The Health Foundation
Inspiring Improvement

Perspectives on context

A selection of essays considering the role of context in successful quality improvement

Original research

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Foreword

Efforts to improve the quality of patient care have tended to focus on defined technical interventions. In recent years we have seen a wide range of such interventions being used in healthcare organisations, from audit and peer review, to Lean and business process re-engineering.

However, there is a growing body of evidence that an intervention that was successful in one location doesn't deliver the same results elsewhere. Why is this? Alongside the importance of what you do (intervention), and how you do it (implementation), the environment or context that you do it in also matters. It is the interaction between these three elements that makes for success.

The importance of context in the health sector has been recognised by social scientists for some time, starting with the Andrew Pettigrew's studies of District Health Authorities in the 1980s. But learning from the academic literature seems to have had little impact on practice. The influence of context on effectiveness is one that would benefit from closer cooperation between the academic and service sectors.

The Health Foundation has been eager to explore the role of context in improving the quality of patient care. In 2011, we invited leading academics in the field to discuss the following questions:

- How do you define and frame context?
- What do you see as the key conceptual and empirical literature in the field?
- How would you identify the main unanswered questions about context and improvement?

The essays they produced in response are presented here and provide a fascinating range of insights into the importance – and challenges – of context.

Despite its widely accepted importance, context continues to be seen as a slippery topic and all of the authors agree that there is no single accepted definition. This partly explains the difficulties of studying it. But perhaps more important than a neat definition, is understanding how context can be expressed to ensure that it is taken into consideration when implementing improvements in care. The use of metaphors is common and can be helpful, as Paul Bate neatly discusses in *Context is everything*. There is surely a role for storytelling to generate narratives that practitioners engage with. However, there is also a danger in this approach, as the use of narrative or metaphor risks being dismissed as not sufficiently grounded in science.

When it comes to conceptualising context, the authors present a range of viewpoints, from it being something that is concrete and measurable to something that is perceived and socially constructed. Context is frequently described as a set of factors or attributes that can affect improvement efforts – for example an organisation's leadership, clarity of purpose, trust, climate or orientation to learning. Questions can then be asked about which factors are modifiable and which are not. Alternatively, experts in the field are increasingly moving beyond lists of factors alone to highlighting the dynamic nature of context – either in terms of the relationship between context, intervention and implementation, or between the various factors that might influence context.

However, as Glenn Robert and Naomi Fulop argue in *The role of context in successful improvement*, there is a middle ground: having both a theory of context and a way to make this theory operational. There is a need to understand which contextual factors matter to improving quality and which can be influenced, how different contextual factors interact, and when context matters most during an improvement initiative.

If there is an iterative, dynamic relationship between context and intervention, what are the implications for improvement efforts? Should efforts be made to change context in order to optimise the effectiveness of improvement efforts, or to try and fit the intervention and its implementation more carefully to whatever the prevailing context might be? It is likely that macro (e.g. policy) level contexts tend to be less amenable to manipulation than meso (organisational) or micro (team) level contexts. In *How does context affect quality improvement?*, John Øvretveit provides some useful guidance on what methods and tools are available to understand specific contexts and their relevance to particular improvement efforts.

Perhaps the most important theme to come out of these essays relates to the skills and knowledge needed to manage context to effectively improve quality. What is it that enables one part of an organisation to implement a quality improvement initiative successfully when another part fails? Why are some individuals good at grasping the flow of political and organisational changes? We all know of the highly successful clinicians who have used government policy and national strategy documents to build their departments into beacons for research and referrals, while others have seen the same policy and strategy as a barrier. We need to better understand how individuals and groups in an organisation experience and make sense of their context as they plan and implement improvement programmes. In other words, how do they develop what is sometimes called 'contextual adroitness'* and why do some practitioners feel less able to influence their environment than others?

Mary Dixon-Woods focuses on this theme in *The problem of context*, the final essay in this collection, discussing the importance to improvement work of 'practical wisdom' – that body of local knowledge that contains the lessons from past failures and current contexts that might make different interventions more or less likely to succeed. Although this local knowledge can sometimes be used to stifle innovation by encouraging people to come up with objections to quality improvement interventions, equally it can identify barriers before they occur and help ensure a project's success.

We are very grateful to all of the authors for their work and insights. The relationship between improvements and context is arguably the most knotty problem in improvement science. We hope these essays will continue to stimulate ideas about how context impacts on the effectiveness of interventions to improve care for patients.

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* See, for example: Gabbay J and le May A. *Practice-based evidence for healthcare: clinical mindlines*. Oxford: Routledge; 2010.

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Context is everything

Professor Paul Bate

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Context is everything

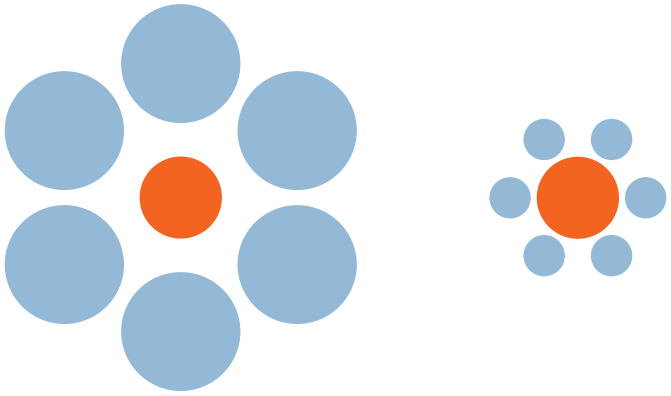
Introduction

'Social scientists of the most varying standpoints agree that human action can be rendered meaningful only by relating it to the contexts in which it takes place. The meaning and consequences of a behaviour pattern will vary with the contexts in which it occurs. This is commonly recognized in the saying that there is a "time and a place for everything".' Alvin Gouldner, 1955[1]

In everyday talk we often hear people talking about the importance of not taking something out of context. This is wise advice. Nothing exists, and therefore can be understood, in isolation from its context, for it is context that gives meaning to what we think and do. As Gouldner[1] said, 'context is everything'. Examples abound:

- **Man in the street:** 'Yelling "move!" is rude in one context, like if it's your little brother standing in front of the TV, but it's entirely appropriate at a fire scene when a wall is coming down. Most actions would be judged appropriate in some contexts but wrong in other contexts. For example, cops carry guns when they walk into banks, and no one thinks anything of it [An example of US context differing from the UK one!]. But if you or I walked into a bank wearing a gun, people would be alarmed. I always chuckle at the bizarre things you get to do as a fireman, because of the context. I get to rip people's clothes off, electrocute them, and cut their cars apart with hydraulic tools.' (US fireman)
- **The cognitive psychologist**: In the Ebbinghaus illusion (Figure 1), the orange dots appear to be different but are in fact exactly the same size. The perceptual size of each dot changes because of what is around it.

Figure 1: The Ebbinghaus illusion



Croskerry[2] goes further to suggest that by ignoring context we are not just being unwise but downright stupid:

'In the National Post in 2008, columnist John Moore related details of a murder: "a man fatally shot his wife in the chest and got away with it". Our reaction is an immediate sense of outrage at the ills of modern society. This is yet another example of wanton domestic violence and of a judicial system that has failed, once again, to bring the perpetrator of a horrifying crime to task – "bleeding heart liberal judges and their hugs for thugs". We later learn that the accused was an elderly man diagnosed with a terminal illness, married for many years to a woman who had developed Alzheimer's disease. He was fearful she would suffer unduly without his care. Knowing, too, that his own death was imminent,

he chose to end her life. He was never charged with the murder and was released home to await his own death, at least content in the knowledge that his wife would not endure prolonged neglect and suffering. The context, says Moore, removes our outrage; we now understand both the husband's and the judge's decisions. After learning this, we might then wonder, on reflection, "How could I have been so stupid to have made the first judgement?"'[2] *(p171)*

And whenever we are perplexed that things don't work out as anticipated or planned, or we have a reversal of causal direction in which cause becomes effect and effect becomes cause, invariably it is 'context' that is the invisible rogue variable:

'Imagine conducting a research study in which you expect variable x to cause variable y but instead discover that y causes x. Imagine doing a study in which you anticipate a strong positive relationship between two variables but instead find a strong negative relationship. Imagine conducting an investigation in which the base rate of some crucial organizational behaviour varies by a ratio of 35:1 between subsamples. Surprises of this nature should surely capture our attention, and they are frequently a product of our failure to consider contextual influence when doing research.'[3]

Given all this, one wonders why so much healthcare research and practice is 'acontextual', having turned its back some time ago on the wider surround, or worse still, come to regard it as an unwelcome noise or interference in what one was trying to get on with 'on the ground'. In the world of evidence-based medicine, all too often context has been relegated to the lowly status of a constant or assumed to be 'controlled for' (a euphemism for disregarded) in some way. In the context (sic) of the above, one must conclude that such myopia is not only unwise but stupid – though hardly surprising. Several courageous people in the bio-medical sciences have freely admitted to being perplexed by the notion of context and the wider quality improvement (QI) intervention to which it belongs, the underlying reason seemingly being that QI and clinical interventions are miles apart in terms of epistemological focus. Stephen Goodman explains:

'It is very difficult to penetrate the bio-medical model when you bring the notion of a "treatment in social change" into it. At some level, they don't understand what you're talking about, because we think of the treatment as the imaging, as the drug, the device, as the actual intervention. And everything around that is simply, sort of, window dressing – you know "context" and all that. I think that's what interferes with the understanding of what a quality and safety intervention is, because it doesn't have the same trappings as the other bio-medical intervention.'[4]

On closer examination, we see that the problem goes much wider than healthcare and medicine. What we find is that context, in whatever field we are talking about, including organisation studies,[5] has not been formally studied in any extensive or intensive way, and in not a single case have I been able to find any explicit or well articulated 'theory of context'. As mentioned above, almost universally, we find context to be an overworked word in everyday dialogue but a massively understudied and misunderstood concept. Teun van Dijk comments:

'It is not surprising… that there are thousands of books that feature the concept of "context" in their titles. Despite this vast amount of "contextual" studies, however, ***there is not a single monograph that provides an explicit theory of context…*** *This means that the notion is commonly used in a more or less informal way, namely to refer to the explanatory situation or environment of some phenomenon, that is, its conditions and consequences.'*[6]

And the same author in another publication:

'…the notion of context as it is used in the social sciences is not a strictly theoretical concept, but rather a more or less fuzzy notion denoting a situational, historical, geographical, social or cultural environment of a phenomenon being studied.'[7]

In the same vein – this time on the context of psychology – David Funder remarks:

'… for all the arguments that the situation is all important…, little is empirically known or even theorized about how situations influence behaviour, or what the basic kinds of situations are (or, alternatively, what variables are useful in comparing one situation with another).'[8] *(p211)*

Healthcare research, I shall argue along with van Dijk, Funder and others, urgently needs both a theory of context, and more extensive operationalisation, such that it becomes routinely exposed to all the rigours of conscious thought and challenge, as well as the acid test of practice. Certainly – recalling Stephen Goodman's words above – it deserves to be more than window dressing.

Berwick eloquently sums up the case 'for' in the Foreword to our 2008 book.[9] He writes:

> *'… neither these researchers [authors] nor their subjects in the complex world of organisational change and improvement can hope to escape "the hazards and uncertainties lying in wait in the punishing contextual terrain that has to be crossed"… I will long remember that phrase – the "punishing contextual terrain" – since it 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 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.'*** *(vii-viii)* [my emphasis].

(I couldn't have put it better myself!)

Although it is too early to say with any certainty, there are one or two promising signs of healthcare research and practice having finally woken up to the importance of context in QI processes and outcomes. For example, summing up their own empirical research into cultural context, Krein et al write:

> *'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.'[10] (p1699)*

They also cite one or two examples of recent studies that have included a specific focus on changing aspects of organisational context in order to facilitate practice change, especially – like their own research – cultural context.[11,12] It remains to be seen whether these are a one-off or part of a bigger trend towards more context-sensitive healthcare QI research, remembering the old adage that two swallows do not a summer make.

To recap: the questions the Health Foundation asked me to address in this brief overview are:

1. What do you define as context?
2. What do you know about context from the literature? We are looking for an accessible summary of your views of the literature, rather than a full review.
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. Defining 'context'

1.1 Some stock definitions

Most people agree that context is a slippery notion that needs to be pinned down in some kind of operational definition. Here are some examples:

> *'… the surroundings associated with phenomena which help to illuminate that [sic] phenomena, typically factors associated with units of analysis above those expressly under investigation.'[5] (p56)*

> *'… stimuli and phenomena that surround and thus exist in the environment external to the individual, most often at a different level of analysis.'[13] (p198).*[i]

> *'… situational opportunities and constraints that affect the occurrence and meaning of organizational behaviour as well as functional relationships between variables.'[3] (p386)*

> *'the interrelated conditions in which something exists or occurs.' (various)*

[i] The authors go on to describe context as consisting of constraints versus opportunities for behaviour, proximal versus distal stimuli, and similarity versus dissimilarity among organisational members.

I have always liked Noel Williams's humorous, but insightful, offering:

> *"'Context" is one of those words you will encounter again and again, without anyone offering anything like a useful definition. It is something of a catch-all word usually used to mean "all those things in the situation which are relevant to meaning in some sense, but which I haven't identified".'*[14]

One definition that might better connect with bio-medicine than some of those above is that context refers to all those variables (z) that influence or could influence the 'independent' (x) and dependent (y) variables directly under study – in other words, context is another name for all the intervening variables. This is, of course playing into the hands of positivism (see later), but at least has the merit of shifting the mindset from simple, linear, one-way, cause–effect 'chains' in a closed system to more of an open systems, multi-factorial mindset.

One area of definition that will need further thought and refinement is whether we should be talking about contextual influences, determinants, factors, forces, frames, enablers, boundaries, attractors, barriers or vectors, since each of these implies something rather different about the nature and effects of context – for example 'determinant' is a lot stronger than 'influence'.

1.2 Defining context through metaphor

Given the dryness and obtuseness of most of these definitions, it is not surprising that many writers have switched tack to define context metaphorically rather than literally. Perhaps the most popularly invoked metaphor in the social and organisational sciences is the notion of 'context as the garden, terrain or domain'. Hence from Kanter[15] all the way back to Simmel[16] we come across reference to the need for a rich, fertile soil (context) in which a thousand flowers (innovations, social forms, QI processes) can bloom, about 'cultivating' and 'nourishing' cultural contexts, and about enclosing and turning the barren wasteland into something altogether more productive.

Writers, such as Shortell et al, can sometimes get quite carried away with such halcyon imagery:

> *'For the CQI rose to flourish it must be carefully cultivated in a rich soil bed (a receptive organisation), given constant attention (sustained leadership), assured of appropriate amounts of light (training and support), and water (measurement and data systems) and protected from damaging pests (overly burdensome regulation). Its strengths may make the 'gardening' worth the effort.'*[17]

In this case, Shortell's exquisite organisational/QI garden was divided into four contexts (strategic, cultural, technical and structural), allowing him and his fellow horticulturalists to speculate on what would happen if any one of them were left fallow and untended (see Figure 2).

Kanter sees such cultivation as being about providing the 'macro-conditions' for change and innovation – a useful definition of context in itself.

> *"'Let a thousand flowers bloom" offers an apt metaphor for innovation and change. Innovations, like flowers, start from tiny seeds and have to be nurtured carefully until they*

Figure 2: Dimensions needed to achieve clinical quality improvement

Strategic	×	Cultural	×	Technical	×	Structural	=	Result
0		1		1		1	=	No significant results on anything really important
1		0		1		1	=	Small, temporary effects; no lasting impact
1		1		0		1	=	Frustration and false starts
1		1		1		0	=	Inability to capture the learning and spread it throughout the organisation
1		1		1		1	=	Lasting organisation-wide impact
0 = absent; 1 = fully present								

blossom; then their essence has to be carried elsewhere for the flowers to spread… They can grow wild, springing up weed-like despite unfavourable circumstances, but they can also be cultivated, blossoming under favourable conditions. If we understand what makes innovations grow – the micro-processes by which they unfold – we can see why some macro-conditions are better for their cultivation.'[15]

This idea is almost identical to the modern notions of 'receptive' and 'non-receptive' contexts encountered in organisation studies (see later), although one has to be careful to avoid assuming that context is a purely 'macro' thing, knowing that there is also such a thing as 'micro-context' and that in any case the distinctions between micro and macro (as well as meso) will always be arbitrary and blurred. Nevertheless, what is attractive about this particular metaphor from the improvement interventionist's point of view is the reassuring notion that context can indeed be 'managed' (tended, tamed, cultivated) – at least with the right tools and treatments, and a good deal of sweat from the brows of those involved.

The danger of this kind of metaphor is that we end up reifying context, thinking of it as a fixed physical space populated by 'things', and forgetting that **temporal context** is a very important topic in its own right, particularly in human and organisational affairs. As our own research has shown,[9] a longitudinal, historical view of a QI programme is essential if one is to understand why it has ended up as it has, where it is heading and what it may be able to achieve in future. Unlike the case of inanimate objects, history/time leaves a permanent and ongoing imprint in the form of cultural context – what Malinowski once neatly described as 'living history'. A lot of organisational/QI practice is present- or future-oriented, which is why in a modern context we also need to look and learn backwards – or as we have said elsewhere hindsight gives insight, which gives foresight. The temporal perspective and the 'weight of history' should not be forgotten in future research and practice.

Another metaphor, this time from communications theory, is the notion of 'context as noise'. From here, the focus shifts away from the notion of providing a fertile ground for change to the importance of being able to distinguish critical signals from the overall background noise – of being able to 'tune in to', 'hear', interpret and make sense of the buzzing, blooming confusion that is the complex context in which one is permanently immersed. For example, in *How Doctors Think*,[18] Montgomery discusses the practical reasoning integral to physicians' judgement. This requires a hermeneutic approach – making sense of and interpreting context. Some part of the context will always be noise and irrelevant to the signal, although the more worrying scenario is when the symptoms of, say bowel cancer are (dis)missed as irrelevant noise rather than real and present 'red light' signals of the disease itself.

In the same vein, Croskerry claims that this notion is of special importance to clinical and healthcare contexts where the whole basis of making good and effective diagnoses and interventions is the actors' ability to pick up the 'signals' amid what are often high levels of basic background 'noise'. Evidence is that clinicians often do get it wrong, not least because of the high levels of contextual noise that confront them as they seek to identify the main signals and arrive at the right decisions and judgements:

'…in medicine, a particular problem for physicians is the degree of overlap between diseases. Pathognomonic conditions (shingles, basal skull fracture or shoulder dislocation)… usually present little challenge for diagnosis; they are relatively unambiguous and readily identified. They are accompanied by very little noise. Other diseases (e.g. pericarditis and acute myocardial infarction)… manifest themselves less clearly and may be mimicked by other conditions. Worse still, some conditions (e.g. ureteral colic and dissecting abdominal aneurysm or subarachnoid haemorrhage and migraine)… may show complete overlap in their symptomatic presentation. With these latter examples, the probability of diagnosing the disease on the basis of clinical presentation may be no better than chance; noise may completely overlap the signal.'[2] *(pp172–173)*

The high noise levels around medical issues might also explain why, in one study, nearly half of patients presenting with clear 'red light' symptoms of colorectal cancer were incorrectly referred by GPs.[19] Another way of putting this is to say that the GPs were clearly unaware of certain key features of the context that presented itself to them.

2. Key themes and focuses of concern in the literature

In progressing beyond the one-liner type of definition, we need to point out some important distinctions within and between the various definitions available, at the same time giving an overview of some of the key themes and dimensions of the literature. This will help to give more shape to the concept of context and help identify some of the focal concerns for future research.

2.1 Subjective versus objective context

Traditionally, and very much in line with the positivist, rational–analytic philosophy that has always dominated in science and medicine, context is usually defined as an 'objective' phenomenon, something 'real', something tangible and 'out there' – factors, variables, objects, events, domains and so on – that impact upon and influence or determine social, organisational and individual culture and everyday behaviour (think of mountains and valleys that shape the course and direction of the stream, or billiard balls that bounce off cushions). Being tangible, these are portrayed as things that can be manipulated and shaped in much the same way as one can shape putty or clay.

In contrast, modern writers[20] are increasingly challenging this objectivist notion of context in favour of a more 'subjectivist', 'constructionist' or interpretivist one. Regardless of what is actually out there (if anything), they say, what is important is how people (selectively) attend to, interpret, and attach significance and relevance to what they perceive as being out there and external to themselves (the reified world), and how that feeds in to their behaviour and interactions with others. This is important to the research endeavour, because it suggests we shouldn't be going out there (wherever there is) looking for some kind of real contextual terrain to map, measure and analyse, as a cartographer might do, but focus instead on how people **make sense** of what they see as being out there (back to the signals and noise metaphor above). One good example of this perspective[7] is how the UK Parliament struggled to make sense of the so-called Iraq and weapons of mass destruction (WMD) contextual 'threat', knowing as we now do that there were no WMDs in the 'real' environment – it was the context in people's heads that was the all-pervasive and important issue at the time. This example also underlines how 'context' is constructed and reconstructed in narrative and stories, and how it can often be little more than a confabulation. Of course, the problem with confabulations – unreal fictions – is that they can have the same consequences as if they were real, in this case invasion and war.

On the other hand, the saying 'out of sight, out of mind' reminds us that if we don't 'see' some contextual thing or other, even if it is staring us in the face, it is generally not relevant to our conscious action. But equally, and more subtly, 'out of mind, out of sight' reminds us that if we don't think a particular aspect of context is relevant we won't even see it. In short, people have to be mindful of context (even in a vague way) before it can be said to assume any significance in what they say and do. Arguably, the study of context therefore begins 'internally' in cognition rather than 'externally' in the environment.

It also follows from this subjectivist viewpoint that, as well as being a social thing, 'context' is also a very personal thing, that there is no common or universal set of contextual interpretations shared by everyone. Just as a botanist walking though a field will see different things from the geologist walking beside them (because of differences in their mental sets), a clinician will see context in a different way, and attend to different aspects of that context, from a manager or IT technician. Again, this is important to contextual research, since it makes the challenge one of immersing oneself deeply in the different actors' point of view and seeing context from their various standpoints (the 'insider' or emic perspective), and not trying to objectively represent it from a single external 'outsider' position (etic perspective). Researchers describe this as a focus on the 'definition of the situation' – on how those involved make the context intelligible **for themselves**. This perspective calls for research methods, approaches and skills that may be very different from the ones that are in mainstream use in 'scientific' and medical research.

2.2 Receptive and non-receptive contexts

Professor Andrew Pettigrew and colleagues at the Universities of Cardiff and Warwick are credited with the authorship of the 'receptive and non-receptive contexts' labels. It is because of their work – initially in the private sector and latterly in the public sector – and, even later, our own work with NHS Leading Modernisation Programmes, that they have become embedded quite deeply in the language, thinking and practices of a

number of QI initiatives. Because of their impact, it may be worth spending a little time exploring their origins and nature.

The phrase 'receptive and non-receptive contexts' may sound a bit dry and academic but behind it, in fact, lies a rich story that touches on a mass of important issues relating to the NHS's past, present and future change/QI agenda: policy and strategy implementation failure (the implementation gap/strategic drift); the diffusion of innovation and change; the issue of sustainable change (contextual embeddedness); cultural change; the politics of change; leadership processes and more. A particular interest of Pettigrew's was why the rate and pace of (successful) change/improvement varied so much between units and localities.

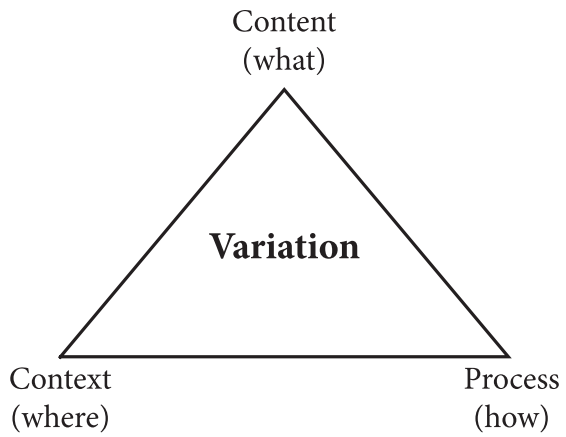
The story begins a long time ago with Pettigrew's solo ethnographic research work at ICI between 1975–83, written up in his classic book *The Awakening Giant*.[21] ICI House at Millbank was the strategic centre and the house for the Main Board that determined the shape of the business and the conduct of its eight divisions. There were three chairmen during Pettigrew's period of work, but it was the last one, John Harvey-Jones, who came to be lionised as the great guru of strategic change leadership (from 1982 onwards). We should say that Pettigrew was not the first person in the world to draw attention to 'organisational context' as he did in this book. For example, prior to his book there had been some classic works on the relationship between structural and environmental context and innovation.[22,23] Pettigrew, however, was the first person to make it empirical and every day, showing how the ups and downs in the fortunes of ICI – levels of performance, rate of innovation and change – were connected to how successfully senior management 'read' and 'managed' context as part of the overall strategic endeavour. Basically 'receptive contexts' (by accident or design) led to increased levels of performance and innovation/change, whereas 'non-receptive contexts' led to decline in performance and organisational stagnation. The role of the strategic leader – what made people like Harvey-Jones and other similar guru leaders like Colin Marshall of BA, and Jack Welch of GE stand out – was their ability to create a receptive context for their organisations, at the same time taking remedial action against the dysfunctional or non-receptive aspects of the wider context. They were also proactive with regard to context, in Weick's words, 'enacting the environment to which they respond', acting towards it, trying to master and outwit it, not just reacting to it (Welch: 'don't wait until the fire is at your door before trying to put it out').

A few years later (1986–90), Pettigrew switched his attention from the private to the public sector with a study of strategic service change processes within the NHS, in the aftermath of the introduction of general management.[24]

This research spanned eight regions (Mersey, NE Thames, North Western, NW Thames, Oxford, SW Thames, W Midlands, Yorkshire) and focused on eight 'high change' districts (DHAs), ie districts that were tackling major strategic issues and trying to work through some big agendas for change. They included St Helens and Knowsley, Paddington and N Kensington (AIDS), Preston (Overspend), Bloomsbury (AIDS), Bromsgrove and Redditch and Milton Keynes (both new district general hospitals), Mid Downs and Huddersfield (closure processes in mental health). The research team concentrated upon the motors of and barriers to change and the skills associated with change management.

As time went on the question of local variability in the achievement of strategic change became more and more central to the project. Why was it that the rate and pace of change varied so much between localities processing the same issue or within the same locality but across different issues (the same as had been found between different divisions of ICI)? The starting point was that variation and differences between DHAs could be explained by a subtle interplay between the content (the what) of change, the context (the where) of change, and the process (the how) of change (see Figure 3).

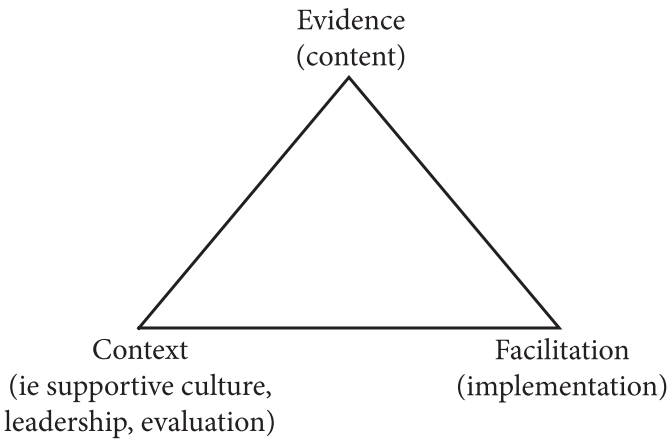
Figure 3: Explaining variance between District Health Authorities[24]



The team identified eight highly interrelated factors which produced receptivity to change in the DHAs they studied – all of them features of context and management action that seem to be associated with forward movement (drivers, attractors, mobilisers, enablers). These are presented in section 3, 'Models taxonomies and frameworks for context'.

Further work on 'receptive context' has been done since then – indeed, as already noted, the phrase itself has become part of the NHS and wider healthcare QI vernacular. A recent example is the work of Greenhalgh et al[25,26] on receptive contexts for organisational innovation (diffusion and adoption) which identified four particular features of organisational context that made an organisation receptive to change: leadership and vision, risk-taking climate, clear goals and priorities, and high quality data capture systems. Before that, we had the work of the Royal College of Nursing in the UK during the 1990s that culminated in the PARiHS research into practice model for healthcare improvement (**P**romoting **A**ction on **R**esearch **i**mplementation in **H**ealth **S**ervices).[27,28] The framework proposed that successful implementation of evidence into practice is a function of three broad interactive elements (evidence, context, and facilitation – see Figure 4). A basic premise is that each of these elements is positioned on a continuum from weak to strong, with regard to support for the implementation project in question.

Figure 4: Functions of successful implementation of evidence



The resemblance to the Pettigrew model is striking here. Unfortunately, as noted by those involved and like many of the frameworks mentioned in this paper, as a conceptual framework, PARiHS still remains untested and therefore its contribution to the overall development and testing of theory in the field of implementation science is largely unquantified.[29] There is an important point here for future research and practice, in that before going out and adding yet more frameworks to the QI field, it may be worth encouraging wider testing, elaboration and synthesis of the many existing ones.

2.3 Inner (micro, experience-near) vs outer (macro, experience-distant) context

An equally important contribution to the context literature, and part of the same body of work, has been Pettigrew's[21] useful distinction between 'inner' (immediate, intra-organisational, micro) context which includes things like organisational and divisional cultures, group norms, leadership, local champions, political processes, and 'outer' (social, political, macro) context – 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, and has to be related to in the same way that a surfer would pick up and ride a wave, that is to say opportunistically, as one looks for an energy source to latch on to that will take one roughly in the direction in which one wants to go. This is what Waterman once referred to as 'informed opportunism', a feature he claimed to be the defining quality of our best strategic leaders:

> *'They are the best of strategists precisely because they are suspicious of forecasts and open to surprise. They know the value of being prepared, and they also know that some of the most important strategic decisions they make are inherently unpredictable. They think strategic planning is great – as long as no one takes that planning too seriously. They often see more value in the process of planning than in the plan itself.'*[30]

Returning to Pettigrew, for him there are two steps in the contextual intervention in relation to inner and outer context. The first is about attending to and then diagnosing, scanning or scrutinising the context:

> *'A key part of the process influencing the innovating/change group's fate rests on their perception of features of the inner and outer context, together with the skill with which they act on that understanding in the light of changing features of context through time. A group*

interested in creating change must itself attempt to fashion a social context in which it can survive and prosper… Context is then being treated neither just as descriptive background, nor as a source of opportunity and constraint for change, but as something which must be accessible and understood by the innovating group, and ultimately mobilised to achieve practical effects.'[21] *(p482)*

Second, there is mobilisation and the intervention itself:

'… part of the executive skill in generating energy and commitment to strategic change rested on the executive's ability to understand, come to terms with, and then alter features of their inner context such as the divisional structure and culture, and to mobilise changes in outer context such as economic trends and business competitive position to help justify and unify action in the change sphere.'[21] *(p481)*

The 'content, inner and outer context, process triangle' devised by Pettigrew and his colleagues has stood up well to the test of time. For example, a recent literature-based study by Damschroder et al[31] investigated why many interventions found to be effective in health services fail to translate into meaningful patient care outcomes across multiple contexts (what change management theorists refer to as the 'implementation gap'). This involved using a comprehensive QI literature review to establish a 'consolidated framework for implementation research' (CFIR). The final framework identified five domains influencing QI effectiveness: the intervention (content), inner context and outer setting (ie context), the individuals involved, and the process by which the implementation is accomplished – four of the five thus being from Pettigrew's original. What is important is their assertion, again reminiscent of Pettigrew, and of our work in this area[9] now usefully linked by them to Pettigrew's, that it is the dynamic and ongoing **interaction** between these domains, rather than any one of them individually or independently, that accounts for the effectiveness of a QI intervention and the striking variation between similar QI interventions in different places. Their account of inner and outer context is sophisticated and worth quoting:

'The next two domains in the CFIR are inner and outer setting. Changes in the outer setting can influence implementation, often mediated through changes in the inner setting. Generally, the outer setting includes the economic, political, and social context within which an organization resides, and the inner setting includes features of structural, political, and cultural contexts through which the implementation process will proceed. However, the line between inner and outer setting is not always clear and the interface is dynamic and sometimes precarious. The specific factors considered 'in' or 'out' will depend on the context of the implementation effort. For example, outlying clinics may be part of the outer setting in one study, but part of the inner setting in another study. The inner setting may be composed of tightly or loosely coupled entities (eg, a loosely affiliated medical centre and outlying contracted clinics or tightly integrated service lines within a health system); tangible and intangible manifestation of structural characteristics, networks and communications, culture, climate, and readiness all interrelate and influence implementation.'[31] *(p5)*

2.4 New and emerging perspectives on context

One important idea that has attracted growing support over the past decade is the notion of context as a **process**, dynamic, fluid and constantly moving, not lumpen, material or static – more like a sea or clouds than the usual collection of terra firma references (see section 1.2 above). This accords very closely to the contemporary systemic perspective that 'requires redefining context as a process (*contexture*) embedded in a system's intrinsic operational "situatedness"'.[32] Karl Weick[33] has always been fond of what he calls 'the innocent little i-n-g', which places emphasis on the process or human actions rather than situation, which in our case is 'contextualising' rather than 'context'.

Dopson and Fitzgerald[34] put it well when they say that context is not just the backcloth to action (symptomatic of a static view of context) but an interacting element in the diffusion process – in short, part of the action itself.

This perspective has important implications for both the research and 'management of context' point of view: because context (like the seas and seasons) is constantly changing these changes and their effects need to be tracked and noted (as one moves with them), and duly taken into account in the timing and nature of the

intervention (a wintery or stormy context may best be postponed to await the calmer spring). To change the metaphor, what we have here is a moving target, the challenge and imperative for the interventionist being, as best as one can, to 'capture the reality in flight'. The success of the intervention will depend a great deal on the ability to use foresight to anticipate what the contextual state will be at any given point. Clearly this requires a longitudinal perspective on one's subject matter, as opposed to, or as well as, a cross-sectional one.

Of all the metaphors that have been offered for the notion of context as a process, perhaps the most engaging is that of change and improvement journeys as 'wagon trains' which move through a multitude of ever-changing, difficult contextual terrains as they inch their way towards their final destination. Comparing such journeys to the nineteenth-century US wagon train heading westward to California from the relative safety of the eastern seaboard, Pettigrew draws our attention to the hazards and uncertainties lying in wait in the punishing contextual terrain that has to be crossed.[35] As the journey proceeds, there are ups and downs of energy as obstacles are rounded and blind canyons and other deadlocks encountered, and there is a sense of emotional relief as landmarks are reached. And context is not just the physical terrain but also the living things that inhabit it and lie in wait, like animals and people, by no means all of them of a friendly disposition (see my later reference to political context).

Reflecting on the literature referred to here in the context of healthcare, I also subscribe to the view that it will be essential to challenge the conventional notion of context as a fixed entity, a convention that all too often results in the production of boring – and highly predictable – lists of 'key factors' or influences that have little academic or practical benefit (eg leadership, culture), to this idea of a change journey that moves through and across an ever-changing context – a practice that will highlight the ongoing interactions between the 'actors' and their environment, and their constant need to adjust and adapt to these changes as they encounter them. As Pettigrew and others have argued, this will require a paradigm shift in the way we would normally do contextual analysis:

> *'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".'*[36]

The other point to make here is that if, as writers are saying, context is not so much removed from the action/process as part of or integral to it, then it would be unwise to promote any kind of research or practice that encourages its treatment in isolation from the rest. In other words, if research and practice are to give greater attention to context, and particularly the dynamics of context, this needs to remain within the context (sic) of the bigger content–context–implementation triangle.

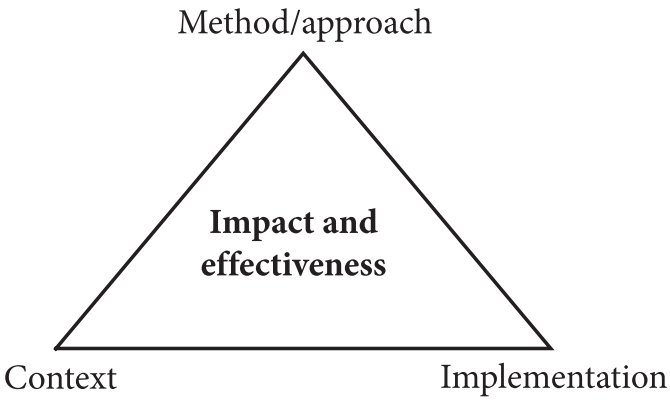
3. Models, taxonomies and frameworks for context

In this section I will illustrate the range of contextual models and taxonomies that have been devised by healthcare and QI researchers in recent years to make sense of their findings, including our own. Most of these have been derived inductively from in-depth (often evaluation) research, and are therefore based upon primary data and empirically 'grounded'. Most did not set off to investigate context but became engaged with it as other explanations failed to provide the necessary answers, especially as to the reasons why there was such wide variation in QI outcomes between different sites, even when, as in the first case, they were following an identical methodology and shared the same improvement targets.

3.1 The Breakthrough Collaboratives: determinants of effectiveness and inter-team performance variation

In this, the first independent academic evaluation of a UK Collaborative (the Orthopaedic Services Collaborative of 2000–02), we found an average improvement in reducing patient length of stay of 12.6% among teams overall, but a range between sites that varied from a 43% to -3% improvement on targets.[37] In trying to account for this variation we pinpointed three broad areas for attention: the way the method was adapted locally, the model of implementation itself, and the 'back-home' context within which the collaborative method was introduced and being made to work (see Figure 5).

Figure 5: Conceptual framework explaining impact and effectiveness of a UK collaborative[37]



Clearly some contexts – at both Trust and microsystem level – were more fertile or receptive than others, particularly in hospitals where there was top level support and sponsorship, good IT, a multi-level leadership system, strong project management, clear roles and adequate communications structures: none of this was surprising. Three contexts stood out above all others: the **leadership context** (style, method, level of support in programme board, faculty board, region, executive team level, local team leaders); the **political context** (level of empowerment, locus of decision making, configuration of top down/bottom up, and mix of allies, adversaries, opponents, bedfellows and fence-sitters); **cultural context** (shared mindsets around quality, risk, participation etc).

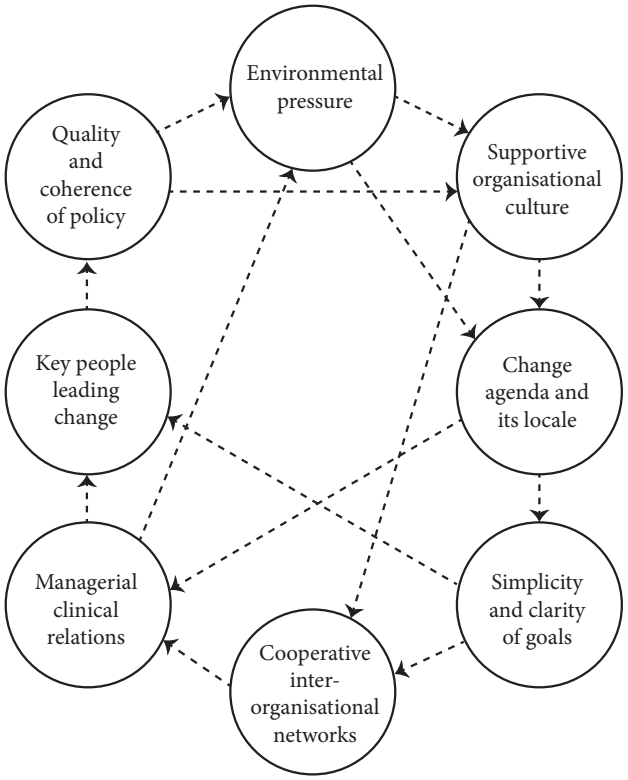
Later research on the UK cancer services and mental health services found similar contextual influences, thus offering additional support for our simple QI 'triangle'.

3.2 Pettigrew and Whipp's study of strategic service change processes in the NHS, in the aftermath of the introduction of general management

I have already made reference to this empirical study of eight 'high change' DHAs in the NHS in the late 1980s.[24] Figure 6 summarises the authors' findings. This highlights eight factors that the authors claim, in combination, offer a highly receptive context for strategic change.

The study is carefully researched and the model visually attractive, but it does begin to raise questions in one's mind as to whether this – and the many models like it, including some of our own – is the kind of model that should be held up as ideal for the next wave of contextualised healthcare research. There are a number of disappointments with it: first, the factors described are depressingly familiar and predictable, indeed might easily have been gleaned from any first-year textbook on organisation studies without the need for or recourse to empirical research. Surely there must be some things about context that we don't already know about. Furthermore, the eight factors are 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 strategists and QI professionals to use them in any practical way. Third, although the attractive 'wheel' graphic – as with so many others like it – shows a complex, dynamic, interactional system, with each of the contextual factors able to influence and be influenced by a myriad of other factors, the study has little to say about the nature, patterns or directions of these interrelationships and interactions. In short, the dynamics of context remain a mystery. The graphic is merely a gesture towards the notion of context as a system and process, and all it really is (if one is allowed to be critical here), is a conventional list of key success factors dressed up as something else. This must be avoided in future research, although this will be difficult given that complex, open systems analysis and measurement are still in their infancy.

Figure 6: Receptive contexts for change: the eight factors[24]



In 1990, Senge had this to say:

> *'Complex organisations are bound by invisible fabrics of interrelated actions… since we are part of that lacework ourselves, it is doubly hard to see the whole pattern. Instead we tend to focus on snapshots of isolated parts of the system and wonder why our deepest problems never get solved… The essence of mastering systems thinking as a management discipline lies in seeing patterns where others see only events and forces to react to.'*[38]

This, I believe, still offers the kind of mindset that we should be taking as our main contextual challenge for the future; one that resists the still prevalent idea of contextual 'factors', and embraces notions of contextual 'patterns' and 'processes'. What this would help do, to paraphrase something Martin Marshall said at the 2010 *Vin McLoughlin Symposium on the Epistemology of Improving Care*, is to position 'context' and context research at the revolutionary rather than evolutionary end of the spectrum, so that there is not just recycling of old models or a skirting of long-standing knowledge lacunae, but the beginning of a search for something new, especially with regard to contextual dynamics. This, of course, implies that we may also need to be looking into as yet unexplored areas of the literature and exploring possibly fruitful links between them and the QI endeavour. For example, one body of literature currently attracting the attention of QI researchers like Øvretveit is the resilience model in ecosystems and organisational dynamics.[39,40,41] Another is the 'new' generative (self-perpetuating) change/generative environment models in organisational development and education which also resonates strongly with the notions of **continuous** improvement found in QI research and practice, and privileges often neglected concepts of unplanned, spontaneous, energy-driven change and improvement.

3.3 HSMC Evaluation of the Booked Admission Programme

Another example of a healthcare context model – not dissimilar from Pettigrew's, in that it too found itself struggling to explain the wide performance variation between the 24 participating trusts and clinical conditions (outpatient appointments, day surgery, inpatient treatment) involved in this QI programme – is the Ham et al's HSMC evaluation of the NHS Booked Admission Programme first wave pilots between 1999 and 2002.[42] The research team's overall finding was that there had been impressive progress towards implementation of booked appointments in the first year, but then some slipping back in the second year, although overall the performance of the pilots was better at the end of the period under review than at the beginning.

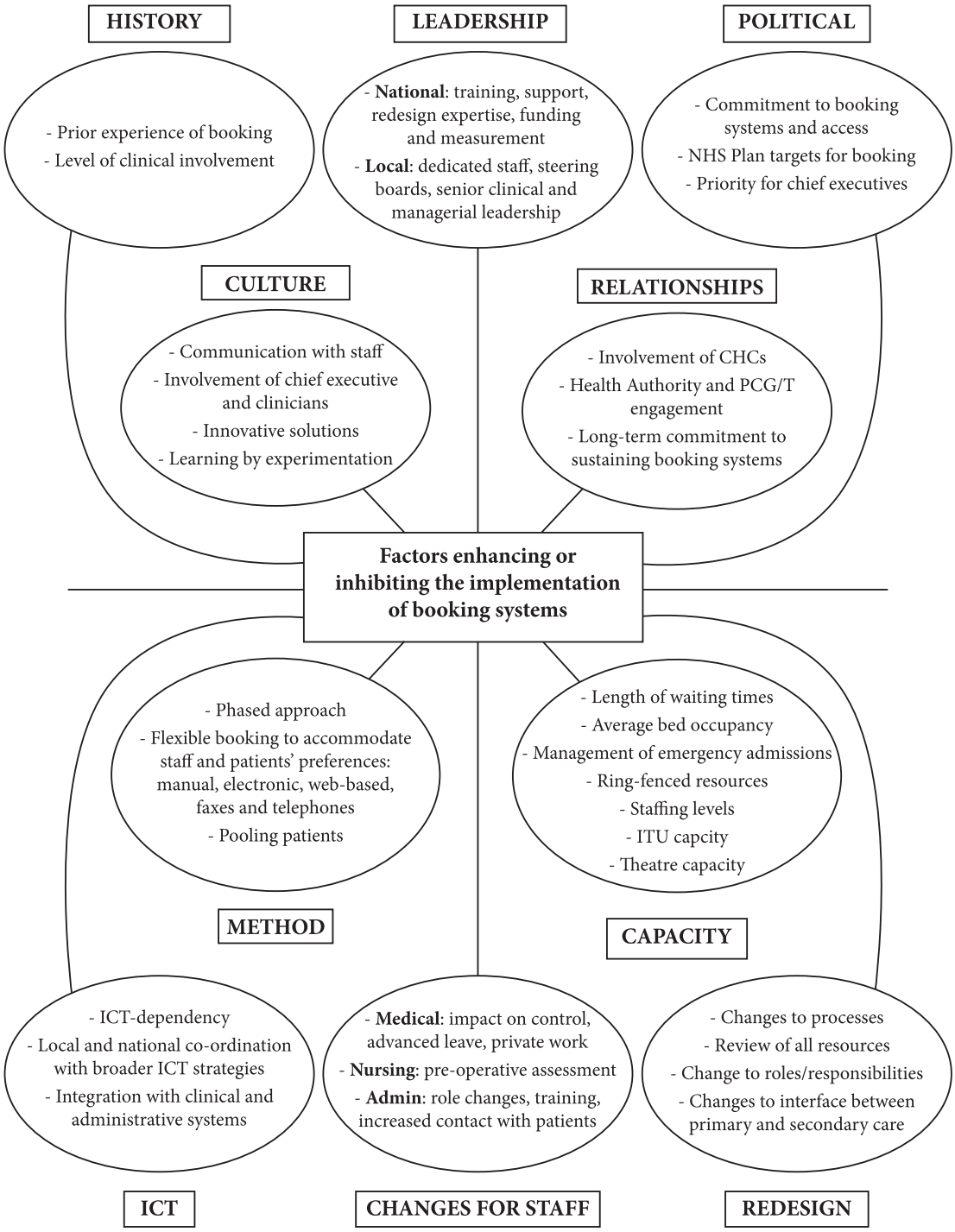
However, variation was again the major issue:

> *'There was wide variation between the pilots in what was achieved. Three pilots achieved a high level of booking across a large proportion of day case work. By comparison, only one pilot achieved a high level of booking in relation to inpatients. Direct booking from general practice was limited to a small number of pilots and relatively few patients experienced this service.*
>
> *'There was also variation between specialties in what was achieved. In relation to day cases, oral surgery and gynaecology had the highest proportion of patients waiting with a date, and general surgery, ophthalmology and urology the lowest proportion. In relation to inpatients, ophthalmology and gynaecology had the highest proportion of patients waiting with a date, and orthopaedics and general surgery the lowest proportion.'*[42] *(xiii)*

The root cause, they concluded, was contextual: 'the most important explanations of variations between the pilots are to be found within the organisations themselves and their local environments'. Drawing on Pettigrew and Whipp's work, they attempted to map those features within the wider environment of the programme that were receptive (enhancing) or non-receptive (inhibiting) to successful implementation and which offered a plausible explanation of the variation they found (see Figure 7).

The similarities and overlaps between the two 'ideal context' models of Ham et al[42] and Pettigrew and Whipp[24] are striking, particularly when one gets behind some of the differences in language and labels to find common issues like leadership, structural and cultural context. However, recalling what I noted earlier about the importance of temporal context, it is reassuring to see history featuring more prominently in Ham *et al*'s work. For example, they say:

Figure 7: Factors inhibiting or enhancing the implementation of booking systems in the first wave booking pilots[42]



'Pilots with a receptive context (especially a history of booking), effective leadership by a chief exec and senior clinicians, a dedicated project manager and team, and a flexibility of approach to clinicians were at an advantage compared with pilot sites without these characteristics.'[42]

They also elaborated further on the four main contextual influences in a QI programme such as this (although again none of them are surprising):

- booking will not work unless consultants and GPs can be persuaded to take part (and you cannot work around doctors)
- starting with enthusiastic doctors and extending booking to others is important to progress
- surgeons must be able to see how they will benefit from booking if scepticism is to be overcome
- a range of contextual incentives is important to encourage doctors to book patients
- national leadership is important in creating the context for local innovation.

They also noted – as have many others – that culture was a particularly important part of the contextual architecture for QI:

'there needs to be a strong and supportive organisational culture of the kind that was present in the sites that made the most progress to enable new working practices to become established then embedded'.

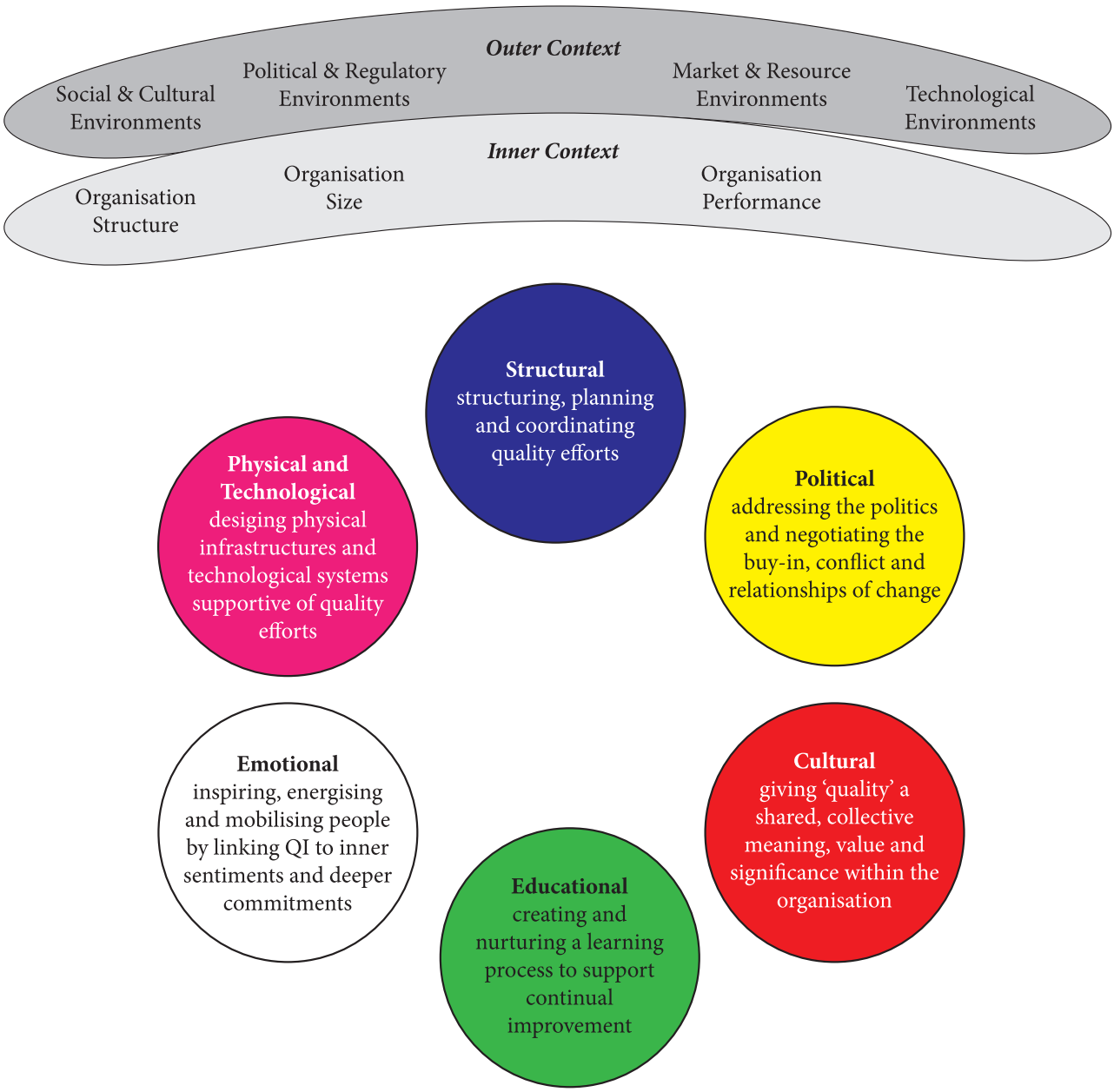
This is the point at which a degree of unease begins to creep in once more, as one asks what they meant by a 'strong culture'? As I have asked previously,[43] is it meant to be like strong tea or a strong heart or pair of lungs – basically the stronger the better? Unfortunately not, for we know that so-called 'strong cultures' – such as some of our previously fallen great companies (BA, IBM) – can also end up being highly resistant to change, that is maladaptive, having become conservative and complacent partly as a result of their very own success, thereby failing to adapt to changing circumstances. We are not saying 'culture' should not be represented in these models' contextual schema, just that much greater clarity is needed on the terms we use. Also, a point I have already made, there is a danger in reifying context, so that in this case culture becomes an external 'variable' or thing, when in fact a constructionist – indeed most anthropologists – would say that culture is not something an organisation 'has' but what an organisation 'is'. My point is that before we throw words like culture or structure at context (itself a definitional minefield) we need a clearer view of what they themselves mean, and should be prepared to adopt new and more sophisticated perspectives towards them.

3.4 Bate, Mendel and Robert's Nuffield-RAND study of QI in US and European healthcare systems

The final illustrative example I want to give is a contextual QI model in healthcare found in our own work.[9] This was a study funded by the Nuffield Trust and RAND, which comprised a dozen in-depth, ethnographic case studies of QI programmes in the US and Europe. Its goal was to identify the factors and processes that lead to success or otherwise of a quality improvement programme. Each case was researched and presented as a detailed narrative or story, tracing, through the eyes and experiences of those involved, the various stages of development the project had gone through, and the challenges and various bumps in the road they had encountered on their way. This in itself highlighted the important temporal context that there is for any QI programme, and the fact that it would be impossible to know why it had developed in the way that it has without knowing where it had come from and what challenges it had encountered en route.

Initially, what struck us was the uniqueness of each of these stories, and the hugely diverse routes each healthcare system had taken to reach their own QI summits (our focus being on exceptional QI programmes). However, the more we read and became familiar with these stories, the more conscious we became that each had been compelled, time and time again, to face up to the same common range or set of challenges; it was only their chosen solutions that had made them varied and different. In the end, as a result of repeated readings of the cases, we were able to boil these down to six common challenges for QI (see Figure 8), their relevance to this paper being that each might be described as an organisational contextual challenge. For example, the structural challenge for any QI process was to create the kind of receptive context within which the QI effort was able to benefit from being well structured, planned and coordinated – an

Figure 8: Organising for quality in healthcare: the six universal challenges[9]



effort that was structurally enabled and constructed on safe foundations. The important thing about the six context bubbles was that context wasn't a set of factors 'out there'. Each 'bubble' represented an area of human agency, management and leadership, an area of often intensive, frenetic collective activity where those involved struggled to 'manage' that particular context, to **shape and make** it receptive: managing the politics (yellow), implementing supportive IT systems (pink), creating teams and shared values that will hopefully see the QI programme to a successful conclusion, and so on.

Looking at the data, we proposed that each of the six organisation contexts was important in some way for the success or otherwise of the QI effort, or to put it the other way, that the absence or weakness of a receptive context in any one of these areas would lead to a particular kind of failure or underachievement:

Absence of…	Leads to…
Planning and coordination	Fragmentation
Political process	Inertia
Cultural process	Evaporation
Learning process	Amnesia/frustration
Mobilisation	Energy-sink/fade-out
Technical and other systems	Exhaustion
	Source: Bate et al[9]

The inner and outer contexts in the graphic (grey) referred to the more fixed, distant and unalterable aspects of the environment, the former including issues like organisational size, market and technology, and the latter the regulatory, financial and market frameworks for an industry or even a country. These influenced the direction in which a local QI programme developed and was able to develop and therefore needed to be taken into account and placed on the horizon of any QI effort, while at the same time accepting that one could have only limited direct influence on it.

Up to this point, it might be said with justification that this model is little different from any of the other models described in this section – that it is little more than an attractive graphic for a bundle of key success factors that may be associated with QI. Acknowledging this, we set out to go further, focusing not so much on the contextual bubbles themselves but the connections, patterns and interactions between them (literally the between-ness aspects). As we put it, our aim was to move from a 'factors-based' model to a full-blown 'process model of organising for quality'.

This is how we laid out our stall:

> *'The reason we need to resist the temptation to merely (and endlessly) list and categorise key variables is that the key to quality – if there is one – is not to be found in the factors as such, but in the processes that connect them… The starting point is to recognise that we cannot approach human factors in the same way as we would technical or clinical factors – as independent and dependent variables in closed cause–effect relationships with each other… organisation researchers have repeatedly drawn attention to the weaknesses and limitations of the variables paradigm and the particular type of scientific language associated with it. Thus, while it is nice if only it were true, there is rarely a single or even dominant set of factors that explain why only 55% of patients receive their recommended care… Rather, studying organisations as systems and processes requires: holistic studies… which at least open up the possibility of our being able to see how system dynamics emerge and play out (especially between the different levels of the system); a way to explore the patterns of relationships, interconnections and interactions among the organisation's or system's parts, ideally over time; a particular sensitivity to the positive and negative feedback loops that link factors and processes together… the positive thermals that can – sometimes slowly, sometimes quite suddenly – take an improvement effort skywards… or the negative downdraughts that can take it crashing to the ground.'*[9] *(pp188–189)*

Our first attempts to model the QI 'system' using social network software were exciting (see Figure 9) since they showed, arguably for the first time, what a complex QI system might look like, but they were too raw and fine-grained to be useful from an interpretive point of view.

Further refinements of the software were more successful, leading to maps like the one in Figure 10 overleaf. Without going into detail: basically the bigger the bubbles and the thicker the lines, the more important the particular context – and its relationships to other contexts – was within the overall improvement system. (In this case, Cedars Sinai, one could look to structural and cultural contexts and the synergies between them as an explanation for its success, at the same time not neglecting the educational aspects.)

Although our framework is still relatively recent, and therefore largely untested beyond the original case studies, there does seem to be growing empirical support for it. For example, Krein and colleagues' in-depth study of six US hospitals engaged in QI projects to reduce hospital acquired infection (and specifically central line-associated bloodstream infections – CLABSI) confirmed that the six contextual domains we identified in our case studies did provide a plausible explanation for why some of their hospitals had been more successful with improvement practice implementation than others:

> *'During the course of our analysis we found that the common organizational challenges to organizing for quality described by Bate and colleagues (Bate et al, 2008), corresponded with our results and provided a useful interpretive framework for our findings. These challenges are grouped into six organizational domains: structure, politics, culture, education, emotions, and physical or technological infrastructure. Four of these domains (structure, politics, culture and emotions) were closely aligned with our key themes (leadership, culture and resources; people issues; and champions). Thus, for the*

Figure 9: Cedars-Sinai 'detailed' sub-process map[9]

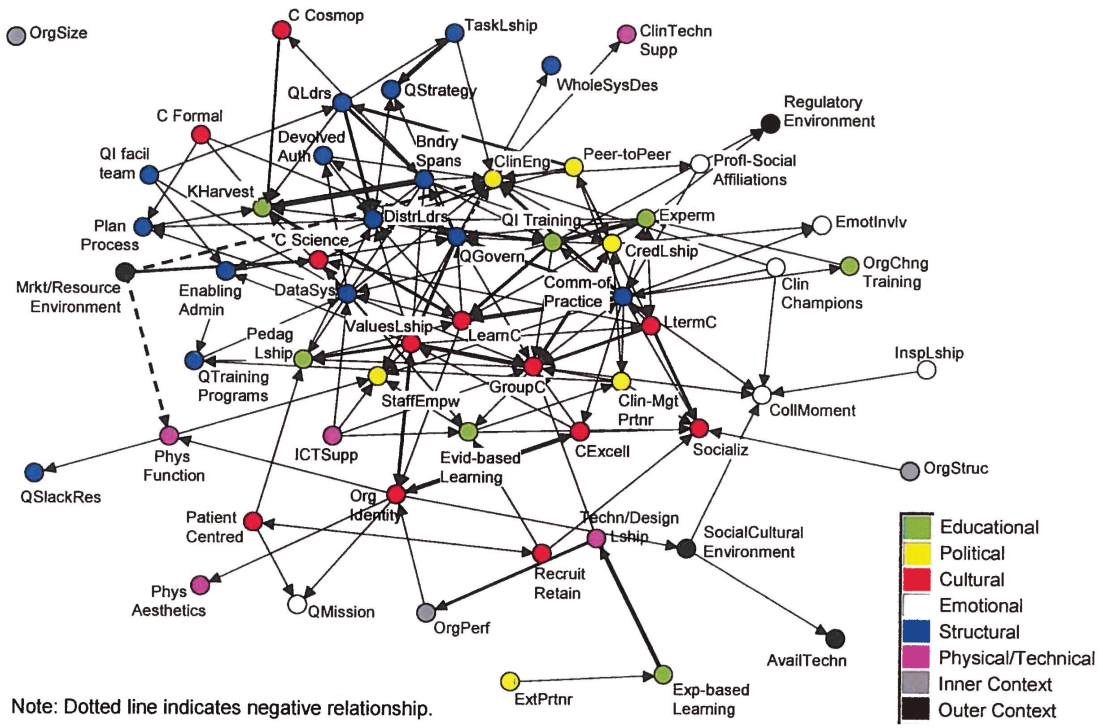
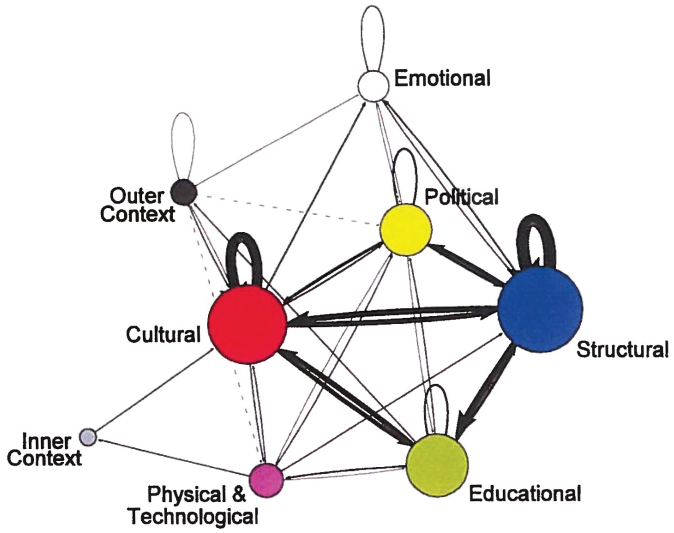


Figure 10: Cedars-Sinai 'high level' process map[9]



Process	Total Sub-Process Ties (#)	W/in process (%)	IN-ties (%)	OUT-ties (%)	Most Central Sub-Processes
Structural	100	31%	24%	45%	Communities-of-Practice, Quality governance systems, Distributed leadership, Boundary-spanner roles, Data and monitoring systems
Cultural	85	28%	40%	32%	Group culture, Values/symbolic leadership, Culture of learning, Organizational identity
Educational	54	7%	52%	41%	QI training, Knowledge harvesting
Political	37	11%	54%	35%	
Emotional	13	15%	62%	23%	
Physical & Technical	16	0%	44%	56%	
Outer Context	9	11%	33%	56%	
Inner Context	4	0%	50%	50%	

remainder of our interpretive work we used these four domains. Structure refers to the elements that influence planning and coordinating quality improvement efforts, such as leadership and resources. Politics refers to relationships within the organization, particularly in negotiating and establishing buy-in and engagement by stakeholders. Culture refers to the shared mindset, common mission or values espoused throughout the organization. The emotional component refers to the degree of commitment and passion for the organization and its mission.'[10] (pp1693-1694)

Work by Marjorie M Godfrey and colleagues at the Dartmouth-Hitchcock Medical Centre[44] also shows how the Bate et al framework, and associated 'QI codebook' for practitioners, was successfully used to identify where and why QI projects had gone well and where and why they had gone badly. Not only was there support for the various categories of contextual influence identified in our book, but the research also showed that the self-help practitioners codebook derived from it could be computerised in SurveyMonkey form for use by those involved in helping to identify their own contextual strengths, gaps and weaknesses in relation to QI. Another piece of as yet unpublished work based on a collaboration with fellow author Glenn Robert is an internal report outlining Yeovil District Hospital's positive experiences of using our 'six challenges' framework as a diagnostic tool for their QI strategy.[45] Interviews with 42 members of staff at all levels showed that the framework and codebook provided both a useful heuristic and a practical method for reflecting on the importance of contextual issues to a QI programme.

4. Key questions for research

If healthcare research is to take the kind of 'contextual turn' some of us have in mind it will almost certainly need to address the following questions.

4.1 What are the compelling arguments for making context and contextual awareness central to intervention research, theory and practice?

Most of the arguments in favour centre on the fact that we cannot even begin to understand or explain our findings or what is happening (or not happening) without looking beyond the focal variables to the wider situation in which they are situated and embedded. For example, why do key variables not work in the expected way or – one of the most vexing problems in the field – why is there such wide study-to-study and place-to-place variation in (our case) improvement outcomes even when the key variables are similar or the same? Context is likely responsible for this, in which case contextual analysis becomes an imperative. Ignoring it is tantamount to being self-delusional.

4.2 What should be the philosophical and epistemological underpinnings of any future context and contextual research in QI?

At first blush this question might seem to have little relevance to the research and daily practice of quality improvement, but on closer examination, I believe, we find that it has everything to do with it. The simple point is that how we **think** about context will determine how we go about researching it and ultimately trying to manage and do something about it. In short, as the next quotation suggests, the issue is not epistemological but functional. Perhaps the main question here is whether we approach context in the usual rational–analytic way (usual, at least, for healthcare and medicine) or in the more constructivist way I have been describing. As I say, the choices we make in this regard are important because they will not only determine how we go about studying context but how we come to know and relate to it, and what we find out and do about it.

'At its heart, the distinction between the rational–analytic and constructionist–synthesis approaches is an epistemological one concerning the nature and manner of the knowledge and learning that is being investigated and produced through the research. Whereas rational approaches veer toward distance, clarity and generalizability, constructionist approaches favour closeness, complexity and locality. The distinction is not necessarily ideological – though advocates often behave as though they occupy rival evaluative camps – so much as functional. Rational–analytic approaches seek to explain social experiences by isolating and classifying elementary parts or variables and understanding how these function within mapped, causal chains of influence. Constructionist–synthesis approaches understand explanation as

materializing from description, where description involves appreciating and recounting social experience through forms of involvement within that experience, whether participating in real time or second hand, through the study of narrative accounts.'[32]

Clearly the pat answer is that we need to do both, but is that really possible, and if the approaches really are incommensurable, are we not asking for trouble as we vainly search for the mythic synthesis? Like it or not, I believe we do need to approach context pluralistically but the question is how we can do this constructively rather than destructively. Leaving things to work themselves out (whether in a research or practice setting) could be a risky strategy. As Tony Watson notes:

'If one constructs a building indiscriminately using bricks of different sizes and shapes, the building is unlikely to stand up… Given that different disciplines tend to be based on fundamentally different assumptions about the world and about knowledge development, their use alongside each other could be as dangerous as building a house without adopting a consistent set of construction principles… The question is how can one achieve the conceptual and methodological integrity one requires to avoid an "anything goes" approach to material from various disciplines.'[46]

However, there is a small literature that is extremely helpful in suggesting ways in which a multi- or trans-disciplinary approach to context of the kind we envisage may be achieved. Notable among these is the work of Stige et al[47] which concentrates on getting a constructive dialogue going between the representatives of the different disciplinary standpoints involved. The key to success, they argue, is to avoid coming up with shared meta-criteria for judging the worth of a piece of work (and we have some experience of this in healthcare) and to focus instead on a common agenda of dialogical themes:

'[The aim should be to identify and discuss] themes that could be relevant across various traditions of research, not to propose the best criteria according to one specific paradigm or research tradition… The solution rests on the notion of having a shared agenda (for reflexive dialogue) rather than shared criteria (for rule-based judgement)… Unlike criteria, an agenda may embrace pluralism, and does not request consensus on ontological, epistemological, and methodological issues, only consensus on what themes warrant discussion.'[47]

I believe their work would reward further investigation in relation to future contextual research and practice, even using the questions we are now asking in this paper as the basis for an initial dialogue.

4.3 How does the process of interpreting and taking account of 'context' work in an everyday practice sense in healthcare interventions?

This question (which flows from taking a constructionist line) refers to all three levels of individual, group and organisational sense making. Another way of putting this is 'how do individuals and organisations attend to and experience context when they are embarking on an improvement intervention?' – something we still know precious little about. For example, drawing upon Selig Perlman's classic work on the Labor Movement,[48] when people 'look out' on their context do they perceive an **abundance of opportunity** or a **scarcity of opportunity**? This is of great practical interest because we know that their view of their context will determine how willing and prepared they will be to take action. Perlman found (not surprisingly) that the more senior people are positioned in a society or organisation the more they see an abundance of opportunity – the world as their oyster. This has implications for mobilising people behind an improvement effort, in terms of who takes the initiative and how one is to activate the 'masses', who may view context in a very different way as threatening and limiting and on the basis of this decide not to participate. This situation is not dissimilar from Seligman's[49] 'learned helplessness' and a major reason why fewer than 25% of people ever participate in an organisational change project and why the majority choose to remain as bystanders throughout. Getting people to see context in a more 'abundant' opportunistic way thus holds one of the keys to successful interventions, this being a theme that runs through the 'change' work of many writers, from Paolo Freire[50] (the role of education being to raise the consciousness of ordinary people of what can be achieved by them) to Daryl Conner[51] (engendering an optimistic/glass half full bias in prospective change agents).

The recent work of the positive organisational scholarship (POS) writers and their Centre at the University of Michigan could also be of help in getting researchers and practitioners to approach context in an optimistic and vital way, reversing a long-standing trend of seeing and talking about it in terms of barriers and constraints rather than opportunities.[52]

4.4 Through what mechanisms, processes and practices does context express and impress itself on healthcare practices in general, and improvement practices in particular?

As already said, we use the term contextual or environmental 'influences' and 'determinants' all the time, yet still know precious little about the mechanisms or processes through which these are expressed and come to impact on thought and practice. This is the 'how' question that needs to be addressed in any future 'contextualised' healthcare research. Multiple disciplinary avenues remain open to be explored in relation to this question. For example, anthropologists – linguistic anthropologists in particular – say that context makes itself felt through everyday language and interaction, in other words it is not 'out there' but part and parcel of the routinely enacted 'inner' discursive life of the society or organisation, with the focus on verbal communication and exchange.[53,54]

4.5 How does one acquire the necessary skills in 'reading' complex contexts as the precursor to constructing intelligent interventions?

In short, how do we get better at 'reading' complex contextual situations? In their book in which they challenge the assumptions behind evidence-based practice, Gabbay and le May[55] (chapter 5) refer to this as 'cultivating contextual adroitness'.

> *'We have explored how mindlines develop as a clinician moves from being a novice to becoming a "contextually adroit expert". Our analysis, which relies on our own ethnographic observations as well as a critique of the existing literature, points to the crucial relevance of "knowledge-in-practice-in-context". In any given context, new information, whether tacit or explicit, becomes transformed by the complex social processes described in the SECI spiral (Socialization, Externalization, Combination, Internalization) that enable clinicians to amalgamate it with other relevant knowledge before using it. Information from research, education or other formal sources becomes practical knowledge only after that social process.'*

At the heart of cultivating contextual adroitness lies a necessary shift in mindset from simple linear cause–effect chains-type explanations to complex, holistic, cross-level, systems explanations. This is the notion of context as a configuration or bundle of stimuli, in which factors mutually influence each other in 'deadly combinations' or powerful ways,[3] creating upward or downward change and influence spirals.[9] As Rousseau and Fried remind us:

> *'A set of factors, when considered together, can sometimes yield a more interpretable and theoretically interesting pattern than any of the factors would show in isolation.'*[56] *(p4)*

The kind of mindset they are thinking of calls for a naturalistic, complex, open-ended, multi-level process- (as opposed to variable-) centred, longitudinally inductive form of inquiry, which understandably will pose a formidable challenge for those brought up in the very different randomised controlled trial (RCT) 'omitted variables' kind of tradition.

4.6 Can context be measured and quantified?

Most of this paper has been about qualitative methods and approaches to context, but it still behoves us to ask whether context can be measured or quantified in any way, and if so how? For example, is it possible to quantify the relative influence and importance of contextual factors within the total system (and their effects), and attach some kind of weighting to the factors, processes and interactions involved? Clearly, it would be of huge benefit to practitioners to know which are the dominant factors that need the greatest attention, and where the gaps or problem areas are, and to have some sense of the degree of impact a contextually focused intervention is likely to have at different intervention points. Qualitative researchers may be good at describing context, but a true understanding of it can only come from better measurement. More ambition is needed here, one role model being

astrophysicists who not only seek to photograph and describe the universe but also to measure and quantify the phenomena they are observing.

Although, the measurement of human systems, processes and contextual effects is still in its infancy (as opposed to the sophisticated measures we find in the traditional variables paradigm) there are several promising areas that might reward further investigation. One such area is the long-established Soft Systems Methodology devised by a team (led mainly by Peter Checkland) from the University of Lancaster during the 1960s and constantly refined and developed since then (see the excellent Wikipedia overview under 'soft systems methodology' but also Checkland and Scholes[57] and Checkland and Poulter[58]). Space and time do not permit detailed exploration of this method here but its attractions may be summarised as follows:

- It lends itself particularly well to dealing with complex situations, like improving healthcare delivery (specifically mentioned by its protagonists).
- Despite the label, it deals with both the soft and the hard aspects of system and context.
- It offers a step-by-step approach to diagnosis and change, and uses methods that anyone can follow and use.
- Given its roots in operations research, it has always had a strong quantitative vein running through it (a welcome antidote to the 'fuzzy' thinking often found within the qualitative research camp), especially latterly in methods such as *Multiview* and *Logico-linguistic modelling*, which are grafted on to established software engineering methods and use all kinds of computerised measurement to achieve their goal.
- The method is participative, coming as it does from Lancaster's strong action research traditions, which means that it has always been trying to gear itself up for the challenge of changing and improving practice.

Another fertile area for our attention is social network analysis techniques,[59,60,61] especially the work of RAND anthropologist Gerry Ryan,[62] and *NetDraw* graphics and computer techniques[63,64,65] that we have used in our research. These, as already said, were adapted and used to compare and analyse our in-depth QI case studies in nine healthcare systems in Europe and the US (chapter 10 in particular).[9] The purpose of these techniques was to try to visually represent the system interconnections between our six organisational contexts and two inner and outer contexts (not least to give a snapshot picture rather than having to plough through page after page of case study material), and using quantitative methods, to show the relative strength of each in accounting for the effectiveness and success of the QI programme. An example of one of the maps is reproduced above (Figure 10).

Although there are many problems still to be ironed out, this research string shows that it is indeed possible to model, measure and quantify various contextual factors and to combine this particular kind of quantitative approach with the ethnographic qualitative case studies so beloved of anthropology and organisation studies. Certainly, we believe there is enough here to encourage organisations like the Health Foundation to put combined, synthetic qualitative–quantitative approaches to context at the centre of its call for research proposals.

4.7 The implementation question: how are we to 'manage' context?

A knowledge and understanding of context is one thing but doing something about it in terms of leading and managing it (Weick's notion of 'enacting one's environment' – acting towards and upon context as opposed to merely reacting to it) is quite another. This is the 'know how' question, which needs to be focused on to a far greater extent in healthcare research and organisational development. Reframed, the question is: what is contextual management and leadership and what does it involve? An excellent introduction to this topic can be found in the special issue of *Human Relations* entitled 'The context of leadership'.[66]

Pettigrew gives an overview of the task of what he calls 'fashioning context' (ie managing context), the first aim being to move it from the periphery to the centre of one's attention:

> *'A group interested in creating change must itself attempt to fashion a social context in which it can survive and prosper… Context is then being treated neither just as descriptive background, nor as a source of opportunity and constraint for change, but as something which must be accessible and understood by the innovating group, and ultimately mobilised to achieve practical effects.'*[21]

This is where leadership comes in. The role of the strategic leader, says Pettigrew and others, is to fashion or cultivate the inner and outer context of the organisation or micro-system in order to liberate, enable or mobilise change – in short to construct a receptive context for change. Smelser's[67] phrase for this is creating 'structural conduciveness' while Unger[68] talks about creating a 'formative context' for change and improvement to take place. There is an important subtlety to this, in the suggestion that the role of the leader is not to 'create' change/improvement or try to 'make' change occur as such, but to create sufficient contextual resilience for change to naturally emerge and grow – contextually enabling conditions for generative change. Whereas all the aforementioned authors in this paragraph have put the emphasis on political context, other writers like Karl Weick[33] have widened this out to include social, organisational, cultural and social psychological contexts.

Also, as previously mentioned, Weick puts sense making at the heart of the leadership challenge, and equally the collapse of sense making as the cause of most organisational failure and disaster.

Many different ways of helping leaders and managers become more attentive to, aware and mindful of context have been suggested. One of the oldest and most popular in organisation development and change management is Kurt Lewin's 'force field analysis'[69] which proposes that a change/improvement diagnosis and intervention needs to focus on identifying and reducing the 'constraining' contextual forces (the blockages, impediments or negative forces) and, at the same time, increasing the 'enabling' forces (drivers, attractors, or facilitating forces). Lewin offers a very simple model for doing this, which has the advantage of heightening people's awareness of their context and how it works as an important precursor to taking 'adroit' action.

One fundamental 'management of context' question that will need to be addressed is whether the task needs to be one of 'fitting' the QI programme to its context, as one would seek to find the right key for a particular lock or a bespoke suit for a particular sized person (the notion of context as 'good guy'), or attempting to conquer and transcend a context that is seen as blocking or impeding progress (context as the 'bad guy'). There is no clear-cut answer here: 'contingency theorists'[70] say the question is always about getting good fit between the organisation and its context, whereas 'movement theorists' say this approach is inherently conservative and cautious, since the real task is to transcend context (get above the clouds and fog) and get second order, transformative change, not the first order incremental change so beloved of contingency theorists. This has obvious implications for QI leadership, and raises the perennial question – are we looking for transactional or transformational context leadership? As usual the pat answer must be 'both', but unfortunately it leaves us with absolutely no idea about what this means in terms of change methodology or the practice aspects of the leadership process. Clearly the topic of 'leading context' requires a good deal more investigation, hopefully freed of some of the well worn dichotomies (such as transactional/transformational) that have dominated the field for too long.

5. An additional question: what methods and designs should we be using to study context?

Johns proposes several essential elements of context-oriented research.[3] He suggests that researchers must:

- do cross-level comparative research in order to examine how higher-level situational factors affect lower-level behaviour and attitudes[71,72]
- study processes over time to appreciate how context affects their development and direction
- study events to show how these affect attitudes and behaviour (to take an extreme example, an occurrence that was obvious anyway but is still illustrative, New York work absenteeism went up after the 9:11 terrorist attack)
- do qualitative research:

> *'Well-conducted qualitative research has great potential to illuminate context effects, for at least two reasons having to do with circumventing the omitted variables problem. First, alert qualitative researchers can be sensitive to the full range of discrete contextual levers (and their interactions) that might affect behaviour in a studied setting. Second, they can be sensitive to the full range of behaviours and attitudes that context might affect, often "working backwards" to make inferences about the situation.'[3] (p402)*

– do measurement and analysis:

> *'One way to both detect and appreciate context effects is to measure multiple dependent variables or to measure dependent variables different from the norm in a particular research area. The exact logic for doing this would vary from study to study but should be grounded in good theory.' (ibid)*

Most academics seem to agree that the case study method offers one of the best routes to contextualised explanation and practice[73,74] (see also the *Handbook of Qualitative Methods for International Business*[75]). Furthermore, Rousseau and Fried[56] suggest comparative case studies as an effective way of illuminating context, as do Bate et al.[9] Obviously, this places the emphasis fairly and squarely on qualitative research, although Bate et al[9] also attempted to show that narrative methods can be combined with quantitative formal mapping techniques to reveal different facets of the interconnection between organisational and contextual factors.

Bate and Robert[76] identified a number of qualitative methods that they believe would assist contextual analysis (see especially chapter 8). Interestingly, most have roots in anthropology and ethnography – fields that are under-represented in healthcare and QI research – the implication being that the kind of future contextual research we have in mind might also benefit greatly from a parallel 'anthropological turn', especially given the fact that anthropology was virtually created to study socio-cultural contexts, and in rebellion against the linear, variables approaches used in science. Examples of such methods include:

– using informants (pointers to which part of context is important)
– ethnographic interviewing (context as seen through the actors' eyes)
– participant and user interactive observation (seeing context with one's own eyes)
– maps, photographs and videotape (obviously good for immediate physical context such as the design of a clinic; anthropologists always began here when entering a tribe)
– storytelling (as patients and staff tell their stories we hear first-hand about the context as they experience it; the stories reveal what is significant, relevant and impactful to them. Therefore, we are not put in the hopeless situation of trying to judge and evaluate them for ourselves. See Randolph Hester's story of Manteo in chapter 8 of the Bate and Robert book[76] for a model example of how to use contextual inquiry and narrative-based methods)
– focus groups and listening labs
– contextual inquiry.

As the label suggests, 'contextual inquiry' is a method that would certainly reward deeper investigation as part of any future initiative, particularly with the bonus of the (as yet untapped) high quality literature that has been written on the subject.[77,78,79,80]

Using key informants and guides to help do a preliminary 'recce' of the area is only part of the bigger activity of carrying out a thoroughgoing 'contextual inquiry'. In a contextual inquiry:

> *'… an experienced interviewer observes users in the context of their actual work situation, performing their usual job tasks… Conducting a contextual inquiry normally involves a team of two, an inquirer and a note-taker/observer. The inquirer and the participant are equals; each is an expert in his or her own work. After the visits, the inquiry team reviews their notes and analyses the information to find patterns, often using affinity diagrams. Contextual inquiries yield rich data from seeing users in their real work context, and thus can identify issues not previously recognised.'*[81]

According to Raven and Flanders,[80] contextual inquiry is based on the following three principles:

– data gathering must take place in the context of the users' work
– the data gatherer and the user form a partnership to explore issues together
– the inquiry is based on a focus; that is, it is based on a clearly defined set of concerns, rather than a list of specific questions (as in a survey).

Contextual inquiry is necessary for two reasons: the first, already mentioned, because meaning and action can only be rendered intelligible in relation to the context in which they occur, indeed are shaped by it ('context' being the commonplace, familiar and everyday world in which people live); the second, because one important consequence of doing contextual inquiry is that the improvement designer is able to help people begin to 'see the familiar in unfamiliar ways':

> *'[Designers] look at what is commonplace and familiar, and they reveal the ways in which it is unique, allowing them to break through existing assumptions and acceptance of things as "the way it's always been done" so that new opportunities for change can be explored.'*[82]

Contextual inquiry has also started to make inroads into the electronic and cyber context of organisations. For example, being given access to a person's email now makes it possible for designers to gain a deep understanding of the work context in which that person's communicative practices are situated and embedded. Most of this recent work is quantitative, illustrating yet again the need to look for contextual methods that draw on both ends of the scale. Therefore, this is another important area that would benefit from focused research.

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The Health Foundation
Inspiring Improvement

Perspectives on context

The role of context in successful improvement

Professor Glenn Robert and Professor Naomi Fulop

About the authors

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Contents

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.

[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.

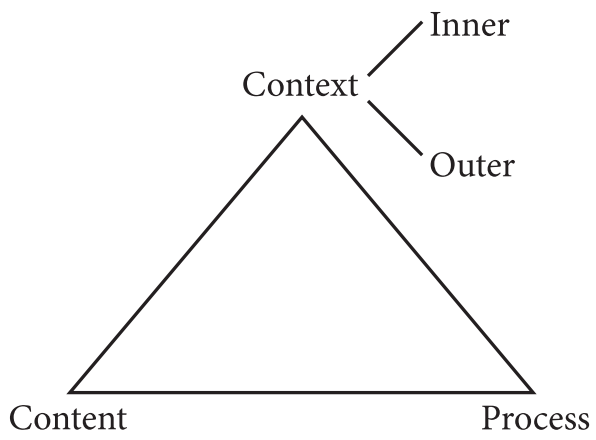
Other important distinctions in the literature are the **level of the system** at which one considers context (for example, the macro-, meso- or micro-system level) and the interactions between them (in other words, context is multilevel, with environmental, organisational, and individual levels intertwined),[12] 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]



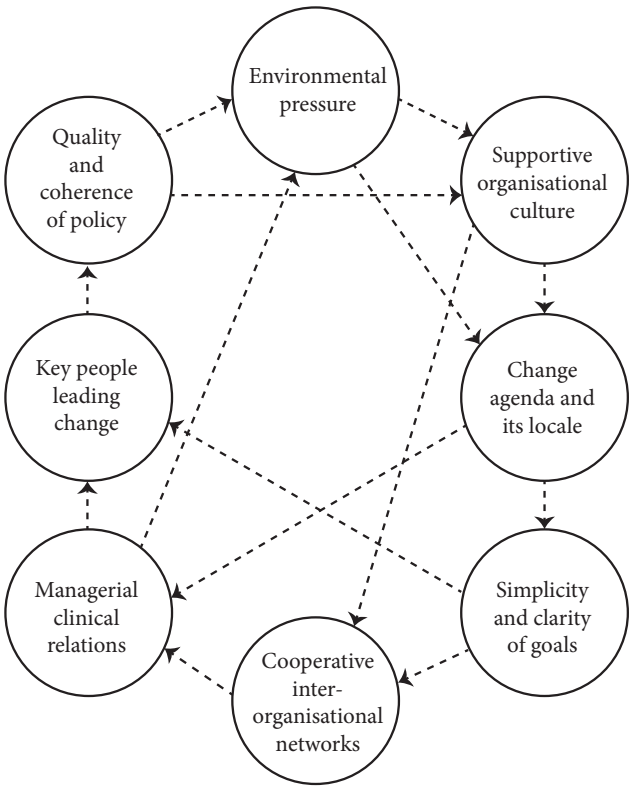
Later Pettigrew et al,[1] drawing on strategic service change in the NHS, developed a model for the management of strategic change which centres on receptive and non-receptive contexts for change. The model outlines key features of the internal and external

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'.

[ii] As reviewed by Greenhalgh et al, 2005[9]

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:

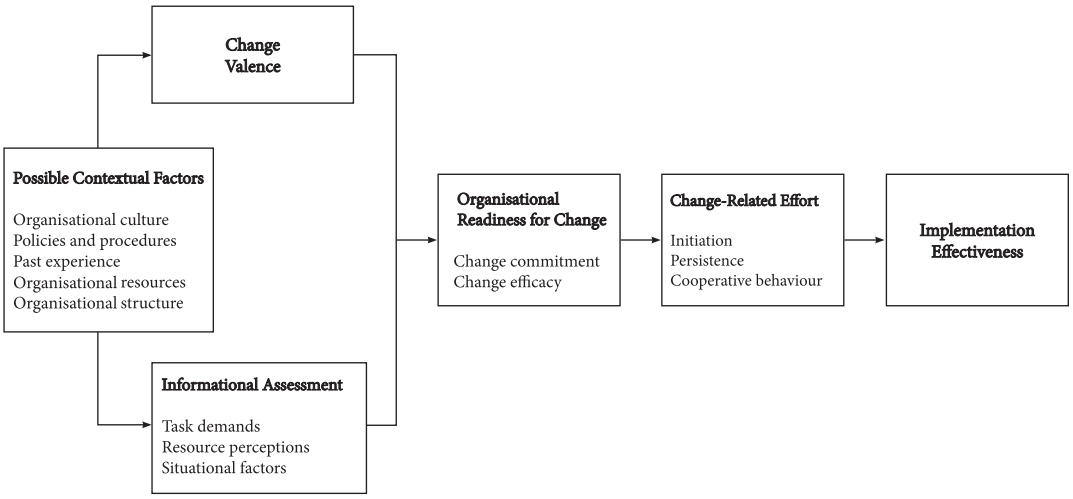
> *'In contrast to much of the literature on the topic, the conceptual definition offered here treats organizational readiness as a shared team property – that is, a shared psychological state in which organizational members feel committed to implementing an organizational change and confident in their 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

[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.

[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

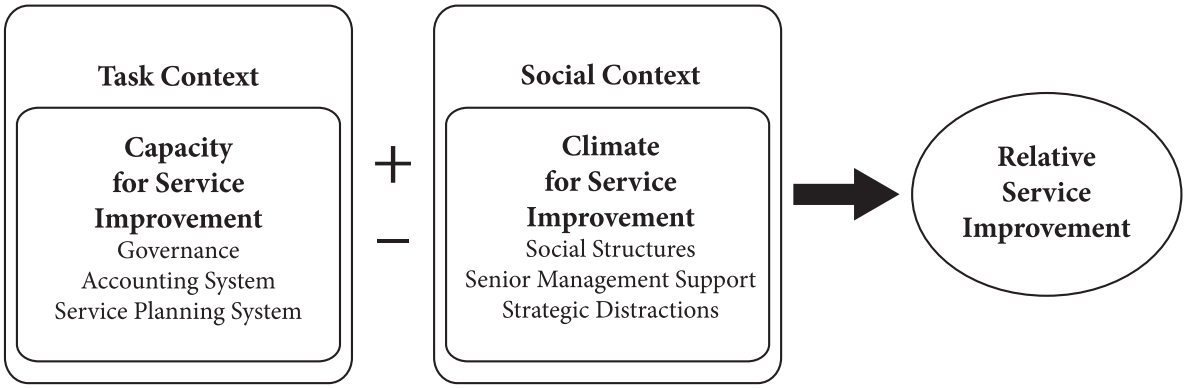
McDermott and Keating,[5] in a recent qualitative study of cardiology services in three Irish hospitals, draw on a further differentiation: that between 'omnibus' and 'discrete' dimensions of context, as provided by Johns.[26] 'Omnibus' refers to broad consideration of context as a whole. In contrast, '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.

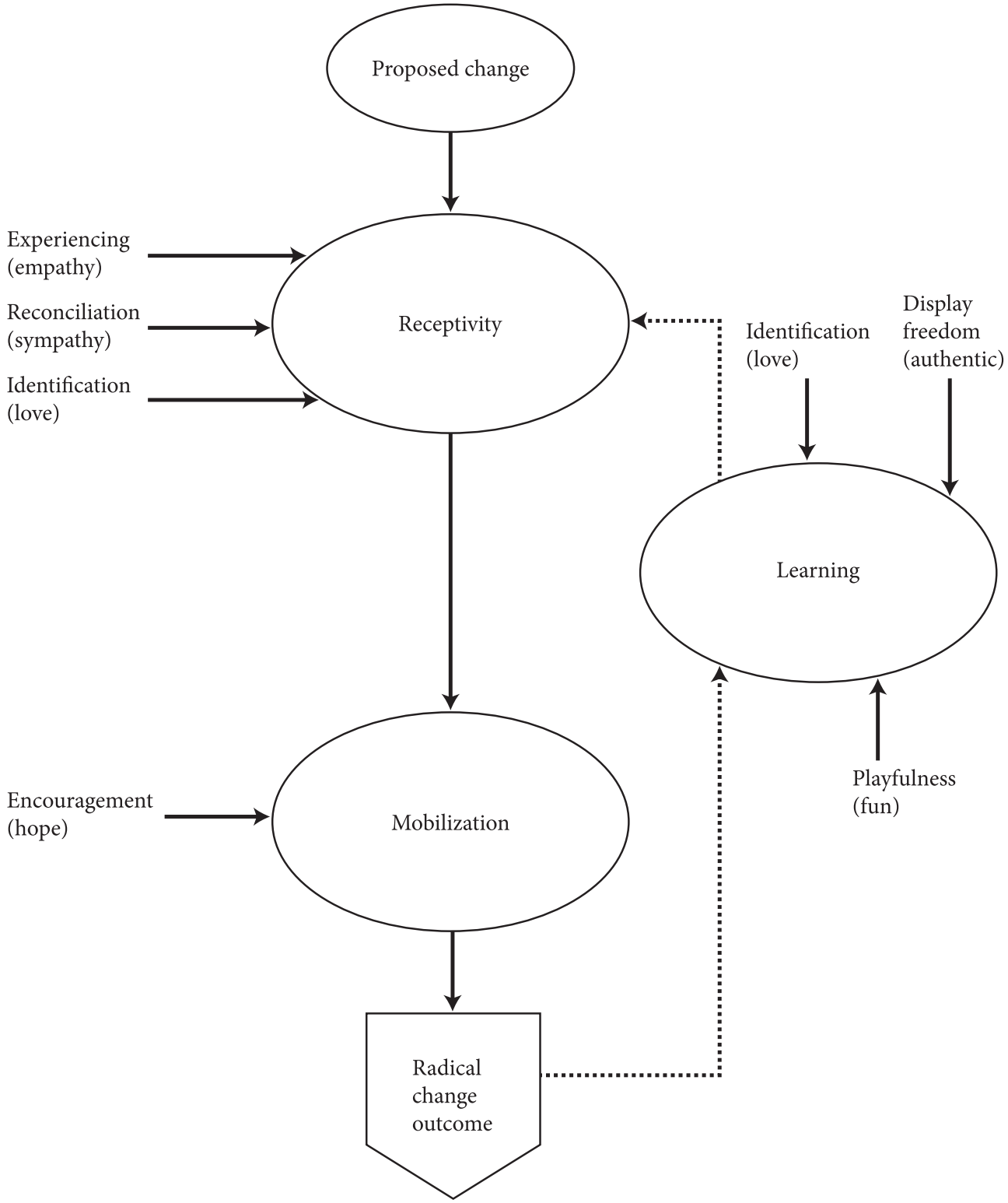
At the individual level, receptivity denotes a person's willingness to consider change, while at the organisational level, receptivity refers to organisation members' willingness to consider – individually and collectively – proposed changes and to recognise the legitimacy of such proposals. Receptivity 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]

[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]



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.

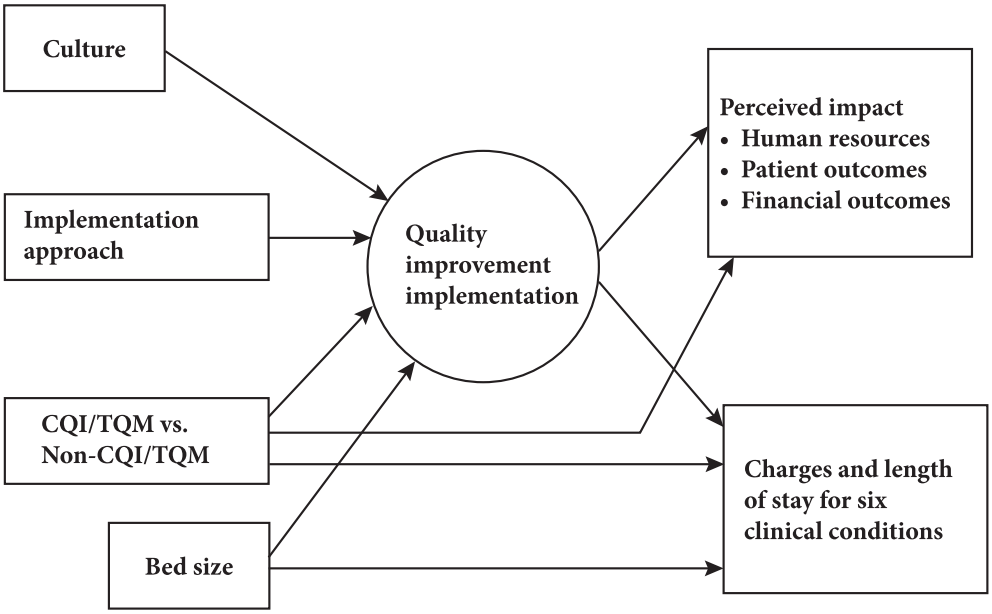
Meyer and Goes[33] studied 12 organisation-level medical innovations introduced into US community hospitals in the late 1970s using a comparative case study design over six years with over 300 interviews, observation and surveys. They found that the assimilation of innovations by organisations is influenced 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'.

[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]

[xi] Based on commentary in Greenhalgh et al, 2005.[6,7,9]

[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.

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.

