# STROCSS 2021: Strengthening the reporting of cohort, cross-sectional and case-control studies in surgery

| Item no. | Item description | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|----------|------------------|------------------------------------|-------------------------------|
| **TITLE** |                  |                                    |                               |
| 1        | Title            |                                    |                               |
|          | - The word cohort or cross-sectional or case-control is included* | Page1/line2-3 | Title/Para1 |
|          | - Temporal design of study is stated (e.g. retrospective or prospective) | Page1/line2-3 | Title/Para1 |
|          | - The focus of the research study is mentioned (e.g. population, setting, disease, exposure/intervention, outcome etc.) | Page1/line2-3 | Title/Para1 |
| **ABSTRACT** |                    |                                    |                               |
| 2a       | Introduction – briefly describe: |                                    |                               |
|          | - Background     |                                    | Abstract/Para1               |
|          | - Scientific rationale for this study | Page2/line31-34 | Abstract/Para1               |
|          | - Aims and objectives | Page2/line31-34 | Abstract/Para1               |
| 2b       | Methods - briefly describe: |                                    |                               |
|          | - Type of study design (e.g. cohort, case-control, cross-sectional etc.) | Page2-3/line35-42 | Abstract/para2               |
|          | - Other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.) | Page2-3/line35-42 | Abstract/para2               |
|          | - Patient populations and/or groups, including control group, if applicable | Page2-3/line35-42 | Abstract/para2               |
|          | - Exposure/interventions (e.g. type, operators, recipients, timeframes etc.) | Page2-3/line35-42 | Abstract/para2               |
|          | - Outcome measures – state primary and secondary outcome(s) | Page2-3/line35-42 | Abstract/para2               |
| 2c       | Results - briefly describe: |                                    |                               |
|          | - Summary data with qualitative descriptions and statistical relevance, where appropriate | Page2-3/line43-54 | Abstract/para3               |
| 2d       | Conclusion - briefly describe: |                                    |                               |
|          | - Key conclusions | Page3/-4line55-58 | Abstract/para4               |
|          | - Implications for clinical practice | Page3/-4line55-58 | Abstract/para4               |
|          | - Need for and direction of future research | Page3/-4line55-58 | Abstract/para4               |
## 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

## 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.)

### 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

### 4c Protocol

- Give details of protocol (\textit{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

## 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.)
| Section | Description |
|---------|-------------|
| 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.) |
| 5c      | Study groups |
|         | - Total number of participants |
|         | - Number of groups |
|         | - Detail exposure/intervention allocated to each group |
|         | - Number of participants in each group |
| 5d      | Subgroup analysis – comprehensively describe: |
|         | - Planned subgroup analyses |
|         | - Methods used to examine subgroups and their interactions |
| 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.) |
| 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 |
| 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 |
| METHODS - INTERVENTION AND CONSIDERATIONS |  |
|------------------------------------------|---|
| **7a** Pre-intervention considerations – comprehensively describe: |  |
| - Preoperative patient optimisation (e.g. weight loss, smoking cessation, glycaemic control etc.) | Page6-9/line103-161 Methods/Para1-4 |
| - Pre-intervention treatment (e.g. medication review, bowel preparation, correcting hypothermia/-volemia/-tension, mitigating bleeding risk, ICU care etc.) | Page6-9/line103-161 Methods/Para1-4 |
| **7b** Intervention – comprehensively describe: |  |
| - Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological etc.) | Page6-9/line103-161 Methods/Para1-4 |
| - Aim of intervention (preventative/therapeutic) | Page6-9/line103-161 Methods/Para1-4 |
| - Concurrent treatments (e.g. antibiotics, analgesia, antiemetics, VTE prophylaxis etc.) | Page6-9/line103-161 Methods/Para1-4 |
| - Manufacturer and model details, where applicable | Page6-9/line103-161 Methods/Para1-4 |
| **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.) | Page6-9/line103-161 Methods/Para1-4 |
| - Details of pharmacological therapies used, including formulation, dosages, routes, and durations | Page6-9/line103-161 Methods/Para1-4 |
| - Figures and other media are used to illustrate | Page6-9/line103-161 Methods/Para1-4 |
| **7d** Operator details – comprehensively describe: |  |
| - Requirement for additional training | Page6-9/line103-161 Methods/Para1-4 |
| - Learning curve for technique | Page6-9/line103-161 Methods/Para1-4 |
| - Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually) | Page6-9/line103-161 Methods/Para1-4 |
| **7e** Quality control – comprehensively describe: |  |
| - Measures taken to reduce inter-operator variability | N/A N/A |
| - Measures taken to ensure consistency in other aspects of intervention delivery | N/A N/A |
| - Measures taken to ensure quality in intervention delivery | N/A N/A |
| **7f** Post-intervention considerations – comprehensively describe: |  |
| - Post-operative instructions (e.g. avoid heavy lifting) and care | Page9-10/line164-174 Methods/Para5 |
| - Follow-up measures | Page9-10/line164-174 Methods/Para5 |
| - Future surveillance requirements (e.g. blood tests, imaging etc.) | Page9-10/line164-174 Methods/Para5 |
### Outcomes
- 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

### Statistics
- 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

### RESULTS
#### 10a Participants
- Flow of participants (recruitment, non-participation, crossover 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

#### 10b Participant comparison
- Include table comparing baseline characteristics of cohort groups
- Give differences, with statistical relevance
- Describe any group matching, with methods

#### 10c Intervention
- Degree of novelty of intervention
- Learning required for interventions
- Any changes to interventions, with rationale and diagram, if appropriate
| 11a | Outcomes – comprehensively describe: |
| --- | ----------------------------------- |
| - Clinician-assessed and patient-reported outcomes for each group | Page10-14/line187-253 |
| - Relevant photographs and imaging are desirable | Page10-14/line187-253 |
| - Any confounding factors and state which ones are adjusted | Page10-14/line187-253 |

| 11b | Tolerance – comprehensively describe: |
| --- | ------------------------------------ |
| - Assessment of tolerability of exposure/intervention | Page10-14/line187-253 |
| - Cross-over with explanation | Page10-14/line187-253 |
| - Loss to follow-up (fraction and percentage), with reasons | Page10-14/line187-253 |

| 11c | Complications – comprehensively describe: |
| --- | ------------------------------------------ |
| - Adverse events and classify according to Clavien-Dindo classification† | Page10-14/line187-253 |
| - Timing of adverse events | Page10-14/line187-253 |
| - Mitigation for adverse events (e.g. blood transfusion, wound care, revision surgery etc.) | Page10-14/line187-253 |

| 12 | Key results – comprehensively describe: |
| --- | -------------------------------------- |
| - Key results with relevant raw data | Page10-14/line187-253 |
| - Statistical analyses with significance | Page10-14/line187-253 |

DISCUSSION

| 13 | Discussion – comprehensively describe: |
| --- | -------------------------------------- |
| - Conclusions and rationale | page14-21/line256-382 |
| - Reference to relevant literature | page14-21/line256-382 |
| - Implications for clinical practice | page14-21/line256-382 |
| - Comparison to current gold standard of care | page14-21/line256-382 |
| - Relevant hypothesis generation | page14-21/line256-382 |
**Strengths and limitations** – comprehensively describe:

| Description                                                                 | Page/Line/Para |
|----------------------------------------------------------------------------|----------------|
| - Strengths of the study                                                   | 14-21/256-382  |
| - Weaknesses and limitations of the study and potential impact on results and their interpretation | 14-21/256-382  |
| - Assessment and management of bias                                        | 14-21/256-382  |
| - Deviations from protocol, with reasons                                   | 14-21/256-382  |

**Relevance and implications** – comprehensively describe:

| Description                                                                 | Page/Line/Para |
|----------------------------------------------------------------------------|----------------|
| - Relevance of findings and potential implications for clinical practice   | 14-21/256-382  |
| - Need for and direction of future research, with optimal study designs mentioned | 14-21/256-382  |

**CONCLUSION**

16 Conclusions

| Description                                                                 | Page/Line/Para |
|----------------------------------------------------------------------------|----------------|
| - Summarise key conclusions                                                 | 21/384-386     |
| - Outline key directions for future research                                | 21/384-386     |

**DECLARATIONS**

17a Conflicts of interest

| Description                                                                 | Page/Line/Para |
|----------------------------------------------------------------------------|----------------|
| - Conflicts of interest, if any, are described                              | 22/412-413     |

17b Funding

| Description                                                                 | Page/Line/Para |
|----------------------------------------------------------------------------|----------------|
| - Sources of funding (e.g. grant details), if any, are clearly stated       | 22/403          |
| - Role of funder                                                           | 22/403          |

17c Contributorship

| Description                                                                 | Page/Line/Para |
|----------------------------------------------------------------------------|----------------|
| - Acknowledge patient and public involvement in research; report the extent of involvement of each contributor | 21/28           |

* STROCSS 2021 guidelines apply to cohort studies as well as other observational studies (e.g. cross-sectional, case-control etc.).

† “Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject”.

‡ 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.