Reviewer's report

Title: A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials - a work in progress

Version: 1 Date: 16 Feb 2016

Reviewer: Matthew Baker

Reviewer's report:

This account of the development of a toolkit to assist researchers with the involvement of patients and the public in research trials is important. It is important because it attempts to take a systemic approach to the process of involvement and because it specifically seeks to identify resources to assist with the measurement and evaluation of the impact of PPI activities. It is to be welcomed as a substantive attempt to provide a comprehensive aid for researchers on the involvement of patients and the public.

There are limitations. These limitations are, in large part, identified by the authors.

Firstly, they admit to not having undertaken a systematic review of this area of activity. The virtue of their approach is that it has been borne out of the opportunistic and pragmatic necessity of their own practice. Can we be confident that they are not themselves retreading or duplicating established territory?

Secondly, they admit to having had no PPI involvement to date. If they had, and if a less opportunistic review of current work had been undertaken, they may have become acquainted with the toolkit developments pioneered by patients and lay people themselves that have been designed to support their peers in becoming effective research partners. Neglect of this evolving strand of activity reflects this limitation.

Finally, I am not sure from the paper how the developed structure of the Toolkit is envisaged. A principle claim is that it will prevent duplication of effort for other researchers in that it will collect together an extensive range of resources around the authors' framework. Perhaps it is clearer to the authors than to me as to how this will occur. Will the Toolkit end up as a pick and mix assortment of resources or will there be an editorial hand guiding users to best practice?
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