

Evidence



Does improving quality save money?

*A review of evidence of which improvements
to quality reduce costs to health service providers*

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Foreword

The most successful hospitals or primary care organisations are not the ones which just deliver the best evidence-based clinical services, or are most focused on safety, or whose services are highly customer-oriented, or which consistently managed to balance their budgets. The most successful healthcare organisations are the ones which recognise the multi-faceted nature of their endeavour and manage to deliver across all of the dimensions of quality. For most of the last decade, organisations have become accustomed to times of plenty – their challenge has been to improve patient care and health outcomes and they have been given the resources to do so. But the impending public sector spending crisis changes this context utterly. Every manager and clinician in the country should now be asking themselves how they can continue to improve quality while also cutting costs.

There are many ways in which savings can be made. At one end of the spectrum are the easy changes, the metaphorical slash and burn activities that we have seen so often in the past but which can be so damaging. At the other end are the kinds of sweeping changes such as implementing Wanless's fully engaged scenario (2002) or reconsidering how healthcare should be funded for which there is no political consensus right now. In the timescale required, these options are unattractive and infeasible. But between these extremes lie solutions with perhaps the greatest potential in the time frame within which the health service has to respond.

The solutions are accessible to those working in or close to the front line of the service. They have their origins outside the health sector but are increasingly being used, tested and adapted to benefit patient care. Sometimes referred to as the 'industrial' approaches to improvement they are based on straightforward and common-sense principles – the centrality of the customer; the importance of work processes and systems; the fundamental importance of measurement and finally recognising and rewarding the expertise of those who work in the front line. We know that these approaches engage staff and there is emerging evidence that they can make a difference. But by improving the efficiency and effectiveness of working practices, can they help to address the need for costs to be saved?

To answer this question the Health Foundation commissioned one of the leading researchers in the field, Professor John Øvretveit from the Karolinska Institute in Sweden, to undertake a review of the published evidence. It was a big ask from the start, hampered by multiple definitions, heterogeneous and sometimes disputed methodologies and complex outcomes. Despite these challenges, Professor Øvretveit has produced this impressive report.

The report suggests that although the scientific evidence is not strong, improvement initiatives can reduce costs to service providers. To achieve this requires careful planning, leadership, expertise, perseverance and not a little healthy scepticism. It especially requires a sustained and relentless focus on high-quality implementation.

The report identifies gaps in our understanding of how to achieve substantive and sustainable change and lays down challenges to managers, clinicians, policy makers and academics. Meanwhile, the Health Foundation is taking a lead in rising to these challenges. We have established a new award scheme aimed at front line clinical teams to support innovative ways of reducing waste. We will continue to work with leading international health economists to improve our understanding of the theory and practice of achieving value for money and we are making this learning accessible to a wide audience. We are working with organisations taking a lead in implementing process improvement methods in order to build a business case for safer care. We are also collaborating with the Institute for Healthcare Improvement to develop a tool to highlight waste in clinical processes of care in order to prioritise areas for action. We hope that our work will make a difference. The challenge is great but we are all compelled to respond.

Martin Marshall
Director of Clinical Quality, the Health Foundation

Abstract

Does improving quality save money? Sometimes, but sometimes not, and mostly we do not know because the research is limited. There is a great potential for savings, but it depends what we mean by quality improvement, who makes the savings and when.

Costs of poor quality. The research reviewed shows that poor quality is common and costly. There is evidence of the high financial and human cost of poor quality in the harm caused by healthcare, and by sub-optimal care in the overuse, misuse and underuse of treatments. It has been estimated that the costs to the UK NHS of hospital-acquired infections are £1.0bn a year (Mayor 2000), and adverse drug events are estimated to be between £0.5bn (Pirmohamed et al 2004) and £1.9bn (Compass 2008). Patients with chronic diseases do not always receive optimal care and the cost of avoidable emergency admissions is high.

Intervention costs of solutions. The evidence shows that some solutions for poor quality are effective, such as prophylaxis before surgery or computer physician order entry. But there is less evidence of the effectiveness of other proposed solutions, especially when generalising to other sites. There is even less evidence of the costs of these interventions in study sites. Local services might find their intervention costs to be considerably higher or possibly lower: research shows great variation in the implementation of solutions and why this may be so. Quality improvement can be costly, especially in services with little experience or infrastructure to support improvement.

Savings or loss from improving quality? It can be misleading to cite savings from interventions which raise quality because of uncertainty about effectiveness and about costs in different situations. The review found that many studies which reported 'savings' did not assess the cost of the intervention, left out some costs, or did not use actual cost data from the service. Savings depend on the financial system, and on who bears the costs that are distributed between different stakeholders. Providers often do not save because the finance system does not measure or reward higher quality. Often, a provider bears the intervention cost of the solution, or cannot get the investment finance, and is financially rewarded for poor quality, giving a triple financial disincentive to improve. Purchasers have been slow to recognise and address these issues. Savings depend also on which timescale is used: interventions usually incur initial high costs and some, such as preventative care, may only return savings many years later, and probably not to the provider.

The lack of evidence and the challenges do not mean that improving quality cannot save money. Research shows that it can, sometimes, and describes the when, where and why. This

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can help to select value improvements, to implement them more effectively, and to make changes to enable development. This can make future efforts that raise quality more likely to make tangible savings.

The framework used to summarise the research is shown in the following equation:

Evidence of an effective change + Effective implementation method + Supportive environment and infrastructure + Improved quality. Øvretveit 2009a

Practical implications. Managers and policy makers can be more sceptical and more adventurous: sceptical of bold statements of savings which do not give details of which intervention costs were considered and in which situations, and more sceptical about the time, effort and support needed to implement a quality solution effectively and to sustain it. But they are more adventurous in adapting and testing interventions which show promise of effectiveness and savings, from research or from the experiences of others, more willing to measure quality and to pay service providers for value not volume.

Research could provide more and better information to help providers decide which solutions to implement, their costs, and to guide effective implementation. There is enough evidence to show which changes to focus on, how to make the changes and the support needed. The cost of inaction and of not using this knowledge is likely to be high, both financially and with regard to human suffering.

Executive summary

All bets are off. We need to move away from the NHS being built for growth to being able to sustain itself in a prolonged limitation of resources...The NHS will need to make efficiency savings of £15–20bn from 2011–14. (NHS CEO David Nicholson, *HSJ*, 4 June 2009, p 4)

How will this 5 per cent reduction in the NHS budget be carried out? By cuts to services or personnel? By other cost reductions? Might some savings come from using quality improvement changes and methods to reduce waste? Can ordinary services, as well as the example projects, raise quality as well as reduce costs?

These are some of the questions which this report seeks to answer through reviewing the research: what is the evidence that improvements to quality also save money for a health service?

Outline of the review

The review presents evidence of a variety of quality problems in healthcare, found by research, and of their financial costs (the ‘potential savings’). It then presents evidence of solutions, their effectiveness, and the intervention costs. Evidence of the subsequent savings, losses or increased revenue is then presented, where there is proof that quality was maintained or increased at the same time (see figure 1). Parts 3 and 4 consider the challenges for enablers to save through improving quality, make research-based recommendations, and propose ways to increase usable knowledge about the subject.

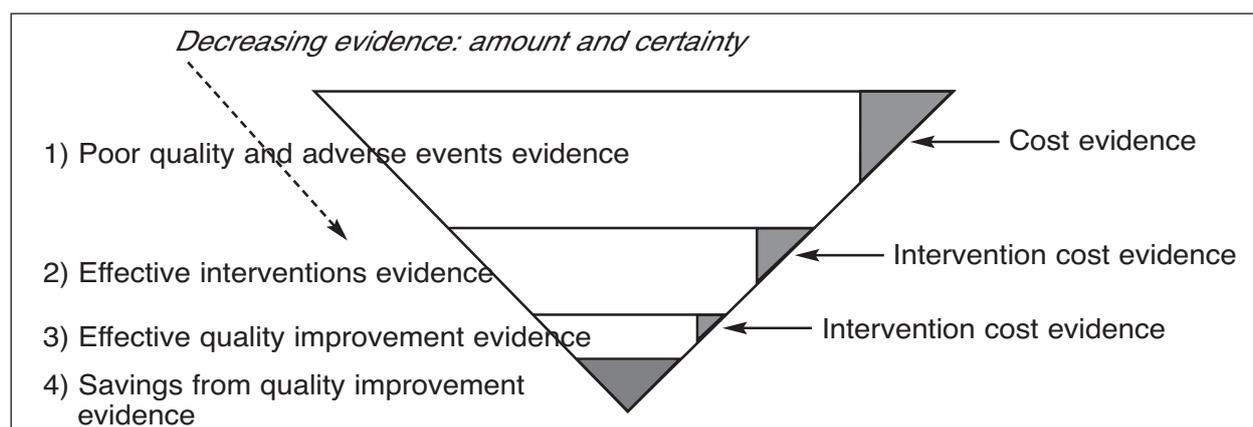


Figure 1: Illustration of amount and certainty of evidence that improvements to quality save money

Poor quality and adverse events are common and costly

One in ten hospital patients suffer an adverse event, and a significant number are harmed and need extra treatment. Common adverse events include infections, adverse drug events, surgical complications, pressure ulcers and falls. Poor quality, which may not result in an adverse event, occurs at higher rates with underuse, misuse and overuse of treatments and poor patient experiences of care, all of which can have a high cost or lose income for providers. There is less evidence of poor quality outside of hospitals, but there is growing failure in transfers, coordination and communication between providers. All are, by definition, avoidable, and represent potential areas for savings. Strong empirical evidence of costs is limited.

Use of ineffective treatments, tests or service delivery organisations could also be considered poor quality. Purchasers, policy makers and professional associations pay less attention to disinvestment in funding or discouraging these than they do to managing the introduction of new treatments, tests or service delivery organisations.

Some interventions are effective, but carry costs which may exceed savings

Whether savings can be made depends in part on whether there is an effective change which prevents the problem, and whether it can be implemented locally at a low cost. There is strong evidence that simple clinical-level changes are effective in reducing adverse events, such as better antibiotic or antithrombotic prophylaxis before surgery. There is less evidence about effective ways to implement these changes in a variety of settings. Training is costly and largely ineffective for implementation without other changes. Audit and standards with feedback can be effective in some circumstances. There is also some evidence that some quality improvement methods can be effective for implementing these proven changes, such as Plan-Do-Study-Act (PDSA) testing, continuous quality improvement projects, and collaboratives.

With regard to more complex process and organisational changes, the potential is greater for reducing waste and poor quality, and making savings, but so are the risks. For these changes, there is less evidence of effectiveness and the uncertainties of attribution at the study site, and generalisation to other sites, is greater. It is possible that the more professions and organisational units that need to change, the higher the risk of failure due to challenges in reaching agreement and coordinating projects.

Whether a quality improvement saves or makes money depends in part on how quality improvement is defined. Sometimes it is defined narrowly as a specific set of methods for making changes (for example, 'improvement methods'), but writers vary in what they include in this definition. Sometimes it is used generically or broadly to refer to any change which may raise quality. This review could not assess whether all changes which have been proven to improve quality did save or make money, but it did consider a broader range of changes than those sometimes categorised as quality improvement methods or approaches (for example, Boaden et al 2008) and considered changes to improve quality, rather than the often, more narrow 'quality improvement' label.

Those studies which do report savings sometimes do not include the cost of the intervention, do not give details of the calculation or make it in a questionable way, and rarely use empirical real-time costing data. Additionally, none of the studies estimate the potential 'meta value added' of increased competence to carry out improvements as a result of the work.

More importantly, many such studies do not thoroughly assess quality, and whether it was maintained on a reasonable range of measures, or was reduced. Thus, with many 'savings' reports, apart from studies published in scientifically refereed health economic or medical journals, we need to question closely whether and which intervention costs were included and whether quality was increased or maintained. Few reports give evidence of sustained changes and savings after two years, or of whether a change can be easily spread, and so may be context-insensitive.

Overall, there is little evidence of how much the intervention costs of quality improvements are, and the evidence is not strong on the cost to providers, but some savings have been reported. The stronger evidence is provided by the following studies:

- \$0.7m annual savings from reducing deep surgical wound infection rates from 1.8 per cent to 0.4 per cent in a continuous quality improvement project (Classen et al 1992, James 1993).
- \$0.47m annual savings from reducing practice variations in peripheral bypass surgery (Mayo Alumni 1995).
- \$2.5m annual savings, or about 30 per cent of total patient care costs, were reported as a result of one collaborative in intensive care units (ICUs) (Clemmer and Spuhler 1998, Clemmer et al 1999).
- \$2.4m annual savings, from \$20,000 reduced cost per case, in an ICU using an improved multidisciplinary approach for caring for ventilator-dependent patients (Young et al 1998).
- \$0.06m in the first year, and \$0.160m annual savings, after reduced operating room cancellations and delays in one 650-bed Norwegian hospital (Øvretveit 2000).
- \$0.01m to \$0.6m annual savings in five different continuous quality improvement projects in Sweden (Øvretveit and Granberg 2006).
- \$0.3m annual savings through earlier patient discharge and a reduction in delays in the pathology specimen reception from thirteen minutes to one minute (Westwood and Silvester 2007).

Not reported in scientifically refereed journals:

- \$0.079m annual savings from process improvement to blood testing processes at Washington Hospital Center (DC) Laboratory (VMS 2004).
- \$1.2m annual savings over two years through reducing hospital-acquired infections in the University of Pennsylvania Medical Center (reported in Martin et al 2009).
- \$5.5m annual savings from reducing the time patients spent on ventilators in the ICU (Intermountain Healthcare, reported in Martin et al 2009).
- \$0.3m annual savings from reduced re-hospitalisation intervention in one Colorado health system.

The cost and benefits of quality are spread over time and between stakeholders

Whether providers make savings depends on how much of the costs they bear: the costs of the poor quality and the intervention cost to make the intervention. The cost of adverse events is sometimes carried by the purchaser, and the provider may be paid extra to treat them. To shift costs to providers, some US purchasers are excluding some 'never event' treatments from reimbursement, introducing financial penalties for not meeting certain standards, or giving incentives. The cost of not giving preventative care is often borne in higher treatment costs by other providers or the purchaser. The savings may occur in the future, by which time the

patient may have moved. In all cases, patients and their families bear financial costs from poor quality, but there is no evidence of the costs of this from research.

The UK focus is on saving. US providers are also interested in increasing revenue from more patients' income in a competitive market. The latter may become important in the UK.

Context factors influence whether a provider saves money from quality improvement

Even if an effective intervention is chosen for a prioritised quality problem, whether it can be implemented and the costs depend on the features of the provider organisation and the external context. There is the 'financial context', which can reward or penalise poor quality through routine reimbursement, and there are special payments by purchasers for quality improvement or support – for example, electronic medical records and computerised physician order entry.

To make it more financially advantageous for providers to increase quality, changes are needed in routine financing systems, in how performance is measured to include quality measures, and in expert support and information on how to make successful improvements.

Progress would be made by designing financing schemes to spread costs in a way more related to who saves, and over what time period. This means designing schemes to:

- ensure that providers bear more of the costs of poor quality, especially for their deficiencies in patient transfer and not providing prevention, which shifts their costs over time and to other stakeholders
- measure quality and quality costs in routine service settings as part of service performance management and financial payment systems
- finance local improvement expertise, much of which can be shared between providers, tied to results in savings
- spread the investment costs for interventions and for developing provider improvement capacity over time and between providers, purchasers and others, in a way proportionate to the savings and when these are made, possibly by using intermediate finance organisations ('intermediate investment and savings distributors').

Providers would be helped by information relevant to their situation

The evidence summarised above shows that whether a provider gains financially from a change to improve quality, through savings or extra income, depends on:

- the cost of the problem
- whether an effective solution exists or can be created and implemented locally
- the context factors which help and hinder solution implementation and can add or reduce costs of implementation, such as available external expertise or regulation requirements
- the cost of the solution as implemented locally
- how much of these costs the provider pays for.

Savings depend on the financing system, both routine reimbursement and special payments, and on non-financial external supports for improvement, such as expertise, which the provider otherwise would have to pay for.

Research could provide more and better information to help providers decide which solutions to apply and to guide effective implementation. Also, research is needed to help design quality

incentive finance schemes and develop measures and accounting systems to support this. More specific research made more accessible can help. But other information is also needed, such as better implementer reports. Part 4 describes how this could be done and what research is needed.

Lack of evidence may be due to a lack of research, challenges in creating clear data, or because good research has failed to find anything substantial. All three are apparent when it comes to evidence of savings with improvements to quality.

Saving avoidable suffering may be speeded up by the business case

This review contributes some evidence and ideas for constructing a system that rewards and supports providers to use improvements which save costs rather than penalising them. These changes will require research and other activities to design and test finance, measurement and support systems which create incentives, and use improvement changes and methods.

Saving money is not a strong motivator for clinical personnel and it is not the only reason to improve quality. There are ethical, moral and professional reasons too, but these alone have not proved sufficient. More political and management support can be gained if there is more certainty that the change will be carried out effectively and produce results, including cost savings, and that it will be a value improvement. This requires more confidence in implementation capacity and effectiveness, which in turn depends on a supportive context. Research into these subjects is needed. But, even now, more use of research and experiential evidence can ensure that investment finance is better targeted and the improvement change better managed.

Summary for health service providers

Does quality improvement save money for a service?

The simple answer is that some ‘improvement’ makes care better for patients. But not all improvement saves money in all situations. Savings have been reported in some cases, but the evidence is weak and research does not give a guide to what to expect locally, or how to ensure savings.

Savings depend on the type of improvement, on who pays the cost of poor quality, and the intervention cost of the solution. The intervention cost locally depends on how well the improvement is implemented, which also depends on the context, which can significantly help or hinder implementation.

For example, changes to reduce pressure ulcers can reduce extra treatments and length of stay. These changes can save the provider money if the intervention cost to the provider of implementing the change is lower than the losses they made from the problem before the change. The cost of implementation will depend on whether there is external support or previous experience with making changes effectively and other context factors.

Defined generically, ‘improvement’ is any change that results in a better health service, usually defined as being better for patients – for example, shorter waiting times because of extra staff. A more limited meaning is whether certain methods are used to make the improvement: this is termed ‘quality improvement method’ in this review. This usually involves health service personnel in project teams using methods to change work and organisation. The theory is that this can reduce waste, increase productivity and raise quality.

There is strong evidence that changing providers’ behaviour to use clinical-level patient safety practices or proven effective treatments will improve outcomes for patients. There is evidence that some of these behaviour changes save money or increase income for some providers.

For a provider wanting to use this research, key questions are: How to implement these changes? How much do they cost? and Does the local financial system reward the change? As regards the first two questions, there is evidence that using certain quality methods to implement these proven changes can increase success and speed: collaborative breakthrough and Plan-Do-Study-Act (PDSA) cycle testing are two examples.

As regards other quality improvement methods for service process redesign, there is no strong evidence to show that these are more cost effective for increasing productivity than other

methods. Little evidence is not enough to prove that these methods cannot make savings: it may be because of a lack of research or challenges in establishing evidence for complex changes. But it may be that some quality improvement approaches and more complex changes to work and organisation require considerable resources to ensure successful change, and that these exceed any savings.

But there is a plausible case, and some implementers report that some of these approaches may be effective, in some situations, if properly applied. But which approaches and in which situations? And how to build the capacity to use the methods properly and create conditions that enable their use? Answers to these more specific questions are most needed to guide how to choose and use effectively the methods which show promise.

What is the actionable knowledge for service providers from the research?

Firstly, savings depend on whether the improvement is implemented effectively. Many improvement projects either cannot prove results, show results not worth the time and effort, or results which might not be sustained. There is a publication bias and a growing industry that gives a misleading impression of the ease and certainty of improvement. Success depends on many factors and is not guaranteed. Many financial and capability constraints hinder the use of the methods.

Secondly, whether the change saves money for a health service depends on whether the service bears the cost of its poor quality and of the solution. In some payment systems, longer stay due to infection, or a re-admission for a second operation due to an avoidable surgical complication, is not a cost but extra income. A service spending time and money improving discharge information might not gain savings, but the next 'downstream' service may do so because it saves them time. Often, a provider bears the intervention cost of the solution, cannot get the investment finance, or is financially rewarded for poor quality, giving a triple financial disincentive to improve. Purchasers have been slow to recognise and address these issues.

Thirdly, it depends on how improvement is defined. Defined narrowly as using specific quality methods, those which focus on process change crossing many professions and services have the potential for the greatest savings, but also carry the greatest risk of failure and need the best implementation management, which may be difficult to achieve in the NHS.

If defined broadly as any change that makes services better for patients, then some improvements have the potential to save money, especially if this includes more day cases, labour substitution or skill-mix changes, shifting services from hospital to primary care, and some reconfigurations. However, there is little evidence of savings from these, mostly because the research has not been done, or has not been able to show the contribution of the change to the saving.

How strong does the evidence need to be before we act?

This should be proportional to the costs, ease of implementation and risk of harm. For launching a national strategy or mandating a change, the evidence has to be strong. But for a provider to test a plausible change, the evidence does not have to be as strong. There is a theory and a plausible case, there are the experiences of others and there is research evidence. This review concentrated on discovering and presenting the best research evidence to answer the questions. But there was little research and few definitive answers. What was effective in the research situation may not be effective in a local service, and would need to be adapted; there was little research which would help guide adaptation.

Strong evidence is a high degree of certainty from a high-quality research study. This may show that a set of actions reduces medication errors. But can these actions be carried out in our local service, how and at what cost? If a systematic review of such studies in different situations has been done, this can help with these practical questions if the different services are described, but often such a review has not been made.

