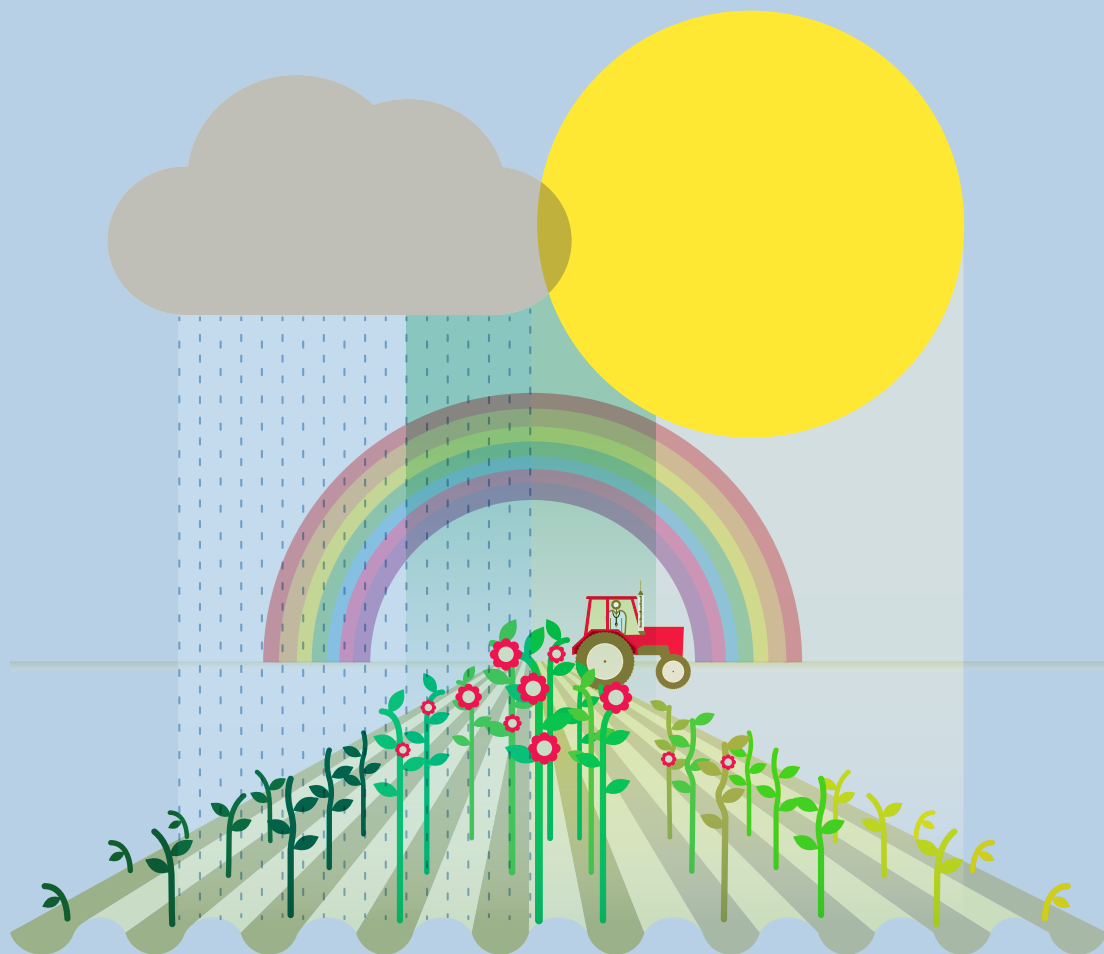


Context for successful quality improvement

Naomi Fulop, Glenn Robert



Evidence review

October 2015

Authors

Naomi Fulop, Professor of Health Care Organisation & Management in the Department for Applied Health Research, University College London, n.fulop@ucl.ac.uk

Glenn Robert, Professor of Healthcare Quality & Innovation at King's College London, glenn.robert@kcl.ac.uk

Acknowledgements

We are very grateful to Rhiannon Walters for her assistance with the systematic review that underpins this report. We are grateful to two anonymous reviewers for their helpful comments on an earlier draft of this report, and to Jonathan Bamber, Nick Barber and Penny Pereira at the Health Foundation for the very useful and insightful discussions we had during the course of the project.

Please note

The systematic review on which this report is based was completed in 2012 (and the electronic search for relevant papers covered the period until September 2011). Subsequent to the completion of the review several important contributions to the literature have been made especially in relation to the further development of the Model for Understanding Success in Quality (MUSIQ). Readers are therefore directed to the following papers for further details:

- Kaplan HC, LP Provost, Froehle CM and Margolis PA. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. *BMJ Qual Saf* 2012, 21: 13-20
- Kaplan HC, Froehle CM, Cassedy A, Provost LP and Margolis PA. An exploratory analysis of the Model for Understanding Success in Quality. *Health Care Management Review* 2013, 38: 325-338

Context for successful quality improvement is published by the Health Foundation, 90 Long Acre, London WC2E 9RA

ISBN 978-1-906461-68-3

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Executive summary

Background

The Health Foundation works to improve service delivery across health care services. Understanding of the role of context in the spread of improvement interventions will enhance the likelihood of success. This study was commissioned to explore which contextual factors support successful improvement and sustainability of quality in health care organisations, and which of these contextual factors are modifiable.

Research and evaluation of quality improvement in health care repeatedly shows that results fall short of expectations; promising interventions shown to be initially successful do not transfer to new settings, or are not sustained. Again and again contextual factors, changing over time or varying between settings, seem to frustrate efforts to improve quality.

Building on a series of thought pieces – published by the Health Foundation in *Perspectives on context*^{1*} – this study combines the ideas of receptive and non-receptive contexts for change (as outlined by Pettigrew *et al*^{2,**}), with a psychological perspective and the proposition that social context is the key facilitator of quality improvement. The review also considers context at structural levels within the health care system:

- macro – the system level
- meso – the organisation level
- micro – the clinical team level.

Crucially, the review considers how all of these factors combine to impact upon the success and sustainability of quality improvement efforts.

* See www.health.org.uk/perspectivesoncontext for the essays and the Health Foundation's 'In brief' summary and analysis.

** The eight factors identified are: Environmental pressure; Supportive organisational culture; Change agenda and its locale; Simplicity and clarity of goals; Cooperative inter-organisational networks; Managerial clinical relations; Key people leading change; Quality and coherence of policy.

Methods

A literature search was undertaken, based on the research questions, agreed quality criteria for abstracts and flexibility in the type of study to be included. The systematic review on which this report is based was completed in 2012 (and the electronic search for relevant papers covered the period until September 2011). This resulted in a total of 195 papers for review; 171 primary research studies and 22 reviews. The researchers selected 10 seminal studies as being both centrally relevant and methodologically outstanding. The reference lists for each of these studies were included and citations of the 10 seminal papers were tracked.

The 171 studies were analysed using distinct contextual factors, grouped as receptive and non-receptive to change. Overlying this grouping, factors were then classified as 'psychological' or 'structural' and then further classified by whether the factor was operating at macro, meso or micro level in the health system.

Findings

The majority of the 171 studies examined were:

- cross-sectional studies of hospitals in the United States (103/171)
- set in acute care organisations (127/171)
- focused on clinical effectiveness rather than patient safety or patient experience (98/171)
- did not evaluate the impact of modifying a contextual factor in order to improve quality (144/171)
- and – most strikingly – did not study interactions between more than one contextual factor (161/171).

Across the papers analysed, the impact of a total of 476 discrete contextual factors on quality improvement were studied. Of the eight features in Pettigrew *et al*,

the most commonly studied in terms of influencing quality improvement were:

- supportive organisational culture (94/476)
- quality and coherence of policy (63/476)
- environmental pressures (60/476).

Very few papers were identified that had studied ‘co-operative inter-organisational networks’ (12/476) or ‘managerial and clinical relations’ (3/476) – although both have been extensively studied from other perspectives.

The vast majority of contextual factors (338/476) were studied at the meso (organisational) level – not surprising given the preponderance of large-scale, cross-sectional surveys. Only 36 studies explored the impact of interactions between contextual factors at more than one level. Again, 338 of the 476 contextual factors studied were structural, as opposed to psychological, factors. Where psychological factors have been studied this was most commonly of ‘a supportive organisational culture’ at the meso level. Only 30 psychological factors had been studied at the micro (frontline team) level.

Summary findings of factor by level in the system

Macro level

At the level of the health system, the review highlights the importance of contextual factors external to organisations relating to ‘environmental pressures’ and ‘change agenda and its locale’. Many of the factors at macro level are not modifiable (at least in the short term) – for example, demography of the population, or location in an urban or rural area. Those that are modifiable at the macro level – for example, pay for performance, levels of competition between providers and public reporting of data – are not (easily) modifiable at the next level down (meso), as organisations have to respond to the requirements within their health systems. However, there is some scope to respond differently to these external factors.

Meso level

Within organisations, some of the most important contextual factors are ‘quality and coherence of policy’ – for example, aligning organisational objectives for improvement with human resource and training strategies. The studies showed consistently positive findings in relation to ‘co-operative inter-organisational networks’ and ‘supportive organisational culture’, for example, the degree to which quality is emphasised and if there is a non-punitive response to error. Factors relating to ‘key people

leading change’ were also reported as linking to positive findings, as were ‘managerial-clinical relations’ and ‘simplicity and clarity of goals’ (but note that only a small number of studies have examined these last two factors).

Lots of meso level structural factors, such as organisation size and the range of services provided, have been studied to see whether they are associated with higher quality of care. Few studies evaluated factors which had been modified and in none of the studies retrieved had contextual factors been modified in an attempt to improve quality.

Micro level

At the frontline clinical team (micro) level the review found consistently positive findings in relation to ‘quality and coherence of policy’ and ‘supportive organisational culture’ (but note that only small number of studies have examined these features). Only one structural contextual factor was found which had been modified at the frontline clinical team level and evaluated for its impact upon quality improvement.

How contextual factors have been studied

There is a very weak evidence base around modification of contextual factors and the impact of this on the outcomes of quality improvement interventions. The few studies that we identified focus on the macro (health system) level, often as the result of ‘natural’ experiments in which researchers have opportunistically studied the impact of a policy intervention in one geographical area, compared to an area where the policy was not introduced, or pre/post studies of system-wide interventions.

Very few studies have explicitly sought to modify a contextual factor in order to test its impact on quality improvement. These mainly relate to macro level interventions such as publication of performance data or payment for performance. These studies conceptualise contextual factors as variables to explain the outcomes of the quality intervention.

Most papers were single level studies, situated at the macro, meso or micro levels but not between levels. However, the largely positive findings relating to ‘quality and coherence of policy’ at the meso level suggest the importance of **multi**-level coherence and of the dynamic interaction between different levels in shaping the impact of quality improvement interventions. This suggests that those leading quality improvement interventions have to attend to multi-level processes rather than focusing solely on meso or micro levels in isolation; however, only a very small number of studies explored interactions between different levels.

In addition, the dynamic relationships between different contextual factors, both within and between levels, rather than any one of them individually or independently, impact on the effectiveness of a quality improvement intervention and account for the striking variation between similar quality improvement interventions in different places. Again, only a small number of studies have explicitly focused on the interactions between several contextual factors.

Discussion

The review significantly extends previous attempts to synthesise what is known about the role of context in quality improvement in health care organisations, by use of multi-factorial analysis: classifying contextual factors as receptive or non-receptive to change, classifying the context by the level of the system, plus classification of contextual factors as structural or psychological. However, the dynamics of context remain a mystery. While there is some evidence about which contextual factors are critical for quality improvement, we do not know if they are necessary in all circumstances, or only for some types of quality improvement.

Contextual factors relating to psychological perspectives seem to be neglected for study and are under-represented in the literature. Future research needs to move away from narrow, purely structural, conceptualisations of ‘context’ which have dominated the literature to date. However, adding further factors to an already well-rehearsed list will not, alone, move forward our understanding of the role of context on quality improvement.

It is difficult (and ultimately unhelpful) to separate ‘context’ from a quality improvement intervention, as there are inevitably interactions between the two. Some studies define the quality improvement intervention very narrowly and as distinct from implementation, some define the intervention as the change to be achieved together with implementation actions, whereas some also include as part of the intervention what others might call context, such as support from the service manager, and this combination is then ‘the intervention’. Reports of quality improvement interventions need to describe precisely the intervention implemented and any evidence of the contextual factors which influenced it.

It can also be difficult to separate psychological from structural factors, for example, it can be argued that the introduction of patient choice (structural) reforms in England were an attempt to change culture (psychological). Determining what is ‘modifiable’ can also be problematic. Some contextual factors cannot be changed and so they have to be actively managed by

those implementing quality improvement interventions. For example, Pettigrew *et al*² make a useful distinction between ‘inner’ context, such as organisational and divisional cultures, group norms, leadership and local champions, and ‘outer’ context, such as broader economic, social and political trends. The former can be directly managed but the latter are usually too big and distant to be managed. Finally, some contextual factors are likely to be more important at different stages of quality improvement, such as at implementation or at assimilation into routine practice, but there is very little processual research available on which to draw any conclusions.

Recommendations

Future work should aim to:

- provide an evidence base for the co-design and dissemination of reflective tools that enable contextual factors to be taken into account before beginning quality improvement interventions
- inform the design (and ‘tailoring’) of quality improvement interventions by systematically embedding the use of such reflective tools in future programmes.

Investing resources to try to create certain contexts prior to implementing quality improvement interventions with the aim of increasing the ‘success’ of the interventions is unlikely to work. Rather, developing a categorisation of quality improvement interventions according to which groups of contextual factors are most important for their success would give practitioners a better way to assess which types of interventions are best suited to their particular context.

The design of future quality improvement interventions should consider how the intervention sits in relation to the three levels of the health care system (macro, meso and micro) and the alignment between them.

Any framework for future empirical research should reject the search for ‘key success factors’ that may be associated with quality improvement success and the testing of these associations through large-scale, cross-sectional surveys.

Longitudinal, process-based, organisational case studies are the preferred research method within complex and dynamic contexts where it is difficult (or unhelpful) to isolate variables or where there are strong interactions between variables. Such comparative case studies can generate hypotheses from exploratory data which can then be tested in wider samples using different methods, and – particularly relevant to quality improvement interventions – they address questions of process as opposed to the input/output model of much quantitative research.

Context for successful quality improvement

Background

The Health Foundation has supported a great deal of research and development, and many frontline projects, on quality improvement in health care. However, it has frequently found that results were disappointing. Promising interventions did not transfer to new settings, or could not be sustained. The usual explanation was a dynamic context; again and again contextual factors, changing over time or varying between settings, seemingly frustrated efforts to improve quality.

The Foundation therefore decided to explore the role of contextual factors in health care improvement further and commissioned a set of ‘think pieces’ from leading researchers in the field.^{3-7,*} This project builds on these and is a best evidence review of the influence of contextual factors on successful improvement of health care quality.

The authors of the think pieces were asked to address four questions:

- how do you define context?
- what is known about context from the literature?
- what models do you suggest using to help explain context?
- what do you see as the principal research questions relating to context?

Mostly the pieces focus on the conceptual and methodological challenges of studying context. The authors took very different approaches, drawing on different literature, but there are some important commonalities.

* See www.health.org.uk/perspectivesoncontext to read these pieces, and the Health Foundation’s ‘In brief’ summary analysis. You can also access a webinar in which Naomi Fulop, John Gabbay and Andrée le May discuss why context needs to be taken into consideration when attempting improvement, and what skills best help professionals to manage context effectively.

In relation to defining ‘context’, most of the authors noted that the term can be used to mean everything other than the quality improvement intervention under study, and therefore would be too unwieldy to research. This led some to propose taking a relatively narrow approach: for example, Shekelle⁷ defined context in terms of four categories (external factors such as regulatory requirements; organisational structural characteristics such as size; teamwork/leadership/patient safety culture; and management tools such as training and audit). Others noted how context has been described metaphorically, most often as a garden where there is a need for a rich, fertile soil (context) in which a thousand flowers (eg, quality improvement interventions) can bloom, and less fertile ground can be ‘nourished’ and ‘cultivated’ to facilitate quality improvement.⁴ As Bate points out, this metaphor may be viewed as helpful in that it suggests that context can be managed, but on the other hand it – he argues – places less emphasis on temporal context, ie the importance of studying quality improvement over time.⁴ This gardening metaphor can be seen – as Bate notes – as the antecedent to the idea of receptive and non-receptive contexts for change.

In terms of conceptualising context, all of the authors note the risk of blurring issues of ‘context’ with either the quality improvement intervention or the problems of implementing quality improvement. For example, is ‘type of or quality of leadership’ a contextual factor/process or an integral aspect of change which needs to be studied?⁶ Or does it change over time, ie start off as a contextual ‘factor’ before becoming incorporated into the implementation of the quality improvement intervention?⁷ Taking this idea further, some discuss the subjective versus objective nature of context and question whether ‘context’ can be reduced to a set of ‘factors’ that can be measured. Is it rather a set of processes which interact with a quality improvement intervention, ie ‘become part of the action itself’?⁴

Therefore, as we propose in this review, it is important to analyse the **interactions** between contextual processes and the implementation of a quality improvement intervention.

All the think pieces note the lack of empirical research into – and evidence about – the role of context in quality improvement, and discuss how such studies should be designed. For example, Dixon-Woods⁵ provides an analysis and critique of Pawson and Tilley’s realist evaluation framework which proposes theorising the mechanisms by which interventions have particular outcomes in relation to their ‘contexts’.⁸

The authors of the think pieces draw on various models or frameworks for studying context, and discuss the various distinctions made in the literature: for example, between inner (usually within the organisation) and outer (external to the organisation) contexts; between structural (eg, size) and psychological (eg, professional cultures) domains; between different levels of the system, for example macro, meso or micro system level;^{4,6} and between ‘omnibus’ (broad consideration of context as a whole) and ‘discrete’ (particular contextual components that shape behaviour or moderate relationships between variables).⁶ Three of the think pieces review various models or frameworks for studying context, some of which specifically relate to contexts for implementing evidence-based practice (EBP). These include:

- the Pettigrew *et al* receptive and non-receptive contexts for change^{2,9}
- the Bate *et al* model for understanding the challenges hospitals need to address for quality improvement^{4,6,10}
- the French *et al* framework¹¹ which drew on a review of 30 tools ‘to measure the organisational context for evidence-based practice’³
- the McCormack *et al*¹² Context Assessment Index which is based on the Promoting Action on Research Implementation in Health Services (PARIHS) model. This is a 37-item instrument which claims it ‘provides clinicians with the means to assess and understand the context in which they work and the effect this has on using evidence in practice’.³

Bate proposes that we do not need a new model or framework to study the role of context in quality improvement; rather, we need to test and synthesise existing ones.⁴

This best evidence review builds particularly on the think piece written by two of the research team (Glenn Robert and Naomi Fulop).⁶ We took as our starting point the Pettigrew *et al* well-known notion of receptive and non-receptive contexts for change² which – although encompassing both ‘hard’ (structural) and ‘soft’ (cultural) factors – we argued now needs to be combined with more contemporary psychological perspectives, such as Weiner’s notion of ‘readiness’ for change,¹³ Huy’s work on ‘emotional receptivity’ at the individual and organisational levels^{14,15} and the proposition that social context is the key facilitator of quality improvement.¹⁶ Overlaying this combination of different perspectives, we argued (following House *et al*¹⁷) that more explicit attention must be paid to the multiple levels of context (macro, meso and micro) and, crucially, how these combine to impact upon the success and sustainability of quality improvement efforts.⁶

Aims, objectives and scope

For this evidence review, the authors and the Health Foundation agreed the following research question:^{*}

- Which contextual factors relate to successful improvement and sustainability of quality in health care organisations, and which of these factors are modifiable?

It comprises three sub-questions:

- Which aspects of context have been found to be important in improvement of quality?
- Which aspects are modifiable (where a specific, deliberate attempt has been made to change a contextual factor in order to improve quality)?
- What evidence is there that these aspects have successfully been modified, and resulted in improvement to quality?

Our review has a considerably broader scope than the 2010 review by Kaplan *et al* on this topic.¹⁹ It includes the range of contextual ‘factors’ at macro, meso and micro levels, and papers using qualitative as well as quantitative methods. For example, financial incentives (eg, the Quality Outcomes Framework (QOF)) and regulatory mechanisms (eg, accreditation and target/standard setting with sanctions) are included as well as organisational contexts (eg, the role of leadership, cultures, etc).

For the purposes of this review, we proposed the following definitions for key terms:

Definitions of key terms

Organisations

- The subjects of included studies are health care organisations at any level providing any kind of health care.

Activities which result in improved quality

- We have adopted Øvretveit’s¹⁸ definition of quality in health care:
 - ‘Quality’ is defined as provision of care that achieves the highest possible clinical effectiveness, guarantees the highest possible standard of patient safety and ensures that the patient experience is as good as possible.
- We include interventions and other activities intended to achieve improved quality at macro, meso and micro levels. Contextual factors in one study may be activities which improve quality in another. Not all studies include an intervention. Some interventions are ‘active’, when a deliberate attempt is made to change quality, and some are ‘passive’, where a quality change – negative or positive – may have been an unintended consequence.

Contextual factors and modifiable contextual factors

- By ‘contextual factors’ we mean both ‘hard’ (structural) and ‘soft’ (cultural) factors and include multiple levels of context at macro (external to the organisation), meso (organisational) and micro (frontline service) levels.
- Factors are considered modifiable where a specific, deliberate attempt has been made to change a contextual factor in order to improve quality, and not simply where they are an explanatory variable

^{*} This was based on a question we recommended be explored in our think piece, (Fulop and Robert, 2011⁶)

(eg, where pay for performance has been introduced at the macro level, or at meso level where a quality improvement intervention has been implemented). We focus on factors modifiable at meso level to meet the needs of the main target audience for the review.

Organisational levels

- Macro contextual factors include health care systems, financial incentives and regulatory mechanisms (eg, national targets with sanctions), competition, professional regulation, technology, geographical factors including urban-rural and demography.
- Meso contextual factors at the level of the organisation include leadership, cultures, climate, organisational experience of quality improvement, organisational size, financial and clinical performance, data and information systems, knowledge and training.
- Micro factors at the level of the team or individual professional include leadership, cultures, climate, team experience of quality improvement, team working, knowledge and training.

Outcome

- The review includes empirical studies that report an objective measure of how contextual factors impact on quality improvement (whether positively or negatively).

Study design

- We include intervention or observational studies using quantitative, qualitative or mixed methods.

Methods

The Health Foundation set out to commission a best evidence review. The term implies the use of a transparent process, *a priori* research questions and quality criteria, but also flexibility in the type of study included and the processes of search and selection. The classic systematic review (eg, CRD 2009²⁰) includes stages of refining research questions, searching for and retrieving details of potentially relevant studies, selecting from among those studies ones which are actually relevant, identifying eligible studies from among the relevant ones and synthesising eligible studies. Our review includes all these stages, but uses an iterative approach to searching and selection, both to reduce the task of selection to a manageable size, and to ensure that a linear approach does not lead to omission of relevant research. This review is not a classic systematic review nor is it a meta-analysis as neither are an appropriate approach to take to our very broad research question.

Searching for and retrieving details of potentially relevant studies

The method developed here draws on Greenhalgh and Peacock who found their greatest yields and best specificity from methods other than electronic review for this type of complex review.²¹

We used the following methods to find potentially relevant articles in English.

We did an electronic database search of Scopus,^{*} using search structures derived from our research question. Scopus was set up in 2004 and covers all journals with ISSN numbers including those indexed by MEDLINE, Cinhal, and EMBASE. It indexes with MeSH and Emtree headings, and has a powerful citation search function for references from 1996 on.

* www.scopus.com

We did an electronic search of HMIC, a database combining the library catalogues of the Department of Health and The King's Fund, which is strong in health service 'grey' literature.

Electronic search strategies were developed, benefitting from the research structure developed by Kaplan,¹⁹ and from 'hedges' (published search strategies) for identifying publications on health care quality.^{22,23} We tested searches for sensitivity and sought to minimise yield of references while maximising sensitivity. Sensitivity was tested by the proportion of the 47 studies accepted by the Kaplan *et al* review and a further seven relevant studies chosen because they would have been ineligible for the Kaplan *et al* study but fell within our broader scope and eligibility criteria. (These 54 references were termed the 'sensitivity test references'.) The search strategy is given in appendix 1.

For the electronic search only, we searched from 1996 onwards. The cut-off date was September 2011. (We have no earliest or latest cut-off date for search methods with better specificity, including reference and citation list searches and appeals to experts – see below.)

We consulted experts to advise on references to add to those found through the electronic and journal contents searches, and to identify seminal studies.

In addition, we searched the contents lists of the following journals for eligible studies not found by other methods, from 2009 to September 2011 inclusive:

- *Academy of Management Review*
- *BMJ Quality and Safety* (formerly *Quality and Safety in Health Care*)
- *Implementation Science*
- *International Journal for Quality in Health Care*.
- *Milbank Quarterly*

We planned to review reference lists and citations of all accepted studies as well as consulting experts. However, after the title and abstract filtering of electronic searches, it was evident that the full review of citations and references was not feasible in the time and was unlikely to add to our understanding of conceptual factors. This was a risk we had anticipated, and raised with the Health Foundation, because of the difficulty of designing a tightly-targeted search for a very broad topic.

In discussion with the Health Foundation, therefore, we adjusted our search method to one which could:

- represent the scope of this extensive literature
- include seminal studies within disciplines which have made major contributions to the literature.

We supplemented the electronic and journal contents searches with the following higher specificity methods:

- Drawing on the knowledge, contacts and personal libraries of the researchers.
- Following the method identified by Greenhalgh *et al.*²¹
 - scanning the reference lists of 10 papers that we judged to be seminal, taking into account advice from three experts chosen for depth of knowledge complementary to that of the researchers, for example in economics and organisation theory and health organisation performance
 - citation tracking 10 papers published more than three years previously (as citation tracking of papers less than three years old produces low yields) that we identified as being both centrally relevant and methodologically outstanding.

Selection of relevant studies

Outputs from electronic searching have poor specificity and needed considerable filtering. As an illustration of the need to ensure that the size of the task of selection remains manageable, the review by Kaplan *et al.*¹⁹ addresses a narrower topic, includes only studies with quantifiable outcomes published before 2008, and retrieved nearly 16,000 references from which, by selecting for relevance and applying inclusion criteria, they identified 47 studies eligible for inclusion in their analysis.

Title and abstract screening

We used the left hand template from figure 1 for screening titles from electronic and journal contents searches to make decisions about whether to review abstracts, and the right hand one for screening abstracts

from all sources to make decisions about whether to retrieve the full text of references. The rejection criteria draw on definitions given earlier in this report.

Figure 1: Title and abstract filter templates

Reject because	Reject because
Recommend No.	Recommend No.
Not health care organisation	Not health care organisation
Not related to quality	Not related to quality
No contextual factors	No contextual factors
No measure of success	No measure of success
Ineligible study design	Ineligible study design
View abstract	Retrieve full text

At title and abstract screening stages, inter-rater reliability tests were conducted with team members. The number of titles and abstracts in the inter-rater reliability tests was agreed pragmatically to keep a large workload manageable. Successive inter-rater reliability tests were conducted as we refined and clarified our criteria, with a final one concurrent with selection of the sample described above which gave results for the three author pairings (Glenn Robert, Naomi Fulop, Rhiannon Walters) of 74% (GR-RW), 73% (NJF-GR) and 58% (NJF-RW).

Quality filtering of full papers

The team shared appraisal of a sample of potentially relevant studies retrieved in full text from the electronic and journal contents searches and the sensitivity test papers, to identify those eligible for synthesis. The sample was drawn systematically: two in seven accepted Scopus search abstracts, one in three journal contents and sensitivity test abstracts – each from a random start point – and one in two HMIC abstracts (using a convenience sample because many of these references were hard to obtain).

At the quality appraisal stage for this selection each paper was appraised by at least two team members, with disagreements resolved by discussion within the team. We used criteria from appraisal tools appropriate to different types of study, adapted to improve appraisal of the generalisability of research findings²⁴ (see appendix 2). Quality appraisal of the remaining papers was conducted by a single reviewer. We set the quality score threshold for inclusion as $\geq 60\%$ and we defined a ‘high quality’ paper as one which scored $\geq 90\%$ on the basis of these criteria.

Synthesising eligible studies

We designed a data extraction form, incorporating dimensions agreed with the Health Foundation at the outset of the project. These were:

- type of study:
 - qualitative/quantitative/mixed methods
 - intervention/'passive'
 - longitudinal/cross-sectional
- setting:
 - country
 - organisation type
 - level of health care (health system/secondary/primary)
- measures of improvement in quality, grouped into:
 - macro/meso/micro
 - clinical effectiveness/patient safety/patient experience/implementation of quality improvement intervention
- contextual factors, grouped into:
 - macro/meso/micro
 - active/passive
- findings.

We also recorded whether economic outcomes were investigated.

Conceptual framework

As we set out in our original think piece,⁶ when thinking about quality improvement in health care organisations our conceptualisation of 'context' is shaped by our belief that the management of change – of which the implementation of a quality improvement programme is just one example – is complex and multifaceted, and that where organisations are multi-layered and diverse (as in health care), a prescriptive or one-dimensional approach to the management of change is likely to be unsuccessful. In part, we explicitly consider 'context' in this way as a counter to what might be termed a 'universalist' or prescriptive approach which might otherwise promote one 'right way' to the management of change. At times 'context' is seen as all the factors and/or processes that relate to organisational change (including quality improvement) (see Kaplan *et al*, 2010,¹⁹ for example). However, we believe it is important to distinguish between specific aspects of context

and other factors and/or processes: for example, is 'leadership' a contextual factor/process OR an integral aspect of change which needs to be studied?

Bearing this in mind, we still find the following definition from Pettigrew² to be the best starting point:

Context refers to the 'why' and 'when' of change and concerns itself both with influence from the outer context (such as the prevailing economic, social, political environment) and influences internal to the focal organisation under study (for example, its resources, capabilities, structure, culture and politics).

This definition highlights one of several key distinctions which we would draw attention to in any consideration of 'context'; between that of the inner context (organisational) (defined as the hard medium of visible organisational structure and the 'soft' medium of culture and ways of working, both of which vary enormously between organisations²⁵) – and the outer context (factors beyond the organisation: eg, social systems, environmental contexts, laws, regulations, etc). In terms of our understanding of 'inner' and 'outer' context, the growth of institutional theory from the late 1970s onwards^{26,27} has been important in highlighting key regulating forces, in particular the State and the professions, influencing/constraining organisational change, especially in the public sector.

Other important distinctions in the literature are:

- the level of the system at which one considers 'context' (for example, the macro, meso or micro system level) and the interactions between them (in other words, context is multi-level, with environmental, organisational and individual levels intertwined)²⁸
- whether one takes a structural or psychological perspective.

In this regard, another important theoretical development was Giddens' concept of structuration,²⁹ where organisational change is seen as a result of the interplay between human agency and context. Much organisational change and quality improvement is based on notions of the relationships between the organisation and its context, and the organisation and the individuals within it (see eg, Child, 1997³⁰). These relationships are illustrated in a study of health care mergers³¹ whereby the process of merger created perceptions of 'takeover' and had a negative effect on staff; these perceptions in turn

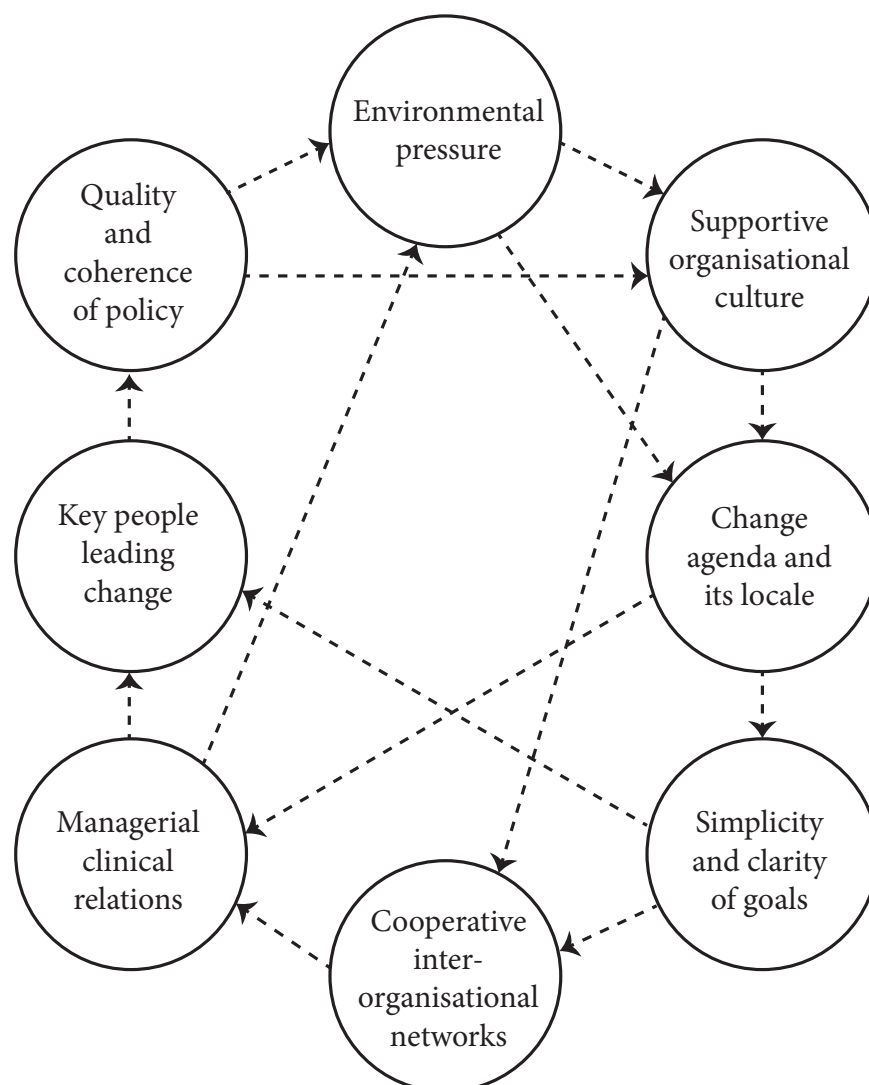
affected the merger process itself. As McNulty and Ferlie found in their study of an attempt to radically transform an organisation,³² it is an example of where management action is 'mediated by very same cognitive and relational structures' that the management action is meant to address. Therefore it is very important to study these relationships and interactions between them.

Such distinctions as those briefly mentioned above are reflected in the various conceptualisations of 'context' which originate to a large extent in the variety of different perspectives that have been brought to bear on the question of the role of 'context' (for example, organisational studies, social psychology, knowledge management and innovation studies). These different perspectives have led to different methodological approaches to studying context. Broadly, on one hand, researchers have viewed contextual factors as discrete variables which can be measured; and on the other hand,

'context' has been viewed as a set of processes which relate both to each other and to change/improvement (see figure 2 and box 1, and Robert and Fulop⁶ for fuller discussion of these different perspectives).

Our methods for this review therefore built on these concepts. As a foundation for our conceptual framework we identified distinct contextual factors, and grouped them by the features of receptivity and non-receptivity to change from Pettigrew *et al.*,⁹ developing further features for those factors which did not fall easily within the categories from Pettigrew *et al.* Overlying this classification, we then divided the factors into those which were psychological and those which were structural. We examined and summarised findings for each factor within these two dimensions, and further divided by whether the factor was operating at macro, meso or micro level (see Definitions of key terms, pages 8-9).

Figure 2: Receptive and non-receptive contexts for change



Source: Pettigrew, Ferlie and McKee 1992²

Box 1: Features of receptive and non-receptive contexts for change

Quality and coherence of policy – analytical and process components

- Quality of ‘policy’ at local level is important in terms of both the quality of analysis (eg, importance of data in making an argument) and the quality of the process (eg, broad vision is important).

Availability of key people leading change

- Not individual, ‘heroic’ leadership, but distributed and exercised in a more subtle and pluralist system. Continuity of leadership is very important and lack of continuity highly detrimental.

Environmental pressure – intensity, scale and orchestration

- Can be both positive and negative. Excessive pressure can drain energy from the system. But if orchestrated skilfully, environmental pressure can produce movement, for example, a financial crisis can be seen as a threat or can be leveraged to achieve change.

A supportive organisational culture

- ‘Culture’ refers to deep-seated assumptions and values far below surface manifestations, officially espoused ideologies or even patterns of behaviour. The past can be very influential in shaping these values, which may be both a strength and a weakness. In health care, the array of sub-cultures is important. Aspects of culture found to be associated with a high rate of change were: flexible working across boundaries rather than formal hierarchies; an open, risk-taking approach; openness to research and evaluation; a strong value base giving focus to a loose network; strong positive self-image and sense of achievement.

Effective managerial/clinical relations

- Relations improve when negative stereotypes are broken down, for example, as a result of mixed/hybrid roles. It is important for managers to understand what clinicians value, and have good understanding of health care operational issues.

Co-operative inter-organisational networks

- This means between health care organisations and between health care and other organisations. The most effective networks are informal and purposeful, but vulnerable to turnover. Factors that can facilitate networks include financial incentives, shared ideologies or history, and existence of ‘boundary spanners’.

Simplicity and clarity of goals and priorities

- Pursuing fewer priorities over a long time period is associated with achieving change. There is a need to insulate against constantly shifting short-term pressures.

The fit between the change agenda and the locale

- How factors in the local environment, which may be outside control (eg, nature of local population, presence or absence of teaching hospitals), are anticipated as potential obstacles of change.

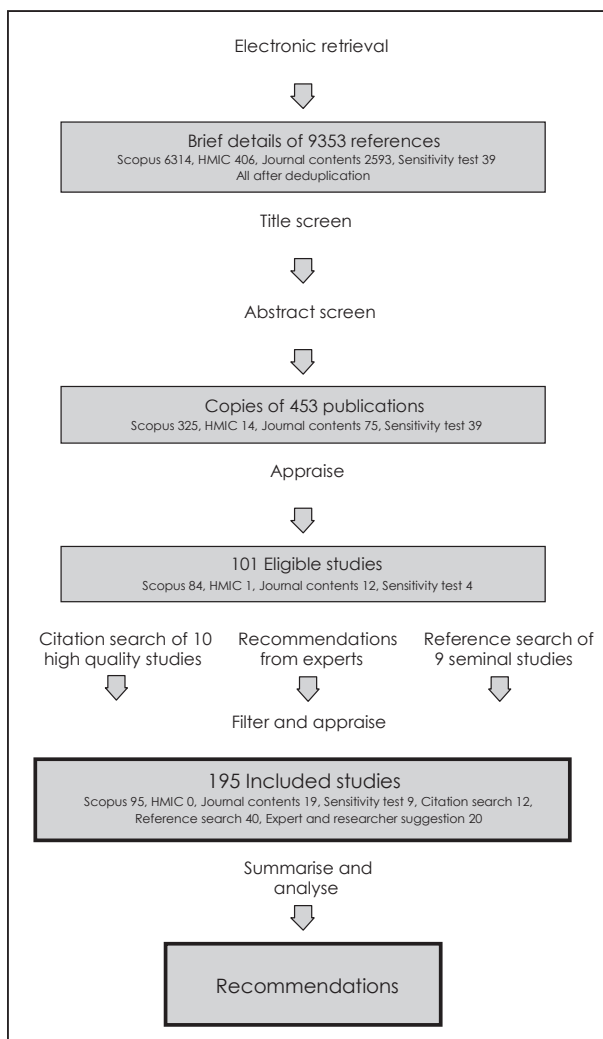
(adapted from Pettigrew *et al*)^{2,9}

Findings

Selection of included studies

The final selection included 195 studies (see figure 3), made up of 171 primary research studies and 22 reviews (reported in 24 studies). All of these studies and reviews and summarised in the *Summary of findings* supplement, available on the Health Foundation website.*

Figure 3: Selection of included studies



Applying our 90% quality score threshold to these 195 studies resulted in the identification of 17 ‘high quality’ primary studies. Of these:

- two relate to macro-structural contextual factors^{33,34}
- 12 relate to meso-structural contextual factors^{34,35,36,37,38,39,40,41,42,43,44,45}
- six relate to meso-psychological contextual factors^{34,35,40,46,47,48}
- two relate to micro-structural contextual factors^{38,45}
- one relates to micro-psychological contextual factors.⁴⁹

We specifically comment on each of these in greater detail in the relevant section of our findings.

There were 19 measures of quality improvement used across these 17 high quality studies. Of the 19 measures:

- 10 relate to clinical effectiveness (39 contextual factors in total: 25 meso-structural, 10 meso-psychological, four macro-structural)
- four relate to patient safety (13 factors: nine meso-structural, two meso-psychological, two micro psychological)
- one relates to patient experience (five factors: two meso-structural, two macro-structural, one micro-structural)
- two relate to implementation of quality improvement (eight factors: four meso-psychological, two macro-structural, two meso-structural)
- two relate to economic measures (two factors: one macro-structural, one meso-psychological).

Two of the 22 reviews also scored over the 90% quality threshold.^{19,50}

* See: www.health.org.uk/publication/context-successful-quality-improvement

Characteristics of included primary studies

The majority of included studies were cross-sectional studies set in hospitals in the United States. Of the 171 primary studies, 103 were cross-sectional quantitative studies, with 24 being qualitative or having a qualitative element. They included 13 studies evaluating interventions by controlled longitudinal designs (randomised or non-randomised), and 31 longitudinal uncontrolled studies, most of which were also evaluating contextual factor changes. US-based studies made up 125 of the 171, and 127 were set in secondary care, with seven studies across health systems and 39 covering primary care (see table 1).

Quality improvement measures were grouped as clinical effectiveness, patient safety, patient experience and implementation of quality improvement, plus composites involving more than one of these measures. At the Health Foundation's request we noted when our eligible studies included an economic measure. There were 21 studies which included an economic or cost measure, either as an outcome or a contextual factor. We recorded two types of evaluative study – those that looked at the impact of contextual factors on the success of a quality improvement intervention, and those that looked at the impact on quality of a change in a contextual factor (27 of each type). Of the 153 quantitative studies, 11 recorded interactions between factors as a main finding. Most included studies looked at between 2 and 10 contextual factors, with a mean of 2.6 (see table 2).

Table 1: Characteristics of included studies

	Number of studies (n=171)
Study design	
Randomised controlled trial (RCT)	1
Non-RCT controlled study	12
Longitudinal quantitative study	31
Cross-sectional quantitative study	103
Mixed methods: longitudinal quantitative, and qualitative interview study	2
Mixed methods: cross-sectional observational quantitative, and qualitative interview study	4
Qualitative interview study longitudinal	3
Qualitative interview study cross-sectional	14
Realist evaluation	1
Country	
US	125
UK	18
Other	26
More than 1 country	2
Health care level	
Health system	7
Secondary	127
Primary and secondary	2
Primary	37
Organisational unit investigated	
Health system	6
Health authority	4
Health insurance plan	6
Hospital	70
Hospital department	22
Hospital team	4
Nursing home	18
Hospice	1
Mental health service	1
Primary practice group	5
Primary practice	15
Primary care clinic	6
Primary care team	1
Home health agency	1
Health care professional	7
More than one type	4

Table 2: Measures used

	Number of studies (n=171)
Type of quality improvement measures (more than one per study)	
Clinical effectiveness	98
Patient safety	24
Patient experience	27
Implementation of quality improvement	25
Composite measure incorporating more than one of above	11
Findings by type of quality improvement measure and level	
<i>Clinical effectiveness</i>	
Macro	46
Meso	154
Micro	40
Total	240
<i>Patient safety</i>	
Macro	4
Meso	66
Micro	15
Total	85
<i>Patient experience</i>	
Macro	6
Meso	54
Micro	12
Total	72
<i>Implementation of quality improvement</i>	
Macro	13
Meso	65
Micro	11
Total	89
<i>Composite measure incorporating more than one of above</i>	
Meso	30
Micro	7
Total	37
<i>Study with economic measure</i>	21
<i>Study associated with quality improvement intervention</i>	27
<i>Study investigating quality impact of change in contextual factor</i>	27
<i>Study (quantitative) looking at interaction between factors</i>	11
<i>Number of contextual factors</i>	
1	86
2 – 10	76
>10	9
Mean	2.58

Within the 171 primary studies, there were 476 findings (associations between factors and outcome measures). The most common category of finding was a meso level factor associated with a clinical effectiveness finding. The *Summary of findings* supplement* gives more detailed findings from each study-factor group.

Of the 22 reviews (reported in 24 studies):

- five explored the impact of ‘pay for performance’ as a contextual factor explaining quality improvement success
- two focused on the publication of performance data
- two compared various types of managed care (eg, health maintenance organisations) versus other insurance types (eg, Fee-for-service)
- two explored incentives for preventive care (eg, immunisation).

