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REVIEW

Forty-two systematic reviews generated 23 items for assessing the risk of bias in values and preferences' studies

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Abstract

Objectives: In systematic reviews of studies of patients' values and preferences, the objective of the study was to summarize items and domains authors have identified when considering the risk of bias (RoB) associated with primary studies.

Study Design and Setting: We conducted a systematic survey of systematic reviews of patients' values and preference studies. Our search included three databases (MEDLINE, EMBASE, and PsycINFO) from their inception to August 2015. We conducted duplicate data extraction, focusing on items that authors used to address RoB in the primary studies included in their reviews and the associated underlying domains, and summarized criteria in descriptive tables.

Results: We identified 42 eligible systematic reviews that addressed 23 items relevant to RoB and grouped the items into 7 domains: appropriate administration of instrument; instrument choice; instrument-described health state presentation; choice of participants group; description, analysis, and presentation of methods and results; patient understanding; and subgroup analysis.

Conclusion: The items and domains identified provide insight into issues of RoB in patients' values and preference studies and establish the basis for an instrument to assess RoB in such studies.

Keywords: Patient satisfaction; Patient preference; Patient views; Evidence-based medicine; Patient outcome assessment; Bias; Risk; Review literature

1. Introduction

People making choices regarding health care face trade-offs between benefits and harms. In making these trade-offs, they must decide on the relative importance of the relevant benefits and harms—a process of applying what we call values and preferences. In the context of clinical decision-making, values and preferences have been defined as "the process that individuals use in considering the potential benefits, harms, costs, and inconvenience of the management options in relation to one another" [1].

Knowledge of patients' values and preferences regarding the outcomes relevant to their health care decisions can inform clinical decision-making, decision analytic modeling (e.g., in cost-utility analysis), and the development of clinical practice guidelines [2]. In keeping with the importance of the issue, systematic reviews that synthesize the evidence addressing values and preferences in specific contexts are becoming more frequent.

Appraisal of risk of bias (RoB) in primary studies represents a key issue in systematic reviews of clinical questions of therapy, harm, or prognosis, and standard instruments exist. RoB can be defined as the extent to which the design and conduct of a study are likely to have deviated from the truth [3]. Although assessment of RoB is equally important in studies that asses values and preferences, methods are not well established and practice is highly variable. To contribute to the development of

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What is new?

Key finding

- Forty-two systematic reviews identified 23 items addressing risk of bias (RoB) of individual studies addressing patients' values and preferences. We grouped these items into seven domains.

What this adds to what was known?

- The results provide a more comprehensive account of issues of RoB in studies of patients' values and preferences than was available in existing checklists.

What are the implications and what should change now?

- Investigators conducting studies of patients' values and preferences can consider the issues we have identified in designing their studies. The items, and the associated domains, provide the basis for critical appraisal of primary studies exploring patients' values and preferences, or the relative importance of outcomes, and for an instrument to assess RoB in such studies.

optimal methods for assessing RoB in primary studies of values and preferences, we summarized items that systematic review authors have used in making this assessment and generated domains to help categorize these items.

2. Methods

2.1. Eligibility criteria

Systematic reviews were eligible if they addressed primary studies that used at least one of the following direct techniques:

- Survey instruments or ad hoc questionnaires.
- Direct methods to elicit patients' values and preferences including the standard gamble (SG), time trade-off (TTO), rating scale (RS), visual analogue scale (VAS), probability trade-off, willingness to pay (WTP), waiting trade-off (WTO), conjoint analysis (CA), and different discrete choice experiment (DCE) techniques such as discrete choice (DC), discrete choice analysis, and DCE choice modeling.
- Methods to help people to make choices among health care options such as decision aids (DAs).

We excluded reviews that were not available in English, conference abstracts, editorials, letters, opinions, qualitative research, and reviews that focus on multiattribute utility measures that provide only an indirect assessment of values and preferences.

2.2. Search strategy

We identified systematic reviews using, via OVID, MEDLINE, EMBASE, and PsycINFO databases. We used search terms for systematic reviews and values and preferences developed by Leen et al. [4] and MacLean et al. [5] (see Appendix A at www.jclinepi.com). These strategies combined broad search terms for both systematic reviews and studies on values and preferences. We searched the three databases from their inception to August 2015.

2.3. Selection of studies

Two reviewers (J.J.Y.N. and Y.Z.) independently screened the titles and abstracts found in the electronic searches and subsequently addressed the eligibility of the full text of all studies that passed the title and abstract screening. The reviewers pilot tested the forms for title and abstract screening, full-text screening, and data extraction before each process was carried out. Chance-corrected agreement for full-text eligibility assessment was addressed using the Kappa statistic. Reviewers resolved disagreement through discussion and, if necessary, by consulting a third reviewer (G.G.).

2.4. Data extraction and data synthesis

Two reviewers (J.J.Y.N. and Y.Z.) read all eligible systematic reviews in detail and independently summarized the pertinent details in a data extraction form. They discussed disagreements and, if necessary, reached agreement by consultation with a third reviewer (G.G.).

The reviewers extracted the following information from eligible systematic reviews: characteristics of participants, type of methods used for measuring the values and preferences, main outcome measures, the study duration, and the sponsor of the study; reviewers also created a narrative summary of the potential biases in the primary studies reported by the review authors and in addition cut and pasted the relevant narrative text into the data extraction form. Reviewers distinguished issues of RoB from those of applicability (e.g., the population to whom the results are applicable).

After independently completing the data synthesis for all eligible systematic reviews, the reviewers conducted an iterative process to arrive at the final list of items and domains. Initially, the two reviewers met to develop a consensus list of items and domains. The consensus process involved each reviewer presenting his observations and results, followed by discussions and debate. The third reviewer (G.G.) then provided input into the consensus categorization, and the two primary reviewers responded to the input, after which the third reviewer responded to the revisions. The process continued iteratively until we