Small Tests of Change and Adaptation: Identifying the commonalities in the underestimated engines of improvement and implementation

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<th>Journal:</th>
<th>BMJ</th>
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<tbody>
<tr>
<td>Manuscript ID</td>
<td>BMJ-2019-053856.R1</td>
</tr>
<tr>
<td>Article Type:</td>
<td>Analysis</td>
</tr>
<tr>
<td>DateSubmitted by the Author:</td>
<td>04-Aug-2020</td>
</tr>
<tr>
<td>Complete List of Authors:</td>
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<tr>
<td>Keywords:</td>
<td>quality improvement, implementation science</td>
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</table>

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Small Tests of Change and Adaptation

Identifying the commonalities in the underestimated engines of improvement and implementation

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Word count: 1400

References: 17

Each author has completed the online BMJ Competing Interest survey.
The Opportunity

Closing gaps in healthcare quality, improving workflows, and implementing evidence-based interventions require change, but not all changes are successful, and most come with unintended consequences. Improving healthcare is complex, requiring input not just from the health care providers, but also from patients and families to identify gaps, develop meaningful interventions, and ensure that interventions address value from their perspective. There are numerous approaches available to making changes in healthcare systems such as lean, six sigma, the model for improvement, healthcare delivery science, and implementation science, among others. When looking to build and disseminate knowledge about making change, how might we best create changes successfully and efficiently?

Quality improvement (QI) and implementation science (IS) are two commonly used systematic approaches to improve the quality, safety, and value of healthcare services and to disseminate what is learned from those efforts. Over the past several years we have recognized a tension and, at times, a competition between QI and IS. The tension is unnecessary and wasteful when there are numerous gaps in healthcare quality that need to be addressed. QI and IS approach change from different philosophical underpinnings, yet we feel they share similarities that suggest combining their lenses could be beneficial. While QI comes from business and IS from behavioral sciences, both recognize that changes occur in a specific context and are impacted by the context itself, requiring that each setting be considered unique. The outcomes of interest in QI are often improving quality: safety, timeliness, effectiveness, equity, efficiency, and patient-centeredness. The outcomes of interest in IS include the uptake and application of
evidence-based care with attention to acceptability, cost, and feasibility. Overall, this tension may accurately be described as the work of moving evidence into practice.

Making and documenting changes to interventions is difficult. We recognized in the development of the SQUIRE publication guidelines that it is also challenging to report in the published literature, whether that work is categorized as QI or IS. The challenges relate to both how changes to the intervention are decided upon, and how they are carried out. Both fields use approaches to solving these problems, and each has something to offer the other. In QI, changes are widely promoted to be accomplished through ‘small tests of change’ to predict, test, and assess the impact in the local microsystem. Careful use of these methods of small tests of change, such as through application of the Plan-Do-Study-Act (PDSA) cycle, are viewed as key to learning about the microsystem and the context to inform the change process. The strength of this approach is the importance placed on the microsystem and context, and in this way, it may inform the IS field, which does not emphasize recursive change as strongly. In IS, the concept for modifying the intervention is referred to as ‘adaptation of the intervention’ and is recognized as key to identifying how to spread effective interventions to new contexts. Making, assessing, and reporting these adaptations are viewed as essential in the generation of new knowledge that can be readily shared with others. The strength of this is found in the methods and approaches to the assessment and reporting of adaptations, and this could be usefully applied to QI, which does not emphasize this as strongly.

Context and Change

In complex systems, context is the ecosystem as it changes in response to alterations of processes, people, personnel, policy, or any other perturbation. Context and healthcare
improvement interventions interact, so it is vital to account for how the context and the intervention itself change over time to be more successful in making sustainable changes. In QI, context is defined as physical and sociocultural makeup of the local environment and the interpretation of these factors by the stakeholders in the environment. It is considered fluid and consists of specific factors but also individuals’ interpretation of the relationships between the factors. Context in QI is identified and assessed through process analysis with tools like process flow and cause-effect diagrams. These tools are used in the design of interventions – tests of change. In IS, models such as the Consolidated Framework for Implementation Research (CFIR) and others provide a framework of domains of context and while used in design, are especially helpful for formative evaluations of change. CFIR domains are pre-specified contextual factors and sub-constructs that include adaptability and trialability of the intervention. CFIR also recognizes that PDSAs are one way to adapt the intervention to a specific context. Both QI and IS note that there is bi-directional interaction of the intervention impacting the context and the context impacting the intervention.

