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A Checklist to Evaluate Patient-Reported Outcome Assessments in Clinical Trials

1. WERE THE HEALTH AND QUALITY OF LIFE OUTCOMES RELEVANT TO PATIENTS, CLINICIANS, FAMILIES, AND DECISION MAKERS MEASURED IN THIS STUDY?

- Did the instruments chosen fit the application and primary objectives of the study?
- Was the rationale for selection of concepts, domains and instruments presented?
- Were there any important aspects of health or quality of life that were omitted in this study from the perspectives of the patient, clinician, significant others, payors, or other administrators and decision-makers?

2. WAS THE INTERVENTION DESCRIBED SUFFICIENTLY TO INTERPRET THE OUTCOME RESULTS?

- Did the article describe or reference the what, how, who, where, and when?
- Was the timing of outcome assessments optimal in relation to the intervention?
- Was the intervention performed by the same group doing the evaluation?

3. DID THE OUTCOMES MATCH THE POPULATION BEING ASSESSED?

- Were the age, gender, ethnicity, reading or cognitive ability of the population described?
- Had the instruments used been validated previously on this population or validated in this study?
- Was evidence of validation for use in this population presented?

4. WERE THE APPROPRIATE TYPES OF PATIENT-REPORTED OUTCOMES USED IN THE STUDY?

- Were all the data collected using same mode of data collection or mixed modes compared for data quality and outcomes?
- Were the appropriate mix of generic and specific instruments used in this study to meet study objectives?
- If there were trade-offs between quality and quantity of life, or an economic evaluation, have the investigators used the right instruments?
- Was the study powered for the patient reported outcome measures?

5. WERE ANY METHODS USED TO MONITOR THE QUALITY OF THE PATIENT-REPORTED OUTCOMES

- Were missing data described?
- If proxy respondents were used, was a comparison made between the patient and proxy reports?



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6. DID THE INSTRUMENTS WORK IN THE WAY THEY WERE SUPPOSED TO WORK?

Did the instruments used detect changes in the domains of primary interest to patients and their families?

Did the instruments detect any unanticipated outcomes of the intervention?

7. DID THE OUTCOMES MATCH THE POPULATION BEING ASSESSED?

Did the article describe or reference the what, how, who, where, and when?

Were any graphical methods used to present the data?

8. WERE THE PATIENT REPORTED OUTCOMES ANALYZED ADEQUATELY?

If patient-reported outcomes data were pooled, i.e. across countries or across centers, were any analyses presented to justify the pooling?

Were any deaths reported? If so, were these taken into account in the analyses of patient reported outcomes, e.g. inclusion of all patient data in analyses up to the point of death or drop-out?

9. WERE THE HEALTH AND QUALITY-OF-LIFE RESULTS TRANSLATED INTO TERMS MEANINGFUL TO CLINICIANS THAT AIDED COMMUNICATION OF RESULTS TO PATIENTS, FAMILIES, AND DECISION MAKERS?

Was an external measure more familiar to stakeholders used to interpret the results?

10. WILL THE OUTCOME RESULTS HELP INFORM PATIENTS AND CLINICIANS ON SELECTION OR ADOPTION OF TREATMENTS?

Were missing data described?

If proxy respondents were used, was a comparison made between the patient and proxy reports?

11. WAS STUDY SPONSORSHIP ADEQUATELY ACKNOWLEDGED?

Was there a statement of study sponsorship included in the article?

Did the authors acknowledge any bias resulting from study funding or sponsorship of all authors on the article?