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Protocol

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Standardised Reporting Outcomes for trials investigating Surgical WOund Complications (ROSWOC): protocol for the development of a core outcomes set for trials evaluating interventions for the prevention of surgical wound complications.

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Abstract

Introduction: Despite advances in surgical technique and wound management surgical wound complications such as surgical site infection and surgical wound dehiscence still pose a considerable global burden. Inconsistencies in measuring and reporting of this phenomenon pervade study designs, analysis and synthesis of the evidence, as such a core outcome set (COS) is required. The Reporting Outcomes for Surgical WOund Complications project (ROSWOC) aims to improve quality of reporting and evidence for surgical site infection and surgical wound dehiscence prevention trials. A core outcome set for trials is required to homogenise outcomes for trials investigating prevention and management of surgical wound complications.

Methods: This project aims to develop a core outcome set following established methods; 1) define scope of work, 2) conduct a scoping review, 3) organising facilitated workshops with service users and 4) conduct Delphi surveys, and 5) conduct face-to-face meetings with key stakeholders.

Discussion: Following obtaining consensus for the core set, further work will be carried out to describe a core outcomes set. The articulation of an agreed set of core outcomes for trials investigating surgical site infections and surgical wound dehiscence will improve prevention studies into surgical wound complications into the future.

Trial registration: The ROSWOC project is registered in the COMET database: (http://www.comet-initiative.org/studies/details/) registered November 2022.

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Introduction

Surgical wound complications such as surgical site infection and surgical wound dehiscence are unwanted outcomes following surgery. While most surgeries today are relatively safe, surgical wound complications (SWCs) arising from breakdown in the skin integrity and incision site often lead to surgical site infection (SSI), sepsis and an increase in morbidity and mortality[1-9]. Surgical site infection is defined as a wound infection occurring within 30 to 90 days after surgery[10]. SWCs such as SSI or surgical wound dehiscence (SWD) are a disruption to the normal healing process and often involve pathogenic activity from skin flora or contamination from exogenous

sources[11,12]. Surgical wound dehiscence is defined as the separation of opposed margins (incisions) without the presence of microbial activity[13]. Separation may occur along the entire incision or at separate locations along the incision and may or may not involve bacterial contamination[13,14].

Occurrence of SWCs varies per surgical discipline, country and region, with multiple factors contributing to occurrence spanning the patient's surgical journey from preoperative to postoperative and home care[15]. Worldwide the prevalence of SSI ranges from 2%[16] to 38%[17], with higher occurrences reported in low to middle income countries[18,19]. Prevalence and incidence data reports the occurrence of surgical site infection in the hospital setting, whereas complications are more commonly identified after discharge and managed in the community and primary care setting so are most likely underreported[1,20]. Decades of research in the field of surgical site infection prevention has resulted in gold standard guidelines[21,22]. However many recommendations within these guidelines are constrained due to a poor strength in evidence grading due to nature and design of studies, which impacts the translation of guidelines and adoption in clinical practice. Inconclusive studies pervade the field, and are a result of inadequate powering of trials, biases, inconsistencies in use of definitions in reporting, and lack of universal trial outcomes. This results in ambiguity and lack of confidence in whether to use an intervention or task for improved patient outcomes. Moreover, the inability to synthesise study results into a collective understanding is an inefficient use of the precious resources required to conduct trials, and a further strain on the shrinking research funding pool.

Rigorous clinical trials and their findings are a central tenant for the development of guidelines that are constructed to inform evidence-based practice and improve health care services and patient outcomes[23,24]. Implementing a core outcome set, as a minimum standard for clinical trials protocols that measure and describe not only surgery-based outcomes but also patient reported outcomes, will allow for more comparable and robust studies across differing healthcare settings. It is only through level one evidence and targeted implementation of research findings that meaningful change in clinical practice can occur. The use of standardised, universal definitions and measurement outcomes are critical to avoid heterogeneous reporting of findings. This will improve the quality of evidence synthesis and ultimately translation of research findings.

The aim of the study was to develop and provide a standardised core outcomes set for the testing of efficacy, effectiveness and validity of prevention interventions for use in clinical trials.

Methods

This project will follow the principles for the standards of COS development.[25] The project will also address the Core Outcome Set – Standards for Development (COS-STAD) recommendations by engaging stakeholders and service users during the development phase[26]. The core outcomes set will be developed via the four following steps (figure 1): (1) Define the scope of work; (2) Conduct a scoping review; (3) Organise workshops with consumer/patient and user advisory group; (4) Undertake Delphi surveys followed by virtual/face to face meetings to establish consensus.

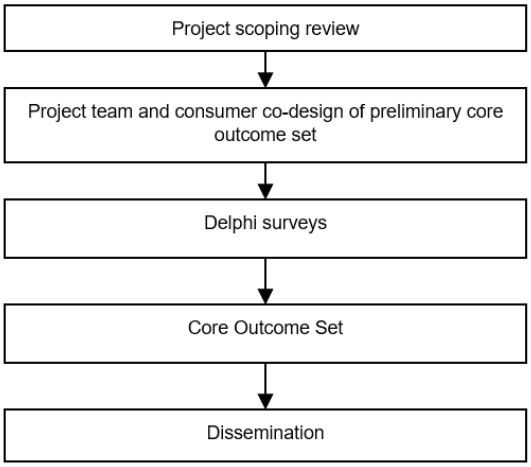

Figure 1: Reporting Outcomes for trials investigating Wound Complications (ROSWOC) study flow.

Project team and stakeholder engagement

The project team will work together to develop, plan and execute the planned outcomes (table 1). All team members have expertise in clinical research including but not limited to clinical trials, epidemiological research, evidence synthesis, consensus and guideline methodology in the field of surgical site infection prevention and/or consumer/patient advisory groups. Stakeholders engaged in the Delphi survey process, including face

Table 1. ROSWOC Project Team

Project Team	Methodology Advisory Board
Kylie Sandy-Hodgetts (AUS) Tomas Serena (USA) Philip Russo (AUS) George Smith, (UK) Tom Wainwright, (UK) Josh Totty, UK (UK) Tom Wallace (UK) Kenneth McLean (UK) Rebecca Aburn (NZ) Aneel Bhangu (UK) Sivesh Kathir Kamarajah (UK) Piers Yates (AUS) Neerod Jha (UAE) Melissa Rochon (UK)	Rhiannon Macefield Melissa Rochon Kylie Sandy-Hodgetts
Tasks: • Identify and specify outcomes through a scoping review • Participating in workshops with service users to determine outcomes not identified in the scoping review • Participate in Delphi surveys and a face-to-face meeting to find consensus on core outcomes set	Tasks: • Methodological and content advice • Participate in Delphi surveys and a face-to-face meeting to find consensus on core outcomes set

to face meetings, will include service users, a patient and consumer representative, health professionals representing various health care settings, representatives of health care management and product manufacturers. Service user participants will have a lived experience of surgical site infection/and/or surgical wound dehiscence or have cared for a person who has had/has a surgical site infection. Engagement of service users (patients, carers, consumers) in the development of the COS is integral to understanding the relevance and translation of COS into clinical practice[27-29]. Furthermore engagement of consumers is in accordance with Australian Standards for Quality and Safety in Healthcare: Standard 2[30]. The Surgical Site Infection Consumer Reference Group (SSICRG) will be involved in the ROSWOC project during consumer advisory workshops and invitation to participate in the Delphi survey.

Scope specification

Following a structured project and methodological team discussion, it was agreed that the intent of the COS should be applicable to all clinical trials investigating efficacy of interventions for prevention of surgical wound complications (SSI, SWD, hematoma, seroma). The COS should be applicable to all adult populations ≥18 y/o and should not be restricted by health care setting or geographical location.

Scoping review

The team will undertake a scoping review to identify and describe outcomes that may be relevant to trials investigation the prevention of surgical wound complications such as surgical site infection and/or surgical wound dehiscence. The scoping review methodology will follow the PRISMA ScR reporting guideline[31] and will be used as examination of the evidence which will require a broad approach, due to the nature of contemporary evidence, and include those studies that may not meet the requirements of a systematic review methodology. A systematic search will be conducted using the following databases: OVID Medline, OVID CINHAL, ClinicalTrials.gov, ANZCTR, WHO International Clinical Trials Registry Platform Search Portal. To be eligible for consideration, any study reporting the efficacy/effectiveness/safety of an intervention for the prevention of SSI and/or SWD will be included. This includes studies that are controlled clinical trials, quasi randomised studies, systematic reviews and meta-analysis of studies, comparative effectiveness studies, health economic evaluations. Further to this, the grey literature such as meeting reports, position papers, white papers on outcomes regarding practice or science will be included. The primary aim of this scoping review is to determine the full scope of outcome measures used in studies. All surgical procedures will be included and only studies published in English will be used. The

date range for publications includes publications after 2017, due to a Cochrane systematic review which has extensively reviewed previous work[32].

References will be stored in the Covidence platform (https://www.covidence.org/), which will be used to screen and check for eligibility. Following duplicate removal, two team members will screen title and abstract and then full article. Where a disagreement arises between the two reviewers this will be resolved within the project team via discussion. Data extraction will be conducted by two reviewers and cross checked by a third member of the project team.

Data extraction includes (a) bibliographic information, (b) study design, (c) type of intervention, (d) outcomes used to assess the efficacy/effectiveness of the intervention (primary and secondary), (e) patient reported outcome measures and (f) quality of life measures and (g) health economic outcomes. Outcomes extracted will be used to create core outcomes sets to inform a new outcome classification system for the COS. Following the completion of the scoping review the project team, in consultation with the methodological advisory board, will develop a preliminary COS considered relevant for SSI/SWD prevention trials. This will form the basis of the Delphi survey content.

