Evidence

The Health Foundation
Inspiring Improvement

Leading improvement effectively

Review of research

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Identify Innovate Demonstrate Encourage

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Foreword by the Health Foundation

Leadership for improvement is central to the work of the Health Foundation. The relationship between leadership and improving the quality of care is of fundamental interest to the public and professionals alike, and both concepts are currently high on the health agenda. We are therefore particularly pleased to be able to make available this comprehensive and considered review of the literature, which explores these concepts.

There are many challenges associated with developing an empirical understanding in this area. For example as the review's author – Dr John Øvretveit – notes, there is always the challenge of 'attribution uncertainty': that is, to what extent a leader's actions can ever be said to have resulted in the improvement described. Similarly, there are difficulties inherent in being able to state with any certainty which leadership actions are likely to work in particular situations. Nevertheless, we believe this review offers a useful foundation to an important yet still emergent debate about what improvement leaders need to do, and how they might be developed.

Executive summary

What do healthcare leaders need to do to stimulate and sustain successful improvements to their services?

Evidence from research supports the common view that the right leader's actions are important for improving quality and safety. However, exactly what should different leaders do to achieve improvements in different healthcare services? Research can provide some answers by using scientific methods to test or build theories using systematic observation. Using other knowledge can reduce the limitations of the research for answering this question, and this review presents such knowledge, where research evidence is not available.

Some of the literature recommends that to lead improvement, leaders should use improvement methods and quality systems. This research review does not cover these methods and systems. However, leaders do need to be aware of different improvement methods, quality systems and safety interventions, so this research review does refer to the best literature for leaders on these subjects. The focus of this review is on the actions which leaders need to be successful in *creating* quality systems, and enabling others to use methods to carry out improvements.

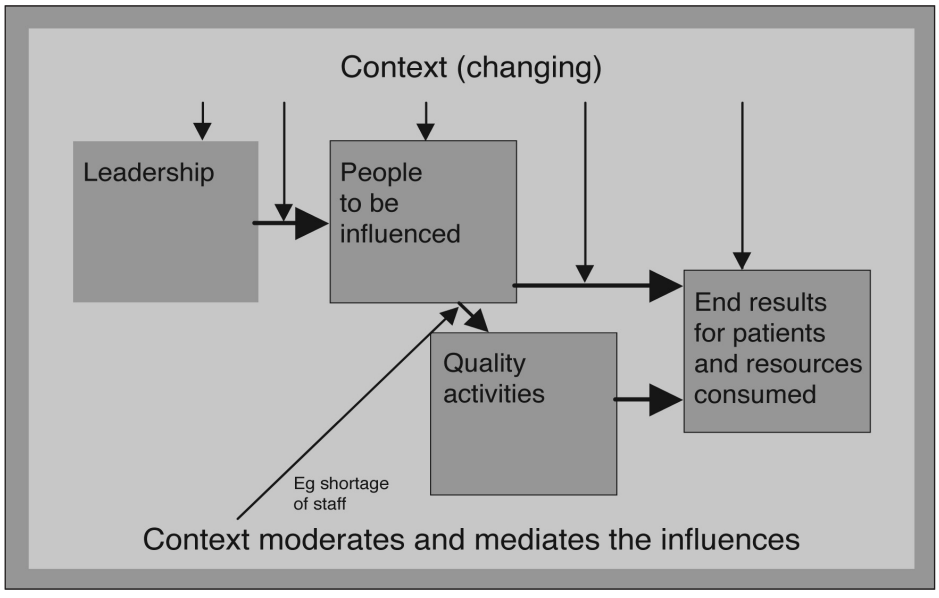
Propositions and questions

This research review proposes that leaders and those who are developing leaders can be more effective if they base their actions on what research has found to work, rather than on ideas that have not been tested, or which come from biased observation or opinion founded on limited experience. This proposition is more likely to hold if a leader's situation is similar to the situation where the research was carried out: there is some evidence that what is effective in one situation may not be in another.

Another proposition is that, where there is no evidence, literature by non-researchers – based on their 'experiential evidence' from working on improvement – can be of use to leaders. So too can literature by experts or those who have considered the issues or have new ideas, but where it is recognised that the ideas have not yet been verified by scientific investigation. Where 'good' research (noted in the text as 'eA') is not available or the evidence is uncertain, this review provides 'less strong' evidence from other research ('eB'), or from reports by consultants or improvement leaders that draw on their experiential evidence ('eC'), or material that summarises conceptual discussions ('eD').

Six questions were defined at the start of the review, to guide the search and review, with the aim of exploring key issues about leadership improvement. One finding of the review is that there are gaps and limitations in the research for answering these questions. One gap is that research is lacking into what frontline and operational leaders have done. Another relates to actions by leaders to improve primary and community healthcare services, while a third concerns actions by leaders to improve co-ordination of care between different services. Existing research also shows limited certainty about how much it was a leader's actions that caused an improvement, or something else (this is termed 'attribution uncertainty'). Added to this is uncertainty about whether the same actions, but in a different situation to that studied, would achieve the same results: recent research suggests that the effectiveness of a leader's actions depends on the situation ('generalisation unknown or qualified'). Indeed, the only generalisation may be that leaders need to choose their actions to suit their situation. There is little strong research evidence to guide which aspects of the situation they need to consider in order to choose the most effective action for improvement.

The model of the simple causal chain sequence below defines the areas the research review considered.



Simple causal chain sequence

Some evidence found in the review suggests that all the arrows are two-way: the leader influences, but is also influenced by all the areas indicated. In the model above, 'Quality activities' includes specific, short-term improvement projects, as well as people creating and running new and relatively permanent support architecture for improvement, such as structures, procedures and systems (for example, for data collection and reporting).

The main findings

The literature defines leadership and improvement in many different ways, and considers many aspects of each. There are few empirical studies of leading improvement, despite a growing view and some evidence that 'active support' and 'commitment' by leaders are essential for improvement.

A few studies have discovered what some leaders do or fail to do to change their organisations, which may then result in changes to outcomes for patients and costs. Literature and some empirical research exists that can give guidance to leaders wishing to initiate and progress improvement: some provide statements of principles; some are situation specific; and most are derived from case study and observational research.

To be most useful to improvement leaders and those who are developing leaders, the research is presented here in terms of:

- the leadership level and type: senior leadership (chief executive officer (CEO) and board); general operational management; medical leadership; nurse and therapist leadership; ordinary and shared leadership; in hospital, primary healthcare and other health organisations (mostly service provision)
- the factors that help and hinder leaders' actions in the environment (organisational and above). Many of these factors are the product of actions by leaders at higher levels
- the best research evidence is presented first, then other evidence, and then other guidance.

Six review questions were posed as part of the research. The answers provide a synthesis of the findings from the empirical and conceptual research. The answers were compiled from the strongest research evidence available, which often involved drawing on a small number of research studies or none at all, and combining this evidence from experiential evidence from reports. (More details of methods are given in the full report.)

Q1: What is improvement leadership?

Starting and enabling improvement: influencing leaders and others to do something the leader and they would not otherwise do to improve the care of patients and reduce waste.

The ability appropriately to apply leadership improvement principles and to adapt to a specific situation the improvement actions that other leaders found to be successful.

Improvement is better patient experience, satisfaction, and clinical practices or outcomes. It is also less waste and more efficient use of resources.

Improvement can be achieved by changing routine clinical practice, or indirectly by changing 'organisational supports' such as data gathering systems for improvement project or organisational culture. 'Implementation actions' for achieving both these types of improvement change include training, or feeding back performance data.

Q2: Can leaders influence improvement?

They can certainly stop improvement, and there is evidence that their actions or failure to act is associated with harm to patients and poor quality care. There is some evidence that leaders can establish structures, systems and processes in their organisation for generating improvement, which, in turn, are thought to improve patient care and reduce waste.

There is some evidence that the actions that are most likely to be successful are to create a social process where those in the service work through the tasks needed by agreeing who does what in a collective way. Specific actions by leaders depend on:

- the level and type of leadership role
- the people to be influenced: for example, one profession or many
- the type of intervention
- the type of improvement method
- the setting or sector: for example, primary care or hospital

- aspects of the organisation: for example, high workload/low staffing or vice versa, culture, previous experience with quality improvement (QI).

After considering general principles of leadership, the specific actions a leader needs to take appear to depend on these factors.

Q3: Which individual leader actions and competencies have been found to be associated with successful and unsuccessful improvement?

The research shows that the following actions by different leaders are associated with successful improvement in some situations:

- **Actions by political leaders:** which communicate visions of higher-quality healthcare, demand and strengthen long-term development of effective quality systems and programmes, and resist short-term actions that undermine these developments when tragedies occur or budgets are cut.
- **Actions by regulator leaders:** which agree and define what is expected of leaders and health staff in relation to safety and quality, and give them and the public feedback about the degree to which providers are achieving these.
- **Actions by purchaser leaders:** which do not financially penalise providers for changes that provide safer care; actions that give effective incentives to improve quality and which move to value-based rather than cost-based purchasing.
- **Actions by board leaders:** to establish and track quality and safety indicators, to establish and develop systems and processes to ensure and improve quality, and actions that guide how managers ensure safety is the number one priority when balanced against conflicting pressures.
- **Actions by CEOs and top management:** which demonstrate the importance of improvement, define improvement vision and objectives, motivate and provide incentives, adjust systems and processes to support quality and safety, as well as creating new ones, and provide the necessary resources and capability for making improvements.
- **Actions by general operational managers:** to discover and take action over poor quality, to set priorities, provide training in improvement, and carry out a set of actions to enable staff to use improvement methods and manage conflicts between everyday demands and improvement work.
- **Actions by senior medical leaders:** to involve doctors in QI through agreeing and providing comparative quality indicator data, financial and other incentives, and providing training that is known to be effective for doctors on the science and practice of improvement.
- **Actions by medical leaders:** to combine medical research with improvement in an appropriate way, facilitate challenging assessments of the opportunities for improvement, and set an example in their safety behaviours (for example, demanding people speak out when they think patients are at risk).
- **Actions by nurse leaders:** to learn and then apply safety and QI methods and systems in their areas; to model improvement attitudes and behaviours.
- **Actions by others:** successful actions that lead improvement by administrators, students, medical assistants, and others.

The research suggests that descriptions of which specific actions leaders take in one place and time may not be generalisable across other situations, roles and types of improvement. Also, the review notes that associations discovered in research between leadership actions

and improvement are not proof of causality: some studies are too ready to imply this but do not have evidence of causality.

Q4: Which concepts, frameworks and models can help guide leaders of improvement?

The research review considered the following research to be the most useful, relevant and accessible:

- for improvement generally in guiding leaders: USA: Berwick 1996; UK, NHS: Crump 2008
- for improving medical practice: USA: Solberg 2007
- for leaders in senior levels of health systems: Institute for Healthcare Improvement 2002
- for spreading improvement to access in outpatient clinics: USA, Veterans Health Administration (VHA) system: Nolan et al 2005
- for safety improvement: Botwinick et al 2006, Reinertsen et al 2008, Conway 2001 and Conway et al 2008
- for clinician involvement: Reinertsen et al 2007
- for the business case for safety and quality: Reiter et al 2006 (the most practical), Leatherman et al 2003 (with cases), Gross et al 2007 (teaching hospital) and Gosfield and Reinertsen 2003
- for the economics of quality: Øvretveit 2004a
- for standards for leaders set in the USA: Baldridge award (National Institute of Standards and Technology 2000) and the JCAHO's standards (Joint Commission on Accreditation of Healthcare Organizations 2008).

Q5: What are the strengths and limitations of research and evidence for helping leaders of improvement?

The search found few good-quality empirical studies of leadership and QI in healthcare, but the amount of literature on the subject had increased considerably. It is possible that the demand for guidance has increased, but at a greater rate than the interest of the subject to researchers, although scientific interest and finance for this research has increased marginally.

The strengths and limitations of the available research for answering the review questions are summarised below.

Strengths of the available research

- Increasing evidence of an association between leadership and process improvement.
- An initial recognition of which different actions different leaders need to take in different situations.
- A developing conceptual clarification of possible 'casual chains' between leadership actions and improvements to patients that can guide future research.
- Increasing evidence of board and CEO actions needed for improvement in US healthcare.

Limitations of the available research

- Little empirical research especially outside of the USA.
- A small amount of research, and of variable quality, specifically on leading improvement.

- No strong evidence of how much influence leadership has over improvement, compared to other factors.
- Few detailed descriptions of specific actions by successful and unsuccessful improvement leaders.
- Uncertainty about how leadership actions influence improvement activities and processes in the organisation, and if this influences patient outcomes and costs.
- Little known about the extent of generalisability of successful actions.
- Little research into how leaders adapt findings from elsewhere to their situation, and no research-based guidance for them about how to do this.
- Little multi-method and multidisciplinary research.
- Few examples of innovation in research design and methods for answering leaders' questions.

The amount and strength of the experiential evidence literature has increased:

Strengths of the experiential evidence literature

- Summaries are available for leaders based on specific improvement.
- This literature is paying more attention to referencing or summarising its evidence base with case examples, and sometimes cites more rigorous research.
- It is easily accessible, well presented and easy to understand.

Limitations of the experiential evidence literature

- There is a lack of precision in defining concepts.
- General and abstract statements which can be interpreted in many different ways.
- Where specific conclusions or guidance is given, there is a failure to reference to which services and situations these apply and to self-critically assess the applicability to other settings.

Overall the main research issues concern attribution/causality: which leadership actions cause or strongly influence which effects?; and generalisation: in which situations do these actions cause these effects?

Q6: Which improvement leadership research is most needed?

The limitations noted mean there is now opportunity for research to be carried out that provides more useful material to leaders at different levels.

There is an opportunity for innovative research to:

- find answers to the challenges in defining success
- find ways of tracing causal links or influences between a leader's actions and improvement outcomes, through intermediate changes that the leader may have produced
- discover how exactly different leaders motivate and enable others to use quality methods systematically to make improvements
- establish what is specific and what can be generalised.

The review concluded that the science of improvement could best be developed, and the practical questions of leaders best be answered, by focusing research on the following:

- **Empirical studies:** studies to discover evidence about which specific leader behaviours are associated with successful and unsuccessful improvement and how much this differs between situations, roles and types of improvement. There is a need to go beyond noting that an improvement had, or did not have, management support. There is also a need for empirically based details about commitment, involvement and engagement, and for research that discovers the many different roles and activities that managers undertake for QI, and that are successful in which situations and for which types of improvement.
- **Leadership actions:** studies of which leadership actions are associated with intermediate improvements (for example, in changes in organisation and staff activities), outside of the USA, in non-hospital services, and for operational leaders.
- **Situation-specific or generalised:** studies to understand what is situation-specific and what may be generalised: testing whether effective actions that a leader takes in one place are also effective elsewhere (for example, with sequential- or parallel-strategic sampling).
- **A range of managers:** studies specifically describing actions that have and have not been unsuccessful in leading improvement by operational managers (middle managers and team leaders), nurse and therapy managers, and purchaser managers.
- **What helps and what hinders:** studies of what helps and hinders leaders to act to generate improvements, and of how they manage competing priorities when they are successful.
- **Collaborative working:** studies that will help leaders to work with others to prioritise specific improvements, to identify which changes are appropriate, and to adapt what is effective elsewhere to their situation.
- **Innovative approaches:** studies using innovative perspectives and methods, and promising concepts, such as the leader–follower relationship, ordinary leadership, and trust. Studies could also focus on the use of stories: how much do improvement stories motivate? Are they effective for learning what needs to be done, for both leaders and others? If leaders use stories in their organisations, does this make improvement more effective?

Conclusion

Research can help healthcare leaders to answer the question, ‘What do healthcare leaders need to do?’, but cannot give a detailed answer for each leader. This review presents what research has found, and recommends what further research is needed. It also summarises experiential evidence from consultants’ and leaders’ observations where the research evidence to guide leaders is weak. The literature summarised here can motivate leaders to do more if they see that leadership actions can be effective. It can also support them to consider what works elsewhere and to adapt it to their particular situation, in order that they can make a real difference to the patients they serve.

PART 1:
INTRODUCTION AND METHODS

Chapter 1
Introduction and methods

1.1 Introduction

This research review considers effective leadership for improvement.

It presents the results of a search and analysis of research into leading improvement published between 2004 and 2008, which was then combined with a previous comprehensive review of the subject (Øvreveit 2004a). It focuses on research and literature that is particularly relevant to successful leadership in line with the UK Health Foundation's leadership programmes and strategy, and identifies the main gaps in the research.

1.1.1 Background and needs

This research review was designed to contribute to the Health Foundation's 'Developing leaders to improve health and healthcare services' programme, which has been running since 2003. In 2007, the Health Foundation wanted to assess whether there was research into leading improvement that could be helpful both to develop the programme and to make decisions about funding future improvement programmes.

The author of this review had undertaken a previous review of research into leading improvement for the Federation of Swedish County Councils (Øvreveit 2004a). This found few studies specifically focusing on leading improvement, and that most studies considered leadership as part of a more general study. It required a wide-ranging search because relevant material was located in different databases, journals and reports. The review found little experimental research, and most of the empirical research was surveys, observational studies and case studies. Most of the literature was theoretical studies, or consultants' experiences, many of which were from outside the healthcare setting.

The Health Foundation wanted a new review that was designed to meet different needs and also an update of research and thinking about leadership since 2004. Discussions clarified that this review would aim to meet the needs of:

- improvement leaders, for research-informed guidance to make their actions more effective

- developers of improvement leaders, to decide how best to develop leaders from the best research and thinking on effective leadership for improvement
- evaluators of the Health Foundation improvement leadership programme, to be better able to build on and contribute to the research on the subject
- the Health Foundation's colleagues, to be better able to decide which research to commission, which type of leadership programmes to support, monitor and evaluate, and how to select and support individual improvement leaders or groups.

The research review started in early 2008, but was given added urgency and relevance as a result of a largescale evaluation of the Health Foundation improvement leadership programmes that started at the same time, and to which the review could contribute. In addition, the Darzi report considered quality and leadership to be central to the next stages of NHS development (DH 2008). A review was completed by August 2008, which was discussed with the Health Foundation and other colleagues. The Health Foundation decided that it would be useful to separate the review of research from any practical guidance and to re-organise the material to make it more accessible for different readers. Further revisions and updating with more recent research was then carried out between August and December 2008.

1.1.2 The objectives and questions of the review

Discussions with the Health Foundation about user needs, and about the findings of the previous review which showed which research was available, led to these questions being defined for this review:

Q1: What is improvement leadership?

Q2: Can leaders influence improvement?

Q3: Which individual leader actions and competencies have been found to be associated with successful and unsuccessful improvement?

Q4: Which concepts, frameworks and models can help guide leaders of improvement?

Q5: What are the strengths and limitations of research and evidence for helping leaders of improvement?

Q6: Which improvement leadership research is most needed?

1.2 Review design principles

The 2004 review found that many different types of research were relevant but that these were located in many different databases, journals and unpublished document repositories. The author used this experience to make this review as productive as possible, and to adopt the following guiding principles, which are also relevant for reviews of other management subjects:

- **Clear questions and objectives:** as the search will need to range widely, the reviewer needs to be clear about the research users' needs and specific questions, so as to judge the relevance of any material found (the search terms alone will not locate relevant material).
- **Limit and focus:** the previous review provided a broad overview of the literature, showing which literature was available: this allowed this review to focus on the most relevant, but also to note the gaps and limitations of the research for the users' needs. The focus in this review was on research that provided evidence of actions by leaders that were and were not effective for initiating and sustaining improvement, so as to be of most use to the users of this review.
- **Best-available evidence:** follow a successive inclusion search strategy. Given the finding of the previous review that few studies focus on the subject and the research

evidence is weak, search first for empirical studies specifically about leading improvement, then search for studies that include this as part of a wider study, or that discover this as a key element. If none of these are available, search for other literature that may be of use to the research users. Note and comment on the strength of the evidence, bias and generalisability.

- **Range widely:** carry out targeted searches for relevant studies in relevant journals and institutions' websites for empirical studies. Then, if none are found, widen the search and materials to consider reports from consultants or others and theoretical studies, using the above focusing principles to select only materials that are relevant to the users' questions.

To some extent a review depends on which research is available and is iterative in defining scope. If the search reveals that little research meets high standards of evidence, the standards may be lowered to include other research so as to show the best available evidence. In management research, an initial scan is useful to help define the scope because it shows how the terms are defined, the types of studies carried out and the strength of the evidence.

The review concentrated on finding, assessing and reviewing the following research that was judged to be most relevant to the questions:

- post-2004 research. This search and review focused on research after 2004 (unless post-2004 research referred to important research that had been overlooked in the review by Øvretveit 2004a)
- empirical research rather than consultant reports or conceptual frameworks
- research achieving an acceptable level of validity for the research approach used (the grading used to assess strength of evidence and criteria for excluding research that is judged to be of inadequate quality is described in Section 1.3.2)
- research into whether or how leadership affects quality improvement (QI) (rather than research into leadership generally, or quality and safety improvement that did not feature leadership as an important part of the study or findings)
- relevance to the six questions above.

1.2.1 Initial definition of subject terms

Reviews of management research need the terms to be used to be defined in order to circumscribe which research will be searched for and which subjects to exclude. There are three ways in which terms are described:

- the researcher's use of the concepts (for example, leadership), and a search picks and reports any research using this term that is also relevant to QI and other criteria for the review
- to allow the database to categorise leadership and other terms in certain ways and to exclude certain research: sometimes the definitions are not given
- for the reviewer to define the terms in ways that exclude some research and not others.

This review chose the first approach – the definitions used by researchers – and the findings are summarised in Section 2. The review also made some initial broad definitions to include and exclude some research.

Often management reviews involve two parts. The first is a general scan and the second a more systematic review. The general scan is to discover the type of research undertaken and different definitions of the subject that researchers used, where there is no agreed common definition.

The 2004 review serves as a general scan for this review in that it discovered different definitions of leadership. The current review then linked this concept to patient care using the models shown below. The general scan was then used to limit and define which research would be searched. Previous World Health Organization (WHO) reviews of quality interventions and methods were also used to define 'quality activities' (Øvretveit 2003e).

Two conceptualisations were needed to define the boundaries of the subject in order to decide which research to search for and to review: the first was how leadership links to patient outcomes, and the second was how to define the key terms 'leadership' and 'quality activities'.

1.2.2 Links between the terms

The first conceptualisation was about how leadership, quality activities and changes in patient outcomes and resources used may be linked. The purpose of this review is to present evidence discovered by research about how leadership influences QI activities and, ultimately, patient care and resources used by a health service (intended end results). The models below separate a subject termed 'leadership' from other domains and direct attention to whether or how leadership affects 'quality activities' as well as to whether or how quality activities affect patient care or resources consumed.

