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The GenderCOS project: study protocol for the development of two international Core Outcome Sets for genital gender affirming surgery

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ABSTRACT

Background: Worldwide an increasing number of transgender and gender diverse individuals are requesting genital Gender Affirming Surgery (gGAS). For both masculinizing and feminizing gGAS various procedures and techniques are employed. Current literature on gGAS reports heterogeneous, non-standardized and often ill-defined outcomes. Presently, no consensus exists on what outcomes should be evaluated in order to assess the clinical results and the effectiveness of these procedures, which precludes development of evidence-based treatment guidelines.

Aims: This international consensus study aims to develop Core Outcome Sets (COS) for both masculinizing and feminizing gGAS. These represent the minimum sets of outcomes recommended to be measured and reported in all clinical trials pertaining to gGAS.

Methods: Two Core Outcome Sets for masculinizing and feminizing gGAS will be developed in parallel by following the Core Outcome Measures in Effectiveness Trials (COMET) guidelines. The stages of development for each set are: i) Identify outcomes measured and reported in previous research through a systematic review of the literature; ii) Identify outcomes suggested by transgender and gender diverse individuals during focus groups and interviews; iii) Combine and structure the outcomes into a preliminary outcome list; iv) Conduct e-Delphi surveys among stakeholders (i.e. professionals in transgender healthcare and transgender individuals) in which all potential outcomes will be rated on level of importance; and v) Decide on the final COS during an online consensus meeting.

Discussion: This study will produce minimum, core sets of relevant outcomes for gGAS, through reaching international consensus with key stakeholders, including transgender individuals. Development of these COS will enable the measurement and reporting of relevant and standardized outcomes, facilitating continued scientific advancement of this field.

List of Abbreviations: COMET: Core Outcome Measurements in Effectiveness Trials; COS: Core Outcome Set(s); COS-STAD: Core Outcome Set-STAndards for Development; COS-STAP: Core Outcome Set-STAndarised Protocol Items; gGAS: Genital Gender Affirming Surgery; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PROSPERO: International Prospective Register of Systematic Reviews; SMG: Study Management Group; SSG: Study Steering Group

KEYWORDS
genital gender affirming surgery; core outcome set; transgender; gender diverse; gender affirming treatment; Delphi

TRIAL REGISTRATION
the project is prospectively registered in the Core Outcome Measures in Effectiveness Trials (COMET) database (nos. 2064 and 2067). The protocol was approved by the Ethical Review Board of the Amsterdam UMC; location VUmc (no. 2022.0102).

Introduction

The number of transgender people seeking gender-affirming medical care continues to increase annually (Wiepjes et al., 2018). Gender affirming care, including psychological, hormonal and surgical interventions, has been shown to improve the well-being and quality of life of transgender individuals (Javier et al., 2022; van de Grift et al., 2018).

As techniques in genital gender affirming surgery (gGAS) continue to improve, more

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transgender individuals are pursuing surgery (Chaya et al., 2022). However, while there are some recognized gold standard gGAS operations, the field is fraught with variability in techniques and surgical training (Frey et al., 2017). As more surgeons perform these procedures, it is paramount that we use evidence-based recommendations to optimize patient care (Coleman et al., 2022). gGAS lacks high quality evidence to drive these recommendations and many leading publications in this field are non-generalizable as they are single center and single technique-based, and most commonly retrospective. Even when higher quality evidence publications are available, they suffer from minimal follow-up and ad hoc approaches to assessment of satisfaction or outcomes (Chen et al., 2019; Horbach et al., 2015; Li et al., 2022). Due to these limitations, surgeons and patients are often left without proper guidance on the optimal techniques for a given scenario (Selvaggi & Bellringer, 2011; Wroblewski et al., 2013). Moreover, there is a lack of evidence on how various techniques compare with regard to safety and effectiveness (Chaya et al., 2022; Frey et al., 2017). In order to drive evidence-based recommendations and standardization in the field of gGAS, well documented comparative studies are urgently needed. Furthermore, there should be a consensus on which outcomes are necessary and required to capture the essential clinical and patient reported outcomes (Barone et al., 2018; Oles et al., 2022). A Core Outcome Set (COS) can be instrumental in achieving this.

Feminizing gGAS

Transgender women and gender diverse individuals may opt for feminizing gGAS (Hadj-Moussa et al., 2018). Creation of the female external genitalia (vulva) includes labiaplasty, urethral and meatal reconstruction, clitoroplasty and perineal flap augmentation. Technical variants exist for each of these procedures. Vaginoplasty is the collective name for surgical techniques in which a vaginal cavity is created. The main difference between vaginoplasty techniques is the choice of tissue used to line the neo-vaginal cavity; i.e. (scrotal) skin, penile skin, pedicled small or large intestinal segments, pedicled peritoneal tissue or a combination (Horbach et al., 2015; Li et al., 2021; Pariser & Kim, 2019). If a vaginal canal is not desired, vulvoplasty (also known as minimal-depth vaginoplasty) is an option. In this case, only the vulva is created (Jiang et al., 2018). Penile inversion vaginoplasty has been described as the gold standard, however, this is primarily based on expert opinion. Currently, due to the lack of evidence, there is no consensus on indications for specific feminizing gGAS procedures nor on the optimal techniques (Castanon et al., 2022; Horbach et al. 2015). Standardizing outcomes and conducting high-quality comparative studies is necessary to enable evidence-based decision making with regard to feminizing gGAS (Horbach et al., 2015; van der Sluis et al., 2022).

Masculinizing gGAS

Procedures for masculinizing gGAS include procedures to create a neo-phallus (with or without urethral lengthening), a neo-scrotum and a neo-corona (Al-Tamimi et al., 2020; Selvaggi et al., 2009; Sommeling et al., 2018). Masculinizing gGAS is considered the most challenging of gender affirming surgical procedures (Frey et al., 2017). Phalloplasty is a surgical procedure in which an average to large sized neo-phallus is created using (multiple) large sized flaps obtained from different donor sites throughout the body. The most frequently used flaps are the radial forearm free flap, superficial circumflex iliac artery perforator flap, and anterolateral thigh pedicled flap. Other less commonly used flaps are the abdominal flap, the suprapubic pedicled flap, fibula free flap, the lateral upper arm flap, and the latissimus dorsi free flap (Al-Tamimi et al., 2020; Boczar et al., 2021; Wang et al., 2022). Metoidioplasty is a surgical procedure which creates a below-average-sized neo-phallus out of hormonally hypertrophied clitoral and labial tissue. Described techniques are the simple, the ring, the extended and the Belgrade metoidioplasty (Djordjevic et al., 2019; Morrison et al., 2022). A wide variety of techniques are used for masculinizing gGAS. Due to the lack of evidence on their value, safety and effectiveness, the choice for performing a specific procedure is currently mostly based on the surgeon's preferences and skill. The need for standardized reporting of outcomes is paramount (Wang et al., 2022).

Core Outcome Set (COS)

A COS is defined as the minimum set of outcomes that should be measured in a standardized manner and reported consistently in all clinical trials for a specific health condition/health area (Williamson et al., 2017). Herein we describe the methodology we propose to use to define two COS: feminizing- and masculinizing gGAS.

Materials and methods

Registration and ethics

The project is prospectively registered with the Core Outcome Measures in Effectiveness Trials (COMET) database under study numbers 2064 and 2067 (*Core Outcome Measures in Effectiveness Trials (COMET) database: registration study number 2064*; *Core Outcome Measures in Effectiveness Trials (COMET) database: registration study number 2067*). It received ethical approval from the Amsterdam UMC, location VUmc Ethical board (Reference number: 2022.0102). The systematic reviews which are part of the project are registered in the International Prospective Register of Systematic Reviews (PROSPERO) under numbers CRD42020223430 and CRD42022347400.

Adhering to the standards for COS development

For the development of both COS within this project, the COMET guidelines will be followed (Williamson et al., 2017). According to the Core Outcome Set-STAndards for Development (COS-STAD), methodology relating to the scope, the stakeholders, and the consensus process should be explicitly described in the protocol for COS development. For this protocol we will adhere to the Core Outcome Set-STAndarised Protocol Items (COS-STAP) checklist, which can be found in Appendix 1 (Kirkham et al., 2019).

Study Steering Group

To guide the development of these COS (here on referred to as "The GenderCOS project"), an international Study Steering Group (SSG) was formed. The SSG consists of experts by lived experience (i.e. transgender individuals) (AB., BC.) and experts by profession (i.e. health care professionals and/or senior researchers) (TR., JBell., JB., MB., SM., WPB., M-BB. and MM.). The Study Management Group (SMG) consisting of physician-scientists (PR., MV., TP. and AC.) is responsible for the day-to-day management of the project. In the event that any protocol modifications need to be made to the protocol by the SSG and SMG during the course of the study, this will be clearly stated in the final publication of the COS. If any protocol modifications are made during phase 2 (see *The GenderCOS project development process below*) of The GenderCOS project all participants will be notified at the start of the next e-Delphi survey round.

Scope

The scope of The GenderCOS project is presented in Table 1.

Stakeholders and recruitment

Stakeholders who will be recruited to participate in the development of The GenderCOS project are described in Table 2. Details of the inclusion and exclusion criteria for each stakeholder group can also be found in Table 2.

Experts by profession will be recruited internationally. Promotion to participate in the project will be done *via* the website (www.gendercos.org), at international meetings (e.g. World Professional Association for Transgender Health, European Professional Association for Transgender Health, European Society for Sexual Medicine) and through the networks of the SSG members. Professional societies will be asked to distribute the recruitment invitation amongst their members. International healthcare centers known for providing the care as stated in the scope will be queried to share the invitation to participate to their healthcare professionals. Through the systematic reviews, authors of published studies will be identified, contacted and invited to participate.

Experts by lived experience will also be recruited internationally. This will be done by online promotion (e.g. social media, website) and

Table 1. COS-STAD as applied to the domain scope specification.

Domain	Standard	Methodology	COS Feminizing gGAS	COS Masculinizing gGAS
Scope specification	1	The research of practice setting(s) in which the COS is to be applied	Clinical research	Clinical research
	2	The health condition(s) covered by the COS	Gender incongruence and/or gender dysphoria	Gender incongruence and/or gender dysphoria
	3	The population(s) covered by the COS	Transgender women and gender diverse individuals, who are of legal age for surgery in the country of care and opt for gGAS	Transgender men and gender diverse individuals, who are of legal age for surgery in the country of care and opt for gGAS
	4	The intervention(s) covered by the COS	All surgical techniques that include the feminization of the genitalia; vaginoplasty, labiaplasty, vulvoplasty and clitoroplasty, either primary or revision	All surgical techniques that include the masculinization of the genitalia, either with or without urethral lengthening; metoidioplasty, phalloplasty, scrotoplasty and coronaplasty, either primary or revision

Table 2. COS-STAD as applied to the domain, and inclusion- and exclusion criteria of, involved stakeholder groups.

Stakeholder group	Standard	Methodology	Inclusion criteria The GenderCOS project		Exclusion criteria The GenderCOS project
Clinical researchers in the field of gGAS	5	Those who will use the COS in research	Authors of at least 5 published studies into one of the surgical techniques as stated in the scope	Read and understand English, Spanish or Dutch	Researchers who have no clinical experience with individuals who have undergone gGAS
Surgeons and other health care professionals with experience in gGAS	6	Healthcare professionals with experience of individuals with the condition	Surgeons specialized in gGAS (e.g. surgeons, urologists, gynecologists, plastic surgeons) or Healthcare professionals who provide care around gGAS (e.g. psychologists, physiotherapist, sexologists, physician assistants)	Read and understand English, Spanish, or Dutch	Professionals in gender healthcare who have no experiences with individuals who have undergone gGAS
Transgender women and gender diverse individuals	7	Individuals with the condition or their representatives	Transgender women or gender diverse individuals who have undergone one of the feminizing gGAS techniques as stated in the scope at least 3 months ago and of legal age for gGAS in the country of surgery	Read and understand English, Spanish, or Dutch	Individuals who are unable to give informed consent, or read and understand the e-Delphi surveys
Transgender men and gender diverse individuals	7	Individuals with the condition or their representatives	Transgender men or gender diverse individuals who have undergone masculinizing gGAS techniques as stated in the scope at least 3 months ago and of legal age for gGAS in the country of surgery	Read and understand English, Spanish, or Dutch	Individuals who are unable to give informed consent, or read and understand the e-Delphi surveys

by approaching support groups and international trans non-governmental organizations (e.g. Transgender Europe, International Lesbian, Gay, Bisexual, Trans and Intersex Association, Asia Pacific Transgender Network). Posters will be made and distributed to be displayed in waiting rooms of health care providing facilities to raise awareness and invite to participate. We invite experts by profession to also raise awareness among potential experts by experience in the consultation room.

Currently, no specific requirements or recommendations exist for a minimum or maximum number of participants to be included (Boulkedid et al., 2011). Theoretically, the more participants included should increase the validity and

generalizability of the consensus reached (Murphy et al., 1998). For this project, we aim to have at least 20 participants in each stakeholder group from both the COS. Furthermore, the number of participants for each stakeholder group will not be limited.

The GenderCOS project development process

An overview of the development process is provided in Figure 1. It is identical for the development of both the feminizing and masculinizing gGAS COS, which will be run in parallel.

Phase 1: Generating lists of potentially relevant outcomes

Systematic literature reviews. A systematic review to obtain all outcomes that have been reported in clinical research related to feminizing gGAS has been published (Pidgeon et al., 2022). At the time of this manuscript submission a systematic review into masculinizing gGAS is being conducted. Both systematic reviews will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline for systematic reviews (Dickson & Yeung, 2022). In these systematic reviews, the following data were manually extracted: author, year of publication, study design, population, number of patients, intervention, mean age, outcomes reported in design and results (including the definitions of outcomes if stated) and any descriptions of measurement instruments used (Williamson et al., 2017). The outcomes were classified using a taxonomy, which was specifically developed for outcomes in medical research (Dodd et al., 2018). This taxonomy was slightly modified for the systematic review for masculinizing gGAS, as 'sexual outcomes' was added to the outcome domain list.

Population focus groups and interviews. Prior to The GenderCOS project, a qualitative study was performed at the Department of Plastic, Reconstructive and Hand Surgery in Amsterdam UMC, the Netherlands to collect data for the

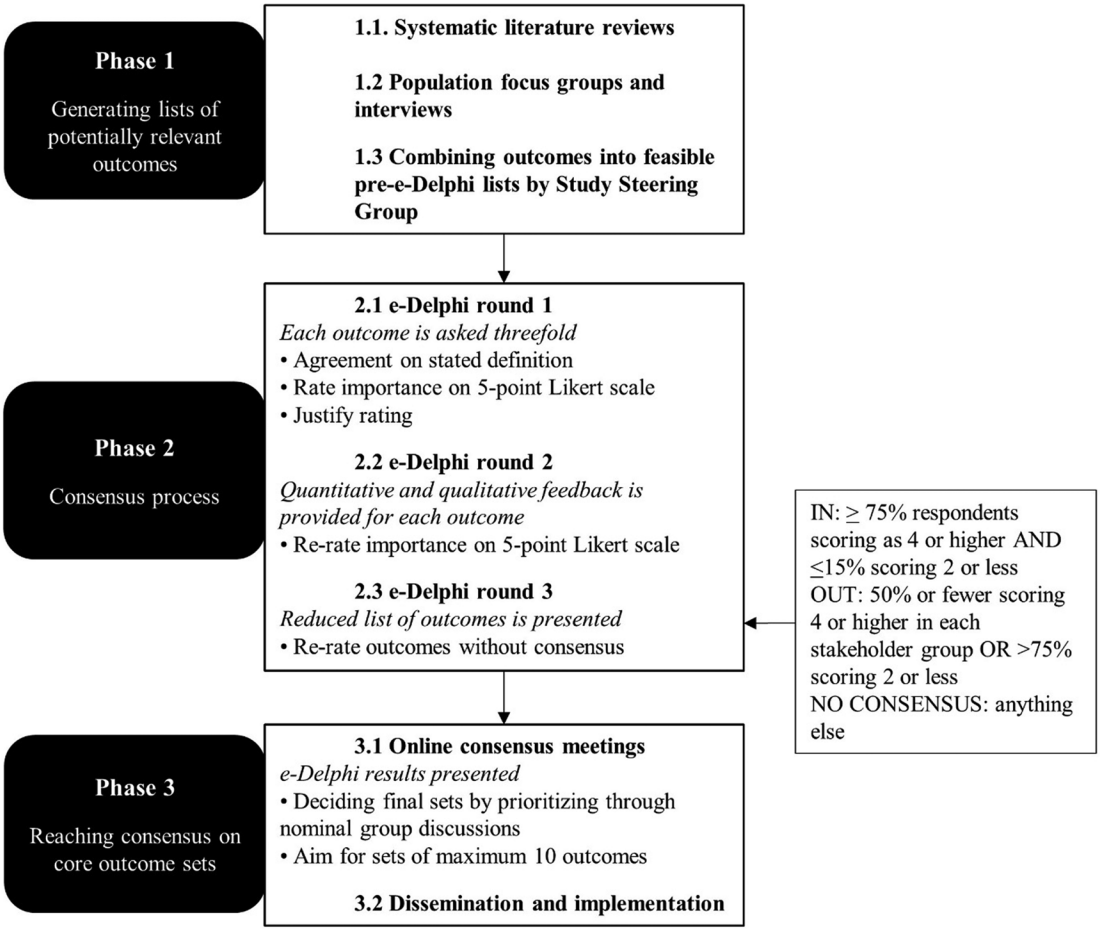

Figure 1. Overview of the GenderCOS project development process.

