

Core Outcome Set-STandardised Protocol Items: COS-STAP Statement (16)

TITLE/ABSTRACT			PAGE AND SECTION REPORTED
Title	1a.	Identify in the title that the paper describes the protocol for the planned development of a COS	Page 1. Title
Abstract	1b.	Provide a structured abstract	Page 1. Abstract
INTRODUCTION			
Background and objectives	2a.	Describe the background and explain the rationale for developing the COS, and identify the reasons why a COS is needed and the potential barriers to its implementation	Page 2. Background
Scope	2b.	Describe the specific objectives with reference to developing a COS	Page 2. Objectives
	3a.	Describe the health condition(s) and population(s) that will be covered by the COS	Page 2. Objectives
	3b.	Describe the intervention(s) that will be covered by the COS	Page 2. Objectives
	3c.	Describe the context of use for which the COS is to be applied	Page 2. Objectives
METHODS			
Stakeholders	4.	Describe the stakeholder groups to be involved in the COS development process, the nature and rationale for their involvement and also how the individuals will be identified; this should cover involvement both as members of the research team and as participants in the study.	Page 4. Delphi process
Information sources	5a.	Describe the information sources that will be used to identify the list of outcomes. Outline the methods or reference other protocols/papers.	Page 3. Systematic Review
	5b.	Describe how outcomes may be dropped/combined with reasons	Page 4. Delphi process
Consensus process	6.	Describe the plans for how the consensus process will be undertaken	Page 4. Delphi process
Consensus definition	7a.	Describe the consensus definition	Page 4. Delphi process
	7b.	Describe the procedure for determining how outcomes will be added/combined/dropped from consideration during the consensus process.	Page 4. Delphi process
ANALYSIS			
Outcome scoring/feedback	8.	Describe how outcomes will be scored and summarised, describe how participants will receive feedback during the consensus process	Page 4. Delphi process
Missing data	9.	Describe how missing data will be handled during the consensus process	Page 4. Delphi process
ETHICS and DISSEMINATION			
Ethics approval/informed consent	10.	Describe any plans for obtaining research ethics committee/ institutional review board approval in relation to the consensus process and describe how informed consent will be obtained (if relevant).	Page 5. Ethics and dissemination
Dissemination	11.	Describe any plans to communicate the results of study participants and COS users, inclusive of methods and timing of dissemination	Page 5. Implementation, dissemination and updating the COS
ADMINISTRATIVE INFORMATION			
Funders	12.	Describe sources of funding, role of funders	Page 6. Funding Statement
Conflicts of interest	13.	Describe any potential conflicts of interest within the study team and how they will be managed.	Page 6. Competing interests

COS – Core outcome set