The remaining reviews studied a range of contextual factors (eg, accreditation, competition and eight versus 12 hour shifts). Findings from reviews are not included in table 3 (see overleaf), to avoid double counting of some primary research studies, but are summarised in the *Summary of findings* supplement.

In the remainder of this section we summarise findings (associations between contextual factors and outcome measures) by combining level (macro, meso, micro), with structural and psychological factors, giving five groups of factors:

- macro-structural (no studies were retrieved of macro-psychological factors)
- meso-structural
- meso-psychological
- micro-structural
- micro-psychological.

Appendix 3 gives a breakdown of how contextual factors are allocated to features of receptivity and non-receptivity to change (both the Pettigrew *et al* and the additional inner context features emerging from our analysis), and by level.

* The *Summary of findings* supplement is available from www.health.org.uk/publication/context-successful-quality-improvement

i. Findings by macro level features (structural)

Table 3: Findings by macro level features (structural)

	Positive	Negative	Variance shown	Mixed/partial	NS	Number of findings (n=70)
Pettigrew <i>et al</i> features						
Change agenda and its locale	8	2	2	2	5	19
Environmental pressures	26	5	1	6	11	49
Non-Pettigrew <i>et al</i> features						
Organisation factor	1					1
Performance factor					1	1
Total	35	7	3	8	17	70

Notes NS=*non-significant or no effect*

Better quality interpreted as positive, even if given in a negative measure (eg, fewer adverse events) in the study
p<0.05 is interpreted as significant for this review

'Mixed/partial' includes studies which have negative and positive findings for measures of the same factor, or a ratio of positive to non-significant findings on measures of the same factor smaller than 1:6

At the macro level, the focus has been on 'structural' rather than 'psychological factors'. No 'psychological factors', as defined in this review, have been studied at the macro level. However, the possible relationship between the two needs to be acknowledged, ie macro initiatives to modify structural factors may also have had the purpose of modifying psychological factors, as it could be argued was the case with certain policy reforms in England.

As table 3 shows, we found 70 'structural' factors have been studied at the macro level in 54 included studies. Of these 70 findings, 35 (50%) were found to have a positive effect, seven (10%) negative, eight (11%) a mixed or partial effect and 17 (24%) had no effect. Forty of the 70 (57%) were investigated using a cross-sectional quantitative study.

In relation to the eight Pettigrew *et al* features, structural factors relating to 'environmental pressures' were the most frequently studied (n=49, 70%) at the macro level. These environmental pressures comprise: population factors such as demographic features (age, sex, etc.), levels of deprivation and social capital; financial incentives (eg, pay for performance); presence of a competitive market; method of payment (eg, Fee-for-service versus Medicaid in the US); and regulatory factors such as accreditation status and public reporting of performance data. Of the 49 findings, 26 were found to have a positive impact (relating to financial incentives, publication of performance, competition and some

population factors), five were found to have a negative impact and 11 had no effect. The next largest group of findings were those relating to 'change agenda and its locale' (n=19). These comprised geographical factors such as comparing urban and rural health care providers in terms of quality/quality improvement. Of these, eight factors were found to have a positive effect (eg, a study of appropriate care for acute myocardial infarction (AMI) in US Medicare hospitals comparing urban, large rural, small rural and remote small rural hospitals), and five no effect (eg, a qualitative study explicitly looking at Pettigrew factors found that fit between change agenda and its locale was not influential in their case studies). One study looked at performance in terms of productivity of health care systems and found no effect.

No studies of structural factors at the macro level relating to the following Pettigrew *et al* features were found: 'quality and coherence of policy', 'key people leading change', 'simplicity and clarity of goals', 'managerial-clinical relations', 'supportive organisational cultures'. No studies of the non-Pettigrew *et al* feature 'patient involvement' were found either.

Just two studies were found which did not fit neatly into the Pettigrew *et al* features: one relating to performance (productivity of health care systems) and one relating to organisation factors (population level study of patient experience in for-profit and not-for-profit insurance plans).

There are two papers meeting our 90% quality threshold which include macro-structural contextual factors. Farrar *et al*³³ studied whether the policy of ‘payment by results’ (PbR – a fixed tariff case mix based payment system) introduced in the English NHS affected the way hospitals provide care (in terms of volume, cost and quality of care). The authors conducted a difference-in-difference analysis comparing English hospitals with Scottish hospitals where the policy was not implemented. They found that length of stay fell more quickly and the proportion of day cases rose more quickly where PbR was implemented, suggesting a reduction in unit costs associated with PbR. They found some association between the introduction of PbR and an increase in acute hospital activity. Little measureable change occurred in the quality of care indicators used in this study (in-hospital mortality, 30 day post-surgical mortality and emergency readmissions) that can be attributed to the introduction of PbR.

Bradley *et al*³⁷ investigated a number of macro-structural factors including urban/rural location, geographic region and socio-economic status (SES) of patients, and their influence on variation in hospital AMI mortality rates (as well as a number of meso-structural factors – see section ii) in a cross-sectional study. Both urban location and particular geographic region correlated with lower 30 day mortality rates (supporting the findings of other studies). They demonstrated a link between lower SES patient profiles and hospital performance but the association was small.

In relation to structural factors at the macro level our review highlights the following:

- The importance of factors relating to ‘environmental pressures’ and ‘change agenda and its locale’, external to organisations.
- A number of these factors are not modifiable (at least in the short term); for example, demography of the population, levels of deprivation, or whether the provider is located in an urban or rural area.
- Some of these factors are modifiable at the macro level, such as pay for performance, levels of competition between providers and public reporting of data, but they are not (easily) modifiable by people working at the meso level (although the organisations at the meso level can respond differently to these external factors).
- Structural contextual factors which have been modified at the macro level and evaluated for their impact on quality/quality improvement are:
 - pay for performance (several studies in England, and the US)

- public reporting of data (eg mandatory reporting of coronary artery bypass graft (CABG) outcomes in the US and several studies of ‘consumer reports’). Some of these studies have compared public reporting with private reporting and no reporting
- competition (eg, studies of the introduction of internal market in England and Sweden, studies of competitive environment in the US)
- regulatory mechanisms such as accreditation or target/standard setting with sanctions
- implementing a physician working time regulation.
- Of these, the following had a positive impact on quality improvement:
 - publication of (a) surgeons’ performance and (b) hospitals’ performance led to an improvement in risk-adjusted mortality rate following CABG
 - publication of ‘consumer reports’ on patient outcomes led to a significant fall in risk-adjusted mortality for some (but not all) of the conditions studied
 - publication of ‘consumer reports’ on obstetric reports led to a significant rise in hospitals with low vaginal-birth-after-caesarean rates and a significant fall in caesarean rates
 - use of financial incentives to enhance feedback led to a significant improvement over time in immunisation indicators and other process indicators.

A systematic review (Fung *et al*⁵¹) evaluated the impact of publication of performance at three levels. One study of health plans showed a positive impact on technical performance and patient experience, although there were unintended consequences – one study reported that lower-scoring health plans were more likely to cease public reporting than high-scoring ones. Three studies in hospital settings reported positive effectiveness and patient safety outcomes and three found non-significant effects of publication. Six hospital studies reported changes to case mix or selection of healthier patients, with implications for outcomes. One study of individual providers found a positive impact on mortality. Three individual provider studies found an association with selection of healthier patients, and one with increased racial and ethnic disparities.

ii. Findings by meso-level features (structural)

Table 4: Findings by meso-level features (structural)

	Positive	Negative	Variance shown	Mixed/partial	NS	Number of findings (n=230)
Pettigrew <i>et al</i> features						
Change agenda and its locale	8	4	1	1	3	17
Co-operative inter-organisation networks	9			1	2	12
Environmental pressures	3	4			1	8
Managerial-clinical relations	2					2
Quality and coherence of policy	36	1		2	10	49
Simplicity and clarity of goals	1					1
Supportive organisational culture	4					4
Non-Pettigrew <i>et al</i> features						
Organisation factor	38	15	4	5	23	85
Patient involvement	1				1	2
Performance factor	4	5			4	13
Workforce factor	15	8		7	2	32
Other non-Pettigrew <i>et al</i> inner context factor	3	1	1			5
Total	124	38	6	16	46	230

Notes NS=non-significant or no effect

Better quality is interpreted as positive, even if given in a negative measure (eg, fewer adverse events) in the study
 $p < 0.05$ is interpreted as significant for this review

'Mixed/partial' includes studies which have negative and positive findings for measures of the same factor, or a ratio of positive to non-significant findings on measures of the same factor smaller than 1:6

As table 4 shows, we found 230 'structural' factors that had been explored at the meso (organisational level) in 104 different studies. This makes studies of financial, material, human and informational factors at the organisational (hospital or primary care organisation) level by far the most commonplace overall in relation to researching the role of context in quality improvement. Of these 230 factors, 124 (54%) were found to have had a positive impact, 38 (17%) a negative impact and 46 (20%) had no effect. The most common study design was to undertake a cross-sectional quantitative survey (152 factors, 66%).

In relation to the eight original Pettigrew *et al* features, structural factors relating to 'quality and coherence of policy' were the most frequently studied (n=49) at the organisational level and 73% of these were found to have a positive impact (for example, studies linking quality improvement and factors such as strategic alignment, quality improvement training and human resource policy). Only one factor (physician-specific performance feedback) was found to have a negative impact. Analysis of the impact of factors relating to 'environmental pressures' (n=8) (for example, reconfiguration of services) and 'change agenda and its locale' (n=17) (for example, patient case mix or financial incentives for quality improvement) revealed more mixed profiles

in both cases. Nine of 12 structural factors relating to 'co-operative inter-organisational networks' were found to have a positive impact; similarly, all four studies of 'supportive organisational culture' factors were positively associated with quality improvement. Although we found only two studies of 'managerial-clinical relations' both of these were reported to have a positive impact, as did the study of 'simplicity and clarity of goals'. No studies of structural factors relating to 'key people leading change' were retrieved.

In addition, a significant number (n=137, 60%) of the 'structural' factors studied at the organisational level could not be neatly categorised within the original Pettigrew *et al* features. We therefore grouped these factors under the additional, broad term of 'inner context' and identified five sub-categories within this:

- organisation factors (for example, organisational size/type or range of services provided)
- factors relating to extent and type of patient involvement
- workforce factors (for example, skills mix or proportion of agency staffing)
- performance factor (for example, financial or operational performance)
- other.

The most common sub-categories related to organisation (n=85) and workforce (n=32) factors. Overall, 61 (45%) of the additional 'inner context' factors were reported to have a positive impact on quality improvement, 29 (21%) a negative impact and 30 (22%) had no effect.

Twelve primary studies of meso-structural contextual factors reached the 90% quality threshold and the findings of these are now described in more detail.

Bradley *et al*³⁴ studied whether quality improvement efforts (using data from a telephone survey of quality management directors) were associated with hospitals' beta-blocker prescription rates after AMI. They found that quality improvement efforts that were associated with higher or medium hospital performance comprised structural contextual factors (as well as specific interventions). The authors report that hospitals with greater support for quality improvement from managers, nurses and doctors as well as greater availability of resources for quality improvement projects were less likely to be in the lower beta-blocker use group and more likely to have medium or higher beta-blocker use. An index of organisational culture

was not significantly associated with performance but it was strongly associated with organisational support, which in turn was associated with better performance. However, neither teaching status nor volume was significantly associated with higher beta-blocker rates. The authors conclude that organisational context may be as least as important to clinical performance as the specific quality improvement interventions that are employed; hospitals without strong administrative support and physician leadership are unlikely to affect desired performance improvement.

In a later cross-sectional study of 4,458 hospitals Bradley *et al*³⁷ found that several hospital structural contextual factors were associated with performance as measured by 30-day risk-standardized mortality rates. These contextual factors were teaching hospital status, greater volume of the marker condition (AMI), larger number of beds, having open heart surgery capability, non-profit versus government ownership and geographical location. However, together these factors explained 17.1% of the variation in outcomes. The authors suggest that targeting certain types of hospitals (for example, lower volume or non-teaching hospitals) for quality improvement may have limited impact. They also argue for better evidence regarding the internal processes of hospitals including interdepartmental and interdisciplinary coordination, needed to identify key determinants of performance and potential levers for change.

Stetler *et al*⁴⁰ explored meso-structural contextual factors that supported routine implementation of evidence-based practice (EBP) using a mixed method exploratory case study in two hospitals. The Pettigrew *et al* model of receptive/non-receptive context was used as the framework for the study. The most influential element that appeared to affect the institutionalisation of EBP was that of multiple, key people leading change (in both formal and informal leadership positions at all organisational levels). The authors conclude that there are a number of meso-structural contextual factors that are modifiable.

Grabowski *et al*⁴² studied the performance of 2,170 nursing homes which converted from non-profit to for-profit or from for-profit to non-profit status in the US. The study found little evidence to suggest a causal relationship between ownership conversions and nursing home performance, although nursing homes converting from non-profit to for-profit status were generally declining performers, while homes converting from for-profit to non-profit were generally improving performers.

Chukmaitov *et al*⁴¹ explored potential associations in US ambulatory surgery centres between two meso-structural contextual factors (specialisation and volume of procedures) and quality performance, operationalised in this particular study as unplanned hospitalisations at 30 days after outpatient arthroscopy and colonoscopy procedures. The study found that higher levels of specialisation and volume of procedures may be associated with a decrease in unplanned hospitalisations.

Curry *et al*³⁵ conducted a qualitative study of 11 US hospitals to identify whether clinical guidelines and protocols were related to better performance in AMI care. They found that none of these quality improvement practices were consistently present in the high performing hospitals or consistently absent in the low performing hospitals.

Weiner *et al*⁴³ explored whether four meso-structural contextual factors were associated with performance on Patient Safety Indicators (PSIs) in 1,784 community hospitals in the US. The factors were: involvement by multiple hospital units in the quality improvement effort; proportion of hospital staff participating in quality improvement teams; proportion of senior managers participating in quality improvement teams; and proportion of physicians participating in quality improvement teams. The study found that involvement by multiple hospital units in the quality improvement effort was associated with worse values on four selected PSIs. While the percentage of physicians participating in quality improvement teams was positively associated with two of the indicators, the percentages of hospital staff and of senior managers participating in quality improvement teams showed no statistically significant association with any of the four indicators. The authors note that these final two results are surprising given the strong emphasis found in the quality improvement literature on active participation of all health care professionals in identifying, assessing and correcting quality problems.

In a related study by the same research team, Alexander *et al*³⁶ examined how the association between quality improvement implementation and clinical quality is moderated by hospital organisational context. The meso-structural contextual factor considered here was the profitability of the hospital, as the authors argued that – for quality improvement – hospitals must have sufficient resources and financial slack. The study found that quality improvement implementation is unlikely to improve quality of care in hospital settings without a commensurate fit with the financial imperatives faced, ie as profitability increases, the association between

hospital focus on improving system processes and better quality indicators strengthens. One surprising finding, however, was that the increased use of quality of care data in support of quality improvement efforts was associated with lower quality when profitability increased.

