Dear Dr. Ogrinc,

Thank you for sending us this paper and giving us the chance to consider your work. We sent it out for external peer review and discussed it at the Analysis manuscript committee meeting (present: Raffaella Bosurgi, Sophie Cook, Cat Chatfield, Bryan Jones).

Unfortunately we do not consider it suitable for publication in its present form. However if you are able to amend it in the light of our and/or reviewers' comments, we would be happy to consider it again.

The reviewers' comments are at the end of this letter.

The editors' comments are listed below:

We thought that the piece isn't an education piece as it stands.
We thought that given the nature of the piece and the argument that implementation science and quality improvement could be thought as a whole rather than two separate entities the article could turn into an analysis piece.

I think that the overall structure you have adopted is not far off an analysis, it's just a bit underdeveloped at the moment but the peer reviewers have made suggestions which will probably make this feel more rounded on revision. please let me know if you need any help revising it. You might want to take into consideration some other published analysis pieces for reference.

We hope that you will be willing to revise your manuscript and submit it within 4-6 weeks. When submitting your revised manuscript please provide a point by point response to our comments and those of any reviewers. We also ask that you keep the revised manuscript within the word count of 1800-2000 words.

Please note that resubmitting your manuscript does not guarantee eventual acceptance, and that your revision may be sent again for review.

Once you have revised your manuscript, go to https://mc.manuscriptcentral.com/bmj and login to your Author Center. Click on “Manuscripts with Decisions,” and then click on “Create a Revision” located next to the manuscript number. Then, follow the steps for resubmitting your manuscript.

You may also click the below link to start the resubmission process (or continue the process if you have already started your revision) for your manuscript. If you use the below link you will not be required to login to ScholarOne Manuscripts.

If accepted, your article will be published online at bmj.com, the canonical form of the journal. Please note that only a proportion of accepted analysis articles will also be published in print.

I hope you will find the comments useful. Please don't hesitate to contact me if you wish to discuss this further.

Yours sincerely,
Reviewer(s)' Comments to Author:

Reviewer: 1

Recommendation:

Comments:
This paper makes a useful contribution to the emerging literature on the intersection of QI and implementation science by focusing on how both approaches can inform (and be informed by) small tests of change (e.g., plan-do-study-act cycles).

Overall, the paper is very well-written and is a good fit for the BMJ audience.

My only major suggestion is that the "Moving forward and learning from each other" section would benefit from a bit more fleshering out to help translate the ideas presented earlier in the paper into explicit recommendations for where we should start when it comes to integrating the learning from QI & IS approaches. (If the authors feel there are things we should *avoid* when trying to do so, that would also be worth mentioning.) Much of this is implied in previous sections and simply needs to be made into a more actionable "take home message." --This should also be reflected in the "What you need to know" and "Education into practice" bullets.

Apart from that, the paper was quite strong and my remaining suggestions are very minor:
1. It's a small thing, but the authors write: "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."

It might be more fair to say that in QI small tests of change are widely promoted as a means of creating change.

The systematic review of PDSA by Taylor, et al., suggests this normative practice may not be implemented in real-world QI anywhere near as often as the rhetoric in our field would suggest.


2. While we're on the topic of the realities of PDSA / small tests of change, I would strongly recommend citing the following article as well:


I hate to second guess an author on whether they should be citing more of their own work, but I think that paper adds some useful context -- and if it were anyone else writing on the same topic, I would certainly ask them to cite it. (It would fit very well in the Comparing PDSA and Adaptation section.)

3. Page 4: "In IS, there may tension between fidelity to the planned implementation strategy and adaptation." Should be: "In IS there may be tension..."

Additional Questions:
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Institution: UC San Diego School of Medicine

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Reviewer: 2

Recommendation:

Comments:
This article makes the case for giving greater emphasis to small tests of change and adaptation of interventions in healthcare improvement. The concluding sentence in the opening section about The Problem is: "Methods and approaches to the assessment and reporting of adaptations unique to IS could be usefully applied to QI." This sentence is referenced to the SQUIRE 2.0 guidelines. I find this surprising because Greg Ogrinc was the lead author on these guidelines, which actually make a very strong case for avoiding the multiplicity of terms that can be used to describe the work of healthcare improvement:

"Improvement work draws on the epistemology of a variety of fields, and depending on one’s field of study, the same words can carry different connotations, a particularly undesirable state of affairs. Terms such as ‘quality improvement’, ‘implementation science’ and ‘improvement science’ refer to approaches that have many similarities, but can also conote important (and often-debated) differences. Other terms such as ‘healthcare delivery science’, ‘patient safety’ and even simply ‘improvement’ are also subject to surprising variation in interpretation. To address this problem in semantics, we created a glossary of terms used in SQUIRE 2.0"1

The SQUIRE 2.0 glossary of terms includes this definition of Healthcare Improvement:

"Any systematic effort intended to raise the quality, safety and value of healthcare services, usually done at the system level. We encourage the use of this phrase rather than ‘quality improvement’, which often refers to more narrowly defined approaches.”1

The SQUIRE 2.0 guidelines encouraged us to develop a Healthcare Improvement theme at our Medical School, which enables students and faculty to see improvement as a way of working rather than an isolated curriculum component or ‘QI project’. In our curriculum learning about improvement is iterative, moving from problem definition to prototype to testing and back to a more refined understanding of the problem. Consequently it seems like a backward step from SQUIRE 2.0 to now argue that the way forward is to attempt to fuse just two of the variety of fields that are relevant to improving healthcare.

