Reviewer’s report

Title: Evaluating complex health interventions: a critical analysis of the 'outcomes' concept

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Reviewer: Thomas Ostermann

Reviewer’s report:

In their article the authors aim at investigating the meaning of “outcome” and “outcome measurement” within the context of medical research.

At the very beginning the authors state that “in the context of medical research into the efficacy or effectiveness of an intervention the term ‘outcomes’ is generally interpreted to mean single endpoints with a linear cause and effect link to an external intervention”. I am not quite sure whether this statement really holds. I have seen several investigations with multimodal endpoints particularly in various kinds of rehabilitation studies. And of course there is no doubt that concepts like “self efficacy” or salutogenesis are far away from a linear causal assumptions.

Later on they state that the above given “interpretation of ‘outcomes’ may narrow the assessment of change to a single quantifiable indicator and divert attention away from the important contextual factors”.

Again I wonder if this is really the state of the art in outcomes research. In particular, Trauer (1998) has raised the discussion in his article on “Issues in the assessment of outcome in mental health” almost 10 years before. Also other author s like Breck (1995) have discussed “The Meaning of "Outcome" which are not referred to. Perhaps it would be easier for the reader to list the different approaches toward a concept of ‘outcomes’ discussed so far in a table.

The authors state that “this paper will trace the evolution of the concept of ‘outcomes’ from its beginnings in clinical trials of pharmaceuticals to its current use in evaluations of complex interventions.” This is really a nice idea and I would recommend to do a MEDLINE search (i.e. for the terms “outcome” “outcomes measure” as a suggestion) for every year and plot the number of hits against the years (starting at 1960 to 2008). This should give a good impression how “outcome” has evolved within the course of time.

Anyway, the authors turn into another direction and derive 8 assumptions “underpinning the concept of ‘outcomes’ as it is usually used within the context of clinical trials” and discuss them very broarly within the context of complex health interventions. Unfortunately (this was happening to me) the reader is lost within this discussion which isn’t getting anywhere in terms of a specifying what to do with the issues raised here.
However, I think this is an important discussion and if the authors would like to be a bit more compact and pick up the suggestions the article is worth publishing.

Major Compulsory Revisions:
- shortening the article
- table of existing articles on principles and meaning of outcome
- diagramm for the evolution of the term "outcome" in MEDLINE

Level of interest: An article whose findings are important to those with closely related research interests

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'