

# Systematic reviews do not comment on applicability for primary care

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Accepted 2 June 2015; Published online 18 June 2015

## Abstract

**Objectives:** How often authors comment on applicability for primary care in systematic reviews of clinical trials.

**Study Design and Setting:** We selected 4% of the Cochrane Database for Systematic Reviews (CDSRs; January 2008 to October 2013). We excluded reviews when primary care trials were not eligible. We extracted whether authors explicitly reported in methods that primary care trials were eligible or this was unclear/missing. Reporting any comment on applicability for primary care in discussion was considered as primary outcome.

**Results:** Of the 163 reviews, 30 (18.4%) stated that primary care trials were eligible, whereas 133 (81.6%) provided no data. Of the 30 reviews, 19 (63.0%) reported in discussion that results might be applicable for primary care and one (4.0%) that were feasible in nonspecialized settings. Of the 133 reviews, 6 (4.5%) mentioned in discussion that results might be applicable for primary care and 12 (9.0%) that were applicable in specialized care only. Commenting on applicability for primary care in discussion was significantly associated with reporting in methods that primary care trials were eligible (odds ratio 6.7, 95% confidence interval 2.6–17.4; *P*-value <0.001).

**Conclusions:** Authors usually do not comment on the applicability of results for primary care. © 2015 Elsevier Inc. All rights reserved.

**Keywords:** Applicability; Clinical trial; External validity; Implementation; Primary care; Systematic review

## 1. Introduction

Guidelines on study methodology and reporting, such as the CONSORT initiative [1], or the PRISMA statement [2], have extensively focused on issues related to internal validity. However, to be clinically useful, the result of a trial or a systematic review must also be likely to be replicated when applied to a definable group of patients in a particular clinical setting [3]. The term “external validity” has been used to describe whether the results are valid for patients other than those in the original study population in a setting that is in all respects equal to the setting of the original study [4]. “Applicability” has been used to describe whether

study results are valid for patients to whom results are generalizable but who are in a different setting than the original study population [4].

As long as clinicians take into account the differences in population baseline risk, research done in hospitals may be relevant to primary care in certain clinical scenarios; however, there is still concern about the generalizability of trials done in secondary or tertiary care to practice in primary care [5–8]. When patients are included in tertiary care referral centers, disease characteristics may differ from patients treated in nonreferral centers or in general practice, which is not accounted for by the eligibility criteria [9]. To date, there has been discussion of how often investigators clearly comment that the results in trials and systematic reviews may have implications in primary care [10–18]. However, to our knowledge, no systematic assessment of reporting applicability for primary care in systematic reviews of clinical trials has been conducted.

Cochrane reviews, as the largest and most comprehensive compilation of systematic reviews on medical interventions, have been a source of highly robust evidence that may support clinical decisions in all clinical settings, including primary care [19–21]. In our study, we explored

Data access: A.T. had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Conflict of interest: None.

Funding: None.

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**What is new?****Key findings**

- Authors usually do not comment on the applicability of results for primary care when they conduct systematic reviews

**What this adds to what was known**

- Reporting applicability has already been proposed by well-known organizations, such as the Cochrane Collaboration; however, authors are not in line with these recommendations

**What is the implication and what should change now?**

- Specific recommendations on assessing applicability for primary care settings may facilitate the process for investigators
- Prospective registration of trials in primary care including explicit information on applicability may provide investigators with adequate data to systematically synthesize evidence relevant to primary care and interpret its meaning to a given clinical setting

in a sample of Cochrane systematic reviews how often authors discuss the potential applicability of their results for primary care settings. In addition, we investigated whether certain characteristics, that is, reporting inclusion of primary care studies in methods, year of publication, the use of International Classification of Primary Care, Second edition (ICPC 2) words in the title, and the type of intervention evaluated in the review, may be associated with commenting on applicability for primary care.

## 2. Materials and methods

### 2.1. Selection of Cochrane systematic reviews

We accessed Cochrane Database for Systematic Reviews (CDSRs) through OVID, and we selected a random sample of 4% of the systematic reviews that mainly evaluated the efficacy of clinical interventions and were published from January 2008 to October 2013. We excluded reviews, which were referred to methodologic issues or were subsequently withdrawn. For each of the reviews included in our sample, we checked methods to identify whether authors had excluded randomized controlled trials (RCTs) conducted in primary care settings or clearly stated that they would consider as eligible only specialized settings, and thus, studies in primary care would have been rejected. Unless authors excluded studies in primary care, the systematic

review was considered as eligible. To our knowledge, there is no globally accepted algorithm on identifying reviews, for which it would have been appropriate for the authors to make a comment on the applicability of the findings to primary care. Therefore, we kept inclusion criteria as broad as possible.

Both investigators (A.M., A.T.) independently reviewed the sample and selected relevant systematic reviews. Discrepancies were resolved with consensus.

### 2.2. Data extraction

For each eligible systematic review, we extracted information on the year of publication, and on CDSR title. We also recorded whether at least one word in the title was also included in the International Classification of Primary Care 2 (ICPC 2) system, and which words were corresponding to ICPC 2. Because ICPC 2 is a classification method for primary care encounters, we hypothesized that authors in a systematic review with ICPC 2 words in the title would be more likely to comment on applicability for primary care in discussion. Additionally, we recorded whether authors clearly reported in methods that primary care studies were eligible for the systematic review or this information was unclear, and thus, studies in primary care could not have been excluded, or information about the setting was totally missing. We considered that authors clearly reported in methods that primary care studies were eligible if they used terms including primary (health) care, general practice, family medicine, general practitioner, or family physician. When authors clearly stated that primary care trials were included, we also recorded the exact phrase that authors had used to refer to primary care settings. We also captured phrases in methods that may have referred to primary care settings but the information was unclear. We considered that a systematic review may have included as eligible primary care RCTs, if in methods, authors had considered as eligible trials, which recruited participants in any setting, or specifically reported recruitment from community settings, that is, outpatient settings and clinics, school, home, trials that recruited nonhospitalized or ambulatory patients, general public, and healthy individuals.

In addition, we recorded whether authors mentioned in discussion potential implications of the results of the systematic review on primary care. In case authors referred to primary care implications, we also recorded the exact phrase. First, we focused on the paragraph on “implications for practice”; however, we went through the whole discussion when information on setting was missing in this paragraph. We also captured whether authors clearly stated in discussion that the results of the systematic review could not be applied in primary care or that they were feasible only in specialized settings. The aim of our study was to identify information in the discussion of systematic reviews that would help potential users of these reviews on whether the results were applicable in primary care settings.

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