Core outcome sets (COS) related to pregnancy and childbirth: a systematic review

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Abstract

Background: Systematic reviews of clinical trials frequently reveal heterogeneity in the number and types of outcomes reported. To counteract this, a Core Outcome Set (COS) may be applied. Objectives: A systematic review of all completed and ongoing COS related to pregnancy and childbirth Search strategy: COMET up to January 2020, Ovid MEDLINE, EMBASE, PsycINFO, Academic Search Elite, CINAHL and SocINDEX up to June 2019. Selection criteria: Studies which prioritized outcomes using some form of consensus method (such as the Delphi technique) were included. Data collection and analysis: All included studies were checked for compliance with the Core Outcome Set–STAndards for Reporting. Information about population, setting, method and outcomes was extracted. Main results: Nineteen completed studies and thirty-nine ongoing studies were included. The number of outcomes included in various COS ranged from 6 to 48. Most COS were for conditions related to physical complications during pregnancy. No COS were identified for perinatal mental health. Conclusion: This review discloses a growing number of COS within the field of pregnancy and childbirth. Many of the completed studies follow the proposed reporting. However, several of the COS included a large number of outcomes. There is a need to consider the number of outcomes which may be included in a COS while retaining its applicability in future research. Funding This article is adapted from a report undertaken by the SBU, who provided funding for the study. Keywords: Childbirth, Core outcome set, Maternal health, Obstetric care, Pregnancy

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Abbreviations

COMET Core Outcome Measures in Effectiveness Trials Initiative

COS Core outcome set/ sets

COS-STAD The Core Outcome Set-STAndards for Development

COS-STAR Core Outcome Set–STAndards for Reporting

CROWN Core Outcomes in Women's and Newborn Health

RCT Randomised Controlled Trial

SBU Swedish agency for health technology assessment and assessment of social services

HTA Health technology assessment

Abstract

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Tweetable abstract

A systematic review of completed and ongoing Core Outcomes Sets (COS) relating to pregnancy and childbirth by @SBU_en

Introduction

Well- designed and well conducted randomized controlled trials (RCTs) determine the effectiveness of different interventions through unbiased comparison of outcomes (events or endpoints). The selection of outcomes

is critical in RCT design, and trials may be regarded as "only as credible as their outcomes". However, outcomes may be defined in various ways, resulting in the reporting of multiple, apparently different outcomes across studies. This has a negative impact on evidence synthesis, contributing to heterogeneity and research waste (1-3).

To overcome these problems, the selection of outcomes and measurement properties in studies need to be standardised. Described and promoted by the Core Outcome Measures in Effectiveness Trials (COMET) initiative group in 2010, Core Outcome Sets (COS) have increasingly been developed for various conditions over time (2). A COS is a minimum set of outcomes to be selected, measured, and reported in trials of a specific condition. These are typically developed by identifying and describing the outcomes used in current research (primary studies as well as systematic reviews) and then allowing stakeholders to prioritize these outcomes by using a consensus process. When a core outcome set has been agreed on, the purpose is that researchers use it in all studies within that condition, adding further outcomes if they wish (Figure 1). The aim of developing and implementing COS is that the results of various studies will be more readily comparable and collated, reinforcing the basis of decisions, to benefit patients and healthcare personnel.

In the research fields of women's health and neonatal health, an international network, called CoRe Outcomes in Women's and Newborn health (CROWN), has been established (4). It is led by journal editors, and aims to address the widespread, unwarranted variation in reporting of outcomes, which makes comparison between and combination of results across studies difficult, if not impossible.

The aim of this article was to systematically identify and describe ongoing and completed studies prioritizing outcomes within the field of pregnancy and childbirth.

Methods

The study consisted of a systematic literature review undertaken to analyse and summarize ongoing and completed COS projects (including all projects where outcomes where prioritized), within the area of obstetric care. The literature search was conducted in June 2019. However, the search of the COMET Initiative database was updated in January 2020.

Protocol and registration

A project plan was established a priori and registered at SBU, the PROSPERO database (5) as well as the COMET database (6). This systematic review was conducted and reported in accordance with the PRISMA statement.

Eligibility criteria

The criteria for eligibility were outlined according to the PICOS model (Population, Intervention, Comparator, Outcome and Study design) and included the following characteristics:

Population: Pregnant women, women giving birth (labour and delivery), women who suffer an injury or other complication related to childbirth, women or men suffering from a mental health disorder during pregnancy or during or after childbirth.

Intervention: No restriction.

Control: Not applicable.

Outcome: A list of outcomes included in the COS.

Study design: Ongoing or completed original studies where outcomes were prioritized using some form of consensus. No restriction applied to publication status.

Language: English and Scandinavian languages.

