Improvement was needed in the standards of development for obstetrics and gynecology core outcome sets

Jiyuan Shi[1], Ya Gao[1], Mingming Niu[1], Yamin Chen[1], Meili Yan[1], Ziwei Song[1], Yuanyuan Li[2], Ming Liu[1], Junhua Zhang[3], and Jinhui Tian[1]

[1]Affiliation not available
[2]Lanzhou University
[3]Tianjin University of Traditional Chinese Medicine

July 21, 2020

Abstract

Abstract Objectives This study aimed to investigate the characteristics of obstetrics and gynecology (OG) core outcome sets (COSs) and assess the report and design standards of OG COSs, and exploring how to improve baseline standards for obstetrics and gynecology COSs development. Study Design and Setting We conducted a comprehensive search of COMET database on December 20, 2019. Two reviewers independently evaluated whether the OG COS met the reporting requirement as stipulated in the Core Outcome Set-STAndards for Reporting (COS-STAR) statement checklist and the minimum design recommendations using the Core Outcome Set-STAndards for Development (COS-STAD) checklist. Results Forty-four OG COSs focused on 26 topics. None met all the 25 standards of COS-STAR statement representing 18 items considered essential for transparent and complete reporting in all COS studies (range: 6.0-24.0, median: 14.0). The compliance rates for the 16 standards of methods and result sections ranged from 27.3% - 68.2%. Total COS-STAR compliance items of OG COSs with the prior protocol was significantly higher than without prior protocol (MD= 3.846, 95% CI: 0.835 - 6.858, P= 0.012). None of the OG COSs met all the 12 criteria of COS-STAD minimum standards (range: 3.0-11.0, median: 5.0). The compliance rates for all three standards of stakeholders involved and all four standards of the consensus process were lower than 60%. Conclusion Methodological and reporting standards of OG COSs should be further improved.

Improvement was needed in the standards of development for obstetrics and gynecology core outcome sets

Jiyuan Shi[a,1], Ya Gao[b,1], MingMing Niu[a], Yamin Chen[a], Meili Yan[a], Ziwei Song[a], Yuanyuan Li[a], Ming Liu[b], Jinhui Tian[a,b,*], Junhua Zhang[c,*]

1. Evidence-Based Nursing Centre, School of nursing, Lanzhou University, Lanzhou City 730000, Gansu Province, China.
2. School of Basic Medical Sciences, Lanzhou University, Lanzhou City, 730000, Gansu Province, China.
3. Evidence-Based Medicine Center, Tianjin University of Traditional Chinese Medicine, Tianjin, China.

[1]Jiyuan Shi and Ya Gao did equal to this work

Correspondence to: Jinhui Tian, Evidence-Based Medicine Centre, School of Basic Medical Sciences, Lanzhou University, No.199, Donggang West Road, Lanzhou City, 730000, Gansu Province, China. (Email:tianjh996@163.com).

Correspondence to: Junhua Zhang, Evidence-Based Medicine Center, Tianjin University of Traditional Chinese Medicine, No. 312 Anshanxi Street, Nankai District, Tianjin 300193, China.(Email:*zjhtcm@foxmail.com.*)

Word count:

Abstract: 227 words

Manuscript: 3719 words

Running title

Obstetrics and gynecology core outcome sets

Abstract

Objectives

This study aimed to investigate the characteristics of obstetrics and gynecology (OG) core outcome sets (COSs) and assess the report and design standards of OG COSs, and exploring how to improve baseline standards for obstetrics and gynecology COSs development.

Study Design and Setting

We conducted a comprehensive search of COMET database on December 20, 2019. Two reviewers independently evaluated whether the OG COS met the reporting requirement as stipulated in the Core Outcome Set-STAndards for Reporting (COS-STAR) statement checklist and the minimum design recommendations using the Core Outcome Set-STAndards for Development (COS-STAD) checklist.

Results

Forty-four OG COSs focused on 26 topics. None met all the 25 standards of COS-STAR statement representing 18 items considered essential for transparent and complete reporting in all COS studies (range: 6.0-24.0, median: 14.0). The compliance rates for the 16 standards of methods and result sections ranged from 27.3% - 68.2%. Total COS-STAR compliance items of OG COSs with the prior protocol was significantly higher than without prior protocol (MD= 3.846, 95% CI: 0.835 - 6.858, P= 0.012). None of the OG COSs met all the 12 criteria of COS-STAD minimum standards (range: 3.0-11.0, median: 5.0). The compliance rates for all three standards of stakeholders involved and all four standards of the consensus process were lower than 60%.