Comparing and Contrasting QI PDSA and IS Adaptation

The Plan-Do-Study-Act (PDSA) cycle is a common methodology in QI for small tests of change in a system. When done well, PDSAs are small, focused, and deliberate. The goal of PDSAs is to try an intervention in a microsystem so as to learn about how the microsystem reacts. Sometimes the test of the intervention is successful and moves closer to the goal. Often, the PDSA test of the change may not be successful, and the team learns how the microsystem absorbs or ignores the intervention. Making successive changes in a system rarely occurs in a straight line…it is often messy and complex. Key to successful PDSAs is collecting the data that
clearly align with the goal, and performing deliberate analysis of each of the cycles. 

“Unsuccessful” PDSAs can sometimes be difficult for healthcare teams because they prefer that each change move closer to the goal. Improvement teams may worry that testing a small change will not lead to the improvement that they seek. While the overall objective is improvement towards the goal, PDSAs are about learning, both from the successes and the failures.

In contrast, designing and implementing change in IS is built upon an initial detailed plan for the implementation process. IS considers the contextual factors in the development of the initial implementation strategy and to determine which will be barriers and which will be facilitators of the intervention. Identifying these factors in advance allows the team to create implementation strategies that address the anticipated barriers; however, the best design and plans will always be confronted with a changing context. IS often addresses this by adapting the intervention. In IS, there may be tension between fidelity to the planned implementation strategy and adaptation. Adaptation, in some ways like QI PDSA cycles, plays a central role in the “fit” between context and the intervention.

Fidelity in QI and IS

Understanding fidelity of the intervention in both PDSA and adaptation is vital to appropriate rigor in the execution of change. Haphazard execution is a risk during iteration and limits learning. Fidelity in IS is the extent to which an intervention adheres to the planned protocol for that intervention. The intervention may adapt, but the core elements are intended to be implemented as designed. In QI, interventions are expected to be modified through each cycle of change (PDSA) as the team gains insight into what works, for whom, and in what
context. In QI, fidelity refers to both the *adherence to the planned protocol* within each cycle of change and to the faithful use of *data to inform the next cycle of change*\(^\text{15}\). This ensures that changes are driven by the findings of the previous iteration and lead to the accumulation of insights about the intervention, thus increasing the possibility that the intervention will be sustained within the system.

7 Moving Forward and Learning from One Another

The unique origins of healthcare QI (business model\(^\text{16}\)) and IS (behavior change focus\(^\text{17}\)) sometimes obscures their common goal of creating improvements in the quality, safety, and value of healthcare services. Each field has much to offer the other in the work of doing and evaluating change efforts. The Figure shows the main characteristics of intervention modification in QI and IS. The common features illustrate the significant overlap between the intent and execution of change in each. While each has a specific approach, there is much in common and much that can be learned. QI can learn from the rigorous development, planning, and outcomes evaluation from IS. IS can learn from QI about the data driven flexibility needed to make interventions successful in a wide variety of contexts. By working together and combining knowledge from both fields, QI and IS can work towards a unified approach with more depth and effectiveness than either has on its own.
Figure. Characteristics and overlap of tests of change in Quality Improvement (QI) and Implementation Science (IS).

**Plan-Do-Study-Act Cycles (QI methods)**
- Focused on local microsystem to identify problem and improvement strategy
- Context assessment for design and iteration of interventions
- Iterate the intervention based on findings of PDSA cycle

**Adaptation (IS methods)**
- Focused on rigor in design of the implementation strategy
- Context and barrier assessment during formative evaluation
- Maintain core components of the interventions

**Common Features**
- Goal is to improve the quality, value, and safety of healthcare services
- Moving evidence into practice is a priority
- Benefits from patient and family input and guidance
- Fidelity in the use of data from each test of change to inform modifications
- Consideration of context
What you need to know

- Implementation science (IS) and quality improvement (QI) both use tests of change to adapt interventions in a particular context. Patients and families provide strong insights into that context.

