

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

February 28 2013

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 decisionmaking with patients.

"The assessment of PROs in <u>clinical trials</u> 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 <u>Journal of the American Medical Association</u> which provides new guidance aimed at promoting improved reporting of PROs in



clinical trials.

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

Provided by University of Birmingham

Citation: New guidance urges improved reporting of important outcomes for patients in trials publications (2013, February 28) retrieved 7 May 2024 from <u>https://medicalxpress.com/news/2013-02-guidance-urges-important-outcomes-patients.html</u>

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