Conclusion

Methodological and reporting standards of OG COSs should be further improved.

Registration number : 1581 (http://www.comet-initiative.org/Studies/Details/1581).

Keywords: Core outcome set; Obstetrics; Gynecology; Research methodology; COS; Report methodology

Tweetable abstract: Methodological and reporting standards of obstetrics and gynecology core outcome sets COSs should be further improved.

Introduction

Selecting outcomes that adequately reflect relevant issues to patients and health care professionals is essential when designing clinical trials to compare the effects of different interventions directly.[1, 2] Core outcome sets (COSs) represent the minimum important outcomes that should be measured and reported in all research studies for a specific condition.[1] The use of high-quality COSs in clinical trials has the following benefits; improves comparability between similar trials, reduces selective reporting of results, increases the relevance of trial and systematic review results,[3] and enhances the quality of evidence used in health care decision-making ultimately translates to improved health care for patients.[4] COSs are increasingly recognized as important for the design, implementation, and reporting of randomized trials, systematic reviews, and other forms of research.[5-7]

The rapid increase in the number of COSs covering a wide range of different health-related areas has seen the standards of COSs definition vary considerably.[6, 8-13] Previous studies have suggested that a high-quality

set of COSs should include a comprehensive scoping process and a consensus process that involves multi-stakeholder groups.[14-16] Whether these published COSs undertook a systematic review of existing outcomes or fully considered the views of different stakeholder groups on the COSs, remains unclear.[17] The Core Outcome SeteSTAndards for Development (COS-STAD) project aimed to identify those aspects of COSs development for which minimum standards can be agreed upon and applied regardless of the consensus method chosen. Recommendations have since been established to improve the methodological approach for developing COSs and help users assess the applicability of a particular COSs.[15] Additionally, the Core Outcome Set-STAndards for Reporting (COS-STAR) statement was developed using the recommended approach for developing medical reporting guidelines.[18] The difference between COS-STAD and COS-STAR is that the former focuses on the principles of design associated with COSs development, while the latter focuses on the reporting of COSs development studies. While applying COS-STAD standards to assess the design quality of cancer COSs, a recent pilot study revealed that the scoping process and consensus process of cancer COSs were not optimistic.[19] Besides, none of the studies met all the 12 standards representing the 11 minimum standards assessed. Therefore, it is valuable to explore ways of improving the existing standards of COSs development.

Obstetrics and gynecology (OG) is a specialty in clinical medicine that focuses on the physiological and pathological changes of the female reproductive system, as well as fertility regulation.[20-22] Well-developed COSs should ensure that outcomes in OG trials reflect prioritize relevant issues to both patients and health care professionals over other disciplines.[21-25] The primary objective of our study is to use COS-STAD and the COS-STAR checklists to assess the methodological and reporting standards of OG COSs. The secondary objectives of our research include: exploring factors that affect the quality of developed COSs standards; and exploring how to improve baseline standards for obstetrics and gynecology COSs development.

Methods

2.1 Inclusion Criteria

In this evaluation, OG COSs that had developed or applied methodologies to determine which outcome areas or outcomes should be measured, or important in clinical trials or other forms of health research, were eligible for inclusion. We used the latest version whenever the COSs had been updated. Studies that; only reported the use of a COS, were systematic reviews of clinical trials, focused on systematic reviews and surveys of outcomes measured in clinical trials or quantitative descriptions (e.g. frequency) of outcomes, or protocol of COS, were excluded. There were no limitations on the year of publication, language, age of participants, and types of interventions.

2.2 Identification and selection of COSs.

COMET has successfully brought together the international COS literature in an online database (http://www.comet-initiative.org/studies/search).[8] We conducted a comprehensive search of COMET database on December 20, 2019, one reviewer (Y.G. or J.Y.S.) exported the entire registered COS study records from the COMET database. The full-text publications that met our inclusion criteria were then filtered. A regularly updated systematic review of COSs was screened to identify OG COSs as a supplement.[8] The list of COSs was reviewed by a COS/methodology expert (J.H.Z). No restriction was placed on language.

