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Uptake of core outcome sets in systematic reviews conducted in China

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Short Report

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Abstract

Background: Core outcome sets (COS) are minimum sets of outcomes that should be measured and reported in all clinical trials in specific areas of health or health care. COS use is recommended by the Cochrane Handbook. Although research has shown that the uptake of COS in Cochrane systematic reviews (SRs) is low, it has improved. Chinese researchers published a large number of SRs each year, however, the uptake of COS in SRs conducted by Chinese researchers is unclear.

Methods: Four diseases (lung cancer, ischemic stroke, type 2 diabetes mellitus, and knee osteoarthritis) have with high-quality COS and are among the top 25 causes of disability-adjusted life-years (DALYs) in China. We will search SRs led by authors from China, published in Chinese- or English-language journals. We will assess the overlap in scope between SRs and COS as well as the extent of overlap between the COS outcomes and the SR outcomes. Then we will conduct an online survey to identify the knowledge and perceptions of COS among authors of included SRs. We will conduct qualitative interviews of systematic reviewers who complete the online survey until is saturation reached.

Discussion: Understanding systematic reviewers' knowledge and perceptions of COS may help the future dissemination and implementation of COS among systematic reviewers in China.

1. BACKGROUND

A core outcome set (COS) is a minimum set of outcomes that should be measured and reported in all clinical trials in a specific area of health or health care [1]. The original aim of COS was to improve the consistency of outcome reporting in clinical trials. However, COS also can be used in clinical practice, systematic reviews (SRs), regulatory guidance, and practice guidelines [2-5].

There have been more than 500 completed COS studies published by 2021[6]. Previous research has shown that the uptake of COS is low in clinical trials and SRs [3]. COS has been recommended by Cochrane Handbook [7], which may improve the awareness of COS among Cochrane systematic reviewers. Although research has shown that the uptake of COS has increased in Cochrane SRs, it still remains low [8]. These COS uptake studies included systematic reviewers largely in high-income countries. The uptake of COS in low- and middle-income countries (LMICs) remains unclear.

We previously explored the uptake of COS in China by clinical trialists [9,10]. Four COS were included, only one COS was developed by clinical trialists in China. The results showed that the uptake of COS was low and that the facilitators and barriers of COS uptake by trialists in China slightly differed from those found in studies of stakeholders from other LMICs. Some trialists mentioned that would like to use the COS in their future clinical trials, however, if there are numerous outcomes included in a COS, its uptake can be limited by the funds available for the trial. The level of uptake of COS in systematic reviews led by researchers in China is unknown. Also unknown is whether the facilitators and barriers for reviewers to use COS differ from those of trialists.

A large number of SRs have been published in China in recent years [10], including duplicated SRs in some specific health areas with different primary studies, outcomes, and results [11]. These factors may cause confusion and reduce the value of SRs. It is important to include COS in SRs, even though the included trials may not report all of the core outcomes, because COS are developed with people who have lived experience of the health conditions of interest, reflecting the priorities of people affected by the primary and secondary research efforts [8]. In addition, using COS in SRs will improve outcome standardization and reduce research waste.

In this systematic review, we would like to (1) explore the extent to which systematic reviewers in China are currently considering COS to inform the choice of outcomes in SRs, both in protocols and completed systematic reviews, and (2) understand the barriers and facilitators regarding the use of COS in systematic reviews conducted in China.

2. METHODS

2.1 Objective 1: Exploring uptake of COS by systematic reviewers in China

We have identified four diseases (lung cancer, ischemic stroke, type 2 diabetes mellitus, and knee osteoarthritis) with high-quality COS among the top 25 causes of disability-adjusted life-years (DALYs) in China in 2019 [9]. We will include COS addressing any of these diseases to compare the differences of uptake of COS by systematic reviewers in China. There are multiple COS in these disease areas. For each disease area, COS published in English or Chinese since 2012 that included patient participation in the development process, and with at least 40 clinical trials with a matching scope to an eligible COS will be included. These comprise four COS, two published in 2019 (hip and/or knee osteoarthritis and type 2 diabetes) and two published in 2022 (lung cancer and ischemic stroke). COS of ischemic stroke was developed by Chinese researchers; all stakeholders are from China. The others were achieved international consensus, however, only COS of hip and/or knee osteoarthritis included one participant from China, who participated in the round 1 of the Delphi survey.

In objective 1, we will examine whether a SR cited a COS, mentioned searching for COS, used core outcomes in related COS, or reported outcome heterogeneity among included studies.

2.1.1 Identification of systematic reviews in China

We will search China National Knowledge Infrastructure (CNKI), Wanfang database, Medline, and Cochrane library. SRs or SR protocols for lung cancer, ischemic stroke, type 2 diabetes mellitus, and knee osteoarthritis published within 2 years after the publication of COS will be identified according to the inclusion and exclusion criteria. The COS of ischemic stroke is for traditional Chinese medicine; we will restrict the intervention when searching for SRs on this topic. Because the COS are for any intervention, the search strategy will not be restricted by intervention. The search strategies are shown in Appendix 1.

Inclusion criteria for SRs:

1. SRs or SR protocols published in journals included in the lists of the key journals of China technology, Chinese Core Journals, or Science Citation Index.

(2) The first authors or the corresponding authors were based at Chinese institutions at the time of publication of the SRs.

Exclusion criteria for SRs

(1) SRs with only one author.

(2) SR that included only qualitative studies.

(3) The aim of the SR was focused only on addressing methodology, prognosis, diagnosis, or etiology;

(4) The SR was withdrawn for any reason.

An online survey will be sent to systematic reviewers who have published a completed SR or SR protocol for which one of the COS is relevant. In previous research, the response rate by Chinese trialists to an online survey was about 20%, and we believe responses from at least 20 systematic reviewers will be necessary to provide a reasonable spread of perspectives regarding use of a particular COS. Therefore, we aim to contact systematic reviewers from approximately 100 published completed SRs or SR protocols relating to each COS to obtain sufficient information about the use of each COS. If the number of eligible SRs or SR protocols that provide the email of the first author or the corresponding author is no more than 100, we will search for SRs or SR protocols published before 2023.

We will search and identify SRs or SR protocols for the four diseases respectively. Two reviewers (SC and SW) will identified potential eligible SRs or SR protocols independently, any discrepancy will be resolved through discussion or consulted the third reviewer (RQ)

2.1.2 Data extraction and analysis

Data extraction will include: the first author's name and email, the corresponding author's name and email, the first author's and the corresponding author's institutions, title, disease focus of SR, population, interventions, comparators, and outcomes. We will examine whether the authors cited a COS in the context of choosing outcomes or mentioned having searched for a COS to choose outcomes. For completed SRs, we will examine whether the authors noted any problems with outcome inconsistency across the included studies.

We will compare the overlap in scope between SRs and COS according to the framework used in previous research [8, 9, 12-15]. The framework is shown in table 1.

Table 1. The framework for assessing overlap in scope between systematic reviews and COS

		Intervention			
		COS is narrower	Exact match	COS is broader	Different intervention
Population	COS is narrower	A	B	C	d
	Exact match	E	F	G	h
	COS is broader	I	J	K	l
	Different subgroup of the population	M	N	O	p

We will examine the extent of overlap between the COS outcomes and the SR outcomes using a framework that have used in previous research [8,9, 12-15]. We will only focus on the outcome domains (the 'what', e.g., pain).

We will calculate the median percentages of outcomes in each SR that were specific matches, general matches, and non-matches with outcomes in each relevant COS. We will analyze the median of the proportion of outcomes that overlap between the COS and SRs for each disease. We will also compare the differences between SRs published in Chinese-language and English-language. We will calculate the number of 100% match between SRs and COS and look for trends over time. Four reviewers (SL, WW, SC, and ZC) will extract information for SRs or SR protocols for each disease. RQ will verify all extracted information.

2.2 Exploring awareness, barriers, and facilitators to uptake COS

We will examine systematic reviewers' knowledge and awareness of COS, as well as barriers and facilitators to uptake COS via an online survey and qualitative interviews.