development of decision aid for gGAS (here on referred to as "The GenderAID") (Mokken. 2023). Focus groups and interviews were held with transgender and gender diverse individuals who had previously undergone gGAS. During these focus groups, transgender individuals were asked about their reasons for choosing certain surgical options, what they value in certain techniques and what outcomes they deem important and why. Since the research questions overlap significantly, the qualitative data from The GenderAID was repurposed for The GenderCOS project. The outcomes have been classified using the same modified taxonomy as described above (Dodd et al., 2018). The decision aid study received ethical approval from the Amsterdam UMC, location VUmc ethical board (Reference numbers: 2020.0653 and 2021.0026). The participants gave written consent for the data to be reused for other research purposes. In Table 3 an overview of the focus groups and interviews can be found.

Combining data into feasible pre-Delphi lists. All extracted and classified outcomes will be used to generate two initial outcome lists. Both lists will undergo deduplication of exact matching outcomes. The remaining outcomes on each list will be further condensed based on similarities, rationalization of outcomes and removal of obsolete outcomes by the SSG. Furthermore, within the SSG there must be consensus reached on the (lay) definition of each exact outcome that will be used in the e-Delphi rounds. Also, the number of items considered will be determined for group review (Gargon et al., 2019). The final lists of outcomes will be translated following standardized cross-cultural translations—to guarantee linguistic appropriateness - into Dutch and Spanish and grouped by domain (Brookes et al., 2018).

Phase 2: Consensus process

Delphi method. Individuals who meet the inclusion criteria will be invited to participate in all three e-Delphi survey rounds *via* the e-mail address they registered with on The GenderCOS project website. All three rounds of e-Delphi surveys will be delivered through Survalyzer survey software (*Survalyzer Survey Software*). At the beginning of the e-Delphi survey, instructions will be given on how to fill in the surveys. Participants will be asked to complete a short demographic questionnaire (Table 4) and provide informed e-Consent. They will also be presented with the option to be named as contributor in the publication regarding the COS concerned. Lastly, participants will be reminded that they are free to withdraw from the surveys at any time. Only the SMG will have access to the study data, which will be encrypted.

The time period that the surveys are open for completion will be set at 6 wk. In between each round there will be a period of 10 wk for analysis of the completed surveys and compilation of data. After 2 wk, reminders will be sent weekly up to a maximum of 4 reminders.

In the first e-Delphi round the participant is, for each outcome, asked about the stated definition, to rate its importance on a 5-point Likert scale (e.g. 1 is not important, 2 is less important, 3 is neutral, 4 is important and 5 is very important) and to justify their rating. Descriptive statistics will be used to summarize the data. In the second round quantitative and qualitative feedback for each outcome from the first round is provided and participants are asked to rate the importance of the outcomes once more (Brookes et al., 2016; Fish et al., 2020; Khodyakov & Chen, 2020). Based on the consensus classification as described in Table 5, a reduced list of outcomes is presented in the third round and the participant is asked to give feedback on the list of excluded outcomes and to rate outcomes without consensus again. After completing all rounds,

Table 3. Overview of qualitative data collection.

Qualitative method	Feminizing gGAS	Masculinizing gGAS
Number of interviews	12	18
Focus groups (number)	(3)	(1)
Number of participants	6, 7, 9	9

Table 4. Demographic data to be collected per stakeholder group.

Experts by profession	Experts by lived experience
Job role (categorized)	Identified gender (categorized)
Years of practice	Age
Current country of practice	Country of received care
If applicable; number of publications on surgical techniques	Number of months post-surgery
	Received surgical technique (categorized)

Table 5. Consensus classification.