2.3 Data extraction and management

All authors involved in this study had previously piloted the form on a random sample of five included COSs to ensure the agreement among the interpretation of data items. One reviewer (J.Y.S., M.L.Y., or Z.W.S.) extracted data from the included COSs using a data extraction sheet from included COSs, and a second reviewer (Y.G., Y.M.C., or M.M.N) verified the extracted data. Any disagreements were adjudicated by the third reviewer (J.H.T). The extracted data included: the number of authors, countries which co-authors came from, whether the COS protocol was registered, published journals and impact factors, number of databases searched (Chinese, English, or both), funding source (industry, government, unfunded, or not reported), and impact factors of journals in which COSs included were retrieved by searching 2018 Journal

Citation Reports (Thomson Reuters, 2018) via Web of Science. Detailed scope of data extraction tables is shown in Appendix Table 1.

2.4 Standards assessment

The COS-STAR was developed using a recommended approach for guiding minimal COS study reporting. We assessed the reporting standards of included COSs using the COS-STAR which contains 25 checklist criteria spread over six domains namely; title/abstract, introduction, methods, results, discussion, and other information. The responses for each item included; "Yes - item fully compliant, partial - item not fully compliant, or No - item not compliant. We further assessed the methodological standards of included COSs used COS-STAD, which contains 12 checklist criteria spread over three domains namely; scope specification, stakeholders involved, and consensus process. These three are considered the minimum design recommendations for all COSs development. To indicate the degree of compliance, each checklist item was defined as: Yes - for total addressed; Partial - for partial addressed; and No - for not addressed. Assessments were compared, and three authors (J.Y.S. M.L.Y., and Y.G.) deliberated on how the process should be applied. The reporting standards assessment using the COS-STAR tool was independently conducted by two independent reviewers (J.Y.S. and M.L.Y.). Similarly, the methodological standards assessment using the COS-STAD checklist was independently conducted by two reviewers (J.Y.S and Y.G). Conflicts were adjudicated by a third reviewer (J.H.Z.). This article is not intended to criticize the quality of the published COSs. Therefore, we only report the compliance rates of items included in the literature, but do not score the standards of individual studies.

2.5 Data analysis methods

Median and range were used to describe continuous data, while frequency and percentage were used for summarizing categorical data. For individual items of the COS-STAD and COS-STAR, we summarized the frequency of "Yes" response for all included systematic reviews. We performed the Chi-square test, calculated odds ratio (OR) with 95% confidence intervals (95% CIs), and obtained a P-value for each item compared between group one (COSs with statistician or epidemiologist, funding, and with prior protocol) and group two (without statistician or epidemiologist, non-funding, and without protocol). Additionally, this method was used to compare the compliance for each item of COS-STAD between OG COSs and cancer COSs (the result of cancer COSs assessment was extracted from a previous study conducted by Elizabeth G).[19] For each of the COS-STAR and COS-STAD checklist items, we calculated the mean compliance items and standard deviation (SD). The mean difference (MD) and 95% CI were calculated for each item to compare the overall compliance items between the groups. The MD value represents the difference in the mean total compliance items between group one and group two. Analyses were conducted using STATA (13.0; Stata Corporation, College Station, Texas, USA), and statistical significance was set at $P < 0.05$. The complete compliance rate of the methodological quality was calculated with the acquired number. Spearman correlation coefficient (r) was estimated to determine the linear association between average citations per year (dates from Web of Science) and the total complete compliance rates of COS-STAD and COS-STAR for each OG COS. The correlation analyses were conducted in IBM SPSS Statistics v. 24.0 (IBM Corp., Armonk, NY, USA), and statistical significance set at $P < 0.05$.

RESULT

3.1 Characteristics of included COSs

The first COS was published in 2000; the majority published year was 2018-2019 (Fig.1). Forty-four COSs focus on 26 topics and mainly focused on pelvic organ prolapse (9%) and maternity care (9%) (Fig.2). The included studies were conducted by the corresponding author from nine countries, mostly in the UK (38.6%), USA (13.6%), Canada (11.4%), and Australia (9%) (Fig.3). The corresponding author of 40 COSs was from the developed country (91%) and four from the developing country (9%). The median journal impact factor (IQR) of OG COSs published was 5.079 (2.103, 5.357). And 13 COSs involved statistic or epidemiologic authors. There are 6 COSs developed with 1 to 3 authors, 15 COSs developed with 4 to 6 authors, 13 COSs developed with 7 to 10 authors, 10 COSs developed with more than ten authors, and twenty-five COSs were

registered with protocol; twenty-four COSs declared funding sources; nine COSs proclaimed that they did not receive funds, and eleven COSs did not state whether they receive funds. Thirty-four COSs conducted a systematic review; twenty-nine COSs reported search strategy; only three COSs used the interview method. In addition, twenty COSs used the Delphi method, eleven of COSs conducted two rounds of Delphi, and nine of COSs conducted three rounds of Delphi, eighteen COSs used consensus meeting method, only sixteen COSs (36.4%) conducted both scoping process and consensus process. The main characteristics of the included COSs were presented in Table 1.

3.2 Compliance rates of COS-STAR standards

The compliance rates of 8 standards, mainly focusing on the introduction and discussion sections, were >85%. Moreover, the development protocol or registration details was accessible in 56.8% of COSs; 68.2 % of COSs described the sources of information for the initial list of outcomes, 65.9% of COSs described how outcomes were dropped/combined, and 56.8% of COSs outlined the final COS. 22 COSs did not describe how outcomes were scored and how scores were summarized; and 14 COSs did not describe whether members of the team had any conflict of interest. The compliance rates of 10 standards on the COS-STAR assessment were less than 55%. These included: "Identify in the title that the paper reports the development of a COS", "Describe the rationale for stakeholder groups involved in the COS", "the sources of information for the initial list of outcomes", "Describe how the consensus process was undertaken", "Provide a statement regarding the ethics and consent issues for the study", "Describe any changes from the protocol", "Present data on the number and relevant characteristics of the people involved at all stages of COS development", "List all outcomes considered at the start of the consensus process", "Describe any new outcomes introduced and any outcomes dropped", and "Describe sources of funding/role of funders". (Fig.4)

Total COS-STAR compliance standards of OG COSs with the prior protocol were significantly higher than without protocol (MD= 3.846, 95% CI: 0.835 - 6.858, P= 0.012) (Table 2). Table 3 shows reporting quality of COSs. We also analyzed total compliance for each of the 25 criteria and observed the significant differences between COSs with a priori protocol and those without a priori protocol related to the criteria "describe sources of funding/role of funders" (OR= 4.94, 95% CI:1.26-19.32, P=0.022), "protocol/registry entry" (OR= 39.23, 95% CI: 2.54,606.03, P= 0.009), "describe the information sources used to identify an initial list of outcomes." (OR= 2.28, 95% CI: 1.33 - 3.89, P= 0.002), "describe how outcomes were dropped/combined" (OR= 2.0, 95% CI: 1.15 - 3.47, P= 0.015), and "describe sources of funding/role of funders" (OR= 2.280 , 95% CI: 1.126 - 4.617, P= 0.022).

3.3 Results of compliance rates of COS-STAD standards

The compliance rates of four criteria related to scope specification were greater than 95%. These included; "research or practice setting(s) in which the COS is to be applied", "health condition covered by COS", "the population covered by COS", and "the intervention covered by COS". Twenty-one studies (52.3%) were not clear whether stakeholders were involved in the COS development. Twenty-three studies (52.3%) clearly declared that health care professionals with experience of patients with the condition participated in the development of COS. Fourteen COSs (31.8%) clearly stated patients with the condition or their representatives were included in the process, but two COSs were not clear whether patients were involved in the study. Thirty-five studies (92.1%) did not consider the views of health care professionals and patients from literature reviews or interviews when compiling the initial list of outcomes. Twenty studies (60.5%) had no prior described scoring process, consensus definition, or criteria for including/dropping/adding outcomes. Besides, only twelve OG COSs (27.3%) had clear accessible registered details or published protocol. Forty-one studies (90%) were excluded to avoid ambiguity of language when COSs was used. (Fig.5) Table 4 shows there was no significant difference in total COS-STAR compliance standards of OG COSs between group one and group two. Compared with COSs without prior protocol or registered detailed, those studies with a priori protocol or registered details had greater compliance rates of the standard "Priori describe scoring process"(OR=8.36, 95% CI:1.18,59.24, P=0.034), "a consensus definition was described a priori" (OR=8.36, 95% CI:1.18,59.24, P=0.034), and "criteria for including/dropping/adding outcomes were described a priori" (OR=8.36, 95% CI:1.18,59.24, P=0.034). COSs which involved a statistician, or epidemiologist authors had

