

COS-STAR

Core Outcome Set-STAndards for Reporting



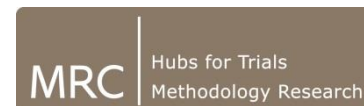
Jamie Kirkham, Sarah Gorst, Elizabeth Gargon, Paula Williamson

Department of Biostatistics, University of Liverpool, UK

Doug Altman (Oxford), **Jane Blazeby** (Bristol), **Mike Clarke** (Belfast),
Declan Devane (Galway), **David Moher** (Ottawa), **Jochen Schmitt**
(Dresden), **Peter Tugwell** (Ottawa), **Sean Tunis** (Baltimore)



This work was supported by the MRC Network of Hubs for Trials Methodology Research (MR/L004933/1-R55)



COS-STAR Statement

GUIDELINES AND GUIDANCE

Core Outcome Set–STAndards for Reporting: The COS-STAR Statement

Jamie J. Kirkham¹, Sarah Gorst¹, Douglas G. Altman², Jane M. Blazeby³, Mike Clarke⁴, Declan Devane⁵, Elizabeth Gargon¹, David Moher⁶, Jochen Schmitt⁷, Peter Tugwell⁸, Sean Tunis⁹, Paula R. Williamson^{1*}

- COS-STAR (18 item checklist)
- Explanation and Elaboration document

COS-STAR development

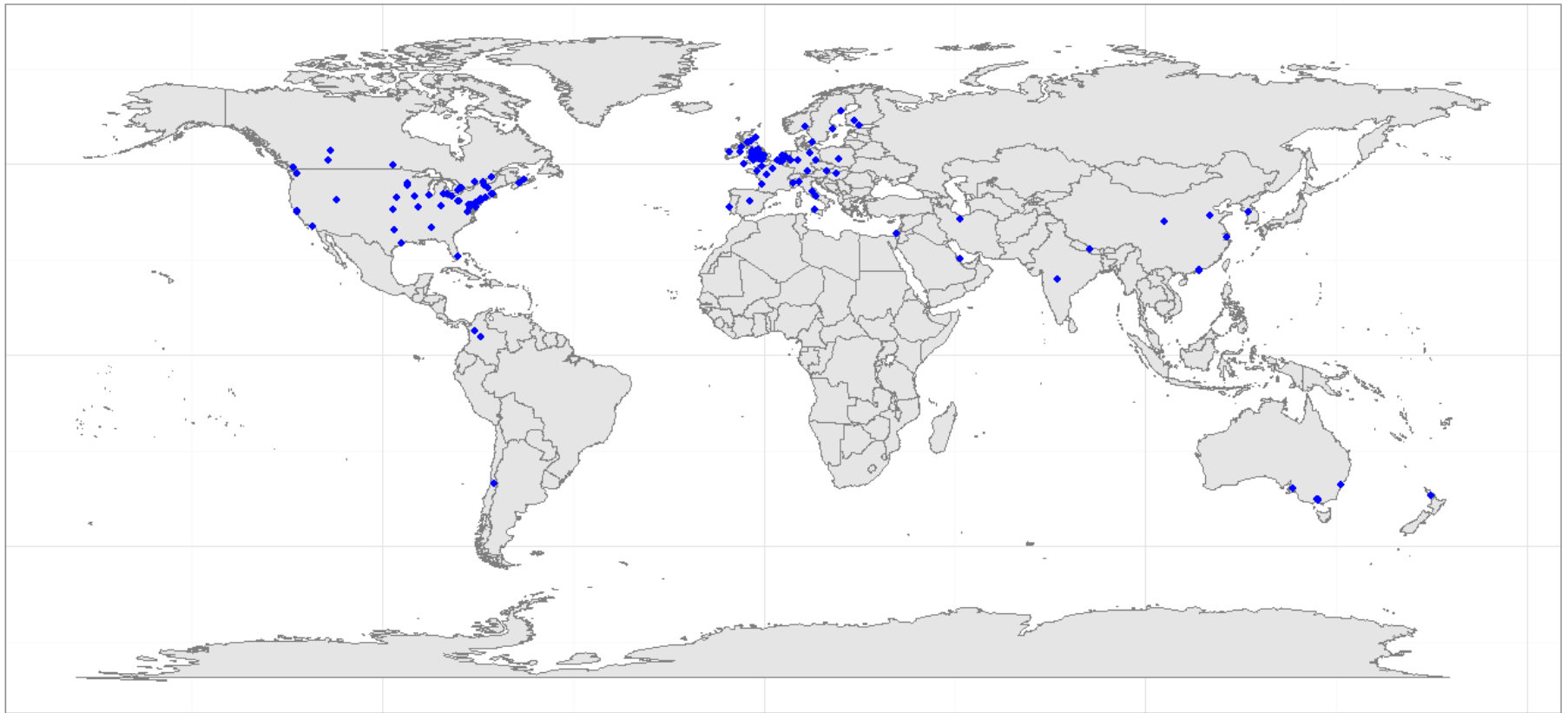
Guideline Development and Consensus Process

