Reviewer's report

Title: Quality Improvement, Quality Improvement Research, Ethical Oversight and Learning Health Care Systems

Version: 3 Date: 4 June 2015

Reviewer: Eman Al Gaai

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Title:
Quality improvement, quality improvement research, ethical oversight and learning health care systems.

Reviewer's Report:
This is an essay of interest addressing the indistinguishability between Quality Improvement (QI) and Quality Improvement Research (QIR) and proposes new approaches for ethical oversight under the context of a learning health care system.

The authors used a logical argument and sound reasoning. It is written well enough for publication.

This paper is appropriate for readers of BMC Medical Ethics. There are some minor issues to be discretionally addressed by the authors and few minor revisions before considering publication as noted below.

Title: Discretionary Revision

The title does not directly convey what has been addressed. The terms are being mentioned in block format as key words rather than an informed title, the following is suggested:

Ethical oversight in quality improvement and quality improvement research: New approaches to promote a learning health care system.

Abstract:
Concise and standalone summary in describing the essay and it does help the readers to understand the paper.

Background: Discretionary Revision

Well written. Suggestion: add a couple of lines outlining what constitutes a learning health care system and its needs under the context of QI/QIR.
Discussion: Discretionary revision
The authors can arrange the headline divisions in a way to serve their flow of discussion.
Existing guidelines distinguish QI and Research
QI and QIR are not reliably distinguishable
a-Rigor of methods
b-Generalizability of findings
c-Other criteria
Balancing competing ethical principles
a-Risk to participants versus the imperative to improve care
b-Ethical review considerations
c-Two-step process
d-Integration of Clinical and Research Ethics Oversight
e-Training of QI/QIR Ethical Oversight Committees
f-Informed consent

Minor essential revisions (typos)
Consistency in writing [learning health care system(s)] versus [learning healthcare system(s)]
Line 178 learning healthcare systems
Line 202 learning healthcare systems
Line 286 a learning healthcare system

Consistency in writing [health care system(s)] versus [healthcare system(s)]
Line 140 healthcare delivery systems
Line 339 healthcare system

Typos
Line 185 the risk (to-add) participants
Line 224 this would (be-delete) occur
Line 244 applying ethical principles to groups (,-add) to members.... Or reword to separate
Line 258 there is wide variation in IRBs’ (vary widely in their-delete) efficiency, perspective..
Line 271 development of learning health (care-add) systems

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests