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Systematic reviews of therapeutic interventions frequently consider patient-important outcomes

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Abstract

Objectives: To determine whether recently published and ongoing systematic reviews of therapeutic interventions assess patient-important outcomes.

Study Design and Setting: For this methodological review, we searched MEDLINE via PubMed for recently published systematic reviews and online registry of systematic reviews (PROSPERO) for ongoing systematic reviews. We selected systematic reviews with meta-analyses of randomized controlled trials. We extracted all outcomes defined in the methods section and categorized them. Mortality, other clinical events, pain, quality of life, function, and therapeutic decisions were considered patient-important outcomes.

Results: We included 420 systematic reviews: 90 Cochrane reviews, 200 other published reviews, and 130 registered ongoing reviews. Primary outcomes were defined in 85 Cochrane reviews (95%), 98 (49%) other published reviews and all ongoing reviews. At least one patient-important outcome was defined as a primary outcome in 81/85 Cochrane reviews (95%), 78/98 other published reviews (80%), and 117/130 ongoing reviews (90%). Considering all outcomes assessed, at least one patient-important outcome was evaluated in 90/90 Cochrane reviews (100%), 189/200 other published reviews (95%), and 121/130 ongoing reviews (93%).

Conclusion: Most recent systematic reviews aim to assess patient-important outcomes, which contrasts with RCTs. These results suggest some important gaps between primary and secondary research.

Keywords: Systematic reviews; Meta-analyses; Outcomes; Patient-important outcomes; Patient-reported outcomes; Patient-centered research; Comparative effectiveness research

1. Background

Randomized controlled trials (RCTs) and systematic reviews are considered the gold standard for assessing the benefits of therapeutic interventions. This benefit must be evaluated in terms of what is most important to patients, namely clinical events such as the occurrence of myocardial infarction or death, functional status, pain or quality of life [1,2]. Unfortunately, many clinical trials do not seem to assess such outcomes. Only 18% of RCTs of diabetes registered in 2007 [1], and 23% of cardiovascular trials published between 2005 and 2008 [3] assessed patient-important outcomes as primary outcomes. The failure to assess outcomes that matter to patients and their physicians does not help in decision-making [2] and can be considered a source of wasted effort and resources [4–6]. In addition, the assessment of surrogate outcomes used as a substitute for clinical outcomes can result in an enhanced impression of benefits as compared with patient-important outcomes [7,8].

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Availability of data and materials: Data available to academic researchers upon request.

Conflict of interest: The authors declare that they have no conflict of interest.

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What is new?

Key findings

- Recently published and ongoing systematic reviews frequently consider patient-important outcomes, especially as primary outcomes.
- We found a limited number of Core Outcome Sets developed for the topics covered by our selected systematic reviews.
- Cochrane reviews were more likely than other published reviews to plan outcomes that were in COSs.

What this adds to what was known?

- This is the first study whose main aim is to assess whether systematic reviews consider patient-important outcomes.
- Our results contrast with previous studies showing that many randomized controlled trials do not assess patient-important outcomes as primary outcomes.
- Such gaps between primary and secondary research are an important source of waste in research.

What is the implication and what should change now?

- Our study reinforces the need to assess patient-important outcomes in primary research.
- Investigators should rely on COSs when planning a trial or a systematic review.

For systematic reviews and meta-analyses, the situation may be different. The Cochrane Collaboration clearly recommends addressing all patient-important outcomes when planning a systematic review, whether the outcomes are available in clinical trials or not [9]. Review authors are encouraged to use various sources, such as their clinical expertise, consumers, and advisory group contributions or evidence from the literature, to develop the list of relevant outcomes to include [9]. They are also increasingly encouraged to use Core Outcome Sets (COSs) [10,11] including all outcomes that should be measured and reported as a minimum in effectiveness trials of a specific condition [12–14]. To our knowledge, few studies have evaluated whether systematic reviews assess patient-important outcomes. One methodological study evaluated the reporting of absolute effect estimates for the most important outcomes in a sample of systematic reviews published in 2010 [15] and in their abstract [16].

The objective of this study was to determine whether recently published and ongoing systematic reviews with meta-analyses of therapeutic interventions assess patient-important outcomes.

2. Methods

2.1. Study design

We performed a methodological review of recently published and ongoing systematic reviews with meta-analyses of therapeutic interventions.

2.2. Search strategy

On February 17, 2015, we searched MEDLINE via PubMed for all systematic reviews with meta-analyses published within a 6-month period between August 1, 2014, and January 31, 2015. A 6-month period was considered necessary to obtain a sufficient number of Cochrane reviews for further evaluation. We developed a multifaceted search equation using a combination of text words and index terms related to meta-analyses, combined with the Cochrane filter, to identify RCTs (Appendix A at www.jclinepi.com). We also searched PROSPERO, an international prospective register of systematic reviews with health-related outcomes [17], for all registered meta-analyses reported as ongoing in the "status" section of the registry during a 3-month period, between November 1, 2014, and January 31, 2015. A 3-month period was considered sufficient to obtain a convenience sample for further evaluation. These periods were based on our experience with a previous methodological review of systematic reviews.

2.3. Study selection

From the references identified by the search equation, we selected relevant systematic reviews based on the title and abstract and if necessary the full text. We selected all systematic reviews with a therapeutic objective that focused on RCTs and included at least one meta-analysis. For the references identified from MEDLINE via PubMed, we excluded published protocols as well as reviews not written in English and those for which the full text was not available. Two reviewers (H.A., C.R.) independently screened all potentially eligible references. All disagreements were resolved by consensus with the help of a third reviewer (A.D.) if necessary. Because of the high number of non-Cochrane reviews identified, we selected a random convenience sample of 200 of these reviews for further evaluation.

2.4. Data collection

A data extraction form was developed by using a Google form and tested with a sample of 10 studies by two reviewers (H.A., F.F.). For each systematic review, we collected the following characteristics: