

## **Assessment of External Validity in Clinical Trials: A Cross-Sectional Study**

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- **Problem:** Inadequate reporting in publications of trials has long been acknowledged as a major limitation of the medical literature and distinguishing effectiveness and efficacy trials.
- **Evidence:** We previously developed a simple and valid tool to distinguish effectiveness from efficacy trials. From this we constructed a questionnaire to assess the adequacy of the reported information necessary for distinguishing effectiveness trials.
- **Strategy:** Using the criteria from this tool as markers for effectiveness we applied the questionnaire to 137 trials included in four systematic reviews.
- **Procedure Evaluated:** We evaluated the adequacy of reporting of information necessary to distinguish effectiveness and efficacy studies.
- **Evaluation:** The primary endpoint was the proportion of effectiveness criteria that could be answered adequately based on the reported information. Additionally, we determined the prevalence of effectiveness studies in this body of literature.
- **Results:** Overall, only 16 (12%) of the included studies answered all seven criteria in a way that would allow readers to reliably distinguish effectiveness from efficacy studies. The biggest gaps of information were seen in the reporting of settings, adverse event assessment and sample size calculations. In the final tally, only seven (5%) trials met the criteria of an effectiveness study.
- **Recommendations:** Substantial shortcomings in reporting exist for some aspects of study design that are important to determine the external validity of a study. Although most of these shortcomings may be attributable to a lack of adherence of authors to CONSORT criteria, in the case of study settings, a more precise definition of the respective CONSORT criterion would probably improve reporting significantly

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