Exclusion criteria:

- Systematic reviews of outcomes
- Qualitative studies identifying important outcomes, without any form of prioritization
- COS studies focusing only on the child (no outcomes related to the women)
- COS studies relating to interventions/conditions prior to pregnancy, such as in vitro fertilization, contraceptives use etc.

Information sources and search strategy.

Studies were identified by searching electronic databases and by scanning the reference lists of studies meeting the eligibility criteria, and of relevant systematic reviews. The electronic databases MEDLINE, Embase, PsycINFO, Academic Search Elite, CINAHL with Full Text and SocINDEX with Full Text and the Core Outcome Measures in Effectiveness Trials (COMET) Initiative database were searched up to June 2019. Subsequently, the search of the COMET Initiative database was updated in January 2020. Electronic searches were conducted using a combination of medical subject headings (MeSH) and relevant text word terms related to the population, in combination with different terms related to core outcome set. (For detailed information about the search strategies, Appendix S1.)

Identification of studies

Two reviewers (MÖ and CH) independently screened the titles and abstracts for eligibility. The abstracts were screened and rated using the scanning tool Rayyan, available online (7). Full text articles were retrieved and reviewed to determine eligibility, independently and in duplicate by two authors (CH and MÖ). Disagreements were resolved by discussion. The reference lists of studies meeting the eligibility criteria and of relevant systematic reviews were screened for additional relevant studies.

Description of methodology in included studies

In order to check the description of the methodology in the included studies, a checklist was compiled using the items from the COS-STAR reporting guide. One further question was added to the checklist: "Are researchers as well as healthcare providers and patients included in the development process?" (Appendix S2). Two of the authors (CH and MÖ) independently reviewed the included articles according to the checklist Disagreements were resolved by discussion.

Data items

The following information was extracted from the included trials: Population, intervention, setting for intended use, consensus method, number and characteristics of participants, number of outcomes at the start of the project and number of outcomes in the final COS, consensus criteria and the degree of compliance with COS-STAR.

Data were extracted from each included study and tabled by one reviewer. A second reviewer audited the data extraction. Any disagreements were resolved by discussion.

Since the results were not suitable for synthesis, the included studies are described narratively.

Patient involvement:

A patient representative (FT) was included in the project management group in order to ensure patient input into all aspects of the work.

Results

Eligible studies

The literature search yielded a total of 2699 citations: after review of the abstracts, 138 were assessed in full. Eighty studies which did not meet the inclusion criteria were excluded, leaving 58 relevant studies. Of these, 19 were completed studies with prioritized outcomes and 39 were COS protocols, where the final COS was not yet published (Figure 2). For detailed information about the included studies, see table S1. Excluded studies and the reason for exclusion can be found in table S2. Of the 39 identified ongoing COS studies, the full protocol was identified for 10. The ongoing studies are described in table S3

Published core outcome sets

Of the completed studies, 12 had an expressed intention to develop a COS (8-19). In the remaining seven studies, outcomes were also prioritized, but the main aim of the studies varied somewhat (20-26). The primary aim of two articles was to prioritize future research questions, and this included prioritizing the outcomes to be assessed (20, 26). Two other articles investigated which outcomes should be prioritized in a composite outcome, while other studies considered which outcomes should be assessed in clinical follow-up of patients (21-25). A brief overview of the included completed studies is presented in Table 1.

Of the completed studies, all were published after 2007 and 52% were published during 2018 and 2019 (Figure 3A). The large number of ongoing COS projects identified also indicates a high degree of activity in the field.

Sorting the studies into categories (figure 3B), discloses that most COS, both completed and ongoing, focus on pregnancy and pregnancy-related complications and conditions. There are surprisingly few COS for labour and delivery and physical conditions associated with giving birth. We could, for example, not find any COS with a focus on vaginal delivery or caesarean section delivery as a whole or COS with a focus on interventions related to the actual delivery process. All the identified COS concerned physical health conditions, no COS where identified with respect to mental health during pregnancy or after childbirth.

Method and representation

Most of the included studies described a 2 or 3 round Delphi survey, followed by a face-to-face consensus meeting to finalize the COS. However, some completed studies included only Delphi surveys and one study by Fiala et only undertook a consensus-meeting. The consensus criteria most commonly used for an outcome to be included in the COS was the 70/15 (more than 70% rates the outcome as critically important and less than 15% rates it as not important). The number of outcomes included in the COS ranged between 6 and 48 (Figure3C, Table 1). Only a few studies had less than 10 outcomes in the final COS. None of the ongoing studies mentioned that they had determined or discussed in advance a possible limit to the number of outcomes to be included in the COS to enable implementation and feasibility in research. Two studies described using a "modified nominal group technique" during the consensus meeting in order to reduce outcomes (17, 18).

