Evidence: **Involving primary care clinicians in quality improvement**

The

Health

Inspiring

Foundation

Improvement

An independent evaluation of the Engaging with Quality in Primary Care programme

April 2012



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Involving primary care clinicians in quality improvement

An independent evaluation of the Health Foundation's Engaging with Quality in Primary Care programme

Final report

Tom Ling Bryony Soper Martin Buxton Stephen Hanney Wija Oortwijn Amanda Scoggins Nick Steel





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Foreword

In 2007 the Health Foundation launched the Engaging with Quality in Primary Care (EwQPC) improvement programme. Building upon a previous initiative in secondary care, it aimed to engage primary care clinicians in clinical quality measurement and enable them to contribute to the knowledge base on improvement.

The Health Foundation funded nine EwQPC projects that would increase the capacity for clinical quality improvement in primary care and engage primary care clinicians in clinical quality improvement. The programme also aimed to enable primary care clinicians to contribute to the knowledge base on improvement and use the evidence generated to embed clinical engagement in efforts to improve the quality of primary healthcare.

The independent evaluation, undertaken by a team from RAND Europe led by Professor Ling, identified a wide set of benefits. The projects secured and maintained the involvement of clinicians and were associated with changes in clinicians' attitudes, behaviours and understanding. Patient involvement was an important and successful element of the programme. The projects also learned a lot about the challenges and opportunities of implementing improvement efforts. Measureable benefits for patients were found, but overall they were modest and patchy. Four of the projects have been able to sustain their work since the programme ended. This thoughtful report also offers a candid critique of quality improvement approaches and evaluation methods.

First, the report asks whether the results could have been achieved by other means. The authors identify some distinctive features of the projects funded:

- the focus on aligning different approaches involving multiple groups and organisations
- a concern with continual, self-conscious change across communities of practice
- an effort to get to and change the internalised and collectively reinforced practices that might be at the root of the problem
- an aim to move emotionally as well as improve rationally.

'The problems they are well placed to address are those difficult to improve with guidelines, audit and financial incentives alone. They are the problems that are found in how knowledge is used in groups or communities of practice, how attitudes are collectively reinforced by organisational life, and how behaviour is collectively sanctioned.' They conclude that that there is a legitimate role for quality improvement projects of the type funded through the programme, but add:

'However, for this to happen well, and for it to generate learning, each QI project requires much greater clarity about its purpose. Complexity and emergence are not an excuse for lack of clarity about purpose – they make such clarity even more important.'

This latter point resonates strongly with the findings of a recent review of the Health Foundation's independent evaluations which was undertaken by Professor Dixon-Woods and colleagues, published in a report called Overcoming challenges to improvement, available from the Health Foundation website. Dixon-Woods argues strongly for the value of developing a theory of change as part of the design of improvement interventions and keeping it under constant review as an initiative proceeds.

Professor Ling and colleagues argue for greater clarity about which improvement approaches are most appropriate to a particular problem. Again, this resonates with Dixon-Woods and colleagues, who say:

'Perhaps the over-riding message is that there is no magic bullet in improvement. This does not mean that nihilism has a place, but it does mean a need to accept the challenges and adopt a solutionfocused approach. Much of what we have found concerns tensions and balances, so solutions need to be nuanced, sensitive, and sensible, while maintaining a firm focus on the benefits of improvement for patients.' Professor Ling and colleagues also consider how to ensure a good fit between improvement approaches and evaluation methods. They maintain that the improvement projects in EwQPC sit between clinical trials and highly complex interventions and encompass some attributes of each. Reflecting on the emergent nature of most of the projects, the evaluators questions the value of the hypothesis testing approach used by some of the projects in their 'local' evaluations. They also raise concerns about the ability of the projects to undertake 'useable' economic evaluation – the absence of good data on patient benefits and costs can clearly limit their ability to make the business case for further investment in improvement work.

In summary, this report provides clear lessons about the challenges of undertaking improvement work and confirms the findings of other similar studies that show differences between ambition and practice. Its observations are likely to make important contributions to the developing field of improvement science.

Dr. Dale Webb Director of Evaluation & Strategy The Health Foundation

Preface

The Health Foundation is an independent charity working to improve the quality of healthcare across the UK and beyond. It has a portfolio of activities including programmes to support leaders, promote innovation and research, and disseminate reports on issues of high importance relating to the UK health system. In 2006 the Health Foundation made available £5 million for an Engaging with Quality in Primary Care programme. The rationale behind the programme was that clinicians need to be fully engaged in efforts to improve quality if the full potential of interventions designed to produce identifiable and measurable improvements for patients is to be realised. Nine projects were selected to receive funding under the programme.

The Health Foundation appointed a consortium of RAND Europe and the Health Economics Research Group (HERG) at Brunel University to undertake an evaluation of the programme. This evaluation team had previously been successful in a competitive bid to conduct an evaluation of a similar, precursor programme operated by the Health Foundation – the Engaging with Quality Initiative. The evaluation of the the Engaging with Quality in Primary Care programme began in 2007 and this is the final report from the evaluation team.

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Executive summary

This report sets out findings from a four-year evaluation of the Health Foundation's Engaging with Quality in Primary Care programme. Nine teams from across the country were funded to design, implement and evaluate quality improvement projects. These projects would engage primary care clinicians in making measurable and sustainable improvements in the quality of clinical care.

There was considerable variation across the projects in terms of the clinical fields covered, and the number of practices and professional groups involved. The extent of change sought also varied, from relatively small, incremental changes to existing systems, to more radical restructuring of organisations and systems.

Quality improvement (QI)

The term 'quality improvement' means different things to different groups in different settings and contexts. Many policy measures introduced over the last 10 years aim to improve the quality of care – such as the creation of national standards, the use of contractual provisions specifying quality of care, and the application of financial incentives to encourage clinicians to meet targets. The findings from this evaluation are based on empirical evidence we collected from the nine projects. The conclusions we draw refer to the approach to quality improvement employed in those projects. Key features of this approach included:

 Formal steps and activities, mapped out in advance and communicated to relevant stakeholders, with activities defined and goals identified.

- Improving a system, rather than focusing solely on improving skills of individuals.
- Identifying new ways for different groups of clinicians and patients to work together.
- Collecting evidence that allows judgements to be made about the worth of the project.
- Changing what happens for patients.

Learning from the projects

The projects secured and maintained the involvement of clinicians and were associated with changes in clinicians' attitudes, behaviour and understanding. Patient involvement was an important and successful element of the programme.

The projects were well led and managed. Many demonstrated there are National Health Service (NHS) teams able to lead demanding projects and integrate groups across a range of organisational settings.

While each project can rightly claim to have done some things well, it is clear that undertaking a QI project is more demanding and its benefits more elusive than project teams initially think. QI projects may be a solution to some problems, but they are not a universal fix for poor quality in the NHS. The measurable benefits for patients achieved during the period of the evaluation were modest and patchy. Projects also prioritised achievement of other, wider benefits and in some instances were able to demonstrate these.

Clear lessons

There are clear lessons from the programme about how to deliver QI projects in primary care. The projects did many difficult things with creativity and brought a palpable level of energy to their work. Consequently, both the evaluation and project teams learned a lot about delivering QI projects in primary care. These lessons, however, should be considered in the context of two caveats.

First, the relationship between QI projects and other approaches to improving healthcare (such as guidelines, financial incentives, setting national standards, and so on) is complicated. QI projects adopt a distinctive framework, but also integrate elements of other approaches. This leaves scope for confusion of purpose and poses challenges for attributing change, or lack of it, to a particular project.

Second, by their design, QI projects have an uneasy relationship with traditional evaluation and hypothesis testing. For evaluation purposes, QI projects fall between and encompass some attributes of clinical trials and complex interventions. This poses challenges for evaluators in selecting the 'tools' for assessing QI projects.

There are also particular difficulties in undertaking economic analysis. Not only did projects find it difficult to provide detailed cost and convincing impact data, but they frequently failed to have specific, time-bound and quantifiable outcomes.

Keys to successful QI projects

Despite these caveats, evidence from the programme highlights four elements that are crucial to the successful delivery of QI projects in primary care:

- Leadership: QI projects in the NHS involve different groups and individuals who are usually not in 'command and control' relationships. Aligning activities therefore requires skilful leadership (which might need to change during a project's life).
- Identity: stakeholders' participation in QI projects is associated with entrenched ways of working and strongly-held identities, and these can either be barriers or facilitators to QI activities.

- **Knowledge and skills**: QI projects often require knowledge and skills which are not part of the routine work of the NHS.
- **Sustaining benefits**: QI projects compete for attention an d resources with other approaches intended to improve the NHS. Careful planning is required to ensure that successful or promising QI projects are sustained and spread.

The role of QI projects

QI projects are one solution among many, but they have a particular contribution to make.

There are many competing solutions to the problem of a gap between achievable and actual healthcare in primary care. QI projects can relate in various ways to other activities intended to improve quality. The relatively clear features of industrial models of QI projects become more diffused and emergent when transposed to a health setting. Other approaches that QI projects relate to, and sometimes absorb, include guidelines; audit/ feedback; use of opinion leaders; financial incentives; setting national standards; clinical governance; annual appraisal; public access to performance information; inspection; and patient safety initiatives.

What differentiates QI projects in the NHS is:

- their focus on aligning these different approaches, involving multiple groups and organisations
- a concern with continual, self-conscious change across communities of practice
- an effort to get to and change the internalised and collectively reinforced practices that might be at the root of a problem.

QI projects aim to move emotionally as well as improve rationally. The problems they are well placed to address are therefore those that are difficult to improve using guidelines, audit and financial incentives alone. They are the problems about how knowledge is used in groups or communities of practice, how attitudes are collectively reinforced by organisational life, and how behaviour is collectively sanctioned.

Chapter 1 Introduction & background

1.1 About the programme

In 2007, the Health Foundation invited bids for funds for projects that would engage primary care clinicians in making measurable and sustainable improvements in clinical care quality.

The Engaging with Quality in Primary Care programme was premised on the argument that active engagement of clinicians provides a sustainable and cost-effective means to improve outcomes for patients.¹

The same rationale underpinned the preceding Engaging with Quality Initiative that ran from April 2005 to June 2010 and focused largely on secondary care.² The four objectives of the programme were to:

- increase the capacity for clinical quality improvement (QI) in primary care
- engage primary care clinicians in clinical QI
- enable primary care clinicians to contribute to the knowledge base on QI
- use evidence from the project to influence healthcare policy in ways that will embed clinical engagement in QI in primary care.

Nine large-scale projects, involving general practitioners (GPs), nurses, allied health professionals, practice and primary care trust (PCT) staff (including commissioners), and patients and patient representatives were commissioned in various areas of primary care.¹

These projects are listed below in the order in which they were completed, with the lead organisations identified in each case. For brevity their short names (in parentheses) will be used throughout the rest of this report.

An overview of the projects is provided in appendix B, and each project is described in more detail in chapter 3.

The projects

- 1. Implementing evidence-based primary care for back pain (IMPACT); Keele University.
- 2. Improving the quality of mental health in schools (QUEST); Institute of Psychiatry, King's College London.
- 3. A whole-systems approach to quality improvement (QUALITY:MK); Milton Keynes PCT.
- 4. Primary care domestic violence programme (IRIS); Queen Mary, University of London.

¹ At the invitation of the Health Foundation, members of the evaluation team had sight of all the applications and contributed to the selection process for the programme. We were aware of the potential conflict of interest in this. As both selectors and evaluators, we might be seen to have an interest in emphasising the success of projects. However, we were very clear that our role in the external evaluation was not to evaluate the success of individual projects, but to support their self-evaluations and to evaluate the programme as a whole.

- 5. A quality outcomes framework for gastrointestinal (GI) disorders (IMAGE); CORE (Digestive Disorders Foundation).
- 6. Improving the management of back pain in the community (LIMBIC); Bournemouth University.
- Equity, ethnicity and expert patients (EQUITY); The Clinical Effectiveness Group (CEG), Centre for Health Sciences, Queen Mary, University of London.
- 8. Quality improvement in chronic kidney disease (CKD); St George's University of London and Kidney Research UK.
- 9. Resources for effective sleep treatment (REST); West Lincolnshire PCT.

In total, the Health Foundation provided £5.5 million. In addition to the funds allocated to the projects (£4.3 million), funding was provided for two external teams to support the projects.

The first of these was the Leading Improvement Teams Programme (LITP). It was developed and implemented by the Improvement Foundation in conjunction with Karen Picking and Associates (an organisation of leadership development consultants).

Their aims were to provide the project teams with enhanced high-level QI skills; develop the leadership capabilities of individual team members and promote effective team working; and support the teams in their efforts to spread and sustain project outcomes.

The second team, from RAND Europe and the Health Economics Research Group (HERG) at Brunel University, was commissioned to undertake the external evaluation of the programme as a whole, having previously successfully bid to evaluate the Health Foundation's precursor programme – the Engaging with Quality Initiative.

Each of the nine projects was expected to cooperate with the external teams as they developed and implemented their QI activities.

Underpinning this approach was the notion that the programme should be developmental in nature and that project protocols should not be fixed and irrevocable from the start. Instead these should be developed as each project was implemented by an iterative process of reflection and redesign.

This report describes the external, programmelevel evaluation of the Engaging with Quality in Primary Care conducted by RAND Europe and HERG (from here on referred to as 'the evaluation').

1.2 Aims and objectives of the evaluation

It was the Health Foundation's intention that the evaluation be conducted at the same time as, and be integral to, the programme, and operate at two levels:

- Self-evaluation evaluation of the individual projects.
- External evaluation evaluation of the overall programme.

At project level, the aims of the self-evaluation were to:

- assess the degree to which individual projects achieve measurable improvements in patient care
- identify the range of factors associated with success

At programme level, the aims of the external evaluation were to:

- work with the projects to develop and implement their evaluation plans, including collecting reliable data on mechanisms, contexts and outcomes (key measures of effect and overall costs)
- synthesise the data and findings from the project-level evaluations
- measure professional engagement in clinical QI.
- measure the effectiveness of the programme in leveraging external commitment to clinical leadership of QI

- evaluate any changes in competency and infrastructure for QI in the organisations benefiting from funding
- assess the policy influence of the programme.

Thus the external evaluation and the project self-evaluations were both expected to determine progress against programme objectives. They would identify and measure outcomes, assess the processes adopted, and explore the thinking behind the projects to identify the factors associated with success.

While the external evaluation was expected to address all four programme objectives, the project self-evaluations were to concentrate mainly on the extent that individual projects had achieved measurable improvements in patient care.

The approach to the external evaluation was shaped by three key factors:

- The developmental approach adopted by the Health Foundation.
- The need to work closely with the project teams on their emergent project designs, in an iterative exchange that reflected their growing understanding of the programme and our growing understanding of their aims and environments.
- The need to retain objectivity as we assessed the programme as a whole.

1.3 The policy context of the programme

Since 2000, the government's 'system reform' agenda for England's National Health Service (NHS) has aimed to create a self-improving NHS that is more responsive to patients' needs.

These reforms aimed to move the NHS away from a reliance on centrally-issued targets. Instead, change would be driven by introducing market-style incentives through competition from new providers, more patient choice and more effective commissioning of services by GP practices and PCTs. In England, the changes established in the *NHS Plan* in 2000 and reiterated in 2004 were continued through the *NHS Next Stage Review* in 2008.³⁻⁵ The plan aimed to put quality at the heart of the NHS, empowering staff and giving patients choice. These policies, together with additional funding for the NHS, created a climate for QI.⁶

One particular concern for the projects was the various changes in policy on commissioning in primary care, and the degree to which competition should be introduced into the NHS. The creation of the NHS internal market in 1991 split purchasers from providers of healthcare.

Health authorities became purchasers and larger general practices could volunteer to become fundholders with an annual budget to purchase elective hospital procedures.

Other general practices continued as before, with their expenditure on healthcare covered by their health authority. Some evidence showed that fundholders were more active purchasers in search of lower prices and better quality, and providers were more responsive to fundholders than to health authorities.

Other studies suggested that inertia and a reluctance to move away from historical patterns left the overall situation largely unchanged.⁷⁻⁹

In 1997, with the change of government, the policy balance shifted from purchasing, contracts, markets and competition towards commissioning, long-term agreements, and collaboration. Fundholding was abolished in April 1999, and budgets for purchasing healthcare were removed from health authorities and devolved to smaller, newly-created, primary care groups (later replaced by PCTs). This moved responsibility for commissioning to primary care organisations.⁷

In the following years, further policy initiatives attempted to strengthen commissioning, but with limited impact. Few primary care organisations felt they had effective leverage over providers.¹⁰

In a further change of policy direction, practicebased commissioning was introduced in 2004 and from April 2005 general practices were once again encouraged to hold budgets for commissioning secondary care.¹¹ Competition also resurfaced with the encouragement of diverse providers of healthcare.

During the Engaging with Quality in Primary Care programme, commissioning of health services took place through two main routes:

- Via PCTs, working with local authorities, other PCTs and primary care clinicians.
- Via a form of practice-based commissioning in which some practices were allocated a notional budget by their PCT.¹²

In December 2007, World Class Commissioning (WCC) was introduced to develop and improve capability and capacity for commissioning .¹³ Again, there was a mixed result. There was some evidence of progress, but problems persisted, including:¹²

- those resulting from the numerous reorganisations of PCTs
- the lack of real budgets for practice-based commissioners
- organisational immaturities
- difficult relationships between practices and PCTs
- limited public involvement and accountability
- weaknesses of clinical leadership and engagement in PCTs
- inadequate capacities for data analysis.^{12,14-16}

In this report we describe how these difficulties appeared to affect the capacity of PCTs to respond to QI efforts in this programme.

In some cases there was a negative impact on projects. Some found they were struggling to get PCT interest and involvement. In other cases it was precisely these difficulties, and the determination to overcome them, that drove the project and its QI work forward.

More recently, in July 2010, the government published a White Paper on the NHS, setting out its long-term vision for the future of the service.¹⁷ These reforms are, at the time of writing, still being debated in parliament. The White Paper maintained the emphasis that had characterised preceding reorganisations – putting patients at the heart of the NHS.

There was a renewed focus on healthcare outcomes and the quality standards required for delivering them. It also set out the intention to devolve responsibility for commissioning by delegating powers to GPs and their practice teams.

They would be working in consortia and operating under the aegis of a new NHS Commissioning Board. The While Paper also set out proposals for the NHS to achieve unprecedented efficiency gains by 2014.

The degree to which these proposals will be implemented remains to be seen.

1.4 The quality gap and clinical engagement

Over 80% of contact between the public and the health service takes place in primary care settings.¹⁸ However, as in other areas of healthcare, there is often a gap between recommended care and actual care received. For example, McGlynn and colleagues produced evidence that in the USA care received matched recommended care on only 55% of occasions.¹⁹ This finding is matched by studies in other developed countries.²⁰⁻²¹

These problems of delivery have been recognised for a long time. Programmes to encourage the implementation of research findings and strengthen evidence-based care were set up in:

- Canada in 1992²² and in 2001²³
- the UK in 1994²⁴
- the USA in 1998.²⁵

In 2001, the US Institute of Medicine raised the profile of QI in healthcare, emphasising the gap between research findings and healthcare practice.^{5,26}

The link between health outcomes, quality of life and QI is now well recognised. But, and as attested by the large number of applicants to this programme, numerous quality gaps remain unaddressed.

1.5 What is QI?

A starting point for thinking about QI is to identify quality in healthcare. Whilst there is no single definition, the Institute of Medicine's definition of quality is widely adopted:

The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.²⁶

It states that quality is concerned with the degree to which the healthcare system is:

- safe
- effective
- patient-centred
- timely
- efficient
- equitable.

The meaning of the term QI in healthcare has itself evolved during the life of this programme. For that matter, the thinking of both the evaluation team and the Health Foundation has also evolved. Despite uncertainties about the precise boundaries defining QI, the core meaning has become much clearer. There is some consensus across different definitions that QI is a systematic approach that uses specific techniques to improve quality. The Health Foundation's definition of QI is provided by John Øvretveit:²⁷

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.

For the Health Foundation, the key elements in this definition are the combination of a 'change' (improvement) combined with a systematic 'method' (an approach or specific tools) to attain a superior outcome:²⁸

[QI] aims to improve patient experience and outcomes by taking a systematic approach that uses specific techniques to improve quality. These approaches are often known as 'organisational' and 'industrial' methods, as their origins are in the manufacturing industries. The approaches help organisations to analyse performance and make systematic changes in order to improve quality.²⁹

The evidence collected from the projects reinforces the evaluation team's view that QI involves deliberate and planned attempts to use specific techniques to bring about systematic changes to an organisation, or set of organisations, to deliver better quality care to patients.

In these projects, individuals matter. This is apparent from the evidence set out in chapter 5, relating to clinical engagement and patient involvement. How individuals are organised to work together in pursuit of institutionally supported and formally identified goals is core to understanding what QI is, and what does and does not work in QI activities.

It is not about individuals, on their own account, identifying and pursuing things to make themselves more personally effective (although this surely has a place in improving healthcare generally). Rather, it is about how individuals work together in groups and organisations.

The techniques designed to deliver quality improvement in healthcare are organisationally oriented but varied. In their industrial origins, such techniques often involved efforts to overcome quality and productivity problems in manufacturing industries associated with the production line.

In general terms, these techniques might be characterised as efforts to improve outcomes by reorganising the system, rather than equipping individuals differently. The focus is on the needs of the end user, rather than the producers; on reducing either waste or errors; and on using evidence and information to support cycles of constant improvement, rather than one-off changes to the production line.

In the settings where QI originally applied, the organisational boundaries were clear, and the range and roles of each stakeholder were clearly defined. If necessary, these were underpinned by human resources departments and labour contracts, and outcomes were focused and clear (happy customers who keep buying the product).

5

Importantly, data on costs and outcomes were readily available. In the health system, much of this is often not true.

All too often, structural elements of the health system that were designed for other purposes, or have just arisen over time, fail to support QI projects – such as data collection arrangements in general practice or the current somewhat hierarchical relations between GPs and other practice staff.²

Unlike in more command and control settings, in healthcare it often takes significant management or leadership capacity to get QI work up and running. Sometimes even greater efforts are needed to overcome entrenched systemic characteristics that impede implementation. In chapter 6 we discuss a framework for analysing QI activities.

In all the Engaging with Quality in Primary Care projects, QI came to involve:

- a concern to improve collaboration
- a concern to change the systematic way healthcare is done, by training, changing attitudes and providing information differently
- using evidence and data produced by the project to help reflection and adaptation
- a concern to embed QI activities in distinct organisational, professional and clinical settings.

There was a difference in the scope and ambition of the improvements sought. Seven of the projects intended to produce relatively small incremental clinical changes in particular areas of healthcare (such as a change in prescribing or referral practice), and through this process increase participants' understanding of QI and QI activities.

Two projects attempted to introduce larger, more transformational, whole-system change across a local health economy, covering several clinical fields and aiming to involve all those working in that economy in ongoing, continuous QI.

The role of clinical engagement

The ultimate test for quality is what happens at the point of care for patients. QI programmes that fail to engage clinicians (including doctors, nurses and other health professionals), and are insensitive to the nature of medical work, tend to have limited impact.³⁰

Clinical engagement is a necessary element of successful improvement. Barriers to clinical engagement include inadequate resources, the pressure of competing demands, lack of appropriate information systems and training, insufficient skills, inadequate rewards, staff turnover, disinterest, and resistance.²

Incentives include the perceived benefits to patients, pressure from respected opinion leaders, commissioners and patients, financial incentives (such as in the Quality and Outcomes Framework – QOF), the availability of suitable training, and public reporting of results.^{2,32}

An important driver of clinical engagement is leadership: 'Effective leaders challenge the status quo both by insisting that the current system cannot remain and by offering clear ideas about superior alternatives'.³³ The link between leadership and QI is well attested in industries such as aviation and car manufacturing .³⁴ It has also been demonstrated in healthcare settings, and its importance was highlighted in the 2008 Darzi review.^{5,35} In the UK, programmes to promote clinical leadership have been established by bodies such as the NHS Institute for Innovation and Improvement, and the Health Foundation.

1.6 Our approach to the evaluation

An evaluation aims to understand what difference a service, regulation or other activity makes, what it costs, who bears the costs, and who receives the benefits. It is concerned with the contribution made to achieving desirable outcomes and minimising undesirable costs and consequences. In this evaluation of the Engaging with Quality in Primary Care programme, we adopted a similar approach to that of our earlier study of the Engaging with Quality Initiative, building on what we learned and adjusting our methodology as necessary.³⁶ We sought to explore the logic of each project's approach within a framework informed by realist evaluation.

Realist evaluation aims to establish clear and measurable relationships between a project and its outcomes. It assumes there is an underlying theory of change behind a project. This theory of change explains how it brought about the measured change and is sensitive to the context in which the project is delivered.³⁷

Applying this approach in this evaluation required consideration of attribution, contribution and causality in the context of complex interventions that evolved over time.

Theory of change approaches and the 'contribution story'

Our approach took as its starting point the argument of Weiss:

The concept of grounding evaluation in theories of changes takes for granted that social programs are based on explicit or implicit theories about how and why the program will work ... The evaluation should surface those theories and lay them out in as fine detail as possible, identifying all the assumptions and sub-assumptions built into the program. The evaluators then construct methods for data collection and analysis to track the unfolding assumptions. The aim is to examine the extent to which program theories hold ... the evaluation should show which of the assumptions underlying the program are best supported by the evidence.³⁸

In this sense, looking at theories of change is an approach rather than a methodology, and its successful delivery requires the harnessing of a range of methodologies. The importance of theories in healthcare and research has long been attested.³⁹ There is growing appreciation for using theories when developing and implementing improvement interventions and understanding the underlying processes.⁴⁰⁻⁴² Our theories of change approach followed five principles, set out below. Individually these are in our view neither controversial nor radical, and taken together they provide a pragmatic base for conducting complex evaluations.

- 1. Examine the outcomes and processes of the programme.
- Work closely with project teams (and also with policy-makers and end users) as an embedded evaluator, without losing our independence. This is to understand the world of the project teams, practitioners and service users, including understanding what motivates their behaviour and the theories of change underlying the projects.
- 3. Reconstruct and represent the sequence of events as the projects were implemented. Explore how these contributed to the outcomes achieved and, where possible, identify the causal mechanisms at work.
- 4. Be sensitive to the possibility that, during the life of a programme or intervention, initial theories of change may be amended in response to learning or exogenous events. The evaluation should capture these changing understandings and actions.
- Be sensitive to different and potentially conflicting theories of change being simultaneously pursued within any one project.

Collectively, these five principles describe:

- an interest in causal effects (what happens when an independent variable changes)
- an interest in causal mechanisms (what connects causes to their effects, what is the dynamic of the project)
- what project teams and practitioners say they do and what the evidence shows they do
- what contribution stories practitioners tell themselves and others, and what really contributes to patient benefit or healthcare improvement.

In putting these rather abstract arguments into practice, we followed what Mayne calls the 'contribution story'.⁴³

We aimed to understand why project teams and participating clinicians, managers and service users believed that their use of resources would contribute to the intended health system and patient benefits, and why side-effects and unintended outcomes would be manageable. We then checked to see how our data supported or weakened these stories.

Pragmatically, we agree with Mayne that in 'most cases what we are doing is measuring with the aim of reducing uncertainty about the contribution made, not proving the contribution made'.⁴⁴ In practice, we needed tools to develop and understand the contribution story and make sense of the claims, sometimes varying, that are made.

These tools were the projects' self-evaluation reports. These encouraged a focus on cause and effect and helped the project teams to develop narratives of change. The information in the self-evaluation reports was supplemented by face-to-face meetings with the project teams, in which the evaluation team explored some of the more informal aspects of these narratives.

From these data sources we aimed to develop descriptions of what each project was trying to do and what they thought would bring about the hoped-for improvements. There was a balance to be struck in doing this. It was important to avoid the implication that because all the projects were branded as QI, they were all essentially similar. We also needed to avoid the risk of becoming so immersed in each project's details that:

- it became hard to compare and contrast them with each other
- it became difficult to compare them with QI activities outside the programme, or with other ways of delivering patient benefit and system improvement.

1.7 Data collection and analysis methods

The Health Foundation set out seven aims for the external evaluation. We identified a series of tasks under each aim. These are summarised box 1 (page 12). In this section we describe the data collection methods employed in pursuit of each task.

Aim 1

Work with projects on the development and implementation of their evaluation plans, in line with established self-evaluation guidance

The first aim was to support the project teams' self-evaluations throughout the programme. We aimed to:

- ensure the project teams understood what was required from the Engaging with Quality in Primary Care evaluations at both project and programme level
- develop our own understanding of the projects
- ensure that the data collected by the project teams supported both levels of evaluation.

We asked project teams to complete a selfevaluation report.³ Project teams were asked to use this as a project diary and update it regularly. The reports became the foundation of our interactions with the project teams and formed the basis of yearly formal discussion between the evaluation team and each project team.⁴

We also had informal contact with the project teams at the programme-wide events run through the LITP, and visited teams to provide further support. We ran occasional general (and, in some cases, individual team) sessions on issues such as identifying costs and assessing cost consequences. This was deep immersion, providing us with both formal and tacit knowledge of the projects.

4 The evaluation team met formally with the projects at four points: between June–August 2007; April–June 2008; December–February 2009; and January–July 2010.

³ Similar reports were produced by the Engaging with Quality Initiative project teams using a common format that was initially designed by the Health Foundation and the external evaluation team (see appendix D).

To assess service-user involvement, we conducted semi-structured interviews with eight service users to explore their role in, and experiences of, the projects.⁵ This information was supplemented by the rich understanding we developed of service-user involvement, how it influenced the projects, and what this told us about successful service-user involvement in the projects.

Aim 2

Analyse and synthese the data from the projects' self-evaluations

In accordance with our commission from the Health Foundation, our evaluation was based on data collected by the project teams. Therefore, it was important that we understood the projects' approaches to data collection, validation and analysis, as well as any significant changes to these approaches as the projects were implemented.

We encouraged the project teams to address important gaps in the data that we thought that we (and the project teams) would need to fill. This detailed work enabled us to proceed on the basis that the final reports received from the project teams were an accurate account of the projects.

The projects were asked to complete an additional submission, covering the following:

- A list of sources of data about improvement in patient care, and other outcomes, from their project.
- An overview of the extent of implementation of the project.
- Data on measurable patient outcomes (including tests of statistical significance).⁶
- A summary of how the project has increased the knowledge base and understanding of QI in healthcare.
- An overview of any sustainable arrangements for improving the quality of care as a result of the project, and whether the project had developed a system of QI that was transferable to other areas of medicine.

This information complemented the understanding we gained from the self-evaluation reports. Some project teams submitted additional reports and presentations. Details of all the sources of data from the projects are given in appendix F.

We undertook a thematic analysis of the reports. In doing this we heeded concerns that:

the overwhelming majority of studies of QI are descriptive rather than explanatory; QI is dominated by a 'menu mentality' – by lists of key factors such as leadership support, team-based structures and composition, IT systems and their failings.⁴⁵

We did not want to produce yet another list. We therefore drew on existing frameworks that have helped others think about QI efforts.

Donabedian provided an original framework with his healthcare triad of structure, process and outcome.⁴⁶ Many years later, Glickman and colleagues updated Donabedian's concept of structure, and developed a framework that linked five key organisational attributes for improving quality: organisational design, culture, executive management, incentives and IT.³⁴

At about the same time, Bate and colleagues undertook an examination of the quality of nine high-performing healthcare organisations (hospitals, rather than primary care organisations) in the UK and the USA, and produced a somewhat similar set of the six common challenges that all the organisations they studied faced: structural (organising, planning and coordinating QI), political, cultural, educational, emotional, and physical and technical.⁴⁵

These frameworks might look like yet more lists, but the crucial difference is that they conceptualise QI as depending on, not only the distinct characteristics of QI, but also the dynamics of organisational and human processes. In theoretical terms, this is a shift from a variance or variables theory (for example, more of X and more of Y produce more of Z) to a process theory (for example, do A and then B to get to C).

⁵ One project team included a young service user with a history of depression who was seeking to 'move on' from that experience; we agreed with that team that it would not be helpful to include this service user.

⁶ Where appropriate, we asked the teams to perform statistical tests on key findings to allow for formal statistical comparison of achievements in relation to patient care across each of the projects.

In empirical terms, it is the shift to seeing QI as more than a method, technique, discipline or set of skills; of seeing it as a human and organisational achievement, and a social process.

In our analysis we sought to understand the theory of change behind each of the initiatives: why the project teams thought that their activities would lead to better outcomes for patients. We also sought to understand the dynamics of each project: what the project teams had achieved, the efforts they had made and the capacities available to them.

Aim 3

Assess increases in professional engagement in clinical QI

Initial meetings with the projects, as well as the projects' original proposals, provided the beginning of an evidence base in relation to the level of professional engagement.

All the projects undertook a survey of clinicians, and we were able to draw on the findings from these where appropriate. Generally these surveys were designed to explore clinicians' confidence in managing a particular clinical condition. There were also some efforts to explore attitudes to clinical engagement in QI more generally. For example:

- REST surveyed 102 practices in Lincolnshire about the relationship between leadership, innovation culture and the uptake of QI methods in general practice, and about the frequency of involvement in QI activities. They achieved a 62% response rate.⁴⁷
- The QUALITY:MK team conducted more generic surveys on attitudes to evidence-based practice and training needs within local practices on three occasions. Each time, they had a very low response rate.
- Some projects undertook qualitative evaluations. These covered either the whole programme (QUALITY:MK and LIMBIC) or significant aspects of it that were particularly importat or had been especially challenging (IMPACT and IMAGE).

These often shed further light on changes in professional engagement and clinical attitudes to QI.

We also undertook our own web-based survey of participating clinicians to explore their experiences of their projects, their attitudes to QI and their views on professional engagement in QI. We asked project managers to send the web survey link to all their participating clinicians.

The nature of the projects meant that it was hard to estimate the total number of potential respondents. We asked the nine project managers to estimate this. Four did so, and gave us a total of 349.

Forty-four clinicians responded, and this low response rate means we treat findings from the web survey cautiously. Further details about the web survey are given in appendix G, which reports our findings in full.

Aim 4

Measure external commitment to QI

We asked project teams to identify their external stakeholders, so that we could map and understand the role of external support in the projects.

Some cited GP practices as their only external stakeholders, while others provided a long list of people in different roles within their local PCT(s). Among the latter, although contacts with PCTs varied, one group that featured repeatedly was primary care commissioners. We therefore conducted seven semi-structured telephone interviews with PCT commissioners in relation to seven projects.⁷

Aim 5

Evaluate the increase in competency and infrastructure for QI in organisations involved in the programme

A major concern for the project was about sustaining any improvement achieved.

⁷ Two projects did not have any contacts with commissioners in PCTs.

Many of the improvements involved service redesign or reconfiguration and, in this, commissioners (whether in PCTs or GP practices) can play an important role.

This evaluation aim was partly realised through the interviews with PCT commissioners. The final self-evaluation reports also included information on this issue.

Aim 6

Assess the influence of the programme on policy and the knowledge base (exploring the wider implications of the programme)

Part of our work under aim one was to support the project teams in developing legacy plans.

The LITP also encouraged them to think about sustainability at an early stage. Our main data source on the sustainability and spread of the projects was the final self-evaluation reports.

Aim 7

Produce summative costs of the programme and its consequences

The need to undertake an economic evaluation alongside studies of the effectiveness of QI interventions is widely recognised.⁴⁸⁻⁵⁰ However, the economic evaluation of implementation strategies is still uncommon and, when it occurs, often unsatisfactory.

The literature discusses a number of reasons for this, including:

- a lack of understanding of the concepts of costs and utility
- researchers not yet trained to integrate cost analysis into their work
- funding limits
- the complexity of interventions and of the systems in which they intervene.

While we worked with the projects to encourage them to identify the costs and, if possible, the cost consequences of their projects, our findings in the programme confirmed this general picture. The main source of data was the final self-evaluation reports.

To conclude the programme evaluation, a roundtable discussion of emerging findings and their implications was held in January 2010. Two project leaders from the programme attended, together with six Health Foundation staff and four members of the evaluation team.

Box 1: Summary of evaluation aims

- 1. Work with projects on the development and implementation of their evaluation plans, in line with self-evaluation guidance
- Work with the project teams to support their self-evaluations, including data identification and validation.
- Assess the experiences of the users as 'active partners' in the projects.
- Consider how the counterfactual for each project can be addressed to assess how much change was attributable to the project, and how much to secular activity.
- 2. Analyse and synthesise the data from the projects' self-evaluations
- Synthesise the data and findings from project-level evaluations.
- 3. Assess increases in professional engagement in clinical QI
- Gauge current professional/clinical engagement through an examination of documentary evidence from the projects.
- Conduct interviews with project teams to explore the state of affairs in the QI context of each project before it has had a chance to influence that setting.
- Conduct a web-based survey of clinicians participating in the programme.
- 4. Measure external commitment to QI
- In-depth interviews with PCT commissioners involved in the programme.
- Assess the contribution made by the PCTs to the programme.

5. Evaluate the increase in competency and infrastructure for QI in organisations involved in the programme

- In-depth interviews with PCT commissioners involved in the programme.
- Assess the contribution made by the PCTs to the programme.
- 6. Assessing the influence of the programme on policy and the knowledge base (exploring the wider implications of the programme)
- Evaluate the projects' legacy plans.
- 7. Produce summative costs of the programme and its consequences
- Work with the projects to explore what data they can provide to estimate costs.

Chapter 2 Conclusions, findings and recommendations of the evaluation

2.1 In this chapter

This chapter sets out the key conclusions, reflections and recommendations of the evaluation of the Engaging with Quality in Primary Care programme. The points made here are developed, explained and evidenced in the following chapters.

The programme aimed to engage clinicians in making measurable and sustainable improvements in the quality of primary care. Nine project teams were given significant grants from the Health Foundation, and they used these to deliver difficult projects under what were often challenging circumstances.

We had access to detailed quantitative and qualitative data from the projects, supporting a very rich narrative account of what each project did and with what consequences. However, our evaluation is constrained by the limited data available from the projects on costs, counterfactuals and context.

The real, measurable benefits for patients, achieved during the period of the evaluation, were modest and patchy. There was a range of important wider benefits.

2.2 The framework for our conclusions and reflections

We have structured our key conclusions and recommendations around three themes:

Why bother with QI in primary care?

First, we discuss what this evaluation tells us about the future of QI in primary care, and whether this has wider implications. Then we pose an important question: can we imagine an approach to QI that builds on the real achievements of the programme, or is it time to rethink how to improve primary care in a more radical way?

Evaluation and QI

We follow with a discussion about the lessons for evaluators and the funders of evaluation. By their design, these projects had uneasy relationships with a traditional approach to evaluating a project. Such an approach requires that the target population is clearly defined, the outcome measures identified, the method for collecting data feasible, and the instruments form an identifiable and bounded package that can be costed.

The scientific method of hypothesis testing requires that the project embody a discrete set of hypotheses that are formulated in a way that can be tested by the production of new data. Not all the projects were set up to be evaluated in this way, nor were all designed to test hypotheses.

We do not think that hypothesis testing is the only way to support learning. We believe that using other evaluation approaches can provide fertile accounts in this situation and lead to improved understanding.

There is a more specific question relating to economic evaluation. As described in chapter 7, the projects have produced a level of economic analysis that is in some cases unusable and overall is not compelling. Our view is that the challenges facing economic evaluation in the projects are a sub-group of the problems facing their evaluation as a whole. These are important challenges; being unable to make a case for QI by identifying patient benefits and costs may mean the marginalisation of these activities.

Delivering QI in primary care

Third, we draw conclusions about delivery. QI project teams would benefit, in terms of delivery and learning, if they were encouraged from the outset to be more explicit about their intended causal pathways, and about how they would know if they were successful.

It is important to note what we mean by this. Each project correctly identified evidence of a gap between actual practice and evidence of good practice. Each project also provided a credible overall approach to how they might go about bridging this gap.

Indeed, each project worked with the evaluation team on developing a descriptive logic map to which project teams then agreed. As projects began to implement their approach, they learned, adapted, redefined and refocused their activities. At the same time, the context in which they were operating often changed – that is, the structural, political, cultural, educational, emotional, and physical and technological environment.⁴⁵

In these circumstances, it requires considerable management and leadership focus (and time) to keep revisiting the causal pathways and be satisfied that the delivery method was the best. There is a trade-off between delivering in a responsive and adaptive way, and being explicit about what is hoped will be achieved and why this is causally connected to the aims of the project. It may be that in demonstration projects, there is a need to fund this ongoing monitoring and evaluation role beyond what would normally be expected in a delivery project.

This is particularly important when significant outcomes are anticipated some time into the future. Many of the changes sought by the projects were changes in processes, such as changes in referral or prescribing rates, rather than final changes in outcomes. The projects also had wider goals. They were concerned with winning clinicians' hearts and minds, and changing attitudes and behaviours. A number of the projects could not give us their full results in time for inclusion in this report (several months after most of them formally completed). This report is therefore a snapshot, based on where the projects are at the moment and not on what they might achieve in the long term.

It is important to know whether a plausible case can be made about whether the projects are producing changes that will result in patient benefit. For example, knowing that referral patterns for domestic violence have changed in the intended manner may not prove that outcomes for women will be better, but it does tell us that this step in the causal chain has been completed successfully.

However, we can only draw this conclusion if the project is explicit about its pathway to improvement. In this respect, as in others, the projects varied.

2.3 Why bother with QI in primary care?

In this section we discuss whether our evaluation indicates that practitioners of QI in primary care should persist with, desist from, or modify their activities. First, we consider what the data from the projects might tell us. We then consider other possible approaches to improving quality in primary care and where, if at all, QI should be a tool to improve healthcare.

What do the project data tell us?

Evidence from the projects can support three different conclusions. The first is that measuring the small and patchy patient benefits of the programme, against the considerable costs, suggests that QI has not been cost effective. There are several possible reasons for this. For example, the projects were on the wrong scale, doing the wrong things, or doing things that could only thrive in a different sort of NHS. From this viewpoint, the conclusion would be that we should not select a QI approach.

A second possible conclusion is that there are real incremental improvements arising from the projects, but we are measuring the wrong things or measuring too early. In this case, we might point to the real and measurable improvements in processes already being reported and say that there is every reason to suppose that these process improvements will result in improvements in patient experiences or health outcomes further down the causal line.

The third possible conclusion is that a focus on incremental change misses the point. QI enables a transformational shift in the delivery of healthcare by creating new attitudes and behaviours among clinicians and others (including service users), new networks, new relationships to the healthcare system, and novel ways of working across organisational boundaries. QI, in this account, has a particular ability to integrate developments across a variety of domains (management, professional, stakeholder, clinical). This makes it unusually well placed to deliver a system shift. In this case, the benefits will be at the functioning level of the whole system, and such transformations often require considerable effort over a long period before there is sometimes a sudden system shift.

The first scenario is sobering. If the programme were a single portfolio looking for further investment, the aggregated outcome and cost data would not make a compelling case even in times of plenty. However, this is to miss the very different conclusions arising from each project.

For example, the IRIS project, which provided training to GPs and practice staff in referral for women who may be experiencing domestic violence, showed that by using a multifaceted approach, focused on a single process change (referral patterns), real benefits could be achieved. It also showed that the chances of demonstrating measurable benefits may be greater when starting from a very low base.

What is especially difficult is to assess the extent that the same improvements could have been achieved through other means. It could plausibly be argued that this improvement would have been harder to achieve through QOF-like provider incentive schemes, because the improvement process involved creating new attitudes among providers (in this case the whole practice team) and service users. Would this have been possible if the financial benefits were evidently monopolised by only one group of stakeholders? Would service users have also been incentivised to change their behaviour?

Evidence from the LIMBIC project suggested that well-known problems in implementing guidelines cannot be remedied simply by incentivising or informing practitioners.⁸ If there was a better way to manage back pain in the community, there would be a ready demand for it from both service users and providers. LIMBIC was able to establish relationships within and across practices that could be used to promote further learning and capacity building, and in the long term that might lead to incremental improvements.

The QUALITY:MK project suggested something different again. It suggested it was possible to bring together a variety of work streams across a whole

⁸ Each of the nine projects are described in detail in chapter 3.

health economy, within an overarching vision, that involved supporting the use of evidence and involving service users in a potentially transformative way.

Implications of 'demonstration project' elements of the programme

Lessons were hard to identify because of the way the projects were set up. First, they included features that were more akin to demonstration or implementation projects. Some projects were more explicit in their self-evaluation reports about their activities, than their reasons for doing these things (their theory of change). In the absence of experimental or quasi-experimental approaches, testing a theory of change can strengthen generalisability, and this is something which can and should be done better in QI projects. But the focus on activities was also a consequence of the way that all the projects learned and adapted as they were implemented.

In this unfolding context, an evaluation that asks, 'What have we learned from this project?', must first ask, 'Which version of the project are we evaluating?'. It is not the case that the projects abandoned their original plans, but each one had to adapt to meet unanticipated challenges and, sometimes, new opportunities.

For the IMAGE project, electronic data collection proved problematic and required a new approach. For IRIS, the training provided for practice staff did not engage practice nurses as anticipated, although it did, unexpectedly, motivate the practice receptionists. The EQUITY project was able to demonstrate how their intervention could be extended beyond the original three conditions, to other conditions such as chronic kidney disease.

What can be learned with certainty from the projects?

First, QI approaches have the ability to involve both clinicians and service users. Second, in the NHS there are teams with the necessary skills and leadership to lead difficult and demanding projects that integrate groups and people across a range of organisational settings. Third, while each project can rightly claim to have done some things well, it is clear that this QI work has been more demanding and its benefits more elusive than the project teams initially hoped.

When and why use QI projects?

Over the past 10 years, in England and across the UK, a number of measures have been introduced as part of a national strategy to improve the quality of primary care. These measures include:

- national standards for the management of major chronic diseases
- clinical governance, using a coordinated approach to local QI activities
- annual appraisal of all NHS doctors
- new contracts that specify the quality of care to be provided
- releasing information publicly on quality of care in individual primary care practices
- financial incentives for doctors to reach a range of quality targets
- a national system of inspection of healthcare providers.

Together, these measures provide a national framework, within which various approaches to improving quality are undertaken. This includes the sort of formal QI projects that were the focus of the Engaging with Quality in Primary Care programme.

When considering when and why to use QI projects, we first need to ask, 'What is meant by QI?'. In our view, it is important to recognise that QI is an essentially contested concept.⁵¹ This means it is a term that people care about, it is seen to be a good thing, but it has different meanings and usages. These differences cannot be resolved with reference to logic, evidence or common usage.

Across the projects there was a shared sense that a QI project involves:

 formal steps – mapped out in advance, communicated to relevant stakeholders, with activities defined and goals identified

- improving a system not focused solely on improving skills of individuals, for example, although this may be part of a QI project
- identifying new ways of doing things together
 different groups, including patients, working together in new ways
- collecting evidence both prospective and retrospective – allowing judgements to be made about the worth of the project
- changing what happens for patients.

The projects also used specific approaches that reflected the origins of QI in industry, such as plan, do, study, act (PDSA) cycles. When seeking to operationalise these approaches in the complex world of the NHS, they sought to align these QI activities to other drivers of change in healthcare. For example, management in industry might not need to draw so explicitly on strong leadership (and professional leadership in particular), but all our projects did. End users were involved in the projects in ways that would not be typical in industrial QI. Different professional and managerial groups had different motivations and identities that the projects found themselves accommodating. More generally, the projects worked within the NHS QI framework, adapting and aligning their improvement interventions to exploit the various measures that constitute that framework. These processes of adaptation and alignment are characteristic of QI projects and are an important part of the learning from any particular project. They also mean that QI projects have a certain necessary fluidity as core activities become embedded within wider approaches.

The key point is that while there are separate approaches to QI, and a myriad of ways of describing them, these approaches are not exclusive. Where possible they can and should be mutually supportive. As Dawda and colleagues note:

It is common for organisations to adopt aspects of more than one framework in their QI endeavours.⁵²

This report focuses on the common core QI activities that were utilised by the nine projects funded through the programme.

The evaluation sought to identify lessons about the circumstances in which this type of programme can contribute to improving the quality of healthcare. We also sought to explore whether there is a particular type of problem to which a QI project, comprising these activities, is well suited.

To place the concerns of the evaluation and this report in context, we might briefly compare the Engaging with Quality in Primary Care projects with some of the other QI measures mentioned at the beginning of this section.

Other QI measures

First, consider financial incentives and targets, in particular the QOF. It provides financial incentive to GPs for meeting certain targets, and evidence shows that it often changed clinicians' behaviour as intended.⁵³ But the QOF can only address problems that are covered by QOF targets.

In this case, compliance, and recording of compliance, places a large burden on GPs and the scope to extend the QOF is limited. Moreover, targets can provide perverse incentives. Not part of the QOF, but an example of an incentive that encouraged perverse behaviour, was the target that all patients should be able to book practice appointments within 48 hours. This resulted in a situation where patients could only book an appointment 'on the day' even when they would prefer to book in advance.

What all this tells us is that financial incentives must be suitably crafted, and any benefits weighed against the costs of collecting data. Formal QI projects might be better placed to address more systemic problems and improve relationships across a range of providers and service users. This would provide solutions that are less about financial incentives and more about complex motivations.

Second, another approach designed to improve quality is registration and revalidation. This focuses on the skills and competencies of the individual clinician and traditionally the main purpose has been to ensure that incompetent clinicians are identified and, where necessary, taken out of the system. By contrast, none of the projects specifically aimed to remove those who were incompetent. Individual incompetence was not regarded as the main problem, in a context where most health professionals work in teams within complex systems that provide variable support for clinicians and their patients.

Third is training and continuing professional development. This can be of particular benefit when the incentive to improve quality exists, but not the necessary skills or knowledge. The projects all included an element of training or developing professional practice, but in each case this was only expected to work as part of a wider process of change.

Fourth are guidelines and various regulatory and quasi-regulatory rules. These range from National Institute for Health and Clinical Excellence (NICE) guidelines through to local referral pathways agreed between acute and primary care. The implementation of guidelines depends on how easily individual cases can be placed into a relevant category, the perceived effectiveness of doing so, and the incentives for adhering to the guidelines (for example, the likelihood of non-compliance being penalised). Guidelines can change practice, but their adoption and use is not automatic.⁵⁴ Additional measures, such as a formal QI project, may be needed to improve adherence.

When might QI projects add value?

The reason for this excursus is to try to discover what is distinctive about QI projects of the sort funded through the programme. What distinguished the projects from other QI approaches was their integration of a range of groups and processes, and not always involving pre-existing local networks and relationships.

When problems arise from the behaviours of communities of practice, or in the tacit understanding of networks, then improving formal guidelines and expanding the evidence base is not enough to deliver improvements for patients.

As LIMBIC reminded us, primary care clinicians interact with a range of colleagues and across various networks when creating an internalised, collectively reinforced tacit guideline.⁵⁵ The literature also tells us that networking can be an important contributor to the success of collaborative initiatives, especially where the network has been developed to give service users more voice and visibility.⁵⁶ Because these changing relationships develop in complex ways, QI projects have the unfolding and learning dynamic identified earlier.

The problems that attracted programme funding were those that were difficult for one group to own alone, and where the solution required some degree of alignment among organisations and individuals not in a hierarchical relationship of control.

For example, the REST project aimed to reduce the rate of Z-drug prescribing by drawing on academic research skills, process redesign skills, embedded experimentation and regular feedback. The activities of GPs, researchers, health service managers and patients were all to be part of the process of change. Others, such as IMPACT, IRIS and IMAGE, sought to empower groups of practitioners, practice staff and patients to think and work beyond their previously defined roles.

With this programme we saw that those working on QI projects may start with a particular approach, but as they adapt to their context the project becomes more integrating and fluid.

