The
Health
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Inspiring
Improvement

Perspectives on context

The role of context in successful improvement

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About the authors

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Executive summary

We take as our starting point Pettigrew et al's[1] well-known notion of receptive and non-receptive contexts for change which – although encompassing both 'hard' (structural) and 'soft' (cultural) factors – we argue now needs to be combined with more contemporary psychological perspectives, such as Weiner's[2] notion of 'readiness' for change, Huy's[3,4] work on 'emotional receptivity' at the individual and organisational levels, and the proposition that social context is the key facilitator of quality improvement (QI).[5] Overlaying this combination of different perspectives we argue (following House et al[6]) that more explicit attention must be paid to the multiple levels of context (macro, meso and micro) and, crucially, how these combine to impact on the success and sustainability of QI efforts.

We recommend that future research that combines these approaches to thinking about 'context' needs to focus on four related questions:

1. Which contextual factors (structural and psychological) are related to QI success and sustainability in healthcare organisations?

2. Which of these contextual factors are modifiable (ie there are some key contextual factors which are more amenable to change and intervention than others) and by whom?

3. How do contextual factors at different levels of the healthcare system impact on QI success and sustainability in healthcare organisations?

4. When are different contextual factors more or less important during a QI initiative (ie different contextual factors have greater or lesser influence at different stages of the adoption–implementation–assimilation process)?

We recommend that the first and second of these questions can be initially addressed through secondary research (scoping reviews of the peer-reviewed and grey literatures across a range of disciplines including several of the recent studies we briefly review here, for example, Bate et al[7] and McDermott and Keating[5] and, in contrast to Kaplan et al's[8] recent systematic review, including qualitative studies). Such secondary research might identify significant gaps in the evidence base that may then require primary research to be commissioned. The third and fourth questions should be studied through primary research and could be broadly based on the principles of realist evaluation: that is to say, contextually-focused (structural and psychological), process-based (longitudinal) and (largely) qualitative case studies that are designed to explore the dynamics between contextual factors at different levels and at different stages of the adoption, implementation and assimilation of similar QI initiatives. Criteria for high quality research studies of this type have been proposed and are included in this paper (see Annex 2).

Given the crucial importance of studying interactions between contextual factors at the macro, meso and micro levels, we recommend that any further research (whether primary or secondary) must include a multi-level and process-based framework. Requiring such a perspective will significantly extend the standard approach to studying the success and sustainability of QI projects in healthcare organisations. The overall aim of such research 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 QI efforts, and acting to make context more receptive where possible, as well as informing the future design (and 'tailoring') of QI programmes themselves.

The role of context in successful improvement

Introduction

This paper was prepared at the request of the Health Foundation during late December 2010 and January 2011. As requested, the paper does not attempt to present a systematic review of the relevant literature but rather reflects the two authors' personal approaches to – and extensive experience of – understanding and researching the role of 'context' in determining the success or otherwise of quality improvement (QI) initiatives. In doing so the paper cites and draws on those studies and bodies of literature that inform the authors' thinking in order to present our views in direct response to the four questions posed by the Health Foundation. For example, rather than limit our scope to the narrow field of studies of QI implementation in healthcare organisations we have taken the view that there are many helpful insights in the broader organisational studies, knowledge management, change and innovation literatures, and so we have included key sources from these fields in our deliberations.[i]

The paper is organised around the Health Foundation's key questions:

1. What do you define as context?

2. What do you know about context from the literature?

3. What models or frameworks do you use to help explain context?

4. What do you see as the principle research questions relating to context?

1. What do you define as context?

When thinking about QI in healthcare organisations our conceptualisation of 'context' is shaped by our belief that the management of change – of which the implementation of a QI programme is just one example – is complex and multifaceted, and that where organisations are multilayered and diverse (as in healthcare), 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 QI) (see Kaplan et al[8] for example – reviewed below). 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 that needs to be studied? The discussion in section 1.5 below of the distinction between 'omnibus' and 'discrete' dimensions of context may be helpful in this regard.

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i   For example, Greenhalgh et al[9] have already reviewed the various meta-analyses that addressed the impact of organisational context on adoption of innovations (Damanpour, 1991; 1992; 1996). Greenhalgh et al summarised the three meta-analyses as strongly supporting the notion that organisational size and complexity (that is, specialisation, functional differentiation and professional knowledge) is associated with innovativeness. However, this relationship is moderated by various factors. On the basis of the Damanpour findings, Greenhalgh et al went on to examine in more detail five dimensions of the 'inner context' which appear to be critical in shaping the medium through which innovations must travel in order to spread and be sustained within organisations: size of organisation (and the association of this with organisational slack), structural complexity, leadership and loci of decision making, organisational climate and receptive context, and initiatives to enable and support knowledge manipulation.

Bearing this in mind we still find – after all these years – the following definition from Pettigrew to be the best starting point for this paper:

'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).'[1]

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 organisations)[9] and the **outer context** (factors beyond the organisation, for example, 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[10,11] has been important in highlighting key regulating forces, in particular the State and the professions, on 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 multilevel, with environmental, organisational, and individual levels intertwined),[12] and secondly, whether one takes a **structural or psychological perspective**. In this regard, another important theoretical development was Giddens's[13] concept of structuration, where organisational change is seen as a result of the interplay between human agency and context. Much organisational change and QI is based on simplistic notions of the relationships between the organisation and its context and the organisation and the individuals within it.[14] These relationships are illustrated in a study of healthcare mergers[15] whereby the process of merger created perceptions of 'takeover' and had a negative effect on staff; these in turn affected the merger process itself. As McNulty and Ferlie found in their study[16] of an attempt to radically transform an organisation, it is an example of where management action is 'mediated by the 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, others view context as a set of processes which relate both to each other and to change/improvement. The following sections (1.1 to 1.6) provide a very brief summary of what we see as the key conceptualisations of context.

1.1 Receptive and non-receptive contexts for change

Pettigrew's extensively used framework (see Figure 1) focuses on three key dimensions of strategic change. The first one refers to the content of the chosen strategy (the what of change), the second one is the process and management of change (the how) and finally, the context in which the strategy unfolds (the why).

**Figure 1: Pettigrew's processual framework[17]**
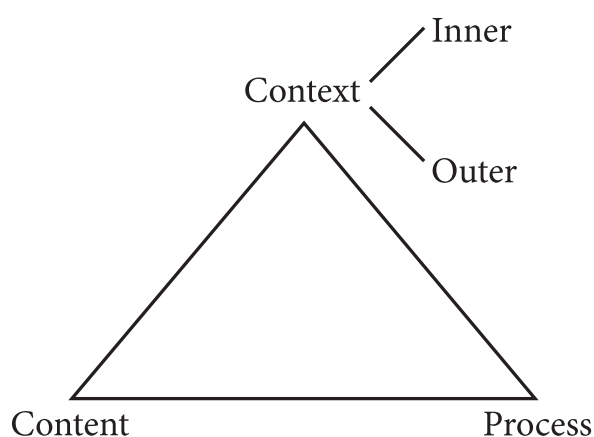
Later Pettigrew et al,[1] drawing on strategic service change in the NHS, developed a model for the management of strategic change which centres on receptive and non-receptive contexts for change. The model outlines key features of the internal and external

contexts[18] and action, whether top-down or bottom-up, or a mixture of both, to explain successes and failures in the management of change, and also to account for differences in the rate and the pace of change from one part of the organisation, national or macro, or regional or micro, to another.

Receptive contexts are defined as situations where there are features of context, and also of management action, that 'seem to be favourable, associated with forward movement'. On the other hand, non-receptive contexts are those situations where a combination of conditions effectively creates blockages or resistances to change. Pettigrew et al suggested eight key factors which created a receptive context for the changes at the heart of their study (see Figure 2).[1] These were:

1. the quality and coherence of policy

2. the availability of key people leading change

3. long-term environmental pressure

4. supportive organisational culture

5. effective managerial-professional relations

6. cooperative inter-organisational networks

7. simplicity and clarity of goals and priorities

8. change agenda and its locale.

Figure 2: Receptive contexts for change[1]
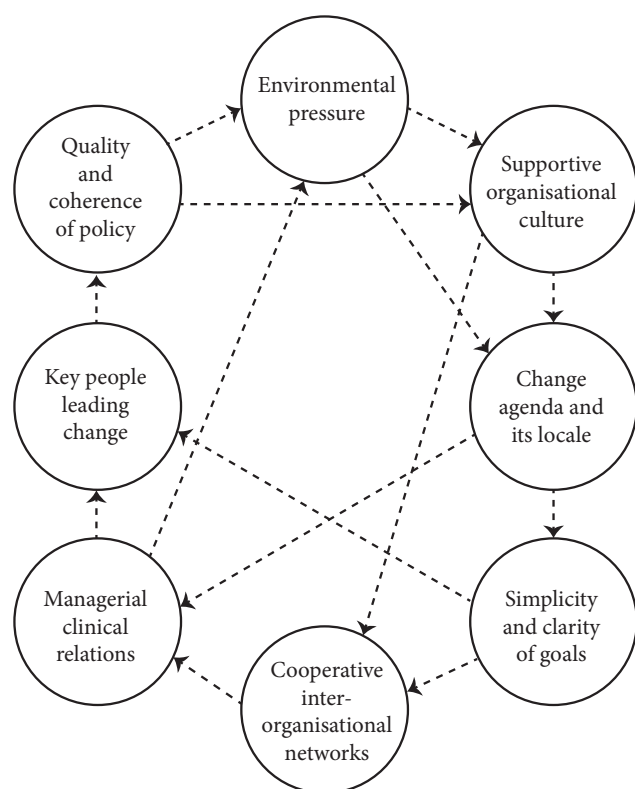
It is important to note that these eight factors are not exhaustive, or prerequisites for successful change. They are closely related to one another and, taken together, they have been identified within one particular context – district health authorities in the NHS – as being significant in creating receptivity for change. Their collective force was especially significant in explaining variations in the rate and pace of change, and the implication is that they may be of general value in determining approaches in other organisations.

The eight factors and associated model (Figure 2) developed by Pettigrew et al have subsequently been tested in empirical studies. For example, Newton et al[19] posed four questions in their study of change within the UK primary health care sector:[ii]

– Is Pettigrew and McKee's receptivity model applicable as a descriptive and conceptualising framework to this setting?

– What patterns of association, if any, are there between the factors?

– Is there a temporal dimension to the salience of the factors?

– To what extent does the change context move from receptivity to non-receptivity during the course of the change?

Using qualitative interviews, meeting observations and documentary analysis, the researchers used 21 'focal questions' for a secondary analysis of their fieldwork data that had taken place within a single primary medical services pilot in the NHS. They found that, while Pettigrew et al had suggested that all eight factors are related to one another, in this study six were significant in the final model. Two factors (long-term environmental pressure and fit between the change agenda and the locale) had weak or no influence. The most significant pattern of association was between quality and coherence of policy, key people leading the change, supportive organisational culture and effective managerial clinical relations. The authors also noted a temporal ordering of factors (for example, as the salience of 'policy' (factor 1) receded then the salience of networks (factor 6) increased) and that the context became much less receptive because of the 'unplanned movement of key personnel, the impact this had on managerial clinical relations and the emerging reservations of the GP partnership'.

Another empirical study (this time from the US) that explicitly tested Pettigrew et al's model was Stetler et al[20] which explored:

1. the key contextual elements that support and facilitate institutionalisation, ie routine implementation of evidence-based practice (EBP) and related projects, within a healthcare system at multiple institutional levels

2. the strategic processes that are used to create institutionalisation of EBP within a healthcare system at multiple institutional levels.

The authors suggest that their findings provide evidence of some of the key contextual elements that may require attention if the institutionalisation of EBP is to be realised. The most critical element in this study appeared to be key people leading change, which in turn impacted on the operationalisation of other key elements of the strategic change model.[iii] The study authors suggest that propositions they put forward (see footnote iii) could be tested in future research and/or considered by those embarking on the institutionalisation of EBP. They argue that their findings indicate that there are a number of contextual factors that are modifiable; and they also show that related modification requires strategic intent and operational follow through, with changes continuously monitored and sustained over time.

1.2 Organisational readiness for change

Weiner[2] considers 'organisational readiness for change' a critical precursor to the successful implementation of complex changes in healthcare settings, while arguing that the concept has not been subject to extensive

empirical study. Weiner describes 'organisational readiness' as referring to organisational members' change commitment and change efficacy to implement organisational change with 'readiness' connoting a state of being both psychologically and behaviourally prepared to take action (ie, willing and able).

Weiner states:

'In contrast to much of the literature on the topic, the conceptual definition offered here treats organizational readiness as a shared team property – that is, a shared psychological state in which organizational members feel committed to implementing an organizational change and confident in their collective abilities to do so. This way of thinking about organizational readiness is best suited for organizational changes where collective, coordinated behaviour change is necessary in order to effectively implement the change and, in some instances, for the change to produce anticipated benefits.'[2]

Weiner argues that quality improvement programmes in healthcare organisations are a good example of this type of organisational change and describes his theory as addressing 'a fundamental conceptual ambiguity that runs through the literature on the topic: is readiness a structural construct or a psychological one?' He argues that his theory 'seeks to reconcile the structural view and psychological view by specifying a relationship between them' (see Figure 3 overleaf).

This recent contribution to theoretical development is worth considering for two reasons. Firstly, 'readiness' is conceived here in psychological terms whereas others describe organisational readiness for change in more structural terms (emphasising the organisation's financial, material, human, and informational resources). In the theory presented by Weiner, organisational structures and resources shape readiness perceptions, ie staff take into consideration the organisation's structural assets and deficits in formulating their change efficacy judgments. Secondly, organisational readiness for change is situational; it is not a general state of affairs. So, while some organisational features do seem to create a more receptive context for innovation and change – see Pettigrew et al[1] as summarised above, for example – receptive context does not translate directly into readiness. In Weiner's view, the content of change matters as much as the context of change. He argues that while

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iii The authors developed a number of propositions from their findings: (1) organisations that achieve a highly receptive context for EBP, as described by Pettigrew et al, are more likely to exhibit a higher level of EBP institutionalisation, (2) organisations with elements of receptivity (as described by Pettigrew et al) and that monitor and act on elements of non-receptivity are more likely to exhibit a higher level of EBP institutionalisation, (3) efforts to transform an organisation for institutionalising EBP requires the proactive, meaningful engagement of formal and informal leaders at all levels of the organisation, including staff nurses, (4) a greater number of positive two-way interconnections between key people leading change and other key contextual elements in the Pettigrew framework will enhance an organisation's potential for institutionalisation, (5) an organisation with a majority of BSN staff nurses and competent, EBP-oriented nurse/ward managers will exhibit greater integration of EBP in routine practice, (6) executive leaders who have the ability to proactively influence an organisation's culture to support EBP and can buffer the related strategic vision from periodic pressures are more likely to institutionalise EBP over time, (7) inconsistent operationalisation of EBP-related infrastructures (coherence in the Pettigrew framework) by formal leaders will negatively impact an organisation's ability to institutionalise EBP, (8) organisations that develop a strategic plan to institutionalise EBP using Pettigrew's key contextual elements as a foundation for professional practice are more likely to have a higher level of EBP activity within three to five years.

Figure 3: Determinants and outcomes of organisational readiness for change[2]
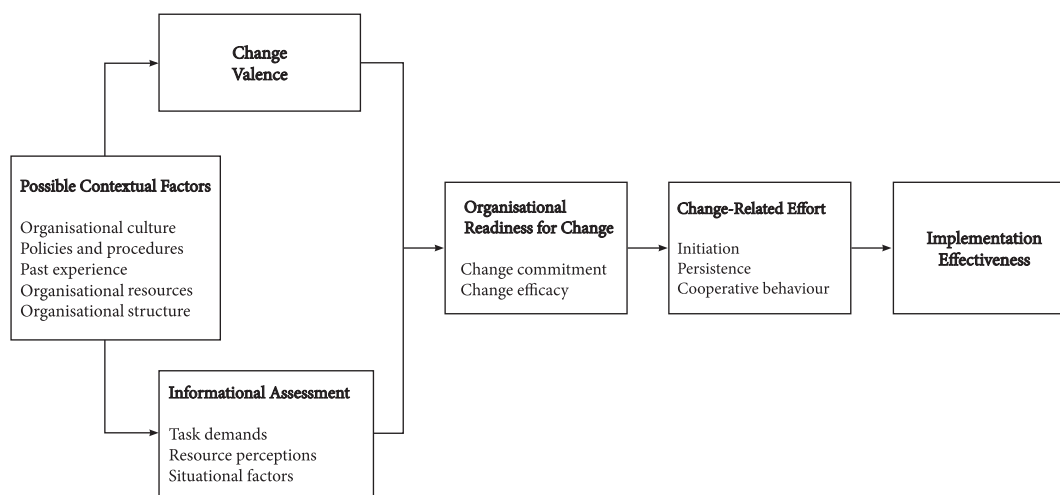
a healthcare organisation could, for example, exhibit a culture that values risk-taking and experimentation, a positive working environment (eg good managerial–clinical relationships) and a history of successful change implementation, this organisation could still exhibit a high readiness to implement electronic medical records, but a low readiness to implement an open access scheduling system. The explanation, in Weiner's view, is that commitment is, in part, change specific and so too are efficacy judgements (ie receptive context is a necessary but not sufficient condition for readiness).[iv]

1.3   Organisational climate[v]

The concept of organisational climate has received considerable attention from applied psychologists and organisational sociologists over the last decade. The term 'organisational climate' was coined in 1939 following a study of children's school clubs by Kurt Lewin and his colleagues. Lewin and his associates characterised leadership within the clubs as corresponding to one of three styles (autocratic, democratic or *laissez-faire*). These styles determined the 'social climate' in the clubs, which led in turn to particular behaviour repertoires displayed by the boys. Lewin subsequently developed his well known field

theory of behaviour, which he linked to the gestalt psychology of holistic perception and expanded to encompass whole organisations.

Although there is continuing controversy surrounding definitions of organisational climate, and especially its differentiation from organisational culture, the most widely adopted definition is that of Benjamin Schneider,[22] who defined organisational climate as a mutually agreed internal environmental description of an organisation's practices and procedures. Within this definition, it should be noted that the focus is on organisational members' agreed perceptions of their organisational environment. This is what distinguishes climate from culture, where the focus is on judgements and values, rather than perceived practices and procedures. These concepts are, however, clearly differentiated ontological perspectives. Daniel Denison, for example, has pointed out that culture refers to deeply embedded values and assumptions.[23] Climate, on the other hand refers to environmental factors that are consciously perceived and, importantly, are subject to organisational control. In this case, as Denison notes, climate is something that can be directly influenced by management polities and leadership, while culture is much more difficult to change and control. Thus, culture is associated with deeply driven desires, while climate is associated with utilitarian strategies that can change as the environment changes.