Researchers were included in all identified studies and healthcare personnel in the majority. Patients were sometimes not included at all in the process (10, 23, 25) or only partly included. Some examples are (8), who used a separate survey consisting of only one round for patients, (21), where patients were included in the Delphi survey, but not in the consensus meeting and (20) where two persons served as proxies for patients . Most of the completed studies involved international participation.

Nine of the studies were assessed as complying to the COS-STAR criteria well in most categories (8, 9, 12-15, 17-19), three showed some deviations (11, 21, 24) and six of the studies were assessed as having major shortcomings in reporting (2, 10, 20, 22, 23, 25-27) table S1. Most of the completed studies lacked information about whether outcomes had been excluded at some stage or if outcomes had been merged. No studies mentioned whether they deviated from the study protocol in any way.

Discussion

Main Findings

Core outcome sets are an agreed standardised collection of outcomes that should be measured and reported for a specific area of health. These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition and are also suitable for use in other types of research and clinical audits. Although there are examples of well-established sets such as Outcome Measures in Rheumatology (OMERACT) for rheumatoid arthritis, they are still relatively rare in most medical fields. The outcomes in the set should represent the minimum to be collected in all trials, but researchers should continue to measure and report additional outcomes of particular relevance to their topic.

This review of pregnancy and childbirth revealed a complete lack of any ongoing or existing COS in the field of mental health, such as postpartum depression, post-traumatic stress disorder after birth, or postpartum psychosis. Consequently, SBU initiated the development of COS for studies of treatment of perinatal depression (2, 27). There are only a few COS on intrapartum care, for such conditions as slow progress in labour, trial of labour after previous caesarean section and postpartum endometritis. One of the topics for which most COS have been compiled is the field of physical conditions and complications during pregnancy.

It is important to consider how many outcomes a COS can include and still be applicable and useful for research. This systematic review discloses that the COS identified range between 6 and 48 outcomes. Only a few of the included finalised COS had less than ten outcomes. None of the identified studies discussed the relationship between the number of outcomes in the COS and the median number of outcomes in the studies for which the COS is intended. Nor did any of the protocols suggest a possible limit to the number of outcomes that might be included in the intended COS. In order to increase the implementation of developed COS, it is important to consider how the number of outcomes included will affect the usefulness of the COS. Some limitation of outcomes might increase the likelihood that the COS will be applied in future research.

It is also important to note that the development of a COS which focuses on *what* to measure may need to be followed by decisions about *how* and *when* to measure these outcomes. Even if the outcomes themselves are consistent across the studies, lack of consistency in how or when outcomes have been measured can undermine efforts by systematic reviewers to compare, contrast and combine the results of multiple studies. Unfortunately, very few of the identified COS mentioned how and when to measure the outcomes in the developed COS.

Strengths and Limitations

Some limitations to the systematic review should be noted. In the systematic review we checked compliance to COS-STAR in the included studies. However, it would have been optimal to be able asses the methodological quality of the included studies using a tool developed for this purpose. We believe that the development of such a tool is desirable and that some of the questions used in this article (Appendix S2) could be helpful. In this systematic review we decided to have an inclusive approach and might have included studies that are not principally intended for research use, but for other purposes, such as clinical follow-up.

This review focuses on maternal health. COS restricted to the infant, which might also be of interest to researchers, were beyond the scope of this review.

A strength of this study is that it is methodologically sound and robust, and all results have continuously been reviewed by experts from the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), as well as by external reviewers. Another strength is the attempt to assess the reporting of the included COS using an assessment tool based on the COS-STAR reporting guide (Appendix S2).

Interpretation

In 2017, Duffy et al published a systematic review of published and ongoing COS related to the health of

women and newborns (28). The scope of their paper is somewhat broader, including conditions other than those related to pregnancy and childbirth. In all, they identified four completed COS, of which three were related to obstetric care. In the last two years, a substantial number of COS have been completed and 39 ongoing studies have been identified.

Conclusion

This systematic review discloses an increasing number of COS for pregnancy and childbirth. This is gratifying, hopefully leading to studies which focus on important outcomes and research that is more readily synthesised in systematic reviews, thus increasing evidence in support of interventions. The review reveals that a large number of the ongoing and completed COS studies address physical conditions and complications during pregnancy. There was a lack of COS for delivery. No COS was identified for perinatal mental health. Accordingly, SBU initiated the development of COS for studies of treatment of perinatal depression (2, 27).

Contribution of authorship: Study concept and design: CH, MÖ, AS, MJ, FT. Literature search AJ. Selection of studies and extraction of the relevant information CH and MÖ. Analysis and interpretation of data: CH, MÖ, AS, MJ, FT. Drafting of the manuscript: CH and MÖ. Critical revision of the manuscript for important intellectual content: AS, MJ, FT, CH, MÖ, SF, AJ.

Data availability Data are available on request.

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