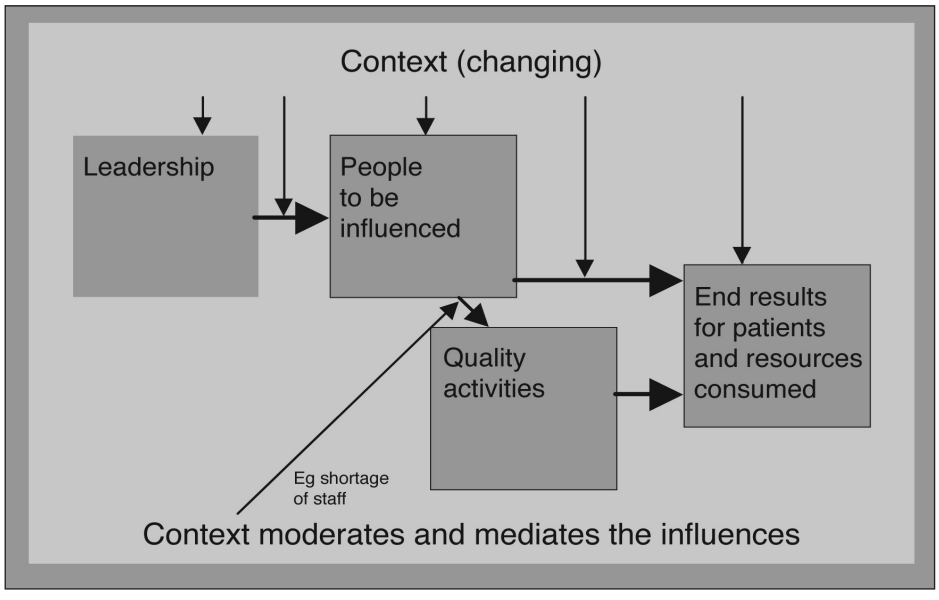


Figure 1: Simple causal chain sequence

A dynamic version of this model is given in Figure 2.

One question to be answered before the search was, 'Should the boundaries of the review be confined to whether, or how, leadership influenced quality activities, or also include whether or how quality activities changed patient outcomes or resources used?' If certain quality activities are known to be ineffective for improving patient outcomes, then evidence from this research should be included in the review to inform leaders and leadership development programmes.

The decision was made not to include an assessment and presentation of research on the effectiveness of quality activities. However, the review does draw on:

- the systematic reviews for the WHO Health Evidence Network of the effectiveness of different strategies for improving hospital quality (Øvretveit 2003e)
- the effectiveness of different quality and safety tools (Øvretveit 2005c)

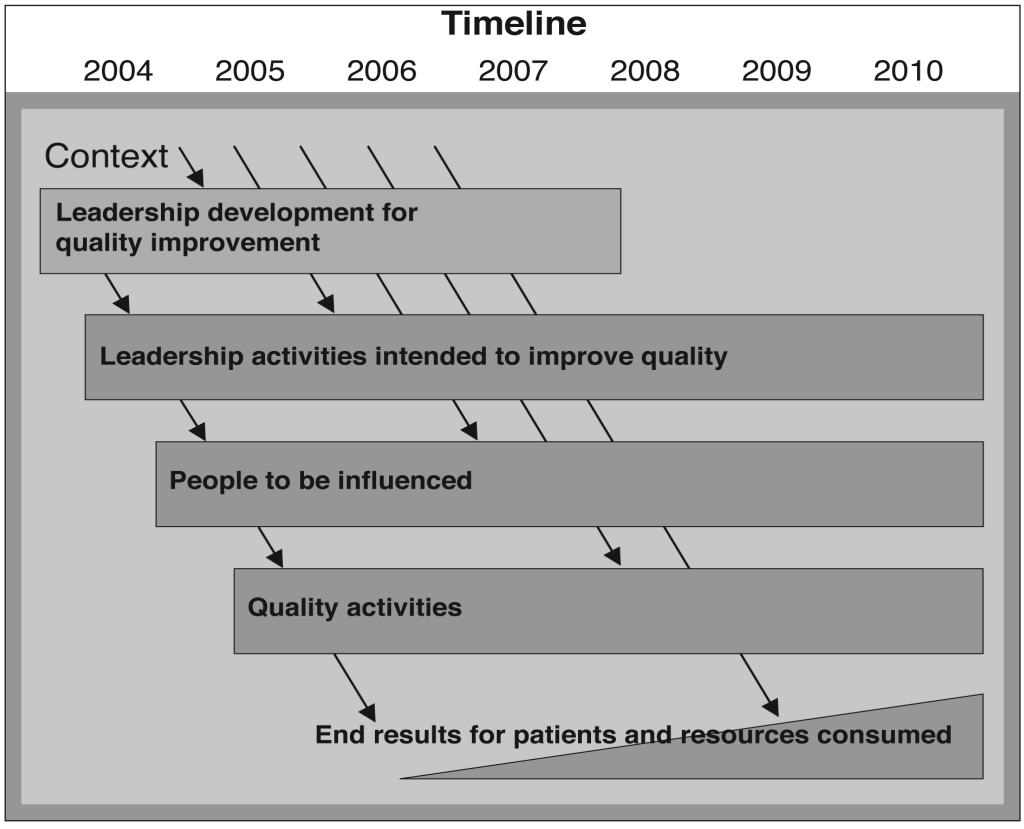


Figure 2: Continuing change in the context, leadership and quality activities over time

- the effectiveness of different patient safety interventions (Øvretveit 2009b)
- a review of the cost effectiveness of safety interventions (Øvretveit 2004c).

Where the review below presents research that discovered, for example, that certain leadership actions were effective in stimulating certain quality activities, it notes what the evidence is that these activities are effective for improving patient care and in which situations this evidence applies. The review therefore only included research that considered leadership and the quality activities of others and of the leader.

1.2.3 Boundary definition of leadership and quality activities

The second review issue was how broadly or narrowly to define 'leadership' and 'quality improvement' for the search: should the search not use any definitions but report researchers' own conceptions or definitions, or should the review exclude some research as outside the review definition of leadership or quality activities? If the review defines leadership as actions taken only by senior managers in an organisation, this excludes studies of other managers' or informal leaders' actions, or other features of leaders such as style. The advantage of an initial pre-search definition is that it makes the search more manageable and achievable given the resources. The disadvantage is that it may not capture innovative concepts of leadership that are unknown to the reviewer.

The decision made was to use the general terms: 'leader', 'leadership', 'leading', 'management' and 'manager' in the search, as well as to note how researchers defined the concepts. Similarly, the terms 'quality improvement', 'quality assurance', 'quality activities' and 'safety improvement' were used in the search where they occurred with the term 'leadership', and it was then noted which specific activities the researchers studied.

Definition of leader terms used in the search and this review

- **Improvement leadership**: Starting and enabling service improvement by influencing leaders and others to do something the leader and they would not otherwise do to improve the care of patients and reduce waste. The ability appropriately to apply leadership improvement principles and to adapt to a specific situation the improvement actions that other leaders found be successful.
- **Leader and manager:** A manager is a person holding a formal position in a hierarchy who is answerable for others' work. 'Leader' describes both them and the staff who influence others in informal ways.
- **Leadership:** Any person, group or organisation exercising influence, not just the actions of managers.
- **Ordinary leadership for improvement:** Leadership by any member of an organisation to influence or support others in carrying out improvement. A leader for improvement is any person who influences others to spend time improving the service for patients.
- **Leadership by teams or groups:** A team or group influencing others outside of the team or group to do something they would not otherwise do.
- **System of leadership for improvement:** All formal and informal leader roles, teams and groups that support improvement as part of the everyday work of an organisation. The term 'system' emphasises connections that enable the actions of each element to be aligned, in order to contribute to the improvement in different, but mutually supporting, ways.

1.3 Search and synthesis methods

The methods for the review and synthesis are those developed for management and some public health subjects, that includes qualitative, observational and other types of evidence that are excluded from traditional systematic reviews (Øvretveit 2003c and 2003e). The review used two null hypotheses to drive the search:

- NH1: there is no evidence that actions by leaders have any influence over improvement – there is no evidence of any effect on intermediate outcomes (the ideas of staff, behaviour or organisation) or on final outcomes
- NH2: there is no evidence of which specific actions by leaders in which situations influence improvement.

The search objective was to discover evidence to the contrary in the research and to assess the strength of the evidence.

Here are some of the stages of the process:

- A search and review of research on the subject up to 2004 had already been completed (Øvretveit 2004a).
- Given the large and diverse literature in this area, the new search was confined to research published between 2004 and 2008 registered in the following databases: PubMed, Medline/Ovid, and Web of Science.
- Searches were made using the following keywords: 'manage', 'lead', 'leadership', 'safety', 'quality' and 'improvement', in different combinations.
- The author also carried out a manual search of his books and filed papers on management.
- 192 reports and papers were retrieved that covered 2004 to 2008.
- 78 relevant studies were chosen to summarise, which covered a variety of different types of evidence, conceptual discussions, and commentary.
- These studies were further sorted for use in this review or for creating other products such as training materials.

1.3.1 Selection summarising and synthesis

Abstracts and papers were chosen according to whether empirical research about a leader's actions was reported, or whether 'significant' conceptual discussion was presented. Also, the author carried out a manual search of his library of English language books and papers on management, quality and safety. The method used for summarising and synthesising this research and writing this review of research was as follows.

Each publication was classified as:

- an empirical research report (what leaders actually do or interventions to change what they do), or a conceptual and normative discussion (ways of conceptualising what successful improvement leaders do, with or without reported evidence, or describing what the author thinks they should do), or a review of research into the leaders' improvement role
- which type and level of leader, on two dimensions: profession or general leaders; and leaders/managers at national, top-system or hospital, middle (for example, departmental leaders), operational team, or project levels.

An overview was written, describing the range of literature, and summarising reviews already undertaken of research into the leader's improvement role, in order to answer the first two questions:

Q1: What is improvement leadership?

Q2: Can leaders influence improvement?

The empirical or conceptual element of the publications that was relevant to each of the following questions was then summarised. A synthesis was written of the empirical and conceptual research contributions in order to answer the following questions:

Q3: Which individual leader actions and competencies have been found to be associated with successful and unsuccessful improvement?

Q4: Which concepts, frameworks and models can help guide leaders of improvement?

Q5: What are the strengths and limitations of research and evidence for helping leaders of improvement?

Q6: Which improvement leadership research is most needed?

1.3.2 Evidence guide

To give the reader a quick and simple indication of the type of evidence presented in the research reviewed, the following classification was used:

- **eA: Empirical research, strong evidence** – independent valid and reliable data gathering, with a design that allows some certainty in relating either leadership actions to improvement or lack of improvement to leader inaction or actions.
- **eB: Empirical research, weak evidence** – independent data gathering, but uncertain association between leadership actions or inactions and improvement, or lack of it.
- **eC: Experiential evidence** – propositions based on observations from experience, with some attention to reporting evidence, reducing bias and increasing objectivity.
- **eD: Unknown evidence** – evidence or experience base for propositions not demonstrated, or conceptual or theoretical discussion with little or selective reference to evidence.

Some eC and eD literature was highly relevant to the questions, and more easily understandable and applicable to leaders than most research publications, but might not result

in more effective leadership for improvement if the propositions were not based on evidence from systematic research. Most eA and eB research gave stronger evidence but indirect and often unclear answers to the questions and were often limited or unclear in their generalisability.

The assessment of strength of evidence also related to whether leadership for improvement was the focus of the study, or the study referred to this as one finding, or whether conclusions for improvement leaders could be derived from the study.

After assessment, some studies that did not meet the 'strength of evidence' criteria were retained because no other evidence was available and/or they were highly relevant to the questions. Examples are detailed self-reports by managers, or conceptual articles that provide useful frameworks for future research.

Literature was excluded if it was:

- not relevant (not about the leader's role in improvement or did not include this subject in part)
- did not meet basic scientific criteria of evidence in this field
- did not engage in 'significant' conceptual analysis. The exclusion criteria were: literature not relevant to the questions, or speculative or exhortative opinion literature that did not cite evidence.

PART 2:

THE RESEARCH INTO LEADING IMPROVEMENT

Table 1 below provides a picture of the type of research found in the search.

Table 1: Type of research and evidence relating to leadership and improvement

	Empirical research evidence presented	**Experience-based or conceptual** discussions
Leader's role – **the focus** of the study	Few studies found	Some studies
Leader's role – **part of** a wider study (sometimes discovered as a critical factor in improvement)	Some studies	Many papers and books discuss or comment on the leader's role in improvement as part of a wider discussion

Summaries of the types of research and their strengths and limitations are provided later in Sections 5 and 6.

Chapter 2
Q1: What is improvement leadership?

> Starting and enabling service improvement by influencing leaders and others to do something the leader and they would not otherwise do to improve the care of patients and reduce waste.
>
> The ability appropriately to apply leadership improvement principles and to adapt to a specific situation the improvement actions that other leaders found to be successful.

The concept of improvement is defined in different ways. Originally the concept referred mainly to quality and safety improvement, but it has been extended to cover reducing waits and increasing access and, broader still, cost savings and productivity improvement. Theories of which leadership actions result in improvement have been informed by theories of improvement about which actions result in process or outcome improvement, but these theories say little about what specifically a leader should do to initiate and support these actions. However, improvement theories do provide a useful starting point to frame data gathering to study which leadership actions are related to improvement.

Improvement is better patient experience, satisfaction, and clinical practices or outcomes. It is also less waste and more efficient use of resources. Improvement can be achieved by changing routine clinical practice, or indirectly by changing 'organisational supports' such as data gathering systems for improvement project or organisational culture. 'Implementation actions' for achieving both these types of improvement change include training, or feeding back performance data (Øvretveit 2009b).

Many definitions of leadership and leader were found in the research, and some overlap with, or try to differentiate the concept from management. The definitions above were derived from the review of the research, but also emphasise a particular view of leadership, and one that focuses on the individual leader.

In most research the term emphasises inspiring and influencing others to do things they would not otherwise do, and is used to describe both formal and informal roles. In this review, managers were defined as people formally appointed and held accountable for fulfilling certain responsibilities, with formally delegated authority over employees and resources to meet these responsibilities. However, not all managers are good leaders, and a leader might not be a manager.

An understanding of what improvement leadership is can also be gained from conclusions from a range of research studies:

- Research suggests that, while most leadership principles and some actions are common to most improvement leaders, the specific actions depend primarily on three sets of variables: the type of improvement and method used; the level and type of role; and the setting and organisational and wider environmental factors, such as the stage of improvement maturity and experience. This third set of variables is termed 'situation' in this review.
- One conclusion of the review is the need to distinguish between improvement leaders' actions and the conditions necessary for improvement. This is for three reasons:
  - Research suggests that which actions the leader takes and the success of their actions depend on the situation and surrounding conditions.
  - Higher-level leaders' actions create many of the conditions that constrain and enable lower-level leaders to act.
  - These situational factors may have more influence over implementation progress than a leader's actions, although there is little evidence of their relative influence.
- There is also evidence from research that successful improvement requires specific measurable targets and measurement data to track progress. The necessary actions by improvement leaders are to ensure that:
  - measurable targets are agreed
  - data is collected and progress tracked
  - resources are available for this.

  Higher-level leaders actions will help or hinder lower-level leaders' ability to use data as they may not have made resources available for data collection and analysis.
- A final point drawn from the research is that leadership for improvement extends beyond the actions that formal leaders make. There is evidence that ordinary leadership for improvement and shared or distributed leadership are important. While this review notes this emerging evidence and new concepts, it concentrates on the formal roles and what leaders can do to nurture and make use of these other forms of leadership.

Research usually does not show with certainty what works as it gives indications not definitive results. Making the same change in one organisation or health system may not achieve the same results in another. However, research does show that leaders need to be precise about what is meant by 'what works'. A leader is interested both in whether:

- a change results in better care or outcomes for patients or lower costs, and
- their actions produce changes (which then may result in another change, which, in turn may lead to better outcomes for patients).

In both cases research finds it challenging to establish causality between an action and a result (the 'attribution' challenge). It is easier to establish whether an action or change leads to an intermediate effect rather than the ultimate result for patients or costs.

Where direct research evidence of leadership actions is not available, research can still help to answer the question 'What is improvement leadership?' in three ways:

1. by giving evidence of the absence of improvement leadership and its consequences
2. by using improvement participants' descriptions of actions by leaders – both local and higher level – that would have helped their work. However, the evidence for this is not strong because participants' perceptions are biased and only a few are usually reported
3. by using research into barriers to improvement to identify those that leaders can influence and to suggest leadership actions to do so.

2.1 What is successful improvement leadership?

There are different implicit or explicit conceptions in the research of what would be evidence of 'success' in leading improvement. The most common concept is the same as the common

criteria of success in improvement: better outcomes for patients and/or lower costs; or intermediate achievements such as process or organisational changes that are thought to result in better outcomes. Some studies consider success as changes in staff awareness, attitudes or skills relating to improvement that the leader has generated. These different conceptions are summarised in Figure 3 below.

Leadership actions and other higher-level factors may influence intermediate and outcome changes. Actions by higher-level leaders set many conditions for lower-level leadership actions.

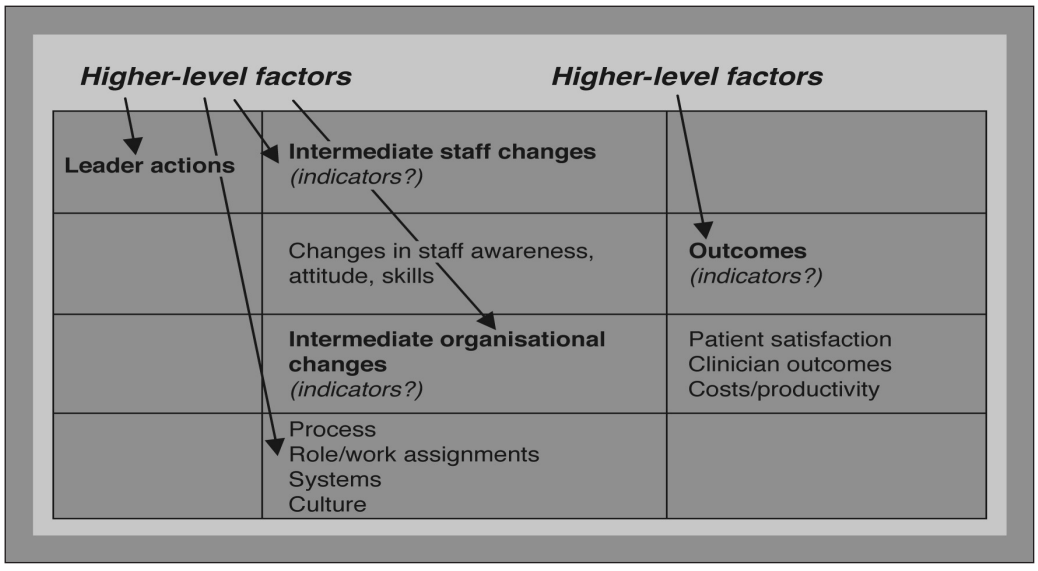


Figure 3: How higher-level factors and leadership actions influence change and outcomes

Some conceptions of success are more easily operationalised in a measure or indicator than others, and the linking between a leader's actions and the measure is easier to establish in some conceptions: it is a long causal link from a leader's actions to outcomes.

Most commentary and some evidence from case studies suggests that the following principles guide all successful improvement leaders:

- a belief in the need for improvement, which is demonstrated in their behaviour
- inspiring and motivating all staff to take responsibility and action for improvement, and influencing those who are hindering improvement
- defining the constraints within which staff must work for improvement and setting priorities and targets in consultation
- developing competencies and time for improvement in staff and themselves
- providing resources, especially for data collection, analysis and expertise
- ensuring project accountability and use of methods
- aligning incentives and systems to support improvement.

There is limited evidence from research about how these principles are best fulfilled by specific leadership actions in different settings. It is possible that successful leadership for improvement is where a leader pursues these principles in ways appropriate to the situation:

> Successful leaders coach, and are adept at communicating the case for change in ways that all of their organisation can relate to. Leaders lead from all levels of the organisation. (Crump 2008)

2.1.1 Conclusions: what is successful improvement leadership?

The research reviewed provides different, and often uncertain, answers to this question. This is because of different definitions and indicators of success, as it is challenging to assess how much a leader's actions – rather than other influences – affect results, and because it is thought that leadership actions that are successful for improvement in one organisation might not produce success in another. The simplest answer from the research review and experience to date is that successful improvement leadership is:

> Starting and enabling service improvement by influencing leaders and others to do something the leader and they would not otherwise do to improve the care of patients and reduce waste.
>
> The ability appropriately to apply leadership improvement principles and to adapt to a specific situation the improvement actions that other leaders found to be successful.

Chapter 3
Q2: Can leaders influence improvement?

3.1 Three types of evidence

An initial question is, ‘Do or can leaders significantly influence improvement?’ What is the evidence? The review found research that can be classified in three groups:

1. evidence that leaders have little or no influence in improvement
2. evidence that leadership actions are one factor needed for improvement
3. evidence that leadership actions are a key or primary factor in improvement.

The evidence is presented below. There is evidence supporting each conclusion, but how much this evidence can be generalised from the study situation to others is unknown. In each group, there is research providing weak and strong evidence for the conclusion.

There is evidence (eA) from two studies that senior leaders have little influence over improvement. A study of minimally invasive technology in 16 cardiac surgery teams found that ‘high level management support for the minimally invasive technology wasn’t decisive in hospitals’ success in implementing it’, although it did find that surgical team leaders had an important role (Edmondson et al 2001).

A second study reported a lack of influence of chief executive officers (CEOs) on the rate of implementation of another type of improvement programme: ‘total quality management’ (TQM) in 25 Australian hospitals (Baldrick et al 1996). In a later paper the researchers reported that ‘Little impact of leadership attributes was found, contrary to studies conducted elsewhere’ (Saunders et al 1997). The explanation proposed was that this could be ‘due to the strong influence of different professional groups within the hospital’. In small private hospitals with a ‘flat structure’ the direct influence of the CEO is high, and they are likely to be better able to influence implementation. The paper reports some evidence of ‘a lack of CEO influence on organisational issues in implementing TQM in large public hospitals’, which may be due to the ‘power gradient’ between the CEO and the ‘delivery interface’, as well as to the ‘complex cultural environment’ (Saunders et al 1997).

A commentary in one paper (Bigelow and Arndt 1998) reports a high failure rates with another type of improvement – reengineering – a finding also reported in UK studies (McNulty and

Ferlie 2002). The commentary suggests that this might not be due to 'poor leadership' but to 'a lack of fit between the practice and characteristics common to most hospitals'.

As regards evidence about whether managers do influence improvement, studies that have addressed this question in other-than-improvement sites (in other words, most normal hospitals) are few. One detailed study found that clinical managers had little involvement in improvement, and it provided an explanation of why this was so (Braithwaite et al 2004): management work for most involved high complexity, pace and responsibility, and managing inputs (money and people) rather than processes, and outcomes. The study found managers to be busy and reactive, and their work fragmented, discontinuous and unpredictable, with many arranged meetings interspersed with unanticipated face-to-face and telephone encounters, and intellectual energy spent on working out 'what is going on around here' (what Weick 1995 refers to as 'sensemaking'). The metaphor of 'perpetual juggler' or 'reactive puppet' was referred to in the Braithwaite study to characterise the role. The conclusion was that clinician managers' ability to pursue improvement was limited, unless there were major changes to their working day and how they carried out their role.

