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Letter to the editor

Patient involvement vs. patient participation in qualitative research in the development of PROMs

I'm writing in response to a recent article published in *HEX*: Wiering et al.[1] I read this article with great deal of interest, given the title and my interest in patient involvement in research and PROMs.

However, I felt a little concerned that the article seemed to combine 'patient involvement' in the form of *qualitative research* to develop PROMs and, to a lesser scale, patient involvement as *active involvement in research*[2] working alongside the PROM development team. However, little detail was provided in the article on the latter other than a few studies with 'patient involvement in developing the domains or framework' (although it is unclear exactly what this involvement entailed).

The authors are correct to state that the views of patients are key to developing PROMs and rightly cited the FDA regulatory requirement for qualitative research with patients to develop PROMs for medical product development and regulatory claims.[3] This guideline advocates the use of (i) open-ended concept elicitation interviews to establish the key concepts important and relevant to patients for inclusion in a conceptual model and framework forming the basis of the PROM content, and (ii) cognitive interviews with patients to confirm the face and content validity of a draft PROM. However, there is a key role for patients to be involved in the research and PROM development process that seems to be missing from this paper, or at least not emphasized enough.

For PROM development, patients can have parallel, but notably different roles: (i) as participants in qualitative research to establish the content and confirm the content/face validity of PROMs and (ii) as active members of the research team working collaboratively in all aspects of the PROM development to 'enhance the quality, relevance and acceptability of PROMs'.[4] The second role may include involvement in a whole range of activities, such as:

- Reviewing the quality and acceptability of existing PROMs (for a particular patient group/research design)
- Identifying the need for the development of a new PROM
- Contributing to the qualitative research design (e.g. recruitment and consent strategies, interview process, topic guide development)
- Conducting the interviews (with appropriate training provided)
- Interpreting the qualitative data to help develop the conceptual model and framework
- Drafting the wording and format of the PROM
- Revising the wording and format of the PROM during an iterative cognitive interview process
- Assessing the cross-cultural equivalence of a translated PROM
- Finalizing the PROM
- Interpreting the psychometric properties of a PROM (especially the Minimal (Clinical) Important Change)
- Dissemination of the study findings and wider public engagement

In summary, I think this article is well intended and, although it might be a matter of

semantics, the role of true patient involvement in PROM development is important and it seems to have been underemphasized.

References

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2 INVOLVE. http://www.invo.org.uk/
3 U.S Food and Drug Administration. Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, 2009. http://www.fda.gov/downloads/Drugs/. . ./Guidances/UCM193282.pdf
4 Staniszewska S, Haywood KL, Brett J, Tutton L. Patient and public involvement in patient-reported outcome measures. *The Patient-Patient-Centered Outcomes Research*, 2012; **5**: 79–87.

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