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Methodological studies evaluating evidence are not systematic reviews

When journal editorial staff evaluates submissions of methodological studies in which unit of analysis is a randomized controlled trial (RCT) or a systematic review (SR), they may ask an author to correct study category into an SR and to provide a PRISMA checklist for reporting of SRs. It appears that it is necessary to highlight that methodological studies on RCTs or SRs are not systematic reviews.

After conducting multiple systematic reviews, and not being able to find explicit responses to certain methodological questions, or clear instructions for some methodological steps, I decided to do a number of methodological studies. In those studies, unit of analysis was an RCT or SR. The first such problem I tried to solve is how to extract data from figures. I was conducting a Cochrane review about celecoxib for osteoarthritis [1] and many of my eligible trials reported data only in graphs. I could not find instructions about extracting data from figures in Cochrane Handbook. I tried to find instructions in published Cochrane reviews and, by random search of the Cochrane Library, found only one review where authors described that they printed a figure, magnified it, and then used a pen and ruler to determine value of data points they needed. Then I decided to do a formal study in which I analyzed a number of Cochrane protocols with the aim to see whether authors mention extraction of data figures and which methods they proposed for such extraction [2]. Our team found that only a few of 589 analyzed Cochrane protocols mentioned methods for extracting data from figures. After this initial methodological study, I conducted many more studies in which our team searched for certain RCTs or SRs, and then we analyzed certain methodological aspects of those studies. In those studies, I usually used certain elements of systematic search or systematic study screening, to find eligible RCTs or SRs.

However, when such studies are submitted to a journal, the editorial staff and reviewers often consider them to be systematic reviews. Editors and peer-reviewers may ask for recategorization of an article from "research" or "original research" into "systematic review." They ask for revision of the manuscript's reporting because "a systematic review should be reported according to the PRISMA checklist." They ask for submission of a PRISMA checklist to make sure that our study is reported in line with requirements for reporting SRs.

Therefore, it should be emphasized that a methodological study that analyzes certain characteristics of evidence is not the same type of study as a systematic review. A systematic review is a study that aims to collect all empirical evidence that fits prespecified inclusion criteria with the aim to answer a specific research question [3]. On the contrary, a methodological study evaluating evidence is aiming to evaluate certain methodological questions and not to collate all empirical evidence on a certain topic. For example, we recently analyzed multiple Cochrane reviews to explore how Cochrane authors analyze risk of bias for included RCTs [4]. Our aim, therefore, was not to collate findings of 721 Cochrane reviews and 10,280 of included RCTs but to analyze certain methodological aspects of that evidence.

In conclusion, editors and reviewers should be cognizant about the existence of methodological studies in the field of evidence synthesis that are not synonymous with systematic reviews. As such, those studies should not be categorized as systematic reviews or requested to be reported as systematic reviews. Such methodological analyses are retrospective cohort studies of certain types of evidence, and not systematic reviews. Systematic searching and screening may be used to identify evidence that will be included, but this does not make a study systematic review.

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Priority setting for Cochrane Review Groups

1. Introduction

The number of clinical questions is almost infinite, whereas the resources to answer them are limited. Accordingly, Cochrane Review Groups (CRGs) must establish priorities. To do so, we need to understand the information needs of patients, their clinicians, and perhaps health administrators responsible for prioritizing health resources. In the past, this was undertaken implicitly, mostly based on pragmatic considerations (Can the proposed team achieve the review without gargantuan input from the CRG? Is there any evidence for the question? Is the question addressing currently used, or at least contemplated, clinical practice?), but we now know that clinicians and clinical researchers make errors in assuming what is important to know for patients. For example, priority setting of an organization setting research outcome measures in rheumatology (OMERACT, https://omeract.org/) had to be completely rejigged after patients with rheumatoid disease were explicitly asked for their research outcome priorities (tiredness being reported by patients as much more important than pain and function, their previously assumed priorities) [1]. This is true for many other clinical areas [2,3].

The acute respiratory infections (ARIs) CRG editorial executive set out to objectively prioritize information needs of patients, clinicians, clinical researchers, and health administrators. The task is not straightforward for two reasons: (1) the range of ARI illnesses and treatments is very large and heterogeneous; (2) simply people find it difficult to declare what they want to know ("I don't even know what I don't know"). Lists generated as a starting point for prioritization to make this easier risk prejudice. We decided to limit our investigation to intervention questions, which make up most Cochrane reviews (although diagnostic and prognostic reviews are being produced now).

We first undertook an audit of the ARI Group's Cochrane (systematic) reviews and compared the topics here with randomized controlled trials (RCTs) that are collected in the ARI CRG's trial register, the largest collection of RCTs available, containing not only what is in standard databases (such as Medline and Embase), but unpublished trials (such as conference proceedings). This identified gaps between the RCTs (a proxy for what research trialists thought important) and Cochrane reviews, which was 41% of the RCTs [4]. There was overrepresentation of some topics (eg, antibiotic vs. placebo for pneumonia had 11 Cochrane Reviews and 205 RCTs), whereas in six Cochrane reviews, there were no RCTs (so-called "empty reviews") [4].

The next step was to present a list of the 649 systematic review topics (selected for lacking a Cochrane Review but with existing RCT evidence), generated by the audit, to stakeholders (who were contacted electronically through listservs inside and outside Cochrane, to obtain as much diversity as possible from consumers, clinicians, researchers—including Cochrane authors—and health administrators) [5]. Stakeholders were given a month to respond for each of the two rounds. The first identified the top 25 systematic review topics, with an option to add in extra topics not listed, and the second round asked the participants to each nominate their top 10, yielding a collective top 20. There was a broad representation with 154 respondents from 33 countries—clinicians and researchers as well as those classifying themselves as "other." That list of 20 priority topics is now available for decision making [5].

Finally, we analyzed a data set of 314,346 clinical questions about ARIs asked by clinicians (and an unknown proportion of consumers) from an evidence-answering service (TRIP database www.tripdatabase.com/). The searches were difficult to analyze, requiring us to infer the question being asked when an illness and clinical management could be identified, which was possible in a minority of patients (45,497). We set out the inferred questions by illness along one axis and management along the other. When both illness and treatment were the same for different clinical questions, we classified them as identical. This method allowed us to address not only treatment questions (which made up 91%) but also diagnostic (5%) and prognosis questions (2%). The 20 most common questions (which addressed 67%) partly overlapped some common questions of the stakeholder survey. All but two already had Cochrane reviews addressing them [6].

These three studies have provided us with objectively derived priority lists, not perfect (eg, we could have collected the data in many other ways, probably yielding different priorities), but providing three incompletely overlapping lists to support our prioritization decisions (Table 1). Clearly, these cannot be used

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