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: 04 Feb 2016

Reviewer: Sue Pavitt

Reviewer's report:

Page 1: Title

The changes requested by the reviewers actually take this away from the recognised MRC Guidelines for complex interventions https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/ that have a development, evaluative and implementation/process evaluation stages. I think the authors have obliged the reviewers but now risk down playing their achievement. My suggestion would be to realign with this MRC Guidelines as a recognised robust methodological approach:

A patient and public involvement (PPI) toolkit for meaningful and flexible involvement in clinical trials - The development stage.

Page 2 Methods Section Line 10-19

They should be permitted to reinstate that this article describes the development stage and that feasibility and evaluation will follow in accordance with the MRC Guidelines for a complex intervention. This means they should be permitted to revert back to the 'development of a toolkit' and acknowledge that subsequent evaluation and process evaluation stages will allow reiterative modifications of the toolkit to ensure it is fit for purpose in a real world scenario.

Their compromise to accommodate the reviewer's feedback to avoid "development" and replace with "developing" deviates from the MRC Guidelines and actually down plays what they have achieved and will likely affect the impact of the paper which would be disappointing given the calibre of the team and the research produced. If the editor permits my suggestion would be that the authors need to acknowledge that they are following the MRC Guidelines e.g. Page 5 lines 35-45 and in the methods section Page 6 Line 28-46 (on Page 6 they need to align this to the 1] Development, 2]Evaluative (feasibility and definitive evaluation) and 3] Implementation (Process Evaluation) stages of the MRC Guidelines and this they should set the scene for this methodological approach and that this paper covers the development stage. I believe that clarity
will really help the reader and addresses the reviewers concerns. This will require a modification of the article but in my opinion it will be a stronger publication.

PPI page 3 line 41

….decisions about research priorities add "that affect them".

PPI page 3 line 39-41

The addition of "or the wider public in the case of public health research", clause here isn't quite working for me I would prefer they reference back to the INVOLVE definition

"…When using the term 'public' we include patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. Whilst all of us are actual, former or indeed potential users of health and social care services, there is an important distinction to be made between the perspectives of the public and the perspectives of people who have a professional role in health and social care services…." http://www.invo.org.uk/posttyperesource/what-is-public-involvement-in-research/

Replace with:

Morally, PPI is advocated on the grounds that people affected by a condition , or the wider public in the case of public health research, have a right to have a say in decisions about research priorities that may affect them.

Page 4 Line 52 - replace 'an' with 'a'

Page 9 line 6 & 7 Page 13 Line 19- replace public contributors with patient/public contributors in alignment with PPI

Page 9 line 32 " …developed a document "Budgeting for Involvement"…” should be referenced

Page 11 line 13 & Line 36"developing" to be replaced with the "development of a PPI toolkit"

Page 13 Line 42 replace "further developed" with "further refined" through a reiterative evaluative and process evaluation stages in line with the MRC Guidelines

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