection of process data is often seen as a central component of QI activity across the different models (TQM/CQI, BPR, Lean, Six Sigma, rapid cycle change).

Caution is needed however in over-generalising the overlap between the approaches, even in their concern with SPC data and measurement. What can appear to be the same technique may be similar in name alone, as interventions are often modified to

suit the requirements of a particular approach (e.g. the large scale audit data of BPR and Lean versus the small scale audits of rapid cycle change). Further to this, approaches evolve and it is particularly true that in their practical application sharp distinctions between the approaches become more blurred, and at implementation many of the approaches deviate quite significantly from the visions promulgated by their champions. Taken together, these arguments suggest that a clear-cut taxonomy of the different approaches and how the practical tools map onto these may be neither tenable nor useful.

Application of the approaches

The different approaches have sometimes seen differential application against each of the six dimensions of quality outlined by the Institute of Medicine noted earlier. Process approaches, for example, are often seen directed at efficiency and timeliness concerns, TQM/CQI approaches have seen some application in patient-centredness, and rapid cycle change has become particularly associated with effectiveness and patient safety.

All of the approaches can – and many of their champions would say, *should* – be used to *enable* quality improvement by ‘inspiring and developing’ (World Health Organisation Europe 2003), but equally, through different processes of implementation, each could be seen as being used more to *mandate* quality improvement through ‘policing, punishing and rewarding’ (World Health Organisation Europe 2003). The same data underpinning the models can be used for rather different ends. Here again, then, it is less about differences in models and more about variations in application, emphasis and implementation.

In practice, as shown in this review, health care organisations have been eclectic and informal in their use of these approaches: organisations have picked tools and principles piecemeal from different approaches, and new combinations of approaches are continually being developed (e.g. the NHS Institute for Innovation and Improvement is promoting Lean Six Sigma (NHS Institute for Innovation and Improvement undated)), and current NHS redesign programmes blend a range of approaches (Locock 2001).

Evaluation and evidence: no one ‘right’ method or approach

What does this degree of variability within models and the propensity for a ‘pick and mix’ approach mean for evaluation and evidence? At its most basic, it means that standard randomised control experiments are likely to prove very difficult to mount and disappointing in the scope of evidence that they produce (indeed evidence from this methodological standpoint is largely absent). However, an absence of tightly controlled experimental evidence does not mean there is no evidence on which to draw. Indeed diverse methodological approaches can often provide richer and more nuanced accounts of great value. Throughout the review (and continuing further into this Discussion) we have been at pains to draw out as many insights as possible consistent with the diverse evidence that we have accumulated and reviewed. Many of these insights necessarily address the details of implementation.

Admittedly, even taking a more inclusive view of what counts as evidence, it remains hard to assess the overall impact of specific programmes in individual organisations, or to make comparisons across a range of studies from different organisations. What

is called TQM in one hospital may have different components and emphases from its use in another (Walshe and Freeman 2002; Smith 2003). The successive use of different quality improvement approaches, as seen in health care across the 1990s, makes it harder to evaluate the impact of any one approach because the effects may be compounded or attenuated (Arndt and Bigelow 1995). However, in practice this may be more of a conceptual problem for researchers than a problem for those charged with considering which tools and approaches might best suit a particular organisation or health care system like NHSScotland. What is clear from this review, and indeed from the broader literature on organisational change (Chassin 1998; Iles and Sutherland 2001; Ovretveit and Staines 2007; Leatherman and Sutherland 2008) is that there is no one 'right' quality improvement method or approach that can be applied that will be effective in all organisations: *"...most quality improvement interventions work some of the time, but rarely live up to the dramatic claims made for them in their early stages. Success is contingent upon multiple factors, including the manner of implementation in each setting and specific local contextual factors"* (Locock 2003: 56).

Other reviews have come to similar conclusions: *"no single quality strategy can be recommended above any other on the basis of effectiveness, ease of implementation or costs"* (World Health Organisation Europe 2003: 4). Such a view is consistent with the broader 'contingency theory' of management, which emphasises that there is no one best or universal way to manage businesses or hospitals; instead, managers need to have a range of tools and approaches, and have to examine a range of staff, task, organisational and environmental characteristics before deciding on a course of action (Trisolini 2002). It is on drawing insights in these areas that we have focused our attention, rather than seeking to identify which methods or approaches work best overall (which we would see as a somewhat quixotic enterprise).