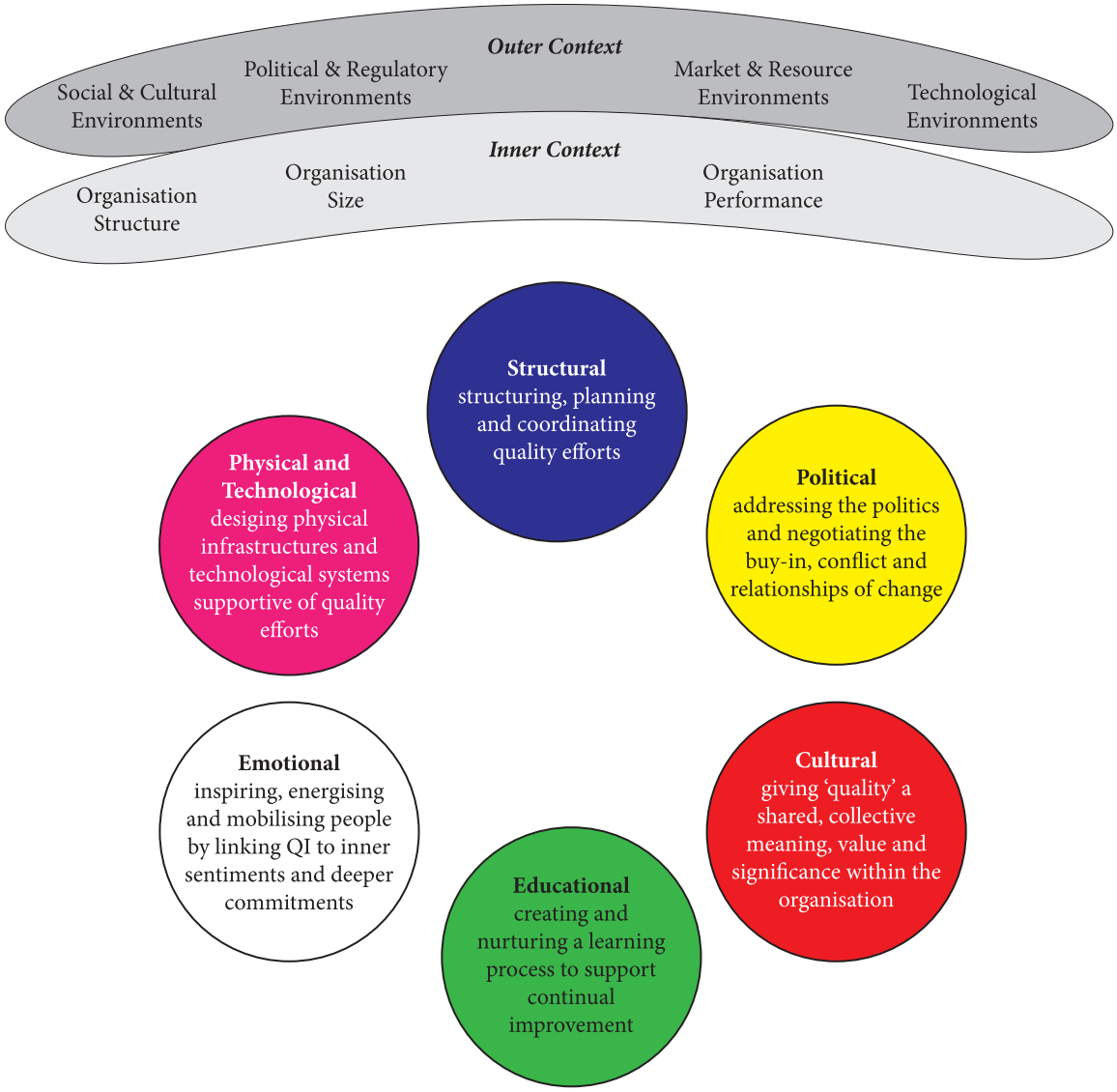
2.7 'Organising for quality'[7]

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:

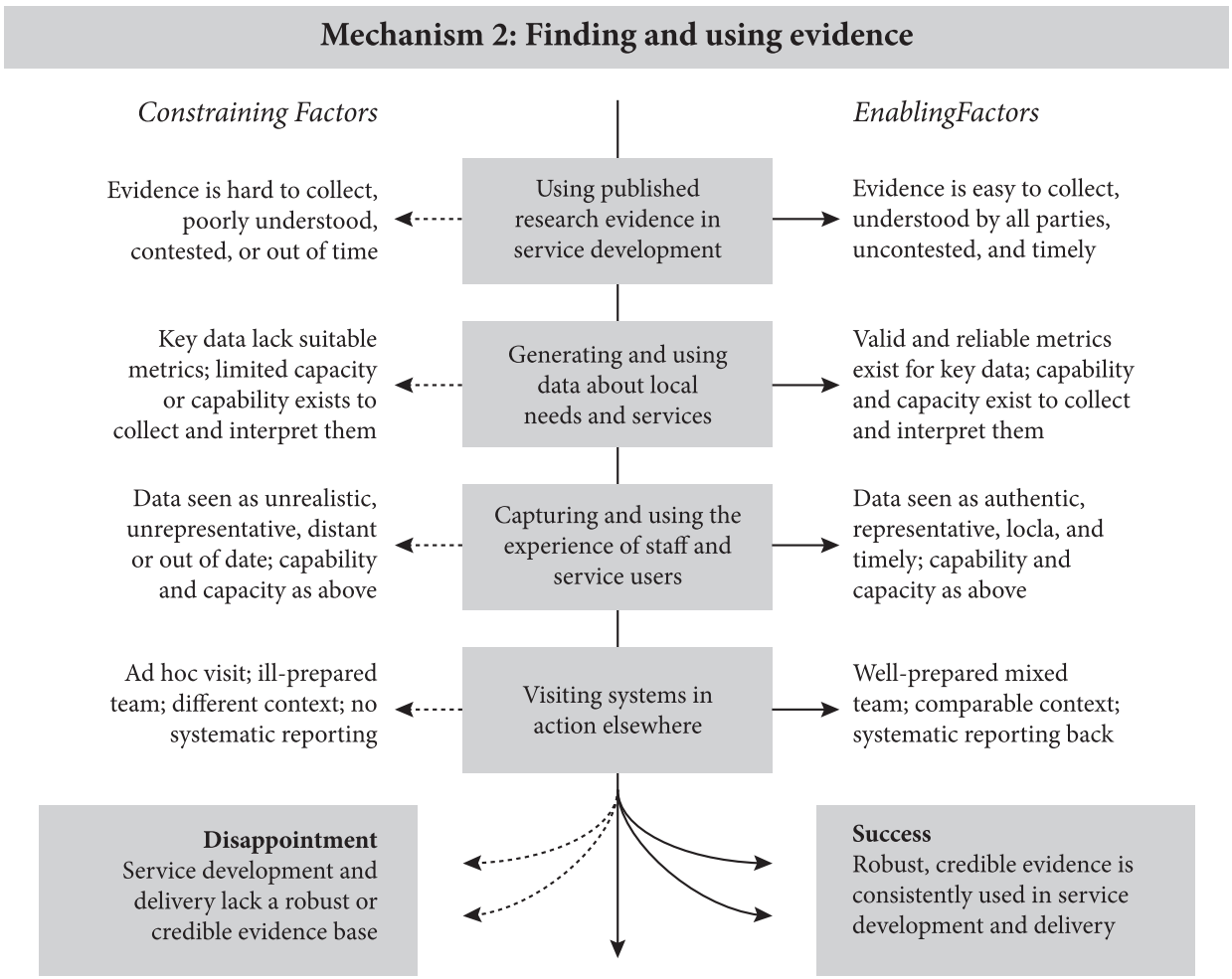
> *'context, whether inner organizational features such as size and performance, or influences from the external environment, appears to have played a relatively minor role in sustaining the quality journeys of these two organizations. This would suggest that although contextual influences or events 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.

[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]



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*

[xv] The authors report that: *'The MI [modernisation initiative under study] was characterised by imaginative and sustained efforts to ensure the long-term sustainability of the various gains achieved during the funding period… they include attention to cultural as well as structural changes; clarification of the resource implications of the new or altered services; the development of strategies for retaining skills and expertise within the local health economy; plans for the continued involvement of users; the maintenance of links with voluntary sector and partner organisations; 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)?

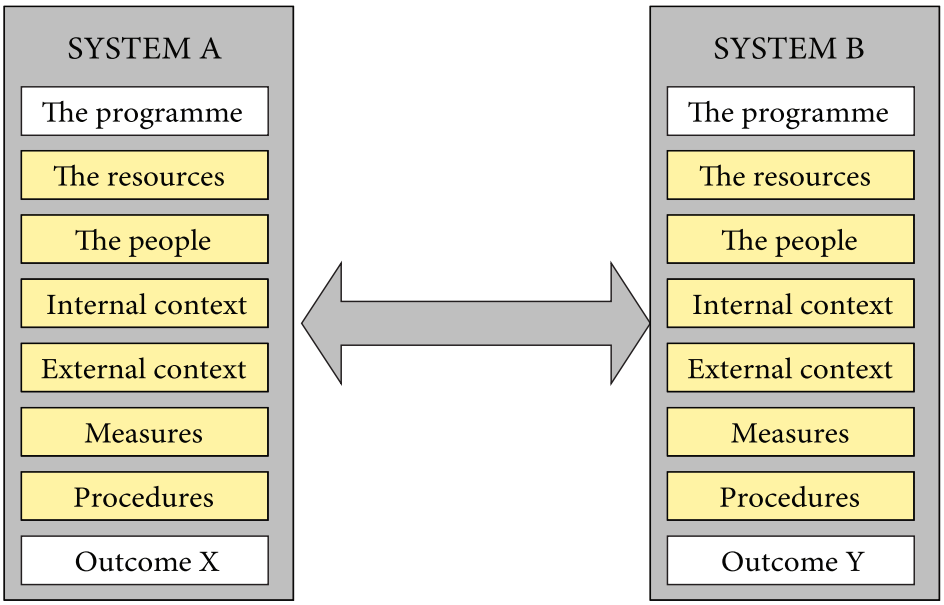
4.2 Research design

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

[xvi] 'Local context, whether it be cultural, structural or economic, is so unique and different as to require a properly tailored QI solution or set of solutions, and this can only mean that the QI system or process has to be home-grown, inside out and bottom up, not appropriated or imported from elsewhere. Wilkins made exactly the same point in relation to organizational culture when he observed, "You cannot buy a distinctive organizational culture and you cannot copy it from someone else. You must grow it." The fact that our quality organizations did exactly this – that their process of selecting and constructing the solution was intelligent and effective – is the main point we want our readers to take away, even though there may be some initial disappointment that (unlike many of the best-selling business book authors) we cannot offer any universal plug-in or off-the-shelf solutions.'

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:

[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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The Health Foundation
Inspiring Improvement

Perspectives on context

How does context affect quality improvement?

Professor John Øvretveit

About the author

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Contents

Executive summary

1. Executive summary

1.1. Summary

Context is everything that is not a quality improvement (QI) – it is the 'environment' within which a quality improvement is carried out. Only some aspects of context influence how easy it is to carry out a quality improvement. There is some evidence about which of these condition-influences are critical for some quality improvements, but we do not know if they are necessary for all, or even if there are only some categories of QI for which they are necessary.

There is also experience and theories that suggest 'critical condition influences' (CCIs) and which also help to consider the relative strength of each influence. It is possible that different CCIs have different influences over the different implementation actions taken when selling, starting, sustaining and spreading a particular improvement.

We can use some of what we know to give guidance to create the conditions which make improvement success more likely and to decide what research is most needed. But, in the same way that we should be cautious about encouraging changes for which there is no evidence of effectiveness, we also need to be cautious about proposing that effort and money is spent creating certain conditions if we are not sure that these make implementing a QI easier. Recommendations for research and funders of health services research are provided, based on this rapid review of evidence, theories and personal experience in implementing QIs of different types in different countries.

1.2. Key concepts

This paper proposes two sets of conceptual distinctions to help consideration of the influence of context on QIs.

1.2.1. Concepts distinguishing context, actions and results

Changes to patients, providers or organisations ('change differences') may be achieved by people taking certain actions and these actions are made within certain surroundings ('context'). Those that help and hinder their actions to bring about improvement are 'critical condition influences' (CCIs).

Most **clinical interventions** are treatments or care practices (actions) intended to accomplish a change difference to a patient (ie 'outcomes').

Quality improvement interventions (QIIs) are actions to change clinician behaviour or care organisation, sometimes to use proven treatments or care practices.

The change difference in clinician behaviour or care organisation:

- may or may not be already proven to result in better patient outcomes
- may be tightly specified, or may allow wide latitude in exactly which change difference is to be achieved
- may be implemented by many different approaches, or may come with a specified method for implementation
- is often implemented and revised through PDSA (plan-do-study-act) test cycles.

1.2.2. Concepts distinguishing types of improvement

These concepts distinguish different categories of improvement, according to characteristics which might be sensitive to context. The categories are formed using the concepts of: level of implementer, level of target, complexity of the intervention, and the fixed or adaptive nature of the intervention. The categories are:

- **Clinical intervention improvement**: a change in how patients are treated, with patients as the target of the new treatment or practice.
- **Change to individual provider's** behaviour, thinking or other provider characteristic.
- **Change to service delivery organisation**: a change to the work or relationships of care providers (eg the change difference is new process steps, new teamwork arrangements, or organisation for a chronic care model).
- **Change to service infrastructure**: a generic change to the support systems, structure or physical environment for service delivery.
- **Implementation strategy or method**: this can be used to carry out any of the above.
- **National programme or regulation**: these aim to achieve a change difference in how organisations function or providers behave. Some define these as implementation strategies.

It is possible that different implementation methods are needed to successfully carry out these different changes. In addition, different context factors are likely to influence the ease and success of implementation, and they have different influences at different phases of implementation.

Interventions carried out by actors at different levels of the health system have different targets to be changed.

Changes at higher levels set the context for, and make easier or more difficult, changes at lower levels.

Experimental research controls possible context influences so as to focus only on whether there is an association between the intervention and measurable results of interest. Naturalistic research approaches, in contrast, can be used to understand and explain which context influences affect the intervention, but give less certainty about how much of the results are associated with the intervention.

1.3. The evidence

Is there evidence that any aspects of context affect implementation or outcomes of any quality improvements?

The research for this paper found only one substantive review and study relevant to this question: Shekelle et al[1] carried out reviews searching for evidence of context influences in five patient safety practices. The conclusions were as follows:

- There is some evidence that context factors influence implementation and that these factors vary between organisations.
- There is limited research on the subject, and limited evidence about context in the research that had been carried out.
- There is little evidence from controlled experimental studies, possibly because they are designed to exclude context factors rather than examine their influence.
- There is some evidence from a few studies using measures of context, and from qualitative research. This showed influences at different levels of the heath system which helped and hindered the implementation of five selected safety improvements, but the evidence was not strong or very specific.[2]

1.3.1. Measures of context

There are no systematic reviews of methods for studying context influences in quality improvement interventions. This paper summarises the two most relevant overviews to date.[1,3]

Probably the single best validated instrument for quality improvement context assessment for the UK NHS to date is the Context Assessment Index (CAI),[4] a 37-item instrument based on the Promoting Action on Research in Health Services (PARiHS) model.

1.4. The theories

Are there evidence-based theories or models about which aspects of context influence which quality improvement changes, and how they do so?

There are many models, frameworks and theories characterising change processes in healthcare and a few of implementing QI. Some describe context influences over implementation, but do so at a very broad level,

replacing a box called environment or context with three or four boxes, such as regulation, financing, leadership and culture. There are different views about how much each is based on research, and many summarise consultancy experience.

This paper summarises these frameworks and notes that they could be classified in terms of:

- strength of evidence or research basis for the framework (often more evidence for the phases of change in the model, than for the context influences)
- the changes most similar to or most relevant for understanding context in certain types of QI.

For implementation of safety improvement, the only framework describing context influences which gives some evidence of their role in implementation was described by Shekelle et al[1] and is summarised in this paper.

A framework which best combines a basis in research and relevance to clinical level QI and provider behaviour change is one version of the many PARiHS models for examining implementation of evidence-based practice; again summarised in this paper.

1.5. Future research

The research for this paper found a lack of empirical research into and evidence about the role of context. It found limited examination in research of the generalisability of QIIs, and of the extent to which QIIs can be adapted. The paper summarises the strengths and limitations of different approaches and research designs for studying context.

1.6. Answers to questions posed by the Health Foundation

1.6.1. What do you define as context?

- All factors that are not part of a quality improvement intervention itself.
- Only some of these 'surroundings' may influence improvements and their effectiveness: these are 'conditions for improvement' or 'improvement-critical conditions'.
- 'Conditions for improvement' are those internal to the implementing organisation (eg information technology) and those external to it (eg payment and regulation systems), and are created by and have influence over different levels of the health system.
- The definition of a boundary between the improvement 'intervention' and the 'context' is relatively arbitrary. 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. Some also include as part of the intervention what others might call context, such as a unit leader's support and actions. This combination is then 'the intervention' that is evaluated, but reports often do not make clear where the study draws the boundary.
- To be useful to others, reports need to describe precisely the intervention implemented and any evidence of the conditions that influenced the intervention.
- The aim of some QI research is to understand which conditions influence improvement and how they do so. Experimental QI research usually excludes and controls for these conditions in order to focus on whether an improvement change is associated with changes in measured outcomes.
- Two aspects of the QI intervention need to be distinguished because the evidence for each is different. These are:
  - the change difference – for example, the before/after clinical intervention change in how patients are treated and in clinical practice (the clinical intervention)
  - the implementation actions – how practice and organisation changes are made: for example, to ensure that the clinical intervention is carried out appropriately every time, on time, with every patient.

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

My theory, some of which is supported by evidence, is as follows.

1. Only implementation actions are sensitive to context. A context factor only influences results through its influence on implementation.
   - The variability in results of QI changes in different places and organisations is because certain context influences make it easier or more difficult to implement the intervention fully, and these influences are present or absent to a greater or lesser degree in different places or in different organisations.

2. Some interventions are more sensitive to context than others.
3. There are different context influences for different interventions:
   - Some interventions are influenced by different context influences to those that influence other interventions. It is likely some context influences are important for implementing all QI interventions, such as management commitment, persistence and allocation of resources for implementation.
4. These context influences are more and less important at different stages in selling, starting, progressing, sustaining and spreading an improvement.
5. Some context influences may need to occur together to have maximum effect in enabling implementation. Coordinated multilevel strategies may be needed.
6. We need to categorise quality improvement interventions into groupings, according to which groups of context influences are most important for their implementation. This would give decision makers a better way to assess which types of interventions they are most likely to have success with, according to whether they have the context necessary for success.

1.6.3. Which models or frameworks do you use to help explain context?

It depends which type of improvement at which level of the health system is to be explained, as different context factors are likely to affect different implementation actions in different ways:

- The 'garden model' best communicates quickly the relevance of context in quality improvement, showing seed (evidence), gardener (implementation) and environment (soil and climate). Some plants cannot grow in some environments, no matter how good the gardener. Some grow anywhere, regardless of environment and gardener skills and care.
- For studying and planning implementation of simple evidence-based treatments the PARiHS model, the Damschroder et al[5] model or, from primary healthcare, one of the Solberg models.[6]
- For studying and planning complex multiple component interventions, either a version of the PARiHS or the Damschroder et al[5] model.
- For studying and planning interventions involving adaptive iterative implementation, the Helfrich et al 'readiness to change' framework[7] and the French et al framework.[3]

1.6.4. What do you see as the principal research questions relating to context?

- If success depends as much on where a change is made as it does on the type of change, how should sites be selected or helped to assess if they have the conditions for success?
- Could readiness for change, or change success prediction assessments, be used to select sites? What type of strength of evidence of their success in prediction would be needed for the instrument to be used partially or wholly in selecting a site or organisation?
- Which evidence or theories about 'helping context influences' could be used, and are these context influences different for different changes?
- Are some interventions 'context robust' and can succeed anywhere, or are some certain to fail wherever they are carried out?
- If so, is it the method of implementation which needs to be different at different sites in order to accomplish the same change difference? In other words, is the change difference valid but different sites more or less able to implement the change difference, and their different results due to greater or lesser implementation of the change difference? If so, does research need to measure the extent to which the change difference is achieved, and to describe the actions and methods used at the site for implementing these?
- How exactly and why do teams revise the intended change difference or implementation approach in response to results from PDSA (plan-do-study-act) testing? How much does PDSA testing cause a team to adjust the content and/or implementation to the local context? Are the better results of some teams because their use of PDSA leads them to adjust the change difference and/or implementation to respond to the context? Could teams be helped to be more effective by better guidance about using PDSA and about understanding context and implementation influences on the measures tracked through PDSA?

– For managers and implementing project teams, how should they decide whether or how to invest in a change? At present they are promised results if they make an evidence-based or 'proven change', but there is little guidance about implementation or about whether some features of their organisation will make it more or less difficult to make the change. The wiser decision makers carry out their own assessments, but the right research could help these assessments, and avoid expensive projects with poor results that damage QI credibility.

Part 1: Introduction, challenges, opportunities and concepts

2. Introduction

This paper aims to answer questions about the role of context in helping or hindering an improvement to healthcare services. Specifically:

- Are there some interventions which require certain conditions to be implemented, and if so what are these conditions?
- Can some interventions which improve quality in one service be reliably expected to improve quality in other services if they are implemented in the same way?
- Is there research which answers these questions, and if not, which type of research could answer these questions?
- What are the practical implications for funding initiatives and projects and in commissioning and using research?

This paper has both practical and research ambitions:

- The immediate practical ambitions are to provide organisations such as the Health Foundation with ways of assessing whether a research proposal is likely to either provide such evidence, or to provide useful information about the conditions under which change is most likely to result in an improvement.
- The larger practical ambitions are to provide decision makers with research-informed guidance to assess whether a change that successfully improved quality in another health service could result in similar improvements in their service, and the conditions they would need for this to happen.
- The research ambitions are to describe the type of research which could best provide such guidance and to present concepts which this author considers necessary to advance the science.

These are ambitions rather than objectives because it is unlikely that this limited paper can fully provide all the above, but the aim is to go as far as possible in providing for these needs.

3. Challenges and opportunities

3.1. Research answers raise more questions

There is some evidence that some quality improvements can be successful, but not always, and we do not know why.

The Health Foundation has invested large sums in assisting hospitals and other services to make quality improvements. Health Foundation programmes and projects in the NHS have usually been based on changes or methods that have some evidence of effectiveness elsewhere. The Foundation has also invested significant amounts in evaluations of these programmes. They have been open to, and led the development of, innovative approaches to evaluating them.

The Health Foundation's experience has been similar to the findings from the most studied and extensively carried out type of improvement, 'guideline implementation'. They have found that:

- implementation activities of all types frequently produce only moderate improvement

- there is great variation in success between sites
- implementation through multiple strategies at multiple levels appears to be the most effective approach[8,9]
- success is patchy, and we do not know why.

These conclusions are similar to those from most of the research into many types of change classified as 'QI' including large-scale programmes and regulation methods. Similar findings were reported in the review of evidence about 'quality tools' for WHO, in another WHO evidence review of approaches for improving hospital quality, and in other reviews of QI strategies.[10,11]

3.1.1. Similar changes in different organisations

The variation in results from improvement changes and our lack of understanding of what might explain this is most clear in some 'breakthrough collaboratives', or similar 'community of practice' improvement programmes. In some of these programmes, project teams from different sites seek to implement similar types of change in their home organisations. In some cases the difference is in the conditions under which each team tries to make the change, not in the change itself. It is possible that the difference is in the degree of implementation of the change, which in turn is affected by the conditions at each site. But research often does not provide enough details of the actions taken by each team so as to be able to assess why there is variation in team success. Is it because the changes they made were different? Is it because they all tried exactly the same change, but only some were able to implement it fully (implementation fidelity varied)? Is it because some kept refining the change and adapting to changing conditions? Others considering similar changes would be helped by answers to these questions.

3.2. Choices and opportunities for quality improvement organisations

The Health Foundation and others seeking to improve quality face a number of challenges and questions. Should funding be allocated to spreading only those changes which have been found effectively to improve quality? Should we wait for evidence about effectiveness in a number of organisations? How much and how strong does the evidence of effectiveness need to be and should these organisations at the same time fund research to find which organisations are successful and why? If so, which type of research is the most cost-effective for providing answers to these questions?

Or should the Foundation and others not worry about research evidence about effectiveness of changes, but rather fund changes that, at face value, look likely to produce results, or for which there is some reported practical experience of success from the field? If so, should they fund research into these to assess results more rigorously and also address questions about the conditions needed to get the results? Or should they do all of the above?

3.2.1. New thinking about quality improvement and research

These choices and opportunities for QI organisations need to be viewed in the light of changes in thinking about QI, QI research, and the funding of research. Worldwide, funders and governments are placing an increasing emphasis on translational research and on the later stages from research to clinical, management and policy practice. Closer links between researchers and practitioners is encouraged as this appears to be one way of speeding research into practice and ensuring more useful research which is used. In service delivery research and the QI field there is an increasing recognition of the limitations of experimental controlled trials but also of the poor generalisability of naturalistic studies which seek to understand context, and often of their unclear implications for action.

One example of the increasing interest in implementation and context is the high priority and funding given to the USA Agency for Healthcare Research and Quality (AHRQ) programme of research into this subject. A senior AHRQ officer recently presented the reasons for this. These related to implementing many parts of the USA healthcare reforms and progressing the 'last translation' (T3) in the USA National Institutes of Health (NIH) translational research programme to put research into practice. The presentation noted that a major limitation of the science at present was that the 'context of intervention/implementation processes' was 'not considered or considered post hoc, and descriptive/idiosyncratic', and that the 'effects of context/variation in context is not considered in assessing results and variation in results', as well as a 'lack of validated measures of contextual variables (leadership, culture, teamwork, resources)'.[12]

3.3. Why describe or study context?

To decide whether to carry out a quality improvement, policy makers or managers and clinicians say they need to know if the change contemplated is effective in improving outcomes. For some improvements, research provides knowledge with a high degree of certainty from using controlled trials, such as trials of whether antibiotic prophylaxis before surgery reduces infection.

