

The STROCSS 2019 Guideline

Item no.	Item description	Page
TITLE		
1	<p>Title:</p> <ul style="list-style-type: none"> - The word cohort or cross-sectional or case-controlled is included - The area of focus is described (e.g. disease, exposure/intervention, outcome) - Key elements of study design are stated (e.g. retrospective or prospective) 	1
ABSTRACT		
2a	<p>Introduction: the following points are briefly described</p> <ul style="list-style-type: none"> - Background - Scientific Rationale for this study 	2
2b	<p>Methods: the following areas are briefly described</p> <ul style="list-style-type: none"> - Study design (cohort, retro-/prospective, single/multi-centred) - Patient populations and/or groups, including control group, if applicable - Interventions (type, operators, recipients, timeframes) - Outcome measures 	2
2c	<p>Results: the following areas are briefly described</p> <ul style="list-style-type: none"> - Summary data (with statistical relevance) with qualitative descriptions, where appropriate 	2 – 3
2d	<p>Conclusion: the following areas are briefly described</p> <ul style="list-style-type: none"> - Key conclusions - Implications to practice - Direction of and need for future research 	3
INTRODUCTION		
3	<p>Introduction: the following areas are described in full</p> <ul style="list-style-type: none"> - Relevant background and scientific rationale - Aims and objectives - Research question and hypotheses, where appropriate 	4
METHODS		
4a	<p>Registration and ethics</p> <ul style="list-style-type: none"> - Research Registry number is stated, in accordance with the declaration of Helsinki* - All studies (including retrospective) should be registered before submission <p><i>*"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject" (this can be obtained from: ResearchRegistry.com or ClinicalTrials.gov or ISRCTN)</i></p>	5
4b	<p>Ethical Approval: the following areas are described in full</p> <ul style="list-style-type: none"> - Necessity for ethical approval - Ethical approval, with relevant judgement reference from ethics committees - Where ethics was unnecessary, reasons are provided 	5
4c	<p>Protocol: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Protocol (<i>a priori</i> or otherwise) details, with access directions - If published, journal mentioned with the reference provided 	5

4d	<p>Patient Involvement in Research</p> <ul style="list-style-type: none"> - Describe how, if at all, patients were involved in study design e.g. were they involved on the study steering committee, did they provide input on outcome selection, etc. 	5
5a	<p>Study Design: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - 'Cohort' study is mentioned - Design (e.g. retro-/prospective, single/multi-centred) 	5
5b	<p>Setting: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Geographical location - Nature of institution (e.g. academic/community, public/private) - Dates (recruitment, exposure, follow-up, data collection) 	5
5c	<p>Cohort Groups: the following areas are described in full</p> <ul style="list-style-type: none"> - Number of groups - Division of intervention between groups 	5
5d	<p>Subgroup Analysis: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Planned subgroup analyses - Methods used to examine subgroups and their interactions 	5
6a	<p>Participants: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Eligibility criteria - Recruitment sources - Length and methods of follow-up 	5
6b	<p>Recruitment: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Methods of recruitment to each patient group - Period of recruitment 	5
6c	<p>Sample Size: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Margin of error calculation - Analysis to determine study population - Power calculations, where appropriate 	5
INTERVENTION AND CONSIDERATIONS		
7a	<p>Pre-intervention Considerations: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Patient optimisation (pre-surgical measures) - Pre-intervention treatment (hypothermia/-volaemia/-tension; ICU care; bleeding problems; medications) 	5
7b	<p>Intervention: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological) - Aim of intervention (preventative/therapeutic) - Concurrent treatments (antibiotics, analgaesia, anti-emetics, NBM, VTE prophylaxis) - Manufacturer and model details where applicable 	5
7c	<p>Intra-Intervention Considerations: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Administration of intervention (location, surgical details, anaesthetic, positioning, equipment needed, preparation, devices, sutures, operative time) - Pharmacological therapies include formulation, dosages, routes and durations - Figures and other media are used to illustrate 	5

7d	Operator Details: the following areas are described comprehensively <ul style="list-style-type: none"> - Training needed - Learning curve for technique - Specialisation and relevant training 	5
7e	Quality Control: the following areas are described comprehensively <ul style="list-style-type: none"> - Measures taken to reduce variation - Measures taken to ensure quality and consistency in intervention delivery 	5
7f	Post-Intervention Considerations: the following areas are described comprehensively <ul style="list-style-type: none"> - Post-operative instructions and care - Follow-up measures - Future surveillance requirements (e.g. imaging, blood tests) 	5
8	Outcomes: the following areas are described comprehensively <ul style="list-style-type: none"> - Primary outcomes, including validation, where applicable - Definitions of outcomes - Secondary outcomes, where appropriate - Follow-up period for outcome assessment, divided by group 	6
9	Statistics: the following areas are described comprehensively <ul style="list-style-type: none"> - Statistical tests, packages/software used, and interpretation of significance - Confounders and their control, if known - Analysis approach (e.g. intention to treat/per protocol) - Sub-group analysis, if any 	6
RESULTS		
10a	Participants: the following areas are described comprehensively <ul style="list-style-type: none"> - Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons) - Population demographics (prognostic features, relevant socioeconomic features, and significant numerical differences) 	6
10b	Participant Comparison: the following areas are described comprehensively <ul style="list-style-type: none"> - Table comparing demographics included - Differences, with statistical relevance - Any group matching, with methods 	6
10c	Intervention: the following areas are described comprehensively <ul style="list-style-type: none"> - Changes to interventions, with rationale and diagram, if appropriate - Learning required for interventions - Degree of novelty for intervention 	7
11a	Outcomes: the following areas are described comprehensively <ul style="list-style-type: none"> - Clinician-assessed and patient-reported outcomes for each group - Relevant photographs and imaging are desirable - Confounders to outcomes and which are adjusted 	7
11b	Tolerance: the following areas are described comprehensively <ul style="list-style-type: none"> - Assessment of tolerance - Loss to follow up, with reasons (percentage and fraction) - Cross-over with explanation 	7
11c	Complications: the following areas are described comprehensively <ul style="list-style-type: none"> - Adverse events described - Classified according to Clavien-Dindo classification* 	7

	<ul style="list-style-type: none"> - Mitigation for adverse events (blood loss, wound care, revision surgery should be specified) <p>*Dindo D, Demartines N, Clavien P-A. Classification of Surgical Complications. A New Proposal with Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg. 2004; 240(2): 205-213</p>	
12	<p>Key Results: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Key results, including relevant raw data - Statistical analyses with significance 	7
DISCUSSION		
13	<p>Discussion: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Conclusions and rationale - Reference to relevant literature - Implications to clinical practice - Comparison to current gold standard of care - Relevant hypothesis generation 	7
14	<p>Strengths and Limitations: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Strengths of the study - Limitations and potential impact on results - Assessment of bias and management 	7 - 9
15	<p>Implications and Relevance: the following areas are described comprehensively</p> <ul style="list-style-type: none"> - Relevance of findings and potential implications to clinical practice are detailed - Future research that is needed is described, with study designs detailed 	8
CONCLUSION		
16	<p>Conclusions:</p> <ul style="list-style-type: none"> - Key conclusions are summarised - Key directions for future research are summarised 	9 – 10
DECLARATIONS		
17a	<p>Conflicts of interest</p> <ul style="list-style-type: none"> - Conflicts of interest, if any, are described 	9
17b	<p>Funding</p> <ul style="list-style-type: none"> - Sources of funding (e.g. grant details), if any, are clearly stated 	9