

Combining the CONSORT Statement and Aspects of the RE-AIM Framework

We propose the following seven additions to the existing CONSORT criteria, which would help greatly to increase awareness of and reporting on external validity. If such criteria were widely adopted, this would greatly enhance not only the quality and information value of individual studies, but also of evidence-based reviews and meta-analyses.

The current state of health promotion research is so biased toward reporting on internal validity issues that it is impossible to draw any conclusions about generalization because of the lack of attention to issues of representativeness, especially at the level of settings and intervention agents (Glasgow et al, in press; Bull, et al, 2002).

This becomes even more problematic when the evidence base upon which meta-analysis and practice recommendations are based consists largely or solely of efficacy studies of unknown generalizability because researchers did not describe context and sampling or this information was not published.

The seven items that we propose below should apply to both efficacy and effectiveness studies. They would not require a great deal of additional journal space and are listed below in the same format as existing CONSORT items. Davidson, K. W., Goldstein, M., Kaplan, R. M., Kaufmann, P. G., Knatterud, G. L., Orleans, C. T., Spring, B., Trudeau, K. J., & Whitlock, E. P. (2003). Evidence-based behavioral medicine: What is it, and how do we achieve it? *Annals of Behavioral Medicine*, 26(3), 161-171.

1. State the target population to which the study intends to generalize.
2. Report the rate of exclusions, the participation rate among those eligible, and the representativeness of participants.
3. Report on methods of recruiting study settings in the same manner as for individual participants, including exclusion rate, participation rate among those approached, and representativeness of settings studied.
4. Describe the participation rate and characteristics of those delivering the intervention. State the population of intervention agents that one would see eventually implementing the program and how the study interventionists compare to eventual users of the intervention.
5. Report the extent to which different components of the intervention are delivered (by different intervention agents) as intended in the protocol.
6. Report specific amounts of time and/or costs required to deliver the intervention.
7. Report on organizational level of continuance (or discontinuance) of the intervention once the trial is completed, as well as individual level maintenance of results.