As Greenhalgh et al[9] suggest, while organisational climate is a popular construct for researchers to measure, it is (intentionally) very focused on one aspect of the organisation's receptivity to innovation and hence may be of limited use in the practical setting.

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iv   So, Weiner argues, organisations with the same resources, endowments, and organisational structures can differ in the effectiveness with which they implement the same organisational change depending on how they utilise, combine and sequence organisational resources and routines. In Weiner's view it is *'preferable to regard organizational structures and resource endowments as capacity to implement change rather than readiness to do so. This distinction between capacity and readiness could move theory and research forward by reducing some of the conceptual ambiguity in the meaning and use of the term "readiness."'*

v   This overview draws on Ashkanasy A, Organizational climate. In SR Clegg and JR Bailey (eds.), *International Encyclopedia of Organization Studies*, Vol 3 (pp. 1028-1030). Thousand Oaks, CA: Sage Publications.[21]

1.4   Absorptive capacity[vi]

In 1990, Cohen and Levinthal[24] introduced the concept of absorptive capacity to denote the capacity of an individual or organisation to: 'value, assimilate and apply new knowledge'. Absorptive capacity is a complex construct incorporating the organisation's existing knowledge base, 'learning organisation' values and goals (that is, those that are explicitly directed towards capturing, sharing, and creating new knowledge), technological infrastructure, leadership and enablement of knowledge sharing, and effective boundary-spanning roles with other organisations. The capacities in the repertoire will be those that are distributed throughout the organisation and are capable of being articulated:

'to understand the sources of a firm's absorptive capacity, we focus on the structure of communication between the external environment and the organisation, as well as among the subunits of the organisation, and also on the character and distribution of expertise within the organisation.'

In a more recent (and very comprehensive) overview of the knowledge utilisation literature, Zahra and George[25] redefined absorptive capacity as: 'a dynamic capability pertaining to knowledge creation and utilisation that enhances a firm's ability to gain and sustain a competitive advantage'. They propose four dimensions:

1. Acquisition (the ability to find and prioritise new knowledge quickly and efficiently).

2. Assimilation (the ability to understand it and link it to existing knowledge).

3. Transformation (the ability to combine, convert and recodify it).

4. Exploitation (the ability to put it to productive use).

Acquisition, of course, requires social contacts **outside** the organisation, whereas assimilation and transformation are critically dependent on the quality of social interaction **within** the organisation.

## 1.5   'Omnibus' and 'discrete' (social, task and physical) dimensions of context

McDermott and Keating,[5] in a recent qualitative study of cardiology services in three Irish hospitals, draw on a further differentiation: that between 'omnibus' and 'discrete' dimensions of context, as provided by Johns.[26] 'Omnibus' refers to broad consideration of context as a whole. In contrast, 'discrete' context refers to particular contextual components that shape behaviour or moderate relationships between variables. Johns notes that 'the effects of omnibus context are mediated by discrete contextual variables or their interactions'. Within discrete context, following Hattrup and Jackson,[27] Johns identifies task, social, and physical components. His examples of task context include uncertainty, autonomy, accountability and resources. Examples of social context include social structure, density and influence. Examples of physical context include the built environment and temperature, and so on.

The authors state that their findings identify the combinations of discrete contextual factors affecting service improvement capacity and climate; specifically, dimensions of the task context that influenced change capacity (ie the governance, accounting, and service-planning system). They also propose dimensions of the social context that influence the internal climate for change (ie the extent of strategic distractions, senior management support and the social structures in place). They argue that their theoretical contribution arises from the integration of service improvement capacity, climate and outcomes across the cases (see Figure 4 overleaf), and that the findings:

'illustrate countervailing contextual influences in action (Johns, 2006) with climate for service improvement, influenced by dimensions of the social context (strategic distractions, senior management support, and the social structures in place), acting in configuration to countervail or enhance capacity, influenced by dimensions of the task context (governance, service-planning system, and accounting system). This provides insight into the relative influence of the task and social dimensions of context across the cases – with the social context emerging as the key facilitator of service improvement.'[5]

vi   From Greenhalgh, Robert et al (2005). *Diffusion of Innovations in Health Service Organisations.* Oxford: Blackwell.[9]

Figure 4: The role of social context in achieving service improvement[5]
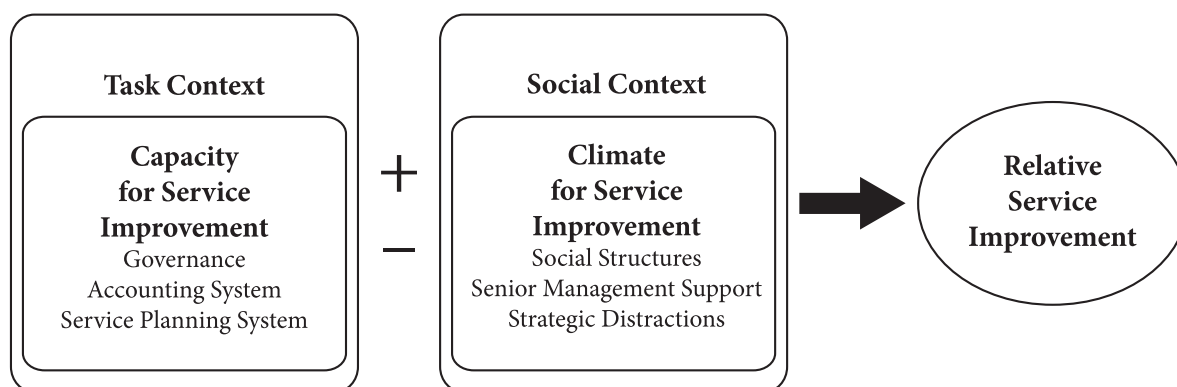
McDermott et al[5] suggest that policy makers should, in the first instance, consider how they might positively influence the social context of organisations to achieve service improvement. For example, their data suggest that job-based autonomy and support are more important than organisational autonomy in facilitating service improvement. Specifically, organisational autonomy and resource availability are less important than the social structures in place and social influence afforded to staff (particularly non-medical staff) in securing service improvement. Hence, exploration of how autonomy and discretion can be facilitated might consider local social structures, management support, and flexibility in job design.

1.6   Emotional intelligence and receptivity to change (at individual and organisational levels)

Huy[3] presents a multilevel theory of emotion and change, which focuses on attributes of emotional intelligence at the individual level and emotional capability at the organisational level. He argues that emotional intelligence facilitates individual adaptation and change, and emotional capability increases the likelihood for organisations to realise radical change. He presents a meso-level framework, relating emotion-attending behaviours to three dynamics of change: receptivity, mobilisation and learning (see Figure 5). These behaviours, which are termed emotional dynamics, constitute the organisation's emotional capability.

At the individual level, receptivity denotes a person's willingness to consider change, while at the organisational level, receptivity refers to organisation members'
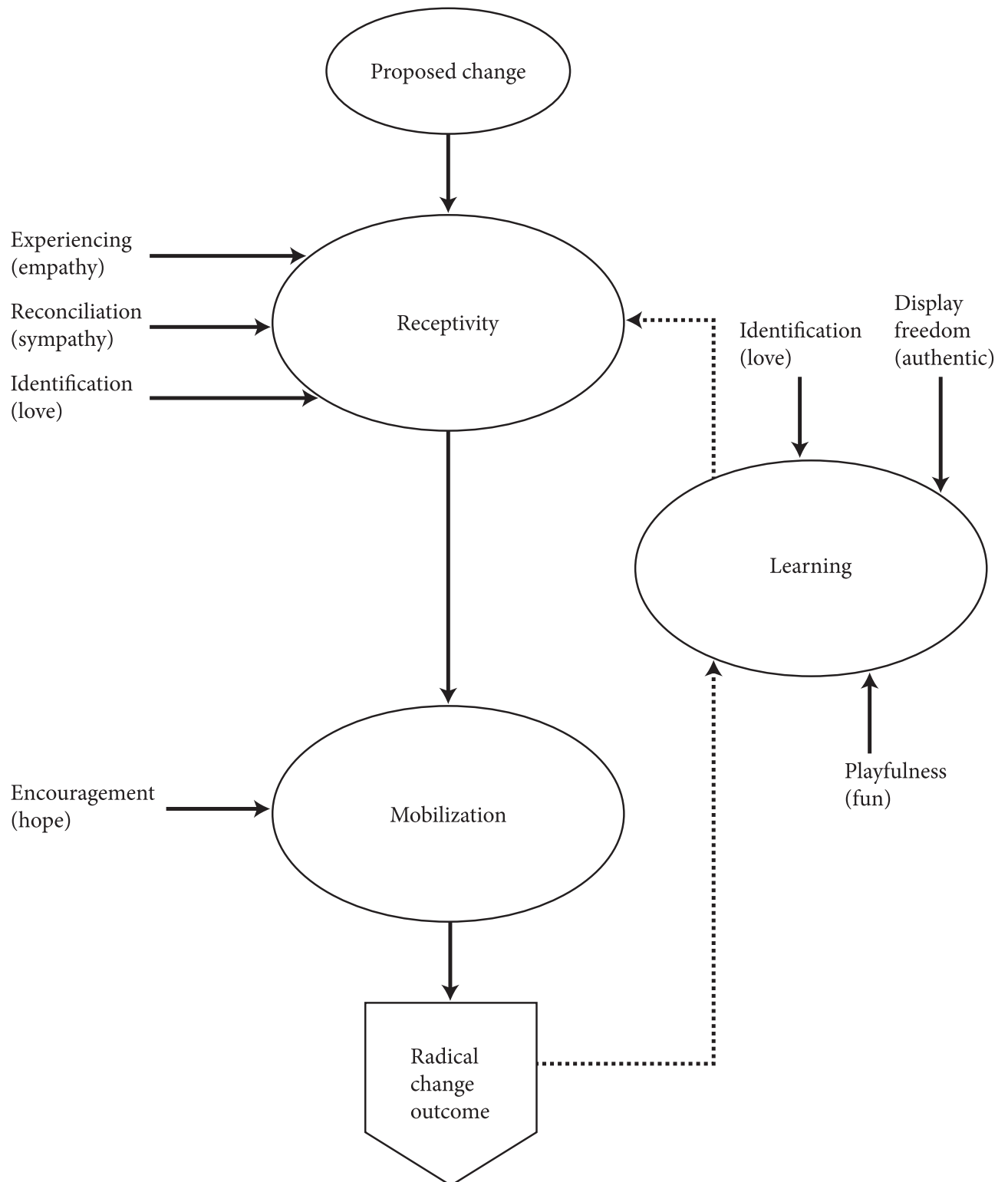
willingness to consider – individually and collectively – proposed changes and to recognise the legitimacy of such proposals. Receptivity as a process shapes, and is shaped by, the continuous sense-making and sense-giving activities conducted among various members of the organisation. Receptivity to change can be characterised by resistance to change through varying gradations of willingness to accept the proposed change, from resigned, passive acceptance to enthusiastic endorsement.

