Reviewer's report

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

Version: 0 Date: 29 Jul 2015

Reviewer: Roger Steele

Reviewer's report:

The process described in the article is well informed as to the scope of current PPI resources and literature are concerned.

The issue of there being a plethora of PPI guidance which is largely underused matches my experience and understanding.

The notion of a toolkit geared towards a very specific audience (CIs) working within a very specific structure (clinical trial pathway) is a useful way to address such a problem. It matches the reviewers experience in achieving better engagement in PPI though specific researcher or research supporter audience targeting, based on the business at hand.

In the background section the author refers to PPI being important for 'both moral and pragmatic reasons'. There is a tendency in the PPI community towards a dichotomy between the two at times so it is refreshing to see both acknowledged as important. However, it is most often the pragmatic aspect that appears to engage the clinical research community in the reviewer's experience. Assuming the toolkit speaks the language of its intended audience and the business that concerns them then it is likely to be useful and engaging. It will be very interesting to see how this rolls out.

However, the emphasis in the tool seems to focus more on the application of PPI approaches rather than the intended impact of the PPI interventions on the trials themselves. Both are important, so I wonder if the latter needs more emphasis. This mapping to the pathway of the trial is very useful but describing the PPI intervention alone may not be enough. By also describing the intended impact of that intervention demonstrates the direct benefits to the trial CI who as a consequence may be better engaged and prompts intelligent consideration of finer aspects of the approach in the specific trial. More emphasis on impact is also consistent with a later evaluation stage that compares actual impacts with intended impacts.

The paper acknowledges the weakness to date of not having a patient and public view in the toolkit development, but it is right to take a business approach in the first instance. It is critical to
improve the utilisation of PPI in clinical trials for patient benefit - and that means a better structure for PPI in the business of trials. At the same time these structures should not be so rigid as to exclude the possibility of patients influencing the evolution of the structures and approaches themselves where they are for better effect, and better patient relevance now and in future.

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