The above research does not provide strong evidence that leaders cannot influence improvement. However, the main findings are that:

- In research carried out in the last century, CEOs in large hospitals were found to have limited influence in one type of clinical improvement and in TQM improvements.
- Major improvement programmes such as re-engineering are difficult to implement in healthcare.
- Leadership may be less important for some types of improvement that may depend more on other factors.

3.1.1 Evidence of management failure

Negative evidence about the importance of leadership for another type of quality comes from investigations into organisational failure, which also give indications of which leadership actions are necessary for improvement.

The Bristol Inquiry (Royal Bristol Infirmary Inquiry 2001) found failures in leadership at all levels, including a lack of oversight by the board. It found deficiencies in clinical teamwork due to 'a clear lack of effective clinical leadership. Those in positions of clinical leadership must bear the responsibility for this failure', and also noted that:

> the systems and culture in place were such as to make open discussion and review more difficult. Staff were not encouraged to share their problems or to speak openly. Those who tried to raise concerns found it hard to have their voice heard.

Overall, the inquiry noted that 'there was power but no leadership. The environment was one in which problems were neither adequately identified nor addressed'.

The NHS inspectorate in the UK reported that breakdown of leadership is likely to have contributed to higher death rates in the UK heart and lung transplant programmes (Commission for Health Improvement 2001). Many other enquiries into tragedies show failures of leadership as a key factor. An investigation into the outbreak of *Clostridium difficile* at Stoke Mandeville Hospital found top managers paid more attention to meeting targets than to staff concerns over safety and cleanliness (Healthcare Commission 2006). There were similar findings about failures in leadership relating to the deaths of older patients related to healthcare acquired infection at Maidstone and Tunbridge Wells Hospital (Healthcare Commission 2007).

One analysis of failures of care in which patients are harmed or lives are lost concluded that 'these problems seem to happen in organisations with inadequate or weak leadership', and many of the other common factors reported are leadership related (Walshe 2003).

There is evidence outside of the UK that an important and common factor in breakdown and poorly performing organisations is leaders failing to ensure quality systems and improvement (Walshe and Shortell 2004). Hindle et al (2006) found leadership failures noted in eight major patient safety inquiries in six countries.

An interview study of UK NHS public sector managers, four 'failed' NHS provider trusts and five trusts at different stages of 'turnaround' identified CEO shortcomings and 'organisational failure of leadership' as key contributors to poor organisational performance. All the 12 risk factors for a failing healthcare organisation identified in the study are leadership factors, or are strongly influenced by leadership. The study concluded that 'changing the CEO is necessary but not sufficient. Other senior and middle management are key to the process. Re-engaging clinical staff is of particular importance'. The UK Commission for Health Improvement's 2001 review of its 50 visits also singled out 'a shortfall in clinical leadership as a major impediment to service redesign'.

3.1.2 Evidence that leadership actions are one factor needed for improvement

Evidence of the importance of leadership in US health system redesign with a high improvement component was found in an interview study of 16 providers and researchers (eB) (Wang el al 2006). Providers reported the following four success factors as being crucial in overcoming redesign barriers:

1. directly involving top- and middle-level leaders
2. strategically aligning and integrating improvement efforts with organisational priorities
3. systematically establishing infrastructure, process, and performance appraisal systems for continuous improvement
4. actively developing champions, teams and staff.

Lack of senior leadership support was one factor identified as contributing to the failure of a US depression care improvement programme (Fischer et al 2001), even though the clinic and medical group leaders were enthusiastic.

3.1.3 Indirect evidence

Indirect evidence of which leadership actions are needed for improvement comes from:

- studies that have included participants' descriptions of actions by leaders that helped, or would have helped, their improvement work
- research into barriers to improvement, some of which are those that leaders can influence
- general research into leadership and performance.

Research into barriers to improvement that leaders can influence

Fischer et al (2001) found that clinic and medical group leaders were initially enthusiastic about a depression care improvement programme. However, the senior management of the medical group gave limited support, which was one factor that contributed to the failure of the programme. Other factors were the departure of the primary care leader championing the project, the inability to finance the time of nurse care managers, and uncertainty about whether improving depression care would save costs.

General research into leadership and performance

There is evidence that leadership that 'engages' staff (to provide 'extra discretionary effort in their work roles'), affects attitudes to work (satisfaction, motivation, commitment) (Alimo-Metcalfe 2000) and that attitudes to work are related to employees' (Judge et al 2001) and organisational performance. The strongest evidence of the type of influence on performance comes from a long-term study that found 'engaging others' to be the strongest predictor of team performance rather than leadership competencies.

3.1.4 Conclusions from the research evidence: leaders can influence improvement

There are many publications stressing the importance of leadership, but only a few studies provide observational evidence to support this view, and no studies have rigorously tested this proposition in healthcare. The evidence reported is negative (lack of involvement is a common factor associated with failure) or positive (certain actions have been found to be associated with success). However, variations in scientific quality of the studies mean that the associations are often weak, and success is often defined subjectively and over the short term:

> Leaders set the whole context for improvement in their organisations... if the leaders within an organisation do not believe in improvement and its importance in achieving their business goals, then improvement simply will not happen. (Crump 2008) (eC)

Chapter 4

Q3: Which individual leader actions and competencies have been found to be associated with successful and unsuccessful improvement?

The search focused on finding evidence about which specific behaviours were associated with successful and unsuccessful improvement, and how much this differed between situations, roles and types of improvement. The relevant evidence and the answers to this question are presented below in different categories for leader roles at different levels and professions. These categories are used because the previous review found that research described different leadership actions depending on the level of a leader's role, and whether the role was general or profession management, although some actions were common to all roles (Øvretveit 2004a).

The level of role often corresponds to a particular type of improvement attempted, which also appears to be associated with which actions are appropriate: for example, lower-level leaders often aimed to introduce small changes to practice, process or roles within their team or area, but not to redesign pathways across units. A fourth variable that appeared to be related to which actions were successful was the health service sector (primary, secondary, tertiary or community care), in addition to the other three noted of level, profession and type of improvement.

Two types of evidence are presented: positive evidence of leadership actions associated with improvement, and negative evidence showing failures of improvement associated with a lack of leadership action.

4.1 Senior management and board level

4.1.1 Best evidence

Early research into quality programmes in US healthcare reports that inadequate leadership was associated with failed Quality and Safety Initiatives (Q&SI) (Hughes 1992, Sullivan and Frentzel 1992, Gann and Restucci 1994).

The best evidence from an early study shows higher (self-reported) top-management 'commitment' was related to higher quality improvement (QI) implementation (Parker et al 1999). It concluded that, 'the extent to which top management becomes directly involved in QI activities determines the degree of QI implementation.' The evidence comes from ten hospitals with high and low QI implementation scores that were selected from a survey of 162 US Veterans Health Administration (VHA) hospitals. The study considered the degree of implementation in relation to top-management commitment (measured by leaders' self-report answers to ten questions), and in relation to organisational culture. Additionally, the study findings suggest that 'a culture emphasising innovation and teamwork provides an important foundation for implementing a QI initiative'. However, other research raises questions about the degree to which leaders can change culture in healthcare (Scott et al 2003b).

Parker et al's study also found that the degree of QI implementation was associated with:

- close working relations within top management
- top management's understanding of QI principles
- a long tenure of QI champions in top leadership
- staff perceiving top management as 'open minded and communicative' and as strong advocates of QI
- whether hospital directors think there is good support for QI, and their creating a programme 'unique for the facility': other studies report skilful choice and adaptation of improvement methods as an important leadership action.

The study also found that 'commitment to QI declines progressively at lower levels' and that, at the high implementation sites, QI was not perceived by employees as 'a distinct programme *per se*, but rather as part of an overall culture with an emphasis on quality'.

Similar early findings were reported from a long-term study of quality programmes in six Norwegian hospitals. Increasing differences over time were found between the hospitals' degree of adoption of quality methods (Øvretveit and Aslaksen 1999, Øvretveit 1999). One factor of the two more successful programmes in this study was the flexibility of the programme, in both cases largely due to 'the preparedness of the hospital director and chief medical director to stop, listen to and understand criticisms and change the direction of the programme'.

Some studies report senior leaders' influence on specific types of improvement. One investigated senior managers' roles and activities in eight US hospitals that were encouraging better prescription of beta-blockers after acute myocardial infarction (AMI) (Bradley et al 2003). The hospitals were rated for their degree of success in beta-blocker usage, and this was related to an analysis of interviews with 45 clinical and administrative staff.

Five common roles and activities were found to represent the variation in management involvement:

1. staff engagement of senior management
2. management's relationship with senior staff
3. the promotion of an organisation culture of QI
4. support of QI with organisational structures
5. securing organisational resources for QI.

The study pointed to the need for details about commitment involvement and engagement: it concluded that it is misleading to represent QI as either having or not having management support, rather there are many different roles and activities that managers undertake for QI.

Some specific activities were more apparent in the higher-performing hospitals: senior managers actively advocated QI within the hospital and with the board, had good working

relationships with medical staff, supported interdepartmental and multidisciplinary collaboration, and ensured resources were available for QI (Bradley et al 2001 and 2003). The study also found evidence consistent with other reports: that managers' personal engagement is necessary (Savitz 2000, Weiner 1997), and the importance of their role in creating culture and structure for QI (Savitz 2000, Brailer 1998, Shortell et al 1998, Gist et al 1987). Other less-strong evidence is reported in the earlier research review (Øvretveit 2004a).

One Swedish study examined characteristics and styles of 'successful improvement leaders' in one county (Olsson and Kammerlind 2003). In common with other research, it found that successful leaders' ideas of what is expected of them were similar to the views of their co-workers. Specifically, it found that successful leaders had these expectations:

- Always have goals for what needs to be done in daily work.
- Focus on the overall aspects, not the minor details.
- Maintain integrity and a very strong ego-drive that both affect co-workers' professional careers.
- Always encourage co-workers to look for new challenges.
- Never reject a challenge even when there is a high risk of failure.
- Focus on skills to strengthen the group identity and build a team spirit.
- Always tell co-workers their honest opinion about their work abilities.
- Keep informed of important political and economic events influencing the world economy.
- Support suggestions for improvement even if they carry a high risk of failure.

The study also investigated leadership styles associated with successful improvement from leaders' questionnaire responses. Organisations with a 'suitable climate for improvement' appeared to have 'a leadership more influenced by the leadership styles of the Captain, the Strategic leader and the Team Builder than the average'. This means that leaders tended to be characterised by these actions:

- **Captain:** commands respect and confidence, leads from the front, professionally competent, communicative, reliable and fair.
- **Strategic leader:** focuses on strategic goals, takes a holistic view of the organisation, a good planner, avoids day-to-day details, process-oriented and trustworthy.
- **Team builder:** tolerant, gives feedback, acts as a coach, motivates, inspires and supportive.

The senior leader role in empowering local leadership – an illustration.

> At Minneapolis Children's Hospitals and Clinics a clinical nurse specialist and a pharmacist in haematology/oncology wanted to do something about patient safety at the local level. With support from the pharmacy manager, the nurse and pharmacist started a safety action team of cross-functional front line service workers to meet monthly to discuss medication safety issues. The consistent and frequent message from senior leadership that patient safety was a priority allowed these employees to overcome numerous barriers such as status differences, already heavy workloads, and general resistance to changes in how things get done in the hospital setting. The concept spread to other departments and then became an organisational initiative for every clinical unit manager.
>
> (Edmondson et al 2001a)

More recent evidence is given in Vaughn et al (2006) from a survey of senior chief executive officers (CEOs) and chief quality officers (CQOs) in hospitals in eight US states to discover what hospital leaders do that strengthens QI (eB). They found that QI was strengthened where the board:

- spends more than 25 per cent of their time on quality issues
- receives a formal quality performance measurement report
- bases the senior executives' compensation in part on QI performance
- interacts frequently with the medical staff about the quality strategy.

They found higher quality in hospitals where the CQO identified the CEO as 'the person with the greatest impact on QI'. Overall the survey found hospital leadership was involved but could do more, and recommended changes in leadership structures and systems relating to boards and senior administrative management teams.

Lack of senior leadership support was one factor discovered in the failure of a US depression care improvement programme (Fischer et al 2001), even though the clinic and medical group leaders were enthusiastic.

Hospital board leadership

One US interview study of CEOs and board chairpersons from 30 US hospitals found a 'mild association' between board engagement in quality and hospital performance in a composite measure of heart failure, heart attack and pneumonia (Joshi and Hines 2006).

The study also found differences between the CEOs' perception of the level of knowledge of their board chairs and the board chairs' self-perception, and made recommendations for strengthening the board's involvement in improvement, including:

- education
- better framing of an agenda for quality
- more quality planning
- focus
- incentives for leadership and governance for QI
- a greater focus on patients.

Other literature considering the leadership role of boards, with different evidence and experience basis, is all from the USA, and includes: Slessor et al 2008, Lukas et al 2007, Healthcare Benchmarks and Quality Improvement 2007, Clarke et al 2007, Botwinick, et al 2006, Reinertsen et al 2008, Conway et al 2008, Bisognano et al 2005 (for the Institute for Healthcare Improvement's 100,000 Lives Campaign) and Glickman et al 2007.

Patient safety 'leadership walk rounds' (eB)

One publication describes specific leadership behaviours to promote safety in a US hospital (Frankel et al 2002). Over a few months, a group of senior executives, joined by a few nurses and 'available personnel', made 47 weekly 'walk rounds' to 48 areas of the hospital. The group asked specific questions about adverse events, near misses and the causes and systems issues that led to them. 'Events' in the walk rounds were entered into a database, classified according to contributing factors, and the data were analysed to highlight root issues. Managers were surveyed quarterly to find actions they took as a direct result of the walk rounds and to discover what they learned.

The publication is a descriptive self-report, which does not fully evaluate these activities, but does give specific ideas for leaders about how to promote patient safety and the systems that could be useful for this. This is no substitute for a systematic reporting system, but can complement such a system. An underlying and plausible assumption is that staff will take safety issues and the safety approach more seriously if leaders reinforce a systematic

approach that the organisation has introduced, and consistently show the time and effort they are committing to the issue.

Only some things can be measured and defined as standards, and there will always be a need for human judgement about whether and how well others follow the standards. Human judgement is flawed but does have strengths in assessing difficult to define aspects of a service, in detecting subtle signs which may suggest deeper issues which require examination, and in synthesising large amounts of information quickly. There are ways of reducing the limitations and supporting the strengths to make the best use of human judgement, rather than to engineer out judgement entirely in a search for objectivity and lower costs. Supported leader walk rounds appear to offer one useful low-cost method which well serve a number of purposes.

4.1.2 Other evidence and ideas

Case studies of improvements provide some evidence of the importance of senior leadership for improvement and some partial descriptions of which actions senior leaders need to take. Summaries of these are followed by less strong or no-evidence discussions of the leader role in Q&SI.

Case studies

One study of improvement at a large Australian hospital reported that 'Little impact of leadership attributes was found, contrary to studies conducted elsewhere' (Saunders et al 1997). The explanation proposed was that this could be 'due to the strong influence of different professional groups within the hospital'. The study identified three factors that most limited the ability of the hospital to improve: 'the use of data, understanding of processes and the formation of supplier partnerships'. In theory, senior management should be able to influence these factors.

A comparative case study of total quality management (TQM) in six Norwegian hospitals (Øvretveit 1999, Øvretveit and Aslaksen 1999) found that the relative success of one hospital in engaging heads of department was due to the credibility and approach of the chief medical officer (appointed as hospital director during the programme):

> It was not that the programme was less top-down than others, or more consultative when formed – heads at 'H' criticized lack of consultation as much as they did in other hospitals. One factor was the credibility of the chief medical officer who led the programme, the way he put forward the ideas, and the particular approach he chose, which was to concentrate on patient flows – this made sense to many heads:
>
> > 'To make it work it is important that the leaders take action. Dr K encouraged and convinced us that this was important.' (Medical head of department of Surgery)
> >
> > 'When the quality project started there were many fears and resistance, but Dr K and others picked out the right leaders to take part in the different project groups.' (Quality co-ordinator)

The study describes other aspects of involving heads of department and doctors, and the choices the leaders faced, in starting and progressing the programmes.

One comparative case study of NHS improvement in the UK noted that:

> Senior management commitment and involvement (as opposed to a passive backing) gives a psychological signal of the importance to the organisation, and can unlock organisational barriers that individual departments cannot control (Locock 2001).

Case studies were carried out in four of seven US paediatric hospitals involved in an Institute for Healthcare Improvement 'Leadership of performance improvement' programme (Adler and Riley 2002). The research suggests the success of improvement projects depends on an

organisation's 'underlying performance improvement capability'. It describes the role of leaders as building this capability by developing new skills, systems, structures, strategy and cultures.

Lukas et al 2007 found five elements that were critical to the successful transformation of patient care from longitudinal comparative case studies of 12 healthcare systems. These were:

1. leadership commitment to quality
2. the impetus to transform
3. improvement initiatives that actively engage staff in meaningful problem-solving
4. alignment to achieve consistency of organisational goals with resource allocation and actions at all levels of the organisation
5. integration to bridge traditional intra-organisational boundaries among individual components.

Other research or experiential evidence of the role of senior leaders in improvement is derived from the following case studies or reports.

Britto et al (2006) describe an improvement programme in a US children's hospital and report that:

> Key factors contributing to ongoing transformation include senior leaders' drive for change, focus on perfection or near-perfection goals, vertical alignment in measures, accountability, improvement capability, commitment to internal and external transparency, and focus on measurement and constancy of purpose.

Yates et al (2005) give an experiential account of one US health system's 'safety journey' since 2002. They report that the 'key to success' was the demonstrated commitment of senior leadership to safety. They included safety in strategic priorities and provided incentives, rewards and recognition, and human resources policies and procedures to promote safety. Safety was prioritised in operational goals to ensure time and resources were available. Other steps leaders were reported to take were:

- involving all staff in each step
- establishing site-based safety initiative teams of operational leaders with the responsibility for leading implementation and ensuring communication across the organisation
- being willing to learn and try safety techniques from organisations outside healthcare.

Another account of a health systems strategy is given in Rose et al 2006, which describes a 'leadership framework for culture change' for improvement, which includes leaders' use of a culture survey for assessing safety and teamwork to discover best practices and track progress in improving performance.

Ryan's (2006) experiential account describes one US health system's 'quality journey' since 1990, including how it won the first Baldridge quality award in healthcare in 2002. Senior leadership started with continuous quality improvement (CQI) projects, took part in the Institute for Healthcare Improvement breakthrough programmes and then used the Baldridge framework to focus the quality work and establish a culture in which leadership was encouraged at all levels (more details of the latter are not provided). Another report, focusing on the 2005 Baldridge winner, also notes the leader's role in an improvement strategy (Knapp 2006). The approach to safety by one US hospital is described in Anderson et al 2007, which notes leadership as one of three components critical to improvement. Stevens et al (2006) describe a 'blueprint' for patient safety based on one US organisation's experience, and describes the necessary 'encompassing role of leadership'.

One UK case study by Wright et al 2006 of a hospital's mortality-reduction programme used a number of strategies to facilitate improvements including:

- audits
- a hospital mortality-reduction group with senior leadership and support

- alignment of hospital departments to achieve a common goal
- measurement and feedback of hospital deaths using statistical process control charts
- 'whole system working'.

> Good leadership, good information, a quality improvement strategy based on good local evidence and a community-wide approach may be effective in improving the quality of processes of care sufficiently to reduce hospital mortality. (Wright et al 2006)

US research into the leader's role in improvement is also summarised in a workshop report of a Centers for Medicare and Medicaid Services (CMS) 'leadership summit' conference (CMS 2006).

Skepticism among senior leaders (eA)

One UK study in 2002 examined senior leaders' skepticism about improvement programmes (Gollop et al 2004). The relevance of this study to the review questions is that it provides leaders with an idea of which types of skepticism to expect and of ways to overcome it. Doing so appears to be a necessary part of generating 'involvement' and 'engagement'.

Nineteen senior managers and twenty medical consultants working in the UK cancer collaborative and national booking programme were interviewed about their experience with skepticism among colleagues. The study reports that many of the clinical leaders of these programmes were initially 'curious skeptics' and only later became real supporters.

Causes of skepticism were reported as:

- misunderstanding about the aims and focus of the initiative
- dislike about how it had been presented
- personal objections to the changes, that it was driven by politics, or that it was about administrative change only
- the 'off putting language'
- disagreement about priorities for change, with many changes being pursued at the same time
- threats to personal power.

The study suggests that time spent by project leaders listening to the concerns of staff was not wasted, and that the 'commitment of doctors was regarded as particularly important'. It also found that interviewees did not always describe skepticism negatively, but sometimes as a healthy questioning.

The report describes 'managing skepticism' by:

- listening and responding to specific individual concerns
- giving real examples of what could be achieved by change
- continuing to give evidence of benefits materialising from the changes
- giving skeptics 'time to step back from daily demands and examine current practice with critical eyes'
- using a variety of skills such as peer pressure and bargaining.

> The process mapping exercises threw up so many absurd practices. So much of what went on just grew up with tradition. That was the turning point… the process mapping had shown us the opportunities. (Gollop 2003)

The best way to reduce resistance was reported to be involving staff early on and 'allowing them freedom to develop changes in ways that make sense to them', and not pressing too

hard with some skeptics, but allowing them to observe improvements elsewhere. Overcoming skepticism was described by many as taking time, patience and persistence, and was seen as a ‘war of attrition’, involving ‘chipping away, week by week, month by month’.

4.1.3 Conceptual and experience-based discussions of the senior leader’s role in improvement

Some reports and discussions give useful details to improvement leaders about their role, which is missing from much of the research, and also present it in a more accessible way, including using stories and examples.

Documents in this category specifically for improvement leaders include the following:

- Nolan (2007) presents the Institute for Healthcare Improvement’s ‘Will-Ideas-Execution’ framework for getting results from strategic improvement, which requires ‘the will of top management to make a new way of working attractive and the status quo uncomfortable’.
- Crump (2008) draws on the experience of the NHS’s National Institute for Innovation and Improvement (NIII) in the UK to suggest critical factors for improvement. The article groups the skills and knowledge needed under four headings: leadership; performance and measures; methods and processes; and relationships/incentives. It proposes that what is required of leaders is:

  > a belief in the need for improvement; insight to determine the what, why, how and when’s of improvement; and ability to create capacity for improvement through clear priorities and resource allocation.

  Crump emphasises the need to understand the principle and methods for improvement, and to communicate why change needs to happen in ways everyone can relate to. Drawing on his experience with a network of CEOs focusing on improvement, he stresses the importance of translating the vision into ‘transformational stories, which make the vision tangible for different groups’, especially clinical groups, in their organisations.

