

Research Reproducibility 2020
Educating for Reproducibility: Pathways to Research Integrity
University of Florida, Gainesville, FL, USA

Using reporting standards to promote research replicability and rigor in clinical trials

Terry Kit Selfe, DC, PhD
University of Florida Health Science Center Libraries

ABSTRACT

Background: Guidelines regarding content to be reported in journal articles exist for numerous study designs. Intended to improve the quality and completeness of research reporting, these standards can be used to enhance research replicability and rigor. This presentation will briefly introduce reporting standards, then focus on those most relevant to replicability and rigor of clinical trials: the Consolidated Standards of Reporting Trials (CONSORT) statement, Template for Intervention Description and Replication (TIDieR), and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

Description: CONSORT is the most well-known of these standards, with many journals recommending or requiring the inclusion of the CONSORT flow diagram and/or checklist with manuscript submissions. TIDieR is focused on the intervention and comparison group descriptions. This is particularly important in trials of non-pharmacologic interventions which are often complex, multi-component therapies requiring detailed explanation of the therapy, its implementation, and the intervention providers. Adherence to these standards enhances research replicability by ensuring the study components are well documented. As these standards address many potential sources of bias, their use during the early stages of study design can also promote research rigor, particularly among novice researchers who might otherwise be unaware of some potential concerns that could be avoided or mitigated if addressed during the planning of the study. Finally, SPIRIT addresses study protocols. This type of publication, with its focus on the study methods, allows authors to provide much more detail regarding the design than is typically found in original research articles reporting study findings. This additional detail allows for greater replicability. Moreover, published study protocols enhance transparency as they document the study design and analysis as planned, and any discrepancies between the original plan and the study as reported after completion can be observed.

Conclusions: Following good reporting practices as described in reporting standards, such as CONSORT, TIDieR, and SPIRIT, promotes research replicability, and use of these standards during the study planning and design stages can have a positive impact on study rigor. [325 words]