In a third and final study by the same research team, Weiner *et al*⁴⁴ focused on the association between the scope of quality improvement implementation on selected indicators of clinical quality (as opposed to PSIs in the Weiner *et al* study⁴³ summarised above). In this third study Weiner *et al* reported that involvement by multiple hospital units in quality improvement was (again surprisingly) associated with worse values on hospital-level quality indicators but that the proportion of hospital staff and senior managers participating in formally organised quality improvement teams was associated with better values on quality indicators. The proportion of physicians participating in quality improvement teams was not associated with better values on quality indicators.

Escarce *et al*³⁸ studied 144 different eye care practices in the US to examine the association between characteristics of eye care practices and patient satisfaction with eye care. The meso-structural contextual factors considered were provider specialty, practice organisation, financial features, and utilisation and quality management systems (all of which, the authors argued, were modifiable). Treatment in a practice which obtained a high proportion of its revenues from capitation payments or in a group practice where providers obtained a high proportion of their incomes from bonuses were associated with lower satisfaction. The authors argue that managed health care plans and provider groups should aim to blunt the negative impact of managed care features on satisfaction.

Lake *et al*³⁹ studied the relationship between Magnet status,* nursing unit staffing and patient falls in a cross-sectional study in 636 hospitals in the US. The meso-structural contextual factors studied were nurse staffing, registered nurse (RN) staff composition and hospital Magnet status. The fall rate was found to be 5% lower in Magnet than non-Magnet hospitals. An additional RN hour per patient day was associated with a 3% lower fall rate in intensive care units (ICUs). An additional licensed practical nurse or nursing assistant hour was associated with a 2-4% higher fall rate in non-ICUs. The authors argue that there are potentially two mechanisms

* Magnet status is an award given by the American Nurses' Credentialing Center (ANCC), an affiliate of the American Nurses Association, to hospitals that satisfy a set of criteria designed to measure the strength and quality of their nursing. www.truthaboutnursing.org/faq/magnet.html

for enhancing patient safety: becoming or emulating a Magnet hospital, or adjusting staffing patterns at the unit level.

Zegers *et al*⁴⁵ conducted structured retrospective patient record reviews of admissions in 21 Dutch hospitals and explored whether hospital characteristics could explain differences in adverse events (AEs). The type of hospital (teaching/non-teaching) explained 35% of the inter-hospital variance in AEs; the authors suggest that unmeasured organisational factors (for example, safety culture or the hospital's quality management systems) may explain the remaining variance. However, the main finding of the study was that there can be significant differences in the rates of preventable AEs between different departments within the same hospital. The authors suggest that interventions tailored for individual hospital departments are necessary to reduce patient safety risks.

In relation to structural factors at the organisational (meso) level our review highlights the following:

- The importance of factors relating to the 'quality and coherence of policy' within organisations: for example, aligning organisational objectives pertaining to quality improvement with human resource and training strategies.
- Consistently positive findings in relation to 'co-operative inter-organisational networks', 'supportive organisational culture', 'managerial-clinical relations' and 'simplicity and clarity of goals' (but note that only small number of studies have examined these features).
- A large number of organisational-level structural factors lie outside the original Pettigrew *et al* features (such as organisation size and the range of services provided) but have been studied to see whether they are associated with higher quality of care.
- The majority of structural factors at the organisational level are modifiable (for example, publication of patient outcomes data) but usually only in the medium to long term.

Structural contextual factors which have been modified at the organisational (meso) level and evaluated for their impact upon quality improvement are:

- introducing an electronic health record
- converting from for-profit to non-profit
- introducing financial incentives to enhance feedback
- introducing target payments relating to quality indicators (several studies)
- introducing a professional development scheme.

Of these, the following had a positive impact on quality improvement: a multifaceted quality improvement intervention including a financial incentive, which led to a significant improvement in adherence to guideline for acute sinusitis care.

A systematic review of RCTs examining the impact of financial incentives on provider (physician) preventive care delivery included six studies and eight financial incentives.⁵² Only one (performance-based physician reimbursement) found a significant relationship between the incentive (Fee-for-service) and preventive care delivery (immunisations). However, the authors note that the financial incentives in these studies tended to be small so conclude that small rewards will not motivate doctors to change their preventive health practices.

iii. Findings by meso-level features (psychological)

Table 5: Findings by meso-level features (psychological)

	Positive	Negative	Variance shown	Mixed/partial	NS	Number of findings (n=108)
Pettigrew <i>et al</i> features						
Key people leading change	21	1			6	28
Managerial-clinical relations	1					1
Quality and coherence of policy	2				1	3
Simplicity and clarity of goals	4					4
Supportive organisational culture	43	3	1		22	69
Non-Pettigrew <i>et al</i> features						
Organisation factor					1	1
Patient involvement	1					1
Other non-Pettigrew <i>et al</i> inner context factor	1					1
Total	73	4	1	0	30	108

Notes NS=non-significant or no effect

Better quality is interpreted as positive, even if given in a negative measure (eg, fewer adverse events) in the study
 $p < 0.05$ is interpreted as significant for this review

'Mixed/partial' includes studies which have negative and positive findings for measures of the same factor, or a ratio of positive to non-significant findings on measures of the same factor smaller than 1:6

As table 5 shows, we found 108 'psychological' factors that had been studied at the meso level in 45 different studies. We found fewer relevant studies, and a fewer number of psychological factors studied, compared to studies of structural factors at this meso (organisational level). Of these 108 findings, 73 (68%) were found to have a positive impact, 4 (4%) a negative impact and 30 (28%) had no effect. The most common study design was quantitative and cross-sectional (63) but a significant proportion (45) used other designs such as longitudinal quantitative methods and qualitative case studies.

In relation to the eight Pettigrew *et al* features, psychological factors relating to 'supportive organisational culture' were the most frequently studied (n=69) at the organisational level. This group includes a wide range of studies on various dimensions of culture, for example, 'collegiality' and 'innovativeness' as well as typologies of organisational culture such as the Competing Values Framework and their relationship to quality/quality

improvement. The majority of these studies (43 findings, 62%) were found to have a positive impact (for example, studies in England⁵³ and in the US³⁵).

The next largest group of findings relate to the feature 'key people leading change' (n=28) and of these, 21 were found to be positive. These include a number of studies on the role of different types of leadership and their impact on quality/quality improvement. There is a much lower number of findings relating to the following features: managerial-clinical relations (1); quality and coherence of policy (3); simplicity and clarity of goals (4). There were a small number of findings which did not fit into the Pettigrew *et al* features: organisation factor (1 on clinical reputation); patient involvement (1 on working with patients at primary and community level); other (1 where innovativeness was measured by a staff survey on whether innovation was encouraged in a primary practice).

Six papers meeting our 90% quality threshold include meso-psychological factors. Two of these papers are cross-sectional studies, one is a natural experiment, two are qualitative studies and one is mixed methods.

Benzer *et al*⁴⁸ used a two-dimensional model of organisational climate to explain variation in diabetes care between primary care clinics in a cross-sectional study. Relational climate (management focus on mutual support and respect) was related to increased likelihood of adherence to diabetes care processes, with significant but small effects for adherence to intermediate outcomes (adherence to particular clinical standards, for example, blood sugar levels and blood pressure). Task climate (management focus on achievement and improvement) was not generally shown to be related to adherence.

Bradley *et al*³⁴ studied whether quality improvement efforts (using data from a telephone survey of quality management directors) were associated with hospitals' beta-blocker prescription rates after AMI. The authors also included a number of meso structural factors. The quality improvement efforts consisted of five domains: quality improvement interventions; data feedback; physician leadership; organisational support for quality improvement; and organisational culture. None of these distinguished between higher and medium performers on beta-block rates. The higher and medium performers were distinguished from lower performers through organisational support and physician leadership.

Doyle *et al*⁴⁶ studied the impact of clinical reputation on the cost of a stay in hospital. Patients (nearly 30,000) were randomly assigned to two clinical teams from one of two academic institutions. One was ranked among the top medical schools in US, the other ranked lower. Patients treated by the programmes had similar observable characteristics and access to a single set of facilities and ancillary staff. Those treated by physicians from higher ranked institution had 10-25% less expensive stays than patients assigned to the lower ranking institution. Health outcomes were not related to physician team assignment. Cost differences were most pronounced for serious conditions and largely related to diagnostic testing rates: the lower ranked programme tended to order more tests and took longer to order them.

Krein *et al*⁴⁷ conducted a multi-centre qualitative study of the influence of organisational context on quality improvement and patient safety efforts. They focused on strategies to reduce central line-associated blood stream infections (CLABSIs). They found that among a number of hospitals that focused on preventing CLABSIs, despite using similar implementation strategies,

the experience and outcomes of these efforts varied considerably given the organisational context. Hospitals with a positive 'emotional' and 'cultural' context appear especially conducive for facilitating internally driven initiatives. Authors argue that these findings are consistent with Weiner's concept of organisational readiness for change.¹³

Curry *et al*³⁵ also conducted a multi-centre qualitative study to identify meso contextual factors that may relate to performance in AMI care and associated mortality rates. Most of the factors studied were psychological ones. Hospitals in the high and low performing groups differed substantially in the domains of organisational values and goals; senior management involvement; broad staff presence and expertise in AMI care; communication and coordination among groups; and problem solving and learning. Diverse care protocols and processes for AMI care were found in the hospitals, but these did not systematically differentiate between the high and low performing hospitals. The authors conclude that the high performing hospitals were characterised by an organisational culture that supported efforts to improve AMI care, and that evidence-based protocols and processes, though important, may not be sufficient for achieving high hospital performance for patients with AMI.

Stetler *et al*⁴⁰ conducted a mixed methods organisational case study of two contrasting sites of EBP implementation (one a 'role model' site, the other a 'beginner' site) in terms of the presence or absence of multiple, inter-related contextual factors and associated strategic approaches required for the institutionalisation of EBP. The two sites differed in relation to their organisational context, level of EBP activity and degree of institutionalisation. The role model site's inner context had a combination of the Pettigrew *et al* receptive factors which appeared to enhance its ability to implement EBP effectively. The beginner site (which had been involved for a few years with EBP activity) had primarily non-receptive conditions, particularly in relation to the lack of leadership in implementing or supporting the implementation of EBP.

In relation to psychological factors at the organisational (meso) level our review highlights the following:

- The importance of factors relating to 'supportive organisational culture' within organisations: for example, the degree to which quality is emphasised, how committed clinicians are to quality, a focus on results and a non-punitive response to error.

- The importance of factors relating to ‘key people leading change’, particularly relating to leadership qualities and leadership change.
- Consistent positive findings in relation to factors relating to both ‘supportive organisational culture’ and ‘key people leading change’.

Surprisingly few studies were retrieved concerning psychological context factors at the organisational level relating to ‘managerial–relations’ in terms of their impact on quality/quality improvement, and similarly in relation to the features of ‘quality and coherence of policy’ and ‘simplicity and clarity of goals’.

The studies retrieved for this review were not evaluating factors which had been modified (except for two studies included in a systematic review). Rather, they are studies of, for example, supportive organisational culture, as an explanatory variable for quality/quality improvement. No studies were retrieved from our search of primary

empirical studies where the contextual factor had deliberately been modified in an attempt to improve quality/quality improvement.

One of the reviews we excluded (Parmelli *et al*⁵⁴), however, systematically reviewed studies of the effectiveness of strategies to modify organisational culture to improve health care performance. The review considered RCTs, controlled clinical trials, controlled before and after studies, and interrupted time series analyses. Main outcomes were measures of professional performance and patient outcomes. While their search strategy yielded 4,239 records, after full text assessment only two controlled before and after studies were included. Both these studies assessed the impact of interventions aimed at changing organisational culture, but one evaluated the impact on work-related and personal outcomes while the other measured clinical outcomes. Both reported positive results but the authors noted that both were at high risk of bias.

iv. Findings by micro level features (structural)

Table 6: Findings by micro level features (structural)

	Positive	Negative	Variance shown	Mixed/partial	NS	Number of findings (n=38)
Pettigrew <i>et al</i> features						
Change agenda and its locale	2	3				5
Environmental pressures	2				1	3
Quality and coherence of policy	6			1	3	10
Supportive organisational culture	1					1
Non-Pettigrew <i>et al</i> features						
Organisation factor	1		1			2
Performance factor				1	1	2
Workforce factor	5	3		1	4	13
Other non-Pettigrew inner context factor	1		1			2
Total	18	6	2	3	9	38

Notes NS=non-significant or no effect

Better quality is interpreted as positive, even if given in a negative measure (eg, fewer adverse events) in the study

$p < 0.05$ is interpreted as significant for this review

‘Mixed/partial’ includes studies which have negative and positive findings for measures of the same factor, or a ratio of positive to non-significant findings on measures of the same factor smaller than 1:6

As table 6 shows, 38 structural factors have been explored at the micro system level (frontline clinical team) in 32 studies. Of the 38 factors, 18 (47%) were found to have a positive impact on quality improvement, 6 (16%) a negative impact and 9 (24%) had no effect.

The largest category of structural factors we found had been studied at the micro system level lay outside the original eight features described by Pettigrew *et al.* Again we labelled this as relating to the broader ‘inner context’ (in this case, of a frontline team) which comprised factors largely relating to the workforce (n=13). The most commonly studied set of factors relating to one of the original features described by Pettigrew *et al* were those concerning the ‘quality and coherence of policy’; results overall were positive, with six positive and three non-significant findings. Findings relating to a ‘supportive organisational culture’ were also positive overall but for the ‘change agenda and its locale’ they were more mixed and the number of studies retrieved for these features was relatively small. In addition, we found three studies relating to structural factors within ‘environmental pressures’ and categories at the micro system level. We did not find any studies relating to ‘managerial-clinical relations’, ‘simplicity and clarity of goals’ and ‘key people leading change’ in terms of structural contextual factors at the micro system level.

Two studies meeting our 90% quality threshold included micro structural factors. Escarce *et al*³⁸ studied the relationship between characteristics of managed care practices and the satisfaction of care of patients with glaucoma and diabetic retinopathy. The micro structural factor they included was treatment by a specialist for these conditions – and patient satisfaction was higher in a practice with a concordant specialist.

Using retrospective record review, Zegers *et al*⁴⁵ studied the variation in the rates of AEs and preventable AEs between hospital departments (they also studied variation between hospitals – see section ii on meso-structural features). The rates of AEs varied significantly between hospital departments. Patient and department characteristics explained 23% of the inter-department variation. Increasing age and co-morbidity were associated with increased risk of preventable AEs. In addition, longer lengths of stay and surgical procedures led to higher risk. The authors conclude that patient safety interventions need to be tailored for specific departments to reduce patient safety risk. Monitoring and comparing performance of hospitals should be extended to include individual departments as there can be significant differences between different departments within the same hospital.