Leading safety improvement

- Reinertsen et al (2008) offer guidance and tools for leaders taking part in the Institute for Healthcare Improvement’s 100,000 Lives Campaign, which is also relevant to other types of improvement.

  The guidance is a ‘descriptive theory’ of ‘seven leverage points’ that are ‘the particular responsibility of the senior leaders to address to bring about system-level change’. They emphasise they are not saying ‘If you as a leader do these seven things, you will get dramatic system-level results’. They describe the basis for their theory in, ‘1 Complex system theory: 2. Observed performance of leaders and health systems: 3. Hunches, intuition, and collective experience’.
- Botwinick et al (2006) give guidance under eight steps for improving patient safety, based on consulting experience at the Institute for Healthcare Improvement:
  1. Address strategic priorities, culture and infrastructure.
  2. Engage key stakeholders.
  3. Communicate and build awareness.
  4. Establish, oversee and communicate system-level aims.
  5. Track/measure performance over time and strengthen analysis.

6. Support staff and patients/families impacted by medical errors.
7. Align system-wide activities and incentives.
8. Redesign systems and improve reliability.

- Conway et al (2008), drawing on the Institute for Healthcare Improvement's 5 Million Lives Campaign experience, briefly summarises how to get 'widespread board engagement' for safety, and the actions senior leadership need to take:
  1. Make a public commitment to measurable QI.
  2. Select and review progress toward safer care as the first agenda item at board meetings.
  3. Establish the use of a small number of measures that are transparent to the entire organisation and its customers.
  4. Create an environment that is respectful, fair and just for all who experience pain and loss from avoidable harm.
  5. Develop the capability of the board.
  6. Oversee the execution of a plan to achieve the board's aims to reduce harm, including executive team accountability for clear QI targets.

  Conway also notes the CMS Hospital Leadership and Quality Assessment Tool as being useful for boards and senior leaders (CMS 2006).
- Conway (2001) gives an assessment tool for hospital leaders to help guide their safety improvement, which suggests detailed actions to take, and he also draws on his experience leading safety at the Dana-Farber Cancer Centre. The Institute for Healthcare Improvement (2006a) gives a short case account of Conway's safety leadership actions at the centre:

  > Leaders need to learn how to listen and start talking about safety concerns continually – with front-line staff and at the highest levels of the organization… If you're not hearing about errors, don't assume they're not happening. Go looking for trouble, probe your staff, ask people 'What feels unsafe?' Your staff are incredibly worried about safety, a situation made worse by financial and staffing pressures. You must provide opportunities for conversations…
  >
  > Organizationally, leaders must an interdisciplinary review process so that when an error occurs everyone involved – nurses, physicians, staff, students, all those 'on the sharp end' – sit around the table 'You have to be there with them at that meeting to support your staff, often devastated by the incident... Leaders must involve the board, trustees and executive committee in safety discussions, by sharing adverse event reports, being included in root-cause analysis meetings... there is nothing that engages a board in safety issues as effectively as a patient's story.
- Federico (2007) describes the leader's role in medication safety using the Institute for Healthcare Improvement's 'Will – Ideas – Execution' framework. The article notes that 'execution requires commitment from senior leaders and clinical leaders, along with the organizational capacity to improve'.
- Denham (2005) provides suggestions about how trustees and CEOs can turn the adoption barriers of awareness, accountability, ability and action into accelerators for patient safety in their organisations.

Other relevant improvement guidance for senior leaders

This literature includes a number of quality awards and assessment systems, such as the US Baldrige award (National Institute of Standards and Technology 2000) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards from LD.1.10 to LD.4.280 (JCAHO 2008).

The first Baldridge criterion for excellence for healthcare organisations requires senior leadership to give 'a patient focus, clear and visible values, and high expectations'. Other criteria also require leadership actions to make QI efforts successful (listed in Appendix 3 of this research review). Although these criteria do not constitute research evidence about which leadership actions are needed, they do represent the views of a number of experienced experts about what senior management needs to do to lead quality. Other criteria in this and other awards are widely used to guide leaders about the specific actions they would need to take to achieve quality performance.

Some of this literature refers to changes in the responsibilities of managers in relation to quality and safety, and this is relevant to the question of whether their influence over Q&SI is limited in healthcare because of professional autonomy. One study (Sausman 2001) describes new responsibilities for senior managers in the UK as a result of the introduction of 'clinical governance':

> Clinical, managerial, and financial responsibilities will no longer be viewed as separate entities. This means that the relationship of the chief executive with clinical staff should be the same as that with non-clinical staff employed in the organisation. The chief executive is responsible for putting in place systems to ensure support for clinical standards including resources and research, training and development opportunities, and is also responsible for monitoring clinical standards and taking action where they are not met.

Other discussions describe changes that call for a new and increased role by senior leaders:

- the increased accountability of healthcare organisations and call for 'transparency'
- the greater role played by systems within organisations and the responsibility of managers for systems
- the need for a systematic approach that requires managers to provide training and time for projects and to be able intelligently to assess projects
- the manager's role in leading culture change: for example, towards a no-blame culture for open reporting.

Other studies in this category are presented in a later section. This includes:

- a discussion of critical tasks for senior leaders (Bisognano 1998)
- the US Institute of Medicine (IOM) report's (IOM 2000) discussion of 'leadership for managing change', in what has been described as 'the transformation' of healthcare called for by the report
- guidance for senior levels in health systems in a report of the six pilot organisations in the US Institute for Healthcare Improvement's 'pursuing perfection' programme (Institute for Healthcare Improvement 2002)
- a detailed and recent discussions of a 'CEO agenda' for organisational transformation (Reinertsen 2004).

> Leaders play an extraordinary role in patient safety. First and foremost, leaders must provide focus, make patient safety not just another 'program de jour' but a priority corporate objective. You must make everyone in the institution understand that safety is part of his or her job description. (Jim Conway, previous chief operating officer of Dana-Farber Cancer Institute, in Botwinick et al 2006)

4.1.4 Conclusions from the research evidence: how senior management and boards can lead improvement

The evidence is that senior leaders do have an important role to play in quality and safety improvement. However, the evidence is not strong, and this conclusion arises because of the

accumulation of similar findings from observational and mostly uncontrolled studies, rather than from well-designed prospective controlled experimental studies. There is also evidence that factors other than leadership are important to successful QI in healthcare, and that leaders are more likely to be successful if they choose strategically significant improvements that are amenable to improvement interventions, skilfully adapt the methods for the situation, and persistently follow and revise the programme.

As regards specific senior or board actions to lead improvement, there are few research-based descriptions, and many of the more detailed descriptions are based on experiential evidence where US health services have implemented specific improvements. Some of the literature provides some guidance in slightly more detail than principles. Current thinking in research literature suggests that the consequences of certain actions depend on the type of organisation, the type of improvement and the surrounding environment. The more specific the description of actions, the more likely it is that the same action in another organisation may not produce the same results.

Weak evidence is available that suggests that a key task of senior leaders is to enable and encourage 'ordinary leadership for improvement' through personal recognition and reward, and by enabling middle managers to do so. There is also some evidence that another task is to develop teamwork at all levels, especially the ability of 'leadership by teams for improvement' through identifying and developing influential teams and groups, and enabling them to lead others in improvement. Studies report that a particularly important area is relationships with doctors and ensuring medical leadership.

4.2 Operational management: team leaders, middle management and project managers

This section presents evidence of actions by first-level or higher middle-management leaders who are general managers, with or without a clinical background. Operational managers are sometimes improvement project team managers. Project managers are those formally appointed to lead improvement projects such as a CQI team project, or to lead programmes that include a number of projects; some are not general managers but are quality co-ordinators or medical or nurse managers.

Less empirical research was found on this subject than for senior leaders.

4.2.1 Best evidence

One study gives details of a programme for developing middle managers to lead improvement in an Australian teaching hospital, but there is no evidence of results (Balding 2005). It reports that middle managers' understanding and ownership of the QI programme and organisational QI implementation significantly increased, although their enjoyment in being involved in QI decreased.

Early in the programme, the first interviews discovered that the managers understood and supported the goals of the QI programme, but had difficulties relating it to their staff and everyday work, due to confusion about the organisational QI process. Managers recommended to the CEO that they form a Service Improvement Steering Committee (SISC), deciding against having 'quality' in the title as this 'appeared to carry negative connotations for the staff'.

The committee represented a range of clinical department heads and specialist managers, such as the manager of human resources and clinical risk. SISC working groups addressed

specific QI programme problems that had been identified, such as clarification of QI and hospital goals, improving education and communication, streamlining the QI process, and QI project resourcing. As a result the SISC:

- refined and streamlined the hospital improvement methodology
- drafted, circulated and held information sessions on the new hospital quality plan
- developed and publicised a QI awards programme, and gave awards to departments best addressing the new QI priority areas
- started a new QI information and education programme
- received the first round of QI 'activity seeding' grant applications from departments
- requested departmental QI plans linking to the organisational QI programme, and received them from 90 per cent of departments.

Middle managers were surveyed before and after the project and the QI implementation progress was assessed with a version of the 'QI maturity scale' (Bessant et al 2001) and an internally developed scale. The data showed that:

- to be fully involved, middle managers wanted more time, rewards, resources, QI education and training, evidence of improvements and support from senior management
- there was a significant drop in numbers of middle managers who believed that organisational communication was easy (which was potentially damaging to the success of the model implementation, as communication is thought to be critical to QI programme success)
- the increased interest by senior managers in the middle manager QI role had both a positive and negative effect on middle managers' attitudes towards their involvement, introducing both more support and scrutiny
- for middle managers, making things better for patients and staff formed the core of their motivation to be involved in QI.

The study comments that:

> Despite a great many perceived differences between the motivations of senior and middle managers, this is one critical area where mutual agreement can be fostered. The values at the base of these motivations may translate into different actions for senior and middle managers, but a clarification of the shared drivers of high quality, effective, efficient patient care may assist in building a common vision. (Balding 2005)

The study provides some evidence to suggest that the intervention used was successful in bringing senior and middle managers together and in allowing working across professional boundaries to implement the QI programme:

> Middle managers can, and will, take ownership of a QI program, given the guidance and opportunity, and over 12 months in this project, were able to make some significant improvements to perceptions of and involvement in the program across the organization.

A comparative case study of 20 US 'high performing clinical microsystems' (Donaldson and Mohr 2000) gave less detail and also little evidence of results of leadership actions. It found from observations and interviews that the 'processes of leading' involved behaviours in three areas: building knowledge, taking action, and reviewing and reflecting. It described these in order to 'enable more people to develop into leaders and more people to share the roles of leading'. Leadership in these units:

> focuses action on the way people are hired and developed and involves the way the work gets done. Reviewing and reflecting provides insight as to how the microsystem's patterns, processes, and structure enable the desired work to get done; what success looks like; and what will be next after that 'success' is created.

There was even less evidence of general manager operational leaders' actions outside of hospitals. One study in UK primary healthcare found that the involvement of a GP practice manager was associated with significantly higher-quality audit activity (Chambers et al 1995).

In nine US primary healthcare clinics, failure of CQI intervention was attributed to poor leader support in a controlled study of improvement for depression care management: 'probably the most important limiting factor was that leadership at both the medical group and clinic level only passively supported this change effort' (Solberg et al 2001).

4.2.2 Other research into operational managers' leadership of improvement

As noted above, no research was found giving strong evidence (eA) of the effects of operational managers' actions on improvement, and there was also little research giving details from empirical research about what operational mangers do to carry out improvement. Li et al (2007) note, as one of their reflections on a quality project in a haemodialysis service, that a key limitation of the project was its reliance on the drive and leadership of the head of department and other local leaders.

There is some literature about the actions that quality project leaders and facilitators take to lead improvement, but again few detailed empirically based descriptions, and no studies provide strong evidence of the effects of their actions. A number of studies of projects in Collaborative Breakthrough programmes have found operational management involvement as one factor contributing to the success of particular projects, notably one review of 43 studies (Newton et al 2003) and a combined analysis of 10 collaborative studies (Øvretveit et al 2002). There is evidence from a survey of participants in one UK breakthrough collaborative that low project manager performance and prestige was associated with less successful projects (Bate et al 2002).

In a general study of managing change in a number of UK health services, Fitzgerald (2006) found that good previous relationships predicted greater success in the change. They found 'dispersed' rather than 'individualistic' approaches to leadership in many successful cases, which involved 'committed duos or trios of change leaders, supported by a wider network of pro-change forces'. They also found differences between hospital and general practice leadership, with clinical managers in the lead in hospitals, and general managers more prominent in leading change in primary care, with poor general practitioner (GP) involvement in a number of cases.

4.2.3 Conclusions from the research evidence: how operational managers can lead improvement

There is far less research and experiential evidence about general operational managers' actions in improvement, and none that provides strong evidence of the effects of their actions. The few descriptions found were of operational managers in hospitals, and no strong evidence was found about general managers' improvement actions in primary healthcare, mental health services or community health services. Little valid or useful guidance for operational-level general managers in the UK can be drawn from the research evidence.

4.3 Medical leadership at different levels

This section summarises evidence of actions by any leader to involve doctors in improvement. It also refers to evidence of medical leaders successfully leading improvement, which usually, but not always, involves leading other doctors. 'Medical leaders' are those in formal

management positions such as a chief medical officer or head of department, but also those in senior positions in the medical hierarchy who influence others, as well as those lower in the organisational or seniority hierarchy.

> Research suggests that strong clinical leadership is perhaps the most important single determinant of the progress of clinical quality improvement in healthcare organizations. (Walshe 1995)
>
> Barriers to physician involvement may turn out to be the most important single issue impeding the success of quality improvement in medical care. (Stern 2002)
>
> Let's be honest, without surgeons actually buying in, we're going to get nowhere, you might as well not even bother. (Neath 2004)

There is some evidence that medical involvement is one factor that contributes to failure or success of an improvement (Walshe 1995, Blumenthal and Kilo 1998). There are different definitions of involvement, and different evidence about how much and which type of involvement or engagement is needed for which types of improvement. Both research and experiential evidence show that there are significant challenges to involving doctors in improvement in public health services where they are employees, as well as in services where they are contractors or independent staff with hospital-admitting privileges.

Is there evidence of specific actions that senior leaders or others have taken to overcome these challenges and to gain medical involvement? Different evidence is reported in the empirical research relating to actions by senior managers and formal medical leaders, by middle-level medical or team leaders, and by informal opinion leaders.

4.3.1 Best evidence

Top leadership actions for medical involvement

'Leadership from the top promotes physician involvement.' This was the conclusion from a survey in 1995 of 2,200 US hospitals (Weiner et al 1997). It found that greater participation in QI by doctors was associated with:

- quality monitoring and involvement by the CEO and board
- active employed doctors' involvement in governance
- longer-running quality programmes
- smaller size hospitals.

The study speculates that top leadership gives credibility and sustainability to QI by linking it to the organisation's mission and strategic objectives, allocating resources, and aligning reward and appraisal systems. 'Involvement' was measured in terms of doctors' participation in QI training and in QI teams, and in whether clinical departments had QI teams and procedures to use quality data in the teams' work.

A more recent study by Solberg et al (2007) found organisational factors that were considered the most important to improvement in 12 successful initiatives in 8 US multispecialty medical groups. An independent group identified 18 potentially important factors, and key local leaders rated the importance of these factors on a scale of 1 to 4. The five most important were judged to be:

1. leadership
2. communication
3. use of evidence-based medicine
4. measurement
5. reporting.

Medical leaders' actions

One US study of an improvement programme for depression care in five organisations found through interviews that success in some organisations was thought to be due to a 'broadly shared vision and commitment among all levels of the organisation, clearly articulated by clinical leadership, for pursuing a systematic change strategy to improve chronic care' (Nutting et al 2007).

Another US study reports the results of a programme for a doctor-led improvement intervention for percutaneous coronary treatment that trained 100 clinicians in clinical practice improvement methods (Rihal et al 2006). It reports significant cost reductions, largely due to medical leadership, which enabled effective design and implementation of changes, resulting from a mean length of stay (LOS) reduction of 0.8 days, with average cost savings of $5430. In mental health services in Australia, success was also reported as a result of training doctors to lead improvement. The conclusion of the study was that 'The handing of "quality" back to clinicians has provided a framework for improved outcomes for patients and carers' (O'Connor et al 2005).

Leadership by medical opinion leaders

Opinion leaders are respected professionals whose opinion is influential when colleagues are uncertain about a new idea or change. However, a broad definition of the term would include respected general managers or non-clinical trade union representatives. Most of the research relevant to the questions posed by this review has focused on medical opinion leaders.

A randomised controlled trail by Majumdar et al (2007) found that opinion leaders' endorsement of evidence summaries about prescribing for patients with cardiovascular disease did improve the quality of prescribing. The study concluded that, 'The influence of local opinion leaders may be useful for improving the quality of cardiovascular prescribing in the community, but the benefits are likely modest and may be disease specific'.

Earlier observational and intervention studies in healthcare found that opinion leaders have a significant role in Q&SI (Borbas et al 2000, Mittman et al 1992, Lomas et al 1991, Soumerai et al 1998, Berner et al 2003). One study reports strategies to encourage clinicians to apply research and clinical guidelines in order to improve clinical care (Borbas et al 2000). The study provides evidence that 'essential to the success of the project [was] opinion leaders' influence, expertise, interpersonal skills, understanding of local practice, and frank advice about why gaps exist between guideline knowledge and practice'.

However, an early review of studies on medical opinion leaders found six showing no significant change in clinical outcomes with the involvement of an opinion leader (Thomson et al 1999). Only two studies showed any evidence that the presence of a medical leader made an impact. This review notes that characteristics of the medical leaders were not described clearly in any of the studies.

These different findings could be due to different medical leaders' roles and characteristics. A study of two QI projects in the UK concluded that definitions of medical opinion leaders were 'oversimplified' (Locock 2001). Another study also notes that a 'lack of clarity about medical leaders in improvement efforts makes it difficult to provide recommendations to guide hospitals that want to involve physicians' (Holmboe et al 2003). This study noted many different terms being used, ranging from 'champions' to 'opinion leaders', and also that:

> Although educating and persuading peers to change their beliefs and behaviours is an important task of any quality improvement initiative, this study demonstrates that this goal alone is probably insufficient to bring about meaningful change. Many non-physicians are involved in the process of

> quality improvement. Thus the characteristics of an effective opinion leader may actually be part of a broader and perhaps more accurate conception of what is a medical leader for improving quality.

This evidence suggests that managers would need to identify these leaders and the communication networks to which they belong, and actively influence them and gain their support for Q&SI.

Medical leader characteristics associated with Q&SI

Holmboe et al 2003 found that medical leader characteristics important for Q&SI were:

- personal commitment
- professional credibility
- QI behaviours and skills
- institutional linkages.

Each medical leader possessed different combinations of the characteristics from the four categories. The study also noted medical leaders may have important influence beyond their peers (eB). This evidence came from 45 interviews with doctors, nurses, quality management, and administrative staff at 8 US hospitals that were successful in increasing the appropriate prescription of beta-blockers.

Engaging doctors

Recent UK interviews with senior leaders from several of the high and low performing UK trusts documented behaviours and approaches that 'should lead to a more positive and effective way of engaging doctors in leadership', and a 'medical engagement scale' was tested in some trusts (Dickinson and Ham 2008).

4.3.2 Other evidence and ideas

Other discussions were found in the search that give specific actions for medical and other leaders to involve leaders in improving care, but this material does not provide supporting evidence (Sangari and Beyt 1998, Gaucher and Coffey 1990, Halder 1995 and Reinertsen et al 2007).

> Very little happens in the health care system without a physician's order… almost all actions in health care are derivative of their decisions and recommendations. Therefore, any changes in the way care is designed and delivered require physician acceptance, either as individuals or as a professional body (Reinertsen et al 2007).

The most up-to-date and useful guidance is drawn from recent US Institute for Healthcare Improvement consulting experience (Reinertsen et al 2007) and shows six elements in a framework for engaging doctors: this is reproduced in this research review as Appendix 4.

An earlier US discussion suggests five phases of quality implementation for clinical leaders (Halder 1995):

1. **Deciding,** involving organisational self-assessment, choosing a framework and committing time and resources.
2. **Preparing**, with education, and forming a quality council; preparing a vision, goals, pilot projects and communication.
3. **Starting implementation**, with pilot projects, by building an infrastructure of measurement, management and other systems and providing training.

4. **An expansion phase**, spreading projects to other units and expanding training.
5. **Integration**, including quality goals as part of the business plan, and cross-unit teams.

As regards medical involvement, many studies comment on its importance to Q&SI (for example, Stern 2002, Weiner et al 1997, Øvretveit 1996, Berwick et al 1990, Neath 2004) but none give empirical data specifically about what this means. Some consider the actions that managers could take to increase involvement, but none provide empirical data about the success of actions or empirical data to support the theory of whether involvement is necessary. The literature does report examples where the role of doctors in quality leadership appeared to be a key component of success (Berwick et al 1990, Øvretveit 1999).

> Barriers to physician involvement may turn out to be the most important single issue impeding the success of quality improvement in medical care. (Stern 2002)

One discussion theorises that a top-down approach is needed (Stern 2002):

- Q&SI first needs to be made a formal organisational priority.
- The hospital director has to carry this priority into practice.
- The commitment of heads of department needs to be gained, giving resources to those who genuinely support the approach.
- After this, every doctor must be made to take part as part of their postgraduate specialty training.

Others propose identifying and working with informal opinion leaders and networks (Green and Plsek 2002). One discussion, based on research into Norwegian quality programmes (Øvretveit 1996), proposes that, to ensure involvement, managers need to:

- ensure that the quality programme responds to doctors' concerns
- provide evidence that the programme is likely to be of benefit to patients and doctors
- tailor a quality education programme specifically for doctors.

Barriers to medical involvement

Some studies discuss professional, psychological, cultural and other barriers that managers would need to address. One study of UK clinical governance suggests the reason of lack of involvement is that 'quality assurance approaches have been perceived to be externally driven by managers or to involve professional inspection' (Buetow and Roland 1999).

Another discussion (Shekelle 2002) speculates that doctors:

- may not agree with how quality is being measured
- see Q&SI as an opportunity to blame them for anything bad that may or may not happen to the patient
- fear financial liability through malpractice litigation
- feel that participation is additional to all their other responsibilities
- do not get clear descriptions of how a real programme works and get evidence of results.

> A US discussion proposes that doctors are often too busy to join teams, are sceptical about the possible effectiveness of quality improvement, and do not view organisational or process change as their responsibility. (Stern 2002)

One part of a report comments on the role of leaders in the US Veterans Health Administration improvement programme (Barber 1998). It describes how leaders tried to provide VHA doctors with a reason for their personal involvement, and how this was gained from many doctors over five years, as well as creating a measurement system (the QI checklist).