Therefore, the principles of measurement, standardisation and so on that Dawda and colleagues apply to QI may need to be modified.⁵²

For example, project measurement was not always focused on impacts. Some projects used small steps and piloting, and some preferred standardised approaches. However, there were features common to all projects:

- a concern to improve collaboration
- a concern to change the systematic way healthcare is done (for example by training, changing attitudes or providing information differently)
- the use of evidence and data produced by the project to help reflection and further work.

Could the projects have used other approaches?

Using this as our understanding of the type of QI project funded through the programme, we might ask if the changes identified as a result of the IRIS project, for example, could have been achieved more easily and cheaply using other means.

Economic incentives might have motivated the participating GPs, but would they have led to the changes in support and advice, and the integration with the voluntary sector, that were necessary for the success achieved in IRIS? Guidelines and professional leadership directed solely at GPs would have similar shortcomings. Registration and revalidation is too blunt an instrument to support specific QI projects, such as IRIS, although they could be used to support participation in QI activities more generally.

Similarly, in IRIS, education and training did a lot of the work, but the team highlighted the importance of the support provided by advocate educators, comparative feedback and its influence, and input of the service user to develop a powerful voice. Therefore, our view is that there is a legitimate role for QI projects of the type funded through the programme. It includes organising, coordinating, managing, informing and leading change. However, for this to happen well, and for it to generate learning, each QI project requires much greater clarity about its purpose. Complexity and emergence are not an excuse for lack of clarity about purpose – they make such clarity even more important.

In summary, there are many competing 'solutions' to the problem of the gap between achievable and actual healthcare. These include guidelines, audit and feedback, opinion leaders, financial incentives, setting national standards, clinical governance, annual appraisal, public access to performance information, inspection, and patient safety initiatives.

What differentiates QI of the type funded through the Engaging with Quality in Primary Care programme is:

- the focus on aligning different approaches involving multiple groups and organisations

- a concern with 'continual, self-conscious change' (QUALITY:MK self-evaluation report) across communities of practice
- an effort to get to and change the internalised and collectively reinforced practices that might be at the root of the problem.

QI projects aim to move emotionally as well as improve rationally. The problems they are well placed to address are those difficult to improve with guidelines, audit and financial incentives alone. They are the problems that are found in how knowledge is used in groups or communities of practice, how attitudes are collectively reinforced by organisational life, and how behaviour is collectively sanctioned.

QI projects: incremental change or system shift?

There is one final question that concerns whether projects of the type funded through the programme are best oriented towards incremental change or system shifts. The REST project aimed for incremental improvements in prescribing practice and included PDSA cycles.

QUALITY:MK was explicitly concerned with supporting a whole-system shift to transform the way evidence is identified and used in health services, with empowered service users playing an important role in this transformation. What is clear is that, whatever approach is taken, time is needed to set up and build a platform for change.

An impression we have gained from the projects – one that requires further research beyond the scope of this evaluation – is that whole-system changes will probably take longer to have observable impacts. Although improvement projects have largely been associated with incremental change in specific clinical fields, all the projects in this category also sought to improve understanding of QI and its activities more generally.⁵⁷ Given this important additional objective, it is possible that such incremental changes can also build towards a system shift at a certain point. There would probably be more, smaller steps along the way, compared with fewer, bigger steps in whole-system changes.

Table 1: Quality evaluation and evaluation tools

H (
Type of intervention	Description, strengths and weaknesses	Tools for evaluators
Clinical trials	 Statistically predictable (even if individually unpredictable). Information deficit; counterfactual evidence can be produced. Key unknowns can become known through further research. 	Data on inputs, processes, outputs and outcomes; statistical analyses; randomisation; understanding (stable) preferences; cost-benefit analysis; actual comparator data from control groups. <i>Aims for certainty about costs and benefits</i>
QI	 A relatively complicated and complex intervention where mutual alignment of many parts is hard to achieve and intervention, 'dose' and 'frequency' are hard to measure and not hierarchically controlled. Multiple counterfactuals. Key unknowns only become better known through practice. Some adaptation and change ensures that the thing being evaluated remains in flux. Can be very context dependent. 	Can be modelled as a theory of change in logic models, causal pathways, simulation models, and described in a narrative of change (or 'contribution story'). Much tacit knowledge is held by stakeholders who have significant degrees of independence and inter-dependence. Evaluators need tools to understand intentions, attitudes and values of stakeholders (e.g. through self- evaluations). Evaluations will usually benefit from real-time data collection. Theoretical comparator data (based on real evidence) may be best available. <i>Aims to reduce uncertainty about contributions and identify possible range of costs</i>
Highly complex intervention	 Adaptive interventions into complex environments: characterised by learning, adaptation and sensitivity to starting point. Thing being evaluated and its context may radically change during the course of the evaluation. No single empirical counterfactual. Intervention and context hard to separate. 	Need to understand both activities and contexts; important to identify how learning and feedback happens; understand both system dynamics but also what makes change 'sticky'; real-time evaluation necessary; no traditional counterfactual available. <i>Aims to support learning and self- improving system</i>

2.4 Evaluation and QI

For evaluation purposes, QI projects sit between clinical trials and highly complex interventions. They encompass some attributes of each. The core principles of QI projects have a degree of planning and structure (even if this is sometimes implicit, unclear and changing), and they seek to move healthcare from one state to another. They engage with the system of healthcare provision. In terms of the systems they engaged with, the projects ranged from less complex (IRIS) to more complex (QUALITY:MK). This section outlines the position of the evaluation team in relation to evaluating QI in general, before commenting on what was learned through the experience of evaluating these projects.

The general view is summarised in table 1. The categories in this table are ideal types. As we have noted, activities often include many 'non-QI' elements. Some have significant similarities to clinical trials and we have seen the use of randomised controlled trials as part of the programme.

It would be entirely possible for a QI project to apply a very clear framework, with a precise protocol and delivery plan, and manage the delivery of this tightly in a variety of settings.

This could also be developed into a randomised controlled trial. Furthermore, projects also had highly complex elements, and a degree of messiness associated with the realities of improving a large and complicated system.

The challenge for evaluators is that QI practitioners may be unclear in their plans, preventing evaluators from finding the right balance of tools.

QI projects which are similar to clinical trials

QI projects may include elements that are similar to clinical trials, or may even be essentially an randomised controlled trial. If so, the tools to evaluate them must reflect this.

Trials are designed to generate statistically valid findings about the efficacy of clearly defined treatments for a specific target population. In these circumstances, appropriate evaluation tools include statistical analysis and cost–benefit analysis.

Randomised controlled trials will also only be possible where, in addition to these characteristics, comparators can be identified. Conclusions are likely to be positive, negative or inconclusive, and be expressed with a high degree of certainty.

QI projects which are similar to complex interventions

Highly complex interventions in complex environments are characterised by multiple interconnected parts forming a system that no single agency controls, and that could produce a system shift that would fundamentally alter the value of the intervention. Such a system would also tend to foster learning and adaptation.

Separating the intervention from the context might be very difficult and unhelpful, and finding a robust counterfactual impossible. It is important to understand that these situations are not chaotic but have degrees of stickiness that create sufficient stability for evaluation to take place.

Appropriate evaluation tools include:

- real-time monitoring of changes in context and intervention
- tracing the reflective learning of participants and capturing their considered views
- building up an informed account of a counterfactual space that reflects the large number of ways that the interconnected parts could interact.

QI projects which are in the middle

We see the centre of gravity of the Engaging with Quality in Primary Care projects as sitting more in the middle of table 1.

QI, like complex interventions, includes multiple parts that need to be aligned but that interact in ways that cannot be controlled by any one agency. Part of the QI project involves stabilising these relationships using planning, coordinating, leadership, incentives and so on.

This degree of stability makes it possible, for example, to conduct cost estimations even if these would necessarily change as the project unfolds. Successful QI projects will often involve a phase of developing, refining and piloting, followed by testing the approach (possibly with a trial or randomised controlled trials) leading to a new and stable system.

Where QI projects are explicit about a phased approach, it is possible to develop clear measures showing whether the new system is an improvement and by how far. This model provides the basis for building comparator data capable of supporting a robust counterfactual. The unfolding nature of many QI projects makes such planning difficult and makes it more useful to collect data in real time.

Participants may find it hard *ex-post* to reconstruct their activities over a period of years and so a true understanding of the processes at work may be lost. The real-time collection of data can also support learning and adaptation within the project.

Experience of evaluating the projects

The experience of conducting this evaluation leaves us believing that our basic approach was right, but it has also made us more sensitive to certain practicalities.

Room for even greater help to the projects to identify costs

As is made clear in chapter 7, the projects struggled to provide cost and economic impact data with the precision that the evaluation team required. This was despite support offered by the team economist, clear plans to conduct the economic analysis, and, in many cases, access to highly competent economists. In our view, the disappointing data were a result not of unwillingness or lack of technical expertise; there was an inability to specify the categories of effort required and, sometimes, identify and quantify positive outcomes. If the projects were in the third category in table 1 (complex interventions in complex environments), then this would be acceptable.

For the reasons argued above, it is reasonable to expect greater clarity around the stabilised QI intervention and, therefore, be able to attach costs to the associated activities. Even if these were sometimes only in the form of hours or days spent by staff at different grades, this would provide us with a sense of the scale of effort required. If we were to conduct a similar evaluation, we would develop a template for projects to fill in that was much more explicit about costs.

The patchwork counterfactual

An evaluation must always arrive at a judgement about the value of the intervention or activity. This judgement can only be made by explicitly or implicitly comparing the intervention with something else. This might be the 'do nothing' scenario, a before-and-after comparison,¹⁰ or a comparison with another situation known to be similar in relevant ways or, if different, with differences that are understood. This is the counterfactual.⁹ Once again, if QI projects are in the first category (trials), then selecting a counterfactual might be technically demanding but the processes and steps involved are well understood. Similarly, in highly complex interventions there is insufficient stability to allow for a meaningful counterfactual.

For many QI projects, however, there is an opportunity to develop counterfactual data despite the absence of a single counterfactual case. By looking at each part of the causal chain it is possible to provide more or less counterfactual data for each stage. Then it is important to step back and ask whether the intended goals could be achieved more effectively with a different causal pathway altogether (for example, regulation rather than a QI project). We have described this as building a patchwork of counterfactual data and it takes the form of developing counterfactuals for different dimensions of the QI project. For example, providing training, conducting audits and re-audits, involving service users, promoting guidelines and so on all have comparator data.

In the end, however, there is still a judgement to be made about how well a particular project worked in a particular context. Because QI projects typically integrate and coordinate groups and processes within a specific (and typically local) context, there may not be a suitable counterfactual. Building on a particular set of relationships to deliver a particular QI project in a particular context will never have a real and perfectly matched counterfactual. One approach to this is through a patchwork of counterfactuals. Another would be to construct a hypothetical counterfactual using modelling (for example, IRIS used Markov modelling for this purpose).

Mapping and accounting for context

In addition to difficulties with costs and counterfactuals, the projects also had problems with integrating contextual factors into their evaluations. Through the self-evaluation reports and our other interactions with the projects, we gained a strong sense of the contexts within which they were working (and indeed these interactions were designed to achieve exactly this).
This is consistent with a wide body of evidence that shows that getting evidence into practice is heavily dependent on local context.⁵⁸⁻⁶¹ Some projects explored this through qualitative research. However, detailing the transformations of networks, the construction of new relationships and identities, and the shaping role of culture was beyond the scope and budget of the external evaluation and was only addressed partially by the projects. Conducting the evaluation reported here makes us even more aware of the importance of systematically collecting data about context in a form that facilitates comparison and contrast. Key issues to include are:

- networks and relationships
- national and local guidelines and policies
- the changing knowledge base and definitions of good practice
- incentives and motivations.

The timeline for impact

We are aware that it takes time for QI projects to produce measurable impacts on patient care and patient outcomes. Our difficulty was that projects remained unclear about set up or implementation. Some were obviously transformational (QUALITY:MK) and some incremental (REST), but it was never clear when they would reach the point that increasing effort would begin to produce measurable impacts. Nor were they clear about the milestones that would help us understand where they had got to on this journey. We would recommend that QI projects be much clearer about the steps towards impact. This would support learning within each project and strengthen external accountability.

Resources

Finally, we would like to comment on the projects' resourcing and the evaluation. In light of the difficulties the projects experienced in producing good cost data and the counterfactual, and in exploring their contexts, it is worth asking whether there would have been better value for money if fewer projects had been even better resourced. In particular, if they had been resourced to support their own data collection and self-evaluation.

This might have included more ethnographic or qualitative analyses (or both) capable of exploring the internal guidelines and cultural dimensions of change, including a more systematic analysis of contextual factors.

2.5 Delivering QI in primary care

The projects did difficult things with creativity and enthusiasm, and brought energy to their work that was often palpable. Consequently we have learned a lot about delivering QI projects in primary care. We distinguish four elements of delivery. These are set out in figure 1, and the findings in relation to each are summarised below. Organising all four in and through a QI project, with strong processes that connect each to the other, strengthens the likelihood of high-impact QI projects. Of course, pursuing a QI project in an inappropriate context will most probably produce low impacts irrespective of how well organised it is.

Planning and delivering – structure and coherence

A QI project involves a continuing process of reflection and adaptation (planning must be constantly revisited). These are some lessons for enhancing planning and delivery:

- Begin a QI project with a pilot phase, in which tools can be tried out, data collection tested, likely challenges identified, and approaches modified for individual practice.
- Projects should be realistic about the time and resources needed to navigate logistical challenges, such as recruiting, using IT systems, ethics and governance procedures.
- Organising data collection, analysis and validation in QI projects requires the ability to be a researcher to produce detailed, reliable data and analysis, whilst also being able to feedback data rapidly and intelligibly to facilitate improvement. This is a challenging balance and skills mix to achieve.
- QI projects should anticipate the need to deploy a broad range of communications tools.



Securing support – overcoming political and emotional challenges

'Political' in this sense relates to how stakeholders with different interests, goals and identities can work together in pursuit of common goals, or how disputes and conflicts are managed and resolved.

- Leadership was crucial to the projects, and the Health Foundation's LITP contributed to effective leadership.
- Effective leadership was commonly joint with other stakeholders, or dispersed – using champions working face-to-face with project teams.
- Projects took account of the politics of change when they aligned themselves with areas and topics that were perceived by key stakeholders as in need of improvement, or that were also important local or national priorities.

Equipping individuals and groups with the values, knowledge and skills required to undertake QI projects – culture, education and information

To secure support for the project and management processes, which were often technically demanding, the core team and the wider groups needed to engage with the values of the project and acquire the skills and knowledge necessary to carry it out.

- To sufficiently take account of the cultural aspects of change, project teams tapped into clinicians' professional identities and engaged champions who were well-respected among a profession.
- A patient-centred approach was at the heart of the programme. This provided something that clinicians could unite behind (with specific patients and their representatives) and share.

- In many of the projects the provision of education and training was at the heart of the QI intervention. Such activities can be effective, but are not a panacea.
- QI projects need to use appropriate IT tools, but can never thrive on IT alone. The experience of the projects was that it was often a barrier to improvement than a facilitator

2.6 Four overarching recommendations for future QI projects

Recommendation one: the need for clarity

There is a need for clarity about where QI projects of the type funded through the programme will be successful.

QI projects sit in a complicated way in relation to other approaches to improve healthcare. They adopt a distinctive framework but often integrate other approaches. Consequently there is room for ambiguity and confusion of purpose. To manage this risk there should be greater clarity about which QI approaches are most appropriate to a particular problem. This evaluation suggests that a QI project of the type funded through this programme is especially relevant where solutions involve:

- internal 'mindlines' more than external guidelines
- motivations more than incentives
- identities more than competencies
- relationships more than roles.

Commissioners and funders of QI projects should establish clear guidelines on where a QI project is likely to be successful. Those undertaking such projects should focus their activities on appropriate problems. Professionals should strengthen the role of professionals within this, and support developments in training and revalidation that strengthen the appropriate use of QI projects.

Recommendation two: evaluating QI projects

Evaluations of QI projects should attend to the particular combination and sequence of improvement activities, and the peculiarities of the context.

QI projects typically involve a degree of emergence and adaptation, but they also involve a degree of stabilisation around a theory and practice of change that can be evaluated. Evaluation and learning would be greatly enhanced by project teams having much greater clarity about their pathways to improvement. Key tools include:

- explicit theories of change
- cost templates and cost estimation
- patchwork or hypothetical counterfactuals
- contextual analysis
- milestones towards impacts.

Evaluators should develop these techniques. Funders should fund QI projects adequately to support such evaluations. Those undertaking QI projects should plan to deliver projects that can be so evaluated. Evaluation journals and practitioners should explore these themes. Health service managers and commissioners should familiarise themselves with these issues.

Recommendation three: four key steps

There are four steps for organising and embedding QI projects.

Delivering QI projects in primary care involves four steps that are easy to list but difficult to manage in practice. QI projects always involve a planned sequence of activities whose successful delivery requires:

- Leadership, relationship building, political understanding and an appreciation of group identities to provide coherent engagement around a project plan.
- Overcoming political and emotional challenges from stakeholders with vested interests and entrenched ways of working.

- Building the values, knowledge and skills needed.
- Planning to spread and sustain the benefits.

Those undertaking QI projects should ensure that such projects have the resources necessary to deliver improvements in primary care.

Funders should require evidence that these capacities exist before funding QI projects, and commissioners should recognise the importance of commissioning healthcare services in ways that maintain these capacities.

Training needs to be provided to ensure that those undertaking QI projects have the relevant knowledge and skills.

Recommendation four: project business case

QI projects should include a business case covering the improvements expected over a given timescale.

QI projects that aim to spread good practice should include the development of a business case to commissioners and policy-makers as part of the project. Part of this involves being clear about what scope of improvements can be expected (incremental, transformational) and what timescale is involved.

This should include:

- description of the activities involved
- assessment of the sorts of context likely to support it
- outline of the costs involves
- outline of the anticipated benefits.

Those undertaking QI projects who wish to see their projects spread should include the development of a business case as part of their activity. Funders of QI projects should require this as a condition of funding. Health researchers should collate and analyse these business cases. Health service managers should attend to the conclusions emerging from them.

Chapter 3 **The projects**

3.1 Introduction

In this chapter we set out the descriptions of the projects and explore what it was they believed they were contributing. Essentially this is the story of how the project teams connected what they were doing to their intended outcomes.

In later chapters we will examine the evidence that they and we have produced that support or weaken these theories. As described in chapter 1, we co-constructed these stories with the project teams, using their self-evaluation reports.

We were interested in what the teams chose to focus on, how they described their activities, the evidence used of output and outcomes, and how they hoped to achieve lasting benefits.

After a section summarising and comparing the projects on a number of key dimensions, we outline the projects in turn, drawing out their explicit and implied theories of change, and noting any significant modifications adopted during implementation.

Looking at the extent of practical implementation is important. If the evidence from a project suggests little has changed on the ground, we might doubt whether any changes in patient care that appear in an evaluation are really due to that project.

3.2 An overview of the projects

Scope and scale of the projects

The aim of the programme was to engage primary care clinicians in projects to improve the quality of clinical care in the UK. There was large variation in the scale and scope of the nine projects, as table 2 illustrates.

The changes that the projects sought to make through QI varied in scale. Four projects were relatively small, focusing on one clearly-defined set of changes in one clinical area in a limited number of practices or sites (IMPACT, QUEST, IRIS, LIMBIC).

Two others had the same tight focus but sought change in a larger number of practices (CKD, REST), and another sought change in four different conditions (within one general specialty) across many practices (IMAGE).

Finally, two projects (EQUITY and QUALITY:MK) promoted change in a variety of conditions across all general practices within a local health economy. In both cases the clinical changes sought were relatively minor, but in QUALITY:MK these clinical changes were accompanied and supported by attempts to change the organisational structure of the local health economy.

Table 2: Scale and scope of the projects

	Scope	Scale	
	Number of clinical fields in which change was sought	Number of practices [and PCTs] involved in the project	Professional group(s) at whom the main intervention was targeted*
IMPACT	1	5[1]	GPs and physiotherapists
QUEST	1	n/a [14]	school nurses
QUALITY:MK	10 (various sub-projects)	27 [1]	GPs (+ various other groups according to the sub-project)
IRIS	1	24 [2]	GPs
IMAGE	4 (all GI diseases)	32 [12]	GPs
LIMBIC	1	9[2]	GPs and physiotherapists
EQUITY	3 (coronary heart disease (CHD), diabetes, chronic obstructive pulmonary disease (COPD))	139 [3]	GPs
CKD	1	127 [11]	GPs
REST	1	8 [1]	GPs

* Projects working with GPs also often worked with other practice staff, including practice managers, nurses and receptionists.

This variation between the nine projects illustrates two different approaches to QI. One that attempts small-scale change within existing systems – described by one project lead as building bridges, and a second that attempts a more radical and fundamental restructuring of organisations and systems.

Output and outcome measures

The ultimate aim of QI in health is to improve patient outcomes. Clinical outcome measures were used by the majority of the projects to assess the impact of their interventions. In some cases process measures such as prescribing rates (REST, QUALITY:MK), referral rates (IRIS) and patient satisfaction with care (IMPACT, LIMBIC, QUEST) were used either to supplement data on clinical outcomes, or as proxies for final outcomes. Another measure used by several projects was change in practitioners' attitudes, skills and behaviours (for example, QUEST, IMPACT). Change in practitioner behaviour - actually using new tools (such as the sub-grouping tool in IMPACT) - was measured by some projects, and provided some indication of levels of professional engagement.

Training and education

All the projects used some form of educational or training intervention. Often this was accompanied by electronic prompts, to act as reminders, and supported by facilitated practice visits. All provided feedback to participants. The projects shared a common view of what works in QI. Within this framework the projects variously encouraged practices to use other QI interventions, such as care bundles, PDSA cycles, audit and feedback, and academic detailing, for which there is growing evidential support.

Project teams

The backgrounds and expertise of project team members differed. Some had considerable experience of QI and a deep understanding of QI methodology; others came primarily from a research background. On occasion, these differences led to initial tension in some teams as they developed their project design, but generally these were fruitful tensions. The teams reported that their projects had been strengthened by the need to justify their approach among themselves.

Understandings of QI

Before attempting a definition of what the evaluation team has come to mean by QI, it is important to note that the projects implicitly used a wide range of approaches. Pragmatically, it is more important that projects should define their intended goals and their anticipated causal chains, along with some milestones, than they should agonise over the definition of QI. However, in a context where the definition of QI is both contested and changing, it is important to be clear about our interpretation. We outline our understanding at the end of this chapter.

A major focus of all the project teams was on effective care. Equitable care was the aim of one project (EQUITY) and the sub-text in at least one other (CKD). A number of projects also intended to explore efficiency through an economic evaluation. Another important dimension was patient-centredness. Three of the projects had patient empowerment sub-projects (QUALITY:MK, EQUITY, CKD), and all teams actively involved patients and their representatives in their projects. Often this was in new and imaginative ways, such as the development of patient-based guidelines (IMAGE), using a patient as a research interviewer (IRIS) and the development of a set of principles of patient engagement (QUALITY:MK). Patient involvement became hugely important in the programme, and was very successful - much more so than the project teams had perhaps anticipated. There was a quantum shift in attitudes, understanding and abilities.

Common challenges

The projects faced common challenges that sometimes caused considerable delays. These included:

- getting ethics and research and development (R&D) approvals
- recruiting and retaining project staff in liaison with local universities
- recruiting practices (often with little assistance from the relatively new primary care research networks)

- retaining these practices in the face of other delays in the project and other urgent pressures on GPs' time (such as the swine flu scare in 2009)
- recruiting patients
- liaising with local PCTs
- working effectively with or perhaps despite
 existing GP computer systems.

3.3 Detailed descriptions of the nine projects

For each project we set out: the lead organisation; the problem addressed; the scale of change sought; the aim of the project; the improvement interventions; and the key outcome measures. We discuss the theories of change, the design of the interventions and any key insights from the projects.

Implementing evidence-based primary care for back pain (IMPACT)

Lead organisation

North Staffordshire and Cheshire Primary Care R&D Consortium (a formal partnership between Keele University and local NHS primary care organisations).

Problem

Concern that current care is too 'biomedical', and that physiotherapists and GPs fail to use guidance on triage of patients, and on physical and psychological management of back pain.

Scale of change sought

Incremental change at general practice level and in primary care physiotherapy services.

Aim of this project

To improve the quality of care for patients suffering from low back pain through the implementation of an evidence-based model of care that sought to change how patients with low back pain are assessed and managed in general practice (a novel 'sub-grouping for targeted treatment' approach). Overall, the project was implemented on time largely as planned. There were expected response rates from patients and a slightly higher than expected response rate from healthcare practitioners. The team added a qualitative component to the study which was funded separately as a PhD programme through the university:

- The start of the project was delayed by several months because of finalising the detailed study protocol, gaining ethical approvals and R&D approvals.
- GP engagement was variable. Attendance at the best-practice updates for GPs varied and information about the study was not always disseminated by lead GPs. Patient recruitment improved after the educational visits to GP practices. Some practices requested and received extra educational sessions. The overall use of the sub-grouping tool for targeted treatment system was variable between and within practices. There was little evidence of long-term continued use after the project finished. One of the five practices asked to continue to use the electronic sub-grouping tool.
- There was very good engagement from the physiotherapists in training and mentoring
 programmes. The introduction of the new sub-grouping tool for targeted treatment approach was
 embraced by the physiotherapy service, facilitating continued use of the approach after the project
 ended. New skills gained, particularly in identifying and addressing psychosocial obstacles to
 recovery, proved transferable to other musculoskeletal conditions.

Improvement interventions

Training and electronic prompts for GPs with feedback of activity data pre- and post-training, and training and support for physiotherapists. The electronic prompt for GPs was a sub-grouping tool that categorised new patients on the basis of potentially modifiable risk factors for chronicity, enabling practitioners to offer targeted treatments.

The intervention was based on the project team's previous research studies (trials, epidemiology and qualitative research) that showed: 'that we can use information about risk prediction to better identify patients at risk of poor outcome with back pain and we have developed training packages for healthcare practitioners which can support them to improve the way in which they treat patients with different risk profiles' (IMPACT selfevaluation report). But while the team built on their existing experience of using education theory to facilitate changes in practices, the project went beyond this: Whilst we have experience in educating and facilitating change of clinical practice within therapy services, this was the first project from our centre that has attempted to change the way GPs assess and manage these patients.

IMPACT self-evaluation report

Outcome measures

Patient outcomes (disability scores, sub-grouping category, pain levels, satisfaction with care); and practitioners' confidence, attitudes and behaviour.

The project was undertaken in five practices in Cheshire as a before-and-after study. It compared two separate cohorts of patients who consulted their GPs for back pain; the first cohort prior to intervention, the second post-intervention.

No single overarching theory of change underpinned this project. The team commented: 'we did not focus on one theory only to inform our intervention. Along the way, we have learned that it is necessary to use a multifaceted strategy when trying to effect change in primary care systems' (IMPACT self-evaluation report). In practice, the team used theory not only to inform their intervention, but also to inform their understanding of how it had worked, applying normalisation process theory to: 'explain the uptake (or lack of) of the new approach by the various health professionals, the context and mechanisms which influenced this, the similarities and differences between the different health professionals, the degree of sustainability and an overall conceptual assessment of the lessons learnt' (IMPACT self-evaluation report).

The qualitative component of this study used the normalisation process framework to assess the contextual aspects of the implementation process. The majority of GPs did not differentiate the new system from current practice, and thus the uptake of the tool and subsequent targeted treatment was only partial. Policy priorities and structural factors, such as payment systems, were limiting factors in readiness for change. In contrast, the physiotherapists demonstrated this readiness and considered the new intervention to enhance their practice. The physiotherapists not only demonstrated a shift in behaviour and practice, but also in attitudes and relationships with patients – towards negotiation and partnership.

Improving the quality of mental health in schools (QUEST)

Lead organisation

Institute of Psychiatry, King's College London, in partnership with the mental health charity Rethink.

Problem

Concern about current lack of skills and confidence among school nurses to identify and manage mental health problems in children.

Scale of change sought

Incremental change in school nurses' knowledge, professional confidence and clinical behaviour.

Aim of this project

To improve the attitudes, knowledge and skills of school nurses in the recognition and management of common mental disorders in young people, and so influence the detection, early intervention and course of these problems.

Improvement intervention

School nurse training. The specially targeted and designed multifaceted training package was based on the relevant literature (including the work of the Cochrane Effective Practice and Organisation of Care Group (EPOC)) educational theory and on the research experience of core team members: 'The intervention has been based on theory and evidence concerning engaging with professionals/ clinicians and modifying their clinical behaviour. Hence a multifaceted professional development approach has been developed, with stakeholder consultation/consensus of the approach/ guidelines, the involvement of local opinion leaders, and clear attention to obstacles to change' (QUEST self-evaluation report). The methods adopted were 'based on tried and tested approaches which link to professional development and research evaluation' (QUEST self-evaluation report). The team also developed information and self-help guides for young people and their families, and some resources for teachers and other members of the school team.

Outcome measures

Changes in knowledge, attitudes and clinical behaviour in school nurses. Clinical behaviour originally included child and adolescent mental health services referrals, but it proved impossible to get reliable data.

The project was designed with an initial one-year scoping and pilot phase (comprising a national survey of school nurses, interviews and a single group pre-test/post-test study in one PCT), followed by a cluster randomised control trial in 13 PCTs in South Thames and the South East area. The project had two arms: a development and implementation arm run by Rethink, and an evaluation arm (the cluster randomised control trial) run by the Institute of Psychiatry. Overall, the two phases of the project were developed and implemented as planned and, despite some delays related to ethical approval and appointment of study personnel in the initial phase, the project was delivered within the planned timescale.

There was excellent participation from school nurses as a professional group, with senior staff providing their time and expertise to the project steering group, as well as participating in consultation exercises.

The development of the training package benefited from the involvement of a broad steering/ consultation group representing varied perspectives, and from the use of a pilot phase to refine materials and approaches to session delivery in response to initial evaluations.

Training delivery and associated data collection and analysis were completed successfully and on time.

The training programme and associated materials were developed and sessions were delivered as planned to the school nurses from six PCTs in the intervention group. Additionally, nurses from four PCTs in the control group received training in the follow-up period.

Several articles detailing the development and evaluation of the project have been published and more are in submission and preparation.

The training materials and associated resources have been made available to clinical staff in a range of accessible formats at a number of national events.

The team's decision to focus on school nurses involved a detailed consideration of the future organisation of services, and was validated by a recently published review of school nursing.⁶²

This indicated: 'in many areas school nurses are feeling greater recognition and more valued concerning their role; with indications that [there are] opportunities for expanding and extending nursing services in schools. There is some evidence of increased investment and improved understanding on the part of commissioners and stakeholders about nurses' potential to contribute to the preventative agenda' (QUEST selfevaluation report).

The project team also built on the enthusiasm and interests of those most closely involved and who 'identify this as an important area for practice development' – school nurses, teachers and young people (QUEST self-evaluation report).

A whole system-approach to quality improvement, Milton Keynes (QUALITY:MK)

Lead organisation

Milton Keynes PCT, with support from the University of Oxford Department of Primary Health Care and Centre for Evidence Based Medicine.

Problem

The gaps between existing care and known best practice in a range of conditions managed in general practice.

Scale of change sought

Whole-system change.





Note: weight management covered two projects: one for adults and one for children. Source: QUALITY:MK project team.

Aim of this project

To embed a whole-system approach to QI across Milton Keynes PCT, driven by primary care, patient engagement and evidence.

This was a complex, multifaceted project operating at multiple levels that eventually involved all 27 GP practices within Milton Keynes PCT.

It was larger in scope and wider in its ambitions than other projects. It was designed as an improvement of the whole PCT and its services, focusing on GPs as providers and as commissioners. The project encouraged people to develop and adopt innovative ways of working with service users, clinicians, librarians, managers and others to deliver improvements founded on the best evidence available. Within this overall framework, specific tasks and clinical topics were identified (some initiated bottom up and others top down), and topic leads were allocated to improve the quality of care in each of these. As each topic was tackled, successes and failures were identified to determine where the system needed to change to create a healthier environment for QI, embracing attitudes and skills as well as system and process.

Overarching interventions

Education and training for GPs in evidence-based care; patient empowerment programme (PEP); feedback of practice activity and support for practices wanting to make changes. QUALITY:MK included 16 component sub-projects, categorised generally as service pathways, practice-based initiatives and overarching pathways. There was a tailored QI intervention for each improvement sought, developed in light of an analysis of the existing evidence and of potential barriers to change. The nature and relationship of the component studies to each other, and to the whole, is represented in figure 2 (developed by the project manager).

Outcome measures

Various measures for each component sub-project.

As figure 2 illustrates, QUALITY:MK is based on three values that set the parameters of what the project team was trying to achieve: clinical engagement in strategic planning and service design; public and patient engagement; and evidence-based approach to commissioning.

Overall the project team described the project as a service improvement programme focused on the 'ongoing process of continual, self-conscious change'.⁶³

They stressed that it is 'not a research project to which hypothesis testing and the generation of new knowledge are central. Rather, QUALITY:MK is an intrinsic part of normal healthcare operations with an explicit focus on [the] learning and improvement process' (QUALITY:MK selfevaluation report).

This did not mean that the project was not firmly based on evidence and relevant theory. At the macro level this included the following:

- Implementation theory and practice:

Our approach is being shaped to address common practical and organisational issues identified by studies of successful implementation.

QUALITY:MK self-evaluation report

 Systems theory, 'which stresses the interdependent and interactional nature of the relationships that exist among all components of the system, supports the different aspects of the QUALITY:MK programme'.

The qualitative evaluation of QUALITY:MK commissioned by the project team was also based on systems theory and action evaluation.⁶⁴

At individual topic level, each sub-project included the prior work of the Improving Medical Practice by Assessing Current Evidence (IMPACTE) groups to explore the evidence base for specific topics. Additional insights developed or strengthened (or both) during the project included the following:

1. The importance of an approach that adopts ideas for QI from different sources, including a bottom-up approach:

Ideas for quality improvement originate from different sources and it is important to recognise and support good ideas for change. Adopting ideas from different sources – whether they come from primary care clinicians, patients, PCT staff or from wider national initiatives or guidelines – encourages a diverse pool of ideas. Choices of projects may originate from a high level but without adoption and support from the bottom up are less likely to result in genuine success. The importance of the bottom-up approach ensures that changes are made that are relevant to the particular patient population served.

QUALITY:MK self-evaluation report

2. The principled use of routinely collected local data: 'the emphasis is on making better use of data that are routinely collected in order to localise research evidence and give it meaning'. The team claimed that this principle was confirmed by their study and came to an important conclusion:

Our work, for example on the diabetes pathway ... confirms our choice to attend to making better use of data that are routinely collected. This work confirms that QOF data are a key enabler for many aspects of the pathway.

QUALITY:MK self-evaluation report

- 3. The importance of adopting a knowledgebased management approach to embedding and sustaining cultural change.
- 4. The centrality of practice-based commissioning: 'This project promotes QI at a macro level, with an evidence-based approach embraced by a whole health economy and used in conjunction, rather than in parallel, with changing NHS policy, largely by strengthening the hand of practice-based commissioners by engendering in them strong evidence-based decision making skills' (QUALITY:MK selfevaluation report).

Identification and referral to improve safety (IRIS)

Lead organisation

Queen Mary, University of London.

Problem

Concern about current rates of identification and referral of women experiencing domestic violence by GPs and practice staff.

Scale of change sought

Incremental change in confidence, abilities and behaviour of GPs and practice staff.

Aim of this project

To determine whether a training and support programme targeted at general practice teams increases the identification of women experiencing domestic violence and their subsequent referral to specialist domestic violence agencies.

Improvement intervention

Training for practice staff with electronic prompts for GPs and ongoing support for all staff, and comparative feedback of practice data. Training was provided to facilitate explicit referral pathways into the appropriate services, with use of prompts and templates within the electronic medical record to guide enquiry and referral, and ongoing support for clinicians to identify and enhance their clinical responses to patients experiencing domestic violence.

Outcome measures

Rates of disclosure and referral of women experiencing domestic violence.

The intervention had a theoretical base in adult learning theory and peer influence. There is evidence that system-level training and organisational change can increase the rate of disclosure of domestic violence to healthcare professionals, and the team commented:

[we] used research findings to guide the development of our intervention. For example, we knew that isolated training interventions have short-lived impacts on practice. We were building on general lessons learnt from our own experience of QI implementation in primary care and specific pilot work we conducted in the domestic violence field.

IRIS self-evaluation report⁶⁵

Flexibility was required. The intervention had to be adapted to 'meet the reality of pressures on clinicians and their willingness to engage – in fact persuading them that the minimum requirement for certified training was 2 x 2 hour sessions was a battle' (IRIS self-evaluation report). And perhaps even more could have been done: 'with hindsight specific training for nurses may have prompted more active engagement' (IRIS self-evaluation report).

This project built on a previous pilot study (the Prevention of Domestic Violence pilot), and was designed as a pragmatic cluster randomised control trial. The general practice was the unit of randomisation to test the effectiveness and cost effectiveness of a training and support programme targeted at general practice teams. The primary outcome was the referral of women to specialist domestic violence agencies. Forty-eight practices in Hackney and Bristol were involved; 24 were randomised to each arm of the trial.

Additional insights developed or strengthened (or both) during the project included the following:

The centrality (and potential generalisability) 1. of the role of the advocate educator. First, because they were visible, named and an easily accessible source of expertise to whom clinicians could refer. Second, they provided regular feedback on referral outcomes for individual patients. Third, they provided training to the practices and reinforcement through attendance at team meetings and through a newsletter and e-mail contact. The role of the advocate educator is potentially generalisable to other QI interventions in primary care, if an intervention combines training around a change in practice with implementation of a new referral pathway (IRIS self-evaluation report).

Overall, the training and support intervention was implemented as planned with a substantial global effect (and individual practice variation) on identification and specialist referral of women experiencing abuse in the 24 intervention practices:

- Data on the primary outcomes, intervention costs, clinician attitudes, knowledge and behaviour and clinician experience of the intervention were successfully collected and the primary outcome data were validated. The team is still collecting interview data from patient participants.
- Initial analysis allowing dissemination of the results at conferences and commissioning meetings was successfully completed.
- Further analysis, including sensitivity analyses, of primary outcomes and clinician questionnaire, interview data, and an economic model are almost complete. Four papers for peer-reviewed journals are in draft form: main trial paper, economic model, clinician survey and clinician interviews.
- Model budget for commissioning of IRIS developed.
- IRIS model funded in trial sites: Bristol, and City & Hackney, and expressions of interest from six other PCTs.
- Two-year implementation project (IRISimp) funded by the Health Foundation.

The CORE questionnaire (intended to measure subjective well-being, psychological symptoms, level of functioning and risk) was not administered by advocates to women identified as abused because of difficulties in administering this measure within the context of providing advocacy.

- 2. The sometimes negative influence of practice champions: 'Practice managers [or] practice champions who were disinterested, disorganised or hostile to the topic or project constrained access to other clinicians' (IRIS self-evaluation report).
- 3. The importance of drawing on the pilot: 'We identified potential barriers from the literature and from our experience with the Prevention of Domestic Violence pilot, and many of these proved to slow up the implementation of the IRIS programme' (IRIS self-evaluation report).

Improving management in gastroenterology (IMAGE)

Lead organisation

CORE (Digestive Disorders Foundation), supported by the National Association for Colitis and Crohn's Disease, Coeliac UK and the Inflammatory Bowel Disease Network, and by King's College, London.

Problem

Substantial gaps between best evidence and the clinical management of four GI disorders in primary care.

Scale of change sought

Incremental change at practice level.

Aim of this project

To contribute to the capacity for QI through a patient-centred method of guideline development and generation of quality criteria for the care of patients with GI disorders. This was based on the assumption that this would work better than 'normal' guideline development for GI disorders: 'very few [of which] have been shown to have an impact on practice' (IMAGE proposal). Users were at the heart of the project and were involved from the start through facilitated patient focus groups to develop patient-based outcomes. These were then incorporated with current guidance into the quality criteria used in the project, with the ultimate aim of including the GI quality criteria in the QOF.

Main interventions

The development of patient-generated outcome criteria and the incorporation of these into current guidance; and the development of electronic prompts with feedback of activity and patient outcome data. The prompts acted as reminders of the guidance to GPs, who also received written patient and practitioner materials to emphasise key messages about diagnosis, treatment and self-care, and face-to-face practice visits. The team noted that 'there is good evidence that a multifaceted approach gives the greatest chance of successful implementation of guidelines and other work on implementation shows that local ownership and an appreciation of local relevance are also success factors.⁶⁶⁻⁷¹ This evidence and theory will inform our project' (IMAGE project protocol, May 2007).

Outcome measures

Symptom severity, quality of life (QOL), anxiety, depression, patient enablement, satisfaction with communication, percentage on antidepressants, appropriateness of treatment (irritable bowel syndrome (IBS), gastro-oesophageal reflux disease (GORD)), and number of GP consultations. This project was designed as a before-and-after study in 39 practices in nine PCTs across England, involving 173 GPs. Patients were recruited:

- 415 with IBS
- 620 with GORD
- 203 with coeliac disease
- 202 with irritable bowel disease (IBD).

An additional 93 patients participated in focus groups. There was a follow-up 12 months after the initial consultation and baseline.

The team noted that the project was not designed with a particular behavioural theory of change in mind. They had been most persuaded by the success of the QOF, under which financial incentives have led to behaviour change though a formalised system of recording and reporting. They were seeking to go beyond the QOF, incorporating an additional patient focus.

Additional insights developed and/or strengthened during the project included the following:

- 1. The importance of pre-existing clinical networks. The project team was able to build on the work of the Primary Care Society for Gastroenterology over the previous 20 years, and this facilitated the engagement of senior clinicians to act as the gastro champions. They then proved to be a major force in recruiting GPs: 'Engagement of the practices was not primarily achieved by the offer of financial rewards/support, but by the enthusiasm with which they were contacted by us and the gastro champions' (IMAGE self-evaluation report).
- 2. The potential usefulness of initial work to develop and pilot the intervention. The point here is that this was not, in fact, done in this project, and the team identified this as a gap. The team commented that, in retrospect, it might overall have been better to have adopted something closer to the Medical Research Council (MRC) model for evaluating complex interventions, and to have spent more time initially developing the interventions used.

The IMAGE project was conducted largely on time, with a three-month extension required because of delays in developing the computerised decision support software. The key phases of the study were:

- Focus groups and literature reviews to generate quality criteria (October 2007 to January 2008).
- Practice and patient recruitment and baseline data collection (April to November 2008).
- Development and installation of computerised decision support software in 39 practices (June to December 2008).
- 12-month follow-up patient data collection (January 2010), with evaluation of system.
- 3. The development and use of computerised decision support software for four different computer systems proved harder than anticipated, but was also central to the project. The team described this as a novel approach, a step up from normal chronic disease templates because it included an educational component. They developed an additional component of the project to evaluate the acceptability, utility and functionality of the computerised decision support software.

Improving the management of back pain in the community(LIMBIC)

Lead organisation

Bournemouth University, with support from BackCare (the charity for healthier backs).

Problem

Concern about inadequacies in the treatment of patients with low back pain in primary care.

Scale of change sought

Incremental change in primary care services.

Aims of this project

To assess changes in patient outcomes following a practice improvement intervention that included patients.

The team wanted to, 'develop and validate a coherent theoretical framework, based on health professional and organisational behaviour and behaviour change, in order to inform people and organisations about how best to intervene in service settings in the face of different barriers and effect modifiers' (LIMBIC self-evaluation report). The aim was to not only improve the management of back pain but also to develop understanding of QI, and the capacity for QI, in the participating practices.

Main improvement intervention

Training for practice teams with feedback of practice activity data. The training package was the introduction to practice teams of new evidence about back pain, combined with information about improvement principles (the Improvement Model) and methods (such as process mapping and PDSA cycles) through eight half-day workshops.⁵⁷ There was further support for practice teams between workshops from a QI facilitator. This project was designed as a casecontrol study using pre- and post-intervention measurement of validated patient outcomes in nine participating practices in two PCTs.

Outcome measures

Disability score; functional outcome, such as pain severity; general health; and satisfaction with care.

The general theoretical underpinning of the project was the team's shared understanding that: 'the best way to learn about improvement is to be supported to actually do improvement in practice. The LIMBIC model embraces an inter-professional learning approach that includes users or patients and fuses improvement methodology with change to meet the needs of service users or patients better. It is based on the key tenet that people do not avoid change but do resist being changed' (LIMBIC self-evaluation report).

More specifically, the team:

- Noted that a previous US study had used a supported educational model of the type they planned to adopt, but had achieved comparatively little. They therefore intended to use: 'a more supported model with each practice identifying their own needs related to the management of low back pain' (LIMBIC proposal).
- Argued for the development, through the project, of a community of practice on the grounds 'it is known that clinicians in primary care access a range of colleagues and networks (also known as communities of practice) when creating an internalised, collectively reinforced tacit guideline.^{55,56} Social networking is an important contributor to the success of collaborative initiatives' (LIMBIC proposal).⁵⁶
- Justified their attention to the process, staff and organisational aspects of improvement knowledge by an appeal to the need to develop learning organisations. They cited Berwick's view that: 'In modern corporations, the best results come when a motivated, trained, and empowered workforce gets the right help from leaders so that people can learn from and teach each other, measure progress, share lessons and good and bad news openly, and celebrate together. Modern management theorists call such a place a learning organisation' (LIMBIC proposal).⁷²

Additional insights developed or strengthened (or both) during the project included the following:

1. Patient involvement: 'The underlying purpose [of QI] must be defined from the point of view of patients and carers and should reflect the requirement for services to improve the way they meet their needs' (LIMBIC proposal). 2. Use of QI facilitators: 'The input from the quality improvement facilitator was reported to be invaluable by the practice team ... Had there not been the provision of in-practice expert support, many of the projects would have failed to progress in the way that they did, many would have failed to truly understand the basic principles of continuous quality improvement, and there could have easily been a decline in numbers attending workshops as a result' (LIMBIC self-evaluation report).

Equity, ethnicity and expert patients (EQUITY)

Lead organisation

The Clinical Effectiveness Group (CEG), Centre for Health Sciences, Queen Mary, University of London.

Problem

Inequity of provision of services in three chronic conditions.

Scale of change sought

Incremental change at practice level across one PCT.

Aim of the project

- 1. To develop a dataset on the equity of service provision (by age, sex and ethnic group) in GP practices at both practice and PCT level that can inform change at both levels; to identify any inequity in the provision of care by age, sex and ethnic group, by practice, for key indicators in CHD, diabetes and COPD; and to determine if feedback and support to Tower Hamlet practices reduces inequalities.
- 2. To increase patient knowledge and self-care through lay-led self-management groups with routine pathways for chronic disease; improving their accessibility and uptake along with improvements in equity.

Overall, this project was implemented in a timely manner, despite challenges regarding patient recruitment in primary care:

- The eight workshops that formed the educational intervention were delivered during 2008 and were evaluated using quantitative (high-level patient outcomes and practice data) and qualitative (practice-level outcomes) methods. Workshops focused on knowledge and learning about the principles and methods of improvement, as well as knowledge about back pain management.
- Nine practice teams were recruited by the start of the workshops in 2008. Focus group interviews
 with all nine practices were undertaken prior to the workshops as planned and again after the
 workshops as planned, within three months of completion of the workshops.
- The project team was involved in supporting the participating practice teams using motivational approaches and the collection of baseline and follow-up data for the high-level evaluation, though questionnaires with patients were delayed by three months for cohort one and nine months for cohort two, due to practices not being able to recruit patients as planned.
- Successful recruitment of patient representatives for the nine practice teams was eventually achieved.
- A QI facilitator supported practices with their improvement projects.
- The project sustained relationships with two PCTs and influenced back pain initiatives.
- The majority of practices were extremely positive about their learning and in particular the positive impact of patient involvement.

Timescales were adjusted but overall the project was successfully completed.

Time constraints were an issue for the practice teams, both in terms of achieving attendance at workshops and of undertaking improvement projects.

Improvement interventions

Audit and feedback with support for poorly performing practices. The project involve a Health Equity audit in Tower Hamlets PCT that built on and developed a long-established audit of local GP data in three PCTs – Tower Hamlets, Newham and Hackney – undertaken by the CEG. The equity audit covered all patients on the CHD, diabetes and COPD registers, with feedback and support for underperforming practices that included facilitated visits from specially trained cardiovascular disease nurses and the GP project leads. Changes were assessed as practice data was returned, and results were compared across practices and across the three PCTs.

EQUITY also involved patient education: a lay-led self-management programme that was integrated into routine care pathways for CHD, diabetes and COPD (developing an existing Tower Hamlets PCT initiative). It provided educational sessions on self-care to patient groups using specialist nurses. This intervention also included the development of a GP referral system for selfmanagement programmes. Overall, the project was implemented on time, although problems due to staff recruitment delayed the start of the project for six months.

- Year 1 audit: Health Equity audit report for GP practices 2008/09. Data collected from CEG (2008).
- Year 1 GP practice facilitation (10 GP practices): Facilitation of the audit report by cardiovascular (CVD) nurses and project clinical leads.
- Feedback collection from the GP practices in the audit report: how it could be improved and what information and support practices may need in the future.
- Year 2 audit: Health Equity audit report for GP practices with all the feedback comments from the previous year taken into consideration. Data collected from Egton Medical Information Systems (EMIS) web data search (2009 and 2010).
- Year 2 network facilitation: The audit report was sent to all GP practices but facilitated at network level (clusters of four to five GP practices working together) with a wider audience and covering more practices.

Later years:

- 2007 mapping of self-management programmes in Tower Hamlets.
- 2008 CEG developing new prompts in CHD, COPD and diabetes template for referrals to self-management groups.
- 2008 SF-36 assessment tool used to pilot feasibility of integrating referrals to self-management programmes.
- 2009 process mapping of the referral pathways, and presenting to PCT strategic self-care and healthy lifestyle group; highlighting gaps and suggestions for improvement.
- 2009 BMedSci student project assessed health professionals' attitude and knowledge of selfmanagement programmes and referrals to these programmes.
- SF-36 evaluation continuous evaluation of SF-36 from 2008 to 2009. Self-management group participants facilitated further funding to the course provider (Social Action for Health (SAfH)) from Tower Hamlets PCT.
- 2010 qualitative study explored patient perspectives on facilitators and barriers to attendance at self-management programmes.

Project findings have been disseminated through conference presentations, workshops and publications. Tower Hamlets public health will include the Health Equity audit data in their joint strategic needs assessment.

Outcomes measures

Specific clinical indicators in CHD, COPD and diabetes. Differences in SF-36 scores for physical and mental health pre- and post-intervention

The ways that these two interventions (audit, education) reinforced each other was an important aspect of this project:

Recognition of the issues by professionals and active engagement of the population groups are necessary aspects for developing appropriate strategies.

A large resource is now directed to professional improvement – guidelines, quality improvement and continuing education.

We are already able to demonstrate above average improvements in the professional management of all three diseases (heart disease, type-2 diabetes and COPD) in our local populations over the last decade. However, user involvement is striking by its absence. This is a political as well as a clinical issue. Visibility and enfranchisement of disadvantaged groups – women, black and ethnic minority groups and elders – has played a key role in establishing rights and responsibilities, and placing equity high on the agenda for change.

We aim to demonstrate that it is feasible and acceptable to patients to integrate lay-led selfmanagement groups with routine care pathways for chronic disease, improving their accessibility and uptake in association with improvements in equity.

EQUITY proposal

Underpinning this team's approach was their experience of facilitating change in chronic disease management in primary care. This derived from the work they had done as the CEG over the preceding decade, using guidelines, QI and continuing education.

Their experience was that clinicians were keen to improve the overall quality of chronic disease management. Once gaps in provision were identified, these could be reduced through multifactorial organisational change.

The team drew on meta-analyses demonstrating that a facilitated educational approach in chronic disease management improves professional and practice team behaviour, and on evidence that specialist nurse education programmes improve outcomes for COPD, diabetes and heart disease.

They also noted that there was 'currently no good evidence that lay-led self-management improves outcomes in the UK' (self-evaluation report).

They planned therefore to combine the lay selfmanagement programme with specialist nurse advice, for which there was some positive evidence.

Improving management of chronic kidney disease in primary care (CKD)

Lead organisations

Kidney Research UK, working with St George's University of London.

Problem

An unprecedented rise in referrals to specialist renal services, and no data on the best way to implement QI in the management of chronic kidney disease in primary care.

Scale of change sought

Incremental change at practice level.

Aim of this project

To provide trial data on the best way to implement QI in the management of chronic kidney disease in primary care. This was a tripartite study of considerable size and complexity. The principal component was a two-year three-arm cluster randomised control trial involving 127 practices in eight localities across England, which compared the effectiveness of two different QI interventions against usual practice.

Improvement intervention

Randomised control trial with guidelines and prompts in one arm, audit-based education (ABE) in second arm, and usual practice in third arm; all were associated with comparative feedback of activity data to the practices.

Underpinning this approach was published guidance that effective management with an emphasis on strict blood pressure control would slow the progression of the disease and reduce cardiovascular risk, and that much of this management could take place in primary care. The QI interventions adopted in the randomised control trial were evidence-based and supported by ongoing work elsewhere.

Overall, the project was due to run from April 2007 until March 2010, but delays were encountered early on when ethical approval was turned down due to its complexity and scope.

A different approach was taken by the team and revisions were made to the protocol, ensuring a robust randomised control trial and interventions, with component parts being separated out and assigned to individual leads. Ethical approval was finally achieved in January 2007, but further delays occurred owing to the length of time required to gain local R&D approval (in some cases this took nine months). The team managed to pull back some of the delays by shortening the time between interventions, and the project completed in October 2010 (with the exception of final data analysis of the randomised control trial, which was not yet complete at the time of writing). Against this sixmonth delay, the team achieved:

- Three rounds of data collection from 127 practices, resulting in 10GB of data from 950,000 patients.
- A full set of patient empowerment tools available for use outside the project.
- Implementation, each in a single practice, of the care bundle (Banstead, Surrey) and patient empowerment programme (PEP) (Leicester).
- Delivery of ABE, guidelines and prompts interventions, as required in the protocol.
- Transcripts of 13 focus groups (five pre-study and eight post-study).
- Development, distribution and analysis of GP confidence questionnaire.
- Significant number of publications, conference posters and other communications activities.

It is not yet clear whether the ABE and guidelines and prompts interventions have achieved a change in practice, or whether the interventions are sustainable. Although the team has considered various models for delivery, these are likely to be made at a local level by PCT, practice-based commissioning or practice groups.

Outcome measure

The primary outcome measures was a reduction of systolic blood pressure.

In addition, the team implemented and evaluated two other QI interventions in small studies in separate single practices:

 Care bundle approach – a systematic attempt to redesign a care system in order to improve its reliability. Previous use has been in acute settings. The team noted: 'Care bundles have not, to the best of our knowledge, been applied outside of the hospital setting ... Nevertheless there is good reason to believe that they may work well within a primary care setting. The concept of bundled, prescribed healthcare interventions is not completely new to GPs as the QOF targets are themselves a form of quasi-bundle' (CKD self-evaluation). The bundle contents used in the project were supported by the 2008 NICE guidance for chronic kidney disease.

2. A PEP intended to complement the randomised control trial without contaminating it. The team reviewed and discussed theories behind empowerment and self-management in order to develop and implement the PEP. In contrast to the relatively well-developed evidence base for the other arms of the project, the team found little evidence about patient empowerment tools: 'With regards to the patient empowerment tools, the expert team found that there is a dearth of patient empowerment literature and materials/resources for patients with chronic kidney disease in primary care settings' (CKD self-evaluation).

Outcome measure

Staff and patient feedback on the programme.

Resources for effective sleep treatment (REST)

Lead organisation

West Lincolnshire PCT, working with the University of Lincoln.

Problem

Concern about high rates of insomniac drug prescriptions in general practice.

Scale of change sought

Incremental change in prescribing rates at practice level.

Aims of this project

To improve the user experience of management of insomnia using validated measures; to increase the use of recorded non-pharmacological measures in insomnia by at least 100% in three years; to reduce the rate (costs) of Z-drug prescribing by 50% in three years; and to reduce the rate (costs) of benzodiazepine hypnotic prescribing by 25% in three years.

The project also aimed to develop the knowledge base for QI and to increase capacity and skills for QI among practice staff (GPs and nurses).

Improvement intervention

GP and practice staff education and feedback of practice prescribing data. A complex educational intervention was introduced using a collaborative approach in eight practices. Over a six-month period the practices were given a bundle of validated tools and techniques to trial in their insomnia consultations, including:

- academic detailing techniques
- rapid experimentation (PDSA cycles)
- process redesign
- monthly feedback of prescribing rates and costs of hypnotic drugs using statistical process control charts.

The practices' remit was to use interventions they liked and devise their own systems of implementation (with the support of the project team). Regular feedback from the practices was obtained about what they were using, how they were using it and how useful it was. Practice prescribing data were collected throughout the project and analysed to identify practices that were high prescribers of hypnotics. Initially the plan was that the NHS Lincolnshire prescribing team would support high prescribing practices by providing training on sleep assessment and nonpharmacological alternatives for sleeping difficulties, but they did not feel confident to do this. Instead this training was provided by the project team.

Outcome measure

Practice prescribing rates.

Following the pilot collaborative, an exploratory randomised control trial involving four practices was set up. It would test the effectiveness, and cost effectiveness, of a brief practice-based educational intervention for practice teams (GPs, primary care nurses and practice managers) to provide problemfocused therapy for insomnia in adults.

The primary outcome measure was global sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI). This study had not reported its findings at the time of writing this report.

A REST education programme was also developed to extend the training to additional practices. This was over six months as a collaborative, with the project team delivering the training, supported this time by GP champions from the original collaborative. A REST e-learning package is currently being developed to enable further engagement with clinicians that can continue beyond the end of the project. The evidence base on best practice about the management of insomnia was derived from evidence and recommendations in the National Service Framework for Mental Health, and guidance from NICE and Prodigy.⁷³

These advocate non-pharmacological measures for insomnia and advise that the use of hypnotic drugs should be reserved as a second line for short-term treatment of severe insomnia (REST project proposal). ⁷⁴⁻⁷⁶ A detailed understanding of QI also underpinned the project. See, for example, the editorial in *Quality in Primary Care* on organisational and educational interventions for QI written by the project lead. ⁷⁷

Box 9: Extent of implementation in REST

Overall, the project was implemented as planned, although delays resulted from the loss of a researcher and problems with ethics approval.

The team had to undertake more than they planned in terms of providing training to the practices. Resource constraints and limited time meant that the pilot randomised control trial ended up being smaller than anticipated.

- Collaborative efforts went ahead as scheduled. Preparatory work to raise awareness of the project with practice managers prior to the invitations being sent out facilitated the uptake of expressions of interest. The offer of funding for the work also facilitated uptake. Once the collaborative was running, the project team's support was a vital part of keeping things on track. Regular communication face-to-face, via e-mail and telephone was also a key facilitator.
- Patient focus groups were delayed due to shortcomings in recruitment strategy. Therefore a
 substantial amendment was submitted to the research ethics committee and the time delay grew.
 Relying on the GPs to recruit for the focus group hindered this aspect of the project.
- The QI survey was sent out on schedule. After three reminder letters, a 60%+ return rate was achieved. Persistence and the careful wording of the letters facilitated this return rate.
- Ethical approval for the pilot randomised control trial was delayed due to misunderstanding of the exploratory method by the ethics committee. It was decided that attendance at the meeting to explain the project would have been effective. The second meeting was duly attended by members of the project team.
- Recruitment of practices for the pilot randomised control trial via the primary care research network was very slow. The concept of the research network was still very new at this point and their relationship with GP practices was not fully established within the county, which may have influenced this.
- Conversely, the revised plans, which incorporated a more personalised approach, were much more productive. These plans involved presentations at practice managers' meetings, revision of materials sent out to practice managers and GPs via e-mail and post, and personalised telephone calls from the project lead (a GP).

Prescribing team collaboration: at the training event for this team it became evident that the original plan for collaboration with the NHS Lincolnshire prescribing team would require a different approach. The prescribing team were uncomfortable about delivering training to GP practices on the non-pharmacological alternatives for sleeplessness.

3.4 Our understanding of 'Quality Improvement'

From the preceding sections it should be clear that the programme provided support for a variety of approaches. Analytically we could adopt an essentialist definition (that is, defining the key attributes to which anything defined as QI should adhere).

This would allow us to compare and contrast different approaches within this definition and between QI and other activities intended to improve healthcare. However, definitions of QI have continued to evolve along with its practice. Since QI is essentially a process of learning and adaptation, it would be strange and arbitrary to ignore this evolution in any definition.

We therefore prefer to define QI as an evolving approach to improving healthcare that includes certain essential characteristics. These essential characteristics are part of a single overall process. This process involves deliberate and organisationally based efforts to change actual behaviour in healthcare settings. This is in line with the best available evidence, using effective communication, the dissemination of local data, feedback loops, and building shared understanding and motivations across previously unaligned groups. Experience suggests that achieving this is more likely with active patient involvement, effective leadership, a clear theory of change, and good project management. Success is also more likely if the QI project can be aligned with other approaches, with shared aims such as national and local guidelines or financial incentives.

As we have noted, the growing recognition that QI can be more effective when it is aligned with other approaches has been an important feature of these projects. As QI becomes more integrated with other approaches, defining what is distinctive about QI is harder and may mean that we need to develop a new vocabulary that works with a less sharp distinction between QI and other approaches.

Chapter 4 Outcomes and achievements

4.1 Measurable benefits for patients

This chapter sets out and assesses the evidence of the projects' achievements and outcomes. The focus is primarily on measurable benefits to patients. The majority of the changes reported by the project teams were improvements in patient care, rather than in health outcomes. Overall we found that, across all projects, the general direction of change was positive but slight. Measurable benefits for patients were achieved but the changes identified were modest and patchy.

Only IRIS reported substantial and statistically significant effects on disclosure and referral rates. The IRIS project team also provided sound evidence from other studies linking these improvements to improvement in health outcomes. Seven projects reported small improvements in patient care. Only in one project (LIMBIC), and against only one measure (number of GP visits), was this change statistically significant. In this instance, the evidential link between this change and health outcome is less clear.

Three projects reported small improvements in patient outcomes. In two of these projects (IMPACT, IMAGE), these changes were statistically significant, although the absence of any comparator in IMAGE means that the changes identified in that study cannot be reliably attributed to the project. Full details of all these changes are given below.

In this chapter we first identify the sources and consider the nature of the data on which the subsequent discussion is based. We then look at the data on measurable benefits for patients achieved by the projects during the period of the evaluation.

In February 2011 we asked the project teams to provide us with detailed tables of their key outcomes and achievements as part of their final reports. These tables were in some cases very lengthy. They are reproduced in appendix A, which should therefore be read in conjunction with this chapter. The two final sections of this chapter cover the gains in knowledge identified by the project teams (either in their own topic area or in relation to QI in general) and their contribution to transferrable QI.

Other outcomes identified by the project teams, including the increased engagement of clinicians and involvement of patients in QI, and the development of sustainable systems of QI, are discussed in chapter 5 and chapter 6, respectively.

4.2 Sources and nature of data

In addition to the final self-evaluation reports, we could access a large quantity of data from the projects. Some project teams produced a final report, separate from the self-evaluation report. Most teams sent us reports on the findings from surveys of clinicians and patients. Some teams provided us with data from audit reports, and so on. We also had access to publications from some teams. A list of data received from the projects is provided in appendix F.

These were demonstration projects working on different problems in differing contexts. They varied in size, approach, study design, and in their interpretation of QI and their brief. The main indicators used varied from project to project. Two projects had no controls and no comparators, making it difficult to attribute their findings solely to the interventions. The majority of the projects reported changes in patient care rather than patient outcomes. There are differences in the strength of the available evidence linking the improvements in patient care identified to eventual health outcomes.

We could not be satisfied in all cases that changes would lead to eventual improvement. Some projects took longer than others. Two projects were not complete when we produced this report, and we can therefore only provide partial information on them. QI is an ongoing activity and this chapter can only provide a partial picture. It describes what had been achieved and reported by the project teams at the time it was written (February 2011). The results presented below and the accompanying discussion need be interpreted in this context.

4.3 Patient outcomes

In this section we summarise the patient outcomes and other achievements reported by the nine projects.

IMPACT

Summary of results from IMPACT

The characteristics of patients involved in the different phases were comparable. Patients in phase three (after the implementation of the subgrouping for targeted treatment system) had better outcomes than phase one patients at six months in terms of pain and allocation to risk sub-group.

However, there were no differences in outcome between the phases for patient satisfaction, general health or quality of life (see table 17, table 18 and table 19, appendix A).

Aside from health outcomes, the project team also reported changes in clinical attitudes and behaviour. Both physiotherapists and GPs became more behaviourally focused. Physiotherapists became less biomedically focused and showed increased confidence after the intervention (table 18, appendix A).

No economic analysis was available as to the cost consequences of the project at the time of writing this report.

The IMPACT team highlighted that physiotherapists were engaged in a training programme of at least three days' duration (some had nine days of training) and an ongoing mentoring programme over 12 months. GPs received best-practice updates and feedback on patient recruitment and use of the sub-grouping tool every two months via e-mail and hard copy.

Approximately 60% of patients in phase three were treated according to protocol. That is, they received treatment according to the recommendation made following the completion of the screening or sub-grouping tool.

Table 3: IMPACT aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To improve the quality of primary care for low back pain by systematic identification and targeted treatment of risk factors for chronicity (barriers to recovery).	 Before-and-after study involving two separate cohorts of patients in five practices. Three phases, from autumn 2007 to September 2010: Assessments in original cohort of patients (ran for an average of six months in each practice). QI intervention. Assessments in new cohort of patients (ran for 12 months in each practice). 	Implementation of an evidence-based sub-grouping tool for targeted treatment. QI intervention (education, feedback, mentoring, funding support, case-led discussion) in phase two and ongoing in phase three. Physiotherapists: three or nine days' training and 12 months' mentoring. GPs: feedback on patient recruitment and use of the sub-grouping tool every two months via e-mail and hard copy.	No comparator.	Assessments just after consultation with GP, and two and six months later, in both phase one and phase two: Practitioners' confidence, attitudes and behaviour. Patient outcomes: • RMDQ* • STarT Back sub-grouping** • NRS-pain in past two weeks • EQ-5D**** • SF-12 PCS***** • SF-12 MCS*****

* Roland Morris Disability Questionnaire
 ** Brief validated tool designed to screen primary care patients with low back pain for prognostic indicators
 *** Numeric rating scale

**** Standardised instrument for use as a measure of health outcomes

***** Medical Outcomes Study 12-Item Short-Form Health Survey – outputs are a Physical Component Summary (PCS) and Mental Component Summary (MCS)

QUEST

Summary of results from QUEST

The 82 school nurses in the intervention group in QUEST were available members of the workforce for the 78 state secondary schools in their respective boroughs. The 84 school nurses in the control group were all available members of the workforce for the 91 state secondary schools in their respective boroughs.

The main finding from QUEST was that the delivery of a specially designed training programme with linked educational resources was associated with small, statistically significant improvements three months following the training on a 24-item knowledge test.

However, at the 10 month follow-up there were no statistically significant improvements in nurses' knowledge about depression, their confidence in working with young people who might be depressed, and their ability to recognise depression in vignettes (table 20, appendix A).

Table 4: QUEST aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To improve the attitudes, knowledge and skills of school nurses in the recognition and management of common mental disorders in young people.	Cluster randomised control trial (RCT) in 13 PCTs.	Training package for 82 school nurses in six intervention PCTs.	84 school nurses in seven control PCTs	At three and 10 months for school nurses: 1. 24-item knowledge test.* 2. Professional confidence: Depression Attitude Questionnaire (DAQ). ⁷⁸ 3. Clinical behaviour: depression recognition using vignettes.**

* This was a specially developed knowledge measure. A panel of health professionals and clinical academics - including school nurses, psychiatrists and GPs, together with a service user and independent consultants with expertise in child and adolescent mental health - participated in its development. A review of relevant clinical guidelines and associated primary care mental health materials, together with consultations with this panel, enabled the development of a 24-item knowledge test. Three rounds of review by the panel were used to assess face and content validity for the knowledge instrument (and to examine expert agreement concerning the depression status of the vignettes). The measure was piloted with an initial group of 26 school nurses and, following amendments, used with a sample of 166 school nurses. ** Depression recognition assessed using a series of 12 vignettes developed, piloted and evaluated specifically for this project.

Table 5: QUALITY:MK aims and study design

Aims	Study method	Outcome measures and time
Overall: To embed a whole-system approach to quality improvement, driven by primary care, patient engagement and evidence.	16 different component sub-projects.	Varied by component sub- project.*
* A full account of the outcome measures is provided in appendix A, table 22,		

Table 6: IRIS aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To determine whether a training and support programme targeted at general practice teams increases the identification of women experiencing domestic violence and their subsequent referral to specialist domestic violence agencies.	Pragmatic cluster RCT in 48 practices in Hackney and Bristol.	Training and support programme in 24 randomly allocated practices.	Usual practice in 24 randomly allocated practices.	Identification of women experiencing domestic violence. Subsequent referral to specialist domestic violence agencies. Cost effectiveness.

QUALITY:MK

Summary of results from QUALITY:MK

As table 23 in appendix A shows, many of the sub-projects involved of QUALITY:MK were pilot initiatives. These served as a vehicle to introduce and embed a raft of different processes and systems into the workings of the PCT and GP practices, and to support QI. In many instances, results in terms of measurable improvements for patients could not be quantified. For those sub-projects that yielded quantitative data, the small sample sizes made effects hard to detect.

The QUALITY:MK team suggested that some sub-project leads may have access to powerful information but do not see the importance, do not have the time or perhaps lacked the knowledge to review and analyse this to inform decision making, or celebrate success. This issue has been recognised and, in response, workshops and training sessions were put in place to address this gap for the future.

Aside from patient outcomes, in describing their results the QUALITY:MK project team highlighted findings from their qualitative evaluation that identified the following factors as critical for the implementation of QUALITY:MK:⁷⁹

- sufficient time and flexibility to develop the programme
- facilitating rather than managing change
- a clear brand
- broad ownership
- champions at every level
- strong programme management
- practical resources to support participants
- maintaining a balance between being process driven and being values led
- developing new images and metaphors.

IRIS

Summary of results from IRIS

The IRIS intervention had substantial and statistically significant effects on disclosure of domestic violence by patients and on referrals received by agencies. The recorded disclosure of domestic violence in the intervention practices was three times greater than in the control practices. The number of referrals received by specialist domestic violence agencies was six times greater in the intervention practices than in the control practices (table 25, appendix A).

IMAGE

Summary of results from IMAGE

Overall, analysis of the 12-month follow-up data provides limited evidence of improvement in patient-related outcomes in this study (table 27, table 28, table 29 and table 30, appendix A).

The IMAGE project team developed quality criteria for the management of IBS, GORD, coeliac disease and IBD. These were developed from a synthesis of the outputs of patient focus groups and an analysis of clinical practice management guidelines relevant to primary care.

These criteria formed the basis of the project's clinical decision support system (CDSS), and were also taken up in other contexts, including consideration for inclusion in the National Patient Care Summary Record as a basis for submissions to the NICE/QOF process.

The CDSS was developed and installed in the computer systems in 39 practices, and was evaluated using qualitative and quantitative methodologies.

The CDSS was used in fewer than 20% of study patients. A qualitative evaluation of the CDSS indicated that whilst substantial numbers of GPs found the protocol useful, its practicality and user-friendliness left much to be desired. There was some concern about adding more quality criteria to an already overburdened QOF.

In relation to IBD (see table 27, appendix A) the IMAGE team reported marginally improved disease-specific QOL at follow-up (24.4 vs 25.2, p=0.018). There were no other significant changes or impact of protocol use.

Table 7: IMAGE aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To contribute to capacity for QI through a more patient-centred method of guideline development and generation of quality criteria.	Before-and-after study in 39 practices – with follow-up 12 months after initial consultation/ baseline.	Quality criteria developed and implemented through CDSS software.	No comparator.	 Patient outcomes in IBD, GORD, IBS and coeliac disease: symptom severity QOL: generic and disease- specific anxiety depression patient enablement satisfaction with communication per cent on antidepressants appropriateness of treatment (IBS and GORD) Number of GP consultations.

In relation to GORD (table 28, appendix A), the project team reported a statistically significant but clinically modest reduction in symptom severity (Gastrointestinal Symptom Score – GIS), 15.1 vs 14.5, p=0.020 (t-tests throughout); a statistically significant but modest improvement in QOL (QOLRAD), 6.1 vs 6.3, p=0.017; and a small but statistically significant fall in patient consultation rates, 0.7 vs 0.5, p=0.012. Protocol use was associated with a significant but modest reduction in anxiety.

For IBS (table 29, appendix A), the team reported that patient questionnaires completed before and after indicated a reduction in symptom severity (IBS severity scoring system – SSS), 214 vs 193, p<0.0005 (t-tests throughout) and in disease specific quality of life (IBS-QOL), 71 v 75, p<0.0005.

For coeliac disease (table 30, appendix A), there were no significant changes in any parameters overall and no significant influence of protocol use.

The project team highlighted that this was a multifaceted intervention. Protocol use and its modest impact on patient outcomes was not the only important measure. The successes of the project included:

- Creation of robust patient-centred quality criteria.
- Generation of new epidemiological and clinical information about the management of these chronic conditions in general practice.
- Useful lessons about the design, implementation and usage of the CDSS for chronic diseases – at present these do not attract payments rewarding the achievement of management targets.

The project's baseline epidemiological data collection produced three important sets of information:

- Prevalence of the conditions under study in general practice in the UK.
- Continuing symptom burden and impact on QOL of the four conditions.
- Levels of anxiety and depression associated with the conditions. Although still unpublished, the project team suggest that these data provide important indications of the scope for improvement in the management of these common GI disorders and underline the need for QI interventions in general practice in future, either as part of QOF or as quality standards embedded in the commissioning of services by the new clinical commissioning groups.

LIMBIC

Summary of results from LIMBIC

There were no statistically significant changes in the primary outcome measure (RMDQ), or other measures in the clinical value compass. This is made up of clinical outcomes, functional outcomes, satisfaction, and cost of care.⁸⁰ Practice activities, costs and patient outcomes changed little after the intervention. There was a statistically significant but small increase in the number of GP visits per patient after the workshop.

In patients seen after the workshops there were small, non-significant improvements in median reductions in disability, back pain bothersomeness and greater satisfaction with care (table 32, appendix A; full results have also been published).⁸¹

Aims	Study method	Intervention	Comparators	Outcome measures and time
To assess changes in patient outcomes following a practice improvement intervention that included patients in the improvement in learning, taking account of prognostic factors.	Before-and-after study in 101 patients in nine practices in two PCTs.	Eight half-day practice workshops, improvement facilitator and PDSA cycles, in 53 patients in nine practice teams in two PCTs.	53 patients before workshops compared to 48 patients eight weeks afterwards in nine practices in two PCTs.	Clinical Value Compass (primary care back pain questionnaires) Clinical outcome; Primary outcome; RMDQ (Roland and Morris Disability Questionnaire). Functional outcomes: • pain severity • back pain bothersomeness • life impact • activity • work. General health: • interference with normal work • feeling calm • having energy • feeling downhearted. Satisfaction with care: • information giving • caring • effectiveness • overall satisfaction.
To identify any changes in practice care patterns and costs for back pain after the above intervention.	Practice database analysis, in nine practices in two PCTs.	n = 648 before workshops.	n = 366 after workshops.	Cost of care Health service utilisation: • GP visits per patient • giving information leaflets, sick notes or referrals to consultant services.

Table 8: LIMBIC aims and study design

LIMBIC aimed to develop and validate a coherent theoretical framework, based on health professional and organisational behaviour, and behaviour change. It would inform people and organisations about how best to intervene in service settings in the face of different barriers and effect modifiers.

In addition to the quantitative outcomes measures, an analysis of discussions in pre- and postworkshop focus groups highlighted two overarching themes: time and learning together. The pre-workshop themes related to participating in the LIMBIC project were 'frustration', 'working people' and 'access to services'. The post-workshop themes were 'value of involving patients' and 'listening'. An increase in evidence-based management was not reflected in either the qualitative or the quantitative analyses at the end of the evaluation period.

At one-year follow-up, the qualitative analysis showed sustained improvements in practice, including reported changes in management of care that were evidence grounded.

EQUITY

Summary of results from EQUITY Part A: Health Equity Audit

Analysis over three years showed steady improvement across all study PCTs for most disease indicators. However, the team commented that they were not able to show a reduction in inequality in Tower Hamlets compared to neighbouring comparison PCTs in City & Hackney and Newham. Health inequalities by ethnicity and age are persistent and need constant re-evaluation.

Considering the background of increasing improvement within all PCTs, it is impossible to ascribe any improvement solely to the efforts of the EQUITY project.

Some of the specific results are:

 The year-on-year difference in target attainment between ethnic groups is statistically significant only for patients on the diabetic register (table 35, appendix A).

- The odds of attaining the systolic blood pressure target increased significantly year-on-year for South Asian patients across all three PCTs (table 36, appendix A).
- The odds of attainment increased significantly for white patients in Tower Hamlets and City & Hackney only. For black patients the odds of attainment increase significantly over time in City & Hackney only and reduce over time in Tower Hamlets. This is visible in the crude percentage achievement in each year (figure 5, figure 6 and figure 7, appendix A).

These results suggest a widening of ethnic differences, particularly because South Asian patients across East London appear to have improvements in systolic blood pressure attainment over and above white and black patients.

- The odds of attaining the glycosylated haemoglobin (HbA1C) target improved in all three ethnic groups across East London – except for white patients in City & Hackney, where there was no change in the odds of target attainment over the study period (table 37, appendix A). This is visible in the crude percentage achievement in each year (figure 8, figure 9 and figure 10, appendix A).
- Significant differences are seen in all PCTs by age group for the HbA1C target (table 38, appendix A). This is driven by higher achievement in older age groups.
- The year-on-year improvement in attainment of the HbA1C target is greater for women than for men in all three PCTs (table 39, appendix A).
- In all three PCTs, the odds of meeting the HbA1C target increased significantly over time for both genders, with the increase in odds higher for women than for men (table 40, appendix A). The crude change in percentage meeting the target illustrates this (figure 11, figure 12 and figure 13, appendix A).
- In all PCTs, statin prescribing was highest for South Asian patients, followed by white and black patients (figure 14, appendix A). For Tower Hamlets and City & Hackney, the odds of being prescribed a statin did not differ significantly by ethnicity (table 35, appendix A). Year-on-year improvements for each ethnic

group ran in parallel, and there was little catchup or convergence between the separate groups over time.

For the three long-term conditions targeted, the data collected in the EQUITY audit demonstrated baseline (2007) inequalities in disease process and outcomes by gender, age and ethnicity at the level of the PCT population.

Summary of results from EQUITY Part B: Lay-led self-management programme results

Comparison of the generic expert patients' programme (EPP) courses with the 'Healthy Moves' courses based on the SF-36 physical and mental health summary scores shows a greater improvement for Good Moves. The Good Moves course was also considered more user-friendly and enjoyable (table 41 and figure 15, appendix A). The project team highlighted that those attending Good Moves were younger and healthier than those attending the EPP courses, and younger people showed greater improvements in physical and mental health. A greater improvement in health might therefore be expected for Good Moves, but the effect remained after adjustment for age, gender and co-morbidities.

CKD

Summary of results from CKD

This project consisted of a large RCT and two smaller studies. Results from the trial were not available from the CKD project team at the time of writing this report (February 2011).

Results from the care bundle study were that compliance with blood pressure targets improved over time (<130/80 mmHg for diabetes). Overall, 95% compliance with the bundle was not achieved during the pilot study.

 Figure 16, appendix A shows how the chronic kidney disease register, rates of proteinuria measurement (ACR) and prescription of blood pressure medication (ACE/ARB) improved over time.

- Figure 17, appendix A shows how the rate of cardiovascular risk assessment improved over time, yet it proved challenging to improve control of blood pressure to NICE targets.
- Figure 18, appendix A shows how the reliability of the application of the care bundle improved over time.

A total 116 people with chronic kidney disease attended the clinic between April 2009 and January 2010. Of these >80% had diabetes. A number of changes were implemented to increase compliance with the bundle. These included: directly identifying people with diabetes and chronic kidney disease by calling them to clinic; the collection of spot urines (rather than early morning urines); and improved levels of albumin-creatinine ratio collection (for proteinuria quantification). The wording of the care bundle was also amended to include specified timeframes within which to act, as it was not realistic to measure and treat proteinuria and blood pressure to target within the same day.

Practice nurses reported that the care bundle could be easily applied within the usual consultation time, taking less than five additional minutes. Additional benefits of applying the care bundle included identification of patients at risk of progressive chronic kidney disease who required referral. From a patient perspective, some people queried why the disease had not been picked up before and this required explanation and assurance.

For the patient empowerment programme, the number of participants who completed this initial work was too small to draw any firm conclusions about the efficacy of the programme.

The project team explained that there were missing data from both staff and patient feedback and monitoring to inform this evaluation. However, the project team highlighted that a suite of empowerment tools had been developed as a result of this programme (patient empowerment programme executive summary).

Table 9: EQUITY aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
Part A: Health Equity Audit To develop a dataset on the equity (by age, sex and ethnic group) of service provision at both general practice and PCT level that can inform change at both levels. To identify any inequity in provision of care by age, sex and ethnic group, by practice, for key indicators in CHD, COPD and diabetes. To determine if feedback to and support of Tower Hamlets practices reduces inequalities.	Analysis of routine data in 38 practices in Tower Hamlets PCT and 113 in City & Hackney and Newham PCTs.	Written feedback to all 38 practices in Tower Hamlets PCT, plus support in year one (2008) for 10 underperforming practices, and in year two (2009) for six of eight networks of four or five practices each.	Usual care in practices in City & Hackney and Newham PCTs (n = 113 practices).	Diabetes indicators: Iipid lowering drugs prescribed HbA1c value retinopathy screening GFR SBP cholesterol BMI smokers. CHD indicators: Iipid lowering drugs prescribed cholesterol beta-blocker prescribed SBP ACEI prescribed aspirin prescribed BMI smokers. COPD indicators: pulmonary rehabilitation exercise referral FEV 1 measured MRC scale smokers.
Part B: Lay-led self- management programmes To increase patient knowledge and self-care through lay-led self- management groups with routine care pathways for chronic disease, improving their accessibility and uptake along with improvements in equity.	Before-and-after study (2007–10).	Lay-led self- management programme in Tower Hamlets PCT: Good Moves.	Existing self- management programme: generic EPP.	SF-36 scores for physical and mental health.

HbA1c: glycosylated haemoglobin; GFR: glomerular filtration rate; SBP: systolic blood pressure; BMI: body mass index; ACEI: angiotensin-converting enzyme inhibitors; FEV: forced vital capacity; SF-36: short form (36) health survey.

Table 10: CKD aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
Overall: To provide trial data on the best way to implement QI in the management of chronic kidney disease in primary care.	Three component studies – see below.			
RCT: To compare the effectiveness of guidelines plus prompts, or audit-based education, with usual practice.	Two-year three- arm cluster RCT involving 125 practices from eight localities across England.	 Guidelines and prompts. Audit-based education. 	Usual practice	SBP
Care bundle: To increase the proportion of chronic kidney disease clinic patients receiving a care bundle.	Time series April 2009 to January 2010.	116 patients attending chronic kidney disease clinic, >80% with diabetes.	N/A	Compliance with care bundle: A. Put patient with stage 3-5 chronic kidney disease on the chronic kidney disease register within five days. B. Measure proteinuria and document within five days. Prescribe ACEI/ARB within 10 days of ACR result if significant proteinuria present. C. Document blood pressure and treat within 10 days if hypertension present. D. Document cardiovascular risk.
Patient empowerment programme: To develop, implement and test a package of empowerment tools which can be delivered in a primary care setting and which enable the patient to be an informed partner in their care and effectively self-manage their condition				A set of tools to facilitate positive interactions between clinicians and patients, including a self efficacy questionnaire, Frequently Asked Questions 'Your Health Concerns' (to allow the patient to set their agenda at consultation) and a goal setting care plan.

REST

Summary of results from REST

This project consisted of two trials, an initial pragmatic controlled trial (A), and a pilot cluster RCT (B) across four practices. Findings from trial B were not available when this report was written (February 2011).

For aims 3 and 4 of the initial pragmatic controlled trial (A), the results were that one practice changed substantially during the six months of the collaborative (figure 19 and figure 20, appendix A). The project reported that practice was small and had high levels of engagement, agreement on new protocols for prescribing hypnotics, and a planned withdrawal programme that involved writing to patients, switching to longer acting drugs and gradually reducing them over a period of several months.

Figure 19, appendix A, shows the average daily quantity per specific therapeutic group age-sex prescribing unit (ADQ per STAR-PU) over time for each of the 102 practices for benzodiazepines for the 24 months prior to, and during the first six months of the project. Figure 20, appendix A show the same for Z-drugs. Longer term follow-up data will be available in the future. These figures show that the collaborative practices cover the range of prescribing levels of ADQ per STAR-PU.

Results from REST are presented as change per month (table 44, appendix A) rather than average prescribing amounts. The project team did this for two reasons. First, there was an underlying trend in prescribing rates before the project began. Second, there was considerable variation between practices (as seen in figure 18 and figure 20, appendix A).

Overall, in the before phase, benzodiazepine prescribing was decreasing in both groups, flattening out in control groups but decreasing more sharply for collaborative practices. Z–drugs were not changing substantially before in either group, but after the intervention the rate decreased for collaborative practices. More detailed results to follow.

For benzodiazepines, the collaborative practices were prescribing 28.5 units more than control practices, but with a wide confidence interval (103 less to 160 more) that included zero. Before the intervention, control practices' rate of prescribing was decreasing at a rate of 1.7 units per month, with a confidence interval from down 2.3 to down 1.1. After the intervention, the decline was 1.2 units per month (from down 3.6 to up 1.2). Collaborative practices even before the intervention were declining faster. They declined by 2.6 units per month more than control practices (from down 4.6 to down 0.6) and after the intervention their decline was steeper at 12.1 units per month (from down 20.5 to down 3.6).

For Z-drugs, collaborative practices prescribed less overall (91.1 units per month – from 572.8 less to 390.5 more). Before the intervention, control practices' prescribing was increasing by 3.2 units per month (from up 0.7 to up 5.6), but after it was decreasing by 2.4 (from down 10.6 to up 5.8). Before the intervention, collaborative practices were decreasing relative to control by 6.6 (down 15.3 to up 2.1), but after the intervention their decrease per month was 54.5 relative to controls (from down 83.7 to down 25.3).

For aims 1, 2 and 5 of the initial pragmatic controlled trial (A), leadership behaviours were infrequently reported. Despite describing a culture of innovation, there was low uptake of QI methods beyond clinical and significant event audit, even after practices participated in a QI programme. Commenting on this, the REST project team said they used a multidisciplinary approach to introduce practitioners to sleep assessment and non-pharmacological interventions for insomnia, examining the impact with mixed methods.

Although any movement towards practices' lessened reliance on medication was welcome, this was not in itself evidence of improved quality of patient care. The project team identified factors promoting collaborative aims, barriers to achievement, and intended and unintended consequences of changes in practice. The REST project collected some evidence that practices needed greater support to enhance leadership competences and develop QI skills to stimulate innovation if improvements in healthcare are to accelerate.
Table 11: REST aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
 To: 1.Improve the user experience of management of insomnia using validated measures. 2. Increase use of recorded non-pharmacological measures in insomnia by at least 100% in three years. 3.Reduce rate (costs) of Z-drug prescribing by 50% in three years (from a baseline average of 4.8 ADQs per STAR-PU). 4. Reduce the rate (costs) of benzodiazepine hypnotic prescribing by 25% in three years (from a baseline average of 0.98 ADQs per STAR-PU). 5. Investigate the effect of QI training on leadership behaviour, culture of innovation and adoption of QI methods in general practice. 	Pragmatic controlled trial (A). Eight general practices selected from 18 who expressed interest based on geographic area. Run in: October 2005 to September 2007.	Complex educational intervention differed between eight local practices. Techniques included: • academic detailing • rapid PDSA cycles • process redesign • monthly feedback using SPC charts.	94 other practices in Lincolnshire.	 Data collected for a two-year period pre-collaborative (October 2005 – September 2007), and for the six months of its operation (October 2007 – March 2008): Aims 1 and 2: qualitative measures. Aim 3: prescribing rates (ADQ per STAR-PU) for Z–drugs. Aim 4: prescribing rates (ADQ per STAR-PU) for benzodiazepines. Aim 5: assessed by questionnaire survey.
To test procedures and collect information in preparation for a larger definitive trial to measure effectiveness and cost- effectiveness of an educational intervention – for general practitioners and primary care nurses a to deliver problem focused therapy to adults.	Pilot cluster randomised trial (B).	Educational intervention (2x2 hours) for patients with sleep problems: comprised assessment and modified CBTi.	Usual care (sleep hygiene advice and hypnotic drugs).	 Primary outcome: PSQI Secondary outcomes: insomnia severity index Epworth sleepiness scale Beck depression inventory PSYCHLOPS at 0, 4, 8 and 13 weeks

ADQ per STAR-PU: Average daily quantity per specific therapeutic group age-sex prescribing unit PDSA: Plan, Do, Study, Act SPC: statistical process control CBTi: cognitive behavioural therapy for insomnia PSQI: Pittsburgh Sleep Quality Index

4.4 Increasing the knowledge base

One of the aims of the Engaging with Quality in Primary Care programme was to increase the knowledge base in relation to the substantive topic areas of the projects, and in relation to QI in healthcare. Table 12 sets out the publications and other outputs of the projects at February 2011.

Increasing QI knowledge and understanding

The aim of the project teams was to change clinical attitudes and behaviours in specific clinical fields to improve patient care. In this process most of the teams also explicitly intended to increase participants' understanding of QI more generally. The publications and presentations listed in table 12 reflect this two-fold aim. In their final selfevaluation reports we asked the teams to consider whether and how they had improved knowledge and understanding of QI generally among project team members and participants, or among other groups or organisations. In response, the project teams made the following points.

Enhancing knowledge of the concept and techniques of QI

Six teams provided examples of what they had done:

- QUALITY:MK provided training to PCT and general practice staff on its QI model, on public and patient engagement, and running an evidence-based journal club.
- LIMBIC reported an improved understanding of QI among the participating practices and the PCT about the benefits of fusing clinical knowledge with improvement in knowledge and learning. They also found that practice teams' learning from each other was enhanced when working in an inter-professional environment.
- CKD provided participants with a practical experience of PDSA cycles, practice liaison and implementation.

- The practice equity reports developed by EQUITY were well received by participants and were extended to other conditions.
- IMPACT generated evidence about the subgrouping approach for targeted treatment in primary care that can be supported with simpleto-use electronic and paper systems.
- REST reported that they were applying the learning and knowledge gained about QI through REST to a new initiative with specialty registrars in general practice in Trent, through a project called Education for Quality Improvement Projects. The team also suggested incorporating QI projects as an alternative to audit in the evidence for appraisal and revalidation of GPs. This has been accepted and included in the latest guidance to clinicians on hypnotic prescribing issued by the National Prescribing Centre.⁸³

Understanding user involvement in QI

User involvement was a programme requirement. All projects reported improved understanding of what this meant among users, project teams and participating clinicians. For example, the IMPACT team reported their user representative gained confidence and skills as a result of her involvement. She went on to be a training adviser for other research users. The LIMBIC team reported that patient involvement in improvement activities had enhanced the learning experience for practice and PCT staff. It was also a powerful motivator of behavioural change among clinicians. Chapter 5 provides further details on user involvement in the programme.

Effective QI topics

The IMAGE team commented that if a clinical topic is of low priority to clinicians (as was the case for low back pain for GPs in this project), engagement in a QI initiative is likely to be, at best, variable. Working with clinical groups who see the topic area as important, and in which they feel they play a key role, increases the likelihood of engagement and behaviour change that is sustainable in the longer term. Related issues mentioned by other teams were the importance of a bottom-up approach to developing QI initiatives. Also mentioned was the difficulty of achieving continuing commitment of practice teams to a project lasting over two years, and the challenges of doing so at a distance

Early preparation and consultation

The QUEST team consulted widely before developing and delivering tailor-made training and resources.

This encouraged wide consideration and discussion of the proposed improvement, namely an enhanced role for school nurses and their colleagues in mental health work.

Other projects, such as REST and IRIS, also ran initial collaborations or pilots that raised the profile of the project at an early stage. IMAGE used early consultation with users to develop the user-based outcome measures for the project.

Project	Articles in peer-reviewed journals	Articles in non- reviewed publications	Conference posters and presentations	Training manuals, handbooks, workbooks, etc.	Other
IMPACT	Five articles in peer-reviewed journals. Clinical and cost outcome papers are due to be submitted, March 2011.	None completed as at December 2010. Plan to summarise results in professional newsletters/ workshops.	Five peer- reviewed abstracts/ posters/ presentations at conferences. Three further presentations planned. Further presentations sought at national meetings.	IMPACT physiotherapy training manual. IMPACT best- practice updates (suitable for use by GP practices).	
QUEST	Three articles in peer-reviewed journals).	Eight articles submitted/ published in professional bulletins and journals.	Eight presentations at conferences/ meetings.		
QUALTIY:MK	Five articles in peer-reviewed journals.		Three peer- reviewed presentations. Four peer- reviewed posters. 10 other presentations.		Newsletters. Seven videos. Three examples of good practice – used nationally. ⁸²
					Table continues

Table 12: Increase in the knowledge base

Table 12: Increase in the knowledge base

IRIS Or pa in joi	ournals Dne protocol baper published n peer-reviewed ournal.	publications One magazine article.	presentations 11 presentations at conferences. Four	workbooks, etc. IRIS handbook for domestic violence aware practices.	One blog.
			presentations to PCTs: Hackney.		
IMAGE Or pe joi	Dne article in beer-reviewed ournal.		11 presentations. 19 poster presentations.		
LIMBIC Tw pe jou Th de	wo articles in beer-reviewed ournal. hree papers in development.	Four articles.	Planned keynote speech at Calgary Chronic Pain Conference.		
EQUITY Fit pu pe joi	Five papers bublished in beer-reviewed ournals.		14 conference presentations. Six posters.	One conference about the project. CVD nurse training for facilitation.	Health Equity Audit reports 2008 and 2009. Interim report March 2010. Final PCT report December 2010.
CKD Si pe jou Fit be	Six articles in beer-reviewed ournals. Five papers have been submitted.	13 articles.	16 posters and eight oral presentations.	Patient empowerment tools. Individual workbooks were produced for use in the ABE workshops, but these would not be suitable for general use.	Presentation at Association of Medical Research Charities All Party Parliamentary Group's summer medical research seminar. E-news to members of Vascular Coalition.

Table 12: Increase in the knowledge base

Project	Articles in peer-reviewed journals	Articles in non- reviewed publications	Conference posters and presentations	Training manuals, handbooks, workbooks, etc.	Other
REST	Seven papers in peer-reviewed journals.	Three editorials in peer-reviewed journals.	28 conference presentations and posters.	Sleep management manual utilised by practice teams.	Enhanced website resources for patients and clinicians, along with e-learning package developed for clinicians.

Using information systems and consulting end users

The IMAGE team cited the challenge of devising and implementing computer designed support systems in primary care computer systems. They noted that almost all GP computer systems contain tick-box questionnaires or templates (mostly related to QOF). These systems are not supported by information explaining the reasons for undertaking particular tasks. This was the feature that distinguished the computer designed support systems approach used in IMAGE.

The team reported that they 'did this [project] extremely well with our patients, but did it rather badly for our doctors. We should have conducted more exploratory qualitative work to find out exactly what kind of computer designed support systems would be most useful, rather than designing our system without taking account of users' views'.

IMAGE also mentioned the problems of collecting data from electronic patient records; a difficulty that other projects, such as IRIS, also encountered.

Discussion

The project self-evaluation reports have demonstrated that the knowledge and understanding of QI gained through the programme ranged wider than the topics identified above. This list is of interest insofar as these are the knowledge gains the project teams specifically mentioned.

4.5 Developing transferable systems of QI

In this section we look at whether the systems, approaches and tools of QI that were developed and used in the projects are being, or could be, transferred to other clinical areas.

We look at each project in turn, considering what the projects had already achieved by February 2011, and where the teams had identified a potential for transferability that had not yet been realised.

IMPACT

The IMPACT team shared lessons about implementing the work with another study at Keele University that focuses on improving primary care for patients with osteoarthritis. This influenced the development of the other study, especially the recruitment of GP practices. The other study is also making use of the normalisation process model, which was used in IMPACT.¹⁰

The team made it a priority to transfer the use of the sub-grouping tool to other areas of musculoskeletal healthcare. The project team validated the discriminative and predictive validity of the screening tool for different clinical conditions in a large cohort of patients with musculoskeletal pain.⁸⁴

Local physiotherapists started using it for other common conditions at the end of 2010.

10 Also referred to as normalisation process theory. This was used by the IMPACT project team to understand how new ways of working were embedded into everyday primary care practice.

The project team secured funding from the National Institute for Health Research (NIHR) Research for Patient Benefit programme to develop the monitoring tool to help clinicians target and monitor treatment progress among high-risk patients.

The new skills acquired by physiotherapists through IMPACT are being applied to the treatment of other common musculoskeletal conditions.

QUEST

The team emphasised the importance of the initial open consultation to develop clinician-led targets for change and associated support, together with a pilot phase to test the approach to engineering change – including its feasibility and acceptability. They noted that this approach is already used in QI projects in other areas of practice.

The vignette and knowledge measures developed for this project have been requested by teams in Ireland and the North of England for use in similar initiatives.

QUALITY:MK

The following were produced by the project team, and describe some of the QI approaches they developed.

The project team consider these as generic and transferable to other settings:

- QUALITY:MK website contains materials and advice on incorporating knowledge and learning zones, supporting a whole-system approach to QI, and ensuring QI is rooted in the planning cycle.
- Document 'Public and patient engagement: getting it right.⁸⁵
- Document 'Clinical engagement: driving improvement'.⁸⁶
- NHS Milton Keynes Commissioning and Contracting Manual.⁸⁷

IRIS

With support from the NIHR, the project team is adapting the IRIS model to train practices to support male victims of domestic violence. The team also noted that the model is potentially transferable to other conditions that are marginalised or stigmatised in current practice and require multi-agency collaboration – for example, safeguarding children and vulnerable adults.

The team also noted that the IRIS model (the training provided by a specialist domestic violence advocate who is also the referral contact, the referral pathway, prompts in the medical record to ask about abuse, and periodic audit of identification and referrals) is applicable to antenatal, sexual health and gynaecology clinics, as well as to accident and emergency departments.

The role of the advocate educator is potentially transferable to other QI interventions in primary care that combine training with a change in practice and implementation of a new referral pathway.

IMAGE

The project team was 'struck by the ways in which our thinking about quality criteria has led to the recognition that a chronic disease management model is appropriate for the care of these common gastrointestinal conditions'.

They went beyond QOF, developing recommendations for disease management that read across to other aspects of the care of chronic conditions in general practice.

The tools and materials generated were identified as the main transferable outputs of the project. The team commented that these were applicable across primary and secondary care, and form an important opportunity for the integration of service planning and delivery between healthcare sectors.

LIMBIC

The LIMBIC team commented that the template for practice computer systems could be used to explore the primary care costs of other conditions.

The team asked participating clinicians how the LIMBIC model (an inter-professional approach, using practice-based learning and involving patients) might be used in other areas of need to inform practice and commissioning. Participants said it would be applicable to any chronic condition, to chronic disease management and to long-term conditions. Many thought it would be widely applicable to their role and their practice as a general structured approach to making and evaluating change.

EQUITY

Assessing equity impacts and review are increasingly a PCT requirement. The project team has developed health equity dashboards to monitor progress in the reduction of health inequalities by age, gender and ethnicity for COPD and CHD, demonstrating the potential for transferability.

CKD

The patient empowerment arm of the project commented that if practitioners have the necessary skills to engage with their patients in a meaningful way, overall the care plan will benefit and influence the degree of self-management undertaken.

The team commented that the tools developed for the patient empowerment intervention could be easily distributed and adapted for other disease areas.

REST

The team reported that the model for PCT/clinician collaboration is effective and is being using by NHS Lincolnshire in other projects.

This includes a Health Foundation funded project to improve the cardiovascular care provided by ambulance services.

Discussion

All teams actively sought to share the lessons they had learned about implementing QI work with others, both locally and nationally. Some projects had already received further funding, and others had considered where the work they had done, and the tools and models they had developed, could be adapted for other clinical conditions and healthcare settings. The project teams were, in general, alert to opportunities to spread good QI practice.

4.6 Conclusion

This chapter has set out some evidence as to the projects' achievements, in terms of patient care, how the projects have increased the knowledge base (either in their topic area or in relation to QI), and whether the projects developed a system of QI that is potentially transferable to other areas of medicine. Measurable benefits for patients achieved during the period of the evaluation were modest and patchy. However, the projects also prioritised the achievement of other, wider benefits, and in some instances were able to demonstrate these.

The following chapter looks at the interactions of individual clinicians and service users with the projects.

Chapter 5 Clinician engagement and service-user involvement

5.1 Introduction

The overarching aim of the programme was to engage primary care clinicians in projects to improve the quality of clinical care in the UK. The programme required that projects were directed and implemented by clinicians. The projects were also required to involve service users and their representatives. This chapter discusses the interaction with these two groups, some of the main challenges that were faced, and the influence that interaction had.

5.2 Summary: key lessons and findings

Overall, we came to the same conclusion in this evaluation as we did in the preceding Engaging with Quality Initiative evaluation: professionallyled QI can successfully mobilise large numbers of clinicians across a wide range of organisational settings. But mobilisation is not sufficient on its own.²

QI requires a high level of commitment from clinicians. Evidence from the Engaging with Quality in Primary Care projects suggests that this commitment involves more than simple involvement. It is much harder to achieve and is consequently less common. Our key lessons and findings are listed below and are supported by the detailed discussion in the remainder of the chapter.

Clinician engagement

- Persuading practice teams to take part in projects was time-consuming and challenging; sufficient time and resource should be planned for this.
- There is a balance to be struck between being clear about what is expected of participating clinicians (time and leadership) and not deterring potential participants by giving the impression that the intervention will be too burdensome.
- Stressing the match between the QI intervention, and the professional concerns and day-to-day interests of GPs (rather than those of their PCTs) was a successful strategy.
- It was helpful to ensure that, in early stages of the project, there was flexibility for practices to test out and modify QI interventions. This ownership increased the chances of continuing clinician engagement.
- A range of practice staff beyond GPs made important and sometimes unanticipated contributions.
- Financial incentive to practices were seen by participating GPs as notionally important, but GPs also valued the opportunities for learning and development.
- The leadership, advocacy and support of project and practice champions were important in fostering and maintaining clinical engagement.

- Clinician engagement was facilitated when the projects had skilled staff to support data extraction and analysis, and develop communications with participants.
- Projects that were perceived by participating clinicians as research rather than QI were less likely to engage clinicians.

Service-user involvement

- Having multiple service users on QI project teams is beneficial. There are various categories of service user and not all need to be involved in all QI projects. What is important is that there is initial understanding of these categories, and the ability to involve those needed in the project as necessary.
- Public/patient groups that formally pursue general patient-centred objectives within the health service have an important role to play in QI.
- Early service-user involvement in QI is important. Only a few service users were proactive at an early stage, although this changed with time. Active service-user involvement is crucial if their voice is to be heard and the project is to address patients' needs.
- The degree of participation of the service users was high, was exemplified by close collaboration, and was achieved with good support from the LITP.

There is one additional and very important consequence of the way that clinicians and service users were able to work together in the projects. This was a shift from viewing the patent as recipient of services, to working in partnership with the patient.

This meant a shift of attention from the concerns of clinicians to the concerns of patients, from what might be termed a medical mindset when identifying and implementing healthcare improvements, to a greater emphasis on identifying and meeting patients' needs.

5.3 Clinician engagement in the projects

This section sets out our findings about clinical engagement. Barriers to clinical engagement are discussed in chapter 6, as part of our wider analysis of organising, sustaining and embedding QI. We begin by looking at the meaning of clinical engagement, then turn to levels of engagement in the nine projects. We set out lessons identified in the evaluation as to how clinical engagement can be facilitated, and conclude with a brief discussion of findings from a survey of clinicians.

Defining clinical engagement

The literature tells us that engaging clinicians is an essential pre-condition for the success of QI initiatives, but how is that engagement understood, and how can it be measured?^{32, 88} The word engagement comes from the French 'engager', meaning to pledge, and the word carries the force of a strong commitment. In the Oxford English Dictionary, 'engagement' is defined, in one sense, as a moral commitment. The projects were asking clinicians to become involved and remain committed. This was not a light request. But nor was it a request made in isolation. We described the context of the programme in chapter 1, and it was against this background that in 2009 the General Medical Council said:

It is not enough for a clinician to act as a practitioner in their own discipline. They must act as partners to their colleagues, accepting shared accountability for the service provided to patients. They are also expected to offer leadership, and to work with others to change systems when it is necessary for the benefit of patients.⁸⁹

Successful engagement in the kind of QI under consideration in this report involves building shared goals and constantly re-energising commitment to them. It means developing agreed performance standards or guidelines that reflect these goals, willingly sharing information and building trust. It requires frameworks within which disputes and differences along the way can be resolved or at least managed.

Leadership and collaboration are key parts of the mix of activities needed to underpin sustainable QI.^{56,89}

The degree of engagement required is considerable. The project teams recognised this:

This project seeks to change the way low back pain is managed in primary care. Whilst we have experience in educating and facilitating change of clinical practice within therapy services, this was the first project from our centre that has attempted to change the way GPs assess and manage these patients. To achieve this requires a greater level of engagement from the GPs than we have sought with previous studies, and may require a different communication strategy from the outset.

IMPACT self-evaluation report

The overall task of engaging clinicians covered several linked sets of activities:

- Recruitment of practices and GPs to the projects
 a task familiar to any primary care researcher.
- Retention keeping people on board in the face of logistical difficulties and the many other pressures on practice time.
- Winning hearts and minds telling people about QI and giving them tools to help them improve care.

Measuring clinician engagement in the projects

The project teams' accounts of clinician engagement were mainly qualitative. Quantitative measures tended to be limited to counting the number and types of people involved (table 13 summarises information from the projects' selfevaluation reports). These measures are not necessarily very informative. They may merely reflect levels of involvement in activities such as education and training, rather than active engagement in improvement.

The IMPACT team's assessment of the use (rather than the availability) of its sub-grouping tool illustrates the point. Of practitioners who had this tool available to them, 41% actually used it.

A similar story emerged from IMAGE, where the project team measured use in all the practices where the protocols were available, and related this to patient outcomes.

Protocol use varied across the different gastrointestinal conditions, but was never higher than 29%. These examples suggest that levels of engagement in the programme were much lower than the levels of involvement.

Our online survey asked respondents for details of their involvement in QI-related activities before and during the projects.

The most commonly reported activities were keeping up-to-date using clinical practice guidelines and other materials, taking part in regular informal and formal discussions, taking part in training, and using IT to improve quality.

All these activities had been undertaken before and during the project and overall there was no indication of a change in activity levels. If anything, activity levels had often been marginally higher before the project.

See table 13 for a summary of healthcare staff involved in each project.

Table 13: Summary of healthcare staff involved in each project

Project	Summary
IMPACT	 The project was conducted in one PCT and involved five practices (out of eight originally recruited). At each practice there was a link GP and a practice manager. The project team estimated that about 60 GPs and 25 physiotherapists were involved in the project (July 2009). Levels of engagement by GPs across the practices varied. Differential engagement of different professional groups: physiotherapists were much more engaged than GPs.
QUEST	 The project was conducted in 13 PCTs (one PCT decided not to be involved, despite initially agreeing; two PCTs could not find a date for staff to attend training). Two school nurses were members of the core project team. The project team reported that the school nurses consistently showed a real enthusiasm for the project.
QUALITY:MK	 The project was conducted in one PCT and involved all 27 practices in the GP practice-based commissioning collaborative, which was 'integral to design, planning and implementation of programme'. In total 161 clinical staff – 88 GPs, 18 GP registrars, 31 nurses, seven pharmacists, seven public health staff, five consultants, and five allied health professionals – were involved via sub-project topic groups, on IMPACTE (Improving Medical Practice by Assessing Current Evidence) groups and on the steering group. Two part-time GP champions were appointed. The project team reported that 'there is a significant awareness of the principles and activities of the QUALITY:MK project in the Milton Keynes health community, but there remains a significant number of clinicians in primary care who are unaware of the project even though they may have been affected by some of the changes that have occurred as a result of it'.
IRIS	 The project involved two PCTs and recruited 48 practices with a low drop-out rate (4%). There was variation in identification, and referral rates and attendance at training events across and within practices. Differential engagement of different professional groups – nurses were less engaged than GPs, but practice receptionists were well engaged. Practice champions were drawn from the whole practice team, not just GPs. The project team reported that 19 out of 24 were active in their role.
IMAGE	 The project involved 39 practices and 173 GPs across nine PCTs. Most practices approached agreed to take part in the study, but actual use of the electronic protocols was lower than expected. There was some variation in practices' willingness to engage (two found it particularly difficult). The project team reported that practices responded more quickly to requests for data at the end of the project than at the start, suggesting engagement had increased during the project. Overall, the project team reported that the involvement of the 'gastro champs' to recruit, retain and chivvy the practices was very important.
	Table continues

Project	Summary
LIMBIC	 The project involved nine practices across two PCTs. Recruitment of practices was slow to start with. Each practice formed a multi-professional team, although maintaining enthusiasm among these teams and achieving consistent and continued engagement of GPs was difficult. The continued engagement of the practices was supported by visits from the QI facilitator and by visits from GP members of the steering group. The QI facilitator found it challenging to arrange access to the practices. Not all members of the practice teams attended the workshops despite an agreed contract with the practices, and there was a particular difficulty with GP attendance. The project team reported that they struggled continuously to maintain the motivation and enthusiasm of the teams. A GP, a senior manager from each of the two PCTs and a GP educator were included on the project steering group.
EQUITY	 The project involved 36 practices in one PCT (practices in two other PCTs were used as comparators). Meetings to discuss equity data with practices were productive: 'there was a desire to have up-to-date information on health inequalities. Practices are keen to know how they perform relative to peers, and relative to national benchmarks'. CVD nurses and GPs from the project team acted as practice facilitators to help identified outliers improve performance. The project team reported a 'considerable improvement in clinician engagement in QI'.
CKD	 The project had three arms. The RCT involved 125 general practices across eight PCTs in England. Delays at the start (largely due to ethics approvals) meant that some practices became disillusioned. The project team reported variation in attendance at workshops among the practices in the ABE arm of the trial (especially at the start). Those who attended were usually multi-professional practice teams, not single GPs. Lead GPs were used to increase participation at workshops. The care bundle and patient empowerment arms involved one practice each. Expert groups were set up for both interventions, and included nephrologists, GPs, a nurse consultant in chronic kidney disease and a pharmacist. Seven practice nurses were involved in the patient empowerment intervention, which was favourably evaluated by patients and staff.
REST	 Eight practices in one PCT were involved in the initial collaboration during the first year to model the intervention. The degree to which practices engaged was variable and depended to some extent on leadership, innovation culture, team working and conflicting priorities of the practices and their staff. The project team also reported that the clinicians who did engage 'seem positive towards their involvement in the QI and are pleased to have a tangible alternative to hypnotics to offer their patient'. Subsequently, GP champions from the collaborative were used to spread learning to other practices in the PCT, and four further practices were recruited to an exploratory RCT to test the intervention.

Table 13: Summary of healthcare staff involved in each project

Lessons about clinical engagement from the projects

Lesson 1: Starting points

The ways the project teams went about recruiting GPs and their practice staff varied. Some projects (such as IMPACT and EQUITY) built on wellestablished links between a research unit and a group of practices. In others, the general practice contacts of the lead clinician were the starting point, and in some cases (such as QUEST, IMAGE and CKD) these included an existing network of practitioners with a specialty interest. QUALITY:MK built on and strengthened an existing practice-based collaborative.

These starting points were important. They helped to define future relations with the practices. In IMPACT, for example, the local practices were accustomed to being part of a research collaborative, and some saw their role in the programme as helping with research rather than doing something for themselves: 'some GPs have used the sub-grouping tool because they perceive it to be for Keele, rather than something which can help them make decisions about the care of their back pain patients. Essentially, some GPs who have been using the new approach/tools are doing so to please us rather than to help them make clinical decisions' (IMPACT self-evaluation report). The self-evaluation reports showed that, whatever the starting point, the task of recruiting practices was often difficult and time consuming (see chapter 6).

In general, the approach to recruitment and retention in the programme was one of winning people over, of shared ownership and voluntary agreement: 'I hope that practices now feel a degree of ownership of this project as they agree to participation. Engagement of the practices was not primarily achieved by the offer of financial rewards or support, but by the enthusiasm with which they were contacted by us and the gastro champions' (IMAGE self-evaluation report). But if enthusiasm and leadership were essential pre-requisites, they alone were not sufficient. The teams also needed good understanding of the primary care contexts in which they were working and an appreciation of existing pressures on practice staff. These issues were discussed at length in the selfevaluation reports and some project teams encapsulated their understanding in lists of key factors, or in web-published 'principles of engagement'.⁸⁶

Lesson 2: Clarity about requirements

Clarity about what practices were being asked to do was seen as a necessary element of successful recruitment. There was a balance to be achieved; too much clarity at the outset might scare clinicians off:

After the project was first launched ... more than ten practices were interested and the team began discussions about how they might select the practices to engage in the project and whether they might need to invite practices to compete for entry into the project. As time progressed and practices began to understand the amount of work involved in the project, some even costed out the impact on the practice, and three practices withdrew their interest.

LIMBIC self-evaluation report

This team did develop service-level contracts with participating practices but reported that 'few seemed to take on board the full extent of these expectations. In a future situation there should be absolute clarity about what is involved for all parties who engage.' The team also said: 'With hindsight, we may have achieved greater success in engaging practices if they had actively volunteered to take part' (LIMBIC self-evaluation report).

Similar concerns were expressed about the level of commitment required from GP champions:

We asked for a GP volunteer from each practice to take the role of 'link' or 'champion' for the study. At the time, we portrayed this role as requiring only a minimal time commitment (so as not to deter people from volunteering) and were not clear enough in defining our expectation of that role. This left our clinical partners unsure of what we expected from them. In future, we would seek to more clearly define these roles at the outset (perhaps within a service-level agreement) and secure a greater sense of ownership from our clinical colleagues.

IMPACT self-evaluation report

Lesson 3: Appealing to clinicians

It was generally seen as important to clinician engagement that the projects were clinically driven. For example, the REST team commented that they had focused on GPs' professional identity (GPs as experts). They emphasised that the project was doing things that GPs were already doing and just adding to their repertoire of behaviours. They steered away from saying the project was about reducing costs and prescribing (from giving the project what might have been perceived as a PCT focus) and did so, it appears, with some success. One GP said: 'One of things I do like about it is that we are dealing with clinical medicine rather than a push from the PCT on financial grounds rather than clinical grounds – it's nice that people are concerned with clinical medicine [rather] than cost cutting all the time' (REST self-evaluation report).

This accords with the findings from our web-survey of clinicians, where cost saving for the organisation was reported to be the least important motivation. Of 44 clinicians, 26 responded that it was not a motivating factor. Elements that respondents said were important motivations for participation were improved professional skills and training, greater evidence-based standardisation of professional practice, improved patient satisfaction or experience, and building a knowledge base on how to improve patient experience.

Even in the most obviously PCT-led project, QUALITY:MK, the aim was to work both top down and bottom up so that practices could make choices about which topics to cover:

At the outset a process was used to select the initial overarching pathway projects through which all three local partner organisations nominated and scored topics ... [but]... the board expected that practices would also contribute component projects led by a GP, i.e. taking a 'bottom up' approach to the planned work rather than a 'top down' PCT-driven agenda. This, it was felt, would support sharing of good practice across practices.

QUALITY:MK self-evaluation report

Engagement levels were affected when clinicians failed to fully commit to a topic. In IMPACT, for example, the physiotherapists for whom back pain was a larger part of their practice responded much more positively to the intervention than GPs.

Lesson 4: Flexibility

Several project teams thought it was important to take time initially to explore the improvement interventions they were offering and determine what clinicians thought worked best. REST noted: 'A factor that facilitated the GP collaborative was the flexibility which allowed clinicians to test the tools and techniques as they wished'. In several projects this early work then led to a more formal trial of the intervention(s) selected.

Successfully selecting and tailoring an improvement intervention depends on a good understanding of the practice context. Many teams felt they could have done more here: 'Understanding authority structure and information flow within practices is important for future studies' (IMPACT self-evaluation report). Some went further, and suggested that this context was so important that a significant degree of freedom was required if QI was to succeed:

The essence of the approach we took was that practices would gain understanding of their processes and needs of their users to enable them to design improvements for their particular situation. The methodology by which they did this would certainly be transferable to other practices and other clinical topics, but by virtue of the bottom-up approach the solutions they designed are likely to be specific to their unique circumstances.

(LIMBIC self-evaluation report).

Such an approach precludes a more formal trial of any specific improvement intervention.

Lesson 5: Involving other practice staff

While GPs were the primary focus of the majority of the projects (as leaders of their practices), other members of the practice team made important contributions. Both IMPACT and LIMBIC targeted physiotherapists. REST involved pharmacists, and several projects made efforts to involve practice nurses, and so on.

Sometimes additional engagement came from unexpected directions:

Communication with receptionists, starting with a one-hour training session, has proved surprisingly successful and benefited the programme through direct referral and improved use of our publicity material in public areas. In part, we believe the success was simply a function of acknowledging the challenging role receptionists have and valuing their potential role in making the project succeed.

IRIS self-evaluation report

The key message is that all the practice team needed to be involved: 'the use of other practice staff (physiotherapists, nurses and support staff) to promote the study amongst their GP colleagues has been effective' (IMPACT self-evaluation report). QUEST, which targeted school nurses rather than practice staff, also recognised the importance of engaging all concerned:

a mono-professional outlook does not adequately reflect the context of school health and involvement of other professionals / members of the broader workforce has been identified as important from the outset. But the balance between a main focus on school nurses, and inclusion of other care staff and of teachers has not been clear-cut.

QUEST self-evaluation report

Lesson 6: Incentives for engagement

Almost all projects offered some financial incentive to practices; usually some form of backfill to allow clinical time to be released. The amounts were not huge and some project teams suggested that it was the gesture that counted as much as the money:

Being able to offer a symbolic financial payment to the link GP at each practice to offset the additional burden of supporting the study was felt by the research team to provide a positive stimulus. However, to date, only two of the five link GPs have raised an invoice for payment, so the added value of this incentive is yet to be determined.

IMPACT self-evaluation report

It was more important to have a range of incentives, of which payment was only a part:

It is clear that some significant incentive is required to ask some GPs to leave their practices to attend a workshop. The team has placed great emphasis on the study agreement, the payment of backfill and the importance of attending the workshops for the overall study.

CKD self-evaluation report

This team also said: 'It should be noted that although payments were made to assist in the development of the interventions, ongoing support has been very forthcoming from various clinicians who have treated the work as a development activity and a shared learning experience. This would have an impact on sustainability going forward'.

The importance of training and mutual learning was echoed by others. QUALITY:MK described their journal clubs as 'a means to engage clinicians with low-key, steady improvement for routine patient care'. REST noted: 'The mutual learning environment experienced between the REST team and the clinicians also proved to be a powerful facilitator'(REST self-evaluation report).

Lesson 7: Influential advocates and champions

One of the ways practice engagement was maintained was through project champions. These were often, but not always, GPs:

We have used GP champions from the early work of REST to help spread the learning during the educational sessions and this has been very well received by GPs...GP champions recounting their own experience of working with the project and using the same tools and techniques worked extremely well and had a very positive influence/ impact on fellow GPs.

REST self-evaluation report

Other projects used GPs (LIMBIC), hospital consultants (IMPACT) and specialist nurses (EQUITY) in this role.

What mattered was having the right person available regularly:

Regular visits to GP practices from a person seen as a peer, and preferably someone who is already known to the link or lead GPs, has been beneficial in promoting GP engagement with the study.

IMPACT self-evaluation report

Other forms of support were also used to promote and maintain practice engagement. In LIMBIC a QI facilitator supported the practices with the development of their improvement projects, sharing of ideas with other practices, and access to improvement tools. In IRIS, the two advocate educators provided visible, easily accessible expertise, regular feedback on referral outcomes and training.

Each practice needed someone to lead the improvement work within the practice and provide a contact point. As with the project champions, this was often, but not always, a GP. IRIS, for example, took the view that:

A practice lead (any member of practice staff) is essential but we were not convinced that this needed to be a clinician, despite the theoretical benefit of peer influence at a practice level.

IRIS self-evaluation report

Lesson 8: Engagement support

Other forms of support were also crucial to maintain engagement. These included:

- help with data identification and collection
- rapid and easily-intelligible feedback of findings to the practices (for example, through the use of statistical process charts)
- communication strategies designed to share ideas between practices, such as newsletters and the LIMBIC wiki (these are discussed in more detail in chapter 6).

Lesson 9: Distinguishing research and QI

Project teams included some individuals with considerable expertise and experience in QI. Others came to the programme from a background in research, and for them QI was relatively new territory. Some teams were clear from the start that they were pursuing QI, albeit with academic rigour. Others saw their projects as research studies.

Findings from an online survey about attitudes to clinical involvement

As described in chapter 1, the evaluation team invited all clinicians involved in the nine projects to take part in an online survey. The findings and detailed methods are outlined in appendix G. The low response rate to the survey urges caution in generalising these findings; however, we think the headline findings remain helpful.

Quality improvement is part of the clinical role

Eighty-eight per cent of respondents reported that engaging in structured QI initiatives was 'to a large extent' an appropriate part of their role. Twelve per cent responded 'to a small extent' and no respondents thought that QI was not an appropriate part of their clinical role.

The vast majority of respondents (9%) agreed that courses on the principles and practices of QI should be included in the training and professional development of clinicians.

One respondent commented that clinicians should be made aware of QI principles early in their career, as it would help develop strong managers/leaders for the future and could lead to new QI initiatives being put into practice. Another felt that such courses are appropriate, but making time to attend them may be an issue. Yet another said that much QI knowledge would be gained experimentally, doing work with support and coaching, but to make that knowledge explicit and recognisable, theoretical teaching and reflection on what has been done would be valuable. The strong agreement that QI is an appropriate part of the clinical role and that courses on QI should be included in the training and professional development of clinicians was reflected in the self-evaluation reports:

We believe that there is a need to identify quality improvement skills as core to the transformation of primary care. Choice of technique remains less significant than the personal effectiveness of both project personnel (the GP champions, librarians, clinical effectiveness pharmacist and facilitators plus the programme manager) and their sponsors (the board members, and opinion leaders involved in the work).

QUALITY:MK self-evaluation report

Evidence of a change in attitudes or behaviour

The survey asked whether 'being involved in the project had changed their attitudes towards engaging in QI'. Only16% of respondents reported that their attitudes had changed a lot; 48% reported that their attitudes had changed a little; and 36% reported their attitudes had not changed at all.

A clinician whose attitude had changed a lot commented that being 'heavily involved in the project allowed me to get a much better understanding of improving practice'. Some whose attitude had not changed were obviously already engaged, commenting that 'this is something I have been trying to achieve for the past 30 years' or that they had 'always been committed to deliver a high-quality service'.

Respondents were also asked whether they would change their professional behaviour as a result of participating in the project. Almost three-quarters (73%) reported they would.

Specific changes mentioned included: 'trying to disseminate quality issues to more practice members'; 'better awareness, identification of, and ability to help sufferers of domestic violence as a result of IRIS project'; 'consolidation and refinement of clinical knowledge'; 'clearer guidelines and safer guidelines to work with'; and 'continued involvement in QI within my team and the larger organisation, as required'.

5.4 Service-user involvement

In this section we start by analysing the nature of the involvement of service users in the projects. We then consider whether service users influenced the projects, and conclude by identifying some principles of service-user involvement.

We are considering service users specifically selected to be actively involved in improving quality in this section. We also touch on how a wider community of service users was involved in the projects. The aim is to provide a focused account of what a specific form of service-user involvement entailed, how it influenced the projects, and what this tells us about service-user involvement in QI. To explore these issues we interviewed eight of the service users involved in the project teams, attempting to include at least one from each project.¹¹ We also draw on the understanding of the projects gained during the external evaluation.

The importance of service-user involvement in health services, in research and in QI, is well attested.⁹⁰⁻⁹² Service users can play a variety of roles in improving the quality of care. These range from making informed choices about their own care, to being active participants in their care (including self-management) and evaluating the care they receive. This means going beyond defining the parameters of quality, to being actively engaged in improving quality and sustaining that improvement.⁹²

The nature of service-user involvement

In analysing service-user involvement we are able to draw on the growing literature on public and patient involvement (PPI) in health services research. We specifically draw on a conceptual framework for analysing involvement developed by Oliver and colleagues.⁹³ This framework was subsequently used by a Cochrane Review of methods of consumer involvement.⁹⁴

The authors of the framework claim: '[it] is potentially applicable to a wide range of reports of public involvement in research and researchrelated activities'.

¹¹ For specific reasons, we agreed with one project team that it would not be

helpful to include their service user in this study.

In what follows we test its applicability to QI studies, using it to analyse our own findings. The framework is based on three dimensions:

- Whether service users were involved as individuals or as members of organised groups.
- Whether their involvement was at the invitation of the project team or in response to action by service users.
- The degree to which service users were involved (this is based loosely on Arnstein's ladder of involvement and distinguishes between consultation, collaboration and service-user control).⁹⁵

Involvement as individuals or as members of organised groups

As Oliver and colleagues note, the designation of service users as individuals or as members of organised groups is not as neat, or as simple, as it appears at first sight.⁹³

Citing Williamson, Oliver and colleagues differentiate three categories:

- patients and carers
- consumers (for example, people from patient organisations troubled about the care of people with particular diseases, such as Kidney Research UK)
- people Williamson, at that stage, called 'consumerists' (people prepared to challenge healthcare structures by focusing on general principles such as access, choice, equity, and so on).^{12,96}

Bearing in mind the increasing emphasis on service-user and public involvement in health services decision making, we would also include those who work in forums established to promote PPI in health services in this last category.⁹⁷

There were people from all these categories among programme service users. Following discussion with the project teams, we interviewed eight people. These were five individual service users, two representatives of specific patient organisations (BackCare and Coeliac UK), and one member of a PCT public/patient forum (LINk:MK). In addition, though not interviewed, there was a representative from a local PCTfunded group (SAfH) working to encourage patient self-management as part of the EQUITY project.

Interviewees commented that having multiple service users on project teams provided mutual support, and brought a wider range of views and expertise to the project. All except one had previous experience of involvement in research or research-related activities, and/or in patient organisations or in other relevant organisations, including formal PCT patient/public structures. Five of the nine project teams included more than one service user, and two of the remaining teams had attempted to do so. Two teams included people from more than one category.

The benefits of having multiple service users on project teams are widely recognised, but not all categories of service user need be involved in all QI projects. What is important is that there is an initial understanding of the various categories of service users, and an ability to involve those needed in the project as necessary.

Public and patient groups that formally pursue patient-centred objectives within the health service have an important role to play in QI.

There has been a lack of understanding and exercise of this role, but this is changing. Oliver and colleagues comment that 'structured forms of community participation with appropriate links to the wider public may have advantages in allowing quick responses and so become part of a good network to work with, rather than react to, health decision making.⁹³ Trailblazers such as EQUITY and QUALITY:MK systematically involved these groups in whole-system approaches to QI.

Proactive or reactive involvement

In this programme, the people who responded to the call for proposals, generally the clinical lead, initiated the involvement of service users. The one exception was CKD. It started as two separate projects, one of which a patient organisation put forward. Project teams then selected people by approaching individuals or organisations known to them.

At the start, most of those approached responded to the invite but did not seek to define their own role in the projects. In this respect, early service-user involvement in the programme was largely reactive. The early, proactive stances of the IMAGE serviceuser representatives, the LINk:MK PPI representative, and the REST service user were exceptions. The first of these produced a significant change in project design, and the other two produced an amendment to the focus of the study.

What happened initially is interesting, but what happened subsequently is more important. QI projects differ from research in that their protocols are less rigid and more emergent. They are necessarily shaped by the changes produced by the implementation of the project. The involvement of service users in the programme reflected this.

In all the projects the roles of the service users changed and grew over time. They became increasingly active in shaping their own involvement: 'My role changed over time ... defined jointly by the clinicians and myself as I performed it'.

Some were able, on the back of previous experience, to grasp this opportunity earlier than others, but all the interviewees were extremely positive about their involvement in the projects and about how this had developed: 'Over time I have gained a full understanding of the project ... The team feels like a family'.

Service users were involved at the formal start of all projects, although some of our interviewees joined later. The importance of early involvement is now widely recognised. One team built on what they had learned and delayed the expansion of their project into other clinical fields until they could involve service users in the early, planning stages.

Few service users were proactive at an early stage, and this changed with time. The importance of active involvement cannot be over-emphasised. As one interviewee said, the service users are there to help. The one thing he sought to change was that: 'in the proposal there is a suggestion that the [PPI] Forum is a body that is being helped, rather than being a body that is helping to help the local community'.

The degree to which service users were involved

The requirement that all the teams took part in the LITP was crucial in shaping the degree of involvement of service users. The aim of LITP was to ensure that award holders developed 'enhanced leadership skills, strategic insight, effective team working and effective use of recognised quality improvement tools and techniques'.⁹⁸ Each team explored its strengths and weaknesses, and came together regularly for mutual learning sessions. This joint programme for clinicians, service users and other members of the project teams produced a strong collaborative ethos within the teams, with clearly defined roles, effective intra-team communication and good mutual support.

A much quoted measure of service-user involvement is Arnstein's ladder.⁹⁵ This represents increasing degrees of participation from nonparticipation or manipulation, through consultation to collaboration (which is where the teams sat), to full citizen control. Genuine involvement incorporates a transfer of power, and this was evident in the project teams.⁹⁹

All the interviewees felt empowered by their involvement: 'I have grown in confidence, and seen the project gain in potential, and so have become ready to give more to the project'. It was the practical aspects of team interaction that underpinned this empowerment, such as the repeated opportunities for involvement in team discussions, good two-way communication, support through training and other resources, and opportunities to be involved in decision making and in efforts to involve the wider community of service users.¹³

An indication of how well this worked is that two organisations (BackCare and Milton Keynes PCT) are developing good practice guidance on serviceuser involvement because of their members' experience in the programme.

¹³ See also discussion in Oliver et al.93

Another measure of successful collaboration is the degree to which initially dominant team members, such as the programme's clinical leads, became increasingly confident about ceding control of specific aspects of the project to others 'as discussions have evolved and she and others have been able to make useful practical suggestions and mutual understanding and respect have developed' (IMPACT). This was particularly evident in the programme when it came to involving the wider community of service users, either through direct collaboration or through consultation. The interviewees gave us examples of how their contacts and in-depth understanding had been put to use, ranging from helping to design a patient questionnaire (IMPACT) to conducting face-toface interviews with other service users (IRIS), and recruiting other service users to the project (LIMBIC, IMAGE).

There was a high degree of service-user participation in the project teams, exemplified by close collaboration. This collaborative model worked well, judging by:

- the service users' satisfaction with the role they played
- what we have learned about their influence on the projects
- what we have learned about the abilities of the teams to collaborate with and consult the wider service-user community.

The influence of service users on the projects

All interviewees gave examples of how they had influenced project design or implementation (or both), and we have set these out in box 10. Overall, service user enthusiasm and growing confidence was clearly evident. This is demonstrated in the five videos produced by the Health Foundation and released on their website.

These accounts are supported by the project teams' positive comments, in their self-evaluation reports, about how much they had learned and valued the input from their service users.

Box 10: Examples of service-user impact on the projects

IMPACT

The service user has a long-term connection with the local university's research user group. This helped her understand the terminology used at project meetings, and enabled her to have a more influential voice in the project, including the redesign of a patient questionnaire.

IMAGE

There were three representatives from different patient organisations in the project team. One brought an experience of previous QI work (in the Engaging with Quality Initiative) that shaped the project from the outset. All three brought a wide range of patient contacts that facilitated recruitment to the patient focus groups that, in turn, helped to develop the patient-informed guidance used in the project.

IRIS

The service user undertook face-to-face interviews with other service users, and helped with GP training.

QUALITY:MK

One service user was actively driving the PCT's involvement with patients and the public (through LINk:MK) and, as part of this work, helped shape the integration of the project with the wider work of the PCT. He was able to widen the scope of the project. Another service user was a patient who took a leading role in the patient empowerment arm of the project.

LIMBIC

One service user from BackCare brought experience in quantitative research, with published work on spinal therapies, and expertise in organising patient-centred focus groups and feedback sessions. The second service user was a patient whose links with the local back pain group facilitated patient recruitment to the project.

CKD

One service user brought experience of producing information for patients, which he was able to apply while working on the patient empowerment arm of the project.

REST

The service user stressed his role in making the project feel grounded, with a greater sense of urgency about improving outcomes for the people involved. He was involved from the start, and was able to broaden the project's original objectives.

Comments included: 'In further projects we are systematically incorporating a user (or patient and public involvement) group to advise on study design, shape of the intervention, conduct and interpretation of results, particularly with regard to acceptability of intervention and research components of the study' (IRIS self-evaluation report); and 'The service users had a great impact on the project by making it more patient focused, in addition the REST team also came to the realisation that the project was not solely about improving prescribing but about improving patients' experience, in line with the NHS agenda.' More generally, the chairman of LINk:MK reported that 'the "patient centred" tenet of QUALITY:MK is having a positive effect in many areas of primary care'.

This last comment was reflected by other project teams. A key outcome of the programme was the shift among many teams from a QI medical mindset to a more patient-centred view of improvement. They went from viewing QI as a change in the clinical care given to patients, to a change introduced in response to patient needs and actively identified by patients.

In CKD, this included introducing a simple, but non-trivial, change of language – talking about 'kidney doctors' rather than 'nephrologists'.

Principles of service-user involvement

In our previous evaluation of the Engaging with Quality Initiative, we developed a list of factors that had been identified as helpful in service-user involvement. These were confirmed by the interviewees, and are reproduced in box 11.

It is possible, on the basis of this list and the work by organisations such as INVOLVE and the Picker Institute, to develop a set of principles that cover the relationship between project teams and service users in QI.^{14, 100} The QUALITY:MK team did this in their patient empowerment sub-project, and published a set of golden rules for patient engagement in NHS decision-making.¹⁰¹

As an example of how such principles might be used to assess service-user involvement, we took the principles developed by Telford and colleagues and applied them to the projects (see box 12).¹⁰²

With the encouragement of the Health Foundation and the support of LITP, the projects complied with the Telford principles. But they did so in special, resource-intensive circumstances; LITP consumed 12% of the total programme budget.

As we have seen, our interviewees reported a variety of procedural gains from their involvement, ranging from the development of better focused, more patient-oriented outcome measures, to more effective liaison with the wider service-user community.

These gains were confirmed by the project teams and by our own understanding of the projects. It has not been possible to disaggregate its impact on project outcomes because service-user involvement was a common requirement in and across all the projects.

The effects of involving consumers in healthcare policy and research, clinical practice guidelines and patient information material remain largely unevaluated.⁹⁴ Evaluation of service-user involvement in QI needs to heed all the factors that contribute to successful QI. An assessment against principles such as those discussed is a useful starting point for evaluation, but is not sufficient alone.

The difficulties of analysing the patterns of serviceuser involvement in QI, and assessing their influence, are echoed in Oliver and colleagues' conclusion about their own conceptual framework:

An analysis of reports, using the framework, found that none of its features guaranteed public influence of research agendas, but nor did any preclude it. Different methods had varying degrees of success in a range of contexts.⁹³

We found that within a wide range of contexts, the programme's collaborative approach to serviceuser involvement produced positive procedural gains in individual projects and enhanced understanding among the project teams.

¹⁴ Picker Institute Europe at: http://www.investinengagement.info/

Box 11: Facilitators of service-user involvement from evaluation of the Engaging with Quality Initiative programme

Service users who had good existing relations with members of the project team and were able to build on these relations.

Steering groups and project teams who recruited multiple service users or patient representatives in an attempt to ensure an appropriate balance of professionals and users in the group.

Positive attempts by project team or steering group members to identify and utilise all the relevant skills and expertise of all their members, including service users.

Chairing meetings in ways that recognised nuances of understanding among members, and people's possible contributions.

Developing relations of trust and understanding among team members, so that people were not afraid to ask questions to clarify something.

Providing external support to service users (including support from external mentors, such as a leadership development consultant or another external 'expert' service user).

Providing training, informally (through involvement in the project) or formally.

It also allowed the service users involved to demonstrate what is possible when they participate in QI as equals.

This chapter has looked at the interactions of individual clinicians and service users with the projects. Throughout, we have distinguished between the engagement of clinicians and the involvement of service users, and suggested that a special level of commitment is required from engagement.

But this begs a question: why does QI require this high level of commitment from clinicians?

If we look to the projects for an answer, we find this is to do with needing to change the procedures that govern everyday practice, and also the ways in which these are seen.

They need to change the goals that are sought, and the culture within which clinicians practice, and within which they reflect on that practice and adapt. This is, or should be, an ongoing, never ending activity.

The QUALITY:MK team put it best when they said: 'Quality is not an activity. It is a habit.' In the following chapter we turn to the organisational processes that can facilitate or impede efforts to improve quality.

Box 12: Measuring the programme against Telford's principles of successful consumer involvement

1. The roles of consumers are agreed between the researchers and consumers involved in the research

Service users agreed their roles and were increasingly active in developing them.

2. Researchers budget appropriately for the costs of consumer involvement in research

Several projects reimbursed service users on their teams for their services, using INVOLVE guidance as appropriate.

3. Researchers respect the differing skills, knowledge and experience of consumers

Teams achieved through mutual involvement in LITP.

4. Consumers are offered training and personal support to enable them to be involved in research

Teams achieved through service-user involvement in LITP.

5. Researchers ensure that they have the necessary skills to involve consumers in the research process

Teams achieved through clinician involvement in LITP.

6. Consumers are involved in decisions about how participants are both recruited and kept informed about the progress of the research

Service users often led on that recruitment and on communications with the wider service-user community.

7. Consumer involvement is described in research reports

Achieved with appropriate input from service users.

8. Research findings are available to consumers, in formats and in language they can easily understand

Achieved with the active involvement of, and input from, service users.

Chapter 6 Learning from the programme

6.1 Organising, embedding and sustaining QI projects

This chapter explores how the projects organised their QI activities, how these were subsequently embedded in the host organisations and beyond, and how persuasive any legacy plans designed to sustain the benefits are.

After a brief chapter summary, we set out the framework for analysis used in this chapter, then address each question in turn. We conclude the chapter by describing what we can learn from the projects about the challenges they faced – and how to avoid the pitfalls.

6.2 Chapter summary

In this chapter we have suggested that delivering QI projects depends on the characteristics the project team possesses and on what the project teams do – how they organise, learn and manage. We have identified some lessons to consider when organising teams and wider stakeholders to deliver a QI project.

The first thing that is apparent from this chapter is just how hard it is to deliver QI projects successfully and how many pitfalls there are to avoid. First, this is not an argument against doing it, but it may explain why QI projects tend to have such patchy results. Second, it suggests that we should take care to undertake QI projects only when we are sure that other, perhaps simpler, approaches to improving quality are not available. Undertaking a QI project is, at heart, a particular form of organising for change. This organising is conducted within a wider organisational setting. In this programme that wider setting was primary healthcare. We have adopted Bate and colleagues' insight that we need to understand the processes of organising for quality, and we used the selfevaluation reports to provide 'thick change narratives' (that is, theoretically informed accounts of the changes that took place).⁴⁵ The narrative to emerge reinforces the belief that there are many routes to improving patient care. Navigating a successful route involves skilful planning and coordination, mobilising support, equipping teams with the values, knowledge and skills, and spreading and sustaining the benefits. Within this, QI projects involve the application of one or more of a set of tools and techniques with their origins in manufacturing.

In practice, these tools and techniques have clearly evolved and been substantially adapted to work in the health setting. In a manufacturing setting, the QI measure is likely to be a statistic that is readily available and set by management. The means to improve the process are largely in the hands of those in the improvement team. The accountability of employees in the improvement team is relatively clear cut. The beneficiaries, customers, are clearly identified and they clearly express their preferences. The project teams have worked hard to accommodate the fact that QI projects in healthcare often are not like this. The improvement measure may be contested or hard to collect, or both. Many of the drivers of quality lie outside the organisation and the team delivering the QI project. There may be multiple organisational and professional accountabilities, and the beneficiaries may be the tax payer, the patient or the public, and the benefit may be more or less tangible.

6.3 Framework for learning how to deliver QI projects

Learning from the projects suggests three key elements. The first is how to organise a QI project. The second is how QI projects are embedded in and transform an organisation or organisations. The third is how such transformations are sustained and spread in a changing and adapting healthcare system. We believe that the evidence from the projects contributes significantly to our understanding of these issues.

To help organise the evidence in relation to these questions, we have used mid-range theorising to structure the argument. We have drawn on the conceptualisation of Bate, Mendel and Robert's Organizing for Quality, which explores the processes involved in improving, and aims to understand how organisational and human factors interact in complex settings to secure improvements in quality.⁴⁵ The authors note that general literature is dominated by a menu mentality, lists of key factors such as leadership support, teambased structures and composition, IT systems and their failings, and question the value of coming up with yet another list of items needed to deliver improvement. Instead they attempt to identify the organisational processes associated with sustained improvement, while recognising there are many paths. Based on nine case studies in three different countries, they distinguish six core challenges:

- structural
- political
- cultural
- educational
- emotional
- physical and technological.

In the following sections we draw on this categorisation, but the argument will be driven by the evidence drawn from the projects. We are interested in what the projects tell us about the organisational processes that might best address these challenges. As an example of mid-range theory, Bate and colleagues' approach supports a theoretically informed conceptual framework without predefining the overarching causal mechanisms at work. Their approach is a way to organise the evidence lightly rather than create a theoretically rigid framework into which the evidence is shoehorned. We use all six categories, but the selfreporting from the projects fitted into the following modified list:

- planning and delivering QI projects: addressing structure and ensuring coherence
- securing support for QI projects: overcoming political and emotional challenges
- equipping individuals and groups with the values, knowledge and skills to undertake QI projects: culture, education and information
- spreading and sustaining the benefits: legacies and future gains.

6.4 Planning and delivering QI projects: addressing structure and ensuring coherence

In our evaluation of the Engaging with Quality Initiative programme, we identified the need for a platform for QI projects.² Similarly, the Engaging with Quality in Primary Care projects reported the importance of core coordinating capacities to successfully deliver QI projects. Without effective planning and coordinating, energy is diffused and commitment dissipated. One learning point from CKD was: 'more emphasis on process (record keeping, management structure etc.), administration and structure early on at project outset would have been beneficial' (CKD selfevaluation report).

Piloting can help build coordinating capacities

Some projects used a pilot to develop the necessary planning and coordination capacities. In a pilot, 'feasibility, acceptability and appropriateness of the measurement tools' could be tested (QUEST self-evaluation report), and each stage of implementation could be managed. This is 'so that success/effectiveness is not purely an all-or-nothing result' (QUEST self-evaluation report).

In some projects, piloting was part of a RCT (REST). Less formally, IMPACT used a pilot study in one practice to test the sub-grouping tool before implementing it more widely. EQUITY used pilots to help evaluate the tools used to assess the feasibility of integrating referrals to selfmanagement programmes. CKD used piloting to understand implementation issues related to the care bundle. In relation specifically to their problems with IT systems, IMAGE noted: 'We might, perhaps, have followed more closely the MRC model for the development and evaluation of complex interventions' (IMAGE self-evaluation report). More widely, IRIS reported that before the project even began they benefited from their experience with what was effectively a pilot for the whole project (Prevention of Domestic Violence).

Especially in relation to the challenges of data collection, piloting emerges as a practice that helps to anticipate and address problems of planning and coordination before up-scaling. In the case of data collection, there is a strong convention in healthcare research to use pilot studies for RCTs.

In QI studies, using pilots is model practice in the US Quality Enhancement Research Initiative and is supported by guidance on the evaluation of complex interventions from the MRC.^{25,103} It can also be a means of ensuring that clinicians have a clear say in the development of the improvement interventions they are seeking to implement.

Logistics of organising QI healthcare projects

Organising QI healthcare projects involves overcoming some specific logistical barriers.

Implementation and sign-up

IRIS noted: 'obtaining honorary contracts, letters confirming the PCT's involvement etc. has been a real headache' (IRIS self-evaluation report). On the positive side, IMPACT reported that the considerable research experience of project team members was a 'fundamentally important platform supporting this study'. They went on to note the benefits of:

- a well-established GP research network
- experience in the realities of recruitment to clinical studies
- links with involved organisations
- experience in delivering educational programmes
- experience of researching electronic pop-up screens.

This prior experience reduced (but did not remove) the logistical barriers they faced. Similarly, for IRIS, the prior experience of running the Prevention of Domestic Violence pilot helped identify implementation problems before they happened. Both EQUITY and LIMBIC also listed the prior experiences of their steering group as a factor that helped their project to succeed.

IT systems

Even with experience and opportunities for prior learning, logistical challenges could be significant. One frequently mentioned barrier was general practice IT systems. IMAGE noted:

The main lesson is that anything to do with IT in healthcare is about ten times as complicated and expensive as you think it's going to be and the second [lesson] is to make sure that you understand the extent of your own ignorance and bring in people who know what they are doing.

IMAGE self-evaluation report

Other project teams reflected on the need for good IT skills. IMPACT made the point that it is not only the technical aspect of IT that needs to work well, but also the content of specific tools, that need to be acceptable to users:

It became clear that we needed something more brief ... given the burden of completing a nineitem tool ... we developed a shorter six-item version ... We pilot tested the six-item version ... which was felt acceptable by those who participated.

IMPACT self-evaluation report

Ethics and R&D governance

A number of projects experienced difficulties and delays in getting ethics and R&D governance approvals. These delays were particularly acute for multi-site projects such as CKD and IMAGE. QUEST mentioned this as a factor that delayed progress. Others, such as CKD, reported that it caused a loss of motivation among potential participants. Delays of up to 122 days for ethics approval and 21 days for research governance approval were recorded.

For others, such as QUALITY:MK, there was no problem. They were clear that their project was service evaluation and did not require ethics approval. As this variation demonstrates, there are different views about what aspects of QI projects require ethics approval. Approval procedures are primarily designed for research, not QI projects, and the teams reported that 'researchers and the ethics committees are struggling with the QI aspects of the projects'. One lesson is that in a long and complex study it might help to seek approval in stages for different arms of the project.

Recruitment

Recruiting team members, practices and patients was also identified as a delaying or obstructing logistical factor. QUEST experienced difficulties in completing their team recruitment and IRIS reported that recruitment was often difficult and time consuming. EQUITY was delayed by six months owing to slow project staff recruitment.

Practice recruitment was also difficult and time consuming. Project teams took varying approaches, building on existing links and contacts. Whatever the approach, there were often hold-ups.

REST's RCT pilot was severely delayed owing to slow recruitment of practices; a problem made worse by a swine flu epidemic.

CKD, with a recruitment target of over 110 practices, faced a particularly challenging task, and suffered consequential delays.

IMPACT faced problems of recruitment but were able to draw on past experience and existing relationships to avoid delays. Although formal help with practice recruitment was available from local clinical research networks, these bodies were still relatively new and not all projects could fully exploit them. Keeping practices on board was also a problem.

Almost all shared the view of IMAGE that retention of practices in the face of time pressure and competing priorities required effort throughout the life of the project.

Patient recruitment to the projects proved no easier. REST described it as a major problem. IMPACT noted that many potential participants were lost to the study because the patient recruitment relied on GPs mentioning the study in a patient's consultation. Often this failed to happen – they achieved a 0% identification rate. For similar reasons, LIMBIC also ended up with a smaller sample of patients than they had hoped (55 compared with 100).

Collecting and analysing data

Collecting and analysing data can be a significant challenge. Although undertaking a QI project is not the same as doing research, it shares some requirements with conducting good research. Data must be collected, analysed and communicated to arrive at relevant, evidence-based findings.

As Dawda and colleagues comment: 'All improvement frameworks make extensive use of data to evaluate needs and opportunities, refine solutions and monitor outcomes.'⁵² Organising data collection, analysis and validation in QI projects requires the ability to be enough of a researcher to produce detailed, reliable data and analysis. It also depends on the ability to feed back data rapidly and intelligibly to facilitate improvement.

IMPACT involved extensive data collection but believed that the research experience of their team had prepared them to achieve this. Similarly, EQUITY built on 10 years' experience of collecting data from local practices and were able to use the EMIS web in their second round of data collection. This 'enabled more up-to-date data being used, and allowed more speedy data extraction'. Other projects found things harder. IRIS reported that 'practice data is not straight forward to collect or interpret. Practices rarely use their systems in the same way and clinicians vary greatly in the clarity with which they record patient data'. IMAGE experienced such major problems with the initial electronic extraction of data from patient records that they requested paper information from practices in the second round.

Data must be collected and analysed, but also validated. IMAGE used previously validated questionnaires and REST provided verbal summaries of focus groups to participants for them to check. IRIS instigated random checks on data extracted from practice databases, used an independent data extractor blinded to the status of practices, and drew on the judgement of an independent outcomes panel to validate their findings. CKD had considerable expertise and experience but faced demanding data requirements:

This has proved far more complex than anticipated. The need for data validation across a variety of differing systems has proved a significant overhead to the data collection team. This overhead was not anticipated on the scale that has been realised – largely due to the fact that the cadaveric renal transplant is of an unprecedented scale in primary care – so far there are over 3,000 variables for 90k patients, resulting in 10GB of data available as a research resource.

CKD self-evaluation report

The role of communications

Successful QI projects require effective communications that will align the various stakeholders involved in delivery and influence others by sharing findings. The balance between these varies among projects.

QUEST segmented its audience into key groups (such as school nurses, PCT lead, parents and pupils) and allocated responsibility for communications to people who had experience of each group. They used newsletters and publications, telephone discussions, personal contacts, and conferences. IRIS placed academic papers at the heart of its communications. They consciously developed their strategy beyond conventional academic routes, including a quarterly IRIS newsletter. The project team saw the two-hour training sessions as the primary mode of communicating with practices, and their practice-based IRIS champion maintained regular communication with each practice.

CKD's conclusion – 'a broad range of communications tools are required to suit preferences across a broad cohort' – resonates with the range of media used across the projects. These included newsletters, magazine articles, press releases, local pathways or guidance, patient mediated approaches, reminder systems, webbased information, reports to stakeholders, e-mails, academic publication, conferences and information packs. Of particular note is the use of a project wiki by LIMBIC.

Flexibility and planning

In chapter 5 we described how some projects built in flexibility at the outset to allow participating clinicians to shape the improvement interventions. Projects also reported that they needed to be flexible and adapt throughout the study:

In order to respond and change [and] add different ways of working in this type of study, the team require considerable flexibility to make those changes in a timely fashion.

IMPACT self-evaluation report

QI projects have an exploratory dimension, and planning and coordination inevitably have to evolve. A QI project is not designed to solve problems that are better addressed through hierarchical control. It is designed to find out more about the problem and about how to minimise or solve it.

In general, QI projects also have a collaborative nature. This results in the involvement of a wider range of interests and views – both from different clinical professions and service users. It also results in some loss of control. It is not always clear how different groups will become involved or what they will do. The dependencies resulting from collaboration can prevent things happening as planned. QUEST faced a problem when an organisation appeared not to follow the procedure in a postal survey, resulting in a reduced response rate. Unanticipated work patterns of school nurses made telephone interviews more difficult than expected, and two PCTs from the control group were unable to arrange suitable dates.

These sorts of challenges were not unusual. IRIS showed flexibility and tenacity but, even so, did not manage to deliver either the education sessions or the quarterly feedback sessions to the planned time-scale, and failed to engage practice nurses or other members of practice teams as planned. They also faced insurmountable difficulties in collecting some outcome data.

Many project teams reported that they needed to learn and adapt. Adaptation was by no means always as a result of difficulties. During data collection, CKD realised that for little extra cost they could also use their data to explore emerging questions concerning people with diabetes.

6.5 Overcoming political and emotional challenges

'Political' in this sense relates to how stakeholders with different interests, goals and identities can work together in pursuit of common goals, or how disputes and conflicts are managed and resolved.

Failure to address political challenge leads to key stakeholders abandoning or disrupting a project, or to short-term deals that lead to long-term problems. Overcoming political and emotional challenges is especially relevant in QI projects because they involve changing clinical and organisational practices. These changes are unlikely to be neutral in relation to the interests, goals and identities of stakeholders.

'Emotional' in this context relates to the inner beliefs and identities that shape individuals' commitment and drive. It includes the emotional reserves that strengthen persistence when things go wrong, and prevent short-term political disputes declining into long-term corrosive conflict. The engagement of clinicians and service users had an important role in overcoming political and emotional challenges.

These elements were discussed in detail in chapter 5.

Leadership and the politics of change

Leadership was an important aspect of the programme. As described in chapter 1, the Health Foundation funded LITP and our evaluation of this found that it resulted in teams that were more capable of delivering QI projects (see the supplement to this report).⁹⁸

None of the projects would dispute the assertion from LIMBIC that 'Strong joint leadership to the project was critical' (LIMBIC self-evaluation report). The use of the word 'joint' in this statement is important.

In the case of LIMBIC it referred specifically to a joint leadership that combined clinical and academic inputs. In other cases, the term referred to the inclusion of other stakeholders within the leadership of the project. These included trusted individuals, such as the chair of a local PCT, who could play an important role in establishing credibility and acceptability (IMPACT).

In all projects leadership was dispersed, often taking the form of local champions who took responsibility for raising a positive profile for the projects among particular stakeholders.

QUEST identified the involvement of an experienced school nurse and an experienced trainer, along with a Rethink supervisor, as helping to provide the necessary skills (including leadership/facilitation skills). CKD noted:

Expertise of the leadership group was excellent once people appreciated each other's skills and were allowed to progress each component part of the study.

CKD self-evaluation report

Leadership is important but it does not exist in a vacuum, as IMAGE noted:

The project would have been immeasurably more difficult without pre-existing personal, professional and institutional 'clinical networks' that were invaluable in conducting all aspects of the study.

IMAGE self-evaluation report

Keeping these networks and relationships alive was sometimes made harder because geographical distance limited face-to-face contact (LIMBIC self-evaluation report). LIMBIC also reported that the use of a project wiki helped to maintain relationships. On the same issue, EQUITY noted that the co-location of the team with existing groups was helpful.

QUALITY:MK reflected the common belief that champions are crucial to organising and activating networks and relationships, and they noted that a mix of expertise and leadership skills is needed for this to succeed. In particular, they saw change resulting less from large-scale networks and more from face-to-face meetings with individuals or very small groups. They also noted that these unmediated relationships can deliver change only when they sit within a wider set of change-making processes (QUALITY:MK self-evaluation report).

Data and the politics of change

The emphasis on data as a change agent varied from one project to another, although data played at least some role in each. New data can re-frame existing political relationships; however, as we have seen, collecting data was often challenging. IMPACT reported that robust data were crucial to securing commitment. But while data remained important, they also went on to note:

Our most recent experience has taught us that regular visits to GP practices from a person seen as a peer, and preferably someone already known to the link or lead GPs, has been beneficial in promoting GP engagement with the study.

IMPACT self-evaluation report

IRIS also noted that comparative data within a performance table can support change, but they located this specific process within a wider process

of training, communication and IRIS champions. Similarly, EQUITY located the role of data within a wider set of softer relationships among stakeholders. QUEST emphasised the links with professional groups as the most important facilitator of change.

Data are therefore an important ally in the politics of change, but the projects suggested that they are most successful when linked to other softer cultural aspects.

Embedding QI projects within general practice, PCT and the wider NHS

Coordinating and planning QI projects is not only about aligning activities within the project, but also about aligning the work of the project with changes, priorities and allocation of resources in the local and national health economies. The projects were sensitive to the need to address the politics of change.

Responding to wider needs for improvement

REST addressed high prescribing costs and a situation where 0% of those prescribed drug therapy for insomnia were prescribed inappropriately, despite the availability of non-drug measures that could be equally effective.

QUALITY:MK sought to address issues at the heart of the NHS agenda around improving patient care, strengthening patient control, reducing inequalities and delivering more accessible care. It also addressed a perceived problem of poor performance in the local health system.

IMAGE had the expressed aim of developing quality criteria for the care of gastrointestinal disorders in general practice, analogous to the criteria already developed for QOF in other specialties, with a more patient-centred approach. The project anticipated success because they thought GPs would be highly receptive to their suggested quality criteria.

The CKD team described the need for their project in terms of its contribution to a health system needing to respond to a relatively newlyrecognised but common long-term condition. Similarly LIMBIC is presented as a direct opportunity to address a situation where, despite widespread knowledge of guidelines, GPs found back pain difficult to manage. A potentially receptive audience of GPs would, it was hoped, improve the chance of success.

Engaging with PCTs

In general, as QUALITY:MK expressed, 'there is a need to consider how QI fits into all levels of the NHS: practice level, PCT level, PCT-collaborations/ amalgamated PCTs and SHA level' (QUALITY:MK self-evaluation report).

QUALITY:MK was, on the face of things, well placed to influence PCT and commissioning decisions. From the outset it was closely integrated with the PCT and worked with PCT public health consultants on service redesign, securing Milton Keynes PCT as a pilot site for the Map of Medicine.¹⁵ QUALITY:MK aligned its activities with PCT and practice work to meet QOF requirements and the Primary Care Improvement Plan, and secured the involvement of the local deanery in a GP leadership programme.

Similarly, EQUITY worked closely with Tower Hamlets PCT and built on existing close relationships with public health staff and other managers. The EQUITY project contributed to other PCT projects and worked closely with a local voluntary organisation, the Expert Patient Programme Community Interest Group. REST recruited key PCT individuals to the project steering group and the REST project lead is also the GP research lead for NHS Lincolnshire.

Challenges to PCT engagement

Each project reached out to its respective PCTs, and later to commissioners, but engagement was often difficult. For example, LIMBIC noted:

at times it proved extremely difficult to maintain the PCT engagement of both managers and clinicians due to conflicting work priorities, but over the course of the LIMBIC project this contact was maintained in a manner that helped influence the PCT in its development of commissioning ideas.

LIMBIC self-evaluation report

Only IRIS secured unequivocal commitment from PCTs (Bristol and Hackney) to commission further work. Having the senior public health manager acting as a domestic violence champion, having an active domestic violence forum, and having associated academic research on gender-based violence were all listed as factors supporting this outcome.

All the projects managed to communicate findings to their PCTs. QUEST, for instance, noted:

Contacts have been made with PCT leads for this area of practice; they have been provided with clear information about the study and will be informed of progress. Commissioning groups for child and adolescent services have been contacted and communicated with via project presentations.

QUEST self-evaluation report

But while the projects were able to inform and influence, they came up against existing priorities and capacities of PCTs/commissioners. They had little control over these. If the priorities of the new commissioning arrangements are unfavourable to QI activities, there is a wider question about whether these priorities should be changed or whether QI activities should be redesigned to fit these priorities.

Linking to national developments

There was evidence that some teams were going with the flow of national and local developments – for example 'IRIS will be cited as an example of best practice in the launch of the report by the Department of Health Task Force report on Violence against Women and Children'.

6.6 Culture, education and information

Projects combined two different change models. The first is more about motivating, informing and leading.

This is by no means a hierarchical top-down approach to change, but it does involve the project leadership in actively steering and guiding the project.

¹⁵ See http://www.mapofmedicine.com

The second approach to managing change, less overt in the self-evaluation reports but nevertheless evident, involves people feeling moved rather than incentivised to act.

It involves stimulating people's curiosity rather than informing them, and inviting people to change their relationship with the healthcare system rather than changing their adherence to guidelines.

These approaches appear to have been simultaneously followed (and they are, in any case, not mutually exclusive). Across the nine projects, some placed most emphasis on motivating, planning and leading, while others attended more to moving, peer learning and new relationships. Building culture relates to both these dimensions.

Building a shared patient-centred world view among all participants

REST identified three reasons (among others) why they thought that the project worked:

- having a well-respected GP visible on the project
- having patient-focused objectives rather than being concerned only with costs
- approaching GPs as experts.

It seems that clinicians can be moved by people they trust and changed by working in new ways with others, and that their role in healthcare can be refocused when engaged as co-producers of change. Or, in QUALITY:MK's terms, it is incentives plus a can do mentality that matters. Incentives may help but so too does culture.

IMPACT recognised the need for peer engagement, but found the mechanics of setting up meetings where this could happen challenging. They reported more success engaging physiotherapists than in engaging GPs, arguably because the perception of GP leadership was less strong in this project than in, say, REST.

LIMBIC aimed to 'embed the core philosophy and tenets of improving in its everyday work', and used a model 'fusing new clinical evidence with new ideas about improvement [which happened at workshops] with learning improvement by actually doing improvement in practice (providing between-workshop facilitation)' (LIMBIC selfevaluation report). This was intended to use new ways of thinking about improvement to create new behaviours.

At the heart of the projects was a determinedly patient-centred ethic. In other respects each project had a different starting point. For QUALITY:MK and EQUITY, the problem was defined in relation to the healthcare system and its failures with respect to using the evidence base and delivering equity respectively.

For the others, with the exception of IRIS, the starting point was an identified gap in clinical care. For IRIS, the starting point was domestic violence and the relevance of primary care was that it was potentially a conduit though which abused women could receive more appropriate support. Although the health of abused women was clearly a driving concern, this was a less medical model than others.

In LIMBIC, the project team felt that their approach had allowed participants to abandon the linear medical model, in which clinicians solve the problem and cure the patient, in favour of a more enabling approach that focused on the patient. They noted that this was 'liberating as many clinicians knew that the medical model did not work' (LIMBIC self-evaluation report).

The same, largely positive picture emerges across the whole programme. It provides a counter to the doctor-led culture that is sometimes thought to stifle improvement in primary care.¹⁰⁴

Champions and facilitators of change

A frequently-mentioned method of supporting a shared understanding and promoting commitment was the use of champions. These are also discussed in chapter 3. IMAGE perceived real benefits from their gastro champions and IMPACT believed they may have suffered from a lack of such champions. QUALITY:MK unambiguously identified champions as helpful, and were referring to GPs and people such as the chief executive or director of public health, the chair of LINk:MK and the programme manager.

Education and training as a driver of change

All projects used some form of educational or training intervention (or both). However, the examples provided below illustrate that training and education is no panacea in QI projects. The projects' self-reporting suggests that educational interventions need to:

- engage the end user in the whole process
- focus on a tool that can easily be applied
- ensure that the training offers something not available elsewhere
- use more than one medium
- be evidence based both in the form of delivery and in the content of the training and education offered.

QUALITY:MK noted that their project was 'an intrinsic part of normal healthcare operations with an explicit focus on the learning and improvement process'. The self-evaluation report said:

It has been learned that the only way to reach the majority of GP practice members is by visits by GP champions to individual practices ... Feedback from GP educators supports the view that there are groups of GPs who are not aware of the project but involving educators in the process will encourage use of the QUALITY:MK principles in newly qualified GPs ... It is worth noting that the plan to launch a regular QUALITY:MK competition ... did not attract interest ... and so this has been quietly set aside ... QUALITY:MK is a service improvement programme focused on 'the ongoing process of continual, self conscious change'.

QUALITY:MK self-evaluation report

In this context it was apposite that QUALITY:MK involved the use of librarian information specialists, a clinical effectiveness pharmacist and a chief knowledge officer.

IRIS engaged practice staff in training that led to significant changes in referral practice. IRIS offered training designed to address barriers the clinicians themselves had identified. Training sessions used case studies and role plays, and 'aimed to empower adult learners to practise skills which were directly applicable to their patients ... [the] educational outreach model we are using has a strong evidence' (IRIS self-evaluation report).

Most striking was the new role of the advocate educator:

[a model that] moves beyond the conventional one-off... sessions by external trainers unknown to the clinical team. We created a precedent in having a title and job description that reflected their hybrid role – provision of training and support to practices and provision of advocacy to patients.

IRIS self-evaluation report

QUEST developed and implemented a skills and resources package for school nurses. This was designed to promote evidence-based practice and included multimedia materials and links to electronic publications. It included materials for young people, their families, teachers and other members of the school team.

[A]s such it is a multi-faceted professional development programme that encompasses a number of the approaches identified by the Cochrane EPOC group: printed guidelines and protocols; health status/risk measures; self-help resources; information materials for professionals, young people and for family members; educational meeting involving experienced trainers.

QUEST self-evaluation report

In their self-evaluation, QUEST reported that the project made considerable effort to involve school nurses in developing materials, with additional consultations with young people.

No significant impact showed in the results. It is possible that a simple time-limited RCT was not adequate to assess the range of effects.

REST and LIMBIC broadly identified QI support, a clinical perspective, expert research skills, statistical support, governance support, finance support, prescribing support, patient expertise and IT skills.

QUEST identified the need to build capacity primarily in the areas of research and QI.

IRIS required (and had access to) the skills needed to 'design a randomised controlled trial of a complex intervention in primary care, implement a specialist intervention on domestic violence, collect data, analyse it, interpret it, disseminate our findings and develop commissioning guidance' (IRIS self-evaluation report).

With a whole-system model, QUALITY:MK identified different capacity issues. They recruited a QI facilitator to bring in skills in managing 'LEAN projects' and PDSA cycles. They also had two librarian information specialists, a clinical effectiveness pharmacist and a chief knowledge officer to build the capacity to communicate and display presentations as well as support evidence-based practice.¹⁶

REST established 'an educational intervention for practice teams to deliver problem-focused therapy for insomnia constructed from the information derived from the modelling studies (questionnaires, focus groups, collaborative)'. This was initially delivered to GPs in two two-hour training sessions. Later this was reinforced and spread to others via an e-learning package. This, along with the wider suite of activities, resulted in variable results. There were some measurable improvements in the practice of doctors and nurses.

Developing the skills and capacities for QI projects

All projects eventually formed a team with the necessary skills to deliver the activities. Skills varied considerably, depending upon the nature of the project (see box 13). Several projects, including EQUITY, CKD, IMAGE, QUEST and IRIS, reported difficulties.

This raises the question as to who should be responsible for developing the necessary skills and knowledge to deliver QI projects in primary care. If there is a role to be played by QI projects in primary care then it would follow that there is a need to attend to the provision of appropriate QI-driven education and training.

There are some indications from the projects that training can improve skills and capacities.

The overall impression from post-training surveys was that participants benefited from training, if they could find the time. It enhanced their confidence in handling unfamiliar clinical situations and improved skills.

The commissioning function is one obvious place for this. The key question is: to what extent are other efforts to improve quality sufficient? Other commissioning-driven incentives included the QOF, which is expected to improve the quality of care for specific conditions. However, QOF does nothing for non-QOF conditions, can distort practice priorities and may not push people hard enough. There was much talk in the programme about going beyond the QOF.

Similarly, revalidation and registration is often seen as a process for setting minimum standards that inhibits rather than helps improvement.

16 Lean is an improvement approach to improve flow and eliminate waste that was developed by Toyota. QUALITY:MK is focusing on using two QI techniques: PDSA and LEAN thinking (taken from http://www.qualitymk.nhs.uk/default.asp?ContentID=3427 accessed 30 June 2011).

It is possible that this more minimalist approach to revalidation will evolve. The royal colleges and others have shown a growing interest in supporting QI (in general) as part of their professional leadership responsibilities.²

Technological support for QI projects

All projects, except QUEST, interacted with existing general practice-based data collection systems.

Many also tried to use them to develop electronic prompts of various sorts. Many experienced problems. Lessons from the projects are that IT works best when it provides electronic linkages to support relationships that are already strong. QI projects can never thrive on IT alone, but the projects' experience showed it was more often a barrier to improvement than a facilitator.

IMAGE was, perhaps, the project worst affected, and after much disruption they opted for a paperbased retrieval of patient data rather than an electronic search. They systematically identified lessons from their difficulties and concluded that many of the problems could in the future be overcome if projects were planned and resourced to take account of restrictive IT systems in GP surgeries.

Less disruptive, but nevertheless unhelpful, was the more general issue of 'the relative inflexibility of the EMIS system' (IMPACT self-evaluation report).¹⁷

Despite these constraints, the IMPACT project team regarded 'organisational support systems that embed the new tools within existing IT systems' as 'a key way of bringing about change', and claimed, contrary to IMAGE, that the barriers to these being more successful were not technological.

In contrast, EQUITY listed the data collection as one of its successes (using the new EMIS web and analysing and developing Health Equity Audit reports at both GP and PCT level).

Like IMPACT, they were able to build on a longstanding arrangement to collect data from local practices, and on an excellent understanding of the limitations and potential of general practice IT systems.

6.7 Spreading and sustaining the benefits: legacies and future gains

Our evaluation included asking the projects to describe their sustainability beyond the period of Health Foundation funding. We distinguished between the following kinds of sustainability:

- Ongoing support for the activity in the original project area – will it continue to be funded beyond the end of the Health Foundation funding?
- Follow-on programmes or roll-out in other areas.
- Materials or tools from the projects that are more widely available.
- Changes in PCT commissioning as a result of the projects.
- Associated policy changes nationally or locally
 influenced by the projects.

Only IRIS reported unconditionally that it had secured funding to continue the improvement work started in the project.

Looking across the other eight projects, there was a mixed, and arguably limited, set of sustainabilities. Many projects reported that there would be at least limited follow-up or roll-out elsewhere; and some pointed to materials and tools developed through the programme that were being used and developed further elsewhere. Changes to commissioning services and to wider policies were also identified.

The projects were to include a section about their plans for sustaining benefits beyond the life of the project in their self-evaluation reports. Many of them suggested that the early years of the project were too soon to start thinking about this. We may wonder whether this should not have been a higher concern from the outset.

Given that some projects could only identify limited benefits, spread would not necessarily be appropriate.

An effective system will only spread innovations that can demonstrably work better than existing practice.

¹⁷ The Egton Medical Information Systems widely used in general practices.

6.8 Pitfalls facing QI projects

By way of concluding this chapter, we draw together its main themes by describing the pitfalls facing the QI project teams, and what we can learn from the projects about how to avoid them.

Insufficient capacity

Projects were open about the challenges faced in management and administration. The projects were selected through a highly competitive process, partly because they could demonstrate a track record of delivery. Furthermore, through the financial support of the Health Foundation and through the support programme, the project teams had access to more assistance than would typically be available to QI projects. This was a benefit that was well received by the project teams.

Lessons from the projects suggest the following are important:

- building on past experiences and relationships
- recruiting project management skills
- piloting and, in general, learning and adapting management and coordination practices as the project unfolds.

Overwhelmed by the logistical challenges of the NHS

The projects described considerable logistical challenges. Gaining ethics approval, securing research passports, setting up meetings, contacting potential recruits, using IT and adapting software were all mentioned as logistical barriers.

These practical barriers, many of them peculiar to the NHS context, could dissipate energy and contributed to a sense that urgency and forward drive was lacking.

Fully solving these problems would require actions beyond the scope of the projects – addressing national ethics procedures, research networks and the national IT system for health. The projects often found the logistics hard to negotiate. Mitigating factors include:

- strengthening personal relationships to improve the working of formal systems, especially face-to-face
- resourcing IT expertise adequately and never assuming that untested software will work as planned
- using multiple means of communication to reinforce research networks and strengthen recruitment.

Unable to collect and analyse sufficient data

Many projects struggled to get access to good quality data that could be easily manipulated. In one case, a project team abandoned efforts to collect data electronically. In others, the data provided from practices were patchy. The lessons are that such problems might be mitigated by projects:

- involving those providing the data in the design of how data were to be collected
- connecting the data and their analyses to problems acknowledged by the data providers
- supporting feedback and learning for those providing the data to maintain engagement.

Breakdown in communication

We have seen challenges in communications across organisational and professional boundaries. The NHS is not a seamless organisation through which information flows easily to the intended target. We have also seen that good communication is at the heart of successful QI projects: identifying improvements, informing participants, enthusing with stories of how things could improve, feeding back findings and experiences, aligning behaviours and spreading messages more widely.

The projects made considerable effort in planning and delivering their communication strategies. The projects' experiences suggest the benefits of:

- developing multiple channels, including faceto-face, paper and electronic, to communicate
- recruiting champions, who are believed not just for what they say but for who they are – whether they are clinicians, service users or others
- creating targeted messages, for example focused on particular professional groups or age groups.

Failure to adjust

Some projects proceeded more to plan than others. All benefited from an ability to review and adapt – for example, on data collection, communications or outputs. Neither the projects nor the evaluation team perceived this as a weakness.

At the outset, all QI projects face some uncertainties about what is feasible, suitable and acceptable. They require the capacity to adapt as these uncertainties are reduced by experience. Successful QI projects require an adaptive capacity comprising the following:

- Fostering a culture and structure for learning. To varying degrees each project absorbed lessons, sometimes publishing these for wider discussion, and generally involving a variety of perspectives (research, professional, service user).
- Establishing adaptive mechanisms. Allow the project to change within agreed boundaries. In practice this appears to have been ad hoc rather than structured.
- Instigating after action review. Each project was invited through their self-evaluation report to comment on how their activities differed from what was planned, and what they would do differently next time.

Overwhelmed by the politics of change

QI projects in healthcare face enormous challenges.

Across many settings and countries these can overwhelm projects. However well founded the plan is, however feasible the implementation, the reality is that a number of organisations, groups and individuals need to act together, sometimes in ways that they find uncomfortable. Benefits are identified at some unspecified time in the future and may not affect those being asked to contribute. Opportunities and incentives for avoiding participation are widespread, but there are positives to be gained.

Ongoing engagement and interest in the projects was supported by the following approaches:

- Showing visible benefits for patients. The visibility and effective power of service users currently suffering unnecessarily can, in the NHS culture, overcome resistance, especially when the advocate is a service user.
- Demonstrating a unique benefit for providers. More hypothetically, where a project was presented as different from previous approaches that had been seen to fail, providers have been more engaged (although further evidence is required for this) – for example, guidelines had existed but not been acted upon, or evidence of a quality gap had proved immune to professional attention.
- Providing a compelling business case. The projects acknowledged that in the current environment commissioners were in a position to drive change, but would require a compelling business case. Arguably, difficulties in doing so account for the limited service legacy of some of the projects.

Embedding with the wider setting

With varying degrees of success, the projects all used the wider healthcare context to support their activities.

All drew on the wider evidence base to identify, design and plan their projects. Some used this to explain the intended outcomes and others used it to identify the best tools to use – for example, using pre-validated instruments in data collecting.

Using existing practices and behaviours to support implementation ranged from knowing how to communicate with different groups, to identifying the easiest ways to make changes to practice. More importantly, perhaps, many projects used existing guidelines, incentives and priorities to support the intended improvements. In some cases, they also sought to influence the further development of these. The three dimensions to embedding the projects were:

- using available health service research evidence to identify and justify the project and contribute to this body of knowledge
- using existing practice to facilitate implementation.
- using existing guidelines, incentives and priorities to support project outcomes and spread learning.

Let down by technology

Where the projects were particularly dependent on untested IT, the story is one of frustration. Back-up was sometimes required, in the form of paperbased systems. Even where the technology was functional, it delivered most effectively when electronic relationships were reinforced by face-toface and other non-electronic relationships. The lessons learned concerned:

- avoiding being dependent upon untested technologies unless, of course, the point of the QI project is to explore the effectiveness of an untested technology
- building non-electronic relationships to support electronic relationships
- having a non-electronic back-up, wherever feasible.

Sharing vision and spreading skills

Improvement projects run the risk of gathering together a small band who share the vision and develop the skills needed for successful delivery but fail to spread this.

Many of the projects countered this with a good communications strategy, and adopting a coproduction approach in many of the projects. By involving service users or professionals (or both) as advocates, making training a central part of the approach and meeting the expressed needs of participants, projects appear to have built the requisite variety of skills and enthusiasm beyond the core teams. Hampering this were the existing institutional boundaries, both within and outside the NHS, competing priorities, especially restricting the time available, and incompatible identities. Developing and spreading the vision and skills required for QI projects involves three dimensions:

- co-producing the project, involving participants as informed partners
- embedding training within the project
- creating a market for the project by ensuring it meets the expressed needs of participants.

Support for project learning

QI projects in general, and those in this programme in particular, should have a demonstration value and an ability to generate learning that can be applied elsewhere. A wider positive profile can help maintain engagement with the project and may also provide help in developing intervention and research tools. Efforts to seek a wider reception for the project in the locality (through involving patients, adjacent organisations and academic researchers) were common in the programme.

More widely, IRIS also developed a strategy for taking the model out to other areas. CKD engaged national organisations, drawing on the skills and resources of the Kidney Research UK Lay Advisory Committee, to support the efficient working of the project, and using links with royal colleges and the Department of Health to publicise findings.

Creating wider support for QI projects may be strengthened by:

- Asking external bodies for practical guidance, information and tools to support the efficient delivery of the project.
- Involving external bodies in communicating and, where possible, endorsing findings to maximise impact.
- Engaging with national and international forums to take learning forward and promote further improvement.

Chapter 7 Economic evaluation

7.1 Introduction

The need to undertake an economic evaluation alongside studies of the effectiveness of QI interventions in healthcare is widely recognised.48,103 Although industry studies show corporations that systematically undertake QI have higher revenues and productivity than their peers, in healthcare the economic evaluation of QI is still uncommon. When it occurs, it is often unsatisfactory. 34,48 The literature discusses a number of reasons for this, including: a lack of understanding of the concepts of costs and utility; that clinicians and clinical researchers are not trained to integrate cost analysis into their work; funding limits; the complexity of interventions; and the complexity of the systems in which they intervene.

The overall objectives for the programme as set out by the Health Foundation (see chapter 1) were not primarily evaluative. They were more relevant to a demonstration programme with nine large-scale but very different projects. One of the requirements of the self-evaluations was that project teams should identify the costs and the main consequences of their projects; measuring and valuing the latter where possible. Throughout the programme we supported the teams' efforts to do this and also prompted them to undertake an economic evaluation where this was feasible.

In this chapter we outline what the projects reported in terms of economic evaluation. We also describe what we learned from the experience that might support improved economic evaluations in the future.

7.2 Chapter summary and key findings

We received less data from the projects than we had hoped. At the time of writing we had limited cost data from only four projects, and no completed economic analyses. In light of this, and of our analysis of the difficulties the project teams faced, we conclude that any economic evaluation of QI interventions needs to:

- Demonstrate that a QI intervention undoubtedly results in improvements in process or outcomes that are seen as valuable by those making decisions about the use of resources.
 Without clear evidence of the beneficial impact of QI interventions, the issue of costs becomes irrelevant. To provide this evidence, clarity and explicitness about the 'counterfactual' – about what would have occurred had the QI intervention not taken place – is essential. This is most problematic when there is not a formal, comparable, control group. As a minimum, some comparator is necessary.
- Understand the nature of QI interventions. QI interventions are, to some degree, complex, involving feedback, learning and adaptation.
 They are therefore subject to change and this change can cause costs to change and make them difficult to identify.
- Establish what data is needed to demonstrate that improvements have occurred – for example, referral patterns. Identify what efforts are required to collect these data, sometimes from external organisations, and at what cost.

- Estimate resource use and costs in multifaceted interventions. This involves identifying, and distinguishing all the relevant costs, including external costs that may be loaded onto the wider society, and deciding what to include.
- Establish the nature and rigour of the economic analysis required. In the health service, it is likely that a well-supported business case will persuade health service commissioners to fund changes based on successful QI.

7.3 Starting points

At the outset of the programme, four projects identified a named health economist to support their studies. Two of these intended to undertake a cost-effectiveness analysis and the other two were less clear about their intentions. Three projects eventually identified health economists to work with them. Initially the expectations of the teams who planned to undertake an economic analysis were positive:

It is expected that the economic aspects of the work will provide sufficient data to assess whether the costs of identifying questions, interpreting evidence and implementing findings are covered by the value of QIs.

QUALITY:MK self-evaluation report

This appeared to be a relatively sound start. But, as table 14 illustrates, at the time of writing, we had received limited costing data from only four projects, and no completed economic analyses. Four projects told us that they had undertaken, or were undertaking, such analyses but these were not yet available (as at February 2011).

We had the published findings of a costeffectiveness analysis of the pilot study that preceded the Health Foundation-funded IRIS project. This concluded:

The incremental cost per woman was estimated to be £23.22. This includes the cost of the screening tool, plus the increased costs of downstream management of identified women, plus any savings as a result of reduced violence. The incremental QALY [quality adjusted life year] outcome was estimated to be 0.0313 per woman. This ICER [incremental cost-effectiveness ratio] was therefore estimated to be £742, which indicates that the intervention is likely to be cost-effective. 105

In what follows we explore why, if such a conclusion was possible in the IRIS pilot, gathering relevant data and undertaking economic evaluation proved so difficult for others.

In understanding this situation we need to go back to the variable way in which the projects specified how they would evaluate the outcomes, and the nature of the outcomes on which they focused.

As set out in chapter 3, four projects undertook a formal cluster RCT, five projects based their assessment on a before-and-after comparison, and one project used a combination of time trends and a before-and-after comparison.

The nature of the outcomes reported on also varied considerably, including:

- knowledge, confidence and clinical skills of school nurses
- GP recording of, and specialist referral for, domestic violence
- variety of outcomes for patients with IBD
- variety of outcomes for patients with back pain
- performance rates for diabetes care compared across ethnic groups
- before and after changes in patient QOL.

It might be reasonable to suppose that the extent of economic evidence provided is related to these differences. Neither the existence of initial plans for an economic evaluation, nor the final availability of cost data appears systematically related to these structural factors.

Nevertheless, the fact remains that for costs, as for patient outcomes, the effect of an intervention can only be measured with an explicit view about what would have occurred without the intervention – here the QI initiative.

Clarity and explicitness about the counterfactual is essential and is most problematic when a formal, comparable, control group is absent.

7.4 Identifying the impact of the intervention on resource use and costs

Without an understanding of the categories of intervention and the scale of costs, any evaluation (let alone economic evaluation) will be deficient. QI activities are to some degree complex, involving feedback, learning and adaptation. Project costs can be difficult to identify. It was the Health Foundation's intention that project teams learn and, where necessary, adapt their projects as they progressed. In this respect, teams were opportunistic, seizing unexpected chances as they arose. Many of the projects also encountered unforeseen complications that affected their plans. As one team put it, 'Every time something changes – for example, change to the computer template and subsequent additional practice visits – additional communications are needed in multiple formats, this ultimately requires resource' (IMPACT). Such changes create ongoing challenges for any evaluation, including an economic evaluation. As projects evolve, changes must be described. Where possible, the consequences of these changes must be assessed. This complex process is represented diagrammatically in figure 3.

Figure 3: Estimating resource use and costs in multifaceted interventions



Selected comments from the final self-evaluation reports	 'Every time something changes this ultimately requires resource'. 'Two distinct economic considerations associated with this project; (i) the costs associated with delivering the project (researchers' time, physiotherapy training, etc; and (ii) the cost-effect differential between the pre- and post-implementation phases' (It is the second that will be covered in their cost-consequence analysis). 	 'Design is appropriate for calculation of some associated costs and potential benefits. The bulk of the costs within this project related to assembling a team for the development and evaluation of the impact of the training'. 'The benefits of this QI package have been evaluated in regard to significant changes in process outcome variables; how these translate to changes in clinical outcomes remains uncertain'. 	 'For IMPACTE groups we have looked to indicate cost consequences. In practice our approach failed to make the business case for continued investment in GP champions to support the IMPACTE groups Hence, In the next phase of IMPACTE there will be a strong focus on gathering information about cost consequences'. 'A key cost consequence may remain unproven – laying in our belief that QUALITY:MK has strengthened the system's ability to respond to the current financial imperatives'. 	 'Cost-effectiveness analysis of IRIS pilot model (PreDoVe) now published, demonstrating cost effectiveness (£/QALY)'. 'RCT evidence of cost effectiveness needed too because domestic violence is considered a marginal issue for health services. As far as dissemination strategy is concerned, explicit commissioning guidance is a necessary bridge between evidence and policy implementation'. 'Inevitable cuts in the NHS over the next five years potentially undermine innovations that require additional funding, although demonstration of cost effectiveness and the potential for "spending to save" may mitigate [against] the cold climate'. 	Table continues
Costing data provided	Not yet	2	Yes (some costings undertaken in some sub-projects and attempts made to develop business case for some specific changes)	Not yet	
Economic evaluation**	Yes (cost- benefit analysis)	°Z	°Z	Yes (cost effectiveness study)	
Economic evaluation*	Yes	2	[Yes]	Yes	
Study method	Before-and-after	Cluster RCT	Mainly before and after	Cluster RCT	
	IMPACT	QUEST	QUALITY:MK	SIRI SIRI	

* planned at outset (or some resource identified later) ** undertaken or ongoing

Table 14: Projects' economic evaluation

Table 14: Projects' economic evaluation

cted comments from the final self-evaluation reports	ie modest or neutral impacts of QOL/EGD measurements make it likely that a detailed health economic evaluation based on 'health ities' will be conducted. We plan to produce a costing summary of the oduction of the quality criteria for inclusion in our main paper'.		tial costing is done but full report will be available at the end of cember 2010. However, we employed a health economist in 2008/09 this work and have concluded that a comprehensive economic aluation is not feasible for this project. We could only provide costing staff and intervention and other resource production and semination costs'. The not however been possible to put values on the outputs and tcomes of the project and therefore they will not attempt any further promic analysis'.	addition to the obvious monetary costs the cost 'in kind' of ntributors (both individual and organisational) needs to be factored ore emphasis on process (record-keeping, management structure,), administration and structure early on at project outset would have en beneficial'.	
Costing data provided Se	No (costing summary • • was due to be provided in the final self-evaluation report but we do not have p this)	Yes (detailed table of costs of practice activity before and after the intervention)	No (costing report was due in December. 2010 but we do not have this) t	Not yet	Yes (some costing data)
Economic evaluation**	Q	°Z	°Z	Yes (cost- consequence analysis)	Yes (cost- consequence study)
Economic evaluation*	Yes	N	[Yes]	[Yes]	Yes
Study method	Before and after	Before and after	Time trend and before and after	Cluster RCT and time series	Before and after compared to control and small exploratory RCT
	IMAGE	LIMBIC	Εαυιτγ	СКР	REST

* planned at outset (or some resource identified later) ** undertaken or ongoing

INVOLVING PRIMARY CARE CLINICIANS IN QUALITY IMPROVEMENT 101

The first difficulty lies in categorising the different elements of cost. This is a challenge even for the visible part of the intervention; the team or resources that were directly viewed as the QI intervention. These include the core costs – the minimum that any other project would incur should the same approach be applied – and all other costs.

First, for grant-funded projects there are the costs associated with being a recipient of a grant. There is information to provide, meetings to attend, reports to write and so on.

Second, the first time any activity is attempted and evaluated in healthcare, there are likely to be trailblazer costs associated with being a pioneer implementer of a new approach, and with evaluating this new approach. These include legal advice, negotiating with the workforce, holding meetings with patient groups, and so forth. These costs would not arise in succeeding projects. For one project, the trailblazer costs were identified as the main component:

The bulk of the costs within this project related to assembling a team for the development and evaluation of the impact of the training. With the package now developed and the controlled evaluation completed, the costs of delivering this training to further staff will be very substantially reduced.

QUEST self-evaluation report

Third, there are external costs such as those imposed on other public, voluntary or private organisations or individuals. For example, when a service is centralised to reduce costs and some service users have to pay more for travel to access that service.

Core costs include capital and running costs. These include the cost of changes in governance (clinical and professional standards), staff (training), information (IT systems), collaboration (partnership working) and so on. The most important aspect may be the incremental costs incurred because of the improvement activity, which can then be weighed against any incremental changes in outcome. For example, service managers are often able to identify the additional staff and equipment required for a change in how a service is delivered, even when they would struggle to calculate total costs. Additionally there are the service utilisation costs. In primary care, practice data can be used to provide some indication of these – see figure 4, provided by LIMBIC. It is also possible to consider the external costs loaded onto wider society. For example, when return to work is delayed by the complications of an illness.

In practice, the net cost implications of a QI are likely to go beyond these core QI costs. The initiative may impose time costs on a wide range of primary care practitioners whose behaviour is changed and, as a result of referrals or other changes in service delivery, the resource implications may ripple out further. Equally, some core team activities may substitute for resources, particularly practitioner time, that the system would have incurred elsewhere in the absence of the QI initiative.

In principle, it is easier to see these changes where a controlled study has been undertaken, rather than where changes are observed over time and are subject to change as a result of other temporal changes. In practice, even a RCT may not accurately measure the individually small, but possibly cumulatively large, resource impacts as they ripple through the system.

Identifying and valuing outcomes

Identifying and valuing outcomes can be problematic in QI projects. There are two basic difficulties: when do you measure, and what do you measure? The problems associated with timing are illustrated by the project outcome results presented in chapter 3; during the time-span of the projects many achieved only limited outcomes.

If we take the QUALITY:MK team (who had been so upbeat at the start) as an example, we find them saying in their final self-evaluation report that 'it is anticipated that there will be few clinical outcomes that can be positively identified and costed for the large-scale pathway changes ... within the timeframe'. Another team noted: 'The modest or neutral impacts of [the outcome] measurements make it unlikely that a detailed health economic evaluation based on "health utilities" will be conducted' (IMAGE).

Limited outcomes meant that, during the project, no firm conclusions could be drawn about cost consequences. As the QUALITY:MK team put it: 'A key cost consequence may remain unproven – laying in our belief that QUALITY:MK has strengthened the system's ability to respond to the current financial imperatives'.

But these difficulties did not mean that people stopped trying. Having failed to make a business case initially on the basis of the data they had gathered, the QUALITY:MK team made a commitment to gather better cost consequences information in the future.

The second difficulty was that often process changes rather than outcomes were measured.

Figure 4: Categories of cost in health interventions

Sometimes, as with IRIS, the links between the process change measured (in this case domestic violence referrals to an advocacy agency) and eventual health outcomes had been previously demonstrated.

In this case, the former process change could stand proxy for the latter, and the key patient outcomes (and service cost implications) could be modelled. This is still the intention of the team. In other studies, the links between the two were not so certain:

The benefits of this QI package have been evaluated in regard to significant changes in process outcome variables; how these translate to changes in clinical outcomes remains uncertain.

QUEST

It also proved hard to value clinical outputs and outcomes: 'It has not been possible to put values on the outputs and outcomes of the project and therefore they will not attempt any further economic analysis' (EQUITY).



Compounding this was the further difficulty of identifying and valuing all outcomes achieved. This means not just clinical outcomes but also less tangible things such as emotional gains for patients (for example, the removal of a sense of hopelessness among back pain patients), and new skills for staff that can be used elsewhere.

7.5 What the projects reported

Three projects provided costing data.

QUALITY:MK

This project was an integral part of the local PCT. With input from the PCT's director of finance, the QUALITY:MK team sought to develop business cases for service redesign on the basis of the findings of some of their sub-projects. Specifically, they explored the cost consequences of the work of the groups and in some cases were able to estimate cost savings. For example, in the carpal tunnel syndrome sub-project the estimated saving of preventing just one referral to surgery was £1,200. In a sub-project to reduce prescribing of antipsychotics to 30 patients with dementia, the estimated saving on all discontinued medication was £6,300 over two years. But these analyses were qualified by concerns about true savings and the possible influence of other secular changes.

The team were could not make a successful business case to the PCT for continued investment in GP champions to support some groups. They did get funding from another source, and with that came a commitment: 'In the next phase of IMPACTE ... [from April 2010] there will be a strong focus on gathering information about cost consequences.'

LIMBIC

Using a before-and-after design, LIMBIC provided the most detailed costing data. This took the form of an activity rates table. It was drawn from practice data, to which they had applied unit costs (table 15).

These figures suggest that overall recorded costs, after the intervention, were slightly lower than before.

At the time of writing, no other project has yet provided such detail.

The availability of detailed resource-use data in the NHS is limited. It is therefore worth quoting the LIMBIC team at some length to illustrate the efforts they made to obtain their data and the importance they attach to this issue:

There were difficulties in identifying the levels of recording clinical information on practice systems as they all seemed to differ. As back pain was not part of the QOF, it seemed there was no consistency between practices about what information was recorded about a back pain consultation. The LIMBIC project developed a template which practices were happy to use and some have commented that they have found this *helpful. It would be useful to extend the use of* templates to other areas of care so that costs can be attributed. However it appears that practices do not have information about costs of services they access and sometimes proved difficult to *identify.* This seems to differ between practices and across PCTs. This formed a major and *significant barrier for projects based in primary* care.

LIMBIC self-evaluation report

These costs reflect the changes in the pattern of services provided to patients by the practices, or on referral from the practices. They do not include the full costs of the LIMBIC initiative itself.

Even in terms of the costs at a practice level, the LIMBIC team noted that there was also a significant investment of time and energy by all practice staff in attending workshops and developing improvement interventions locally. Bursaries were provided to the practice teams but these probably failed to cover the real costs: 'It is likely these were underestimated by between 20% and 0%'.

Several other project teams made the same point. CKD commented on possible consequences for sustainability:

It should be noted that although payments were made to assist in the development of the interventions, ongoing support has been very forthcoming from various clinicians who have treated the work as a development activity and a shared learning experience. This would have an impact on sustainability going forward.

CKD self-evaluation report

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	Berore worksn	lops (n=648)	Alter workshop	12 (n=300)		Betore Worksn	ops (n=648)	Atter worksnop)S (N=300)
	Rateµ	Cost/ patientΩ (£)	Rateµ	Cost/ patientΩ (£)		Rateµ	Cost/ patientΩ (£)	Rateµ	Cost/ patientΩ (£)
In practice					Sick certification				
Self-help literature	0.116	0.162	0.156	0.218	Given Med 3, 5 or 6	0.263	0.000	0.314	0.000
Self-help advice	0.003	0.077	0.000	0.000	Treatment modalities				
Exercise advice	0.008	0.193	0.003	0.068	Ultrasound	0.002	0.116	0.003	0.205
Lifestyle advice	0.002	0.039	0.000	0.000	Epidural**	0.026	3.416	0.003	0.355
Advice about attending physiotherapy	0.005	0.116	0.000	000.0	Other injection	0.003	0.464	0.000	0.000
Contraceptive leaflet	0.000	0.000	0.000	0.000	Consultant referral				
Referral for inve	stigations				Gastroenterology	0.003	0.519	0.003	0.459
X-ray	0.053	0.946	0.063	1.131	Gynecology	0.003	0.448	0.003	0.396
MRI	0.009	2.921	0.005	1.721	Cardiology	0.005	0.900	0.008	1.590
Blood test	0.002	0.031	0.000	0.000	Rheumatology	0.020	5.184	0.027	7.049
Referral to comn	nunity services				Rheumatologist acute back pain service	0.012	3.190	0.000	0.000
Stop smoking clinic	0.012	0.495	0.005	0.219	Back pain clinic	0.023	4.544	0.036	6.962
Other GP	0.005	0.515	0.000	0.000	Hospital spinal assessment clinic	0.002	0.235	0.000	0.000
Physiotherapy	0.189	20.176	0.172	18.418	Geriatrics	0.000	0.000	0.003	0.773
Private physiotherapy	600.0	0.371	0.000	0.000	Vascular surgeon	0.000	0.000	0.003	0.473
Chiropractor	0.008	0.425	0.011	0.601	Neurologist	0.005	0.946	0.008	1.672
Private chiropractor	0.002	0.085	0.000	0.000	Urologist	0.003	0.495	0.000	0.000
Sum of Costs before = *=Significant (p<0.05 ct μRate = number of occ Ω = rate X NHS tariff ¥ The drop in rates for	£104.78; after = £103.1 aange in proportion of p urrences/number of pai epidurals largely reflect	70 aatients offered service (titients in cohort ts one practice	(Fisher Exact Test)						

Table 15: LIMBIC: activity rates and costs recorded by nine practices before and after the workshops

	Before worksh	10ps (n=648)	After workshop	os (n=366)		Before worksh	ops (n=648)	After workshop	s (n=366)
	Rateµ	Cost/ patientΩ (£)	Rateµ	Cost/ patientΩ (£)		Rateµ	Cost/ patientΩ (£)	Rateµ	Cost/ patientΩ (£)
Osteopath*	0.020	1.005	0.000	0.000	Orthopaedic surgeon	0.040	6.108	0.044	6.645
Private osteopath	0.005	0.232	0.000	0.000	Colorectal surgeon	0.002	0.278	0.000	0.000
Exercise therapy	0.005	0.139	0.000	0.000	General surgeon	0.005	0.751	0.011	1.770
Acupuncture	0.002	0.085	0.003	0.150	Plastic surgeon	0.002	0.207	0.003	0.366
Private acupuncture	0.002	0.085	0.000	0.000	ENT	600.0	1.122	0.000	0.000
Dietician	0.002	0.062	0.000	0.000	Opthalmology	0.003	0.328	0.005	0.579
Midwifery	0.002	0.077	0.000	0.000	Dermatology	0.006	0.736	0.005	0.650
Counsellor	0.003	0.124	0.000	0.000	Psychiatry	0.002	0.377	0.000	0.000
Continence nurse	0.000	0.000	0.003	0.109	Unspecified				
Rehabilitation	0.000	0.000	0.003	0.109	Further care*	0.026	1.445	0.071	3.907
Community matron	0.002	0.062	0.000	0.000	Hospital admission				
Pulmonary rehab	0.002	0.062	0.000	0.000	Emergency admission	0.016	1.597	0.008	0.844
Other	0.006	0.247	0.005	0.219	Other admission	0.014	1.391	0.008	0.820
Sum of Costs before *=Significant (p<0.05 (µRate = number of oc	= \pounds 104.78; after = \pounds 103. change in proportion of p currences/number of pa	70 patients offered service (titents in cohort	Fisher Exact Test)						

 Ω = rate X NHS tariff # The drop in rates for epidurals largely reflects one practice

Source: LIMBIC project team

REST

This team had a close relationship with their local PCT, and were able to provide details of the costs to the PCT of various project activities (table 16). We do not have any further details, but the team is undertaking an analysis of costs and consequences.

Of specific interest in the REST table is the uncosted input to the pilot RCT from the mental health research network and the primary care research network.

Across the UK, various clinical research networks pay practices to participate in studies and help with practice recruitment. Variable support was provided by these networks and, with regard to payment, this support proved a mixed blessing.

The CKD team pointed out that rates vary across the UK:

- some areas (such as South West London) pay a flat rate to any participating practice
- some pay nothing unless individual patients (as opposed to practices) are recruited
- others (such as Surrey and Sussex) provide detailed service support costs.

The CKD team commented that the project time spent negotiating with these various bodies was noteworthy and, while the resulting payments were an added incentive, the inequity of the existing arrangements led to some dissatisfaction. One advantage was that the service support costs estimated by the Surrey and Sussex Clinical Research Network did give an indication of implementation cost.

For the CKD project, the figures given for each arm of the RCT (we have no indication over what period) were:

- normal practice = \pounds 1,390
- guidelines and prompts = \pounds 1,420
- audit-based education = \pounds 2,000.

But these costs by themselves give us little sense of how much an ongoing QI initiative (without an RCT to set up) would cost. Four projects are conducting an economic analysis:

- IRIS is undertaking a formal cost-effectiveness analysis, based on the approach used in their pilot study and modelling from the specific process end-point of changes in referral rates.
- IMPACT is doing a cost-benefit analysis.
- CKD and REST plan to do cost-consequence evaluations.

We do not have the results of any of these at the time of writing. The remaining projects have not produced any costing data (although two intend to do so). None will be doing any economic evaluation.

7.6 What type of economic analysis is needed?

In most instances, the prime requirement is to clearly demonstrate that a QI initiative undoubtedly results in desired improvements in process or outcomes that are seen as valuable.

Without clear evidence of the beneficial impact of such interventions as have been studied here, none of which was easy to implement, and none of which was predicated on reducing the overall cost of care, the issue of costs can be irrelevant.

In these studies the ambiguous and variable evidence of beneficial outcomes may have reduced the willingness of some of the teams to struggle to assemble cost data. It may have reduced the willingness of health economists who had initially agreed to help to devote their scarce resources to difficult analyses.

Where results are promising, good-quality cost and consequence data are essential for convincing commissioners of the value of successful improvements. We have discussed the difficulties the teams faced, and the efforts made to overcome them. Including designing a template that could be used to identify practice costs and working with research networks to estimate service support costs.

Efforts involved working with others to identify and collect data – such as practice teams or staff from organisations outside the project. This raises questions about the amount of data needed, what efforts are required to obtain them and what the system can withstand. Table 16: REST project activities and costs to local PCT

Activity (not inc. initial organisation, data input or analysis)	Hours	Cost				
GP QI survey carrying out						
REST	18					
Practice	37					
PCT		£356				
1st GP collaborative						
REST (meetings and visits)	87					
Practice (meetings and visits)	272					
PCT		£116				
Focus groups						
REST	66.5					
Practice	22					
PCT		£100				
Pilot RCT (training and data collection coordination – not GP time to recruit or deliver inte	ervention)					
REST	252.5					
Practice	83					
PCT		£913				
MHRN	186					
PCRN	15					
REST Ed sessions (including GP champion time and evaluation interviews)						
REST	81					
Practice	216.5					
PCT		£346				
Insomnia management seminars						
REST	15					
Practice	40					
PCT		£42				
Main steering group meetings (bimonthly)						
REST	450					
PCT		£336				
Smaller REST meetings (bi-weekly average)						
REST	378					
PCT misc. support						
Printing posters		£240				

Source: REST project team

LIMBIC initially had no plans for an economic evaluation but nevertheless addressed the issue of costs and developed a template for collecting practice activity on back pain. They did this because back pain is not part of the QOF, and there was no consistency between practices about what information was recorded. They hope this clinical field will eventually become part of the QOF.

Currently, the QOF covers four domains (clinical, organisational, patient experience and additional services) and 134 indicators.¹⁰⁶ The demands this places on practices is already large:

A major problem cited by all practices was the competing demands on their time especially round year end for QOF mandatory reporting. It would be appropriate in a future project to aim to synchronise project activities with the other ongoing practice activities to achieve a workable balance for the team.

LIMBIC self evaluation report

Is it realistic to extend this reporting requirement still further and, if not, can the quality of primary care be improved and maintained outside the QOF?

Several projects used referral rates as a measure of outcome. Liaising with, and collecting data from, organisations outside the practice proved problematic.

IRIS found it impossible to get accurate data on referrals from advocacy agencies not directly involved in the study.

QUEST were unable to get reliable information on referrals from the Child and Adolescent Health Service (CAMHS) audit data. This was despite their extensive prior contacts with CAMHS teams.

LIMBIC produced a long list of information they would like to have accessed to explore and identify referrals to, and utilisation of, secondary care and community services.

For various reasons, they could not obtain these data. This illustrates the need for careful and detailed planning before undertaking any economic assessment or costing study. IRIS successfully built on their pilot, but a pilot is not always sufficient. QUEST had no problems with CAMHS data in their initial single-PCT study, but it was a major stumbling block in the main project. Another lesson is that failures to integrate care pathways across traditional boundaries, and to align the information that supports them, can seriously impede QI efforts.

A further issue is the nature and rigour of economic analysis. In the end, this comes down to what information is needed to persuade health service commissioners to fund changes based on successful QI work. As IRIS put it:

Inevitable cuts in the NHS over the next five years potentially undermine innovations that require additional funding, although demonstration of cost effectiveness and the potential for 'spending to save' may mitigate the cold climate.

Teams that have been unable to identify clear beneficial changes resulting from the initiative would be unlikely to convince commissioners. Cost data would be unnecessary.

It is possible that a QI project might change the pattern of service delivery and reduce costs, while patient outcomes remain unchanged, and this would be attractive as the service searches for cost savings.

Opinions differed on what economic approach was needed, and on what was feasible. These different views closely aligned with individual projects aims and the project design selected.

There was considerable variation. The IRIS team, determined that a cost-effectiveness analysis, and nothing less, was required. This was 'because of the hidden healthcare costs of unrecognised domestic violence-related acute and chronic health consequences'.

IRIS was a relatively small project, designed as a pragmatic cluster RCT. Comparison was built into the study.

They had the advantage of a pilot that had already incorporated a successful cost-effectiveness analysis.

It was less straightforward for others. The REST team summed up the challenge rather well:

This was not easy because some economic models are not applicable to the REST project. The project involved a whole range of activities with a number of different outcomes and this is not amenable to a simple analysis.

EQUITY addressed an issue that is usually difficult for economic evaluation. In principle, improvements in chronic disease self-management could be conventionally modelled to demonstrate cost effectiveness. However, an outcome that reduced differences in access without improving access overall might be seen as an improvement in equity, but would be difficult to assess in conventional economic terms.

At the other end of the spectrum, QUALITY:MK was a multifaceted programme seeking wholesystem change. The project was described by the team as:

A service improvement programme focused on 'the ongoing process of continual, self-conscious change'... It is not a research project to which hypothesis testing and the generation of new knowledge are central. Rather, QUALITY:MK is an intrinsic part of normal healthcare operations with an explicit focus on the learning and improvement process.

There was no obvious comparator. This team hoped to undertake a cost-consequence evaluation of the project as a whole. This proved unachievable within the timeframe. Moreover, when they did provide early estimates of cost consequences from some sub-projects, these did not convince their commissioners.

This brings us back to the commissioners. What do they want, and what, realistically, should they be seeking? The two may not be the same.

The project teams were asked to look at cost consequences. They did this with varying degrees of success. This does not mean this should not be attempted, quite the reverse, but it does indicate how difficult this task is.

It also highlights how inadequately this is supported by existing arrangements within the NHS for collecting and costing activity data.

