

Prevalence of Common Outcomes From

Randomized Controlled Trials

Preston Le, BS, MD Candidate^{1,2}, Stephanie Qi, BS^{1,2}, Phat Luong, BS, MS^{1,2}, Liron Caplan, MD, PhD^{1,2}

¹ Rocky Mountain Regional Veterans Affairs Medical Center, Denver, CO²; University of Colorado School of Medicine, Aurora, CO

Background

Optimal clinical practice is often defined by treatment guidelines that depend on the conclusions drawn from systematic reviews (SRs) and meta-analyses, which, in turn, typically depend on randomized controlled trial (RCTs) data. However, the degree to which RCTs employ consistent outcomes and report the results sufficiently to allow for aggregation remains unknown. Without uniform outcomes (known as core-outcome sets), systematic reviews cannot aggregate data, thereby frustrating their essential function and affecting treatment guidelines.¹

Aim: We assessed the proportion of reported common outcomes (PORCO) across a broad spectrum of medical disciplines.

Methods

To ensure all medical disciplines were represented, a convenience sample of SRs, RCTs, and outcomes were drawn from 21 medical topics (those directly related to a medical discipline) in the Cochrane Database of Systematic Reviews. The primary outcome was the proportion of included RCTs that reported a common outcome within each SR. We evaluated SR characteristics associated with this proportion, including the number of RCTs within the SR, the total number of study subjects/participants, the duration of the SR period, and the number of outcomes in each SR.

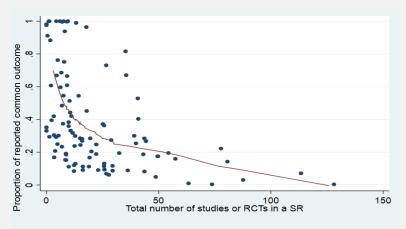


Figure 1. Correlation between number of included randomized controlled trials common outcomes (p=0.01). in a systematic review and proportion of reported common outcomes.

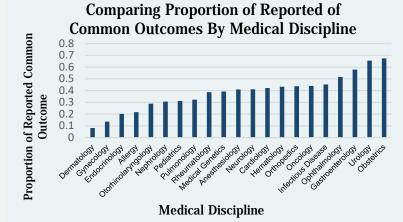


Figure 2. Comparing proportion of reported common outcomes by medical discipline.



U.S. Department

of Veterans Affairs

Only 14.3% of 105 meta-analyses shared a common outcome among all contributing RCTs. When comparing by medical discipline, we found that SRs under Obstetrics had the largest PORCO while SRs under Dermatology had the smallest (Figure 2). Our meta-analysis revealed a statistically significant negative correlation between the number of included RCTs within a SR and likelihood of reporting a common outcome (p<0.001; Figure 1). We also found a positive correlation between the total number of participants summed across all contributing RCTs in each SR and the proportion of reported common outcomes (p<0.001). Finally, we found a negative correlation between the time interval covered by a SR and the proportion of reported

Conclusions

The failure to report a common RCT outcome may have harmful consequences, including the inability to compare results of a given RCT with similar RCTs and the weakening of evidence underlying a clinical practice guideline. This may cause patient harm and unethical scientific conduct. Journal guidelines must be improved and outcomes must be made more consistent in order to produce results that can be aggregated.

References

Williamson PR, Altman DG, Blazdy JM, et al. Developing core outcome sets for clinical trials: Issues to consider. Trials 2012;13:1-8.
Easterbrook PJ, Gopalan R, Berlin JA, Matthews DR, Gopalan R, Matthews DR. Publication bias in clinical research. Lancet 1991;37(8740):867–72.
Chan A-W, Manna DG. Identifying outcome reporting bias in randomized trials on Public-treview of publications and survey of authors. Bmj 2005;330(7494):753.
Chan A-W, Manna DG. Hentrying outcome reporting bias in randomized trials funded by the Canadian Institutes of Health Research. Cmaj 2004;17(17):755-40.
Chan A-W, Hrödyarson A, Haahr MT, Gotzeche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: Comparison of protocols to publishearticles. J Am Med Assoc 2004;291(20):2457-65.

De Oliveira GS, Chang R, Kendall MC, Fitzgerald PC, McCarthy RJ. Publication bias in the anesthesiology literature. Anesth Analg. 2012;11:45):1042–8.
Yassair Ghaenis S, Shirazi AA, Failowski M, Publication bias and the pharmacentical industry: the case of lamoritagine in bipolar disorder. Medseage J Med 2008;10(9):211.
Rayhill ML, Sharon R, Burch R, Loder E, Registration status and outcome reporting of trials published in core beadache medicine journals. Neurology 2015;85(20):1789–94.
Kirkham JJ, Dwan KM, Altmann DC, et al. The impact of outcome reporting bias in randomized costrolled trials on a cohort of systematic reviews. BMJ 2010;340(7747):637–40.
Wyst NA dyn M, Aero M, Marguey 2 Stata command to perform note analysis of biosmali data. Anh Public Hall [Internet] 301472(9):1–10. Available fors.