STROCSS 2021 guidelines: What is new?

Adhering to good reporting standards enables readers to meaningfully assess research, making the research worthwhile [1]. Improvement in reporting quality has been noted among various types of studies, with the existence of reporting guidelines and compulsory implementation of these guidelines by journals [2-4].

Poor reporting quality has been noted among observational studies in surgery [5]. In order to improve the reporting quality of observational studies in surgery, Strengthening The Reporting Of Cohort Studies in Surgery (STROCSS) guidelines were composed in 2017 and updated in 2019; STROCSS guidelines have received tremendous acceptance within the surgical research community, having been cited over 1000 times since inception [6,7]. In order to maintain relevance and continue endorsing good reporting quality among surgical observational studies, we aimed to update STROCSS 2019 guidelines by forming a steering group who came up with proposals for improvement which were then put to an expert panel of researchers for scrutiny and consensus using the Delphi technique [8]. A high level of agreement was noted with the proposed changes to all the items, among the 42 Delphi group members [9,10]. This article aims to highlight the key updates to note in STROCSS 2021 guidelines.

Although STROCSS guidelines aimed to improve the reporting quality of all surgical observational studies, including cohort, cross-sectional and case-control studies, the title “Strengthening The Reporting Of Cohort Studies in Surgery” implied that they applied to cohort studies only. In order to highlight the relevance of STROCSS guidelines to other observational studies in surgery, such as cross-sectional and case-control studies, as well as cohort studies, the title has been modified to read “Strengthening The Reporting of Cohort, Cross-sectional and Case-control Studies in Surgery”. Additionally, items 1, 2b and 5a have been modified to highlight the relevance of STROCSS guidelines to all surgical observational studies (i.e. cohort, cross-sectional and case-control studies).

Item 3 has been modified to urge authors to provide reference to key literature within their introduction section, in addition to describing the background and scientific rationale for their study, to allow readers to better contextualise the research.

In the methods section, item 4a was modified to prompt authors to state if their research was retrospectively registered. Although prospective research registration may be the gold standard as per the Declaration of Helsinki, research conducted by Harriman and Patel showed that 67% of clinical trials, published in the BMC series over the course of 2013, that they studied were retrospectively registered; they highlighted the importance of avoiding non-publication of research involving humans and recommended authors to declare if their research has been retrospectively registered [11-13]. In keeping with this outlook, we have modified item 4a to not only prompt authors to register their research but also declare if research registration has been done retrospectively.

Increasingly, patient and public involvement (PPI) in research is being noted and there is growing evidence on the benefits of PPI in research [14]. However, poor reporting of PPI has been noted within surgical research [15]. Hence, item 4d in the methods section was modified to improve reporting quality of PPI among surgical observational studies. Additionally, a new item 17c in the declarations section calls for transparent reporting of contributorship by acknowledging PPI in research and disclosing the extent of involvement of each contributor.

Items 6a and 6b in the methods section have been modified to provide examples of sources of participant recruitment and methods of recruitment to each patient group, respectively, in order to improve clarity and enable authors to easily distinguish between the two.

Further modifications have been made to item 6b such as recommending authors to declare any monetary incentivisation of patients for recruitment/retention and clarifying the nature of incentives provided as well as recommending authors to declare the nature of informed consent. Providing financial incentives to research participants can encourage research participation and retention; however, with concerns surrounding the ethics and the trustworthiness of outcomes where research participants have been financially incentivised, the former modification has been made to item 6b [16]. The latter modification to item 6b, regarding informed consent, has been made in line with the recommendations provided in the declaration of Helsinki [11].

In the results section, item 10a has been modified to prompt authors to provide a figure to illustrate the flow of participants while item 12 has been modified to encourage authors to display a table showing research findings and statistical analyses with significance. Inclusion of such figures and tables allows readers to better engage with the research paper [17].
In the discussion section, item 14 has been modified to urge authors to declare any deviations from the protocol with reasons; deviations from the protocol may have an impact on the trustworthiness of the data as well as potentially compromising the safety, rights and welfare of the research participants [18].

In addition to the key changes described in detail above, numerous other changes have been made to improve the clarity and readability of the guidelines. Table 1 presents both STROCSS 2021 and STROCSS 2019 guidelines side by side for comparison.