I also disagree with the assertion that Improvement Science has a unique approach to assessment and reporting of adaptations. Contemporary thinking in ergonomics and human factors science emphasizes the importance of temporal phenomena such as adaptation to improving systems. Adaptation is central to models that apply design and engineering principles to healthcare.3, 4

However, in addition to adaptation of interventions, these approaches emphasize the importance of
studying how systems adapt to change by including feedback loops that capture all of the consequences of intervention. In contrast the consolidated framework for advancing implementation science focuses solely on adaptation of the intervention. The framework is linear, with no feedback loops. The development of the framework included Rogers’ Diffusion of Innovations Theory but does not emphasize the importance of the consequences of innovation, which contributed a whole new section to the 4th Edition of Rogers’ book in 1995. The application of Rogers’ theory of consequences provides a framework for balanced accounting of the impact of improvement interventions, which proposes that “improvers and leaders should seek a balanced accounting of all consequences of improvement across the life of an improvement programme, including deliberately pausing after implementation to identify and quantitatively or qualitatively evaluate any pleasant or unpleasant surprises.”

The Implementation Science approach provides a rigorous method for studying and reporting adaptation of interventions in research studies that provide generalizable evidence. However, application of that evidence in healthcare requires additional evidence about adaptation of complex systems to change.

In conclusion, I strongly support the importance of small tests of change and adaptation to improving healthcare. I also agree that we can and should learn from integration of different fields that are relevant to improvement. However, I cannot see much value in identifying a few common features between Quality Improvement and Implementation Science, which are just two of a variety of fields that are relevant to healthcare improvement.

Peter Davey
Medical School Lead for Healthcare Improvement, University of Dundee

Additional Questions:
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Please enter your name: Peter Davey
Job Title: Professor
Institution: University of Dundee Medical School
Reimbursement for attending a symposium?: No
A fee for speaking?: No
Reviewer: 3

Recommendation:

Comments:
This manuscript addresses an important overlap in the conceptual landscape of Quality Improvement on the one hand, and Implementation Science on the other. For two fields so closely related, there is surprisingly little literature explicitly focused on mutual sharing of learning. This is therefore a welcome contribution, aimed at helping people involved in the practice of improvement and implementation to benefit from knowledge in both fields. Thank you for the opportunity to review this manuscript.

Overall the manuscript is written in an accessible style, however there were several places where I was unsure of precisely the point being made, or of how the conclusion had been arrived at. In addition the article would benefit from some additional referencing to anchor it more in the existing literature and potentially to point readers at some examples, provided that additional references are permitted by the journal.

Specific comments:

The Problem

The problem description comes across as informal yet uses some terminology that a general readership may not be familiar with. For example, even “implementing evidence-based interventions” may mean quite different things to different people. This could be made clearer. At present there is only limited appeal to the available literature on this problem – providing more references may also help with the above issue by making it easier for readers not so familiar with the translational gaps to seek further information.

To what extent are the arguments made in this article new? Others have touched on at least some of the points made e.g. Shojania and Grimshaw Health Affairs 2005, Reed et al. BMC Medicine 2018, Marshall et al. The Lancet 2013, there may be others.

In the second paragraph it is stated that “In IS, the concept for creating change is ‘adaption of the intervention’” – with the implication that adaption alone is responsible for change. In e.g. Damschroder’s Consolidated Framework for Implementation Research, adaptability is one of eight sub-constructs of the main construct “Intervention characteristics”, itself one of five such constructs in
the model. In Normalization Process Theory, “reconfiguration” is one of four components of the core construct “reflexive monitoring”. It is therefore probably more accurate to say something along the lines that adaption is *one* of the key aspects of the process of change as conceptualised in IS.

In the last sentence of this para it is not clear whether it is the adaptations that are referred to as unique of the methods and approaches – I suspect the latter but this should be clarified.

In the “Context and Iteration” paragraph it is not clear what is meant by “context is ecological”.

Comparing PDSA and Adaptation

Page 4 lines 5-22 – this section of text does not have a clear message, each sentence seems to be making a separate point and the result is disjointed. More broadly the section “Comparing PDSA and Adaptation” whilst articulating some characteristics of PDSAs as used in QI and adaption as a concept in IS, does not actually do much in the way of comparing the two. Perhaps this could be outline and illustrated through some real examples in the literature, perhaps in a box or table?

In the section “Fidelity in QI and IS”, the example of fidelity in use of PDSA cycles is given – this is an example of fidelity to a method intended to support change. The example given for IS is of fidelity to the intervention itself, this is a different concept (related in a complicated manner to the concept of adaption). Is the intention here to argue that these different concepts of fidelity are each typical in their respective fields – i.e. in QI fidelity most often refers to fidelity of use of methods to support change, whereas in IS fidelity most often refers to fidelity of interventions – or are they simply intended as two different examples?

Moving forward and learning from each other

Page 5 line 28: Would “origins” be more accurate than “underpinnings” here? Whilst QI originated in industry, I wonder whether it is accurate to describe it as a business model as it currently manifests in healthcare?

How were the characteristics outlined in the figure arrived at? Is this intended to be exhaustive or illustrative? If the latter, are these the most important characteristics, and in what sense?

The messages in the “Education into practice” section at the end are not obviously related to the content of the article – this is the first time we hear of asking a specific question, choice of method and the role of context in the effectiveness (specifically) of small tests of change. This section should summarise the implications of the article clearly.

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Please enter your name: Thomas Woodcock

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Institution: Imperial College London

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**Date Sent:** 18-May-2020