In relation to structural factors at the frontline clinical team (micro) level our review highlights the following:

- Consistently positive findings in relation to ‘quality and coherence of policy’ and ‘supportive organisational culture’ (but note that only a small number of studies have examined these features).
- A number of frontline clinical team structural factors relating particularly to the workforce that lie outside the original Pettigrew *et al* features.
- We found only one structural contextual factor which had been modified at the frontline clinical team (micro) level and evaluated for its impact on quality improvement:
 - a multifaceted quality improvement intervention including a financial incentive which had led to a significant improvement in adherence to a guideline for acute sinusitis care.

v. Findings by micro level features (psychological)

Table 7: Findings by micro level features (psychological)

	Positive	Negative	Variance shown	Mixed/partial	NS	Number of findings (n=30)
Pettigrew <i>et al</i> features						
Key people leading change	4				4	8
Quality and coherence of policy	1					1
Simplicity and clarity of goals					1	1
Supportive organisational culture	13	1		2	4	20
Total	18	1	0	2	9	30

Notes NS=non-significant or no effect

Better quality is interpreted as positive, even if given in a negative measure (eg, fewer adverse events) in the study
 $p < 0.05$ is interpreted as significant for this review

'Mixed/partial' includes studies which have negative and positive findings for measures of the same factor, or a ratio of positive to non-significant findings on measures of the same factor smaller than 1:6

As table 7 shows, only 30 psychological factors have been explored at the micro system level (frontline clinical team) in 11 studies. This makes studies of psychological factors at the micro system level the least common of our research categories in relation to the role of context in quality improvement. Of the 30 factors that have been studied, 18 (60%) were found to have a positive impact, one a negative impact and 9 (30%) had no effect.

'Supportive organisational culture' factors (for example, various measures of different dimensions of team 'climate' or teamwork) were the most commonly studied and typically found to be positively associated with quality improvement (albeit with one negative finding where there was a lack of commitment to quality improvement). Studies of psychological factors relating to 'key people leading change' at the micro system level included those focusing on supportive and/or physician leadership.

One study met our 90% quality threshold. Hansen *et al*⁴⁹ examined the relationship between measures of hospital safety climate and hospital performance on selected PSIs using data from several secondary sources in a cross-sectional study of 91 hospitals. The study found that hospitals with a better safety climate overall had lower relative incidence of PSIs, as did hospitals with better scores on safety climate dimensions measuring interpersonal beliefs regarding shame and blame. Frontline personnel's perceptions of a better

safety climate predicted lower risk of experiencing PSIs, but senior managers' perceptions did not. The authors concluded that perceptions about safety climate among some groups, such as frontline staff, are more closely related than perceptions in other groups.

In relation to psychological factors at the frontline clinical team (micro) level our review highlights the following:

- There was a relatively small number of studies focusing on these factors.
- We did not find any studies that had sought to modify a psychological factor at the frontline clinical team (micro) level and which had then been evaluated for its impact upon quality improvement.

Quantitative studies reporting interactions between contextual factors

Our count of studies reporting interactions included only those quantitative studies which reported an interaction as a main finding. While many studies, particularly those with a regression analysis, have the potential to look at the mediating effect of one factor, most use this tool to ‘clear other factors out of the way’ and show an independent impact of a primary factor. However we found 11 studies where the authors were interested in, and highlighted, interactions between factors.

Studies could be grouped into those where the interaction increased an effect on quality or implementation of a quality improvement intervention, those where it was reduced or explained away and ones where there was no interaction found.

Among enhancing effects (six interactions), patient days per registered day increased the negative impact of nurse absenteeism, established staffing affected the quality impact of agency nurse use,⁵⁵ market factors and profitability strengthened the impact of quality improvement tool use on quality,³⁶ and organisational network ties strengthened the association of late or early total quality management (TQM) adoption with conformity to a standard TQM model.⁵⁶ Allowing for productivity changed the impact of the introduction of an internal market from a non-significant to a positive one as measured by mortality,⁵⁷ and the association of safety climate assessed by frontline was negative whereas that assessed by senior staff showed no effect.⁵⁸

Factors explaining away the impact of other factors (two interactions) included perceived team effectiveness reducing the impact of culture on a quality improvement intervention⁵⁹ and quality climate mediating the effect of leadership effectiveness on number of patient complaints.⁶⁰

Finally, for the no effect findings (three interactions) use of nursing home restraint varied by organisational factor, showing increases and decreases over a period when restraint use was regulated;⁶¹ the impact of various organisational measures did not vary between Veterans Administration (VA) and non-VA hospitals in the US;⁶² and the impact of physician working time regulation did not vary between teaching and non-teaching hospitals.⁶³

Studies with economic measures

At the explicit request of the Health Foundation, we also collated findings from studies which were eligible and included an economic or cost measure. We identified 21 studies using economic measures, both as contextual factors and outcomes, and in both cases we were interested in whether there was a trade-off or a mutually beneficial relationship between quality improvement and economic performance.

There were nine findings in seven studies where an economic measure was a contextual factor. Of the five studies that looked at efficiency of health care organisations as a contextual factor, three had no effect on quality, one a positive effect and one a negative effect. Of those that looked at health care organisation financial performance, two had a positive effect and one no effect. There were two which looked at spending per patient, one with a positive effect and one with a negative effect.

We grouped the 16 findings across 13 studies eligible for our review, which included economic outcomes, into:

- those where the impact of a contextual factor went in the same direction for quality and economic performance, or there was no economic loss (‘no conflict’ – eight findings)
- those where the effects were conflicting (four findings)
- those where a contextual factor had no impact on quality and an adverse economic impact (two findings)
- ones with no effect on either outcome type (two findings).

Among the no conflict findings, ie no economic loss, there were good outcomes from teams with a good clinical reputation,⁴⁶ payment by results,³³ organisation size and belonging to a hospital system or health system,⁶⁴ innovativeness,⁶⁵ and a quality improvement intervention.⁶⁶ Both quality and economic outcomes worsened by not providing specialist services in a US medical group⁶⁴ and following a report card intervention.⁶⁷ There were conflicts between economic performance in two studies of introduction of internal markets,^{57,68} and introduction of a quality intervention did not improve billing practice, but did improve quality.⁶⁹ One study found better quality and worse efficiency in teaching hospitals.⁷⁰ Public ownership had no quality impact and worse efficiency in the same study, as did membership of a hospital system.

Discussion

We reviewed 171 empirical studies of the impact of a total of 476 contextual factors in quality improvement, as retrieved by our search strategy (see Methods). It is important to note *a priori* that the majority of the studies we reviewed were cross-sectional studies of hospitals in the United States (103/171), were set in acute care organisations (127/171), focused on clinical effectiveness rather than patient safety or patient experience as an outcome measure (98/171), did not evaluate the impact of modifying a contextual factor in order to improve quality (144/171), and – perhaps most strikingly – did not study interactions between more than one contextual factor (161/171).

As outlined above, we have taken as our starting point the well-known notion of receptive and non-receptive contexts for change from Pettigrew *et al.*⁹ We categorised these either into one of the eight features from Pettigrew *et al.* (see figure 2) or additional contextual factors that we felt lay outside the Pettigrew *et al.* features. We did this so we could explore where research attention had been focused in terms of a widely recognised framework for thinking about and understanding contextual influences on change interventions, and to enable us to identify any important gaps in existing evidence. In short, we felt it was as good a place to start as any in trying to make initial sense of what we knew would be diverse and disparate literature. We found that – of the Pettigrew *et al.* eight features – the most common to have been studied in terms of contextual factors influencing quality improvement were a ‘supportive organisational culture’ (94/476), ‘quality and coherence of policy’ (63/476) and ‘environmental pressures’ (60/476). Surprisingly, we found that ‘co-operative inter-organisational networks’ (12/476) and ‘managerial and clinical relations’ (3/476) had been only rarely studied as contextual factors influencing the outcomes of quality improvement interventions (although both have, of course, been extensively studied from other

perspectives). We also found a significant number of contextual factors studied lay outside the original features from Pettigrew *et al.* (158/476), mostly relating to factors such as organisational size, range of services offered and workforce configurations.

We then categorised all the contextual factors in terms of the level of the health care system (macro, meso or micro) at which they were situated in terms of quality improvement. The justification for this explicit attention to multiple levels of context is our assumption that it is the interactions between these levels that impact significantly on the success and sustainability of quality improvement efforts. Such a multi-level perspective has been largely lacking in much quality improvement research despite calls for such an approach from other disciplines.^{17,71,72} We wanted to discover at which levels of the health care system research attention relating to quality improvement interventions had been focused in the past, and whether there were significant gaps in the knowledge base that might limit the design of future interventions. We found that the vast majority of the contextual factors studied (338/476) were explored at the meso (organisational) level, an unsurprising finding given the preponderance of large-scale, cross-sectional surveys found by our review. We found only 36 studies that explored the impact of interactions between contextual factors situated at more than one level.

Thirdly, we explored whether the contextual factors that had been studied previously related to ‘psychological’ or ‘structural’ factors. We have previously argued⁶ that contemporary psychological perspectives need to be considered alongside more ‘traditional’ structural perspectives of how context shapes the outcomes of quality improvement interventions. We expected to find that most attention had been paid by previous research studies to structural factors (such as an organisation’s policies, resources or systems) rather than psychological factors (such as staff commitment to

change or other social dynamics). We found that 338 of the 476 contextual factors studied related to structural as opposed to psychological factors. Where psychological factors had been studied, this was most commonly in terms of ‘a supportive organisational culture’ at the meso (organisational) level (69/138). Significantly, only 30 psychological factors had been studied at the micro (frontline team) level.

What are the implications for those sponsoring and leading quality improvement interventions?

Consistent with other recently published – but much narrower – reviews focusing on the role of context in quality improvement,^{19,73} we found that the evidence base for intervening to modify contextual factors in order to positively impact on the outcomes of quality improvement interventions is currently very weak. The few studies that have sought to do so have largely been focused on the macro (health system) level, often as the result of ‘natural’ experiments in which researchers have opportunistically studied either the impact of a policy intervention in one geographical area compared to another area where the policy was not introduced, or pre/post studies of system-wide interventions. We found only 28 contextual factors (26 structural and only two psychological) that had been purposively modified in order to test their impact on quality improvement, and these mainly related – again – to macro level interventions (such as publication of performance data or payment for performance). In short, very few studies have explicitly sought to modify a contextual factor in order to test its impact on quality improvement (ie intervention studies); rather the vast majority conceptualise contextual factors as variables to explain the outcomes of quality interventions (and do this mainly through large-scale cross-sectional studies). In this manner we did find generally positive findings in relation to the impact on quality improvement of contextual factors relating to ‘co-operative inter-organisational networks’, ‘supportive organisational culture’, ‘managerial-clinical relations’ and ‘simplicity and clarity of goals’, but note that only a small number of studies have examined contextual factors within these features.

While our review found mostly single level studies (ie at the macro, meso or micro levels but not between levels), it is interesting to note the largely positive findings relating to ‘quality and coherence of policy’ at the meso level. In our view, this suggests the importance of **multi**-level coherence and of the dynamic interaction between different levels in shaping the impact of quality

improvement interventions. This suggests that those leading quality improvement interventions have to attend to multi-level processes rather than focusing solely on meso or micro levels in isolation, and yet our review found only a very small number of studies that have actually explored interactions between different levels.

However, it is not only the interactions between levels that shape the outcomes of quality improvement interventions but also the dynamic relationships between different contextual factors, both within and between levels. Again, we found only a small number of studies that explicitly sought to study the interactions between several contextual factors. As Bate⁴ summarises, a recent literature-based study by Damschroder *et al*⁷⁴ investigated why many interventions found to be effective in one or more health care organisations fail to translate into meaningful patient care outcomes across multiple contexts. The study identified five domains that influenced the impact of quality improvement interventions: the intervention itself (content), inner context and outer setting (ie context), the individuals involved, and the process by which the implementation is accomplished. Reminiscent of Pettigrew, and of other more recent work in this area,¹⁰ this study again argues that it is the dynamic and ongoing **interaction** between contextual factors and levels, rather than any one of them individually or independently, that accounts for the effectiveness of a quality improvement intervention and the striking variation between similar quality improvement interventions in different places.

Study limitations*

It is important to note that there are several limitations to our review. Firstly, and most importantly, and as Bate argues, the contextual features described by Pettigrew *et al* ‘are depressingly familiar and predictable’ and:

expressed at such a high level of abstraction that it would be difficult for any researchers to go out and test or replicate them, or a strategist and quality

* The systematic review on which this report is based was completed in 2012 (and the electronic search for relevant papers covered the period until September 2011). Subsequent to the completion of the review several important contributions to the literature have been made especially in relation to the further development of the Model for Understanding Success in Quality (MUSIQ). Readers are therefore directed to the following papers for further details:

- Kaplan HC, LP Provost, Froehle CM and Margolis PA. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. *BMJ Qual Saf* 2012, 21: 13-20
- Kaplan HC, Froehle CM, Cassidy A, Provost LP and Margolis PA. An exploratory analysis of the Model for Understanding Success in Quality. *Health Care Management Review* 2013, 38: 325-338

*improvement professionals to use them in any practical way... Nor does the model say a great deal about the nature, patterns or directions of the interrelationships and interactions between the features.*⁴

While our review has significantly extended previous attempts to synthesise what is known about the role of context in quality improvement in health care organisations (by exploring what is known about contextual factors at different levels of health care systems and conceptualising a very disparate and large number of individual factors by using the Pettigrew *et al* eight features, as well as applying the psychological/structural distinction to them), the dynamics of context remain a mystery. As Øvretveit suggests,³ there is some evidence about which of these contextual factors are critical for quality improvement, but we do not know if they are necessary for all, or even if there are only some categories of quality improvement (eg, interventions at certain levels or those seeking certain outcomes) for which they are necessary. Of course, Pettigrew *et al* focused on local variability in the achievement of strategic change rather than quality improvement *per se* (as did, for example, later attempts to visually 'map' the interactions between factors).¹⁰

However, one seemingly neglected group of contextual factors emerging from our findings are those relating to psychological perspectives. As described above, it is striking that they were so underrepresented in our review: for example, studies of psychological factors at the micro system level were the least common of our groups of factors in relation to the role of context in quality improvement. As we previously argued,⁶ Weiner's notion of 'readiness' for change,¹³ Huy's work on 'emotional receptivity' at the individual and organisational levels,^{14,15} the identification by Bate *et al* of the 'emotional challenge' facing health care organisations wishing to 'organise for quality'¹⁰ and the proposition that social context is the key facilitator of quality improvement¹⁶ offer good starting points for moving away from narrow, purely structural, conceptualisations of 'context' which have dominated the literature to date. However, adding further factors to an already well-rehearsed list will not, alone, move our understanding of the role of context in quality improvement forward.

Secondly, and as noted by several commentators, it is also often difficult (and ultimately unhelpful) to separate 'context' from a quality improvement intervention, not least because there are inevitably interactions over time

between the two. Øvretveit³ argues that the definition of a boundary between the improvement 'intervention' and the 'context' is relatively arbitrary, describing how some studies define the intervention narrowly and as distinct from implementation, some define the intervention as the change difference to be achieved and the implementation actions, whereas some also include as part of the intervention what others might call context, such as a unit leader's support and actions, and that this combination is then 'the intervention' to be evaluated. Øvretveit³ suggests that studies often do not make clear where this boundary is drawn and that, to be useful to others, reports of quality improvement interventions need to describe precisely the intervention implemented and any evidence of the contextual factors which influenced it. Similarly, it was difficult on occasion to separate psychological from structural factors (for example, Mannion *et al* argue that the introduction of patient choice reforms in England were an attempt to change culture⁷⁵).