Local contextual fit

It follows from the above, therefore, that the specific approach (or combination of approaches) may be less important than the thoughtful consideration of the match and 'best fit' (however imperfect) for the particular circumstances in the local organisations using it: *"...the organisational context for quality improvement initiatives is a crucial determinant of their effectiveness"* (Walshe and Freeman 2002: 85).

Moreover, the details of *how* any programme is introduced and implemented, and the ability to ensure its careful sustained application in a way that is congruent with key considerations in change management (Iles and Sutherland 2001), may be the crucial factors in any long-term results:

"Which approach to quality improvement is used in an organisation may matter much less than how and by whom it is used. The between-approach variation may be no greater than (or even less than) the within-approach variation. It may be that what matters is that an organisation chooses its approach to quality improvement carefully and then sticks to it in the long term" (Walshe and Freeman 2002: 86).

What is also very clear from the literature is that individual organisations have their own networks, structures, organisational histories and challenges which need to be

considered in relation to the choice and implementation of quality improvement programmes. This strongly suggests a need for not just careful selection before adoption, and thoughtful and sustained implementation, but also for considerable *local adaptation*. Despite this, there is not ‘infinite microvariability’ (Dopson and Fitzgerald 2005): organisations within the NHS *do* share many common factors (e.g. national resources, curricula for training health professionals, some aspects of culture in relation to professional attitudes, health care reforms and financial constraints). These potentially provide a foundation on which to build generic support for locally-led quality improvement initiatives.

Linking in to broader themes

Quality improvement models do not themselves stand alone: “*every aspect of care is accomplished through organization – or, more accurately, processes of organizing – and therefore...organizational and human processes can be expected to play a huge part in determining the level and quality of care patients receive*” (Bate et al. 2008: 4). This emphasis on ‘organizational and human processes’ is paramount: “*safety improvement tools and techniques are not pieces of machinery that can simply be plugged in, turned on and then forgotten; rather, they are part of an organic organizational growth process that must be nurtured over a prolonged period of time*” (McCarthy and Blumenthal 2006: 193). Thus implementation of whatever quality improvement model is chosen should pay proper heed to contemporary sources of evidence and guidance on the wider issues of organisational design, development and change (Box I).

Box I: Wider relevant literature and reviews on engagement, organising and change

- *Healthcare professionals’ views on clinician engagement in quality improvement: a literature review*
Davies, Powell and Rushmer/The Health Foundation (2006)
- *Changing provider behavior: An overview of systematic reviews of interventions*
Grimshaw et al (2001)
- *Engaging doctors in leadership: review of the literature*
Dickinson and Ham/Academy of Medical Royal Colleges/University of Birmingham/NHS Institute for Innovation and Improvement (2008)
- *Quality Improvement: Theory and Practice in Healthcare*
Boaden et al/University of Manchester/NHS Institute for Innovation and Improvement (2008)
(NB: This report covers similar ground to parts of the current review; as it only emerged during the final stages of review the two documents should be seen as complementary.)
- *How to spread good ideas: a systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery and organisation*
Greenhalgh et al/NCCSDO (2004)

- *Improving patient care: the implementation of change in clinical practice*
Grol et al (2005)
- *Managing change and role enactment in the professionalised organisation*
Fitzgerald et al/NCCSDO (2006)
- *Measuring and reporting the quality of health care: issues and evidence from the international research literature*
Davies/NHS QIS (2005)
- *Regulation and quality improvement: A review of the evidence*
Sutherland and Leatherman/The Health Foundation (2006)

In particular, clinical expertise and discretion over the delivery of clinical services ensures that professional groups, especially doctors, have considerable capacity to resist or undermine change efforts (Pollitt 1996; Leverment et al. 1998; McNulty and Ferlie 2002; Ham et al. 2003; Ferlie et al. 2005; Ovretveit 1997). Indeed, most models of quality improvement have been developed first in the private sector – where managers exercise stronger direction over business activity – and hence this issue of professional discretion is little addressed in the original quality improvement literatures. However, where quality improvement models have been applied to health care, all the approaches stress that without health care professionals’ full engagement, quality improvement simply does not occur. Among the strategies which have been successful in engaging health professionals in some organisations have been bringing in peers from other services who have achieved changes through using the methods, asking influential internal groups to propose how best to ensure professional involvement and giving resources to credible professionals who will act as ambassadors for quality changes (Ovretveit 1997).

