Reviewer's report

Title: The challenge of complexity in evaluating health policies and programs: The case of Women's Participatory Groups to improve antenatal outcomes

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Reviewer: Mara Airoldi

Reviewer's report:

This article contributes to a fundamental methodological debate on the evaluation of complex interventions, on the role of process evaluation, if and how it can interface with RCTs and how it can inform the analysis of data.

The authors present an argument against the use of RCTs and meta-analysis of RCTs for evaluating complex interventions involving participatory learning and action (PLA). The original criticism appeared in a correspondence in the Lancet in 2013 (references 5 and 6), revisiting the ideas presented by Rifkin in the 90s on appropriate methods to understand community participation (reference 7). The current article articulates and updates that argument with an emphasis of the role of realist evaluation and scientific realism as well as recent guidance on the evaluation of complex intervention produced by MRC.

As pointed out in the abstract, the authors believe that the choice of research design should fit the nature of the question rather than being driven by methodological preferences. It would be helpful if the authors could relate their position to existing ideas on how to do this, e.g. Lucy Gilson's methodological reader (http://www.who.int/alliance-hpsr/alliancehpsr_reader.pdf).

It would be helpful if the authors could say explicitly if they see any role of RCTs in assessing whether PLA produces any change in antenatal outcomes and hence if it could complement a realist evaluation. If so, how? If not, is this an issue with PAL or with studying the impact of any complex "intervention"?

The distinction between mechanism-oriented, case-based approaches and RCTs (p5 line 18-30) brings the core argument of the paper to life. Again, it would be helpful if the authors could say if they think the two approaches can in any way complement each other in shedding light on what mechanism are at play, when and the extent to which they make a difference on outcomes of interest.

I would also find it helpful to understand more how a mechanism-oriented approach to causal explanation can produce certainty ("the mechanism will always produce the outcome of interest", line 22 p5) rather than a strong belief that the mechanism would produce the outcome in a similar context. Perhaps in the example of how realist evaluation would be used in the specific
example of PAL, it may be helpful to read how the purposive sampling of cases and respondent would generate that certainty.

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

Unable to assess

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