



UvA-DARE (Digital Academic Repository)

Reply to the rejoinders of Landsheer and Verschuren: The significance of external validity

Tavecchio, L.

Publication date

2015

Document Version

Final published version

Published in

Methodological Review of Applied Research

[Link to publication](#)

Citation for published version (APA):

Tavecchio, L. (2015). Reply to the rejoinders of Landsheer and Verschuren: The significance of external validity. *Methodological Review of Applied Research*, 2(1), 76-77.
<http://www.nosmojournals.nl/ojs/index.php/MRAR/article/view/41/51>

General rights

It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations

If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: <https://uba.uva.nl/en/contact>, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.

Reply to the rejoinders of Landsheer and Verschuren: The significance of external validity

Louis Tavecchio

Hogeschool van Amsterdam (HvA), Amsterdam, The Netherlands,

l.w.c.tavecchio@uva.nl

“Far better an approximate answer to the right question, which is often vague, than an exact answer to the wrong question, which can always be made precise” (Tukey, 1962, p. 13).

Thirty years ago, Brian Flay wrote a highly influential article, “Efficacy and Effectiveness Trials (and Other Phases of Research) in the Development of Health Promotion Programs,” in which he introduced a model that both emphasizes internal and external validity at different stages of the research process, and that would lead to the translation of research to practice. He distinguished between two main levels of research, “efficacy trials” and “effectiveness trials” (Flay, 1986; cf. Steckler & McLeroy, 2008). As explained extensively in my article, a study’s internal validity has been and still is of crucial importance to efficacy research in which traditional (‘explanatory’) RCTs are used to minimize bias by isolating the effect of an intervention from other potential causes. In this way, traditional RCTs provide internally valid estimates of program effects, which means that they are accurate for the given setting and the subjects with whom they are tested. I do not deny that, for this particular purpose, the RCT could be a reliable method of determining treatment or intervention effects. In this respect, the opinions of Landsheer and me do not differ substantially from each other.

On the other hand, research into internal validity of RCTs far outweighs the number of studies devoted to how results should best be used in practice (Rothwell, 2005). Reliance on RCTs alone would limit our understanding of the manner in which evidence from efficacy trials translates into professional practice. And this is exactly the issue at hand. After all, to be useful for public health professionals and practitioners, the results of a trial should be replicable when applied to a definable group of subjects in a particular ‘clinical’ setting. This is in accordance with Flay’s model, in which effectiveness trials were to follow efficacy trials and were to be studies that carry out the proposed intervention or treatment in less controlled and more real-life situations. His argument was that public health interventions should be successful in both types of trials before they were ready for dissemination to and by public health professionals and practitioners. The extent to which a result can be extrapolated in this way has been variously termed as “external validity, applicability or generalizability” (Rothwell, 2010, p. 94). We cannot, of course, expect the results of RCTs to be relevant to all subjects and all settings – that is not what is meant by external validity – but they should be designed and reported in a way that allows

health care professionals, practitioners or clinicians to determine to whom they can reasonably be applied (cf. Rothwell, 2005). And when it comes to addressing questions about the benefits of treatments or interventions, effectiveness studies should be conducted to – at least - complement RCTs.

Unfortunately, Verschuren does not adequately represent the issues I have raised and he misunderstood the main purpose of my argument, which was not primarily to reopen the discussion about the value of RCTs in comparison to other methods. The shortcomings of RCTs have indeed already been identified and discussed repeatedly over several decades in an international methodological debate on fundamental issues such as internal and external validity regarding efficacy and effectiveness, respectively. Instead, the purpose of my argument was to question why the outcome of this international debate has not yet made its way to the Dutch practice-oriented research landscape, where RCT is still often considered the gold standard. It is precisely because of this remarkable mismatch between the international insights gained and RCT's unfaltering reputation in the field that I was invited to share my thoughts in an English publication, for a broader audience, thoughts that I had indeed previously presented in Dutch, for a Dutch audience.

In order to close the gap between research and practice, we need to accept and study the complexity of the world, rather than attempting to ignore or reduce it by studying only isolated - and quite often unrepresentative - situations. This implies that we need to consider not only individual participants, but also the settings within which they reside and receive interventions or treatment (cf. Glasgow, Lichtenstein & Marcus, 2003).

References

- Flay, B.R. (1986). Efficacy and Effectiveness (and Other Phases of Research) in the Development of Health Promotion Programs. *Preventive Medicine*, 15, 451-474.
- Glasgow, R.E., Lichtenstein, E., & Marcus A.C. (2003). Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *American Journal of Public Health*, 93, 1261–1267.
- Rothwell, P.M. (2005). Treating individuals 1. External validity of randomized controlled trials: To whom do the results of this trial apply?" *The Lancet*, 365, 82-93.
- Rothwell, P.M. (2010). Commentary: External validity of results of randomized trials: disentangling a complex concept. *International Journal of Epidemiology*, 39, 94-96.
- Steckler, A., & McLeroy, K.R. (2008). Editorial: The Importance of External Validity. *American Journal of Public Health*, 98 (1), 9-10.
- Tukey, J.W. (1962). The future of data analysis. *The Annals of Mathematical Statistics*, 33, 13-14.