Consensus classification	Description	Definition
Consensus IN	Outcome recommended to be included in the COS	≥ 75% respondents scoring as 4 or higher AND ≤15% scoring 2 or less
Consensus OUT	Outcome recommended to be excluded from the COS	50% or fewer scoring 4 or higher in each stakeholder group OR >75% scoring 2 or less
No consensus	Uncertainty regarding importance of outcome	Anything else

participants are asked whether they may be approached to partake in the consensus meeting (phase 3).

Phase 3: Reaching consensus on core outcomes sets

Defining the final COS. The final COS for masculinizing and feminizing gGAS will be defined during two separate online consensus meetings (one for each COS). An equal, viable number of stakeholders from each stakeholder group will be invited to participate from those who indicated a willingness to partake in the meeting during the e-Delphi survey rounds. The meetings will be guided by an independent, trained facilitator, who is neither an expert by experience nor profession, but who has understanding of the methodology to reduce the risk of bias in the facilitation process (Harman et al., 2015; Williamson et al., 2017). The results from the final e-Delphi surveys will be presented during the meetings. Contingent upon this, retaining or removing outcomes from the final lists will be done by prioritization through discussion using a nominal group technique (Harvey & Holmes, 2012). Although there is no gold standard for the ideal number of outcomes within a COS, it is advised to generate a list of approximately 10 outcomes to maximize implementation and feasibility (Hughes et al., 2021; Maxwell et al., 2019). The COS will be complete once agreement is reached by all stakeholders on the final lists.

Dissemination and implementation. The two final COS will be disseminated as extensively and as efficiently as possible. We aim to publish both sets open-access in relevant and leading scientific journal(s). Furthermore, we will use the project website for online promotion, as well as other online outlets, such as social media. International patient organizations, healthcare professional organizations and other relevant societies will be approached and asked to cooperate in the dissemination. Also, we aim to present the final set during international scientific congresses. By including various key relevant international stakeholders in the development and by promoting the awareness of the COS we aim to maximize the uptake and thus implementation of the COS (Hughes et al., 2021).

Discussion

The development, dissemination and implementation of COS for gGAS will ensure that key relevant outcomes will be measured and reported in future research. This will enhance the comparison of reported outcomes between studies and facilitate guideline-development and evidence-based informed decision-making. Evaluation and consensus on how and when the core outcomes should be measured, will be the subject of an ensuing study. Through the use of the COS, we endeavor to improve the quality of clinical research. By developing the COS, an international network will be established, which can be leveraged for further collaboration within the field.

Authors' contributions

PR and MV led the proposal and protocol development. All authors contributed to the study design and development of the protocol, and based on this PR, MV and MM drafted the manuscript. All authors revised the final manuscript and approved the submitted version.

Disclosure statement

The authors declare that they have no conflict of interest.

Ethics approval and consent to participate

Ethical approval has been received from the Amsterdam UMC, location VUmc Ethical board Reference number: 2022.0102. All future participants of the study have to provide e-Consent before the start of the first e-Delphi survey round. This article does not contain any studies with human participants or animals performed by any of the authors.

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Appendix

Appendix 1. Core Outcome Set-STAndardised Protocol Items: the COS-STAP Statement checklist.

Item	Item No	Description	Addressed on page number
TITLE/ABSTRACT			
Title	1a	Identify in the title that the paper describes the protocol for the planned development of a COS	1
Abstract	1b	Provide a structured abstract	2
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	4-6
	2b	Describe the specific objectives with reference to developing a COS	4-6
Scope	3a	Describe the health condition(s) and population(s) that will be covered by the COS	8
	3b	Describe the intervention(s) that will be covered by the COS	8
	3c	Describe the context of use for which the COS is to be applied	8
METHODS			
Stakeholders	4	Describe the stakeholder groups to be involved in the COS development process, the nature of 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	11-12
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	13-14
	5b	Describe how outcomes may be dropped/combined, with reasons	15-16
Consensus process	6	Describe the plans for how the consensus process will be undertaken	16-17
Consensus definition	7a	Describe the consensus definition	16
	7b	Describe the procedure for determining how outcomes will be added/combined/dropped from consideration during the consensus process	16-17
ANALYSIS			
Outcome scoring/feedback	8	Describe how outcomes will be scored and summarized, describe how participants will receive feedback during the consensus process	15-16
Missing data	9	Describe how missing data will be handled during the consensus process	15
ETHICS & 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)	19
Dissemination	11	Describe any plans to communicate the results to study participants and COS users, inclusive of methods and timing of dissemination	17