7.7 Conclusions

The account we have given of the projects' economic evaluations is still incomplete. Due to the variations in available data it has been necessary to focus on:

- cost data, of variable completeness, provided by three projects
- explanations by five projects that have not done economic analyses
- intentions of the four that are doing analyses that were not available at the time of writing.

Whether this has led to an overemphasis on the difficulties of making an economic evaluation of improvement interventions will only become apparent when all findings are available. But, and as we suggested at the start of this chapter, the literature suggests otherwise.

The UK healthcare system faces unprecedented financial pressures. Any proposed change will need to fight against many competing demands. When competing with health technologies that have proven effectiveness and cost effectiveness, goodquality cost and consequence information will be essential.

The belief that QI is a good thing will no longer suffice, even where that belief may be passionate. We need to take the case for QI beyond belief and root it firmly in the science of high-quality evaluation and the implementation of improvements for which cost effectiveness has been demonstrated.

This means developing better information across the service about costs. It means building on the work already being done to identify and value outcomes. And it means improving the evidence base on the cost effectiveness of interventions, and then encouraging commissioners to adopt proven quality improvements.

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Appendices

Acronyms in use throughout appendices

Acronym	Description	Acronym	Description
ABE	audit-based education	DAQ	Depression Attitude Questionnaire
ACEI	angiotensin-converting enzyme inhibitors	DEN	doctor's educational need (see also PUN)
ADQ per	average daily quantity per specific	EMIS	Egton Medical Information Systems
STAR-PU	therapeutic group age-sex prescribing unit	EPOC	Effective Practice and Organisation of Care Group
ASCQI	Ambulance Services Cardiovascular Ouality Initiative	EPP	expert patients' programme
BMA	British Medical Association	EQUITY	PROJECT: Equity, ethnicity and expert patients project
BMI	Body mass index	EwQI	Engaging with Quality
CAMHS	Child and Adolescent Health		Improvement
	Service	EwQPC	Engaging with Quality in Primary
CBT	cognitive behavioural therapy		Care
CBTi	cognitive behavioural therapy for	FEV	forced vital capacity
25.00	insomnia	GFR	glomerular filtration rate
CDSS	computerised decision support	GI	gastrointestinal
CEG	Clinical Effectiveness Group	GIS	Gastrointestinal Symptom Score
CEG	(Queen Mary, University of	GORD	gastro-oesophageal reflux disease
	London)	GP	general practitioner
CHD	coronary heart disease	HbA1C	glycosylated haemoglobin
CI	confidence interval	HERG	Health Economics Research Group
CKD	PROJECT: Quality improvement in	IBD	inflammatory bowel disease
	chronic kidney disease	IBS	irritable bowel syndrome
СМО	Context-Mechanism-Outcomes	IBS-SSS	irritable bowel syndrome severity
COPD	chronic obstructive pulmonary		scoring system
	disease	ICER	incremental cost-effectiveness ratio
CORE	Digestive Disorders Foundation	IMAGE	PROJECT: Improving management
CTS	carpal tunnel syndrome		in gastroenterology
CVD	cardiovascular disease nurses		

Acronym	Description
IMPACT	PROJECT: Implementing evidence- based primary care for back pain
IMPACTE	Improving Medical Practice by Assessing Current Evidence
IoP	Institute of Psychiatry
IRIS	PROJECT: Identification and referral to improve safety
IRR	inter-rater reliability
ISI	Insomnia Severity Index
LES	local enhanced service(s)
LIMBIC	PROJECT: Improving the management of back pain in the community
LINk:MK	Milton Keynes Local Involvement Network
LITP	Leading Improvement Teams Programme
MCS	mental component summary measure(s)
MHRN	Mental Health Research Network
МК	Milton Keynes
MRC	Medical Research Council
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
NRS	numeric rating scale
NSF	National Service Framework
PABS	pain attitudes and beliefs scale
PCRN	Primary Care Research Network
PCS	physical component summary measure(s)

Acronym	Description
РСТ	primary care trust
PDSA	plan-do-study-act
PEP	patient empowerment programme
PPE	public and patient engagement
PPI	public/patient involvement
PreDoVe	prevention of domestic violence
PSQI	Pittsburgh Sleep Quality Index
PUN	patient's unmet needs (see also DEN)
QALY	quality adjusted life year
QI	quality improvement
QOF	quality outcomes framework
QOL	quality of life
QOLRAD	quality of life in reflux and dyspepsia
QUALITY:MK	PROJECT: A whole-system approach to quality improvement (Milton Keynes)
QUEST	PROJECT: Improving the quality of mental health in schools
RCGP	Royal College of General Practitioners
RCT	randomised controlled trial
REST	PROJECT: Resources for effective sleep treatment
RMDQ	Roland Morris Disability Questionnaire
SAfH	Social Action for Health
SBP	systolic blood pressure
SF-36	short form (36) health survey
SHA	Strategic Health Authority
SPC	statistical process control
UC	ulcerative colitis
WCC	World class commissioning

Appendix A Tables of projects' outcomes and achievements

1 IMPACT

Table 17: IMPACT aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To improve the quality of primary care for low back pain by systematic identification and targeted treatment of risk factors for chronicity (barriers to recovery).	 Before-and-after study involving two separate cohorts of patients in five practices. Three phases, from autumn 2007 to Sept. 2010: Assessments in original cohort of patients (ran for an average of 6 months in each practice). QI intervention. Assessments in new cohort of patients (ran for 12 months in each practice). 	Implementation of an evidence-based sub-grouping tool for targeted treatment. QI intervention (education, feedback, mentoring, funding support, case-led discussion) in phase two and ongoing in phase three. Physiotherapists: three or nine days' training and 12 months' mentoring. GPs: feedback on patient recruitment and use of the sub-grouping tool every two months via e-mail and hard copy.	No comparator.	Assessments just after consultation with GP, and two and six months later, in both phase one and phase two: Practitioners' confidence, attitudes and behaviour. Patient outcomes: • RMDQ • STarT Back sub-grouping • NRS-pain in past 2 weeks • EQ-5D • SF-12 PCS • SF-12 PCS • SF-12 MCS

Table 18: IMPACT results: Healthcare professionals' confidence, attitudes, beliefs and behaviour

Outcome measure	Phase 1	Phase 2a	Phase 2b	Phase 3a	Phase 3	P-value*
	Before training	After training	After training		End of study	Difference between phases
GPs						
Number	44	27			33	
Confidence scale, mean (sd)	8.8 (2.4)	9.0 (1.8)	NA	NA	8.0 (1.3)	0.10
PABS – behavioural, mean (sd)	33.6 (3.5)	35.6 (3.1)			35.0 (2.5)	0.02*
PABS – biomedical, mean (sd)	30.1 (5.5)	27.8 (7.1)			28.5 (6.0)	0.27
Physiotherapists		After 3 days' training	After 9 days' training	After 6 months' mentoring (mid-point)	After 12 months' mentoring	
Number	31	21	8	14	16	
Confidence scale, mean (sd)	8.4 (3.0)	7.8 (2.3)	7.3 (1.4)	6.2 (2.3)	6.3 (2.4)	0.03*
PABS – behavioural, mean (sd)	33.7 (4.0)	36.6 (2.9)	40.0 (2.9)	38.5 (3.9)	38.1 (4.4)	<0.01*
PABS – biomedical, mean (sd)	29.8 (6.6)	24.3 (5.9)	20.1 (7.3)	23.1 (6.5)	21.6 (5.7)	<0.01*

Confidence scale: Note that the lower the score, the more confident in treating back pain the healthcare professional. PABS – behavioural: range 9-54 (9 = minimum behavioural focus of therapy, 54 = maximum behavioural focus) PABS – biomedical: range 10-60 (9 = minimum biomedical focus) * P<0.05 by ANOVA (for between-group differences of numerical scales relating to independent samples)

Table 19: IMPACT results: Patient outcome data

Outcome measure	Phase 1	Phase 1	Phase 3	Phase 3	P-value*	P-value*
	Baseline (just after consult- ation)	6-month follow-up	Baseline (just after consult- ation)	6-month follow-up	Baseline phase 1 vs phase 3	6-month assessment phase 1 vs phase 3
Number of patients analysed	373	235	554	314		
RMDQ, mean (sd)	8.7 (5.9)	6.4 (5.9)	8.4 (5.7)	5.6 (5.4)	0.38	0.08
STarTBack sub-grouping, n (%)						
'Low' risk	138 (37%)	159 (68%)	212 (38%)	233 (76%)	0.42	0.02*
'Medium' risk	151 (41%)	53 (23%)	232 (42%)	59 (19%)		
'High' risk	83 (22%)	22 (9%)	108 (20%)	15 (5%)		
Average NRS-pain in past 2 weeks, mean (sd)	6.1 (2.6)	3.8 (2.8)	5.8 (2.7)	3.3 (2.7)	0.08	0.04*
EQ-5D, mean (sd)	0.60 (0.31)	0.72 (0.25)	0.63 (0.29)	0.74 (0.24)	0.23	0.35
SF-12 PCS, mean (sd)	39.2 (10.5)	42.4 (11.6)	40.1 (10.7)	42.9 (11.6)	0.24	0.61
SF-12 MCS, mean (sd)	49.3 (10.2)	51.2 (10.6)	50.0 (10.9)	52.6 (10.1)	0.39	0.12
Satisfaction with care received, n (%)						
Not at all satisfied		7 (3%)		11 (4%)	0.22	
Not very satisfied		38 (17%)		41 (13%)		
No opinion		24 (10%)		41 (13%)		
Quite satisfied		116 (50%)		125 (41%)		
Very satisfied		45 (20%)		90 (29%)		

RMDQ: range 0–24 (0 = no disability; 24 = maximum disability)

NRS-pain: 0 = no pain; 10 = pain at worst as it could be

EQ-5D: range -0.59 to 1.00 (-0.59 = worst general health; 1.00 = best general health)

SF-12 PCS: range 0 to 100 (0 = worst physical health; 100 = best physical health) Results are observed results and tests of statistical significance are based on unadjusted observed data (final results will be based on

imputed data for missing data adjusted for baseline covariates).

* P<0.05 by t-test for numerical measures and chi square test for categorical measures.

2 QUEST

Table 20: QUEST aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To improve the attitudes, knowledge and skills of school nurses in the recognition and management of common mental disorders in young people.	Cluster RCT in 13 PCTs.	Training package for 82 school nurses in six intervention PCTs.	84 school nurses in seven control PCTs	At three and 10 months for school nurses: 1. 24-item knowledge test. 2. Professional confidence: Depression attitude questionnaire. 3. Clinical behaviour: depression recognition using vignettes.

Table 21: QUEST results

Outcome measure in school nurses	School nurses in intervention and control groups	Baseline score (pre- training)	3-month score	10-month score	Difference between intervention and control at 3 months (95% confidence interval), p-value*	Difference between intervention and control at 10 months (95% confidence interval), p-value**
Knowledge All	l = 80	l = 12.34	l = 14.09	l = 12.77	2.65 (1.51–3.78)	0.89 (-0.50–2.28)
	C = 66	C = 11.79	C = 11.45	C = 11.88	P<0.001	P=0.23
#Specialist	l = 43	l = 12.77	l = 14.97	l = 12.59	3.78 (1.97–5.60)	1.32 (-0.74–3.38)
	C = 28	C = 11.86	C = 11.19	C = 11.27	P<0.001	P=0.38
Attitudes –confidence	l = 81	l = 61.61	l = 67.85	l = 61.95	9.19 (3.28–15.11)	4.57 (-2.62–11.74)
(DAQ) All	C = 65	C = 60.09	C = 58.64	C = 57.38	P<0.001	P=0.26
#Specialist	= 43	l = 61.81	l = 68.49	l = 60.45	7.05 (-1.98 – 16.08)	4.28 (-6.72–15.29)
	C = 28	C = 60.27	C = 61.44	C = 56.17	P = 0.004	P=0.16
Depression recognition when present (sensitivity) All	l = 82 C = 67	I = 63.4% C = 66.6%	l = 64.5% C = 61.9%	l = 65.2% C = 65.2%	2.6% (-8.5–3.8) P=0.35	0
#Specialist	= 43	l = 70.0%	l = 65.2%	l = 71.8%	17.8% (0.7–34.9)	8.2% (-12.2–28.7)
	C = 28	C = 64.2%	C = 47.4%	C = 63.5%	P=0.035	P=0.43
Depression recognised to be absent (specificity) All	l = 82 C = 66	I = 46.5% C = 47.0%	l = 56.9% C = 48.1%	l = 52.1% C = 46.3%	8.8% (0.81–16.8) P=0.029	5.5% (-5.2 – 16.8) P = 0.057
#Specialist	= 43	l = 50.5%	I = 58.1%	l = 55.5%	9.8% (-3.2–22.9)	12.6% (-2.8–27.9)
	C = 28	C = 51.5%	C = 48.3%	C = 42.9%	P=0.097	P=0.084

I = intervention group (n at baseline) C = control group * regression covariates: baseline value of dependent variable, specialist training qualification. ** regression covariate: baseline value of dependent variable. # sub-group analysis of specialist practitioner school nurses (nurses who had undertaken additional post-registration school nurse training).

3 QUALITY:MK

Table 22: QUALITY:MK aims and study design

Aims	Study method	Outcome measures and time
Overall: To embed a whole-system approach to quality improvement, driven by primary care, patient engagement and evidence.	16 different component projects.	
Pathway reviews – Service redesign projects		
 Brief interventions for alcohol misuse: Small pilot project to test use of brief interventions as a tool for GPs towards meeting long term ambitions set out below: To improve the identification, assessment and intervention services for individuals who are hazardous or harmful drinkers. To increase awareness of alcohol related ill health and its social impact amongst healthcare staff. To prevent the moderate or entrenched dependent drinkers being above the national prevalence level of 3.6% of the population. To reduce the number of hazardous or harmful drinkers in MK to below the national prevalence level of 23%. To reduce the number of A&E attendances which are alcohol related. To improve the health outcomes of people who are drinking at hazardous or harmful levels. To ensure better value for money through effective commissioning of primary care services for people who are drinking at hazardous or harmful levels. 	Time series in 5 practices, 150 patients February 09 – February 10	 Numbers of patients recorded as having received advice from their GP, Community pharmacists or A&E department. Number of GPs positive about the use of brief interventions as a tool for assisting them and their patients in identifying and responding to unrecognised alcohol problems. Alcohol related attendances in A&E. Number and source of patients referred to the Brief Intervention Alcohol Pilot. Percentage of patients engaged in the Brief Intervention Alcohol Pilot. Number of clients referred on from the Brief Intervention Alcohol Pilot. Proportion of patients reducing alcohol consumption – full AUDIT assessment as set by government guidelines. Number of hazardous or harmful drinkers in MK.
 2. Diabetes To improve quality of diabetic care for patients. To bring services closer to home. To improve consistency and continuity of care. To make services more cost effective. Patients are empowered and educated to a high level that promotes self care. 	Time series comparing rates in 2007-08 and 2008-09 with 2009-10 in a pilot of 4 practices, later MK wide – 28 practices.	 Admissions for diabetic ketoacidosis. Admissions with diabetes as the primary diagnosis. Number of practices successfully implementing the care planning approach. Number of practices who initiate insulin. Improvements in access to diabetes education and understanding by patients.
3. Dyspepsia: information tool to support LES To test the feasibility of enhancing the impact of LES as an incentive for QI by accompanying them with information management tools that address the monitoring and audit requirements written into each agreement.	2009	Templates to support Dyspepsia LES developed in in both EMIS and VISION.
 Mild to moderate depression To ensure that any service for people with mild to moderate depression in MK is patient centred, primary care and evidence based. 	Focus groups	 Views of Primary care reflected in specification. Views of patients taken into account.

Table 22: QUALITY:MK aims and study design

Aims	Study method	Outcome measures and time
 5. Smoking cessation To develop services to achieve and sustain the national target for adult smokers who have not smoked for four weeks after setting a quit date. To change the attitudes and behaviour of health professionals to smoking cessation services. To produce demonstrable and measurable successes – increasing referrals and 4-week quitters. To achieve 85% quitter validation by CO monitoring. 	Time series comparing rates in 2007-08 and 2008-09 with 2009-10 in 28 practices and 25 pharmacies.	 Number of 4-week quitters. Quit rate per 100,000 population. Number of those setting a quit date. % of quitters established using carbon monoxide monitoring – target 8%. Number of practices and pharmacists signed up to the LES.
 Stroke pathway improvement programme To facilitate a multidisciplinary workshop to identify key principles the stakeholders would expect to be included within the pathway. 	March 2009	Workshop delivered.
 7. Weight management – children To address and treat the issue of overweight and obesity by introducing a systematic evidence based approach to weight management for children in primary care. Localised pathway for children published in the Map of Medicine made available in as many ways as possible and disseminated to all health professionals. Childhood overweight/obesity reduction (long term outcomes): By 2010 lower the number of reception year and Year 6 pupils who are obese in line with the Healthy weight, Healthy lives strategy and the PSA target: by 2020 reduce the proportion of overweight and obese children to 2000 levels. Business cases for funding of children's weight management pathway submitted for April 2009. An increase in the number of practices aware of and using the pathways/services. 	Time series comparing rates in 2007/08 with 2008/09.	 Proportion of reception and year 6 pupils who are overweight and obese (data from the National Child Measurement programme). Number of referrals to weight management service. Percentage of referrals who maintained/lost weight or reached optimal weight. Publication of localised pathway in the Map of Medicine. Confidence and knowledge (online survey before and after the work has been completed). Success of business cases.
 8. Weight management – adults To treat overweight and obesity by introducing a systematic evidence based approach to weight management in primary care. To develop local specialised services to support the work of primary care clinicians in treating overweight and obese adults and to feed into a system-wide approach and supported development to weight management. 	2008-09	 Number of views per month of the localised pathway for adults published in the Map of Medicine. Height and weight of patients (QOF recording). Knowledge and confidence on treating. overweight and obese patients (online survey). Number of practices aware and using the pathways and number of referrals to the newly developed services.
Spreading bright ideas	0000 10	
9.Patient empowerment To set up, resource and operate a process whereby patients of Parkside Medical Centre can be given the information they need in respect of their conditions, to enable them to better understand and manage their own care, ask appropriate questions of healthcare professionals and access approved literature by means of internet access, library services, printed leaflets, information prescriptions or any other relevant means and access further help and support via local voluntary groups.	2008-10	 Impact of the new resources (patient survey). Resources provided in the surgery and elsewhere. Hospitalisations, visits to Out-of-Hours services and visits to GP (PCT data). Attitudes of both patients and staff within the practice.

Table 22: QUALITY:MK aims and study design

Aims	Study method	Outcome measures and time
10. Managing medication for patients with complex conditions To improve care for patients receiving polypharmacy with one or more long-term conditions using a holistic patient-focused evidence-based approach by a specialist nurse and practice pharmacist based at The Grove.	Time series in 1 practice, 40 patients over one year 2008-09.	 Prescribing cost savings by reducing inappropriate medication. Out-of-hours presentations. Hospital admissions.
Embedding evidence into practice		
 IMPACTE groups: Improving Medical Practice by Assessing CurrenT Evidence To support individual General Practices to research, evaluate and pilot changes in practice by the establishment of evidence based discussion groups. An example of IMPACTe discussion: To reduce prescribing of anti-psychotics in elderly patients with dementia. 	Time series 2007-09 in 30 care home patients.	Prescribing levels.
12. Carpal tunnel syndrome (CTS) To establish an evidence-based pathway for the treatment of CTS at Parkside Medical Centre.	Time series June 2008- December 2008 in 1 practice, 5 GPs, 10 patients.	 Referrals to secondary care for mild to moderate CTS. Number of CTS injections carried out in the surgery.
Prescribing toolkits		
13. Delayed prescribing To delay antibiotic prescribing for upper respiratory infections.	Time series June 2008- December 2009 in 1 practice.	Prescribing levels.
14. Safer prescribing Using glitazones as an example: to reduce prescribing of rosiglitazone.	Time series 2007-08 in 2 practices.	Prescribing levels.
15. Implementing NICE guidance Using lipid modification as an example: to support local implementation of NICE guidance to enable improvement in prescribing levels.		Development of process.
Overarching workstream		
 16. Patient engagement To enable and train commissioners to involve patients and the public appropriately. To capture experiences and lessons learned about patient and public engagement. To develop practice patient representative groups across Milton Keynes to promote patient participation and involvement. 	2008-10	 Number of commissioners participating in training. Level of satisfaction with the training. Number of hits on the QUALITY:MK website since its launch. Service users experience of contributing to the commissioning process. Attitudes and perceptions. Number and level of activity of practice patient representative groups.

Table 23: QUALITY:MK results

		us programme ue to financial									cost per client at	practices and acted on Milton	odel for long e pathways.			
Further results		The brief interventic was not rolled out d restrictions.									'Exceptionally high' £970.	This was a pilot in 5 would not have imp Keynes figures.	Process formed a m term conditions car			
Difference between baseline and follow- up (value, confidence interval, p-value)			n/a											Reduction of 5 per 1000 patients	22 (7 per 1000)	
Follow up			59 (39%)	55 (36%)	36 (24%)	77 (52%)	119 (79%)	74 (96%) reduced consumption by 20% or more.	61%	Data inaccurate		n/a		1 for every 150 registered patients 2009/10	205 in 2009/10 (23 per 1000 registered patients)	18
Baseline			n/a	n/a	n/a	n/a				Data inaccurate		n/a		1 for every 100 registered patients 2007/08	227 in 2007/08 (30 per 1000 registered patients)	0
z		5 practices, 150 patients referred to Brief intervention pilot	150	150	150	150	150	77					28 practices			28
Project and outcome measure	Pathway reviews	1. Alcohol brief interventions	Patients referred by GP	Patients self referred	Patients referred by other agencies	Patients engaging with Brief Alcohol intervention worker	Patients referred to other agencies	Patients reducing alcohol consumption	GPs positive about brief interventions	Alcohol related A&E attendances	Cost of intervention per client	Number of hazardous/ harmful drinkers in Milton Keynes	2. Diabetes	Admissions for ketoacidosis	Admissions for diabetes	Practices using Care Planning

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Project and outcome measure	z	Baseline	Follow up	Difference between baseline and follow- up (value, confidence interval, p-value)	Further results	
Practices who initiate insulin		Q	11 (2009) 14 (2010)	S		
Patient education & understanding					Increase in people completing DESMOND course (new type 2 diabetes) and reduction in waiting times (from 4 months to 4-6 weeks).	
3. Dyspepsia						
Templates to support Dyspepsia LES in both EMIS and VISION					Templates produced.	
4. Depression - mild to moderate					No qualitative data.	
Views of patients taken into account					Service specification modified e.g. service initially offered in GP practice, although other locations are available if this is the patient's choice.	
Primary care focussed					GP focus group was used.	
5. Smoking cessation						
Number of practices and pharmacies signed up to LES	28 practices	0			All practices in Milton Keynes signed up.	
Number of 4 week quitters		2007-08 1,425 target 2008-09 1610 target 2009-10 1700 target	2007-08 1337 actual 2008-09 1597 actual 2009/10 2,678 actual	2009/10 Overachieved by 58%, and increase of 68% from 2008-09		
Quit rate per 100,000 population		2009-10 620 target	2009/10 970 actual	2009/10 Overachieved by 56%	Highest across south central region.	
Percentage of quitters established using CO monitoring	2678		1714 64% (2009/10)	36%		
Number of those setting a quit date		2,170 (2007/08) 2,617 (2008/09)	3,712 (2009/10)	2009/10 42% increase over 2008-9		
6. Stroke pathway improvement programme					Workshop delivered March 2009.	

Further results		Data from National Child Measurement programme.	This includes previous referrals to former programmes and new programme Motiv8. Number of referrals to the Children's Specialist Obesity Clinic: 17.		Pathway complete and disseminated through drop-in events in practices.	
Difference between baseline and follow- up (value, confidence interval, p-value)			120			
Follow up		2008/09 Overweight R: 12.6% Y6: 14.7% Obese R: 9.4% Y6: 15.9% 2009/10 Overweight R: 12.7% Y6: 14.5% Obese R: 9.5% Y6: 17.3%	270 (2009/10)	Data unavailable		47% increase in the awareness and engagement with the services. 1/14 respondents not aware of Motiv8 in post survey. 5/14 had referred in the last month
Baseline		2007/08 Overweight R:13.3% Y6: 13.9% Obese R: 12.1% Y6: 16.1%	150 (2008/09)	Data unavailable		
z						 T5 responses to each survey from a total of 18 practices
Project and outcome measure	7. Weight management (children)	Proportion of reception R) and year 6 (Y6) pupils who are overweight and obese	Referrals to weight management service	Percentage of referrals who maintained/lost weight	Publication of localised pathway in the Map of Medicine and dissemination	An online survey measuring knowledge and confidence on treating overweight and obese patients, repeated both before and after the work has been completed

Table 23: QUALITY:MK results

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er results	usiness cases were successful 09: an obesity clinic for dly obese patients and a unity weight management imme.	is now a formal approach to t management.	ta available. Publication of d pathway delayed.		
Difference between Furthe baseline and follow- up (value, confidence interval, p-value)	Two bu for 200 morbic comm	There i weight	No dat revised	0.4% increase from 2008-9	
Follow up				2009-10 8.5% prevalence	Followup survey AMKers 15/15 respondents aware of services 13/15 had referred in the last month HALO 14/15 respondents aware of service 5/14 had referred in the last vear.
Baseline				2007-08 8.9% prevalence 2008-9 8.1% prevalence	
z					15 responses to each survey from a total of 18 practices
Project and outcome measure	Business cases for weight management services	8. Weight management (adult)	Number of views per month of the localised pathway for adults published in the Map of Medicine	QOF recording of adult height and weight of patients	Online survey measuring knowledge and confidence on treating overweight and obese patients

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Project and outcome measure Number of referrals to the newly developed services Output Bright Ideas Output Determent	z 8	Baseline 2008/09 220 to HALO 220 to HALO Data for AMKers not available 2008/09 22009: 17 (30%) had talked to advisor 28 (50%) accessed internet 28 (50%) accessed internet information 36 (64%) had better able to cope 25 (45%) able to have a more meaningful consultation 25 (45%) able to have a more meaningful	Follow up 2009-10 Awating data for HALO Snapshot Jan – May 2010 - Out of 274 of the patients referred into the Active MK Exercise referral scheme, 165 of those patients were clinically obese.	Difference between baseline and follow- up (value, confidence interval, p-value)	Further results
Measure the use of the resources provided in the surgery and elsewhere	56	December 2009: 35 (62%) patients or carers used books in waiting room. June – Nov 09: 52 books borrowed			
Reduction in hospitalisations, visits to out-of-hours services and visits to GP (measureable via PCT data)					Data not available

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Project and outcome measure	z	Baseline	Follow up	Difference between baseline and follow- up (value, confidence interval, p-value)	Further results
Changing attitudes of both patients and staff within the practice through interaction		Jan – May 2009 325 patients	June – Dec 2009 706 patients	Increase of 381	Change of attitude in GPs measured by number of times printed information given out by GP during consultation as measured by READ code.
10. Complex patients/conditions	40 patients				
Prescribing cost		n/a	n/a	Reduction of £24,500	Total prescribing costs for surgery not available
Out of Hours presentations		95 presentations by 5 patients	2 presentations by 2 patients	93	
Hospital Admissions		34 admissions	2 admissions	32	
Embedding Evidence into Practice					
11. IMPACTE* groups					Team building and morale, support for evidence-based practice.
Number of regular (meeting at least quarterly) IMPACTE groups	n/a		4 (Dec 2008) 9 (March 2010) 11 (Dec 2010)		6 IMPACTE groups have also been set up within other clinical teams.
Changes made within practices as a result of review of the evidence	94		61 (64%)	Some of the remaining 33 confirmed the GPs in their current practice.	Many changes were straightforward, such as follow up and/or audit.
e.g. anti-psychotic prescribing in dementia	30 patients	60 items per month Dec 07	58 items per month Dec 09		Small decline over time, but this was already occurring before IMPACTE.
12. Carpal tunnel syndrome	1 practice, 5 GPs, 10-20 patients,				Outcome fed into the PCT wide muscoskeletal pathway review.
Referrals to secondary care		50%	25%	25% reduction	
Referrals to physiotherapy		18%	25%	7% increase	
Wait		27%	%0		
Injections in the surgery		5%	50%	45% increase	
Prescribing toolkits					
13. Delayed prescribing for respiratory infections	1 practice	0 (2007)	157 Jan -Mar 08 170 Jan-Mar 09	163 average for Jan-Mar	The lower figure of 99 reflects seasonal variations.
14. Rosiglitazone prescribing cost	2 practices	£16441 (2007)	£7352 (2008)	£9089	

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Project and outcome measure	z	Baseline	Follow up	Difference between baseline and follow- up (value, confidence interval, p-value)	Further results
15. Implementing NICE guidance using Lipid Modification as an example					Toolkit produced, including clinical information, the evidence base, patient letters, flowchart and poster.
Overarching work-stream					
16. Public & patient engagement					Produced and disseminated 'Golden rules for engagement' which includes involving patients and the public in the planning cycle, and the Patient Participation Group (PPG) guide.
Commissioners participating in PPE training		0	2 training sessions	39 attended training	34/39 rated training as good or very good.
Hits on the QUALITY:MK web site		0	345,445 (1,637 per day)		
Number of patient representative groups within practices	28	ო	28	25	
South Central Strategic Health Authority/ICM public perception survey question: How satisfied are you with the opportunities for participation in decision-making about your local NHS?	C1100 (2008) 1103 (2010)	8% (March 2008)	30% (June-Aug 2010)	30% - highest level in South Central region.	Only percentages are provided in the reporting of this survey conducted by South Central SHA.
Further details available from the Project Report (Ju *IMPACTE = Improving Medical Practice by Assessi	une 2010): http:/ ing CurrenT Evide	//www.qualitymk.nhs.uk/defaul ence.	t-ContentID-3011.htm		
4 IRIS

Table 24: IRIS aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To determine whether a training and support programme targeted at general practice teams increases the identification of women experiencing domestic violence and their subsequent referral to specialist domestic violence agencies.	Pragmatic cluster RCT in 48 practices in Hackney and Bristol.	Training and support programme in 24 randomly allocated practices.	Usual practice in 24 randomly allocated practices.	Identification of women experiencing domestic violence. Subsequent referral to specialist domestic violence agencies. Cost effectiveness.

Table 25: IRIS results: final data at 12 months

Outcome measure	Control n = 24	Intervention n = 24	Total n = 48	Unadjusted intervention group incident rate ratio (95% Cl)	Adjusted** intervention group incident rate ratio (95% CI)	
Number of eligible women	73,347	70,521	143,868			
Number per practice*	3,088 (2,043, 4,173)	2,945 (1,747, 4,083)	3,013 (1,804, 4,168)			
Recorded referral in the general practice electronic medical record						
Number	12	223	235	21.0 **** (10.7, 41.1)	22.1 (11.5, 42.4)	
Number per practice*	0 (0, 1)	9 (4, 14)	2 (0, 9)			
Recorded disclosure of domestic violence in the general practice electronic medical record						
Number	236	641	877	3.4 (2.1, 5.4)	3.1 (2.2, 4.3)	
Number per practice*	5 (2, 20)	25 (9, 40)	13 (3, 29)			
Referrals received by specialist domestic violence agencies (Next Link and the Nia Project)***						
Number	40	238	278	6.58 (4.06, 10.65)	6.43 (4.15, 9.97)	
Number per practice*	0.5 (0, 3)	9.0 (5, 15)	3.5 (0, 9)			

* Data are median (IQR). A random effect has been fitted for practice. **Adjusted analysis has been adjusted for area stratification and for minimisation factors (size of practice, deprivation score and proportion of women doctors). *** The referrals received by the agencies included referrals from other sources and self-referrals of patients registered in IRIS practices. **** The explanation for the very high IRR of 21 for recorded referrals is that the GPs in the intervention practices were using the referral code to record

discussion of referral as well as actual referral.

5 IMAGE

Table 26: IMAGE aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To contribute to capacity for QI through a more patient-centred method of guideline development and generation of quality criteria.	Before and after study in 39 practices – with follow-up 12 months after initial consultation/ baseline.	Quality criteria developed and implemented through CDSS software.	No comparator.	 Patient outcomes in IBD, GORD, IBS and coeliac disease: symptom severity QOL: generic and disease- specific anxiety depression patient enablement satisfaction with communication % on antidepressant appropriateness of treatment (IBS and GORD) No. of GP consultations.
IBD: inflammatory bowel disea GORD: gastro-oesophageal re	ase eflux disease			

Table 27: IMAGE results – inflammatory bowel disease changes over time (n=129)

Patient outcome	Measure (scale range)	Pre	Post	Significant difference?
Symptom severity UC Crohn's	UC index (0–21) Crohn's index (0–600)	4.3 160.7	4.0 198.4	No No
QOL Disease specific Generic	UK-SIBDQ (8–32) EQ-D (0–100)	24.4 72.5	2.2 74.7	p = 0.018 No
Anxiety	HADS (0-21)	6.7	6.3	No
Depression	HADS (0-21)	4.4	4.1	No
Patient enablement	PEI (0–12)	3.7	3.4	No
Satisfaction with communication	GPAQ (0–100)	74.9	74.2	No
% on antidepressants	Medical records	6%	10%	No
No. of GP consultations	Medical records	0.7	0.8	No
UC: ulcerative colitis				

Table 28: IMAGE results	- Gastro-oesophagea	l reflux disease: change	s over time (n=360)
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Patient outcome	Measure (scale range)	Pre	Post	Significant difference?
Symptom severity	GIS (9–36)	15.1	14.5	p = 0.020
QOL Disease specific Generic	QOLRAD (1–7) EQ-5D (0–100)	6.1 72.3	6.3 71.5	p = 0.017, p<0.05 on all sub-scales No
Anxiety	HADS (0-21)	5.7	5.1	p = 0.001
Depression	HADS (0-21)	3.7	3.7	No
Patient enablement	PEI (0–12)	3.5	3.2	No
Satisfaction with communication	GPAQ (0–100)	74.9	72.9	p = 0.022
% on antidepressants	Medical records	7%	7%	No
% on PPI	Medical records	70%	74%	No
No. of GP consultations	Medical records	0.7	0.5	p = 0.012

Table 29: IMAGE results – Irritable bowel syndrome: changes over time (n=240)

Patient outcome	Measure (scale range)	Pre	Post	Significant difference?
Symptom severity	IBS-SSS (0-500)	213.7	193.3	p<0.0005
QOL				
Disease specific Generic	IBS-QOL (0–100) EQ-5D (0–100)	70.7 70.8	74.8 70.9	p<0.0005 No
Anxiety	HADS (0-21)	8.4	8.1	No
Depression	HADS (0-21)	4.6	4.7	No
Patient enablement	PEI (0–12)	2.8	2.7	No
Satisfaction with communication	GPAQ (0–100)	71.8	71.8	No
% on standard dose antidepressants	Medical records	11%	13%	No
% on low-dose antidepressants	Medical records	1%	2%	No
% on Mebeverine	Medical records	25%	21%	No
No. of GP consultations	Medical records	0.6	0.7	No

Table 30: IMAGE results – Coeliac disease: changes over time (n=139)

Patient outcome	Measure (scale range)	Pre	Post	Significant difference?
Symptom severity	CDQ GI sub-scale (7–49)	38.1	38.7	No
QOL				
Disease specific Generic	CDQ (28–196) EQ-5D (0–100)	158.4 74.1	159.3 72.1	No No
Anxiety	HADS (0-21)	6.6	6.5	No
Depression	HADS (0-21)	4.5	4.7	No
Patient enablement	PEI (0–12)	2.7	2.2	No
Satisfaction with communication	GPAQ (0–100)	69.6	69.3	No
% on antidepressants	Medical records	10%	10%	No
No. of GP consultations	Medical records	0.5	0.6	No

6 LIMBIC

Table 31 LIMBIC aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
To assess changes in patient outcomes following a practice improvement intervention that included patients in the improvement in learning, taking account of prognostic factors.	Before-and-after study in 101 patients in nine practices in two PCTs.	Eight half-day practice workshops, improvement facilitator and PDSA cycles, in 53 patients in nine practice teams in two PCTs.	53 patients before workshops compared to 48 patients eight weeks afterwards in nine practices in two PCTs.	Clinical value compass (primary care back pain questionnaires): Clinical outcome: Primary outcome: RMDQ (Roland and Morris Disability Questionnaire). Functional outcomes: • pain severity • back pain bothersomeness • life impact • activity • work. General health: • interference with normal work • feeling calm • having energy • feeling downhearted. Satisfaction with care: • information giving • caring • effectiveness • overall satisfaction.
To identify any changes in practice care patterns and costs for back pain after the above intervention.	Practice database analysis, in nine practices in two PCTs.	n = 648 before workshops.	n = 366 after workshops.	Cost of care Health service utilisation: • GP visits per patient • giving information leaflets, sick notes or referrals to consultant services.

Table 32: LIMBIC results

Outcome measure	Baseline before workshops	Follow-up 8 weeks after workshops	Difference between before and after (p-value)
		(unierent patients)	
Patient outcomes: based on data fro satisfaction (n = 101 patients)	m the Clinical Value Co	ompass questionnaires on	clinical outcomes, functionality and
	n = 53	n = 48	
Clinical outcomes			
Reduction in median disability score (RMDQ/24)	8	9	1 (0.276, Mann-Whitney)
Patients improved	27 (51%)	31 (64%)	13% (p = 0.240, Fisher exact test)
Functional outcomes			
Reduction in back pain bothersomeness (/4)	1.0	1.5	0.5 (0.625, Mann-Whitney)
Reduction in days when back pain interfered with activity (/28)	2.0	5.0	3.0 (0.252, Mann-Whitney)
Satisfaction with care in terms of caring (/4)	2.0	2.3	0.3 (0.300, Mann Whitney)
Cost and processes: estimated from	data on GP computer	systems (n = 1024 patient	s)
	n = 648	n = 366	
Cost per patient*	£104.78	£103.70	£1.08
Mean number of GP visits per patient	1.65	1.81	0.16 (p = 0.078, unpaired t-test)
Giving information leaflets, sick notes Referral to consultant	13% 26% 14%	15% 31% 15%	+2% +5% +1% (>0.05, 2-sided Fisher exact test)

*Cost was calculated by multiplying the number of activities per patient by the relevant NHS tariff for each activity.

7 EQUITY

Table 33: EQUITY aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
Part A: Health Equity Audit To develop a data set on the equity (by age, sex and ethnic group) of service provision at both general practice and PCT level that can inform change at both levels.	Analysis of routine data in 38 practices in Tower Hamlets PCT and 113 in City & Hackney and Newham PCTs.	Written feedback to all 38 practices in Tower Hamlets PCT, plus support in year one (2008) for 10 underperforming practices, and in year two (2009) for six of eight networks of four or five practices each.	Usual care in practices in City & Hackney and Newham PCTs (n = 113 practices).	 Diabetes indicators: lipid lowering drugs prescribed HbA1c value retinopathy screening GFR systolic blood pressure cholesterol BMI smokers. CHD indicators:
To identify any inequity in provision of care by age, sex and ethnic group, by practice, for key indicators in CHD, COPD and diabetes.				 lipid lowering drugs prescribed cholesterol beta-blocker prescribed SBP ACEI prescribed aspirin prescribed BMI
To determine if feedback to and support of Tower Hamlets practices reduces inequalities.				 smokers. COPD indicators: pulmonary rehabilitation exercise referral FEV 1 measured MRC scale smokers.
Part B: Lay-led self- management programmes To increase patient knowledge and self-care through lay-led self- management groups with routine care pathways for chronic disease, improving their accessibility and uptake along with improvements in equity.	Before-and-after study (2007–10).	Lay-led self- management programme in Tower Hamlets PCT: Good Moves.	Existing self- management programme: Generic expert patients' programme (EPP).	SF-36 scores for physical and mental health.

HbA1c: glycosylated haemoglobin; GFR: glomerular filtration rate; SBP: systolic blood pressure; BMI: body mass index; ACEI: angiotensin-converting enzyme inhibitors; FEV: forced vital capacity; SF-36: short form (36) health survey.

Table 34: EQUITY results - Part A (Health Equity Audit results)

Odds ratio relative to the previous year for outcomes within each PCT 2007–10 by ethnicity. Regression analysis adjusted for age and sex and clustered by practice

PCT	Ethnic group	CHD patients	CHD patients	COPD patients	COPD patients	Diabetes patients	Diabetes patients
		% statin prescription odds ratio (9% CI)	% chol. target odds ratio (9% Cl)	% current smokers odds ratio (9% CI)	% with FEV1 odds ratio (9% CI)	% below 140 SBP odds ratio (9% CI)	% HbA1c ≤7.5 odds ratio (9% Cl)
Tower	White	1.2 (1.2,1.3)	1.0 (0.9,1.0)	1.1(1.0,1.1)	1.3 (1.2,1.5)	1.1 (1.0,1.1)	1.2 (1.2,1.3)
Hamlets	S Asian	1.3 (1.1, 1.4)	1.1 (1.1, 1.2)	1.0 (0.9, 1.1)	1.3 (1.1, 1.5)	1.1 (1.1, 1.2)	1.2 (1.2,1.3)
	Black	1.2 (1.0, 1.4)	1.0 (0.8, 1.2)	1.1 (0.8, 1.5)	0.4 (0.7, 2.6)	0.9 (0.9, 1.0)	1.1 (1.1,1.2)
City & Hackney	White	1.2 (1.1, 1.2)	1.7 (1.6, 1.8)	1.0 (0.9, 1.0)	1.4 (1.3, 1.5)	1.3 (1.2, 1.3)	1.0 (1.0,1.1)
	S Asian	1.2 (1.0, 1.4)	2.0 (1.7, 2.3)	1.1 (0.8, 1.4)	1.2 (0.8, 1.7)	1.4 (1.2, 1.5)	1.2 (1.1,1.2)
		1.1 (1.0, 1.2)	1.7 (1.5, 1.9)	1.0 (0.8, 1.2)	1.5 (1.2, 1.9)	1.1 (1.0, 1.1)	1.1 (1.0,1.1)
Newham	White	1.1 (1.1, 1.2)	1.6 (1.5, 1.7)	1.0 (0.9, 1.0)	1.2 (1.1, 1.3)	1.0 (0.9, 1.0)	1.2 (1.1,1.2)
	S Asian	1.3 (1.2, 1.4)	1.6 (1.5, 1.7)	1.0 (0.9, 1.1)	1.3 (1.1, 1.5)	1.1 (1.0, 1.1)	1.2 (1.2,1.2)
	Black	1.1 (1.0, 1.3)	1.5 (1.3, 1.7)	0.9 (0.7, 1.1)	1.5 (1.2, 1.9)	1.0 (0.9, 1.0)	1.2 (1.2,1.3)

Table 35: EQUITY results - Part A: Difference in indicators between ethnic groups within each PCT

	CHD patients		COPD patients		Diabetes patients	
PCT	Statin prescription p = value	Cholesterol target p = value	Current smokers p = value	FEV1 p = value	SBP <140 p = value	HbA1c ≤7.5 p = value
Tower Hamlets	0.94	0.02	0.91	0.81	<0.01	<0.01
City & Hackney	0.33	0.36	0.72	0.22	<0.01	<0.01

Table 36: EQUITY results – Part A: Changes in percentage with SBP< = 140 for patients on the diabetic register by ethnic group 2007–10

PCT and ethnic group	Ν	2007% meeting target	2008 % meeting target	2009 % meeting target	2010% meeting target	Odds ratio for change in % meeting target as year increases(95% CI)
Tower Hamlets	31,548	73.9	72.0	75.3	78.4	
White	11,444	72.9	72.9	73.5	77.4	1.07* (1.03-1.12)
SAsian	14,862	74.0	77.4	78.2	80.7	1.12* (1.07-1.17)
Black	5,242	74.8	63.6	66.0	69.6	0.91* (0.86-0.96)
City & Hackney	29,073	68.5	78.5	74.3	76.0	
White	11,400	67.0	75.5	77.1	80.0	1.23* (1.18-1.28)
SAsian	7,686	69.4	76.8	80.8	80.3	1.24* (1.18-1.31)
Black	9,987	68.1	67.0	69.5	70.6	1.06* (1.01-1.11)
Newham	49,140	77.9	78.5	78.2	78.3	
White	12,921	77.5	75.2	75.2	74.6	0.98 (0.94-1.01)
SAsian	25,773	78.0	82.6	82.1	82.1	1.05* (1.02-1.09)
Black	10,466	78.2	72.4	72.4	72.9	0.96 (0.92-1.00)
*p value <0.05 Bl	P: systolic blood p	ressure				

Figure 5: EQUITY results – Part A: Percentage of patients achieving the SBP target of < = 140 by ethnicity in Tower Hamlets



Source: EQUITY project team



Figure 6: EQUITY results – Part A: Percentage of patients achieving the SBP target of < = 140 by ethnicity in City & Hackney

Source: EQUITY project team

Figure 7: EQUITY results – Part A: Percentage of patients achieving the SBP target of < = 140 by ethnicity in Newham



Source: EQUITY project team

Table 37: EQUITY results – Part A

PCT and ethnic group	n	2007% meeting target	2008 % meeting target	2009 % meeting target	2010% meeting target	Odds ratio for change in % meeting target as year increases(9% CI)
Tower Hamlets	31,498	42.8	51.7	51.3	57.8	
White	11,417	47.0	60.5	57.6	67.1	1.22* (1.18-1.27)
SAsian	14,756	39.3	45.2	46.4	51.6	1.23* (1.18-1.27)
Black	5,325	40.6	53.6	55.3	59.7	1.14* (1.10-1.18)
City & Hackney	28,946	49.8	53.1 55.6		57.3	
White	11,361	59.0	57.3	57.7	59.8	1.01 (0.98-1.05)
S Asian	7,719	44.3	50.5	53.0	55.7	1.19* (1.14-1.24)
Black	9,866	52.3	50.1	54.5	55.3	1.08* (1.03-1.13)
Newham	49,048	46.4	51.0	55.3	58.6	
White	12,834	51.6	56.1	59.1	64.3	1.17* (1.14-1.22)
SAsian	25,799	44.3	48.7	53.2	55.6	1.17* (1.15-1.20)
Black	10,415	44.9	50.2	55.8	59.6	1.22* (1.18-1.27)
*n value <0.0HbA	1C: alveosylatod b	aomoglobin				

Changes in per centage with HbA1C< = 7. for patients on the diabetic register by ethnic group 2007–10

*p value <0.0HbA1C: glycosylated haemoglobin



Figure 8: EQUITY results – Part A: Percentage of patients achieving the HbA1C target of <= 7.5 by ethnicity in Tower Hamlets

Source: EQUITY project team.

Figure 9: EQUITY results – Part A: Percentage of patients achieving the HbA1C target of < = 7.5 by ethnicity in City & Hackney



Source: EQUITY project team.



Figure 10: EQUITY results – Part A: Percentage of patients achieving the HbA1C target of < = 7.5 by ethnicity in Newham

Source: EQUITY project team.

Table 38: EQUITY results – Part A: Difference in indicators between age groups within each PCT

	CHD patients		COPD patients		Diabetes patients	
РСТ	Statin prescription p = value	Cholesterol target p = value	Current smokers p = value	FEV1 p = value	SBP <140 p = value	HbA1c ≤7.5 p = value
Tower Hamlets	0.97	0.77	0.02	0.4	<0.01	<0.01
City & Hackney	0.25	0.44	0.39	0.46	0.1	<0.01
Newham	0.74	0.19	0.84	0.42	0.16	<0.01

Table 39: EQUITY results - Part A: Difference in indicators between genders within each PCT

	CHD patients		COPD patients		Diabetes patients	
PCT	Statin prescription p = value	Cholesterol target p = value	Current smokers p = value	FEV1 p = value	SBP <140 p = value	HbA1c ≤7.5 p = value
Tower Hamlets	0.38	0.82	0.51		0.46	<0.01
City & Hackney	0.04	0.09	0.92		0.51	<0.01
Newham	0.01	0.19	0.86		0.18	<0.01

Table 40: EQUITY results – Part A: Changes in percentage with HbA1C < = 7.5 for patients on the diabetic register by gender 2007–10

PCT and ethnic group	Րand ethnic n up		2008 % meeting target	2009 % meeting target	2010% meeting target	Odds ratio for change in % meeting target as year increases (95% CI)
Tower Hamlets	31,498	42.8	51.7	51.3	57.8	
Male	16,019	43.2	50.6	49.6	55.8	1.18* (1.14–1.22)
Female	15,479	42.4	52.8	53.0	59.9	1.25* (1.22–1.29)
City & Hackney	28,946	49.8	53.1	55.6	57.3	
Male	14,421	50.6	51.0	52.4	55.6	1.05* (1.02–1.08)
Female	14,525	49.1	55.2	58.7	58.9	1.12* (1.08–1.16)
Newham	49,048	46.4	51.0	55.3	58.6	
Male	25,652	46.4	49.1	53.6	56.2	1.15* (1.13–1.18)
Female	23,396	46.4	53.1	57.1	61.3	1.22* (1.19–1.25)
*n value <0.0						

HbA1C: glycosylated haemoglobin

Figure 11: EQUITY results – Part A: Percentage of patients achieving the HbA1C target of < = 7.5 by gender in Tower Hamlets



Source: EQUITY project team

Figure 12: EQUITY results - Part A: Percentage of patients achieving the HbA1C target of < = 7.5 by gender in City & Hackney



Source: EQUITY project team.

Figure 13: EQUITY results - Part A: Percentage of patients achieving the HbA1C target of < = 7.5 by gender in Newham



Source: EQUITY project team.



Figure 14: EQUITY results - Part A Crude percentage of CHD patients prescribed a statin, by ethnicity and PCT, over time

Source: EQUITY project team

Table 40: EQUITY results - Part B: Increase in SF-36 scores after different self-management programmes

Increase in SF-36 physical score pre- to post- Good Moves course	Increase in SF-36 physical score pre- to post- EPP course	Greater increase in SF-36 physical score pre- to post- Good Moves course compared with EPP (9% CI), p-value*	Increase in SF-36 mental score pre- to post- Good Moves course	Increase in SF-36 mental score pre- to post- EPP course	Greater increase in SF-36 mental score pre- to post- Good Moves course compared with EPP (9% CI), p-value*
14.9	9.3	6.4 (1.3, 11.5), 0.015	17.9	5.9	11.2 (5.7, 16.6), <0.001

Good Moves: 166 people attended 1 of 20 courses between Jan. and June 2009, and had pre- and post-course SF-36 scores. EPP: 137 people attended 1 of 17 courses between July 2007 and April 2009, and had pre- and post-course SF-36 scores. *Multiple logistic regression adjusting for gender, age and co-morbidities.



Figure 15: EQUITY results - Part B: change in SF-36 scores after self-management programme

8 CKD

Table 42: CKD aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
Overall: To provide trial data on the best way to implement QI in the management of chronic kidney disease in primary care.	Three component studies – see below.			
Randomised Control Trial: To compare the effectiveness of guidelines plus prompts, or audit- based education, with usual practice.	Two-year three-arm cluster RCT involving 125 practices from eight localities across England.	 Guidelines and prompts. Audit-based education. 	Usual practice	Systolic BP
Care bundle: To increase the proportion of chronic kidney disease clinic patients receiving a care bundle.	Time series April 2009 to January 2010.	116 patients attending chronic kidney disease clinic, >80% with diabetes.	N/A	Compliance with care bundle: A. Put patient with stage 3-5 chronic kidney disease on the chronic kidney disease register within five days. B. Measure proteinuria and document within five days. Prescribe ACEI/ARB within 10 days of ACR result if significant proteinuria present. C. Document BP and treat within 10 days if hypertension present D. Document cardio-vascular risk
Patient empowerment programme: To develop, implement and test a package of empowerment tools which can be delivered in a primary care setting and which enable the patient to be an informed partner in their care and effectively self-manage their condition.				A set of tools to facilitate positive interactions between clinicians and patients, including a self-efficacy questionnaire, Frequently Asked Questions 'Your Health Concerns' (to allow the patient to set their agenda at consultation), a goal setting care plan.

Figure 16: CKD results – care bundle study: CKD Register, proteinuria measurement (ACR) and prescription of blood pressure medication (ACE/ARB) over time



Source: CKD project team





Source: CKD project team



Figure 18: CKD results – care bundle study: Application of care bundle over time

Source: CKD project team

9 REST

Table 43: REST aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time
 To: 1.Improve the user experience of management of insomnia using validated measures. 2. Increase use of recorded non-pharmacological measures in insomnia by at least 100% in three years. 3.Reduce rate (costs) of Z-drug prescribing by 50% in 3 years (from a baseline average of 4.8 ADQs per STAR-PU). 4. Reduce the rate (costs) of benzodiazepine hypnotic prescribing by 2% in 3 years (from a baseline average of 0.98 ADQs per STAR-PU) 5. Investigate the effect of quality. improvement training on leadership behaviour, culture of innovation and adoption of QI methods in general practice. 	Pragmatic controlled trial (A). Eight general practices selected from 18 who expressed interest based on geographic area. Run in: October 2005 to September 2007.	Complex educational intervention differed between eight local practices. Techniques included: • academic detailing • rapid PDSA cycles • process redesign • monthly feedback using SPC charts.	94 other practices in Lincolnshire.	Data collected for a two-year period pre collaborative (Oct 2005 – Sept 2007), and for the six months of its operation (Oct 2007 – Mar 2008): Aims 1&2: qualitative measures. Aim 3: Prescribing rates (ADQ per STAR–PU) for Z–drugs. Aim 4: Prescribing rates (ADQ per STAR–PU) for benzodiazepines. Aim 5: assessed by questionnaire survey.

Table 43: REST aims and study design

Aims	Study method	Intervention	Comparators	Outcome measures and time			
To test procedures and collect information in preparation for a larger definitive trial to measure effectiveness and cost-effectiveness of an educational intervention – for general practitioners and primary care nurses a to deliver problem focused therapy to adults.	Pilot cluster randomised trial (B).	Educational intervention (2x2 hours) for patients with sleep problems: comprised assessment and modified CBTi.	Usual care (sleep hygiene advice and hypnotic drugs).	 Primary outcome: PSQI Secondary outcomes: insomnia severity index Epworth sleepiness scale Beck depression inventory PSYCHLOPS at 0, 4, 8 and 13 weeks 			
ADQ per STAR-PU: Average daily of PDSA: Plan, Do, Study, Act SPC: statistical process control CBTi: Cognitive behavioural therap PSQI: Pittsburgh Sleep Quality Inde	ADQ per STAR-PU: Average daily quantity per specific therapeutic group age-sex prescribing unit PDSA: Plan, Do, Study, Act SPC: statistical process control CBTi: Cognitive behavioural therapy for insomnia PSQI: Pittsburgh Sleep Quality Index						

Table 44: REST results (A) – Aims 3 and 4: Change in drug prescribing before and after the intervention, in collaborative and control practices, coefficients from the mixed effects models

	Benzodiazepine Increase in ADQ per STAR–PU (95% confidence intervals)	Z–drugs Increase in ADQ per STAR–PU (95% confidence intervals)
Control	Reference	Reference
Collaborative	28.5 (-103.0, 160.1)	-91.1 (-72.8, 390.5)
Effect of time (per month)		
- before	-1.7 (-2.3, -1.1)	3.2 (0.7, 5.6)
- after	-1.2 (-3.6, 1.2)	-2.4 (-10.6, .8)
Interaction group:time		
Collaborative by before	-2.6 (-4.6, -0.6)	-6.6 (-1.3, 2.1)
Collaborative by after	-12.1 (-20., -3.6)	-54.5 (-83.7, -2.3)
'Before' refers to the slope during the initial 24 month	as and 'after' to the slope during the 6 months of opera	ation of the collaborative

Figure 19: REST results (A) – Aims 3 and 4: ADQ per STAR–PU over time for each practice for benzodiazepines. Includes the 24 months baseline run in, with the intervention starting at month 25



Source: REST project team.

Figure 20: REST results (A) – Aims 3 and 4: ADQ per STAR–PU over time for each practice for Z–drugs. Includes the 24 months baseline run in, with the intervention starting at month 25



Source: REST project team.

REST results A

Aims 1 and 2: Qualitative themes suggested that engaging staff, implementing sleep tools and techniques, identifying educational needs of patients and staff, recognising barriers to implementing sleep tools and techniques, and changing the organisation of care were important for QI.

Aim 5: Leadership behaviour, culture of innovation and adoption of QI methods in general practice. Sixty-three completed questionnaires (62%) were returned in 2007 and 47 (46%) in 2010; 32 practices completed both surveys. Although leadership behaviours were not commonly expressed, many practices reported a positive culture of innovation with significant positive correlation between leadership and innovation (r = 0.57; P < 0.001); apart from clinical audit and significant event analysis, QI methods were not reported as having been adopted by most participating practices. Percentage leadership score changed little over three years (increase 4.0 points, 95% CI -8.9 to 16.9) with little difference between participating and non-participating practices (7.6, -6.4 to 21.6) and no evidence of differential change (-1.5, -17.0 to 14.0). Percentage innovation culture scores showed a similar pattern (time -4.1 points, -15.1 to 6.9, group -1.6, -12.7 to 9.4, differential change 5.3, -7.8 to 18.5).

REST results B

Pilot cluster RCT: Out of 64 participants recruited, 37 completed the trial. There was no overall change over time (PSQI score increase per week 0.06 (95% CI -0.03 to 0.16) nor differential change between intervention and control groups 0.10 (-0.03 to 0.23) although the study was not powered to detect such a change. This pilot study confirmed that it was feasible to undertake a trial of education for primary care clinicians to deliver problemfocused therapy for insomnia in general practice. It also exposed problems with study recruitment, drop-out, and intervention fidelity, which should be addressed in the design of a full trial.

Appendix B **The projects**

This appendix provides an overview of each of the nine projects funded by the Health Foundation as part of the Engaging with Quality in Primary Care programme.

Total funding	£413,225			£417,603		£461,356		£408,649	
End date [final analyses received]	April 2010 [Final analysis of outcome data received Nov 2010] [Economic analysis not yet received]			April 2010 [Final self-	evaluation report received July 2010]	April 2010	[Final self- evaluation report received July 2010]	July 2010 [Final analysis of	outcome data received Nov 2010] [Economic analysis not yet received]
Project extension	Not applicable	:		Not applicable	:	Not	applicable	3 months	
Funding duration	3 years			3 years		3 years		3 years	
Improvement intervention	Education - structured training and support for	Education - structured training and support for GPs and physiotherapist Electronic prompt (sub-grouping tool) Training and support		Training and support programme. for school	nurses, with nurses recording their own practice	Tailored QI intervention	for each improvement developed, in light of analysis of barriers	2hr multidisciplinary training session w	periodic reinforcement provided by advocate educators Electronic prompts Reg. feedback to practices of data on
Scope	5 practices in one PCT	5 practices in one PCT 14 PCTs in		14 PCTs in South Thames	and the SE	27 practices in	one PCT	48 practices in 2 PCTs	
Study design	Before-and-after study	Comparison of two cohorts of patients who consult GP for back pain	First cohort prior to intervention; second cohort post-intervention	A cluster RCT of a training package for	school nurses	16 component projects	with differing approaches and outcome measures No comparators	Pragmatic cluster RCT comparing disclosure	and referral rates and service quality between 24 practices receiving intervention and 24 control practices (which received intervention in
Lead organisation	Keele University		Institute of Psychiatry, King's	College London	Milton Keynes	Primary Care Trust	Queen Mary, University of	London	
Project title and rationale	IMPACT	Current care 'biomedical'. physiotherapists and GPs fail to use current guidance on triage of patients and on	physical and psychological management of back pain.	QUEST	To improve the attitudes, knowledge and skills of school nurses in the recognition and management of common mental disorders in young people.	QUALITY:MK	 16 component sub-projects To embed a whole system approach to quality improvement, driven by primary care, patient engagement and evidence. 	IRIS	Lack of enquiry about domestic violence in primary care seen as a service failure by women experiencing abuse.

Table 45: Overview of projects

Project title and rationale	Lead organisation	Study design	Scope	Improvement intervention	Funding duration	Project extension	End date [final analyses received]	Total funding
IMAGE	CORE (The Digestive	Before and after study – with a follow up 12	39 practices in 9 PCTs across	Patient generated outcomes developed and	3 years	3 months	July 2010 [Final analysis of	£525,700
Current guidance is top- down, lacks patient input, and not well used.	Disorders Foundation)	months after initial consultation/baseline. No comparator.	England	incorporated intopractice guidelines Computerised decision support and written practitioner/patient material, support from local 'Gastro-champions'			outcome data received Nov 2010]	
LIMBIC	Bournemouth University	Case-control design Comparison of two	9 practices in 2 PCTs	8 half-day practice workshops + continuous	3 years	3 months	July 2010 [Final self-	£456,298
Failure to implement guidelines on rehabilitation of patients with back pain.	,	cohorts of patients who consulted GPs for back pain First cohort prior to intervention; second cohort post-intervention		improvement facilitator to support each practice to identify own learning needs, using PDSA cycles with clear action plans.			evaluation report received July 2010]	
EQUITY	Queen Mary University of	a) Before and after measurements as part	38 practices in Tower Hamlets	a) Health Equity Audit covering all 12000	3 years	3 months	July 2010 [Final self-	£431,660
Two-part project	London	of established audit of GP data. Comparison		patients on 3 disease registers with feedback			evaluation report received Oct 2010]	
a) Health equity audit with feedback and support to address inequities in		between practices in intervention PCT and 2 neighbouring PCTs.b) Refore-and-after		and support for underperforming practices. but av-led self-				
diseases (heart disease, type 2 diabetes, & COPD).		measurement of patient reported SF-36 physical and mental health		management programme, integrated into routine care pathways for chronic				
 b) Patient empowerment programme to increase patient knowledge and self care. 		scores .		diseases (developing existing PCT initiative).				

Table 45: Overview of projects

ß	200			850
Total fundir	£771,			£400,
End date [final analyses received]	October 2010 [Final self- evaluation report received Oct 2010] [No analysis of trial data yet received] [No economic evaluation yet received]			Oct 2010 [Final self- evaluation report received oct2010] [No analysis of trial data yet received] [No economic evaluation yet received]
Project extension	6 months			6 months
Funding duration	3.5 years			3.5 years
Improvement intervention	a) Trial arms: normal practice, an audit-based education package, and guidelines & prompts). with regular feedback of data			Intervention was a six month modelling exercise to allow GPs to select the final improvement intervention Two practices using the final improvement intervention selected in initial collaboration
Scope	127 practices across 8 localities in England	Single practice	Single practice	8 intervention practices in 1 PCT 4 practices in 1 PCT
Study design	a) Three armed cluster RCT with 3 arms	b) Measurement of compliance with care bundle	c) Qualitative evaluation	Pilot collaborative study: comparison of before and after prescribing rates for 8 practices in the intervention group with 94 other practices in same PCT. An exploratory RCT across 4 practices.
Lead organisation	Kidney Research UK and St George's, University of London			West Lincolnshire Primary Care Trust
Project title and rationale	CKD Three part project: a) To provide trial data on the best way to implement quality improvement in the management of chronic kidney disease in primary care.	b) To develop and implement a CKD care bundle in primary care.	c) To develop and test a package of patient empowerment tools that can be used in primary care.	REST Guidelines not followed, over prescribing of hypnotics, particularly expensive Z-drugs.

Table 45: Overview of projects

Appendix C The projects' logic models

This appendix sets out the logic models developed by the programmes.

Table 46: IMPACT logic model – developed June 2007

	Inputs	Outputs	Outcomes
Problem	Resources	Quantitative data on:	Anticipated outcomes
 Low back pain affects over 1/3 adults at any time; more than 70% of population in developed countries have at least one episode. Commonest reason why middle-aged people visit GP. Commonest reason why middle-aged people visit GP. Overall costs 1-2% of gnp; direct costs approx £251m pa. Accounts for half of the physios' workload (they see about 1/5 of all patients). Current care 'biomedical'. Physiostherapists and GPs fail to use current guidance on triage of patients and on physical and psychological management of back pain. 	 <i>People and expertise</i> Established Users Forum Established Users Forum Established and experienced multidisciplinary project team Existing primary Research Consortium in N Staffs and Cheshire IT support to develop computerised prompts <i>Knowledge/policy base</i> <i>Knowledge/policy base</i> RCGP Guidelines, 1999 European guidelines, 2006 ARMA Standards of care, 2004 Department of Health Muscloskeletal Strategy Plus strong evidence for importance of psychological factors and of effectiveness of CBT etc 	 Changes in clinical attitudes of GPs and physiotherapists (from questionnaire on attitudes pre- and post- training). Changes in self-reported behaviour (using standardised clinical vignettes). Changes in clinical practice, including: enhanced diagnostic triage (from questionnaire) linked interventions (using standardised summaries) healthcare utilisation (using 	 Improved outcomes for patients. Increased engagement of clinicians in QI. Enhanced capacity of participating practices for QI. Sustainable system of continued quality improvement for patients with back pain in participating practices. Unanticipated outcomes
 Study population 20 physios in the Central and East Cheshire PCT back pain service – 1500 patients a year managed on 11 sites. 20 GPs from referring practices. 	 Back-pain related READ data Back-pain related READ data Validated questionnaire on clinical attitudes: PABS.PT Validated screening tool Time/opportunity of costs those recruited into projects (clinicians, project team, patients). 	 baseline and post-training READ data). Patient outcomes – patients' perceptions of success (from interviews + follow-up questionnaire (GAS)). Evaluated training package 	evidence emerges.
 To actively engage local GPs, physios and NHS managers in the project. To change GPs' and physios' clinical behaviour to deliver evidence-based care- using 'screening for targeted treatment' approach. To improve outcomes for patients. To show project is sustainable – organisationally and economically. 	 Primary improvement interventions Education – structured training and support for GPs and physios. Organisational and financial prompts – new IT support. Study design Implementation of improvement interventions plus feedback to participating clinicians and patients. Comparison of process data (e.g. referrals) from participating practices with data from other practices held by the Research Centre in CiPCA. 	Assessment of cost consequences of the project.	

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Table 47: QUEST logic model – developed July 2007

	Inputs	Outputs	Outcomes
	Resources	 Recruitment of local PCTs. 	Anticipated outcomes
children aged 5-15 have a psychiatric rr (this includes 4% with anxiety and sion). % of children w diagnosed mental rr have contact with specialist MH ss.	 People and expertise Experienced service-user led multidisciplinary project team. Established working relation between IoP and Rethink. Clear divide between intervention component, and evaluation component of project. 	 Identified school nurse champions in each PCT. Results of national survey of school nurses (on best practice). Results of interviews with school nurses and teachers (exploring current practice and 	 Improvement in case detection. Evaluated training and support programme for school nurses. Changes in knowledge, attitudes and clinical
proportion of young people w mental ers remain undetected. nurses well placed to help but lack ence, knowledge, training and support. ppulation	 'Every Child Matters' 'Every Children and young people, 2004 NICE guidance, 2005 BMAguidance, 2006 EPOC report on QI, 2003 	 obstacles to change). Measures of clinical knowledge, skills and behaviour and monitoring systems (audits) that are feasible and acceptable to 	 benaviour or school nurses in participating PCTs. Improved integration of school nurses within primary care mental
te in Sutton and Merton PCT. tudy: 13 PCTs in SE England, SE and ndon - 10 school nurses per PCT.	 Existing data collection tools WHO primary care mental health materials (nurses' knowledge). Adapted version of Depression Attitude Questionnaire (nurses' attitude). 	 project participants. Data on volume and appropriateness of referrals by nurses to CAMHS and other convinces 	 nealth networks in participating PCTs. Virtual peer support network for school nurses (potentially UK wide).
s cant improvement in case detection of illness among school children. pment and evaluation of sustainable	Time/opportunity of costs those recruited into projects (clinicians, project team, patients). Project team, patients). Primary improvement interventions		Unanticipated outcomes To be completed as evidence emerges.
g and support programme for school and teachers. ed integration of school nurses within / care MH networks	 Development of training and support programme targeted at school nurses and teachers. Delivery of training to intervention group. Study design 1st year: pilot, developed in 1 PCT. 2nd year: cluster RCT in 13 PCTs (randomised by PCT). 		

Table 48: QUALITY:MK logic model – developed July 2007

Table 49: IRIS logic model – developed June 2007

	Outcomes	Anticipated outcomes
Q	Outputs	 Practices recruited in London and Bristol, and 24 practice champions identified. Domestic violence rates from participating practices (from READ data). Rates of referral to advocacy and/or counselling for each participating practice. Results of HEVAN assessment of domestic violence in healthcare setting. Results of CORE assessments from patients who take up specialist support - "Measures of Safety". Self-reported measures from participating clinicians – from PREMIS survey.
المستقد	Inputs	 Resources People and expertise Mutidiscipilinary project team and steering group (including patients) Support of senior management in both PCTs Knowledge/policy base Systematic reviews, 2006 Systematic reviews, 2006 Systematic reviews, 2006 Bestand and a collection tools Differentional guidelines, 2006 Existing data collection tools Existing data collection tools Survey monkey (clinician surveys) Survey monkey (clinician surveys) Time/opportunity of costs those recruited into projects (clinicians, project team, patients). Primary improvement interventions Mutifiaceted - designed to change individual clinical practice and organisation of care, comprising. Dur training session for clinicians with periodic reinforcement sessions (at practice meetings) feeding back practice counsellors and practice consellors in practice counsellors and referral Hundia domestic violence advocate Dor training session for clinicians with periodic reinforcement sessions (at practice meetings) feeding back practice counsellors and practice champions Hanned domestic violence advocate Dor training session for clinicians with periodic reinforcement sessions (at practice meetings) feeding back practice counsellors and practice champions Hanned domestic violence advocate Dor training for admit staff and practice counsellors and practice champions Hanned domestic violence advocate Patient of project admit of the project admit project admiterial practices counsellors and practice champions Hanney intervention in first 2 years.
		 Problem 25% of women in England and Wales are physically, emotionally or financially abused or threatened at some time. 89% of people who suffer 4 or more assaults are women. Prevalence of domestic violence among women seeking health-care is higher than in the gen. population; abused women experience many chronic health and psychological problems. Cost (per annum?) £23 billion primary care first port of call but women typically make 7-8 visits before disclosure; historically primary care has failed to respond adequately. Study population Cross section of practices from 2 PCTs: 12 in Hackney, 12 in Bristol. Plus 24 control practices Priorities Improve quality of care by: Priorities Improve quality of care by: Priorities Providing non-judgmental support. Offering referral to specialist advocacy service.

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	Inputs	Outputs	Outcomes
Problem	Resources	 Practices recruited 	Anticipated outcomes
GI disorders represent 10% of clinical workload of GPs and hospital	People and expertise	 8 GI champions identified and 	 Improved diagnosis of CD and IBD
specialists, and account for 15% of	Strong user involvement	 Patient centred 	 Improved care
 IBD, CD, IBS and GORD contribute 	 Experienced multidisciplinary project team Existing network of GPs – the Primary Care Society for Gastroenterology (PCSG 	outcome measures.	 A more patient centred
substantially to morbidity, impaired QOL and disability – 10-20% of	Knowledge/policy base	process of care and	and appropriate method of guideline
population regularly experience	 PCSG guidelines and report of national survey of current practice (2004/5) PSG midelines 	symptom/quality or life measures.	development and the
Many evidence-based guidelines are	NICE guidelines	 Details of interaction between patient- 	criteria.
available, but otten developed in a top-down manner mainly by		generated outcomes	and adherence to
secondary care clinicians. Little	Existing data collection tools	and the evidence base at practice and	guidance among
 Battent input: Guidelines fail to deal with some key 	 Routinely collected clinical data through EMIS computer systems in practices IBS QOL; QOLRAD; GSRS 	PCT level.	Addition of GI quality
aspects of management, stop short of innormation few have an innorm	EuroQol EQ-D	practice and of	criteria to the QOF.
on practice in primary care.	Time/opportunity of costs those recruited into projects (clinicians, project team, patients).	 Changes in practice. Assessment of cost 	Unanticipated
 GPs unaware of guidance or do not follow it. 	Primary improvement interventions	consequences of the	To be completed and
Study population	 Identification of quality criteria for each condition Implementation of quality criteria agreed with primary care clinicians and incorporation 	project.	to be completed as evidence emerges.
IBS and GORD: 500-600 prevalent	patient-based quality criteria, using:		
cases from small number of medium- large practices (population base approx	 local training programmes computerised decision support written practice and patient material 		
30,000).			
IBD and CD: 100-150 patients from a cluster of practices with population base of approx. 40,000.	 Study design Time series, comparison of baseline and follow-up data at 8 paired sites. 		
Priorities			
 To develop patient-based quality criteria. 			
 To raise awareness of and adherence to guidance among GPs. 			
 To reduce under-diagnosis (of CD and IBD). 			
 To identify, support and implement appropriate care pathways for patients 			
paulolito.			

Table 51: LIMBIC logic model – developed June 2007

	Inputs	Outputs	Outcomes
Problem Estimated 12 month prevalence rate of low back pain of 44%. 2nd highest cause of work loss. 1/10th visits to GPs; costing £1 billion per year. GPs' confidence in abilities to assess and treat patients is low. GPs are failing to implement guidelines on care and rehabilitation.	Resources People and expertise • Experienced project team: GP and nurse as joint leads and patients fully involved • Multidisciplinary Steering Group, including patient reps and commissioners Knowledge/policy base • European Commission Cost Action B13 Guidelines, 2006 • HTA trial – UK BEAM 2004 • NHMRC, 2003 • NICE, 2001 • NICE, 2001 • Plus extensive evidence of existing failures to comply with guidance • Plus literature on improvement practice • Existing data collection tools	 10 practices recruited. List of identified patient needs. An 'active inter- professional learning team' (including patients) developed in each practice. RMDQ change scores for each patient from baseline measurement and 3 month follow-up. Data on functional change, through Deyo Index and SF-12. Data on patient satisfaction, through 	 Anticipated outcomes Improved clinical outcomes for patients with back pain. Specific improvements in everyday practice. Teams that continue to learn and improve after project ends. Improvements in team working relationships. Personal growth and development in individual practitioners. Increased confidence to manage low back pain.
Study population 10 practices in 2 PCTs (B'mth and Poole, and S. Wilts):20,000 patients. Sample of 200 patients for 2 stage high evel evaluation.	 Clinical Value Compass: Includes: Clinical: Roland and Morris Disability Questionnaire (RMDQ) Functional: Deyo Index and SF-12 Satisfaction: Cherkin and Deyo Scale Costs: sickness certification Time/opportunity of costs those recruited into projects (clinicians, project team, patients). Primary improvement interventions 	Patient Satisfaction Scale. Assessment of cost consequences of the project.	Unanticipated outcomes To be completed as evidence emerges.
To improve clinical outcomes of treatment of low back pain (e.g. impact on function, psychosocial outcomes, return to work). To improve practice (e.g. implementation of national guidelines, team working, treatment planning, etc). To improve understanding and develop capacity for continuous improvement learning in participating practices.	 18½ day training workshops in each practice with feedback continuous improvement facilitator serial rapid PDSA cycles, coupled with evidence-based practice reflexive participant diaries Study design Case control study w control and intervention groups at different times: Pre- and post- measurement of validated outcomes. Patient questionnaires Clinician questionnaires. 		

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Dutcomes	 D00 patients recruited into blay led self- anagement groups D1ay led self- anagement groups D20% of new cases on 3 isease registers). D20% of new cases on 3 isease registers). D30% of new cases on 3 isease registers). D31% led self- anagement self-management programmes. D31% led self- management programmes. D31% led self-management programmes. D40% led self-management progr
Inputs 0	 Resources People and expertise Prople and expertise Strong user involvement (SAH). Ung-established, experienced multidisciplinary project team. High lexisting CEG facilitators. Knowledge/policy base Knowledge/policy base Knowledge/policy base National consensus on best practices for all 3 diseases. Established national and local guidelines. Inding courses. Existing data collection tools Well-developed IT base with routine use of CEG data entry templates and disease registers for 95% of GP practices (generally using EMIS software). MGUEST searches for reports. Itime/opportunity of costs those recruited into projects (clinicians, project team, pattents). Primary improvement interventions Filmicity recording by PCT. Primary improvement interventions Health equity audit of practices (generally using EMIS software). Multifactorial organisational change to reduce identified inequities + targeted intervention. Primary improvement interventions. Promotion of patient-led self-management groups. Lay-led and and and and and and and and and an
	 Problem The 3 selected health issues (CHD and heart failure; type 2 diabetes, and COPD) are major contributors to long-term morbidity, premature mortality, utilisation of NHS services. For each there is good evidence of substantial inequity, and good evidence and consensus for programmes for improvement. Tower Hamlets (TH) has large black/ ethnic minority population and is one of most deprived communities in UK with substantial variation between practices and between PCTs. Until recently, there has been little attempt to promote and integrate equity of delivery into routine primary care. Study population Interventions - all 44 practices in TH PCT (12,000 patients on 3 disease registers). To control practices in Newham and Hackney. To control practices in Newham and Hackney. To inform professionals about areas of inequity in their practices and support them to improve this. To encourage professionals about areas of inequity in their recommended care pathways. Help patients understand and manage their conditions, make best use of services and contribute to reducing inequality.

Table 53: CKD logic model – developed June 2007

. (Outcomes	 Anticipated outcomes Better management of chronic kidney disease and related morbidities: primary outcome is management of systolic BP to 130 mmHG in patients with stage 3 to 5 chronic kidney disease. Enhanced liaison between clinicians and individuals. Better liaison and secondary care. Adoption of new approaches across non-participating PCTs. New chronic kidney disease QOF targets. Unanticipated outcomes To be completed as evidence emerges.
	Outputs	 Practices recruited in 8 localities and 8 locality lead GPs identified. 'Expert' patients identified and recruited. Development of 3 principal quality measures for patients covering their: understanding, trust in care system; self- management. Development of 2 novel improvement interventions covering: primary care based pathways; patient empowerment. Data from participating practices on: clinical management; patient empowerment; patient empowerment; patient empowerment; patient empowerment; patient crecognised Competencies for clinicians. Development of recognised Competencies for clinicians.
	Inputs	Resources People and expertise People and expertise Advisory/Dissemination Board includes all national stakeholders in chronic kidney disease Unitik with NHS management at all levels Wutdisciplinary project team (including patients) Links with NHS management at all levels Knowledge/policy base Stronkedge/policy base Connoic kidney disease and related evidence base Chronic kidney disease and related evidence base Chronic kidney disease and related evidence base Connoic kidney disease and related evidence base Matter connomised primary care data) Time/opportunity of costs those recruited into projects (clinicians, project team, patients). Time/opportunity of costs those recruited into projects (clinicians, project team, patients). Guidelines and prompts Guidelines and prompts Guidelines and prompts Guidelines and prompts Firmary rane based education or the tenpowerment Costs those recruited into projects (clinicians, project team, patients). Time/opportunity of costs those recruited into projects (clinicians, project team, patients). Primary improvement interventions Guidelines and prompts Time of the based education Timery care based education or the tentowerment Timery care based education or the tert endowerment Timery care based but with control arm (usual practice) and 2 arms for interventions 3 and 4. Or the relater randomised study with control arm (usual practice) and 2 arms for interventions 3 and 4. Outour of the veide primery of terventions 3
		 Problem Chronic kidney disease is a chronic condition affecting 10% of population at different stages. Chronic kidney disease is an independent risk factor for CHD, ERF and all-cause mortality. Early identification and management (through tight control of BP) of the disease minimises consequences. Introduction of eGFR should enable more effective diagnosis and management in general practice, but in fact referral rates to specialists have increased, undiagnosed chronic kidney disease remains common and patients lack information. Study population B clusters of practices across England (12 practices (50,000 patients) in each cluster). Priorities To develop, implement and evaluate a range of QI interventions for chronic kidney disease QDF.

Table 54: REST logic model – developed July 2007

Outputs Outcomes	 Recruitment and engagement of local practices and practices and practitioners. Improved outcome practices and practices and practitioners. Reduced rate o Z-drug prescrit by 50% (in 3 ye survey (re QI tools?). Results from focus survey (re QI tools?). Results from focus groups. Results from initial pilot. Analysis and regular hypnotic prescribing to participating practices over 3 years). Ansessment of cost consistent, more 	 Improvement in practitioner knowle of and attitude to C and attitude to C and attitude to C techniques in participating pract integrating change general practice. New quality indica hypnotic prescribit QOF. Configurating to participated outcomes to participated as evidence emerges.
nputs	Resources People and expertise Established and experienced multidisciplinary project team, ir Lincolnshire Innovation and Change Collaboration (LINNC) PCT Patient Forum East Midlands Health Research Network <i>Chowledge/policy base</i> NSF for Mental Health, 2000 NICE guidance on insomnia, 2006 MedRec briefing (no. 17), 2002 Survey of GPs' beliefs about prescribing for insomnia, 2006 Existing data collection tools PACT (prescribing) data Validated instruments to measure clinical attitudes	Measures of sleep quality improvement: ISI; PSQI; STQ <i>Time/opportunity of costs those recruited into projects (clinician</i> <i>batients).</i> Primary improvement interventions Mill design interventions with patients and practitioners, to inclu Minimal: GP letter Academic detailing and educational outreach (selected practi Mass media influence – practitioners and patients Feedback of performance Possible use of psychological therapies (e.g. CBT) Study design Implementation of improvement interventions plus feedback t clinicians and patients. Observation of trends in treatment over time (12 months pre- intervention) Cost consequences analysis
	 Problem Insomnia is a common disorder affecting 6-48% of UK population, often accompanied by psychiatric/ neurological conditions. 1/2 those affected seek help, and are often given inappropriate long-term drug therapy despite evidence that non-drug measures are more effective. Z drugs increasingly prescribed compared w older, cheaper, more effective hypnotics. High costs to NHS. 	 Study population 5–10 pilot practices initially, with spread to 80% of 106 local practices (700,000 patients) within 3 years. Priorities Reduce rate of Z-drug prescribing by 50% in 3 years. Reduce rate of benzodiazepine hypnotic prescribing by 25% over 3 years. Increase use of non-drug measures by at least 100% in 3 years. Improve users' experience of management of insomnia.
Appendix D Evaluation protocol

This appendix sets out an abridged version of the original protocol for the programme evaluation by the RAND/ HERG team, as agreed with the Health Foundation in October 2007. As explained elsewhere in this report, we have made some amendments to our evaluation approach since this version was agreed.

1 Introduction

The evaluation of EwQPC will be undertaken at two levels – project level and scheme level. This proposal outlines the protocol for a four-year scheme-level evaluation of EwQPC, beginning June 2006 and ending June 2010. As a condition of their award, the project teams will develop projectlevel evaluation plans (i.e. self-evaluation). In developing this protocol we anticipate that the project teams and the external evaluators will work closely together.

Since July 2005 RAND Europe and the Health Economics Research Group (HERG) at Brunel University have undertaken a four-year initiativewide evaluation of EwQI. Given the similar rationale between both schemes, the evaluation team intend to follow a similar mixedmethodology evaluation. This will enable us to apply the lessons learnt during EwQI to this second evaluation, and to draw general conclusions from both. Our approach will include a modified logic model method and realist evaluation designed to identify mechanisms (or interventions), contexts and outcomes for each of the projects.

This will enable us to get inside the 'black box' of the projects and to achieve an understanding of clinical and organisational processes, and of clinicians' and users' experiences. We will also use surveys, interviews and workshops. In addition we will gather qualitative and quantitative data produced by the projects in their self-evaluations.

Overall we will seek to encourage a reflexive approach through which the evaluation contributes to learning during the life of the Scheme and helps to support a community of practice across the EwQPC projects.

The evaluation protocol developed originally for EwQI has been amended to reflect the differences between that programme and EwQPC: some activities have been expanded, others reduced.¹⁸

 As with the evaluation of EwQI, we anticipate that the development of the final EwQPC evaluation protocol will be an iterative process, drawing on the work and diversity of the projects. The lessons learnt in the first round should make this second iteration less demanding.

18 Similarities between EwQPC and EwQI (1) commitment to engaging clinicians in quality improvement (2) fully involving patients, service users and carers (2) emphasise the importance of sound evidence to support best practice (3) aim to produce robust, generalisable findings (4) aim to produce a sustainable enhancement of the capacity for quality improvement. Differences: EwQ1 explores the hypothesis that professional bodies can act effectively as catalysts for change, with clinical audit and feedback as the mechanism of choice and a general focus on secondary care, whereas EwQPC aims to enhance the capacities of primary care organisations and individual clinicians to improve the quality of care over a wide range of health issues and geographical settings.

- A framework for the project self assessments developed for The Engaging with Quality Initiative will be amended for the EwQPC projects.
- Our experience of how the EwQI projects used the self assessment framework will inform our discussions with/ guidance to EwQPC projects about the self assessment process.
- Our experience of the importance (and difficulties) of engaging with the EwQI projects, explaining our mutual roles and fully understanding their aims and objectives, suggest it is necessary to expand these activities, and we have allocated additional time for them.
- We will be able to use, and build on, the work we have already done in EwQI on the requirements of ethics approval for quality improvement projects.
- We will use, and build on, the work we have already done in EwQI to understand the state of quality improvement across areas of healthcare covered by both schemes.

2 Summary of key aims and methods

Aim one: To work with award holders on the development and implementation of their evaluation plans, in line with self-evaluation guidance that has already been produced, by:

- Supporting projects to collect reliable and valid data and to identify mechanisms (i.e. the specific aspects of their activities designed to produce the intended outcomes), contexts and outcomes, including overall costs and key measures of effect (including the presentation of a counterfactual i.e. what would have happened in the absence of the intervention).
- Where appropriate, helping projects to overcome the practical and methodological difficulties associated with measuring outcomes, including clinical data, non-clinical measurable

improvements, users' views, and process improvements as agreed with the Health Foundation and projects.¹⁹

Aim two: To synthesise the data and findings from the project level evaluations by:

- Supporting the projects to identify and analyse the evidence base for the impact of their inputs and processes on outputs and outcomes in a form that can be aggregated, where possible and practical, at Scheme level.
- From Scheme-wide data, analysing and estimating which improvement interventions, associated with which contexts, produce which improvements in clinical outcomes, which process improvements and which changes in users' views of the care they receive.
- Ensuring that these data include detailed evidence of the role and consequence of patients as active partners.

Aim three: To measure increase in professional engagement in clinical quality improvement by:

- Gauging the current state of clinical engagement in clinical quality improvement in each of the areas covered by the projects in two ways. First by an examination of the documentary evidence (including their original proposal) made available to us by the projects. Second, by following this up with interviews with project team members and key informants. This will include consideration of current organisational culture.
- Assessing the change achieved during the life of the Scheme by supporting each project in designing, implementing and analysing a survey of relevant participants towards the end of each project. This support will include guidance on content and on managing the survey itself. Some of the questions asked in the survey will be Scheme-wide (and will be the same for all projects) and some will be project specific.

They will include questions on clinician and patient engagement, and on cultural change. Returns will be anonymised but will allow us to identify respondents by function and clinical area. This will include a systematic evaluation of the Improvement Foundation's development programme, to cover the whole three years.

Aim four: To measure the effectiveness of the award scheme in leveraging external commitment to clinical leadership of quality improvement

- Identifying project-based evidence showing the influence of EwQ PC on public policies and on organisations seeking to engage primary care clinicians in quality improvement. This could mean, for example: standard setting (such as NICE guidelines and QOFs), development of quality measures, data collection and analysis, peer review and the evidence-based design of improvement strategies. This will require ongoing monitoring by the projects. This will be followed by a workshop identifying barriers, facilitators, processes and illustrations of externally-supported, clinically-led quality improvement. We will also encourage the collection of vignettes and illustrations by the projects to add force and vitality to the final report.

Aim five: To evaluate the increase in competency and infrastructure for quality improvement in the organisations benefiting from the awards by

 Alongside the outcomes of Aim 4, including questions in the end of project surveys (under Aim 3) which identify how the organisations benefiting from the awards have supported quality improvement. These activities will be supported by in-depth interviews with members of relevant organisations focusing on their contribution to the quality agenda including development of quality measures, data collection and analysis, peer review, and quality interventions.

Aim six: To assess the influence of the scheme on policy and on the knowledge base by:

 Assessing the likely legacy of the projects through an appraisal of the suitability, feasibility, sustainability and acceptability of the legacy plans and through a wider assessment of their impact on the environment of quality improvement.

Aim seven: To produce summative costs of the scheme and its consequences

We will complete a summative assessment of the overall cost of the Scheme and its consequences.
 This will necessarily include our interpretation and assessment of the projects' self-evaluations.
 We will invite feedback from the projects for factual accuracy but we will arrive at our own judgement about their interpretations.

3 Summary of tasks to achieve each aim

We have outlined the key tasks and outputs associated with each aim.

Aim one: To work with award holders on the development and implementation of their evaluation plans, in line with self-evaluation guidance that has already been produced.

Task 1.1

We will work with the project teams to support their self-evaluation plans, including data identification and validation. Based on our experience in EwQI, we have allocated three days of activity with each project.

Before the first meeting with each project the evaluation team will produce a logic model for each project based on the project's proposal. The logic models will help the external evaluators and the project teams reach a common level of understanding of the context, inputs, outputs, outcomes, and anticipated outcomes of each project.

Discussions with the project teams will involve:

- Supporting the project-level evaluations throughout the life of the Scheme, on the basis of the amended EwQI self-assessment guidance. This involves defining the objectives of the project self-evaluations, and identifying all the relevant data, including data related to the experiences of users.
- Encouraging systematic data collection on costs and on anticipated key effects.
- Working with project teams to identify inputs, processes, outputs and outcomes in order to specify more precisely which inputs, associated with which processes, and in which contexts produced the intended outputs and outcomes.
- Working with each project team to help them develop, and agree with us, a 'counter-factual'. (The counterfactual will allow the teams to assess how much change during the life of the Scheme was attributable to the Scheme and how much to 'secular' activity). These discussions will be supported by a "diary" (developed with input from the projects) of contemporaneous quality improvement activities in primary care ('secular' activities) during EwQPC that might act as confounders.
- Supporting projects' understanding of the broad conceptual model for building systemic capacity outlined in Leatherman and Sutherland.²⁰
- Supporting projects' understanding of the layers of organisational culture outlined in Leatherman and Sutherland, which demonstrate what needs to be changed if quality is to be improved, i.e. beliefs, values, behaviour etc.²¹
- Ensuring projects' understanding of factors associated with success that are identified in the Health Foundation tender.

- Ensuring that the data collected by the projects can be effectively brought together in our final report and that all projects collect some categories of data (on costs, for example).
- Maintaining a 'diary' showing what has been learnt from the external evaluation team's involvement with the projects.

Outputs of task 1.1

The evaluation team will review the EwQI selfassessment guidance to ensure that it is pertinent to the EwQPC projects. Each project team will produce an initial self-evaluation plan (based on the guidance notes) after the first six months of their award. Projects will also be required to submit updated self-evaluation reports to the Health Foundation on a six monthly basis. We will produce a review of these plans and provide feedback to the projects. We will also introduce each project to logic models and encourage them to construct and update logic models of each intervention. We will review with the Health Foundation and teams the usefulness of these as a means to describe project developments.

Task 1.2

All the projects are required to involve patients, service users, and, where appropriate, carers. We will assess the experiences of the users as "active partners" in the projects, seeking to establish, for example, their role in defining outcome measures and their contribution to the design and implementation of improvement interventions and to governance arrangements.²² If projects are planning surveys of users, we will discuss these surveys with the project teams to ensure that they meet the requirements of both levels of evaluation.

Outputs of task 1.2:

 A paper on user involvement across EwQPC, covering users' roles, responsibilities and perceptions, discussed with the project teams and produced at the end of the Scheme.

²⁰ Leatherman and Sutherland in *The Quest for Quality in the NHS* pps. 26 & 28. Leatherman and Sutherland make relatively few specific analytical comments on primary care as a site for quality improvement not least because, at the time they were writing there was evidence of a lot of new activity but it was too soon to collect evidence on the impact of this on patients.

²¹ Leatherman and Sutherland in The Quest for Quality in the NHS p. 170.

²² Leatherman and Sutherland in The Quest for Quality in the NHS p. 174.

 The evaluation team will discuss user involvement with project teams during the second round of face-to-face meetings (Jan/Feb 2008). The evaluation team will include initial findings in their first Annual Report (April 2008) to the Health Foundation.

Task 1.3

Discussions with project teams will also consider how the counterfactual can be addressed. In the context of other simultaneous efforts to improve quality in healthcare, we need as far as possible to identify the confounding effect of such developments on our data.

- There is no single approach to this problem that is right for every healthcare context. One approach is to benchmark not just the work of clinicians to whom EwQPC improvement interventions apply (for example, those in receipt of specific training schemes), but also the work of comparable groups outside the Scheme. Another approach is to use existing historic trend data to support assessment of the impact of the intervention. We will explore planned approaches with each project team.
- To set the context, we will provide an ongoing list of key quality initiatives in primary care in the UK during EwQPC, developed with input from the projects, and will ask the project teams to consider what impact, if any, each has had on their project.

Outputs from task 1.3:

- An agreed approach on addressing the counterfactual with each project team, developed as part of their work on their end-ofproject self-assessments
- The evaluation team will discuss projects teams' approach on addressing the counterfactual during the second round of face-to-face meetings (Jan/Feb 2008). The evaluation team will include initial findings in their first Annual Report (April 2008) to the Health Foundation.
- A discussion paper on the counterfactual for EwQPC as a whole.

Timing for aim one

On balance, the tasks under Aim 1 will occupy most time in the first nine months of the Scheme, but there will be continuing support for the projects until their final reports are completed. The reflexive approach mentioned above will continue throughout the evaluation.

Aim two: To synthesise the data and findings from project level evaluations.

Task 2.1

We will synthesise the data and findings from project level evaluations using a modified form of logic modellingor other mapping activity within an overall framework informed by realist evaluation and develop a logic model or other conceptual map for the Scheme as a whole.^{23,24} This generic model will seek to illustrate how - at each level within the health system (which might be labelled macro, meso and micro), and within the broad context described above - schemes such as EwQPC influence prior determinants such as beliefs, values, and patterns of behaviour to produce changes in clinical and non-clinical outputs. This will be an iterative and reflexive process, developed collaboratively with the Health Foundation, the projects and the development team, and will provide an important tool for informing and influencing others. Data from the projects should include detailed evidence on the role of patients as active partners in quality improvement. The evaluation team anticipates that the data generated by the projects will be sufficient and accurate enough to allow conclusions to be drawn. It is not able to quality assure these data and nor can it provide a data collecting function. Should the evaluation team become anxious about the extent or quality of the data they will make the Health Foundation aware of this and discuss ways of addressing this. If data collection by the projects has slipped there will be a review, in or around June 2008, where we either push back the activities of years 3-4 or we find some other way to ensure the availability and completeness of the evidence. June 2008 might also be an appropriate time to review the level of support to be made available to the projects.

²³ http://www.wkk.org/Programming/|ResourceOverview.aspx

²⁴ Pawson R and Tilley N. Realistic Evaluation. London: Sage; 1997.

Outputs from aim two

A regularly updated conceptual map of how the scheme is functioning to track its evolution over time (six monthly) for the EwQPC as a whole which will form the basis for work on subsequent aims and for later papers and reports.

Timing of aim 2

Most of the activities under Aim 2 will take place during the first and second year as they will involve working with the projects to ensure that data are collected that are relevant to the aims of the Scheme and, where possible, that these data are collected in a way that facilitates comparison and contrast. However, as with Aim 1, these activities will also continue, probably in a less time-consuming way, until the end of the projects.

Aim three: To measure increases in professional engagement in clinical quality improvement

Task 3.1

Our first task will be to gauge current professional/ clinical engagement through an examination of the documentary evidence, using the projects' original proposals and other evidence made available to us by the projects.

Task 3.2

Following this we will conduct interviews with project team members and key informants, who will be identified following advice from the projects. These interviews will take place at the October 17th and 18th 2007 residential event in Northampton, and if necessary by telephone. Through these interviews we will explore the state of affairs in the quality improvement context of each project before it has had a chance to influence that setting. This will include exploring the influence of factors such as organisational culture, team building, team support, organisational support, patient, service user or carer involvement, and so forth on clinical engagement in quality improvement. We envisage interviewing some two to three people with an understanding of the context of each project.

Typically these should be selected from clinicians and patient groups but might also include expert academics working in this area.

Task 3.2

Alongside this, we will complete a systematic evaluation of the EwQPC Leading Improvement Team Programme (Improvement Foundation (IF)/ Karen Picking and Associations (KPA)). Our proposed approach was decided upon as a result of a three-way discussion on 19th July 2007.

Task 3.4

We will assess the change achieved during the life of the Scheme by supporting each project in designing, implementing and analysing a survey of relevant clinicians towards the end of the project. Each survey will ask project-specific questions, and will also ask questions relevant to the scheme as a whole - answers to which will be analysed by the evaluation team. The surveys will be sent to a population selected by each project to ensure that the views of all clinicians involved in the projects are represented. Our support for these surveys will include guidance on content and on managing the survey itself. Questions on the role of relevant primary care organisations, on patient engagement, and on cultural change will be included. These surveys will be anonymised but will allow us to identify respondents by function and clinical area. Both the Scheme-wide and project specific questions will attempt to identify how far credit for change can be attached to the activities of EwQPC, as opposed to other pressures (in the medical profession in general, in their institution, or in their specialty/profession). These surveys will take place towards the end of each project to allow the impact of the Scheme to be felt.

Task 3.5

In the final year of the Scheme, we will also conduct a web-based Delphi survey to identify: how professionals can best be engaged in quality improvement initiatives; what impact this is thought to have on clinical outcomes; and how this work best interfaces with the engagement of patients, other professionals and health services managers to leverage external commitment to clinical leadership of quality improvement. Given persisting confusions about the ethical requirements re surveys of NHS staff, we will approach NRES for a view on whether or not this requires ethics approval, and, if so, obtain the necessary approval. There appear to be no overwhelming problems with securing approval.²⁵

Outputs of aim three

To enhance the impact of any findings, these data will be presented in a series of before and after spidergrams showing our summary of the situation at the start of the Scheme and the subjective views of clinicians in each project area at the end of the Scheme. These are intended to facilitate communication of findings (rather than being an analytical tool to create findings).

We will also produce a short briefing paper to inform Aim 4 (September 2009).

Timing of aim three

The documentary assessment and interviews will take place between February and July, 2008. The surveys will take place in the final year of each project and the Delphi in the final year of the Scheme.

Aim four: To measure the effectiveness of the award scheme (during its life) in leveraging external commitment to clinical leadership of quality improvement

Task 4.1

The web-based Delphi survey described under Aim 3 will be used to deepen our understanding of this question.

Task 4.2

The results of the Delphi, and the short briefing paper produced on the basis of the project surveys under Aim 3, will be used to support a workshop on leveraging external commitment at which one or two representatives from each project will identify barriers, facilitators, processes, outcomes and illustrations.

Output from aim four

The output of this workshop will be a paper on facilitators, barriers, processes, outcomes and illustrations drawing upon the experience of project teams throughout the Scheme. This output will directly feed into the delivery of Aimsand 6 which consider the contribution of EwQPC to the infrastructure for quality improvement in primary care and the long-term sustainability of its aims.

Timing of aim four

The initial aspects of this aim will be delivered through delivering Aims 2 and 3. The briefing paper and workshop will be produced in the final year of the Scheme (January 2010).

Aim five: To evaluate the increase in competency and infrastructure for quality improvement in primary care organisations.

Task 5.1

In pursuit of Aim 4, we will by this stage know which QI supports are considered by clinicians, patients and others to be the most relevant to clinician-led quality improvement in each projects' context. Based on this understanding we will conduct in-depth interviews with members of the primary care organisations focusing on the extent to which those organisations have engaged in a set of critical tasks, including: standard setting, development of quality measures, data collection and analysis, peer review and the design, based on evidence, of interventions to predictably improve patient care. In particular, we will work with engaged Primary Care Trusts in order to better understand the impact of, for example reorganisation, payment by results, Quality Outcomes Framework, and practice-based commissioning.

Task 5.2

We will also know how the project teams think organisations in and around primary care might more effectively support clinician-led quality improvement.

25 'Building on Improvement' Implementing the Recommendations of the Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees Department of Health August 2006.

Here we intend to identify how changes in the competency and infrastructure of primary care organisations during the course of EwQPC have enhanced clinician-led quality improvement. We therefore propose to look at what these organisations have done to support quality improvement relevant to the Scheme. How effectively have they involved users? We expect that the surveys and Delphi will also cast further light on this.

Task 5.3

We will in particular include questions about the role of patients (either individually or through their organisations) in contributing to the infrastructure for quality improvement.

Outputs of aim five

A briefing paper to inform the appraisal workshop in Aim 6 (February/March 2010).

Timing of aim five

The main activities under Aimwill be carried out in the final 18 months of the Scheme.

Aim six: To assess the influence of the scheme on policy and on the knowledge base.

Task 6.1

We will systematically evaluate the projects' legacy plans, using the evidence collected during the evaluation to identify the acceptability, suitability, feasibility and sustainability of the plans. This will provide an opportunity both to evaluate likely impact but also, in the reflexive spirit of both levels of evaluation, to enable the project teams to adjust their legacy plans to provide a more sustainable influence. ('Sustainability' refers to the extent to which the aims and objectives of the project are likely to be sustained into the future. The 'legacy plan' concerns the specific steps taken by each project to secure this.)

Task 6.2

We will ask the project teams to identify the impact their work has had on the development and implementation of other quality schemes, such as, for example, the development of a relevant QOF.

Task 6.3

We will ask the project teams to identify any de facto or planned publications, reports, or presentations arising from the project. We will also list our own.

Task 6.4

We will then take the finalised legacy plans and combine them with the key findings of the Scheme in a brief report.

Task 6.

Using this as background together with the workshop findings delivered under Aim 4, we will run an appraisal workshop with stakeholders (professionals bodies, NHS Confederation, Healthcare Commission, Audit bodies, NICE, NHS R&D, PCTs, NHS Institute for Innovation and Improvement etc) and with policy makers (Department of Health, HM Treasury etc).

Task 6.6

Conceptually, we intend to consider different levels of quality improvement in primary care and their interactions. These levels are: specialism; local/ institutional; national; and international.

Outputs from aim six

A briefing paper outlining the approach and key findings of the appraisal workshop. As noted below we will also feed the results of this task directly into the final report (April/May 2010).

Aim seven: To produce summative costs of the scheme and its consequences.

Task 7.1

We will work with the projects to explore what data they can provide to estimate costs.

This will involve records/estimates of the time resources (by classes/levels of staff) devoted to the project (that would not otherwise have been incurred) by those most directly involved/affected. This is time regardless of who is paying for it. Project teams will also need to set out all the (main) consequences: describing them, measuring them and valuing where possible/easy. These consequences might include improved patient satisfaction (using some index); reduced serious events (estimated number, possibly monetized); fewer formal complaints (number only); changes in demands on specialist advice (frequency and numbers, possibly costed); and reduced risk of subsequent serious events (expressed as a reduction in some risk score).

Task 7.2

We will provide further advice on these requirements to the project teams, and, in particular, will work in the early months of the EwQPC to ensure that the projects establish mechanisms to collect suitable data.

Task 7.3

We will also collect data throughout the EwQPC on the 'central' costs of the scheme, i.e. the costs to the Health Foundation, including the costs of the contracts with the development team and the external evaluators.

Task 7.4

The budget also includes the cost of a junior economist from HERG to help estimate the costs and consequences. We have allocated this person to spend two days per project.

Outputs from aim seven

The outputs of this Aim (and Aim 6) will feed directly into the final report for wider dissemination. However, we would also like to reflect on the findings in a more academic setting – for example peer reviewed journals or academic conferences - (as yet to be determined).

Timing of aim seven

Much of this work will be on-going throughout the Award Scheme.

The appraisal workshop will be planned at the end of the Award Scheme. The final reports and papers will be produced at the end of the Award Scheme.

4 Additional tasks

The evaluation team will provide initial support to the Health Foundation as follows: commenting on the draft invitation to quote for the development programme; commenting on the draft guidance for full applications, particularly concerning self evaluation; contributing to the selection process for the awards. Twelve days have been allocated in the budget for undertaking these tasks.

Dissemination: We will work actively with the Health Foundation and the projects to maximise the impact of the evaluation. In addition to publication in academic and practitioner journals we will publicise findings through RAND Europe's own mechanisms and participate in wider activities in collaboration with the Health Foundation. We acknowledge that the dissemination strategy will be led by the Health Foundation and we will work to support this strategy.

Ethics approval: We are satisfied that the work of the evaluation team does not require separate ethical approval with the possible exception of the web-based Delphi detailed in Aim 3 task 4. We will seek advice from NRES on this and act on their advice. However, we identify the need for the projects to secure ethics approval as an important risk facing the Scheme as a whole.

Quality Assurance: RAND Europe has a strong and well-established quality assurance process. This starts with the assumption of responsibility for quality lying with individual researchers and their managers but it is reinforced through an internal quality assurance process led by senior researchers within the organisation. Given the complexity of this evaluation, we propose to engage with Quality Assurance throughout the life of the evaluation (rather than the more typical quality assurance of the final report). We have identified this as eleven days work throughout the project. More can be found about RAND's quality assurance system at http://www.rand.org/randeurope/about/quality. html Management Team: The evaluation of the EwQ in Primary Care Award Scheme will be undertaken by the Engaging with Quality Initiative evaluation team. Professor Tom Ling will be project leader, and Amanda Scoggins will assume the project manager role from Wija Oortwijn. The Health Foundation has already obtained CV's of the evaluation team and any additional CV's can be provided on request.

5 Methods

The proposed evaluation is methodologically pluralistic. There is disagreement in the literature concerning whether evaluation should have the primary purpose of proving that standards have been achieved or improved (Peryer) or of improving delivery or policy (Weiss). Our evaluation is concerned to do both; there will be both a summative element intended to measure delivery (as far as possible) and a formative element intended to assist learning and improvement. In this section we clarify how we propose to use logic modelling or other conceptual mapping, realist evaluation, and appraisal workshops.

The methodological approach used to 'get inside the black box' in the projects combines a form of logic modelling in an over-arching framework informed by 'realist evaluation'. There are a number of reasons for (and some limitations resulting from) this choice. Realist evaluation is particularly appropriate in this context for a number of reasons. First, it aims to establish clear relationships between the project and outcome. Secondly, it assumes that there is an underlying theory of change behind the programme explaining how it brought about the measured change. Finally, it is sensitive to the context in which the programme is to be delivered. These are persuasive claims on behalf of this approach and they immediately address some of the limitations of experimental and quasi-experimental methods (such as identifying control groups that are both cooperative and sufficiently similar, and understanding causal mechanisms). However, there are risks and limitations and we guard against these in our proposal.

First, the underlying theory, according to realist evaluation, is identified through the use of a series of Context-Mechanism-Outcomes (CMO) for each intervention. In improving clinical quality in primary care the context might be higher than normal referrals to specialist care and the mechanism might be a new approach to professional training. Behind the apparent simplicity of this, however, there are methodological and practical difficulties. Any intervention could have many CMOs each of which, in theory, could form the basis of a 'miniexperiment'. Logically, only when all of these experiments have been completed can absolutely unequivocal transferable lessons be learned.

At a methodological level, there are also difficulties in establishing how local and how global the CMOs should be. To address these limitations we propose working with the projects and the Health Foundation to construct logic models where they can use their professional, tacit and formal knowledge to identify the inputs, processes, outputs and outcomes associated with particular interventions to improve the quality of clinical interventions. In effect we are narrowing down the possible range of CMOs by drawing upon practitioner and other expertise. Consequently, only a manageable number of mechanisms will be considered in each project after discussions with the project participants and the Health Foundation. This guards against the challenge that realist evaluation approaches can lead to a large and unmanageable number of CMOs. It also draws upon the skills and expertise of clinicians in understanding the logic connecting programmes with outcomes. This guards against the risk that any external researchers will have only a limited knowledge of the local context. In addition, it guards against the danger that realist evaluation might be unable to distinguish between a failed theory and a failed implementation. By focusing on the logic model, as we propose, it should be possible to identify and explain more easily failures and successes. Thirdly, it brings experienced clinical judgement into the data collection processes of the project. Synthesis of the data and findings will be done using global logic models or using other conceptual mapping.

We will use the Delphi method for conducting a survey of clinicians. The Delphi method was developed at RAND in the late 1950's as a way to collect and synthesize expert judgments.²⁶ The Delphi method differs from a conventional survey in that participants are invited to reassess (in several rounds) their initial judgments in the light of the overall pattern of results, including the average or median of responses and reasons of participants for holding extreme positions.²⁷ By keeping the process of questionnaires and feedback anonymous, Delphi is intended to avoid undesirable group effects (i.e. social desirable answers, assertive individuals are often leading the discussion etc).²⁸Although the process tends to move to consensus, this is not necessarily the objective of the Delphi method. A median score may reflect considerable divergence in views, but the survey results will allow the experts to understand the reasoning that lies behind divergent views. This knowledge may lead to some secondary convergence of views, but not necessarily.

The appraisal workshop builds on a process RAND has developed during recent years, particularly with work at the Medical Research Council, the Department of Health and Breakthrough Breast Cancer. It involves working with a group of informed people to identify suitability (i.e. is it the right tool for the job), acceptability (will key stakeholders support it), feasibility (how easy is it to implement) and sustainability (will it be more than a short-term solution).

We will provide an evidence base to support judgments about the overall cost-consequences of the scheme. We do not propose to arrive at a single economic ratio but we will provide a strong evidential base to allow others to make a judgment.

6 Risk Assessment

Data availability and time risk

There is a significant risk that projects will collect incomplete data, and/or that they will not be able to

collect and analyse the completed data set to agreed timetables.

Following from this, there is a risk that meaningful data will not be readily available to make comparisons across EwQPC as a whole.

This risk will be managed by the evaluation team providing substantial early support to the projects as they devise their evaluations. Both through the expertise we have assembled, and in the time allocated, we have ensured that these risks will be minimised. We will also be aware of the quality of data being produced by the projects and will alert the Health Foundation as soon as potential problems are identified. We will have a review meeting with the Health Foundation on or around June 2009 to review the accuracy and completeness of data coming from the projects. The Health Foundation will also have an important role in ensuring that the projects meet their contractual obligations and, if necessary, responding flexibly to support failing projects.

Biases in information

There is a risk of a 'conspiracy of optimism' where all involved wish to make the Scheme succeed and this may encourage a reporting bias. Similarly, there is the danger of a 'Hawthorn effect' where the act of measuring would itself create turbulence in the data. This risk will be minimised by relying wherever possible on objective data and by communicating the danger of this risk to the projects and so encouraging a reflexive management of the risk within the projects themselves.

Non-cooperation by projects

Some of the data required to make Scheme-wide comparisons will involve self-reporting by healthcare professionals. As busy people, they may not complete this or, perhaps under pressure of time, produce a less than accurate picture of their engagement with quality.

27 Methodology of the Fistera Delphi. FISTERA – THEMATIC NETWORK – IST-2001-37627 FISTERA DELPHI Report, 2005. Available at: http://fistera.jrc.es/docs/RP_The_FISTERA_Delphi.pdf

28 Delphi Method. Available at: http://www2.chass.ncsu.edu/garson/PA765/delpi.htm

²⁶ Gordon T, Pease A. *RT Delphi: An efficient 'round-less' almost real time Delphi method.* Technological Forecasting and Social Change, 2006; 73: 321-333.

This risk cannot be removed but we can be aware of it and where emerging findings differ radically from other projects, then we may need to go back to the projects concerned for further reassurance.

We do not believe that the demands on the time of professionals and others are unreasonable and we will minimise this risk by ensuring at a very early stage to ensure that all involved are aware of the information needs of both levels of evaluation, and of what data they are expected to provide.

In the Engaging with Quality Initiative we have achieved good relationships with the projects, which suggest that this risk will be manageable.

Ethics Approval for projects

The evaluation team have indicated from the outset that project teams will need to apply for ethics approval at the earliest opportunity. Delays in this could significantly compromise the ability of the projects to carry out their work. This risk may need to be actively managed by the Health Foundation. Members of the evaluation team worked hard with the Health Foundation and the Support Team to ensure that NRES's predecessor, COREC, understood The Engaging with Quality Initiative and, as a result, was supportive. This eased some of these risks. We also made COREC aware of EwQPC, and anticipate the same result in this instance.

Management

This is a complex project involving internal and external players and different disciplines from within RAND Europe and HERG.

However, we have a long track record of working to tight timescales and in close collaboration. To manage the relationship with the projects, we will spend time making ourselves known and accessible to the project teams. Through The Engaging with Quality Initiative we have already established a close relationship with the Health Foundation, with Tom Ling as the key contact point. In addition we will seek to develop a good working relationship with the development team. The management of the project has been fully resourced.

Financial Risks

Under the terms of the contract, RAND Europe will be responsible.

Dissemination: Perhaps the greatest risk of all is that EwQPC has no impact or legacy. The proposed methods outlined above are intended to be engaging and to some degree, the dissemination will be achieved through the evaluation. However, we would want to work with the Health Foundation early on to devise a dissemination strategy aimed at key policy makers, in the first instance, and then at the practitioner and professional community.

Appendix E Guide to the self evaluations completed by the projects

This appendix sets out an abridged version of the guide to completing the self-evaluations issued to projects by the RAND/ HERG evaluation team in February 2007.

1 Introduction

This short guide has been produced by the Health Foundation and the external evaluation team to help EwQPC projects plan for their self-evaluation. It outlines the Health Foundation's brief for the project self-evaluation and then lists nine key questions which this should address. This is followed by brief guidance on the sorts of information you will require.

Our hope is that this guidance will help the projects in at least three ways. First, it should clarify the relationship between the projects' self-evaluation and the programme evaluation, which will be the responsibility of the external evaluation team. Second, it should allow projects to treat their self-evaluation as a 'living document' or diary, for which they can begin to collect data and complete from the start of the project, thus avoiding the common difficulties associated with pulling together the final report at the very end of the project. Third, it should provide a focus for data collection which may save projects from collecting data which are not used.

We do not anticipate that this document will be the primary vehicle for disseminating results to your colleagues and more widely. Its primary audience will be your fellow stakeholders in the project. But it is anticipated that the projects will use this as the basis for any wider dissemination. Neither do we anticipate that completing this document should involve disproportionate effort; indeed by using it at this early stage we hope to save both time and effort.

2 The Health Foundation's brief for project self-evaluations

You should explain how you will evaluate your project against the aims of the scheme. In particular, you should tell us how your evaluation will address the following questions:

- How will you tell whether the project achieves measurable improvements in patient care?
- How will you assess improved engagement of clinicians in QI?
- How will you assess whether capacity for QI in primary care has been enhanced?
- How will you assess the cost consequences of the project?
- How will you assess how the project achieved what it did? (For example we expect the evaluation to illuminate the barriers to change and the methods used to overcome them)
- How will you assess whether chance is in fact improvement?

- How will you assess whether the QI identified as a result of the project is attributable to the project itself, rather than to external QI initiatives that are happening at the same time?

3 Key questions to be answered in the project self-evaluation, and guidance notes for each question.

Project self-evaluations should cover all the objectives outlined in the the Health Foundation brief. The sorts of information the end-of-project self-evaluations will need to address are outlined below. Further details are given in the guidance in the boxes that follow.

Q1. Background

Why was this project needed? Why did you think that your approach would be effective? Did you consider other approaches? If so, why were these rejected?

What was the project team's understanding of the self-evaluation and its purpose? Did this change during the project?

Guidance on Q1

- Provide the background information for the project presented in the proposal.
- Describe the purposes of this self-evaluation.
- List the intended users of the results of the project. How did you communicate with them?
- List the broad questions that you have sought to answer through this self-assessment

Q 2. Process – what improvement intervention was introduced, to whom and how?

What did the project team do? Who did they involve? How were these activities evaluated?

Guidance on Q2

2a. Development and implementation of improvement interventions

- Describe what improvement interventions were implemented
- Who developed the intervention?
- Who delivered it, how and when?
- To whom was it directed?
- What factors facilitated/hindered its implementation
- How was the intervention evaluated, what performance measures were used and by whom were they developed?

2b Data collection, analysis and feedback

- Describe what data were collected to support the project, and how those collections were organised.
- What sorts of data were collected, e.g. audit/survey data, qualitative/quantitative data etc?
- How were these data validated?
- How were collection processes (proposed or existing audit, survey etc) developed and evaluated, by whom and when?
- How were data analysed and fed back to the participants?
- How were data subsequently used in the project, and by whom?

2c Involvement/engagement of primary care clinicians

- How were primary care clinicians involved in the processes covered by 2a and 2b, what were their roles and responsibilities?
- What were their self-perceived roles in QI?

2d Involvement/engagement of other groups

- How were patient representatives/client groups involved and what were their roles? The potential role of patient representatives in EwQPC was emphasised in the original information made available to projects as they developed their proposals. This question is intended to explore what happened in practice and how that role might be developed, and evaluated, in the future.
- In addition, and where it seems relevant to the project, we would also like to explore whether others,, such as healthcare managers, were involved in the project and its implementation. If so, what were their roles and responsibilities?

Q 3. Outputs

What did these activities produce? How were these outputs evaluated?

Guidance on Q3

- Which parts of the project were implemented as planned?
- Were they implemented to time?
- Which were not fully realised?
- What factors facilitated/hindered these achievements?
- How did the recipients of the improvement intervention perceive it?

Q4. Who did what?

Who was involved in designing, implementing and evaluating the project? What was their contribution?

Guidance on Q4

List the members of the project team

- Were all these people also involved in the self-evaluation?
- Were patient representatives included? If so what role did they play?

List the skills and expertise required in designing, implementing and evaluating the project

- Was the range of skills available in-house appropriate and comprehensive?
- If not, what were the identified gaps, and were you able to fill them with eternal support?

Identify sources of external support, including support from the external evaluators and the Improvement Foundation as well as from other outside sources

- Describe how this support was used.
- Comment on its value to the self-evaluation.

Q5. Outcomes - did the project work?

What did these activities achieve in terms of:

- Measurable improvements in patient care.
- Increase in the levels of professional engagement in QI.
- Increase in the knowledge base.
- Sustainable arrangements for improving quality of care in this field of medicine?

How were these changes measured?

Guidance on Q5

List the anticipated outcomes. These include:

- Improvements in patient care
- An increased engagement of primary care clinicians in quality improvement
- A sustainable system of quality improvement in the area of medicine covered by the project
- A transferable system of quality improvement to other areas of medicine
- An increase in knowledge and understanding of quality improvement in healthcare

Were these realised? Can identified improvements be quantified? List any unintended outcomes

Q 6. What difference did the project make?

The EwQPC is only one of a number of initiatives currently addressing quality improvement in the UK health system generally, and in particular specialties. How much difference was really made by the project itself in the context of all this other work?

Guidance on Q6

This is the key question in any evaluation. It applies equally at project level and to the external evaluation. What would have happened anyway without the project? Without the benefit of a randomized controlled trial this question is difficult to answer, although appropriate study design can help. It requires a detailed understanding not only of the outcomes of the project, but also of why those outcomes occurred and what caused those changes to happen. It also requires a detailed understanding of other quality initiatives and their potential impact on the outcomes of the project.

The exchange of influence is not just one way. The converse of this question concerns the overall influence of EwQPC on healthcare policy. This is something the external evaluators have been asked to assess. Here the project teams can help by considering, perhaps through the development and appraisal of their plans for spread and sustainability, what identified impact their work has had on the development and implementation of other quality initiatives, for example on the development of a relevant QOF.

Q 7. What are the cost consequences of the project?

Without attempting to provide a monetary value to the outcomes of the project, how much did the project cost in real terms and with what benefits? Could this have been achieved more easily in other ways?

Guidance on Q7

The external evaluation will include an examination of the cost consequences of the initiative. To do this, the external evaluators will need the projects to provide data to estimate costs. This will involve keeping records/producing estimates of the time resources (by classes/levels of staff) devoted to the project (that would not otherwise have been incurred) by those most directly involved/affected. This is time regardless of who is paying for it. Project teams will also need to set out all the (main) consequences: describing them, measuring them and valuing them where possible/easy. These consequences might include: improved patient satisfaction (using some index); reduced serious events (estimated number, possibly costed); fewer formal complaints (number only); increased demands on specialist advice (frequency and numbers, possibly costed); and reduced risk of subsequent serious events (expressed as a reduction in some risk score). Further advice on these requirements will be available from the external evaluators.

Q 8. Why did the project work?

- Factors that helped/hindered.
- How were clinicians and patient groups engaged and with what consequences?
- What were the key ways of bringing about change (for example, repeat audit, training, information provision) and how well did these work?
- Could the project be seen to have worked for some people but not for others?

Guidance on Q8

Describe the factors that contributed to the success of the project.

Describe the factors that impeded the project.

For example: 'We set out thinking that if we were to engage X, we would need to develop Y, for Z. However, in the course of developing Y we realized B. That led us to redesign C and D. We extended this approach and found that

Q 9. What arrangements are in place to ensure the spread and sustainability of the project's work?

How might the result of the project 'fit' with wider changes (for example, in the professions, funding, training, organisational context)?

Guidance on Q9

- What arrangements are there for the spread and sustainability of the project?
- Whose responsibility are they?
- How robust are they?
- How will wider changes in the healthcare system support or undermine the improvement processes identified by the project?
- In retrospect, how would you have modified your project in the light of this self evaluation?

Appendix F Evidence base for the programme evaluation

This appendix outlines the data sources from the nine projects which the RAND/HERG team have used to conduct the external evaluation of the Engaging with Quality in Primary Care programme.

The data sources upon which this evaluation is based can be divided into two sources:

First, there are data which we asked the project teams to produce especially for our evaluation. These sources are set out in table 55.

Second, there are the data which individual projects chose to provide to the evaluation team. These are set out below.

Third, we have set out in a separate table (Table 56) the measures of clinician engagement available to the evaluation team from each project.

1 Summary of data required from the projects for the evaluation

Table 55: Data collected from the projects for the programme evaluation

Data collection mechanism	Collection period	Participants
Appraisal workshop to discuss implications of the emerging findings.	January 2011	Attended by representatives from 2 EwQPC projects; 6 representatives from the Health Foundation; 4 members of the RAND/ HERG evaluation team.
 Submission of summary tables, providing overview of: sources of data on outcomes overview of implementation measurable patient outcomes increase in the knowledge base sustainable arrangements for improving the quality of care a transferable system of QI to other areas of medicine. 	June 2010–December 2010	9 EwQPC projects.
Submission of interim and final self- evaluation reports.	Final reports submitted between June and December 2010	9 EwQPC projects.
Meetings throughout the award period with project teams to discuss self- evaluation reports (including final meeting to discuss final self-evaluation report).	Final meetings between January and July 2010	All 9 EwQPC projects.
Telephone interviews with PCT commissioners.	September–October 2010	8 key informants involved in commissioning in areas which 7 EwQPC projects were operating.
Web-based survey of clinicians.	April 2010–August 2010	Participating clinicians in EwQPC projects (n=44).
Interviews with service users.	April 2009	8 service users from the EwQPC projects.
Interim and final evaluation of the Leading Improvement Teams Programme.	March 2007–June 2008 (interim) July 2008–July 2009 (final)	Interim: Interviews: project leaders and managers from the nine EwQPC projects (n=17); The Health Foundation (n=2); and LITP (n=2) Final: Interviews: project I leaders and managers from the nine EwQPC projects (n=18); and LITP (n=2).

2 Additional data collected

Moving onto the other data produced by the projects which, although not specifically requested to support the programme evaluation, the evaluation team had sight of and drew upon where possible.

These are outlined on the following pages.

It should be noted that we have only listed information that the evaluation team have drawn from in producing this final report.

2.1 IMPACT

Data on outcomes from IMPACT were submitted in the summary tables. They did not provide any separate final report.

2.2 QUEST

Data on outcomes from QUEST were submitted in the summary tables. They did not provide any separate final report.

2.3 QUALITY:MK

The QUALITY:MK project team provided a number of additional reports, in addition to that outlined in Table 55. These were as follows:

- An overview and summary of the QUALITY:MK story.
- Summary report and full report on the qualitative evaluation study commissioned by Milton Keynes PCT.
- Report on the alcohol brief intervention, including description of the intervention, outcomes of the pilot (number of referrals, referral source, patients engaged in the intervention, referrals on from the intervention, measures of proportion of patients who reduced alcohol consumption and case studies of client satisfaction).
- Report on the complex patient medication management, including description and background to the project, outcome data

(number of patients involved, costs saved) and learning points.

- Report on diabetes service redesign, including description and background to the project and some quantitative outcome data and qualitative outcome data.
- Report on observations from project team about the information management tools to support LES, including a description of the project.
- Report on public and patient engagement, including description and background to the project, qualitative and quantitative data about, for example, number of commissioners participating in training about PPE, participant-reported satisfaction with training and number of hits on Q:MK website.
- Report on the smoking cessation project, including background and description of the intervention, and quantitative data on: number of four-week quitters; quit rate per 100,000 population; % of quitters established using CO monitoring 85%; number of those setting a quit date; number of practices and pharmacists signed up to the LES.
- Final report on weight management project, including background and description of the project and outcome measures such as % of year six pupils considered obese, results of an online survey measuring knowledge and confidence on treating overweight and obese patients, numbers of referrals to weightmanagement service.
- Final report on IMPACTE groups, including background and description of the groups, results (in the form of the number of groups and indicators of their activity levels) some of the results from practices who had used IMPACTE groups (for example, changes in prescribing over time), results of a survey of practices about attitudes to evidence-based medicine at the beginning and at the end of the project.
- Booklet from IMPACTE groups on Patients Unmet Needs and Doctors Educational Needs.
- Report of a workshop on patient and public involvement.

- Publication by the Q:MK team guidance on setting up patient participation groups.
- Publication by the Q:MK team principles of public engagement.
- Report of a workshop to review learning on clinician engagement in Q:MK.
- Slides giving numbers of clinicians engaged in Q:MK.
- Publication by the Q:MK team principles of clinical engagement.
- List of reports and websites.

2.4 IRIS

In addition to the data in table 55, the IRIS team provided:

- Report on the randomised cluster trial. Includes data on:
 - Primary outcome measure: rates of referral to advocacy and/or specialist domestic violence agencies.
 - Secondary outcome measures: domestic violence disclosure rate; results of Physician Readiness to Manage Partner Violence Survey (PREMIS) – looking at whether individual physician attitudes, knowledge and behaviour in relation to domestic violence has changed after the intervention.
 - Paper on 'Clinical Roles and Barriers Among General Practitioners and Nurses in Addressing Domestic Violence' – results of a Qualitative study nested in a pragmatic clustered randomised controlled trial.

2.5 IMAGE

The IMAGE team submitted a report on summary findings – baseline data and one-year follow-up data.

2.6 LIMBIC

The LIMBIC team provided an appendix to their final self-evaluation diary. This included:

- Dissemination strategy.

- A report of review visits to practices in 2008.
- A report on participants' reflections on LIMBIC workshops.
- Summaries of the practice improvement projects.
- Report on the roles and responsibilities exercise.
- List of presentations and posters.
- Publications by the LIMBIC team in back care journal.
- LIMBIC practice profiles.
- Report on experiences of the project team on using templates in primary care.
- Note on attendance at workshops.
- Description of the clinical value compass.
- Results of on-line survey evaluating the wicki.
- Report on the LIMBIC master class.

2.7 EQUITY

The project team produce a final report, a summary report and an appendix to the final report, which included:

- Description of project, methodology and time line.
- Baseline data in three chronic conditions in three localities.
- Information on the dissemination of the health equity reports and feedback from practices.
- Year two report.
- Report on mapping self-management groups in Tower Hamlets for patients with COPD, ischaemic heart disease and heart failure, and diabetes.
- Findings and results:
 - Health equity audit data.
 - Findings of a survey assessing primary care clinicians' understanding of self management groups.
 - Analysis of the 'Healthy Moves' SMG run by Social Action for Health, based on data from the SF-36.
 - Findings of a qualitative study exploring factors influencing attendance at selfmanagement programmes in Tower Hamlets.

2.8 CKD

The CKD team provided the following additional information about their project:

- A first draft of a report on findings from qualitative research (focus groups) with GPs and practice nurses about their perceptions of the national guidelines and framework for managing chronic kidney disease.
- A report on the development, implementation and evaluation of the care bundle for chronic kidney disease, including a description of producing the care bundle, reliability of different parts of the care bundle.
- A summary of communication and dissemination activity.
- A report summarising the development, testing and implementation of the confidence questionnaire (practitioners' confidence in managing hypertension in patients with chronic kidney disease).
- A summary of the final report, outlining key lessons learned in the project, and the final report (describing the project, its aims, approach and activities).

- A spreadsheet outlining participating practices and their involvement at different stages of the project.
- Executive summary of the CKD Patient Empowerment programme.
- Report on challenges and successes experienced by the project team in recruiting practices.
- Report on the methods used in the process evaluation (not completed at time of writing) of the CKD project (consisting of focus groups; post-investigation questionnaire; questionnaire administered at the start and end of the project examining clinicians' confidence in managing CKD; case study of one practice).

2.9 REST

The REST team project provided only the data shown in Table 55.

Measures of engagement and attitude	Findings	Project teams' comments [evaluation team comments]
IMPACT Engagement: Measure: use of the sub-grouping tool by the GPs (from practice activity data) Attitudes: Practitioner questionnaire	Use varied between GP practices, and also at an individual level within practices The sub-grouping tool was used on average approximately 41% of the time when it would have been appropriate to do so. In 2008, the project team said: 'We have captured baseline information about the attitudes, beliefs and reported behaviours of 45 GPs and 32 physiotherapists; and post-training data from 21 GPs and 21 physiotherapists.'	Attempting to maximise engagement of GPs in the use of the new sub- grouping tool and clinical software has required consistent input from the study team. We have provided feedback on recruitment at both Practice and individual level in electronic and hard copy form at two-monthly intervals. We have offered to visit each practice to meet with GPs either individually or in small groups to reinforce the messages from the best practice updates (for those who attended), or to introduce the study to any new members of staff. [We do not have further details or the results of this questionnaire.]

Measures of engagement and attitude	Findings	Project teams' comments [evaluation team comments]
QUEST Engagement: Measure1: Referrals to CAMHS teams Measure 2: Change in levels of skill, examined through nurse interviews using patient vignettes Attitudes: Attitudes of school nurses measured by means of the Depression Attitude Questionnaire	These data were either unavailable or of very limited relevance, making it impossible to infer any realistic projections concerning the impact of the package on the quantity and quality of psychiatric referrals between schools and specialist services. The skill of participating nurses in detecting depression showed no significant change after the training within the sample as a whole. Confidence in working with people with depression showed significant change associated with the training programme. The extent of increase in this confidence indicator at the 3-month post-training measurement had a mean value of 9.2 (95% CI 3.3 to 15.1) (measure range: 0-100).	The baseline level was reasonably good, and it is possible that there are limits on the change in a complex clinical behaviour that can be derived from a relatively brief training package.
QUALITY:MK Engagement: Measure: 1. General, numbers involved in QI activities. 2. Specific activity - IMPACTE groups. Attitudes: 2007 – baseline assessment of attitudes towards evidence-based practice.	GPs from 23/28 practices involved Protected Learning Time e.g. Jan 2010 – 32 GPs Pathway reviews/service redesign – 13 GPs CEBM training workshops in Oxford – 6 GPs QUALITY:MK Steering Group - 4 GPs QUALITY:MK GP champions : 4 in all. IMPACTE groups: 50 GPs + 17 GPs in training. The 6 main groups (3 are too new to evaluate) have discussed at least 84 topics and made 56 practice changes.Level of response was very low; results not statistically significant. Level of response was very low; results not statistically significant.	Documenting these practice changes has been a challenge within the limits of the project resources. The wide spread of the topics and groups has made such documentation problematic. For many topics there were not readily available markers such as prescribing.
Late 2008 – online survey of training needs in this area Spring 2009 – online survey to identify current behaviours and training needs around quality improvement techniques.	Response level was very low.	

Measures of engagement and attitude	Findings	Project teams' comments [evaluation team comments]
CKD RCT arm	Sent to 30 practices (201 individual clinicians). 148 questionnaires were returned (74% response rate) from 93% (28/30) practices.	Practitioners were less confident at the start of the study in managing chronic kidney disease than hypertension or diabetes. There was also a lack of
Attitudes: Confidence questionnaire in managing chronic kidney disease.	Most participants (86.5%, n=128) at the start of the study were confident in managing hypertension, whereas only 58.8% (n=87) were confident in the management of hypertension in patients with chronic kidney disease, and 60.8% (n=90) were confident in managing hypertension in patients with chronic kidney disease and diabetes. Over half of the respondents (49.3%, n=73) were confident in achieving lowered blood pressure in patients with chronic kidney disease. Confidence was especially low in the management of patients with chronic kidney disease and significant proteinuria, who are at higher risk of adverse renal and cardiovascular outcomes. 42.6 % (n=63) of respondents lack confidence with identifying significant proteinuria in patients with chronic kidney disease and only 41.9% (n=62) are familiar with using urine protein results to manage chronic kidney disease. Patients with chronic kidney disease and both proteinuria and diabetes are a high risk group in whom lowering systolic blood pressure is particularly important. There appears to be a lack of confidence in treating these patients and this is reinforced by a low achievement of blood pressure targets, with only 31.3% patients meeting at goal of 130mmHg as recommended by NICE.	confidence in managing proteinuria, combined with a knowledge gap in interpreting proteinuria test results. Clinicians are least confident in managing individuals with chronic kidney disease who are at highest risk, i.e. those with proteinuria. The quality of care in chronic kidney disease, measured by ascertainment of standards in national guidance and for QOF payment thresholds, is lower where confidence is low. This is particularly apparent in chronic kidney disease and in people with chronic kidney disease and diabetes. [A more detailed analysis of the findings is being published. A modified confidence questionnaire was sent out to participants towards the end of the study to measure the effects of the intervention. These data are still being analysed.]

Measures of engagement and attitude	Findings	Project teams' comments [evaluation team comments]
IMAGE	Coeliac disease: 179 patients, protocol used 52 times (29%)	Disappointing usage of protocols.
Engagement: Measure: protocol use by condition (from practice activity data). Attitudes: Questionnaire to establish how participating GPs regarded the IMAGE templates, used them and assessed their value, or otherwise, in the management of their patients.	GORD: 573 patients, protocol used 79 times (14%) IBS: 373 patients, protocol used 68 times (18%) Colitis: 106 patients, protocol used 13 times	Looking at protocol usage against patient outcomes showed that it was associated with greater improvement in some psychological measures, had an inconsistent impact on resource utilisation such as consultation rates, and had a positive effect on appropriateness of prescribing.
	(12%) Crohn's: 76 patents, protocol used 12 times (16%)	
	Sent to 173 GPs in 39 practices. Responses from 95 (54%).	
	55% of GPs who used the protocol took less than 10 minutes to complete it, the remainder completing in between 11 -20 minutes.	
	29.5% said the protocol had changed their practice, 52.5% said that it hadn't and 5.5% didn't know.	
	24.6% said the protocol had benefited their patients, 37.8% said that it hadn't and 42.6% didn't know.	
EQUITY Self-management arm	100 healthcare professionals (37%) responded from 31 of the 38 practices. 88% of responders had heard of the EPP and 76% were aware of the courses based within Tower Hamlets	
Attitudes: Survey of all healthcare professionals (GPs, nurse practitioners, practice nurses) from all GP practices in Tower Hamlets to explore understanding of and current referral rates to generic self-management groups such as the expert patient programme (EPP) and disease-specific self-management courses such as HAMLET (for diabetes).	52% were not aware of the referral process to self-management groups.	
	The perception of disease-specific courses was more positive than for the generic EPP.	
IRIS	463 primary care clinicians were asked to complete PREMIS: 171 in east London and	
Attitudes: A cross-sectional survey (PREMIS) to investigate whether a training and support programme targeted at general practice teams increased the identification of women experiencing domestic violence and subsequent referral to specialist agencies.	292 in Bristol. Responses from 272 clinicians (overall response rate 59%). The response rate was higher in Bristol (64%) than in East London (50%). Demographic characteristics of the study sample (183 general practitioners and 89 practice nurses).	

Measures of engagement and attitude	Findings	Project teams' comments [evaluation team comments]
LIMBIC	Most practice teams had 4-6 members.	Most teams had between 4 and 6 practice members and had between 7
Engagement:	The percentage of overall attendance at workshops ranged from 44% to 88% across	- 8 facilitated meetings over the project duration. Practice teams were usually
Measure: team working (illustrated by attendance at workshops and facilitated practice meetings). Attitudes: 1. A questionnaire to assess GP attitudes to the management of back pain before and after the learning workshops. (The 'Attitudes to Back Pain for General Practitioners' Questionnaire (ABQ-GP).) 2. Other clinical staff were also asked to complete a questionnaire.	 the 9 practices. The percentage of overall attendances at facilitated practice meetings ranged from 0% to 80%. 1. GPs had moderately positive attitudes to back pain management (103/168) both before and after the workshops. Attitudes to managing back pain were generally positive both before (mean 103/168) and after (mean 104/168) the workshops with no significant difference between them (p=0.821, Mann Whitney test). 2. Most staff did not complete this, results not used. 	by a GP but some with the exception of practice D which had shared leadership with a physio and GP and practice A, which had an HCA as the champion. The characteristics of the two teams which had the most quorate team meetings and attendance at workshops (C,E & F) included: team 'preparedness for the project', all rating their patient involvement positively, each emphasising good communication and teamwork within the team and sharing their work across practices. Conversely for those teams with low attendance at practice meetings and workshops (A & D) reflections suggested the teams were not cohesive, with poor communication both within the team and across the practice. Time to meet was an issue for all practice but clearly some managed this better than others. Commitment to the project and prioritising it would appear to be critical. It might have been that early patient involvement was the catalyst for this.
REST	Sent to 102 practices in Lincolnshire at start of the project.	Second round of QI survey will provide clearer picture of the effects of the
Attitudes: Baseline survey to explore frequency of involvement in QI activities, experience of QI tools and techniques, and existing practice culture.	63 responses (62%). 'Most practices reported a positive culture of innovation, featuring relationship most strongly, followed by targets and information but rated lower on other dimensions of rewards, risk and resources. There was a significant positive correlation between leadership behaviour and the culture of innovation ($r = 0.57$; $P < 0.001$). Apart from clinical audit and significant event analysis, quality improvement methods were	REST project on professional engagement in QI. [It is not clear this has yet be undertaken].

²⁹ Apekey T, McSorley G, Tilling M, Siriwardena, N. Room for Improvement? Leadership, innovation and uptake of quality improvement methods in general practice. *Journal of Evaluation in Clinical Practice* 2010; ISSN 1356-1294.

Appendix G Clinicians' survey report

This appendix sets out the findings from a webbased survey of clinicians on their views of the Engaging with Quality in Primary Care programme, regarding:

- motivations for participating in their project; at the outset and during the project
- activities undertaken as part of and before their project
- support for their project from general practices (GPs) and Primary Care Trusts (PCTs)
- barriers to engaging clinicians in QI
- attitudes towards engaging clinicians in QI
- changes to future professional behaviour as a result of participation in their project.

1 Identifying and approaching participants

In this study, the population targeted was the clinicians involved in the projects. To help improve the response rate, each project manager of the nine projects was asked to forward, by email, a letter to participating clinicians inviting them to complete the online survey. In most cases, project managers forwarded the survey to clinical leads, who then forwarded it to participating staff since not all the project managers knew the email addresses of participating staff. The web-based survey took around 10 minutes to complete. We asked the project managers of each project to give an indication of the potential number of respondents. Some were unable to provide that information. The four that did provided the following:

- IMPACT: 60 GPs and 25 physiotherapists
- QUEST: 140 clinicians
- IRIS: About 94 clinicians
- LIMBIC: 30 clinicians.

Five projects (QUALITY:MK, IMAGE, EQUITY, CKD, REST) were not able to estimate the potential number of respondents. The survey was online for four months (30 April – 30 August 2010).

Four projects delayed inviting clinicians to complete the survey until June or July 2010 to avoid clashes with their own project activities, and this resulted in the survey being available online for longer than anticipated.

While the survey was in the field we asked project managers to forward one reminder by e-mail to potential respondents.

2 Response rate of the survey

By 30 August 2010, a total of 44 clinicians had responded to this survey. This included GPs, nurses, physiotherapists and others (see figure 21 for distribution). The findings from this survey now follow.

Figure 21: Job title of respondents



Note: Nurse includes school nurse, practice nurses and other specialist nurse.

We did not analyse responses across the different projects because the number of respondents by project were too small, as shown in table 57.

3 Findings

The following sub-sections and figures summarise the views of participating clinicians about their Engaging with Quality in Primary Care project. Below we present overall results.

3.1 Participants' motivations

We asked the clinicians about their motivations for participating in their project, both at the outset and during the life of the project. We presented them with a list of factors and asked them to rate the factors as 'a very strong factor', 'a motivating factor' and 'not a factor'.

We analysed the clinicians' responses using a scoring method: a score of two is given if the factor was indicated as 'a very strong factor'; a score of one is given if it is considered as 'a motivating factor'; and a score of zero if it is 'not a factor'. Blanks and 'don't knows' are excluded. The average score for each factor is reported in Figure 22.

The key motivations cited for participating were improved professional skills and training, greater evidence-based standardisation of professional

Table 57	Response rate to	on-line survey	v hv	project
Table 57	Response rate to	on-me survey	y Dy	project

IMPACT	14
QUEST	10
QUALITY:MK	0
IRIS	6
IMAGE	1
LIMBIC	4
EQUITY	4
CKD	5
REST	0
Total	44

practice, improved patient satisfaction/experience and building a knowledge base on how to improve patient experience.

Cost saving for the organisation was cited as the least important motivation, with 26 out of 44 clinicians responding that it is not a motivating factor.

The scores for the factors at the outset were generally similar to the scores during the project, although the latter were slightly higher. The only exception was 'decreased patients' waiting time', which received a slightly lower score during the project than at the outset. See figure 22.

3.2 Activities involved

We asked the clinicians about QI related activities which might have been part of their project, and whether they had undertaken these before their involvement in their project. Keeping up-to-date with how best to provide care, drawing on materials other than clinical practice guidelines, and keeping up-to-date with the clinical practical guidelines were the two most common activities. The former was slightly more common before their project; but as part of their project, the latter become slightly more common. See figure 23.

Other activities, such as taking part in regular informal and formal discussions, and in training for clinicians and managers, were also common. Becoming a member of the clinical governance committees was the least common activity, with only 10 respondents undertaking it previously and three respondents undertaking it as part of their projects.

3.3 Support received

When asked about the kind of support the project might receive from GP practices and PCTs, clinicians cited securing good inter-professional relationships as the most common support. This is true for support received from both GP practices and PCTs. See figure 24.

Compared to GP practices, PCTs provided more support in terms of committing the trust/board to engaging healthcare professionals to improve the quality of healthcare (also in figure 24).



Figure 22: Participant motivations

Note: Blanks and don't knows excluded





Figure 24: Support received



3.4 Barriers

We presented the clinicians with a list of factors that might serve as barriers to engaging clinicians in QI and asked them to indicate the extent to which these barriers featured in their project. Clinicians were asked to rate each one as 'not an obstacle', 'a small obstacle', or 'a large obstacle'. We analysed the clinicians' responses using a scoring method: a score of two was given if the potential obstacle was indicated as 'a large obstacle'; a score of one was given if it was considered as 'a small obstacle'; and a score of zero if it was 'not a obstacle'. Blanks and 'don't knows' were excluded. The average score for each factor is reported in table 15. The limited number of staff available for QI was considered the most important obstacle, followed by lack of technical QI skills among clinicians (for example, skills in measuring impacts or costs) and lack of financial rewards (figure 25). Generally, the option of 'a large obstacle' was rarely chosen.

3.5 Attitudes

We asked clinicians to indicate the extent to which they thought that engaging in structured QI initiatives, such as Engaging with Quality in Primary Care projects, was an appropriate part of their role. Eighty-eight per cent of the clinicians responded that QI was 'to a large extent' part of their roles while 12% responded that it was 'to a small extent' part of their roles (figure 26).

No one thought that QI was 'not at all' an appropriate part of their clinical role. One clinician commented that 'quality improvement is an essential part of every clinician's role'.

Figure 25: Perceived obstacles



Note: Blanks and 'don't knows' are excluded





Figure 27: Do you think courses on the principles and practices of QI should be included in the training and professional development of clinicians?





Figure 28: To what extent your involvement in project has changed your attitude towards engaging in QI?

Figure 29: Do you anticipate that you will change your professional behaviour as a result of your participation in your project?



When asked whether courses on the principles and practices of QI should be included in the training and professional development of clinicians, the vast majority (95%) answered yes (see figure 27). One clinician commented that clinicians should be made aware of QI principles early in their career as it would help 'develop strong managers/leaders for our future' and could lead to 'new quality improvement initiatives being put into practice'. Another clinician felt that 'such courses are appropriate, but making time to attend them may be an issue'. Another clinician highlighted that 'much quality improvement knowledge will be gained experimentally doing work with support and coaching, however to make that knowledge explicit and recognisable theoretical teaching and reflection on what has been done will be valuable?

When asked if involvement in their project has changed their attitudes towards engaging in QI, 16% reported that their attitude changed a lot, 48% reported their attitude changed a little, and 36% reported their attitude had not changed at all (see figure 28).

Clinicians who felt their attitude towards QI had changed a lot commented that by being heavily involved in the project allowed them to get a much better understanding of improving practice.

One clinician commented they had 'gained expertise in techniques linked into literature' and another said they would 'use the principles learnt earlier rather than wondering why something has not worked'. Two clinicians who felt their attitudes had not changed commented that they have 'always been committed to deliver a high quality service' and 'this is something I have been trying to achieve for the past 30 years'.

3.6 Changes to future professional behaviour

When asked whether they anticipated that they would change their professional behaviour as a result of their participation in their project, almost three-quarters (73%) of the respondents responded that they thought they would change their behaviour. See figure 29. The changes in behaviour mentioned by clinicians included 'trying to disseminate quality issues to more practice members'; 'better awareness, identification of, and ability to help sufferers of domestic violence as a result of IRIS project'; 'consolidation and refinement of clinical knowledge'; 'clearer guidelines and safer guidelines to work with'; and 'continued involvement in quality improvement within my team and the larger organisation, as required'.
4 Annex: detailed responses to each question in the Engaging with Quality in Primary Care clinicians' survey

This Annex sets out the responses to each question in the survey. (DK = don't know)

Section A: Motivations for participating in your project: at the outset and during the life of the project

A1: Please indicate the extent to which each factor motivated you to participate in your project, both at the outset and during the project, on a scale of 1 - 3.

At the outset						
	1	2	3	DK	Blank	Total
Improved patient satisfaction/experience	1	16	25	1	1	44
Greater evidence-based standardisation of professional practice	0	17	27	0	0	44
More cost-effective services	17	17	8	1	1	44
More equitable care	5	19	18	1	1	44
Better sharing of information through uniform patient reports (e.g. standardised discharge letter)	16	12	10	6	0	44
Less unacceptable variation in the quality of care	6	17	20	1	0	44
Improved guidelines, legislation and regulations	7	16	21	0	0	44
To decrease patient waiting times	17	16	8	3	0	44
Cost savings for the organisation	26	12	2	3	1	44
Improved inter-disciplinary working	7	16	20	0	1	44
Improved professional skills and training	2	10	31	1	0	44
Building knowledge base on how to improve patient care	2	15	26	0	1	44

During the project						
	1	2	3	DK	Blank	Total
Improved patient satisfaction/experience	2	14	26	1	1	44
Greater evidence-based standardisation of professional practice	0	13	29	1	1	44
More cost-effective services	11	21	8	2	2	44
More equitable care	4	18	17	2	3	44
Better sharing of information through uniform patient reports (e.g. standardised discharge letter)	12	13	11	7	1	44
Less unacceptable variation in the quality of care	5	16	18	3	2	44
Improved guidelines, legislation and regulations	5	17	19	2	1	44
To decrease patient waiting times	19	9	9	5	2	44
Cost savings for the organisation	23	13	2	4	2	44
Improved inter-disciplinary working	7	10	24	1	2	44
Improved professional skills and training	2	7	33	1	1	44
Building knowledge base on how to improve patient care	2	11	27	2	2	44

Section B: Activities involved as part of your project

B1: Please indicate whether or not you have undertaken each of these as part of your project, and whether you had undertaken each of these before your involvement in your project.

Undertaken as part of their Engaging with Quality in Primary Care project						
	Ν	DK	blank	Total	Total	
Participating in clinical audit	24	16	1	3	44	
Taking part in training for clinicians and managers (e.g. continuous medical education)	37	5	1	1	44	
Keeping up-to-date with clinical practice guidelines	41	1	1	1	44	
Taking part in regular formal discussions with colleagues about improving healthcare quality (e.g. gaining formal feedback and advice from colleagues or attending clinical review meetings)	33	7	2	2	44	
Taking part in regular informal discussions with colleagues about improving healthcare quality (e.g. discussing how patient plans can be improved)	36	7	1	0	44	
Doing rapid learning cycles (e.g. Plan-Do-Study-Act)	11	22	10	1	44	
Performing peer review of practice with the aim of improving quality	24	17	2	1	44	
Participating in clinical networks	23	15	5	1	44	
Being a member of clinical governance committee(s)	3	38	2	1	44	
Keeping up-to-date with how best to provide best care to each patient, other than clinical practice guidelines (e.g. reading journals)	37	5	1	1	44	
Using appropriate IT support systems to support healthcare quality improvements	34	10	0	0	44	
Writing about how to improve healthcare quality (in peer or non-peer reviewed literature)	8	31	5	0	44	
Helping patients and service users to participate in improving healthcare quality	29	12	1	2	44	

Undertaken before their Engaging with Quality in Primary Care project						
	Ν	DK	blank	Total	Total	
Participating in clinical audit	32	9	1	2	44	
Taking part in training for clinicians and managers (e.g. continuous medical education)	37	5	2	0	44	
Keeping up-to-date with clinical practice guidelines	40	2	2	0	44	
Taking part in regular formal discussions with colleagues about improving healthcare quality (e.g. gaining formal feedback and advice from colleagues or attending clinical review meetings)	38	6	0	0	44	
Taking part in regular informal discussions with colleagues about improving healthcare quality (e.g. discussing how patient plans can be improved)	40	3	0	1	44	
Doing rapid learning cycles (e.g. Plan-Do-Study-Act)	15	22	7	0	44	
Performing peer review of practice with the aim of improving quality	32	10	1	1	44	
Participating in clinical networks	25	16	3	0	44	
Being a member of clinical governance committee(s)	10	32	2	0	44	
Keeping up-to-date with how best to provide best care to each patient, other than clinical practice guidelines (e.g. reading journals)	43	1	0	0	44	
Using appropriate IT support systems to support healthcare quality improvements	33	8	1	2	44	
Writing about how to improve healthcare quality (in peer or non-peer reviewed literature)	11	30	3	0	44	
Helping patients and service users to participate in improving healthcare quality	27	16	1	0	44	

Section C: Support for your project from general practices (GPs) and primary care trusts (PCT)

C1: Please indicate whether your GP practice and PCT provided each kind of support to your project.

GP practice						
	Y	Ν	DK	NA	Blank	Total
Involving patient representatives or groups	7	15	10	6	6	44
Securing good inter-professional relationships	29	1	3	4	7	44
Allocating time to QI activities	23	7	4	4	6	44
Allocating budget to QI activities	10	13	9	5	7	44
Availability of champions (i.e. leaders in QI)	17	10	8	3	6	44
Communicating candidly and often about QI	19	7	8	3	7	44
Securing interest of trust/board	9	7	11	10	7	44
Applying reward systems	6	17	8	7	6	44
Committing the trust/board to engaging healthcare professionals to improve the quality of healthcare	8	9	11	9	7	44
Providing leadership	17	6	8	5	8	44
PCT						
	Y	Ν	DK	NA	Blank	Total
Involving patient representatives or groups	5	18	14	4	3	44
Securing good inter-professional relationships	21	10	7	4	2	44
Allocating time to QI activities	12	13	14	3	2	44
Allocating budget to QI activities	11	11	17	2	3	44
Availability of champions (i.e. leaders in QI)	15	10	14	2	3	44
Communicating candidly and often about QI	13	11	14	3	3	44
Securing interest of trust/board	10	8	20	3	3	44
Applying reward systems	7	14	18	3	2	44
Committing the trust/board to engaging healthcare professionals to improve the guality of healthcare	16	7	17	2	2	44

quality of healthcare Providing leadership

16 11 10 3 4

44

Section D: Barriers to engaging clinicians in QI

D1: Please indicate the extent to which these barriers featured in your project.

	Not an obstacle	A small obstacle	A large obstacle	Don't know	Blank	Total
Limited number of staff available for quality improvement	10	18	12	4	0	44
Lack of leadership from key organisations and individuals (e.g. from local PCT or lead GP practice)	23	13	6	2	0	44
Lack of your personal leadership skills	33	8	1	1	1	44
Lack of widely shared information (e.g. access to performance data)	23	11	4	6	0	44
Lack of technical quality improvement skills amongst clinicians (e.g. skills in measuring impact or cost)	14	16	8	6	0	44
Lack of other skills needed for quality improvement (for example, skills in negotiation and collaboration)	16	15	3	9	1	44
Poor handover from other staff	22	11	3	8	0	44
Lack of financial rewards	14	13	8	8	1	44
The existence of financial disincentives	15	10	6	12	1	44
Lack of non-financial rewards	20	11	6	7	0	44
Lack of performance targets	25	5	5	9	0	44
Lack of standardisation of the care pathway	21	12	6	5	0	44
Lack of patient or service-user involvement	23	10	4	7	0	44
Poor protocols	26	7	6	5	0	44
Lack of support from professional associations	26	7	6	4	1	44
Lack of support from management at all levels (including chief executive and board level)	24	6	9	3	2	44

Section E: Your attitudes towards engaging clinicians in quality improvement

E1: Please indicate the extent to which you think that engaging in structured quality improvement initiatives such as your project is an appropriate part of your clinical role.

	Count
Quality improvement is not at all an appropriate part of my clinical role	0
Quality improvement is, to a small extent, an appropriate part of my clinical role	5
Quality improvement is, to a large extent, an appropriate part of my clinical role	38
Blank	1
Total	44

E2: Do you think that courses on the principles and practices of quality improvement should be included in the training and professional development of clinicians?

	Count
Yes	38
No	2
Blank	4
Total	44

E3: Please indicate the extent to which involvement in your project has change your attitude towards engaging in quality improvement.

	Count
Not changed at all	16
Changed a little	21
Changed a lot	7
Blank	0
Total	44

Section F: Changes to future professional behaviour

F1: Do you anticipate that you will change your professional behaviour as a result of your participation in your project?

	Count
Yes	32
No	12
Blank	0
Total	44

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