But to make use of this 'efficacy knowledge', decision makers say they also need to know if it is likely to be effective in their setting, and how to implement it. This knowledge can come from number of controlled trials of the same intervention in different settings, and this can help decision makers to answer the 'will it work here?' question: it can help discover how 'context-sensitive' or 'robust' an improvement change is.

However, it is expensive and time-consuming to repeat traditional controlled trial efficacy research designs to explore effectiveness in different settings. It gives limited help with the 'how do we implement it?' question, which controlled trials are not designed to answer. Neither does this type of research answer the question about why an intervention varies by setting, because many features of the setting context are 'controlled out' in order to answer the efficacy question.

3.3.1. Practical help to reduce unnecessary suffering and costs

Research into, and theory about, context influences on improvement attempts could help speed up and spread improvements. First, it helps answer efficacy questions where controlled trials are not possible. In these studies, knowledge about context influences can help to assess how much the quality intervention and how much the context influences affected the outcomes. Second, it helps answer the 'will it work here?' and 'how do we implement it?' questions: a theory about context could show which context factors influenced implementation at the study site, and thus help others to assess how similar they are, and make their own judgment about likely implementation success. Such context theory allows generalisation to settings other than those in which the study was undertaken, through analytic rather than statistical generalisation.

In summary, more recognise the issues but few see exactly which way forward. Those who are convinced they do sometimes do not recognise the value of what has already been achieved in research. Alternative 'ethnographic', 'realist' and 'action research' approaches to date have not provided clear answers. The time and climate of opinion is right for taking calculated risks to advance research which shows promise for giving actionable answers to questions about context influence.

4. QI research – concepts

Conceptual distinctions and theory are the basis of science. This paper proposes two sets of conceptual distinctions. These are related to a simple theory about actions taken by actors at different levels of the health system to bring about changes in how other actors think or behave and about adaptive improvement or less directed change involving iterative implementation.

4.1. Concepts distinguishing actions from results

4.1.1. Actions, change differences and outcomes

The following distinguishes an **implementation action** from a **result** of the action. The latter is termed an **outcome** of the implementation action if causality can be proven, or is probable.

- Example: a physician prescribes an antibiotic, the patient takes it, and the medication enters the bloodstream (implementation actions). Research can discover if one outcome is a reduction in an infection in the patient.

A **change difference** is a difference in a phenomenon of interest between two time points, often referred to as the before/after difference. It may be a difference in a patient's physiology, in a provider's behaviour, or in how care is organised. Such change differences may be the outcome of an implementation action, or they may be caused by other influences. The term 'change difference' is used here because:

- 'Outcome' is often used to refer only to clinical outcomes for patients. QI is often concerned with intermediate outcomes, in the sense of whether providers change their behaviour, especially when such behaviour has been proved to result in better patient outcomes (eg hand washing). Using change difference rather than outcome invites a clarification of 'change difference to what or whom?'

- Change difference does not assume one thing caused the difference, whereas outcome assumes a difference 'coming out' of an action. Outcome originates from experimental medical research which focuses on one intervention, whereas this paper is about the possibility of many influences resulting in an observed change difference, even if the predominant influence was one collection of actions categorised as an intervention.
- Change difference emphasises difference between two times, and leaves open the likely further changes. 'Implementation' suggests an end point to the actions – that there is a point at which the change is 'fully implemented', whereas QI is continuous. New concepts and language – like 'change difference' and 'implementation actions' – are needed that do not carry over assumptions from controlled trials for QI and QI research to develop.

The term 'clinical intervention' will be used in this document to describe a treatment or care practice intended to alter a patient (eg their physiology, psychology or behaviour). A different clinical intervention may result in different patient outcomes. This change difference in treatment can be brought about intentionally by implementation actions. If research finds the different treatment or care practice results in better patient outcomes, then one way to improve quality of outcomes for more patients is to get clinicians and patients to use the proven better treatment or care practice. This is sometimes termed the 'evidence-based practice approach to quality improvement' (EBPQI). A 'clinical intervention improvement' is a new clinical intervention that has resulted in, or may result in, improved patient outcomes.

4.1.2. Separating the change difference from the implementation action

Most controlled trials focus on whether a different treatment or care practice produces different results. The method requires that the treatment or care practice is specified, does not change and is fully implemented. The trial does not evaluate how clinicians or patients are persuaded to use the different treatment or care practice. Implementation is ensured through actions to get clinicians and patients to change what they do. Most clinical trials separate a fixed and specified clinical intervention from its implementation.

Many QI changes aim to achieve a change difference in provider behaviour or in care organisation. The question of whether this change, if it is made, then results in improved patient outcomes is a different and sometimes second question. This is especially so if the intended change difference is to use a new proven treatment, practice or organisation of care that is known to be effective. In these cases the improved patient outcomes are likely to result from implementation actions which effectively change provider behaviour to use the proven treatment or practice, or effectively change the organisation of care which is already proven to be effective.

One example of an intended change difference that could improve patient outcomes is more appropriate prescribing of antibiotics by physicians. There are different methods for implementing this change difference in provider behaviour: training, computer reminders, performance feedback, prescribing budgets, or all of these together. QI research is often interested in which implementation methods are more effective for achieving the desired change difference in provider behaviour. And it is here that the interest in the role of context arises, in whether some factors help or hinder the implementation actions, for example, the availability of finance and credits for training.

4.1.3. Many QI interventions are not fixed and prescribed

Some QI interventions start out with a broad concept of a change difference to be made in organisation of care and test different versions for implementability and for results. For example:

- After testing several models of chronic disease management and care coordination, Sutter arrived at the following approach.[13] The Sutter Care Coordination Program (SCCP) consists of two main elements. The primary element is a team of registered nurses (RNs), medical social workers and general healthcare coordinators that works with patients and their families/caregivers to keep those with multiple chronic conditions as healthy as possible through: coordination of care; patient education; referral to appropriate medical, psychosocial, and community services; and ongoing monitoring and troubleshooting as needed. The team is supplemented, when appropriate, by specific disease management programmes for those patients with heart disease, diabetes and/or asthma, as well as those in need of anticoagulation management.

One view is that we have no idea whether this is more or less effective or costly than the old approach. Another view is that if implementers did practical research or QI testing then there was some data to guide them which suggests the new model is effective. Another is that the various models of chronic disease management and care coordination are not tightly specified, the evidence of their effectiveness is inconclusive, and even if there was good evidence, it may not apply in the local situation and would need testing.

For improvements where the change difference has not been evaluated in a controlled trial, or where the change difference is altered with feedback from testing, then evaluators have more interest in assessing ultimate outcomes for patients. These improvements are typically those difficult to evaluate in controlled trials, and which are often changes to organisation of care.

4.1.4. Summary

Clinical interventions are treatments for patients.

- Medical research trial design usually focuses on the efficacy of the intervention and is not concerned with implementation – how providers and patients in the trial are persuaded to change what they do so as to use a new clinical intervention.

Improvements to patient outcomes can come from introducing a new proven clinical intervention.

Quality improvement interventions are actions to change clinician behaviour or care organisation.

- The intended change difference is not to a patient but to clinician behaviour or care organisation.

Some quality improvement interventions aim to **change clinician behaviour** to use proven treatments appropriately with patients.

- The change difference to be achieved in clinician behaviour may be tightly specified with little latitude so as to replicate the intervention proved in clinical research. But there may be many ways to achieve this change difference in clinician behaviour by using different implementation actions, and some actions may be more suited to some contexts and settings than others (eg old IT systems may not allow for adding prompts or reminders).

Some QI projects use PDSA testing and then the project team revises their implementation actions to try to get a greater change difference, for example by providing more training. They sometimes also revise the change difference to clinician behaviour or care organisation they are aiming for, possibly as a result of feedback from those who are trying to change, for example because they say the full change will take too much of their time away from direct patient care.

Some QI interventions start out with a broad concept of a change difference to be made to organisation of care, and test different versions of this for implementability and for results. There is latitude in the change difference and in the way this is implemented – neither are fixed. Often a PDSA testing method is used both to help guide the implementation method and shape the change difference being made.

4.2. Concepts of types of improvement

It is also important to distinguish interventions carried out by actors at different levels of the health system that have different targets to be changed. It is possible that different implementation methods are needed to carry out these different changes successfully. In addition, different context factors are likely to influence the ease and success of implementation, and may be more or less influential at different phases of implementation, in selling, starting, sustaining, and spreading. In an earlier article, I distinguish different interventions as follows.[2]

- **Clinical intervention improvement**: a change in how patients are treated, with patients as the target of the new treatment or practice. These changes may be described either as objectives to be achieved or methods for achieving them, and as simple (eg antibiotic prophylaxis before surgery or hand washing between patients) or complex (eg ventilator-associated pneumonia or central line-associated bloodstream infection prevention bundles).
  - Many of these interventions can be standardised and controlled in their implementation in an experimental trial.
  - The immediate context of the intervention is the patient's physiology, and this can be controlled in experimental trials by selecting patients most likely to be sensitive to the intervention (with specific disease, body mass, age, sex).
  - The wider context is the social situation of the patient, which may help or hinder their compliance with the treatment and their attitude to the treatment – these are 'controlled out' in a trial.

- **Change to individual provider behaviour**, thinking or other provider characteristic.
  - Often a change difference is that the provider uses a treatment or care practice more appropriately, for example hand washing between touching patients. Different methods can be used to achieve this same change difference in provider behaviour.
- **Change to service delivery organisation**: a change to the work or relationships of care providers (eg the change difference is new process steps, new teamwork arrangements, or use of a chronic care model).
  - A few of these change differences can be standardised and controlled in an experimental trial; many cannot. Indeed it is possible that broad change differences need to be adapted by local implementers. The context of the intervention is the broader organisation structure, culture and systems, which are difficult to control in experimental trials by selecting organisations.
- **Change to service infrastructure**: a generic change to the support systems, structure or physical environment for service delivery (eg non-slip floor mats, ICT system, electronic medical records, computer decision support, new HR system or peer review process). These may help implement changes to provider behaviour or service delivery organisation and may be viewed as necessary local contexts for successful implementation of these changes.
- **Implementation strategy or method**: this can be used to carry out any of the above. A method or approach involves the actions used to enable, encourage or require organisations to introduce a change, or to enable individual providers (or patients) to change their behaviour (eg training, financial incentives, penalties, campaign approach, collaborative, network or community of practice spread approach).
- **National programme or regulation**: these aim to achieve a change difference in how organisations function or providers behave (eg accreditation or inspection programme, new pay for quality or no pay for never events, national 100k lives campaign). Some define these as implementation strategies.

Thus, a type of national programme will use a type of implementation strategy to encourage a particular before/after change. The change may be to get organisations to make an intervention to their infrastructure (eg introduce computer decision support for X), or to introduce a new form of service delivery in one type of service (eg dedicated stroke service, critical care outreach team), or change provider behaviour, or all of these.

Changes at higher levels set the context for and make easier or more difficult changes at lower levels. For example, a national regulation may be introduced allowing item payments for different services to be 'bundled', and this creates incentives for these organisations to collaborate. This makes it easier to establish a chronic care model (intervention to service delivery organisation), but then an implementation strategy would be needed locally to make the changes to different services and provider behaviour to set up this model.

4.3. Conclusions to Part 1

Projects in different places implementing the same change appear to get different results. We are not sure why, and it may be because:

- the data are unreliable (the results in fact are more similar, or more different, than shown by the data from the projects)
- different clinical interventions were made (but we have no details)
- the same clinical interventions were made but were implemented differently (but we have no details)
- the initial change difference was revised as a result of PDSA testing (but we have no details – some teams may have done this, and more than one PDSA cycle with significant revisions; others may have not used PDSA)
- something other than the clinical intervention or implementation strategy caused the results.

The practical implications are that there is no good evidence on which to base choices about types of changes or projects to invest in, despite the many years' experience and effort spent on evaluation.

4.3.1. New questions

Using the concepts above, the practical questions are clearer:

- If success depends as much on where a change is made as it does on the type of change, how should sites be selected or helped to assess if they have the conditions for success?
- Which evidence or theories about 'helping context influences' could be used, and are these context influences different for different changes?
- Are some changes 'context robust', and can succeed, or are certain to fail, wherever they are carried out?
- If so, is it the method of implementation which needs to be different at different sites in order to accomplish the same change difference? In other words, is the change difference proven, but different sites were more or less able to implement it, and their different results were due to greater or lesser implementation of the change? If so, does research need to measure the extent to which the change is achieved, and to describe the actions and methods used at the site for implementing the change?
- How exactly and why do teams revise the initial intended change difference or implementation in response to results from PDSA testing? How much does PDSA testing cause a team to adjust the change and/or implementation to the local context? Are the better results of some teams because their use of PDSA leads them to adjust the change and/or implementation to respond to the context? Could teams be helped to be more effective by better guidance about using PDSA and about understanding context and implementation influences on the measures tracked through PDSA?
- For managers and implementing project teams, how should they decide whether or how to invest in a change? At present they are promised results if they make an evidence-based or proven change, but there is little guidance about implementation, or about whether some features of their organisation will make it more or less difficult to make the change. The wiser decision makers carry out their own assessments, but the right research could help these assessments, and avoid expensive projects with poor results that damage QI credibility.

Part 2: Toward solutions

Introduction to Part 2

This section considers the answers research can give to the questions listed in the introduction. The answers draw on three sources: empirical evidence from research into quality improvement, the author's and others' experience in planning, carrying out and evaluating quality projects, and theories relevant to understanding context.

As this is a paper, and the Health Foundation request was for a short, clear summary with practical recommendations, the sections below do not give details but outline the main points and list studies that give details.

Finding the evidence in the literature

Few systematic reviews have been done on the role of context on QI implementation or results. Few empirical studies have focused on and been designed to assess or understand the role of context on QI. The evidence is usually part of a larger study, and difficult to find without reading many studies – some studies report on context as one part of a study designed primarily to investigate other issues.

5. The evidence

Is there evidence that any aspects of context affect implementation or outcomes of any quality improvements? If so which aspects, how does this influence work, are some aspects much more important than others, and are some needed in combination or do they work separately?

The following summarises the main evidence relevant to these questions.

5.1. Classifications of more or less context-sensitive QIIs

There is no taxonomy or classification of quality improvement interventions (QIIs) in terms of which are more or less sensitive to context (which relates to the question of which are more or less generalisable or might require more or less local adaptation).

There is no grouping of QIIs to test the hypothesis that one cluster of context influences is most important for those in the grouping, and this cluster is different to the cluster of context influences that are important for another grouping. It is possible that the following classifications of QIIs could provide a starting point for such an analysis:

- Shojania et al[14] classify QIIs as: provider reminder systems; facilitated relay of clinical data to providers; audit and feedback; provider education; patient education; promotion of self-management; patient reminders; organisational change; financial, regulatory or legislative incentives.
- Cochrane EPOC classification:[15] professional interventions; financial interventions; provider interventions; patient interventions; organisational interventions; structural interventions; regulatory interventions.
- The levels framework described earlier in this paper (section 4.2), with, for each level, three subgroups of simple, complex and adaptive change.

5.2. Evidence from reviews of research

The only substantive review and study undertaken to date is the Shekelle et al[1] study for the Agency for Healthcare Research and Quality (AHRQ), part of which was summarised in a 2011 review by this author.[2] Five safety interventions were selected, and a search, summary and assessment made of the evidence of any context influence over implementation success or results. See Table 1 for a summary of the findings.

This review found many other discussions and studies which commented on the role of context but did not provide empirical data showing evidence of impact. Just one example is a paper surveying implementers to find out which context barriers and facilitators they experienced when implementing interventions to improve depression care in primary care settings.[17]

The summary of findings from this review about context influences in five safety improvement interventions was as follows:

- There is some evidence that context factors influence implementation and that these factors vary between organisations.
- There is limited research on the subject, and limited evidence about context in the research that had been carried out.
- There is little evidence from controlled experimental studies, possibly because they are designed to exclude context factors rather than examine their influence.
- There is some evidence from a few studies using measures of context, and from qualitative research. This showed influences at different levels of the heath system which helped and hindered the implementation of five selected safety improvements, but the evidence was not strong or very specific.

A summary of the study concluded:

> *'Patient safety could be speeded and costs saved with a recognition that many "interventions" are not single time changes but evolve over time in interaction with their context – perhaps better described as "inno-volutions". Studies would be more useful to implementers ... if they defined more clearly what is the intervention and what is not ("context"), and which aspects of context were or may be important to implementation and outcome effectiveness.'*[16]

5.2.1. Evidence of different context influences for different interventions

The above review was of context influences of five very different safety interventions. It showed some (weak) evidence that different context factors were important for different interventions.

One infrastructure intervention which can improve quality is an electronic medical record (EMR), and this is an example of a different type of quality intervention. There is some evidence that different context factors are important for EMR implementation.

One implementation study reported this evidence, and is also an example of case study research for studying the subject.[18] Also, it did not make a sharp separation between the EMR 'intervention' and local context. It used theory from previous research to test hypotheses on data from two case studies about which factors were important for success (see Table 2).

Table 1: Summary of findings from reviewing evidence presented in studies of five safety improvements

	Falls in institutions	Medication reconciliation toll and process redesign	Prevention of catheter-related bloodstream infections (CRBSI)	Universal protocol for wrong site surgery	Computer physician order entry (CPOE) and computer decision support system (CDSS)
Number of studies found reporting context	Two studies (7) (e.g. 8)	Nine studies	Five studies (11, 12, 13, 14, 16)	Two studies (17, 18)	Twenty-three papers (19)
Context factors reported to influence implementation or effectiveness	No strong evidence for or against context factors either helping or hindering implementation of falls interventions in institutions	'Blocking functions' in electronic systems to increase compliance with medication reconciliation steps (10)	Leadership involvement, teamwork, nursing staff empowerment and interdisciplinary rounds, and training resources (11) Barriers: insufficient time or resources, organisational and regulatory barriers, and lack of a quality improvement infrastructure within the organisation (12) Involvement of hospital leadership, project leadership, quality improvement experience, education, and motivation (13). Hand washing campaigns (14). Safety culture (16) Previous education, teamwork and culture interventions, and leadership, feedback and support of outside quality improvement expertise (16)	Participation of the surgeon in preoperative verification, participation of all surgical team members in the 'time out'. and the surgeon explicitly empowering team members to speak up if concerned and acknowledging concerns when expressed (17). Strong correlation between technical error and teamwork failures (18).	Regulation (100% of the 23 papers reviewed), external incentives (100%), organisational size and type (100%), teamwork (74%), leadership (30%), culture (9%), training (61%), internal incentives (52%), audit and feedback (35%), and quality improvement consultants (13%)
Other relevant evidence reported	Limited evidence that unit leadership may be important for implementing falls interventions successfully, and a positive safety culture is a helpful context factor, the absence of which can influence implementation (8)	Only a general description of context factors given in some other studies	The intervention may also change context (safety culture) (10)	Several risk factors differentiated near misses from actual occurrences – reported many contexts that appear related (17)	Most important context factors are related to the implementation process or the technical features of the CPOE systems (19)

Source: Øvretveit J, Shekelle P, Dy S, McDonald K, Hempel S, Pronovost P, et al. (2011) How does context affect interventions to improve patient safety? *BMJ Qual Saf* 2011;20(7):604-610.[16] p606.

References cited are given in source article.

Table 2: Presence of factors identified in previous research as important for successful EMR implementation

Factor important for implementation	Kaiser	Karolinska
The EMR system		
Ease of navigation, efficiency in use and accessibility	No	Yes
Physician acceptance and implementer's responsiveness to concerns	No	Yes
Absence of system failures	No	Yes
No conflicting suitability (managerial/ clinical)	No	Yes
Relative advantage (perceived as better)	Yes (in theory) No (in practice)	Yes (in theory) Yes (in practice)
Compatibility (consistent with values and needs)	No (EMR felt by physicians to be chosen for business needs not clinical work needs)	Yes
Complexity (ease of understanding and use)	No	Yes
Trialability (possibility of experimentation)	Little (system not fully developed). Pilot was a different system and setting to the implementation site	Yes
Observability (visible examples elsewhere)	Yes (in theory) No (in practice, apart from a few personnel)	Yes (at the other hospital site and pilot department)
Implementation process		
User involvement in selection and development	No	Yes
Education provided at the right times, amount and quality	Yes	Yes
Previous computer or EMR experience	Little	Yes
Leadership		
Strong management support	Yes	Yes
Physician champion	No	Yes
Resources		
Adequate people and financial resources	Yes	Yes
Organisation culture and climate		
Familiarity with and capacity for change ('change readiness')	No	Yes

Source: Øvretveit J, Scott T, Rundall T, Shortell S. Implementation of electronic medical records in hospitals: two case studies. *Health Policy*. 84:2, 181-190, 2007.[18]

5.3. Measures of context

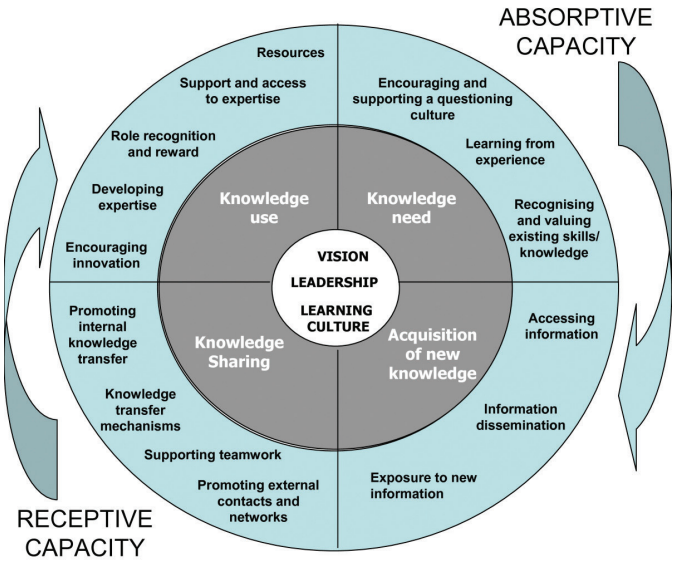
There are no systematic reviews of methods for studying context influences in QIIs. The two most relevant overviews to date are:

- the French et al study,[3] which reviewed instruments that could be used to 'measure the organisational context for evidence-based practice (EBP) in healthcare'
- the Shekelle et al study,[1] one aspect of which was to describe measuring instruments that could be used to assess the influence of different aspects of context on safety interventions.

5.3.1. French et al[3] overview of context measures for evidence-based practice (EBP) studies

This study is of interest because it viewed the implementation of evidence as a socially mediated process. In this light, it considered the organisational context of EBP from four knowledge fields which had examined the social aspects of implementation, and which are often not considered in quality improvement: research utilisation (RU), research activity (RA), knowledge management (KM), and organisational learning (OL). The aim was to produce a synthesis measurement tool from tools used in these domains. Thirty measurement tools were identified and 18 tools from the four domains were selected. The synthesis framework covered seven categories relating to three core organisational attributes (vision, leadership and a learning culture) and four stages of knowledge management (knowledge need, acquisition of new knowledge, knowledge sharing and knowledge use). The framework is summarised in Figure 1 below.

Figure 1: Model of categories and organisational attributes



Source: French et al. What can management theories offer evidence-based practice? A comparative analysis of measurement tools for organisational context. *Implementation Science* 2009 4:28.[3]

5.3.2. Shekelle et al[1] listing of measures of context for patient safety

The conclusion of this study was that:

> *'The evidence base is too thin and agreement among experts insufficient to make strong recommendations about which measures are preferred for assessments of patient safety culture, teamwork and leadership, suggesting the need for ongoing dialogue among researchers.*
>
> *However, for patient safety culture, the most support was given to the various AHRQ surveys relevant to this topic, plus the Patient Safety Climate[19,20] and the Safety Climate Survey.[20]*
>
> *For teamwork, the most support was given to the ICU Nurse–Physician Questionnaire:[21] no other measure received more than half the votes of respondents.*
>
> *For leadership, the measures receiving the most support were the ICU Nurse–Physician Questionnaire,[21] the Leadership Practice Inventory,[22] and the Practice Environment Scale.[23]*
>
> *No other measure received more than half the votes of respondents.'*

5.3.3. Probably the single best validated instrument for QI context assessment for the UK NHS to date

This is the Context Assessment Index (CAI),[4] which is a 37-item instrument based on the PARiHS model. It was tested through principal components analysis, exploratory factor analysis and expert panel feedback with tests for psychometric properties of internal consistency and test–retest scores, and assessed usability with telephone interviews with expert nurses. The report on the measure 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'.