Thirdly, we also found it problematic to determine what is 'modifiable'. Of course, some contextual factors cannot be changed – or at least not in the short to medium term – and so they have to be actively managed by those implementing quality improvement interventions rather than 'modified'. For example, and as Bate⁴ describes, Pettigrew⁷⁶ makes the useful distinction between 'inner' (immediate, intra-organisational, micro) context, which includes factors like organisational and divisional cultures, group norms, leadership, local champions and political processes, and 'outer' (social, political, macro) context, which includes for example, NHS and broader economic, social and political trends and events. According to Pettigrew, the former can be directly managed but the latter is usually too big and distant to be managed. Finally, a further 'missing piece' is the temporal element of interventions to improve quality; that is to say, some contextual factors are likely to be more important at different stages of quality improvement – ie adoption, implementation and assimilation into routine practice – but there is very little processual research available on which to draw any conclusions.

Recommendations

Proposed ‘new’ framework for studying the role of context in quality improvement

Following Bate’s plea not to devise an entirely new framework but test and synthesise those that already exist, we propose the following framework which is based on the ideas in our original think piece,⁶ important considerations from the other four think pieces and key findings from this review.

As we argued in our think piece and outlined at the beginning of this report, the starting point for our proposed framework is the Pettigrew *et al* notion of receptive and non-receptive contexts for change which encompasses both ‘hard’ (structural) and ‘soft’ (cultural) factors. We argue that now this needs to be combined with more contemporary psychological perspectives, and the proposition that social context is the key facilitator of quality improvement. Overlaying this combination of different perspectives, we have argued that more attention must be paid to the multiple levels of context (macro, meso and micro) and how these combine to impact upon the success and sustainability of quality improvement efforts.

The basis for our proposed framework for studying the role of context in quality improvement is shown in appendix 3. For each of the levels (macro, meso, micro), we have applied the findings from our review to the relevant features of the Pettigrew *et al* framework (for example, at macro level, there are ‘environmental pressures’ which have been studied such as accreditation status, financial incentives and regulatory frameworks). From our review, however, we have added a number of other features to each of the three levels which Pettigrew *et al* had not explicitly considered: organisation factors (eg, size, length of stay, cost per admission),

performance factors (eg, productivity), patient involvement factors and workforce factors (eg, skill mix, staffing levels).

However, while this approach was appropriate for a review of the literature dominated by cross-sectional studies of contextual factors treated as ‘variables’, it now needs to be **combined** with a focus on processes and interactions which would enable the study of these contextual factors over time. Such an approach could help counterbalance the customary preference for single (and simple) cause–effect ‘variable’ explanations for quality differences (‘variance theory’) over systems or process explanations (‘process theory’) – a preference which we see as a key reason as to why we lack good explanations for why some health care organisations perform better than others. We would therefore agree that there is an urgent need to find out how these system effects (what Pettigrew *et al* call ‘complementarities’) work.* A shift to greater attention to the application of process theory would lead to the investigation of interactions and dynamics over time between different contextual factors at different levels. The challenge is that, although well-established methods do exist for identifying and measuring cause–effect relationships of the traditional kind, this is not the case with ‘systems’ and process models (despite the contributions of theorists such as Langley and Van de Ven). Potentially useful theoretical frameworks that might be applied to the process-based approaches advocated by such theorists may include structuration theory and actor–network theory.

* Pettigrew *et al*. define the task as: ‘Focusing on interaction moves away from the variables paradigm toward a form of holistic explanation. The intellectual task is to examine how and why constellations of forces shape the character of change processes rather than “fixed entities” with variable qualities.’

Leading and implementing quality improvement programmes and interventions

We recommend that the overall aim of any future work in this area should be to provide an evidence base for the co-design and dissemination of reflective tools that enable practitioners to:

- take important contextual factors into account before beginning future quality improvement interventions
- act to make context more receptive where possible
- inform the future design (and ‘tailoring’) of quality improvement programmes themselves.

Øvretveit³ proposes that probably the single best validated instrument for quality improvement context assessment for the UK NHS to date is the recently published Context Assessment Index (CAI),¹² a 37-item instrument based on the PARIHS model); although we are aware that other reflective tools have been developed and tested by practitioners.¹⁰ Piloting the acceptability, feasibility and value of these tools – and other potential tools – to practitioners and then systematically embedding their use in future programmes would be valuable.

We agree with Øvretveit³ and recommend that, given the large gaps in the evidence base we have reviewed, that there is a need to be cautious about proposing that effort and money is invested in striving to create particular contexts when the likelihood of such attempts leading to greater ‘success’ in quality improvement remains uncertain. Rather, categorising quality interventions into groupings – on the basis of the evidence from the piloting and embedding of reflective tools into a range of quality improvement interventions and programmes (see above) – according to which groups of contextual factors are most important for their implementation would give practitioners a better way to assess which types of interventions they are most likely to have success with, according to whether they are operating in a context most suited to success.

We recommend that the design of future quality improvement interventions should be required to attend to all three levels of the health care system (macro, meso and micro) and the alignment between them.

Future research priorities

We recommend that any framework for future empirical research must reject the search for traditional lists of ‘key success factors’ that may be associated with quality improvement success and the testing of these associations through large-scale cross-sectional surveys.

We recommend that longitudinal, process-based, organisational case studies are the preferred research method within complex and dynamic contexts where it is difficult (or unhelpful) to isolate variables or where there are strong interactions between variables.⁷⁷ Such comparative case studies (see Robert *et al*, 2011⁷⁸ for an example of research protocol) can generate hypotheses from exploratory data which can then be tested in wider samples using different methods. In addition – particularly relevant to quality improvement interventions – they address questions of process as opposed to the input/output model of much quantitative research (which we have shown dominates in this field and usually excludes and controls for contextual factors in order to focus on whether an improvement change is associated with changes in measured outcomes). In contrast, process research is characterised by the dynamic study of behaviour within organisations, focusing on organisational context, activity and actions which unfold over time.^{79,80} As Dixon-Woods argues,⁵ the attribution of causality in case studies can be supported by iterative pattern-matching processes that develop explanations, deduce implications of those explanations and seek additional information to further explore these explanations.

Appendices

Appendix 1:

Scopus search strategy

Organisation terms

INDEXTERMS('ambulatory care' OR 'community health' OR 'dental care' OR 'family practice' OR 'general practice' OR 'general practitioner' OR 'group practice' OR 'health care' OR 'Health Maintenance Organizations' OR 'health services' OR 'hospital' OR 'managed care programs' OR 'nursing homes' OR 'outpatients' OR 'Patient Care Team' OR 'physicians, family' OR 'primary health')

Quality terms

INDEXTERMS('health care quality' OR 'Quality Assurance, Health Care' OR 'quality control' OR 'Quality Indicators, Health Care' OR 'total quality management')

Contextual factors terms

INDEXTERMS('health personnel' OR 'Efficiency, Organizational' OR 'health care organization' OR 'hospital organization' OR 'Models, Organizational' OR 'organization and management' OR 'Organizational Case Studies' OR 'Organizational Culture' OR 'Organizational Innovation' OR 'Organizational learning' OR 'Organizational Objectives' OR 'motivation' OR 'leadership')

Outcome terms

INDEXTERMS('customer satisfaction' OR 'patient satisfaction') OR INDEXTERMS('accident prevention' OR 'infection control' OR 'patient safety' OR 'risk management' OR 'safety management') OR INDEXTERMS('efficiency, organizational' OR 'evaluation studies' OR 'outcome and process assessment' OR 'outcome assessment' OR 'program evaluation' OR 'quality indicators')

Study design terms

INDEXTERMS('cohort stud*' OR 'controlled stud*' OR 'cross-sectional stud*' OR 'evaluation stud*' OR 'follow-up stud*' OR 'health care survey' OR 'health services research' OR 'health survey' OR 'interview' OR 'multicenter stud*' OR 'organizational case stud*' OR 'outcomes research' OR 'prospective stud*' OR 'qualitative analysis' OR 'qualitative research' OR 'questionnaire' OR 'randomized controlled trial' OR 'retrospective stud*')

Limits

PUBYEAR > 1995 AND LANGUAGE(english) AND (SUBJAREA(medi) OR SUBJAREA(nurs) OR SUBJAREA(psyc) OR SUBJAREA(soci) OR SUBJAREA(dent) OR SUBJAREA(heal) OR SUBJAREA(multi)) AND (DOCTYPE(ar) OR DOCTYPE(ip) OR DOCTYPE(bk) OR DOCTYPE(cp) OR DOCTYPE(rp))

Appendix 2:

Standard quality assessment criteria for evaluating primary research papers from a variety of fields

This 'Standard quality assessment criteria for evaluating primary research papers from a variety of fields' was developed by the Alberta Heritage Foundation for Medical Research

Quantitative studies

How to calculate the summary score

Total sum = (number of 'yes' * 2) + (number of 'partials' * 1)

Total possible sum = 28 – (number of 'N/A' * 2)

Summary score: total sum / total possible sum

Quality assessment

1. Question or objective sufficiently described?

Yes: Is easily identified in the introductory section (or first paragraph of methods section). Specifies (where applicable, depending on study design) all of the following: purpose, subjects/target population, and the specific intervention(s) /association(s)/descriptive parameter(s) under investigation. A study purpose that only becomes apparent after studying other parts of the paper is not considered sufficiently described.

Partial: Vaguely/incompletely reported (eg, 'describe the effect of' or 'examine the role of' or 'assess opinion on many issues' or 'explore the general attitudes...'); or some information has to be gathered from parts of the paper other than the introduction/background/objective section.

No: Question or objective is not reported, or is incomprehensible.

N/A: Should not be checked for this question.

2. Design evident and appropriate to answer study question? (If the study question is not given, infer from the conclusions)

Yes: Design is easily identified and is appropriate to address the study question / objective.

Partial: Design and /or study question not clearly identified, but gross inappropriateness is not evident; or design is easily identified but only partially addresses the study question.

No: Design used does not answer study question (eg, a comparison group is required to answer the study question, but none was used); or design cannot be identified.

N/A: Should not be checked for this question.

3. Method of subject selection (and comparison group selection, if applicable) or source of information/input variables (eg, for decision analysis) is described and appropriate

Yes: Described and appropriate. Selection strategy *designed* (ie, consider sampling frame and strategy) to obtain an unbiased sample of the relevant target population or the entire target population of interest (eg, consecutive patients for clinical trials, population-based random sample for case-control studies or surveys). Where applicable, inclusion/exclusion criteria are described and defined (eg, 'cancer' – ICD code or equivalent should be provided). *Studies of volunteers:* methods and setting of recruitment reported. *Surveys:* sampling frame/ strategy clearly described and appropriate.

Partial: Selection methods (and inclusion/exclusion criteria, where applicable) are not completely described, but no obvious inappropriateness. Or selection strategy is not ideal (ie, likely introduced bias) but did not

likely seriously distort the results (eg, telephone survey sampled from listed phone numbers only; hospital based case-control study identified all cases admitted during the study period, but recruited controls admitted during the day/evening only). Any study describing participants only as ‘volunteers’ or ‘healthy volunteers’. *Surveys*: target population mentioned but sampling strategy unclear.

No: No information provided. Or obviously inappropriate selection procedures (eg inappropriate comparison group if intervention in women is compared to intervention in men). Or presence of selection bias which likely seriously distorted the results (eg, obvious selection on ‘exposure’ in a case-control study).

N/A: Descriptive case series/reports.

4. Subject (and comparison group, if applicable) characteristics or input variables/information (eg, for decision analyses) sufficiently described?

Yes: Sufficient relevant baseline/demographic information clearly characterizing the participants is provided (or reference to previously published baseline data is provided). Where applicable, reproducible criteria used to describe/categorize the participants are clearly defined (eg, ever-smokers, depression scores, systolic blood pressure > 140). If ‘healthy volunteers’ are used, age and sex must be reported (at minimum). *Decision analyses*: baseline estimates for input variables are clearly specified.

Partial: Poorly defined criteria (eg ‘hypertension’, ‘healthy volunteers’, ‘smoking’). Or incomplete relevant baseline / demographic information (eg, information on likely confounders not reported). *Decision analyses*: incomplete reporting of baseline estimates for input variables.

No: No baseline / demographic information provided. *Decision analyses*: baseline estimates of input variables not given.

N/A: Should not be checked for this question.

5. If random allocation to treatment group was possible, is it described?

Yes: True randomization done – requires a description of the method used (eg, use of random numbers).

Partial: Randomization mentioned, but method is not (ie it may have been possible that randomization was not true).

No: Random allocation not mentioned although it would have been feasible and appropriate (and was possibly done).

N/A: Observational analytic studies. Uncontrolled experimental studies. Surveys. Descriptive case series / reports. Decision analyses.

6. If interventional and blinding of investigators to intervention was possible, is it reported?

Yes: Blinding reported.

Partial: Blinding reported but it is not clear who was blinded.

No: Blinding would have been possible (and was possibly done) but is not reported.

N/A: Observational analytic studies. Uncontrolled experimental studies. Surveys. Descriptive case series / reports. Decision analyses.

7. If interventional and blinding of subjects to intervention was possible, is it reported?

Yes: Blinding reported.

Partial: Blinding reported but it is not clear who was blinded.

No: Blinding would have been possible (and was possibly done) but is not reported.

N/A: Observational studies. Uncontrolled experimental studies. Surveys. Descriptive case series / reports.

8. Outcome and (if applicable) exposure measure(s) well defined and robust to measurement / misclassification bias? Means of assessment reported?

Yes: Defined (or reference to complete definitions is provided) and measured according to reproducible, ‘objective’ criteria (eg, death, test completion – yes/no, clinical scores). Little or minimal potential for measurement / misclassification errors. *Surveys*: clear description (or reference to clear description) of questionnaire/interview content and response options. *Decision analyses*: sources of uncertainty are defined for all input variables.

Partial: Definition of measures leaves room for subjectivity, or not sure (ie, not reported in detail, but probably acceptable). Or precise definition(s) are missing, but no evidence or problems in the paper that would lead one to assume major problems. Or

instrument/mode of assessment(s) not reported. Or misclassification errors may have occurred, but they did not likely seriously distort the results (eg, slight difficulty with recall of long-ago events; exposure is measured only at baseline in a long cohort study). *Surveys*: description of questionnaire/interview content incomplete; response options unclear. *Decision analyses*: sources of uncertainty are defined only for some input variables.

No: Measures not defined, or are inconsistent throughout the paper. Or measures employ only ill-defined, subjective assessments, eg 'anxiety' or 'pain.' Or obvious misclassification errors/measurement bias likely seriously distorted the results (eg, a prospective cohort relies on self-reported outcomes among the 'unexposed' but requires clinical assessment of the 'exposed'). *Surveys*: no description of questionnaire/interview content or response options. *Decision analyses*: sources of uncertainty are not defined for input variables.

