CORRESPONDENCE

RE: Recommended Patient-Reported Core Set of Symptoms to Measure in Adult Cancer Treatment Trials

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We read with interest the editorial (1) and four linked papers (2–5) exploring the important issue of core sets in cancer trials. The editorial highlights the need for a clear rationale for core outcome sets (COS) and for better approaches to their development. We welcome this attention to core outcome sets and here refer to the rationale and approach promoted by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative (www.comet-initiative.org) (6).

The primary justification for developing and using COS in oncology is the need for consensus in the selection, measurement, and reporting of outcomes in trials to improve data synthesis, reduce outcome reporting bias, and optimize the relevance of evidence for decision-making. Currently, the heterogeneity of outcome reporting in all cancer types prevents meaningful comparisons of data (7), but the mandatory use of a minimal set of outcomes (including both clinical and patient-reported outcomes) for specific cancer types should address these issues. However, careful consideration needs to be given to the scope of any COS, including whether it is to apply to one or all modes of treatment for the particular condition.

 Whilst we agree that consensus methods are required to define a COS, the methods used in the linked papers do not fully address how patients can be involved (8). For example, Chera et al. state that, “experts on this panel agreed that these symptoms and health-related quality of life (HRQoL) domains are relevant to most head and neck cancer patients” (2). The panel, however, included only one patient representative. It is recommended that real canvassing of the opinion of a representative sample of people who have been treated for the disease is required to justify inclusion of items in a COS. Whether symptom prevalence equates to symptoms that patients prioritize is unknown, and we consider that the emphasis given to patients’ views should be in similar or greater proportions to those of health professionals.

Core outcome sets represent an important step in improving the quality, reporting, and understanding of the results of clinical trials. It is essential to optimize methods for development. The work should gain the views of key stakeholders and be iterative, with registration of studies at the outset to develop international collaboration and avoid unnecessary duplication of work. The work presented in the four papers should be considered alongside ongoing research in this field with the aim of working toward a global consensus about core outcomes that are most relevant to patients and health care professionals (9,10).

References