6. The theories

Are there evidence-based theories or models about which aspects of context influence which quality improvement changes, and how they do so?

In the absence of evidence, experience or evidence-based theories, are there theories which conceptualise the role of context and/or how it may work, and which might be useful to decision makers or for deciding which data to gather about context in research?

6.1. Evidence-based theories

6.1.1. Safety improvements

For implementation of safety improvement, the only framework describing context influences which gives some evidence of their role in implementation was described by Shekelle et al.[1] This grouped context factors into four domains:

a. Structural organizational characteristics (such as size, location, financial status, existing quality and safety infrastructure).

b. External factors (such as regulatory requirements, the presence in the external environment of payments or penalties such as pay-for-performance or public reporting, national patient safety campaigns or collaboratives, or local sentinel patient safety events).

c. Patient safety culture (not to be confused with the larger organizational culture), teamwork, and leadership at the level of the unit.

d. Availability of implementation and management tools (such as staff education and training, presence of dedicated time for training, use of internal audit-and-feedback, presence of internal or external individuals responsible for the implementation, or degree of local tailoring of any intervention).[1]

The authors noted that 'while all four contextual domains may not apply equally to all patient safety practice implementations, evaluators should consider all as potentially applicable'.

6.2. Other theories

There are many models, frameworks and theories which describe context influences over implementation of different types of change and interventions, some of which are similar to certain types of QI. There are different views about how much each is based on research, and many summarise consultancy experience.

These frameworks may be classified into:

- strength of evidence or research basis for the framework (often more for the phases of change than for the context influences)
- most similar to or most relevant for understanding context in a certain type of QI.

A generic change framework with a good research basis, which shows certain context influences over many types of change implemented in healthcare (eg Gustafson[24]) may be less relevant to a particular improvement intervention (eg implementing guidelines in primary care) than a framework based on consultancy and QI project experience carried out on this type of improvement intervention (eg some frameworks by Solberg[6]).

This author's view is that generic change frameworks are only useful if a specific framework cannot be found which is about a change similar to the improvement to be studied.

6.2.1. Frameworks

A framework which best combines a basis in research and relevance to clinical level QI and provider behaviour change is one version of the many PARiHS models for examining implementation of evidence-based practice. The part highlighting context influences in the Rycroft-Malone et al[25] version is shown in Figure 2 overleaf.

Figure 2: Context influences

Context	**Receptive context**	Physical Social Cultural Structural System Professional/social networks } boundaries clearly defined and acknowledged Appropriate and transparent decision making processes Power and authority processes Resources – human, financial, equipment – allocated and Information and feedback Initiative fits with strategic goals and is a key practice/patient issue Receptiveness to change
	Culture	Able to define culture(s) in terms of prevailing values/beliefs Values individual staff and clients Promotes learning organisation Consistency of individuals role/experience to value: – relationship with others – teamwork – power and authority – rewards/recognition
	Leadership	Transformational leadership Role clarity Effective teamwork Effective organisational structures Democratic inclusive decision making processes Enabling/empowering approach to teaching/learning/managing

Source: Rycroft-Malone J, Harvey G, Seers K, Kitson A, McCormack B, Titchen A. An exploration of the factors that influence the implementation of evidence into practice. *J Clin Nurs* 2004;13(8):913-924.[25] p922

This model is more elaborated than most, provides more detail about different aspects of context which is useful for building a data gathering framework, and also has been operationalised in survey instruments.

The Stetler et al[26] framework also used a version of the Pettigrew et al[27] model to investigate context in the implementation of evidence-based practice at the bedside, and had context as one of its three domains: why (context of change); what (content changed); how (process of change). The context section is shown in Table 3 overleaf.

Damschroder et al[5] carried out a synthesis of other frameworks and studies and give a 'consolidated framework' on how to implement health services research findings into practice. This also provides a basis for studying context influences.

Table 3: Relationships between Pettigrew et al framework and data collection approaches: context

'Pettigrew' essential dimensions/questions	Signs and symptoms/ characteristics of receptive contexts	Data collection approaches/ tools (across characteristics)	Level of participants	Specific question examples (Will always explore both targeted or single EBP change and broad EBP change across a case's timeline)
WHY (context, relative to motivation for strategic change towards EBP): • *Why do nursing departments/ directorates, and their embedded levels, wish to/implement EBP?*	• Environmental pressure • Supportive organisational culture • Key people leading change	1. Individual interviews and Focus groups: a. Motivation b. Driving or restraining forces 2. Surveys a. Goh's Org. [58] Learning Survey b. MLQ Leadership Tool [59] c. NWI [60] 3. Document review	1. Unit leaders 2. Unit staff 3. Hospital leadership 4. Relevant project or committee staff	1. What was the motivation for change: 'Why did unit/hospital wish to implement EBP (specific project; general approach)? 2. What enabling/ driving or restraining/ hindering forces over time influenced that motivation (internal and external environment)?

Source: Stetler CB, Ritchie J, Rycroft-Malone J, Schultz A, Charns M. Improving quality of care through routine, successful implementation of evidence-based practice at the bedside: an organizational case study protocol using the Pettigrew and Whipp model of strategic change. *Implement Sci* 2007;2:3.[26]

7. Future research

The summary above reveals a lack of empirical research and evidence about the role of context, and a limited examination in research about the generalisability of QIIs and about the extent to which they can be adapted. It is possible that a more extensive search and review would discover more evidence, but this author's experience in reviewing the evidence as part of the Shekelle et al[1] study of this subject suggests that this is not likely.

In the light of this, which research approaches and designs might be used to study the role of context in different types of QI, and build an evidence base for practical decisions and for the science of improvement? The following considers the strengths and limitations of different approaches and research designs for studying context.

7.1. How to study context?

Randomised controlled trials assume that context could influence outcomes. The design aims to exclude many context influences by using comparison groups that are the same, apart from the fact that they do not get the intervention. However, if control is not possible, or if the aim is to discover which aspects of context influence implementation and outcomes, which research designs and methods are best?

7.1.1. Context in uncontrolled experimental trials and PDSA tests

Collecting and reporting data about context is an added burden to research and may not be possible for simple before/after PDSA practitioner reports, although two case report repositories do provide some of this 'background'. Any such data collection in these designs needs to be focused on documenting the aspects most likely to affect the outcomes, and analysis focused on assessing their relative influence. Reviews of research to discover which aspects have been reported previously would help researchers and practitioners to select which aspects to collect data about, and how to collect the data. For example, effectiveness studies of health information technology have found aspects of the host organisation's staffing, size, previous experience and financing to be important.

Context in 'naturalistic studies'

This is a broad category of designs for studying QI change in natural settings, and more suited to developing theory about context. Some designs describe implementation only (eg case study) but some may also assess intermediate outcomes (eg some types of programme evaluation). Such designs are more often used for studies of large-scale programmes, policies or regulatory changes than for studying smaller projects, although many such large-scale changes include local projects. Two more recent examples are Benn et al's mixed method study of a UK patient safety initiative[28] and Greenhalgh et al's study of a large-scale complex improvement programme in London.[29]

One approach to developing a theory of context is to collect a cross-section of informants' views about aspects of context which they suggest were important at different stages of implementation. Validity can be enhanced by selecting a sample of informants from different organisational levels and perspectives, who are knowledgeable about the change and may be able to cite evidence to support their insights. Observers' views can then be cross-checked against documentary or other data to assess the influence of context factors repeatedly mentioned, thus building inductively an understanding of context influences. However, informants may not be aware of some influences, and their 'observer theories' need to be supplemented with scientific theory, which may direct attention to other data to test hypotheses about possible influences. This approach starts with a model or theory, preferably based on previous research into similar QI changes and suggesting aspects of context that were important. This can then be used to plan data collection about these aspects of context or specify these as hypotheses to be tested.

One of the challenges of this type of research is to capture changes over time and the dynamics of intervention condition interactions. To do so requires documenting how any influencing conditions change over the period of implementation (eg a senior manager leaves who was supportive of the change, or there are sudden cuts to budget).

There are also challenges in understanding exactly how these changes influence the QI implementation. Generalisation in these types of studies could be helped by better understanding exactly how a condition influence interacts with parts of the intervention. For example, why what a leader does affects how personnel respond to training about use of a checklist. This approach moves towards examining how an idea is adapted and evolves in a setting through 'enabled adaptive change'. In some action research or collaborative research studies, this may involve the researchers contributing to the change, for example by giving feedback to implementers.

These type of studies can be enhanced by specifying the 'change theory' of the implementers – the assumptions about which actions lead to which results through which steps – or by defining the researchers' 'programme theory' before and after data gathering. These 'theories' could also include ideas about which aspects of context help and hinder the implementation. It is also possible that pragmatic testing using PDSA cycles would be enhanced by implementers stating their assumptions about the conditions they need and the steps through which changes might affect outcomes. By making explicit their assumptions (theories = T) before testing, and revising these after testing (T–PDSA–T), improvers could learn not just whether a change affected outcomes, but why.

7.1.2. Realist evaluation

Realist evaluations identify context-mechanism-outcome (CMO) configurations in complex interventions in different settings, and aim to establish 'what works for whom in which settings'. The assumption, based on some evidence from education and criminal programmes, is that in social interventions outcomes are a function of the 'mechanism' through which the intervention works, and the context (which includes multiple levels) in which it is applied: there are different effects in different settings even if the same intervention is used.

The aim is not only to describe the intervention but also to clarify the 'generative mechanism': the essential idea or 'active ingredient' which is the basis for the intervention (eg performance feedback). Using this approach, superficially different interventions can be grouped and compared through their underlying logic. Another aim is to examine how much and how the mechanism depends on or interacts with the context to produce different effects.

The aims are to use a programme model or theory (sometimes called a logic model) to select programmes and test hypotheses about CMO configuration for one intervention in one setting, and then to study 'similar' programmes in other settings to examine how the interactions between C, M and O vary. Interventions are viewed as 'theories in practice'. Discovering poor or no outcomes from a similar intervention in a different setting is an opportunity to refine the logic model of the CMO configuration.

This approach thus emphasises studying in a variety of situations the mechanism which is thought to generate certain results rather than one intervention at one site. It is similar to a case study approach in describing and understanding outcomes as the product of an intervention implementation in context, but differs from some case study evaluations in emphasising the logic model testing and the comparison between different implementations, as well as elucidating the essential feature of the mechanism to allow comparison of a variety of superficially different changes.

A possible limitation of the realist approach for studying QI changes is that the concepts of context, mechanism and outcome are not well defined and only illustrated in a few studies. For example, it is unclear exactly how 'mechanism' is elucidated and how this high level conceptualisation is created. The realist approach does not just describe the intervention components or implementing actions, but how the actions work ('generative mechanism'); however, this is different from their interaction with context.

7.2. Improving the research base for QI

What could best help develop more knowledge about how context influences implementation and outcomes? Two research questions to be addressed are:

- which specific details about context influences should be collected?
- do different influences affect different types of improvement?

Is, for example, a strong safety culture a much stronger condition for improving hand hygiene interventions than for medication reconciliation or computer decision support for prescribing?

7.2.1. Learn from other disciplines

A number of disciplines have developed methods to study implementation, including public health, sociology, educational studies, business studies, programme evaluation, and implementation and innovation science. Some approaches draw on critical realist philosophy which emphasises the study of mechanisms which trigger effects under certain circumstances rather than using other types of cause–effect understanding.

These bodies of knowledge provide methods and frameworks for the description of interventions' actions, and also seek to assess intermediate changes to behaviour or organisation, or even final outcomes using a theory about how the actions taken then influence outcomes. Such methods are being applied to understand improvements in healthcare. However, research including context factors in these 'causal' theories is at the early stages.

7.2.2. More specific assessments of context are required

Research would be more useful and cumulative if it moved beyond general statements about variations in implementation and outcomes being due to 'leadership' or 'culture'. More specific data are needed about, for example, which aspects of leadership by which leaders are important for which QI changes and how what leaders do has this influence. In the case of culture as a context factor, there are different data gathering instruments which can be used. Helfrich et al[7] describe a method to assess organisational readiness to change, which may be an important context factor. Some context factors are difficult to operationalise as measures, but the discipline of seeking measures or defining concepts more precisely is necessary for data gathering and for understanding the influence of these factors.

There are frameworks and research from different knowledge domains which can provide a starting point for researchers, ideally drawing on previous research into changes similar to the particular QI being studied. These frameworks often distinguish context influences external to the implementing organisation, and those internal to it, or separate context influences which originate at different organisational levels. French et al[3] provide a useful general overview of frameworks from different knowledge domains, and Rycroft-Malone[25] gives a study protocol for studying context. Context factors found to affect implementation of evidence-based practices were summarised earlier in this paper.

7.2.3. Categorise QI changes according to the impact of context

It is possible that the implementation of some types of QI depends more on context than others. Further, that similar context factors are important for certain groupings of QI (eg the groupings proposed by Shojania et al[14]). For example, equipment or automation changes may form one grouping of improvements, with computer-based changes a subgrouping. Taxonomies of improvement interventions and of context influences are underdeveloped and the lack of a common language is hindering scientific progress. At present researchers have little guidance from previous research about which aspects of context to document, and there is possibly an assumption that all types of QI are equally affected by the same types of context influences. Theoretical research is needed to produce groupings of QI interventions according to which aspects of context are important for their implementation and which are different from other groupings of QI. The synthesis of implementation frameworks by Damschroder et al[5] might provide one starting point. Such a categorisation could then be the basis for specifying the context elements for reporting for uncontrolled studies (eg of the SQUIRE (Standards for Quality Improvement Reporting Excellence) reporting guidance).

7.2.4. Interventions, multiple component changes, or system changes?

Quality improvements have traditionally been conceptualised as interventions – discrete changes separated from their surroundings – in order to assess whether they cause other changes in outcome variables such as patient outcomes. If the change is an improvement, the assumption is they can be repeated elsewhere to cause the same outcome changes. Some limitations in this way of understanding QI have been noted when applied to complex interventions such as QI 'bundles'. If an intervention is separated conceptually from its surroundings, then one research agenda is to explore how the intervention changes context, as well as vice versa.

Another research agenda is not to conceptualise such a sharp separation, and to view improvement less as a specific change but more as an interdependent set of actions that result in many types of changes, which in turn may result in better patient outcomes. Including context in understanding implementation and in improvement theory can advance improvement science and practice. It allows exploration of whether and how aligned changes at different levels may result, through complex influences, in better outcomes, and how these can be sustained. It moves from cause–effect understanding to conditional attribution, which allows qualified generalisations by discovering which conditions were necessary for the improvement to be carried out and its effects. This in turn allows decision makers to better assess likely results locally and how to adapt the change.

7.3. Summary

In QI, nothing ever happens for one reason or cause. It would be convenient to package changes as a QI that could work anywhere, like an effective drug. But a number of factors influence the implementability and success of social interventions to change social systems. Some useful knowledge can be generated using medical treatment research designs like RCTs, some using well documented pragmatic PDSA testing, but some also requires non-experimental naturalistic methods more often used in the social sciences. An understanding of the conditions influencing an improvement in one place is important for spreading this change if it proves effective in this place. Such an understanding can be advanced by better descriptions of implementation and likely significant context factors, and also by developing theory in different ways about how specific changes are best implemented in different environments, and how they work through a pathway of influences to change outcomes. More improvement research could usefully aim for 'conditional attribution' explanations and 'qualified generalisations': showing the conditions under which improvement changes are likely to be successful, and thus integrating, rather than trading off, internal and external validity.

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Perspectives on context

The problem of context in quality improvement

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Contents

The problem of context in quality improvement

1. Introduction

Though (formal) quality improvement in healthcare has only a brief history, it is history littered with examples of showpiece programmes that do not consistently manage to export their success once transplanted beyond the home soil of early iterations,[1] or that demonstrate startling variability in their impact in apparently similar settings. Quality improvement (QI) collaboratives – involving multidisciplinary teams working across departments or organisations to address quality issues – are, despite their popularity, a good example of both of these effects.[2] It has been estimated that only 30% of organisations involved in collaboratives may achieve 'significant improvements' and that another 30% may drop out before the end.[3] One of the explanations most often advanced to explain the differential impact of QI efforts is that of context.[4,5] Jonathan Lomas[6] goes as far as suggesting that the 'overriding influence of context' may go a long way towards explaining why there remains no clear advice on how to go about improving quality in healthcare. But a review of strategies for improving quality and safety in healthcare has deplored the absence of attention to context and implementation factors.[7]

The term 'context' has its etymological roots in the Latin *contextus*, meaning 'joining together'. Understanding what happens when a particular QI intervention is joined together with a team, organisation, or health system, through multiple interacting contextual layers, is a challenge both for science and for practice and policy. Though the need for serious attention to questions of context has become increasingly well recognised across a range of disciplines, including politics,[8,9] only latterly has the context sensitivity of many QI initiatives in healthcare become properly recognised.[10,11] The challenge now is twofold: how to study interactions between contexts and interventions to develop a more credible science of quality improvement, and how to deal with contextual effects in implementing quality improvement interventions. But how we should structure thinking about context remains a stubborn puzzle.

In this paper, I want to make some proposals that may be helpful in moving the field forward. I will suggest that no account of context can be decoupled from a broader understanding of causation, and that our view of causation must include both assessment of whether inputs and outputs of interventions are correlated, **and why** such a correlation occurs. I will suggest that QI studies have much to learn from the clinical sciences, but I will also argue that current clinical science methodologies are not enough to gain a proper understanding of QI. Along the way, I will take issue with various arguments put forward by the advocates for 'realist evaluation', suggesting that some of these arguments offer little that is distinctive and that others are mistaken. In particular, I will propose that while the need to construct explanatory accounts of interventions (or identify the causal mechanisms, as realists have it) is essential, abandoning a correlational approach in the process is reckless and misguided. I will suggest that a focus on **practical wisdom** and a blend of methods from the clinical and social sciences is likely to offer the best way forward.

2. Context and causality

Consideration of context goes hand in hand with the problem of establishing causality. In clinical epidemiology, the standard approach to determining causality is based on statistical reasoning. Determining whether an intervention is responsible for an observed effect is worked out through **correlational** logic. Studies using this approach are concerned with assessing whether, **on average**, the independent variable (the intervention) has made a measurable difference to the dependent variables (the outcomes). This can be done by following those that received the intervention over time, but it can be hard to rule out the possibility that any improvement detected was not really due to the intervention but to some other cause or causes. These possible influences on the outcomes other than the intervention include 'contextual factors'. Attempts to isolate the effect of an intervention therefore seek to consider systematically (for example, through regression modelling techniques) the extent to which 'confounding' factors might be responsible for any observed change. The ease with which the effects of these confounders can be detected and assessed is greatly improved by manipulating the inputs – for example, by having one group receive the intervention and another act as the control (a controlled study). Randomised controlled trials (RCTs) are therefore seen as the most powerful design for establishing a causal relationship.

Realist evaluation

A series of challenges to this standard approach has been offered in recent years, most prominently by those working within the 'realist evaluation' paradigm. This approach seeks to abandon the correlational view of causality and substitute it with one focused on identifying and assessing the **mechanisms** that explain configurations of contexts-mechanisms-outcomes. The social scientists Ray Pawson and Nick Tilley are most strongly associated with this approach, which is presented in manifesto form in their 1997 book *Realistic Evaluation*.[12] Because they have become well known (and to some extent influential) within the health sciences, their work provides a useful point in which to anchor discussion.

Pawson and Tilley[12] argue that experimental approaches are 'black boxes' that only describe outcomes, not explanations of why programmes work or fail. Such approaches are argued to neglect the significance of context. Pawson and Tilley condemn what they see as the **successionist** logic underlying the RCT model, urging instead adoption of a **generative** theory of causation. Successionist approaches, they argue, determine causality on the basis of co-variation, and assume that the cause of change is external and will consistently produce the same effect. Generative theories – by contrast, they argue – accept that causal relationships may be linked to an external intervention but assume that the impact of the intervention also depends on internal features or characteristics of the context in which the intervention is introduced. A key assumption of realist evaluation is that programmes have differential effects because the mechanisms responsible may not be activated in all contexts.

Rejecting the tendency to treat contextual variables as 'confounding', Pawson and Tilley propose that the contexts within which causal mechanisms operate should be the focus for understanding. They seek to identify the different ways in which contexts, mechanisms, and outcomes can be 'configured', and propose that theory can be tested and developed though a process of comparison of 'families of configurations'. Realist evaluations typically reject the idea that programme 'success' can be determined through the performance measures characteristic of correlational evaluation, as a recent study in this tradition again demonstrates.[13]

Pawson and Tilley's exhortation to identify 'what works for whom in what circumstances' is certainly beguiling rhetoric. It probably explains the appeal of realist evaluation to those frustrated by the zealotry associated with some of the evidence-based medicine movement, including the insistence that the only legitimate source of knowledge is that which is countable or measurable. Pawson and Tilley are right to emphasise the need to theorise about the links between interventions and outcomes, and right about the need to attend to context. But while they are asking the right questions and giving some of the right answers, they are very far from unique in this in either the social or the clinical sciences; nor, in the end, do they offer a **methodological** solution for studying context and causation.

Theory building in the clinical sciences

It is a mistake, as Pawson and Tilley do, to dismiss controlled studies in medical sciences as relying on a flawed 'successionist' logic. Much scientific progress in clinical medicine is achieved through careful theorisation about possible mechanisms that might bring about desired outcomes, and through iterative testing of these theories through a range of study designs, of which the controlled study is a key element. A new therapeutic agent, for example, is typically based on theory (or a set of theories) about disease processes and the likely action of the agent in targeting these – the mechanism. Thus, for instance, the action of temozolomide in the treatment of brain tumours is theorised to involve methylation of DNA and consequent death of tumour cells. The development of this theory of the mechanism underlying the observed outcomes proceeded not through mechanistic deductions, but through an iterative, creative, and sometimes messy process of discovery, abduction, and testing.[14]

Therapeutic agents, far from being black boxes, typically go through multiple sequences and feedback loops of theory testing and refinement aimed at understanding how the agent will be processed by the body, and at determining the likely outcomes of the drug – both intended and unwanted. This kind of research thus follows the route commended by realist evaluation. Pharmacokinetic studies will be one of the earliest in the sequence of challenges to which the theory is exposed. Such studies attempt to determine the processing of the drug once in the body, by looking at how it is metabolised, what systems it acts on, and what kinds of biochemical and other changes it produces. Pharmacokinetic studies are, in Pawson and Tilley's terms, classically **generative** in their orientation (given the internal characteristics of the human body, what is the likely destiny of this external agent?). Such studies often result in what appear to be promising agents being abandoned, or in adjustments being made to the formulation of the drug, because the data emerging from the study improves knowledge (theory) about the likely mechanism of action. It seems clear that, if converted into Pawson and Tilley's terms, the proper way of understanding the drug in the body is to see it as an example of context + mechanism.

Such an understanding comes even more plainly into view in the latest developments in clinical science, which are increasingly showing how variations at the molecular level in individual patients influence the fate of drugs in the body. Variations in the genotypes of both individuals and population groups are now known to have profound influences on responses to drugs in terms both of effectiveness and adverse effects. For example, cancers that appear histologically similar (on examination by microscope) may turn out to be very different at the molecular level.[15] Pawson and Tilley make a great deal of their claim that different mechanisms can produce the same outcomes, and suggest that different context-mechanism configurations may produce the same outcome or the same context-mechanism configurations may produce different outcomes. They are not wrong, but theirs is not a unique insight: it is one that has been accepted within medicine for decades. Clinical research is increasingly showing how the same phenotype (say, asthma) may have its origins in very different genotypes, while the same genotypes may produce very different phenotypes.

Arguing that 'causal outcomes follow from mechanisms acting in contexts', Pawson and Tilley propose that interventions provide a trigger for change only if the prevailing conditions can support change: 'programmes work (have successful "outcomes") only in so far as they introduce the appropriate ideas and opportunities ("mechanisms") to groups in the appropriate social and cultural conditions ("contexts")'. They further argue that:

> *'Context describes those features of the conditions in which programmes are introduced that are relevant to the programme mechanisms... For realism, it is axiomatic that certain conditions will be supportive to the programme theory and some will not. And that gives realist evaluation the crucial task of sorting the one from the other.'*[16]

Again, Pawson and Tilley are right, but there is nothing specific to realist evaluation about their programmatic claims or aims. Modern clinical science is preoccupied with exactly the same kinds of tasks. Genetic heterogeneity may mean that only some patients in a target population have diseases that are treatment sensitive.[17] For example, variations in the MGMT gene strongly influence positive response to temozolomide,[18] but the existence of such a mechanism

can be established only through sophisticated application of a range of methods, including controlled experiments. Contrary to Pawson's claim that 'It would be an absurdity in most medical trials to imagine that the patient transforms the treatment',[19] that is precisely what happens. Some interventions are effective in some patients; some are not. This is because of genetic – that is to say, contextual – variation. Bodies are not regarded in modern clinical science as passive objects, nor is explanation of mechanism written out. It is no exaggeration to say that modern clinical science is now as much concerned with what bodies do to drugs (the impact of context on intervention) as it is with what drugs do to bodies (the impact of interventions on specific contexts). Further, clinical trials only exist and advance because of continual efforts to improve the theoretical bases of postulated mechanisms. For example, to continue with the temozolomide illustration, work is currently underway to improve treatments by combining the drug with other agents that are theorised to increase its potency in killing tumour cells. There is thus little that is distinctive about many of the programmatic aspirations of realist evaluation. Its conceptualisation both of the significance of context and of the need to identify the conditions supportive of an intervention, as well as theoretically informed explications of causal mechanisms, seems so closely to mirror that of modern, molecularly based clinical science as to be indistinguishable. 'What works for whom in what circumstances' seems as good a description of the aims of molecularly oriented clinical science as any.