- Establish a preliminary checklist of reporting items (Stage 1).
- Conduct a 2-Stage Delphi survey (Stage 2).
- Hold a consensus meeting (Stage 3).
- Develop a high-quality reporting guideline and a detailed E+E (Stage 4).
- **Post-development activities: pilot testing and dissemination (Stage 5).**

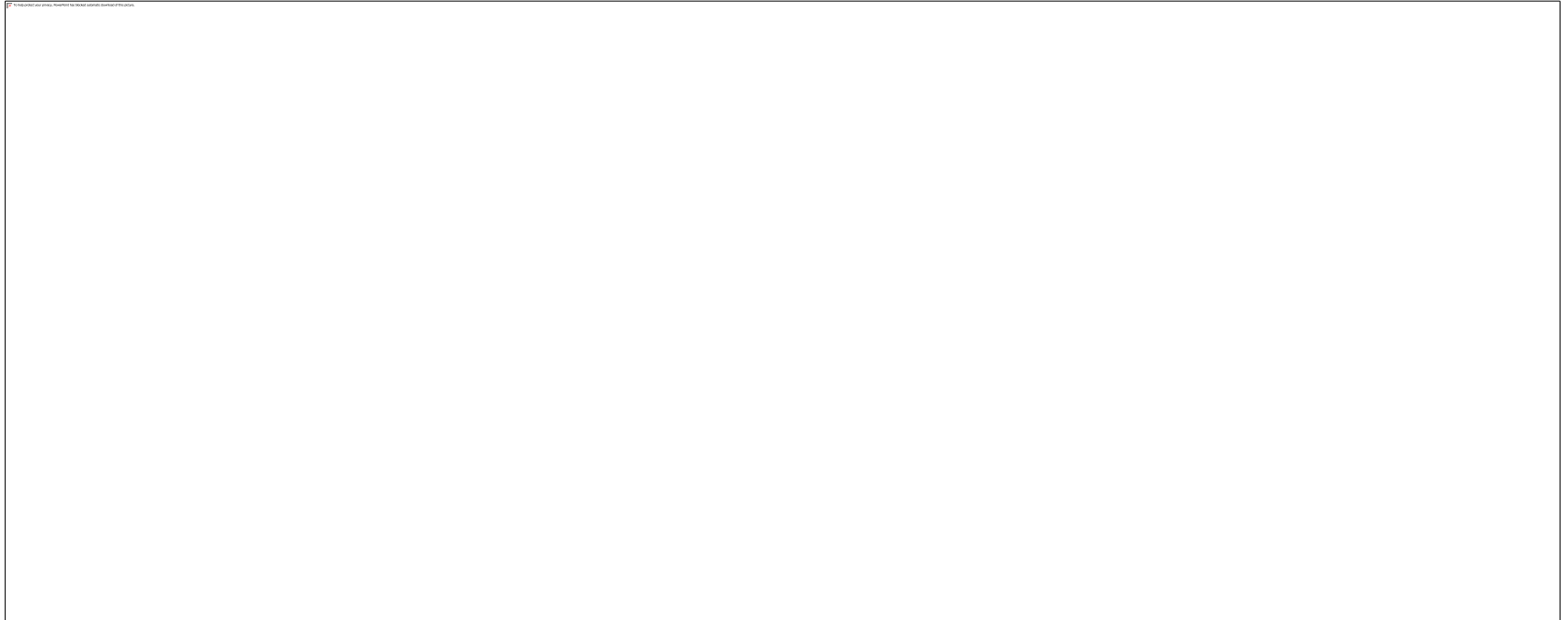
Stakeholders

- COS developers
 - Lead authors of published COS (COMET database)
- Journal Editors
 - EiC of journals that have published COS (COMET)
 - EiC of CROWN journals
- COS Users
 - Trialists (registered ongoing trials on clinicaltrials.gov)
 - Systematic reviewers (Cochrane CRG Co-Eds)
 - Clinical guideline developers (NICE, GIN)
- Patient representatives: PoPPIE / COMET PPI events