2.2.1 Online survey

2.2.1.1 Eligibility criteria for participants

A survey will be sent to the authors of the included SRs. We will send Chinese translation of the COS deemed relevant to the SRs with the survey. If the corresponding author of the SR does not respond within 2 weeks, we will send the survey to the first author. We will not contact other authors because Chinese-language journals do not consistently provide the contact information for other authors of SRs. We will examine systematic reviewers' knowledge and awareness of COS. An online survey will be sent to systematic reviewers, with one of three versions of the survey: 1) systematic reviewers who report a full COS in their research; 2) systematic reviewers who report only a few of outcomes in the COS; and 3) systematic reviewers who do not report any outcome in the COS. Respondents will receive 200 CNY compensation for participating in the survey.

2.2.1.2 Survey design and implementation

The questionnaire will be adapted from the survey developed for trialists in China [9]. It will include both closed and open-ended questions. General information, such as participants' role, work experience, professional qualification, and education background will be collected. We will refer the facilitators and barriers identified in previous research [8, 9, 16, 17] to develop open-ended and closed questions to ask all participants.

The survey will include questions related to the: (1) methods used for choosing outcomes for the SR; (2) awareness of COS in general; (3) whether the authors searched for COS; (4) reasons for nonuse of relevant COS; (5) perceived facilitators of using COS; and (6) perceived barriers to using COS.

We will email the author(s) of each relevant SR one of three versions of the survey (using Wenjuanxing in Chinese) as follows:

Version A: For SRs that cited/mentioned searching for a COS and used all core outcomes. Questions regarding awareness of COS, facilitators of using COS, or whether the systematic reviewers searched a COS will not be included.

Version B: For SRs that cited/mentioned searching for a COS and used some but not all core outcomes. Questions regarding awareness of COS or whether the review authors searched a COS will not be included.

Version C: For SRs that did not cite/mention searching for a COS. This version will include all questions.

The questionnaire is shown in Appendix 2.

2.2.1.3 Statistical analysis

We will use descriptive statistics for closed-ended questions. For open-ended questions, we will use thematic analysis.

2.2.2 Qualitative interviews

2.2.2.1 The process of semi-structured interview

At the end of each survey, survey respondents will be asked if they are interested in taking part in an interview. We will randomly select authors from those expressing interest in being interviewed, until saturation is reached. The relevant COS publication and its Chinese translation will be sent to participants before the interview. The interview questions will be amended from interview questions used for Chinese trialists. The topic guide is shown in Appendix 3.

We will use Tencent video conference to interview. Participants will receive 500 CNY compensation for participating in the interview.

2.2.2.2 Data analysis

The interviews will be analysed by RQ and SL. The audio recordings will be transcribed verbatim after the interview. Thematic analysis will be used. We will use Nvivo 15.0 for coding and analysis.

3. DISCUSSION

With the increasing number of completed COS published, the dissemination and implementation of COS is an important task for COS developers. There have been increases in LMIC stakeholder participation in COS development [18]. However, only a few COS are initiated from LMICs. Therefore, the perspectives in the COS development are mainly contributed by stakeholders from high-income countries, the included outcomes may be different from LMICs. Previous research explored the uptake of COS in trialists in China, the perspectives of them are different from trialists in HICs, for example, the available funds and length of follow-up are important factors for them to use COS.

Previous research explored the uptake of COS in SRs published in English-language journals, including Cochrane SRs. However, it is necessary to identify the uptake of COS in SRs conducted by authors in China because only a few COS included stakeholders from China. It is unclear whether COS will be used by systematic reviewers based in China. The results will help COS researchers to understand the facilitators for and barriers to using COS among systematic reviewers in China.

Abbreviations

Abbreviation	Full Name
COS	Core outcome sets
SRs	Systematic reviews
DALYs	Disability-adjusted life-years
LMICs	Low- and middle-income countries
HICs	High-income countries
CNKI	China National Knowledge Infrastructure
TCM	Traditional Chinese medicine
MeSH	Medical Subject Headings
FDA	Food and Drug Administration
EMA	European Medicines Agency
NIDDM	Non-Insulin-Dependent Diabetes Mellitus
KOA	Knee Osteoarthritis
OA	Osteoarthritis

Declarations

Ethics and consent

The project was approved by the Ethics Committee of Dongzhimen Hospital, Beijing University of Chinese Medicine (2023DZMEC-175-01). The participants are systematic reviewers being asked about their professional activities, informed consent will be acquired from participants.

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