What can quality improvement learn from the clinical sciences?

The key point in the discussion thus far is not simply to argue that, in some of its fundamentals, realist evaluation has far more in common with clinical science than its proponents might think (or want to accept). Rather, I have three aims. First, comparing clinical science and realist evaluation allows us to dispose of the idea that controlled study and experimental designs are somehow fatal to efforts to investigate context and identify causal mechanisms. Embracing a correlational logic does not mean that context is somehow ignored or distorted, and that interest in characterising causal mechanisms evaporates. Pawson and Tilley argue that *'when we explain a regularity generatively, we are not coming up with variables or correlates which associate one with the other; rather we are trying to explain how the association itself comes about'*. Yet without a sound understanding of whether and how variables or correlates are associated, many attempts to construct explanation are doomed.

Without using quantitative modelling, for example, many structural-level influences relevant to theory building may remain obscured. Kieran Healy's work, for instance, shows that any effect of presumed consent laws on rates of organ donation can be explained by attention to the social organisation of transplant systems in countries that have implemented such laws.[20] High-yield countries such as Spain and Italy do not owe their success to different legal rules from those in opt-in countries, but to effective investment in system logistics and management: they have more staff dedicated to the procurement process, more training in getting consent from families, and improved coordination within the system. This conclusion about the contextual influences on organ donation, and the mechanisms implicated in donation, was reached by Healy following detailed quantitative analysis **and** highly sophisticated application of theory from institutional and economic sociology. In throwing out the correlational baby with the bathwater, realist evaluation risks failing to provide the kind of evidence needed to establish the effectiveness of interventions or to identify the institutional and structural aspects of context that are potentially open to remedy.

Second, claims about the supposed defects of controlled trials and experimental design are a distraction from the real work of improving the science underlying quality improvement in healthcare, including the problems of context. The problem lies not so much in fundamental defects of the clinical science/clinical trials approach to drug development, as in the unsophisticated application – or non-application – of many of its more useful principles **to implementation and study of QI interventions**. By the usual standards of clinical epidemiology, QI research is a field – ironically – beset by quality problems, including widespread use of study designs that limit the confidence with which change can reliably be attributed to the intervention,[21] use of poorly operationalised measures of both programme inputs and outcomes, poor quality of data collection, and reluctance to search for unintended consequences or determine the cost-effectiveness of interventions.

One striking feature of the development of QI interventions, for instance, is their tendency to neglect the equivalents of the laboratory and the pre-clinical and pharmacokinetic stages of drug development. QI interventions tend to move straight to implementation, bypassing the stages of characterising the intervention and exploring how it is that individuals, teams or organisations 'metabolise' the intervention, what likely contextual influences might neutralise or subvert the intervention, what the unwanted effects might be, or how any observed effects can be properly explained. Thus, for instance, QI interventions have been routinely imported from very different sectors – such as aviation – without adequate consideration of whether these sectors are more like different species (zebras being compared with lions). Improving the design and execution of studies of QI in order to provide more reliable evidence is a priority.

This links to the third reason for drawing attention to the evolving paradigm within the clinical sciences, which is to highlight the level and quality of methodological innovation now occurring to deal with the recognition of the complexity of gene–environment interactions. For example, it is clear that unrecognised molecular heterogeneity can reduce the power of randomised trials to detect therapies that may be beneficial for specific subgroups, and statistical techniques are under development to deal with this challenge. New and emerging techniques in genetic epidemiology[22] also represent a rich treasury of methods. With some adaptation, such approaches might be applied to modelling contextual variables relevant to QI efforts, and thus enhance the ability to make much better assessment of risk factors for the implementation of QI activities – including the kinds of factors likely to leave such activities incapable of delivering any benefits. A recent review by Shekelle et al[11] identified four salient areas of context influencing patient safety practices in healthcare organisations:

a. Structural organizational characteristics (such as size, location, financial status, existing quality and safety infrastructure).

b. External factors (such as regulatory requirements, the presence in the external environment of payments or penalties such as pay-for-performance or public reporting, national patient safety campaigns or collaboratives, or local sentinel patient safety events).

c. Patient safety culture (not to be confused with the larger organizational culture), teamwork, and leadership at the level of the unit.

d. Availability of implementation and management tools (such as staff education and training, presence of dedicated time for training, use of internal audit-and-feedback, presence of internal or external individuals responsible for the implementation, or degree of local tailoring of any intervention).[11]

It is likely that many (though not all) of these contextual variables are capable of being measured and then modelled. This kind of analysis can help in building insights into where efforts need to be targeted, and what preparations organisations need to make when introducing QI initiatives. However, as I shall emphasise later, quantitative models on their own will never be enough to ensure a full accounting for context both in the study and implementation of quality improvement efforts, nor a full explanation of how interventions lead to outcomes.

3. Why the clinical science approach is not enough

One of the real achievements of those working within the mechanismic paradigm (including realist evaluation) has been to refocus attention on the need for better understanding of **what it is that is causing the changes observed** rather than being content simply to determine a causal effect and the confounding variables that modify such effects. Yet studies of QI typically suffer from two major problems. First, they are often remarkably poor at describing exactly what the intervention comprises within reports, and often fail to characterise the intervention and its activities in such a way that it can easily be reproduced. Second, such studies are equally poor at describing the theoretical basis of their interventions (what is the means by which this intervention might reasonably be expected to achieve the hoped-for effects?).[7] Further, attempts to update theories in response to the findings of empirical studies based either on process evaluation or learning acquired during the running of the intervention remain rare in QI, so that theory evolution remains stunted. As Shojania and Grimshaw note:

'From the perspectives of clinical medicine and the research enterprise, we regard it as absurd to proceed directly from a patient's poorly

understood complaints to reaching for a bottle of pills simply because they are handy and resemble ones recommended anecdotally by a colleague. The decision to administer these pills without any understanding of their active ingredients or their mode of action would be completely unsupportable. Yet comparably unsupportable activities occur routinely in quality improvement (QI) research.'[23]

Cargo cult quality improvement

The failure to produce good quality accounts of what the intervention involved (what were the activities undertaken?) and the theory explaining how the intervention achieved its effects (what mechanisms were at work?) leads to a number of important problems for QI, including the problem that might be termed 'cargo cult quality improvement'. Cargo cult science was famously described by Richard Feynman in a 1974 Caltech commencement address:

'In the South Seas there is a Cargo Cult of people. During the war they saw airplanes land with lots of good materials, and they want the same thing to happen now. So they've arranged to make things like runways, to put fires along the runways, to make a wooden hut for a man to sit in, with two wooden pieces on his head like headphones and bars of bamboo sticking out like antennas – he's the controller – and they wait for airplanes to land. They're doing everything right. The form is perfect. It looks exactly the way it looked before. But it doesn't work. No airplanes land. So I call these things Cargo Cult Science, because they follow all the apparent precepts and forms of scientific investigation, but they're missing something essential, because the planes don't land.'[24]

When QI initiatives are implemented without proper understanding of what they involve and how they work, they similarly risk becoming pale and distorted imitations that succeed only in reproducing the superficial outer appearance, but not the mechanisms (or set of mechanisms) that produced the outcomes in the first instance.

There can be little doubt that cargo cult QI explains some of the variability in the outcomes of QI efforts. Take the example of the renowned Keystone Intensive Care Unit (ICU) project, which received international attention when it reported a dramatic fall in rates of central venous catheter bloodstream infections in over 100 ICUs in Michigan.[25] Its success has been mistakenly and repeatedly attributed solely to the introduction of a 'simple checklist' rather than a highly complex social intervention.[26] The Michigan programme is likely to have achieved many of its effects through its success in creating a networked community structure that promoted social norms and shared learning. It could therefore be hypothesised that the more attempts to replicate its success rely on single aspects of the programme (such as a checklist), and the more these efforts acquire features of a hierarchy (command-based rather than cooperation-based), the less likely they are to reproduce the original characteristics that contributed to its effectiveness. Cargo cult implementation – it looks like the programme, but it is really not the programme – may explain many of the difficulties that have been experienced in rolling the project out on a wider basis.[27]

This is important, because when an intervention does not work in a new context despite having worked in a demonstration project, there is a danger of mistaking problems of **programme implementation** for problems of **context**. It might be assumed, for example, that the new context was ill-suited to the intervention or incapable of supporting it, and thus abandoned. This means that there is a risk of throwing out interventions that are in fact likely to improve quality of care, based on false assumptions about the interventions.

The problem of describing QI interventions

A sound, full, explicit and theoretically grounded account of QI interventions is clearly indispensable. However, achieving a good understanding of what an intervention **is** and how it works is far from straightforward, and this is where the comparison with the drug development model begins to show strain. Drugs can be specified in precise pharmacological terms, and their causal mechanisms, even if complex, can often (though not always) be reasonably neatly described. Describing a QI project and explicating its mechanisms may be far more challenging.

At a minimum, an explicit description of the components and activities of the QI programme should be produced. Such descriptions are often absent in published reports of QI. But the challenge is more

fundamental than providing a shopping list of what was planned to be done when. Those running programmes may not agree what the programme comprises, may have only a poor grasp of what is going on, or may be obliged to articulate claims for the programme that render it acceptable to various stakeholders but have little to do with how the programme really works or is intended to work. Because of the nature of social interventions, what people implementing a programme say they will do may be quite different from what they do, perhaps because it is very difficult to do what they originally proposed, or because their ideas and actions evolve over time as they learn from their experiences in trying to implement the programme.[28] Decades of evaluation science, particularly in the theory-based evaluation (TBE) tradition, have also taught us that many programmes involving a social or behavioural component have an irreducible tendency to adapt and mutate as the programme proceeds.

For these reasons, contrary to Pawson and Tilley, programmes are not 'theories incarnate', where incarnate means (by dictionary definition) 'turn into concrete form'. Pawson and Tilley argue that:

> *'Programmes are [...] shaped by a vision of change and they succeed or fail according to the veracity of that vision. Evaluation, by these lights, has the task of testing out the underlying programme theories. When one evaluates realistically one always returns to the core theories about how a programme is supposed to work and then interrogates it – is that basic plan sound, plausible, durable, practical and, above all, valid.'*[16]

Yet even identifying the 'basic plan' is often not easy, and **whose** version of the programme theories and visions is to be tested out is far from straightforward.

I propose that QI programmes, initiatives and activities are **what actually happens**, not a manifestation of a theory. In the same way, the behaviour of a drug in the body is what actually happens to the drug, not the concrete realisation of a theory about that drug. What actually happens in social and behavioural interventions – the activities actually undertaken, the emphasis placed on different components, the properties holding the programme together – may bear only a limited resemblance to a formal logic model or protocol specified at the outset of a programme. The importance of focusing on **what actually happens** (in so far as it is possible to access and describe this) is vital because without this there is no possibility of understanding the programme components, explaining how the programme worked, or learning about the contextual influences that buffer or modify programme effects.

The role of practical wisdom in getting QI to work

One of the reasons for focusing on what actually happens in programmes, like QI, that have social and behaviour dimensions, is the role of **practical wisdom**. I want to suggest that practical wisdom is important in QI first in getting programmes to work (and therefore is implicated in what actually happens), and second in studying programmes (recognising and understanding what actually happens). When QI initiatives work, they often do so because practical wisdom is deployed both in the design and running of the programme. If, for example, a programme demonstrates dynamic properties – such as adjusting programme components in response to feedback from participants, and creating bespoke versions of the programme to suit local contexts – it may be precisely practical wisdom that gets the programme to work. Practical wisdom is likely, for example, to have been a critical element of the success of the Michigan programme mentioned earlier. Properties of responsiveness, improvisation, dynamic adaptation and focusing on enabling of participants were just as much part of the programme as activities specified in the project protocol. A focus solely on the formal components leads straight to the cargo cult problem.

Practical wisdom is an idea dating back to Aristotle, and has been more or less continuously rediscovered and renamed ever since, often as forms of practical rationality, practical reasoning, and tacit knowledge. Baumard[29] helpfully summarises the distinctions made by Greek philosophers between four different types of knowledge as follows:

- **Episteme**: abstract generalisation, the kind of universal knowledge that is shared and circulated, taught and preserved. It can be seen as knowledge **about** things.
- **Techne**: the capability and capacity to accomplish tasks.
- **Phronesis**: practical and social wisdom, which is the result of experience and social practice. It is singular and idiosyncratic, acquired by trial and error, and cannot be shared easily.

– **Metis**: conjectural knowledge, which is unpredictable and intuitive. It is like a kind of cunning, that uses ruses, shortcuts, and other tactics to get results, and is embodied into purpose. Like phronesis, it is complex, tacit and difficult to communicate.

The idea of 'metis' is put to use in James Scott's book *Seeing like a state*.[30] The book has nothing to do with healthcare. It concerns top-down interventions by states into complex social systems, where such interventions are assumed to be guided by scientific rationality. Scott argues that where interventions involve 'thin simplifications' of the reality of the systems in which they are being introduced, they may erupt into disaster or end in failure. He discusses examples such as 'scientific forestry' in the 19th century (which created monocrop forests vulnerable to pests and storm-felling), and the 'villagisation' of tribal peoples in Tanzania (which was catastrophic for range conservation and pastoral livelihoods, as well as encouraging cholera and livestock epidemics). Scott sees part of the problem of such interventions as lying in hubris about the superiority of scientific knowledge and a corresponding under-valuing of insider, local, experience-based, contextual knowledge (metis). Those in possession of metis - which Scott defines as involving 'a wide array of practical skills and acquired intelligence in responding to a constantly changing natural and human environment',[30] have the ability to adjust and improvise in response to the complexities of dynamic situations. Metis is, Scott suggests, the form of ad hoc reasoning best suited to complex social tasks where the uncertainties are so daunting that intuition and 'feeling the way' is most likely to succeed.

Scott's argument that some practical choices cannot be adequately and completely captured in a system of universal rules has some evident parallels with quality improvement. Metis is 'plastic, local and divergent', and one of its key strengths is that it allows contextually appropriate adaptations to be made by mobilising local knowledge. Metis can be indispensable both to those designing and leading QI programmes, and to those implementing QI locally. It is thus crucially implicated in enabling context to be taken into account.

QI programme leaders can certainly draw on the epidemiology of known risk factors for QI programmes when they are designing and running their interventions. But they need metis to be able to recognise what is important and relevant about context for their programme, at the multiple different levels at which context is likely to be important. For example, neo-institutional sociology is now teaching us that institutional context is likely to be critical. Institutions include not only formal organisations and structures (for example, the law courts, insurance and payment systems, hospitals) but also non-codified, informal conventions and collective scripts that regulate human behaviour.[31] Institutional structures mediate the extent to which mechanisms of change can be activated, and thus help to explain variability in outcomes. A programme that was successful in a country with a third-party payer system may well encounter stony soil in a system based on national insurance, or in a country where a recent and similar programme ended in bitter failure and recrimination. Practical wisdom is required to apprehend the significance of institutional context.

Practical wisdom is also needed to identify the 'initial conditions' for a QI effort. Many of these are likely to be historically contingent and have a profound impact on what happens to the intervention. Ansell and Gash[32] for example, show that conditions present at the outset can have a critical impact on the ability of collaborative efforts to succeed. Three, they suggest, may be especially important: imbalances in the resources or power of different stakeholders; the incentives that the stakeholders have to collaborate; and the history of conflict or cooperation among stakeholders. Initial starting conditions can help to explain some of the variability seen across organisations participating in QI interventions both in the extent to which they persist with their efforts and in the outcomes they achieve. This can result in massive variability in success. The sociologist RK Merton famously drew attention to the 'Matthew effect':[33] initial advantage begets further advantage, and initial disadvantage begets further disadvantage. For example, prestigious scientists and institutions tend to attract more attention and resource, thus accumulating further prestige. The overall effect is to amplify inequalities. Merton comments that

> *'initial comparative advantages of trained capacity, structural location and available resources make for successive increments of advantage such that the gaps between the haves and the have-nots in science (and other domains of social life) widen until dampened by countervailing processes'.*

The job of the QI leader is to recognise comparative disadvantages and provide the countervailing processes needed to correct for these.

I must emphasise that QI programme leaders do need to be clear about the principles or activities of programmes that should be invariant – the scientific principles of infection control, in the case of the Michigan programme, for instance. Some elements of QI need to be highly standardised, and there is no getting away from that. But at the same time, those leading QI can engage the wisdom and resources of the community of participants (metis) to make local customisations that increase the chance that the programme will work **here**, even if being implemented in a rather different way from how it is being done **there**. In his book, Scott gives the example of the captain of a large passenger ship, who typically turns over control of the vessel to a local pilot to bring it into the harbour because the local pilot has the local contextual skills and knowledge to get the berthing of the ship right in that particular location. A simple example of this in the Michigan project was that each participating unit came up with its own version of the checklist for good practice in central venous catheter insertion: every unit had a checklist, and every checklist contained the same minimum checks, but each one was different because each drew on the practical skills and knowledge of local participants about what was likely to work where they were.

Metis is generally indispensable to the dealing with challenges known locally – who is the doctor likely to create a ruckus about being asked to do this; what are the levers for getting management to authorise the budget; and which individuals and committees will need to be consulted to ensure harmony, for example. Recognising the place of metis in running programmes helps to avert thin, formulaic simplifications of interventions that are likely to lead to disappointment. It is consistent with a recent turn within management theory towards regarding some aspects of quality improvement as more like an art, and requiring qualities of flexibility, dynamism, and creativity that a purely standardised approach cannot hope to achieve.[34]

This has a number of implications.

- First, a proper understanding of **what a QI intervention is** needs to be at the right level of specification. It cannot be derived from an inspection of formal specifications, any more than what an organisation is really like can be derived from an organisation and management chart. It needs to include a role for practical wisdom.
- Second, QI efforts need to accept that, in contrast with drugs, its interventions are never likely to be completely standardisable and fully specified, and that this is indeed desirable. Many aspects of a programme will be immutable, but some aspects will forever escape reduction to a set of executable instructions. QI efforts will always involve trade-offs between explicitness and flexibility if they are to work.
- Third, understanding **what a programme is** (rather than what its designers or other stakeholders think it is) requires studying it in action. This is where the second use for practical wisdom comes in.

The role of practical wisdom in studying and understanding QI activities

I would suggest that when an intervention that worked before does not work when moved to a new context, then:

1. it did not work in the first place (the observed improvement in that first place was really due to something else), or
2. the intervention in the new place is not the same as the intervention in the first place, even if it bears a seeming resemblance (there is heterogeneity in implementing the intervention), or
3. the new place is so different to the first place that the intervention cannot work, or can only work much less effectively (there is heterogeneity in the context), or
4. some combination of 2 and 3 has occurred.

In order to understand which of these applies, there is an equally important role for practical wisdom in **studying** QI initiatives and gaining real insight into how they work. Without well-designed, well-informed social inquiry, it is impossible to understand **what actually happens** in QI, it is impossible to identify the mechanisms that link outcomes to inputs, and it is impossible to account for context. This form of social inquiry, I suggest, requires deployment of a range of methods not often found together in the study of QI at present, and use of practical wisdom in interpreting and synthesising the findings and in feeding them back to the people charged with designing and implementing programmes.

Finding out what actually happens in a QI programme is no mean feat. It is most likely to involve ethnographic methods, including observations of programme team meetings, programme events, and programme implementation at the sharp end; analysis of documents; and interviews with those involved or affected by a QI intervention. Conducting such work across a range of contexts can enable rich insights into the extent to which what is happening conforms to the designers' expectations, and what explains any deviations. It offers the ability to identify the contextual influences on the capacity and willingness of organisations, teams or individuals to implement the initiative – the awkward clerk, the absence of a functioning IT system, the depressed consultant, the history of many previous failed attempts to solve the same problem, the 'normalisation of deviance'[35] that means that people in a specific context are falsely reassured that the problem facing them is not really a problem at all. And, used wisely, such work can be used formatively to feed back directly into the programme, and enhance the wisdom of the programme leaders while the intervention is running. There are still far too few examples of this kind of study in QI, and some of the major methodological and ethical issues have still to be resolved.

Constructing explanations that get inside the black box of causation and that account for context is the next critical, and linked, task for social science inquiry in QI. There can be little doubt that epidemiological studies of the contextual modifiers of QI interventions are badly needed, not least so that those implementing QI interventions have better risk-assessment tools to use. Some of these models may, as I suggested earlier, benefit from the increasing sophistication of statistical techniques now appearing in the clinical sciences. But a science of causation and context cannot be built on such models alone: correlation is not causation, and even though correlational work is indispensable to theory building, a full understanding of what gets a programme to work will elude measurement.

Before discussing this further, it is perhaps worth acknowledging the explosion of the literature devoted to mechanism-based approaches to theory building in the social sciences. Realist evaluation is just one example among very many; Hedstrom and Swedberg's book *Social Mechanisms: an analytic approach to social theory,*[36] published around the same time as *Realistic Evaluation,* for example, makes the same argument as Pawson and Tilley in suggesting that any understanding of mechanisms cannot be derived from correlational analysis alone:

> *'Assume that we have observed a systematic relationship between two entities, say I and O. In order to explain the relationship between them we search for a mechanism, M, which is such that on the occurrence of the cause or input, I, it generates the effect or outcome, O. The search for mechanism means that we are not satisfied with merely establishing systematic co-variation between variables or events: a satisfactory explanation requires that we also be able to specify the social "cogs and wheels" that have brought the relationship into existence.'*[36]

The mechanismic literature demonstrates surprisingly little consensus on what might constitute a mechanism, however.[37] Most social phenomena, as Diego Gambetta points out,[38] require more than one mechanism to explain, but mechanisms do not simply pile up on top of one another. Rather, mechanisms interact with each other, forming what Gambetta terms 'concatenations of mechanisms'.

I am inclined towards the view that discussions of what constitutes a mechanism rapidly become unproductive (and tedious), and that it is often impossible, close up, to distinguish mechanism from context. I prefer to revert to the idea that what social science in QI is about is building middle-range theories. Robert Merton defined mid-range theories at some length,[39] seeing them as lying somewhere between the minor hypotheses used in day-to-day research and attempts to build more all-encompassing 'big' theories of social life. Such theories include a focus on mechanisms, but typically provide a broader narrative.

How we should build mid-range theories in QI seems to me one of the most important challenges. Practical wisdom is needed to interpret the results of ethnographic work and quantitative evaluative research, but it may be that new approaches need to be added to the armoury to ensure the deepest understanding. Some of the most exciting and innovative methodological work is now taking place in the area of case studies. This is beginning to show how 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 check these explanations out.[40,41] Charles Ragin's work on fuzzy-set qualitative comparative analysis (fsQCA)[42] is also offering methods that can be used to summarise and order findings from case studies to provide a systematic means of assessing whether causes can reasonably be attributed to effects, and that avoid the pitfalls associated with assuming unit heterogeneity. Much of this work is focused on the identification of **necessary** and **sufficient** conditions for change, and seems to offer a rich source of thinking about context.

4. The principal research questions relating to context

1. What are the best methods for investigating the influence of context on QI activities?
2. Can elements of the social and clinical sciences be blended to produce a framework for the study and implementation of QI?
3. What is the role of pilot studies in clarifying the theories underlying QI efforts and the likely contextual modifiers?
4. How can the toxic effects of QI efforts across different contexts best be assessed?
5. In order to avoid cargo cult QI, can we produce better accounts of what actually happens in QI efforts, and what is the method by which such accounts can best be obtained?
6. Can good epidemiological models of contextual modifiers in QI be built, and can they be used to conduct risk assessments in local settings?
7. Can social science studies running alongside QI efforts provide formative feedback that enhances the ability to adjust for context?
8. How can the role of practical wisdom in running QI programmes be accounted for, and how can current editorial policies in major peer-reviewed journals accommodate it?
9. What is the role of new case study methods in understanding context in QI?
10. What is the best way of synthesising scientific evidence of different types across contexts to produce good programme theories for QI?

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