The STROCSS 2021 Guideline		
Item no.	**Item description**	**Page**
TITLE		
1	**Title** • The word cohort or cross-sectional or case-control is included* • Temporal design of study is stated (e.g. retrospective or prospective) • The focus of the research study is mentioned (e.g. population, setting, disease, exposure/intervention, outcome etc.) *STROCSS 2021 guidelines apply to cohort studies as well as other observational studies (e.g. cross-sectional, case-control etc.)	Title Page
ABSTRACT		
2a	**Introduction** – briefly describe: • Background • Scientific rationale for this study • Aims and objectives	P1, L2-6
2b	**Methods** - briefly describe: • Type of study design (e.g. cohort, case-control, cross-sectional etc.) • Other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.) • Patient populations and/or groups, including control group, if applicable • Exposure/interventions (e.g. type, operators, recipients, timeframes etc.) • Outcome measures – state primary and secondary outcome(s)	P1, L8-17
2c	**Results** - briefly describe: • Summary data with qualitative descriptions and statistical relevance, where appropriate	P1-2, L19-27
2d	**Conclusion** - briefly describe: • Key conclusions • Implications for clinical practice • Need for and direction of future research	P2, L29-34
INTRODUCTION		
3	**Introduction** – comprehensively describe: • Relevant background and scientific rationale for study with reference to key literature • Research question and hypotheses, where appropriate • Aims and objectives	P2-4, L40-96
METHODS		
4a	**Registration** • In accordance with the Declaration of Helsinki*, state the research registration number and where it was registered, with a hyperlink to the registry entry (this can be obtained from ResearchRegistry.com, ClinicalTrials.gov, ISRCTN etc.) • All retrospective studies should be registered before submission; it should be stated that the research was retrospectively registered ** "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject"*	P5, L118-120
4b	**Ethical approval** • Reason(s) why ethical approval was needed • Name of body giving ethical approval and approval number • Where ethical approval wasn't necessary, reason(s) are provided	P5, L114-118

4c	**Protocol** • Give details of protocol (*a priori* or otherwise) including how to access it (e.g. web address, protocol registration number etc.) • If published in a journal, cite and provide full reference	P4, L99-104
4d	**Patient and public involvement in research** • Declare any patient and public involvement in research • State the stages of the research process where patients and the public were involved (e.g. patient recruitment, defining research outcomes, dissemination of results etc.) and describe the extent to which they were involved.	P4, L104-108
5a	**Study design** • State type of study design used (e.g. cohort, cross-sectional, case-control etc.) • Describe other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.)	P5, L111-114
5b	**Setting and timeframe of research** – comprehensively describe: • Geographical location • Nature of institution (e.g. primary/secondary/tertiary care setting, district general hospital/teaching hospital, public/private, low-resource setting etc.) • Dates (e.g. recruitment, exposure, follow-up, data collection etc.)	P5, L111-114
5c	**Study groups** • Total number of participants • Number of groups • Detail exposure/intervention allocated to each group • Number of participants in each group	P5, L111-114
5d	**Subgroup analysis** – comprehensively describe: • Planned subgroup analyses • Methods used to examine subgroups and their interactions	P5,L111-114
6a	**Participants** – comprehensively describe: • Inclusion and exclusion criteria with clear definitions • Sources of recruitment (e.g. physician referral, study website, social media, posters etc.) • Length, frequency and methods of follow-up (e.g. mail, telephone etc.)	P4-5, L108-111
6b	**Recruitment** – comprehensively describe: • Methods of recruitment to each patient group (e.g. all at once, in batches, continuously till desired sample size is reached etc.) • Any monetary incentivisation of patients for recruitment and retention should be declared; clarify the nature of any incentives provided • Nature of informed consent (e.g. written, verbal etc.) • Period of recruitment	P4-5, L99-120
6c	**Sample size** – comprehensively describe: • Analysis to determine optimal sample size for study accounting for population/effect size • Power calculations, where appropriate • Margin of error calculation	P5, L111-114
METHODS - INTERVENTION AND CONSIDERATIONS		
7a	**Pre-intervention considerations** – comprehensively describe: • Preoperative patient optimisation (e.g. weight loss, smoking cessation, glycaemic control etc.) • Pre-intervention treatment (e.g. medication review, bowel preparation, correcting hypothermia/-volemia/-tension, mitigating bleeding risk, ICU care etc.)	P5, L111-114