Outcomes workshops

At least three service user workshops will be conducted across several continents. The purpose of these user workshops is threefold: (1) to describe COS development within the group to inform the approach in the later stages of the project; (2) to identify outcomes which are important from a user perspective; (3) to identify outcomes relevant to users that were not identified by the scoping review.

Participants of the workshops are from the established Surgical Site Infection Consumer Reference Group (SSICRG), Perth, Western Australia who comprise patients and their carers with a lived experience of a surgical wound. During the workshops a project overview will be presented describing the aims, methods and preliminary findings. An experienced PPI/ Consumer Advisory Manager will develop and deliver the presentation in lay terms. The workshop will be using the COMET information leaflet 'Involving patients and the public in improving research'[33] to explain outcomes and how the findings can be translated to SWC research.

Delphi surveys

A global Delphi survey process will be used to conduct a formal consensus-based approach to develop the COS. Delphi surveys consist of a number of sequential surveys which rely on an iterative approach, via a representative sample of key stakeholders who are asked to respond to questions that provide either qualitative or quantitative information.[33] A draft version of the survey will be circulated to the project team and the methodological advisory board and will be refined. Data will be collected using an online survey platform COMET Delphi Manager and will allow participants to rate the relevance of the proposed core outcome set via a numeric scale. Rating of items for inclusion in the core outcome set will use the GRADE approach, and has been used elsewhere to develop a core outcome set for pressure injury prevention.[34] The numeric scale will follow the GRADE approach and is as follows; 1 to 3 indicate outcomes of limited importance, 4 to 6 indicate outcomes of non-critical importance and 7 to 9 indicates outcomes of critical importance.[35] Participants will also have the ability to add comments on each of the proposed outcomes as well as an option to include other outcomes (free text) not included in the survey.

Decisions regarding the inclusion of outcomes will follow previous study protocols whereby a standardised consensus definition is stated.[36,37] Participant responses may fall into the following three categories and are defined as: (1) the outcome *should* be part of the COS (≥ 70% participants score 7 to 9 and ≥ 15% participants score 1 to 3); (2) the outcome *should not* be a part of the COS (≥ 70% participants score 1 to 3 and ≤ 15% score 7 to 9); (3) no consensus (any other scoring distributions).

Delphi Round 1: results will be disseminated to the project group and newly added outcomes from stakeholders will be included. Feedback will be provided and will give the opportunity for stakeholders to reflect and revise their responses in subsequent round 2. *Delphi Round 2*: Results from the survey respondents will be classified as above and either the outcomes will be in included or excluded in the preliminary core outcome set. Those excluded will not be for further consideration. *Delphi Round 3*: For those outcomes that fall into category 3 a third Delphi survey may be conducted.

For each outcome, statistical analysis per stakeholder group will be conducted to determine descriptive statistics such as frequency, interquartile range (IQR),

mean and median. Demographic information will also be recorded in the first round to describe survey participant descriptive statistics and will include the following: (a) healthcare professional classification, (b) country, (c) age and gender, (d) highest education obtained.

Face to face meeting

Following the completion of the Delphi survey process, a face-to-face meeting will be held to reach a final consensus on outcomes for inclusion in the core outcome set. The meeting will follow the COMET guidance on consensus meetings[38].

Discussion

This project aims to undertake the development of a core outcome set for clinical trials investigating the use of interventions for the prevention of surgical site infection and surgical wound dehiscence. The project will adhere to the COMET Framework[25] for development of the COS and reporting guidelines and ethical considerations relevant to each stage of the project[31,33].

This study will engage key stakeholders and survey participants from a global perspective. Key stakeholders and survey participants will be sourced from Europe, UK, Australia, New Zealand, Malaysia, Thailand, Asia Pacific, USA, Middle East and the UAE. While all attempts are made to engage those active in this area of research and clinical practice, some countries or regions may be absent from the sample.

Authors contributions: KSH is the Chief Investigator, she conceived the study, led the proposal and protocol development. GS, TW, RM, PY, RA, KM, MR contributed to development of the proposal. KSH and RM are the lead methodologists. All authors read and approved the final manuscript.

Funding: No funding has been provided.

Availability of data and materials: The final core outcome set will be submitted for peer review and reported according to the Core Outcome Set-Standards for Reporting (COS-STAR).

Ethics approval and consent to participate: Before conducting the consumer workshops, approval from Murdoch University Human Research Ethics Committee in Western Australia will be obtained. All information collected during the project will be anonymised and consent from participants for recording and usage will be obtained.

Competing interests: KSH has undertaken private work for Essity, Molnlyke and Smith & Nephew. PLR has undertaken private work for Johnson & Johnson, Essity, and 3M.

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