

Review of: "Quality improvement and research differences: A guide for DNP and PhD faculty"

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This is a timely and interesting paper that aims to provide people undertaking research in service improvement or a quality improvement project to understand when they need to apply for IRB approval, i.e. when does a project move from quality improvement into the research domain.

The key principle applied is that there is not much difference between the two, though the methodology may differ. What the paper needs to provide is an answer to the question most people have: is this human subject research or quality improvement?

There is a clear difference between quality improvement, – implementing what is known in a reliable way and quality improvement research i.e. discovering what works, which then can be spread or scaled up. Discovering new knowledge clearly is research. Applying new knowledge may be research, i.e. discovering how to implement in different contexts or maybe only an improvement or implementation project.

I agree that it is not the matter of methodology as some QI projects clearly impact on humans and therefore will require ethical approval, or at the least asking the question of how the human subjects may be affected. Yet if the project is to apply what is known and therefore is determining whether this can be applied in different contexts, then the improvement may be in the realm of implementation science.

The authors attempt to overcome this dilemma by suggesting that the Bailly definition regarding the development of generalisable knowledge is one way to decide whether the QI project is research or not. Another is where the initiative is undertaken.

Hunt et al (2021) suggested one way forward is to ask the following questions:

- Have patients and families been engaged and informed
- Are the aims of the project clear to them
- Is there a need for informed consent?
- If there is qualitative data to be collected, has this been in a way that protects the participants?
- Have staff been engaged and will they have time, training, support for the project?
- Is there any potential for physical or psychological harm to either staff or patients and families?

Fiscella, et al., (2015) argue the distinction between quality improvement and quality improvement research is not distinct, especially if one considers internal validity of the outcome, i.e. if the findings are invalid or the intervention did not

succeed and resources were wasted. Generalisability is present in both

- Therefore one needs to ask a few key questions and if the answer is affirmative to any, then ethics is required i.e. it is more on the human subjects research side of the spectrum. (a few listed for example)
 - Does the project create new, generalisable knowledge?
 - Is it part of normal clinical care?
 - Does it include human tissue?
 - Is there randomisation for the intervention ?
 - Is there potential for harm – physical or mental?
 - Are Vulnerable individuals or groups are involved?
 - Is the data sensitive and or secondary to normal use?
 - Can one identify individuals ?
 - Will there be benefit from the initiative and to whom?
- I think they also need to consider the work of Mary Dixon Woods at the [THIS Institute](#), and that of Lloyd Provost among others to consider the fidelity of QI.

For example:

Provost LP. Analytical studies: a framework for quality improvement design and analysis. *BMJ Qual Saf.* 2011 Apr;20 Suppl 1(Suppl_1):i92-6. doi: 10.1136/bmjqs.2011.051557.

Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. *BMJ Qual Saf.* 2015 Mar;24(3):228-38. doi: 10.1136/bmjqs-2014-003627. Epub 2015 Jan 23.

Dixon-Woods M. How to improve healthcare improvement-an essay by Mary Dixon-Woods. *BMJ.* 2019 Oct 1;367:l5514. doi: 10.1136/bmj.l5514.

- QI needs the same amount of rigour as research and perhaps that is where the problem has been in the success or failure of QI initiatives. Finally, the paper needs to provide a clear guide for the researcher. It provides a good theoretical construct and at the end the reader needs to know what to do.

References

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Hunt, D.F., Dunn, M., Harrison, G. and Bailey, J. (2021). Ethical considerations in quality improvement: key questions and a practical guide. *BMJ Open Quality*, [online] 10(3), p.e001497. doi:10.1136/bmjopen-2021-001497.