4.3.3 Conclusions from the research evidence: how to lead doctors in making improvement – actions by medical leaders and others

In summary, empirical research shows that engaging doctors is essential to QI, and there is also some evidence of successful involvement, and the role of senior leaders in winning involvement. Identifying and influencing opinion leaders to promote QI appears to be one successful way to achieve involvement, but other actions are also needed such as providing time, resources, data, evidence of results and incentives.

4.4 Nurse and therapist leadership at different levels

4.4.1 Best evidence

The search did not find any systematic empirical studies into nurse leadership for improvement that could be used to formulate evidence-based actions for different nurse leaders. No strong evidence was reported in any studies of leadership actions that resulted in improvement, and few detailed descriptions of leadership actions from research have been published.

Scott-Cawiezell and Vogelsmeier (2006) reviewed 69 selected studies of safety in nursing homes and found that teamwork, communication and leadership were all 'critical for resident and staff outcomes'. The review described the need for research that described how nursing leaders could create an environment where open and accurate communication is possible between the diverse roles, 'This will help all members of the team to identify care improvement opportunities'.

A paper by Ferguson et al (2007) describes how a cohort of clinical leaders undertaking a leadership development programme successfully used a patient-focused intervention called the 'observation of care' to focus their clinical team's attention on areas for improvement within the clinical setting.

Ginsburg et al (2005) describe another educational intervention for nurse leaders, and the results were assessed in terms of the impact on safety culture scores in two Canadian multi-site teaching hospitals (study and control). The conclusions were that training for nurse leaders can help to foster a safety culture, but that 'organizational leadership support for improvement is, however, also critical for fostering a culture of safety' and that 'together, training interventions and leadership support may have the most significant impact on patient safety culture'.

One of the most relevant nursing leader studies found in the search was a self-report giving a detailed account of what one clinical nurse leader did to improve quality in a UK service for older patients (Clegg 2000). This description draws on the 'transformational' leadership concept, and provides some evidence of success. The study describes leading a visioning process to build high expectations, setting small achievable goals, encouraging staff to make changes, and celebrating success.

Practical and tangible actions were reported to be important for morale and to give credibility to the idea of achieving change. This included:

- the leader working in the units, supporting senior ward staff and guiding their leadership styles
- making temporary contracts permanent
- refurbishing the units
- replacing obsolete equipment
- investing more in staff training and personal development.

The report also notes the need to address poor performance and sickness through 'transactional' leadership behaviours:

> Most staff perceived this direct and challenging management style in a positive way… There was a perception among the staff that some of the decisions were tough, but they were fair. Effective members of the teams were clearly tired of carrying colleagues with a history of poor performance and unmanaged sickness.

The report concludes that:

> Transformational leadership is the ability to motivate others to pursue high standards and long-term goals. This humanistic approach is defined by an open, empowering culture where communication, strong values and mutual respect are paramount… The leader keeps hope and determination alive by sharing and investing in vision.

Another self-report, by a nurse leader of a US ambulatory care centre, gives a detailed description of involving staff in CQI, and summarises the lessons learned (Flarey 1996). A commentary on the report highlights essential elements of leadership for improvement that can be defined as 'skill sets': visioning, empowerment, communication, and commitment.

Wallin et al (2002) report on Swedish research that is useful for leaders who are planning how to sustain nurses' work on QI (eB). A postal questionnaire to 240 nurses, 4 years after 4-day QI training courses, gave self-report data indicating that 39 per cent of all nurses were still involved in QI work. Three factors were significantly related to nurses continuing their involvement in QI projects: remaining employed on the same unit, taking courses in nursing science, and maintenance of the same QI model.

Reported motives for remaining active in QI work were the enhancement of knowledge, influence over clinical practice, and development as a nurse. Reasons for discontinuation were organisational restructuring, a lack of facilitation and knowledge, and change of workplace. It was noted that participation in a national guideline project for some of the nurses 'seems to have enhanced the ability to carry out the process of QI, but not to sustain the QI work over a longer period'.

Two early studies reported the lack of professional leader involvement as one factor in slow progress in a quality audit in nursing (Cheater and Keane 1998), and in therapy professions in the NHS in the UK (Robinson 1996).

4.4.2 Other evidence and ideas

Leadership actions for adverse event and near-miss reporting

One set of studies gives evidence of leadership actions that are needed for effective safety reporting. Many studies refer to a 'supportive leadership style' that results in staff reporting more errors or near misses. There is some evidence for this from a study of QI in one US teaching hospital (eB) (Edmondson et al 2001): units whose nurse manager had a 'hands on', and 'supportive' style reported far more adverse drug events than those with a 'distant' and 'stringent' manager. Analysis showed that this was not due to a higher true error rate, but from staff being 'far more willing to treat error data as friendly and therefore record them than were staff in units led by more evaluative nurse managers'.

Byock et al (2006) describe a programme to improve palliative care by convening 'national peer-professional workgroups' of recognised authorities or leaders to advance palliative aspects of practice in their respective specialties. The national programme office used a small-group process design in convening the groups, and provided co-ordination, oversight and administrative support, along with funds to support telephone and face-to-face meetings. A workgroup 'charter' guided groups in determining the scope of efforts, and set specific, time-limited goals. No strong evidence of results are provided but the report concludes that:

> Results of this experimental venture in professional change suggest that the workgroup model may be a useful, cost-effective, rapid-change strategy for quality improvement in other areas of professional practice and service delivery. (Byock et al 2006)

Advice for nurse leaders in the literature

Other articles in the nursing leadership literature suggest approaches for nurse leaders. One example proposed that:

> Nurses maintain a unique role in identifying and guiding the intervention processes central to quality care, which prepares them to become key players/designers of a paradigm that demonstrates commitment to establishing and maintaining quality care. However, without recognition and support from organization leadership and physicians, the opportunity to effectively use the capabilities of nursing may be lost. (Gantz et al 2003)

It suggested that leaders needed to 'shift the paradigm from just meeting the standards to continual readiness and performance improvement throughout the organization'.

Another example is an article by Ebright el at 2002, which describes an untested framework that suggested 'how the clinical nurse specialist can lead efforts using the "New Look" human performance-based approach' in four areas:

1. changing to a non-punitive culture
2. learning about system complexity
3. learning about healthcare worker resiliency
4. preparing for the complexity of introducing change.

4.4.3 Conclusions from the research evidence: nurse and therapist leadership of hospital services

There is little empirical research into which actions by nurse or therapist leaders are associated with successful or unsuccessful improvement. The research that has been carried out provides few details and shows weak or questionable links between leadership actions and improvement processes or activities. No detailed leader research was found into leading improvement in primary, community and mental health nursing and therapy services, although there were some nursing home leadership studies (Bonner et al 2007 and Scott-Cawiezell and Vogelsmeier 2006 refer to others).

4.5 Purchaser leadership of improvement

The review did not carry out a systematic search and analysis of the literature for evidence of leadership quality and safety improvement by purchaser organisations or by leaders in these organisations. This was because the review focused on specific leadership roles in provider organisations. However, purchasers create part of the environment that influences provider leaders' actions, and there is evidence that purchaser policies, initiatives and actions can help and hinder improvement. There is also evidence that purchasing leaders can use quality methods to improve the quality of purchasing as a service (Øvretveit 2003d, 1994b and 1995). Some of this research is therefore summarised below, drawing on some research found in the search for the review and a previous review on safety and quality interventions (Øvretveit 2005a).

The little research that exists on purchaser leadership of improvement is descriptive and conceptual, and there is little strong evidence of the effects of any of the actions noted below.

4.5.1 Purchaser actions hinder improvement

Some research suggests that improvement is more difficult when purchasers focus on cost and quantity in their purchasing decisions (Øvretveit 1995). Øvretveit (2005a) notes that, in a money-

driven system, paying providers regardless of quality and safety could have a perverse effect of rewarding providers whose costs and quality are lower. This is assuming that other mechanisms – such as accreditation, regulation and public quality performance information, provider ethics and professionalism – are not strong enough to overcome the economic pressures.

4.5.2 Purchaser actions support improvement

Research shows a number of actions and phases in purchasers' increasing concern with quality and safety as part of the 'value-for-money-triangle' of cost, quantity and quality (Øvretveit 1994b). The general trend in the USA shown by a number of studies is:

Phase 1: defining accreditation and or certification requirements as a condition of contracting (Øvretveit 1995, Velasco-Garrido et al 2005, Duran et al 2005)

Phase 2: defining quality standards in contracts (Øvretveit 1995, Velasco-Garrido et al 2005, Duran et al 2005)

Phase 3: measuring quality performance against standards, often by requiring providers to report performance on specific indicators (Velasco-Garrido et al 2005)

Phase 4: encouraging patients, referrers or employers to use providers with higher-quality performance (and often lower costs) by providing information on providers' performance

Phase 5: joining coalitions to encourage providers to take part in quality or safety campaigns with specific targets

Phase 6: paying or not paying for quality or safety performance, using different approaches:

- paying for specific initiatives: for example, for the provider to take part in a quality project, which may reduce costs, or increased payments (for example, medical fees) to providers, such as doctors, medical groups or hospitals, for providing preventative care and better management of chronic diseases
- paying for achieving quality or safety process or outcome performance levels: for example, for UK GPs, special payments for clinical and service standards: there are different views about whether the scheme has really improved care for patients, but it has improved clinical data recording (Carlisle 2005)
- withholding payments for failure to meet defined quality and safety performance levels
- financial incentives (for example, reduced co-payments) to patients to choose providers with better quality or safety or lower costs (in order to get more patients to use published 'consumer report card' quality information).

(Schemes for all the above in Phase 6 are summarised in Øvretveit 2005a.)

Most of the literature is about quality-related payments (for example, extra fees for preventative care) – there is less specifically about safety-related payments.

A review for the Agency for Healthcare Research and Quality (AHRQ) (Dudley et al 2004) of 'quality based purchasing' (QBP) of healthcare found eight trials, all with significant limitations. Few incentives were specifically safety related: most were for QI, such as providing preventative vaccination or smoking cessation. The analysis did not find that the more the payment, the greater the response. However, it did find that hospitals with low-quality performance were more likely to engage in QI, especially if the data were public.

The AHRQ review reports current research that will add to the evidence on this subject in 2006 (the CMS premier hospital quality incentive demonstration) and also reports the results of simulating the likely effects of incentive systems. The report concludes that there is some

evidence that, in some circumstances, QBP can have the desired effect, one circumstance being patients' responses. In addition, providers are more likely to respond if they think they can make money: the response is related to the perceived balance of the cost of achieving the performance goal compared to the increase in revenue from the incentive. This AHRQ review confirms the conclusion of this research review: there is limited evidence of the effect of incentives or penalties for doctors, medical groups or hospitals for patient safety.

4.6 Other types of leadership for improvement: ordinary, shared and distributed leadership

This section presents evidence found in the search for research on improvement leadership by people or groups without formal leader positions.

> Organisations have recognised the need for leadership to provide the necessary commitment and investment in change, they have also recognised that change needs to come from the bottom-up as front line teams recognise opportunities for redesigning care processes and acquire the skills to implement these new approaches successfully. (Institute of Medicine 2000)

4.6.1 Best evidence

Whistle-blowers represent one type of leadership that is sometimes successful for improvement, although at some cost (Hindle et al 2006). Literature has documented ordinary staff exercising leadership by reporting unacceptable treatment of patients, their concerns about quality and seeking to influence improvement both internally and externally (Kennedy 2001). This also illustrates how the type of leadership is shaped by the situation: research reports that in organisations that are receptive to improvement, staff are encouraged to propose and be involved in improvement, although safety reporting of adverse events is often not high (Leape 2002).

Trainee doctors may represent an underused resource for QI according to one study (Weingart 1998). This study (eB) found them to be 'skilled at identifying problems, but have difficulty executing sustained and complex QI initiatives'. It shows that peer leadership is a powerful way to mobilise participation by resident doctors, but requires faculty or staff involvement and support to guarantee continuity.

Students and nursing assistants together were found to be able successfully to lead improvements, which resulted in fewer falls in US nursing homes (Bonner et al 2007). Certified nursing assistant 'champions' were identified and given peer leadership training. Graduate students led interdisciplinary 'environmental rounds' weekly, and the interdisciplinary team reviewed new falls on a daily basis. The fall rate before training was 16.1 per cent; the 30-day post-training fall rate was 12.3 per cent; and the 60-day post-intervention fall rate was 9 per cent. The study concluded that 'student-led projects designed to teach community service learning can be meaningful and can lead to changes in patient safety and quality of care'.

An unpublished evaluation of the Health Foundation's 'Shared leadership for change' scheme (Burgoyne and Williams 2008) did not give evidence about specific leadership actions, but did define the concept in terms of characteristics of a team displaying 'shared leadership'. These were:

- a shared vision
- a strategy and plans for implementation
- members being jointly accountable for progress
- team processes that are fit for purpose

- a recognised leader, but shared responsibility for outcomes
- teams not being dependent on one or two key individuals
- teams with identified key stakeholders and means by which they keep in touch.

The evaluation noted that the Health Foundation considered that many improvement activities had tended to neglect 'people development' in favour of developing capabilities to use technical methods.

The intervention evaluated in this study was for leadership development to the whole team, tailored to the local context. The study found different understandings of the concept after the intervention:

> All the interviewees felt that their team had a single leader. They also felt that this was essential in diabetes teams and that one person needed to be able to take the overall responsibility and to be the final arbiter of decisions… It does, however, indicate the scheme participants believed that the Foundation expected that 'shared leadership' would displace individual leadership…
>
> A significant number of participants understood 'shared leadership' to mean that there was no one team leader. Although this had not been the Foundation's definition, the term led to misunderstanding. (Burgoyne and Williams 2008)
>
> All teams reported improvements in 'shared leadership':
> - increased levels of activity and achievement
> - improvements in multidisciplinary working
> - a greater sense of team cohesiveness, mutual respect
> - improvements in individual leadership skills for team members
> - a cascade effect through individual participants using their newly acquired skills in other contexts
> - increased status within the local health community, credibility to be listened to by senior management
> - able to sustain performance at a time of turbulence in the healthcare system.

4.6.2 Other evidence and ideas

Ordinary leaders

Research that considers the sociology of organisations shows that there are many staff who, through their position and informal roles in the organisation, can block or slow change. If inspired and allowed to contribute to improvement, they can have a significant role to play in adapting ideas to the local situation, encouraging others to co-operate, and in testing and implementing changes.

There is evidence of 'ordinary leadership for improvement' from observations of successful Nordic healthcare project teams (Øvretveit 1999) and in collaboratives, as well as evidence from an NHS project report (Neath 2004). Ordinary leaders are employees who have detailed knowledge of how current work is organised – who does what and how – and who know who to contact to get things done. They are also known widely in the organisation, often as a result of working in the same area or role for some time. They are often respected as 'the expert on how things work around here'. In some cases they will give emotional and technical support to each other in their improvement work, sometimes forming an 'undercover guerrilla network' for improvement, which works in spite of formal leaders. Observations suggest that the project organisation and methods provide opportunities for these staff to contribute, and the confidence and support to lead in this way (Øvretveit 1999). However, this opportunity is not normally available in healthcare, and the resource is often untapped.

Shared leadership

The origins of the term ‘shared leadership’ are unclear, but it became more prevalent in leadership research literature in the late 1990s and early 2000s. The concept is also sometimes referred to as ‘collective’, ‘distributed’ or ‘blended’ leadership.

The current trend is towards seeing leadership as:

- involving more people than has traditionally been the case
- a collective as well as an individual activity
- permeating through all levels of the organisation.

It is also considered as an organisational rather than a personalised commodity, and a process rather than an individual attribute.

The concept of shared leadership was largely neglected in leadership research literature until relatively recently. O’Toole et al (2002) argue that resistance to the notion of shared leadership reflects deeply held beliefs about the nature of leadership, which they suggest stems from:

> thousands of years of cultural conditioning that leadership is a rare trait… typically possessed by only one person in any society, an individual who has a unique lock on wisdom and truth… Shared leadership for most people is simply counterintuitive: leadership is obviously and manifestly an individual trait and activity.

4.6.3 Achieving ordinary, shared and distributed leadership through empowerment

The active involvement in improvement work of frontline employees and all staff is a continual theme in quality and safety literature, but has been difficult to achieve. For those concerned about ‘time away from my normal work’ the question is, ‘Which precise activities would we like to carry out, and which are feasible, and how much time is available?’ Leaders need to consider this, as well as asking, ‘How do I enable staff to take on this new work?’ Discussions around shared leadership and empowerment provide some answers to these questions and to what leaders need to do to develop ordinary leadership. Conceptual discussions with examples of shared leadership are given in O’Toole et al (2002) and in Miller et al (2007), which focuses on healthcare.

The research review found different views about whether and what type of empowerment was needed for staff to be involved in improvement work.

Many quality theorists propose that most poor quality is due to inadequacies in systems. Early theorists suggested that managers should view themselves as ‘keepers of the system’ who should increasingly step into a leadership role to change the system (Deming 1986). From this perspective, employees are ‘victims of the system’ and it is management’s responsibility to change the system:

> Oh those words! Empowerment? Nonsense! They only need to know what their jobs are. (Attributed to Deming by Clutterbuck and Kernaghan 1994)

Some theories propose not only involving employees in process and organisational redesign, but also empowering employees to make changes: a role that traditionally belonged to managers. Theorists appear to differ over the degree of delegation and responsibility-sharing for systems redesign that managers should undertake. In healthcare there appears to be a greater role proposed for employees than in other industries, if only on a project basis, and this role is also circumscribed by others’ power, and policies.

Is there a contradiction between the importance of strong top leadership of quality and safety initiatives and empowerment? Is there empirical research that shows empowerment being

achieved, and about the manager's role in creating this and the consequences? Should employees change organisation and systems, or should managers do this, or both, depending on the nature of the change?

There is little empirical research from healthcare to answer this question. Management theory suggests the following: empowerment should be clear and specific to the task and include accountability. Older management theory proposes that managers should clearly delegate responsibility to staff for tasks they are capable of undertaking, as well as the necessary authority, and then hold staff accountable for the task. This is how organisations get work done, but also ensures that work is co-ordinated, and is one way of developing staff (Jaques 1989). Accountability should match authority: holding people accountable for work that they do not have the resources, skills and authority to complete is persecutory and unjust. However, not holding staff accountable can be wasteful and denies staff getting the feedback that they need for their development. 'General empowerment' is an abdication of the manager's responsibilities, or a meaningless phrase where action does not match the words.

More recent management and service quality theory tends to emphasise encouraging staff to take initiatives and empowering them to make quick decisions and changes (Bennis 1994, Edvardsson et al 1996, Byham and Nelson 1994, Scholtes 1998). Many quality theorists are influenced by this literature, for example:

> At present, prevailing strategies rely largely on outmoded theories of control and standardisation of work. More modern, and much more effective, theories of production seek to harness the imagination and participation of the workforce in reinventing the system. This requires a workforce capable of setting bold aims, measuring progress, finding alternative designs for the work itself, and testing changes rapidly and informatively. (Berwick 2003)

This approach emphasises managers delegating, or staff assuming responsibility for organisation, at least for testing changes, but managers still retaining their authority to decide whether the change will be permanent. Many such theories do not stress a need for clarity about delegation and accountability – that is, specifying what is expected and giving feedback – on the basis that specification in this way is bureaucratic, drains creativity and is not possible in a fast changing situation. However, one discussion comments that 'in an empowering organisation, effective leaders work with staff to define areas of responsibility, establish measurement methods and goals, and then empower staff to hit well defined targets' (Byham and Nelson 1994). Berwick (1996), in the context of discussing 'change concepts', comments that:

> leaders cannot get by simply by 'empowering' people to discover better ways to work. In practice the workforce rarely comes up with a new concept bolder than one the leaders have already put on the table as the alternative to the status quo.

Doctors and some other health staff are already empowered in the sense of having degrees of independence in their clinical- and work-practice decisions. Their authority to change organisation and procedures is limited, but they have the power to refuse to follow changes if they view them as infringing on the clinical autonomy they need to provide the best care for individual patients.

Nurses traditionally have worked within a hierarchy that allows less independence and has a culture and structure that discourages empowerment. Research has found that nurses in some organisations who report more autonomy also report higher perceptions of quality of care and job satisfaction (Rafferty et al 2001). Higher reported levels of teamwork also correlated with nurse-assessed quality of care. This research also found a strong association between teamwork and autonomy. The study concluded that:

> It is not possible to specify whether teamwork is a pre-condition for autonomy or vice versa, but their interaction would suggest synergy rather than conflict. Organisations could therefore be encouraged to promote nurse autonomy without fearing that it might undermine teamwork.

A discussion paper considers other issues of participation and empowerment in healthcare, proposing that 'power issues' affect the degree of empowerment an organisation will allow (Marriot and Harris 2000).

4.6.4 Conclusions from the research evidence: other types of leadership improvement

Conclusions from the research review are that there is weak evidence of the importance of ordinary leaders in creating improvement. There is some discussion of shared leadership but little evidence of effects, how leaders might develop it or detailed descriptions from empirical research in healthcare. In relation to empowerment:

- One set of issues relates to empowerment to make clinical decisions about individual patients. Another set of issues concerns empowerment to change organisation and procedures – test changes or permanent changes – which, in turn, influences clinical decisions about individual patients.
- In both, clarity about the limits to empowerment and the authority delegated is important, as is holding staff accountable.
- Managers would need to be consulted about and have a veto on decisions to change organisation and procedures that affect a number of patients and other staff.
- Long and bureaucratic decision-making about such changes could damage staff motivation to carry out Q&SI.
- Managers cannot not handover their responsibility for organisation and systems to staff, but do need to share this responsibility in an appropriate way.

4.7 Summary

The evidence shows that senior leaders' actions are important to Q&SI, but there are also limits to their influence. Research also shows the importance of leadership by middle-level and respected medical leaders, but there is far less evidence or guidance for leaders in these roles. There is also some evidence of other parties in health organisations playing an important role in leading Q&SI, such as purchaser leaders and ordinary leaders.

Overall, the research suggests different actions and competencies are required for improvement, depending on three groups of variables: the level and type of role; the type of improvement objectives and method used; and the setting, and organisational and wider environmental factors.

4.7.1 The level and type of role

The research suggests the key variable is whether the leader has authority and responsibility for the staff and processes to be changed, or whether they are in a facilitatory or advisory role – for example, a quality co-ordinator.

Research suggests that the level and type of role determine which leadership actions and competencies are needed for improvement. These are presented in Table 2 below.

4.7.2 The type of improvement and method used

Specific leadership actions depend in part on which type of improvement a leader wants to initiate and sustain, and the methods to be used.

Table 2: Levels and types of role that determine leadership actions

	Type of role			
	General manager/ leader	**Profession manager/leader**	**Formal quality leader/adviser**	**Informal leader** with no formal authority
Level of role Regional or national	CEO, chairperson, senior directors	Chief Medical Officer (CMO), Chief Nursing Officer (CNO)	Quality co-ordinator	Opinion leaders
Health system or local purchaser	CEO, chairperson, senior directors	CMO, CNO,	Quality co-ordinator	Opinion leaders
Hospital or community trust	CEO, chairperson, senior directors	CMO, CNO	Quality co-ordinator	Opinion leaders
Department/unit/ primary or community care centre	Unit head	Unit head	Quality co-ordinator	Unit member or other staff
Team	Team leader	Team leader	Facilitator	Team member or other staff

- **Simple change to administrative or clinical behaviour or process:** confined to one or a few staff within a bounded unit or team for which the leader is responsible (for example, a new handover reporting form). If the leader is a nurse who wants to improve nursing practices, many successful actions and competences will be different to those of a medical leader who wants to change medical practices in their area of responsibility. The actions and competencies for this type of change depend on the mix of professions of the staff: that is, whether single or multiple professions are involved.
- **Complex change to administrative or clinical behaviour, or to a process or organisation:** confined to staff within a bounded unit or team for which the leader is responsible. This involves more than one type of change to the practices and processes of one or more profession, such as an ‘improvement bundle’.
- **Complex change to multiple areas:** covering more than one team or unit, which involves some change for which the leader is not responsible.
- **Complex change covering a whole organisation or system:** for which the leader may or may not be responsible.

4.7.3 Setting, and organisational and wider environmental factors

Research suggests that different leadership actions are needed depending on:

- **The setting:** whether it is a teaching hospital, a local hospital, primary healthcare or a community service.
- **Organisational factors:**
  - the degree of management support from higher levels
  - the stage of improvement maturity, experience and capacity
  - current changes in progress
  - data support for improvement measurement
  - finance or resources to invest
  - private or public

  - organisational culture
  - comparative improvement measures
  - comparisons and history, especially with similar changes to those contemplated.
- **Wider environmental factors:** degree of management support from higher levels; available external expertise and support; expectations, targets or performance requirements by higher levels or regulators.

Chapter 5

Q4: Which concepts, frameworks and models can help guide leaders of improvement?

The main findings of this research review is that:

- There are some common principles that characterise successful leadership of improvement.
- The more specific descriptions of leadership actions in one situation might not be generalisable across different situations, roles and types of improvement.

Bearing in mind these cautions about generalisation, and the need for leaders to adapt research findings to their particular situation, the following notes some models and literature that provide useful guidance for improvement leaders. More details about these models are given in Appendix 2. There are two types of guidance: general literature specifically for improvement leaders, often based on consulting experience; and general literature on improvement that also provides useful guidance for leaders. Appendix 2 also refers to research and guidance on programmes for leadership development for improvement.

5.1 General literature specifically for improvement leaders

Some of this literature has already been summarised in Section 4.1 and includes guidance from the NHS in the UK (Crump 2008), and from safety improvement experience in the USA (Botwinick et al 2006, Reinertsen et al 2008).

Nolan et al (2005) present a 'framework for spread' based on experience in spreading access improvements to 1,800 US Veterans Health Administration (VHA) outpatient clinics, and this study provides some details about leaders' responsibilities. Solberg (2007) offers a useful conceptual leadership framework for 'improving medical practice', which summarises the lessons learned from his experience with a variety of quality improvement (QI) research studies over 30 years. He concludes that three things are critical: 'organizational leadership with an urgent vision for change, ability to manage the change process, and selection of systematic changes capable of fulfilling the vision'.

Useful guidance from research and experience is given in the Centers for Medicare and Medicaid Services 2006 workshop summary. In this, Kroch summarises characteristics of those hospitals presented in a number of recent US studies that managed to make improvements:

Leadership

1. Chief executive officer (CEO) dedication to quality as job one. CEOs exhibit vision and passion, a deep commitment, and solid support for QI.
2. Direct board involvement. Boards understand the difference between measuring quality and using these measures to promote and reward QI.
3. Leadership understanding and communication of the business case for quality. Articulating a compelling case so that these shared goals become understood goals.
4. Support for a culture of quality. Quality improvement pervades the organisation's rituals, traditions, and tools, and is not just another department.
5. Support for evidence-based medicine (EBM), which includes rewards for higher performance and implementation of EBM.

Structure and process

6. Medical and nursing leadership engagement at all levels. This leadership may be co-ordinated between these two groups or may be demonstrated separately.
7. Attraction and retention of the right people. Includes clear incentives and signals and does not require significant resources. Small differences in incentive compensation may result in large differences in behaviour.
8. Developing effective in-house processes. Not only using these for root cause analysis and feedback, but embedding them into the organisation's daily operations.
9. Monitoring and use of benchmarks. This is the only characteristic across the studies that did not show consistent results in terms of factors correlated with high performing hospitals.
10. Exploitation of the power of information technology (IT). Implementing IT for measuring, benchmarking, monitoring, and communicating QI.

External resources

11. Engagement with consumers. The small amount of research indicates that collaboration with consumers in areas such as EBM is related to high performance.
12. Access to external support and assistance from peers. Little research but indications are that it does assist QI.

5.1.1 Earlier guidance for leaders of improvement

Earlier (pre-2004) guidance specifically for leaders of improvement is summarised in Appendix 2. This guidance covers different levels of detail and is based on varying levels of experience. It summarises:

- an article by Berwick (1996) that identifies 11 key points for leading improvement
- guidance by Bisognano (1998), who notes two critical tasks for senior leaders: setting an 'aggressive rate of improvement as the organisation can tolerate' ('stretch goals'); and setting specific aims: 'the leadership team needs to determine five or six important areas that must be radically improved over the next 12 months'. He also suggests using a checklist to assess the team's change-management ability (for example, Gustafson's checklist, reproduced in Bisognano 1998, p 23)
- a report for senior levels in health systems detailing the experiences of six pilot organisations in the US Institute for Healthcare Improvement's 'pursuing perfection' programme (Institute for Healthcare Improvement 2002)

- the influential US Institute of Medicine (IOM) report (IOM 2000), which considers the 'leadership for managing change' in 'the transformation' of healthcare called for by the report
- a detailed and recent discussion of a 'CEO agenda' for organisational transformation, provided by a former CEO of two US health systems, drawing on his experience of 13 healthcare organisations in the USA, UK, Sweden and the Netherlands as part of the Institute for Healthcare Improvement's 'pursuing perfection' programme (Reinertsen 2004).

Other leadership guidance is also included by Gaucher and Coffey (1990), Gaucher and Kratochwill (1993), Morath (1999), Bisognano and Schellekens (2000), Conway (2001), Reinertsen (2004), and the Institute for Healthcare Improvement (2002).

5.1.2 Summary of guidance literature for leaders of improvement

Some proposals for senior managers that are common in this guidance literature are:

- **Strategically important improvements:** choosing such improvements and a vision for improvement, in order to motivate and give direction
- **A strategy for improvement:** setting up a strategy that involves specific plans and resources to be allocated
- **Structural changes:**
  - Top-level and lower-level quality and safety groups
  - Redefining managers' responsibilities to include quality and safety
  - Appointing professionals to lead other professionals in clinical improvement
  - Appointing quality and safety experts
  - Forming QI teams
- **Management process changes:** ensuring such changes happen and that they include quality and safety reports in regular reports and review processes
- **Systems changes:**
  - Changing reporting systems to include quality and safety indicators with financial and production data
  - Changing IT systems to allow low time-cost collection of quality data for projects and routine information
  - Improving communications systems, including quality and safety items in all training
  - Changing appraisal, recognition and reward systems to align with the strategy
- **Commitment, symbolic leadership and management style:** ensuring senior leaders visibly spend time on quality work and show their concern through:
  - Asking questions and acting on quality and safety issues
  - Modelling improvement behaviours
  - Encouraging innovation
  - Avoiding blame-seeking but acting swiftly over unacceptable behaviour
  - Ensuring the management team is perceived as unified on the subject and continuity of commitment
- **Strategies for human resources, empowerment and team development:**
  - Providing development to lower-level managers to enable them to empower staff, understand the methods and manage improvement
  - Providing training and support for all staff, and management and clinical team development, to enable differences to be expressed and worked through.

5.2 General improvement literature providing useful guidance for leaders

Appendix 2 summarises general improvement literature that offers useful guidance for specific leadership actions for improvement. The literature includes discussions of:

- **Tailoring action to an organisation's quality maturity and transition phases:** research suggests leadership actions need to be tailored to the stage that their organisation has reached in 'quality maturity', which is a combination of experience and willingness to use quality methods and change capacity (Øvretveit 1995).
- **Understanding the business case and the economics of quality and safety:** the costs and possible savings of quality and safety programmes are one factor that informs leadership decisions about which interventions to pursue. Lower-level leaders can influence higher management to support improvement by making estimates and presenting these to higher levels (an example of how leaders at lower levels can be a necessary source of information for senior and board decisions). The following literature considers the 'business case for quality': (Reiter et al 2006 (the most practical); Leatherman et al 2003 (with cases); Gross et al 2007 (teaching hospital); and Gosfield and Reinertsen 2003). Øvretveit 2004 reviews research and literature on the economics of quality literature, while other literature provides useful guidance on costing studies (Reiter et al 2006) and on how to present the case to senior management (Collins 2007).
- **Safety culture:** Cohen et al (2004) propose that an environment for Q&SI can be created by focusing on purpose, structure, rewards, helpful mechanisms, relationships and leadership, and that the role of leadership is to keep all of these in balance. Whether leaders can change culture or not, the literature agrees on the need for leaders to understand organisational culture. To do so, a number of culture assessment tools have been developed, and two reviews describe tools for managers (Scott et al 2003c, Nieva and Sorra 2003). Both reviews note that some tools are unspecific so, by implication, they may not be very useful.
- **Conditions that leaders need to influence:** other conditions that leaders can influence that are important to improvement include the following:
  - conditions for implementing clinical guidelines (Solberg 2000)
  - conditions for sustaining improvement work in nursing (Wallin et al 2002)
  - conditions that affected QI (Lindberg et al 2003)
  - three preconditions for effective CQI in clinical practice (Shortell et al 1998).

  Some reports include details about regional quality councils that provide information about quality of care, but some also have a central role in supporting quality improvement activities (for example, Chan et al 2006 in Saskatchewan).

Other literature that provides guidance to improvement leaders includes:

- literature about resistance and barriers to improvement change
- 'organisational receptivity' and the 'receptive context' for change: Greenhalgh et al 2004, Pettigrew et al 1992, Bate et al 2002, Newton et al 2003, Dopson et al 2002
- 'change readiness': Lewin 1947, Prochaska et al 1992, Cunningham et al 2002
- 'absorptive capacity': Cohen and Levinthal 1990
- concepts from general change management: Iles and Southerland 2001
- a summary provided by one synthesis of seven studies on implementing clinical evidence, which provides useful ideas for managerial action: Dopson et al 2002.

5.2.1 Summary: conditions for improvement change

The relevance of the above research to the review questions is that it provides senior and other managers with ideas about which factors to strengthen and what to look for to assess the chances of success in Q&SI change.

A number of related concepts are relevant, the broadest reported being context, defined as:

> a layered set of influences, which commence at the outer layer with influences from government health policy and move inward to local influences, and finally influences that are specific to a single organisation and individual practitioner. (Dopson et al 2002)

However, the author of this review considers that existing research does not give enough attention to the extra time, resources and skills needed by many staff for successful change. Also, a receptive climate, context or culture alone may not ensure that a change or innovation is adopted: the change may also need to fit with the needs and values of staff (Klein and Sorra 1996).

Thus, in theory, Q&SI change requires low resistance, high readiness (expectations and perceptions), the objective existence of the resources, an objective need for change as well as a subjective desire for change including 'a sense of urgency and pain'. In addition a suitable 'fit' of the change with the organisation may be needed. Therefore, all of the above elements may be needed to ensure effective improvement. However, research does not give specific guidance because the success factors may be different for different types of change and in different types of organisation (Øvretveit 2004b): available evidence is specific to certain changes and is not strong.

The evidence does suggest that management can contribute to a receptive context for change, by providing a vision, communicating the consequences of not changing, and giving training and time to staff. The concept of 'conditions for improvement' draws on these ideas specifically for Q&SI and can be defined as:

> the circumstances 'surrounding' the quality intervention, which are separate and distinct from it, but which help and hinder how the intervention is implemented and its effectiveness, as perceived by staff. (Øvretveit 2004b)

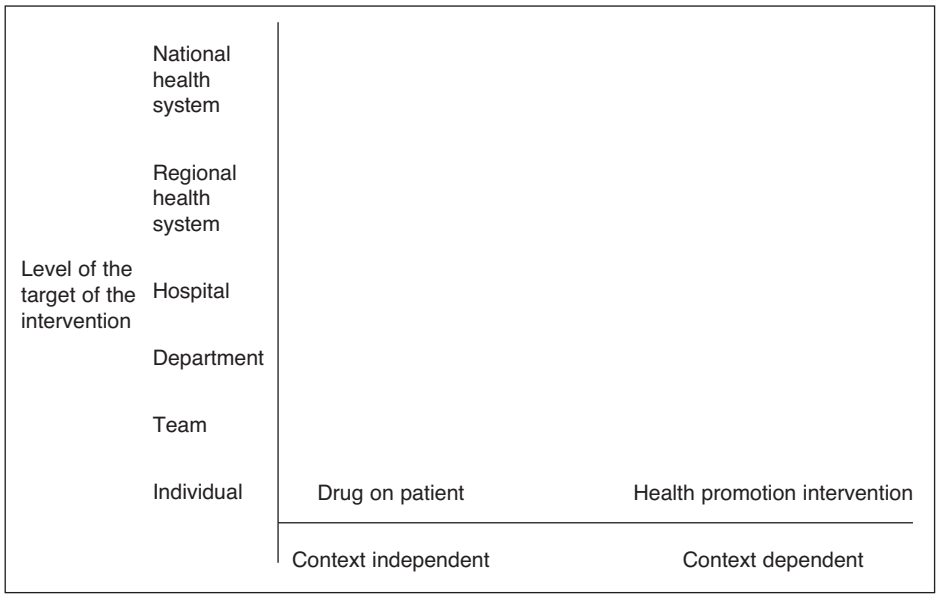


Figure 4: Likely effect of context on implementation and on the effects of the intervention

A recent research study provides evidence of the relationship between leadership roles, situational factors and progress with clinical improvement (although it does not examine specific leadership actions). Fitzgerald (2006) carried out a comparative case study of 11 cases of clinical service change in NHS cancer, maternity and primary health diabetes care. The study found that groups of characteristics in the organisational context were important to the change capacity of the organisation. These were related to progress in improvements. The study found that the following elements, if combined, could lead to progress:

- the executive team focuses on that particular service, for whatever reason
- the absence of other pressing agendas to divert senior management attention in other directions
- dispersed leadership for change; organisations with the capacity for change leadership at senior, executive and clinical service management levels
- a positive history of previous changes that have generated trust and have encouraged a culture for co-operation and proactive improvement over the long term
- the presence of strong external pressures and relevant leverage
- a sound foundation of interprofessional relationships
- key service improvement roles are populated, and are rapidly filled when they become vacant.

The secondary factors were continuity of leadership, and resources.

The study found that configurations of characteristics affected progress in service improvements. The research specified that 'conjunctures of combinations' led to positive or negative progress, and that the actions and relationships of different leaders were critical. These findings and relevance for leadership are best portrayed by presenting the study's summary of how factors affected progress in one case: a prostate cancer service where the intended improvement made no progress, where the context was summarised as 'resistance':

> Firstly, senior management's attention is focused elsewhere. They have a major development in train, and this requires much management effort and they are therefore 'distracted' from paying direct attention to cancer care despite government targets for cancer. Secondly, and significantly, due to an earlier merger of two hospitals, many of the established consultants in urological cancers resigned and new clinicians were appointed. This has had two effects. The conflicts, which existed historically, including between clinicians have been reabsorbed and continue, despite changed staff. And the new clinicians are resisting the extension of their roles and are unwilling to adopt improvement roles.
>
> The overall consequences of this context are that no one at the senior management level wishes to prioritise the poor relationships between the consultants even though there was evidence within the period of study that this caused a breakdown in improvement projects. So no attempt is made to embark on a process of reconciliation or seek the means to break out of this negative frame. (It is notable that despite the fact that this is a major trust hospital, there was no evidence at all that the (human resources) HR function was actively supporting clinical management development).
>
> So what are the effects of this context? Within the area of cancer care, there is very limited evidence of any improvements in care for urological cancers. So progress towards improvements in this site has been labelled 'inactive'. It is clear that one key reason for this is that there is no clinical opinion leader or champion who is prepared and able to lead change within this site. So the only progress which has been achieved has been the result of activity and leadership from the urological consultant at a neighbouring, collaborative trust. The clinical staff at our site have been virtually 'hangers on'. From the management's perspective, it is evident that many managers (not clinically trained) do not feel competent to intervene (or interfere?) in disagreements between medical colleagues. Perhaps also, many managers may suspect that, if they were to become involved in repairing such relationship tangles, their interventions may be ineffective, and could perhaps make matters worse, particularly if they were perceived to be 'taking sides' in any respect. Clearly, the role of the medical director is highlighted within such a situation, as is the professionalism of the HR function, already mentioned. (Fitzgerald 2006)

Bevan et al (2008) carried out a more recent review of experience and research into improvement, which emphasises change capacity and its relation to the leader's role. The study concludes that the 'biggest challenge for leaders lies in building greater capacity and capability for change within NHS organisations and the public'. From experience with 'high performing organisations' the authors note that bringing 'outside in' change capability can add momentum, new perspectives and skills. However, it is 'inside out' change – the capability of the system to change itself – that will lead to sustainable improvements. This review proposes investing in leadership-level skills for large-scale change. Specifically:

> Leaders need to know how to mobilise individuals, teams and communities to the cause of change; how to strategically align goals, measures and implementation initiatives; how to work explicitly with models and theories of large-scale change; and how to balance short-term operational results with longer term transformation. (Bevan et al 2008)

They also suggest leadership by patients and the public:

> Devoting resources to build even more capacity in members of the public to play constructive roles in driving improvement work might be the most rewarding investment the service will ever make.

Chapter 6

Q5: What are the strengths and limitations of research and evidence for helping leaders of improvement?

Sections 6.1 and 6.2 summarise the answer to this question, while Section 6.3 considers limitations of the review, and Section 6.4 discusses the type of research found in the search and its usefulness for guiding leaders.

6.1 Strengths and limitations of the research

The search found few good-quality empirical studies of leadership and quality improvement (QI) in healthcare, but the amount of literature on the subject had increased considerably. It is possible that the demand for guidance has increased, but at a greater rate than the interest of the subject to researchers, although scientific interest and finance for this research has increased marginally.

The strengths and limitations of the available research for answering the review questions can be summarised as:

Strengths

- Increasing evidence of an association between leadership and process improvement.
- An initial recognition of which different actions different leaders need to take in different situations.
- A developing conceptual clarification of possible ‘casual chains’ between leadership actions and improvements to patients that can guide future research.
- Increasing evidence of board and chief executive officer (CEO) actions needed for improvement in US healthcare.

Limitations

- Little empirical research, especially outside of the USA.
- A small amount of research, and of variable quality, specifically on leading improvement.
- No strong evidence of how much influence leadership has over improvement, compared to other factors.
- Few detailed descriptions of specific actions by successful and unsuccessful improvement leaders.
- Uncertainty about how leadership actions influence improvement activities and processes in the organisation, and if this influences patient outcomes and costs.
- Little known about the extent of generalisability of successful actions.
- Little research into how leaders adapt findings from elsewhere to their situation and no research-based guidance for them about how to do this.
- Little multi-method and multidisciplinary research.
- Few examples of innovation in research design and methods for answering leaders' questions.

6.2 Strengths and limitations of the experiential evidence

Strengths

The amount and strength of the experiential evidence literature has increased:

- Summaries are available for leaders based on specific improvement.
- This literature is paying more attention to referencing or summarising its evidence base with case examples, and sometimes cites more rigorous research.
- It is easily accessible, well presented and easy to understand.

Limitations

- There is a lack of precision in defining concepts.
- Abstract findings are over-generalised.
- Where specific conclusions or guidance is given, there is a failure to reference to which services and situations these apply and to self-critically assess the applicability to other settings.

6.3 Limitations of the review

The review was systematic, but did not follow systematic review procedures used in biomedical reviews (Mulrow and Oxman 1997). Although reasonably comprehensive, the review could have missed some empirical studies relevant to the questions, partly because of the wide range of literature that could not be fully searched and reviewed in the time available.

Space and time did not permit a full description here of the research methods of each study, which would have allowed the reader to judge independently the validity and reliability of the study and the strength of evidence.

Combining findings from different studies can allow more reliable and valid answers than would be possible from presenting the findings of just one study. However, combining findings from different countries, or from studies using different methods, can sometimes lead to

misleading conclusions. The specific guidance for leaders given in this research review does not indicate which guidance is based on research evidence and which is based on reported experiential evidence, or the relative mix of each type of evidence.

This research review does offer general guidance for leaders that draws on findings that appear to be common in different healthcare systems for different leaders. However, the more detailed the guidance, the more likely it is to apply to only one type of leader role, in one type of organisation, for one type of approach to improvement. There is therefore a tension between the need for specific guidance, and the likelihood that this will be different for different leaders in different situations. This issue is discussed further in the review.

6.4 The type of research and its usefulness for leader guidance

The main issues that were raised throughout the research concern causality: which leadership actions cause or strongly influence which effects?, and generalisation: in which situations do these actions cause these effects? These issues are considered in more detail below.

The research found in the search for this review can be categorised as follows, including an estimate of the proportion of the studies falling into this category:

- empirical studies focusing on the relationship between leadership and QI: focused empirical study (5 per cent)
- empirical studies that discovered a relationship between leadership and QI, but did not have this as the focus of the study (10 per cent). Few of these describe which aspects of leadership influenced QI, and most refer to the general presence or absence of leadership or management ‘support’, without giving details.
- empirical studies of QI, which comment on leadership but do not present systematic evidence of a relationship (60 per cent)
- experiential evidence reports that describe a relationship between leadership and QI, such as a leader or project manager describing a ‘quality journey’ (10 per cent)
- conceptual or theoretical papers that include leadership and QI (15 per cent).

There were many studies published after 2004 where the objective was not to assess leadership impact on QI, but which still identified leadership as an important factor. The resources available for this review precluded a systematic search and review of these studies, but some were noted.

The search found that leadership was conceptualised in different ways: leader characteristics, leader style, leadership actions or behaviours, leader–follower relationships, groups as performing leadership and institutions exercising leadership.

Some studies investigated barriers to QI, many of which were caused by, and solvable by, leadership actions at higher levels.

6.4.1 Research required in specific fields

One of the findings of this review is that leadership and QI refer to many different phenomena. An analysis of the research suggests these phenomena can be classified as follows, in order to separate and organise the different findings, and to further investigate what is specific to certain situations:

- **Leadership role:** the level, whether the leader is a formal appointment or an informal influencer, profession led.

