New guidance urges improved reporting of important outcomes for patients in trials publications

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Clinical trials provide us with the best evidence to guide patient treatment and inform health policy. Yet, crucial information, on outcomes reported directly by patients such as their quality of life, is often left out of clinical trial publications, according to international researchers.

Patient Reported Outcomes (PROs) include assessments of quality of life, symptoms and satisfaction with care. They can provide important information about the patients' perceptions and experiences of their disease and treatment. This information can be used to inform patient centered care.

Clinical trial publications often do not report these outcomes, or incompletely report or omit important information. As a result clinicians are unlikely to use the information in practice and in shared decision-making with patients.

"The assessment of PROs in clinical trials takes valuable patient time and is costly. Poor quality reporting may limit the use of PRO data to inform patient care. This may be viewed as unethical and wasteful of limited resources." says Dr Melanie Calvert of the University of Birmingham, first author of the study published online today (February 27) in the Journal of the American Medical Association which provides new guidance aimed at promoting improved reporting of PROs in clinical trials.

Evidence-based recommendations to improve the completeness of reporting of randomized controlled trials from the CONSORT (Consolidated Standards of Reporting Trials) group are widely endorsed by journal editors and have led to improvements in trial reporting over time. However, the existing guidance did not include key items relevant to optimal PRO reporting.

The current research was led by University of Birmingham, Queens University Ontario, Bristol University, the International Society for Quality of Life Research and the CONSORT Group and was funded by the Medical Research Council, UK and the Canadian Institutes for Health Research. The international collaboration involved key stakeholders, including journal editors, funders, policy makers and patient representatives. It extends the existing CONSORT guidance with the aim of ensuring the transparent reporting of PRO data to inform patient care.

For media enquiries please contact Niki McAllister, press office, University of Birmingham, +44 (0)121 414 5134.

Notes to editors

The CONSORT Statement was first published in 1996 and most recently revised in 2010. It provides evidence-based recommendations to improve the completeness of reporting of randomized controlled trials. A number of extensions have been developed to improve reporting of different trial designs, interventions and specific data (http://www.consort-statement.org/).

The CONSORT Statement is endorsed by major journals and editorial groups, such as the International Committee of Medical Journal Editors, and its use has been associated with improved reporting of trials.

The CONSORT PRO extension should be used in conjunction with the existing CONSORT statements and consists of five items:

- PROs to be identified in abstracts to facilitate easy identification of studies to inform clinical care and evidence synthesis.
- PRO hypothesis to be described in order to reduce the risk of multiple statistical testing and selective reporting.
- Evidence of the PRO questionnaire validity and reliability in relation to the study target population should be provided to allow readers to assess the quality and appropriateness of the PRO being used.
- Explicit statement of statistical approaches for dealing with missing data should be reported so readers can assess the implications including any potential bias.
- Finally, limitations and the generalisability of study findings should be described to ensure correct interpretation of results in clinical practice.

Further information on PROs research led by Dr Calvert at the University of Birmingham is available at:

http://www.birmingham.ac.uk/patient-reported-outcomes (http://www.birmingham.ac.uk/patient-reported-outcomes)

* The CONSORT PRO extension is the result of collaboration between the MRC Midland Hub for Trials Methodology Research at the University of Birmingham UK (Dr Melanie Calvert), International Society for Quality of Life Research Reporting Guidelines Taskforce (ISOQOL) (chaired by Professor Michael Brundage, Queens University Ontario and including Profs Blazeby, Revicki and Dr Calvert plus international collaborators), the CONSORT Executive (Professors Moher and Altman) and the MRC ConDuCT Hub for Trials Methodology Research, University of Bristol UK (Professor Jane Blazeby) working closely with leading international journal editors, funders, policy makers and patient representatives.

Reporting of Patient-Reported Outcomes in Randomized Trials: The CONSORT PRO Extension