Strong evidence for action can come from experiential evidence. It can also come from good enough documentation and measurement from colleagues in a similar service who have implemented such a set of actions or developed their own. The evidence of results may be less strong but is a better guide to the likely results in a similar service, and there is other useful experiential evidence about implementation that can come from such documentation. On balance, stronger evidence for local action might come from documented experiential evidence and a plausible case rather than from a high-quality research study, which may be lacking anyway.

How can providers ensure saving through quality improvement?

The available evidence suggests that savings are possible through careful choice of change solutions, skilful implementation using quality methods and attention to the political and people aspects of change. The chance of success is higher if there are certain enabling conditions, such as financial incentives.

- Choose improvements already proven to make services better for patients and reduce costs, especially in a similar service.
- Where there is little research, use reported experiential evidence to guide action, but speak personally to the implementers, ask what helped and hindered and be positivity sceptical.
- Make your own estimates of the current poor quality cost, the intervention cost for a 50 per cent solution, when the intervention costs will start paying for themselves (time to pay off) and the annual potential savings. Then track these costs. Research has shown this can be done well enough for practical purposes using routinely available data.
- Adapt the change and manage implementation skilfully, especially the people aspect, using the methods, expertise and experiences of others.
- Measure and monitor progress and make corrections according to changing circumstances.
- Join with others to change financial systems, and other external hindrances, to help you invest in changes and build improvement capacity.

PART 1: INTRODUCTION, OBJECTIVES AND METHODS

Chapter 1

Introduction

The purpose of this review was to find and present evidence of resources saved by health service providers which resulted from improving quality. The methods were designed to search for, and summarise, evidence to answer the following sub-questions.

- Costs and savings: for different health service providers, what are the costs of poor quality, the intervention costs, and are there any savings?
- What are the trade-offs, benefits and costs of quality improvement to different stakeholders?
- What are the barriers and solutions to investment in those improvements that have also been shown to save costs and increase productivity?
- What are the strengths, weaknesses and gaps in the research into quality costs and savings and tools available to providers?

Section 1.1 gives an overview of the literature and shows how the evidence found was organised to answer the questions. It then defines quality improvement to show which activities were and were not included in the report and defines related terms. Then it describes how strength or certainty of evidence were assessed and reported, and presents the method used for the search, summary and synthesis to achieve the aims of the review, within the time and budget constraints.

1.1 A map of the literature

As regards strength of evidence and study design, the literature reviewed included intervention, observational and costing research by researchers and health service personnel. Many of the latter studies are published as internal documents and conference presentations. These are reported in the text if no evidence was found in the published scientific journals.

As regards the areas covered in this review, the literature was grouped into six main categories which relate to the earlier questions:

- 1) Poor quality and adverse events – incidence rates and costings.
- 2) Effectiveness of interventions for improving quality and the intervention costs.

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- 3) Effectiveness of quality improvement interventions and the intervention costs.
- 4) Savings made by quality improvement.
- 5) Studies of what helps and hinders implementation of an investment in improvement interventions proven to save costs.

1.1.1 Improving quality or quality improvement?

Whether quality improvement saves money depends in part on what we mean by 'quality improvement', and the term is used in many different ways in the literature. It can mean any change that improves quality, or more narrowly a change made using a specific approach. The following meanings were found in the research:

- an improvement to quality: in patient experience and/or clinical outcome (the result)
- a quality improvement change: a change made, which results in an improvement to quality (the before/after change)
- any method for making a quality improvement change, such as training, merging two clinics, increasing the number of nurses, setting standards and inspecting or giving feedback on performance (generic method)
- a specific method for making a quality improvement change, often called a continuous quality improvement tool, such as a fishbone diagram, PDSA or a process flow diagram (improvement method)
- an approach for improving quality, using a collection of ideas and tools, and which also aims to develop organisations' capacity to use these ideas and tools, such as patient pathway flow, re-engineering, Six Sigma, Lean or total quality management (improvement approach)
- a change that raises quality and lowers costs (value improvement) (Øvretveit 2009a).

(The brackets at the end of each give the terms used in this review to refer to each of these meanings.)

More recently, quality improvement has been used to mean improving quality by implementing a change proven to improve quality by using 'an improvement method'. This combination of change and method is thought to be the most effective in different situations (for example, as used in quality breakthrough collaboratives).

Health service quality is defined as provision of care that exceeds patient expectations and achieves the highest possible clinical outcomes with the resources available (Øvretveit 1992). Some low-quality care or events may not be unsafe, but they are below standard. The definition includes three dimensions of quality:

- patient quality: whether a service exceeds patient expectations, provides a satisfactory experience and meets objective standards of humanity
- professional quality: whether the service is provided according to current best professional practice and processes, and results in optimal clinical outcomes
- management quality: whether the service makes the best use of resources, without waste, and operates within higher-level requirements.

This definition includes low cost as well as patient and professional quality, more recently emphasised in the concept of value improvement: an action or a result that increases quality and reduces cost or increases provider income (Øvretveit 2009a).

1.1.2 The literature

Figure 1 uses these terms to represent the amount and certainty of the evidence found in the review.

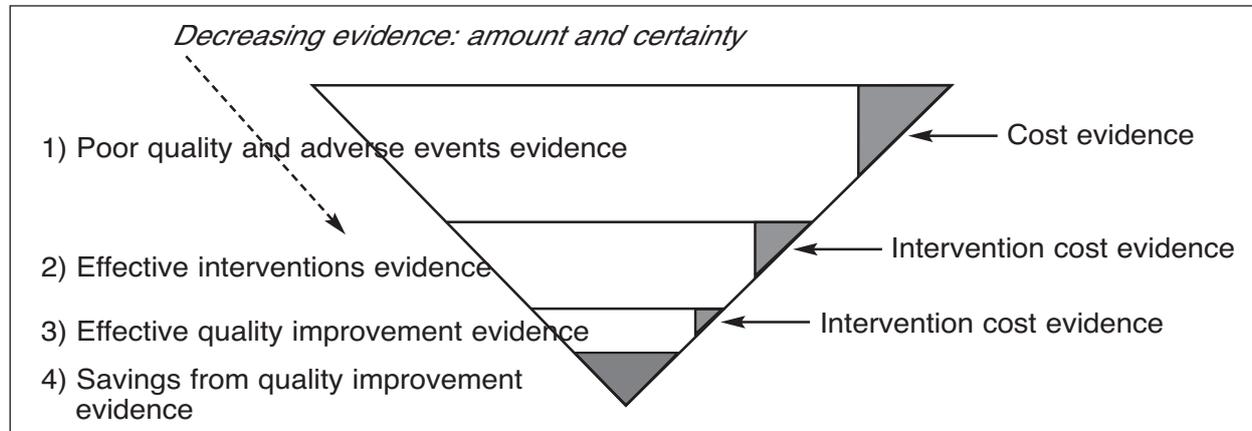


Figure 1: Illustration of amount and certainty of evidence that improvements to quality save money

The following provides more detail of the studies in each grouping to give an overview of the literature.

- 1) Poor quality and adverse events – incidence rates and costing: these studies present evidence of the rates of poor quality in one or more hospitals or services. Some studies give evidence of one category, such as emergency department waiting times exceeding a standard or adverse drug events. Some studies provide evidence of rates of specific subcategories such as undiagnosed hypertension or incidence of known allergic reactions. These, by definition, are avoidable, and represent potential savings to the provider – that is, if the rates can be reduced by any intervention, the intervention cost of which to the provider is less than the cost of the events. This category thus also includes studies that have estimated the cost of the poor quality events in addition to the rates evidence, although the emphasis in this review is on the cost borne by the provider. There is a limited amount and quality of evidence on this, and variations in estimates, especially between countries with different provider financing and legal systems.
- 2) Effectiveness of interventions for improving quality and the intervention costs: these studies are on the effectiveness of any intervention for improving patient experience or outcomes, such as increasing staffing. There is more evidence, and more concrete proof, of the effectiveness of clinical-level standardisable interventions (for example, timely antibiotics before surgery to reduce infection) than of organisational-level interventions (critical care outreach teams or electronic medical records). There is little evidence of the costs of resources used to make these interventions, especially in a variety of settings where the intervention cost for implementation may be different. These interventions can be grouped into specific interventions for single types of adverse events (pressure ulcers, patient falls) or poor quality (training on giving patient information); or generic interventions intended to improve quality in many aspects (for example, computer physician order entry, leader walk-rounds).
- 3) Effectiveness of quality improvement interventions and the intervention costs: this is a subcategory of methods and approaches for making changes to improve quality. The grouping used by Boaden et al (2008) describes many of these: PDSA cycle, statistical process control, Six Sigma, Lean, theory of constraints and mass customisation. This

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relatively narrow grouping excludes studies of interventions, such as clinical audit, guideline implementation, accreditation and inspection, and financial incentive schemes, some of which can be grouped in a subcategory of methods for implementing changes that have been found to improve quality.

- 4) Savings made by quality improvement: this grouping of studies are those which have estimated savings resulting from resources consumed by improvement changes and implementation actions. There are few studies reporting savings by quality improvement, in part because of the challenges in establishing causality between the activity and patient outcomes, but also because of the costing challenges. The review notes show an increasing use of the PDSA test cycle for piloting and implementation of safety interventions which were not previously defined as quality improvement; the dividing line between interventions that improve outcomes and quality improvement interventions is changing and arbitrary.
- 5) Studies of what helps and hinders implementation of, and investment in, improvement interventions proven to save costs: there is a growing body of studies that consider barriers and enablers to implement quality change, notably of guideline implementation. Some of this research is considered in chapters 8 and 9.

Chapter 2 elaborates on some of the issues touched on in the discussion of the research above, and shows how the search and review was limited in order to answer the questions within the time and budget allocated.

Chapter 2

Concepts and terms

This report is about whether making certain types of changes will result in using less resources and in better patient care and outcomes than otherwise. The choice of which types of changes to consider decides the scope of the evidence to be examined and frames the answers to the questions. The choice of which costs to include decides whether the improvement saves money. Hence, how the terms are defined shapes the answer to the question and the search and review strategy.

In general usage, 'improvement' means better patient experience and outcomes, or possibly better working conditions regardless of patient outcomes. 'Quality improvement' can also mean this or it can mean using specific methods to achieve this. The initial search used the latter narrow definition but found limited research relevant to the review questions and that more recent literature had broadened the meaning. The approach taken was thus to make an initial narrow working definition to start the search and to refine the definition as a result of reflection on what different studies defined as quality improvement: iteration between the reviewers' definition and the explicit and implicit definitions in the literature. The review is thus also a report on what the literature defines as quality improvement, shaped by the reviewers' need to limit and make explicit the definition used.

There are as many definitions of improvement and quality improvement as there are attempts at change to make care better for patients. In healthcare, the more narrow meaning referred (usually implicitly) to teams of personnel using methods commonly used in total quality management and continuous quality improvement, such as PDSA, data collection and analysis methods, underpinned with theories of work as a process and systems thinking. Historically, this has been contrasted with standards-based approaches such as accreditation and inspection. More recently, quality improvement has become viewed as using these methods to test and implement either change concepts (for example, parallel processing) or evidence-based changes, as in changes to organisations or treatments that have been proven effective in evaluations, termed 'evidence informed value improvement' (Øvretveit 2009a).

The definition used in the search for this review was initially limited by only considering improvements that had been achieved using specific methods or strategies commonly classified as systematic, organisationally focused, methods for change.

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The initial definition considered quality improvement as including safety improvement using approaches that focus on changing how work is organised using project teams and systematic methods to test and make alterations. Safety and quality were viewed as freedom from harm caused by healthcare but also patient experiences that were better than expected, and patient outcomes that were expected from using best practices.

The conception of improvement finally reached as a result of the review was to define improvement as

better patient experience and outcomes achieved through changing provider behaviour and organisation through using a systematic change method and strategies.

It classified quality improvements in terms of the following:

The change:

- patient quality or safety practice: a change in provider behaviour resulting in better patient outcomes (for example, hand hygiene, and either a single, or combined 'bundle' of changes)
- provider organisation improvement: a change in work organisation resulting directly in better patient outcomes
- provider support infrastructure improvement: a change in systems and culture supporting other changes, and hence indirectly resulting in better patient outcomes, and reducing latent causes of failure.

How the change is made:

- implementation process, strategy or method: actions, steps and methods used to achieve a change that results in better patient outcomes.

A change may be proven effective for improving patient outcomes, but the way it is implemented (the implementation strategy) might not. There is little research into the effectiveness of different implementation strategies in different situations.

Solving each problem can save resources, depending on the solution used. This review searched for evidence that any of these solutions had saved resources.

2.1 Costs and savings

Similarly, the choice of which types of resource use to consider as costs and as savings (and to which stakeholder) also determines the scope of the evidence to be examined and frames the answers to the questions. Whether savings are made depends in part on the amount of resources used to achieve the change, and whether the new behaviour or organisation consumes more resources than the old. Who makes the savings depends on who bears the cost of the poor quality and the intervention cost to reduce it.

For examining resource use and savings through improvement activities, the review took a similar iterative approach to that used for defining quality improvement. Initially the search began by asking, are savings for a health provider service reported?

The review then broadened and arrived at the following conceptualisation of costing and savings: the stakeholder costing matrix below.

Stakeholder	Cost	Intervention cost	Save/loss/ increased income
Provider			
Purchaser			
Other public services			
Patient/relatives			

Figure 2: The stakeholder costing matrix for assessing savings or losses from an improvement

The review focused on studies that found savings to providers, but noted costs and savings to others, and the potential for provider savings if other ‘context’ changes were made – for example, to provider payment or publicising quality data.

Another choice was whether to limit consideration to savings made only as a result of cost-effectively resolving safety problems, or whether also to include extra income accruing to a provider because of higher quality, which attracted more patients, where income is related to number of patients. Part-way into the search, the decision was made to include both quality savings and quality income, depending on the strength of evidence.

The search therefore considered three main categories of findings:

- High certainty of savings or loss from a research study that had produced evidence of the costs of one or more quality problems, and/or the intervention costs and/or extra income gained as a result of quality improvement, and a sub-classification of: a) likely anywhere, b) dependent on context.
- Probable savings or loss from a research study without strong evidence, but finding indications or good reason to believe this (evidence of occurrence of adverse events alone suggests costs, but not possible savings, unless there is a cost-effective solution).
- No clear evidence of savings or loss, conflicting or ambiguous findings (for example, other explanations) or no research or reports at all.

2.1.1 A comment on the evidence

As regards the evidence, certain features of the literature stand out. The lack of strong research evidence, and the challenges in establishing an adequate level of certainty that improvements produce certain outcomes, or even intermediate results. This contrasts with the evidence reported by implementers, which is almost wholly positive and selects only successful projects.

There is publication bias and a strong bias in the grey literature and conference reports, which favour success stories. Notwithstanding the lack of evidence and the neutral view that research should adopt, one recent scientific paper characterised much of the research in declaring that ‘Six Sigma is one of the most powerful performance improvement methodologies that are changing the face of modern healthcare delivery today’ (Taner 2009).

The literature does not reflect this author’s field experience of the high proportion of projects without measures, without evidence of attribution, and/or mediocre or no results. Neither does

this literature report the time, effort and costs to achieve results. Many reports do not take into account all the costs to providers, or cost the external facilitation and support that is often necessary for most services, which have little change capacity or expertise.

One sub-objective of the review was to find and present research into the relationship between quality improvement and productivity. However, on reflection and feedback from peer review, this area was not pursued. The reviewers felt that it broadened the scope of the research too far and is a topic that needs to be covered in more detail elsewhere. The research review undertaken into productivity is available from the author.

2.2 Summary of conceptual distinctions made in this report

In summary, distinctions were made between the following:

- Safety (absence of harm caused by healthcare) and quality (which includes safety, but also optimal patient experiences, outcomes and recommended practices).
- Change (a before and after difference) and improvement (a change that results in better patient experiences and outcomes).
- A defined intervention and implementation (a defined intervention is a change that may or may not include a description of how it was implemented. Implementation is the action intended to achieve the before/after difference).
- Improvement and quality improvement, the latter being improvement made using effective types of changes and defined methods, and in a supportive context. Some quality improvement methods are used to implement changes proven elsewhere. Some quality improvement methods are used to analyse problems, design changes and implement them.
- Cost of a quality problem, the intervention cost to solve it, the savings or loss made, or extra income gained as a result of higher quality.
- Costs, spends and savings made by different stakeholders.
- Evidence of savings or loss: high certainty (E1), probable (E2), and no clear evidence (NE).

Other terms are defined in appendices 1 and 1b. The following model for improvement is used in this review (Øvretveit 2009a):

Evidence of an effective change + Effective implementation method + Supportive environment and infrastructure = Improved quality.

Chapter 3

Objectives, methods, and how the findings are presented

The primary purpose of this review was to find and present evidence of resources saved by health service providers that resulted from improved quality.

The objectives were to:

- find, assess and summarise the best evidence from research on the above subjects
- present the findings in an easy-to-understand way so as to be useable by practitioners, managers and policy makers to consider priorities for action or research, and by researchers to inform their studies of patient safety and quality
- comment on the research, including the limitations.

The methods and structure for the review were designed to provide the most efficient way to find and simply present the best research evidence to answer the review questions listed in the 'Introduction', within the constraints of time and costs set for the review.

Research into poor quality, patient safety, quality improvement, changes that improve quality and the economics of the subject can be found in many different refereed journals, publications and databases. A review was undertaken using the following search strategy and sources.

Some traditional systematic review principles were followed, but a more iterative method used in previous reviews of management research was applied because of the diversity of sources of evidence and research designs and the number of questions to be answered. Details of this method are described in Øvretveit 2003a, 2003b, 2005a,b, 2007 and 2009b.

The initial conceptualisation of terms discussed above formed part of the method for the review. It did this by limiting the search to including studies and evidence within the definitions but also noting how others had defined the terms and making adjustments, as well as noting other evidence relevant to the questions. An electronic search was undertaken during June 2009 of PubMed limited to research after 1999, for 'medical error' OR 'adverse events' AND 'strategy/strategies' AND 'cost/costs' (n=264 references) as well as for other research into the costs of poor quality and waste in healthcare using other search word combinations such as 'quality improvement' and 'costs', 'economics', 'finance', 'productivity' and 'business case'.

Some of this research had already been reviewed (Øvretveit 2004a, 2005b, 2007). These reviews were updated and extended to include research into the business case and productivity. In addition, relevant literature, which the author had collected since 1985, was brought together and then assessed for relevance to the question, yielding eight journal papers, five books and nine reports and relevant presentations from conferences.

The following terms are used in this review (full list in appendices 1 and 1b):

- poor quality, or imperfect quality, or quality deficiency: failure to conform to written authoritative quality and safety specifications or professional standards, or to meet the expectations of patients or purchasers
- patient safety: freedom from accidental injury or harm to patients as a result of healthcare activities meant to help them
- error: failure of a planned action to be completed as intended or use of the wrong plan to achieve an aim
- adverse event: undesired events, causing patients harm, not by the underlying disease, but as a consequence of examination, treatment or care or an unintended injury or complication which results in disability, death or prolonged hospital stay and is caused by healthcare management (rather than a patient's disease)
- adverse drug event: an injury resulting from medical intervention relating to a drug
- medication error: a mistake in writing prescriptions, dispensing or administering drugs (one type of adverse drug event).

The review concentrated on studies with valid and reliable evidence and those which were relevant to the review questions. In the absence of strong evidence, the most relevant studies were selected. The purpose of the review was to discover, summarise and give practical implications from research that was valid and reliable.

An initial overview of the literature showed few primary research studies on the cost of adverse events or poor quality, or that had estimated costs as part of a primary study on the quantity of adverse events. There were even fewer studies that had estimated the intervention costs of improvement activities and any savings made.

Excluding studies that did not use systematic health economics methods would have ruled out a considerable amount of research and relevant health service provider reports or business case estimates. Thus, costing studies that had not used rigorous health economic methods but were judged to meet acceptable standards of evidence for validity and reliability were also included.

Studies were excluded where the reviewer judged that:

- the conclusions did not follow from the empirical evidence (for example, lack of certainty that savings were caused by the improvement activity rather than something else or may have happened because of secular trends)
- the data gathering methods were invalid or unreliable.

Studies where no evidence was reported to support the propositions were only included where the discussion gave relevant hypotheses for testing or useful frameworks.

After assessment, some studies that did not meet the 'strength of evidence' criteria were retained because no other evidence was available and/or they had strong relevance to the questions. Examples were 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 adverse events, poor quality or costs, or did not include this subject)

- did not meet basic scientific criteria of evidence in this field
- did not engage in ‘significant’ conceptual analysis.

The exclusion criteria were thus not relevant to the questions, were speculative or were exhortative opinion literature that did not cite evidence. The material was then organised into evidence showing: high certainty of savings or loss; probable savings or loss; and no clear evidence of savings or loss, as described above.

This review was limited in the evidence it covered and in the sources it searched. There were relevant studies which were missed, especially about subjects that might not be defined as improvement changes, or some costing studies published in the business literature. A balance had to be struck between searching/summarising and providing synthesis and analysis, and continual redrafting to ensure that the material was organised and presented in an understandable and actionable way.

However, it is likely that most of the key studies and best available evidence were presented, drawing on the 2004 and 2007 comprehensive reviews and tracing referenced studies. If twice the time and budget were spent, probably only another 10 per cent more relevant studies would have been found, and it is possible they would not have changed the conclusions substantially.

3.1 How the research is presented to answer the questions

Five research questions form the main headings of the report, under which the evidence and research found in the search relevant to the questions are presented.

Most of the evidence is grouped in Part 2 and answers the following question, ‘For different health service providers, what are the costs of poor quality, the intervention costs, and are there any savings?’

The organising framework for presenting the selected studies is given below (there are overlaps between the cells of the table):

Interventions to patients or providers	Leading to adverse event	Leading to poor quality
Overuse	Some medications – for example, some antibiotics	Unnecessary tests
Misuse	Inappropriate anticoagulant prescription	Poorly designed computer systems, or treatments patients would not have wanted if they were fully informed
Underuse	Preventative treatments Interventions for hand hygiene	Interventions to improve communications
Under-coordination	Hospital doctor prescribes medication which conflicts with primary care doctors prescription causing ADE	Failure to pass critical information between services, or different services give patient conflicting information

A third dimension to this would be ‘savings’, shown as: likely in any service, probable, possible, unlikely.

Part 3 considers evidence and theories about what helps and hinders changes that reduce costs and improve quality. It answers the following questions:

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- What are the trade-offs, benefits and costs of quality improvement to different stakeholders?
- What are the barriers and solutions to investment in those improvements proven also to save costs and increase productivity?

Part 4 makes an assessment of the strengths, weaknesses and gaps in the research into quality costs and savings, and of the tools available to providers. It also considers the research into quality improvement and productivity.

PART 2: EVIDENCE ABOUT COSTS AND SAVINGS

The search found a growing body of research in healthcare which reports quality problems and quantifies the size of the problem. Most recent research is about adverse events to patients and failure to use effective treatments, rather than about other quality problems that may have less impact on clinical outcomes, such as poor patient experiences, long waiting times, or wasted personnel time and materials. Some research is over ten years old, much is from the USA, and may not represent the current situation in the UK. There is little research that has systematically assessed the costs of each quality problem, or the total costs to an organisation of different quality problems.

The following chapters report some of the research on the volume and costs of quality problems in general. They present research about the number of adverse events, which gives some indication of the possible high cost of poor quality in healthcare, and report studies that have costed poor quality before presenting the effectiveness and intervention costs of solutions.

Chapter 4

Evidence of poor quality and costs

This chapter presents research evidence about poor quality, which may or may not harm patients, then evidence about adverse events – by most definitions, caused by health services. Where the costs have been estimated, they are also presented, whether or not the cost is borne by the provider, purchaser or other stakeholder.

4.1 General studies of poor quality

4.1.1 Poor quality patient issues, dissatisfaction, complaints and negligence claims

Poor quality patient issues reported in the research include: patients failing to attend scheduled appointments; patients failing to continue treatment because of their dissatisfaction with the quality of the service; dissatisfied patients telling others about their experience, leading to lost referrals and income to a service, and to time used dealing with complaints.

If the complaints process does not lead to a peaceful outcome, then there may be court and compensation costs. One US health system calculated that the cost of unresolved patient complaints was \$4m a year for a service with 88,000 patient discharges. The costs of litigation, most of which are related to adverse events, are considered in section 4.2.

Other poor quality issues reported in the research, which represent waste, include: the time wasted due to patient records going missing; patients telling the same story to different personnel; test results which are not used because there is a delay in getting them to the ordering clinician; and delay in treatment due to late test results. Errors in cancer screening in the UK have led to many patients being recalled or re-tested, and high compensation for mistreatment or failure to treat. Other poor quality includes: illegible and incomplete prescriptions that take up technician, nurse and pharmacist time; hospitalisation of patients with diabetes, asthma and other chronic diseases who did not get preventive care; patient falls and pressure ulcers; wrong surgery and other adverse events, discussed further below.

4.1.2 Overuse, underuse, misuse and waste

Overuse, underuse and misuse of treatments sometimes result in adverse events, but this section considers the problem in general and the cost implications.

Wide variations in the utilisation of procedures have been found which suggest over-treatment in some areas of the USA (Chassin et al 1986). Sweden has half the rate of hip revisions (replacements) as any other country as a result of a database and research which found certain prostheses and cement fixation had reduced re-operation. More recently, the 'evidence-based medicine movement' has shown that many procedures continue to be used many years after research has found them to be ineffective. 'Appropriate' treatment is where the expected benefits are greater than the expected harm. Rand Corporation studies in the USA have estimated that 25 per cent of hospital days and clinical procedures were inappropriate, and 40 per cent of medications were unnecessary. The Royal College of Radiologists, London, estimated that 25 per cent of radiological procedures were not necessary.

A recent UK trial of patient-reported medical outcome questionnaires may also indicate possible overuse, or at least defensive medicine where there are potential cost savings, although the study is controversial. The study raised the question of whether surgical procedures were needed for patients reporting no problems before surgery, and for those with no change or worse after surgery for groin hernia, varicose veins, and hip and knee replacement (West 2009). Professor Nancy Devlin, the Office of Health Economics study director, is reported as saying, 'If a [primary care trust] is responsible for a budget and has a third of patients not reporting a problem before surgery, you have to wonder whether it is defensible.'

One systematic review of research into poor quality was found in the search (IOM 2000). This reported 73 studies with evidence of overuse, misuse and underuse of medical procedures, including underuse of influenza vaccine and beta blockers, overuse of antibiotics, and misuse of antidepressant medications. Flum and Koepsell (2002) estimated that 39,901 of the 261,134 appendectomies performed in the USA in 1997 were unnecessary (15.3 per cent); the total cost of these misdiagnosed cases could be \$741.5m annually.

A study by the US Juran Institute (2003) estimated costs of poor quality in the USA due to 'outmoded and inefficient medical procedures' to be \$390bn, or \$1,700 to \$2,000 per employee covered by insurance. These costs were estimated from data on 'unnecessary administrative activity' (the largest waste): overuse of hysterectomy, cardiac catheterisation, antibiotics, tranquilisers, sedatives, cardiac enderectomy, cardiac pacemakers, upper gastrointestinal endoscopy, and non-steroidal anti-inflammatory drugs; and from data on underuse of tests for patients with heart attacks, diabetes and congestive heart failure, flu and pneumonia vaccine, and screening tests for depression and breast cancer.

4.2 Adverse events and quality costs: general studies

4.2.1 General adverse events studies

The overall rate of adverse events ('avoidable', in most definitions) in studies of hospital patient records is reported to be between 3.8 per cent and 16.6 per cent: in the original study, in the USA, the rate was 3.8 per cent (Leape et al 1991); in the UK, 11.7 per cent (Vincent et al 2001); in Denmark, 9 per cent (Schioler et al 2001); in Australia, 16.6 per cent (Wilson et al 1995); in New Zealand, 12.9 per cent (Davies et al 2001); and in Canada, 7.5 per cent (Baker et al 2004).

One UK study found that 45 per cent of patients experienced some medical mismanagement and 17 per cent suffered errors that led to a longer hospital stay or more serious problems

(Andrews et al 1997). A review of research found, 'The reported rates of adverse events vary remarkably (0.0037–39.0 per cent) because of different detection methods used, the different definitions applied and different health care settings studied' (von Laue et al 2003).

The Agency for Healthcare Research and Quality (AHRQ 2000) study found that medical injuries in the USA during hospitalisation resulted in longer hospital stays, higher costs and a higher risk of death, with specific estimates of these waste categories for 18 of the 20 AHRQ Patient Safety Indicators. Excess length of stay due to adverse events ranged from no days for injury to a neonate, to 10.89 days for post-operative sepsis, and excess charges ranged from nothing for obstetric trauma (without vaginal instrumentation), to \$57,727 for post-operative sepsis. After post-operative sepsis, the second most serious event was post-operative wound dehiscence, with 9.42 extra days costing \$40,323 in excess charges. Infection due to medical care was associated with 9.58 extra days and \$38,656 in excess charges (Zhan and Miller 2003).

Most of the research is in and about adverse events in hospitals, and was undertaken in the USA. A New Zealand study found that 20 per cent of the adverse events identified from hospital record reviews occurred before admission to hospital (from the 12.9 per cent of all patients admitted) (Davies et al 2002). One study of adverse events after discharge found that 20 per cent of discharged medical patients experienced an adverse event within a month, 33 per cent of which were preventable (Forster et al 2003). One study estimated that 12 per cent of US nursing home residents (total 1.6 million) were receiving warfarin on a chronic basis and that adverse events related to warfarin therapy (primarily bleeds) were 'very common'. The study estimated that there were nearly 34,000 fatal, life-threatening, or serious adverse warfarin-related events per year (Gurwitz et al 2000, 2005).

A systematic search of studies for enhancing safety in primary care found 31 relevant articles (Wilson and Sheika 2002). Reported studies included: one finding a high number of diagnostic errors in a self-report study, and most often involving asthma, cancer, dermatological conditions, substance misuse and depression; one finding problems with 3 to 5 per cent of all primary care prescriptions and a third as 'major safety concerns'; one finding that 24 per cent of people over 65 living at home (21 per cent were in nursing homes) were prescribed a contraindicated drug; particular safety concerns for non-steroidal anti-inflammatory drugs, lithium, warfarin, corticosteroids and antidepressants; and one finding that 4 per cent of drugs dispensed by a pharmacy were incorrect. These are studies of error, which may or may not have resulted in a patient experiencing an adverse event.

As regards costings from these general studies, Vincent et al (2001) estimated an 8 per cent average increase in length of stay for patients who had experienced an adverse event, with a total cost of \$4.7bn (USD) to the Australian health system, and £1bn to the UK for increased length of stay. Double the latter figure (£2bn) was the estimate of a UK expert group for increased length of stay (DH 2000). The costings for the Dutch study found that over 3 per cent of all bed days were due to adverse events in 2004 (Hoonhout et al 2009). Rigby and Litt (2000) also used the data from an Australian study (Wilson et al 1995) together with data about costs from Australian disease-related groups. They concluded that 'the cost of just 12 preventable iatrogenic injuries is significant and accounts for two to three per cent of the annual budget of a 120-bed community hospital'. The study did not give predictions of possible savings because it did not calculate the costs of effective interventions. The injuries were (in ranking of frequency): wound infections; pressure sores; urinary tract infections; inadequate manipulation of fractures; pulmonary embolism; unnecessary operations; falls admitted; warfarin related; bleeding due to non-steroidal anti-inflammatory drugs; deep vein thrombosis; post-operative nausea and vomiting; and pneumothorax.

Costing estimates for all adverse events for New Zealand are reported in Brown et al (2002): each adverse event cost an average of \$NZ10,264 per patient, with a total cost of \$NZ870m

or 30 per cent of total public hospital expenditure, of which \$NZ590m was associated with a preventable adverse event. An Australian study found rates of adverse events at 6.9 per cent in hospitals with an average extra stay of ten days and extra costs of \$A6,826 (Ehsani et al 2006). Other estimates are given in Plowman et al (2001), Kirkland et al (1999), Vincent et al (2001), Johnson et al (1992) (adverse events in New York state), and Thomas et al (1999) (adverse events in Utah and Colorado).

As regards the costs of settled litigation claims, most of which are due to adverse events, the UK National Audit Office (2005) estimated costs to the NHS of £423m for 2003–04. The expected costs of outstanding claims for the same year were estimated as £2bn.

Potential savings for US hospitals by addressing the five most frequent adverse events can be deduced from Zhan and Friedman's (2006) study. At this time there were no penalties for adverse events, so the extra costs for Medicare patients were still paid when the hospital claimed for the extra treatment and longer stay. However, the study shows the extra payment does not cover the extra cost of the adverse events. The losses to the average provider after reimbursement under Medicare for the extra treatment for each of the following adverse events were: pressure ulcer \$2,400; post-operative sepsis \$16,000; post-operative embolism and deep vein thrombosis \$8,500; post-operative haemorrhage and haematoma \$6,000; and iatrogenic pneumothorax \$10,200 (see also HFMA 2006).

4.3 Categories of adverse events: potential savings

4.3.1 Hospital-acquired infections

A report by a parliamentary committee in the UK estimated that there were 100,000 cases of hospital-acquired infections in England, causing 5,000 deaths and costing £1.0bn a year. Estimates vary about how many could be prevented, from 15–30 per cent (HCPAC 2000).

4.3.2 Adverse drug events

Based on the literature, there was a strong consensus that errors around the administration of drugs were the most critical problem contributing to adverse events. These can result from any mix of incorrect writing of prescriptions by physicians, illegibility of the written orders, the prescribing of inappropriate meds, the incorrect interpretation/transcription of written orders by nurses, or the incorrect administration and documentation of the meds.

(Chief of Surgery at Toronto University Health Network, quoted in Anderson et al 2006)

In a study of 424 randomly selected visits to a hospital emergency department, 47 per cent resulted in the patient receiving a prescription for a medication (Beers et al 1990). In 10 per cent, the new medication could potentially harm the patient due to an avoidable drug–drug interaction. In all of these cases, a medication history had been recorded and was available to the prescribing physicians.

One of the strongest early studies assessed costs for 109 patients at one US hospital (Schneider et al 1995). Costs included extra laboratory tests and treatments, non-invasive procedures and invasive monitoring or procedures, increased length of stay, and intensive care. The mean cost varied from \$95 for additional laboratory tests to \$2,640 for intensive care. The next most costly outcomes were increased length of stay and invasive monitoring or procedures.

A US study of adverse drug events originally estimated that the cost to the hospital was \$2,000 per event and about \$3.8m per hospital per year, and that \$1m was preventable. A later study found that patients stayed an additional 2.2 days, with an increased cost of

\$3,244 per patient. The extrapolated costs would be \$2.8m a year for a 700-bed teaching hospital, notwithstanding the human cost (Bates et al 1997).

A probability model was used in one study to estimate the total cost of drug-related morbidity and mortality in the USA. The data input into the model came from 32 published studies and other sources (Johnson and Bootman 1995). The estimate was a total likely cost of \$76.6bn a year in ambulatory care (range of \$30.1bn to \$136.8bn).

Some of the best evidence in this field of research was provided by a matched case control study by Classen et al (1997). In the USA over the four years between 1990 and 1993, 2.43 adverse drug events per 100 admissions were discovered. Using regression analysis to control for all matching variables, the study reported an extra 1.91 days in hospital, with an increased cost of \$2,262 per person, as well as an increased risk of death, and for severe adverse drug events, the cost was \$3,634 (Classen et al 1997).

One of the most recent studies to make economic calculations found in the review used patient safety indicators to identify 'medical injuries' in 7.5 million discharge abstracts from 994 hospitals in 28 states in 2000 (Zhan and Miller 2003). Of these AHRQ indicators, post-operative sepsis was found to be the event leading to highest mortality (22 per cent of all mortalities), the longest extra stay (10.9 days) and the highest excess charges (\$57,700). The second most serious event was post-operative wound dehiscence (reopening of a surgical incision), (9.6 per cent of all mortalities, 9.4 extra days, and \$40,300 excess charges), and the third was 'selected infection due to medical care' (4.3 per cent of all mortalities, 9.6 extra days, and \$38,700 excess charges).

Medication errors, one type of adverse drug event, were reported in a study of 2–14 per cent of patients admitted to a sample of US hospitals (Leape 1994). Another study estimated that the average hospital administers one to two million prescriptions a year: 10 per cent of prescriptions contain errors, and account for 25 per cent of claims. One study found that 19 per cent of all adverse events were adverse drug events, 58 per cent were preventable, and 28 per cent were due to negligence. According to this study, antimicrobial drugs were the class of agents most commonly associated with adverse drug events (Wilf-Miron et al 2003).

As with other adverse events, non-hospital evidence is scarce. One review of research into inappropriate prescribing for older people found 11 studies (Liu and Christensen 2002). Either observational or claims data methods were used, revealing a rate of inappropriate prescribing from a high of 40 per cent (for nursing home residents) to 21 per cent (for patients in their own homes aged over 65). No research was reported in this paper which costed the consequences of inappropriate prescribing. However, one study was found which estimated the cost of wasted medications in an outpatient population of older people (n=73) (Morgan 2001). The study found an average waste cost of \$30.

Overall estimates made by Gurwitz et al (2000, 2005) were of 1.9 million adverse drug events per year in the 1.6 million US nursing home residents (40 per cent of which were preventable) and 86,000 life-threatening or fatal adverse drug events (70 per cent of which were preventable). Another study estimated that 20 per cent of preventable adverse drug events among elderly patients in ambulatory settings are due to patient-related errors, including problems with medication adherence (Forster et al 2003). Many of these incidents of poor quality may be caused by communication and coordination failures, considered later.

4.3.3 Adverse events associated with surgery

The earliest empirical research study found in the review which costed adverse events is Couch et al (1981). Thirty-six adverse events were found in 5,612 surgical admissions over

one year in a US hospital, 11 of which caused death. The total costs associated with the 36 adverse events were estimated at \$1,732,432. A study in 1991 interviewed 794 patients experiencing adverse events in the Harvard Medical Practice Study in order to estimate the lifetime healthcare costs of the injury (Johnson et al 1992). The study estimated that the total costs of all adverse events in New York state would be \$21.4bn a year.

A US study used an observer's record, journals and other data to identify 'adverse events' in surgical care (Krizek 2000). It found that 46 per cent of patients experienced adverse events (2,183 errors, 21 per cent serious), 18 per cent experienced serious events ('potentially life or limb-threatening') and a 32-day stay average for serious error cases, compared to a normal 8.8 days.

The additional costs for surgical complications during or after major surgery were estimated in one study by using routine administrative data on 372,684 discharges from 404 Californian acute care hospitals (Kalish et al 1995). With one in-hospital complication for 10.8 per cent of patients the costs were estimated to be \$9,239 to \$30,896 from 5.4 to 13.5 extra days length of stay.

4.3.4 Pressure ulcers

One study found that pressure ulcers occurred in 4–10 per cent of patients admitted to a UK district hospital in 1991. Another study estimated that failure to prevent bed sores causes unnecessary suffering and costs a 600-bed hospital over \$1m every year (Øvretveit 2004a). The mean cost per US hospital admission for patients who developed a pressure ulcer in 1999 was reported to be \$37,288 (Allman 1999), giving a cost of \$2.2bn to \$3.6bn for acute care settings (Beckrich and Aronovitch 1999). Most cases are avoidable by regular turning and repositioning of the patient and by using special mattresses and covers for those at risk.

One study concludes that, given the high costs of this quality problem, and the relatively low-cost and effective remedies which could be implemented easily, it is likely that a hospital or health organisation could save considerable amounts of its annual budget with a programme to reduce pressure ulcers in hospitals by 50 per cent from current rates (Øvretveit 2004a).

4.3.5 Patient falls

One UK study estimated the costs associated with a patient fall which had resulted in a fractured neck of femur to be £11,452, from an extra cost per day of £234 for geriatric and rehabilitation care, and orthopaedic and theatre costs of £584 per day (Walsh and Antony 2009).

4.3.6 Adverse events associated with 'failure to rescue'

The most common adverse events are in-hospital cardiac or respiratory arrests, which could have been prevented by risk assessment, monitoring and timely action. Estimates vary, but some indication comes from studies of avoidable admissions to the ICU, which McQuillan et al (1998) found to be between 4.5 per cent and 41 per cent (see also Hillman et al 2001, Kause et al 2004, Goldhill 1999).

4.3.7 Communication and coordination failures

The most dangerous period for the patient is the handover between one clinical team and another.

(Professor Michael Thick, Clinical Director UK, Connecting for Health, IT programme, quoted in Carlisle 2009)

The most common cause of poor quality is failures in care communication and coordination, often due to failures in management systems to ensure this. This is evident from this reviewer's practical experience as a clinician and in leading and studying improvement since 1985, and from the Joint Commission analysis of sentinel events (JC 2007). These failures include many I have witnessed and grouped under communication with patients, between work-shifts, between professions, between internal services, and between care facilities and external services. But what is the research evidence?

There is no systematic review of all the above types of poor quality. Different studies attribute the cause of an adverse event differently and may or may not define the cause as communication or coordination failure. Full consideration of this subject was outside the scope of this review, but some key studies and their findings relevant to this review are described in Bodenheimer (2008).

