

BMJ Quality & Safety

<http://qualitysafety.bmj.com>

Policy on ethics review for quality improvement reports

Background

The editors of *BMJ Quality & Safety* recognize that requirements for ethics review for quality improvement work or “service improvements” pose challenges in practice. We also know that widely accepted principles and consensus statements have yet to emerge in terms of criteria for identifying improvement projects that should be exempt from traditional ethics review by institutional review boards for research on human subjects. Finally, we also recognise that guidelines or protocols for reviewing and monitoring quality improvement projects vary from country to country, and sometimes even within countries.

Given this variation and until greater clarity emerges, *BMJ Quality & Safety* has adopted the following policy regarding statements about the need for ethics review in manuscripts submitted to the journal.

Policy

BMJ Quality & Safety will accept statements to the effect that ethics review was not sought because the study met criteria for exemption from such review according to an institutional policy (e.g. because the work was deemed an improvement activity and not human subjects research).

This statement – i.e. that the work being reported was deemed exempt from ethics review according to local (or regional or national) policy – should be included in the main text of the manuscript. Authors will also need to complete the section of the submission template on study approval, stating the policy followed and indicating in what way the study met the criteria for exemption from ethics review. They should also state whether or not the policy leaves it to authors to determine if the work is exempt. Example statements are shown below:

- *Example statement for main text of the manuscript:* “According to the policy activities that constitute research at the <institution/organisation name>, this work met criteria for operational improvement activities exempt from ethics review.”
- *Example explanation for the study approval section of the submission template:* “<Institution/organisation name> uses the following criteria for determining if improvement activities require ethics review:
 - Policy criterion: The work is primarily intended to improve local care, not provide generalizable knowledge in a field of inquiry.
Explanation: The work reported here meets this criterion because hand hygiene is a universally recommended practice. We sought only to evaluate the improvements in compliance with hand hygiene as a result of auditing and feedback of compliance rates to hospital staff.
 - Etc

Authors should be prepared to offer documentation for such a policy, especially if the improvement activity involved interactions with patients, trainees or staff that potentially placed them in vulnerable positions. For instance, in the above example of an audit and feedback project involving hand hygiene compliance, if the identities of individual staff were tracked, with penalties for personnel with poor performance, then we would expect some form of ethics review or a written statement from the local ethics review board that a project of this sort would be considered exempt from ethics review.

In other words, the editors reserve the right to inquire into decisions not to pursue ethics review when the work involved seems clearly to constitute research, especially if the work poses more than minimal risk and/or involves vulnerable populations of patients, or places staff or trainees in vulnerable positions. We do not anticipate ever refusing to review a paper on the basis of disagreement with the policy at authors' institutions. But, we reserve the right to request documentation surrounding a decision to exempt from ethics review the work described in submitted manuscripts.

Rationale

While we completely appreciate the difference in ethical issues between quality improvement projects and clinical research, unilateral judgments by authors not to seek ethics review are potentially self-serving. The persons undertaking (or evaluating) an improvement project cannot by themselves make the decision regarding the need for ethics review entirely. There must be a local standard that has been applied—institutional, regional or national policy—and a statement of how the study meets the criteria in this protocol for exemption from ethics review.

Again, we recognize that policies on ethics review vary across and within countries. However, we believe that authors should be familiar with local criteria or policies for ethics review and should explicitly state how they applied such policies to their work.

Relevant Resources

1. Lynn J, Baily MA, Bottrell M, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med.* May 1 2007; 146(9):666-673.
2. Eccles MP, Weijer C, Mittman B. Requirements for ethics committee review for studies submitted to Implementation Science. *Implement Sci.* 2011; 6:32.
3. Flaming D, Barrett-Smith L, Brown N, Corcoran J. "Ethics? But it's only quality improvement!". *Healthc Q.* 2009; 12(2):50-55.
4. Hagen B, O'Beirne M, Desai S, Stingl M, Pachnowski CA, Hayward S. Innovations in the Ethical Review of Health-Related Quality Improvement and Research: The Alberta Research Ethics Community Consensus Initiative (ARECCI). *Healthc Policy.* May 2007; 2(4):e164-177.
5. Lo B, Groman M. Oversight of quality improvement: focusing on benefits and risks. *Arch Intern Med.* Jun 23 2003; 163(12):1481-1486.
6. Taylor HA, Pronovost PJ, Sugarman J. Ethics, oversight and quality improvement initiatives. *Qual Saf Health Care.* Aug 2010; 19(4):271-274.