Huy[vii] thus moved emotional intelligence from the individual level to the organisational one, arguing that some organisations develop routines or practices that make them more emotionally intelligent than other organisations (regardless of the innate traits of their members). Consequently, emotional intelligence enters the realm of organisational capabilities that need to be developed and nurtured as they can foster beneficial outcomes for organisations, including receptivity to change and organisational learning. Huy[4] then identified five emotion-related organisational routines – or emotion-based capabilities – that help an organisation manage change, with each routine potentially critical to the success of various sub-processes related to organisational change.[viii] Huy argues that attention to these emotional states fosters attitudes and behaviours that open up individuals to consider and mobilise for ambitious and difficult change. In this regard Huy's work relates closely to some of the key constructs that Weiner (reviewed above) later drew on when developing his theory of 'organisational readiness for change'.[2]

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vii   Summary based on: Van der Heyden and Huy (2008). 'Fair process and emotional intelligence'. Workshop of the IESE International Family-Owned Business Conference.[28]

viii   The five emotions are: emotional authenticity, constructive discontent, sympathy/empathy, fun (or passion), and hope.

Figure 5: How emotional dynamics influence change dynamics[3]

Proposed change

Experiencing (empathy)

Reconciliation (sympathy)

Identification (love)

Receptivity

Identification (love)

Display freedom (authentic)

Learning

Playfulness (fun)

Encouragement (hope)

Mobilization

Radical change outcome

2. What do you know about context from the literature?

As Pettigrew noted some years ago we are (still) faced largely with a general literature on healthcare quality that, reflecting the wider field of health services research, for the most part remains atheoretical, aprocessual, acontextual and/or ahistorical. While recent years have seen an increased interest (for example, Kaplan et al,[8] Krein et al,[29] McDermott et al[5]) in viewing context as a key variable for QI success in healthcare, as others have noted, 'studies in which the examination of context is a declared and substantive research objective are rare' (849).[30] For instance, Kaplan et al's[8] systematic review on this very topic found only four studies that examined the interactions between different contextual factors (although by deliberately excluding all qualitative studies we would argue they were neglecting a larger body of very relevant studies).

Below we briefly summarise key empirical studies of the impact of context on organisational change (including but not limited to QI) in healthcare beginning in the 1980s and 1990s with examples of largely cross-sectional, survey-based studies of the adoption of innovations, moving onto largely qualitative case study-based evaluations of QI in the 2000s, on to more recent applications of a realist evaluation approach and studies which have sought to test and extend previous models and frameworks. This overview also includes two highly relevant systematic reviews.[8,9]

2.1 Examples of 1980–1990s studies of organisational innovations in healthcare settings

Typically these early studies, mainly in the US, deal with 'adoption' as their outcome, rather than successful implementation or assimilation into routine practice. As one of the authors has argued elsewhere[31] 'adoption' should be seen as a process rather than as a discrete event (as it is in the four papers described below), and as a process that comprises both 'formal' organisational decisions and a series of 'informal' decisions by individual users (shaped by discussions with their peers and colleagues, reminiscent of the 'social context' described by McDermott and Keating above) which ultimately leads to the assimilation of the innovation into routine practice or not.

Kimberly and Evanisko[32] studied technological and administrative innovations in US hospitals in the late 1970s through a mixed methodology study with questionnaires. The variables under study included (a) the characteristics of individuals in authority; (b) organisational characteristics; and (c) contextual factors. Size was most significantly and consistently associated with innovation; other organisational variables also impacted on technological, but not administrative, innovations. The variables tested were much better predictors of the adoption of new medical technologies than of administrative innovations.

Meyer and Goes[33] studied 12 organisation-level medical innovations introduced into US community hospitals in the late 1970s using a comparative case study design over six years with over 300 interviews, observation and surveys. They found that the assimilation of innovations by organisations is influenced by (a) environment, organisational context and leadership, (b) the attributes of the innovation, and (c) the interaction between these. They reported that contextual factors accounted for only about 11% of the observed variation and that environmental variables had little demonstrable impact.[ix]

Burns and Wholey[34] studied unit/matrix management in US general hospitals through retrospective and longitudinal questionnaire surveys (study specific and national data) focusing on several measures of organisational structure plus embeddedness in external networks and normative institutional pressures (including (a) diversification and scale (a measure of size); (b) sociometric location in network; (c) dissemination of information; and (d) inter-organisational norms). They reported that a combination of inner context and outer context factors were both found to be significant (while there was no overall effect of organisational size, small hospitals were excluded from the sample).

Goes and Park[35] studied 15 innovations in Californian acute care hospitals (six technical and 11 administrative) through a prospective longitudinal study over 10 years. The authors tracked year-to-year changes and found a positive association between (a) size and (b) inter-organisational links and adoption of both technical and administrative innovations. Hospitals exhibiting multiple and extensive inter-organisational links were more likely to be large; and large hospitals were consistently more innovative than small hospitals.

[ix]   These results closely resemble those of Kimberly and Evanisko.[32]

Figure 6: Study framework for assessing the impact of quality improvement[36]
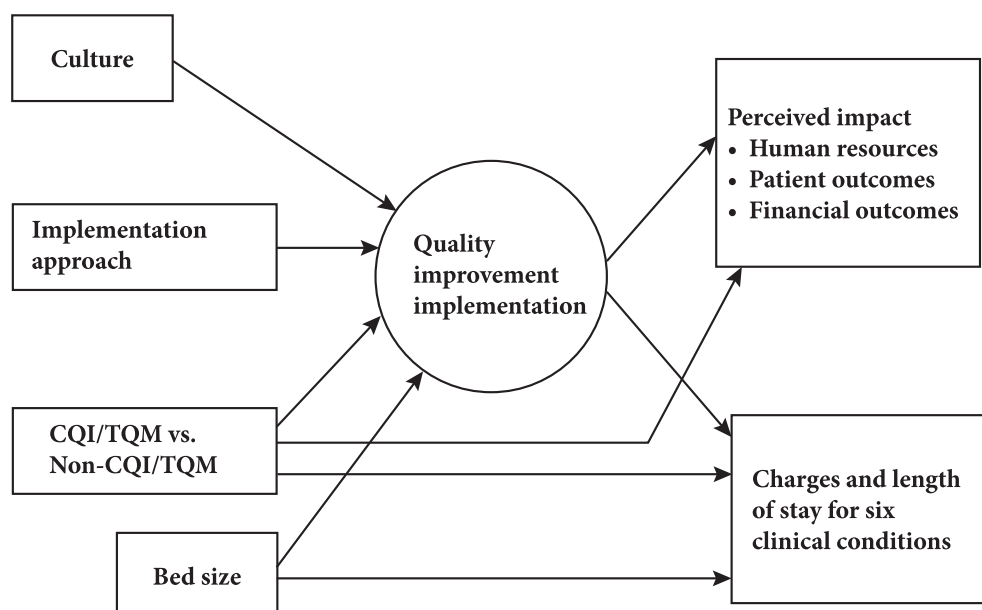
2.2 Shortell's US studies[36,37]

Shortell et al,[37] in conducting a systematic review of the clinical application of continuous quality improvement (CQI) in order to identify its strengths and limitations, characterise CQI as a 'beautiful rose growing in an unruly garden filled with weeds', the weeds being other organisational factors which work against it. The problems, they suggest, lie not so much with CQI itself as with the infrastructure required for its success and the high demands it makes on individuals and organisations:

'For the CQI rose to flourish it must be carefully cultivated in a rich soil bed (eg a receptive organisation), given constant attention (eg sustained leadership), assured of appropriate amounts of light (eg training and support) and water (eg measurement and data systems) and protected from damaging pests (eg overly burdensome regulation and parochial views). Its strengths may make the "gardening" worth the effort.'[37]

Shortell et al argue that CQI applications were more likely to be effective under 'certain conditions' (with the latter two reminiscent of inner and outer context):

– when they are carefully focused on areas of real importance to the organisation and addressed with clearly formulated interventions

– when the organisation is ready for change and has prepared itself by appointing capable leadership, creating relationships of trust with physicians, and developing adequate information systems

– when there is a conducive external environment relative to beneficial regulatory, payment policy and competitive factors.

Earlier work by Shortell et al, examining the relationships among organisational culture, quality improvement processes and selected outcomes for a sample of up to 61 US hospitals, supported this hypothesis:

'a participative, flexible, risk-taking organisational culture was significantly related to quality improvement implementation… what really matters is whether or not a hospital has a culture that supports quality improvement work and an approach that encourages flexible implementation.'[36]

The study was based on the framework shown in Figure 6 which comprises both 'soft' (culture)[x] and 'hard' (bed size) inner context factors.

Later, Ferlie and Shortell[38] suggested that the development of a receptive context is an 'important force for any change'.

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x   In this study,[36] organizational culture was measured using a 20-item self-administered questionnaire developed by Zammuto and Krakower (1991) based on Quinn and Kimberly's original competing-values typology (1984) involving underlying dimensions of flexibility/control and external versus internal orientation. The survey asked respondents to distribute 100 points between various descriptions of what constitutes a group culture, a developmental culture, a hierarchical culture, and a rational culture.

2.3 Evaluations of Breakthrough Collaboratives in the NHS[39]

Bate et al[39] undertook an evaluation of one of the first IHI Breakthrough Collaboratives in the NHS and – following Pettigrew's model (see Figure 1 on page 35) – identified three general contextual aspects which shaped and influenced the effectiveness of the collaborative: leadership, power and cultural contexts. These contexts together made up one element of the study hypothesis: that the effectiveness of the Collaborative was not just a function of the **method/ approach** but the **way it was implemented** and the **context** within which it was implemented. The authors concluded that:

> 'One factor that appears to have been largely overlooked is how to prepare the receptive context… within the participating Trusts and a similar lack of receptivity in the "outer context" of the NHS… differing local receptive contexts may help to explain why it is that the rate and pace of change vary between different organisations when the content of change is broadly similar and where there may be some equivalence in the outer context framing the change process… a much closer examination of "top", "middle" and "bottom" performers would be required to establish the precise nature and significance of these differences… the general conclusion to be drawn is… to give greater attention to building the receptive context for change: in leadership, power and cultural terms.'

2.4 Gustafson's 'Organisational Change Model'[40]

As discussed above, much material relevant to this topic is to be found in the general change management literature, which we were unable to review comprehensively. However, one recently published and high quality paper from that literature deserves mention here.[xi] Gustafson et al[40] invited a panel of experts in organisational theory to suggest critical factors to account for the successful (or unsuccessful) implementation of organisational change (in this case healthcare improvement) projects. They combined this with a narrative review of the organisational change literature to produce an 18-item

survey instrument (the Organisational Change Model (OCM)), which measured the Bayesian probability of successful change. They then tested this instrument retrospectively against independent retrospective data on 221 healthcare improvement projects in the United States, Canada, and the Netherlands between 1996 and 2000. They found that the instrument had very high sensitivity and specificity (area under the Receiver Operator Characteristic curve >0.84) for distinguishing projects that were successfully implemented from those that failed or had only marginal success. Greenhalgh et al[9] suggested that seven of the 18 items incorporated into the OCM could be categorised under the broad concept of 'organisational readiness',[xii] although no such categorisation was made by the original authors, and nor did the Gustafson study itself explicitly address the concept of 'context' as a key variable.

2.5 Greenhalgh et al systematic review[9]

As Greenhalgh et al[9] point out, there has been growing interest in how particular types of climate and receptive context lead to (or inhibit) organisational innovation and how they can enhance the organisation's capacity to diffuse innovation. Several commentators have observed[26,41] that contextual features are often studied in a piecemeal fashion, without attention to their configurational or cumulative impact. Greenhalgh et al's extensive review found seven empirical studies that looked at the impact of (inner) organisational climate, receptive context, or absorptive capacity on the implementation of innovations in health service delivery and organisation.[xiii]

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xi Based on commentary in Greenhalgh et al, 2005.[679]

xii Tension for change; leader goals, involvement and support; funding; middle manager goals, involvement and support; supporters and opponents; staff changes required; and monitoring and feedback.

xiii Further details and critiques of each of these six studies are available in Greenhalgh et al, 2005.[9] Perhaps the most relevant of the studies here is that of Dopson et al (2002) who undertook an extensive secondary analysis of a group of seven studies previously published by the same group of authors. All the primary studies were comparative case studies based on in-depth qualitative methods (chiefly semi-structured interviews), and involving a total of some 1,400 in-depth interviews across 49 in-depth cases. The studies had all been based in UK health care organisations (primary and secondary care) and explored the reasons behind actors' (mostly clinicians') decisions to use (or not to use) research evidence, and what makes this information credible for utilisation. Their study underlined the role of a receptive context for change for the effective diffusion of research evidence. They identified a number of characteristics of a receptive context including (Dopson et al, 2002:45): a favourable history of relationships between professional and managerial groups and between professional groups; sustained political and managerial support and pressure for clearly defined change at a local level; the creation of a supportive local organisational culture, clear goals for change, appropriate infrastructure and resources are critical; effective

They concluded that:

'The creation of a receptive context is a major challenge for organisations, and can undoubtedly be increased by management intervention (eg by making training readily and broadly available to targeted employees; by giving ample time to staff so that they can both learn about the innovation and use it on an ongoing basis and so on and by ensuring that the innovation can be accessed easily… However… effective implementation needs both a receptive context and a good fit between the innovation and intended adopters' needs and values.'

Greenhalgh et al also found eight studies that examined a wide range of factors associated with the wider environmental (outer) context within which organisations function and which have been suggested as having an impact on the adoption of innovations. Earlier, Damanpour's 1996 meta-analysis of studies[42] showed a positive but – in quantitative terms – unimpressive impact of environmental uncertainty on organisational innovativeness and the empirical studies reviewed by Greenhalgh et al largely confirmed that finding in the service sector.

The authors also found four studies that considered the political and policy-making environment, all of which demonstrated the critical importance not merely of political and policy-making forces but of their dynamic interaction with other variables. Such conclusions chime with the 'outer context' components of what Pettigrew et al called 'receptive context for organisational change'; in short the sensitivity of implementation teams to these external forces and their ability to respond adaptively to them seems critical to implementation success.

2.6   Lukas et al evaluation of Pursuing Perfection in US[43]

Lukas et al[43] reported on their evaluation of the 'Pursuing Perfection' QI initiative in the US and highlighted the interactions between (what we would consider) largely 'inner' context factors as being critical to successful transformation of patient care. The factors were:

– impetus to transform

– leadership commitment to quality

– improvement initiatives that actively engage staff in meaningful problem solving

– alignment to achieve consistency of organisation goals with resource allocation and actions at all levels of the organisation

– integration to bridge traditional intra-organisational boundaries among individual components.

The authors suggest that these elements drive change by affecting the components of the complex healthcare organisation in which they operate, namely the:

1. mission, vision, and strategies that set its direction and priorities

2. culture that reflects its informal values and norms

3. operational functions and processes that embody the work done in patient care

4. infrastructure such as information technology and human resources that support the delivery of patient care.

It is important to note, however, that this evaluation is largely silent on the importance or otherwise of the 'outer' context. In contrast, other studies – such as one reported by one of the authors of this paper[44] – have explicitly explored the relationship between outer (external) and inner (local) contextual factors on, for example, patient safety issues such as healthcare-associated infections and medication errors.

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and good-quality relationships within and among local groups; access to opportunities to share information and ideas within the local context; and the introduction of organisational innovations to foster improved and effective interchanges among groups.

2.7 'Organising for quality'[7]

Bate et al[7] examined healthcare organisations that have earned reputations for sustained achievement of QI with the goal of understanding the process of improving quality. They found that QI processes are interconnected and symbiotic. While there are many different routes to sustained QI, they concluded that all the successful organisations shared an ability to address multiple challenges (see Figure 7) simultaneously and a talent for adapting solutions to their own organisational context:

'Because local conditions and contexts vary so much, particular solutions also need to vary, and therefore need to be locally cultivated, home-grown and situation-specific. In this sense it is better to assume that "solutions" travel poorly and cannot simply be copied or co-opted from elsewhere. Furthermore, most or all of the case studies describe key interactions and pressures with parties or influences external to their organization, hence the need to factor in the effect of the wider institutional and social environment. Without this "contextualist" and "institutionalist" framework, any attempt at making sense of the stories would risk overlooking or misattributing critical sources of organizational behaviour and change'.[7]

'Context' in this study was defined as 'features and dynamics of the environment of organisations that are receptive or non-receptive, enabling or disabling of improvement and the organisational supports and processes needed to sustain it'. The authors identified significant inner and outer contextual factors from their

Figure 7: Organising for quality in healthcare: the six universal challenges[7]
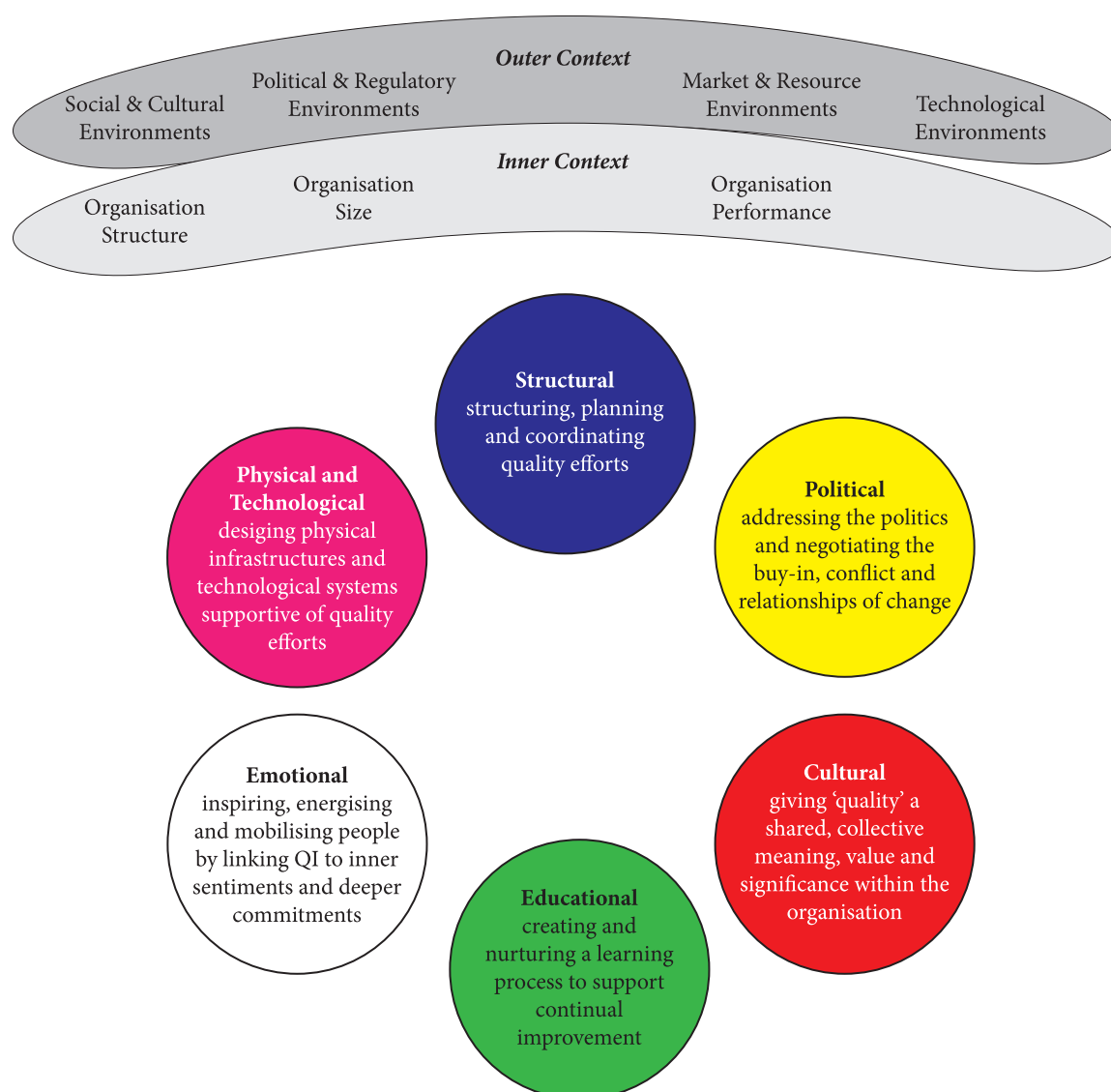
case study-based research into the 'journey to quality' of leading healthcare organisations in the US and Europe (see Annex 1 for a list of factors). The authors identified key lessons for quality improvement, and call for greater research into how to incorporate improvement strategies into organisational contexts. Donald Berwick, in the foreword to the book, noted that:

> *'neither these researchers nor their subjects in the complex world of organizational change and improvement can hope to escape "... the hazards and uncertainties lying in wait in the punishing contextual terrain that has to be crossed ...". That phrase – "the punishing contextual terrain"… so clearly labels the facts-on-the-ground for the ambitious, even courageous clinicians, managers, executives, and others in healthcare who seek to make care far better. They have discovered that almost nothing about effective action in improvement is installable without constant, recursive adjustments to ever-changing local context. Researchers who wish to understand how improvement works, and why and when it fails, will never succeed if they regard context as experimental noise and the control of context as a useful design principle.'*[7]

Bate et al also distinguished between the role of the macro- and micro-system levels in organisations with regard to context (see Table 1).

Table 1: Different but interlocking and complementary roles[7]

Macro: Standardizing	Micro: Individualizing
framing and gaming!	the 'doing' of quality
protecting	challenging and redefining
visioning	socializing
resourcing	mobilizing
devolving	bonding and team building
structuring/embedding	'retrospecting' and learning
knowledge harvesting and diffusing	redesigning, improvising and customizing
measuring and evaluating	
protocolizing	

For example, they argue that one of the unique contributions of the macro-system is creating a 'receptive context' for change and learning within the organisation. This includes a number of features – such as strategic vision, good managerial relations, visionary staff in

pivotal positions, a climate conducive to experimentation and risk taking, and effective data capture systems – associated with the capacity to embrace new ideas and implement innovations within and across units of an organisational system. An equally important facet of creating this receptive context entails macro-level actions to enhance trust, which the authors see as an essential enabling condition for organisational learning and improvement (ie where senior management feel confident in empowering lower levels and frontline staff believe in the espoused motives of senior management with regard to the quality agenda). Clearly, another fundamental role of the macro-system in creating a receptive context for change and learning is to provide the funding and resources required to support the QI process and to implement service improvements.[xiv]

This study also raises the question of when context is an important variable in QI success over a period of time:

> *'context, whether inner organizational features such as size and performance, or influences from the external environment, appears to have played a relatively minor role in sustaining the quality journeys of these two organizations. This would suggest that although contextual influences or events may provide an important initial impetus to an organization's quality journey… whether the quality journey is sustained may depend more on how the organization responds and acts (or does not act) to these stimuli.'*[7]
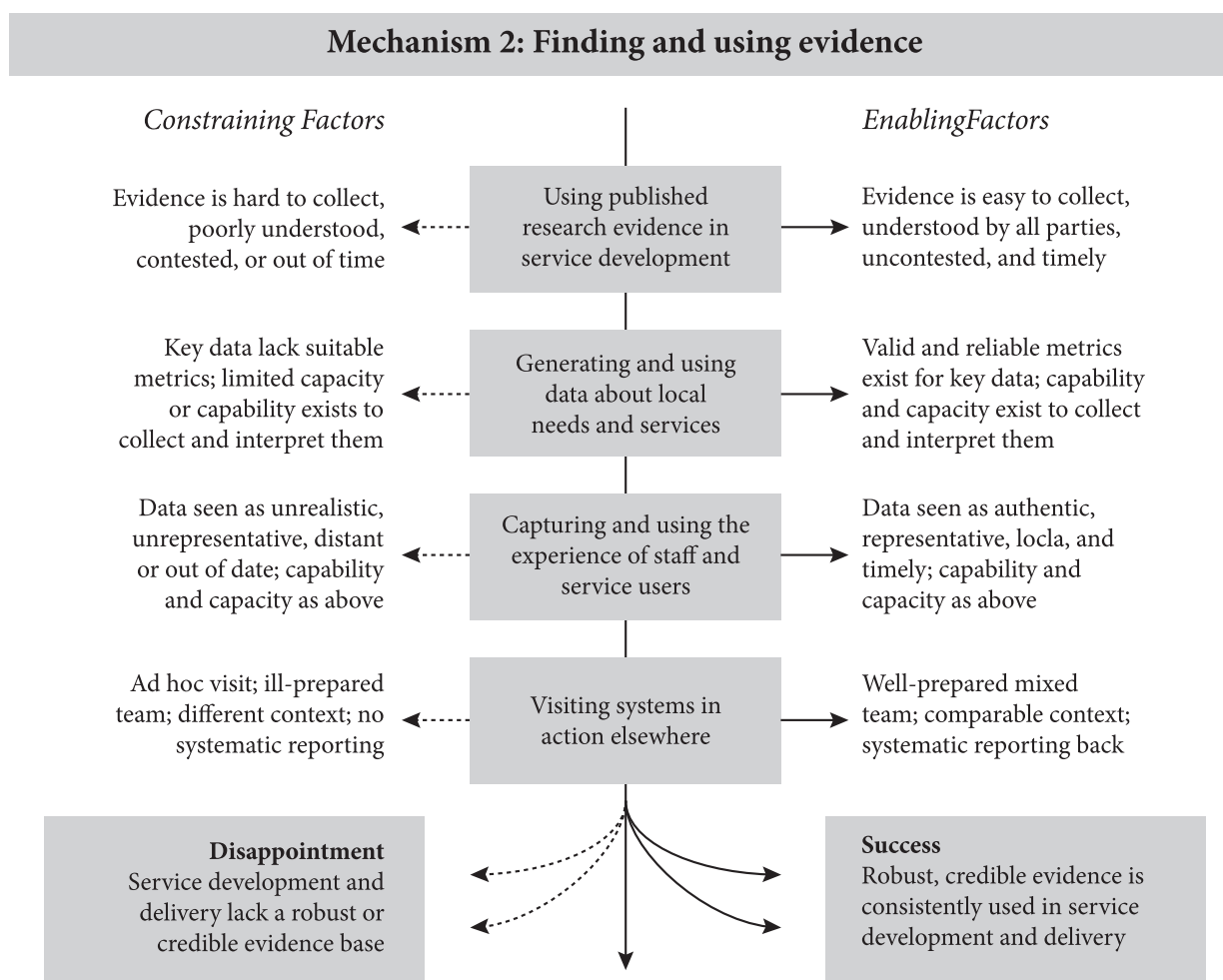
2.8 Realist evaluation of large-scale QI programmes[45]

Greenhalgh et al[45] evaluated a major change effort in inner London that spanned four large healthcare organisations, covered three services (stroke, kidney and sexual health) and sought to 'modernise' these services with a view to making healthcare more efficient, effective and patient-centred. Their organisational case study drew on the principles of realist evaluation, a largely qualitative approach that is centrally concerned with testing and refining programme theories by exploring the complex and dynamic interaction among context, mechanism, and outcome.

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xiv The 'Organising for Quality' Framework is the basis for a three year EU FP7 funded study being led by the Department of Applied Health Research at UCL. The QUASER study investigated organisational and cultural factors affecting hospital quality improvement initiatives in five European countries: England, the Netherlands, Norway, Portugal and Sweden. See: https://www.ucl.ac.uk/dahr/quaser

Figure 8: Realist analysis of attempts to modernise by finding and using evidence[45]

Mechanism 2: Finding and using evidence

Constraining Factors		Enabling Factors
Evidence is hard to collect, poorly understood, contested, or out of time	Using published research evidence in service development	Evidence is easy to collect, understood by all parties, uncontested, and timely
Key data lack suitable metrics; limited capacity or capability exists to collect and interpret them	Generating and using data about local needs and services	Valid and reliable metrics exist for key data; capability and capacity exist to collect and interpret them
Data seen as unrealistic, unrepresentative, distant or out of date; capability and capacity as above	Capturing and using the experience of staff and service users	Data seen as authentic, representative, locla, and timely; capability and capacity as above
Ad hoc visit; ill-prepared team; different context; no systematic reporting	Visiting systems in action elsewhere	Well-prepared mixed team; comparable context; systematic reporting back
Disappointment Service development and delivery lack a robust or credible evidence base		**Success** Robust, credible evidence is consistently used in service development and delivery

The researchers undertook an interpretive analysis, which explored the context–mechanism–outcome relationship using the guiding question 'what works, for whom, under what circumstances?' They found that six broad mechanisms appeared to be driving the efforts of change agents: integrating services across providers, finding and using evidence (see Figure 8, for example), involving service users in the modernisation effort, supporting self-care, developing the workforce, and extending the range of services. Within each of these mechanisms, different teams chose widely differing approaches and met with differing success. The realist analysis of the fortunes of different subprojects identified aspects of context and mechanism that accounted for observed outcomes (both intended and unintended).[xv]

Noting recent calls by others for the greater use of realist evaluation in healthcare, the authors considered some of the challenges and limitations of this method in the light of this experience and suggest that its use will require some fundamental changes in the world view of some health services researchers.

2.9   Krein application of 'Organising for Quality' framework[29]

Krein et al[29] explore why QI efforts are successful in some hospitals and not others by means of a mixed methods study incorporating qualitative interviews and site visits to six hospitals in the US. This study applied the 'Organising for quality' framework[7] (see above) to interpret its findings. The authors report that:

'among a number of hospitals that focused on preventing central line-associated bloodstream infections (CLABSI), despite using similar

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and a sustained inter-organisational structure for governance and formal communication'.

implementation strategies the experience and outcomes of these efforts varied considerably given the organisational context',

and that their findings were consistent with the theory of organisational readiness for change proposed by Weiner (see above).[2]

They found that hospitals with a positive emotional and cultural context, as evidenced by strong emotional commitment to patients, a unified culture focused on patient care and active and engaged clinical leadership, appear especially conducive for fostering and encouraging internally motivated initiatives. Activities promoted through quality collaboratives or other externally facilitated efforts may also be successful in these types of organisations, although their contribution to what might already be an effective initiative could be marginal. In contrast, for hospitals with a negative emotional, cultural and political context (ie lack of emotion, weak cultural identity and poor relationships among stakeholders), externally facilitated initiatives might be effective in providing the motivation, and sometimes resources, needed for implementation. However, this may still not be enough to produce the changes needed to significantly improve outcomes, especially if the practices to be implemented involve behaviour changes, and the facility lacks actively engaged clinical leadership and/or dedicated resources to encourage, monitor and ensure adherence.

On the issue of 'context' the authors conclude that:

'Supporting the emphasis on the importance of context in healthcare settings and implementation research (Benn et al, 2009; Rycroft-Malone et al, 2009; Rousseau and Fried, 2001), our findings highlight the potential impact and the need to measure or at least consider organizational context as a source of heterogeneity when evaluating and implementing quality improvement efforts across organizations. Some quality improvement interventions now include an explicit focus on changing certain aspects of organizational context to facilitate practice change (Jain, Miller, Belt, King, and Berwick, 2006; Pronovost, 2008). Given the complexity and number of factors that define organizational context, however, we believe that for some situations it may not be feasible to readily change the context and thus we also need to identify potential strategies that might be a

better fit with, or tailored to, the current context. While tailoring is not an entirely new concept, its application to date has been limited (Bosch, van der Weijden, Wensing and Grol, 2007) and additional research is clearly warranted.'[29]

2.10   Kaplan et al review of influence of context on QI success in healthcare[8]

Kaplan et al[8] reported on the results of a systematic review that explored the influence of context on QI success in healthcare (albeit one that excluded studies that did not formally test the association between context and improvement using statistical methods). For the purpose of this particular review 'context' was defined as:

'anything not directly part of the technical quality improvement process that includes the quality improvement methods themselves and the clinical interventions… context may include factors relating to the characteristics of the organisational setting, the individual, his or her role in the organisation, and the environment'.

The authors report that 47 articles were included in their review, 72% of which were cross-sectional studies (and 78% were US studies). Only four studies examined interactions between different contextual factors. In total 66 contextual factors were identified but the authors report that – on the basis of their review of the studies – they 'cannot make definitive conclusions about the influence of particular contextual factors in QI success'. They highlight key limitations in the existing literature as:

1. lack of a practical conceptual model

2. lack of clear definitions of contextual factors

3. lack of well specified measures.

It is important to note that this systematic review excluded **all** qualitative studies and the vast majority of included studies were cross-sectional.

3.   What models or frameworks do you use to help explain context?

We take as our starting point Pettigrew et al's[1] well known notion of receptive and non-receptive contexts for change which – although encompassing both 'hard' (structural) and 'soft' (cultural) factors – we argue now needs to

be combined with more contemporary psychological perspectives (such as Weiner's notion of 'readiness' for change,[2] Huy's work on 'emotional receptivity' at the individual and organisational levels,[3,4] and the proposition that social context is the key facilitator of QI[5]). Overlaying this combination of different perspectives, we argue (following House et al[6]) that more attention must be paid to the multiple levels of context (macro, meso and micro) and how these combine to impact on the success and sustainability of QI efforts.

4. What do you see as the principle research questions relating to context?

We address this question in two stages:

1. identifying key research questions

2. designing appropriate research to answer those questions.

Our recommendations relating to both these stages are predicated on the basis that the overall aim of any such research 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 QI efforts, and acting to make context more receptive where possible, as well as informing the future design (and 'tailoring') of QI programmes themselves. As Bate et al[7] suggest, the guiding belief for any future research in this area should therefore be that once we know why and how something works in one organisation we can avoid the trap of (invariably) failed replication in another and begin to construct specific, targeted interventions and home-grown, context-specific solutions that stand a more reasonable chance of working.[xvi]

4.1 Key research questions

We recommend that future research that combines a structural and psychological approach to thinking about 'context' needs to focus on four related questions.

1. Which contextual factors (structural and psychological, outer and inner) are related to QI success and sustainability in healthcare organisations?

2. Which of these contextual factors are modifiable (ie there are some key contextual factors which are more amenable to change and intervention than others) and by whom? (For example, while hospital professionals/managers may not be able to change aspects of their macro context, eg the regulatory framework, they can change how they make sense of it and respond to it.)

3. How do contextual factors at different levels of the healthcare system impact on QI success and sustainability in healthcare organisations (following House's macro, meso and micro framework[6] which bears resemblance to notions of outer and inner context)?

4. When are different contextual factors more or less important during a QI initiative (ie different contextual factors have greater or lesser influence at different stages of the adoption–implementation–assimilation process, see for example section 1.4 on absorptive capacity)?

4.2 Research design

We recommend that the first and second of these questions can be initially addressed through secondary research (scoping reviews of the peer-reviewed and grey literatures across a range of disciplines, including several of the studies we briefly review here, for example, Bate et al[7] and McDermott and Keating,[5] and, in contrast to Kaplan et al's recent systematic review,[8] including qualitative studies). Such secondary research might identify significant gaps in the evidence base that may then require primary research to be commissioned.