4.3.8 Hospital discharge communications

Jones and Mitchell (2006) report one study by Bolton Hospital, which found 250 communication hand-offs between personnel to discharge one patient with complex care needs illustrated in the figure below:

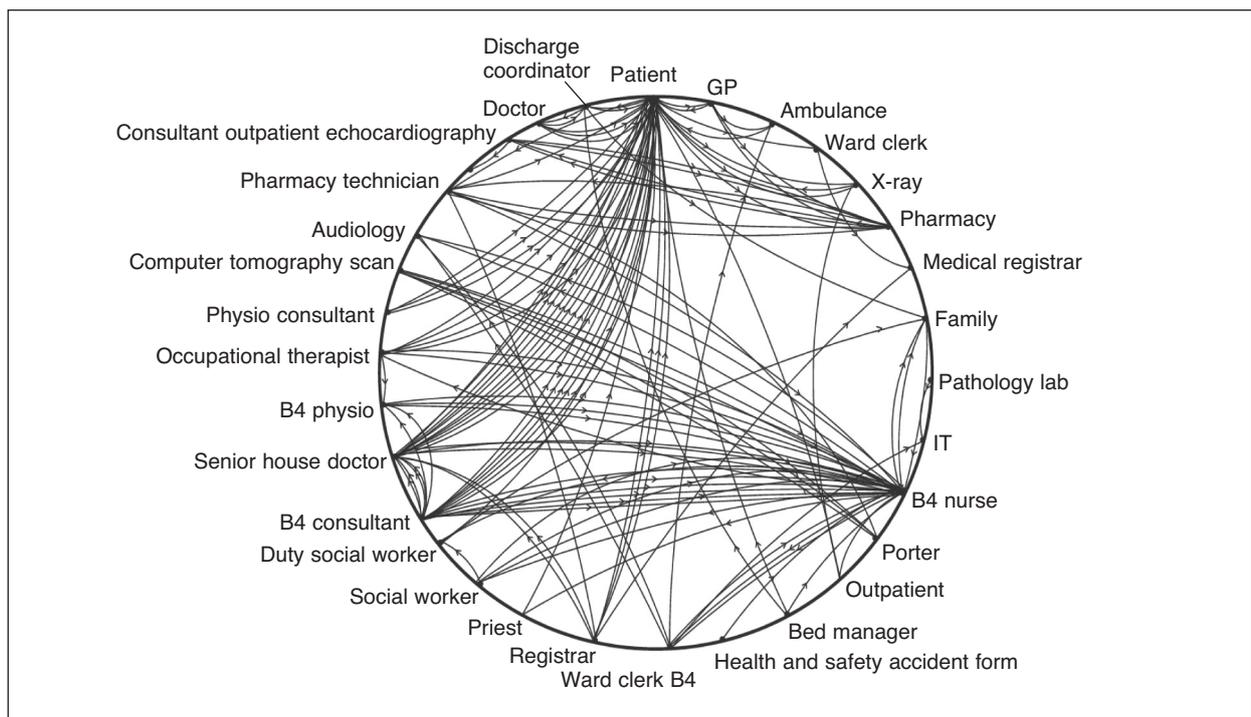


Figure 3: Communications hand-off between personnel to discharge one patient with complex care needs.

The 2007 NHS Alliance survey of 500 general practitioners (GPs) found that 70 per cent of GPs reported late discharge summaries 'often' or 'very often', and of these, 90 per cent reported that it 'compromised clinical care' and 68 per cent that it 'compromised patient safety'. One summary arrived 11 years late, and many were incorrect, illegible, with unknown

acronyms, and no patient name, diagnosis or changes in medication were noted. The 2008 survey was similar, but remarked specifically about the financial costs: 'One doctor estimates she spends half a day a week chasing up information from the hospitals which was not provided... further costs are incurred due to re-admissions.' Financial penalties are being introduced by purchasers for discharge summaries five or three days late (described later under 'trade-offs'), with some using the summary with coding information included as a proxy invoice.

One US study found that 59 per cent of surgical and medical residents reported one or more patients had been harmed during their most recent clinical rotation because of poor hand-offs, and 12 per cent reported that this harm had been major (relative risk 68 per cent of 238 surveyed). Thirty-seven per cent reported that one or more interruptions during the receipt of hand-offs occurred, either most of the time or always. The study notes that information was often missing, incomplete or inaccurate but that 'many best practice recommendations for hand-offs are not observed, although the extent to which improvement of these practices could reduce patient harm is not known' (Kitch et al 2008).

4.3.9 Other adverse events

Venous thromboembolism (VTE) occurs in 40–60 per cent of orthopaedic surgery patients, with the risk of pulmonary embolism in hip fracture surgery patients being 7.5 per cent, which can be fatal. It can be prevented with pre-surgical drug prophylaxis. Bullano et al (2005) found that post-discharge treatment of recurrent VTE cost on average \$12,000, mainly from the need for hospital re-admission, which was found to occur in 2.4 per cent of all hip and knee replacement patients. Up to 40 per cent of at-risk surgical patients were found not to receive guideline-recommended prophylaxis.

4.4 Conclusions: costs of poor quality and adverse events

There is strong evidence of a considerable volume of adverse events and poor quality, which includes failure to provide effective treatments. This represents potential savings to a health service or a health system. There is less evidence of their costs. There is little evidence of the rates of poor quality or resultant costs outside of hospitals, or due to poor quality transfers between services.

The highest costs for which there is evidence are for overuse of certain treatments and underuse of others, leading to higher cost care later, and for hospital-acquired infections, adverse drug events, complications in surgery, and hospital 'failure to rescue' before arrest or respiratory failure. There is probably a high cost of poor quality as a result of misdiagnosis and poor coordination and communication.

The following summarises the above research findings and estimates, showing some potential savings through improving quality.

US estimates are as follows:

- 15 per cent of appendectomies in 1997 were assessed as unnecessary (15.3 per cent), costing \$740m annually.
- 25 per cent of hospital days and clinical procedures are inappropriate and 40 per cent of medications unnecessary.
- 'Outmoded and inefficient medical procedures' cost \$390bn.
- There is likely to be a high cost of error in diagnosis and prescribing, especially outside of hospitals.

- Avoidable post-operative sepsis can cost up to \$57,700 per patient; reopening of a surgical incision \$40,300 excess charges and 'selected infection due to medical care' \$38,700.
- 10 per cent of prescriptions contain errors and account for 25 per cent of claims; 19 per cent of all adverse events are adverse drug events, and 58 per cent are preventable; 28 per cent were due to negligence.
- The cost to a hospital of each adverse drug event is \$2,000 per event and about \$3.8m per hospital per year (\$1m preventable). Another study found that adverse drug events cost \$3,244 per patient or \$2.8m a year for a 700-bed teaching hospital.
- There are 1.9 million adverse drug events per year in 1.6 million nursing home residents, 40 per cent preventable, and 86,000 life-threatening or fatal adverse drug events, 70 per cent preventable; 20 per cent of preventable adverse drug events in elderly patients occur in ambulatory settings.
- Inappropriate prescribing can be up to 40 per cent for nursing home residents and 21 per cent for patients in their own homes aged over 65.
- The cost of wasted medications in an outpatient population of older people (n=73) averages \$30 per prescription.
- The study reported 24 extra days stay for the 8 per cent of surgical patients who experienced 'serious error'.
- One in-hospital complication found in 10.8 per cent of patients costs between \$9,239 and \$30,896 for each.
- One hospital pressure ulcer on average cost \$37,288 in 1999 (nationally a cost of \$2.2bn to \$3.6bn).
- 73 studies give evidence of overuse, misuse and underuse of medical procedures, including: underuse of influenza vaccine and beta blockers; overuse of antibiotics; and misuse of antidepressant medications.

UK estimates are as follows:

- Hospital-acquired infection costs £1.0bn a year ('15–30 per cent preventable').
- 25 per cent of radiological procedures are unnecessary.
- One patient fall, causing a fractured neck of femur, costs £11,452.
- Pressure ulcers occurred in 4–10 per cent of patients admitted to a UK district hospital in 1991 (with an estimated cost in Sweden for a 600-bed hospital of over \$1m every year).
- The costs of adverse drug events are £0.6bn ('The problem is that nobody really knows the extent of the problem').

Chapter 5

Solutions: evidence of effectiveness of interventions to reduce poor quality, and their costs

5.1 Introduction

While there is growing evidence of the amount and cost of adverse events, this evidence is of little practical use unless there are effective interventions for reducing poor quality, or such interventions can be created. Many of these interventions were reviewed by AHRQ (2001) and Øvretveit (2007, 2009b). However, this review found few studies which had also estimated the costs of the interventions or the savings, and few estimates were based on empirical data.

5.1.1 'Reader alerts'

The presentation of the research below needs to be prefaced with the following.

The effectiveness and cost of a solution found at one study site does not predict effectiveness and cost elsewhere. Part 3 describes how implementation varies considerably and how this is influenced by context factors, such as experience with, and support for, improving quality.

The distinction between a 'before and after' change, and the implementation of the change, is important. Most of the studies reviewed concentrate on whether the change was effective for improving quality, and say little about how it was implemented.

Studies that do report savings sometimes do not include the cost of the intervention, do so in a questionable way, or do not give details of the calculation. More importantly, many such studies do not thoroughly assess quality: whether quality was maintained on a reasonable range, was measured or was reduced. Many 'savings' reports outside of scientifically refereed journals need to be assessed critically for whether and which intervention costs were included, and whether quality was also increased or maintained.

The findings about intervention costs and savings for providers are presented first for general improvements: any change that improves quality. Then evidence is considered for quality improvement falling within the Boaden (2008) definition.

5.2 General improvement: evidence of effectiveness and intervention costs

Defined broadly as any change that makes services better for patients, then some improvement has the potential to save money. Examples are changes such as more day cases, labour substitution or skill-mix changes, shifting services from hospital to primary care and some reconfigurations.

The ten high-impact changes proposed by the NHS Modernisation Agency (NHSMA 2004) include a mix of generic and quality improvement changes, and some uncosted claims about potential savings. The list also shows the 'mixing' typical in the literature of specific changes with methods or approaches to making a change:

- 1) Treating day surgery (rather than inpatient surgery) as the norm for elective surgery could release nearly half a million inpatient bed days each year.
- 2) Improving patient flow across the whole NHS by improving access to key diagnostic tests could save 25 million weeks of unnecessary patient waiting time.
- 3) Managing variation in patient discharge, thereby reducing length of stay, could release 10 per cent of total bed days for other activity.
- 4) Managing variation in the patient admission process could cut the 70,000 operations cancelled each year for non-clinical reasons by 40 per cent.
- 5) Avoiding unnecessary follow-ups for patients and providing necessary follow-ups in the right care setting could save half a million appointments in orthopaedics, ear, nose and throat, ophthalmology and dermatology.
- 6) Increasing the reliability of performing therapeutic interventions through a care bundle approach in critical care alone could release approximately 14,000 bed days by reducing length of stay.
- 7) Applying a systematic approach to care for people with long-term conditions could prevent a quarter of a million emergency admissions to hospital.
- 8) Improving patient access by reducing the number of queues could reduce the number of additional First Finished Consultant Episodes required to hit elective access targets by 165,000.
- 9) Optimising patient flow through service bottlenecks using process templates could free up 15–20 per cent of current capacity to address waiting times.
- 10) Redesigning and extending roles in line with efficient patient pathways to attract and retain an effective workforce could free up more than 1,500 whole-time equivalents of GP/consultant time, creating 80,000 extra patient interactions per week.

These are 'coulds', as in potential savings. The estimates are not arbitrary and are based on some evidence, but they are not certain. There is likely to be variation between services and, more importantly, they do not include the costs of the intervention.

Another example is the NHS Institute for Innovation and Improvement (NIII 2006) list, which overlaps with the above:

- 1) Reduce avoidable emergency admissions.
- 2) Reduce unnecessary outpatient appointments, follow-ups and 'do not attends'.

- 3) Avoid unnecessary procedures.
- 4) Improve day-case performance.
- 5) Reduce wasted bed days.
- 6) Improve the accuracy of clinical coding.
- 7) Reduce variation in length of stay.
- 8) Improve staff productivity.
- 9) Actively manage staff and recruitment costs.

These lists and the details in the literature illustrate some important points about the knowledge available to providers and others for choosing and making improvements to quality that save money. Savings depend on implementation effectiveness (which decides much of the intervention cost of the change). Implementation effectiveness will vary in different services, so each service will need to make their own assessment of costs and potential savings and monitor the effect of the change on different measures of quality.

5.2.1 Nurse staffing

Another general much discussed type of change, which could produce savings and increase quality, is better matching of nurse numbers and skills to patient needs, usually by increasing nurse to patient ratios. It is also an example of a change that reduces productivity as conventionally measured, but could increase productivity if quality rather than output-only measures are used. This general change is also noted here because of the theorised way in which this change might work: through better coordination and communication. Potentially this could also reduce waste and costs.

Pappas (2008) reports linking US hospital patient-level clinical and financial data to estimate that the cost per case of an adverse event was on average \$1,000, ranging from \$300 to \$2,400. She notes that the methods developed which could be used in any hospital could give nurse managers information to 'determine specific patient groups wherein increased costs of nurse staffing should be incurred to avoid the cost of an adverse event', and provide a business case for increased staffing. The methods made it possible to examine whether there was a relationship between an adverse event, nurse staffing, and the acute care cost per case of a hospital inpatient. The report found that the actual direct cost of an adverse event was \$1,029 per case for congestive heart failure, and \$903 for surgical cases. It reports that, 'There was a significant increase in the cost per case in medical patients with urinary tract infection and pressure ulcers and in surgical patients with urinary tract infection and pneumonia. The odds of pneumonia occurring in surgical patients decreased with additional registered nurse hours per patient day.'

Research by Needleman et al (2001, 2002, 2007) found an association between low hospital nurse staffing and quality of care. The study was based on an analysis of 6 million patient discharge records from 799 hospitals in 11 US states during 1997. The relationship between the amount of care provided by nurses, including registered nurses (RNs), licensed practical nurses (LPNs), and nurses' aides, and patient outcomes were studied, controlling for patients' risk and mix. Patients at hospitals with a lower proportion of RNs had significantly higher rates of six complications (longer hospital stays, higher rates of urinary tract infections, pneumonia, shock/cardiac arrest, upper gastrointestinal bleeding, and failure to rescue) when compared with patients in hospitals that had more RNs. Among surgical patients, low RN staffing correlated with increased rates of failure to rescue and urinary tract infections.

Hospitals with high RN staffing had lengths of stay that were 3–5 per cent shorter, and complication rates 2–9 per cent lower than hospitals with low RN staffing. RN staffing appeared to have a greater impact on quality of care than did staffing by LPNs or aides,

positions that require less training and education. The study found no association between outcomes and staffing by LPNs or aides. Three scenarios for increased nurse staffing were estimated to reduce adverse outcomes, hospital days and deaths to varying degrees. Increasing the proportion of care hours provided by RNs offered the greatest potential cost savings, because the costs of changing the RN/LPN mix without changing total nursing hours is relatively low.

One paper provides theory of how extra nurse staffing may work to increase safety and suggests how extra nurse staffing should be targeted for maximum impact: to focus the extra nurse time on coordination (Mitchell 2006). This is considered later in section 5.2.5 under communications and coordination solutions.

5.2.2 Intensive care

One set of solutions avoid the need for admission to an ICU – for example, preventing infections that cannot be treated on the ward. Here, we note solutions to poor quality which occur in ICUs. Intensive care accounts for nearly 30 per cent of acute hospital costs or, in the USA, \$180bn annually. Studies have found that: almost every ICU patient suffers a preventable adverse event; staffing ICUs with intensivists (specialists) can reduce hospital mortality by 30 per cent (one of the three ‘leapfrog group’ standards); and this could save 162,000 lives if implemented in non-rural US hospitals (Pronovost et al 1999).

This intervention was estimated in one report to reduce risks of hospital mortality by 10 per cent (Birkmeyer 2001). Pronovost et al (2001) estimate that a 12 ICU-bed hospital would save over \$2m annually with this intervention, while an 18 ICU-bed hospital would save \$3.5m (without counting training costs).

As regards who would benefit financially, if hospitals are paid on a per day rate, then funders would save money from this intervention. But if paid a case-based rate (for example, Medicare in the USA), then hospitals would make the savings in the USA. In both cases, reduced ICU length of stay could result in increased hospital revenue.

5.2.3 Interventions to reduce adverse drug events

There are a number of solutions to reduce adverse drug events, including communications improvements. Some have been assessed for effectiveness, but only a few have been costed. Some of the computer-based solutions are noted presently.

Classen et al (1997) reported excess costs to treat adverse drug events at one US hospital of \$4,483,000 over the four years covered by the study. The annual savings from reducing adverse drug events at the study hospital were estimated to be more than \$500,000. Extended to all US hospitals, the estimated annual marginal treatment costs for moderate and severe adverse drug events were \$79bn.

The research reported a number of examples of the effective use of automation to reduce quality problems and adverse events. Automatic drug dispensing is effective and likely to be cost effective. Gebhart (1999) reports a 70 per cent reduction in medication errors in US Veterans Health Administration facilities using a low-cost hand-held wireless bar coding system.

5.2.4 Computer solutions

Computer solutions are a good example of a group of changes that can improve quality and reduce costs, but the choice of system and implementation effectiveness is critical to whether

the change achieves this. They are costly to implement; the intervention is not, for example, 'computer clinical decision support', but one particular type of system implemented in one way, in one place at one time. The potential is great for improving productivity and quality in a labour- and communications-intensive industry. Some computer solutions can impact multiple problems (they are interventions providing organisational support for quality). For example, electronic medical records can reduce adverse drug events and other adverse events that result from miscommunication or late communications between providers and, by providing quickly accessible patient histories, can also improve quality of diagnosis.

Birkmeyer and Dimick (2004) estimate that a computerised physician order entry system in which doctors write all drug orders online could reduce adverse drug events by 55 per cent. Grandville et al (2006) estimate a 62 per cent reduction. A study with reliable evidence reports the results from introducing this system (Bates 1998). Medication errors were audited before and after the introduction, using the three adverse drug event data collection methods noted above, in a US teaching hospital. Use of the system prevented more than half of the serious medication errors. There were 11 per 1,000 patient days at baseline, and under 5 per 1,000 patient days during use of the system. The number of potential errors, which had not been intercepted, fell by 84 per cent and the number of preventable errors fell by 17 per cent.

The study showed that the cost of the system for teaching hospitals would be about the same as the savings. But when other costs, like extra work caused by serious drug events or malpractice litigation, were included, it could save \$5m to \$10m a year.

One study reports a different intervention to reduce adverse drug events, again in a US teaching hospital (Raschke et al 1998). This was a modification to a system, so that if circumstances arose where an adverse drug event might occur (digoxin toxicity was one example), then a pharmacist or radiologist was alerted. If necessary, the physician attending the patient was contacted. The study reports 1,116 alerts for 9,306 non-obstetric admissions. Of these, 53 per cent were true potential adverse drug events which would not have been discovered. Physicians needed to be contacted 794 times, and 596 times the event had not been recognised. The average time taken for each contact was 15 minutes. The rates of clinically unrecognised events varied for different clinical circumstances. For instance, more than half of the potential problems for renal toxicity with the use of radio contrast media had been previously recognised, but it was felt that potential benefit outweighed potential harm. Using literature data on costs, the report calculated that the potential saving in a 650-bed hospital was \$3m a year, and could be more if the system were extended to other areas.

These two are the few studies with reliable evidence. They report different interventions to reduce adverse drug events. One depends on putting systems in place to stop mistakes happening. The other depends on real-time interventions to stop mistakes when they happen. Both were effective for reducing medication errors, and would improve patient care and costs.

Computer clinical decision support systems

A systematic review of computer-based clinical decision support systems also provides evidence of the effectiveness of these systems for reducing errors, but none of the studies show reliable costings. Hunt et al (1998) and Wilson and Sheika (2002) also report that computer systems in primary healthcare could reduce errors because they can show drug interactions and use patient histories to highlight contraindications, and show some evidence of this, but no costing is provided.

Studies describe computer-based decision support to improve inpatient antibiotic prescribing. One early study reported fewer doses and fewer antibiotics per regimen, with antibiotic costs reduced by \$81 per patient treated, from 24.8 per cent of total pharmacy medication costs to

12.9 per cent of total pharmacy medication costs, and from \$987,550 to \$612,500 total expense (in 1988 dollars) (Pestotnik et al 1990, 1996, also Evans et al 1991, 1993, 1998).

A systematic review of interventions using computerised advice on drug dosage in hospitals for a limited range of medications (theophylline, warfarin, heparin, aminoglycosides, nitroprusside, lignocaine, oxytocin, fentanyl and midazolam) was carried out by Walton (2002). Fifteen studies of varying quality using interventions involving doctors were reviewed. The conclusions were that computer support for drug dosage gave significant benefits, shortening the time to achieve therapeutic control, reducing toxic drug levels, reducing adverse reactions by 6 per cent, and reducing hospital stay. It also noted higher doses of drugs with computer support systems, but no costing data were reported.

One of the latest systematic reviews of computerised physician order entry and clinical decision support systems looked at the effects of these interventions on medication error rates (Kaushal et al 2003). The review reported five adequate (but not perfect) studies of computerised physician order entry, two showing a decrease in the serious medication error rate, one an improvement in corollary orders, one an improvement in prescribing behaviour, and one an improvement in nephrotoxic drug dose and frequency. Of seven adequate studies of clinical decision support systems, three showed significant improvements in antibiotic-associated medication errors or adverse drug events, and one an improvement in theophylline-associated medication errors. No studies made reliable costing estimates.

As regards costs and savings of hospital-wide strategies, one computerised physician order entry implementation was reported by implementers at Toronto University Health Network over three hospital sites, the total costs of which were reported to be \$C5m (\$C4m capital costs) over five years. No estimate of whether savings were made are reported, while the uncosted benefits are not described.

Birkmeyer and Dimick (2004) report that costs are high and a barrier to computerised physician order entry implementation at many hospitals. Estimates range from \$0.5m to \$15m per hospital, with recurring annual operational costs ranging from \$0.2m to \$2m. Potential savings from fewer medication errors and adverse drug events are estimated to be between \$0.18m and \$0.9m per year, depending on hospital size, with other potential savings from such as medication substitution, reduced laboratory testing and imaging, increased use of clinical pathways, and gains in clinician efficiency. Birkmeyer et al (2002) report that some hospitals estimate annual savings from the implementation of a computerised physician order entry of \$5m.