In sum, quality improvement programmes – whichever ‘model’ is chosen – are no different from other programmes that seek to achieve change in the NHS, bringing to the fore the issues and challenges of effecting behaviour and system change in large complex professional settings (Mintzberg 1979; Ham et al. 2003; Dickinson and Ham 2008).

Roles and responsibilities

All of the programmed approaches we have reviewed seek to encourage quality improvement around pre-set programmes of timetabled change; all require the simultaneous input of managers and frontline practitioners to carry out the work. As so much rests upon successful implementation (with the devil being in the detail) it is worth focusing on the tasks asked of each group and their roles in the overall process.

Most commonly it is multi-professional clinical teams that are tasked to carry out quality improvement activity. Managers must often rely heavily on health professionals’ frontline ‘lived expertise’ on work routines, care processes and contextual constraints to build realism into the process and feasibility into the solution. Simultaneously, practitioner involvement and discretion at early stages helps prompt ownership and acceptability, side-stepping the kinds of resistance expected

with imposed change (Thor et al. 2004; Crofts et al. 2007; Rushmer and Voigt 2008). Moreover, frontline engagement in diagnosing the quality improvements needed raises awareness of quality issues in local care provision that may have previously gone unnoticed and unacknowledged (Crofts et al. 2007; Smith and Rushmer 2007). By placing the locus of change at this level the people who will be required to change what they do and how they do it are immersed in ‘diagnosing’ the need to change and (by default) making their colleagues similarly aware. Where quality improvement makes sense to practitioners, and is seen to be useful and relevant to what they do, engagement is improved (Joss and Kogan 1995; Kosseff and Niemeier 2001; Ham et al. 2003; Thor et al. 2004).

Different models emphasise multi-professional teams undertaking different activities (e.g. to eliminate stages in a process that add little value – lean and BPR; to enhance satisfaction – TQM; or to reduce variation – Six Sigma). Some programmed approaches – such as Collaboratives – suggest wider cross-cutting activity. All approaches rely upon the local clinical teams to collect quantifiable local data as part of their activities, and propose that such measurements be repeated regularly to assess change and improvement. What data are collected, and how they are analysed and reported, varies according to the guiding model and the focus of change, and varying amounts of prior training are required to achieve competence in this area (Six Sigma requiring most technical expertise within the organisation, rapid cycle change requiring least).

From the evidence we have reviewed, involving clinical teams in counting and collating data on their own services and care processes seems to achieve several things: it identifies quality issues; makes apparent differences between perceived and actual service delivery; tags and tracks indicators that gauge if change is an improvement; and provides data on early gains as evidence that changes can be secured with little risk to patients or disruption to service-as-normal (Crofts et al. 2007; Rushmer and Voigt 2008). Data are also said to fulfil several other valuable functions. They can provide timely feedback by tracking the impact of certain tools (PDSAs, process control charts and others); prompt critical questioning; allow shared learning; provide motivation and, when displayed visually, act to ‘advertise’ quality activity to other practitioners and patients alike (Crofts et al. 2007). Of course, if mis-handled, local data may also lead to false starts, wasted effort or undue complacency (Davies 2005; Thor et al. 2007).

For clinical teams to be able to realise these benefits from counting and collating data on their own services requires appropriate and user-friendly data collection systems that meet clinical and organisational needs and that are well supported (e.g. by technical and statistical support, back-up and maintenance systems and high quality training for clinicians). The NHS as a whole has severe deficits in this area: data collection has generally been poor, haphazard and inadequately resourced (Leatherman and Sutherland 2003; Audit Commission 2004; Royal College of Physicians 2006).