The third and fourth questions should be studied through primary research and could be broadly based on the principles of realist evaluation: that is to say, contextually focused (structural and psychological), process-based (longitudinal) and (largely) qualitative case studies that are designed to explore the dynamics

Figure 9: Realistic synthesis framework for considering spread and sustainability initiatives across different organisations and projects[9]
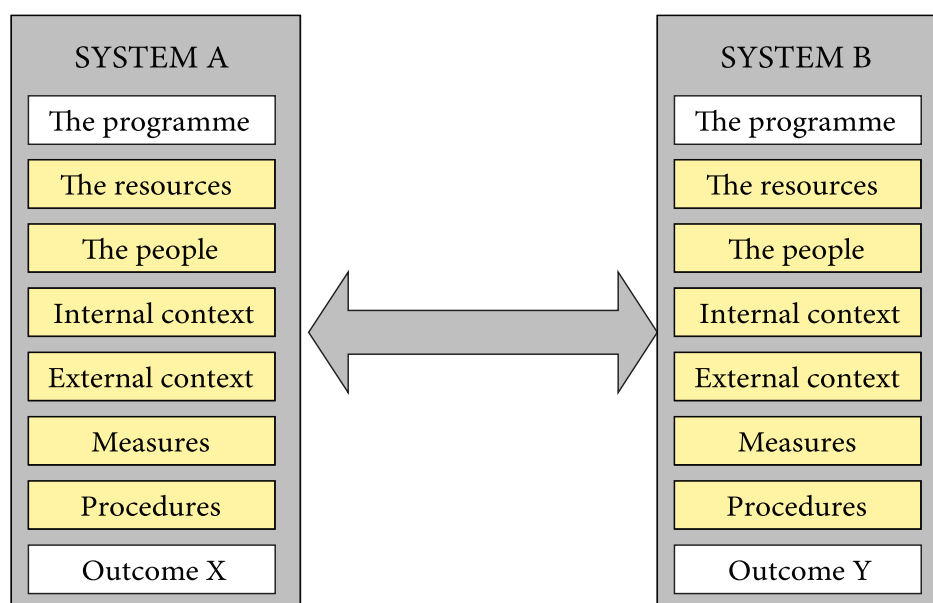
between contextual factors at different levels and at different stages of the adoption, implementation and assimilation of similar QI initiatives. Criteria for high quality research studies of this type have been proposed and are included within this paper (see Annex 2). Greenhalgh et al[9] recommend:

> '… a more pragmatic approach in which the potential interaction between these variables is considered in relation to a specific local context and setting, perhaps using… a realist evaluation framework [modified] specifically for the context-sensitive evaluation of innovations in health service delivery and organisation.'

The goal of realistic evaluation is to critically examine the mechanisms of success or failure in different efforts to implement an innovative practice throughout a sector, and hence, in general terms, address the question 'what works for whom under what circumstances?'[xvii,46] Proponents of this approach have also proposed a framework for synthesising results from different projects (see Figure 9) which could also be an important component of any future research strategy.

While strongly supporting this 'direction of enquiry'[xviii] they also set out a set of principles for ensuring the quality of such research (see Annex 2) that funders of health services research may wish to consider when commissioning future primary research studies in this area.

Such an approach could help counterbalance – as Bate et al[7] have argued – 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 healthcare 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.[xix] One key theorist in the healthcare domain is Ann Langley, who describes what this is likely to involve:

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xvii Pawson advocates an in-depth case study approach, focusing on both the context and the detailed mechanism of each separate implementation project. Using the headings illustrated in Figure 7, the researcher should ask for each of them 'what are the differences and to what extent do these differences explain the outcome?'

xviii Greenhalgh et al[9] suggest that: *'most of the existing empirical research relating to the spread and sustainability of innovations [QI included] has focused on a limited number of components… often based on experimental (and, some would argue, reductionist) designs. Such research has produced findings that may or may not be generalisable to the complex realities of real-world implementation in particular contexts. A relatively new research tradition is emerging… this research is qualitative, interpretive and emergent rather than experimental, and is arguably better suited to drawing meaningful lessons from complex implementation projects.'*

xix Pettigrew et al[1] define the task thus: *'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'.*

'Process research is concerned with understanding how things evolve over time and why they evolve in this way, and process data therefore consist largely of stories about what happened and who did what when – that is, events, activities, and choices ordered over time… Whereas variance theories provide explanations for phenomena in terms of relationships among dependent and independent variables (eg more of X and more of Y produce more of Z), process theories provide explanations in terms of the sequence of events leading to an outcome (eg do A and then B to get C). Temporal ordering and probabilistic interaction between entities are important here. Understanding patterns in events is thus key to developing 'process theory.'[47]

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 (see Robert et al[31] for a fuller description and potential benefits of applying these).

Finally, given what we (and others)[xx] see as the crucial importance of studying interactions between contextual factors at the macro, meso and micro levels, we recommend that any further research (whether primary or secondary) must include such a multilevel framework.[44] Requiring just such a multilevel, process-based perspective will significantly extend the standard approach to studying the success and sustainability of QI projects in healthcare organisations.

[xx] As Greenhalgh et al[9] state, a consistent theme in high-quality overviews and commentaries on the spread and sustainability of innovations is that empirical research has generally been restricted to a single level of analysis (individual or team or organisation or inter-organisational); has implicitly or explicitly assumed simple causal relationships between variables; has failed to address important interactions between different levels (for example, how different organisational settings moderate individual behaviour and decision making) and between both measured and unmeasured variables within these levels; and has failed to take due account of contingent and contextual issues. In moving to adequately address the multilevel and configurational nature of context in organisational research, contextualisation (Rousseau and Fried, 2001) and context theorising (Bamberger, 2008) have been advocated and could be explored further.

Annexes

Annex 1: Significant contextual factors, as identified by Bate et al (2008)[7]

Inner context

Organisation size and scale

– large or small player relative to like or competing organisations

– number of staff and patient episodes

– scope of services and research activities

– teaching hospital/tertiary centre or not

Organisation structure

– public/private ownership

– for-profit/non-profit legal/tax status

– integrated or stand-alone/degree of autonomy

– degree of clinical specialisation

– degree of organisational stability (eg continuity in leadership, structure, etc)

– affiliations (system membership, research and education affiliations)

– mergers and reorganisations

Organisation performance

– financial situation (eg revenue, turnover, profit and loss, bankruptcy, receivership)

– clinical performance (eg quality of care process, such as adherence to clinical guidelines/standards of care, health outcomes such as mortality, readmissions)

– patient and customer satisfaction (eg patient survey ratings, patient/customer complaints)

Outer context

Political and regulatory environments

– accreditation and certification bodies (eg Joint Commission for Accreditation of Healthcare Organizations (JCAHO) in the US)

– government health- and healthcare-related authorities (eg Department of Health and Human Services, Centers for Medicare and Medicaid Services, National Institutes of Health in the US; Royal Colleges in UK)

– external performance measures, such as National Service Frameworks and the Healthcare Commission in the UK, and JCAHO core measures, HIVQUAL, and the Healthcare Effectiveness Data and Information Set (HEDIS) in the US

– medical and healthcare policies (eg managed care in the US)

– formal status and recognition: Foundation Trust (UK) and other absolute and comparable ratings and rankings (including mortality statistics, and national staff and patient surveys)

– local community authorities and other organisational stakeholders (links to)

Market and resource environments

– competitive environment (eg degree of competition, stable/dynamic, certain/uncertain)

– degree of service specialisation/differentiation

– local versus tertiary balance

– demand factors (eg customer–patient socio-economic demographics, including education, income, class, race/ethnicity, case mix for different medical/health conditions, population/market size)

– supply factors (eg funding and reimbursements, such as limitations or new sources provided by health insurance plans or government programmes; labour market supply, such as availability/shortages of qualified staff, nurses, general or specialty physicians)

Social, cultural and professional environments

– social and ideological movements, such as consumer rights, gay rights, human rights, anti-poverty

– health-related social and ideological movements, such as patient rights, alternative/complementary health, HIV-AIDS

– quality improvement professions, associations and industry organisations (eg IHI, Juran Institute)

– medical and related professions associations and industry organisations (eg American Medical Association)

– national awards for quality and customer care (eg Baldridge (US), Health Services Journal (UK) Awards, reputation and level of national recognition)

Technological environments

– advances in and availability of clinical therapies (eg anti-retroviral therapies, chronic disease management)

– advances in and availability of medical equipment (eg MRI, ultrasound)

– advances in and availability of information and communication technologies (eg electronic record-keeping, computerised physician ordering systems, computerised pharmacy dispensing, pagers/cell phones, internet applications)

Annex 2: Recommended characteristics of an applied, 'whole-systems' research agenda (Greenhalgh et al, 2005)[9]

Applied research into the process of dissemination, implementation and routinisation should be:

– *Theory-driven*: it should aim to explore an explicit hypothecated link between the determinants of a particular problem, the specific mechanism of the programme, and expected changes in the original situation.

– *Process rather than 'package' oriented*: it should explicitly avoid questions framed with a view to causal inferences, such as 'Does programme X work?' or 'Does strategy Y have this effect?' Rather, research questions should be framed with a view to illuminating a process – for example, 'What features account for the success of programme X in this context and the failure of a comparable programme in a different context?'

– *Participatory*: it should engage practitioners as partners in the research process. In experimental research, the researcher is 'in charge' of the study, frames the problem, makes any key manipulations, and interprets the data, but in process evaluation it is the practitioners who frame the problem, make the manipulations and interpret the data while the researcher observes. Locally owned and driven programmes will produce more useful research questions and data that are more valid and reliable.

– *Collaborative and coordinated*: it should aim to prioritise and study key research questions across multiple programmes in a variety of contexts, rather than small isolated teams 'doing their own thing'. In this way, the impact of place, setting and context can be systematically studied.

– *Addressed using common definitions, measures and tools*: it should adopt standardised approaches to measuring key variables and confounders (for example, quality of life, implementation success) to enable valid comparisons across studies.

– *Multidisciplinary and multi-method*: it should recognise the inherent limitations of experimental approaches for researching open systems, and embrace a broad range of research methods with the emphasis on interpretive approaches.

– *Meticulously detailed*: it should document extensively the unique aspects of different programmes and their respective contexts and settings to allow for meaningful comparisons across programmes. Such detailed descriptions can be used by future research teams to interpret idiosyncratic findings and test rival hypotheses about mechanisms.

– *Ecological*: it should recognise the critical reciprocal interaction between the programme that is the explicit focus of research and the wider setting in which the programme takes place. The latter provides a dynamic, shifting baseline against which any programme-related activity will occur; each will influence the other. Programme-setting interactions form a key element of data, and are a particularly rich source of new hypotheses about mechanisms of success or failure.

Source: adapted from Potvin, 1996; Rootman et al, 2001; Green, 2001.

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