A review of tele-rehabilitation interventions in the community (neurological rehabilitation, cardiac rehabilitation, follow-up of individuals with spinal cord injuries, rehabilitation for speech-language impairments) found that outcomes were improved compared to alternative interventions. Clinical process outcomes, such as attendance and compliance, were high with tele-rehabilitation, although few comparisons were made to alternative interventions. Consultation times were longer and satisfaction was consistently high, although it was higher for patients than therapists. Few studies examined healthcare utilisation measures and those that did reported mixed findings about adverse events, use of emergency rooms and doctor visits. Only five of the studies examined costs. This review shows some early evidence of potential cost savings for the provider (Kairy et al 2009).

5.2.5 Improvements to communication and coordination: effectiveness

Mitchell (2006) describes coordination as being the most important contribution of nurses to patient safety. She suggests this 'integrative function' is probably 'a component of the oft-repeated finding that richer staffing (greater percentage of registered nurses to other nursing

staff) is associated with fewer complications and lower mortality' (for example, the Tourangeau et al (2006) review). Mitchell proposes that the mechanism of this association is not shown in correlational studies, but that it may work through the role of professional nurses in integrating care (which includes interception of errors by others), as well as in monitoring and surveillance, which identifies hazards and patient deterioration before they become errors and adverse events. This idea is elaborated further in Mitchell and Lang (2004), but there is no evidence of the effectiveness of extra nurse staffing for patient safety being higher if the extra staffing time is focused on coordination, or whether other methods and systems are more cost effective separately, or in combination.

Communication improvements

Improvement solutions have been designed for hand-overs, hand-offs, transfers and transitions in care, which often mean the same thing, although the latter two usually refer to movement of patients as well as provider responsibility, and the former two often refer to responsibility for hand-over only.

Coordination improvements

Older patients with fractures often have other medical problems at the same time, which complicates treatment and requires a number of specialists to communicate and coordinate care. In the UK, Bolton Hospitals Trust used a Toyota-inspired work team or 'cell' concept to create a physically separate trauma unit and team combining geriatricians, orthopaedic surgeons, internal medicine specialists and other clinical specialists (Fillingham, 2008). The project then created standardised processes for the hand-offs between each team member so that issues are identified and addressed as and when they need to be, regardless of who is present. The study reports that early indications suggest that post-operative mortality rates for fractured hips halved as a result.

5.2.6 Other interventions

Only those with cost evidence, or that are otherwise relevant to the review questions, are noted here.

Electronic medical record systems in US primary healthcare

Wang (1998) carried out a cost-benefit study of electronic medical record systems in ambulatory primary care settings (also Wang et al 2003). The estimated financial benefit from using an electronic medical record for a five-year period was \$86,400 per provider. The benefits quantified in the study were savings in drug expenditures, improved utilisation of radiology tests, better capture of charges and decreased billing errors, rather than any impact of adverse events on patient outcomes.

Pharmacist participation on medical rounds

Leape et al (1999) evaluated pharmacist participation on medical rounds in the ICU of one US hospital in terms of reducing preventable adverse drug events caused by ordering errors. The error rate was 3/75 in the intervention group and 8/75 in the control group, a risk ratio of 0.38 ($p < 0.001$), showing that this simple intervention could reduce error rates by approximately 60 per cent. However, this intervention was not costed.

Fall prevention

Chang et al (2004) reviewed 40 randomised controlled trials and concluded that effective interventions for preventing falls were multifactorial falls risk assessment and a falls management programme (11.8 fewer falls in treatment group per 100 patients per month). The review does not make clear whether this was an in-hospital programme or not. The study recommended targeting those with a history of falls, but no estimates of the cost of the programmes were reported. No research was found in the search that has estimated the costs of falls interventions.

Intensive care unit interventions

Clemmer et al (1998, 1999) reported severity-adjusted cost reduction of more than \$2.5m per year (in 1991 dollars), or about 30 per cent of total patient care costs were reported as a result of one collaborative in ICUs through improvements to glucose control, use of enteral feeding, antibiotic use, acute respiratory distress syndrome survival, laboratory use, blood gas use, radiograph use, and appropriate use of sedation.

Young et al (1998) report an improved multidisciplinary approach on caring for ventilator-dependent patients, which reduced risk-adjusted cost per case by more than \$20,000 for patients managed on a mechanical ventilator for more than 72 hours in a medical ICU, with annual savings at the study hospital of \$2.5m.

Behavioural, educational, informational and management interventions for reducing adverse events

A systematic review of research into behavioural, educational, informational and management interventions for reducing adverse events was carried out by Ioannidis and Lau (2001). Of the 13 trials included, the review found large variations in patient populations, study setting, definition of errors, and interventions, which made synthesis difficult. It reported interventions found to be effective in 9 of the 13 studies, and evidence of harm or no significant difference in four studies. The review commented on the limitations of the research: a lack of evidence that could be generalised from specific settings to other settings; sub-optimal randomisation methods leaving room for potential bias; the lack of established connection between the medical errors observed and any consequent harm or health consequences; and the lack of evidence of costs or cost effectiveness.

Avoidable re-admissions

A number of interventions to reduce hospital admissions have been developed and tested, and some of these also show improvements in the quality of care for patients. One set of interventions which does both are nurse-led and team-post-hospital interventions for congestive heart failure. Seven of the eight randomised controlled trials which reported cost data saved money. Re-admission rates in the studies decreased by between 22 per cent and 45 per cent (McAlister et al 2001, Rich et al 1995, 2001). But US studies later showed that these interventions are not cost effective for all patients with congestive heart failure (CBO 2004, DeBusk 2004). Those that reduce costs are started before or soon after discharge, focusing on high-risk patients, and include face-to-face encounters with nurse care managers rather than telephone-only contact (Wagner 2004). But, as noted later in this review, these reduce hospital income in the USA and usually do not result in provider savings.

Large-scale quality programmes: improvement to depression care

One of the few detailed intervention cost studies of a large-scale quality improvement programme is by Liu et al (2008). This study estimated the intervention costs of a depression care quality improvement programme in the US public Veterans Health Administration (VHA) system. They considered all activities, including time spent reading email and holding conference calls, payments to participants, and time of the technical support. The cost of implementation was \$100,000 per region for each of three regions; 85 per cent of these quality improvement costs were for preparation and design. A third of the costs were on integration of the programme into the VHA's electronic health record system and the addition of the new model into standard policies and culture was also costly. The savings were not estimated. Also, the report was not able to assess whether intervention costs would be less as it was spread to other regions.

Other intervention cost reports for large-scale programmes include a similar depression quality improvement programme in Kaiser Permanente, which spent \$166,503 on improvement design and implementation in three practices (Rubenstein et al 1995, 2002). The Institute for Healthcare Improvement estimates of costs for breakthrough collaboratives from an evaluation of three on congestive heart failure or diabetes (Cretin et al 2004) ranged from \$81,000 per organisation to \$148,000. In a similar depression collaborative, six privately funded organisations paid \$12,500 each to participate (Meredith et al 2006).

One study did report estimates of potential costs and savings to the NHS of three improvements, but the costs and savings to providers were not reported (Bevan et al 2007). This study is noted here because it used two measures to estimate the value of improvement benefits and gains in NHS productivity: quality-adjusted life years (QALYs) (valued at \$30,000 each) and the value of a statistical life (£1m).

Improving prescribing statins: NHS intervention costs £500m (direct costs) and £55m (net costs) annually. Savings £15bn from 'avoidable' deaths and £6bn from QALYs gained.

Intensive glucose control: NHS intervention cost £250m, less than the monetary value of the benefits and 'likely to worsen NHS productivity if introduced to all diabetic patients in the short term (with net annual loss of £300m)'. But this would improve NHS productivity in the long term if introduced at early onset (annual gain of £250m).

National Suicide Prevention Strategy (NSPS): intervention cost £20m annually (but 'minimal impact'), savings £700m from 'avoidable' deaths, £300m from QALYs gained. 'While this would improve NHS productivity, it would not have a significant impact.'

5.3 Quality improvement interventions: evidence of effectiveness and intervention costs

The review now turns from the studies of interventions that improved quality and considered costs, to studies of interventions classified as 'quality improvement' and cost information about these.

The review used Boaden et al's (2008) definition of quality improvement as including the PDSA cycle, statistical process control, Six Sigma, Lean, theory of constraints and mass customisation, but also the approaches traditionally reported and accepted as quality improvement, which are total quality management and continuous quality improvement (Øvretveit 1992, 2003).

5.3.1 Total quality management

The earliest estimate for a quality improvement intervention found in the search was described in a report of an Australian clinical chemistry laboratory using a major total quality improvement programme. The study reports turning a trend of 16 quarters of increasing expenditure into 8 consecutive quarters of declining expenditure. The costs reported include those associated with: increasing the percentage of staff salaries spent on training from 1 per cent to 6 per cent; a decrease in staff turnover from 8 per cent to 1 per cent; lower cost per specimen than comparable laboratories; and a 17-fold sustained reduction in incorrectly addressed test reports (Banning et al 1993).

Berte and Nevalainen (1997) report a number of clinical support service examples but do not give details of the methods used to calculate the costs or describe interventions. They report one European blood centre reducing its 'cost of wastage' of blood bags by 13.4 per cent over two years, using a mix of quality improvement interventions (not reported). The cost of non-conforming units (blood bags) in the first year was found to be 8.6 per cent of the centre's operations expenditure, compared to 7.6 per cent in year two.

5.3.2 Continuous quality improvement projects

Another early study, by the US Mayo Clinic, reported a team continuous quality improvement project that saved \$473,000 a year by reducing practice variations in peripheral bypass surgery. Patient length of stay was also reduced by 44 per cent in another project for patients undergoing carotid endarterectomy (Mayo Alumni 1995). Reductions in post-surgical complications and shorter length of stay were reported by a team that developed and applied guidelines to identify at-risk patients and reduced risk factors in pre-, intra- and post-operative phases (Burton 1995). Guidelines are a common intervention to improve quality, but there are different reports of the effectiveness of specific guideline interventions. Haycox and Bagust (1999) report some of the hidden costs. Guideline interventions were not classified by Boaden et al (2008) as quality improvement and similarly this review considered these as one of the generic interventions.

James and Baley (2006) report evidence from a quasi-experimental controlled comparative study of continuous quality improvement projects that successfully introduced a best practice guideline for community-acquired pneumonia. This care process model reduced complication rates from 15.3 per cent to 11.6 per cent and costs to \$572 per case (11.9 per cent drop in cost per case). The intervention cost of the project was not reported but it was noted that the income payment dropped by 16.9 per cent (\$894) per case, and savings flowed back to purchasers. The reason was the extra reimbursement to pay for the patients' treatment resulting from complications which were avoidable by using the new guidelines.

One study of savings of a standard set of interventions for ventilator-associated pneumonia using continuous quality improvement methods found 400 fewer hospital days, reduced unreimbursed cost of care by \$442,789, reduced hospital costs by \$2,353,222, and reduced cost to payers by \$2,653,710 for the financial years 2006 and 2007 combined (Brilli et al 2008). However, as with most studies, the costs of the intervention were not well estimated.

A Norwegian study, which estimated the intervention cost of the solution using the cost, spend, save model, reported savings from a continuous quality improvement project to reduce operating room cancellations and delays as \$62,000 for the first year, and \$160,000 for future years if the 50 per cent reduction achieved could be sustained at no cost (Øvretveit 2000).

One Swedish study of five continuous quality improvement projects using the cost, spend, save model on routine accounting data reported the following savings. The potential savings from improving coordinated care planning before discharge in a geriatric unit were estimated

by one team to be £103,541 in the first year (2006). The estimate of savings for the review of medications intervention in one home for older people was £14,633 (£73 per patient per year, the first year). The estimate of savings made through reducing sphincter injury in delivery from 5.3 to 3.9 per cent was £23,912 (2006) and £65,283 (2007). The estimate of savings for the emergency unit patient vital signs assessment was between £71,329 and £631,727 in the first year, depending on accounting assumptions (Øvretveit and Granberg 2006).

Improvements to clinical processes were reported to reduce deep surgical wound infections by Classen et al (1992) and James (1993). Cost savings of more than \$700,000 per year were reported as a result of reducing deep surgical wound infection rates from 1.8 per cent to 0.4 per cent in a continuous quality improvement project.

5.3.3 Plan-Do-Study-Act cycle

Both PDSA and statistical process control, discussed below, are methods used as part of other approaches. Their effectiveness and costs depend on how they are used and are difficult to separate from other aspects of the approach in question (for example, as part of a breakthrough collaborative or a continuous quality improvement project within a breakthrough programme or as a stand-alone project). Boaden et al (2008) do not present evidence of outcomes or costing for use of this method but do discuss its use in the context of breakthrough collaboratives. The review concludes that 'there is little evidence (to date) to suggest it is more cost-effective than any other approach'.

5.3.4 Statistical process control

The main evidence of the effectiveness of applications of this method was presented in a review by Thor et al (2007). This does not present evidence of costing but lists benefits as: improving communication between clinicians, managers and patients by providing a shared language; describing and quantifying variation; identifying areas for potential improvement; and assessing the impact of change interventions. Boaden et al (2008) conclude that:

Its application may be limited by the extent to which the objective of improvement is the reduction of variation, the complexity and appropriateness of data sets representing aggregations of different types of patients or management units and the implications on the underlying statistics of having very small or very large data sets.

5.3.5 Process redesign, re-engineering, and Lean manufacturing

Lean manufacturing concepts are similar to, and a development of, process and re-engineering concepts, but rely more on logistics concepts. The ideas have been interpreted and applied in healthcare in different ways. The aims are:

- to identify work in one service which differs in pace and process ('value streams') and separate and organise them into different flows
- better matching of demand to capacity, by smoothing the demand, developing flexibility to respond to unavoidable variation, and avoiding 'batching' (too much work in some areas and too little in others) (Womack and Jones 1998, 2007).

Lean concepts appear to allow the potential savings and sources of waste to be more clearly identified than other methods. Using waste identification methods based on Lean concepts, D'Angelo and Zarbo (2006) provide empirical data of the sources of waste, defects, misidentifications, and other opportunities arising in all phases of surgical pathology testing. They estimated that these misidentification defects for three weeks required 159 hours of manual re-work, or an annualised 1.3 full-time equivalent employees.

As regards effectiveness, intervention costs and savings, the evidence is sparse and mostly consists of reports from implementers. The search found other implementer evidence, including the experience of Flinders Medical Centre in Adelaide with Lean process redesign:

For the past three years we have been experimenting with the application of 'lean thinking' to care processes across our teaching general hospital...Over three years, we have halved the number of serious safety events that have had to be reported to our insurers, despite a substantial increase in the numbers of patients seeking care in our hospital. At the beginning of our lean thinking journey, our hospital was struggling to contain a deficit. In the last financial year, we were several million dollars in the black accomplished without extreme measures such as shedding staff. (Ben-Tovim 2007)

Some results from this programme were also published in a reviewed journal. Empirical evidence of some improvements, but no costing data, were presented. The emergency room (ER) applied these ideas to triage, separated physically and organised different work streams, for those needing admission and for those who could be treated and discharged quickly. Waiting times were reduced by 25 per cent and 41 per cent fewer were able to leave the ER without needing to see a doctor. Capacity was raised from 140 patients a day to between 180 and 210, using the same resources. The loss of nurses due to stress declined as well as serious adverse events (Ben-Tovim et al 2008). Bassham (2005) reported four to five less patients in the ER at any hour of the day (report from the Flinders website).

Similar ideas and time savings have been reported from using similar methods in the NHS Modernisation Agency's Emergency Service Collaborative (Jones and Mitchell 2006). Some project outcomes are reported in Boaden et al (2008), mostly implementer reports, including: Reinertsen (2006) reporting that patients contracting pneumonia while on a ventilator reduced from 40 to 2 per year, with costs reduced from \$1.6m to \$0.1m (intervention costs unclear); Miller (2005) reporting \$3.3m savings in 2004, including from reducing accounts receivable from 56 to 44 days in 2004, equating to about \$12m in cash flow (intervention costs unclear); Thompson et al (2003) recording that the preparation time for antibiotics reduced by four minutes per dose, with nurse savings of over 5,000 hours per year (no costings); and from the UK, pathology productivity improved by 252 per cent, with an estimated £365,000 annual savings, through earlier patient discharge, and delays in specimen reception reduced from 13 minutes to 1 minute (Westwood and Silvester 2007).

Boaden et al (2008) conclude that in healthcare there are 'numerous reports of the application of Lean but, as with Six Sigma, these are not comparative, independent or critical'.

5.3.6 Six Sigma

James et al (2007) and Savitz (2007) describe research into potential savings from projects using Six Sigma and the Toyota production system at Providence Health System, and from the Intermountain Healthcare advanced training programme.

At one hospital, 29,700 between-meal snacks were ordered and produced annually. Only 56 per cent ever reached the patient. Of the snacks delivered, 70 per cent were consumed. Overall only 39 per cent of all snacks produced were consumed by patients. Annualised waste was \$32,000.

A project reduced length of stay for hip fracture patients discharged to skilled nursing facilities, by assigning acute care managers and improving the timely removal of urinary catheters. Length of stay fell from 120 hours to 94 hours, a 21 per cent reduction.

A project reduced length of stay for stroke patients. Patients were discharged an average of 20 hours sooner if stroke pre-printed orders were used and a care manager reviewed their chart within 24 hours. Length of stay fell by 25 per cent from 78.9 to 58.6 hours.

Using the Toyota production system and Lean analysis, the research estimated that cost per hour per worker across all staffing groups was \$7.40 (low), \$13.20 (medium) and \$18.98 (high). The observations revealed that 35 per cent of clinical staff time was involved in direct patient care, and workers spent less than half of their time in value-adding operations. Non-operational activities were divided between clarifying (20 per cent), processing (19 per cent), and motion (17 per cent). Interruptions and location changes occurred at an average rate of 8 and 13 times per hour respectively (Wallace and Savitz 2007). The study found that the lowest cost of waste in caregiver activities for a 12-hour shift on one 46-bed medical unit (staffed with eight registered nurses, eight patient care technicians, two care managers, one social worker, one physical therapist, one pharmacist, one respiratory therapist, two clerks, and two hospitalists) was \$2,309 (12 hours × 26 workers × \$7.40 per hour); with an annual cost for the same unit of \$843,000 (\$2,309 × 365). They suggested that because of conservative assumptions, the figures underestimate the level of waste. The study concluded that waste was found in inefficient systems, there was a wide variability in work processes, and that a 'work around' culture existed.

In a 400-bed Dutch hospital, van den Heuvel et al (2006) reported total savings to the hospital of \$1.4m (2004) for an average saving of \$67,000 for each of the completed 21 projects using Six Sigma methods, but the study did not describe sufficiently how it estimated intervention costs.

Regarding the research they reviewed on Six Sigma, Boaden et al (2008) conclude that the evidence is descriptive, 'with no fundamental critique or examination of its effectiveness, or independent evaluation'.

5.3.7 Theory of constraints and mass customisation

The theory is that analysing where the bottlenecks are and placing those that are not easy to remove where they can best be managed can increase throughput and productivity. The entire value of the system is represented by what flows through the bottleneck so it needs to be operated at maximum throughput. The theory suggests that, for example, if the operating room is the bottleneck then lower ward occupancy will reduce costs by matching the ward to the theatre's throughput, even though some of the ward resources (heating, lighting, fixed staff costs, and so on) are wasted (Young et al 2004). No strong evidence of effectiveness and cost savings in healthcare was found in the search for this review, neither was any reported in the Boaden et al (2008) review, or for mass customisation.

5.3.8 What is a 'quality improvement intervention' and what is an 'intervention to improve quality'?

In this section presenting the evidence of effectiveness and costs of interventions that improve quality, we present one final study. This illustrates the arbitrariness of the above distinction on which this section of the review is structured, especially for multiple component interventions. Increasingly, quality methods are entering the mainstream, especially PDSA and process analysis. More services are using as their 'intervention' a variety of methods and changes that have face value. The following is an example of one intervention with savings implications that could be classified as a generic or a quality improvement intervention, albeit a multiple-component one.

The Magee-Womens Hospital of the University of Pittsburgh Medical Center used a number of methods to redesign care for patients undergoing hip and knee replacements. Medical students shadowed patients from the initial diagnostic visit, through surgery and the hospital stay to their return home. The improvement team then introduced changes to: perioperative

testing and teaching; group meetings to coach patients; pre-surgery discharge planning; complete pain management; and 'wellness' design in the orthopaedics unit.

The redesign was reported to have resulted in lower mortality and infection rates, 98 per cent compliance with recommended antibiotic administration (SCIP 2009), high patient satisfaction and a higher rate of patients being discharged directly to their homes without assistance. As regards costing, there are no reported data but the savings may be high as a result of the now lower length of stay for these patients of 2.8 days for total knee replacement (compared with a national average of 3.9 days) and 2.7 days for total hip replacement (compared with a national average of 5.0 days) (DiGioia 2007).

Chapter 6

Conclusions: savings to providers from improving quality

For different health service providers, what are the costs of poor quality, the intervention costs, and are there any savings?

For practical decisions about quality investments and actions, the size and cost of a quality problem is irrelevant if the costs of a solution are not known. To make economic decisions about investments and actions, estimates are needed of the cost and effectiveness of interventions, as well as the cost of the poor quality problems.

Similarly, for practical decisions about whether to use an intervention to improve quality, whether or not it is classified as a 'quality improvement', methods are not relevant. Thus this review considered research into interventions which had as their aim an improvement to the quality of the service, and also described the cost of the intervention. It reported findings for generic interventions and then 'quality improvement' interventions using specific methods defined by Boaden et al (2008), but there was considerable overlap. The review noted a trend to use some quality improvement methods to implement treatments and organisational changes found effective in research – for example, using PDSA to test changes to organisation to ensure correct antibiotic prophylaxis before surgery to reduce post-surgical infection.