Table 1
STROCSS 2021 and STROCSS 2019 guidelines side by side for comparison.

| STROCSS guideline | Item no. | Item description | STROCSS 2021 | STROCSS 2019 |
|-------------------|---------|------------------|--------------|--------------|
| **Title** | 1 | Title |  | Title: |
|  |  | • The word cohort or cross-sectional or case-control is included* |  | • The word cohort or cross-sectional or case-controlled is included |
|  |  | • Temporal design of study is stated (e.g. retrospective or prospective) |  | • The area of focus is described (e.g. disease, exposure/intervention, outcome) |
|  |  | • The focus of the research study is mentioned (e.g. population, setting, disease, exposure/intervention, outcome etc.) |  | • Key elements of study design are stated (e.g. retrospective or prospective) |
|  |  | *STROCSS 2021 guidelines apply to cohort studies as well as other observational studies (e.g. cross-sectional, case-control etc.) |  |  |
| **Abstract** | 2a | Introduction – briefly describe: |  | Introduction: the following points are briefly described |
|  |  | • Background |  | • Background |
|  |  | • Scientific rationale for this study |  | • Scientific Rationale for this study |
|  |  | • Aims and objectives |  |  |
|  |  | Methods - briefly describe: |  | Methods: the following areas are briefly described |
|  |  | • Type of study design (e.g. cohort, case-control, cross-sectional etc.) |  | • Study design (cohort, retro-/prospective, single/multi-centred 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 |
|  |  | • Patient populations and/or groups, including control group, if applicable |  | • Interventions (type, operators, recipients, timeframes etc.) |
|  |  | • Exposure/interventions (e.g. type, operators, recipients, timeframes etc.) |  | • Outcome measures |
|  |  | • Outcome measures – state primary and secondary outcome(s) |  |  |
|  |  | 2c Results - briefly describe: |  | Results: the following areas are briefly described |
|  |  | • Summary data with qualitative descriptions and statistical relevance, where appropriate |  | • Summary data (with statistical relevance) with qualitative descriptions, where appropriate |
|  |  | 2d Conclusion - briefly describe: |  | Conclusion: the following areas are briefly described |
|  |  | • Key conclusions |  | • Key conclusions |
|  |  | • Implications for clinical practice |  | • Implications to practice |
|  |  | • Need for and direction of future research |  | • Direction of and need for future research |
| **Introduction** | 3 | Introduction – comprehensively describe: |  | Introduction: the following areas are described in full |
|  |  | • Relevant background and scientific rationale for study with reference to key literature |  | • Relevant background and scientific rationale |
|  |  | • Research question and hypotheses, where appropriate |  | • Aims and objectives |
|  |  | • Aims and objectives |  | • Research question and hypotheses, where appropriate |
| **Methods** | 4a | Registration |  | Registration and ethics |
|  |  | • 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.) |  | • Research Registry number is stated, in accordance with the declaration of Helsinki* |
|  |  | • All retrospective studies should be registered before submission; it should be stated that the research was retrospectively registered |  | • All studies (including retrospective) should be registered before submission |
|  |  | * ‘Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject’ |  | “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) |
|  |  | 4b Ethical approval |  | Ethical Approval: the following areas are described in full |
|  |  | • Reason(s) why ethical approval was needed |  | • Necessity for ethical approval |
|  |  | • Name of body giving ethical approval and approval number |  | • Ethical approval, with relevant judgement reference from ethics committees |
|  |  | • Where ethical approval wasn’t necessary, reason(s) are provided |  | • Where ethics was unnecessary, reasons are provided |
|  |  | 4c Protocol |  | Protocol: the following areas are described comprehensively |
|  |  | • Give details of protocol (a priori or otherwise) including how to access it (e.g. web address, protocol registration number etc.) |  | • Protocol (a priori or otherwise) details, with access directions |
|  |  | • If published in a journal, cite and provide full reference |  | • If published, journal mentioned with the reference provided |

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| Item no. | Item description | STROCSS 2021 | STROCSS 2019 |
|----------|------------------|--------------|--------------|
| 4d       | Patient and public involvement in research | Patient Involvement in Research | Study Design: the following areas are described comprehensively |
| 5a       | Study design | | Study Design: the following areas are described comprehensively |
| 5b       | Setting and timeframe of research – comprehensively describe: | | Setting: the following areas are described comprehensively |
| 5c       | Study groups | | Cohort Groups: the following areas are described in full |
| 5d       | Subgroup analysis – comprehensively describe: | | Subgroup Analysis: the following areas are described comprehensively |
| 6a       | Participants – comprehensively describe: | | Participants: the following areas are described comprehensively |
| 6b       | Recruitment – comprehensively describe: | | Recruitment: the following areas are described comprehensively |
| 6c       | Sample size – comprehensively describe: | | Sample Size: the following areas are described comprehensively |
| Methods - intervention and considerations | Pre-intervention considerations – comprehensively describe: | | Pre-intervention Considerations: the following areas are described comprehensively |
| 7a       | Preoperative patient optimisation (e.g. weight loss, smoking cessation, glycaemic control etc.) | | Patient optimisation (pre-surgical measures) |
| 7b       | Intervention – comprehensively describe: | | Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological) |
| 7c       | Intra-intervention considerations – comprehensively describe: | | Administration of intervention (location, surgical details, anesthetic, positioning, equipment needed, preparation, devices, sutures, operative techniques, operative time etc.) |

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| STROCSS guideline | Item description |
|-------------------|------------------|
| 7d Operator details – comprehensively describe: | Operator Details: the following areas are described comprehensively |
| • Requirement for additional training | • Training needed |
| • Learning curve for technique | • Learning curve for technique |
| • Relevant training, specialisation and operator's experience (e.g. average number of the relevant procedures performed annually) | • Specialisation and relevant training |
| 7e Quality control – comprehensively describe: | Quality Control: the following areas are described comprehensively |
| • Measures taken to reduce inter-operator variability | • Measures taken to reduce variation |
| • Measures taken to ensure consistency in other aspects of intervention delivery | • Measures taken to ensure quality in intervention delivery |
| • Measures taken to ensure quality in intervention delivery | |
| 7f Post-intervention considerations – comprehensively describe: | Post-Intervention Considerations: the following areas are described comprehensively |
| • Post-operative instructions (e.g. avoid heavy lifting) and care | • Follow-up measures |
| • Follow-up measures | • Follow-up instructions and care |
| • Future surveillance requirements (e.g. blood tests, imaging etc.) | • Follow-up measures |
| • Measures taken to reduce inter-operator variability | • Measures taken to reduce variation |
| 8 Outcomes – comprehensively describe: | Outcomes: the following areas are described comprehensively |
| • Primary outcomes, including validation, where applicable | • Primary outcomes, including validation, where applicable |
| • Secondary outcomes, where appropriate | • Definitions of outcomes |
| • Definition of outcomes | • Secondary outcomes, where appropriate |
| • If any validated outcome measurement tools are used, give full reference | • Follow-up period for outcome assessment, divided by group |
| • Follow-up period for outcome assessment, divided by group | |
| 9 Statistics – comprehensively describe: | Statistics: the following areas are described comprehensively |
| • Statistical tests and statistical package(s)/software used | • Statistical tests, packages/software used, and interpretation of significance |
| • Confounders and their control, if known | • Confounders and their control, if known |
| • Analysis approach (e.g. intention to treat/per protocol) | • Analysis approach (e.g. intention to treat/per protocol) |
| • Any sub-group analyses | • Sub-group analysis, if any |
| • Level of statistical significance | |

Results

10a Participants – comprehensively describe:

| Item no. | Item description |
|----------|------------------|
| • Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons). Use figure to illustrate. | • Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons) |
| • Population demographics (e.g. age, gender, relevant socioeconomic features, prognostic features etc.) | • Population demographics (prognostic features, relevant socioeconomic features, and significant numerical differences) |
| • Any significant numerical differences should be highlighted | |

10b Participant comparison

| Item no. | Item description |
|----------|------------------|
| • Include table comparing baseline characteristics of cohort groups | • Table comparing demographics included |
| • Give differences, with statistical relevance | • Differences, with statistical relevance |
| • Describe any group matching, with methods | • Any group matching, with methods |

10c Intervention – comprehensively describe:

| Item no. | Item description |
|----------|------------------|
| • Degree of novelty of intervention | • Changes to interventions, with rationale and diagram, if appropriate |
| • Learning required for interventions | • Learning required for interventions |
| • Any changes to interventions, with rationale and diagram, if appropriate | • Degree of novelty for intervention |

11a Outcomes – comprehensively describe:

| Item no. | Item description |
|----------|------------------|
| • Clinician-assessed and patient-reported outcomes for each group | • Clinician-assessed and patient-reported outcomes for each group |
| • Relevant photographs and imaging are desirable | • Relevant photographs and imaging are desirable |
| • Any confounding factors and state which ones are adjusted | • Confounders to outcomes and which are adjusted |

11b Tolerance – comprehensively describe:

| Item no. | Item description |
|----------|------------------|
| • Assessment of tolerability of exposure/intervention | • Assessment of tolerance |
| • Cross-over with explanation | • Loss to follow up, with reasons (percentage and fraction) |
| • Loss to follow-up (fraction and percentage), with reasons | • Cross-over with explanation |

11c Complications – comprehensively describe:

| Item no. | Item description |
|----------|------------------|
| • Adverse events and classify according to Clavien-Dindo classification* | • Adverse events described |
| • Timing of adverse events | • Classified according to Clavien-Dindo classification* |
| • Mitigation for adverse events (e.g. blood transfusion, wound care, revision surgery etc.) | • Mitigation for adverse events (blood loss, wound care, revision surgery should be specified) |

* 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

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