Reviewer’s report

Title: PATIENT LED PROMs MUST TAKE CENTRE STAGE IN CANCER RESEARCH

Version: 0 Date: 09 Jan 2017

Reviewer: D.G Kyte

Reviewer's report:

Minor point: 'PROMs' should appear with a small 's' throughout.

I would broadly agree with the statement on pg.7: "...while data on the outcomes patients worry about are missing." Emerging evidence in oncology trials points to worryingly high rates of under-reporting with regards to patient-reported outcomes (PROs).

The following statement on pg. 7 is a little unclear: "Academic studies which involve patients in their development processes may be exempt from these criticisms, though we cannot be sure because Tannock reviewed all published studies during the time when involvement started." I would suggest revising and clarifying. I am not aware of evidence to suggest patient involvement in oncology trial design leads to higher PRO reporting rates, but I think that this is an interesting research question that would merit investigation - perhaps the author could call for this?

Also pg. 7: "It can be argued that most of these drugs will work best early in the disease when a single pathway mutation is causing the cancer but clinical and regulatory structures discourage that from happening." Can the author explain why this is the case?

Minor point pg. 7 - should read 'déjà vu'

I can understand the author's slightly provocative stance in parts, as presumably this article is to serve as catalyst to start a meaningful debate around the improvement of PROMs utilisation in cancer research. However, my own view is the statement appearing on pg. 10 "Quality of life appraisal in research is currently a shambles." is too strong. I would not agree that QoL methods
are poor across the board. This is too much of a sweeping statement and ignores those trialists currently conducting robust QoL work (of which there are certainly examples - as we are seeing in our current review of pre-2014 UK Portfolio Cancer trials that include a PRO primary or secondary endpoint [the Macmillan-funded 'EPiC' project]). However, I do agree that there is too much variation in quality and overall standards need to be consistently higher.

I also agree with the central tenet of the piece: "We need to move quality-of-life research on, to become a new centre of influence in cancer care. The first priority is that we must have a single, consistent quality of life approach. The data must be produced and analysed in a way which facilitates comparison be described from a patient viewpoint."

I have to disagree with the statement on pg.10-11 re the development of the National QoL metric. Having been party to some of the discussions surrounding this initiative, it is not my belief that the development is being run by a 'marketing company'. Rather, the initial work on this is being led by a respected oncology research group at the University of Leeds, coordinated by an experienced oncology clinician and researcher, backed by a patient advisory group.

It is good to see reference to the SISAQOL initiative, however, there is much more work underway, across many organisations, that has not been sufficiently highlighted. I would think it essential to mention the work of both CPROR and ISOQOL with regards the development of the 2013 CONSORT PRO reporting guidelines and the forthcoming SPIRIT PRO Extension - both of which will be extremely important in driving up standards of PRO research internationally. In fact, there is early evidence that the CONSORT PRO extension is already having such an impact. In addition, the COSMIN group have developed guidelines to improve the development/evaluation of PROMs and the COMET group have conducted important work surrounding the development of 'Core Outcome Sets' in cancer research in order to improve the comparability of PRO trial results in this field. Moreover, CPROR (launched Nov 2016) is currently implementing its strategy to: (i) build capacity for applied and methodological PROs research, (ii) support clinicians, trials units, ethics committees, funders, regulators and policy makers to ensure high quality, ethical, efficient PRO data collection, (iii) provide education, training and support for optimal use and integration of PROs in clinical trials and routine care,
(iv) ensure that PRO data collected in routine care and trials meets the needs of patients and the public, clinicians and policy makers.

The conclusion is strong and makes a compelling case for the use of QoL 'pathways'.

**Level of interest**
Please indicate how interesting you found the manuscript:
An article of importance in its field

**Quality of written English**
Please indicate the quality of language in the manuscript:
Acceptable

**Declaration of competing interests**
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?
3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?
4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?
5. Do you have any other financial competing interests?
6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

Co-PI on a PRO research project funded by Macmillan Cancer Support.

Assistant Director of the Centre for Patient-Reported Outcome Research (CPROR) at the University of Birmingham, UK.
I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal