

## The STROCSS 2019 Guideline

Item no.	Item description	Page
<b>TITLE</b>		
1	<p>Title:</p> <ul style="list-style-type: none"> <li>- The word cohort or cross-sectional or case-controlled is included</li> <li>- The area of focus is described (e.g. disease, exposure/intervention, outcome)</li> <li>- Key elements of study design are stated (e.g. retrospective or prospective)</li> </ul>	<p>-Title Page</p> <p>-Title Page</p> <p>-Title Page</p>
<b>ABSTRACT</b>		
2a	<p>Introduction: the following points are briefly described</p> <ul style="list-style-type: none"> <li>- Background</li> <li>- Scientific Rationale for this study</li> </ul>	Abstract pg.1
2b	<p>Methods: the following areas are briefly described</p> <ul style="list-style-type: none"> <li>- Study design (cohort, retro-/prospective, single/multi-centred)</li> <li>- Patient populations and/or groups, including control group, if applicable</li> <li>- Interventions (type, operators, recipients, timeframes)</li> <li>- Outcome measures</li> </ul>	Abstract pg.1
2c	<p>Results: the following areas are briefly described</p> <ul style="list-style-type: none"> <li>- Summary data (with statistical relevance) with qualitative descriptions, where appropriate</li> </ul>	Abstract pg.1
2d	<p>Conclusion: the following areas are briefly described</p> <ul style="list-style-type: none"> <li>- Key conclusions</li> <li>- Implications to practice</li> <li>- Direction of and need for future research</li> </ul>	Abstract pg.1
<b>INTRODUCTION</b>		
3	<p>Introduction: the following areas are described in full</p> <ul style="list-style-type: none"> <li>- Relevant background and scientific rationale</li> <li>- Aims and objectives</li> <li>- Research question and hypotheses, where appropriate</li> </ul>	<p>Sec 1 pg.2</p> <p>Sec 2 pg. 2</p>
<b>METHODS</b>		
4a	<p>Registration and ethics</p> <ul style="list-style-type: none"> <li>- Research Registry number is stated, in accordance with the declaration of Helsinki*</li> <li>- All studies (including retrospective) should be registered before submission</li> </ul> <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>	<p>Sec 2 pg.2</p> <p>Clinical Trials.gov (NCT 0196 1687)</p>
4b	<p>Ethical Approval: the following areas are described in full</p> <ul style="list-style-type: none"> <li>- Necessity for ethical approval</li> <li>- Ethical approval, with relevant judgement reference from ethics committees</li> <li>- Where ethics was unnecessary, reasons are provided</li> </ul>	Sec 2 pg.3

4c	Protocol: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Protocol (<i>a priori</i> or otherwise) details, with access directions</li> <li>- If published, journal mentioned with the reference provided</li> </ul>	Sec 2 pg. 2-4
4d	Patient Involvement in Research <ul style="list-style-type: none"> <li>- 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.</li> </ul>	n/a
5a	Study Design: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- 'Cohort' study is mentioned</li> <li>- Design (e.g. retro-/prospective, single/multi-centred)</li> </ul>	Sec 2.1 pg. 2
5b	Setting: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Geographical location</li> <li>- Nature of institution (e.g. academic/community, public/private)</li> <li>- Dates (recruitment, exposure, follow-up, data collection)</li> </ul>	Sec 2.1 pg. 3  See Title page for institution names, locations, and types.  Sec 2.2 pg. 3  Sec 2.4 pg. 4
5c	Cohort Groups: the following areas are described in full <ul style="list-style-type: none"> <li>- Number of groups</li> <li>- Division of intervention between groups</li> </ul>	Sec 2.2 pg. 3 Incl and Excl criteria
5d	Subgroup Analysis: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Planned subgroup analyses</li> <li>- Methods used to examine subgroups and their interactions</li> </ul>	Sec 2.6 pg. 4
6a	Participants: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Eligibility criteria</li> <li>- Recruitment sources</li> <li>- Length and methods of follow-up</li> </ul>	Sec 2.2 pg. 3 Incl and Excl criteria  Sec 2.4-2.5 pg. 4
6b	Recruitment: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Methods of recruitment to each patient group</li> <li>- Period of recruitment</li> </ul>	Sec 2.2 pg. 3
6c	Sample Size: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Margin of error calculation</li> <li>- Analysis to determine study population</li> <li>- Power calculations, where appropriate</li> </ul>	Sec 2.1 pg. 3
<b>INTERVENTION AND CONSIDERATIONS</b>		
7a	Pre-intervention Considerations: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Patient optimisation (pre-surgical measures)</li> <li>- Pre-intervention treatment (hypothermia/-volaemia/-tension; ICU care; bleeding problems; medications)</li> </ul>	n/a
7b	Intervention: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological)</li> <li>- Aim of intervention (preventative/therapeutic)</li> <li>- Concurrent treatments (antibiotics, analgesia, anti-emetics, NBM, VTE prophylaxis)</li> </ul>	Sec 2.1-2.3 pg. 2-4