It is crucial to note how local data feed into either ‘enabling’ or ‘policing’ approaches. ‘Enabling’ approaches permit data to be retained locally for learning; ‘policing’ approaches require centralised reporting for scrutiny and judgement. Judging too soon may make teams constrain their efforts to what can be shown to work quickly,

robbing them of valuable insights to be gained where previous learning and approaches do not work as predicted. It is this deeper, trickier, adjustment work that, if left undone, can increase the likelihood of long-term failures in the implementation process (Rushmer; unpublished field notes). If clinical teams are to be actively engaged in the regular collection and analysis of quality improvement data, important issues about the use of such data at organisational and supra-organisational level need to be addressed: there are substantial concerns about the use (and abuse) of such data for revalidation or accreditation of individual professionals or whole organisations and about the implications of publishing such data (Davies 2005).

Alongside the multi-professional care teams, it may be helpful for specialist IT roles to be established (e.g. to assist with Six Sigma approaches, or to enable data entry to produce process control run charts). In addition, expert quality improvement facilitators – as part of a support system for the clinical teams – may help in managing and facilitating the bottom-up changes identified within the team. Such support should work alongside and be integrated with the care team, not serve as a replacement to which quality improvement activities can be outsourced (McNulty and Ferlie 2002).

Several roles emerge for middle and senior organisational leaders in supporting the application of quality improvement models. First, they need to acknowledge the time and development effort required to effect local solutions, giving quality improvement teams permission to experiment. Such trust requires corresponding knowledge that the tools being used are soundly based, and confirmation that there is practitioner commitment to evidence-based change. Data made available to management might most effectively be used to identify and address system barriers. Individual quality improvement teams will not necessarily have the authority to change system-wide processes (e.g. redesigned SEWS and MEWS charts¹⁴) and the support of management will be needed.

Strategic leaders will also need to ensure that quality improvement activity aligns with other strategic objectives and is pursued consistently and coherently through the organisation (streamlining conflicting demands where possible) (Joss and Kogan 1995; Mills and Weeks 2004; Leatherman and Sutherland 2008). This may require them to pace changes for frontline staff, ameliorating the effects of change overload and the competing demands of other national and local initiatives (Leatherman and Sutherland 2008). Senior organisational leaders also need to be ‘system aware’: health care organisations are complex adaptive systems and quality improvement activity in one area may inadvertently cause pressure in other areas (e.g. early discharge resulting in high readmission rates). Other system ripples may be caused as one area undertaking quality improvement changes processes shared by other areas of the organisation. These decisions require judgement about spreading a change across the whole system (about, for example, scheduling or sequencing). This rests upon organisational and collective learning and requires judgement in timing when the whole system needs to change in response to (successful) incremental frontline changes. All of these wider issues should be the focus of sustained senior management attention.

¹⁴ These charts are used with patients identified as at risk of deterioration. The charts are used to record ‘vital signs’ (e.g. blood pressure, respiratory rate) frequently to trigger prompt remedial action (often by summoning a ‘rapid response team’) if they fall outside defined parameters.

Across Scotland, given that many boards will face similar challenges, it may be useful to consider certain overarching support, for example: identifying proven tools; centralising training in their use; helping health care organisations identify their quality improvement needs, and perhaps training volunteers to collect baseline data. Specific training may also be needed at board level for executives, non-executives and senior organisational leaders in the rationale behind practitioner-led quality improvement activity. This would need to raise awareness on: how to examine quality improvement data locally for improvement; how best to offer support to encourage frontline efforts; and how to change reporting channels to embed new reporting requirements into routine organisational processes without duplication of effort or data.

While evidence suggests that not all learning will be transferable, some will be and national arrangements could be put in place to support this. In common with the VA programme (Brown et al. 2008) and the Collaboratives approach (Bate et al. 2002) discussed earlier in this review, NHS Scotland could make opportunities for learning to be shared across settings, as workshops and learning-sets, or it could promote and support quality improvement networks. As implementation needs to be localised, site-visits would provide opportunities to meet staff undertaking improvement activity (at all levels: frontline professional, middle and senior managers), to comment on specific local issues and prompt timely resolution to maintain momentum. Internal organisational blockages could be addressed here with external facilitation helping to broker independent and mutually acceptable solutions. An expectation of the need to collect data and prepare for external visits would re-emphasise the importance of the work and its timely progress. In between times, an IT supported intra-net on quality issues could offer support to a wider community of local practitioners and thus help reemphasise involvement in work underway nationally. Many of these activities are in place as part of the Scottish Patient Safety Programme (SPSP).¹⁵ Also of prime importance (as a task that cannot be achieved by boards alone) is to rationalise where possible the number of change initiatives underway at any one time to permit concerted effort on agreed quality improvement plans (Leatherman and Sutherland 2008).

