The Health Foundation
Inspiring Improvement

Perspectives on context

How does context affect quality improvement?

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About the author

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Dr. Øvretveit's work is based on the belief that organisation and management can bring out the best and worst in people, and that the right organisation design is critical for effective healthcare. A theme underlying his work is how practical research can contribute both to better care for patients and to 'healthy work organisation'. Much of his work uses different social sciences to explain and predict events and processes in healthcare and clinical practice.

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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

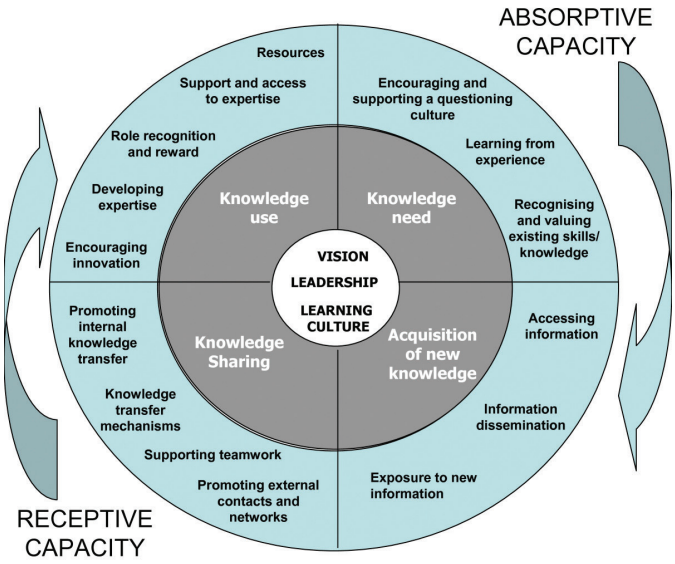
There are no systematic reviews of methods for studying context influences in QIIs. The two most relevant overviews to date are:

- 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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