Delphi Participants



Consensus Meeting



London UK, January 2016

Checklist

SECTION/TOPIC TITLE/ABSTRACT	ITEM No.	CHECKLIST ITEM
Title	1a	Identify in the title that the paper reports the development of a COS
Abstract	1b	Provide a structured summary
INTRODUCTION Background and objectives	INTRODUCTION	
Scope	2a	Describe the background and explain the rationale for developing the COS
METHODS Protocol/Registry Entry		
Participants	2b	Describe the specific objectives with reference to developing a COS
Information sources		
Consensus process Outcome scoring Consensus definition	3a	Describe the health condition(s) and population(s) covered by the COS
Ethics and consent		
RESULTS Protocol deviations		
Participants	3b	Describe the intervention(s) covered by the COS
Outcomes	3c	Describe the setting(s) in which the COS is to be applied
Core outcome set		
DISCUSSION Limitations	15	Discuss any limitations in the COS development process
Conclusions	16	Provide an interpretation of the final COS in the context of other evidence, and implications for future research
OTHER INFORMATION		
Funding	17	Describe sources of funding, role of funders
Conflicts of interest	18	Describe any conflicts of interest within the study team and how these were managed

Explanation and Elaboration

Item 3a: SCOPE (Health condition and population): Describe the *health condition(s)* and *population(s)* covered by the COS

The health condition and population covered by the COS should be adequately described. For example in cancer, the COS may cover cancer generally or it may be specific to a particular cancer type such as head and neck cancer. Similarly, a COS may be developed for all patients but it could also be developed for a specific subset of the population in mind, such as localised prostate cancer patients or advanced prostate cancer patients, women or children.

Example: “The aim of this study, therefore, was to develop and pilot a method by which to identify outcomes of particular relevance when evaluating the effects of regular therapies for chronic childhood asthma [health condition]...of children with asthma... younger than 18 years [population].”

Limitations

- COS-STAR is not a quality assessment tool
- Based on a minimal set of reporting items
 - Clear understanding of COS development methods
- Based on consensus opinion from mostly North America/Europe
- Included only patient representatives
(with knowledge of COS development)

Post-development activities

- Endorsement and Adherence
 - Journals
 - COS developers
- Training
- Feedback
 - Comments
 - Experiences
 - Criticisms
- Evaluation
- Update



Enhancing the QUALity and
Transparency Of health Research

[Home](#) [Library](#) [Toolkits](#) [Courses & events](#) [News](#) [Blog](#) [Librarian](#)

[Home](#) > [Library](#) > [Reporting guideline](#) > Core Outcome Set-STAndards for Reporting: The COS-STAR Statement

Search for reporting guidelines

Use your browser's Back button to return to your search results



Core Outcome Set-STAndards for Reporting: The COS-STAR Statement

Reporting guideline provided for?
(i.e. exactly what the authors state in the paper)

Reporting core outcome set studies

Full bibliographic reference

Kirkham JJ, Gorst S, Altman DG, Blazeby JM, Clarke M, Devane D, Gargon E, Moher D, Schmitt J, Tugwell P, Tunis S, Williamson PR. Core Outcome Set-STAndards for Reporting: The COS-STAR Statement. PLoS Med. 2016;13(10):e1002148.

Language

English

PubMed ID

[27755541](#)

Future Work...

- Quality assessment tool
 - No 'gold standard' approach for COS development
- Minimal standards
 - What COS developers should consider
 - No judgement on the methods used/contextual
- Delphi survey about to be launched
 - It's coming your way...

Initial feedback / comments?



ijk@liv.ac.uk



[@COMETinitiative](https://twitter.com/COMETinitiative)