higher compliance rates on item 6 "health care professionals with experience of patients with the condition involved with COS developed" (OR=0.82, 95% CI: 0.47-1.45, P= 0.512). Moreover, we observed significant differences between funding COSs and non-funding COSs related to the "patients with the condition or their representatives" (OR= 3.35, 95% CI: 1.08 - 10.38, P= 0.036). (Table 5). Spearman's correlation analysis revealed a statistically significant ($p < 0.05$) positive correlation between average citations per year and the compliance rates of COS-STAD for OG COSs. (Table 6).

3.4 Comparisons between cancer COSs and OG COSs

A previous study conducted by Elizabeth G about the minimum standard assessments of cancer COSs showed that compliance rates for both four standards in scope domain were greater than 95%, which was consistent with OG COSs.[19] The compliance rates for "Patients with the condition or their representatives" were both less than 35% in cancer COSs and OG COSs. Compared to OG COSs, the cancer COSs had the same low compliance rate for all five standards in consensus process standards (<30%), but had lower compliance rates for "A scoring process was described a priori" (OR=0.37, 95% CI: 0.14 - 0.97, P=0.045) and "Criteria for including/dropping/adding outcomes were described a priori" (OR=0.15, 95% CI:0.03 - 1.09, P=0.63). Further, no significant difference was found in the compliance rates in other criteria between cancer COSs and OG COSs. (Table 7).

1. **Discussion**
2. **Summary of characteristics of included COSs**

We identified 44 OG COSs from 26 research topics, with pelvic organ prolapse, and maternity care being the most common. The first OG COSs was published in 2000, and the number has gradually increased over the years. Most OG COSs were published between 2017 2018. 91% of the published COSs were published by corresponding authors from the developed countries, and 86.4% of COSs were developed by more than three authors. Identification of an inclusive list of outcomes from the existing literature is critical to the development of a core outcome set.[7] The main data sources include systematic reviews of published studies, reviews of published qualitative work, reviews of criteria in the national audit data set, and interviews with key stakeholders.[16, 26] However, only three COSs interviewed key stakeholders to understand their views of important outcomes, and 16 % of COSs did not conduct systematic/literature review to identify existing knowledge about outcomes. Given that the comprehensiveness of the results of the systematic review is highly dependent on the results of the underlying data, there is a need for thorough verification of reported results. Unfortunately, only 34.1% of COSs searched more than three databases. Nevertheless, it should be noted that the systematic review of the results merely aggregates the opinions of previous researchers. Therefore, it is crucial to subsequently strike a consensus with the wider community of stakeholders on the outcomes to be included in a COS. In the present study, only twenty COSs (45.5%) conducted two or more rounds of Delphi survey, 40.9% of COSs used the consensus meeting method, and 36.4% of studies used both the systematic review and consensus methods.

4.2 Reporting standards of included COSs

For the COS-STAR checklist, only 34.1% of studies can identify in the title that the paper reports the development of a COS. The compliance rates of 8 criteria belonging to "introduction" and "discussion" sections were greater than 85%, and the compliance rates of 9 criteria in the methods section ranged from 27.3% - 68.2%. The influence of methodology on the quality of COSs was considered significant. More than a third of the studies did not fully report protocol/registry entry, information sources, and funding sources, which may reduce the transparency of the COS developed. Moreover, only a few studies published their protocol on peer-reviewed journals, and most registered with limited information. We could not find any registration information or published protocol for more than 40% of COSs. Given that no study met the item 11 criterion (describe any changes from the protocol), further consideration is needed whether COS not deviating from the protocol should report this item. This would improve the applicability and suitability of this criterion. The characteristics of the people involved were not presented in 61.4% of studies. All outcomes considered at the start of the consensus process and descriptions of any other outcomes introduced/dropped

during the consensus process were absent in more than half of the studies. The recommended outcomes in 43.2% of COSs were unclear or ambiguous, which may limit their use. Only twenty-four (54.5%) COSs met all two other information criteria (sources of funding and conficts of Interest). Total COS-STAR compliance criteria of OG COSs was significantly positively correlated with prior protocol, indicating that COS developed with prior protocol may improve the reporting quality of COS reporting. Therefore, further studies should consider improving the transparency and robustness of the reporting standard through publishing a previous protocol based on Core Outcome Set-STAndardised Protocol Items (COS-STAP) statement.[3]

4.3 Methodological standards of included COSs

For COS-STAD checklist, more than 95% of COSs met all four standards for scope specification. In addition, most clearly described the research or practice setting in which COS was applied, and the health condition, population, and intervention covered by the COS. The decision as to which outcomes are core to measure, and why is an important process. Fourteen COSs (31.8%) met all the three standards for the domain of stakeholders involved; based on the author affiliations or participant lists, twenty-four (54.5%) of COSs were developed by people intending to use the COS in research, and health care professionals with experience of patients with the condition; sixteen COSs (36.4%) did not describe the inclusion of patients with the condition or their representatives. All the stakeholders involved in the COS development should be reported to ascertain whether the COS fully reflects the views of important outcomes for the target population in the forthcoming research. This would be conducive to the utilization and promotion of the COS.[23] Given the difficulty to judge the standards of COS-STAD in the consensus process that was set in advance, we determined whether the studies that met this standard rely on the registration information and published protocol.[19]Only 27.3% of COSs priori described a consensus protocol, and some registration information was inadequately reported, making it difficult to judge whether some standards were set prior. We suggest that the registration platform could improve the standards for COS registration, thereby promoting the integrity and transparency of COS developed. 92.1% of COSs did not report whether the patient representatives received a glossary of terms before completing the survey, which may cause ambiguity of language. Compared with COSs without prior protocol or registered detailed, those studies with a priori protocol or registered detailed had higher compliance rates of "describe consensus definition" and "criteria for including/dropping/adding outcomes consensus process in advance." Besides, we found that COSs developed with statistical or epidemiologist authors incorporated the views of healthcare professionals on important outcomes. Compared to cancer COSs, OG COSs similarly had a high compliance rate for standards in the scope domain, and low compliance rates for the standards in the field of stakeholders involved and consensus process.[19]

4.4 Strengths and limitations

To the best of our knowledge, this is the first study to investigate the characteristics of OG COSs and assess whether the OG COSs meet the minimum design standards and minimal COS study reporting requirements set by COS-STAD checklist. In addition, we explore the potential factors that may impact the methodological and reporting standards of COSs.

This work had the following limitations. First, some studies only conducted the scoping process or consensus process which led to the low reporting rate of some criteria. However, because we focused on investigating the current issues of COSs and explored how to improve the COS standards instead of criticizing the quality of the existing COSs, the impact of this limitation was limited. Second, some of the included COSs were published before the COMET initiative was set up, hence were not registered. Therefore, our definition of COSs developed with the protocol was not limited to this website, but also other registration platforms, and protocols published in the peer-reviewed journal that met our set criteria. Third, we applied the same COS-STAD criteria to compare the standards between OG COSs with cancer COSs based on previous research. Moreover, variation in standards for item compliance may also exist in the assessment progress between different reviewers. Given that COS-STAD and COS-STAR did not provide a standard to score the overall quality of COSs, our analysis was limited to the compliance rate. Further studies are required to explore the appropriate statistical methods for estimating an average value of the quality scores of multiple COSs.

Conclusion

The compliance of COS-STAD and COS-STAR criteria in OG COSs are not optimistic. Therefore, the reporting and methodological standards of OG COSs should be further improved, especially, the design of important stakeholders involved and consensus process; and reporting standards in methods, results, and other information specifications. OG COS developed with the prior protocol is beneficial to improve the reporting standards.

Disclosure of interests: We declare that we have no competing interests

Contribution to authorship:

Jiyuan Shi: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Visualization, Writing - original draft, Writing - review & editing. **Ya Gao:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Software, Writing - review & editing. **Mingming Niu:** Data curation, Investigation, Resources. **Meili Yan:** Formal analysis, Data curation, Resources, Software, Validation. **Yamin Chen:**Investigation, Resources, Data curation. **Ziwei Song,** Data curation, Resources. **Yuanyuan Li,** Data curation, Resources.**Liu Ming,** Data curation, Resources. **Jinhui Tian:**Conceptualization, Formal analysis, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing - original draft, Writing - review & editing. **Junhua Zhang:** Conceptualization, Formal analysis, Methodology, Project administration, Resources, Software, Supervision, Validation, Writing - original draft, Writing - review & editing.

Details of ethics approval: Not applicable.

Funding: None.

Acknowledgements: We would like to acknowledge: (1) the COMET Initiative team for methodological support; (2) Methodological guidance: Elizabeth Gargon , University of Liverpool, United Kingdom.

Ethics approval and consent to participate: Not applicable.

REFERENCES:

1. Williamson PR, Altman DG, Bagley H, Barnes KL, Blazeby JM, Brookes ST, et al. The COMET Handbook: version 1.0. Trials 2017, 18(Suppl 3):280.
2. Li X, Ya Z, Chen Y, Yang K, Zhang Z. The reporting characteristics and methodological quality of Cochrane reviews about health policy research. Health policy 2015, 119(4):503-510.
3. Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Tunis S, et al. Core Outcome Set-STAndardised Protocol Items: the COS-STAP Statement. Trials 2019, 20(1):116.
4. Kirkham JJ, Dwan KM, Altman DG, Gamble C, Dodd S, Smyth R, et al The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews. BMJ 2010, 340:c365.
5. Gorst SL, Prinsen CA, Salcher-Konrad M, Matvienko-Sikar K, Williamson PR, Terwee CB. Methods used in the selection of instruments for outcomes included in Core Outcome Sets have improved since the publication of the COSMIN/COMET guideline. J Clin Epidemiol 2020 26;125:64-75.
6. Davis K, Gorst SL, Harman N, Smith V, Gargon E, Altman DG, et al. Choosing important health outcomes for comparative effectiveness research: An updated systematic review and involvement of low and middle income countries. PloS one 2018, 13(2):e0190695.
7. Kirkham JJ, Altman DG, Chan AW, Gamble C, Dwan KM, Williamson PR. Outcome reporting bias in trials: a methodological approach for assessment and adjustment in systematic reviews. BMJ 2018, 362:k3802.
8. Gargon E, Gorst SL, Williamson PR. Choosing important health outcomes for comparative effectiveness research: 5th annual update to a systematic review of core outcome sets for research. PloS one 2019, 14(12):e0225980.
9. Gargon E, Gorst SL, Harman NL, Smith V, Matvienko-Sikar K, Williamson PR. Choosing important health outcomes for comparative effectiveness research: 4th annual update to a systematic review of

core outcome sets for research. PloS one 2018, 13(12):e0209869.
10. Wuytack F, Smith V, Clarke M, Williamson P, Gargon E. Towards core outcome set (COS) development: a follow-up descriptive survey of outcomes in Cochrane reviews. Syst Rev 2015, 4:73.
11. Gargon E, Gurung B, Medley N, Altman DG, Blazeby JM, Clarke M, et al. Choosing important health outcomes for comparative effectiveness research: a systematic review. PloS one 2014, 9(6):e99111.
12. Gorst SL, Gargon E, Clarke M, Smith V, Williamson PR. Choosing Important Health Outcomes for Comparative Effectiveness Research: An Updated Review and Identification of Gaps. PloS one 2016, 11(12):e0168403.
13. Gorst SL, Gargon E, Clarke M, Blazeby JM, Altman DG, Williamson PR. Choosing Important Health Outcomes for Comparative Effectiveness Research: An Updated Review and User Survey. PloS one 2016, 11(1):e0146444.
14. Gorst SL, Young B, Williamson PR, Wilding JPH, Harman NL. Incorporating patients' perspectives into the initial stages of core outcome set development: a rapid review of qualitative studies of type 2 diabetes. BMJ Open Diabetes Res Care 2019, 7(1):e000615.
15. Kirkham JJ, Davis K, Altman DG, Blazeby JM, Clarke M, Tunis S, et al. Core Outcome Set-STAndards for Development: The COS-STAD recommendations. PLoS Med 2017, 14(11):e1002447.
16. Biggane AM, Brading L, Ravaud P, Young B, Williamson PR. Survey indicated that core outcome set development is increasingly including patients, being conducted internationally and using Delphi surveys. Trials 2018, 19(1):113.
17. Kirkham JJ, Bracken M, Hind L, Pennington K, Clarke M, Williamson PR. Industry funding was associated with increased use of core outcome sets. J Clin Epidemiol 2019, 115:90-97.
18. Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, et al. Core Outcome Set-STAndards for Reporting: The COS-STAR Statement. PLoS Med 2016, 13(10):e1002148.
19. Gargon E, Williamson PR, Blazeby JM, Kirkham JJ. Improvement was needed in the standards of development for cancer core outcome sets. J Clin Epidemiol 2019, 112:36-44.
20. De la Fuente-Solana EI, Suleiman-Martos N, Pradas-Hernández L, Gomez-Urquiza JL, Cañadas-De la Fuente GA, Albendín-García L. Prevalence, Related Factors, and Levels of Burnout Syndrome Among Nurses Working in Gynecology and Obstetrics Services: A Systematic Review and Meta-Analysis. Int J Environ Res Public Health 2019, 16(14).
21. Al Wattar BH, Tamilselvan K, Khan R, Kelso A, Sinha A, Pirie AM, et al. Development of a core outcome set for epilepsy in pregnancy (E-CORE): a national multi-stakeholder modified Delphi consensus study. BJOG 2017, 124(4):661-667.
22. Pergialiotis V, Durnea C, Elfituri A, Duffy JMN, Doumouchtsis SK. Do we need a core outcome set for childbirth perineal trauma research? A systematic review of outcome reporting in randomised trials evaluating the management of childbirth trauma. BJOG 125(12):1522-1531.
23. Gargon E, Williamson PR, Young B. Improving core outcome set development: qualitative interviews with developers provided pointers to inform guidance. J Clin Epidemiol 2017, 86:140-152.
24. Tunis SR, Clarke M, Gorst SL, Gargon E, Blazeby JM, Altman DG, et al. Improving the relevance and consistency of outcomes in comparative effectiveness research. J Comp Eff Res 2016, 5(2):193-205.
25. Duffy JMN, Thompson T, Hinton L, Salinas M, McManus RJ, Ziebland S, et al. What outcomes should researchers select, collect and report in pre-eclampsia research? A qualitative study exploring the views of women with lived experience of pre-eclampsia. BJOG 2019, 126(5):637-646.
26. Gorst SL, Altman DG, Blazeby JM, Clarke M, Gargon E, Tunis S, et al. Proceedings of the 5th Meeting of the Core Outcome Measures in Effectiveness Trials (COMET) Initiative. Trials 2015, 16 Suppl 3(Suppl 3):A1-p11.

Hosted file

`Table 1 Characteristics of the included COSs.docx` available at https://authorea.com/users/344833/articles/471219-improvement-was-needed-in-the-standards-of-development-for-obstetrics-and-gynecology-core-outcome-sets

Hosted file

Table 2. Stratified analyses of reporting quality assessm.docx available at https://authorea.com/users/344833/articles/471219-improvement-was-needed-in-the-standards-of-development-for-obstetrics-and-gynecology-core-outcome-sets

Hosted file

Table 3 Stratified analyses of reporting quality a.docx available at https://authorea.com/users/344833/articles/471219-improvement-was-needed-in-the-standards-of-development-for-obstetrics-and-gynecology-core-outcome-sets

Hosted file

Table 4 Stratified analyses of reporting quality a.docx available at https://authorea.com/users/344833/articles/471219-improvement-was-needed-in-the-standards-of-development-for-obstetrics-and-gynecology-core-outcome-sets

Hosted file

Table 5. Stratified analyses of metho.docx available at https://authorea.com/users/344833/articles/471219-improvement-was-needed-in-the-standards-of-development-for-obstetrics-and-gynecology-core-outcome-sets

Hosted file

Table 6. Correlation analysis of report or design.docx available at https://authorea.com/users/344833/articles/471219-improvement-was-needed-in-the-standards-of-development-for-obstetrics-and-gynecology-core-outcome-sets

Hosted file

Table 7. Stratified analyses of COS-STAD compliance.docx available at https://authorea.com/users/344833/articles/471219-improvement-was-needed-in-the-standards-of-development-for-obstetrics-and-gynecology-core-outcome-sets