

A new evidence-informed and consensus based reporting Instrument for reporting of Planned Endpoints in CTs (InSPECT)

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Health care is not adequately informed by evidence. From neonatology to geriatrics, patients, families and clinicians rely on research to inform treatment decisions. Without appropriate selection and complete reporting of the outcomes that have been studied in clinical trials (CT), researchers cannot replicate or build on existing research findings and decision makers cannot reliably choose safe and effective interventions. Also, the development of Core Outcome Sets (COS) is impaired. Recent evidence demonstrates that, despite its widely acknowledged importance, outcome reporting quality remains poor in 40-90% of CTs.

To improve the quality of outcome reporting, ensuring they are accurate and informative for clinical decision making, informing health policy and for regulatory purposes, an international group of experts and stakeholders currently develops, validates and will implement an outcome-reporting standard: the Instrument for reporting of Planned Endpoints in CTs (InsPECT).

From a scoping review six important reporting themes have been identified: 1) What: description of outcome 2) Why: Qualification for condition and population i.e. scientific rationale for selecting an outcome; 3) How: Measurement instrument and details on its validity, feasibility, reliability and responsiveness; 4) Who: Source of information; 5) Where: Location, and 6) When: Timing of outcome measurement.

While in the development of InSPECT the emphasis is on CTs, the evidence generated on outcome reporting applies across all evaluative study designs. Enabling transparent and evidence based outcome reporting, the InsPECT standard will reduce research waste by facilitating COS development and evidence synthesis. Increasing informed decision making at the bedside, InsPECT will ultimately improve patient and health system outcomes.

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