Reviewer’s report

Title: Co-design and implementation research: challenges and solutions for ethics committees

Version: 0 Date: 20 Oct 2015

Reviewer: Sabi Redwood

Reviewer's report:

Thank you for inviting me to review this debate paper which I thought was beautifully written and clearly argued. The authors describe the problem of applying the regulatory approach to ethical scrutiny, based on bioethical principles, and its genesis in relation to the emergent and flexible nature of implementation research. The latter is based on the principles of co-design which seeks to establish democratic partnerships between researchers and the beneficiaries of the research. While the regulatory approach seeks to protect participants from potential harm, applying it to coproduction and collaboration for implementation constrains the very possibilities that coproduction offers, especially in relation to the need for adaptation and flexibility, and the consideration of context and feedback which make pre-specified outcomes and procedures unworkable. The authors clearly set out the problem and discuss the implications for implementation research and coproduction. Of course these are similar challenges for any researcher using an approach which does not fit neatly with the bioethical framework for research. The latter makes specific assumptions about the nature of research and what research participation entails which may be incommensurate or contradict more values-based or emergent approaches.

I have some minor concerns about the principles offered by the authors to guide ethics committees when considering applications:

The way the first three principles are laid out makes it difficult to ascertain exactly who needs to address, or think about addressing, what is being proposed. The researchers? Policy makers? Ethics committee members/ chairs? All three, or more groups? It would helpful if the authors clarified who they would like to take a lead in bringing about the desired changes in practice. The first principle is very board and many researchers using approaches with emergent designs will want to exhort the ethics committee community to learn more about their methodology in order more accurately to assess the ethical implications of what is being proposed in their applications. Is there scope for discussing whether conventional ethics committees are the most appropriate place to review these types of participatory implementation and co-design studies? The second and third principles contain much more specific examples of where the authors think the direction of travel lies, but they do not go on to suggest how the framework they suggest in principle 2 and the power sharing arrangement in principle 3 could be translated into workable practices in the healthcare research ethics context. Again, the question is raised for me if
conventional ethics committees are appropriate for this sort of review although the authors stress the importance of robust governance arrangements which, by implication, they suggest are best safeguarded by ethics committees.

The fourth principle is not so much a principle as an invitation for people involved in participatory research to learn from each other, to build on experience and to continue the debate. While the authors give some concrete examples of studies and suggestions from the literature, I was surprised not to see included in the discussion any reference to the work by Sarah Banks and colleagues at the University of Durham. Their work relates to community based participatory research which although not equivalent to implementation research and co-design, shares many of the features the authors refer to including power-sharing and emerging, flexible designs.


Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Unable to assess

Does the work include the necessary controls?
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Are the conclusions drawn adequately supported by the data shown?
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