Concluding remarks

Health care organisations share a range of generic characteristics that make them particularly challenging for quality improvement programmes: complex care processes; multiple stakeholders; long-standing inter- and intra- professional ‘turf wars’; an emphasis on individual proficiency rather than team-working; a history of challenging relationships between managers and health professionals; varying standards of data and infrastructure support for data collection/analysis; and a long history of successive top-down reorganisations and change programmes. These characteristics need to be borne in mind when considering which approaches to quality improvement will have greatest application in health services.

Importing quality improvement techniques from outside health care is a perilous business, but even repeated experience of these perils has barely slowed the rate of adaptation and adoption of such techniques in the NHS. Importing quality improvement techniques from outside health care may have the benefit that the tools

¹⁵ www.patientsafetyalliance.scot.nhs.uk/programme/

and approaches have been tested to some degree, but the complexity of health care and the contingencies of the particular local and organisational circumstances (Walshe and Freeman 2002) can combine to overwhelm these potential advantages.

Nonetheless, the accumulated knowledge from more than two decades of research, evaluation and experience has highlighted that, whatever quality improvement methods or approaches are used, there are core conditions that need to be met. Health care organisations need to:

- Apply methods consistently over a sufficiently long timescale with demonstrated sustained organisational commitment and support;
- Involve doctors and other health professionals in a wide team effort while providing adequate training and development;
- Seek active involvement of middle and senior managers, the board (including non-executive directors) and, most obviously and visibly, the chief executive;
- Integrate quality improvement into the organisation's other activities (so that it is part of the organisation's strategic plans and priorities, targets etc);
- Tailor the selected methods to local circumstances;
- Create robust IT systems that enable the measurement of processes and impacts, iteratively refining the approaches used;
- Acknowledge – and ameliorate as far as possible – the impact of competing activities/changes.

The review of the models and system-wide approaches shows that there are strong commonalities between them: although they may have different emphases, many share similar underlying objectives and the distinctions between the approaches are often blurred in practice. Moreover, each of the approaches and the data used to underpin them can be used either to *enable* quality improvement by 'inspiring and developing' or to *mandate* quality improvement through 'policing, punishing and rewarding.'

Despite the many insights into implementation that can be drawn from the studies, it remains hard to assess the overall impact of specific programmes in individual organisations or to make comparisons of approaches across a range of studies. What is clear from this review and from the broader literature on organisational change is that there is no one 'right' quality improvement method. Instead, successful implementation may be more about the interaction between any given programme and its implementation in the local context. This suggests that the following inter-linked processes are important:

- the thoughtful consideration of local circumstances and selection of the approach (or combination of approaches) that is the 'best fit' (however imperfect) for the local organisation;
- the adaptation of the approach so that it best reflects the local circumstances at the outset and responds to emerging developments as implementation unfolds; and
- the careful and sustained application of the approach in a way that is congruent with current knowledge on key considerations in change management in health care.

Thus quality improvement programmes – of whatever hue – will place simultaneous responsibilities on front-line health professionals and on managers at all levels. Managers need to be actively involved with quality improvement for both symbolic and practical purposes: to ensure that quality improvement activities are aligned with the strategic objectives of the organisation and are resourced effectively; to address system barriers to changes; to embed effective practice into routine processes; and to ensure that the organisation makes full use of the external resources available to support local quality improvement.

Finally, so that quality improvement work contributes to its own evidence base, it is essential to put in place some form of ongoing evaluation (both qualitative and quantitative): *“in a sense we should view every quality improvement programme as a kind of experiment, and design it to be ‘auto-evaluative’ so that the programme itself produces information about its own effectiveness.”* (Walshe and Freeman 2002: 87).

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