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

A recent article in *JAMA* [1] reports the extension of the Consolidated Standards of Reporting Trials (CONSORT) Patient-Reported Outcome (PRO) group on recommendations for what should be included when reporting the results of PROs in randomized controlled trials (RCTs) as primary or secondary outcomes. Five CONSORT PRO checklist items are recommended as follows:

- that PROS be identified as a primary or secondary outcome in the abstract;
- that a description of the hypothesis of PROs and relevant domains be provided (i.e., if a multidimensional PRO tool has been used);
- that evidence of the PRO instrument's validity and reliability be provided or cited;
- that statistical approaches for dealing with missing data be explicitly stated; and
- that PRO-specific limitation of study findings and generalizability of results to other populations and clinical practice be discussed.

PRO extension was deemed unnecessary for many CONSORT checklist items.

These recommendations are important for editors, reviewers, and readers of *Value in Health* (VIH). *VIH* may report PRO findings separate from the main results of the RCT, which are often found in journals targeted to clinicians. These recommendations also hold implications for ISPOR members in the documentation of study protocols, statistical analysis plans, and other elements of RCTs. Special attention can be given to these checklist items on PROs when developing sources of documentation for PRO outcomes used in the trial or analyses of PROs presented in trial data.

PROs in this Consort Extension refer to outcomes labeled as *health status*, *health-related quality of life*, *symptoms*, *utilities*, *satisfaction with care*, *and adherence*. This wide-ranging definition is particularly relevant to the ISPOR audience because some of these concepts may not be part of current medical product regulatory review or labeling or considered in reviews by reimbursement authorities. The Extension requests that the rationale for including each PRO and its constituent parts or domains be presented along with hypotheses. This rationale is often important in the selection of preference-based or utility measures as well as other PROs frequently used by ISPOR members and seen in *VIH*. The recommendations point to sometimes-neglected aspects of data collection and analysis, such as mode of administration, use of any proxy reporting, loss to follow-up, and methods used to account for missing data.

Of major importance is the recommendation that interpretation of PRO results be made in relation to clinical outcomes, including survival data. PRO end points used in clinical trials may not always be closely associated with clinical outcomes or survival, because different concepts are being measured or an important clinical measure, such as lung function, may not be associated with changes in symptoms, behaviors, or other outcomes more distal in impact. Nonetheless, patients, families, and other stakeholders are interested in considering the benefits and harms seen in both clinical and PRO outcomes. Interpretation of trial results may be incomplete without all outcomes that are patient-important. Distinctions in this Extension are made between primary and secondary outcomes or key secondary outcomes, particularly when the sample size is taken into account or alpha is spent in statistical analysis of these PRO outcomes. This distinction is familiar to the ISPOR audience where end point models and statistical analyses of trial data are often-considered topics.

This CONSORT extension does not currently apply to other clinical outcome assessments. These include, in addition to PROs, clinician-reported outcomes or observer-reported outcomes [2]. Nevertheless, the same principles may apply to these outcomes. CONSORT and its extensions are "living documents," and further consideration may be given to the full range of clinical outcome assessments as more and more trial publications use these outcomes in different combinations.

This CONSORT extension provides additional instructions to authors preparing journal submissions, including presentation of technical material in appendices when space limitations prohibit this in the source article. *VIH* has the important policy to include such appendices for technical material [3]. The PRO extension recommendation could well find a place in modified instructions to *VIH* contributors.

Acknowledgments

Members of the ISPOR PRO Special Interest Group participated in a survey of key stakeholders using candidate reporting items from a systematic review. Results are available in eAppendix 1 available at http://www.jama.com for Calvert et al. [1]. Donald Patrick and Mike Drummond attended a 2-day meeting in London representing ISPOR where consensus was achieved among 29

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participants from leading journals, CONSORT, and key stakeholder groups. This process is described in eAppendix 2 and eFigure 1 and eFigure 2 in Calvert et al. [1].

Donald Patrick, PhD, MSPH
University of Washington - Health Services, Seattle, WA, USA

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