N/A: Descriptive case series / reports.

9. Sample size appropriate?

Yes: Seems reasonable with respect to the outcome under study and the study design. When statistically significant results are achieved for major outcomes, appropriate sample size can usually be assumed, unless large standard errors ($SE > 1/2$ effect size) and/or problems with multiple testing are evident. *Decision analyses*: size of modeled cohort / number of iterations specified and justified.

Partial: Insufficient data to assess sample size (eg, sample seems 'small' and there is no mention of power/sample size/effect size of interest and/or variance estimates aren't provided). Or some statistically significant results with standard errors $> 1/2$ effect size (ie, imprecise results). Or some statistically significant results in the absence of variance estimates. *Decision analyses*: incomplete description or justification of size of modeled cohort / number of iterations.

No: Obviously inadequate (eg, statistically non-significant results and standard errors $> 1/2$ effect size; or standard deviations $> _$ of effect size; or statistically non-significant results with no variance estimates and obviously inadequate sample size). *Decision analyses*: size of modeled cohort / number of iterations not specified.

N/A: Most surveys (except surveys comparing responses between groups or change over time). Descriptive case series / reports.

10. Analysis described and appropriate?

Yes: Analytic methods are described (eg 'chi square' / 't-tests'/'Kaplan-Meier with log rank tests', etc.) and appropriate.

Partial: Analytic methods are not reported and have to be guessed at, but are probably appropriate. Or minor flaws or some tests appropriate, some not (eg, parametric tests used, but unsure whether appropriate; control group exists but is not used for statistical analysis). Or multiple testing problems not addressed.

No: Analysis methods not described and cannot be determined. Or obviously inappropriate analysis methods (eg, chi-square tests for continuous data, SE given where normality is highly unlikely, etc.). Or a study with a descriptive goal / objective is over-analyzed.

N/A: Descriptive case series / reports.

11. Some estimate of variance (eg, confidence intervals, standard errors) is reported for the main results/outcomes (ie, those directly addressing the study question/objective upon which the conclusions are based)?

Yes: Appropriate variances estimate(s) is/are provided (eg, range, distribution, confidence intervals, etc.). *Decision analyses*: sensitivity analysis includes all variables in the model.

Partial: Undefined '+/-' expressions. Or no specific data given, but insufficient power acknowledged as a problem. Or variance estimates not provided for all main results/outcomes. Or inappropriate variance estimates (eg, a study examining change over time provides a variance around the parameter of interest at 'time 1' or 'time 2', but does not provide an estimate of the variance around the difference). *Decision analyses*: sensitivity analysis is limited, including only some variables in the model.

No: No information regarding uncertainty of the estimates. *Decision analyses*: No sensitivity analysis.

N/A: Descriptive case series / reports. Descriptive surveys collecting information using open-ended questions.

12. Controlled for confounding?

Yes: Randomized study, with comparability of baseline characteristics reported (or non-comparability controlled for in the analysis). Or appropriate control at the design or analysis stage (eg, matching, subgroup

analysis, multivariate models, etc.). *Decision analyses:* dependencies between variables fully accounted for (eg, joint variables are considered).

Partial: Incomplete control of confounding. Or control of confounding reportedly done but not completely described. Or randomized study without report of comparability of baseline characteristics. Or confounding not considered, but not likely to have seriously distorted the results. *Decision analyses:* incomplete consideration of dependencies between variables.

No: Confounding not considered, and may have seriously distorted the results. *Decision analyses:* dependencies between variables not considered.

N/A: Cross-sectional surveys of a single group (ie, surveys examining change over time or surveys comparing different groups should address the potential for confounding). Descriptive studies. Studies explicitly stating the analysis is strictly descriptive/exploratory in nature.

13. Results reported in sufficient detail?

Yes: Results include major outcomes and all mentioned secondary outcomes.

Partial: Quantitative results reported only for some outcomes. Or difficult to assess as study question/objective not fully described (and is not made clear in the methods section), but results seem appropriate.

No: Quantitative results are reported for a subsample only, or 'n' changes continually across the denominator (eg, reported proportions do not account for the entire study sample, but are reported only for those with complete data – ie, the category of 'unknown' is not used where needed). Or results for some major or mentioned secondary outcomes are only qualitatively reported when quantitative reporting would have been possible (eg, results include vague comments such as 'more likely' without quantitative report of actual numbers).

N/A: Should not be checked for this question.

14. Do the results support the conclusions?

Yes: All the conclusions are supported by the data (even if analysis was inappropriate). Conclusions are based on all results relevant to the study question, negative as well as positive ones (eg, they aren't based on the sole significant finding while ignoring the negative results). Part of the conclusions may expand beyond the results, if made in addition to rather than instead of those strictly supported by data, and if including indicators of their interpretative nature (eg, 'suggesting,' 'possibly').

Partial: Some of the major conclusions are supported by the data, some are not. Or speculative interpretations are not indicated as such. Or low (or unreported) response rates call into question the validity of generalizing the results to the target population of interest (ie, the population defined by the sampling frame/strategy).

No: None or a very small minority of the major conclusions are supported by the data. Or negative findings clearly due to low power are reported as definitive evidence against the alternate hypothesis. Or conclusions are missing. Or extremely low response rates invalidate generalizing the results to the target population of interest (ie, the population defined by the sampling frame/strategy).

N/A: Should not be checked for this question.

Qualitative Studies

How to calculate the summary score

Total sum = (number of 'yes' * 2) + (number of 'partials' * 1)

Total possible sum = 20

Summary score: total sum / total possible sum

Quality assessment

1. Question / objective clearly described?

Yes: Research question or objective is clear by the end of the research process (if not at the outset).

Partial: Research question or objective is vaguely/incompletely reported.

No: Question or objective is not reported, or is incomprehensible.

2. Design evident and appropriate to answer study question? (If the study question is not clearly identified, infer appropriateness from results/conclusions)

Yes: Design is easily identified and is appropriate to address the study question.

Partial: Design is not clearly identified, but gross inappropriateness is not evident; or design is easily identified but a different method would have been more appropriate.

No: Design used is not appropriate to the study question (eg a causal hypothesis is tested using qualitative methods); or design cannot be identified.

3. Context for the study is clear?

Yes: The context/setting is adequately described, permitting the reader to relate the findings to other settings.

Partial: The context/setting is partially described.

No: The context/setting is not described.

4. Connection to a theoretical framework / wider body of knowledge?

Yes: The theoretical framework/wider body of knowledge informing the study and the methods used is sufficiently described and justified.

Partial: The theoretical framework/wider body of knowledge is not well described or justified; link to the study methods is not clear.

No: Theoretical framework/wider body of knowledge is not discussed.

5. Sampling strategy described, relevant and justified?

Yes: The sampling strategy is clearly described and justified. The sample includes the full range of relevant, possible cases/settings (ie, more than simple convenience sampling), permitting conceptual (rather than statistical) generalizations.

Partial: The sampling strategy is not completely described, or is not fully justified. Or the sample does not include the full range of relevant, possible cases/settings (ie, includes a convenience sample only).

No: Sampling strategy is not described.

6. Data collection methods clearly described and systematic?

Yes: The data collection procedures are systematic, and clearly described, permitting an 'audit trail' such that the procedures could be replicated.

Partial: Data collection procedures are not clearly described; difficult to determine if systematic or replicable.

No: Data collection procedures are not described.

7. Data analysis clearly described, complete and systematic?

Yes: Systematic analytic methods are clearly described, permitting an 'audit trail' such that the procedures could be replicated. The iteration between the data and the explanations for the data (ie, the theory) is clear – it is apparent how early, simple classifications evolved into more sophisticated coding structures which then evolved into clearly defined concepts/explanations for the data). Sufficient data is provided to allow the reader to judge whether the interpretation offered is adequately supported by the data.

Partial: Analytic methods are not fully described. Or the iterative link between data and theory is not clear.

No: The analytic methods are not described. Or it is not apparent that a link to theory informs the analysis.

8. Use of verification procedure(s) to establish credibility of the study?

Yes: One or more verification procedures were used to help establish credibility/ trustworthiness of the study (eg, prolonged engagement in the field, triangulation, peer review or debriefing, negative case analysis, member checks, external audits/inter-rater reliability, 'batch' analysis).

No: Verification procedure(s) not evident.

9. Conclusions supported by the results?

Yes: Sufficient original evidence supports the conclusions. A link to theory informs any claims of generalizability.

Partial: The conclusions are only partly supported by the data. Or claims of generalizability are not supported.

No: The conclusions are not supported by the data. Or conclusions are absent.

10. Reflexivity of the account?

Yes: The researcher explicitly assessed the likely impact of their own personal characteristics (such as age, sex and professional status) and the methods used on the data obtained.

Partial: Possible sources of influence on the data obtained were mentioned, but the likely impact of the influence or influences was not discussed.

No: There is no evidence of reflexivity in the study report.

Appendix 3:

Factor groupings

The following tables give a breakdown of how contextual factors are allocated to features of receptivity and non-receptivity to change (both the Pettigrew *et al* and the additional inner context features emerging from our analysis), and by level.

Contextual factors by level and features of a receptive or non-receptive context

Macro level

Feature		Contextual factor
Change agenda and its locale		<ul style="list-style-type: none"> Financial incentive Fit between change agenda and its locale Geography Geography: urban-rural
Environmental pressures		<ul style="list-style-type: none"> Accreditation status Care quality: quality of care deficiency citations Competition Environmental pressure External reporting of quality performance Financial incentive Health system re-engineering National policy emphasis on health quality management Payment method Population factors Publication of performance State health agency per capita spending
Non-Pettigrew <i>et al</i> inner context factors	Organisation factor	<ul style="list-style-type: none"> Organisation type
	Performance factor	<ul style="list-style-type: none"> Productivity

Meso level

Feature	Contextual factor
Change agenda and its locale	<ul style="list-style-type: none"> • Patient factors • Payment method • Quality improvement capacity
Co-operative inter-organisation networks	<ul style="list-style-type: none"> • Co-operative inter-organisation networks • External relationships • Networking • Quality improvement capacity • Relationships and Engaging stakeholders
Environmental pressures	<ul style="list-style-type: none"> • Emergency room crowding • Environmental change: environmental shocks • Environmental change: no major reorganizations • Health plan characteristics • Population factors • Publication of performance • Reconfiguration • Weighted per capita cost of health care in health system
Key people leading change	<ul style="list-style-type: none"> • Commitment to quality: senior management • Leadership • Shared sense of purpose • Structure (Co-ordination, Resources, Leadership)
Managerial–clinical relations	<ul style="list-style-type: none"> • Managerial-clinical relations • Physician organisation structure
Quality and coherence of policy	<ul style="list-style-type: none"> • Accountability • Care processes • Communication and coordination among groups • Data/information systems • Financial incentive • Human resource policy • Measures patient satisfaction • Outpatient health treatment costs as percentage of all health treatment costs • Performance feedback • Process composite: resident care planning and communications regarding end of life preferences • Quality improvement capacity • Quality and coherence of policy • Quality as a business strategy • Receptive and non-receptive contexts for change: structure • Strategic alignment and integration of improvement efforts with organization priorities • Strategic approach (Defender, Analyzer, Prospector) • Team working: structures
Simplicity and clarity of goals	<ul style="list-style-type: none"> • Characteristics of goals (content, specificity, challenge, sharedness) • Focus on results • Organisational values and goals • Simplicity and clarity of goals and priorities

Feature		Contextual factor
Supportive organisational culture		<ul style="list-style-type: none"> • Archetype (Technophile, Motivated Team, Care Enterprise) • Broad staff presence and expertise • Capacity for change • Climate • Commitment to quality: clinicians • Culture • Emotion • Innovativeness: Science-based innovativeness Score (measure of research activity) • Nurse work environment index • Positive problem-solving approach • Receptive and non-receptive contexts for change: culture and leadership • Relentless quest for quality • Safety climate and culture • Scientific/systematic approach • Staff engagement • Supportive practices/structures • Systemic perspective of responsibility • Team working: strength, processes • Workforce job satisfaction
Non-Pettigrew <i>et al</i> inner context factors	Organisation factor	<ul style="list-style-type: none"> • Bed occupancy • Capital per bed • Clinical reputation • Commercial innovation • Cost per admission • Health treatment costs • Innovativeness: science-based innovativeness score (measure of research activity) • Length of stay • Organisation age • Organisation type • Organisation/ unit size • Organisational level • Primary practice characteristics • Research activity • Services provided • Specialisation (provision of specialist services vs primary care services) • Sufficient time or resources • Volume of cases
	Patient involvement	<ul style="list-style-type: none"> • Consumer involvement • Volume of complaints • Works in partnership with patients

Feature		Contextual factor
	Performance factor	<ul style="list-style-type: none"> • Clinical performance • Efficiency • Financial performance • Operational performance • Perceived effectiveness • Profitability
	Workforce factor	<ul style="list-style-type: none"> • Nurse education • Skill mix • Staffing level, workload, shift length and overtime, Agency staffing, Working time regulation • Knowledge/training
	Other non-Pettigrew <i>et al</i> inner context factor	<ul style="list-style-type: none"> • % of admissions Medicaid • Innovation attribute • Innovativeness: Practice-based innovativeness Score from staff survey) • Strategic groups Composite • Structure composite Technology

Micro level

Feature		Contextual factor
Change agenda and its locale		<ul style="list-style-type: none"> • Patient factors: case mix • Payment method • Quality improvement capacity
Environmental pressures		<ul style="list-style-type: none"> • Length of ownership • Population factors
Key people leading change		<ul style="list-style-type: none"> • Leadership • Personal interest in diabetes
Quality and coherence of policy		<ul style="list-style-type: none"> • Care processes • Data/information systems • Employee empowerment structures • Gathers data from patients • Number of co-ordination mechanisms • Quality improvement capacity • Team working: structures
Simplicity and clarity of goals		<ul style="list-style-type: none"> • Shared vision of project goals
Supportive organisational culture		<ul style="list-style-type: none"> • Capacity for change • Climate • Commitment to quality • Culture • Emotion • Nurse burnout • Recognises need to overcome obstacles • Resuscitation management • Safety climate and culture • Team working: strength, processes • Workforce job satisfaction
Non-Pettigrew <i>et al</i> inner context factors	Organisation factor	<ul style="list-style-type: none"> • Organisational level • Volume of cases
	Performance factor	<ul style="list-style-type: none"> • Efficiency • Perceived effectiveness
	Workforce factor	<ul style="list-style-type: none"> • Nurse education • Nurse experience • Skill mix • Staffing level • Workforce knowledge/training • Workforce shift length and overtime
	Other non-Pettigrew <i>et al</i> inner context factor	<ul style="list-style-type: none"> • Specialism (does quality vary by specialism?)

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The Health Foundation
90 Long Acre
London WC2E 9RA

T 020 7257 8000
E info@health.org.uk

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ISBN 978-1-906461-68-3

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