	- Manufacturer and model details where applicable	
7c	Intra-Intervention Considerations: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Administration of intervention (location, surgical details, anaesthetic, positioning, equipment needed, preparation, devices, sutures, operative time)</li> <li>- Pharmacological therapies include formulation, dosages, routes and durations</li> <li>- Figures and other media are used to illustrate</li> </ul>	Sec 2.3 pg. 3-4
7d	Operator Details: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Training needed</li> <li>- Learning curve for technique</li> <li>- Specialisation and relevant training</li> </ul>	Sec 2.3 pg. 3-4
7e	Quality Control: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Measures taken to reduce variation</li> <li>- Measures taken to ensure quality and consistency in intervention delivery</li> </ul>	Sec 2.3 pg. 3-4
7f	Post-Intervention Considerations: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Post-operative instructions and care</li> <li>- Follow-up measures</li> <li>- Future surveillance requirements (e.g. imaging, blood tests)</li> </ul>	Sec 2.3 pg. 3-4  Sec 2.4 pg. 4
8	Outcomes: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Primary outcomes, including validation, where applicable</li> <li>- Definitions of outcomes</li> <li>- Secondary outcomes, where appropriate</li> <li>- Follow-up period for outcome assessment, divided by group</li> </ul>	Sec 2.4-2.5 pg. 4
9	Statistics: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Statistical tests, packages/software used, and interpretation of significance</li> <li>- Confounders and their control, if known</li> <li>- Analysis approach (e.g. intention to treat/per protocol)</li> <li>- Sub-group analysis, if any</li> </ul>	Sec 2.6 pg. 4
<b>RESULTS</b>		
10a	Participants: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons)</li> <li>- Population demographics (prognostic features, relevant socioeconomic features, and significant numerical differences)</li> </ul>	Table 1 & 2 pg. 9  Sec 3.1-3.2 pg. 4-5  Sec 3.4 pg. 5
10b	Participant Comparison: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Table comparing demographics included</li> <li>- Differences, with statistical relevance</li> <li>- Any group matching, with methods</li> </ul>	Tables 2 & 3  pg. 9
10c	Intervention: the following areas are described comprehensively <ul style="list-style-type: none"> <li>- Changes to interventions, with rationale and diagram, if appropriate</li> <li>- Learning required for interventions</li> <li>- Degree of novelty for intervention</li> </ul>	Sec 3.3 pg. 5  Table 4 pg. 10

11a	<p>Outcomes: the following areas are described comprehensively</p> <ul style="list-style-type: none"> <li>- Clinician-assessed and patient-reported outcomes for each group</li> <li>- Relevant photographs and imaging are desirable</li> <li>- Confounders to outcomes and which are adjusted</li> </ul>	<p>Sec 3.4 pg. 5</p> <p>Figures 1 &amp; 2 pg. 8</p> <p>Tables 5 &amp; 6 pg. 10</p>
11b	<p>Tolerance: the following areas are described comprehensively</p> <ul style="list-style-type: none"> <li>- Assessment of tolerance</li> <li>- Loss to follow up, with reasons (percentage and fraction)</li> <li>- Cross-over with explanation</li> </ul>	<p>Sec 3.4 pg. 5</p> <p>Table 1 pg. 9</p>
11c	<p>Complications: the following areas are described comprehensively</p> <ul style="list-style-type: none"> <li>- Adverse events described</li> <li>- Classified according to Clavien-Dindo classification*</li> <li>- Mitigation for adverse events (blood loss, wound care, revision surgery should be specified)</li> </ul> <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>	<p>Sec 3.4 pg. 5</p> <p>Tables 5 &amp; 6 pg. 10</p>
12	<p>Key Results: the following areas are described comprehensively</p> <ul style="list-style-type: none"> <li>- Key results, including relevant raw data</li> <li>- Statistical analyses with significance</li> </ul>	<p>Sec 3.1-3.4 pg. 4-5</p> <p>Figures 1 &amp; 2 pg. 8</p> <p>Tables 1-6 pg. 9-10</p>
<b>DISCUSSION</b>		
13	<p>Discussion: the following areas are described comprehensively</p> <ul style="list-style-type: none"> <li>- Conclusions and rationale</li> <li>- Reference to relevant literature</li> <li>- Implications to clinical practice</li> <li>- Comparison to current gold standard of care</li> <li>- Relevant hypothesis generation</li> </ul>	<p>Sec 4 pg. 5-7</p>
14	<p>Strengths and Limitations: the following areas are described comprehensively</p> <ul style="list-style-type: none"> <li>- Strengths of the study</li> <li>- Limitations and potential impact on results</li> <li>- Assessment of bias and management</li> </ul>	<p>Sec 4 pg. 5-7, especially final paragraph</p>
15	<p>Implications and Relevance: the following areas are described comprehensively</p> <ul style="list-style-type: none"> <li>- Relevance of findings and potential implications to clinical practice are detailed</li> <li>- Future research that is needed is described, with study designs detailed</li> </ul>	<p>Sec 4 pg. 6</p> <p>Sec 4 pg. 7</p>
<b>CONCLUSION</b>		
16	<p>Conclusions:</p> <ul style="list-style-type: none"> <li>- Key conclusions are summarised</li> <li>- Key directions for future research are summarised</li> </ul>	<p>Sec 5 pg. 7</p>
<b>DECLARATIONS</b>		

17a	Conflicts of interest - Conflicts of interest, if any, are described	Title Page & Author Declar.
17b	Funding - Sources of funding (e.g. grant details), if any, are clearly stated	Title Page & Author Declar.