Overall, the review found little strong evidence of the effectiveness of many interventions to reduce poor quality and even less about the costs of these interventions. Further, the costs and effectiveness of the solutions are likely to be context-specific, depending on the organisation's culture and other variables. This, in turn, affects the main intervention cost of the change: the time and effort of the implementation. Studies may not provide a good guide to what could be expected in non-study settings. The lack of evidence of the effectiveness and cost of interventions is a hindrance to investment planning to reduce the cost of poor quality, and especially evidence in different situations.

Those studies that do report savings sometimes do not include the cost of the intervention, do not give details of the calculation, or make it in a questionable way, and rarely use empirical real-time costing data. Additionally, none estimate the potential 'meta value added' of increased competence to carry out improvements as a result of the work.

More importantly, many such studies do not thoroughly assess quality: whether quality was maintained on a reasonable range of measures, or was reduced. Thus, with many 'savings' reports, apart from studies published in scientifically refereed health economic or medical journals, we need to question closely whether and which intervention costs were included and whether quality was increased or maintained. Few reports give evidence of sustained changes and sustained savings after two years, or of whether a change can be easily spread, and may be context-insensitive.

As regards financial data availability from operational systems, two different findings were reported. Martin et al (2009) reported difficulties finding and using these data from US hospital systems in their business case calculations, 'identifying... actual savings resulting from [quality improvement] projects... has proved very challenging; although hospitals often claim cost savings from such projects, it is rarely (if ever) possible to track the savings to a specific budget line item' (Martin et al 2009). In contrast, Øvretveit and Granberg (2006) and Øvretveit and Andreen Sachs (2005c) report no difficulties in obtaining data for costing estimates from Swedish systems. There are different explanations for these different reports.

There is little costing evidence and the evidence is not strong for providers, but some savings have been reported (which have taken account of the cost of the intervention and quality has been increased and maintained). The stronger evidence comes from the following studies:

- \$0.7m annual savings from reducing deep surgical wound infection rates from 1.8 per cent to 0.4 per cent in a continuous quality improvement project (Classen et al 1992, James 1993).
- \$0.47m annual savings from reducing practice variations in peripheral bypass surgery (Mayo Alumni 1995).
- \$2.5m annual savings, or about 30 per cent of total patient care costs, were reported as a result of one collaborative in ICUs (Clemmer et al 1998, 1999).
- \$2.4m annual savings, from \$20,000 reduced cost per case, in an ICU using an improved multidisciplinary approach for caring for ventilator-dependent patients (Young et al 1998).
- \$0.06m in the first year, and \$0.160m annual savings, after reduced operating room cancellations and delays in one 650-bed Norwegian hospital (Øvretveit 2000).
- \$0.01m to \$0.6m annual savings in five different continuous quality improvement projects in Sweden (Øvretveit and Granberg 2006).
- \$3.3m annual savings in a US health insurer's administrative processes using process improvement (Miller 2005).
- \$0.3m annual savings through earlier patient discharge and a reduction in delays in the pathology specimen reception reduced from 13 minutes to 1 minute (Westwood and Silvester 2007).

Not reported in a scientifically refereed journal:

- \$0.079m annual savings from process improvement to blood testing processes at Washington Hospital Center (DC) Laboratory (VMS 2004).
- \$1.2m annual savings over two years through reducing hospital-acquired infections in the University of Pennsylvania Medical Center (reported in Martin et al 2009).
- \$5.5m annual savings from reducing the time patients spent on ventilators in the ICU (Intermountain Healthcare, reported in Martin et al 2009).
- \$0.3m annual savings from reduced re-hospitalisation intervention in one Colorado health system.

PART 3: CHALLENGES AND ENABLERS TO SAVING BY IMPROVING QUALITY

Whether a provider saves or makes money from improving quality depends largely on the financial system and finance for investing in changes, and how well they choose and implement the change. The research and theories about this are considered in the next few chapters.

There are also context factors other than finance that are important, such as whether there are adequate measures of quality for deciding payment, and for other purposes. Context factors affect the choice of what to improve and the speed and completeness of implementation and sustainability. Different changes and implementation processes are affected differently by different context factors, and some are more influential at the start than later in the change. Through their effect on implementation, these factors affect the cost of implementation and also make it more difficult to predict savings, which is why general statements about savings are only very rough guides. These context factors are considered in chapter 8.

This section concludes by drawing on the evidence and the analysis below to suggest financial and other changes needed to enable and support improvements to quality that could also make savings.

Chapter 7

The financial issues

This chapter presents the empirical research and the analysis carried out by this review to answer the question:

- What are the trade-offs, benefits and costs of quality improvement to different stakeholders?

It focuses on the financial aspects of the answer to this question.

An analysis of research and the author's experience working with this subject suggests there are features of the finance system for providers which shape who bears the costs and savings of improvement. These features are: the routine payment system (revenue), special payments or penalties for actions to improve quality or their results, and availability of investment finance.

7.1 Features of finance systems

7.1.1 Routine service payment schemes

Many service payments are for services that caused poor quality, which is avoidable on the part of the provider. Examples are some readmissions, some emergency admissions for chronic diabetes or asthma, and some longer stays due to infections, surgical complications or for failure to use effective treatments.

Fee per patient, per health/diagnostic resource group or fee for service methods give more incentives than block funding to increase service productivity, and there is evidence supporting this. However, increased productivity can occur at the expense of quality, if quality is not in the productivity measure or managed by purchasers – for example, by refusing to reimburse some treatments. Thus such methods can give incentives to provide ineffective or unsafe treatments and can reward poor quality through extra payment for readmission or re-treatment, if there is no assessment of quality related to the payment.

7.1.2 Penalties

Penalty fines have been introduced locally and nationally in the UK. There is a nationally mandated fine for a hospital failing to meet *Clostridium difficile* targets of £12m. One UK

hospital was reported to be at risk of paying £20m in fines for failing to meet national and local infection standards (Santry 2009). These penalties can lead to improvements that also increase productivity and reduce waste.

7.1.3 Incentives

There are financial incentives for improving patient-perceived quality. One is the increased income or loss of payment to a provider if the patient chooses another service and if patients have a choice and are prepared and informed to exercise it.

A more direct incentive for quality and NHS productivity, which is arguably a service payment scheme, is the UK Quality and Outcomes Framework (QOF) of incentives for GPs. Since 2004 about 20 per cent of the GP's or group practice income depends on achieving these standards. There are different views about whether the scheme has really improved care for patients, but it has improved clinical data recording.

There are direct incentives in the USA through payments to adopt certain practices or IT systems that are quality related. The purchasers in the USA 'leapfrog group' introduced measures for quality of care and the efficiency with which hospitals use resources in five clinical areas: coronary artery bypass graft, percutaneous coronary intervention, acute myocardial infarction, community-acquired pneumonia, and deliveries/newborn care. Hospitals are scored and, if they demonstrate sustained excellence or improvement, they may get financial rewards and more contracts and gain market share. In the original federal medicine quality payment scheme on which the Leapfrog groups scheme is based, the quality measures are used in treatment of heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacements. Hospitals in the top 10 per cent get a 2 per cent bonus of their Medicare payments for the measured condition, while hospitals in the second 10 per cent get a 1 per cent bonus. More details are given in the review in appendix 2.

All the above influence whether a provider gains or loses money from improving quality directly or indirectly. In this review, no strong evidence was found from research about whether the schemes improved quality or productivity. The general conclusion in the literature is that there is some evidence that, in some circumstances, quality-based purchasing and finance systems increase quality, 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 cost of achieving the performance goal compared to the increase in revenue from the incentive. A review of 'quality-based purchasing' confirms this: there is limited evidence of the effect of incentives or penalties for physicians, medical groups or hospitals for patient safety or quality (Dudley et al 2004).

7.2 Costs and savings

Whether savings are made depends in part on how many resources are used to achieve the change, and whether the new behaviour or organisation consumes more resources than the old.

Who makes the savings depends on who bears the cost of the poor quality and the intervention cost to reduce the poor quality. If an intervention or method is cost effective then the critical issue is how the costs and savings are spread over time and between stakeholders. This is shown below in Figure 2, the stakeholder costing matrix:

Stakeholder	Cost	Intervention cost	Save/loss/ increased income
Provider			
Purchaser			
Other public services			
Patient/relatives			

Figure 2: The stakeholder costing matrix for assessing savings or losses from an improvement

In the US system, two critical considerations are whether and to what extent the intervention will be reimbursed, and how long it takes before savings are realised by providers if they invest in making the improvement. This is well illustrated in two of the cases presented in Leatherman et al (2003). They carried out a detailed stakeholder costing of seven cases of quality improvement and published four, two of which are relevant to providers.

One case at Henry Ford health system, considered management of two improvements in medication use. The first was use of low molecular weight heparin (LMWH) for treatment of deep vein thrombosis (DVT). The estimate was that LMWH had a ratio of cost to savings of 1:5 compared with usual care for DVT. Although it was about \$47 more expensive, it could reduce hospitalisations and laboratory testing, shorten lengths of stay, and reduce overall costs by \$800 per patient. The intervention took time and was costly because it needed coordination between emergency department staff, primary care clinicians and specialty physicians. In the first six months, only 29 of a possible 500 patients were involved in producing a net saving of \$22,000, mostly from reduced hospital stays, although both the costs and patient benefits are in the short term. However, the financial case is reduced with different payment arrangements and the fact that Medicare does not pay for LMWH as an outpatient drug. In the current financial system it was estimated that to realise a large portion of the \$360,000 per year opportunity, the health plan would need to spread the intervention to all eligible patients per year. Further, it would need policies to stop using LMWH on patients for whom it was not clinically approved.

The second drug management intervention was a lipid clinic to monitor statin therapy more effectively and to improve management of patients with high serum cholesterol levels, especially those with a history of coronary heart disease. The frequency and mortality rates of heart attacks can be reduced by effective identification of the need for, and then use of, statin therapy. The estimate was that savings would be made which would be twice the costs, given the estimates of the longer-term costs of repeated heart attacks. The clinic used pharmacists to track patients' lipid levels, modify dosage, provide behaviour modification counselling, and encourage patients to exercise and reduce fats in their diet. The intervention was effective: 84 per cent of the clinic patients achieved the desired levels of blood lipids (compared to 53 per cent before). The costs were about \$145 annually per patient, but the costs of monitoring patients were not reimbursed. In addition, because the benefits in reduced heart attacks and costs were some time ahead, and because many patients moved between providers, it was considered unlikely that savings would be made.

The second case example was better diabetes management. Although large savings could be made, again the length of time over which the savings would be made and the likelihood of the patient moving to another provider made it unlikely that the provider would save money from the investment. Estimated savings from lower service use were \$405 per patient. The

intervention practice was guidelines, provider and member education, patient screening and reminders, performance feedback to physicians, and case management. The costs to the provider were \$330 per patient over a ten-year period, which would have produced a saving of \$75 per patient. There were high initial costs to start the programme, and the benefits of lower complications were likely towards the end, so the return on investment required a full ten years to be realised, at which time, in year ten, the annual benefit was expected to exceed costs by \$1,500 per patient. By this time, however, the patient was judged likely to be using another provider. The stakeholder costing matrices summarises this evidence to demonstrate the distribution of costs and savings.

Stakeholder costing matrix: diabetes management improvement

Stakeholder	Cost	Intervention cost	Save/loss
Provider	\$330/patient/10 years	Not reported	\$75/patient or 10-year saving \$1,500
Purchaser	Same as above as integrated provider/purchaser		\$405/patient through lower service use

Stakeholder costing matrix: DVT improvement using LMWH

Stakeholder	Cost	Intervention cost	Save/loss
Provider	\$47	Reported as 'costly'	\$800/patient 6-month savings for 29 patients \$22,000 (reduced hospital stays)
Purchaser	Same as above as integrated provider/purchaser		Same as above as integrated provider/purchaser

To relate these findings to the UK, the following needs to be noted. Both interventions would probably be carried out in primary care, in which case reduced admissions would not benefit the primary care providers financially and they would bear the costs. In the case of the pharmacist-led statin clinic, a special partnership would be needed. However, the returns may be more certain for the NHS and in some areas with more stable populations, but not to the provider of the improvement, who would bear the costs unless special financing or full fund-holder financing were used.

Accreditation value for money

Finally, we can note that the cost, spend, save/loss model could be used to assess the value added (or lost) by accreditation for patients or providers. Accreditation and standards inspection, and preparations by organisations for these, are interventions or activities to improve quality. The relation between these activities and patient outcomes has some face validity, but has not been conclusively demonstrated and is thought to work through different influences. The cost of accreditation and standards inspection has been questioned in relation to the benefits for patients and the value to the organisation. The cost, spend, save/loss model can be used to estimate the added value of accreditation to an organisation.

List all types of adverse or poor quality events that accreditation may impact, and draw up a shortlist of which are most likely to be reduced, and estimate the range of the percentage reduction likely before and after accreditation:

- Cost: the cost to the organisation of any adverse or poor quality that accreditation may reduce (potential savings).

- Intervention cost: costs to the organisation of preparing for and undergoing accreditation.
- Savings/loss: estimate the actual savings or losses as a result of accreditation.

7.3 Conclusions

Costs and savings of improvement are spread over time and between different organisations. The exact distribution depends on the financial payment and incentive system and on the type of improvement (for example, preventative treatment, safety or quality improvement).

Savings for a provider depend on how much of the cost of the poor quality or of the intervention they bear. The costs of failures to provide preventative care are often borne in higher treatment costs by other providers or the purchaser. The savings may occur some time in the future, by which time the patient may have moved.

The costs of adverse events are sometimes carried by the purchaser, and the provider may be paid extra to treat them. To shift these costs to providers, some US purchasers are excluding some 'never event' treatments from reimbursement, introducing financial penalties for not meeting certain standards, or giving incentives. In all cases, patients and their families bear financial costs from poor quality, but there is no costing evidence of this from research.

Chapter 8

The support issues

Finance for making an improvement change and finance to reward it are two 'environmental conditions' for saving from improving quality. But there are other conditions that are critical for effective implementation, and which affect the cost of implementing the change. This chapter summarises the research into both the financial and non-financial context to answer the following review question and to derive suggestions for how to enable changes that save money and improve quality:

- What are the barriers and solutions to investment in those improvements proven also to save costs and increase productivity?

8.1 Non-financial barriers to effective improvement

Before savings can be made, an effective change has to be carried out. Research has found that change to provider behaviour and organisation in healthcare is difficult. There are many internal and external constraints, and few enablers to implement change. There is a limited 'change capacity' in the experience, skills and systems of the average provider, and often not a 'change-ready' or 'receptive' culture.

There is some evidence that the specific constraints differ according to the type of improvement and type of provider organisation. The constraints to consistent hand hygiene to reduce infections are different to those for implementing a computer physician order entry system to reduce adverse drug events, or to redesign a pathway process for stroke patients. At a high level of abstraction, similar categories of constraints, such as lack of leadership or of resources, recur in the research reports. The challenges to making quality improvement in healthcare have been well documented and will not be repeated in detail here (IOM 2000, Berwick 1989, 1996, Øvretveit 1992, 2003a, 2007).

It is only recently that more empirical research has become available about the context hindrances and helpers for effective improvement. Some are reviewed in appendix 3. The following summarises one study to show some of the evidence discovered in the search to answer this question. This is the review by Johnson et al (2000) of research into clinical audit. This review found the barriers most often reported were fear of litigation, hierarchical and

territorial suspicions, diminished clinical ownership, professional isolation, lack of resources, lack of expertise in project design and analysis, problems between groups and group members, lack of an overall plan for auditing, and 'organisational impediments'. The source of, and solutions to, the barriers are at different levels of the health system.

The current thinking, supported by some evidence, can be summarised as:

Evidence of effective change + Supportive environment + Effective implementation = Improvement.

This means that effective improvement is achieved by choosing a change proven elsewhere and implementing it effectively in a supportive context. The challenges for an ordinary service in doing this can be summarised, from the research into different types of improvement, as shown below.

8.1.1 Information

- A lack of local service information to identify and then prioritise quality problems (leading to choice of too difficult problems, ones not considered important by personnel/implementers, or not organisationally significant).
- Lack of information about efficacy or local effectiveness of a solution to allow prioritisation of quality work (a service needs to choose a solution that can be effectively implemented locally, but good evidence is lacking to make this choice, and 'crowded out' by publicity about atypical demonstration projects).
- A lack of quality comparison data or their use by patients or providers, or no negative consequences resulting from comparisons (for example, through no choice of alternatives).

8.1.2 Uncertainty and skill deficiencies

Uncertainty, underestimation, or scepticism about the likely amount of time and effort required to implement the change and the likely results. Lack of skills or time for improvement in an ordinary service or easy access to facilitation and support to make the change effectively. Unfamiliarity with how to apply change or quality methods and lack of data or capacity to gather and analyse data.

8.1.3 Other urgent demands

Lack of time, skills and motivation to do all of the above in the face of other urgent demands. Immediate patient needs overcome long-term systematic work that has uncertain results.

As regards 'improvement capacity' (a term rarely defined), a telephone survey by Walley et al (2006) of senior managers in 19 trusts and 10 primary care trusts (PCTs) responsible for process improvement found capacity in acute trusts to be 'patchy, with some organisations having highly developed capability which is applied in many parts of the organisation, while others have very limited improvement skills and capacity'. They found 'only limited improvement capability in most PCTs' and that two trusts stated that the costs of improvement could not be afforded. Other findings were:

- Neither acute trusts nor PCTs had 'clinical systems improvement culture or techniques embedded in their organisations'.
- Improvements were not linked to the organisation's strategy.
- 'Command and control styles' hindered engagement of front-line staff in service improvement.
- Traditional training methods were ineffective and did not use interactive learning.

8.2 Enabling factors for improvement

Many of the enabling factors found in research were the absence of the constraints and barriers noted above. We should not generalise from factors that enabled one type of improvement to others, but Johnston et al's (2000) study shows some which are frequently found for studies of many types of improvement. Johnston et al's review of studies of clinical audit methods found that the main facilitating factors were modern medical record systems, effective training, dedicated staff, protected time, structured programmes and a dialogue between purchasers and providers (Johnson et al). Similar in some respects, Walley et al (2006) found that trusts were most successful in the following improvements:

- senior management with awareness of the process and systems issues that they face
- strong leadership able to implement difficult and sensitive change and harness staff-driven process improvement
- a workforce receptive to new ideas or lacking 'change fatigue'
- strategies that have reconciled conflicting priorities and tensions between short- and long-term improvement pressures
- a critical mass of people trained in the use of improvement tools and techniques.

One plausible enabling factor, but for which there is no evidence of effectiveness, is more research-based guidance to managers and implementers to choose, design and implement cost-saving improvements. There is a reasonable amount of evidence about the rates and costs of poor quality, and this gives a good guide to the likely costs for an average provider. However, there is less evidence of the effectiveness and intervention costs of solutions, and some evidence that this is different for different providers. There is even less evidence to guide providers in how to adapt and implement improvements to ensure savings in their local service, and little experience-based support to advise.

The Boaden et al (2008) review of quality improvement approaches concludes that:

While a number of lists of success factors have been produced, some of which are based on extensive empirical evidence, it is clear that the main issue is the way in which the improvement is implemented, rather than the nature of the improvement itself.

8.3 Financial and resource barriers to improvement

We return to the financial context factors discussed in an earlier section (chapter 7), but now summarise these and consider possible changes to the financial system to enable improvements that save money.

Chapter 7 showed that, even if a change is certain to make an improvement, there are often financial factors which make it difficult for an ordinary service to get the resources or to make savings. The following financial constraints were described in the research, although there is little empirical evidence reported confirming whether these did constrain specific programmes.

8.3.1 Cost displacement ('revenue displacement')

Often, the provider does not bear the cost of poor quality, but this cost is borne by purchasers, patients, families, employers or other stakeholders. If a patient is dissatisfied with a service, there may be no alternative.

Poor quality is often reimbursed by purchasers, such as over treatments or mistreatments, avoidable re-treatment, and extra length of stay (for example, from pressure ulcers or an

adverse drug event), or admission for surgery that could be done on a day-case basis. The costs of improving discharge and transfer information are not recouped by the provider, unless they are penalised for late or poor information, but this would save costs for the next 'downstream' service for the patient. Preventative services or disease management might not be fully reimbursed, especially if they involve new e-services or patient support groups. If a provider does not provide these and some other services, their failure to provide such 'quality service' may be borne by other providers, or purchasers at a later date.

8.3.2 Investment resources and high initial intervention cost ('capital costs')

Making an improvement and developing 'improvement capacity' requires time and money to be spent. This is short term for a specific change, but also long term to build capacity for continual improvement and to spread improvements. At a minimum, resources are needed to develop the skills of personnel and project management skills and systems, but ideally also to develop quality data collection and analysis skills. Investment finance for capital equipment is often easier than for training and personnel development, not least because of the more uncertain returns on the latter. Personnel need time off from service provision and agency or other staff to 'back-fill', and there are often freezes or constraints on these budgets. There is a high initial investment to establish project management and data systems, before staff become familiar with the methods and make improvement part of routine work.

8.3.3 Savings displacement

Often, a change takes time to be made and to have its effects on the problem, and savings are delayed one or more years ahead. This is demonstrated in the 'time to pay off' measure for reporting quality costing in the Stockholm 'saving through quality' programme (Øvretveit 2007). For some quality improvement, such as disease management or preventative treatments, potential savings to a provider funded through capitation may take time to accrue, by which time the patient may have moved to another service.