- **Type and objective of QI activity:**
  - the level of the activity: for example, whether in a local project team, organisational programme or health system programme
  - whether the programme or strategy is regional, national or international
  - the level of the organisation or group targeted by the activity
  - the complexity of the change attempted.
- **Setting and situation:** within which the leadership activity is performed, and the target audience of the leader's behaviour (for example, whether in primary healthcare or hospital, and specialty).

6.4.2 Attribution methods

A further finding is that different methods were used in studies to assess the influence of leadership on quality activities. One method used was to study leadership variables and quality activity (or other quality-related outcomes) and establish if the two were associated, and if there was a possible causal influence, using statistical methods, or by using observer/participant attribution, or by combining data sources. Research where the primary objective was to study leadership influence on quality used this method, which can be called 'forward attribution discovery'.

A second method – 'backward attribution discovery' – refers to when QI (results or activities) is discovered and research is carried out to explain how the improvement was achieved and whether leadership was a factor.

6.4.3 Generalisation

Even with precisely defined interventions, the implementation and effects of leadership improvement activity vary according to features of the audience (person or group) and the situation. The evidence suggests that the only generalisation that can be made about leadership actions that are, or are not, effective for improvement is that it depends on the type of improvement and situation. A productive approach is likely to be to aim for qualified generalisations, stating which results are likely to be expected in which types of situation, and where these results might be less likely.

6.4.4 Other comments on the research

The subject is theory rich but data poor, especially concerning leading improvement in public healthcare services. There is little theory testing or even theory linking: that is, the research shows little use of theories to shape which data to gather in order to describe what leaders do, and to assess whether – and how – it influences improvement.

Knowledge has tended not to be cumulative, in part because of weak linking of studies to previous research. This may also be because knowledge accumulation may not be possible in this field in that actions that are successful for leadership improvement may change, even in the same organisation.

Research from the USA on the subject tends to be more positivist, reflecting the predominantly medical research context in which much of the research is carried out. The empirical research that has been carried out in the UK and Europe tends to emphasise inductive theory building from qualitative research, with a focus on subjective perceptions of leaders.

Research on this subject in healthcare has been slow to consider perspectives that have proven fruitful in this field of inquiry in other sectors. Approaches likely to be worth pursuing include:

- how leaders build trust and how this is related to improvement – 'relational trust' (Connell and Mannion 2006, Bryk and Schneider 2004)
- sense-making (Weick 1995, Parry 2003, Battles et al 2006) and the use of stories to lead improvement (Conway 2006).

The limitations noted offer a considerable opportunity for research to be carried out that provides material that is more useful to leaders at different levels. There is an opportunity for innovative research to:

- find answers to the challenges in defining success
- find ways of tracing causal links or influences between a leader's actions and improvement outcomes, through intermediate changes that the leader may have produced
- establish what is specific and what can be generalised.

Chapter 7
Q6: Which improvement leadership research is most needed?

The answers to this question, drawn from analysing the limitations presented in Section 6, are:

- **Empirical studies:** studies to discover evidence about which specific leader behaviours are associated with successful and unsuccessful improvement and how much this differs between situations, roles and types of improvement. There is a need to go beyond noting that an improvement had, or did not have, management support. There is also a need for empirically based details about commitment, involvement and engagement, and for research that discovers the many different roles and activities that managers undertake for quality improvement (QI), and that are successful in which situations and for which types of improvement.
- **Leadership actions:** studies of which leadership actions are associated with intermediate improvements (for example, in changes in organisation and staff activities), outside of the USA, in non-hospital services, and for operational leaders.
- **Situation-specific or generalised:** studies to understand what is situation-specific and what may be generalised: testing whether effective actions that a leader takes in one place are also effective elsewhere (for example, with sequential- or parallel-strategic sampling).
- **A range of managers:** studies specifically describing actions that have and have not been unsuccessful in leading improvement by operational managers (middle managers and team leaders), nurse and therapy managers, and purchaser managers.
- **What helps and what hinders:** studies of what helps and hinders leaders to act to generate improvements, and of how they manage competing priorities when they are successful.
- **Collaborative working:** studies that will help leaders to work with others to prioritise specific improvements, to identify which changes are appropriate, and to adapt what is effective elsewhere to their situation.
- **Innovative approaches:** studies using innovative perspectives and methods, and promising concepts, such as the leader–follower relationship, ordinary leadership, and

trust. Studies could also focus on the use of stories: how much do improvement stories motivate? Are they effective for learning what needs to be done, for both leaders and others? If leaders use stories in their organisations, does this make improvement more effective?

PART 3:

CONCLUSIONS

Chapter 8
Conclusions

This review discovered that there was research evidence to support the growing recognition that leadership is associated with, and influences, successful improvement, and is also one factor that contributes to slow, partial or failed improvement. However, the evidence for this is not strong, especially concerning the degree of influence compared with other situational factors; therefore, there are questions about the extent to which findings can be generalised beyond the leaders and situation studied.

Researchers define and study many different phenomena when they consider the terms ‘leadership’ or ‘leading’ in relation to improvement. ‘Improvement’ is also defined differently: for example, as a result for a patient, or as an activity by providers, or as a process or programme that an organisation undertakes. Research exists that indicates the influence of leadership on many different types of improvement.

8.1 Key variables for effective leadership

The overall picture from the research suggests that effective leadership actions to stimulate and progress quality improvement (QI) depend on:

- the leader’s role (the level, whether formal or informal, profession led)
- the type of improvement, the objective, and the method used
- situational factors (resources available, organisational priorities, culture, and external pressures and requirements)
- the stage of QI (starting, securing results, spreading, sustaining).

No generalisations can be made from the research evidence about which behaviours are effective for leaders in all roles and in all situations for stimulating all types of quality activities.

Studies in healthcare have revealed that senior leadership of improvement is often missing, but also that, when present, it is not sufficient. Leadership of many types at different levels appears to be needed at all stages to initiate and maintain improvement: by national leaders to create the climate of rewards and attitudes for senior and accountable line managers in organisations; by purchaser and regulator leaders; by formally appointed clinical leaders; by local informal opinion leaders and also by ordinary leaders, such as clerks and cleaners.

The research suggests that the leadership that is required:

- envisions the future and inspires
- builds alliances for change
- spends time on improvement
- demonstrates commitment in different behaviours
- works persistently with others on a daily basis to raise the possibility of ‘a better way’
- creates systems
- changes procedures
- confronts poor performance.

8.2 A leadership system for improvement

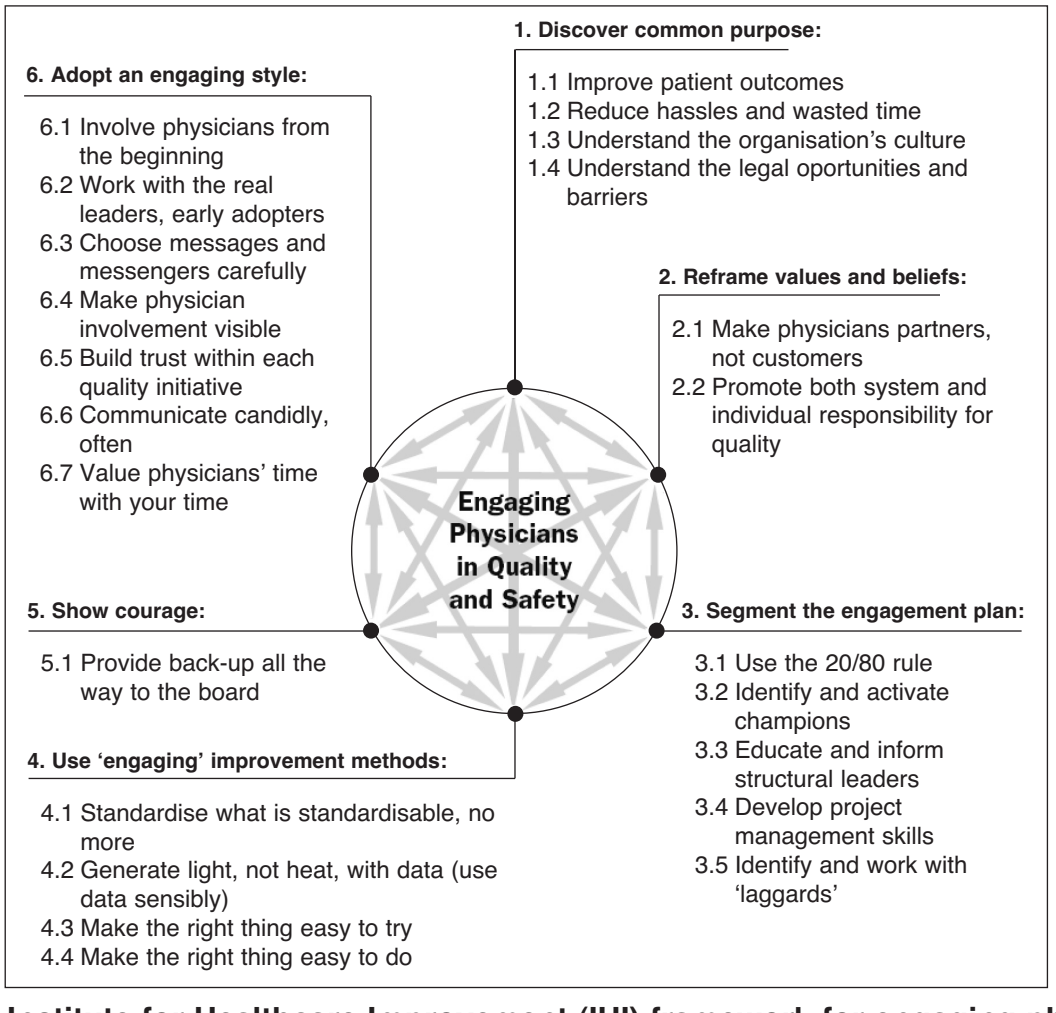
This research review did not find strong evidence showing which specific actions that different leaders need to take. This shows that tested hypotheses are needed about which leadership actions are required against the evidence of results. The available research does suggest that an organisation needs to create a leadership system for improvement. This means multi-level leadership where leaders at each level create conditions that support improvement for those in the level below. A multi-type of leadership is also needed, where formal and informal leaders – and ordinary staff – lead different actions at different times. The evidence suggests that improvement may depend on the consistency and persistence with which leaders throughout the organisation communicate their vision of improvement and act on a daily basis to carry it out.

PART 4:

APPENDICES AND REFERENCES

Appendices

Appendix 1: Institute for Healthcare Improvement framework for engaging physicians in improvement



Institute for Healthcare Improvement (IHI) framework for engaging physicians in quality and safety. Source: Reinertsen JL et al 2007.

Appendix 2: Concepts, frameworks and models for guiding leaders of improvement

The review found that the most specific and useful guidance for leaders was provided in experience-based reports rather than research. The following notes some models and literature that provide useful guidance to improvement leaders.

There are three types of guidance presented below: general literature specifically for improvement leaders; general improvement literature that includes useful guidance for leaders; and case studies that describe leadership actions in specific programmes.

2.1 General literature specifically for improvement leaders

Some of this literature has already been summarised in Section 4.1 and includes guidance from the NHS in the UK (Crump 2008), and from safety improvement experience in the USA (Botwinick et al 2006, Reinertsen et al 2008).

Nolan et al (2005) present a 'framework for spread' based on experience in spreading access improvements to 1,800 US Veterans Health Administration (VHA) outpatient clinics, and this study provides some details about leaders' responsibilities.

Some earlier literature gives guidance for leaders for improvement, with different levels of detail and extent of experience on which it is based (Gaucher and Coffey 1990, Gaucher and Kratochwill 1993, Morath 1999, Bisognano and Schellekens 2000, Conway 2001, Reinertsen 2004, Institute for Healthcare Improvement 2002).

A discussion about leadership in general in healthcare lists 11 learning points for leading improvement (Berwick 1996). Little supporting evidence is provided, but the guidance draws on experience with a number of improvement programmes. It is rewritten here as a set of actions that leaders need to take:

- Concentrate on changing the system for a higher level of performance, not on stressing the existing system to do more.
- Challenge the status quo, by insisting the current system cannot remain and by offering clear ideas about superior alternatives.
- Use a simple framework for systematic actions to test small changes, and ensure all staff know about it and use it.
- Set up and support project teams to use this framework and hold them accountable.
- Ensure the use of quality measures for improvement, and provide systems to support data collection and analysis.
- Enable staff to find and test ideas that have been used elsewhere to achieve improvement, and ensure they do this.
- Provide staff with the time and authority to learn about and carry out systematic improvement work.

One discussion of strategy for improvement (Bisognano 1998) describes two critical tasks for senior leaders: setting an 'aggressive rate of improvement as the organisation can tolerate' ('stretch goals'), and setting specific aims: 'the leadership team needs to determine five or six important areas that must be radically improved over the next 12 months'. The discussion also proposes:

- developing a learning plan for the senior team, a system for customer feedback and targets for waste reduction
- using a checklist to assess the team's change-management ability (for example, Gustafson's checklist, reproduced in Bisognano 1998, p 23) and designing strategies for communicating the vision and replicating innovations to achieve this

- building partnerships with staff, by leaders spending time on improvement, working with managers on process actions and results, and reviewing data with clinicians
- focusing on education and development: ensuring that improvement is part of all training, as well as specific programmes; involving all managers in cascade training; using adult learning methods
- encouraging performance feedback and recognition
- developing a healthy workplace
- tracking progress and developing
- using improvement measurement systems.

The influential US Institute of Medicine (IOM) report (IOM 2000) also considers the 'leadership for managing change' in 'the transformation' of healthcare that the report calls for. It describes the leader's role as defining and communicating the purpose of the organisation clearly and making the 'work of practice teams as being of the highest strategic importance'.

The report proposes that leaders must:

- create and communicate the organisation's vision and goal
- listen to the needs and aspirations of those working on the front lines
- provide direction
- create incentives for change
- align and integrate improvement efforts
- create a supportive environment and culture of continuous improvement that encourages and enables success.

It refers to the need for leadership at many levels to consistently give clear direction, values and incentives in order to guide group and individual action.

The report proposes that leaders must fill five roles:

- identifying and prioritising community health needs and supporting the organisation's ability to meet these needs
- helping obtain resources and respond to changes in the environment
- optimising the performance of teams, not just supporting some, and making use of measures to do so
- ensuring reward and recognition systems support Quality and Safety Initiatives (Q&SI)
- investing in their workforce.

The report describes the need to recognise the interdependence of change at all levels: for example, providing error correction training to individuals without recognising that they work in a team will have little effect.

Guidance for senior levels in health systems is provided by a report focusing on the six pilot organisations in the US Institute for Healthcare Improvement's 'pursuing perfection' programme (Institute for Healthcare Improvement 2002). The programme sets ambitious visionary goals in response to the US IOM reports (Kohn 1999, IOM 2000): 'not just incremental improvement but theoretical ideal performance'.

One of the aims is for each organisation to use their experience from their pilot projects to 'transform the entire organisation towards a pursuit of perfection'. Five issues were identified for senior leaders:

1. Establish a system to review the pilot teams progress, connect the lessons to the management team and the wider organisation, as well as encourage teams and take action if the team is floundering.

2. Support innovation: for example, backing teams that want to test radical but promising changes.
3. Build the capability to generate improvements across the continuum of care, including communications systems and relationships between services:
   Senior managers must work with middle managers to assure past policies can be suspended to test some innovations in care. (Institute for Healthcare Improvement 2002)
4. Build the business case for changing care, taking a long-term and systems view.
5. Provide resources, support and guidance to enable the specific changes and the infrastructure required.

Other suggestions for leaders relating to spreading improvement and the chronic care improvement programme are provided on the Institute for Healthcare Improvement's website at www.ihi.org

Leadership for transforming organisations

One of the most detailed and recent discussions of a 'CEO agenda' for organisational transformation is provided by a former chief executive officer (CEO) of two US health systems, drawing on his experience of 13 healthcare organisations in the USA, UK, Sweden and the Netherlands as part of the Institute for Healthcare Improvement's 'pursuing perfection' programme (Reinertsen 2004). This paper discusses the leader's role for a set of revolutionary changes to health systems to achieve the programmes goals. It is questionable how feasible these proposals are for senior leaders of ordinary hospitals or health centres, but they do provide more detail and fuller integration of safety concepts than other discussions of this type.

Following Berwick's suggestion (1996), Reinertsen reports senior leaders' views of what a transformed organisation would be like, with 'no needless deaths, pain, waits, helplessness and waste'. One element reported is 'a place where the CEO is the "master teacher" of quality, which is an operational management responsibility throughout the organisation, rather than delegated to a few quality professionals'. Reinertsen's discussion considers the question: What theory do we have about what an organisation would need to do to produce this future?

Six types of change are considered as challenges for leadership:

1. Reframing core cultural values.
2. Creating improvement capability.
3. Collaborating across competitive boundaries.
4. Creating a business environment that simultaneously drives business results and community benefit.
5. Driving system level, rather than project level, results.
6. Maintaining constancy of purpose.

Regarding the first challenge, the paper proposes that changing health professionals' values about autonomy, and their view of quality as only an individual responsibility, is a 'transformational' task. Changing values, not just processes, depends on 'a combination of traits and behaviours that generate authenticity in leaders', and this means considering what leaders 'at all levels must be' not just what they should do. The discussion suggests that leaders should be selected for the values they possess that are important for the 'authenticity necessary to influence their colleagues to change deeply held values', and describes how to reframe core values.

A model to guide the content of the work of the 'things leaders must make happen' is presented that combines the Institute for Healthcare Improvement's model of leadership with

the three themes of the IOM report (IOM 2000) and is reproduced as Appendix 4. The elements of this model are discussed in Reinertsen's paper (2004) as a 'theory of leadership for transformation':

1. **Set Direction:** State the aim, the 'commander's intent'
2. **Build the Foundation:** Transform yourself (the CEO); Transform, and remake, if necessary, the senior executive team; Build organisational improvement capability
3. **Build Will:** Obtain Board adoption of system-level aims for performance; Publicly declare your aims to improve system-level measures; Define the business case, and make the financial linkages between projects and financial performance; Make a logical, quantitative connection between quality work and key strategic goals
4. **Generate Ideas:** Know the best performance in the world; Actively seek new ideas; Develop the ability to try new ideas quickly
5. **Execute Change:** Use a well-grounded improvement method, such as the 'Model for Improvement' to lead project-level change; Use a solid change leadership model to spread and scale useful improvements; Focus on results; Make improvement results a line management responsibility; Make sure everyone in the organisation knows her part in achieving the strategic aims; Channel leadership attention to improvement projects
6. **Use the Science we Know:** Take intentional action to achieve local change in MD culture: practice the science of medicine as a team, practice the art of medicine as individuals; Ensure that administrators and physicians know improvement science; Develop and use evidence-based 'operating systems'
7. **Centre Care on the Patient:** Put patients in the lead on care design committees; Develop and use care plans that incorporate the patients' goals; Place patients on your senior executive team, and on all major policy committees
8. **Co-operate as a System:** Promote a culture of teamwork among physicians and nurses; Put patients on your 'cross-institutional' working groups; Build containment vessels across the community; Give permission to staff to work cooperatively outside the boundaries of your system. (Reinertsen 2004)

Another discussion paper by the same author emphasises the importance of well-chosen, strategically significant projects, and proposes that senior leaders give them their personal attention (Reinertsen et al 2004). It proposes that 'projects are key leverage points – high visibility moments – in the long-term transformation process' and that the successful ones 'send a message throughout the organisation' that Q&SI is not a side activity. For these reasons, the paper proposes a review method for CEOs and senior leaders to support and progress key projects.

2.1.1 Summary of guidance literature for leaders of improvement

Some proposals for senior managers that are common in the guidance literature reviewed are:

- **Strategically important improvements:** choosing such improvements and a vision for improvement, in order to motivate and give direction
- **A strategy for improvement:** setting up a strategy that involves specific plans and resources to be allocated
- **Structural changes:**
  - Top-level and lower-level quality and safety groups
  - Redefining managers' responsibilities to include quality and safety
  - Appointing professionals to lead other professionals in clinical improvement
  - Appointing quality and safety experts
  - Forming quality improvement (QI) teams
- **Management process changes:** ensuring such changes happen and that they include quality and safety reports in regular reports and review processes

- **Systems changes:**
  - Changing reporting systems to include quality and safety indicators with financial and production data
  - Changing information technology (IT) systems to allow low time-cost collection of quality data for projects and routine information
  - Improving communications systems, including quality and safety items in all training
  - Changing appraisal, recognition and reward systems to align with the strategy
- **Commitment, symbolic leadership and management style:** ensuring senior leaders visibly spend time on quality work and show their concern through:
  - Asking questions and acting on quality and safety issues
  - Modelling improvement behaviours
  - Encouraging innovation
  - Avoiding blame-seeking but acting swiftly over unacceptable behaviour
  - Ensuring the management team is perceived as unified on the subject and continuity of commitment
- **Strategies for human resources, empowerment and team development:**
  - Providing development to lower-level managers to enable them to empower staff, understand the methods and manage improvement
  - Providing training and support for all staff, and management and clinical team development, to enable differences to be expressed and worked through.

2.2 General improvement literature giving useful guidance for leaders

2.2.1 Stages of organisational quality maturity and transition phases

Research suggests that leaders will need to adapt the leadership actions that worked in other organisations to their particular situation, but does research exist that helps them to make such translations? One factor may be tailoring leadership actions to the stage that an organisation has reached in terms of its quality maturity, which is a combination of experience and the willingness to use quality methods and change capacity. Øvretveit (1995) observed that quality programmes moved through different phases and that leaders' actions needed to alter for different phases, although the research did not discover in which specific ways they needed to change and which actions needed to continue. His study found that programmes faced turning points or transitions where top management must face and make key decisions about the future of the programme, typically at two-yearly intervals. Sometimes the decisions are not faced or are avoided, but the transition still happens. In some organisations, quality ideas may be introduced and tested in specific areas, and then decline.

Phase 1: Formulation A core group write a proposal for a programme of training, projects, quality roles and structures, and present this proposal to the management team for a decision about how to proceed.

Transition 1 Top management make a decision about which type of quality programme to introduce, the timetable, plan and responsibilities, and how many resources to allocate. Without this transition or turning point, quality activities remain local or profession specific.

Phase 2: Education Training programme is started – there are many different approaches, notably whether to have a comprehensive or limited training and whether to have special training for different professions or multidisciplinary or specialty service specific training.

Phase 3: Projects Quality projects are begun, which aim to make changes to improve quality.

Transition 2 Two years after starting, top management review progress and decide how best to spread the ideas and the methods which have been found to be successful.

Phase 4: Decline or spreading Action is taken to spread the ideas and lessons about which methods and team projects have been successful to other areas. More attention is given to departments and services that have done little to prove or improve quality and where there may be uncertainties about the quality of service and the risks. If the decisions made in the second transition were poor, or not made, then the quality programme will decline and the ideas will not be taken-up across the organisation.

Phase 5: Routinisation or acceleration If the programme continues through the last phase it will move by year 4 into one of two phases. In 'routinisation' the methods and ideas are subsumed within existing practices and management styles. In 'acceleration' the ideas are taken-up and renewed and spread to all parts of the organisation. A critical mass of quality enthusiasts work to update the ideas and the programme gains momentum and a life of its own.

