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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,

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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** • 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:** • The word cohort or cross-sectional or case-controlled is included • The area of focus is described (e.g. disease, exposure/intervention, outcome) • Key elements of study design are stated (e.g. retrospective or prospective)	
ABSTRACT			
2a	**Introduction** – briefly describe: • Background • Scientific rationale for this study • Aims and objectives	**Introduction:** the following points are briefly described • Background • Scientific Rationale for this study	
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)	**Methods:** the following areas are briefly described • Study design (cohort, retro-/prospective, single/multi-centred) • Patient populations and/or groups, including control group, if applicable • Interventions (type, operators, recipients, timeframes) • Outcome measures	
2c	**Results** - briefly describe: • Summary data with qualitative descriptions and statistical relevance, where appropriate	**Results:** the following areas are briefly described • Summary data (with statistical relevance) with qualitative descriptions, where appropriate	
2d	**Conclusion** - briefly describe: • Key conclusions • Implications for clinical practice • Need for and direction of future research	**Conclusion:** the following areas are briefly described • Key conclusions • Implications to practice • Direction of and need for future research	
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	**Introduction:** the following areas are described in full • Relevant background and scientific rationale • Aims and objectives • Research question and hypotheses, where appropriate	
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"*	**Registration and ethics** • Research Registry number is stated, in accordance with the declaration of Helsinki* • 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)	
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	**Ethical Approval:** the following areas are described in full • Necessity for ethical approval • Ethical approval, with relevant judgement reference from ethics committees • Where ethics was unnecessary, reasons are provided	
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	**Protocol:** the following areas are described comprehensively • Protocol (a priori or otherwise) details, with access directions • If published, journal mentioned with the reference provided	
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.	**Patient Involvement in Research** • 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.	
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.)	**Study Design:** the following areas are described comprehensively • 'Cohort' study is mentioned • Design (e.g. retro-/prospective, single/multi-centred)	
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.)	**Setting:** the following areas are described comprehensively • Geographical location • Nature of institution (e.g. academic/community, public/private) • Dates (recruitment, exposure, follow-up, data collection)	
5c	**Study groups** • Total number of participants • Number of groups	**Cohort Groups:** the following areas are described in full • Number of groups	

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Table 1 (*continued*)

STROCSS Guideline		
Item no.	Item description	
	STROCSS 2021	**STROCSS 2019**
	• Detail exposure/intervention allocated to each group • Number of participants in each group	• Division of intervention between groups
5d	**Subgroup analysis** – comprehensively describe: • Planned subgroup analyses • Methods used to examine subgroups and their interactions	**Subgroup Analysis:** the following areas are described comprehensively • 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.)	**Participants:** the following areas are described comprehensively • Eligibility criteria • Recruitment sources • Length and methods of follow-up
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	**Recruitment:** the following areas are described comprehensively • Methods of recruitment to each patient group • 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	**Sample Size:** the following areas are described comprehensively • Margin of error calculation • Analysis to determine study population • Power calculations, where appropriate
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.)	**Pre-intervention Considerations:** the following areas are described comprehensively • Patient optimisation (pre-surgical measures) • Pre-intervention treatment (hypothermia/-volaemia/-tension; ICU care; bleeding problems; medications)
7b	**Intervention** – comprehensively describe: • Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological etc.) • Aim of intervention (preventative/therapeutic)	**Intervention**: the following areas are described comprehensively • Type of intervention and reasoning (e.g. pharmacological, surgical, physiotherapy, psychological) • Aim of intervention (preventative/therapeutic)

Table 1 (*continued*)

STROCSS Guideline		
Item no.	Item description	
	STROCSS 2021	**STROCSS 2019**
	• Concurrent treatments (e.g. antibiotics, analgesia, anti-emetics, VTE prophylaxis etc.) • Manufacturer and model details, where applicable	• Concurrent treatments (antibiotics, analgaesia, anti-emetics, NBM, VTE prophylaxis) • Manufacturer and model details where applicable
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	**Intra-Intervention Considerations**: the following areas are described comprehensively • Administration of intervention (location, surgical details, anaesthetic, positioning, equipment needed, preparation, devices, sutures, operative time) • Pharmacological therapies include formulation, dosages, routes and durations • Figures and other media are used to illustrate
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)	**Operator Details:** the following areas are described comprehensively • Training needed • Learning curve for technique • Specialisation and relevant training
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	**Quality Control:** the following areas are described comprehensively • Measures taken to reduce variation • Measures taken to ensure quality and consistency in intervention delivery
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.)	**Post-Intervention Considerations:** the following areas are described comprehensively • Post-operative instructions and care • Follow-up measures • Future surveillance requirements (e.g. imaging, blood tests
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	**Outcomes:** the following areas are described comprehensively • Primary outcomes, including validation, where applicable • Definitions of outcomes • Secondary outcomes, where appropriate • Follow-up period for outcome assessment, divided by group
9	**Statistics** – comprehensively describe: • Statistical tests and statistical package(s)/software used	**Statistics:** the following areas are described comprehensively • Statistical tests, packages/ software used, and interpretation of significance

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Table 1 (*continued*)

STROCSS Guideline		
Item no.	Item description	
	STROCSS 2021	**STROCSS 2019**
	• Confounders and their control, if known • Analysis approach (e.g. intention to treat/per protocol) • Any sub-group analyses • Level of statistical significance	• Confounders and their control, if known • Analysis approach (e.g. intention to treat/per protocol) • Sub-group analysis, if any
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	**Participants:** the following areas are described comprehensively • Flow of participants (recruitment, non-participation, cross-over and withdrawal, with reasons) • Population demographics (prognostic features, relevant socioeconomic features, and significant numerical differences)
10b	**Participant comparison** • Include table comparing baseline characteristics of cohort groups • Give differences, with statistical relevance • Describe any group matching, with methods	**Participant Comparison:** the following areas are described comprehensively • Table comparing demographics included • Differences, with statistical relevance • Any group matching, with methods
10c	**Intervention** – comprehensively describe: • Degree of novelty of intervention • Learning required for interventions • Any changes to interventions, with rationale and diagram, if appropriate	**Intervention:** the following areas are described comprehensively • Changes to interventions, with rationale and diagram, if appropriate • Learning required for interventions • Degree of novelty for intervention
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	**Outcomes:** the following areas are described comprehensively • Clinician-assessed and patient-reported outcomes for each group • Relevant photographs and imaging are desirable • Confounders to outcomes and which are adjusted
11b	**Tolerance** – comprehensively describe: • Assessment of tolerability of exposure/intervention • Cross-over with explanation • Loss to follow-up (fraction and percentage), with reasons	**Tolerance:** the following areas are described comprehensively • Assessment of tolerance • Loss to follow up, with reasons (percentage and fraction) • Cross-over with explanation
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	**Complications:** the following areas are described comprehensively • Adverse events described • Classified according to Clavien-Dindo classification* • 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
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	**Key Results:** the following areas are described comprehensively • Key results, including relevant raw data • Statistical analyses with significance
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	**Discussion:** the following areas are described comprehensively • Conclusions and rationale • Reference to relevant literature • Implications to clinical practice • Comparison to current gold standard of care • Relevant hypothesis generation
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	**Strengths and Limitations:** the following areas are described comprehensively • Strengths of the study • Limitations and potential impact on results • Assessment of bias and management
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	**Implications and Relevance:** the following areas are described comprehensively • Relevance of findings and potential implications to clinical practice are detailed • Future research that is needed is described, with study designs detailed
CONCLUSION		
16	**Conclusions** • Summarise key conclusions • Outline key directions for future research	**Conclusions:** • Key conclusions are summarised • Key directions for future research are summarised
DECLARATIONS		
17a	**Conflicts of interest** • Conflicts of interest, if any, are described	**Conflicts of interest** • Conflicts of interest, if any, are described
17b	**Funding** • Sources of funding (e.g. grant details), if any, are clearly stated • Role of funder	**Funding** • Sources of funding (e.g. grant details), if any, are clearly stated
17c	**Contributorship** • Acknowledge patient and public involvement in research; report the extent of involvement of each contributor	

institutional, and other relationships that might lead to bias or conflict of interest.

Sources of funding

None.

Ethical approval

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

Riaz Agha

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