As noted above, savings for improving transfer information are more likely to be made by the next 'downstream' service for the patient. Preventative services or disease management may not be fully reimbursed and savings from reduced admissions would be made by the purchaser not the provider. The system rewards providers not for prevention but for treating sick patients, even if the illness is caused by the service itself.

8.4 Financial and resource enablers for improvement

The following does not provide evidence from research about which financial and resource items have been found to enable improvement, but rather summarises the discussion in the literature and the few studies that have considered these aspects. Three types of enablers are possible: financial systems that penalise providers giving poor quality service; financial systems that reward higher quality and quality improvement; and finance to invest in improvement projects and improvement capacity.

8.4.1 Provider bears the cost of poor quality

Financial systems that penalise providers giving poor quality service include systems that detect and penalise for failure to use recommended practices, or that withhold payment for poor quality events.

Instead of paying for extra care caused by poor quality healthcare, the provider causing the extra care could be penalised: for example, extra length of stay for treatment for an adverse

drug event. If the extra care is given by providers causing the need for this care, then payment could be withheld from them. If another provider has to give the extra care, then a penalty could be raised against the provider causing the need for this care (for example, some referrals to NHS hospitals from private providers for complications they cannot manage caused by them). The challenge is proving cause of harm, and the administration costs of this could exceed the benefits and savings.

Payment by diagnosis-related group or health resource group moves in this direction by giving incentives for reducing length of stay and costs per patient. However, this might be at the expense of quality. Another approach is not to pay for treatments that are known to be linked to adverse events caused by the provider such as the USA CMS 'never events no pay list' (see appendix 2 and CMMS 2008), which includes no pay for surgery on the wrong body part, wrong patient, wrong surgery, foreign object retained, and 'care management events' such as death or disability associated with medication error, incompatible blood, or hypoglycaemia, and stage three or four pressure ulcers after admission.

Nationally, the UK has introduced penalty fines and withholds payment for some poor quality (for example, failure to meet *Clostridium difficile* targets), and local purchasers are also introducing contract penalties (for example, for infection rates above the expected). Financial penalties are being introduced by UK purchasers for discharge summaries five or three days late, with some using the summary with coding information included as a proxy invoice (Carlisle 2009).

8.4.2 Investment and capacity costs

This category includes short-term resources for projects and long-term investments in the expertise, skills and systems to support change such as data gathering, reporting and project management systems. These are the capital costs of developing human capital and equipment for improvement. One enabler is to spread the costs between providers who cannot afford large investments, so that purchasers or a higher-level agency provide the expertise and systems (for example, the Institute for Healthcare Improvement breakthrough collaboratives).

The survey by Walley et al (2006) gave proposals for improving change capacity by actions at different levels, which reflects some of the evidence in the reviewed research:

- Acute trusts and PCTs should set up improvement departments with a core of trained individuals to support and promote the methods.
- The methods should be further adapted to healthcare to assist uptake.
- Increase the awareness of senior managers and policy makers of the methods and potential advantages.
- PCTs' use of the methods in commissioning can also help to spread the message of the advantages.
- Disseminate UK case studies of successful implementation.
- Develop an educational programme in the methods for NHS clinicians and managers to allow a continuous development of knowledge and skills from initial training to expert status.
- Leadership and team working need to be incorporated into future training.
- A programme to disseminate best improvement practice should be established.
- The methods and their application need more exposure in academic and health journals.

8.5 Conclusions

Even if an effective intervention is chosen for a prioritised quality problem, whether it can be implemented and how much it costs to do so depends on the features of the provider organisation and external context. There is the financial context, which can reward or penalise poor quality through routine reimbursement, and special payments by purchasers for quality improvement, or for support – for example, systems for quality data or electronic medical records.

To make it more financially advantageous for providers to increase quality, changes are needed in routine financing systems, in how performance is measured to include quality measures, and in expert support and information on how to make successful improvement, which ordinary single services or facilities cannot afford to develop.

PART 4: FUTURE RESEARCH AND CONCLUSIONS

Productivity improvements could only be realised through quality improvements and advances in innovation.

(NHS CEO, David Nicholson, annual report, reported in *HSJ*, 28 May 2009, p 9)

Chapter 9

Future research

9.1 Future research

Where there are differences of opinion, evidence can sometimes help. However, evidence at present cannot resolve the differences about whether or how much improving quality can save the NHS mainly because of the lack of research and different understandings of 'improvement'.

Because researchers have not reported evidence does not necessarily mean something is not effective, or that services are going to wait for it. Lack of evidence may be because of a lack of research, or because of challenges in creating clear data. Or it may be because there is good research, and large amounts of it in different settings, but which have failed to find evidence. We have less of the latter, proven ineffective in many settings, and much of the former two when it comes to evidence of savings with improvements to quality. The section below answers the review question:

- What are the strengths, weaknesses and gaps in the research into quality costs and savings and tools available to providers?

It also considers which future research is most needed to provide better answers to the other review questions.

9.1.1 Overall, how well does the research provide answers to the review questions and where are the gaps?

Costs and savings: what are the costs of poor quality, the intervention costs, and any savings for improvements?

There is good evidence of the amount of poor quality and some estimates of potential savings, especially in hospitals. There is less evidence outside of hospitals or about poor quality in transfers and coordination failures, where the potential savings are high.

Empirical evidence of the costs of poor quality is very limited; there is less evidence of the intervention cost of interventions, and even less of any savings, losses or extra income from improvement. None estimate the potential 'meta value added' of increased competence to

carry out improvements as a result of the work. Few reports give evidence of changes and sustained savings after two years, or of whether a change can be easily spread, and may be context-insensitive (Øvretveit 2009a). Other limitations are as follows:

- Quality not assessed: some of the costing research does not measure quality after the intervention to have enough certainty that it was maintained, increased, or decreased on a range of quality dimensions.
- Intervention costs not considered: many 'savings' studies do not consider the initial and recurring intervention costs of the solution. Even so-called 'business case' studies published in refereed journals do not consider intervention costs of the intervention they assessed (Brilli et al 2008).
- Extrapolated estimates: many studies that do consider intervention costs make estimates which are extrapolations, and not based on empirical intervention cost data.
- Data variations: there are large variations between empirical studies in the items included in intervention cost and in costing data validity.

There is little research using social science methods to strengthen understanding of whether these and other outcomes can be attributed to the interventions. Most notably, there is a lack of research into variations in implementation success with different safety or quality changes, and of explanations of these variations. This knowledge is critical to providers wanting to assess local costs of implementing improvements, and to guide their implementation strategies.

If context is critical for implementation speed, costs and success, then more knowledge of context is essential, so that higher levels of the health system can target their actions to create the enabling conditions for savings.

What are the trade-offs, benefits and costs of quality improvement to different stakeholders?

Again, there is some theory, but only a few studies with empirical data, and the best study considers distribution between a limited number of stakeholders in the USA. There is no UK research which has given empirical assessments of different stakeholder costs and benefits outside of some studies of preventative care.

What are the barriers and solutions to investing in those improvements proven also to save costs and increase productivity?

Research has only just begun to investigate empirically what helps and hinders improvement. In part this is because this was not the focus of the experimental and observational research paradigms that are financed and preferred by improvement researchers. The research that has been done has focused on clinician behaviour change.

There is little empirical research into organisational and process improvement barriers and enablers, or systematic studies of these at different levels of the health system and how they combine. No research has systematically explored which barriers and enablers are similar and different for different improvements, or theorised about this. The studies that have been done have not focused on improvements proven to save costs and increase productivity.

What is the relation between quality improvement and productivity?

There are some theoretical studies that allow a theoretical answer to this question, but little empirical research which has tested the theories. Most theoretical development has been

carried out by consultant implementers, reflecting on practical experience, and in 'intellectual dialogue' with research outside of healthcare.

What are the strengths, weaknesses and gaps in the research into quality costs and savings and tools available to providers?

In addition to the above-noted strengths and weaknesses, two of the main observations of this review are as follows.

No research-based knowledge is available to implementers to help them prioritise improvements on the basis of potential savings and the context factors needed for success, or to help implement chosen improvements. Research into context factors for change success of different interventions could be used to develop tools to enable providers to assess which context factors, apart from the implementation actions, are needed for successful implementation.

There is little evidence of poor quality, costs and potential savings outside of hospitals in the UK. Theory and some US research suggests that between-service transfers provide opportunity for improvement and high potential for system savings. There is no UK research on this subject, or assessments of cost and benefit distribution, or of which changes to financing would be needed to provide incentives for improvement.

9.1.2 Other observations about the research

This and earlier reviews noted the small amount of research into the effectiveness and cost of quality improvement, and of empirical studies of financial savings or loss to different parties. The quality of much of the research is also limited. Experimental studies often have design flaws resulting in inconclusive findings, and there are questions about generalisation, especially between health systems. Few have parallel process evaluations to describe implementation and what helped and hindered. Social science and case study research often are not sufficiently concerned about attribution issues, or contributing to theory, or the practical questions of decision-makers. A further limitation is how concisely and clearly the findings are communicated to decision-makers, either in reports or in summaries.

Costing research (of costs, intervention costs and savings) is not the main methods challenge. Studies have shown that it is relatively easy to gather and analyse the needed data from routine service databases, and to cost improvement projects to an acceptable level of validity and reliability (Øvretveit 2000, Øvretveit and Granberg (2006), 2007, Øvretveit and Andreen Sachs 2005). The challenges are rather in designing research that allows:

- a reasonable certainty about whether outcomes and cost savings are due to the intervention or quality method, rather than something else
- defining the extent and limits to generalisation of the findings to other services
- development of theory about which context factors helped and hindered implementation, and which aspects of context are specific to certain changes.

9.1.3 Future types of research needed

These limitations of the research suggest a need for both more and better research, and also the development of other strategies to help decision-makers make better-informed decisions about whether and how to invest in improvement. There is an over-reliance on research for answers which it cannot give or is slow to provide, and an underuse of other forms of useful

knowledge such as practitioner reports, and a lack of attention to strengthening these forms of knowledge and making them more accessible.

The gaps and weaknesses of the research for answering practical questions which this review set out to answer indicate that the following is needed:

- Integrated improvement research. Research that combines costing and implementation investigation with study of the effectiveness of quality improvement, through three parallel studies. These could be funded all together or, where a study is to be made of one type, two other studies can be added.
- Collaborative or action research into implementation and costing. Deep access to service personnel and data are needed for good implementation and costing research. Service providers' time and data will not be forthcoming unless they gain something from the research and agree contracts to participate. Collaborative or action research approaches can provide access and early benefits for the organisations studied.
- Develop implementer reporting. Outsider researchers are not the only way to provide better information to answer the questions; external research takes time, is costly, and only partially shares the objectives. Implementers can be supported to organise their learning and communicate it to provide others with faster and more useful information of the type needed (for example, AHRQ 'innovations exchange' and IHI case studies on their websites). A danger is that the information may not be sufficiently valid and could be misleading, especially as regards attribution. It is possible that research or expert support can be given to implementers to avoid misleading reports, and to improve designs. Implementers would need time, motivation and support to structure and communicate their experience and learning in ways that are accessible and useful, and good national report databases and search facilities are necessary for this to succeed.

9.1.4 Future research in the UK: proposed subjects

- Empirical evidence of the overall cost of poor quality for a typical provider and of which are the highest cost subject.
- Empirical evidence of the overall cost of poor quality for patients and family.
- Empirical evidence of intervention cost of interventions, and of any savings or losses.
- Empirical research into poor quality, costs and potential savings outside of hospitals in the UK, especially with regard to patient transfers and the incentives needed to improve these.
- Empirical research into the distribution of costs, intervention costs and savings/losses over time and between stakeholders in the UK, for different interventions, or using already published costing reports (for example, interventions to reduce pressure ulcers, adverse drug events, infections, falls).
- Research into what would help providers strengthen their 'practical research' and reports, especially the evidence of outcomes (attribution) and costing, and contribute reports and case examples (for example, the Stockholm quality costs programme).
- Add costing studies to conventional research (especially intervention costs).
- Research to develop quality measures as part of financing systems (or part of productivity measures) for different services: feasible but not misleading measures.
- Empirical research into the relationship between quality and productivity for different providers.
- Empirical research into factors at each level of the health system that help and hinder changes which improve quality and save costs, and assessment of whether factors are similar or different for different improvements.

- Independent rigorous case study of two leading Lean programmes: Bolton NHS Trust and Flinders Medical Centre, Adelaide.

9.2 Conclusions

The system rewards providers not for prevention but for treating sick patients, even if the illness is caused by the service itself. We need a system that pays providers to develop and run services which keep patients well away, not least because one in ten will be harmed from using sickness services, adding extra costs. We need a system that rewards and supports providers to use improvements which save costs for them and the system, rather than penalising them.

The executive summary gives other conclusions from this review and synthesis of the literature about the costs and savings of improvements to quality and the effects on productivity.

The evidence reveals how the system often rewards providers not for preventing adverse events or ill health, but for treating patients even if the illness is caused by the service itself. This review contributed some evidence and ideas for constructing a system that rewards and supports providers to use improvements which save costs, rather than penalising them. These changes will require research and other activities to design and test the finance, measurement and support systems that could create incentives and enablers to use improvement changes and methods.

APPENDICES AND BIBLIOGRAPHY

Appendix 1a

Definition of terms used in the report

Adverse event: harm experienced by a person that could have been avoided.

Health service quality: 'A quality health service is one which organizes resources in the most effective way to meet the health needs of those most in need, safely, without waste and within higher-level requirements' (Øvretveit and Klazinger 2008). In this report, an unsafe health service is one that causes avoidable harm to a patient. Poor quality service includes unsafe service, but also service which is less than expected or below standard, but does not cause harm. Failure to use treatments proven to be effective and recommended for normal services may or may not cause harm, but may be considered to be poor quality.

Quality activities: any work to ensure and improve quality, including making, performing or meeting regulatory quality and safety requirements.

Quality improvement: actions by provider personnel working in project teams using methods to change organisation and behaviour to produce measurable improvements in patient outcomes, including avoiding adverse events. Sometimes used more broadly to describe any actions taken to ensure and improve quality and safety, including regulatory activities or increasing the number of personnel or qualification level. The Boaden et al (2008) review included interventions using the following methods and approaches: Plan-Do-Study-Act cycle, statistical process control, Six Sigma, Lean, theory of constraints and mass customisation. Walley et al (2006) defined clinical service improvement as: generic improvement methods, such as Lean thinking, Six Sigma, theory of constraints, reliability and safety engineering, as well as context-specific improvement knowledge, such as reducing hospital mortality, improving emergency flows in hospitals, and increasing productivity on wards and elsewhere.

Quality costs: extra resources used because of poor quality, quantified in money terms. Examples for providers: extra nursing time and materials treating pressure ulcers; non-payment for readmission where this is due to poor previous treatment or discharge and not paid for by the purchaser; time and cost dealing with a complaint or negligence claim; loss of income due to failure to meet quality requirements. Not included are: costs to other stakeholders (for example, loss of patients' working time); costs difficult to quantify in money terms, such as suffering.

Quality intervention spend cost, or intervention cost: extra resources used to improve quality, quantified in money terms.

Examples for providers: cost of training in quality methods, cost of personnel time on quality improvement activities and on other quality activities. Not included are: costs difficult to quantify in money terms such as opportunity costs of management time spent on quality improvement rather than other activities.

Quality savings: resources gained as a result of quality improvement, which would otherwise have been lost, quantified in money terms. Examples for providers: saved personnel time and materials; savings on claims insurance; savings on labour costs due to lower personnel turnover attributable to higher quality; extra income from purchasers or patients because of quality being higher than otherwise. Not included are: costs of meeting regulatory quality requirements or other activities not classified as 'quality improvement'; costs difficult to quantify in money terms, such as opportunity costs of management time spent on quality improvement rather than other activities.

Productivity: number of outputs per input, measured in different ways. Examples for providers: number of hip replacements per orthopaedic surgeon or per total time of labour for one episode of care. Definitions by the Office of National Statistics (2006) and Black et al (2006) are: 'level of activity in the NHS (such as numbers of consultations and hospital admissions) to the resources used (for example, money and the numbers of staff)'. Previously, this was the definition of efficiency, and productivity was only the total outputs produced during a defined period.

Appendix 1b

Other common definitions and meanings

Adverse event: an unintended and undesired occurrence in the healthcare process because of the performance, or lack of it, of a healthcare provider and/or the healthcare system (SIMPATIE definition (Kristensen et al 2007)).

Adverse drug event: an injury resulting from medical intervention relating to a drug.

Clinical safety practices: specific actions taken by care providers in their work to reduce certain types of adverse events experienced by patients. Examples include hand hygiene practices to reduce infection, or performing a number of practices in ‘bundles’ targeted at a specific problem such as ventilator-associated pneumonia (Resar et al 2005). These practices are often presented as desirable actions to be performed by care providers, which would be an end result of an implementation intervention. Research has tested a number of these practices and the synthesis presents the evidence about which are most effective for which types of adverse events experienced by patients. However, which interventions are effective for implementing and sustaining these practices is another question.

Generic safety interventions: create favourable conditions to choose, implement and support safety practices and create safer environments. They are less time-limited than implementation interventions and include organisational structures, systems, processes and culture. Examples include an information system for collecting safety data, a safety committee reviewing adverse events, finance systems which reward safer care, or laws – for example, to limit working hours. Generic safety interventions may be carried out at a national, local or team level, and have as their ‘change target’ individuals, teams or organisations.

Healthcare quality: provision of care which exceeds expectations and achieves the highest possible outcomes with the resources available. Some low-quality care or events may not be unsafe but they are below standard.

Implementation: actions taken to adapt a safety intervention idea locally and to carry out changes which put the idea into everyday activities. Implementation actions may be carried out by actors at different levels of the system: a department head supervises and reminds personnel about hand hygiene; a training department gives education on the subject; management purchases alcohol rubs and creates policies, procedures and protocols; a profession creates and disseminates guidelines; government runs a national publicity campaign. It is thought that implementation is more effective if coordinated actions are taken by each level.

Patient safety: freedom from injury caused by healthcare and actions to prevent such injury.

Patient safety intervention: any action taken to prevent or minimise harm to a patient. It is both a change made and the actions used to make the change. A common change is to caregivers' behaviour, such as hand washing between patients, and a common action to implement change is training or feedback on performance.

Medical error: 'the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim' (IOM 2000).

Medication error: a mistake in writing prescriptions, dispensing or administering drugs (a common cause of adverse drug events).

Near miss: an occasion where an error was narrowly avoided. Or 'an event where the error was detected and intercepted before harm was done'. There is evidence from one US study that there are at least seven times as many near misses as adverse events.

Risk: the chance of disaster or loss (Oxford English Dictionary). For other definitions, see the USA Veterans Health Administration glossary, at www.va.gov/ncps/glossary.html or SIMPATIE definitions.

Dimensions of quality (the Health Foundation)

- Effectiveness: the evidence base for good outcomes from care.
- Access: concerns care being provided when needed in the appropriate setting. Delay may impair effective treatment (as, for example in cancers), or cause suffering by patients that would be relieved by timely treatment (without an adverse effect on outcomes). Inappropriateness results from design faults of healthcare.
- Capacity: care being well resourced to ensure appropriate care.
- Safety.
- Patient-centredness: the dynamic partnership between providers and patients (and, when appropriate, their families) and treating patients as individuals who will be cared for with compassion, empathy and responsiveness.
- Equity.

Appendix 2

Financial incentive schemes for improvement

This appendix reviews knowledge about the effects of supplying financial incentives to providers for proven improvements in patient safety, or for actions that are thought likely to produce improvements.

2.1 An overview of the relevant literature

In the USA it is recognised that healthcare is primarily a business and that economic incentives are necessary (but may not be sufficient) for change. Payment systems for providers are for quantity of care and often do not reward either higher quality (for example, patient education, continuity of care) or safety. 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 other mechanisms such as accreditation, regulation and public quality performance information, and provider ethics and professionalism are not strong enough to overcome the economic pressures.

There are obstacles to providers to borrow or invest in some of the more expensive actions for improving safety, such as new technologies, especially if the financial savings and other results are uncertain. This is expressed in some US literature as ‘the economic imbalance that exists between the purchasers of safety interventions and those who benefit – patients and purchasers’ (for example, DeBrantes 2004).

To address this imbalance and to accelerate quality and safety improvement in the USA, a number of financial incentive schemes are being used. The different types of schemes are:

- increased payments to providers (for example, physician fees) for providing preventative care and better management of chronic diseases (physicians, medical groups or hospitals)
- increased fee or bonus payments to providers for practices or equipment thought to improve quality or safety (for example, different forms of information technology)
- increased fee or bonus payments to providers for achieving improved quality, safety or cost outcomes

- specific grants (for example, for information technology)
- financial incentives (for example, reduced co-payments) to patients to choose providers with better quality, safety or lower costs (in order to get more patients to use published 'consumer report card' quality information).

Most of the literature is about quality-related payments (for example, extra physician fees for preventative care); there is less specifically about safety-related payments. The research into quality-related payments can give some indication of the likely effects of safety payments. Some of this research is considered in the following summary, which otherwise concentrates on safety-specific payments.

