Reviewer’s report
Title: PATIENT LED PROMs MUST TAKE CENTRE STAGE IN CANCER RESEARCH

Version: 0 Date: 17 Apr 2017

Reviewer: Kirstie Haywood

Reviewer's report:
General comment
Many thanks for inviting me to review this compelling and considered personal reflection on the
status of quality of life assessment and the importance of patient involvement. It is powerful and
insightful paper.
Unfortunately, I am not able to comment on the cancer-specific detail – and would recommend
review by an oncology clinical academic.
However, the focus on the importance of appropriately involving patients in the generation, use
and interpretation of PROMs is a concern that I fully endorse.

Specific comments - PROMs section

I think that the points that the authors make are of note. However, I do believe that it’s important
that that the author recognises that, whilst that most certainly are limitations in many areas and
with many available PROMs, in certain areas there is significant progress. There is a dearth of
references in support of the arguments put forward. And, whilst I appreciate that this is an
important document written from the perspective as an involved and experienced patient, I
wonder if a collaborative approach which involves a collaborator who could supplement the
PROMs element (and probably a clinician who could supplement the Cancer-specific aspects?),
would strengthen the paper further. In particular, I would like to see a stronger counter-argument
which evidences where PROMs were, where we are now, and the direction that (we hope)
PROMs should be heading in.
Reference should also be made to the 2009 FDA guidance for PROM development which
recognised the limitations of many PROMs used to support drug evaluations. This specifically
highlighted the limited engagement with patients to inform PROM content (hence, the limited face and content validity – and hence, most likely limited relevance to patients!) – and recommendations for greater transparency and a clearer audit trail from the voice of the patient to the derived item content of PROMs was recommended. Whilst the FDA did not ‘engage’ with patient engagement as research partners, this was an important step forward in ensuring greater transparency in the way in which the patients voice was incorporated into future PROMs - and specifically, where these are used to support drug evaluation.

Similarly, whilst I concur with the importance of engaging with patients as partners in PROM development, there are some groups that have made important moves towards greater patient involvement – the author should refer to the work of OMERACT in the Rheumatology field and more specifically de Wit, Hewlett, Kirwan and Dures.

I’m a little confused by the distinction that the author makes between PROMs and QoL assessment – eg, ‘PROMs and quality of life could work together…’ (p11, lines 16-17). The term patient-reported outcome came out of the FDA report – to provide some consistency in the way in which authors were referring to patient-completed measures or questionnaires. It’s an over-riding concept that highlights the importance of assessment reflecting the patients’ perspective about how they feel, what they can and cannot and how they live their lives because of their health and associated healthcare (please see Patrick et al, 2007 Value Health for original definition). The ‘M’ is added (mostly in the UK) to indicate the operationalization of this concept into a measurement instrument. Moreover, numerous authors have described the dynamic, multi-dimensional aspects of quality of life – and linked this to the challenges of measurement. It would be helpful for the author to refer to such papers. For example, Ferrans et al (2005 – Conceptual Model of Health-related Quality of Life); Bakas et al (2012 – Review of HRQoL models); Pietersma et al (2014 – Domains of QoL); and Huber et al (2011 – How should we define Health? BMJ).

Minor points:

Page 7: line 8 and 9: I suggest that the author should revise the relation between Industry and patient involvement. Whilst, historically, one might argue that the PI focus was limited, this has / is changing and many companies have now appointed PPI leads.
The suggested split between the EORTC and CPROR is too simplistic. As I am sure that author is aware, the EORTC was responsible for the development of one of the most widely used cancer-specific PROMs. The suggested division should be revised.

Lines 32-40: Please edit to improve accuracy: The Royal College of Nursing Research Institute (RCNRI) at Warwick Medical School has two core work-streams that are relevant to this article: patient reported outcomes and patient and public involvement. It is important to note that it is not the RCNRI, per se, that is lobbying ISOQOL. Rather, leads for the PRO and PPI work-streams, who are members of ISOQOL. Moreover, I think that it’s important to recognise that, informed by work of its members (ref to Haywood et al, 2015; 2016), ISOQOL has recently highlighted patient engagement as part of its future vision and mission statement (http://www.isoqol.org/about-isoqol).


Refs:
Refs 11 and 12 don’t appear in the text.
Standard formatting of ref list is required.

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