Editorial

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.

Conflicts of interest

None declared - the authors have no financial, consultative,
STROCSS 2021 and STROCSS 2019 guidelines side by side for comparison.

| STROCSS Guideline | STROCSS 2021 | STROCSS 2019 |
|-------------------|--------------|--------------|
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |
| **STROCSS 2021**  | **STROCSS 2019** |

**Table 1**

**STROCSS Guideline**

| Item no. | Item description |
|----------|------------------|
| 1 | **Annals of Medicine and Surgery 72 (2021) 103121** |
| 2 | **Introduction** – briefly describe: |
| 3 | **Methods** – briefly describe: |
| 4 | **Results** - briefly describe: |
| 5 | **Conclusion** - briefly describe: |
| 6 | **Protocol** |
| 7 | **Patient and public involvement in research** |
| 8 | **Study design** |
| 9 | **Setting and timeframe of research** – comprehensively describe: |
| 10 | **Study groups** |
| 11 | **Cohort Groups** |

**ABSTRACT**

**Introduction:** the followings points are briefly described

| Item no. | Item description |
|----------|------------------|
| 1 | **Background** |
| 2 | **Scientific rationale for this study** |
| 3 | **Aims and objectives** |

**Methods:** the following areas are briefly described

| Item no. | Item description |
|----------|------------------|
| 1 | **Study design (cohort, retro-/prospective, single/multi-centred)** |
| 2 | **Patient populations and/or groups, including control group, if applicable** |
| 3 | **Interventions (type, operators, recipients, timeframes)** |
| 4 | **Outcome measures** |

**Results:** the following areas are briefly described

| Item no. | Item description |
|----------|------------------|
| 1 | **Summary data with qualitative descriptions and statistical relevance, where appropriate** |
| 2 | **Geographical location** |
| 3 | **Nature of institution (e.g. primary/secondary/tertiary care setting, district general hospital/teaching hospital, public/private, low-resource setting etc.)** |
| 4 | **Dates (e.g. recruitment, exposure, follow-up, data collection etc.)** |
| 5 | **Number of groups** |

**Conclusion:** the following areas are briefly described

| Item no. | Item description |
|----------|------------------|
| 1 | **Key conclusions** |
| 2 | **Implications for clinical practice** |
| 3 | **Need for and direction of future research** |

**Study design:** the following areas are briefly described

| Item no. | Item description |
|----------|------------------|
| 1 | **State type of study design used (e.g. cohort, cross-sectional, case-control etc.)** |
| 2 | **Describe other key elements of study design (e.g. retro-/prospective, single/multi-centred etc.)** |

**Setting and timeframe of research:** – comprehensively describe:

| Item no. | Item description |
|----------|------------------|
| 1 | **Geographical location** |
| 2 | **Nature of institution (e.g. academic/community, public/private)** |
| 3 | **Dates (recruitment, exposure, follow-up, data collection etc.)** |

**STROCSS 2021** (this can be obtained from ResearchRegistry.com, ClinicalTrials.gov, ISRCTN etc.)

- 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” (this can be obtained from ResearchRegistry.com or ClinicalTrials.gov or ISRCTN)

**Ethical approval**

| Item no. | Item description |
|----------|------------------|
| 1 | **Reason(s) why ethical approval was needed** |
| 2 | **Place of body giving ethical approval and approval number** |
| 3 | **Where ethical approval wasn’t necessary, reason(s) are provided** |

**Patient involvement in Research**

| Item no. | Item description |
|----------|------------------|
| 1 | **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.** |

**Study Design:** the following areas are described comprehensively

| Item no. | Item description |
|----------|------------------|
| 1 | **‘Cohort’ study is mentioned** |
| 2 | **Design (e.g. retro-/prospective, single/multi-centred)** |

**Setting:** the following areas are described comprehensively

| Item no. | Item description |
|----------|------------------|
| 1 | **Geographical location** |
| 2 | **Nature of institution (e.g. academic/community, public/private)** |
| 3 | **Dates (recruitment, exposure, follow-up, data collection etc.)** |

**Cohort Groups:** the following areas are described in full

| Item no. | Item description |
|----------|------------------|
| 1 | **Number of groups** |
| Table 1 (continued) | Table 1 (continued) |
|----------------------|----------------------|
| STROCSS Guideline    | STROCSS Guideline    |
| Item no.            | Item description     |
| STROCSS 2021 | STROCSS 2019 |
| 5d Subgroup analysis – comprehensively describe: | 7d Operator details – comprehensively describe: |
| • Detail exposure/intervention allocated to each group | • Concurrent treatments (e.g. antibiotics, analgesia, anti-emetics, VTE prophylaxis etc.) |
| • Number of participants in each group | • Manufacturer and model details, where applicable |
| Subgroup Analysis: the following areas are described comprehensively | Intra-intervention considerations – comprehensively describe: |
| • Planned subgroup analyses | • Details pertaining to administration of intervention (e.g. anaesthetic, positioning, location, preparation, equipment needed, devices, sutures, operative techniques, operative time etc.) |
| • Methods used to examine subgroups and their interactions | • Details of pharmacological therapies used, including formulation, dosages, routes, and durations |
| 6a Participants – comprehensively describe: | • Figures and other media are used to illustrate |
| • Inclusion and exclusion criteria with clear definitions | • Administration of intervention (location, surgical details, anaesthetic, positioning, equipment needed, preparation, devices, sutures, operative time) |
| • Sources of recruitment (e.g. physician referral, study website, social media, posters etc.) | • Pharmacological therapies include formulation, dosages, routes and durations |
| • Length, frequency and methods of follow-up (e.g. mail, telephone etc.) | • Figures and other media are used to illustrate |
| Recruitment: the following areas are described comprehensively | • Methods of recruitment to each patient group |
| • Methods of recruitment to each patient group | • Period of recruitment |
| • Margin of error calculation | Recruitment sources |
| Sample Size: the following areas are described comprehensively | Length and methods of follow-up |
| • Analysis to determine optimal sample size for study accounting for population/effect size | • Patients enrolled (e.g. all at once, in batches, continuously till desired sample size is reached etc.) |
| • Power calculations, where appropriate | • Any monetary incentivisation of patients for recruitment and retention should be declared; clarify the nature of any incentives provided |
| • Margin of error calculation | • Nature of informed consent (e.g. written, verbal etc.) |
| METHODS – INTERVENTION AND CONSIDERATIONS | 7e Quality control – comprehensively describe: |
| Pre-intervention considerations – comprehensively describe: | • Measures taken to reduce inter-operator variability |
| • Preoperative patient optimisation (e.g. weight loss, smoking cessation, glycaemic control etc.) | • Measures taken to ensure consistency in other aspects of intervention delivery |
| • Pre-intervention treatment (e.g. medication review, bowel preparation, correcting hypothermia/-volaemia/-tension, mitigating bleeding risk, ICU care etc.) | • Measures taken to ensure quality in intervention delivery |
| Pre-intervention Considerations: the following areas are described comprehensively | • Follow-up measures |
| • Patient optimisation (pre-surgical measures) | • Future surveillance requirements (e.g. blood tests, imaging etc.) |
| • Pre-intervention treatment (hypothermia/-volaemia/-tension; ICU care; bleeding problems; medications) | • Post-operative instructions (e.g. avoid heavy lifting) and care |
| Intervention: the following areas are described comprehensively | • Follow-up period for outcome assessment, divided by group |
| • Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological etc.) | Statistics – comprehensively describe: |
| • Aim of intervention (preventative/therapeutic) | • Statistical tests and statistical package(s)/software used |
| • Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological etc.) | • Statistical tests, packages/software used, and interpretation of significance |
| • Aim of intervention (preventative/therapeutic) | (continued on next page) |
Table 1 (continued)

| STROCSS Guideline | Item description |
|-------------------|------------------|
| **STROCSS 2021** | **STROCSS 2019** |
| **10a Participants** | **Participants**: the following areas are described comprehensively |
| - 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** | **RESULTS** |
| **10b Participant comparison** | **Participant Comparison**: the following areas are described comprehensively |
| - 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 | |
| **10c Intervention** | **Intervention**: the following areas are described comprehensively |
| - 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 |
| **Outcomes** | **Outcomes**: the following areas are described comprehensively |
| - 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 |
| **11a Tolerance** | **Tolerance**: the following areas are described comprehensively |
| - 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 |
| **Complications** | **Complications**: the following areas are described comprehensively |
| - 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. 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 | +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 |
| **DISCUSSION** | **DISCUSSION** |
| **11b Tolerance** | **Tolerance**: the following areas are described comprehensively |
| - 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 |
| **Complications** | **Complications**: the following areas are described comprehensively |
| - 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 (blood loss, wound care, revision surgery should be specified) | - 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
institutional, and other relationships that might lead to bias or conflict of interest.

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Not applicable.

Research registration Unique Identifying number (UIN)
1. Name of the registry: Not applicable
2. Unique Identifying number or registration ID: Not applicable
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): Not applicable

Author contribution
RA: concept, drafting, revision and approval of final manuscript. GM: drafting, revision and approval of final manuscript.

Guarantor
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