Other introductory comments about the literature on financial incentives for patient safety are:

- **Context of the incentives.** There is evidence from research into financial incentives in general, and for quality, that the way providers respond to schemes depends on the context for the scheme. For example, whether performance data are public, the amount of competition, or whether IT is also needed for managing physician practices. Context modifiers are especially important when considering possible effects in Swedish public healthcare with physicians and providers who may react differently to financial incentives.
- **Verifying or measuring a provider's response.** Scheme-payers need to assess a provider's response – for example, by collecting measures or assessing reports of their responses. The schemes reviewed below all have methods for assessing responses, many of which use existing independent quality or safety data monitoring systems. Verification adds administrative costs to the scheme.
- **Caution** is especially necessary in using non-research literature: most of the debate is from the USA and, even in scientific journals, many authors are not neutral and have significant material interests in promoting incentives for different actions or data systems.

2.2 Financial incentives and penalties

2.2.1 What are some of the schemes in operation?

Generally, there is little published research specifically about financial incentives for organisations to pursue safety interventions. The research on the effects of the schemes is summarised later in this section. First, the review presents knowledge in the form of reports and assessments of possible consequences and discussions of the issues involved. In the absence of research evidence, these discussions, although almost entirely by US writers about US schemes, may help to assess the likely positive and negative effects of the schemes.

UK Quality and Outcomes Framework incentives for general practitioners

This scheme is not specifically to improve safety, but does provide significant financial incentives to UK general practitioners (GPs) if they reach certain quality standards, some of which are clinical and some service-oriented, such as access times. This scheme is part of the April 2004 national contract negotiated between the NHS and GPs, and about 20 per cent of the GP's or group practice income depends on achieving these standards. Points are awarded for achieving the standards (measured by local assessors of the primary care trusts administering the schemes) and about 1,000 points could in principle be achieved. At £80 per point, this amounts to considerable income being tied to quality performance as part of general income, rather than as a specific bonus. The scheme was set up with the idea that most GPs would achieve 750 points. But, as some commentators expected, GPs responded well and the

costs of the scheme are much higher than predicted by the scheme originators. There are different views about whether the scheme has really improved care for patients, but it has improved clinical data recording (Carlisle 2005).

US Leapfrog Group

One of the first major schemes was the Leapfrog Group initiative. This is a group of major employer purchasers of healthcare, which, among other things, started a financial incentives scheme. This measures the quality of care and the efficiency with which hospitals use resources in five clinical areas: coronary artery bypass graft, percutaneous coronary intervention, acute myocardial infarction, community-acquired pneumonia, and deliveries/newborn care. These were selected because they represent approximately 33 per cent of admissions and 20 per cent of commercial payers' inpatient expenditures, and hold promise for quality and efficiency improvements. Hospitals are scored and, if they demonstrate sustained excellence or improvement, may get financial rewards and more contracts for an increased market share. The first payments were expected to be made in 2006. These scores can become the basis for financial incentives for consumers, such as waived co-pays or deductibles for choosing care at high-performing or improving hospitals.

This scheme draws on the experience of the Premier hospitals and CMS scheme noted below, as well as the measures in the Hospital Quality Alliance initiative. The scheme uses quality measures that are endorsed by the National Quality Forum and collected through the Joint Commission on the Accreditation of Healthcare Organisations' ORYX initiative and the Leapfrog Hospital Quality and Safety Survey. Measures of efficiency are: severity-adjusted average length of stay and readmission rates for each of the five clinical areas.

US Bridges to Excellence

The Bridges to Excellence scheme focuses on physician quality in doctors' offices. It is based on three schemes run by the National Committee on Quality Assurance covering diabetes and heart care, as well as patient education and use of healthcare information technology.

US Premier/CMS scheme

The Premier/CMS (CMS 2006) scheme covers Medicare and Medicaid patients and gives bonuses to hospitals for their performance on evidence-based quality measures for inpatients with: heart attack, heart failure, pneumonia, coronary artery bypass graft, and hip and knee replacements. The Premier hospitals were chosen for this demonstration because their database can track and report quality data for 34 quality measures for each hospital. Hospitals in the top 20 per cent of quality for those clinical areas are given a payment. Hospitals in the top 10 per cent for a given diagnosis get a 2 per cent bonus of their Medicare payments for the measured condition, while hospitals in the second 10 per cent get a 1 per cent bonus. The cost of the bonuses to Medicare was estimated at \$7m a year, or \$21m over three years.

Hospitals that have not improved from the 'demonstration baseline' by year three get lower diagnostic related group payments. The 'demonstration baseline' is clinical thresholds set at year one for the lower 9th and 10th 10 per cent of hospitals. The payments are 1 per cent lower payment for clinical conditions that score below the 9th decile baseline level and 2 per cent less if they score below the 10th decile baseline level. The first year results were reported in 2005 recognising those hospitals with the highest quality and noting those that received bonus awards. Participation in the demonstration was voluntary, starting in early 2003. A total of 274 hospitals participated in the demonstration; more details are provided in the appendix.

California HealthCare Foundation Programme

The California HealthCare Foundation Programme, Rewarding Results started in 2002 with awards of \$5m for hospitals and physicians for higher quality. The scheme is run by the National Health Care Purchasing Institute and is evaluated by Boston University.

Grants were awarded to:

- develop incentives for clinical performance in six areas, including breast cancer and cervical cancer screening, asthma and diabetes, as well as patient satisfaction and information technology investments (to Integrated Healthcare Association)
- develop incentives to paediatric providers for higher performance and information system improvements, as well as better identification and management of childhood obesity (to Integrated Healthcare Association)
- develop incentives for improved care for chronic conditions such as cancer, diabetes, asthma and heart failure, as well as improved doctor–patient relationships (to Blue Cross of California)
- develop an incentive pool to reward hospitals based on their use of best clinical practices and best medication safety practices (Blue Cross Blue Shield of Michigan)
- provide incentives for improved prevention and treatment of chronic conditions such as diabetes, asthma and coronary artery disease (Excellus Health Plan, Inc)
- provide and evaluate physician incentives for improving preventive care and chronic disease management (Massachusetts Health Quality Partners).

There's no question that it's going to be expensive for hospitals to implement measuring systems, but they can start without having a system in place. Just pick one disease, for example, and gather and report data on your success in treating it. It's urgent that you begin somewhere now because in the future you will certainly be differentiated on the value you provide.

(Aetna health system senior manager, 2004)

2.2.2 Pay for performance

The above are referred to as pay for performance schemes. The term is slightly misleading if one understands performance to be outcomes: the payments are often not for outcome performance, but for whether providers have adopted practices which are thought to result in better outcomes or certain information technologies. Most pay for performance schemes provide one of three types of incentives described below and share a pool generated by cost savings against a benchmark (Gosfield 2004).

- 1) Threshold bonuses are paid to physicians achieving certain process and outcomes measures, as determined by the National Committee for Quality Assurance (for example, \$100 per patient with diabetes) for every patient with the diagnosis in their practice. The Bridges to Excellence scheme is one example, which started with patients suffering from diabetes and cardiac conditions. There are additional payments for infrastructure (for example, information technology) that make these initiatives easier. (Bridges to Excellence is a not-for-profit organisation with a board of representatives from employers, providers and plans, including the director of the Leapfrog Group.)
- 2) In tiering bonus schemes, bonuses are paid to providers who are on the top tier of the participating providers. Second-tier providers get lower payments, and third-tier providers get nothing. A provider taking part will not know if they will get a payment because they do not know what the other providers are doing. Examples are schemes run by the California Integrated Healthcare Association and the Central Florida HealthCare Coalition.

- 3) The third type involves tiering providers, but assessing them against a benchmark of cost savings. If providers do not make cost savings above the comparison level, they will not receive a bonus. With tiering bonus systems, providers do not know if they will receive a financial reward for their efforts.

The systems are different for physicians and for hospitals. For physicians, pay for performance involves a per-patient, a capitation payment or some administrative reward such as no required pre-authorisation. Other types of scheme involve quality scorecard bonuses, increased fee-for-service with a withhold or refusal to pay, and similar (Leapfrog 2004; Rosenthal et al 2004).

There are also incentive and reward schemes for introducing certain information technologies (IT). The UK NHS has provided grants to GPs and hospitals for introducing IT. In the USA, the four main types of schemes are:

- payment differentials: bonuses rewarding clinicians and other providers for IT
- cost differentials: using co-payment and deductible incentives to steer patients towards clinicians and other providers that have adopted IT
- direct reimbursement: for a new category of service using IT such as 'online consultation'
- shared withholds: withhold part of a provider reimbursement until IT adoption.

More details of US IT schemes are given in ehealth (2003).

2.2.3 No pay for never events

As regards the more recent US CMS (CMMS 2006) Medicare never events, this scheme is taking the first steps towards better and aligned incentives for improvement by not paying for treatments known to be caused by provider poor quality. These include:

- **Surgical events**
Surgery on wrong body part, wrong patient, wrong surgery, foreign object left in patient after surgery, post-operative death in normal health patient, implantation of wrong egg.
- **Product or device events**
Death/disability associated with use of contaminated drugs, devices or biologics, death/disability associated with use of device other than as intended, death/disability associated with intravascular air embolism.
- **Patient protection events**
Infant discharged to wrong person, death/disability due to patient elopement, patient suicide or attempted suicide resulting in disability.
- **Care management events**
Death/disability associated with medication error, death/disability associated with incompatible blood, maternal death/disability with low-risk delivery, death/disability associated with hypoglycaemia, death/disability associated with hyperbilirubinaemia in neonates, stage three or four pressure ulcers after admission, death/disability due to spinal manipulative therapy.
- **Environment events**
Death/disability associated with electric shock, incident due to wrong oxygen or other gas, death/disability associated with a burn incurred within facility, death/disability associated with a fall within facility, death/disability associated with use of restraints within facility.
- **Criminal events**
Impersonating a healthcare provider (for example, physician, nurse), abduction of a patient, sexual assault of a patient within or on facility grounds, death/disability resulting from physical assault within or on facility grounds.

2.2.4 Discussion of schemes

Most commentators note that these schemes need to be assessed in relation to an existing payment system – they are supplementary to the system, with all the disadvantages that most systems have. Recognising this and that many commentators have material interests, the literature on the subject can be summarised as follows:

- Providers with the poorest quality often need significant investments to improve, yet will lose finance from many schemes. In a system of competition where the best survive, this is less of a problem than in a public system where there are few alternatives.
- Often the incentive schemes are introduced without considering:
 - the actual costs to providers of compliance relative to the income realised – the payment may not be a sufficient financial incentive
 - how they interact with existing payment systems.
- Providers criticise schemes which appear to be taking finance from one provider to reward another (for example, some insurance schemes). In contrast, some schemes add new finance for healthcare – for example, from employers in the Bridges to Excellence scheme.
- There are questions about what will happen after most providers have achieved the levels rewarded. For example, for quality schemes for chronic care patients: will the reward payers then stop these incentives? Will the money saved be used for other diagnoses?

The review for the health foundation of financial incentives for improving hospital quality by Chirstianson et al 2007 concluded that ‘The published research to date in this area is too limited to draw conclusions with confidence’. Other studies have not so far found a significant effect of the financial incentives on different quality indicators (Glickman et al 2007; Vutler et al 2007; Coleman et al 2007). Nonetheless, many purchasers are introducing different schemes, notwithstanding the challenges in linking quality indicators to payments for a few or many services (eg NHS North west 2008).

2.2.5 Do financial interventions, such as payments or other financial rewards to providers or patients, improve safety?

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

The review reports research significantly adding to the evidence on this subject in 2006 (the CMS Premier hospital quality incentive demonstration) and also the results of simulating the likely effects of incentive systems. The general conclusion was that there is some evidence that, in some circumstances, quality-based purchasing 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 cost of achieving the performance goal compared to the increase in revenue from the incentive.

The AHRQ review confirms the conclusion of the review of national initiatives above: there is limited evidence of the effect of incentives or penalties for physicians, medical groups or hospitals for patient safety.

2.2.6 Relevant literature on issues related to financial incentives for safety

The Joint Commission on the Accreditation of Healthcare Organisations has recently issued principles for quality and safety pay for performance schemes applicable to all types of providers:

- The goal is to align reimbursement with the practice of high-quality, safe healthcare for all consumers.
- Schemes should include a mix of financial and non-financial incentives (such as differential intensity of oversight; reduction of administrative and regulatory burdens; public acknowledgement of performance).
- When selecting the areas of clinical focus, schemes should not conflict with other quality and safety initiatives and should focus on clinical areas showing promise for improvements because they represent areas where unwarranted differences in performance have been documented.
- Data on which incentive payments are based should be credible, valid and reliable.
- Schemes should reward team and inter-service approaches needed for quality and safety, and the united approach necessary combining professionals and managers, interprofessional cooperation, and inter-service cooperation.
- Schemes should support an interconnected healthcare system and the implementation of 'interoperable' standards for collecting, transmitting and reporting information.
- Providers need to be clear why they have or have not received the incentive and payments should be made in a timely manner as near to the change period as possible.
- Schemes should be independently evaluated and regularly reviewed.

These principles are similar to those proposed by a review undertaken by a consulting company, which draws on experience as well as research to present the growing case for using physician incentives to improve healthcare quality (NHCPPI 2001). This review concluded that financial incentives to improve quality of care are generally more influential than non-financial incentives, and incentive strategies are more effective when based on each individual physician's performance rather than at the group or plan level. It proposed that factors influencing the extent to which an incentive strategy is effective in improving physicians' performance include:

- the level of trust between the physicians, the individuals and organisations implementing the incentives
- the size of the financial incentive
- peer and/or consumer knowledge of individual provider performance
- perceived and actual accuracy of the data on which the incentives are based
- the stimulus and need for change recognised among physicians
- the level of support for the incentive programme in the medical leadership
- practising physicians' knowledge and understanding of the performance incentives/sanctions
- the simplicity and directness of the incentive.

Other relevant reports are the lessons learned by 14 different providers participating in quality incentive schemes included in the National Healthcare Purchasing Institute 'profiles' report (2002). The limitations of financial incentives for changing physicians' performance in the right directions are well described by Marshall and Harrison (2005).

2.2.7 Information technology and financial incentives

The safety cases for incentives for IT are presented by DeBrantes (2004). This paper proposes that the Bridges to Excellence and Integrated Healthcare Association schemes demonstrate that incentives to physicians do result in adoption and use of IT, although the paper does not provide evidence of better patient outcomes. It reports an increase from 5 to 15 per cent of the physicians' practices targeted for incentives who have adopted IT, in Massachusetts and one region of New York state, where the Bridges to Excellence scheme was carried out.

A report by the US ehealth initiative describes principles and actions for financing information technology in physician practices for quality purposes, developed by a group of different stakeholders. Any scheme should:

- include an incentive for the health information technology infrastructure required to support improvements in quality
- result in improvements in quality, safety, efficiency and effectiveness in healthcare
- reward only those applications and systems that are standards-based to enable interoperability and connectivity (for transfer of information)
- allow for internal quality improvement or external performance reporting.

The report also proposes 'incentives staging' to introduce the incentives sequentially and allow for natural experiment:

- Phase I: reward reporting of measures relying on manual chart extraction; reward usage of standards-based, interoperable IT.
- Phase II: reward more advanced functionalities requiring IT; reward transmission of measures utilising clinical data sources.
- Phase III: reward outcomes measures; phase out rewards for IT infrastructure.

These are referred to as 'ex-post incentives'. 'Ex-ante incentives' are those that are provided 'up front' to the physician.

A recent visit by the author of this review to the US Kaiser Health System found that it was also using financial incentives for quality and safety and that it was common, however, for IT to be poorly or partially implemented (*LA Times* 2003).

Appendix 3

Context for quality improvement

3.1 Contexts for successful implementation

Each of the clinical-level interventions are implemented within a particular organisational context, which itself exists within a regional and national context. For example, a system for gathering employee reports of adverse events operates within the context of an organisation's culture and policies. This then exists within a national financial context, which may provide extra resources and support to implement the system, and a legal and professional environment that may or may not require reporting or give protection to employees from disciplinary action for making reports. The extent to which the reporting system can be implemented, and its effectiveness, are helped and hindered by these surrounding contexts. National interventions, such as laws, or educational programmes change the context for safety improvement as well as having a direct effect.

'What is the necessary context for the successful implementation of a safety intervention and for the intervention to be effective and sustained?' is a different question to, 'What were the antecedents and causes of this adverse event?' There is research from other industries, and increasingly from healthcare, which describes factors and conditions that can contribute to error and which need to be assessed for their role in any adverse event analysis. For example, Vincent et al (1998) propose a framework to analyse the 'latent factors' and 'background conditions that predispose to risk and unsafe practice'. This framework is not only proposed for analysis of adverse events which have occurred, but for interventions to prevent adverse events before any take place: these factors are directly and routinely monitored to assess the risk potential for patients as they are in other industries.

The two questions noted above concern contexts for events, but the events are different: an adverse event is different to an intentional active intervention to prevent future adverse events. However, it is possible that interventions directed at each of the factors which can cause adverse events could prevent future occurrences if such events have not happened.

Current research suggests that success in implementing many safety interventions, as well as their effectiveness, depends on the presence and absence of certain context factors. A discussion paper suggested that complementary and coordinated action at each level of the system is required (Ferlie and Shortell 2001). The factors which help and hinder actions may

well depend on the type of action and the type of situation: factors for improving professionals' reporting of errors may be different from the factors for implementing root cause analysis or increasing hand washing. However, there is little evidence of which factors are necessary for implementing which interventions in which situations, and whether some factors are common and necessary for most interventions in most settings.

There is increasing recognition of the importance of organisational and wider contexts to effective implementation of safety intervention, and much discussion of a necessary 'culture of safety'. However, there is little empirical research which proves evidence about the context for safety improvement. The review below summarises the best empirical research found in the search, and presents theories about which factors could be significant and which can form the basis for planning and future research in the absence of evidence.

Some weak evidence of the results of the absence of certain context factors comes from studies of patient tragedies and 'failed health organisations', which highlight poor leadership as one factor (Walshe and Shortell 2004).

3.1.1 Safety culture

A 'culture of safety' has been suggested as both a necessary condition and an outcome of culture change interventions. Empirical research into this subject is at an early stage, with many varied definitions of culture (Sorensen 2002, Scott et al 2001, 2003) and few validated instruments for measuring safety culture (for example, the AHRQ 2004 culture survey instrument). Evidence is not sufficiently strong to draw conclusions about which type of culture or which aspects of culture are most necessary for implementing different strategies, or about effective ways to change culture.

Probably the most discussed in the literature is how to achieve an 'open' and 'no-blame' culture, and the belief that this is necessary for effective reporting of incidents by personnel (Leape 2002).

An even tougher issue, but one that goes to the heart of creating the much vaunted culture of safety that we are striving for in health care, is the hierarchical social/organizational structure of departments and services in hospitals. Residents and nurses are still too often put down or humiliated if they question the judgment of a senior physician. This is especially true in the operating room. This needs to change. Modern health care is too complicated for any individual to always know exactly the right thing to do. We need to do a much better job of learning to work in teams. (Leape, in Schyve 2004)

3.1.2 Protection for and accountability of healthcare providers

Actions to require reporting and to protect workers from sanctions are interventions which provide the context for other local interventions. Much discussion but little empirical research was found in the literature about anonymous reporting of adverse events (Runciman et al 2001), freedom from disciplinary action, and policies on disclosure of these events and near misses to the public. These are all important conditions that affect data collection and clinical practice. Other context issues in implementing known effective solutions or methods are considered in chapter 8.

3.1.3 Context factors – general research

Other research has also suggested that the following factors are necessary for effective safety improvement in healthcare organisations:

- committed and sustained senior and middle-level leadership (see review of research in Øvretveit 2009d)

- active participation by physicians
- willingness and ability to address cross-professional, cross-unit and cross-service issues and to make changes
- sufficient financial and expert resources
- information technology systems for gathering data, electronic medical records, computer order entry and decision support.

A recent paper by leading US experts describes 'system barriers' to safe healthcare. It proposes that methods which are used in other industries do not need significant changes for healthcare, but that changes are needed in beliefs about performance and autonomy. Features of healthcare that are barriers to it becoming an 'ultra safe industrial system' are proposed as: the need to limit the discretion of workers; the need to reduce worker autonomy; the need to move from a 'craftsmanship mindset' to 'equivalent actors'; the need for senior leaders to arbitrate to optimise safety strategies; and the need for simplification. The paper suggests that three unique problems need to be overcome: the wide range in risk between medical specialties; difficulty in defining medical error; and different structural constraints (public demand, teaching role, personnel shortages) (Amalberti et al 2005).

Other research that describes conditions for successful clinical change include Borbas et al (2000), Greenhalgh et al (2004), Cabana et al (1999), Dopson et al (2002), NHS Centre for Reviews Dissemination (1999), Davis et al (2003), Solberg et al (2000), Grol et al (2004) and Bradley et al (2003, 2004). Michie et al (2005) describe psychological and social factors which may be important in implementing safety changes.

The secret of culture change is, I believe, quite simple: leadership and champions. Putting it in the negative, culture change cannot happen without strong leadership from the top and active leaders, physician champions, at the front line. Leaders must articulate the goals, demonstrate their commitment in everyday life, and persuade others to make the changes needed. In those institutions and systems where the leaders have truly made safety the top priority, dramatic changes have occurred. The challenge is how to get more of them aboard. (Leape, in Schyve 2004)

3.1.4 Specific interventions – evidence of necessary conditions

A number of factors have been suggested as necessary for effective implementation of different safety interventions; however, there is little strong evidence about which factors are critical for success. This research field is in its infancy – to date, the safety interventions for which there is the best evidence of necessary conditions for implementation are clinical guidelines, infection control and hand hygiene.

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