7b	**Intervention** – comprehensively describe: • Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological etc.) • Aim of intervention (preventative/therapeutic) • Concurrent treatments (e.g. antibiotics, analgesia, anti-emetics, VTE prophylaxis etc.) • Manufacturer and model details, where applicable	P5, L111-114
7c	**Intra-intervention considerations** – comprehensively describe: • Details pertaining to administration of intervention (e.g. anaesthetic, positioning, location, preparation, equipment needed, devices, sutures, operative techniques, operative time etc.) • Details of pharmacological therapies used, including formulation, dosages, routes, and durations • Figures and other media are used to illustrate	P5, L111-114
7d	**Operator details** – comprehensively describe: • Requirement for additional training • Learning curve for technique • Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually)	P5, L111-114
7e	**Quality control** – comprehensively describe: • Measures taken to reduce inter-operator variability • Measures taken to ensure consistency in other aspects of intervention delivery • Measures taken to ensure quality in intervention delivery	P4, L101-108
7f	**Post-intervention considerations** – comprehensively describe: • Post-operative instructions (e.g. avoid heavy lifting) and care • Follow-up measures • Future surveillance requirements (e.g. blood tests, imaging etc.)	P5, L111-114
8	**Outcomes** – comprehensively describe: • Primary outcomes, including validation, where applicable • Secondary outcomes, where appropriate • Definition of outcomes • If any validated outcome measurement tools are used, give full reference • Follow-up period for outcome assessment, divided by group	P5, L122-134
9	**Statistics** – comprehensively describe: • Statistical tests and statistical package(s)/software used • Confounders and their control, if known • Analysis approach (e.g. intention to treat/per protocol) • Any sub-group analyses • Level of statistical significance	P6, L136-159
RESULTS		
10a	**Participants** – comprehensively describe: • Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons). Use figure to illustrate. • Population demographics (e.g. age, gender, relevant socioeconomic features, prognostic features etc.) • Any significant numerical differences should be highlighted	P6-7, L162-170
10b	**Participant comparison** • Include table comparing baseline characteristics of cohort groups • Give differences, with statistical relevance • Describe any group matching, with methods	P6-7, L162-170
10c	**Intervention** – comprehensively describe:	

	• Degree of novelty of intervention • Learning required for interventions • Any changes to interventions, with rationale and diagram, if appropriate	P6-7, L162-170
11a	**Outcomes** – comprehensively describe: • Clinician-assessed and patient-reported outcomes for each group • Relevant photographs and imaging are desirable • Any confounding factors and state which ones are adjusted	P7-9, L173-239
11b	**Tolerance** – comprehensively describe: • Assessment of tolerability of exposure/intervention • Cross-over with explanation • Loss to follow-up (fraction and percentage), with reasons	P7-9, L173-239
11c	**Complications** – comprehensively describe: • Adverse events and classify according to Clavien-Dindo classification* • Timing of adverse events • Mitigation for adverse events (e.g. blood transfusion, wound care, revision surgery etc.) *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	P7-9, L173-239
12	**Key results** – comprehensively describe: • Key results with relevant raw data • Statistical analyses with significance • Include table showing research findings and statistical analyses with significance	P7-9, L173-239
DISCUSSION		
13	**Discussion** – comprehensively describe: • Conclusions and rationale • Reference to relevant literature • Implications for clinical practice • Comparison to current gold standard of care • Relevant hypothesis generation	P9-11, L241-308
14	**Strengths and limitations** – comprehensively describe: • Strengths of the study • Weaknesses and limitations of the study and potential impact on results and their interpretation • Assessment and management of bias • Deviations from protocol, with reasons	P11-12, L290-308
15	**Relevance and implications** – comprehensively describe: • Relevance of findings and potential implications for clinical practice • Need for and direction of future research, with optimal study designs mentioned	P11-12, L297-308
CONCLUSION		
16	**Conclusions** • Summarise key conclusions • Outline key directions for future research	P12, L310-315
DECLARATIONS		
17a	**Conflicts of interest** • Conflicts of interest, if any, are described	P12, L326
17b	**Funding** • Sources of funding (e.g. grant details), if any, are clearly stated • Role of funder	P12, L329

17c	**Contributorship** • Acknowledge patient and public involvement in research; report the extent of involvement of each contributor	P12, L333

Table 2: The full revised STROCSS 2021 checklist