Transition 3 About four years after starting the programme will either move into a phase of transformation, or will settle down and become fully incorporated. Again, the choices faced and decisions made by the management team and key leaders are critical to moving through this transition.

Phase 6: Accommodation or transformation By year five or six the programme will have either declined, been routinised, or will be beginning to transform the organisation. 'Accommodation' is where the ideas are incorporated into existing structures, roles and culture, and change in a controlled way how the organisation works. Transformation is a phase where most managers and professionals are now using management styles and professional practices that are quite different from those before the programme started.

2.2.2 The business case and the economics of quality and safety

The costs and possible savings of quality and safety programmes are one factor that informs leaders' decisions about which interventions to pursue. Making estimates and presenting these to higher levels are one way that lower-level leaders can influence higher management to support improvement (an example of how leaders at lower levels can be a necessary source of information for senior and board decisions). Øvretveit (2004c) reviews research and literature on the economics of quality, and other literature provides useful guidance for costing studies (Reiter et al 2006) and how to present the case to senior management (Collins 2007). The 'business case for quality' is considered in Reiter et al 2006 (the most practical), Leatherman et al 2003 (with cases), Gross et al 2007 (teaching hospital) and Gosfield and Reinertsen 2003.

2.2.3 Safety culture

'Culture of safety' and 'safety culture' are terms that increasingly appear in healthcare quality literature since 1995, and are possibly now more frequent than 'quality culture'. One of the few empirical studies found was a self-report case description (Cohen et al 2004). This presents the experience of a US hospital in changing the culture of patient safety from one of blame to one in which 'everyone is held accountable for patient safety and management is responsive to raised concerns'. No evidence of results is presented. The study uses Weisbord's theory of 'where to look for trouble when diagnosing organisational problems' to propose that an environment for Q&SI can be created by focusing on purpose, structure, rewards, helpful mechanisms, relationships, and leadership, with the role of leadership being to keep all of these in balance.

The actions taken on each of these subjects, with the most relevant to the leader's role being:

- prioritising medical involvement
- education by all managers of the medical leaders
- identifying and recruiting medical opinion leaders to safety committees
- proving evidence by participation in the Institute for Safe Medication Practices (ISMP 2004) medication self-assessment survey
- taking part in the Institute for Healthcare Improvement patient safety collaborative
- getting early successes to demonstrate what could be achieved
- nurturing the chief executive officer–chief medical officer (CEO–CMO) relationship and using this as a model for similar administrative–medical relationships at lower levels
- adding measures of quality and safety to the central organisational objectives and relating these to executive incentive payments
- top management team-building.

The case report recommends that leaders take the following actions:

- Change culture from one in which individuals are punished for making mistakes to one that is non-punitive, just and supportive of those who have made mistakes.
- Continually address the 'five realities' of purpose, structure, rewards, helpful mechanisms, and relationships: 'This takes time, and positive outcomes can be expected only over a longer rather than shorter time frame'.
- Select leaders at all levels while considering their integration in, and ability to work in, management teams, and continuity.
- Appoint a doctor as chief quality officer, or have them report to the CMO, and make CMOs responsible for patient quality and safety, and ensure they are active and enthusiastic about this work.
- Develop partnerships between administrative and medical leaders at each level: 'mutual trust and respect, usually developed over an extended period of time, are crucial'.

The case report concludes that a set of planned interventions to improve safety culture:

> can, if led by senior hospital executives, lead to a substantial, profound, and lasting increase in error reporting and improvement in employee perceptions of the organization's safety culture. (Cohen et al 2004)

Understanding culture

Whether leaders can change culture or not, the literature agrees on the need for leaders to understand organisational culture. To do so, a number of culture assessment tools have been developed, and two reviews describe tools for managers (Scott et al 2003c, Nieva and Sorra 2003). Both reviews note that some tools are unspecific so, by implication, they may not be very useful. Deeper aspects of culture are not likely to be captured by a self-report survey tool. To counter this, one review suggests also using qualitative information from staff interviews and focus groups, or procedural safety checklists used in traditional safety audits (Scott et al 2003c).

One review focuses on safety culture assessment and shows the use of a number of tools: for diagnosis of safety culture and raising awareness; for evaluation of patient safety interventions and tracking change over time; and for internal and external benchmarking (Nieva and Sorra 2003). It proposes that assessment should be viewed as the starting point from which action planning begins and changes emerge, and that the usefulness of the data depends on involving key stakeholders, selecting a suitable safety culture assessment tool, using effective data-collection procedures, and having a plan for acting on the data.

2.2.4 Conditions that leaders need to influence

The importance of creating the right conditions for QI was felt to be central to implementing clinical guidelines, according to 12 clinic leaders experienced in this subject whose views were reported in one US study (Solberg et al 2000). The conclusions were:

> the very large number of variables that these experienced implementers believe can have an important effect on their ability to implement guidelines in their medical groups, and the large number of strategies needed. Similarly striking is the emphasis they give to various organizational and change management characteristics; only 2 of the top 22 variables relate even tangentially to individual clinicians or the guideline.

The leaders agreed that 'Organizational Capability for Planned Change' was the most important of the six categories of factors they identified, including specifically: strong support and interest at all levels of leadership, a well-developed infrastructure, capability, and a culture for continuous quality improvement (CQI) and change management. They conclude that:

> To learn about how to enact the various strategies studied for guideline implementation, it is necessary to read the literature from the fields of QI, organizational change, management, or the diffusion of innovations, rather than the literature about guideline implementation. (Solberg 2000 et al)

Wallin et al (2002) report on Swedish research that is useful for leaders who are planning how to sustain nurses' work on QI (eB). A postal questionnaire to 240 nurses, 4 years after 4-day QI training courses, gave self-report data indicating that 39 per cent of all nurses were still involved in QI work. Three factors were significantly related to nurses continuing their involvement in QI projects: remaining employed on the same unit, taking courses in nursing science, and maintenance of the same QI model.

Reported motives for remaining active in QI work were the enhancement of knowledge, influence over clinical practice, and development as a nurse. Reasons for discontinuation were organisational restructuring, a lack of facilitation and knowledge, and change of workplace. It was noted that participation in a national guideline project for some of the nurses 'seems to have enhanced the ability to carry out the process of QI, but not to sustain the QI work over a longer period'.

One study of six managers' understanding of their work found conditions that affected QI (Lindberg et al 2003). The managers' work included QI in an intensive care unit during a merger of two hospitals. The thematic analysis of the interviews found four themes, and reported two principle findings: 'a possible contradiction between developmental work and daily work' (constant interruptions, time pressures, lack of planning and order, insufficient support); and 'the management of how to lead "at the edge of chaos" '.

One discussion draws on conclusions from previous studies to propose three preconditions for effective CQI in clinical practice (Shortell et al 1998a):

1. Improvement subjects of real importance to the organisation are chosen, and clearly formulated interventions are used.
2. The organisation is change ready and has prepared by appointing able leadership, creating relationships of trust with clinicians, and establishing adequate IT.
3. Regulatory, payment and competitive external conditions are conducive to CQI.

2.2.5 Resistance and barriers to improvement change

One study organises its analysis of organisational barriers according to a five-part systems model of the organisation, categorising barriers as: technical, structural, psychosocial, managerial, goals and values (Ziegenfuss 1991). No evidence is presented but the categorisation and discussion provide a useful framework for managers to assess their current

situation with respect to conditions for QI. All of the barriers mentioned could be influenced by leaders' actions.

The five 'managerial barriers' are:

1. The lack of a 'planned approach' to the development of a QI system.
2. The lack of 'support resources' for such a system.
3. The lack of information and education for groups and individuals ('development needs').
4. The lack of medical staff leadership, senior management, and board support ('leadership support').
5. 'Medical control' over quality assessment.

2.2.6 'Organisational receptivity' and 'receptive context' for change

Research into the context for change shows that change is more likely if certain conditions are present. Such research suggests some factors that senior leaders at national and local levels can influence, and also allows leaders at other levels to decide which factors they can alter, and whether a change has a chance of success. This section gives an overview of this research and considers the implications for leaders' actions.

One review of the dissemination of innovations in healthcare proposes that 'receptivity to change' is the degree of resistance to change, observed through different levels of willingness to accept the change, from a resigned passive acceptance to enthusiastic endorsement (Greenhalgh et al 2004). The concept was originally proposed in a NHS study in the UK, which found that strategic changes were more successful in cases where eight factors were present and that the factors were interrelated (Pettigrew et al 1992). These were redefined in a later study of NHS collaboratives in the UK (Bate et al 2002) as:

- the role of intense environmental pressure in triggering periods of radical change
- the availability of visionary key people in critical posts leading change
- good managerial and clinical relations
- a supportive organisational culture (which is closely related to the three preceding factors)
- the quality and coherence of policy generated at a local level (and the 'necessary' prerequisite of having data and being able to perform testing to substantiate a case)
- the development and management of a co-operative, inter-organisational network
- simplicity and clarity of goals and priorities
- the change agenda and its 'fit' with the locale (for example, with the local workforce).

A study of an NHS primary medical services pilot in the UK found that six of these factors appear to be important for successful change (Newton et al 2003). A strong association was found between quality and coherence of policy, key people leading the change, supportive organisational culture and effective managerial clinical relations. The factors of 'environmental pressure' and the change agenda's 'fit with the locale' were not significant. The importance of factors appeared to change over time, with the policy factor declining and the importance of networks increasing. The study notes that the context became less receptive because of the impact of 'unplanned movement of key personnel' on managerial–clinician relations, and the increasing reservations of the general practitioners.

A synthesis of seven studies into evidence-based clinical change (Dopson et al 2002) proposes the following conditions for successful change:

- The context (government policy and resources, local financial situation, history of relationships, service problems) drives staff to seek new solutions: for example, to reduce waiting times.

- The evidence resonates with experiential knowledge (see Rogers 1995 for an exploration of compatibility).
- Professional networks shape behaviour through access to trusted colleagues for advice and peer comparison (for example, Continuing Professional Development).
- Professional boundaries and competition that inhibit knowledge diffusion (within specialties, professions and between professions) are broken down.
- Opinion leaders support the change – both expert and peer.

2.2.7 Change readiness

A related but different concept originates from Lewin's work on resistance to change in groups (Lewin 1947). Later studies of addiction proposed that individuals move through stages of change from precontemplation to contemplation, to preparation, to action and then maintaining the change (Prochaska et al 1992). These stage models suggest that staff at the precontemplative or contemplative stages may respond to different interventions to those at the preparatory or action stages (Prochaska et al 1992, Prochaska and Velicer 1997). Individual readiness is about expectations, and is influenced by the readiness of others, as perceived and discussed in group or organisational settings.

One empirical study examined readiness for organisational change in a Canadian hospital re-engineering programme (Cunningham et al 2002). The study found that high scores on a readiness for change, and an active work problem-solving approach, predicted active participation in the re-engineering programme. It discovered that staff were more prepared for initiating or contributing to this organisational change if they had 'active jobs' that gave them control over challenging tasks, and if conditions were in place that optimised health and emotional well-being. The study suggests that active involvement in organisational change, reducing barriers to participation (such as shift work), building problem-solving strategies, and enhancing staff perceptions of their ability to cope with change (change self-efficacy), should enhance commitment to Q&SI and reduce the stress of organisational change.

The studies reviewed consider that 'readiness for organisational change' relates both to individual resistance and individual readiness, but is a different concept. Actions to reduce resistance can enhance readiness, but readiness also involves people perceiving that they or their organisation have 'the financial support, the well defined mission and leadership structure, the cohesive work team, or the technical skills needed to adopt a particular innovation' (Backer 1995). Whether these are actually present is a separate matter.

In this way, staff might not be resistant to change, but they and their organisation might not be change ready. If they are change ready, objectively the resources for change might not be in place, or the changes might not be compatible with or 'fit' the values and type of the organisation. The studies also appear not to give enough attention to readiness involving an objective need for change, as well as a subjective desire for change, resulting from rational and emotional discomfort with the current situation, and shown in people's sense of urgency and pain.

2.2.8 Absorptive capacity

A final concept, and one that relates to those above, is the 'absorptive capacity' of an organisation: a concept proposed in a study of the ability of companies to apply new knowledge (Cohen and Levinthal 1990). This concept also suggests areas that senior managers might consider when assessing and developing an organisation's ability to spread quality and safety improvements:

> The ability to exploit external knowledge is thus a critical component of innovative capabilities… An organisation's absorptive capacity does not simply depend on the organisation's direct interface with the external environment. It also depends on transfer of knowledge across and within sub-units that may be quite removed from the original point of entry. Thus, to understand the sources of a firm's absorptive capacity, we focus on the structure of communication between the external environment and the organisation, as well as among the subunits of the organisation, and also on the character and distribution of expertise within the organisation.

2.2.9 Change management literature

Other bodies of literature relevant to the questions of this review relate to organisational change and change management. This research is too extensive to review here, and has been reviewed for managers in one document (Iles and Southerland 2001). However, one theorist worth noting, as the generic steps for managing change suggest actions for leader of improvement.

Kotter (1990) proposes six key tasks that are needed for any organisational change:

1. Establishing direction.
2. Aligning people.
3. Motivating and inspiring people.
4. Planning and budgeting.
5. Organising and staffing.
6. Controlling and problem-solving.

A later study by the same author notes eight errors that undermine successful efforts at change, restated here as necessary actions:

1. Create a sense of urgency.
2. Build a powerful coalition to guide direction.
3. Create a compelling vision.
4. Constantly communicate the vision.
5. Remove obstacles to the new vision.
6. Plan and create short-term wins.
7. Do not declare victory too soon.
8. Anchor change in the organisation's culture.

2.2.10 Summary: conditions for improvement change

The relevance of the above research to the review questions is that it provides senior and other managers with ideas about which factors to strengthen and what to look for to assess the chances of success in Q&SI change.

A number of related concepts are relevant, the broadest reported being context, defined as:

> a layered set of influences, which commence at the outer layer with influences from government health policy and move inward to local influences, and finally influences that are specific to a single organisation and individual practitioner. (Dopson et al 2002)

However, the author of this review considers that existing research does not give enough attention to the extra time, resources and skills needed by many staff for successful change. Also, a receptive climate, context or culture alone may not ensure that a change or innovation is adopted: the change may also need to fit with the needs and values of staff (Klein and Sorra 1996).

Thus, in theory, Q&SI change requires low resistance, high readiness (expectations and perceptions), the objective existence of the resources, an objective need for change as well as a subjective desire for change including 'a sense of urgency and pain'. In addition a suitable 'fit' of the change with the organisation may be needed. Therefore, all of the above elements may be needed to ensure effective improvement. However, research does not give specific guidance because the success factors may be different for different types of change and in different types of organisation (Øvretveit 2004a): available evidence is specific to certain changes and is not strong.

The evidence does suggest that management can contribute to a receptive context for change, by providing a vision, communicating the consequences of not changing, and giving training and time to staff. The concept of 'conditions for improvement' draws on these ideas specifically for Q&SI and can be defined as:

> the circumstances 'surrounding' the quality intervention, which are separate and distinct from it, but which help and hinder how the intervention is implemented and its effectiveness, as perceived by staff. (Øvretveit 2004)

The summary provided by one synthesis of seven studies on implementing clinical evidence provides useful ideas for managerial action (Dopson et al 2002):

- Build and sustain a receptive context for putting clinical evidence into practice and for change.
- Build good relationships between professional and managerial groups and between professional groups (people inherit a history of relationships that may need to be changed, power struggles, negative attitudes or competition with other specialists or units).
- Provide sustained political and managerial support and pressure for clearly defined change at the local level.
- Create a supportive local organisational culture, clear goals for change, appropriate infrastructure and resources.
- Enable professionals to take part in groups and networks that regularly debate the evidence and exchange experience of making changes.
- Gain the support of local opinion leaders.

The implications are that managers and professional leaders together need to assess the presence and absence of the above barriers and facilitators, in a strategy to promote the use of evidence and improvement.

Appendix 3: Summary of findings on developing and supporting leaders for Quality and Safety Initiatives work

The review concentrated on finding empirical research that described real programmes for leaders for Quality and Safety Initiatives (Q&SI) and, ideally, the results. However, few studies were found. Most of the small literature on this subject are commentaries that rarely cite evidence or experience.

3.1 Designing and running improvement leadership development programmes

The available research and experience suggests the following guidance for designing and running improvement leader development programmes:

- Clarify who it is for and not for – for example, all possible 'leaders for improvement' in all units; senior executives; heads of clinical departments; a mix of managers at different level; or another combination.

- Clarify the purpose in terms of outcomes required, and whether leader development for all types of improvement change is needed, or leader development for specific quality or safety approaches.
- Consider the stage of quality development of the participants' organisations and the type of organisation, and whether the programme needs to emphasise different skills at different times.
- Assess the advantages and disadvantages of a profession- or sector-specific programme, compared to one for mixed participants, in relation to the programme's purpose.
- Use the useful checklist by Harden et al (1999) of questions for designing a programme:
  - What will the learner be able to do – are they prepared to do the right thing?
  - How will they approach their practice – are they prepared to do the thing right?
  - What, as a professional, will they bring to practice – are they the right person to do it?
  - Which type of educational experience is therefore appropriate, given our understanding of how people learn, the importance of the learning environment, and pedagogic methods and approaches that might be adopted?

  Different types of education experience can be provided according to the answers to the above (Hunt 2004): an educational course, at the work place or at another site, in one block or many smaller sessions over time; conferences; study visits; action learning sets; guided informal seminars with colleagues at work or from other organisations; carrying out an activity or project with access to an expert adviser; acting as a reviewer for a quality award or audit system; coaching; mentoring; secondment; peer review or peer assessment; personal reading; seeking others views about what needs to be done; or giving a presentation on leadership for Q&SI or a related subject. (Harden et al 1999)
- Base the programme on adult learning principles, and on participants' experience of leading or being lead in other organisational changes.
- Mirror quality improvement principles in the way the programme is run, with customer research and feedback, participant involvement in designing the programme, and by continually using methods to improve the programme.
- Make explicit the assumptions about leadership on which the programme is based.
- Base course content and learning materials on the best available evidence about which leadership actions are successful and unsuccessful, and ensure that presentations are by leaders with real experience.
- Build skills to work with staff to adapt quality methods to the local situation, without loosing the method's effectiveness, and to identify, influence and build relations with key professional opinion leaders.
- Include in the course content an examination of conflicting influences on managers in relation to quality (for example, about a no-blame culture in a media and political culture that tries to blame individuals), and apparent or actual contradictory guidance from the literature (for example, about strong direction and empowerment).
- Use theoretical and academic content to help participants draw lessons for the future from reflecting on their own and others' personal observations and experience.
- Provide a variety of learning experiences, not just taught courses, according to the participants' needs and the required learning outcomes.

3.2 Guidance to support leaders to initiate and sustain Quality and Safety Initiatives work

Guidance to support leaders to initiate and sustain Q&SI activity is as follows.

The employing organisation, through its higher-level managers, should arrange support services that are based on:

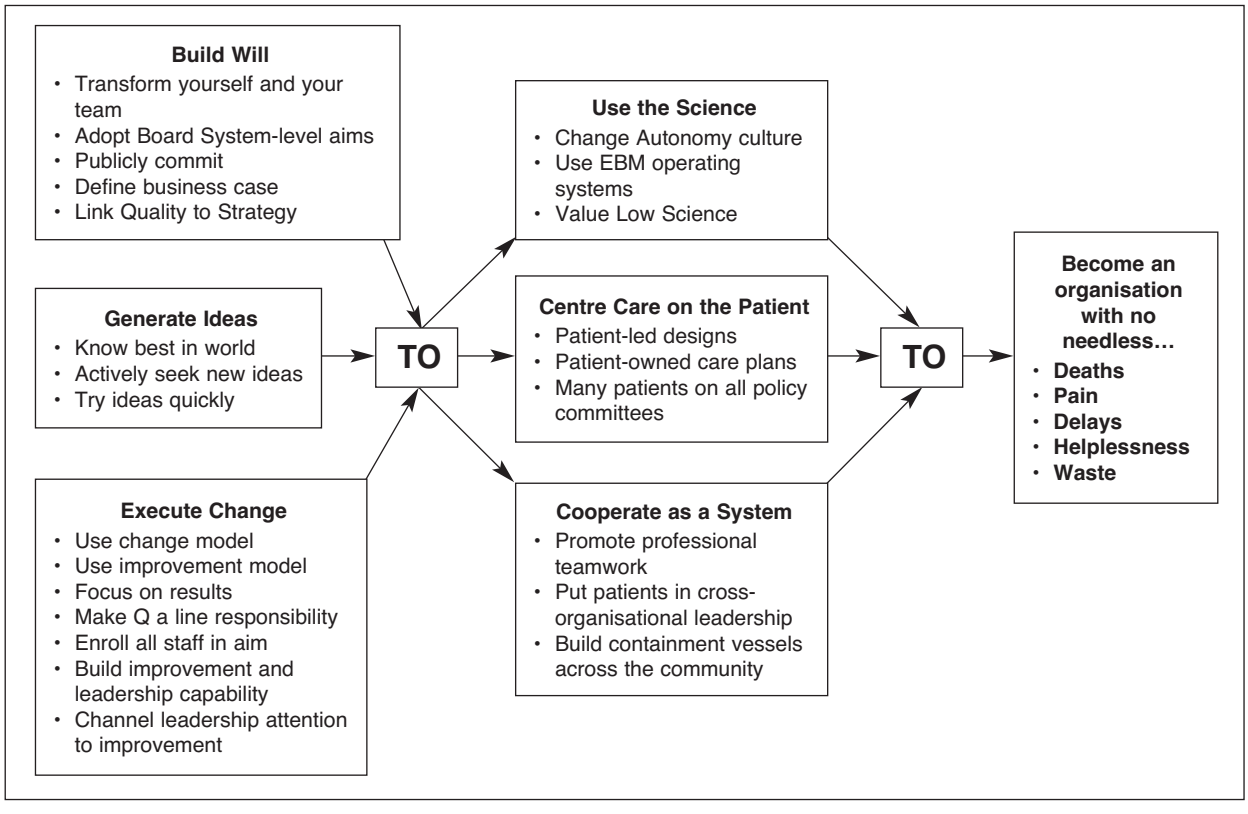
- the strategic objectives for Q&SI
- clarity about what is expected of different leaders at different levels
- leaders' views about the support they need, informed by their knowledge of Q&SI (that is, after some education in Q&SI)
- research evidence about which support for leaders was needed or was lacking in other organisations for Q&SI (presented above in this review).

3.3 Support provided by regional and national associations and networks

Support provided by regional and national associations and networks should include:

- setting up regular meetings to exchange experience in leading Q&SI and study sessions
- providing advisory, educational and information resources
- funding usable research into this subject
- helping to disseminate research to leaders and development programme providers.

Appendix 4: A model of leadership for transformation



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