- The context where the changes are made plays a significant role in the effectiveness of small tests of change, irrespective of the methods that are used.

- Fidelity in tests of change refers to both the faithful use of data to drive the changes, and implementation of the intervention as designed.

- IS and QI share some common features that can be drawn upon to improve conduct and reporting of changes to interventions more broadly.
Contributors and Sources

Drs. Ogrinc, Dolansky, and Davies have worked on developing methods and publishing guidelines for quality improvement. Dr. Berman is Senior Program Manager at the John A. Hartford Foundation with extensive knowledge and experience as a patient and working to improve care for patients, families, and communities. Dr. Chambers is internationally known for his leadership of implementation science. This article used a combination of articles that are cited often in the literature. We focused on those references that provide a strong foundation for understanding how small tests of change are employed in quality improvement and implementation science.

Patient Involvement

Dr. Berman’s role as a co-author in this manuscript was representing the patients, families, and communities who are served by healthcare. She has extensive experience both as a patient and focuses on facilitating the development of innovative delivery methods for older adults.
2. Corrigan JM. Crossing the quality chasm. *Building a better delivery system* 2005
The Underestimated Engine in Improvement and Implementation: Small Tests of Change and Adaptation

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Word count: 1062

References: 15

Each of the authors has completed the online BMJ Competing Interest survey.

Authorship

Ogrinc: conception and design, drafting of manuscript and critical revision, administrative and material support, supervision

Dolansky: conception and design, drafting of manuscript and critical revision, administrative and material support

Berman: visualization, drafting of manuscript and critical revision, supervision

Chambers: conception and design, drafting of manuscript and critical revision, preparation of figure

Davies: conception and design, drafting of manuscript and critical revision, supervision

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The Problem

Closing gaps in healthcare quality, improving workflows, and implementing evidence-based interventions require change, but not all are successful, and most come with unintended consequences. The work is complex, requiring input not just from the health care providers, but also from patients and families to identify gaps, develop meaningful interventions, and ensure that interventions address value from their perspective\(^1\). How can we best create changes successfully and efficiently? The fields of quality improvement (QI) and implementation science (IS) approach change creation from different philosophical underpinnings; however, they share similarities that suggest that combining their lenses could be beneficial. QI comes from business and IS from behavioral sciences, but both share the realization that changes occur in a specific context and are impacted by the context itself, requiring that each setting be considered as unique. The outcomes in QI are often focused improving quality: safety, timeliness, effectiveness, equity, efficiency, and patient-centeredness\(^2\). The outcomes of interest in IS are the uptake and application of evidence-based care with attention to acceptability, cost, and feasibility\(^3\). We outline how key ideas from each field might strengthen the other in the search for efficient paths to the creation of positive change.

In QI, creating change occurs primarily through the concept of ‘small tests of change’ which are used to predict, test, and assess the impact in the local microsystem. Careful use of methods of small tests of change, such as the Plan-Do-Study-Act (PDSA) cycle, are viewed as key to learning about the microsystem and the context to inform the change process\(^4\). PDSA offers a specific framework that may also support the IS field. In IS, the concept for creating change is ‘adaptation of the intervention’ and is recognized as key to spreading effective interventions to new contexts. Making, assessing, and reporting these adaptations are viewed as
essential in the generation of new knowledge that can be readily shared with others. Methods and approaches to the assessment and reporting of adaptations unique to IS could be usefully applied to QI.

**Context and Iteration**

In complex systems, context is ecological as it changes in response to personnel, policy, and any perturbation to the system. Context and interventions interact, so it is vital to account for how the intervention itself changes over time to be more successful in making sustainable changes. In QI, context is defined as physical and sociocultural makeup of the local environment and the interpretation of these factors by the stakeholders in the environment. It is considered fluid and consists of specific factors but also individuals’ interpretation of the relationships between the factors. Context in QI is identified and assessed through process analysis with tools like process flow and cause-effect diagrams, which are used in the design of interventions – tests of change. In IS, models such as the Consolidated Framework for Implementation Research (CFIR) provide a framework of domains of context and while used in design, are especially helpful for formative evaluations of change.

**Comparing PDSA and Adaptation**

The Plan-Do-Study-Act (PDSA) cycle is the most common methodology for testing small changes in a system. When done well, PDSAs are small, focused, and deliberate. The goal of PDSAs is to initiate changes in the microsystem to learn about how it reacts. Sometimes the change is successful, and the team moves closer to the overall goal. Often, it may not be
successful, and the team learns about how the system absorbs or ignores the intervention. Making successive changes in a system rarely occurs in a straight line…it is often messy and complex. Key to successful PDSAs is collecting the data that clearly align with the goal, and performing deliberate analysis of each of the cycles. “Unsuccessful” PDSAs can be difficult because healthcare teams prefer that each change move closer to the goal. Healthcare teams do not like to fail and may feel more comfortable deliberating about rather than trying a change. Teams may worry that a change is too small and that it will not lead to the improvement that they seek. While the eventual goal is improvement, PDSAs are about learning, both from the successes and the failures.

Designing and implementing change in IS is built upon a detailed plan for the implementation process. IS considers the contextual factors in the development of the initial implementation strategy and to determine which will be barriers and which will be facilitators of the intervention. Identifying these factors in advance allows the team to create implementation strategies that address the anticipated barriers; however, the best design and plans will always be confronted with a changing context. IS addresses this by adapting the intervention. In IS, there may tension between fidelity to the planned implementation strategy and adaptation. Adaptation, in some ways like QI PDSA cycles, plays a central role in the “fit” between context and the intervention.

Fidelity in QI and IS

Understanding fidelity in both PDSA and adaptation is vital to rigor in execution. Haphazard execution is a risk of iteration, and limits learning. The definition of fidelity
commonly used in IS is the extent to which an intervention adheres to the planned protocol for that intervention. In QI, interventions are expected to be modified through each cycle of change (PDSA) as the team gains insight into what works, for whom, and in what context. In QI, fidelity refers to both the **adherence to the planned protocol** within each cycle of change and to the faithful use of **data to inform the next cycle** of change\(^\text{13}\). This ensures that changes are driven by the findings of the previous iteration and lead to the accumulation of insights about the intervention, thus increasing the possibility that the intervention will be sustained within the system.

**Moving forward and learning from each other**

The unique underpinnings of healthcare QI (business model\(^\text{14}\)) and IS (behavior change focus\(^\text{15}\)) sometimes obscures their common goal of creating improvements in the quality, safety, and value of healthcare services. Each field has much to offer the other in the work of doing and evaluating change efforts (**Figure**). QI can learn from the rigorous development, planning, and outcomes evaluation from IS. IS can learn about the data driven flexibility needed to make interventions successful in a wide variety of contexts. By working together and combining knowledge from both fields, QI and IS can work towards a unified approach with more depth and effectiveness than either has on its own.
Figure. Characteristics and overlap of tests of change in Quality Improvement (QI) and Implementation Science (IS).

**QI Plan-Do-Study-Act Cycles**
- Focused on local microsystem
- Context rich assessment to drive local improvement
- Flexibility to change or modify an intervention based on what is learned from each PDSA cycle

**IS Adaptation**
- Research rigor in design of the implementation strategy
- Context and barrier assessment at the outset
- Deep understanding of the core components of the interventions

**Common Features**
- Goal is to improve the quality, value, and safety of healthcare services
- Moving evidence into practice is a priority
- Benefits from patient and family input and guidance
- Fidelity in the use of data from each test of change to inform the next iteration
- Continuous monitoring and evaluation of context
What you need to know

- Implementation science (IS) and quality improvement (QI) both use small tests of change to adapt interventions in a particular context. Patients and families provide strong insights into that context.

- Fidelity in tests of change refers to both the implementation of the initial intervention and to the faithful use of data to iterate the changes in a particular context.

- IS and QI share some common features and each can learn from the other field.
Education into practice

- Teams and organizations need to ask a specific question, engage patients and families in QI and IS activities, and choose the right method to improve the quality, value, and safety of healthcare services.
- The context where the changes are made plays a strong role in the effectiveness of small tests of change, irrespective of the methods that are used.
Sources and Selection Criteria

This article used a combination of articles that are cited often in the literature. We focused on those articles and books that provide a strong foundation for understanding how small tests of change are employed in quality improvement and implementation science.
References

2. Corrigan JM. Crossing the quality chasm. *Building a better delivery system* 2005